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Hispanic Community Children's Health/ Study of Latino Youth (SOL Youth)

Manual 1 Field Center Procedures

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Study website - <http://www.csc.unc.edu/hchs/>

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1. FOREWORD

This manual, entitled **Field Center Procedures** is a series of protocols and manuals of operation for the Hispanic Community Children's Health/Study of Latino Youth (SOL Youth) ancillary study. This manual provides an overview of the interviews and clinical measurements conducted as part of the field center examination and appendices of forms and question by question instructions for their administration. The interview blocks are presented in the order in which they occur (i.e., reception, interviews, procedures, medical data review); the descriptions of the individual interviews and procedures are presented in alphabetical order of form code. Table 1a lists the main components of the field center examination administered to the child(ren) and Table 1b lists the main components of the field center examination administered to the parent/legal guardian of the child(ren).

Because high quality of data and a strict standardization of the examination and interview techniques across all field sites are essential it is important that SOL Youth field center personnel be familiar with this manual of procedures. To meet our scientific goals and to make this study a success, all SOL Youth field center technicians must be fully trained and certified in the procedures described in this manual, and must remain standardized throughout the data collection phase. A complete knowledge of the procedures detailed in this manual is required so that patterns in the SOL Youth data can reflect differences between study participants (children and parents) and between groups of Hispanic ancestry, as opposed to differences between study technicians or deviations from study protocol. Strict and sustained adherence to study protocol by all SOL Youth personnel is required for us to be able to meet our obligations to all study participants, to the scientific community and to our funding agencies.

To the degree that this is applicable, the description of each interview/exam component in this manual includes a brief rationale for its use, operational procedures, an overview of training requirements and certification criteria, routine quality assurance measures, and data collection procedures.

Table 1a. Outline of SOL Youth Baseline Field Center Examination Visit with Child, with Reference to the Corresponding Study Form Codes

Exam Procedure, fasting status specification (F)	Form codes
Pre-visit screening of child (eligibility, safety)	ELE, PSE
Reception, itinerary checklist form (F)	CKC
Informed assent (F)	IAC
Change clothes, if necessary (F)	--
Anthropometry (F)	ANT
Seated BP (F)	SBP
Phlebotomy (F)	BIO
Snack	--
Blood processing / lab	BIO, PHT
24-hr dietary recall, supplements	--
Other interviews:	--
After School Environment- Child	AEE
Away from Home Foods- Child	AFE
Acculturative Stress - Both	ASE
Alcohol Susceptibility- Child	AUE
ARSMA Scale - Both	BAE
Body Image- Child	BIE
Child Depression Inventory - Child	CDE
Demographics - Child	DCE
Ethnic Affirmation and Belonging - Both	EAE
Eating Disorders- Child	EDE
Family Function - Both	FFE
Dietary/PA Family Support- Child	FSE
How I Feel (Lie) Scale- Child	LSE
MASC-10- Child	MAE
Physical Activity- Child	PAE
Parenting for Eating and PA - Child	PCE
Family Relationship - Child	RCE
Social Attitudes Towards Weight- Child	SAE
School Food Environment- Child	SFE
Sleep Duration- Child	SLE
Social Support from Friends - Child	SSE
Tobacco Susceptibility- Child	TUE
Food Practices with TV/Video viewing- Child	TVE
AHISMA Scale- Child	UNE
Workout Equipment in Home- Child	WEE
Pubertal Development	PDE
Fitness Step Test	FST
Tanner Staging (random sample)	TSM, TSF
Exit interview	--
Activity monitoring instructions and tracking	CKC

Table 1b. Outline of SOL Youth Baseline Field Center Examination Visit with Parent, with Reference to the Corresponding Study Form Codes

Exam Procedure, fasting status specification (F)	Form codes
Pre-visit screening (eligibility of child, safety of child)	ELE, PSE, PSS
Reception, itinerary checklist form	CKP
Informed consent	ICC
Anthropometry	ANT
24-hr dietary recall, supplements (verify child's response)	--
Other interviews:	--
Authoritative Parenting Index - Parent (each child)	APE
Acculturative Stress - Both	ASE
ARSMa Scale - Both	BAE
Barriers to Activity in Neighborhood - Parent	BNE
Demographics - Parent	DPE
Demographics - Partner/Spouse - Parent	DSE
Ethnic Affirmation and Belonging - Both	EAE
Equipment Checklist in Home - Parent	ECE
Familism - Parent	FAE
Family Function - Both	FFE
Foods in the Home - Parent	FHE
Family Meals - Parent	FME
Food and Neighborhood Environment - Parent	FNE
Food Security - Parent	FOE
Health Insurance - Parent (each child)	HCE
Health Insurance - Parent	HPE
Medical History - Parent (each child)	MHE
Medication Use/Suppl. - Parent (each child)	MUE
Neighborhood SES - Parent	NSE
Pre-Migration of Child- Parent (each child)	PME
Parenting for Eating and PA - Parent	PPE
Family Relationship - Parent (each child)	RPE
SES - Parent	SPE
School Type - Parent (each child)	STE
Exit interview	--
Activity monitoring instructions and tracking (with child)	CKC

2. RECRUITMENT

2.1 Overview

This section contains information to help field centers manage recruitment for the SOL Youth study. A study of 1,600 Hispanic/Latino boys and girls who are under the custody of Hispanic Community Health Study/Study of Latinos (HCHS/SOL) participants in the Bronx, Chicago, Miami and San Diego. This study is funded by the National Institutes of Health.

2.2 SOL Youth Study Sample

The study aims to recruit 1,600 boys and girls aged 8 to 14 years old whose parent or legal guardian completed the core components of the HCHS/SOL study. [**Note:** Protocol revision for increasing the eligible age range from 8-14 to 8-16 years old for SOL Youth was unanimously approved by the HCHS/SOL Ancillary Study Subcommittee and HCHS/SOL Steering Committee on August 8, 2012. All subsequent reference to the eligible age range in the remainder of this MOP will indicate the approved protocol change to 8-16 years old.] Each field center is responsible for recruiting 400 youth, including securing involvement from the parent/legal guardian to complete an additional interview.

2.3 Recruitment Plan

The recruitment plan consists of two basic steps, initial mailing and telephone contact, both of which are discussed further in the Recruitment Steps section.

2.3.1 Monitoring and Mid-course Corrections

The SOL Youth recruitment period is 21 months in duration. The University of North Carolina (SOL Youth Coordinating Center) will monitor the recruitment rates on an ongoing basis. Adjustments to the recruitment procedures may occur as a result of this monitoring and are referred to as mid-course corrections. For example, the age group and number of participants on the recruitment list can be altered to meet recruitment goals. All mid-course corrections, if any, will be discussed and approved by the SOL Youth Steering Committee.

2.3.2 Recruitment List

The coordinating center provides each field center with a randomized list of potential eligible households. This list includes active HCHS/SOL participants who have completed core components of HCHS/SOL and who may have children living in their households. To maintain the integrity of randomization order, field centers begin recruitment at the top of the list. The information in this list will be used to prepare for phone recruitment. Recruiters need to have all names and contact information readily available prior to calling.

2.4 Recruitment Steps

2.4.1 Initial Mailing

After receiving the participant recruitment list from the coordinating center, field centers will select participants off the top of the list to create the first mailing. The invitation letter will be mailed in batches of 100 to 300 depending on the field center preference. The SOL Youth invitation letter provides information about the SOL Youth study to the HCHS/SOL participant or household (field center specific). The recruitment telephone number must be included in the letter for potential participants to call the corresponding field center and inquire about the study.

2.4.2 Screening

Screening potential SOL Youth participants will be done via telephone. Recruitment attempts will be made at varying times of the day and days of the week to maximize the possibility of contact. Contact will be made with the HCHS/SOL participants using the information provided in the recruitment list. All children who live in the household of the HCHS/SOL participant will be rostered and screened for the SOL Youth Study. The SOL Youth screening process determines the eligibility and the interest of the potential SOL Youth participants. If the HCHS/SOL participant has multiple children who are eligible for the SOL Youth study, all children will be invited to participate. Younger children who are rostered will be allowed to participate once they are of age. The field centers will contact the family after the younger child's 8th birthday. HCHS/SOL participants will also be encouraged to contact their field center to schedule an appointment.

2.4.3 Number of Phone Calls

Phone call attempts should average 10-12 before declaring the household as unable to contact, code 1 in the SCT form. It is recommended that only 2 weekly calls be made to each household. Each call should be separated by 2-3 days. Up to 7 messages can be left with a person or voice mail. The full number of recruitment calls and contact attempts can most likely be accomplished in approximately 4-6 weeks. Each call attempt should be noted on a screening and recruitment call tracking worksheet (SCT) which will be kept at each field center for internal use.

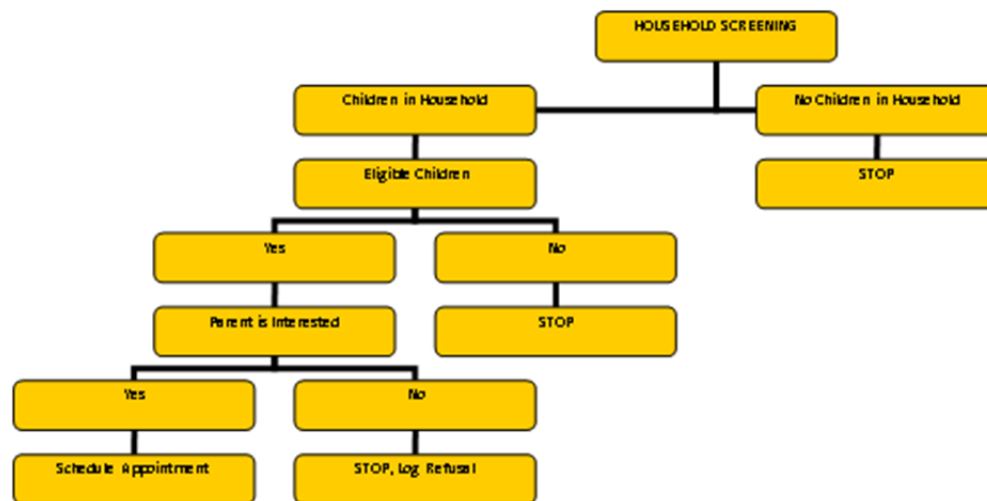
2.4.4 Reporting Screening Outcomes

Recruitment staff is responsible for completing the following forms:

- Household Screening Roster (HSR)
- Screening Call Tracking (SCT)
- Individual Eligibility Checklist (ELE)
- Participant Safety Screening (PSE)

Record the information on these forms into the SOL Youth study data management system live or within 48-72 hours after collection depending on the field site. Data entry for these forms is important for coordination between the field sites, the recruitment team, and the coordinating center; the latter will use these data to monitor the recruitment process.

2.4.5 Recruitment Flow Chart



2.5 Forms

2.5.1 Household Screening Roster Form (HSR)

The Household Screening Roster (HSR) is used to determine the number of children who live in the participant's household and assess their interest in the SOL Youth Study. This form can only be completed by an HCHS/SOL participant. If a household has moved entirely from the original household from the HCHS/SOL main study, a new household ID must be assigned to the current household for screening. In cases when an original household has been split (original HCHS/SOL household is now two separate households at two locations), a new household ID must be assigned to the household(s) that reside at a different address than the original HCHS/SOL household. Once a new household ID is assigned, the screening process continues for each specific household separately.

Although the initial goal is to recruit 8-16 year olds for the SOL Youth study, it is very important that all children who live in the household are rostered. Include all children between the ages of 0-17 on this form. Refer to the HSR QxQ for further instructions on how to complete the form.

2.5.2 Screening Call Tracking Form (SCT)

The Screening Call Tracking Form (SCT) has a final result code that documents the outcome of the household. The coordinating center monitors the screening outcomes centrally; local tracking systems are also used for directing and evaluating recruitment efforts. Refer to the SCT QxQ for further instructions on how to complete the form.

2.5.3 Individual Eligibility Checklist (ELE)

The Individual Eligibility Checklist Form (ELE) records the primary inclusion (e.g., language preference, age, individual participation status) and exclusion (e.g., developmental disabilities)

criteria. Recruiters are responsible for verifying that all individuals meet the eligibility criteria for inclusion in the study. Refer to the ELE QxQ for further instructions on how to complete the form.

2.5.4 Participant Safety Screening Safety Form (PSE)

This form is completed after the Individual Eligibility Checklist Form (ELE) to assess individual safety measures. Unless instructed, record only one response and complete only one form per child. Only an HCHS/SOL participant who is a parent/legal guardian can answer these questions. Refer to the PSE QxQ for further instructions on how to complete the form.

2.6 Eligibility Criteria

All children of or under custody of HCHS/SOL participants who meet the eligibility criteria are invited to participate in the SOL Youth study. The child does not need to be biologically related to the HCHS/SOL adult participant; the child can be an adoptee or a foster child.

If the parent/legal guardian of an eligible child is not available to participate in the SOL Youth study, the second parent/legal guardian who did not participate in the main study (because of race/ethnicity/other reasons) will be able to accompany the child to his/her appointment (regardless of race/ethnic group). The full name of the parent accompanying the child will be noted in the ELE. A study ID for the non-HCHS/SOL participant parent will be created.

Inclusion

- Child within the 8-16 years old age group at the time of scheduled examination.
- At least one parent or legal guardian has completed the core components of the HCHS/SOL baseline examination.
- Child resides in the home of the HCHS/SOL participant at least 5 days/week and 9 months/year.
- Child is able to communicate by reading, listening and writing in English or Spanish.

Exclusion

- Child has significant cognitive or mental deficits (e.g., autism, mental retardation) that interfere with the child's ability to complete a 3-hour examination.
- Child is permanently unable to use legs to ambulate.
- Child has been diagnosed or is under treatment for the following chronic conditions: type 1 diabetes, hemophilia, cancer, sickle cell trait, cystic fibrosis, Turner's syndrome, kidney disease or major organ transplant.
- Current use of growth hormone.

Temporary Exclusions

- Child is currently pregnant (schedule examination when child is no longer pregnant).
- Child is currently suffering from a physical injury (schedule examination after recovery).

2.7 Recruiters

2.7.1 Overview

Recruiters will be people oriented, organized, confident, and knowledgeable of the HCHS/SOL and the SOL Youth study. Recruiters must have the ability to develop and maintain a positive demeanor with the participant, should be non-judgmental, and be able to establish trust. It is important that the recruiter always maintain a professional and friendly demeanor. Recruiters are required to read the study manual of operations and review all pertinent recruitment material. They also need to review and understand the recruitment flow chart and understand the reasons for ineligibility. In addition, recruiters will be expected to maintain their IRB certificate current and be able to demonstrate knowledge of the IRB regulations.

2.7.2 Training

All recruitment staff will be provided with adequate training prior to their first contact with SOL Youth study participants. The following are certification that the SOL Youth study recruitment staff needs to complete (**see recruitment certification check list provided by the CC**):

- Human Subjects Protection
 - Overview of principles, regulations, and policies which affect research involving human subjects in research
- General Interview Techniques
 - Overview of questionnaire administration and interviewing techniques
- Recruitment and Screening
 - Overview of the recruitment and screening process for the SOL Youth study
- Web-based Data Management System (DMS)
 - Overview of the DMS, data entry, and training on the use of SOL Youth study forms

2.7.3 Privacy and Confidentiality

Confidentiality in research means keeping the information that the participant provides during the study private. It is very important that recruiters remind participants that all information collected is confidential and protecting their privacy is a priority to the study.

Because of the risks involved with a breach of confidentiality, it is very important to implement appropriate confidentiality procedures to protect information collected from participants in research studies. Adherence to general protocol guidelines helps to protect the confidentiality of information provided by participants during a research study. These include:

- Carefully store research materials in locked filing cabinets and do not leave them unattended on desktops or in unlocked filing cabinets.
- Use password protection, log off, and shut down your computers when leaving your workstation for any length of time.
- When referring to participants, use their study ID number.
- When transporting study materials (completed forms), remove the materials from car as soon as possible to avoid loss, theft or damage.
- When working with participants from the community, do not discuss their participation in the study with family and friends or other members of your community.

- Remove any information that will identify the participant when study materials are stored for future analysis.

2.7.4 Professional Ethics and Participants' Rights

As a recruiter, there is a professional responsibility to adhere to the highest possible standards of ethical practices and to protect the rights of the participant. Each recruiter is responsible for taking and passing the required Human Subjects Protection course through their institution. As a professional it is important for the recruiter to make sure that individuals understand what is involved when participating in a study and are able to ask questions before and during their voluntary participation. Any study participant has the right to autonomy, privacy, and the freedom of action.

2.7.5 Using Scripts/Guidelines for Probing

A script is provided for uniformity between all sites during the household screening process. Although scripts may be modified for each field center, according to the needs of the community, the core script content needs to be followed in order to maintain consistency across field centers. Deviations to the scripts may occur when potential participants ask questions about the study. A copy of the recruitment script is provided (Appendix 1).

Potential participants may be hesitant to give the type of personal information we are requesting for recruitment. If a recruiter is having difficulty obtaining all the information needed to complete the recruitment phase of the study, he/she may use probing techniques. Probing techniques encourage the potential participant to express his/her thoughts completely and help to maintain focus on the questions being asked. Probing techniques include repeating the question, pausing, and clarifying the question. Additional probing techniques are reviewed in the recruiter's interviewing technique training. This training must be completed by all recruitment staff before the start of the SOL Youth study recruitment process.

2.8 Collaborations

It is highly recommended that a good communication plan is developed within each field center in order to be able to efficiently address any inquiries from HCHS/SOL participants on current ancillary studies. The SOL Youth Study recruitment team will be in contact with the HCHS/SOL Annual Follow Up team and other ancillary studies to minimize burden to HCHS/SOL participants and their contacts. In order to use the most updated contact information, staff needs to cross reference the SOL Youth study recruitment list with the Annual Follow Up files. Special attention should be paid to those cases where HCHS/SOL participants terminated their participation with the parent study and requested no further contact. HCHS/SOL participants are to be invited to only two ancillaries in a calendar year. Other studies/ancillaries will be made aware once an HCHS/SOL participant becomes part of SOL Youth.

3. CONTACTING PARTICIPANTS / MAKING THE FIELD CENTER EXAMINATION APPOINTMENT

SOL Youth participants who meet the eligibility criteria (see ELE form) are scheduled along with their parent/legal guardian to a field center examination. The field center recruitment personnel coordinates the process of scheduling appointments. Contacting potential participants is accomplished by phone calls and mailed materials in a sequence and combination considered to be optimal by each field center. Household Screening Rosters (HSR form), Screening Call logs and Tracking sheets (SCT form) are used in managing recruitment outcomes. The eligibility of each child is determined using the Eligibility Checklist (ELE form) which is also used to record the date of the field center examination. Field centers schedule appointments taking into consideration the parent/legal guardian and child's availability. Each field center is responsible for entering information promptly into the Data Entering System (DES) to keep track of recruitment efforts. The coordinating center keeps updated records of recruited SOL Youth participants and their parent/legal guardian and sends periodic reports for tracking purposes.

Before calling a HCHS/SOL participant, field center personnel must have appropriate scheduling forms, worksheets, available examination appointment dates/times, and all relevant scripts. The SOL Youth recruitment personnel makes the appropriate number of call attempts and is responsible for tracking them on a call tracking worksheet.

Key scheduling tasks are to explain where the field center examination is located; identify an appointment time; establish how the parent/legal guardian of the child intends to get to the field center examination site; identify any special medical conditions; and provide brief but complete instructions. The interviewer also mentions that a confirmation letter will be mailed to the parent/legal guardian of the child with the specifics of the appointment just made, a bag for the child's medications, along with instructions. Lastly, remaining questions are answered and (optionally) personnel can mention that a reminder call will be made the day prior to the visit.

Parents/legal guardians of children are reminded that the blood tests and other examination procedures require fasting for at least 10 hours prior to drawing blood and that a snack is provided to the child about one hour after the start of the field center examination. Fasting means no consumption of food or drinks (including alcohol), with the exception of water. Parents/legal guardians will be informed that their children should not consume food or drinks after 10:00 p.m. the day before the field center examination visit and to refrain from smoking for the same length of time, or for 10 hours prior to the scheduled arrival time at the field center. Parents/legal guardians of children will be asked if there are medical reasons for his/her child to not fast for this length of time and alternate arrangements are made if necessary after consultation with the Field Center Clinic Manager. Parents/legal guardians of children are told what the options are for snacks at the field center and asked whether their children have any dietary needs that are not met by these choices.

3.1. Participant Safety Screening

Verification of eligibility for all study procedures and pre-screening to ensure safety are part of the visit scheduling procedures. For this purpose, SOL Youth personnel use the Participant Safety Screening Form (PSE), supported by the DES. Following an explanation of the SOL

Youth study and the procedures involved, the interviewer requests an opportunity to verify the child's eligibility for all procedures. The conditions reviewed during this interview (and listed on the form) include pregnancy, asthma, orthopedic disorders, and screening questions for conditions that would preclude the step test and assessment of body fat. If a child is pregnant, the parent/legal guardian is asked to schedule an examination visit at three months after delivery, and to provide a date by which the SOL Youth can re-contact them for this purpose. Breast-feeding is not an impediment for SOL Youth participation nor a reason for rescheduling; field centers work with the nursing mother to accommodate her needs. The presence of implanted devices and a positive response to electronic devices questions are recorded on the PSE form and the parent/legal guardian and child are told of the procedures to avoid and that a sticker will be placed on their respective name tags to make the study personnel aware of this during the field center examination.

During the interview, study personnel also inquires about special needs, such as any medical conditions that would affect the examination or the appointment time, or impediments in hearing or reading. Arrangements for a safe and comfortable examination visit are made, consulting with the Field Center Clinic Manager as appropriate. Parents should be reminded to bring all of their child's medications to the field center.

3.2. Scheduling the Participant's Medications on the Day of the Examination

There are no safety concerns associated with aspirin, anticoagulants and antiplatelet aggregation agents, although these medications may increase bruising and minimal bleeding at the venipuncture site. Parents/legal guardians of children participating in SOL Youth are required to review the following instructions prior to the day of their field center examination:

- Parents/legal guardians of children using inhalers should be instructed to tell their children to take their inhalers as early as possible the morning of their field center examination. SOL Youth personnel review the use of inhalers on the day of the field center examination to confirm that the child meets inclusion to perform the Step Test. This is because 4 hours should elapse since the last use of the bronchodilator and the step test.
- Parents/legal guardians of children who have diabetes and take oral hypoglycemic or insulin medications can withhold these medications until the blood draw and their snack to avoid a drop in the child's blood sugar level. Parents/legal guardians of children with diabetes should be advised to bring needles, strips and a device to measure their children's blood sugar levels, if needed.
- Medications for HIV, autoimmune and neurological disorders should be taken as prescribed by the child's physician. Some of these medications may need to be taken with food, and at set times. Field centers make it possible for the child to take these medications accordingly; if this is not practicable, the parent/ legal guardian of the child is asked to consult with his/her physician.

3.3. Appointment Reminders and Instructions for the Field Center Examinations

After a successful scheduling call, study personnel process the child's ID; name, address and phone number; appointment time and transportation preference; and any special instructions. The instructions for the visit to the field center are specified on an information sheet prepared by

each field center, and mailed to the parent/legal guardian of the child soon after the appointment is made. The instructions include:

1. Appointment date and time.
2. Preparations:
 - a) Instructions on how to complete the 10-hour fast;
 - b) Instructions on proper hydration while maintaining the fast;
 - c) Instructions concerning restrictions on the use of tobacco and vigorous physical activity the morning prior to the visit;
 - d) Instructions on appropriate clothing to wear for the examinations.
3. Items to bring to the field center:
 - a) Eyeglasses and hearing aid for parent/legal guardian and/or child, if needed;
 - b) Name and address of the child's primary care physician;
 - c) Name, address, and phone number of contact persons of the parent/legal guardian;
 - d) Medication Instruction Sheet: Instructions to bring all the prescription and over-the-counter medications the child takes, including vitamins and mineral supplements, taken within one month prior to the examination. This includes pills, liquid medications, skin patches, inhalers, and injections. A bag for parents/legal guardians to bring their children's medications and supplements to the field center is enclosed.
4. Overview of Field Center Operations:
 - a) A listing of the interviews and procedures for the examination (optional);
 - b) A reminder that a snack for the child is provided during the exam;
 - c) Field Center Examination hours and phone number for questions or rescheduling appointment.
5. Directions to the Field Center (e.g., a map) and to parking facilities:
 - a) A reminder of the arrangements for parking and/or reimbursement.
6. Transportation, if applicable (some centers provide transportation and arrange for participant pick-up).

3.4. Split Baseline Examinations

Baseline examinations may be scheduled as split exams if the parent/legal guardian and/or child is unable to commit to a full examination, or split to accommodate circumstances not anticipated at the time the examination was scheduled. The full sequence of split examinations must be completed no more than 15 days apart. Options for home visits to complete interviews can be offered to the participants upon approval of the field center's Clinic Manager.

Under exceptional circumstances field center Clinic Managers may authorize scheduling split examination beyond 15 days. Weather conditions, the unforeseen absence of key personnel, illnesses, and a child's inability to complete an examination within the time period specified by protocol represent such exceptional circumstances. The frequency of split examinations that

occur more than 15 days apart must not exceed 5% of a field center's baseline examinations during one year.

On occasion a child's baseline interview or examination component may be missing, inadvertently or to accommodate various circumstances in the field. Completion of the missing component may be scheduled at the time the parent/legal guardian of the child is at the field center or subsequently, once flagged in the Data Entry System (DES) report. Missing exam components must be completed within 90 days of the initial visit to maintain the temporal alignment in the baseline characterization of the SOL Youth participants.

4. RECEPTION

Reception is the first workstation for the family's examination visit. Parents/legal guardians and their children are welcomed, informed consent and assent are obtained, participants' questions are answered, demographic and tracking information are updated, fasting status is determined, child's safety screening form (PSE) is reviewed, and the child's medication bag is logged and labeled.

Prior to the child's visit, information on morbidity and special needs recorded on the safety screening form (PSE) are transferred to Clinic Exam Checklist Form (CKC) (see Appendix under this section heading). At the time of the family's arrival to the reception station, display the Clinic Exam Checklist Form (CKP/CKC) on the Data Entry System (DES) and monitor and confirm the identifying information on the form with the parent/legal guardian. Staff confirms that special needs are noted on the participant's Clinic Exam Checklist Form (CKP/CKC). Parents/legal guardians' and children's language preferences for the interviews to be conducted during the visit are recorded on the Clinic Exam Checklist Form (CKP/CKC) which is then printed and attached to the participants' labeled folder to accompany them throughout the examination visit.

After the medication bag is labeled, its contents are inspected with the parent/legal guardian of the child to determine if it contains any medications that require refrigeration. Medications requiring refrigeration are labeled with the child's ID number and placed in the refrigerator. The location of the medication is noted on the Clinic Exam Checklist Form (CKC). Since parents/legal guardians may bring more than one child to the visit, special attention should be made to confirm that each medication bag is labeled with the correct child's ID number.

As soon as the initial steps of welcome and reception mentioned above have been addressed and participants are comfortable, they are given the opportunity to read and review the informed consent/ assent as described below. No data collection can take place before informed consent/assent has been obtained.

Once consenting/assenting procedures are complete (Section 5 of this manual) participants who are selected for the Tanner staging (Chicago and Miami Field Centers) are shown where to change into an examination gown/robe. Participants are offered to place personal apparel and valuables in a secured locker, and told to keep eye glasses with them.

If during the course of the reception procedures the parent/legal guardian or the child appears to be acutely ill or has flu-like symptoms, study personnel will ask the participant if s/he is not feeling well. If this is the case, the field center Clinic Manager is consulted to determine whether the exam should be rescheduled.

Study personnel are trained for the reception workstation by the Field Center Clinic Manager at each field center. Certification requirements include the training on general interviewing techniques, Human Subjects Protection, Informed Consent/Assent, the Informed Consent and Assent Tracking forms, and the Data Entry System. Although there is no formal certification process for study personnel at the reception workstation, personnel working at the reception

workstation are observed by the field center Clinic Manager for quality assurance and standardization.

5. INFORMED CONSENT AND ASSENT

Informed consent is the first data collection form administered during the course of the exam. Its core content complies with guidelines from the National Heart, Lung, and Blood Institute and the SOL Youth Steering Committee. Its content, format and consent/assent administration process are tailored to meet the specific requirements of each field center's Institutional Review Board.

The primary objective of administering informed consent/assent is to inform the parent/legal guardian of the child of the SOL Youth procedures, protect the rights of the study participants, meet local Institutional Review Board requirements, and to identify the parent/legal guardian's instructions for the type of information and biospecimens to be collected, their long term storage and disposition. The informed consent/assent makes the study participants aware of their right to withdraw from the study, to not participate in a procedure, or to decline to answer question(s) without penalty. Also at this time the participants are asked for authorization for subsequent contacts by SOL Youth personnel and for instructions on distribution of the SOL Youth study results.

5.1. Administration

The purpose of SOL Youth measurements are to be reviewed with the participants. Informational materials about SOL Youth, its goals, measurements and procedures are mailed to the parents/legal guardians of the children prior to their examination visit. The informed consent/assent forms are available in Spanish and English, and bilingual SOL Youth personnel are available to review and administer. Early on in this process find out whether the participants prefer to communicate in Spanish or English and record language preference on the Clinic Exam Checklist Form (CKP/CKC) for easy access during the remainder of the exam visit.

Before proceeding, assess whether the participants use glasses or a hearing aid. Record this information on the Clinic Exam Checklist Form (CKP/CKC) and explain to the participants to have the hearing aid /glasses conveniently available throughout the field center examination visit.

After introducing the informed consent/assent forms to the participants in a private area ask whether they prefer to read the informed consent/assent forms or to have it read by the study personnel. Record this preference on the Clinic Exam Checklist Form (CKP/CKC) to make this information easily accessible to interviewers throughout the field center examination visit and avoid repeated questions about whether the participant is comfortable reading.

Field centers should review the informed consent/assent with study participants in great detail regardless of whether a copy of the forms has been mailed prior to the field center visit. Questions are encouraged and time is allowed for the parent/legal guardian and child to read and sign the informed consent and assent document in the presence of SOL Youth personnel serving as witness.

If the parent/legal guardian or child is visually handicapped or otherwise incapable of reading the study description and informed consent/assent forms, the narrative portion is read to him/her and then the participant is asked to sign the document. The original informed consent/assent document is filed in the participant's study folder. A copy of the informed consent/assent is given to the parent/legal guardian of the child if requested or required by the Field Center Institutional Review Board.

5.2. Training and Certification

Study coordinators are responsible for providing training to field center study personnel. Certification by the Study Coordinator is required, as listed in Section 4. Quality Assurance is provided at each field center by means of observation by the local study coordinator.

5.3. Data Collection

The informed consent/assent is a paper form. In some field centers the informed consent may be split into two forms (main consent and consent for specimen storage). When the parent/legal guardian receives COPIES of the informed consent/assent, the field center has the option of providing a copy of the entire form, or signed consent pages. In all cases, the original signature pages must be kept at the field center and stored in the participants' study folder.

5.4. Ability to Comprehend the Informed Consent and Assent

Although the capacity to provide informed consent and assent is required for SOL Youth to be conducted in an ethical manner, it can be challenging to identify individuals who may not have the ability to comprehend the informed consent/assent. There are no nationally recognized standards for this purpose and somewhat different findings have emerged when some states (and courts) have taken up this issue. As a result, each field center follows the guidance of its local IRB on whether specific procedures are required for identification of such individuals.

Unless impairment is obvious, recognizing cognitive impairment in a potential participant is difficult (even for professionals), particularly since social skills can remain intact for participants who otherwise do not perform well on tests. As an added consideration, decision-making capacity is frequently task specific. As a result, depending on the type and extent of impairment, cognitively impaired individuals can remain fully capable of making a variety of decisions, including whether or not to participate in a study. Field center personnel need to be attentive to indicators of potential cognitive impairment, such as repetition (i.e., repeating questions/stories over the course of just a few minutes) and empty or poor responses (i.e., the participant who frequently responds with "I don't know"). A child who seems to always be looking to their parent/legal guardian for help to answer questions also warrant consideration for a limited capacity to answer all SOL Youth questionnaires.

Unless an IRB specifies procedures for vulnerable individuals, there is no need for guidelines common to the SOL Youth field centers for the understanding of the informed consent and assent processes. To ensure that participants understand the informed consent and assent, personnel can ask the participants to explain back (in their own words) certain portions of the study. This can be introduced by stating that it is very important that participants understand their rights and the process by which the SOL Youth study protects the confidentiality of the participant's information. If the responses from a participant suggest that s/he has difficulty

comprehending the consent/assent process or the form contents, field center personnel brings this to the attention of the field center Clinic Manager.

5.5. Consent and Assent Tracking Forms

The informed consent and assent forms signed by the parent/legal guardian and the child during the visit are used to complete the Informed Consent and Informed Assent Tracking forms, which are NOT administered to participants. The purpose of these tracking forms are to document the level of consent/assent and to track any changes (revisions) following the field center examination visit to a participants' consent/assent on (a) the use of DNA, (b) the use of other study data and (c) reporting the results to parent/legal guardian and others designated for that purpose. Changes to the consent/assent are not actively solicited, but any change in consent or child's assent status is documented as soon as the parent/legal guardian or the child requests that a change be made to his or her consent/assent status. Parent/legal guardian approval is not necessary to make changes in the child's assent status.

The Informed Consent and Informed Assent Tracking Forms are internal forms to monitor the level of consent/assent given by study participants to participate in the SOL Youth and records all restrictions specified by the parent/legal guardian of the child (see Informed Consent Tracking/Informed Assent Tracking forms). These forms track each participant's type of consent (full or partial), restrictions on use or storage of DNA, type of restrictions on the participant's data for different types of research questions, the ability to share de-identified data with investigators not affiliated with HCHS/SOL, or restrictions on the release of results to child's physician. These forms are completed by study personnel, and not administered to participants.

At the option of each field center, as part of the informed consent and assent process or following its completion, a schedule for reporting the participant's study results is reviewed with the child and parent/legal guardian. The parent/legal guardian and child are told that a summary of results will be reviewed at the conclusion of the examination visit with the SOL Youth personnel. They are informed that a written summary report, including additional tests results, will be mailed to the home and the child's physician (or alternate) six to eight weeks after the field center exam. The participants are encouraged not to ask the personnel for the results of their procedures at individual stations to avoid distracting the technicians. The reporting of results is described in detail in Section 21 of this manual.

6. TRACKING

To establish the ability of SOL Youth personnel to maintain contact with its participants, during the field center examination visit the parent/legal guardian of the child are asked to confirm changes in their information (e.g., address, telephone/cellphone number, email and contacts information), as well as for 3 individuals who can serve as new contacts and their respective information. Local tracking mechanisms can be implemented to record new changes in participants' information.

6.1 Procedure to remove a Participant from the Study

It is possible to remove a consented study participant for administrative reasons if the field center lead investigator notifies the coordinating center that one or more of the following conditions are true:

- (1) The parent/legal guardian parental permission form or the child's assent was invalid due to cognitive impairment, substance abuse, or equivalent.
- (2) The informed consent/assent was revoked by the child or his/her parent/legal guardian, wishing a full withdrawal from the study and no further contact.
- (3) Threatening / antisocial behavior by the child or his/her parent/legal guardian towards the staff or other study participants.

Administrative exclusion of an eligible participant recruited and/or examined by SOL Youth must be initiated or approved by the field center PI, and communicated to the coordinating center for adjustments to the field center's list of eligible enrollees, purging of the biospecimen repositories, adjustments to the collaborative database and analysis files, and to enable recognition of the former study participant by various study management tools.

6.2 Procedures to Document Changes to Participant's Informed Consent

Consent to participate in a long term cohort study is a dynamic process. In the event that a study child or his/her parent/legal guardian wants to modify the former scope of their consent to participate in the different elements, proper documentation of that change is required. An Informed Consent Update form (ICU) and an Informed Assent Update form (IAU) serve to administratively capture those changes to any element of consent/assent and preserve it in the study database. The ICU or IAU when keyed for a parent/legal guardian or child will automatically pre-fill with the responses from the elements of consents from the existing informed consent tracking form. The field center representative who is making the change will need to enter the date this change becomes effective and tab (jump) to the consent/assent element(s) being changed from "yes" (allow) to "no" (dis-allow). Study personnel should modify the responses as needed and save the record. If any aspect of consent/assent is modified again by the child or his/her parent/legal guardian at a later date, such as adding or removing a restriction, then update the ICU or IAU completion date, staff ID fields, and save the changes in the DES. Every time a change is made to the original scope of informed consent/assent, field center personnel must document the change by printing the tracking form and saving it in the participant file.

7. PARTICIPANT FLOW AND ITINERARY

The sequence of examination procedures (participant flow) includes a series of fixed and flexible components which are organized to accommodate the collection of informed consent and assent prior to any data collection, followed by the collection of a group of measurements that must be obtained in the fasting state. During Reception, study personnel will collect medications the parent/legal guardian brought that the child(ren) uses, refrigerating any that need to be refrigerated. Study personnel can then list the medications in the MUE form during the consent process, or during the Anthropometry or Seated Blood Pressure stage. Collection and listing of medication in MUE must be done before the Fitness Step Test. Study personnel completing the MUE should make the form available to study personnel conducting the Fitness Step Test as soon as possible to determine eligibility for the Fitness Step Test.

The fast is broken by a snack that corresponds to dietary preferences/needs identified during the examination visit scheduling process. The time of administration of each procedure and interview is recorded on the Clinic Exam Checklist Form (CKP/CKC) (one for the parent/legal guardian and one for the child), and also in the DES at the study personnel's earliest convenience so that the information can be made available to the lab technician completing the Biospecimen Collection form (BIO).

Following this point, each participant's itinerary is structured with exchangeable blocks of procedures and interviews that optimize participant and study personnel time (Tables 1a and 1b). These blocks are divided at suggested break points should the participant need a break. At the field center's discretion, the participant's itinerary and Clinic Exam Checklist Forms (CKP/CKC) are prepared one day in advance according to the number of study participants scheduled and the available personnel. Clinic Exam Checklist Forms (CKP/CKC) are printed or displayed on a board for convenient consultation by staff during the examination, also at the discretion of the field center. Flexibility in restructuring such participant flow itinerary and Clinic Exam Checklist Forms (CKP/CKC) is desirable to accommodate last minute cancellations or delays that occur during the participant's progression through the sequence of examinations and interviews.

Table 1a. Examples of SOL-Youth Child Procedure & Interview Blocks

Exam Procedure, fasting status specification (F)	Estimated time (min)
Fasting Block	60
Reception, Video (FC-specific), informed consent and assent, MUE (Med Use/Supplements– collect from parent/legal guardian for each child)	25
Numbing Cream Application (at the discretion of each FC, applied to opposite arm usually used for SBP)	1
Anthropometry (F)	10
Seated BP (F)	15
Phlebotomy (F) (ensure it has been at least 30 min and no more than 60 min since numbing cream application, if used)	05
Snack	05
Procedures, flexible sequence	10-25
Fitness Step Test	10
Tanner Staging (random sample of children), change clothes	15
Blocks of interviews, flexible sequence: A	45
24-hr dietary recall, supplements	45
Sample interview (administered at the beginning of first sequence)	2
Blocks of interviews, flexible sequence: B	22
Demographics – Child (DCE)	02
ARSMA Scale (BAE)	03
Ethnic Affirmation and Belonging (EAE)	02
AHIMSA Scale (UNE)	02
Acculturative Stress (ASE)	03
**Child Depression Inventory – Short (CDE)	05
**MASC-10 (MAE)	05
Blocks of interviews, flexible sequence: C	25
Eating Disorders (EDE)	03
Family Relationship – Child (RCE)	02
Family Function (FFE)	03
Social Support from Friends (SSE)	01
Dietary/Physical Activity Support (FSE)	04
Parenting for Eating and PA – Child (PCE)	12

Blocks of Interviews, flexible sequence: D	22
Body Image (BIE)	04
Social Attitudes Towards Weight (SAE)	07
Physical Activity (PAE)	12
Blocks of Interviews, flexible sequence: E	14
Workout Equipment Use in Home (WEE)	04
After-School Environment (AEE)	01
Away from Home Foods (AFE)	03
School Food Environment (SFE)	04
Food Practices w/TV/Video Viewing (TVE)	01
Sleep Duration (SLE)	01
Blocks of interviews, flexible sequence: F	12
**Pubertal Development Scale (PDE)	03
**Tobacco Susceptibility (TUE)	03
**Alcohol Susceptibility (AUE)	03
**How I feel (LIE) Scale (LSE)	03
Visit Termination	20
Exit interview & Incentive	10
Activity monitoring instructions and tracking	10

Table 1b. Examples of SOL-Youth Parent Procedure & Interview Blocks

Exam Procedure	Estimated time (min)
Procedures, flexible sequence	32
Reception & MUE (Med Use/Supplements – collect from parent/legal guardian for each child), informed consent and assent	25
Anthropometry	07
Blocks of interviews, flexible sequence: A	10
24-hr dietary recall, supplements (confirm child's response)	10
Blocks of interviews, flexible sequence: B	31
Demographics – Parent (DPE)	06
Family Function (FFE)	03
ARSMA Scale (BAE)	03
Ethnic Affirmation and Belonging (EAE)	02
Acculturative Stress (ASE)	03
Family Meals (FME)	02
Parenting for Eating and PA – Parent (PPE)	12
Blocks of interviews, flexible sequence: C	17-22
Medical History – Parent (each child) (MHE)	05
Family Relationship – Parent (each child) (RPE)	03
Child Health Insurance – Parent (each child) (HCE)	02
School Type – Parent (each child) (STE)	01
Auth. Parenting Index – Parent (each child) (APE)	04
Pre-Migration of Child – Parent (each child, if needed) (PME)	02
Blocks of interviews, flexible sequence: D	21
SES – Parent (SPE)	06
Demographics – Partner/Spouse (DSE)	04
Health Insurance – Parent (HPE)	02
Familism (FAE)	02
Neighborhood SES (NSE)	01
Foods in the Home (FHE)	06
Blocks of interviews, flexible sequence: E	22
Food Security (FOE)	12
Food and Neighborhood Environment (FNE)	04
Barriers to Activity in Neighborhood (BNE)	03
Equipment Checklist in Home (ECE)	03

Visit Termination	20
Exit interview & Incentive	10
Activity monitoring instructions and tracking	10

The termination of the examination visit also represents a fixed sequence to assure that a DMS-based data inventory is run to prevent inadvertent omissions in data collection. Clinically relevant study results available at this point are reviewed with the parent/legal guardian of the child, and the instructions for the physical activity monitor are discussed with the study participant prior to departure. The parent/legal guardian will have the option to have results discussed with the child(ren) in the room or with just the parent/legal guardian. Modification of a fixed sequence is a matter of study protocol and requires SOL Youth Steering Committee approval.

The start and end time of individual procedures and of blocks of interviews are recorded on the Clinic Exam Checklist Form (CKP/CKC), as well as the completion of status of individual tasks. While the DMS tracks both the completion status and clock times for procedures and interviews, recording the information on the Clinic Exam Checklist Form (CKP/CKC) provides a convenient visual record as different study personnel interact with the study participant in the course of the field center visit. The sequence and timing of data acquisition documented on the Clinic Exam Checklist Form (CKP/CKC) serves additional purposes: it reminds study personnel of a participant's special needs or medical conditions; it serves to monitor the amount of time it takes to complete each component of the examination; it provides the study personnel with information about where the participant is in the process; it can be used to indicate the participant's pre-established sequence of procedures and interviews, and it serves to record unforeseen events.

Because of the length of the field center examination visit, participant comfort and safety are of concern. Interviewers and technicians are attentive to signs of fatigue or physical and/or emotional discomfort. When any one of these conditions is observed, participants are offered the opportunity to rest. The termination of any interview or procedure is documented on the participant's Clinic Exam Checklist Form (CKP/CKC).

8. RECORDING MEDICATIONS AND SUPPLEMENTS

The Medication Use Questionnaire (MUE) records all prescription and over-the-counter medications, including cold and allergy medications, vitamins, herbals or supplements used by participants (children only) in the four weeks preceding their interviews. The MUE and the Question-by-Question instructions for its use are found in the Appendix under this section heading. The survey ascertains usage of up to 10 medications. Ascertainment includes scanning of twelve-digit Universal Product Code (UPC) bar code symbols when available. Medical Therapeutic Classification (coding) is automated where possible. Otherwise, manual coding is centralized (performed only in the Coordinating Center).

The goal of the MUE is to ascertain usage of all prescription and over-the-counter medications, vitamins, herbals, and supplements. This information assists in measuring patterns of medication use in the study communities, temporal changes in medical care practice, diagnostic classification of cardiovascular diseases, interpretation of laboratory results, and predictors of study end points.

8.1. Administration of the MUE

The MUE is divided into two major sections: (A) Reception and (B) Medication Record, administered as described below. Section A should be administered to the parent of the child participant close to the beginning of the examination. To reduce the length of the visit it is important that staff complete section B, Medication Record, while the participant is occupied with interviews or procedures but still on site so any issues can be resolved in person.

8.1.1. Reception

Trained and certified study personnel places identification labels on the participant's medication bag and MUE. Once the medication bag is logged and labeled, the interviewer checks with the participant's parent to determine if it contains any medications that require refrigeration. Medications that require refrigeration are labeled with the child participant's ID and placed in the refrigerator. The interviewer then determines and records whether the participant's parent has brought in all medications taken within the last four weeks. If the participant's parent has not brought in any (all) medications, the interviewer inquires to differentiate between non-compliance with pre-visit instructions or non-use of medications in the prior four weeks. In case of inadvertent omissions, the interviewer makes arrangements for obtaining the information, preferably by having the participant's parent return at a later date to the Field Center with the medications for scanning or transcription. The interviewer records deliberate omissions of medications on the MUE and on the Clinic Exam Checklist Form so that the interviewer can attempt to convince the participant's parent to bring in omitted medications. Staff can administer subsequent parts of the MUE during Reception (if the work area affords the opportunity for maintaining confidentiality) or later, in areas of the field center usually designated for conducting interviews.

8.2. Medication Record

The interviewer first verifies that the name on the medication bag matches the child participant's name. Then the interviewer removes all medication containers from the medication bag and places them on the work area. When there are more than 10 medications for scanning / transcription, staff uses the following algorithm to guide prioritization: [1] prescription

medications; then [2] aspirin, aspirin-containing medications and anti-inflammatory drugs (see Appendix, Question-by-Question instructions, List #1 and List #2); followed by [3] over-the-counter medications; and finally [4] vitamins, herbals, and supplements.

The interviewer scans / transcribes the UPC (part a of Items 5-14) into the Data Entry System. The Data Entry System will try to match a Medical Therapeutic Classification (MTC) to the UPC. If MTC-UPC matching is successful, the Data Entry System will skip the rest of the fields (parts b-d) for this medication item and move to the next medication. If an UPC is not available or the Data Entry System does not successfully match the UPC, the interviewer transcribes the medication National Drug Code (NDC) (part a). If an NDC is not available or the Data Entry System does not successfully match the NDC, the interviewer transcribes the medication name (part b), strength (part c) and units (part d).

If this is done in the presence of the study participant's parent the interviewer shows each medication to the participant's parent as it is scanned / transcribed, while keeping the other medications in view. The interviewer verifies scanned / transcribed information against container labels, making corrections when necessary to ensure accuracy. If a bar code label is not on the medication container or a bar code cannot be successfully scanned and a medication name exceeds the number of spaces for the medication name (b) in the Data Entry System, the interviewer starts writing the name using as many spaces as are available without abbreviating the name in any other fashion. After successfully scanning / transcribing each medication, the interviewer returns corresponding containers to the medication bag to minimize confusion and to assure that all medications are returned to the participant's parent.

Loose pills and medications in containers that are unmarked are examined only in the presence of the participant's parent. With his/her permission and help, the interviewer examines loose pills and unclearly labeled containers, or those which hold more than one medication (e.g. medisets). The interviewer uses pill imprints, the Facts and Comparisons Drug Identifier on the desktop computer, and the Ident-A-Drug Reference on the web to identify these medications.

8.3. Training

Interviewers are centrally trained and when certified, assume responsibility for providing local staff training in medication scanning / transcription.

8.4. Certification

Interviewers are certified to administer the MUE by attending the central training, completing the scanning / transcription exercise designed by the central trainer, and passing with a score of $\geq 80\%$. New staff, unable to attend central training, are eligible for remote certification when:

- The candidate is trained by the lead certified interviewer at the corresponding Field Center.
- The candidate has completed five taped interviews demonstrating adequate technique based on review and approval by the lead interviewer.
- The Study Coordinator has submitted a request for certification to the Coordinating Center on behalf of the candidate.

- The Coordinating Center has sent to the Study Coordinator a mock medication bag with detailed instructions for the candidate's certification.
- The candidate independently completes an MUE and enters it into the Data Entry System.
- The Study Coordinator returns the medication bag with all of its contents, the instructions, and printouts of the MUE screens to the Coordinating Center for evaluation.
- The candidate passes with a score of $\geq 80\%$.

8.5. Quality Assurance

With participant's parent's approval, most staff-administered interviews are taped for quality control. The Coordinating Center Monitors also observe technique and adherence to protocol. The Quality Control Committee monitors data quality semi-annually.

8.6. Data Collection

The MUE is designed to be interviewer-administered and collected by direct data entry unless a workstation is not available. A paper version of the form is available for back-up and delayed data entry. Medication UPC/NDCs (part a of Items 5-14), medication names (part b), strengths (part c), and units (part d) are listed alphabetically in hard copy and Data Entry System versions. Details of data collection are provided in the Question-by-Question instructions for the MUE (see Appendix).

9. ANTHROPOMETRY

Anthropometric measures include height, weight, waist and hip circumference and body fat. These measures are used to assess the relationship between obesity and risk of disease. We will obtain anthropometry measures from every child enrolled in the study and his/her parent/guardian.

The procedures outlined in this document are applicable for both children and adults.
Parents do not need to fast for this procedure.

9.1. Equipment and Supplies

The equipment and supplies necessary for body measurements are as follows:

- Tanita Body Composition Analyzer, TBF-300A
- Wall mounted stadiometer
- Gulick II 150 and 250 cm anthropometric tape
- Full length mirror
- Balance weight scale (available at all times as back up)
- Calibration weights (10 kg)
- Antiseptic wipes
- Markers (i.e. to mark bony landmarks for waist circumference)
- Saline solution (any over the counter saline solution such as those sold for eye care) or water
- Plastic dropper for the saline solution or water

9.2. Staff

The examiner is responsible for positioning the participant, taking each measurement, and inputting the information into the computer data entry system. The data entry system is programmed to flag any out-of-range messages; the examiner is responsible for verifying data collection by repeating the measurement protocol and double-checking his/her data entry. To ensure that all possibilities for the out-of-range message are considered (i.e., measurement error vs. data entry error), data entry will ideally take place with the participant present and before he/she moves to the next measurement in the protocol. Once data entry is verified, the examiner proceeds to the next measurement in the sequence established by the protocol.

9.2.1. Anthropometry Form (ANT)

The ANT form records anthropometry measurements in three sections: (A) ability to stand, pregnancy and safety questions, (B) height, (C) weight and bio-impedance output values from the Tanita scale (D) body circumference measures. If a participant cannot stand with both feet, only the body circumference measures are taken. Height, waist, and hip circumferences are to be repeated 3 times by the same examiner and all these repeated measures must be documented on the ANT form. As the technician progress through the examination procedures, they will record results into the ANT form. Ideally, data entry into the computer should be completed before the participant moves to the next stage.

IF MOTHER/GUARDIAN OF CHILD IS PREGNANT, EXCLUDE THEM FROM ALL ANTHROPOMETRY MEASURES. OBTAIN SELF-REPORTED HEIGHT AND WEIGHT INSTEAD.

ASKING ABOUT PREGNANCY IN GIRLS IS ACQUIRING SENSITIVE INFORMATION. THIS INFORMATION IS PROTECTED BY LAW IN THE STATES OF CALIFORNIA, FLORIDA, ILLINOIS AND NEW YORK. THIS QUESTION HAS TO BE ASKED ENSURING TOTAL PRIVACY. THE GIRL MUST BE ALONE, AND THE EXAMINER HAS TO REASSURE HER THAT THE INFORMATION SHE PROVIDES WILL BE KEPT STRICKLY CONFIDENTAL, UNLESS THE CHILD IS IN DANGER.

BEFORE ASKING QUESTION ABOUT PREGNANCY. THE EXAMINER READS TO THE CHILD THE FOLLOWING STATEMENT:

In the state of [CA, FL, IL, NY] some information a child reports is confidential which means that we cannot tell this information to your parents without your permission. This includes information about pregnancy. The only exception to this is if you are in danger of hurting yourself or others or if others have hurt or threatened you. In this case we would want to make sure you get the help you need from adults that can help you.

IF GIRL IS PREGNANT, CONTINUE WITH ALL ANTHRO MEASURES, BUT USE THE TANITA SCALE IN WEIGHT MODE ONLY. NOTE IT ON THE ANT FORM. REMEMBER THAT A GIRL HAS THE RIGHT TO HER PRIVACY. **EXAMINERS CANNOT DISCLOSE THIS INFORMATION TO HER PARENT.**

9.3. Examination Procedures

For all measurements, participants should wear light clothing but no shoes (thin socks or pillow slippers are OK). Ask participants to empty their pockets and remove their belt, jacket, heavy sweater, watches and jewelry or accessories (e.g. hair piece) that could affect weight measurement.

9.3.1. Standing Height

Standing height is an assessment of maximum vertical size. Standing height is measured with a fixed (wall mounted) stadiometer with a vertical backboard and a moveable headboard. Have the participant remove his/her eyeglasses. If a participant has a hair accessory or hairstyle which interferes with the measurement, she will be asked to remove the accessory or change her hairstyle (e.g., take out ponytail band). If she/he refuses to comply with regard to hairstyle or accessory, the participant will still be measured, following the procedure in Section 11.3.3. Make a note in the comment section of the data collection form, stating ‘inflexible hairdo.’

Have the participant stand on the floor (see Figure 1) with the heels of both feet together and the toes pointed slightly outward at approximately a 60° angle. Make sure the body weight is evenly distributed and both feet are flat on the floor. Check the position of the heels, the buttocks,

shoulder blades, and the back of the head for contact with the vertical backboard. **Make sure the child is not standing on his/her tiptoes; that shoulders are not shrugged and buttocks are not pushed out.**

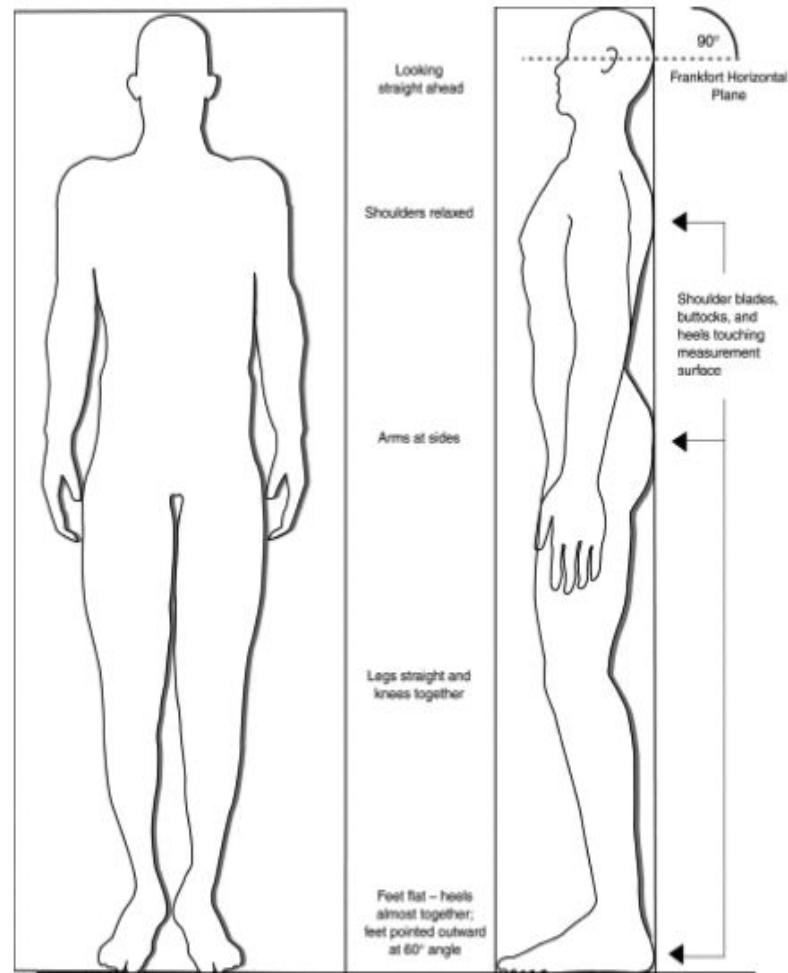
Depending on the overall body conformation of the individual, all points may not touch. In such case, make sure the participant's trunk is vertical above the waist, and the arms and shoulders are relaxed.

Align the head in the Frankfort horizontal plane. The head is in the Frankfort plane when the horizontal line from the ear canal to the lower border of the orbit of the eye is parallel to the floor and perpendicular to the vertical backboard. Many people assume this position naturally, but for some it may be necessary to make a minor adjustment. If required, gently tilt the head up or down until proper alignment is achieved with eyes looking straight ahead. Once correctly positioned, lower the headboard and **instruct the participant to take a deep breath and stand as tall as possible (for example, you can say to the child “hold your breath and stand straight like a soldier”)**. A deep breath allows the spine to straighten, yielding a more consistent and reproducible stature measurement.

Position the headboard firmly on top of the head with sufficient pressure to compress the hair. Then have the participant relax and step away from the stadiometer and record the participant's height on the computer system. The examiner should read the height at eye level to avoid parallax; a small stool may be required. Repeat the height two more times, to complete 3 measures for each participant.

Some participants may have conditions that interfere with the specific procedure for measuring stature. One of the more common conditions is kyphosis. Kyphosis is a forward curvature of the spine that appears as a hump or crooked back condition. In these cases it is important to get the best measure possible according to the protocol. If a participant cannot stand erect or cannot stand on both feet, choose the appropriate code on the first section of the form (Section A. Q1 Determination of ability to stand).

Figure 1. Position for Standing Height



9.3.2. Inflexible hairdo:

There may be occasions when a participant's hairdo is inflexible, cannot be "taken down," and interferes with the measurement of standing height. If the hairdo appears to be less than $\frac{1}{2}$ cm above the top of her head, measure his/her height according to the standard protocol by compressing the hairdo down with the sliding part of the height board as far as you can without making the subject uncomfortable. An example of this would be a subject who has cornrows (e.g. braids laid in rows that are tight to the scalp) in his/her hair or a Mohawk (e.g. hair standing up in a stripe down the center of the hair) that is secured firmly in place by hair gel that the participant does not want disturbed. On those occasions where the hairdo is higher than $\frac{1}{2}$ cm and is inflexible, follow the modified procedure for measuring height outlined below:

- Position the participant according to the standard protocol.
- With the head in the Frankfurt plane, and viewing the head from the side, identify as accurately as possible the crown (i.e., the highest point of the skull, where height would usually be measured). It may help to palpate the top of the head, around the inflexible hairdo.

Ask permission to touch the participant. If the hairdo covers the crown, palpate around the hairdo and “estimate” the location of the crown. If you are unable to tell where the crown is, ask the participant to locate it. Make the best guess you can.

- c. Position a straight edge adjacent to the crown, parallel to the floor, along the level of the crown, so that the end contacts the ruler on the stadiometer. Adjust the head into the Frankfurt plane, and then measure the height using the movable headboard.
- d. Read and record height according to the standard protocol.
- e. Note in the comments section of the form “inflexible hairdo.”

9.3.3. Weight and Body Composition

The participant’s weight and body composition analysis are measured using the Tanita scale. This scale calculates the weight of the participant and using a bioelectrical impedance method provides percentage body fat, fat mass, lean body mass and total body water. All these measures are recorded on the SOL Youth Anthropometry Form in section C Q3 through Q8.

IMPORTANT: BEFORE USING THE SCALE MAKE SURE TO ASK THE PARENT THE SAFETY QUESTIONS. PARTICIPANTS WITH A PACE MAKER OR OTHER INTERNAL ELECTRONIC DEVICE (E.G. DEFIBRILLATOR, COCHLEAR IMPLANT) SHOULD BE MEASURED IN ‘WEIGHT ONLY’ MODE.

The control panel of the Tanita scale is depicted in Figure 2. A number of settings must be specified before using the scale for the first time. Once the settings are selected, these are recorded automatically and there is no need to make changes. Just press ON/OFF key to start.

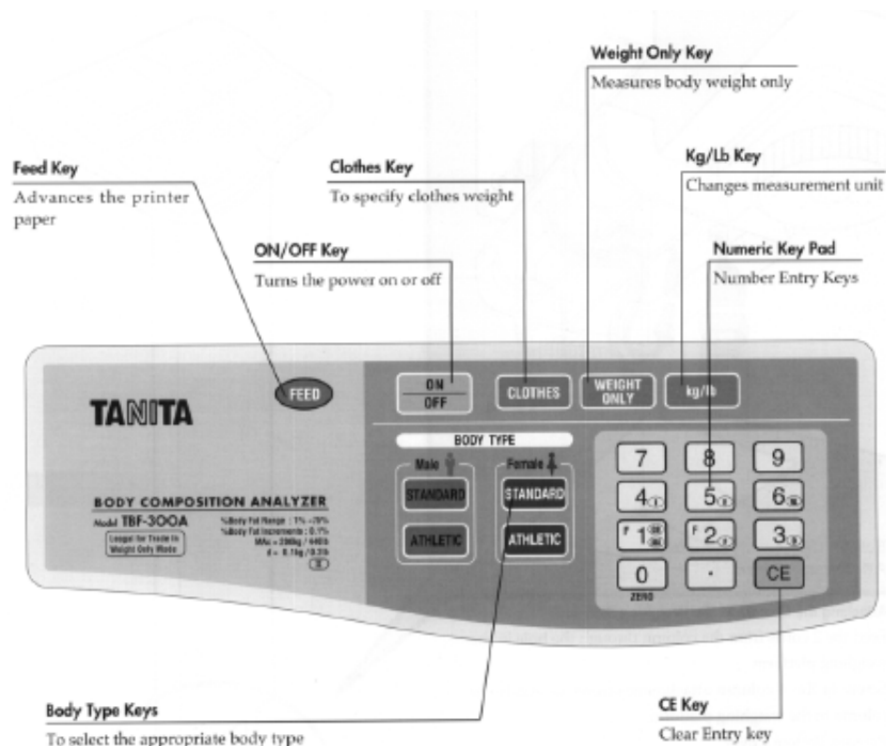


Figure 2. Control Panel of Tanita Body Composition Analyzer, TBF-300A

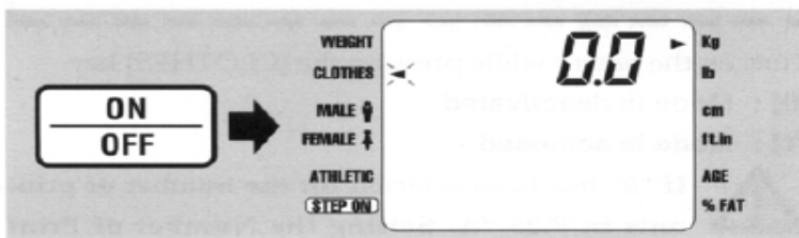
a. Initial set up

1. Place the scale platform on a flat and level surface as possible, preferably not on carpet. Don't worry if balance bubble indicates it is not exactly leveled.
2. Connect the keyboard to the scale with the gray cord attached to the scale and plug it into the back of the keyboard in the socket marked "input."
3. Connect the keyboard to an electrical outlet using the black power cord and AC adapter. Plug the black cord into the socket on the back of the keyboard marked "DC5V."

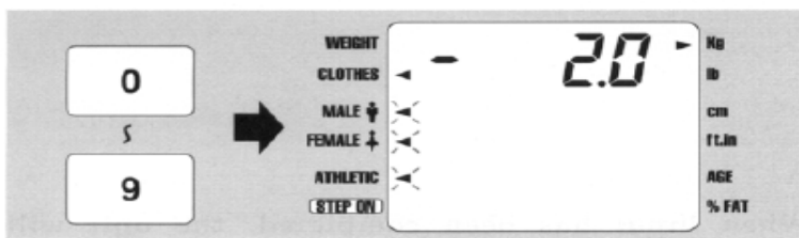
b. Setting the number of print outs and printing language

Press and hold the 0 key, and press the ON/OFF key once. Release the 0 key after "Prt-1" is displayed on the screen. Select 0 (no print out). When no print out is selected there is no need to select the printing language. The panel will switch to the measurement screen.

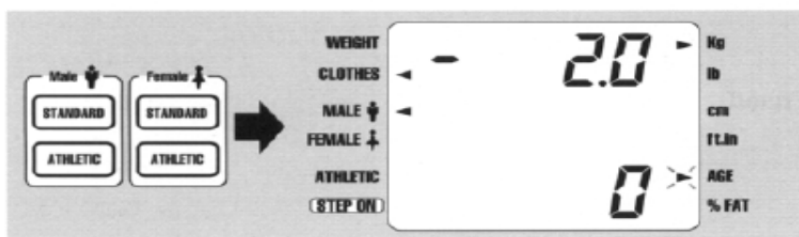
Operating instructions



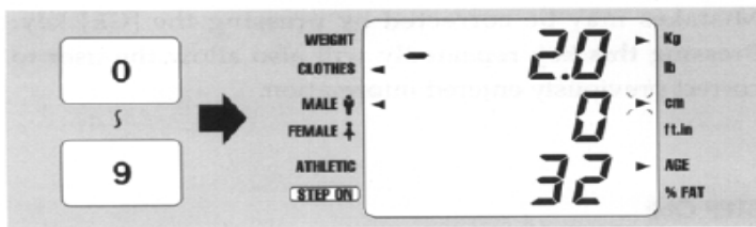
Press ON/OFF key to turn the machine on. Wait until 0.0 and an arrow appear on the screen. Check that the arrow points to "Kg". If arrow point to "lb", press the Kg/Lb key on the control panel and the arrow will shift to "Kg"



Enter Clothes weight: 1.0 kg using the numeric pad on the control panel



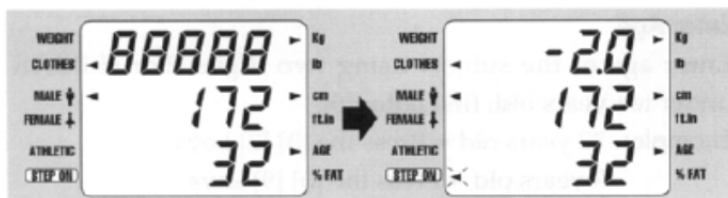
Select Gender and Body type: Standard Female or Standard Male



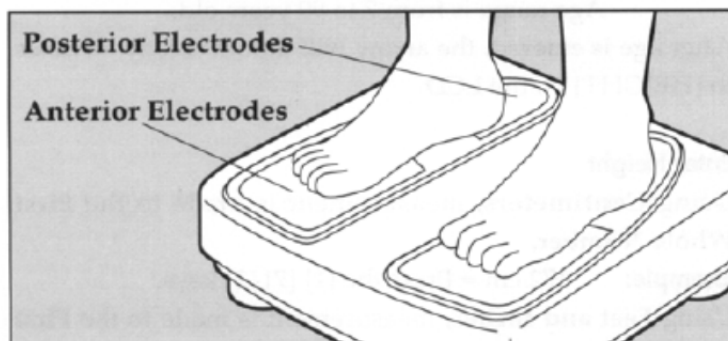
Enter age of participant using the numeric pad of the control panel. After age is entered, the arrow will direct you automatically to enter the height.



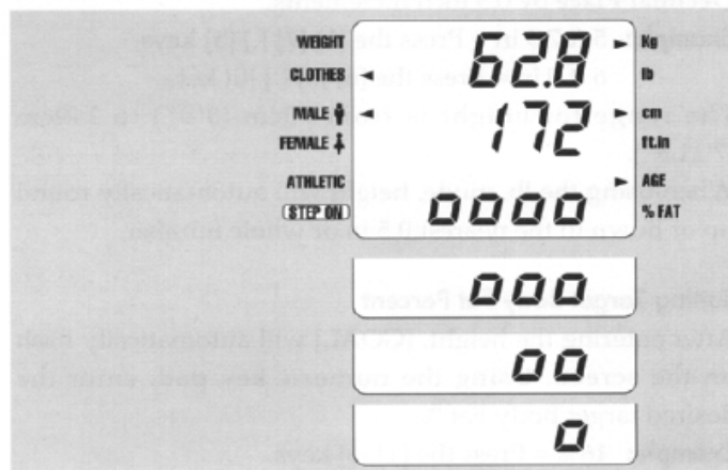
Enter height in cm. For example, for 172 cm, press the [1] [7] [2] keys. The height entered should be the repeated height (of the 3 measures) from the standing height measures (section 9.3.1).



Mistakes may be corrected by pressing the [CE] key. Pressing this key repeatedly will allow correcting the previous information



Wait until the screen displays “88888” and then ask the participant to step on the scale. Participants should be bare-foot. Each foot should be touching both the heel and toe plates, with weight evenly distributed on both feet.



Weight will be displayed on the upper section of the screen. After weight stabilizes, impedance measurement is taken. Bubbles “oooo” will appear on the bottom half of the screen as these measurements are being analyzed. Once body composition measurements are ready, the bubbles will disappear one by one. Record weight and each body composition measurement including impedance on the Anthropometry form. Ask the participant to step off the scale.

If the screen returns to “----” for weight, the participant weighs more than 440 lb. Record 999.9 for weight and 99.9 for % body fat on the data form.

If screen returns error messages **E-01** or **E-16** it means that the unit could not get a good reading, either because: 1) the participant stepped off the scales before the beep; or 2) the participant was wearing socks or has thick calluses on his/her feet. If the problem appears to be #1, just repeat the measurement procedure.

If the problem appears to be #2, place a drop or two of saline solution or water on each scale plate to help signal conduction. If the error messages appear again after adding saline, turn the unit off, turn the unit on, press **WEIGHT ONLY**, and only record a weight on the data form. Record **99.9** for % body fat on the data form.

Once measurements are completed, the machine will automatically return to the Gender and Body Type screen in about 10 seconds. Leave keyboard on. Wipe off plates on scale with antiseptic wipes. You can then measure the next participant.

IMPORTANT: PARTICIPANTS WITH A PACE MAKER OR OTHER INTERNAL ELECTRONIC DEVICE SHOULD BE MEASURED IN ‘WEIGHT ONLY’ MODE.

Do not weigh participants who have a cast that cannot easily be removed, or that the participant is comfortable removing, if larger than a finger splint. If a participant has a prosthetic limb, measure weight with limb in the “Weight Only” mode, make a note in the comment section of the form.

In the event of a power outage or if the scale is not functioning properly, notify the project manager. Participants may need to come back on a different day to complete this measure.

9.3.4. Waist Circumference

To define the level at which the waist abdominal circumference is measured, you must first locate the lateral and superior border of the ilium (bony landmark). Have the participant stand and hold their t-shirt above the waist. Lower the pants and underclothing of the participant slightly, and standing behind and to the right of the participant, palpate the hip area to locate the right ilium (see Figure 3). If the participant or caregiver refuses to have the shirt raised, the measurement may be taken over light clothing, with this indicated in the ‘comments’ section.

Draw a horizontal line just above the uppermost lateral border of the right ilium and then cross the line to indicate the midaxillary line of the body.

Standing on the participant’s right side, place the measuring tape around the trunk in a horizontal plane at the level marked on the right side of the trunk.

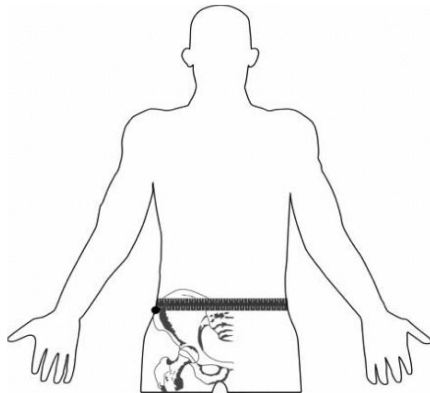
Hold the zero end below the measurement value. Make sure that the tape is parallel to the floor and that the tape is snug, but does not compress the skin. Use the wall mirror to ensure correct horizontal alignment of the measuring tape.

Ask the subject to take in a normal breath and let it out normally.

Make the measurement at the end of a normal expiration and round it to the nearest cm. Three measurements should be made. At the end of each measurement, exam staff should remove the tape from the waist, record the measurement, and then continue with the hip measurement.

We will obtain 3 waist and hip measurements per participant. If the three measures vary by more than 2 centimeters, the protocol should be repeated again collecting three new measurements.

Figure 3. Measuring tape position for waist circumference



9.3.5. Hip Circumference

Instruct the participant to stand erect but relaxed, with weight distributed equally over both feet. The hip girth is measured at the level of maximal posterior protrusion of the gluteal muscles (buttocks). Keep the anthropometric tape horizontal at this level and record the measurement to the nearest centimeter.

The greatest source of error for this measurement is due to not having the tape horizontal. Before making the measurement the observer verifies the position of the tape from both the front and back to assure its correct position and that the tape is horizontal. Use the wall mirror to confirm that the tape is horizontal.

The tape should be snug, but not tight enough to compress tissue. The measurement should be made at the right side of the participant.

Three measurements are made. At the end of each measurement, exam staff should remove the tape from the hip, record the measurement, and then obtain the next waist measurement. Repeat until 3 sets of waist/hip measures are completed. If the three measures vary by more than 2 centimeters, the protocol should be repeated again collecting three new measurements.

Figure 4. Measuring tape for hip measurement



9.4. Quality Assurance/Quality Control

9.4.1. Calibration Procedures and Equipment Check

The Tanita scale is calibrated weekly or when moved. Calibrate the scale by pressing **WEIGHT ONLY** key. Make sure the arrow pointing to weight is in Kg units.

Place the calibration weight (10 Kg) in the middle of the scale, and record the weight indicated on the LED in the daily log. If the calibration weight is less than 8.5 kg or more than 11.5 kg, use the back-up scale, and notify the clinic coordinator to have the scale recalibrated by the manufacturer or by the appropriate institution personnel.

Wipe off plates on scale with antiseptic wipes.

Turn off scale by pressing the ON/OFF key. **The unit needs to be turned off after running in the “WEIGHT ONLY” mode before it can be used for body composition determinations.**

Examine anthropometry tapes on a weekly basis for sign of wear.

Each day check that headboard of the stadiometer moves up and down the track smoothly.

9.4.2. Training, Certification and Quality Control

Field technicians or examiners are centrally trained in all anthropometric measures. Technicians who cannot attend the central training can be trained and certified locally by the clinic coordinator. Each technician performs a minimum of 3 observed procedures to receive certification. Agreement between the expert and the trainer must be within 0.5 cm for height, 0.5 kg for weight, and 1 cm for the waist/hip measurement.

Technicians are observed by the clinic coordinator twice monthly for the first month and then quarterly, to ensure standardization. The Supervisor Checklist is used to document these observations and deviations from the protocol are reviewed with the technicians. A minimum of 4 procedures every month is required in order to maintain certification.

Following a schedule set by the Quality Control Committee a sample of participants is automatically selected by the data management system software during data entry for repeat measurements by a different technician during the examination visit and recorded on the Anthropometry Quality Control form (AQC). Inter-technician agreement serves as a criterion for recertification. Retraining sessions are scheduled when a lack of standardization is observed among the technicians.

References

NHANES Anthropometry Procedures Manual (http://www.cdc.gov/nchs/nhanes/nhanes2003-2004/exam03_04.htm)

Tanita Body Composition Analyzer TBA-300A/TBF-300/310/410. Instruction Manual. Tanita Corporation, Tokyo, Japan (<http://www.tanita.com/en/tbf-300a/>; last accessed 9/12/2011)

Q x Q ANTHROPOMETRY FORM (ANT) AND SCRIPTS

Instructions: Enter the answer given by the participant for each response. If a response is unknown or cannot be measured then enter the special missing value, “==”, in the item. In order to measure bioimpedance, the participant must be barefoot. Set the Tanita analyzer to report *metric* units (cm/kg).

GENERAL INSTRUCTIONS:

The same ANT form is used to record anthropometry form for both children and their parents. However, one form should be completed for each individual. That is, fill out one form for the child, and another separate form for the parent.

Also, as described below, parents have to answer the question about internal electronic devices for themselves and for their children. Children, especially young children may not report this information adequately, thus, it is better to ask the parent.

Before the start of the procedure introduce yourself to the participant if this is the first time you are seeing him/her:

Hi, my name is *[your name]* and I am going to be doing some measurements..

I’m going to measure how tall you are on the board right there *[point to the board]*, how much you weigh on the scale *[point to the scale]*, I’m going to measure your waist and hip *[point to your waist and hip]*, and I’m going to do all these measures 3 times.

Can you please take everything out of your pockets and take off any jewelry you have on and put everything in this basket. Please take your shoes off too. *[If the participant is wearing a sweater, sweatshirt, or jacket over his/her shirt, ask him/her to remove it also to reduce excess weight. Make sure belts, cell phones, etc. are removed as well.]*

Before I take your measures I need to ask you some questions about you and your child *[proceed to safety questions as described below]*

A. SAFETY QUESTIONS

Q1. This question is always answered by parents/legal guardians.

If you are taking measures on the parent, ask:

Do you have either a heart pacemaker or defibrillator or any other internal electronic device inserted in the body that you cannot remove?

If you are taking measures on a child, you should ask the parent not the child:

Does your child has either a heart pacemaker or defibrillator or any other internal electronic device inserted in the body that you or your child cannot remove?

If a participant's answer YES, then use the Tanita Scale in weight only setting.

Other examples of internal electronic device include cochlear implants, insulin pump. However, if the child has an insulin pump, ask if the child has Type 1 diabetes (also called juvenile diabetes). A child with type 1 diabetes is not eligible for SOL Youth. Notify the study coordinator.

Q2. This question applies only to mothers or female legal guardians. For parents or male legal guardians, skip and go to Q2.

If the mother/female guardian is pregnant, ask questions 2b and 2c. Skip anthropometric measures (skip section B).

If mother/female guardian is not pregnant, continue with the rest of the protocol/form.

Q3. This question applies only to girls between 10 and 18 years old. SKIP this question for girls < 10 years old and for boys.

ASKING ABOUT PREGNANCY IN GIRLS IS ACQUIRING SENSITIVE INFORMATION. THIS INFORMATION IS PROTECTED BY LAW IN THE STATES OF CALIFORNIA, FLORIDA, ILLINOIS AND NEW YORK. THIS QUESTION HAS TO BE ASKED ENSURING TOTAL PRIVACY. THE GIRL MUST BE ALONE, AND THE EXAMINER HAS TO REASSURE HER THAT THE INFORMATION SHE PROVIDES WILL BE KEPT STRICTLY CONFIDENTIAL, UNLESS THE CHILD IS IN DANGER.

BEFORE ASKING QUESTION ABOUT PREGNANCY. THE EXAMINER READS TO THE CHILD THE FOLLOWING STATEMENT:

In the state of [CA, FL, IL, NY] some information a child reports is confidential which means that we cannot tell this information to your parents without your permission. This includes information about pregnancy. The only exception to this is if you are in danger of hurting yourself or others or if others have hurt or threatened you. In this case we would want to make sure you get the help you need from adults that can help you..

IF GIRL IS PREGNANT, CONTINUE WITH ALL ANTHRO MEASURES, BUT USE THE TANITA SCALE IN WEIGHT MODE ONLY. NOTE IT ON THE ANT FORM. REMEMBER THAT A GIRL HAS THE RIGHT TO HER PRIVACY. **EXAMINERS CANNOT DISCLOSE THIS INFORMATION TO HER PARENT.**

B.1. Establish ability to stand erect according to procedures outlined in section 9.3.1. of MOP #1.

B2.-D. Follow procedures outlined in chapter 9 of MOP #1.

B.2. HEIGHT MEASUREMENT

OK, first I'm going to measure your height.

[If the person has a hair accessory or hair is up, ask them to remove it. If it would be too difficult to remove or if he/she refuses, allow him/her to keep it in and follow the instructions in Section 9.3.2. "Inflexible hairdos" (depending on the hairdo) and write "inflexible hairdo" in the 'comments' section on the ANT form.]

Please step backward onto the board until the first part of your body touches the board (like your heels, shoulders, or bottom). Now, bring your feet toward each other like this [demonstrate for them] until your ankles or knees touch each other, whichever touch first. Stand up nice and tall against the board. Put your arms straight down at your sides with your palms facing in [like this & demonstrate].

[Check that the participant is properly aligned, both from front and from left side.]

Now, I am going to position your head so you can be the tallest you can be. I will tell you to move it up or down, just move it a little at a time.

[Position head in the Frankfurt horizontal plane so an imaginary horizontal line can be drawn between the bottom of the eye socket and the center of the opening of the ear.]

Please keep your head just like that until we finish. Now, hold your head still, keep your feet flat on the floor, and take a deep breath and hold it. Stand up nice and tall.

[Verify body is properly aligned and head position did not shift with deep breath. Move the headboard down onto the head with sufficient pressure to compress hair. Record the height on the form.]

Now let your breath out and you can step off the board.

C. WEIGHT MEASUREMENT

Now, I'm going to measure your weight. Please do not step on the scale until I ask you to.

[Follow procedures for starting the scale described in section 9.3.3 of Mop #1]

Ok, please step onto the scale. Stand with your feet next to each other in the center of the scale. Make sure your weight is balanced between your two feet. Keep your hands at your sides and look straight ahead at the [sticker or poster or any other reference point] on the wall.

Great! Now you may step off the scale.

D. WAIST MEASUREMENT

Next I am going to measure your waist and your hip.

I need to take a look at your waist and hip for these measurements. Can you please lift up your shirt just above your belly button and hold it for me so that it is out of the way?

Also, to make sure I get it right; could you point where your hip bone is? Just to make sure I have it right, I need to make some marks on your hip with this marker *[show the marker]*. **It will not hurt, and you can take it easily right after we are finish.**
Now I am going to put this tape measure around your waist so I can measure it. Please bring your feet together *[they should be just slightly apart]*, **stand up straight.** *[Wrap tape measure around participant's waist as described in the protocol. Adjust as necessary.]*

I just need to make sure the tape is in the same place in the front and back. *[Get tape in place in one horizontal plane around the entire waist.]* **Now take a nice, easy breath in and let it out.** *[Once the child lets his/her breath out, take the measurement at the end of the exhale.]*
[Remove tape from around waist, and record measure.]

Great, now I need to take your hip.

Now we are going to do each of those measures two more times.

I need to do some math really quick to be sure I did all of the measures okay? *[Verify that the measures for all 3 are within the edit specifications. If not, perform an additional set of measures as necessary.]*

Thank you so much for all of your help today with our measures. You did a great job! Go ahead and put your shoes back on *[and remind to collect or put on anything else they removed]* **now we have a few other things to complete** *[continue with the rest of the protocol]*

10. SITTING BLOOD PRESSURE

10.1. Introduction, Equipment and Supplies

Because accurate blood pressure measurements are critical for the estimation of the national prevalence of high blood pressure for different age, ethnic and sex groups, it is important to use state-of-the-art measurement techniques that are comparable to other national datasets. For many years the “gold standard” blood pressure measuring device has been the mercury sphygmomanometer. However, because of the recent increase in awareness of the serious adverse health effects of mercury contamination in the environment, many institutions, including the National Institutes of Health, have banned or discouraged the continued use of mercury sphygmomanometers and thermometers. Further, the Environmental Protection Agency (EPA) and the American Hospital Association (AHA) have taken steps to eliminate mercury-containing waste by 2005. For these reasons, many institutions and clinics have switched to alternate sphygmomanometers such as aneroid or automated devices that do not contain mercury. In line with these developments and for the best repeatability of measurements, a tested, automatic sphygmomanometer (the OMRON HEM-907 XL) is used in SOL Youth. This model has been validated in 4 other studies, including CARDIA, NHANES, and HCHS/SOL. Field center technicians are responsible for verifying that all equipment and supplies are in the examination room.

<u>Equipment</u>	<u>Supplies</u>
OMRON HEM -907XL	Wipes
sphygmomanometer	Alcohol
4 cuffs	Tissues
Gulick II tape measure	Water soluble ink pens
Foot stool	Gauze (4 x 4)
Room Thermometer	

Figure 4 OMRON sphygmomanometer and 4 cuffs



OMRON HEM907XL – with four cuffs

10.1.1. The Sitting Blood Pressure (SBP) form

The SBP form records arm measurements used to guide blood pressure cuff size selection and serial measurements of both blood pressure and pulse rate. The form is divided into five corresponding sections: (A) Arm Measurements and (B-E) the Average and First-Third Blood Pressure / Pulse Rate.

10.2. Blood Pressure Measurement Procedures

The technician greets the child participant and explains that his/her blood pressure will be measured next. To choose the appropriate cuff size the participant's arm will be measured first, followed by a period of quiet rest and three blood pressure measurements taken by a machine. The technician asks if the participant has questions, following which the participant is reminded that the results of the measurements will be provided at the end of the visit with a printed report.

10.2.1. Selection of the Arm

For the purpose of standardization, both pulse and blood pressure are measured using the right arm unless specific participant conditions prohibit the use of the right arm, or, if participant self-reports any reason that the blood pressure procedure should not use the right arm. If the measurements cannot be taken in the right arm, they are taken in the left arm. Use of the right or left arm must be recorded on the SBP form in Item A.1. Measurements are not done on any arm that has rashes, small gauze/adhesive dressings, casts, are withered, puffy, have tubes, open sores, hematomas, wounds, arteriovenous (AV) shunt, or any other intravenous access device. In all cases, if there is a problem with both arms, the blood pressure is not measured.

10.2.2. Cuff Size Selection and Application

It is important to select the appropriate size cuff that properly fits the participant's arm. The length and width of the bladder inside the cuff should encircle at least 80 percent and 40 percent of an arm respectively. The index lines on the cuff are not used in this study. Using a centimeter tape, determine the midpoint of the upper arm by measuring the length of the arm between the acromion and olecranon process (between the shoulder and elbow).

10.2.3. Measurement of Arm Circumference

Have the participant remove his/her upper garment or clear the upper arm area so that an unencumbered measurement may be made.

- i. Have the participant stand, with the right arm hanging and bending the elbow so that the forearm is horizontal (parallel) to the floor.
- ii. Measure arm length from the acromion (bony protuberance at the shoulder) to the olecranon (tip of the elbow), using the Gulick II anthropometric tape.
- iii. Mark the midpoint on the dorsal surface of the arm.
- iv. Have the participant relax arm along side of the body.
- v. Draw the tape snugly around the arm at the midpoint mark. NOTE: Keep the tape horizontal. Tape should not indent the skin.
- vi. Measure and record the arm circumference on the SBP form in Item A.2.

10.2.4. Choosing the Correct Cuff Size

Identify the measured arm circumference under column 1 in Table 3 below. Use the cuff size from column 2 associated with the arm circumference in column 1. (Example: If the arm

circumference at midpoint is 20 cm, use the small child cuff marked CS19.) Record the cuff size on the SBP form in Item A.3.

Table 3.

<u>Arm Circumference (cm)</u>	<u>OMRON CUFF SIZE</u>
17.0 to 21.9	index 17- 22cm (CS19)
22.0 to 32.5	index 22-32cm (CR19)
32.5 to 42.5	index 32-42cm (CL19)
42.6 to 50.0+	index 42-50cm (CX19)

10.2.5. Positioning the SOL Youth Participant and Placing the Cuff

Ask the participant to sit and rest quietly in the chair after adjusting it, if necessary, to allow participant's feet to rest flat on the floor when legs are in the uncrossed position. The technician then explains the next steps using the following script: "Before taking your first blood pressure reading, there will be a 5 minutes waiting period. When I inflate the cuff, it may feel tight and you will feel some pressure on your upper arm. While we are measuring your blood pressure, we ask you not to talk and I will not talk either because talking and moving changes your blood pressure. Do you have any questions?"

The right arm and back should be supported and the legs should be uncrossed with both feet flat on the floor. The right arm should be bared and unrestricted by clothing with the palm of the hand turned upward and the elbow slightly flexed.

The arm should be positioned so that the midpoint of the upper arm is at the level of the heart. The location of the heart is taken as the junction of the fourth intercostal space and the lower left sternal border. Small or short participants may have to raise their body to the correct position by changing the chair position up or down. If necessary, especially with short participants, place the participant's feet on the footstool provided to stabilize their feet in a flat position. Very tall participants may need to place their arm on a book or pillow to bring their upper arm to the correct position.

10.2.6. Locating the Pulse Points

Figure 5: Locating the brachial pulse



Locate the brachial artery by palpation and mark the skin with a small dot, using a black pen. (The brachial artery is usually found just medial and superior to the cubital fossa posterior to the biceps muscle and slightly towards the body). For brachial artery palpitation, fingertips or thumb may be used.

10.2.7. Wrapping the Blood Pressure Cuff around the Arm

Position the rubber bladder with the “art” label on the bottom of the cuff, just above the pen mark over the brachial artery pulse determined earlier at least 1” above the crease of the elbow. The cuff tubing should be at the outer (lateral) edge of the arm if the cuff is placed correctly.

For short or fat conical arms, if the cuff that matches the arm circumference is too wide to fit on the upper arm with space above the brachial artery pulse point at the cubital fossa then choose the next smaller cuff size and enter the cuff size chosen on the SBP form in Item A.3.

Figure 6: Placing the cuff. Place the “art” marker on the inner part of the cuff directly over the brachial artery. The cuff should be wrapped in a circular manner. Do not wrap the cuff in any spiral direction. Check the fit of the cuff to ensure that it is secure but not tight.

Figure 6



10.3. Procedure for the OMRON HEM-907XL

This protocol is written for use with the OMRON HEM-907XL automated blood pressure monitor. Special attention must be placed on assessment and maintenance of the instrument's accuracy as per the manual that accompanies the instrument. The design and operation of the OMRON HEM-907XL are based upon the combined principles of compression of the brachial artery under an elastic, inflatable cuff and estimation of the systolic and diastolic blood pressure levels by detection of oscillometric waves.

10.3.1. Setting up the OMRON

At a start of each session check that the monitor is attached to the AC adapter to the DC jack and plugged in (Figure 7) and AC sign (Figure 8) is visible in the lower window.

Figure 7

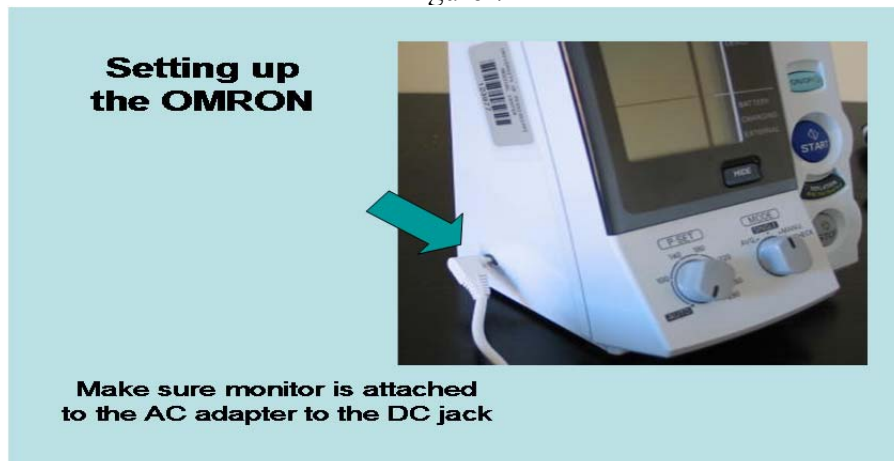


Figure 8



When the power is OFF, push the ON/OFF (power) button for more than three seconds while holding the START button simultaneously: F1 is displayed in the first window and three inflation (3) is displayed in the middle window (Figure 9). If needed push the DEFLATION (deflation control)/Measurement Result Display Switch Button to change the set value to 3 inflations.

Figure 9



Push the START button and F2 function is displayed in the first window and 0 waiting time is displayed in the middle window (Figure 10)

Figure 10



If needed push the DEFLATION (deflation control)/Measurement Result Display Switch Button and change the set value to 0 sec waiting time. Push the START button and F3 function is displayed in the first window and inflation interval 30 second time is displayed in the bottom window (Figure 11).

Figure 11



If needed push the DEFLATION (deflation control)/Measurement Result Display Switch Button and change the set value to 30 sec measurement interval.

Table 4 summarizes the needed setting for the exam

Function #	Items to set	Set value
F1	Number of inflations	3 times
F2	Waiting time to start the first inflation	0 sec
F3	Inflation interval	30 sec

10.3.2. Measuring the Blood Pressure

Once these settings are validated the exam can start. Turn off the OMRON by pushing the ON/OFF button. To measure blood pressure in average mode, push the ON/OFF button to turn on the power. Set the MODE selection to AVG, set the P-SET (inflation level) knob to AUTO (Figure 12).

Figure 12



AUTO AVG

Next, connect the air tube to the cuff (Figure 13).

Figure 13



For all cuff sizes small, medium, large, and thigh connect the air tube to the main unit by attaching the air plug to the base of the air connector. Connect the cuff to the air tube attached to OMRON unit Wrap and secure the appropriate cuff to the participant's upper right arm as set out in section 12.2.7, above.

Record the time of blood pressure measurement in Item A.4, then push the START button to start the measurements. The cuff will inflate automatically and deflation will begin after the OMRON detects no oscillometric waves. The dial will show sequentially in the bottom panel of the LCD screen 1st, 2nd, and 3rd measurements with 30 seconds between each listing (Figure 14).

Figure 14



After each inflation and deflation the systolic blood pressure, diastolic blood pressure and pulse rate will be displayed in the top, middle and bottom sections of the LCD screen.

After the first and second measurements are displayed there will be a preset 30 second interval before the beginning of the next measurement. During this time have the participant raise their cuffed arm above their heads as in Figure 15 below for the count of 5 and then return to the original resting position with the arm supported with the cubital fossa at heart level. Do not clench the fist. This action is to avoid venous congestion in the arm that may not have dissipated after inflation of the cuff – which in turn could increase the pressure recorded on subsequent measurements.

Figure 15



10.4. Recording the OMRON Results

After all the inflations are finished, the average of the three systolic pressures, diastolic pressures and pulse rates is displayed. Record these average measures on the SBP form in Items B.5-B.7. Push the DEFLATION button to toggle to the first set of measures and record the 1st set on the SBP form in Items C.8-C.10. Repeat this process by pushing the DEFLATION button to display and record the 2nd and 3rd sets of measures on the SBP form in Items D.11-D.13 and Items E.14-E.16, respectively.

Push the ON/OFF button. This terminates the exam and you are ready for the next participant

10.5. Reporting the Blood Pressure Values

The participant's blood pressure values are not discussed at the blood pressure station nor during the measurement process. The technician will have informed the participant that the blood pressure values and other results will be printed out and discussed with the participant's parent at the end of the visit. If pressed, the technician can add that the research protocol requires that results not be discussed during the examination. The OMRON display and the computer monitor should be turned away from the participant so that the blood pressure values being recorded are not easily visible.

The average systolic and diastolic blood values are reported to the study participant's parent at the end of the field center examination and also as part of the consolidated report of study results that field centers send to the study participants (and his/her medical practitioner, if so instructed by the parent). In each case the average systolic and diastolic pressure values recorded on the form are retrieved by the data management system and displayed in the report, with the narrative statement that corresponds to that value and whether the participant has reported being on antihypertensive treatment. The blood pressure results are reviewed with the parent and participant during the exit interview, at which time SOL Youth personnel explains the recommended follow-up for the pertinent blood pressure level according to the recommendations of the Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC 7).

As a child participant safety procedure, if the average blood pressure is equal to or greater than 170 mmHg systolic or equal to or greater than 110 mmHg diastolic, the technician tells the participant that the procedure will be repeated as part of study protocol, removes the cuff and locates the brachial artery by palpation as shown in Figure 5 of this section, and repeats the blood pressure measurement steps. The resulting blood pressure values are recorded on the form and entered into the data entry system. If the average blood pressure is still equal to or greater than 170 mmHg systolic or equal to or greater than 110 mmHg diastolic, the technician closes out the data entry screen per protocol, interrupts the field center examination and notifies the supervisor of this immediate alert situation. With input from the supervisor or clinic manager, SOL Youth personnel then notify the child participant's parent/legal guardian and assists the parent/legal guardian in scheduling a visit to his/her provider of care during the same day, or arranges transportation to the nearest emergency room for a medical evaluation of the participant's blood pressure. Section 20 of this manual of operations describes the participant safety procedures and Section 21 describes the procedures used to report study results.

10.6. Equipment Maintenance

Technicians maintain all blood pressure equipment used in their clinic. The following sections specifically state the steps that technicians follow to check equipment and maintain equipment used for the technician examination.

OMRON HEM-907XL: Weekly - wipe the monitor with a soft, damp cloth diluted with disinfectant alcohol, or diluted detergent. Complete cleaning by wiping the monitor with a soft, dry cloth.

Blood Pressure Cuffs: Check the inflation cuff for cleanliness, and wipe between each use with disinfectant wipes.

10.7. Inspection and Validation of the OMRON Sphygmomanometer

10.7.1. Daily Check points

1. Check function settings on the OMRON machine (0 waiting, 3 inflations, 30 seconds interval between inflations)
2. Check Mode and P-setting on OMRON unit
3. Make sure that the AC adapter cord of the OMRON unit is securely plugged in (it has a tendency to get disconnected from the unit).
4. Check the OMRON unit AC adapter cord and tubing for cracks.
5. Clean all the equipment.

10.7.2. Quarterly Validation of the OMRON Sphygmomanometer

Each OMRON unit is checked every 3 months as described in this section. The results of the calibration checks are recorded on the OMRON calibration log (together with the unit number, the date and the technician ID) and sent to the SOL Youth Coordinating Center for inclusion in the quality control reports. A copy of the calibration log is found in Appendix 4.

10.7.3 Equipment Required for Accuracy Check

The calibration equipment is the Pressure-Vacuum Meter (Shown in Figure 16. Netech DigiMano Digital Pressure/ Vacuum Meter model 2000 for a range of 0 to 300 mmHg). The following adaptors are used and are kept at the field center: **Y tubing** – with 2 arms and an inflation bulb attached to the middle arm of the Y tubing; **Y- adapter** with appropriate male/female connectors Adaptors for tubing connection; OMRON cuff with short tubing attached. Once a year each DigiMano device is shipped to the manufacturer for calibration. Completion of this check by Netech is reported to the Quality Control Committee.

Figure 16



10.7.4 Testing protocol

The following sequence of steps detail the OMRON accuracy testing protocol.

1. Inspect the OMRON sphygmomanometer for signs of damage to the case, and wall mount bracket if applicable.
2. Inspect the tubing for holes or cracks, which would allow air to leak out. Cracking is commonly found around the connection points to the sphygmomanometer, and cuff. If cracking

is seen the tubing is replaced from that point by trimming the damaged area with scissors and reconnecting the tubing. In extreme cases, the entire tubing is replaced.

3. Inspect the cuff(s) for signs of wear and tear to the outer cloth casing and Velcro fabric. Also, inflate the unit (with the cuff connected to the OMRON and wrapped around a rigid cylinder and the OMRON MODE knob set on CHECK) enough to determine if the bladder within the cuff is leak- proof. If leaks or damage are noted to the cuff or bladder, it should be replaced.
4. Disconnect the cuff from the long adaptor tubing that stays connected to the OMRON sphygmomanometer.
5. Connect one upper arm of the Y adaptor to the short tubing from the cuff and attach the other upper arm to the long tubing attached to the OMRON.
6. Connect the bottom arm of the Y **adapter** to one arm of the Y **tubing**..
7. Connect other end of the Y **tubing** to the pressure-vacuum meter.
8. Turn the pressure-vacuum meter on. Use the accompanying AC adapter if necessary.
9. Following manufacturer's instructions, select "mm Hg" as the type of unit to be tested.
10. Zero the pressure-vacuum meter per manufacturer's instruction.
11. Pump up the aneroid unit to 280 mm Hg. Release the pressure slowly and observe the changing OMRON LED mm Hg for a smooth descent along the range to 20 mm Hg
12. Again, pump the aneroid unit to above 250 mm Hg (but less than 300 mmHg) using the bulb and tighten the valve as tightly as possible
13. Check to see if the aneroid unit is within ± 3 mm Hg of the readout on the pressure-vacuum meter.
14. Continue to compare the readout of the OMRON unit to the pressure-vacuum meter approximately every 20 mm Hg along the entire range – down to 30mm Hg. Variations greater than ± 3 mm Hg requires the OMRON unit be removed from service and repaired or replaced.
15. Record the results of the calibration checks on the OMRON calibration log (together with the unit number, the date and the technician ID) and send the log to the HCHS Coordinating Center. A copy of the calibration log is found in Appendix 4.

10.8. Glossary and References

Systolic blood pressure is defined as the highest arterial blood pressure of a cardiac cycle occurring immediately after contraction of the left ventricle of the heart.

Diastolic blood pressure the lowest arterial blood pressure of a cardiac cycle occurring during the passive rhythmical expansion or dilation of the cavities of the heart during which they fill with blood.

Auscultatory method detects sounds of pulsatile blood flow in the artery using a stethoscope held over the artery just below an inflated blood pressure cuff. As the blood pressure cuff gradually deflated, pulsatile blood flow is re-established and accompanied by sounds that can be detected by the stethoscope. The pulsatile sound corresponds to a reading of a mercury column (mercury sphygmomanometer) or a dial (aneroid) device connected to the blood pressure cuff.

Oscillometric method uses a transducer to measure the oscillations of pressure in the blood pressure cuff corresponding to the pulsatile blood flow in the artery under the cuff. The oscillometric method is used by all automated blood pressure machine.

11. BIOSPECIMEN COLLECTION AND PROCESSING

Blood specimen samples are collected at the SOL Youth baseline visit to perform selected laboratory tests and for long term storage of biospecimen. The collection and processing of the biospecimens are performed according to a common, standardized protocol detailed in Manual 2. Centrally trained and certified SOL Youth personnel draw, label and process the blood samples. The SOL Youth Central Laboratory performs the tests on the blood; DNA is prepared from the packed cells of EDTA blood; and aliquots of serum and plasma prepared at the field centers are stored at the Central Laboratory. A list of the tests performed is located in Appendix 1 of Manual 2.

Assay results of demonstrated value for medical diagnosis or treatment are reported to the study child participant and parent/legal guardian, as described in Section 21.

12. 24-HOUR DIETARY AND SUPPLEMENT INTERVIEW

A 24-hour dietary and supplement interview is conducted on two occasions. The first is an in-person interview conducted at the baseline clinic visit, and the second interview will be conducted by telephone within one month (preferably 7-14 days) of the first interview. The data collection includes both the dietary and supplement recalls. The dietary interviewer conducts the interviews using direct data entry into NDSR software, and refers to the amount estimation tools and Food Amount Booklet to aid in quantifying amounts of foods and beverages.

Each field center installs the NDSR software on two or more computers and has at least two bilingual interviewers for the dietary and supplement recalls. Each dietary interviewer also has a headset for use in conducting the telephone dietary and supplement recall. NCC provides each field center with two sets of amount-estimation tools (standardized cups, bowls, etc.) and a supply of the Food Amount Booklets which are used during the in-person and telephone interview, respectively.

The NDSR program automatically guides the dietary and supplement interview through standardized passes for collecting the dietary data: PASS 1, Using the NDSR Quick List; PASS 2, Reviewing the Quick List; PASS 3, Collecting complete meal, food, and amount detail; and PASS 4, Reviewing the recall. The Dietary Supplement Assessment Module follows the 24-hour recall and consists of three tiers: Tier 1, Screening for the use of dietary supplements; Tier 2, Entering the dietary supplements; and Tier 3, Reviewing the supplement details. The dietary interviewer asks the participant regarding all supplements taken during the past 24 hours and during the past 30 days. Interviews may be conducted in Spanish and/or English at the discretion of the participant. It is important to conduct the interviews in a space that is quiet and free from distractions.

Due to the need to fast prior to the exam visit, the 24-hour interval covered by the in-person dietary interview begins with the first food or beverage the participant had from 10:00 PM the day previous to the recall until 10:00 PM the night prior to the interview. During the in-person interview, the participant will be oriented to the process of the 24-hour recall and will learn how the food models and the Food Amounts Booklet are used to help estimate the quantities of foods consumed.

At the end of each in-person recall, the Telephone Recall Availability form is completed for each participant listing several potential days and times to receive the telephone recall. The participant identifies several best days and times, since the exact timing of the telephone recall is unannounced. After the in-person interview, the dietary interviewer provides a copy of the Food Amounts Booklet to each participant to keep for use in the subsequent telephone recall.

The telephone interview is collected at least five days, but no more than 30 days, following the child's initial examination interview. The 24-hour interval covered by the second recall is the 24 hours preceding 12:00 AM (midnight) of the previous night. The exact day of the week for the telephone recall is chosen by field center staff from available participant times, with an aim that the distribution of days across participants includes all days of the week possible, given clinic schedules. The 24-hour dietary recall should not be collected without the Food Amounts Booklet. If at the time of the call, the participant no longer has the Food Amounts Booklet, a

replacement should be mailed to him/her and the telephone recall should be attempted a few days later.

The SOL-Youth Dietary and Supplement Recall Checklist (one per dietary and supplement recall collected) is completed with each dietary recall and serves to document each step of field-site quality control. A Telephone Contact Log is kept for each participant to record all attempts to contact him/her for the telephone recall.

The dietary interviewer should review and edit dietary and supplement recalls as soon as possible after administration. At the end of each dietary and supplement recall, the dietary interviewer prints NDSR reports that are used for local quality assurance and that also serve as a secondary backup of the dietary and supplement recall.

The lead interviewer at each field center is responsible for ensuring the overall quality of the dietary data collection. The dietary interviewers review the diet and supplement interviews, document unusual foods and amounts, and flag unreliable recalls. Field-site quality control includes two steps: review and editing of each dietary recall by dietary interviewers within one or two days of collection; and review and editing of dietary recalls by the lead interviewer within one week, with feedback provided to the respective dietary interviewer.

On a weekly basis, after quality assurance activities have been completed, the lead interviewer combines the recalls collected into a single NDSR project, creates a new NDSR backup file, and submits it to NCC.

See Manual 3 for details on the procedures summarized above for the dietary and supplement interview.

13. PHYSICAL ACTIVITY MONITORING (ACCELEROMETRY)

13. PHYSICAL ACTIVITY MONITORING (ACCELEROMETRY)

13.1 Rationale

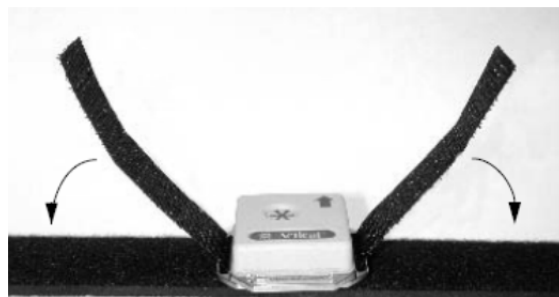
Study participants will wear a portable motion sensor (i.e., accelerometer) to measure the frequency, duration, and intensity of physical activity over 7 days. The accelerometer provides an objective measure of physical activity that will supplement the interviews for self-reported regular physical activity. Clinic staff will give parent and child participants the instructions for wearing the device near the end of the clinic examination and provide participants with instructions on how to return the accelerometer to the Field Center.

13.2 Technical Information about the ActiCal Accelerometer

The ActiCal™ (MiniMitter Respironics®, Bend, OR) accelerometer (model 198-0200-03) is a small, lightweight motion sensor that is attached to a belt and worn on the body. The ActiCal device measures the occurrence and intensity of motion in all directions by generating an electrical signal proportional to the force of the displacement. A microprocessor inside the accelerometer digitizes the signals, sums and stores them as “activity counts” over a user-defined time interval that can be as short as 1 second. Data can be collected and stored for approximately 6 weeks before being downloaded for data analysis. In addition to the activity counts per unit of time, the average time spent in light, moderate, and vigorous activity can be estimated.

13.3 Protocol

Clinic staff will give the child participants accelerometers following all of the physical examinations at the clinic examination. Study staff will select the appropriate size waist strap for the participant. The waist strap should be about 2-3 inches greater than the participant’s waist. Thread the Actical unit onto the waist strap as pictured below. With the belt loop on the right, the orientation of the arrow on the monitor should be facing up.



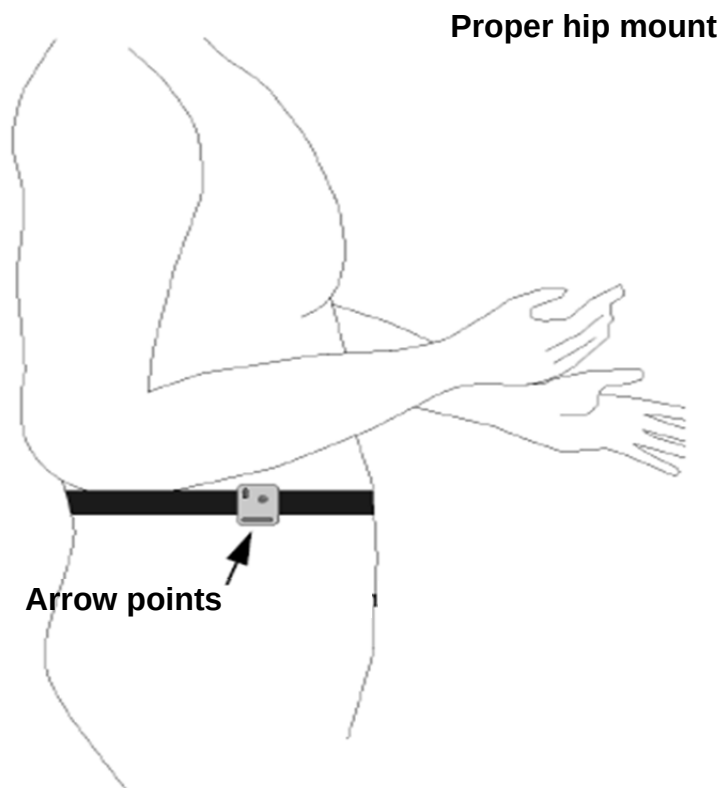
Study staff will briefly describe the purpose of physical activity monitoring and ask participants to undertake their normal activities for the week while wearing the monitor. Staff will

emphasize that participants should not engage in activities that they ordinarily would not specifically because they are wearing activity monitors.

Staff will demonstrate how the device is worn, and specify that it is worn over the right hip on the waist strap. The belt should be mounted on the body so that the device rests on the iliac crest (the uppermost and widest of the three bones constituting either of the lateral halves of the pelvis) of the hip with the arrow pointed up (toward the head). The Actical should be snug against the body (but not tight) so that it does not bounce around. The unit can be worn underneath or on top of clothing, whichever is most comfortable to participants. During the clinic examination, participants will practice putting the monitor on properly with study staff present to provide feedback.

Generally, based on best research practices recommendations, we will measure 7 days of recording so that we can capture intra-individual variability in total, moderate and vigorous activity and increase the likelihood of capturing at least four days of activity—the length at which reliability is at least 0.80. Participants are asked to wear the accelerometer continuously over 7-days and to remove it only for swimming, showering, and sleeping.

Figure 1: Proper placement of the Actical



Participants are told that on the third day of recording a staff member will telephone them to answer any questions or concerns about the device and to make sure that the instructions are clear. The telephone call also provides staff with the opportunity to remind participants to wear

the monitor continuously. Before leaving the clinical examination, staff will give participants a dated reminder card indicating when they should stop wearing the device and instructions for using the ActiCal. Depending on local Field Center procedures, participants will either drop-off the Actical on the date specified during the in-clinic examination or a staff person will call to schedule a pick-up time. Staff will call participants again two weeks after completion of the recording period if their accelerometer has not been returned to the examination clinic.

13.4 Equipment and Supplies

Each field center will receive 100 Actical accelerometers. In addition to the accelerometers, the coordinating center will provide the following items to each field center:

- 100 waist straps of varying sizes
- 1 ActiReader unit
- Cables w/ USB adapter for connecting the ActiReader to the computer
- Actical software to load onto study computer
- User's manual for the Actical
- Flathead screwdriver for opening accelerometer and changing battery
- "O-rings (to be checked when replacing batteries)
- CR2025 lithium Coin cell ion batteries: Each field center is responsible for purchasing

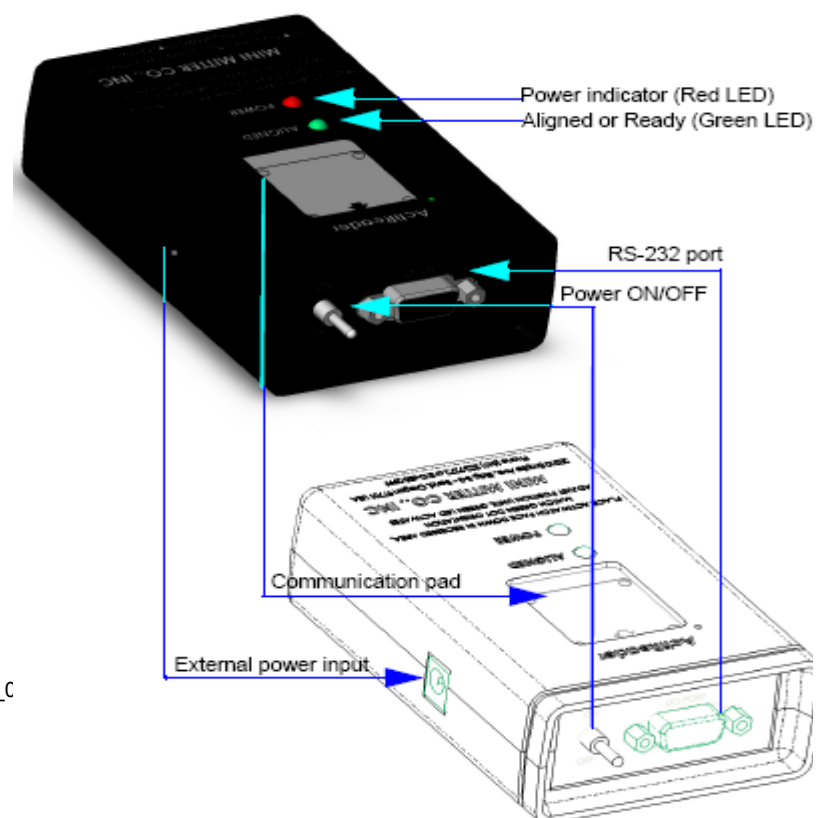
The ActiReader will be connected to the study computer. The computer do not need to be dedicated to collecting the accelerometry data; however, they should be available whenever units are returned so that data can be downloaded and stored when the units are received.

13.5 Initial Hardware and Software Set up

Actical software must be installed on each PC (lap top or desk top) that will be used for initializing and reading Actical data. Detailed installation instructions are provided in the Actical User's Manual found on-line at [[\]. A hard copy should be present at each field center and the coordinating center.](http://www.healthcare.philips.com/wpd.aspx?p=/us_en/homehealth/manualsandliterature.wpd&)

1. Install the Actical software by loading the installation CD into your drive and follow software installation

Figure 2: The ActiReader Device



instructions (page 1-11 of User's manual)

2. Connect one end of the serial communication cable to a COM Port on the PC and the other end to the ActiReader (**Figure 2**)
3. Test the ActiReader set up by opening the Actical software, selecting: Reader > Test Reader. Follow the prompts through the test procedure. If the test fails, follow the prompts to correct the problem.
4. If the problem cannot be corrected, contact Steven Edwards at 800-685-2999 ext 83837 (steve.edwards@philips.com).

This procedure should be repeated for each computer/ActiReader used in the study.

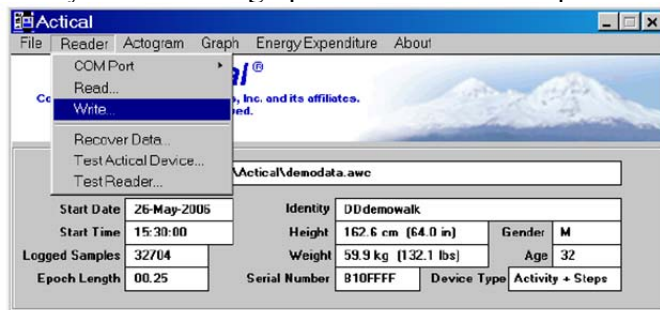
13.6 Initializing the Actical device

Before a participant arrives at the clinic, the clinic staff should carry out the following steps:

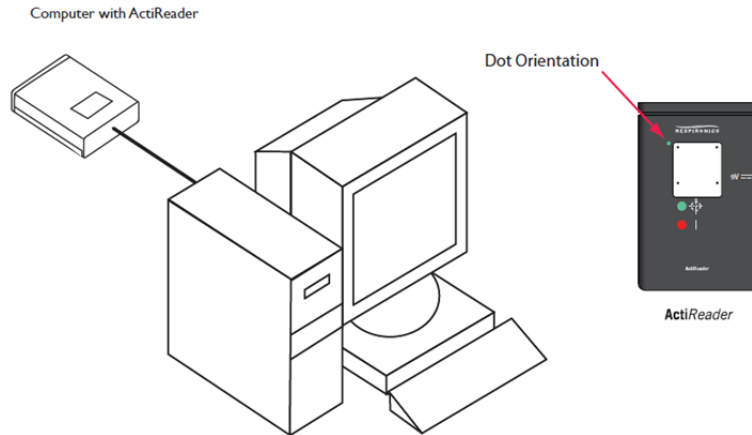
1. Select an Actical and record the monitor serial number, participant ID (ID) and participant name into the accelerometry tracking system.
2. Initialization should not take place before the participant arrives.
3. Initialize the accelerometer using the following steps:

Each ActiCal device must be uploaded with setup information (initialization) prior to collecting data. This is done within the ActiCal software and then loaded onto the ActiCal device using the ActiReader.

1. Open the Actical main window and select Reader > Write and follow the prompts that alert you that setting up a device will erase previously stored data.



2. Click "yes" in response to the question "Do you want to continue?"
3. Place the Actical device on the ActiReader by aligning the green dot in the metal back of the Actical device with the green dot on the ActiReader. If it is properly in place on the communication pad, the green LED will light up. The "communication" bar at the bottom of the screen will demonstrate a connection.



4. The following setup screen will appear:

The screenshot shows the 'Actical Setup' window. It contains several input fields for setting up the device. The fields are organized as follows:

- Identity**: A text input field.
- Gender**: A dropdown menu.
- Age**: A text input field.
- Start Date**: A date selection field.
- Start Time**: A time selection field.
- Epoch Length**: A text input field.
- Battery Fitted Date**: A date selection field.
- Serial Number**: A text input field.
- Recording Time (approximate)**: A text input field.
- Battery Life (approximate)**: A text input field.
- Memory**: A text input field.

There is also a section for **Height and Weight** with two rows of input fields:

- Row 1: **0.0** cm, **0.0** kg
- Row 2: **0.0** inches, **0.0** pounds

5. Check the battery life displayed under the battery fitted date. If the value is less than 5 days, then replace the battery even if the battery was not scheduled to be replaced.
6. Under "Identity" enter the participant ID number. Enter gender and age as appropriate and enter the start date as the day of the scheduled visit and start time as 05:00 (5AM) on the day of the visit. Epoch length should be set to 15 seconds by entering 00.25. Enter 1.0 for height and weight because these values will not be used for the SOL/Youth Study.
7. When all information has been entered, click "Send". The Information will be sent to the Actical device.
8. The initialization progress will be shown by the red bar at the bottom of the window.
9. Remove the device from the reader and place it in the belt for use.

13.7 Instructions for using Accelerometer

Instructions for use and return of the accelerometer should be given to the parent and child before they leave the clinic, and should include the following points (see Appendix):

1. What the accelerometer is and what it records;
2. Importance of wearing it every day, all day; see the script in Appendix A.
3. Proper placement of the accelerometer;
4. Importance of returning the accelerometer promptly;
5. Expect telephone call the 3rd day after the clinic visit to make sure the child is wearing the accelerometer and understands the instructions;

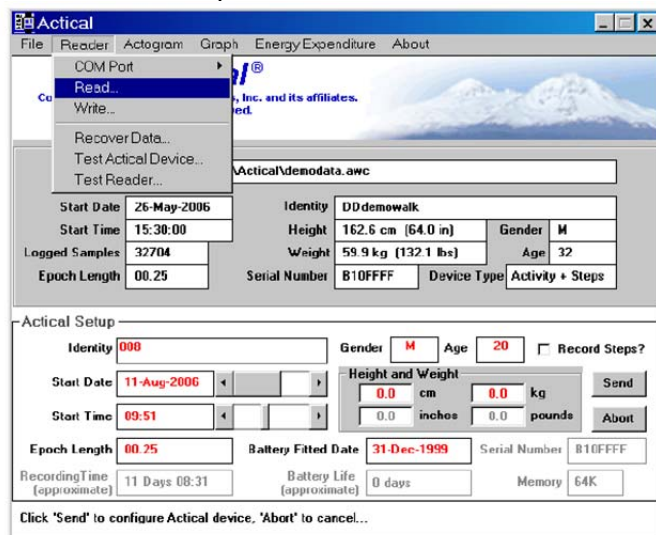
6. Expect telephone call to check up on the return of the accelerometer if it is not received back within two weeks of completing the protocol.

Arrangements for the return of the accelerometer are established at the time, according to the procedures in place at each field center.

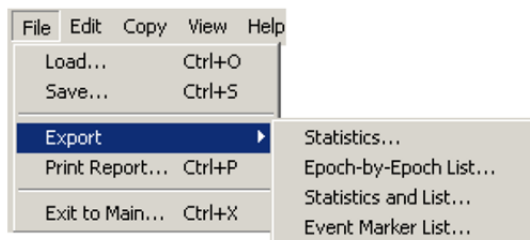
13.8 Downloading the data

As soon as the accelerometer is returned, download the data. This should be done on the same computer on which the accelerometer was initialized.

1. Place the device into the ActiReader and open the Actical software
2. Click on Reader > Read and follow the prompts. The data download will be shown by the red progress bars at the bottom of the window. A prompt will tell you when the download is complete.



3. To review the data downloaded from the device, click on ActiGram at the top-left of the screen to be sure at least 4 days of data are collected.
4. Click on File > Export > Epoch-by-Epoch List.



5. Select the default file name, but remove the “_list” part. Therefore, the file name is the participant ID and will have extension awc.

13.9 Transmitting data to the Coordinating Center

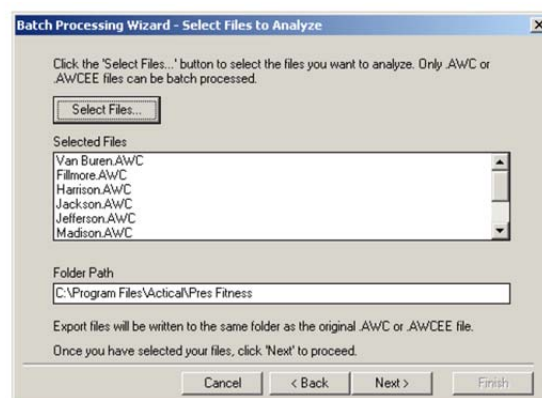
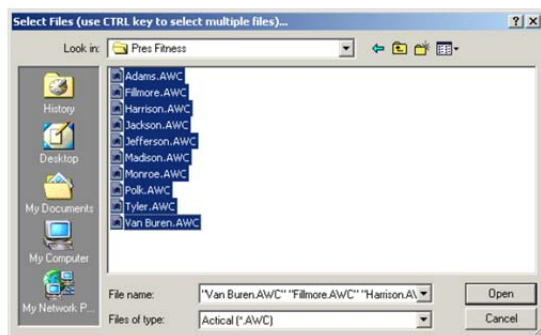
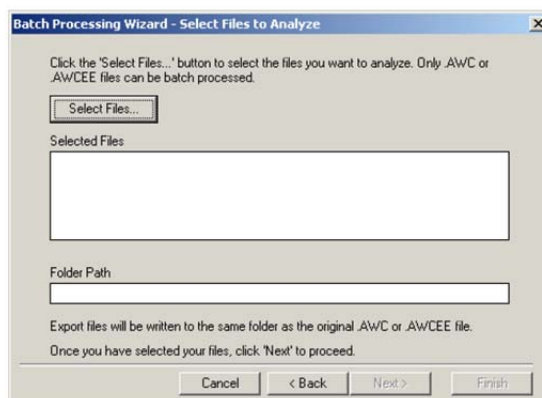
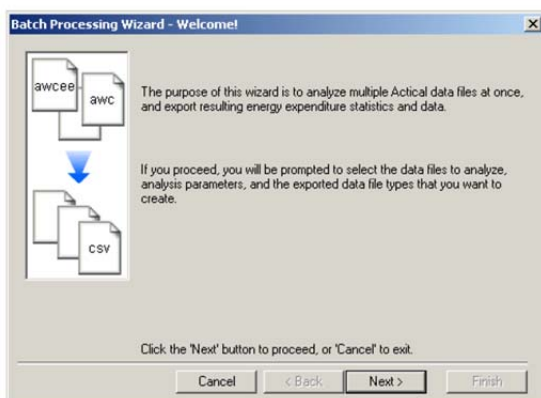
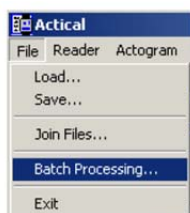
There are three steps: 1) convert data to csv format, 2) zip file and 3) upload to DMS.

Please see “Appendix 4.1” of the Data Management MOP (MOP 5) for step-by-step instructions on how to upload the Actical data to the CDART.

1. Convert data to csv format with batch processing:

Batch processing is a function that allows processing simultaneously multiple files with similar characteristics. This will still work if you have only one file (*.awc).

From the Main window, select File->batch processing and follow the wizard



2. ZIP file
3. Upload to DMS

13.10 Equipment Maintenance

The User’s Manual provides the most complete information about accelerometer equipment maintenance. Each field center should have one hard copy of the manual. A version is available

on-line for download at the study website

http://www.healthcare.philips.com/us_en/homehealth/sleep/actical/

13.10.1 Cleaning

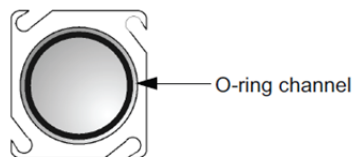
The Actical devices should be disinfected after each participant use by wiping the surface with a non-alcohol based germicide such as Lysol disinfectant wipes. Cleaning should only be carried when the battery cover is in place and fully sealed.

Waist straps should be rinsed in a cleansing solution such as Tide after each use.

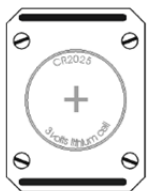
13.10.2 Battery Replacement

The Actical unit runs on a CR2025, 3-volt, 220-m-Amp-hour Lithium Manganese cell battery. The battery is required for data collection, reading, and writing. Although stored data are not lost after the battery has run down, it is important to change the batteries after every other use. A battery indicator light on the reading device will display a green light when the battery is charged. **A log of battery changes (Appendix) should be kept for each Actical device.** Detailed instructions with graphics can be found in the product manual. The steps are as follows:

1. Remove the strap from the watch and use the flathead screwdriver supplied with the devices to loosen and remove the 4 screws on the slots in the battery cover of the device.
2. Turn the cover clockwise to display the battery (if the screws are loosened). Lift the cover off if the screws are removed.
3. Remove the battery and discard.
4. Clean the O-ring channel with a dry, lint-free cloth (DO NOT USE ALCOHOL).

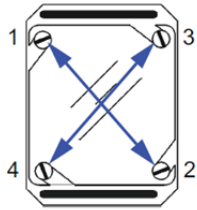


5. Place the clean O-ring into the channel on the back cover by pre-stretching the O-ring by gently flexing it in several directions. Be sure that it is properly sealed in the channel and is not twisted or deformed.
6. Place a new battery into the Actical case, positive (+) side up.



7. With the green dot in the upper-left corner and the back cover upright to be able to read the wording, rotate the back cover counterclockwise until the slots in the back are firmly sealed around the screws and the back is square with the case (or replace the cover and screw it firmly back on).
8. Tighten all 4 screws in an "X" pattern until snug.

CAUTION! DO NOT over-tighten the screws. They can be stripped easily.



9. Test the ActiCal battery by placing it on the ActiReader. A green LED light indicates successful battery replacement and installation.
10. Record the Battery Fitted Date in the Actical set up.

All other service related questions should be managed through our contact person for support Philips Respironics:

Philips Respironics
Philips Home Healthcare Solutions
Toll Free : 800-685-2999
(or ext 83837 for Steven Edwards)
Steve.edwards@philips.com

13.11 Quality Control

It is important that each Actical unit not be worn more than 4 times since the quality of data collected can diminish after 5+ uses. The number of times an Actical unit is used will also be tracked in the Battery Changes log to ensure it does not exceed 4 uses. After 4 wears, each ActiCal unit will be removed from circulation.

Appendix A

Instructions for Wearing Accelerometer (sample script)

Initial script for distributing the accelerometer in clinic (read to child with parent/legal guardian present):

“This is the activity monitor that we are asking you to wear for the next 7 days. It’s small, light weight and there is no way to know that it’s running. I have activated it to start today, and it will run continuously now, on a small battery, until you send it back to us and we download the data. We have put the monitor on an elastic waistband with an adjustable buckle. Put the band around your waist, with this notch here pointing up at you on your right side, underneath or over your clothing. We need you to wear the monitor from the time you wake up in the morning to the time you actually go to bed. You do not need to wear the monitor while showering, bathing or swimming, but don’t worry about getting it wet. It will still work and record your movements. Also you don’t need to wear it while you’re sleeping. If you fall asleep with the monitor on it won’t hurt you or the data; it may just be a bit uncomfortable. In the morning if you’re the type of person to go directly from bed to the shower, put it on after your shower. But if you’re going to be up for 15 minutes or more before getting into the shower, go ahead and put it on, then take it off prior to your shower and then put it back on when you’ve finished showering.

Please do wear the monitor until you actually go to sleep at night, even if you’re just sitting reading or watching TV. If you just get up to answer the phone or go to the bathroom, the monitor will collect these movements as you walk through the house. Does this all make sense?”

After waiting for participants to ask questions, continue:

“Finally, we will need to collect the activity monitor from you. Please remember to drop it off with us on (set date) [OR] We will call to schedule a pick-up time that works for you. If we don’t receive them within a week of the end of your recording period, we will call you to find out where they are. Also, please remember that we can’t reimburse you for your study participation until the monitor is returned to the study center.

If any questions arise during this next week, please call the clinic phone number at (Field Center phone). We’ll also be calling you in the next day or so to see if you have any questions or problems. Do you have any questions?”

Appendix B ActiCal check-up call

Participants should be contacted on the 3rd day after leaving the clinic. This call is to ensure that participants are wearing the monitor correctly and to answer any questions that the participant has. The call is meant to be brief. When calling the child participant, ask to speak to the parent/legal guardian first and then ask for permission to speak to the child.

“Hello, I am (full name), from the Youth Study of Latinos (SOL-Youth) at (Fill in University). Can I speak to _____?”

<i>If the desired person is on the phone</i>	<i>When the desired person gets to the phone</i>	<i>If that person is not available</i>
“Hello Mr./Ms. _____ Continue	“Hello Mr./Ms. _____. I am (first name) from the Studies of Latino Health Youth Study at (University). Continue	“Is there a better day and time to reach Mr./Ms. _____? Note days and times Thank you. I will try to call back then. Terminate Call

“I am calling to make sure that the directions for wearing the activity monitor made sense and to ask whether you or your child have any questions about wearing the activity monitor? Is (child’s name) available?”

If child is available continue with script below. If child is not available, ask for a better day and time he/she will be available.

Optional script:

- “It is important that you wear it on your waist, not in a pocket or in a bag, with the monitor right above your right hip bone.
- Wear it snugly around your waist, either underneath or over your clothing.
- Wear it for 7 whole days, preferably on consecutive days”

Also, remind the parent/legal guardian and child of the pick-up or drop-off arrangement to return the ActiCal to the clinic.

If during the call the child mentions he/she has not been wearing the ActiCal properly or has not been wearing it continuously during the day or at all, and the child is still willing to continue with this procedure, then remind him/her how and when to wear it.

Optional script:

- Starting tomorrow morning, we will need you to wear the monitor from the time you wake up in the morning to the time you actually go to bed. You will need to do this for the next 7 days.

- You do not need to wear the monitor while showering, bathing or swimming, but don't worry about getting it wet. It will still work and record your movements.
- You don't need to wear it while you're sleeping. If you fall asleep with the monitor on it won't hurt you or the data; it may just be a bit uncomfortable. In the morning if you're the type of person to go directly from bed to the shower, put it on after your shower. But if you're going to be up for 15 minutes or more before getting into the shower, go ahead and put it on, then take it off prior to your shower and then put it back on when you've finished showering.
- Please do wear the monitor until you actually go to sleep at night, even if you're just sitting reading or watching TV. If you just get up to answer the phone or go to the bathroom, the monitor will collect these movements as you walk through the house.
- I will call again on DATE (day 3) to make sure you are wearing it right, but feel free to call me at (Field Center number) if you have any questions or problems with the monitor.

Ask the child if he/she has any questions. Then ask to speak to the parent/legal guardian to reschedule the pick-up or drop-off return date and time of the ActiCal monitor.

If child decides he/she does not want to participate in this procedure, thank the child for his/her time and confirm the pick-up or drop-off date and time to return the ActiCal with the parent/legal guardian (you may want to reschedule for an earlier return date). Follow procedures for marking this examination as a partial examination in the DMS.

If you reach an answering machine:

“Hello, I am (full name) calling from Study of Latinos Youth Study (SOL-Youth) at the (University). I am calling because I want to make sure that the directions for wearing the activity monitor make sense. I will try to call back tomorrow or the day afterwards, but you can also call me if you have any questions about wearing the monitor.”

Appendix C

Frequently Asked Questions about the Physical Activity Monitor (Portable Motion Sensor)

What is a portable motion sensor?

The portable motion sensor, or physical activity monitor (accelerometer), is a small, light-weight device similar to a watch that will automatically record the frequency, duration, and intensity of your physical activity during your routine activities.

How do I wear the physical activity monitor?

The physical activity device will be worn as a belt. Simply put the belt on your body so that the unit rests on the top of the right hip with the “Respiroics” logo on the top and the “Actical” logo on the bottom.

Can I wear the physical activity monitor underneath my clothes?

Yes. The unit can be worn underneath or on top of clothing, whichever is most comfortable to you.

Should I wear the physical activity monitor while sleeping, taking a shower, or swimming?

You may remove the monitor while sleeping, taking a shower, or swimming. However, the unit is water proof. If the device gets wet, gently dry it with a paper towel or soft cloth. If you think that you may forget to put it on in the morning, you may sleep with the device and just take it off while taking a shower or swimming.

How long should I wear the physical activity monitor?

You should wear the device every day, for 7 days for at least 10 hours each day.

How do I know if the physical activity monitor’s power is “On”?

The unit is already “On.” The physical activity monitor was initialized the day of your visit to our clinic, before it was handed out to you. There are no lights, sounds, or indicators in the device that let you know if the unit’s power is “On.”

I wore the physical activity monitor for 7 days. How do I return it to the clinic?

Before you take home the unit, instructions on how to return the device will be given to you. You can always stop by our clinic (*Field Center address*) from 7:30am – 3pm to return the monitor.

What if I have any questions or problems with the physical activity monitor?

We will gladly answer any questions or help you through any issues. Feel free to contact us at (*Field Center number*) for physical activity monitoring.

Preguntas Frecuentes Sobre el Monitor de Actividad Física (Sensor de Movimiento Portátil)

¿Qué es un sensor de movimiento portátil?

El sensor de movimiento portátil, o monitor de actividad física, es un aparato pequeño y liviano parecido a un reloj de mano que automáticamente graba la frecuencia, duración e intensidad de su actividad física durante sus actividades rutinarias diarias.

¿Cómo debo ponerme el monitor de actividad física?

El aparato de actividad física se coloca como un cinturón. Simplemente colóquese el cinturón en el cuerpo y acomode el dispositivo arriba de su cadera derecha con el logotipo de “Respironics” (la estrellita) en la parte superior y el logotipo de “Actical” en la parte inferior.

¿Me puedo poner el monitor de actividad física debajo de la ropa?

Sí. Puede colocarse el monitor de actividad física por debajo o por encima de la ropa, de la manera que sea más cómodo para usted.

¿Puedo ponerme el monitor de actividad física mientras duermo, cuando me baño, o nadando?

Puede quitarse la unidad mientras duerme, se baña, o cuando está nadando. Sin embargo, el aparato es resistente al agua. Si el dispositivo se moja, debe secarlo con cuidado con una toalla de papel o tela suave. Si piensa que se le puede olvidar ponérselo en las mañanas, usted puede incluso dormir con él.

¿Por cuánto tiempo debo ponerme el monitor de actividad física?

Debe colocarse el aparato continuamente por 7 días por lo menos 10 horas cada día.

¿Cómo puedo saber si el monitor de actividad física está encendido?

El aparato ya está encendido. El monitor de actividad física fue programado el día de su visita a nuestra clínica, antes de proveérselo. No hay luces, sonidos, u otra indicación que le demuestre que el monitor está encendido pero ya está trabajando desde el momento en que lo recibe.

¿Ya me puse el monitor de actividad física por 7 días. ¿Cómo lo devuelvo a la clínica?

Antes de entregarle el monitor le daremos instrucciones acerca de como devolverlo. Puede visitar la clínica (*Field Center address*) entre 7:30am a 3:00pm para devolver el dispositivo.

¿Qué puedo hacer si tengo preguntas o problemas con el monitor de actividad física?

Con gusto contestaremos cualquier pregunta y lo ayudaremos con problemas técnicos. Comuníquese con nuestra clínica llamando al (*Field Center number*).

14. STEP TEST

14.1 Overview

The step test is a means of estimating aerobic fitness or maximal oxygen uptake (VO_2max). The method has been validated using 146 boys and 140 girls ranging in age from 6 to 18 years. The test has a correlation with measured VO_2max of $r = 0.80$ (Francis & Feinstein, 1991), which is as good as, or better, than other methods of estimating aerobic fitness using cycle ergometry or treadmill testing ($r = 0.60\text{-}0.82$), but not as good as the 20-meter shuttle run. It is easy to administer and takes a total of approximately 10 minutes. It requires a technician able to accurately measure the child's pulse. One technician can administer the test, but a second should be nearby in case of an emergency.

14.2. Equipment

Stop watch

A black, blue, red or green non-permanent felt marker

Metronome to set step cadence

A one inch thick piece of plywood, approximately 30 inches by 24 inches

One, 18 inch ruler

Step benches: Steck Autobody 20350 Pro Step Heavy Duty Adjustable Work Platform

This bench allows for 2 inch changes in step height. The one-inch piece of wood is used to provide the smaller changes in height required by the step-test protocol.

Available from "the toolwarehouse.net" \$114.50

<http://www.thetoolwarehouse.net/p-6553-steck-autobody-20350.aspx>

A chair. If a chair is not available the step-bench can be used.

14.3. Procedures

1. Ensure that bench is properly set up and that there is a chair nearby for child to sit on at the end of the test. Procedures for setting up the bench are as follows (also found in the Steck Autobody 20350 manual):
 1. Lay step-bench on the floor with the non-slip strips facing up.
 2. Slide the foam collars up the legs and set both legs into the platform. Set the platform in place using the quick-release pins on the four corners.
 3. With the Step-bench on its side, bolt caster rails to the second hole up.
 4. Do not attach the casters to the rails. Using the casters can make the base unstable during the step test.
2. Be sure that the floor under the bench is fairly level and free of obstruction. The bench can be placed facing the wall and if so, should be about 12 inches from the wall, with adequate space behind the bench for the participant to freely move and a space very nearby for a chair.
- 3.. Set the metronome for 88 counts or 22 assents per minute.

At 88 counts, each click represents a foot movement (up with one foot, up with the other; down with the first foot down with the other)

4. Verify that the child is in good health by administering Participant Safety Checklist (see appendix). Also, verify the proper footwear (no flip-flops) and any shoe laces are tied. If the child is pregnant and has indicated the parent/legal guardian is unaware of the pregnancy, then the Step Test will be rescheduled, 10-12 weeks after giving birth or when the child is no longer pregnant. If the parent questions why the procedure is not completed, personnel can inform the parent this test is a “random selection” and will not be done this day. Refer to Participant Safety MOP for guidelines to follow to ensure participant confidentiality in such cases.
5. Measure the height of the child in centimeters without shoes.
6. Adjust the bench height based on the child’s height using the 18 inch ruler. If the desired height is between the 2 inch setting on the platform, slip the plywood sheet under the feet of the platform. Check to be sure the entire platform and plywood are not slipping. The table below presents the correct bench height for the height of the child:

Bench Height Used	Child's Height	Pin holes on side braces (W=use of plywood)
1	95-105 cm	1
2	106-115 cm	1W
3	116-125 cm	2
4	126-140 cm	2W
5	141-155 cm	3
6	156-165 cm	3W
7	166-180 cm	4
8	181+ cm	4W

7. Show the child how to perform the test and then let the child practice for 15-30 seconds. Script at this point: **“During this next test I will be measuring your aerobic fitness. I will ask you to step up and down on this bench to the sound of the beat for a total of three minutes. I am going to show you how you will do the test. You will step up with one foot then, step up with the other, step down with the first foot and then step down with the second foot. You do this to each beat you’ll hear. Let me show you how to do it. Then I’ll let you practice.”**

Turn on the metronome and demonstrate, while saying Up, Up, Down, Down, repeat a few times. Emphasize that the person must straighten both legs when at the top of the step. If you need to change feet at any time during the test take an extra step in place (DEMONSTRATE). Let the child practice for about 15 to 30 seconds.

Script: **“When you are done you will sit down immediately on the chair and put your hands on your thighs and sit quietly for the next minute while I record your heart rate. I’ll ask that you do not talk during this one minute so we can accurately measure your heart rate. For a few seconds after you sit down you can gently raise and lower your heels alternately keeping your toes on the floor (DEMONSTRATE), to prevent dizziness. If at any time**

during the test, or when you sit down at the end of the test, you feel dizzy, sick, or fatigued, please stop and let me know immediately.”

8. Have the child sit for approximately 5 minutes after practicing.
9. During the rest period find the child’s radial pulse. Place the child’s palm of the dominant arm facing up. Feel between the tendon on the thumb side and the bone near the wrist. Do not use your thumb to find the pulse; use the sides of your fingers. Be sure not to press too hard or the pulse will be occluded – not felt. If no radial pulse is found, check for a carotid pulse. This can be found by gently palpating between the Trachea (throat) and the sternocleidomastoid muscle on the outside of the neck with the sides of the fingers. Once again, **do not press too hard**. Some individual are very sensitive to the pressure and may pass out.
10. Once a pulse is found mark the location with the felt pen. Then take a resting heart rate for 15 seconds and record on the data form.
11. Check to be sure the metronome is set for 88 counts or 22 assents per minute.
12. On the “**go**” SIGNAL the child starts stepping, the stopwatch is started and continues for three minutes. Provide verbal instructions and encouragement to be sure the child is stepping at the desired rate throughout the three minutes.
13. As the child nears the end of the exercise period. Instruct them as to what you want them to do at the end of the test. **“You are about finished. I will count down your last for steps. The please immediately sit down in the chair so that I can get an accurate pulse rate. Here we go, up, up down, down, stop and sit down in the chair.”**
14. At the end of assessment the child immediately sits down on the bench or a chair with his hands on his thighs.
15. Wait exactly 5 seconds and then count the number of pulse beats for the next fifteen (15) seconds. Do not try to reset the watch at the end of the 5 seconds. There is not sufficient time. Simply start the count at the 5 second mark and measure to the 20 second mark. Count the total number of beats for the 15 seconds not the heart rate.
Use the initial 5 seconds to find the pulse.
Remind the child not to talk and keep his/her hands on the thighs.
16. Record the total number of heart beats on the data form.
17. For your information, aerobic fitness (VO₂max) can be estimated using that 15 second heart beat count by the following formula: $VO_2\text{max} = 105.4 - 1.64(\text{HR})$. However, the CC will make the calculation.
18. **NOTE: If the child does not finish all three minutes of the exercise test, the test is invalid. If the child could only finish one minute (or less) of the exercise, then they probably could not complete the test if given a second try, so do not ask them to repeat the test. If the child completes more than two minutes of the exercise, there is a likelihood that they could repeat the test and complete it. For such children, it is appropriate to ask if they would be willing to try the test again. If the child agrees, they can repeat the test once, but only after their heart rate has recovered to below 100 beats. This may take an additional 10 minutes for recovery.**

14.4 Quality Assurance

14.4.1 Training & Certification

All research associates (RAs) who will be administering the step test should be certified. A minimum of two RAs at each site should be trained to administer the step test.

The process requires each RA to administer step tests to 1) 8-9 yr old, 2) 10-12 yr old, and a 3) 13-14 yr old. That is a total of three step tests. The same subject should be used for all RAs who wish to be certified, but each person seeking certification will run the test separately. For example, if three RAs are to be certified, then the same 8-9 yr old does three separate tests. If all three tests are to be completed in the same session then allow 10 minutes between tests. The 15-second post exercise heart rate results from the RAs are then sent to the coordinating center. If the heart rates of the tests on the same subject are within 5 beats, then all RAs are certified. If some RAs are within the 5 beat range, then those are certified and any found out of range will need to be re-examined after practice with those RAs who are certified. All RAs must pass all three tests to be certified.

For local training purposes, the Master Trainer will show the new RA how to conduct the step test. The Master Trainer will teach the RA how to take a radial pulse and then the RA will do the step test on other site personnel. Finally, the RA will do the test on a child from each of the three age groups and the Master Trainer will also take the pulses of the child on the opposite arm the RA uses to verify results. If the RA is within 5 beats, the RA is certified and the Coordinating Center will add the person to the approved list of personnel.

14.4.2 Quality Control

Every tenth subject who completes the step-test will have this test administered by two RAs. One RA will use the right arm and the other RA will use the left arm. The one using the right arm will be considered the actual test, while the RA on the left arm will be the QC check. Data from both RAs will be sent to the Coordinating Center and comparisons made. The heart rates should agree within 5 beats. If not, then the data from the RA using the right arm is deemed the correct results and added to the data base. However, the RAs are not allowed to administer further step-tests until they have been retrained on measuring heart rates. Once the Site Coordinator is satisfied as to the accuracy, the Site Coordinator submits a memo to the coordinating center and the RA is again used for testing.

14.5. Safety Procedures

Before beginning the step test, ask the participant the Safety Checklist questions to determine eligibility (see Appendix).

IF PARTICIPANTS BEGIN TO FEEL SICK OR DIZZY: Tell them to sit down and help them lower their head toward their knees. If they continue to feel dizzy help them to lie down on their back with their legs elevated on a chair or bench. Monitor them for facial color change (e.g., ashen or pale). If the dizziness does not resolve in a couple of minutes, and/or they appear pale or disoriented, you may have to call 911.

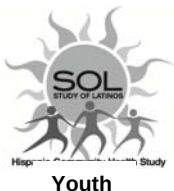
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Appendix 1:
Medications that Contra-indicate Participation in the PWC170 Work Capacity Test

<u>Generic Name</u>	<u>Trade Name</u>	<u>Generic Name</u>	<u>Trade Name</u>
Dipyridamole	Persantine	Methylphenidate	Ritalin, Concerta
Pentoxifylline	Trental	Propafenone	Rythmol
Warfarin	Coumadin		
Acebutolol	Sectral	Amitriptyline	Elavil
Atenolol	Tenorium	Desipramine	Norpramin
Carteolol	Cartol	Imipramine	Tofranil
Betaxolol	Kerlone	Nortipityline	Aventyl
Bisoprolol	Zebtata		
Labetalol	Normodyne or Trandate		
Penbutolol	Levatol		
Propranolol	Inderol		
Timolol	Blocadren		
Clonidine	Captapres		
Guanabenz	Wyntensin		
Guanadrel	Hylorel		
Guanethidine	Ismelin		
Guanfacine	Tenex		
Metyldopa	Aldomet		
Reserpine	Serapasil		
Amlodipine	Norvasc		
Bepridil	Vascor		
Diltiazem	Cardizem		
Felodipine	Plendil		
Isradipine	DynaCirc		
Nifedipine	Procardia or Adalat		
Nicardipine	Cardene		
Nimodipine	Nimotop		
Verapamil	Calan or Isoptin		
Disopyramide	Norpase		
Procainamide	Pronestyl, Procan SR		

Appendix 2:
Participant Safety Checklist for Step Test



SOL Youth Safety Checklist for Fitness Step Test

ID NUMBER:		FORM CODE: SST VERSION: 1 9/13/11	Contact Occasion		SEQ #	

Administrative Information

0a. Completion Date:

/

/

Month

Day

Year

0b. Staff ID:

Instructions: Enter the answer given by the participant for each response. If a response is unknown or cannot be measured then enter the special missing value, “==”, in the item.

1. Are you currently under a doctor or health care provider's orders to not exercise?

No.....0 ☐

Yes.....1 ☐ **INELIGIBLE**

2. Has a doctor ever told you that you have asthma?

No.....0 ☐ **GO TO QUESTION 3**

Yes.....1 ☐

2a. If yes, do you use medications (e.g., inhaler) to control your asthma symptoms?

No.....0 ☐ **GO TO QUESTION 3**

Yes.....1 ☐

2b. If yes, how often do you use your rescue inhaler (i.e., albuterol)?

0-2 Times a Week.....0 ☐

3 or More Times a Week.....1 ☐ **INELIGIBLE**

2c. When is the last time you used your rescue inhaler? (ask for the specific time of day)

a. Time of day:

:

H

H

M

M

b. AM or PM

AM A

PM P

[if they respond to having used it within 4 hours, they are INELIGIBLE]

3. Do you have any foot, ankle, leg, or hip injuries that would make it painful for you to step up and down on this bench?

No.....0 ☐

Yes.....1 ☐ **INELIGIBLE**

4. Have you had surgery on your feet, ankles, legs, or hips that would make it painful for you to step up and down on this bench?

No.....0 ☐

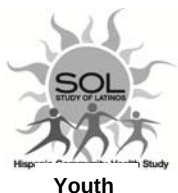
Yes.....1 ☐ **INELIGIBLE**

5. **For interviewer only:** Is the participant taking any contraindicated medications (listed in appendix)? Review the list of medications recorded.

No.....0 ☐

Yes.....1 ☐ **INELIGIBLE**

Appendix 3:
Step Test Data Form



SOL-Youth Fitness Step Test

ID NUMBER:							

FORM CODE: FST
VERSION: 1
11/10/11

Contact Occasion			SEQ #		

Administrative Information

0a. Completion Date:

 /

 /

Month Day Year

0b. Staff ID:

Instructions: Enter the answer given by the participant for each response. If a response is unknown or cannot be measured then enter the special missing value, "=", in the item.

6. Standing height:

 cm

7. Bench height used:

Bench Height Used	Child's Height	Pin holes on side braces (W=use of plywood)
1	95-105 cm	1
2	106-115 cm	1W
3	116-125 cm	2
4	126-140 cm	2W
5	141-155 cm	3
6	156-165 cm	3W
7	166-180 cm	4
8	181+ cm	4W

8. Find radial pulse rate before exercise

No.....0

Yes.....1

9. Resting heart rate (pre-test): Total heart rate counts for 15 seconds

 total beats

10. Post Exercise Heart Rate (5 to 20 seconds): Total counts for 15 seconds

 total beats

11. Heart Rate at discharge: Total counts for 15 seconds

 total beats
(Count should be ≤ 25 at the time of release)

12. Was this procedure completed?

No.....0 ☐
Yes.....1 ☐ **GO TO END**

7a. If no, please explain

15. Tanner Assessment

15.1 Overview

Children go through many biological changes during puberty. Some of these changes include maturation of their bodies. We would like to determine the stage of maturation of SOL Youth participants. In order to accurately assess the stage of maturation, 80 participants will briefly be visually examined. This examination will be similar to how a doctor periodically assesses a child, except this assessment will only be visual and there will be no touching involved. For girls, we will view their breasts and genitalia and for boys we will only view their genitalia. This visual inspection will take less than 1-2 minutes. Parents may stay in the room with the child during this part of the visual examination.

Because the onset and progression of puberty are so variable, Tanner has proposed a scale, which is now uniformly accepted, to describe the onset and progression of pubertal changes (see Appendix 3 for females, 4 for males). Boys and girls are rated on a 5 point scale. Boys are rated for genital development and pubic hair growth, and girls are rated for breast development and pubic hair growth.

15.2 Equipment and Supplies

Hospital gown

Tanner Assessment Forms (see Appendix)

15.3 Procedures

1. Introduce self and read the following script to ask permission for visual examination:

“Children go through many biological changes around the same age as your own child(ren). Some of these changes include maturation of their bodies. We would like to determine at what stage of maturation your child is in. In order to accurately assess this, we would like to briefly visually examine your child. This examination will be similar to how your own doctor periodically assesses your child, except we will not touch your child. For girls, we will view their breasts and genitalia and for boys we will only view their genitalia. This visual inspection will take less than 1-2 minutes. You may stay in the room with your child during this part of the visual examination.”

2. If the parent(s) and child AGREES, then a physician will perform the visual assessment. Give the participant a few minutes to fully disrobe and put on the examination gown.

When the physician returns, he/she will simply check off the box next to the Vermont Department of Health Tanner Stage picture and description that best represents the participants’ Tanner Stage (see Appendix 3 for females, 4 for males).

If the parent DISAGREES then the physician or staff person will ask if it is okay for the child to self-asses his/her maturation level by viewing Tanner stage drawings. If

the parent agrees to the self-assessment, then the physician or staff person will read the text to the child and ask the child to cross the box that is closest to their current stage of development (see Appendix 1 for males, 2 for females). If the parent declines the self-assessment, then we will thank the parent for their consideration and no Tanner assessment will be done.

3. If the parent has agreed to the visual examination, then following the examination ask the parent and child if they will also agree to a self-assessment. The self-assessment in conjunction with the visual examination is done for quality control purposes, in order to assess whether a child's perception of their maturation is in agreement with the examiner's.

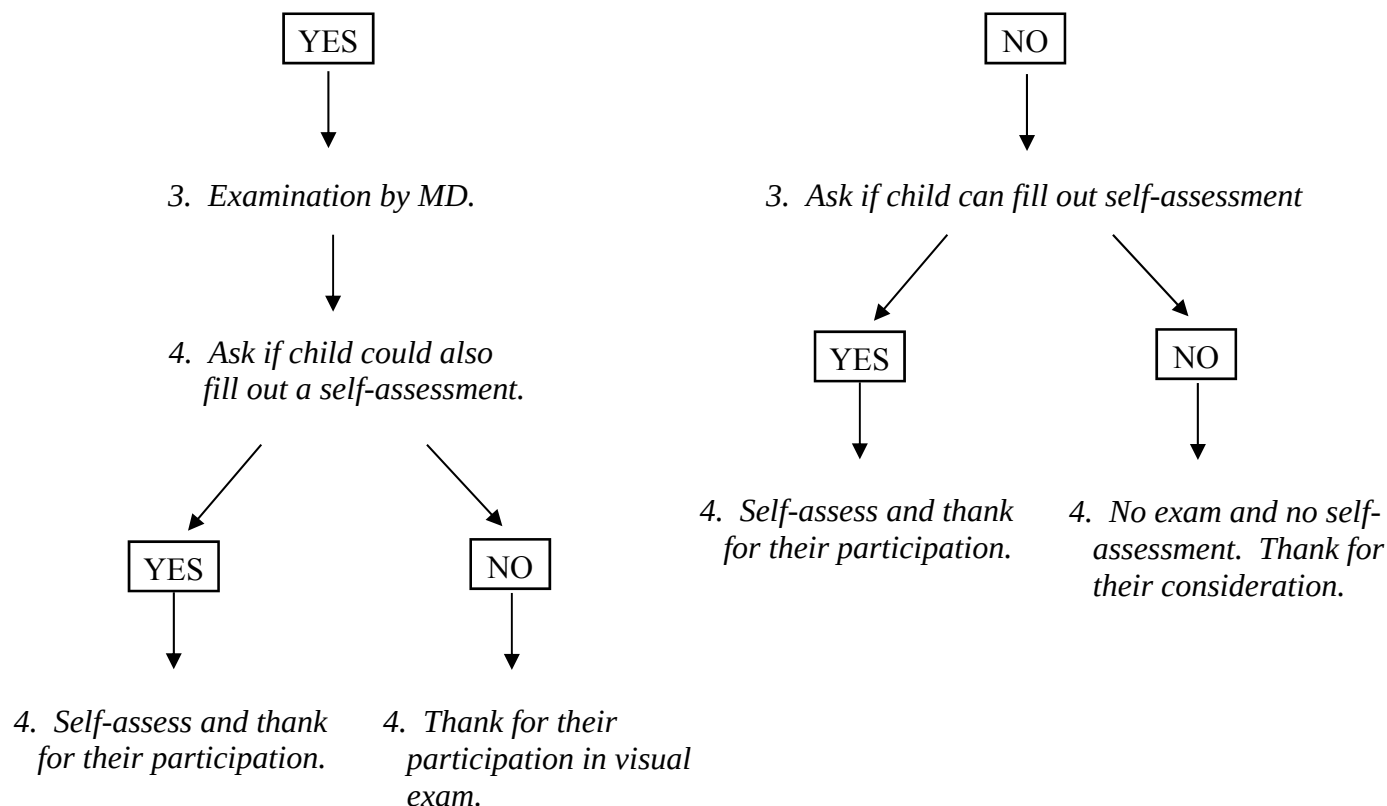
If the parent and child AGREE to the self-assessment, then the physician will administer the Self-Assessment form (see Appendix 1 for males, 2 for females). The physician will read the text to the child and ask the child to cross the box that is closest to their current stage of development.

If the parent or child DISAGREES to do the self-assessment, then thank the parent and child for their participation in the Tanner Stage visual examination assessment.

A summary overview of the protocol steps is shown below:

1. *Introduce self and read script.*

2. *Ask permission for visual examination.*



15.4 Quality Assurance

15.4.1 Training & Certification

Visual examinations will only be conducted by a physician.

15.4.2 Quality Control Procedures

For quality control purposes, every child that agrees to a visual examination will also be asked to conduct a self-assessment to determine if his or her perception of stage of maturation is in line with the examiner's perception. Finding the degree of alignment is particularly important in order to determine the validity of self-assessment measures in children that decline the visual examination.

15.5 Safety Procedures

Since this part of the study only requires a visual examination and/or written self-assessment, there is no physical risk involved. However, to minimize discomfort, parents are encouraged to remain in the room with the child during the examination.

15.6 References

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Appendix 1.
HCHS SOL Youth, Tanner Stage Self-Assessment for Males

We would like to assess the stage of your physical development using the drawings on the next pages. These show various stages commonly used by doctors to assess the growth and development of boys. We need to know which drawings most closely match your stage of development at the moment. Not all teenagers follow the same pattern of development. Just pick the stage that is closest, based on both the picture and the description.

Part A. Instructions

Teenagers go through the various stages of physical development at different ages. Some start as early as 6, others not until they are 20. We need your help in letting us know what stage you are at. **Please look at each of the drawings.** It is also important to read the descriptions.

Cross the box that is **closest** to your current stage:



1) ☐

The size and shape of the testes, scrotum (the sac holding the testes) and penis are about the same as when you were younger.



2) ☐

The penis is a little bit bigger. The scrotum has dropped and the skin of the scrotum has changed. The testes are bigger.



3) ☐

The penis has grown longer, the testes have grown and dropped lower.



4) ☐

The penis is longer and wider. The head of the penis is bigger, the scrotum is a darker colour and bigger. The testes are bigger.



5) ☐

The penis, scrotum and testes are the size and shape of a man's.

Part B. Instructions

As part of development, at some stage hair will start to grow just above the penis. **Please look at each of the drawings.** It is also important to read the descriptions. If you have shaved or trimmed your hair, please rate how much you would have if you have not shaved.

Cross the box that is **closest** to the amount of **pubic hair** that you have.



- 1) ☐ There is no hair at all.
- 2) ☐ There is a little soft, long, lightly colored hair at the base of the penis. It may be straight or a little curly.
- 3) ☐ The hair is darker and more curly. It has spread out and thinly covers a bigger area.
- 4) ☐ The hair is as dark and curly as that of a man, but it hasn't spread out to the legs.
- 5) ☐ The hair is like that of a man. It has spread out to the legs.

**Source:*

University of Bristol. Department of Social Medicine. Oakfield Grove, Bristol, UK. Avon Longitudinal Study of Parents and Children. Growing and Changing (8), Male Teenager Questionnaire. Question numbers B1-B5 and C1-C5.

Participant from Source: Males aged 6-20 years

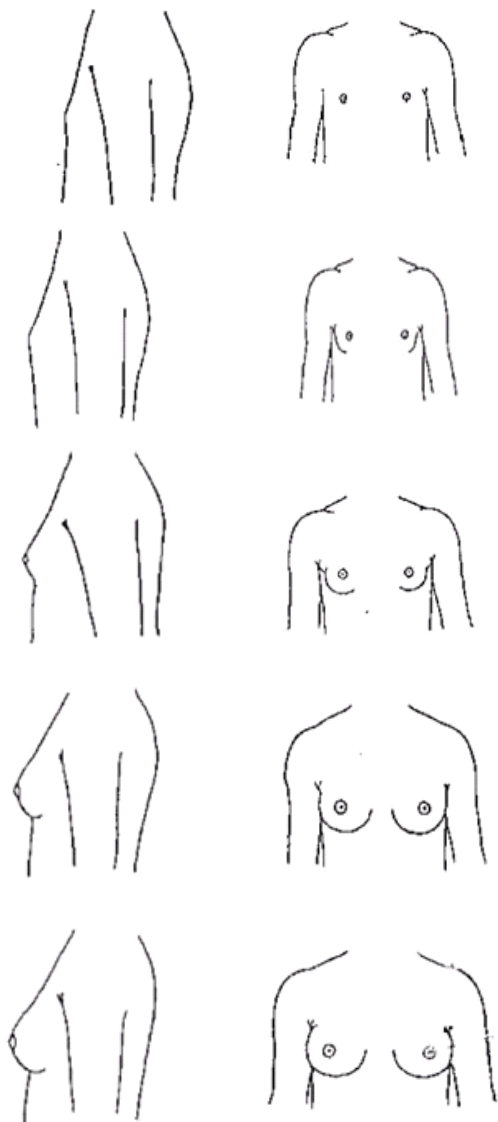
Appendix 2. HCHS SOL Youth, Tanner Stage Self-Assessment for Females

We would like to assess the stage of your physical development using the drawings on the next pages. These show various stages commonly used by doctors to assess the growth and development of girls. We need to know which drawings most closely match your stage of development at the moment. Not all teenagers follow the same pattern of development. Just pick the stage that is closest, based on both the picture and the description.

Part A. Instructions

The drawings below show stages of the way the **breasts** develop. A teenager can go through each of the five stages shown, although some teenagers skip some stages. **Please look at each of the drawings.** It is also important to read the descriptions.

Cross the box that is **closest** to your current breast stage.



- 1) ☐ The nipple is raised a little in this stage. The rest of the breast is still flat.

- 2) ☐ This is the breast bud stage. In this stage the nipple is raised more than in stage 1. The breast is a small mound. The dark area around the nipple (areola) is larger than in stage 1.

- 3) ☐ The areola and the breast are both larger than in stage 2. The areola does not stick out away from the breast.

- 4) ☐ The areola and the nipple make up a mound that sticks up above the shape of the breast. (Note: This stage may not happen at all for some teenagers. Some teenagers develop from stage 3 to stage 5 with no stage 4.)

- 5) ☐ This is the mature adult stage. The breasts are fully developed. Only the nipple sticks out in this stage. The areola has moved back in the general shape of the breast.

Part B. Instructions

The drawings below show different amounts of **female pubic hair**. A teenager can go through each of the five stages shown. **Please look at each of the drawings.** It is also important to read the descriptions.

Cross the box that is the **closest** to the amount of pubic hair you have. If you have shaved or trimmed your hair, please rate how much you would have if you have not shaved.



1) ☐ There is no pubic hair



2) ☐ There is a little long, lightly colored hair. This hair may be straight or a little curly.



3) ☐ The hair is darker in this stage. It is coarser and more curled. It has spread out and thinly covers a bigger area.



4) ☐ The hair is now as dark, curly, and coarse as that of an adult woman. However, the area that the hair covers is not as large as that of an adult woman. The hair has not spread out to the legs.



5) ☐ The hair is like that of an adult woman. It also covers the same area as that of an adult woman. The hair usually forms a triangular pattern as it spreads out to the legs.

NOTE: Your pubic hair stage may or may not be the same as your stage of breast development.

**Source:*

University of Bristol. Department of Social Medicine. Oakfield Grove, Bristol, UK. Avon Longitudinal Study of Parents and Children.

Growing and Changing (8), Girl Teenager Questionnaire. Question numbers B1-B5 and C1-C5.

Appendix 3. HCHS SOL Youth, Tanner Stage Physician Assessment for Females

If the participant has no pubic hair or seems to shave, ask:

Have you shaved or trimmed your pubic hair recently?

- ☐ Yes → Have participant fill out a self-administration form for pubic hair development. Only conduct breast development assessment.
- ☐ No → Continue with pubic hair development assessment and breast development assessment.

Part A: Pubic Hair Development



1) **Stage I (Preadolescent)**

Vellus hair develops over the pubes in a manner not greater than that over the anterior wall. There is no sexual hair.

☐


2) **Stage II**

Sparse, long, pigmented, downy hair, which is straight or only slightly curled, appears. These hairs are seen mainly along the labia. This stage is difficult to quantitate on black and white photographs, particularly when pictures are of fair-haired subjects.

☐


3) **Stage III**

Considerably darker, coarser, and curlier sexual hair appears. The hair has now spread sparsely over the junction of the pubes.

☐


4) **Stage IV**

The hair distribution is adult in type but decreased in total quantity. There is no spread to the medial surface of the thighs.

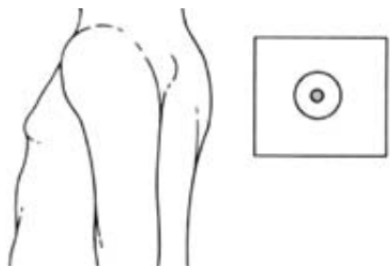
☐


5) **Stage V**

Hair is adult in quantity and type and appears to have an inverse triangle of the classically feminine type. There is spread to the medial surface of the thighs but not above the base of the inverse triangle.

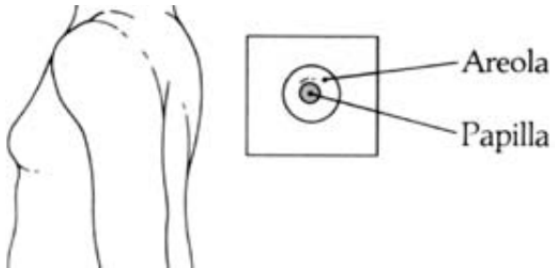
☐

Part B: Breast Development



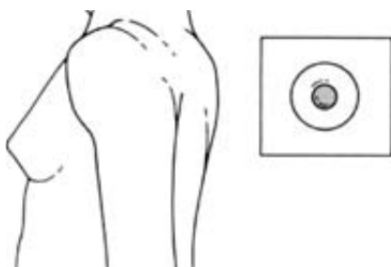
1) **Stage I (Preadolescent)**

Only the papilla is elevated above the level of the chest wall.

☐


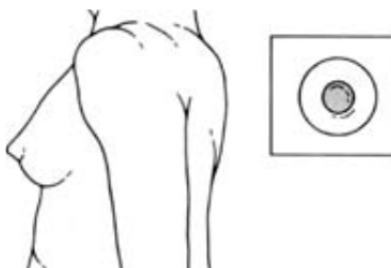
2) **Stage II (Breast Budding)**

Elevation of the breasts and papillae may occur as small mounds along with some increased diameter of the areolae.

☐


3) **Stage III**

The breasts and areolae continue to enlarge, although they show no separation of contour.

☐


4) **Stage IV**

The areolae and papillae elevate above the level of the breasts and form secondary mounds with further development of the overall breast tissue.

☐


5) **Stage V**

Mature female breasts have developed. The papillae may extend slightly above the contour of the breasts as the result of the recession of the areolae.

☐

Appendix 4.

HCHS SOL Youth, Tanner Stage Physician Assessment for Male

If the participant has no pubic hair or seems to shave, ask:

Have you shaved or trimmed your pubic hair recently?

- ☐ Yes → Have participant fill out a self-administration form for pubic hair development. Only conduct genitalia development assessment.
- ☐ No → Continue with pubic hair development and genitalia development assessment.

Part A: Pubic Hair Development



1) **Stage I (Preadolescent)**

Vellus hair appears over the pubes with a degree of development similar to that over the abdominal wall. There is no androgen-sensitive pubic hair.

☐


2) **Stage II**

There is sparse development of long pigmented downy hair, which is only slightly curled or straight. The hair is seen chiefly at the base of penis. This stage may be difficult to evaluate on a photograph, especially if the subject has fair hair.

☐

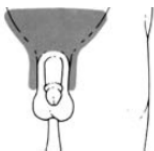

3) **Stage III**

The pubic hair is considerably darker, coarser, and curlier. The distribution is now spread over the junction of the pubes, and at this point that hair may be recognized easily on black and white photographs.

☐


4) **Stage IV**

The hair distribution is now adult in type but still is considerably less than seen in adults. There is no spread to the medial surface of the thighs.

☐


5) **Stage V**

Hair distribution is adult in quantity and type and is described in the inverse triangle. There can be spread to the medial surface of the thighs.

☐

Part B: Male Genitalia Development



1) **Stage I (Preadolescent)**

The testes, scrotal sac, and penis have a size and proportion similar to those seen in early childhood.

☐

2) **Stage II**

There is enlargement of the scrotum and testes and a change in the texture of the scrotal skin. The scrotal skin may also be reddened, a finding not obvious when viewed on a black and white photograph.

☐

3) **Stage III**

Further growth of the penis has occurred, initially in length, although with some increase in circumference. There also is increased growth of the testes and scrotum.

☐

4) **Stage IV**

The penis is significantly enlarged in length and circumference, with further development of the glans penis. The testes and scrotum continue to enlarge, and there is distinct darkening of the scrotal skin. This is difficult to evaluate on a black-and-white photograph.

☐

5) **Stage V**

The genitalia are adult with regard to size and shape.

☐

16. INTERVIEWS

Interviewing is a collaboration between the SOL Youth staff and the study participants (children and parents) to collect study data, using standardized techniques common to each examination site, that are unchanged for the duration of the baseline examination. This section of Manual 1 presents a general description of interviewing in the intake examination of SOL Youth. Specialized interviews such as the 24-hours dietary recall and dietary supplements are detailed in a separate manual.

Interviews in SOL Youth study are administered in English or Spanish – at the preference of the study participant (child and parent independently) – by trained and certified personnel who are bilingual. Participants need not be consistent in their use of Spanish or English between forms; for each form the language of administration will be recorded in the database for quality assurance purposes. Interviews conducted at the SOL Youth field center are administered using the SOL Youth Data Entry and Management System (DES) which supports the interviewer with automatic skip pattern implementation auto-fill features, and provides quality assurance features such as on-entry editing. Questionnaires that are not administered using the SOL Youth DES include the 24-hour dietary recall. The most important factor influencing the study participant's satisfaction and the quality of the interview data is the interviewer, his/her skills and adherence to the study protocol.

16.1. Characteristics of a Good Interview

Interviews are friendly but businesslike. At the beginning of each encounter the interviewer makes introductions and verifies the participant's name. Participants are always thanked at the conclusion of interview sessions. Interview areas should be as quiet and private as possible. Although this is often out of the control of the interviewer, participants should be accommodated to have their interviews take place at a time when these conditions are possible.

Interviews are the structured, one-sided transfer of information, not a conversation. The pacing of questions is based on the comfort and comprehension of the participant with each interview; it may vary depending on interviewing the child versus the parent but also as the content, complexity or period of recall of the person or subject matter changes. During an interview, questions from the participant are answered with neutral, nonjudgmental responses and questions to the participant are limited to probes to clarify or resolve incomplete, ambiguous or inconsistent responses. Repeating a question is most appropriate when the participant does not appear to understand the intent or meaning of the question. Gently stressing the portion of the question which was not understood when the question is repeated (e.g., "has a doctor ever") is often more efficacious than rereading it in exactly the same manner.

16.2. Characteristics of a Good Interviewer

Interviewers are responsible for being fully familiar with the questions, response categories and skip patterns of each interview. At the beginning of an interview the study participants may wish to be reassured that of the confidentiality of each response/measurement. Interviewers use a conversational tone and establish a pace consistent with the interest and ability of the participant. A good interviewer projects the importance of the interview to the participant and attempts to gain his/her confidence, while remaining impartial and nonjudgmental. For example, a verbal response (or body language when the interview is being conducted in person) which indicates positive feedback is inappropriate, even in the light of participant reports of behavioral modifications

which in a clinical setting would result in praise and encouragement. Participant confidence in the confidentiality of each response/measurement is established.

16.3. Communication Traps and Obstacles to Standardization

Communication traps include: (1) anticipating or answering questions directed to the participant with the interviewer's own thoughts; (2) hearing what one expects to hear; or (3) being drawn into a conversation. The likely sensitivity of a question is often as much a perceptual problem of the interviewer as it is the participant. Questions thought to be "sensitive" should be asked in a neutral manner which does not differ from the normal professional flow of the interview.

The most frequent obstacles to the administration of a standardized interview are: (1) a perceived conflict by the interviewer between the need to standardize the question with the desire to obtain the truth; (2) a conflict between the interviewer's desire to achieve rapport with the participant and adherence to standardization; (3) inadequate training of the interviewer; and (4) inadequate training of the respondent.

16.4. Interviewer Bias

The use of standardized interviewing techniques is employed to reduce one of the many potential sources of misclassification; i.e., interviewer bias, a *systematic* difference between responses obtained by different interviewers. Although introductory scripts may be modified to respond to different situations an interviewer may encounter, administration of each question exactly as written and use of standardized definitions or explanations are critically important to avoid bias.

16.5. Conducting the Interview

Interviewers must keep in mind that the interviewee is not familiar with the questions, their sequence and response categories. Many interviews require the interviewer to "train" the respondent, mostly using verbal instructions and at times using response cards handed to the study participant. For example, responses may follow a series of patterned questions, e.g., a doctor diagnosed condition, age at onset, and age at treatment during the participant's lifetime or may require the selection of the most appropriate category from a series of descriptors, e.g., almost never, sometimes, often and almost always. Unless a response card is used, these instructions should be repeated until it is clear that the respondent understands them, and then subsequently offered only as needed. When the pattern of questions in a form changes to another repeated sequence of responses the interviewer should assist the study participant in making this transition.

The most important technique for conducting a rigorously standardized interview is to read the question in the exact words and in the exact sequence as printed in the questionnaire. With experience the interviewer can memorize specific questions. This helps in maintaining eye contact with the study participant, but care must be taken to avoid changing the wording of the question(s) that are not being read. The review of taped interviews assists in maintaining standardization in that it can alert interviewers who inadvertently change the wording of a question. Every question must be asked, even if the participant appears to have provided the information in the answer to another question. If based on a previous answer a question is asked out of the printed sequence, a skip pattern instruction is printed on the form (and presented on the monitor screen).

Reading the transition statements exactly as they are worded is equally important in maintaining standardization. The transition statements are designed to inform the participant about the nature

of a question or a series of questions, to define a term, establish a time frame or describe what is being asked in the question.

Response styles of an interviewer influence the willingness of the participant to respond to questions and the quality of the response. Inappropriate styles include those that are evaluative or judgmental, interpretive or pedantic. Interrupting responses for reasons other than to focus or channel the participant's answer should be avoided.

Appropriate styles of interviewing include providing neutral noises to reassure, pacify or reduce the intensity of the respondent's feelings. These include general clucking or an understanding murmur, as well as nondirective or understanding statements such as a repetition of what the respondent has just said (in contrast to paraphrasing). These are intended to reassure that participant or show interest without intruding on the flow of the response.

Probing is appropriate to seek further information, provoke further discussion along a certain line of thought or explanation, or to present a question to the respondent. In general, and unless specifically countermanded in the QxQ instructions of the interview, probing is appropriate when an answer is unclear, incomplete, inconsistent or no response is given. The best and most frequently employed probe is silence. In a silent probe, the interviewer pauses or hesitates and looks to the participant for an answer. What appears to be dead time to the interviewer may allow the participant to review a lifetime of events. Other types of probing include repetition of the original question, channeling ("tell me more about ..."), clarification ("when did your doctor tell you that?"), elaboration/ continuation ("what happened next?"), encouragement ("I see, um, uhuh") and completion ("anything else?"; "can you tell me anything more about that?").

The most effective, spoken probes are neutral, such as:

"How do you mean that?", instead of "Why?"

"Can you tell me more about this?"

"Can you give me an example?" or "Can you explain that in a little more detail?"

"How are you using that term?"

"If you had to choose, which would you say?"

"What else can you tell me about that?" instead of "Anything else?"

The cautions in using probes are similar to those for the other interviewing techniques: do not interrupt; do not give the impression you are not listening; do not paraphrase the respondent's words and do not suggest an answer.

16.6. Administration of the Interviews

SOL Youth questionnaires are interviewer-administered to both the parent and the child participants, using a specialized data entry and management system, except for several sensitive topic child-only questionnaires that are self-administered on paper forms to the child. An

interviewer in present in the room only in case any questions or clarifications about the questionnaires are needed. The data entry and management system used by SOL Youth is designed to enhance data accuracy and security, while minimizing the burden for the participant and staff. The system displays screens that resemble the paper forms. The interviewer reads the items from the screen and keys the response into the computer. As data are entered, they are edited by the system. Values failing the edit checks cause an error message to be displayed prompting the interviewer to confirm the value, correct it, or flag it as in need of further investigation. Data from the self-administered paper forms should be entered into the data entry system as soon as possible and prior to the participant's departure in case values failing the edit checks cause an error message to be displayed.

Questionnaires are available in English/Spanish combined versions. Questionnaires for which no existing Spanish translations are available were translated by a certified translator with expertise in multilingual instrument development for large-scale surveys. New as well as existing translations were reviewed by members of the SOL Youth Translation Subcommittee with representation from the four field centers and the coordinating center who are bilingual and represent the four regions of origin for the study (Mexican, Cuban, Puerto-Rican, and Central/South American). The final translations were certified prior to release for programming at the coordinating center.

16.7. Quality Assurance of Interviews

The quality of data collected during interviews is maintained through a series of quality assurance procedures. All interviewer-administered interviews are based on the reading of written questionnaires, supported by a Manual of Operations and question by question (QxQ) instructions for each form. Interviewers are trained and certified in interviewing techniques, in the subject matter, terminology, and flow of each data collection form. Certification requires attendance at the central training workshop at the beginning of the study, local practice, and the successful completion of three taped interviews on surrogate, age and sex appropriate participants.

Successful completion consists of demonstrated ability in the following five areas:

- (1) Knowledge of the substantive matter in the interview;
- (2) Use of an even pace and conversational tone;
- (3) Demonstration of a professional and nonjudgmental demeanor;
- (4) Use of appropriate probing techniques;
- (5) Ability to accurately record the participant's response.

Interviewers unable to attend central training are trained at each SOL Youth field center by the interviewer supervisor, using the SOL Youth training materials, standards and certification procedures.

Monitoring of the interviewing skills of each interviewer through direct observation by the supervisor is conducted monthly, as described in Manual 4 – Quality Control. Interviewers who experience difficulty in maintaining their skills are retrained. Interviewers are re-certified at least

once a year by the interviewer supervisor listening to interviews the staff member conducts with actual participants, and reviewing the contents of the respective for form. Field centers report their certification activities to the coordinating center for the central repository of certification status. The Coordinating Center informs study coordinators when the interviewer certification status is about to lapse.

A round robin review of taped interviews is organized by the coordinating center on a quarterly schedule. One tape with three interviews and their corresponding paper forms for each interviewer are assembled and participant identifiers on the study form are removed/masked. The taped interviews only specify the interviewer code and field center name. One field center's supervisor reviews another center's taped interviews with the help of the certification check list (see Manual 4 – Quality Control).

According to round robin comments returned to the field center supervisor and to the coordinating center, field center supervisors determine whether interviewers require additional training. If the retraining is extensive, a new tape with three interviews is prepared and submitted for review by the original round robin partner.

At the conclusion of the round robin, each field center's supervisor sends the following materials to the coordinating center:

- (1) one check list for each interviewer; and
- (2) three interviews recorded on tape(s) and three paper forms per interviewer.

17. DATA ENTRY SYSTEM (CDART)

Carolina Data Acquisition and Reporting Tool (CDART) is designed to be scalable, utilizing web-based, customizable technology options to support studies ranging from a multi-center clinical trial, observational study or patient registry involving thousands of patients to a 40-patient research study conducted wholly within a single hospital or community clinic. Technology components are designed to provide maximum flexibility and re-use, with minimal customization required for each new study application.

Standard features of traditional clinical research data management systems are available with the CDART. These include interactive web-based data entry with real-time field validation, audit logs to record database modifications, database integrity checks, security (in logins, permissions based on need, and encrypted data transmission), standard reporting, forms inventory, ETL (extract, transform, load) capability and data export for analysis. The systems allow researchers to design and configure data input screens to match study-specific case report forms.

To facilitate data sharing, optional components CDART conform to the CDISC CDASH and ODM standards. CDASH, Clinical Data Acquisition Standards Harmonization, focuses on content standards for basic data collection fields in 16 domains focusing on safety. The ODM, Operation Data Model, was designed to support the electronic acquisition, exchange and archive of electronic data and meta-data in a standard XML-based format. The ODM defines structures to represent clinical study metadata, clinical study administrative data and clinical study patient data.

The secure server environment where the systems that host CDART reside is located within a hardened data center on the UNC campus, and is governed by standard UNC information security guidelines. Weekly vulnerability detection scans are performed by a third party vendor, which include full administrative credentials to perform maximum detection techniques. Real-time virus protection software is implemented, and weekly full system virus scans are performed. Daily backups of the data are made and stored in an off-site location.

Refer to Manual 5 for more details about running reports and use of the CDART DMS in general.

18. DATA INVENTORY AND REPORT PREPARATION

The data inventory is done after all interviews and examination procedures have been completed and prior to the Exit Interview. At the field center's discretion, this can be done while the study participant changes into street clothes. Because participant data are collected by various means during the course of the exam, the objective of this inventory is to verify that all data items have been collected before the participant leaves the study center. In order to perform the data inventory, run the Participant Inventory Report found on the "Reports" page of the study Data Management System (CDART DMS). Supply the SOL Youth child participant ID and the application will list the set of completed forms and procedures, noting which ones are missing. Repeat this report using the parent's participant ID as well. Refer to Manual 5 for more details about running reports and use of the CDART DMS in general. As part of this inventory the "end of visit" report of study results is personalized and printed for review with the participant during the exit interview. All materials need for the exit interview and the instructions for the physical activity monitoring are assembled and placed in the participant's folder at this time.

19. EXIT INTERVIEW

The end of visit debriefing provides an opportunity to ask for feed-back about the visit and to identify aspects that the child and/or parent participants may have perceived as stressful or unpleasant. It also provides an opportunity to further develop rapport with the study participants and to seek commitment for a long-term association with SOL Youth. The child participant's parent is reminded of the dietary recall follow-up call (about 7-14 days), and at the field center's discretion, the call can be scheduled at that time.

The schedule of notification for the full set of study results also is reviewed at this time. These materials are shown in Section 21 of this manual. Before proceeding to the instructions for the physical activity monitoring, the participants (child and parent) are asked whether they have any remaining questions about the study, the results to be received, or any concerns.

20. PARTICIPANT SAFETY

The safety of the SOL Youth participants is ensured through strict adherence to the study examination protocol which has been developed to ensure participant safety. The following chapter describes procedures for handling potential emergencies as well as circumstances that require consultation with field center Principal Investigators, medical and/or social services personnel.

20.1 Safe Clinic Environment

Overview

Standard procedures pertaining to clinic cleanliness, professionalism and safety should be adhered to. When parent/guardians are not accompanying their children, clinic staff members are responsible for supervising the youth. Youth should be accompanied at all times by a staff member if their parent/guardian is not with them, and if there are left alone in room, that room should be free from debris and all hazardous equipment and material should be out of reach. Youth may be more “curious” than adult participants and so staff members should complete a walk-through of the clinic and clinic rooms to identify items that might be appealing to a child and to secure those items. Making child-focused magazines, coloring books or comic books or even safe toys available may provide positive distractions for children who may need to entertain themselves while waiting for a sibling or parent and deter them from “playing with” dangerous items.

Child care

In most clinics, the staff members are not certified child care providers and so should not function in that manner. Clinics are encouraged to discourage participants from bringing children who will not participate in the study to the clinic with them if they are not able to bring along another adult to supervise them. If a parent brings along more than one age-eligible child to the examination and both children are not engaged in the examination simultaneously, it is appropriate (and preferable) for a staff member to remain with the unoccupied child. If all study elements are completed for that child, then it is appropriate for the staff member to engage with the child using materials that should be available in the clinic.

Food

Allergic reactions to certain foods are a potentially serious problem for a subset of children. Peanuts are a common allergen that can lead to severe anaphylaxis. All clinics should consider offering snacks that do not include peanuts or peanut butter.

20.2 Participant Safety Screening Form (PSE)

The master record used in SOL Youth to document and monitor safety is the Participant Safety Screening Form (PSE). Although some exclusion conditions are also recorded on other study forms as well as on a check list, the Participant Safety Screening Form (PSE) serves as the summary record of safety items in the SOL Youth database and is the register by which the Study monitors compliance with the safety protocol. Thus, if the study participant or an authorized SOL Youth clinic staff person updates information provided previously (such as prior to the blood draw) the PSE form must be updated. This is done by (a) changing the pertinent response on the PSE in the DMS, and (b) by adding a note log to that item with a brief explanation for this action and the staff person’s SOL Youth ID.

The Participant Safety Screening form (PSE) must be completed before a participant can proceed through the SOL Youth baseline examination. The form can be completed on paper or in the SOL Youth DMS. A completed copy of the Participant Safety Screening form (PSE, whether completed on paper or a printed copy of the form completed in the DMS) accompanies the SOL Youth participant throughout the course of the baseline examination. The PSE form must be available to the staff member who performs an examination procedure. Notations should be made on each participant's Clinic Exam Checklist if there is a positive response to any questions on the PSE that might preclude participants from completing that element of the study. Before beginning the examination, staff should confirm with the youth and the parent/guardian of the procedures that will be completed on that day.

Modifying and verifying the PSE

As the youth and parent/guardian proceed through the examination, the technician should confirm the safety exclusion when preparing for that study component. In the event that the child's reporting contradicts that of the parent/guardian, the parent should be consulted before making the final decision. The one exception is for pregnancy, which should not be verified with the parent/guardian if the youth does not want that information disclosed.

To modify a previous entry on the PSE form the extant entry is crossed out on the paper form and the appropriate entry is marked, adding the initials of the technician (and reference to the supervisor if pertinent) as well as a brief note to document the occurrence. The latter will be keyed as a note log in the DMS for the item in question. Items on the PSE that are changed from 'No' to 'Yes' by a technician after asking the safety question prior to a test or procedure are recorded on the PSE form following the same procedure. The SOL Youth staff person conducting the Exit Interview reviews the procedures performed and verifies the agreement with the exclusion conditions noted on the PSE form.

20.3 Pregnancy

Staff will attempt to ascertain current pregnancy during the recruitment call; however, it is possible that the parent/guardian may be unaware of the condition. If the youth discloses the pregnancy at the time of the examination, only interview data will be collected in a manner that will maintain the youth's privacy if she requests it. The remaining elements—phlebotomy, anthropometry, bioimpedance measures and Fitness Step Test will be rescheduled after the due date. Study personnel cannot reveal the pregnancy to the parent/legal guardian, but if the parent/legal guardian inquires why these procedures are not being conducted, study personnel will inform the parent/legal guardian that these procedures are being conducted on a random sample of participants and will not be conducted on the child that day (see Sample Script in Appendix). A notation should be made on each component examination form that was not completed and on the Participant Safety Screening (PSE) form. The staff member should discretely alert other personnel who would have collected those measurements on that day so that the clinic schedule can be adjusted accordingly. **Care should be taken not to show these forms to the parents so as not to risk inadvertent disclosure.**

20.4 Cancell/Rescheduling Clinical Components

Because the study poses minimal risk to youth and their parents, the only two safety-related exclusions are for:

1. Bioimpedance analysis (for determination of body fatness): use of a pacemaker or defibrillator
2. Step test (for determination of cardiorespiratory fitness): use of an asthma rescue inhaler within 4 hours of the examination, orthopedic disorders or permanent injury that impede mobility, or the use of contraindicated medications.

As detailed in the Anthropometry and Fitness test chapters, the presence of these conditions is ascertained during recruitment and scheduling (in order to plan the exam visit accordingly) and queried again during the examination by the staff member attending to the participant. However, as the result of time elapsed between recruitment and examination, discrepancies may arise between eligibility initially ascertained and eligibility on that given day. Those discrepancies should be resolved using the information collected on the day of the examination and added to the PSE. That information should be verified by the parents of the youth. The top priority is the safety of the child/adolescent participant and if uncertainty remains, the exam component in question should be skipped.

Weight will not be measured in girls or female adult participants who indicate that they are pregnant. However, those participants will be invited to return to the clinic to have those elements measured when they are no longer pregnant.

Participants who are not eligible for bioimpedance analysis because of a pacemaker or defibrillator will not be rescheduled for that component.

20.5 Procedures for Handling Emergencies

For persons with conditions which require emergency and immediate referrals to a physician, each field center should follow their specific procedures. If appropriate, the clinic exam should be terminated at the onset of emergency and field-center specific emergency procedures should be followed (Field center specific emergency procedures are included in Appendix X). All field centers are encouraged to generate their own local alert/referral document for handling emergencies according to their local guidelines.

All life threatening emergencies (e.g., seizure, difficulty of breathing) require immediate evaluation of the participant at an acute care facility. In addition, there are minor emergencies (hypotension, fainting, orthopedic injuries from the step test, etc.) which may require treatment on the premises only. Although most emergencies are of the less severe nature, SOL Youth Field Center clinics are prepared for both types. All emergencies, whether serious or minor, are documented. This requires filling out an institutionally-approved form identifying the type of emergency. This is done by the person in charge at the time, and all reports are co-signed by a field center principal investigator and are filed at each clinic.

Major emergencies

In a serious event, the primary concern of the clinic staff is to implement pre-established procedures to get the participant to the nearest medical facility. All SOL Youth clinics are located

within a few city blocks of a large, general, acute-care hospital. Each field center should post the following in conspicuous places (e.g., the reception area): phone number of police and fire stations; ambulance services; and specific phone numbers or codes to alert medical teams, if applicable. Each SOL Youth field center should include in the appendix to this chapter specific manual specific emergency procedures, which define:

1. Who is in charge during the emergency.
2. Who is to administer treatments, including basic life support.
3. Who is to be notified.
4. What action clinic staff is to take.
5. Which reports are to be filed.

Minor emergencies

The most common minor emergencies are simple syncope (fainting) and near syncope from venipuncture or abrasions resulting from a stumble during the step test.

Syncope may occur during venipuncture or (rarely) during the step test. The management of simple syncope or near syncope follows the procedures detailed in Manual 2.

Many syncopal episodes can be prevented if clinic staff are alert to early signs. In any situation in which syncope is likely, e.g., after the venipuncture, staff should verify that the participant does not look or feel faint. If the participant looks faint or feels faint in the venipuncture area:

1. Have the person remain in the chair and sit with head between the knees or recline if the appropriate chair is used at the field center.
2. Provide the participant with a basin and a towel if he/she feels nauseous;
3. Have the participant stay in the chair until he/she feels better and the color returns.

If the participant continues to feel sick, recline the chair, place a cold wet towel on the back of the person's neck, and notify the supervisor to bring the parent/guardian to the examination room. If a participant faints, he/she is carefully lowered to the supine position on the floor and the study coordinator should be called to bring the parent/guardian to the examination room. The remaining staff member should raise the patient's legs above the plane of the body to increase venous return. Prior to this, the staff member momentarily palpates for a carotid pulse and checks to be sure the subject is breathing. If the participant is not breathing and life support measures are needed, clinic staff should call 911 immediately.

2. Minor abrasions from a stumble during the step test

If a youth participant stumbles or falls during the fitness step test, the staff member should first inquire whether the participant is able to continue the test (as some stumbles and falls do not result in injuries). If the participant is unable to continue or once the test is over (for those who stumbled and continued), the staff member should ask the youth participant where they are injured and should carefully view all areas that made contact with the ground or the step. Where minor scrapes and abrasions are apparent, the staff member should clean the area with antiseptic from a First Aid kit and bandage the area if possible. If an orthopedic injury is apparent (e.g., sprained

ankle or wrist), the staff member should have the youth participant sit down to rest and the parent/guardian should be brought to the room during the subsequent injury evaluation. If the youth participant appears to be in too much discomfort from the injury to continue the examination, their examination should be terminated and reasonable accommodations should be made to ensure that the youth participant and parent/guardian are able to return to their home. If they wish to seek medical attention immediately, clinic staff should permit the parent/guardian to call the physician office from a telephone in the clinic.

Emergency Equipment

A basic first aid kit is maintained at each field center. The kit contains a reference guide of its contents, and is checked every year and immediately after each use. At each field center the Study Coordinator identifies a person responsible for its maintenance.

20.6 Procedures to Document Adverse Events and Emergencies

Adverse Event Definition and Reporting in SOL Youth

An adverse event (AE) is an adverse change in health or "side-effect" that occurs in a person who participates in SOL Youth, which may or may not be caused by participation in the study. Serious adverse events (SAEs) and adverse events that are not anticipated in the study protocol or referred to in the informed consent must be reported to the local Institutional Review Board (IRB) and to the study sponsor (NHLBI).

AEs must be addressed promptly according to institutional safety guidelines and the SOL Youth study protocol, to resolve any safety concerns or participant discomfort. The supervisor, medical director and/or principal investigator are notified according to the perceived severity of the event and the safety protocol.

AE Classification in SOL Youth

Serious (vs. minor or not serious)

An adverse event is serious if it affected a pregnant study participant, a fetus or a newborn, or if it results in any of the following outcomes:

1. Death
2. A threat to life
3. Requires (inpatient) hospitalization
4. Likely causes persistent or significant disability or incapacity
5. Likely associated with a congenital anomaly or birth defect
6. Requires treatment to prevent one of the outcomes listed above, other than for pre-existing conditions detected as a result of participation in Sol Youth, its tests and examination protocol.

Expected (vs. unexpected)

An adverse event is unexpected if the risk information is not mentioned in the consent form, if the AE is not mentioned in the study protocol, or if the AE is not reasonably expected to be related to study procedures. The study procedures in SOL Youth are deemed to be safe. Serious adverse events (SAEs) are therefore unanticipated and unexpected, whether study related or otherwise.

Study-related, possibly study-related, or not study-related.

- **Related AE** – An adverse event which is related to the use of a device, procedure or an ingested substance in a way that supports a reasonable possibility (such as strong temporal relationship) that the adverse event may have been caused by the device, procedure or intervention used in SOL Youth.
- **Possibly Related AE** – An adverse event which is possibly study-related is one that may have been caused by a procedure, device, or ingested substance, with insufficient information to determine the likelihood of this possibility.
- **Unrelated AE** – An adverse event that has no apparent relationship to the study.

Reporting of Adverse Events and Information Flow

Once the participant safety and comfort concerns have been addressed all AEs are recorded in the SOL Youth DMS, and the Institutional Review Board (IRB) is notified according to each IRB's guidelines. All adverse events (whether serious or not serious) are recorded in the SOL Youth DMS. The Serious Adverse Event form or the Minor (not serious) Adverse Event form according to each field center's IRB, is used for this purpose. Completion of an Adverse Event form in the DMS results in a report of the SAE to the NHLBI by the Coordinating Center, within 72 hours. No direct notification of an adverse event to NHLBI is required of the field center unless additional information is needed. Adverse events not considered serious are summarized periodically by the Coordinating Center for the NHLBI, the OSMB, and/or the Steering Committee, as required. Summary tables of adverse events are included in the management reports prepared by the Coordinating Center. The reporting schedule of AEs in the SOL Youth is presented in Table 20.3 (below)

Table 20.3 Adverse Events - Actions by the SOL Youth Study Agencies and Timing						
Type of AE	SOL Youth Field Center			Coordinating Center	SOL Youth Steering Committee	
Serious (SAE)	Address any ppt. safety issues; inform Study physicians and/or PI	Record SAE in the SOL Youth DMS	Report AE to IRB	Notify NHLBI Review event & report to SC, FC Managers, Lab, as appropriate	Review study procedures with experts; propose revisions if required	Review report of AE and study procedures; modify protocol if required
Time / Schedule	Immediate	48 hrs.	72 hrs.	72 hrs.	2 weeks	4 weeks
Unexpected (AE, not serious) whether Related, Possibly Related, or Unrelated	Address any ppt. safety / comfort issues	Record AE in the SOL Youth DMS	Report AE to IRB	Notify NHLBI, SC, FC Managers & Centers if warranted	Review study procedures with experts; propose revisions if required	Review report of AE and study procedures; modify protocol if required
Time / Schedule	Immediate	72 hrs.	72 hrs.	Quarterly	4 weeks	As needed
Expected (AE, not deemed serious)	Address any ppt. safety / comfort issues	Record AE in the SOL Youth DMS	No	Update SOL Youth management report	N.A.	N.A.
Time / Schedule	Immediate	72 hrs.	N.A.	Quarterly	N.A.	N.A.

20.7 Participant Safety/Alert Thresholds on Study Measurements

If a participant feels unwell or if an alert value is met on a study measurement the participant is referred to health care and the remainder of the field center examination may be deferred, according to the action levels identified in previous sections of this manual. If the health care referral is an alert value or if the examination is discontinued field center personnel explain the urgent need to seek medical care and assist the participant in making an appointment if this is helpful. The study participant is also told that SOL Youth personnel will contact him/her within 48 hours as a courtesy follow up. During this follow-up call field center personnel confirm that the participant has seen a doctor, or has understood the need to seek medical care.

Within 3 months after the initial visit the SOL parent/guardian is contacted so that they or their child can reschedule and complete the examination. Sections 20.3 and 20.4 of this manual describe the procedures by which to follow up on an examination that was deferred because of pregnancy or any other unexpected emergency.

For blood test results that meet alert values, research study members will promptly mail the summary of results letter to the parent/legal guardian and child following the guidelines for reporting results found in Section 21.

Fatigue/Discomfort

Interviewers and technicians observe participants for signs of fatigue or physical and/or emotional discomfort. When any one of these conditions are observed, participants are offered the opportunity to discontinue the interview or procedure, and are given an opportunity to rest before being taken to the next work station. If in the course of the field center visit a participant seems to exhibit anxiety when instructed to perform tasks or shows a pattern of repetition or empty responses during interviews and/or seeks assistance from others during interviews, the staff person uses a break between procedures to bring this to the attention of the Field Center supervisor. The Field Center supervisor can decide whether the participant should be asked to complete the longer interviews that remain on the participant's schedule. Persons incapable of completing the full field center exam are invited to change back into their street clothes and participate in the exit review and reschedule the clinic exam on another day.

20.8 Mental Health Emergency Procedures

Besides clinical emergencies, participants may experience mental health emergencies unrelated to the examination, but that are detected either through structured interviews or casual discussion. These mental health emergencies could include statements indicating suicidal or homicidal intent, indications of abuse.

While several of these situations will not be directly assessed in SOL Youth, procedures are in place at the SOL Youth field center for the eventuality that any of these issues arise during the course of the study. Each of these instances must be handled with caution and sensitivity, in a way that ensures that the appropriate clinical decisions are made. Information regarding each of these separate circumstances is presented below.

As with all emergencies, mental health emergencies require that the staff member who was alerted to the situation contact the supervisor and that they jointly initiate the emergency action plan. Action should be taken and resolved prior to the participant's departure from the premises. An incident report is filed and documented within 24 hours of an incident in order to provide a record of the actions taken by the staff and supervisors. The study principal investigator is informed of the incident and of any action taken by the study personnel.

a. Suicidal Ideation

In instances in which the participant can be assessed to be in moderate or extreme danger of attempting suicide, the medical personnel identified as responder for emergencies should be notified to obtain guidance prior to the participant's departure from the building. In addition, the

parent of the SOL-Youth participant must be notified and a plan made with them for ensuring that their child receive appropriate care.

Any spontaneous comments or circumstances indicative of suicidal ideation made by the participant (i.e., “life not worth living,” “be better off dead,” etc.) at any point during the study should be explored with the participant. If suicidal ideation (thoughts of suicide or wanting to take one’s life) is present, it is the responsibility of the staff to determine the imminence/dangerousness of risk. Research staff should consult with site-specific study physicians or psychologists whenever suicidal ideation first becomes evident.

Assessments of imminence/dangerousness can be completed in a number of ways, depending on the degree to which the participant appears to be forthcoming about her or his suicidality. First, the participant should be asked directly, “Are you feeling suicidal right now?” This should be followed by another direct question: “Have you felt suicidal in the past?” and then, “When was the last time you felt suicidal?” Care should be taken to use age-appropriate language so that statements a youth participant might make indicating an intent to harm herself/his-self are not overlooked.

The following items may also be used as a general framework in which to formulate questions about suicide for the participant you believe to be potentially at risk.

1. What is her current motivation for suicide? Current level of depression?
2. Does he/she have any prior suicide attempts?
3. What has stopped her from committing suicide up to this point?
4. What is his current affect? (is it blunt or flat?) Current mood?
5. Does she have a plan? Is it well-formulated? Is it lethal? Does it allow for rescue?
6. What environmental support does he have? What's his support network like? What are his perceptions of support from others?
7. What has he done? What arrangements have been made? Has he already begun to follow some type of plan?

If the suicidal threat is judged to be immediate (the participant cannot categorically state that he/she will not hurt him/herself), the staff must maintain contact with the participant, talk with the participant’s parent or the responsible adult who brought the child to the clinic, contact Dr. [field center specific physician or psychologist] for consultation, and ensure that the subject is taken to a psychiatric emergency setting. A crisis mental health unit or equivalent emergency facility located in proximity to the field center is referenced in this manual (_____). If this information is conveyed by phone or the participant is unwilling to accept a voluntary evaluation and requires commitment (Baker Act), the police department may be contacted for transport (call 911 or (Security / Police)).

A suicidal threat is judged to be significant but not immediate, if it is of concern and questionable risk. In this situation, the staff person must maintain contact with the participant and contact Dr. [field center specific physician] to discuss an assessment and disposition. Recommendations for further action will be made by this individual. In most cases, the participant will be provided with a comprehensive list of community referrals (see appended). The following script may be used in speaking with the youth and his/her parents:

[Parent name]_____, I'm concerned that your child is expressing thoughts of hurting him/herself. Any time a youth expresses thoughts like these, we must take them very seriously and ensure that they are safe. We would like for your child to be evaluated by a health professional to make sure that they are safe and can receive whatever treatments may be needed to help them.

[Youth name] _____, I'm concerned to hear that you have been feeling this way. A lot of kids who have had similar symptoms have found several things helpful – first to talk to their parents about their concerns, then to talk with a doctor about possible medication to help with your symptoms, and also to talk to a mental health service provider to treat these symptoms.

Research staff should discuss the following with both the parent and child:
Have you thought about seeking help for this? You should talk to your doctor or contact any of these mental health service providers in your community (hand them community referral list).

Once the participant leaves, write a clear report of what has occurred immediately, co-signed by Dr. _____. The report should document:

- 1) What the participant initially said to warrant further assessment,
- 2) How the participant was assessed,
- 3) The conclusions that were drawn,
- 4) Who was consulted, and
- 5) What was done to protect the participant's well-being.

c. Participant (or Parent of Participant) Threatens to Harm Another Person

Although clinical determinations about the lethality of a person's homicidal ideations are quite inaccurate the following basic rules to follow are suggested:

- If the participant (youth or parent/guardian) has a plan and a means for carrying out the threat, lethality is considered to be high.
- If the intended victim is in immediate danger, it may be necessary to contact the intended victim and warn him or her of the threat. It is also necessary to contact police and attempt to have the participant placed on a 72-hour hold. Contact your field center Principal Investigator and Field Center supervisor to help you make this determination.
- If the participant indicates that s/he has not formulated a plan, it may only be necessary to establish a contract with the participant to prevent the attack. This decision must be made in consultation with the project coordinator and field center principal investigator.

Very rarely will a participant openly state an intent to harm and elaborate on the plan without direct questioning. Instead, s/he might say, "I get so mad I could kill." Rather than assume that the participant was speaking figuratively, it is important to investigate further without making the participant defensive. For instance, the interviewer might say, "When you feel like killing, who do you want to kill?" Even in the face of denial, interviewers may proceed with this line of questioning by asking, "Have you ever imagined what you might do if you were going to kill someone (or the person's name if known)?" Another question is, "You say that you'd never do it. What keeps you from killing [person's name]?" Then, using the person's response, "How far are you now from losing control and killing [person's name]?"

If the person has a weapon (such as a gun) s/he is planning to use specifically, it may be appropriate to request that the participant arrange for safe keeping of the weapon. Calm, explicit questioning is usually the best way to approach such an assessment, but the interviewer should be continuously gauging the extent to which they might be antagonizing the person and putting him or herself in danger. Be cautious enough to recognize when enough information has been gathered, or when a consultation break is required. It may be necessary to request that a supervisor join the session in order to add comfort and security. Consultation or follow-up with the study Principal Investigator and/or study physicians, psychologists, or other affiliated health professionals is always required when a lethality assessment has been necessary with a potentially homicidal participant.

When interacting with a homicidal person it is necessary to identify the victim. It may be appropriate to inform the participant that a warning may be required. The interviewer may inform the participant that s/he will act to prevent harm to the intended victim, but it is not necessary to specifically describe the different courses of action available. Finally, if the interviewer considers the homicidal lethality to be high, the interviewer should always follow the emergency procedure. As stated above, the emergency procedure entails contacting the designated clinical psychologist – and upon recommendation contacting the police and attempt to have the client placed in a 72-hour hold. A detailed documentation of the incident and actions taken by the interviewer should be completed.

20.9 Procedure for Reporting Child Maltreatment

Law mandates the report of any suspicion of child maltreatment, including abuse and neglect. Mandated reporters are protected under the law from civil suit, should the report prove to be false. This protects those who are carrying out the law from being sued for false reports.

If study personnel discover information that leads to a concern about child maltreatment (refer to definitions below), several steps are important.

First, consult the Field Center supervisor. In addition, a licensed health professional should be asked to consult. You will most likely need to ask follow up questions.

Second, if you and your supervisor feel the information warrants a report, a report must be made to the state's abuse hotline; research staff at each center should have that phone number available in the clinic.

Third, it is in the best interest of the child and the family if the family does the reporting. If appropriate, the Field Center supervisor can determine how to talk with the family about the need for reporting, and the family can be offered the following options.

- The best is for the family to call. Staff is responsible for making sure that they do so, however. Therefore, staff may offer to be in the room with them.
- Most families find it very difficult to self-report. Therefore, another very good option is for staff to call the hotline with the family in the room.

- Staff can also let the family know that if they don't want to call in that way, staff will be making the call and ask them if there are specific things they want to make sure you inform Department of Child and Family Services or State Child Protective Services about (especially efforts they are making to ameliorate the maltreatment).

Other important issues when calling in an abuse report:

1. Call in the morning if that is when the child is in the clinic – DCF has strict timelines for investigations; a call in the morning makes it more likely that the case is addressed at a time when staff can be reached.
2. Ask to be either the “first point of contact” or “a point of contact.” If you are the first point of contact, they will contact you first, before contacting the family or child. This may be important if you are worried about retribution to the child or other issues. Asking to be a point of contact allows you to give the information you would like to make sure that DCF has. This is an important step to remember.

Statutory definitions of child abuse are kept in at a field center, conveniently retrievable by the supervisors and staff.

Appendix 1.

Safety Script to Confirm/Update PSE

After a parent/legal guardian and the child(ren) have assented during the informed consent process to be in the study and take part in all or certain portions of the exam, staff personnel needs to review safety precautions and confirm or update conditions in the Participant Safety Screening form (PSE). The goal of the review is to confirm all reported conditions with the participant prior to excluding him/her from a test or procedure, or to update conditions that may have changed between recruitment and appointment time and that may now exclude him/her from a test or procedure. The study personnel can use the following script to review safety:

“Before we start any of the exam procedures, we need to make sure that (child’s name) is in good health and does not have a condition that would make him/her ineligible to take part in any of the procedures. The questions I’ll ask were already asked during the recruitment call, but we need to confirm these responses or update any conditions that may have changed. We want to keep your child’s safety a priority.”

The study personnel will then go through the PSE form with the parent and child, noting any changes if needed, by crossing out the pertinent information and adding a new note on the PSE with the Staff ID included. If staff is using the DMS, the change will be keyed as a note log in the DMS for the item in question.

If no changes are made, staff reads the following script:

“(child’s name) is eligible for the following procedures, as discussed over the phone: *(list the procedures he/she will take part in, in the order to be done)*. Before each procedure takes place, the technician in charge may also ask (child’s name) a few questions that will further determine eligibility for each particular procedure.”

If changes have been made to the PSE, staff reads the following script:

“(child’s name) is eligible for the following procedures *(list the procedures he/she will take part in, in the order to be done)*. He/she will not need to do *(list the procedures the child is now excluded from)*. But, we will contact you to reschedule these procedures when the child is healthy enough to go through them.”

The staff member reading the script must also notify appropriate personnel of procedures that will or will not take place.

21. REPORT OF STUDY RESULTS, MEDICAL REFERRALS AND NOTIFICATIONS

SOL Youth is committed to serve its child and adult study participants, their families, and their communities by returning as much scientific information that has applicability and translational value as is possible. In the same spirit, all study results that have value in the context of medical diagnosis or treatment are reported to the study participants, in ways that are consistent with current guidelines endorsed by professional societies and governmental agencies. Laboratory tests and examinations performed by SOL Youth that are of research value only and not directly relevant in the context of current guidelines are not reported, to avoid burden to the study participants and their medical practitioners. As part of the informed consent process, study examinees are told that they are participating in a research study which is guided by a research protocol. They are informed that procedures are not identical to those performed in a regular clinical examination, and that they will only receive study results that are of known value to medical practitioners.

Information on examination test results are shared with SOL Youth participant's parent(s) during an interview at the end of their field center examination visit. Laboratory test results are made available to the participant after the information has been submitted by the SOL Youth central laboratory and reading centers responsible for the central and standardized processing of the data. The reporting schedule incorporated into this process is a function of alert ranges that define emergent, urgent or routine notification. This process is described in the following sections.

21.1. Procedures for Medical Referrals and Notification of Results

Although SOL Youth does not diagnose or treat any medical condition, the child or adult participant's safety is of paramount concern. Therefore, data collected during the examination that could indicate the need for referral for medical care are reviewed with the participant's parent prior to the completion of the examination. The type of study result to be reported to the study participant's parent and the schedule of notification are also reviewed at this time. The secondary purposes of the exit interview are to verify that all components of the field center clinic visit have been completed, to solicit comments and feed-back from both the participant and his/her parent, to return the participant's medications, and answer any remaining questions. An additional purpose of the exit interview is to instruct the study participant and his/her parent on the use of the physical activity monitor.

21.2. Reporting of Results to SOL Youth Participants

In its feedback to the participants, the study relies on established guidelines and other evidence-based documentation that practitioners in the community refer to. Values or measurement results that exceed the thresholds underwritten by treatment guidelines are identified to the participant's parent with a recommendation for review and or confirmation in consultation with their provider of medical care. The study defines these notifications as a referral, although such notifications emphasize to the study participant's parent and his/her provider of care that the results originate from a research protocol and cannot be equated to a clinical evaluation.

21.3. Medically Relevant Information

Medically relevant information is provided to the study participant's parent and their providers of medical care, if so authorized by the study participant's parent. If consent to provide this information to the person's physician was given as part of the informed consent process, copies of

the reports of study results are sent to the participant's physician. No study information is shared with other persons or entities, except with the written authorization of the participant's parent, or as required by law. Copies of prototype reports are shown in the Appendix.

Procedures are in place throughout SOL Youth to identify clinically relevant values in the study data that are so abnormal as to be considered an "alert value." This applies to measurements performed at the field centers and to study data processed at the Central Laboratory and the central reading centers. Alert values are reported to the study participant parent, notification process described below. Study results that are identified as "alert values," because they exceed the study guidelines, are reported to the parent of the child and consultation with their provider of medical care for purposes of confirmation is recommended (Field Center specific protocol will be followed for these cases.) Lastly, measurements and assay results that are within normal ranges according to the guidelines in use in SOL Youth are reported in a consolidated summary report to the participant once all information has converged to the collaborative database. This report includes any results previously reported to the study participant on an expedited schedule (such as "alert values").

Medical information is provided to participants at the following points:

(1) During the exit interview at the conclusion of the field center examination, a staff member gives the participant's parent a "clinic visit report" and reviews their child's weight, height, and current blood pressure. This "clinic visit report" also indicates to participant's parent that they will receive by mail a copy of the interpretation of selected blood tests and feedback on their meaning.

(2) Study data processed by the SOL Youth central laboratory and the SOL Youth reading centers are transmitted to the Coordinating Center. The Coordinating Center will make this information available to the Field Center through a secure server data management system. The Field Center coordinators will generate Reports for the SOL participants as soon as the data is available. If an "alert value" is identified by the report, the Field Center staff will follow Field Center specific protocol to inform the SOL participant's parent of the need to follow up on the alerted value.

(3) Once results from the central laboratory and the central reading centers are received at the Coordinating Center, the Field Centers will be able to generate a **Summary of Results using the Reports section of the study data management** system-CDART. These reports are provided with customized cover letters by the field centers and sent to the study participants' parents following specified protocol for their Field Center. The date of the Summary of Results sent is also recorded in the Report and Referral Tracking Form.

21.4. Study Results Reporting Schedule

SOL Youth implements an expedited notification schedule for study results of potential medical significance that may require prompt attention by the participant's parent(s.) The Field Centers generate Reports that will indicate presence of "alert values" for the study participant utilizing the data management system CDART. The presence of these "alert values" will prompt the Field Center to follow their protocol for the alerted values, the threshold levels identified in Table 5 (see below.)

Report alerts present at clinic visit evaluation will be notified immediately to the study participant parent- during the Exit interview. Depending on the field center procedures, and gravity of the alert, a phone call to the participant's physician may be granted. The field center staff will follow up with the participant parent to find out whether the recommended referral was implemented. If the study personnel have been instructed to report results to participant parent only, not their physician, it is important for staff to verify that the study participant parent is aware of the nature of the condition being reported as an alert and its potential health indications.

It takes 4-6 weeks for results to be made available by the Central Lab to the Coordinating Center data management system CDART. As soon as the data is available on CDART the field centers will have access to the data and will be able to generate study participant report with the results. If "alert values" are present the field center staff will implement center specific protocol for the alerted value and follow same caution procedures described above.

Alert reports are important referrals made for abnormalities that require medical attention but not on an emergency basis. An alert report to the participant's parent is sent within the week of the field center receiving the information. The report can be made available to the physician is requested by the participant's parent.

21.5. Thresholds for Referral and Reference Ranges for Study Results

21.5.1. Seated Blood Pressure

Three measurements of seated blood pressure are recorded with a OMRON HEM-907XL IntelliSense® digital blood pressure monitor, after a five-minute rest period. The averaged value of the three measurements is reported to the study participant's parent during the exit interview. The blood pressure measurements and the actions to be taken are reviewed according to The Fourth Report on the Diagnosis, Evaluation, and Treatment of High Blood Pressure in Children and Adolescents (2004 NHBPEP). These guidelines are used by the SOL Youth personnel in communications with the study participant and in making follow-up recommendations as summarized below.

Table 5. Classification of Blood Pressure in Children Aged XX to XX years, and Recommended Action per 2004 NHBPEP*

Category	SBP or DBP(mmHg)
Normal	value <90 th percentile
Pre-hypertension	90 th <= value < 95 th percentile
Hypertension, Stage 1**	95 th <= value < 99 th percentile
Hypertension, Stage 2**	value >99 th percentile not reported in the Alert Report

SBP= systolic blood pressure. DBP= diastolic blood pressure.

* Source: The 2004 NHBPEP Report. Pediatrics, 2004; 114: 555-576.

** Diagnosis of hypertension must be based on two or more readings taken at each of two or more visits following an initial screening.

2004 NHBPEP states that blood pressure classifications and referral recommendations are based on the average of two or more readings on two or more occasions. SOL Youth uses the average of the 2nd and 3rd blood pressure readings in order to reduce the impact of reactivity (first readings are usually higher) on the estimate of the value of the underlying blood pressure. In deciding whether a participant meets criteria for an alert level, the average of the 2nd and 3rd readings are used. The data forms include fields for these averaged values and for any actions taken.

Safety alert notifications based on blood pressure values are described below. Unless an immediate referral (Diastolic BP $\geq$ 110 mmHg or Systolic BP $\geq$ 170 mmHg) has been initiated at the time the participant's blood pressure was measured, a referral may take place during the Exit Interview.

21.5.2. Blood Chemistries

All laboratory assays are performed at the SOL Youth Central Laboratory at the University of Minnesota, which also maintains the SOL Youth biospecimen repository. The reference and alert values used by the Central Laboratory, summarized in Appendix 1 of Manual 2 – Biospecimen Collection and Processing, correspond to current recommendations by the National Cholesterol Education Program and national professional associations. The Bronx Field Center has received assurances that glycosylated hemoglobin (hemoglobin A1c) for the SOL Youth examinees need not be reported to the NYC Health Department.

21.6 Conveying the Report of results to the study participant

Given the lack of familiarity of the public with study results, and possible language barriers since the results are provided in English, SOL Youth field centers highlight relevant study results to the participants and their accompanying parent. The SOL Youth study provides a user-friendly overview of the study results to facilitate their comprehension and reduce the chance for participants to miss potentially important information.

To implement this approach field centers prepare a personalized cover letter in the parent's preferred language, to accompany the report of results and identify key results (if any are clinically significant). In turn, to assist field center personnel in reviewing a participant's results and prepare the cover letter, an algorithm has been developed that prints the results that exceed laboratory or clinical guideline thresholds (see below). From this – and an awareness of the participants' age, possible comorbidity and other elements – the field center clinician can ascertain whether a result that exceeds threshold is trivial or potentially important.

21.7 Quality Assurance

Actions taken in response to an alert value are documented on the Report Tracking form. The occurrence of an alert condition and its processing from the originating laboratory or reading center to the notification of a study participant and/or the physician is journaled by the data management system maintained by the Coordinating Center. The timeliness of this process and its successful completion according to study protocol are included in the quality analyses performed by the Coordinating Center and are periodically reviewed by the Quality Control Committee.

22. SOL YOUTH RECRUITMENT SCRIPT



HCHS/SOL Youth Study Recruitment Screening Script

A. No answer - Leave a message:

Hello, my name is **(recruiter name)**, I am calling from the Hispanic Community Health Study/Study of Latinos (SOL), the study in which **(Name of participant/s)** participated in the past. I would like to talk about the letter that we recently mailed, which describes a new study designed to learn more about the health of Hispanic/Latino youth in the United States. The SOL Youth study is available to the children of SOL participants like you. Today it's my pleasure to talk to you about the SOL Youth Study and ask you some questions to determine if your child is eligible for participation. Please feel free to call us at **(field center's phone number)** if you are interested. Information on your children's health will help us better understand the ways in which your health and your children's health are connected. Thank you very much, have a nice day.

B. On the phone:

Hello, my name is **(recruiter name)**, I am calling from **(Institution)**. May I speak with **(Name of main study participant)**? *If participant is the one who answers the phone, go to script 2a*

1. Not available:

Refer to your recruitment list for this household and ask for all other HCHS/SOL participants

- a. Even if **(Main study participant name)** is not available at the moment. May I speak with **(Name of other participant/s)** or **(Name of other participant/s)**.

If multiple study participants are recorded for this HSR.

If another SOL study participant is available, proceed to section 2b. If SOL participants are NOT available, then ask for availability, see script below in 1b.

- b. When would be a good time to call him/her back? **(Obtain date and time)**
Thank you, I will call again. *Call is ended.*

2. HCHS/SOL study participant is available:

a. I work with the Hispanic Community Health Study/Study of Latinos (SOL), the study you participated (in back in **insert date**) *Continue with script below 2b.*

b. Hello, Mr/Ms ____(**main study participant name**)____, my name is____(**recruiter name**)____. I work with the Hispanic Community Health Study/Study of Latinos (SOL), the study you participated in back in (**insert date**). We can't thank you enough for having participated in this study. *Continue with the following script.*

We recently mailed you a letter describing a new study designed to learn more about the health of Hispanic/Latino youth in the United States. This study is available to children of SOL participants. Before I tell you more about the study, let me verify your address. Are you still living at **[participant's address]**?

If yes, continue with script

If no, collect the participant's information and assign new household ID.

Could you please tell me your new address to keep our records updated?

Thank you very much. Since you are an active SOL participant, now it is my pleasure to invite your children to participate in SOL Youth Study. Information on your children's health will help us better understand the ways in which your health and your children's health are connected.

Please answer the following questions. *Go to → **HOUSEHOLD SCREENING FORM** and complete all questions, see HSR QxQ for guidance.*

If participant refuses to be screened → May we know why you/your child would not like to participate?

If yes and given a reason, record answer in [Form XX].

If no, document "No reason given" in Form XX → Ok no problem, thank you for your time.

3. Review of Data Collected.

a. *If Q2 of Household screening form = 0 No child in the household — Stop, confirm current address, thank him/her for taking the call.*

Thanks for answering all my questions. It does not appear that you have a child who is eligible to participate. However, I would like to confirm your current address once again. Thank you for taking the time to speak with me today, and for your participation in SOL study.

Depending on your center, follow up with the appropriate person or center procedure to record any address updates.

- b. If Q2 of Household screening form = 1 or more (child in the household) – Go to question 3 in the HSR form.**
- c. If Q3 of Household screening form = 0 (no children between 8-16 in the household) – read the script below after rostering the children:**

If there are NO children younger than 8:

Thank you for answering all my questions. At this time we are only inviting children between the ages of 8 to 16 to participate in the SOL Youth study. Once again, thank you for your time and for your participation in SOL.

If there are children younger than 8:

Thank you for answering all my questions. At this time we are only inviting children between the ages of 8 to 16 to participate in the SOL Youth study. Your younger children were rostered and will be allowed to participate once they turn 8. Our field center will contact you after they become eligible. Once again, thank you for your time and for your participation in SOL.

- d. If Q3 of Household screening form = 1 or more (children between 8-16) and children are under the legal custody of a SOL participant, explain the study and invite to participate – read the script below after rostering the children:**

Children who are between 8 to 16 years of age and whose parent or legal guardian participated in the HCHS/SOL study are eligible to participate in the SOL Youth study. If you and one or more of the children living in your home choose to participate, will be asked to come to the SOL Youth center located at **(INSERT SITE SPECIFIC LOCATION)** at a date convenient for you.

We expect that the entire examination will take up to 4 hours. If you and your children agree to participate, you will be reimbursed for [field center specific.] Each child who participates will receive [field center specific]. As the child is completing the clinic examination, we will ask you a set of questions; about your children's health, medication use, birthplace, school performance, family rules, and meal patterns. We will also ask your child to participate in an interview about their eating habits, physical activity, tobacco use, relationships with family and friends, and about the Hispanic/Latino culture.

During the visit, we will measure your child's blood pressure, height, weight, and collect some blood to get an assessment of overall health. We will also ask your child to perform a step test so that we can measure their fitness.

All of these measurements are similar to an annual physical in addition to some questionnaires.

To get more information on your child's physical activity, we will ask your child to wear the same small physical activity monitor that you wore for 7 days in the HCHS/SOL study. We will call two times during the 7 days to check how things are going and to answer any questions about the physical activity monitor. During your visit we will provide you with instructions on returning the physical activity monitor. Within the following 4 weeks after the exam, your child will have a phone interview. During this interview we will ask about what food your child may have eaten over the past 24 hours. This phone call will take approximately 30 minutes and a parent must be home for the interview.

Participating in this study is voluntary. If you choose not to participate, the relationship you have with the HCHS/SOL study will not change. You will still be a HCHS/SOL participant and part of all HCHS/SOL activities.

4. Would you like to participate in this SOL Youth Study?

- a. **No, I'm not interested** → May we know why you/your child would not like to participate?

If yes and given a reason, record answer in [Form XX].

If no, document "No reason given" in Form XX → Ok no problem, thank you for your time.

- b. **Not sure** → Would you like me to send you more information about this study? I can send you a copy of the SOL Youth Study informed consent and also give you another call sometime next week.

If they agree to receive more information and receive an additional call, then

When is a good day and time to call you back? Date:

_____ Time _____ am

- c. **Yes, I am interested** → **COMPLETE ELE AND PSE FORMS FOR EVERY ELIGIBLE CHILD.**

If ELE Q. 12=4 (Eligible, Parent or child refuses to participate) → May we know why you/your child would not like to participate?

If yes and given a reason, record answer in [Form XX].

If no, document "No reason given" in Form XX → Ok no problem, thank you for your time.

If there is an eligible child (ELE Q.12=5), proceed with the following script.

When would be a good time for you and your child to come to the SOL Youth research center? Please remember that your child will need to be fasting for 12 hours before the visit so that the results of our blood tests are accurate.

Your appointment is on _(date)_____ at _(time)_____am

Let me remind you that the clinic is located at _____. Our phone number is _____. Also, I'd like to inform you that you (parent) do not need to fast for this study. However, we will provide a hearty snack for you and your child.

A day before your appointment you will receive a call to remind you and your child of your appointment.

(Field center specific) Will you need a ride to our clinic? If so, we can arrange for a driver to pick you up.

(Field center specific) You should expect a package of instructions for your appointment before your appointment date. This package includes a copy of the SOL Youth informed consent forms, appointment instructions, a bag for your child's medications and a map with directions to our research center. We hope these materials explain what you and your child should expect the day of your visit. If you have any questions or concerns about the forms, or your family's participation in the study, feel free to call _____**(field site phone number)**_____.



HCHS/SOL Youth Study HOUSEHOLD SCREENING Spanish SCRIPT

B. No answer - Leave a message:

Hola, mi nombre es (**recruiter name**), estoy llamando del Estudio de la Salud de la Comunidad Hispana/Estudio de los Latinos (HCHS/SOL), el estudio en el que (**Name of participant/s**) participó anteriormente. Me gustaría hablarle acerca de la carta que recientemente le enviamos, que describe un nuevo estudio diseñado para aprender más sobre la salud de los jóvenes hispanos/latinos en los Estados Unidos. El estudio Juventud SOL está disponible para los niños de los participantes de HCHS/SOL como usted. Hoy es un placer para mí hablarle sobre el estudio Juventud SOL y hacerle algunas preguntas para determinar la elegibilidad para la participación de su niño. Por favor siéntase con la libertad de llamarnos al (**field center's phone number**) si está interesado. La información sobre la salud de sus niños nos ayudará a entender mejor la forma en que su salud y la salud de sus niños están conectadas. Muchas gracias, tenga un buen día.

C. On the phone:

Hola, mi nombre es (**recruiter name**), estoy llamando de la (**Institution**). ¿Puedo hablar con (**Name of main study participant**)? *If participant is the one who answers the phone, go to script 2a*

4. Not available:

Refer to your recruitment list for this household and ask for all other HCHS/SOL participants

- a. Aunque (**Main study participant name**) no está disponible en este momento, puedo hablar con, (**Name of other participant/s**) o con (**Name of other participant/s**).

If multiple study participants are recorded for this HSR

If another HCHS/SOL study participant is available, proceed to the section 2b. If HCHS/SOL participants are NOT available, then you will ask for availability, see script below in 1b.

- b. ¿En qué momento podría volver a llamarlo/a? (Date/time)_____.
Gracias, volveré a llamar. *Call is ended*

5. HCHS/SOL study participant is available:

- c. Trabajo con el Estudio de la Salud de la Comunidad Hispana/Estudio de los Latinos (HCHS/SOL), el estudio en el que usted participó en el pasado (en **insert date**) *Continue with script*
- d. Hola, Sr/Sra. (**main study participant name**), mi nombre es (**recruiter name**). Trabajo con el Estudio de la Salud de la Comunidad Hispana/Estudio de los Latinos (HCHS/SOL), el estudio en el que usted participó en el pasado (en **insert date**). Le agradecemos mucho por haber participado. *Continue with the following script*

Recientemente le enviamos una carta describiendo un estudio nuevo, llamado Estudio de la Salud en la Juventud Latina/Juventud SOL, diseñado para aprender sobre la salud de los jóvenes hispanos/latinos en los Estados Unidos. Este estudio esta disponible para los niños de participantes de SOL. Antes de que le cuente más acerca del estudio, déjeme verificar su dirección. ¿Aun sigue viviendo en **[participant's address]**?

If yes, continue with script

If no, collect the participant's information and assign new household ID.

¿Podría decirme su nueva dirección para mantener nuestros archivos actualizados?

Muchas gracias. Como usted es participante activo de HCHS/SOL, tengo el placer de invitar a sus niños a participar en Juventud SOL. La información sobre la salud de sus niños nos ayudará a entender mejor las formas en que su salud y la salud de sus niños están relacionadas.

Por favor responda las siguientes preguntas. *Go to → **HOUSEHOLD SCREENING FORM** and complete all questions, see HSR QxQ for guidance.*

If participant refuses to be screened → ¿Podríamos saber porque usted/su niño no quiere participar?

If yes and given a reason, record answer in [Form XX].

If no, document "No reason given" in Form XX → Ok no hay problema, muchas gracias por su tiempo.

6. Review of Data Collected.

- a. *If Q2 of Household screening form = 0 No child in the household — Stop, confirm their current address, thank them for taking the call.*

Gracias por haber contestado todas mis preguntas. Al parecer, usted no tiene un niño/a elegible para participar. Sin embargo, me gustaría confirmar

su dirección de nuevo. Gracias por haber tomado tiempo para hablar conmigo y por su participación en el estudio HCHS/SOL.

Depending on your center, follow up with the appropriate person or center procedure to record any address updates.

- b. If Q2 of Household screening form = 1 or more (child in the household) – Go to question 3 in the HSR form.**
- c. If Q3 of Household screening form = 0 (no children between 8-16 in the household) – read the script below after rostering the children:**

If there are NO children younger than 8:

Gracias por haber contestado todas mis preguntas. En este momento estamos invitando solamente a niños de 8 a 16 años de edad para participar en el estudio de Juventud-SOL. De nuevo, gracias por su tiempo y participación en SOL.

If there are children younger than 8:

Gracias por haber contestado todas mis preguntas. En este momento estamos invitando solamente a niños de 8 a 16 años de edad a participar en el estudio de Juventud-SOL. Sus niños más jóvenes han sido puestos en una lista y serán elegibles para participar cuando cumplan 8 años de edad. Nuestro centro se comunicará con usted cuando su niño/a sea elegible. Una vez mas, gracias por su tiempo y su participación en HCHS/SOL.

- d. If Q3 of Household screening form = 1 or more (children between 8-16) and children are under the legal custody of a SOL participant, explain the study and invite to participate – read the script below after rostering the children:**

Niños que están entre los 8 y 16 años de edad y que uno de sus padres o tutor legal haya participado en el estudio HCHS/SOL, son elegibles para participar en el estudio Juventud SOL. Si usted y uno o más de sus niños que viven en su hogar deciden participar, se le pedirá que venga al centro de Juventud SOL localizada en **(INSERT SITE SPECIFIC LOCATION)** en un día conveniente para usted.

Esperamos que el examen completo no dure más de 4 horas. Si usted y sus niños deciden participar, se le reembolsará el costo de [field-center specific]. Cada niño que participe recibirá [field-center specific]. Durante la examinación del niño, le haremos a usted una serie de preguntas sobre la salud de su niño; el uso de medicamentos, lugar de nacimiento, rendimiento escolar, reglas familiares, y patrones de alimentación. También le pediremos a su niño que participe en una entrevista sobre los hábitos

alimenticios, actividad física, uso de tabaco, relaciones familiares, amistades y sobre la cultura hispana/latina.

Durante la visita le mediremos a su niño la presión arterial, la estatura, el peso corporal y tomaremos una muestra de sangre para evaluar la salud de su niño. También se le pedirá a su niño que realice una prueba para medir su capacidad física. Todas las medidas son similares a un examen físico anual más algunos cuestionarios.

Para obtener más información sobre la actividad física de su niño, le pediremos a su niño que use el mismo monitor pequeño de actividad física que usted usó por 7 días en el estudio HCHS/SOL. Le llamaremos dos veces durante los 7 días para ver cómo van las cosas y para contestar cualquier pregunta que tengan sobre el monitor. Durante su visita, se le proveerán instrucciones para devolver el monitor de actividad física. Dentro de las próximas 4 semanas después del examen le haremos una entrevista telefónica a su niño. En esta entrevista se le preguntará a su niño lo que posiblemente haya comido durante las últimas 24 horas. Esta llamada durará aproximadamente 30 minutos y un padre debe de estar en casa para la entrevista.

La participación en este estudio es voluntaria. Si decide no participar en este estudio, la relación que usted tiene con HCHS/SOL no cambiará. Usted continuará siendo participante de HCHS/SOL y parte de todas las actividades de HCHS/SOL.

4. ¿Quiere participar en el estudio Juventud SOL?

- d. **No, I'm not interested** → ¿Podríamos saber porque usted/su niño no quiere participar?

If yes and given a reason, record answer in [Form XX].

If no, document "No reason given" in Form XX → Ok no hay problema. Gracias por su tiempo.

- e. **Not sure** → ¿Le gustaría que le envié más información sobre el estudio? Le puedo enviar una copia del Consentimiento Informado del Estudio Juventud SOL y también podría volver a llamarlo/a en algún momento la próxima semana.

If they agree to receive more information and receive an additional call, then

¿Cuándo es un buen día y hora para llamarlo/a de nuevo?

Date: _____ Time _____ am/pm

- f. **Yes, I am interested** → **COMPLETE ELE AND PSE FORMS FOR EVERY ELIGIBLE CHILD.**

If ELE Q. 12=4 (Eligible, Parent or child refuses to participate) →

¿Podríamos saber porque usted/su niño no quiere participar?

If yes and given a reason, record answer in [Form XX].

If no, document “No reason given” in Form XX → Ok no hay problema. Gracias por su tiempo.

If there is an eligible child (ELE Q 12=5), proceed with the following script.

¿Cuándo es la mejor fecha para que usted y su niño vengan al centro de investigación Juventud SOL? Por favor acuérdesse que su niño tiene que estar en ayuna por 12 horas antes de la visita para que los resultados de la prueba de sangre sean precisos.

Su visita está programada para: **Date** _____ at **Time** _____ am

Déjeme recordarle que estamos localizados en (field-center specific). Nuestro número telefónico es (field-center specific). También le quiero informar que usted no tiene que estar en ayuna para el estudio. Se le dará una buena merienda a usted y a su niño.

Un día antes de su cita recibirá una llamada telefónica para acordarle a usted y a su niño de la cita.

(Field center specific) ¿Usted va necesitara transportación al centro de investigación? Si es así, podemos mandar al chofer para que los recojan.

(Field center specific) Antes del día de su cita le vamos a enviar un paquete de instrucciones. Este paquete incluye una copia del Consentimiento Informado, instrucciones para la cita, una bolsa para los medicamentos de su niño y un mapa con las instrucciones de cómo llegar a nuestro centro de investigación. Es nuestro deseo que los materiales le expliquen a usted y a su niño de lo que deben esperar el día de la visita. Si tiene alguna pregunta o preocupación sobre las formas o sobre la participación de su familia en el estudio, siéntase en libertad de llamar al _____ **(field site phone number)** _____.



**Hispanic Community Children's Health
Study of Latino Youth (SOL Youth)
Manual 2
Biospecimen Collection and Processing**

October 9, 2012- Version 3.1

Study website - <http://www.csc.unc.edu/hchs/>

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1. BIOSPECIMEN COLLECTION AND PROCESSING

The Hispanic Community Children's Health Study – Study of Latino Youth is a multi-site, interdisciplinary epidemiologic study in Hispanic populations in the U.S. sponsored by the National Heart, Lung, and Blood Institute (NHLBI) and six other institutes, centers, and offices of the National Institutes of Health (NIH). In recent years, the prevalence of overweight and obesity has increased among children and adolescents. The incidence of metabolic syndrome and type 2 diabetes has risen concurrently with obesity among youth. The goal of the SOL Youth Study is to evaluate the prevalence of increased obesity in Hispanic youth and how parental and youth situational, environmental, and personal factors increase the risk for obesity and its related cardiometabolic health complications. Blood samples are collected to study these factors through specialized, state-of-the-art laboratory assays.

The target population of 1600 boys and girls of Hispanic origin, specifically Cuban, Puerto Rican, Mexican, and Central American, aged 8-14 years old, who live in the homes of HCHS/SOL cohort participants.

[**Note:** Protocol revision for increasing the eligible age range from 8-14 to 8-16 years old for SOL Youth was unanimously approved by the HCHS/SOL Ancillary Study Subcommittee and HCHS/SOL Steering Committee on August 8, 2012. All subsequent reference to the eligible age range in the remainder of this MOP will indicate the approved protocol change to 8-16 years old.].

The participants will be recruited through four Field Centers affiliated with San Diego State University, Northwestern University in Chicago, Einstein College of Medicine in New York, and the University of Miami. Additional academic centers will serve as scientific and logistical support centers.

The Central Laboratory performs the tests on the blood specimens donated by the study participants who have been asked to fast for 12 hours. DNA is prepared from the packed cells of EDTA blood, and aliquots of serum, Na Citrate plasma, and EDTA plasma are prepared at the field centers and will be stored at the Central Laboratory. The Central Laboratory is located at the University of Minnesota Advanced Research and Diagnostic Laboratory in Minneapolis MN. A complete list of the tests performed is located in Appendix 1.

Laboratory tests are performed on specimen samples that are collected and processed by the technicians at each of the four SOL Youth field centers. Probably the most important step in this process (and potentially the most difficult to standardize) is the collection and field center processing of the blood samples. Laboratory tests can be repeated, but if the blood sample itself is not correctly drawn, labeled, and processed, the laboratory results may not be accurate even if the laboratory assays are precise. For the study to succeed, it is important that variation in measurement values reflect true differences between the study participants rather than differences in blood drawing or processing procedures. Thus, it is important that all field center technicians are well-trained, certified, fully compliant with the protocol for drawing and processing the specimens in the field, and also willing to take pride and responsibility in their work.

2. PREPARATION

Since participation in this study is voluntary, every effort must be made to make the entire procedure as easy and painless as possible for participants. Technicians must remain calm and project an attitude of competence even when faced with the most nervous or inquiring participant. The best way to achieve this is for the technicians to be thoroughly knowledgeable about all aspects of the procedures. The SOL Youth study collects approximately 25 mL of blood from each participant. Five tubes of blood are collected. The technician should reassure any participant who is concerned about the volume of blood collected that the total amount drawn is only about 2 tablespoons, although it may look like more to them. The technician may also assure participants that they donate almost 10 times as much blood (450 mL) when they donate a pint of blood.

2.1. Staff Certification Requirements

Blood drawing and processing are performed by a certified SOL Youth technician(s) at each field center. The technicians complete a training course taught by certified laboratory staff. Each technician must complete the training and pass both written and practical exams before becoming SOL Youth certified. Recertification takes place annually and is authorized by the supervisory personnel.

2.2. Blood Collection Trays and Tubes

One day prior to a scheduled participant visit, the technician prepares two trays: one to hold the blood collection tubes, another to hold the plastic vials which will hold the final packed cells, serum, and plasma aliquots until they are frozen and ultimately transferred to the Central Laboratory for analysis. Label these sets of tubes with the appropriate code numbers for the participant. A list of equipment, suppliers, and vendors is provided in Appendix 2.

2.2.1 Blood Collection Tray

First, the technician organizes and prepares the blood collection tray. The blood collection tray is made of hard unbreakable plastic that can be easily cleaned. The tray has individual compartments that are filled with the following supplies:

- test tube rack that holds at least to 10 blood collection tubes (described in the next section)
- sterile, disposable 23 or 21 gauge butterfly needles (23 G is usually the size of needle that is used with a pediatric age group but a 21 G needle may be used on an older child; 25 G needles available for smaller veins; only use for extremely difficult draws, as the smaller gauge needle may cause samples to become hemolyzed).
- plastic vacutainer tube guides
- vacutainer Luer adapters
- sterile alcohol swabs
- gauze sponges
- tourniquet
- bandages ("Band Aids")

Smelling salts, ice packs, and wash cloths should be readily available in the blood collection area for participants who become faint during the blood collection.

2.2.2 Blood Collection Tubes

Technicians must be familiar with: the arrangement of blood collection tubes, the order in which the tubes are to be filled, the type of anticoagulant in each tube, and the possible sources of error in handling each tube. These tubes are organized in the test tube rack in the following sequence:

Tubes #1 and #2 are 5 mL red stoppered tubes. Although these tubes do not contain anticoagulant, they do have a clot activator and therefore require mixing following collection. The serum from these tubes will be used for testing lipids (fats) and other biochemical markers.

Tube #3 is a 4.5 mL blue-stoppered tube containing Sodium Citrate anticoagulant. The plasma from these tubes is used for coagulation studies. These tubes must be filled completely in order to standardize the blood to liquid anticoagulant ratio. Partially filled tubes will result in erroneous test results.

Tubes #4 and #5 are 5 mL lavender-stoppered tubes containing EDTA anticoagulant. The plasma from these tubes is used for several analytical tests including glucose (sugar). The cells will be used to isolate DNA.

Note: Tube Priority for a difficult draw: #1, #4, #3: These tubes will provide a sample type of each kind (serum, EDTA plasma, and Citrate) and will provide enough sample for immediate testing. In a difficult draw situation draw tubes in this specific order: #1, #4, and #3. Immediate testing is done on tubes #1 and #4.

2.2.3 Blood Collection Tubes: Labeling and Set-Up

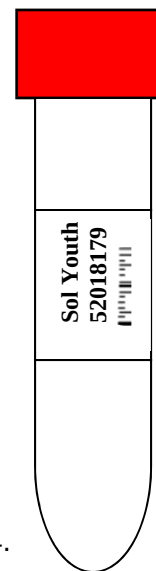
Blood collection tubes can be set up in advance of the participant visit.

1. Apply pre-numbered barcode laboratory ID labels to each blood collection tube. Place the labels on the tubes vertically, with the bar-code oriented from the bottom of the tube to the top of the tube. Handle only one participant's specimens at a time so the chance of mislabeling is minimized.
2. Arrange the blood collection tubes in the test tube rack in the same order in which they are to be collected. The five tubes are collected in the following order:

Tube #1: 5 mL red stoppered tube (Serum)
Tube #2: 5 mL red stoppered tube (Serum)
Tube #3: 4.5 mL blue stoppered tube (Citrate)
Tube #4: 5 mL lavender stoppered tube (EDTA)
Tube #5: 5 mL lavender stoppered tube (EDTA)

3. Additional laboratory ID number labels will be used when the participant arrives to provide a documented match between their SOL Youth participant ID number and the laboratory specimen ID number on the Biospecimen Collection form (BIO).

A number of SOL Youth participants will be asked to donate one additional tube of blood for quality control purposes. The duplicate sample will be assigned a different laboratory ID number, called a Phantom ID, and shipped to the Central Laboratory. This quality control procedure is described more completely below, in Sections 6.1 – 6.4.



2.2.4 Sample Aliquot Trays

The technician prepares a tray of the plastic freezer microvials, which will contain the aliquots to be shipped to the Central Lab for each participant. Each type of serum/plasma storage tube has a corresponding color-coded screw cap that fits onto it. The technicians are trained to organize the tray for the sample processing and aliquotting as follows:

The tray itself should be a flexible sponge test tube rack, which will fit tubes from 10-16 mm in diameter. The tray has 5 rows and 10 columns. The columns are numbered 1-10 from left to right. The rows are lettered A-E from top to bottom. See Appendix 11 for cleaning instructions for these trays.

2.2.5 Organization

The technicians need the following supplies for each sample tray. Supplies are organized in the order of centrifugation and processing.

- 8 – 2 mL polypropylene tubes (purple top)
- 1 – 2 mL amber polypropylene tube (purple top)
- 1 – 5 mL polypropylene tube (clear top)
- 1 – 5 mL polypropylene tube (blue top)
- 4 – 2 mL polypropylene tubes (blue top)
- 8 – 2 mL polypropylene tubes (red top)
- 1 – 2 mL amber polypropylene tube (red top)

2.2.6 Labeling

Vertically label (in the same manner as the collection tubes) the plastic sample aliquot tubes with the laboratory ID number and arrange in the sample aliquot trays in the following order (see Figure 1. Aliquot Tray Layout):

Tray 1(for stages 1 – 3 processing):

- Col 1: 2 mL purple top *amber* tube; row B
- Col 1: 2 mL purple top clear tubes; rows A, C, D
- Col 2: 2 mL purple top clear tubes; rows A – E
- Col 3: 5 mL clear top clear tube; row A
- Col 4: 5 mL blue top clear tube; row A
- Col 5: Empty
- Col 6: 2 mL blue top clear tubes; rows A – D
- Col 7: Empty
- Col 8: 2 mL red top *amber* tube; row B
- Col 8: 2 mL red top clear tubes; rows A, C, D
- Col 9: 2 mL red top clear tubes; rows A - E
- Col 10: Empty

Figure 1. Aliquot Tray Layout

Aliquot Tray 1 Layout (Stages 1 - 3 Processing)										
Col Row	1	2	3	4	5	6	7	8	9	10
A	0.250 mL plasma, Tube #4	minimum 0.5 mL plasma, Tube #5	Whole Blood Tube #4 1 mL	packed cells, Tubes #4 & #5 4-5 mL	Empty	minimum 0.5 mL plasma, Tube #3	Empty	0.250 mL serum, Tube #1	minimum 0.500 mL serum, Tube #2	Empty
B	minimum 0.5 mL plasma, amber vial, Tube #4	minimum 0.5 mL plasma, Tube #5	Empty	Empty	Empty	minimum 0.5 mL plasma, Tube #3	Empty	minimum 0.500 mL serum, amber vial, Tube #1	minimum 0.500 mL serum, Tube #2	Empty
C	minimum 0.5 mL plasma, Tube #4	minimum 0.5 mL plasma, Tube #5	Empty	Empty	Empty	minimum 0.5 mL plasma, Tube #3	Empty	minimum 0.500 mL serum, Tube #1	minimum 0.500 mL serum, Tube #2	Empty
D	minimum 0.5 mL plasma, Tube #4	minimum 0.5 mL plasma, Tube #5	Empty	Empty	Empty	minimum 0.5 mL plasma, Tube #3	Empty	minimum 0.500 mL serum, Tube #1	minimum 0.500 mL serum, Tube #2	Empty
E	Empty	minimum 0.5 mL plasma, Tube #5	Empty	Empty	Empty	Empty	Empty	Empty	minimum 0.500 mL serum, Tube #2	Empty

2.2.7 Preparation for Specimen Collection

In the morning, prior to drawing blood from the participants:

1. Check to make sure the blood collection tray is properly equipped. Every item on the checklist must be ready before proceeding.
2. Check that each Vacutainer tube is properly labeled with the correct laboratory barcode ID label.
3. Check that the sample aliquot trays are properly equipped. Every item on the checklist must be ready and in its proper position.
4. Check that each aliquot storage container is labeled with the correct laboratory barcode ID label.
5. Perform and record quality control (QC) check on centrifuge temperature ($15^{\circ}\text{C} \pm 2^{\circ}\text{C}$).
6. Perform and record QC check on refrigerator temperature ($4^{\circ}\text{C} \pm 2^{\circ}\text{C}$).
7. Perform and record QC check on freezer temperature ($-70^{\circ}\text{C} \pm 5^{\circ}\text{C}$) and ($-20^{\circ}\text{C} \pm 2^{\circ}\text{C}$).
8. Perform and record QC check on room temperature.

2.2.8 At Participant Arrival

1. Check that the participant's SOL Youth Participant ID number on the Biospecimen Collection form (BIO) is correct. Place the laboratory ID label that matches the label on the collection tubes and aliquot containers onto the Biospecimen Collection form (see Appendix 3).
2. Confirm the match between the participant name, the SOL YOUTH participant ID number, and the laboratory ID number on the blood collection tubes, aliquot containers, and the Biospecimen Collection form.
3. Check that duplicate Quality Control tubes are prepared and labeled, if needed.

2.3. Biospecimen Collection form

Complete the safety questions (section A1 – A3) and the fasting question (section B) of the Biospecimen Collection form (see Appendix 3). **Note: The participant should be fasting for preferably 12 hours, a minimum of 8 hours and a maximum of 16 hours. If the participant has been fasting for less than 8 hours or more than 16 hours, then a fasting blood collection should be re-scheduled for a different day.**

The remaining sections can be completed after the venipuncture. Any deviations from the routine collection or processing protocol are recorded in the section on venipuncture / processing incidents of the Biospecimen Collection form.

3. VENIPUNCTURE PROCEDURE

Handle all specimens as potentially infectious for laboratory workers. Blood borne pathogens such as hepatitis B and human immunodeficiency virus (HIV) can be transmitted following contact of a tainted blood sample through "broken skin" or intact mucous membrane (mouth, eyes, or nose) or as a result of an inadvertent needle stick. Examples of "broken skin" include open cuts, nicks and abrasions, dermatitis, and acne. OSHA rules mandate that technicians always wear disposable protective gloves when collecting and processing specimens. When performing a venipuncture, the protective gloves worn by the phlebotomist must be intact (e.g., a fingertip cannot be torn off of the glove in order to locate a venipuncture site). If the phlebotomist accidentally sustains a stick with a contaminated needle, clean the wound thoroughly with disinfectant soap and water, notify a supervisor, and consult the SOL YOUTH physician. Never take lab coats worn during the collection and processing of samples outside of the laboratory area except for laundering. Before leaving the laboratory, the technician will remove the lab coat and disposable gloves and wash hands with a disinfectant soap.

Use OSHA-approved cleaning solution to clean up any spills of blood, plasma, or serum. Use this solution to clean all laboratory work surfaces at the completion of work activities. OSHA regulations require that all needles and sharp instruments be discarded into puncture resistant containers. Do not attempt to bend, break, or recap any needle before discarding it. Discard the butterfly set following each specimen collection. Do not perform any pipetting by mouth; especially of any blood, plasma, or serum.

Avoid formation of potentially infectious aerosols when removing the rubber stoppers from Vacutainer tubes. In addition to wearing protective gloves, hold a piece of gauze over the stopper while slowly removing it from the tube. Creation of aerosols can also be diminished by careful pipetting and centrifugation techniques. Further steps to minimize infection risk while processing samples are described in the OSHA regulations stated in the Federal Register of December 6, 1991 (Vol. 56, No. 235, page 64177). Wear a mask in combination with an eye protection device, such as goggles or glasses with solid side shields or a chin-length face shield when working with potentially infectious materials that have the potential for splashing, spraying, or spattering. An alternative to these devices would be a desk-mounted or under-shelf-mounted clear plastic shield, which would offer similar protection from possible infectious splashes or sprays.

Place all used Vacutainer tubes and blood-contaminated products in biohazard bags for proper disposal.

Pediatric Phlebotomy Techniques

See detailed techniques in Appendix 9

Technical Tips for Phlebotomy on Children

1. Use 2 smaller sized tubes versus 1 larger one, e.g. two 5 mL serum rather than one 10 mL serum collection tube.
2. Always have a 2nd person to hold the child's arm steady.

3. Use a 23 or 21 gauge needle (start with a 23G but 21G can be used on an older child with good veins) and have 25 gauge needle available for smaller veins (*only use 25 gauge needle for extremely difficult draws*)
4. Always use a butterfly type of collection set-up.
5. Keep hot packs available to help bring out the vein.
6. Make sure the child is well hydrated.
7. LMX4 (4% lidocaine topical anesthetic cream): LMX4 is an optional OTC numbing medicine that can be used to ease the pain of the blood draw.

LMX4 (4% lidocaine topical anesthetic cream) Instructions: *Optional OTC numbing medicine; use if participant appears apprehensive about phlebotomy during the informed consent process.*

1. LMX4 cream is placed on the participant preferably by a medical caregiver (nurse, etc...) **30-45 minutes before phlebotomy.** If a medical caregiver is not available, then a certified SOL Youth staff member may apply the LMX4 cream on the participant.
2. The SOL Youth staff member will inform the participant/family of the purpose of local anesthetic prior to venipuncture and possible side effects
3. Note: The LMX4 cream can cause blood vessels to constrict in some cases. This could slightly prolong the needle procedure itself. **In most cases, the cream does not constrict the vessels enough to cause difficulty with the blood draw and eases the pain of the needle stick. Many pediatric clinics routinely use LMX4 cream on their patients.**
4. The SOL Youth staff member will verify that the participant has no allergy to lidocaine or LMX4 cream (no allergic reaction to any "amide-type" anesthetics such as Novacain)
5. Make sure participant has intact skin (Do NOT apply to a site that has an open wound such as a cut or scratch)
6. If child weighs 22 pounds or more, place a quarter sized spot (approximately 1 mL) on each antecubital fossa and cover with a clear Tegaderm bandage (do NOT use more cream than directed)
7. Leave the LMX4 cream in place 30-45 minutes prior to venipuncture
8. The phlebotomist will remove the LMX4 cream before the venipuncture procedure
9. The phlebotomist will document the use of LMX4 cream on the Biospecimen Collection form

Expected Side effects of LMX4 cream:

- 1) Blanching (whitening) of the skin
- 2) Tightening of blood vessels (possible, but rarely causes enough vasoconstriction to interfere with the blood draw)

If localized reaction to cream (mild irritation, redness, or swelling at application site) follow these steps:

- 1) Remove LMX4 cream with soap and water
- 2) Apply cool compress if application site is red and swollen

Rare Side Effects of LMX4 cream: (If too much cream is used)

- 1) Nervousness
- 2) Dizziness, lightheadedness
- 3) Confusion

- 4) Tremors
- 5) Slow Breathing
- 6) Methemoglobinemia (lower blood oxygen capacity)

****Important: If any rare side effects listed above are experienced or signs of allergic reaction (fever or chills, rash or hives, wheezing, or shortness of breath) occur from the LMX4 cream; a SOL/ Youth staff member must call 911 and the participant needs to be transported immediately to an emergency room.***

3.1. Phlebotomy Room

The blood drawing takes place in an isolated room or in a room with dividers. The room is equipped with all of the necessary blood drawing supplies. A separate work area is equipped with all of the supplies that are used in the blood processing. The centrifuge, refrigerator, and freezers should be nearby.

3.2. Participant Preparation

Informed consent must be obtained before drawing any blood, to ensure that the participants understand the purpose and possible complications of the venipuncture procedure. A standard informed consent has been prepared for this study. The consent statement informs study participants that although there may be some minor discomfort, their blood (about 2 tablespoons) will be drawn by trained technicians. The consent also states that a copy of clinically important test results will be sent to them (and their physician if they authorized it) and that they will be contacted if clinically important tests are abnormal.

Complete the Biospecimen Collection form (BIO) sections A and B with the participant (Appendix 3). Before blood is collected, the participant is asked the following safety questions (section A, 1-3):

1. ...if they have had any surgery where lymph nodes were removed from their armpits. If they have, blood should not be collected from the arm where this has occurred.
2. ...whether he/she has a bleeding disorder. If such a disorder is present, ask the participant whether he/she has had blood drawn previously and if so, whether he/she had any problems with excessive bleeding or bruising at the venipuncture site. When the participant reports a bleeding disorder, specify the type of bleeding disorder(s) as briefly as possible in Item 15 of the Biospecimen Collection form. In general, a bleeding disorder is not a reason for participant deferral. A gauze and tape bandage is applied. The participant is instructed to maintain pressure on the venipuncture site for 2 minutes and to keep the bandage on the site for the remainder of the examination visit.
3. ...if they have ever had a graft or shunt for kidney dialysis. If they have, blood should not be collected from the arm where this has occurred.

If blood is to be drawn, complete the fasting blood collection information with the participant (section B, 4-5). Fill in date and time of blood collection (section C, 6-7).

The participant should be seated during the blood draw. It is difficult to standardize the length of time that a person is in the sitting position prior to venipuncture, but to the extent possible attempt to have the participant be sitting for a minimum of five minutes. This allows the participant to relax before the venipuncture takes place.

**If LMX4 anesthetic cream has been placed on participant, remove the clear Tegaderm bandage and wipe off cream with a paper towel prior to venipuncture. Note the use of LMX4 cream in item 15 of the Biospecimen Collection form.*

Perform venipuncture with a 23 or 21 gauge butterfly needle (25-gauge if smaller vein) and 12 inches of plastic tubing between the venipuncture site and the blood collection tubes. The butterfly has a small thin-walled needle that minimizes trauma to the skin and vein. The use of 12 inches of tubing allows tubes to be changed without any movement of the needle in the vein. Give the participant enough time to feel comfortable both before and after the blood collection. In many cases the most memorable part of the experience for participants will be the contact with the technicians who draw the blood and their general attitude and competence.

If the participant is nervous or excited, the technician briefly describes the procedure, e.g., "I am going to be drawing about 2 tablespoons of blood. This blood will be used in tests for lipids (fats), glucose (sugar), and other biochemistry tests. We hope to be able to use the results of these tests to better understand the health issues of Hispanic youth." HANDLING PARTICIPANTS WHO ARE EXTREMELY APPREHENSIVE ABOUT HAVING BLOOD DRAWN: Do not under any circumstances force the participant to have blood drawn. It may help to explain to the participant that the blood drawing is designed to be as nearly painless as possible. It is sometimes best to let the participant go on with another part of the visit. It may also be helpful to have the participant relax in the blood drawing chair just so the phlebotomist can check the veins in the participant's arms, without actually drawing blood. If the participant is very anxious, he/she may lie down during the blood collection. A reclining individual will undergo an extravascular water shift, resulting in a dilutional effect on lipid values. If this option is taken, note it on the Biospecimen Collection form by placing an "X" in the appropriate boxes. (Appendix 3, Item 10).

3.3. Venipuncture

With jacket or sweater removed, have the participant sit upright with the sleeves rolled up to expose the antecubital fossa (elbow). ***If LMX4 anesthetic cream has been placed on participant, remove the clear Tegaderm bandage and wipe off cream with a paper towel prior to venipuncture. Note the use of LMX4 cream in item 11 of the Biospecimen Collection form.*** Use a tourniquet to increase venous filling. This makes the veins more prominent and easier to enter. The preferred arm to draw from is the left arm. Use the right arm only if blood collection is not possible from the left arm. This does not mean you must stick the left arm. Only do so if an adequate vein is apparent.

PRECAUTIONS WHEN USING A TOURNIQUET: The tourniquet should be on the arm for the shortest time possible. Never leave the tourniquet on for longer than two minutes. To do so may result in hemoconcentration or a variation in blood test values. If a tourniquet must be applied for preliminary vein selection, and it remains on the arm for longer than two minutes, it should be released and reapplied after a wait of two minutes. Instruct the participant that he/she should not clench their fist prior to the venipuncture. Doing so could cause fluctuations in the results in several of the analytes being measured. If the participant has a skin problem, put the tourniquet over the participant's shirt or use a piece of gauze or paper tissue so as not to pinch the skin.

Note: If LMX4 anesthetic cream has been placed on participant, remove the clear Tegaderm bandage and wipe off cream with a paper towel prior to venipuncture. Note

the use of LMX4 cream in item 11 of the Biospecimen Collection form. Proceed with phlebotomy procedure.

- A. Apply tourniquet.
 - 1. Wrap the tourniquet around the arm 3 to 4 inches (7.5 to 10.0 cm) above the venipuncture site.
 - 2. Tuck the end of the tourniquet under the last round.
 - 3. If a Velcro tourniquet is used, adhere the ends to each other.
- B. Identify vein: Palpate and trace the path of veins several times with the index finger. Unlike veins, arteries pulsate, are more elastic, and have a thick wall. Thrombosed veins lack resilience, feel cord-like, and roll easily. If superficial veins are not readily apparent, lowering the extremity over the arm of the chair will allow the veins to fill to capacity. Identify the best available vein.
- C. Assemble the butterfly-Vacutainer set.
 - 1. Attach the Luer adapter to the Vacutainer holder.
 - 2. Attach the Luer end of the butterfly needle set to the Luer adapter.
- D. Cleanse the venipuncture site.
 - 1. Remove alcohol prep from its sterile package.
 - 2. Cleanse the vein site with the alcohol prep using a circular motion from the center to the periphery.
 - 3. Allow the area to dry to prevent possible hemolysis of the specimen and a burning sensation to the patient when the venipuncture is performed.
 - 4. If venipuncture becomes difficult, the vein may need to be touched again with a gloved hand. If this happens, cleanse the site again with alcohol.
- E. Perform venipuncture.
 - 1. Grasp the participant's arm firmly, using your thumb to draw the skin taut. This anchors the vein. The thumb should be 1 or 2 inches (2.5 or 5.0 cm) below the venipuncture site.
 - 2. With the needle bevel upward, enter the vein in a smooth continuous motion.
 - 3. Once blood appears in the butterfly tubing, place tube #1 (5 mL red top) into the Vacutainer holder. Grasp the flange of the needle holder and push the tube forward until the butt end of the needle punctures the stopper, exposing the full lumen of the needle.
 - 4. Make sure the participant's arm is in a flat or downward position while maintaining the tube below the site when the needle is in the vein. It may be helpful to have the participant make a fist with the opposite hand and place it under the elbow for support. **DO NOT HAVE THE PARTICIPANT MAKE A FIST IN THE HAND OF THE ARM FROM WHICH BLOOD IS TO BE DRAWN.**
 - 5. Remove the tourniquet after tube #3 fills. Once the draw has started, do not change the position of a tube until it is withdrawn from the needle. The tourniquet may be reapplied if blood flow is slow without it. If the color of the arm turns red or blue, the tourniquet is applied too tightly. Loosen it and continue. If the tourniquet is loosened or reapplied, note this on the Biospecimen Collection form.
 - 6. Keep a constant, slight forward pressure (in the direction of the adapter) on the end of the tube. This prevents release of the shutoff valve and stopping of blood flow. Do not vary pressure nor reintroduce pressure after completion of the draw.

7. Fill each Vacutainer tube as completely as possible; i.e., until the vacuum is exhausted and blood flow ceases. If a Vacutainer tube fills only partially, remove the tube and attach another without removing needle from vein.
8. When the blood flow into the collection tube ceases, remove the tube from the holder. The shutoff valve covers the point, stopping blood flow until the next tube is inserted (if necessary). Gently invert each tube eight times immediately following removal of the tube from the adapter while the next tube is filling. (See section 7.3.5 for mixing instructions.)
9. To remove the needle, lightly place clean gauze over venipuncture site. Remove the needle quickly and immediately apply pressure to the site with a gauze pad. Discard needle with its cap into needle box. **DO NOT ATTEMPT TO RECAP NEEDLES!** Have the participant hold the gauze pad firmly for one to two minutes to prevent bruising.
10. If the blood flow stops before collecting all of the tubes, repeat the venipuncture on the participant beginning with the first unfilled tube. Because of the ratio of anticoagulant to blood, tube #3 must be completely filled in order to perform the analyses. As always, the tourniquet must never be on for longer than two minutes.
11. If phlebotomy is interrupted on tube #3 (Citrate tube) collect 2mL of blood into a red SST tube before collecting tube #3. (The SST tube blood is discarded.)

F. If a blood sample is not forthcoming, the following manipulations may be helpful.

1. If there is a sucking sound, turn needle slightly or lift the holder in an effort to move the bevel away from the wall of the vein.
2. If no blood appears, move needle slightly in hope of entering vein. Do not probe. If not successful, release tourniquet and remove needle. A second attempt can be made on the other arm. The same technician should not attempt a venipuncture more than twice (once in each arm). If a third attempt is necessary, a different phlebotomist should attempt the venipuncture.
3. Loosen the tourniquet. It may have been applied too tightly, thereby stopping the blood flow. Reapply the tourniquet loosely. If the tourniquet is a Velcro type, quickly release and press back together. Be sure, however, that the tourniquet remains on for no longer than two minutes at a time.

G. Bandaging the arm.

1. Under normal conditions:
 - a. Slip the gauze pad down over the site, continuing mild pressure.
 - b. Apply an adhesive or gauze bandage over the venipuncture site after making sure that blood flow has stopped.
2. If the participant continues to bleed:
 - a. Apply pressure to the site with a gauze pad. Keep the arm elevated until the bleeding stops.
 - b. Wrap a gauze bandage tightly around the arm over the pad.
 - c. Tell the participant to leave the bandage on for at least 15 minutes.

H. PRECAUTIONS - When a Participant Feels/Looks Faint Following the Blood Drawing:

1. Have the person remain in the chair. If necessary, have him/her lie on the floor with legs elevated. Use of a transfer belt may be indicated in this situation.
2. Take an ampule of smelling salts, crush it, and wave it under the person's nose for a few seconds.
3. Provide the person with a basin if he/she feels nauseous.
4. Have the person stay seated until the color returns and he/she feels better.

5. Have someone stay with the person to prevent them from falling and injuring themselves if he/she should faint.
6. Place a cold wet cloth on the back of the person's neck or on their forehead.
7. Once the episode has passed, some fruit juice may be given to the participant in order to counteract any possible hypoglycemia due to their pre-clinic visit fast.
8. If the person continues to feel sick, take a blood pressure and pulse reading. Contact a medical staff member for further direction.

3.4. Blood Tube Mixing and Storage During Venipuncture

All tubes must be mixed with the anticoagulant to prevent clotting. Even tubes #1 and #2 that do not contain an anticoagulant, have a clot activator that needs to be mixed with the blood. Begin by holding the tube horizontal to the floor. Gently tip the stopper end down while watching the air bubble rise to the butt (1st inversion). Now, lower the butt end slightly while watching the bubble float to the stopper (2nd inversion). Lower the stopper end again when the bubble reaches the stopper. This is the third inversion. Invert each tube eight times. Eight inversions should take 6 to 8 seconds.

Tube #1 and #2: 5 mL red stoppered tube containing no anticoagulant. Invert tube gently 8 times immediately after collection. Place tubes in room temperature rack and allow the blood to clot for 30 minutes after collection. Protect tubes from light by placing a box over the rack until centrifugation.

Tube #3: 4.5 mL blue-stoppered tube contains sodium citrate anticoagulant. Place the tubes in room temperature rack until centrifugation at 15° C. (These tubes can be placed under the box, but do not require protection from light).

Tube #4 and #5: 5 mL lavender-stoppered tube contains EDTA anticoagulant. Invert gently 8 times immediately after collection. Place the tubes #4 and #5 in a cup with ice slush and protect them from light by placing a box over the cup of ice slush until centrifugation.

4. BLOOD PROCESSING

4.1 Stage One: Immediate Processing

After completion of venipuncture:

1. Tubes #1 and #2 remain at room temperature for 30-45 minutes to allow the blood to clot (blood at 4°C clots extremely slowly). Keep these covered with a box to protect them from light. Set a timer for 30 minutes as a reminder to centrifuge these tubes.
2. **Before centrifuging tube #4**, remove purple stopper and using a plastic pipette, transfer 1 mL of whole blood into a labeled 5-mL vial with a clear cap (Position A3 in aliquot tray). Place the 5-mL vial of whole blood into position A3 of the aliquot tray. **Replace the purple stopper tightly into tube #4 before centrifugation.**
3. Within 15 minutes of collection, place tubes, #3, #4, and #5 in the centrifuge runions. Place tubes in the centrifuge buckets in a balanced manner (see description of balancing the centrifuge in 4.1 "Operating the Centrifuge"). Spin these tubes at 3,000 x g for 30 minutes at 15°C. Record on the Biospecimen Collection form the time at which these tubes began to spin.

4.1.1 Operating the Centrifuge

Refer to Centrifuge Operating Manual for specific operating and balancing instructions. In order to achieve a 3000 x g centrifugal force (rcf) within the centrifuge, the corresponding revolutions per minute (RPM) may vary from centrifuge to centrifuge depending on radius of the centrifuge's rotor. Consult the centrifuge's operating manual for the appropriate RPM for each centrifuge. If the field center's centrifuge is not capable of creating a 3000 rcf, increase the centrifugation time until the rcf-minutes total 90,000. If, for example, the maximum force is 2000 rcf, then increase the time from 30 to 45 minutes. To balance the centrifuge, place tubes of the same size and with equal volume of blood as determined visually in opposite positions in the bucket adaptors. For tubes of blood that do not have another tube of equivalent blood volume, use a "balance tube" of the same size containing an equivalent volume of water. Wait for centrifuge to come to a complete stop before opening the lid. Proceed to stage 2 processing.

4.2. Stage Two: Processing of Plasma

Stage two begins approximately 30 minutes after venipuncture. Eye protection, gloves and lab coat must be used for all blood processing. All other rules regarding the safe blood specimen handling must also be observed.

When removing the plasma after centrifugation do not disturb the white blood cells layer, also called the buffy coat, which forms a thin layer between the upper plasma layer and the lower layer of packed red blood cells. This is especially true in tube #3 because the platelets which are found near the top of the buffy coat contain some of the analytes which are to be measured and could cause erroneous result if aspirated with the plasma. If some of the buffy coat is accidentally aspirated while removing the plasma, re-centrifuge the tube using the initial processing conditions. Indicate on Item 18 of the Biospecimen Collection form (Appendix 3) that the tube was re-centrifuged.

Aspiration of the lipid layer that may float to the surface after centrifugation could also adversely affect the test results. Thus, it is critical that only the clear plasma or serum between the buffy coat and the upper lipid layer be aspirated when preparing these sample aliquots. If lipids floated to the top of the plasma, indicate on Item 19 of the Biospecimen Collection form (Appendix 3) "lipids present on top of plasma/serum were not pipetted".

Unless otherwise specified, place at least 0.5 mL and up to, but not more than approximately 1.5 mL of serum or plasma into the 2 mL vials.

1. Remove tubes #3, #4, and #5 from the centrifuge and place them in a wire rack in front of the sample aliquot tray 1.. Remove the stoppers. Be careful not to disturb the cell layers.
2. Tubes # 4, and #5: Using a plastic transfer pipet and being careful not to disturb the red or white blood cell layers, remove the clear plasma supernatant from tube #4. Aspirate slowly starting at the top of the plasma (or just below the lipid layer if one is present on the top). The pipet tip does not get any closer than $\frac{1}{4}$ inch from the cell layer. Leave $\frac{1}{4}$ to $\frac{1}{2}$ inch layer of plasma above the buffy coat/red blood cells. Place approximately 0.250 mL of plasma into the first clear 2 mL vial in position A1 of the sample aliquot tray 1. (Use the "0.250 mL template" vial and 0.250 indicator notch on the plastic pipette as a

guide for an approximate 0.250 mL volume.) Distribute the remaining plasma equally (approximate 0.5 mL volume) into one amber vial in position B1 and two clear 2 mL vials in positions C1 through D1. Process tube #5 similarly, distributing the plasma equally (approximate 0.5mL volume) into five 2 mL clear vials in positions A2 through E2. (Use "0.5 mL template vial" and the 0.5 indicator notch on the plastic pipette as a guide for 0.5 mL volume).

3. Fasten the lavender screw caps onto the vials in columns 1 and 2 and place them in the cup with ice slush.
4. Using the same plastic transfer pipette, slowly aspirate the remaining plasma, buffy coat layer, and some of the red cells from tube #4. (Do not let the buffy coat aspirate into the bulb of the disposable pipette.) Transfer this to the 5 mL vial in position A4. Now transfer the remaining red blood cells from tube #4 to this same vial. (This ensures that the buffy coat is adequately rinsed from the transfer pipet.) Repeat these steps for tube #5 and place the liquid into the same 5 mL vial in position A4. Fasten the blue screw cap onto this vial.
5. Re-stopper tubes #4, and #5 and discard them in a biohazard waste container.
6. Tube #3: Using a plastic transfer pipet and being careful not to disturb the red or white blood cell layers, remove the clear plasma supernatant from tube #3. Aspirate slowly starting at the top of the plasma (or just below the lipid layer if one is present on the top). The pipet tip does not get any closer than $\frac{1}{4}$ inch from the cell layer. Leave $\frac{1}{4}$ to $\frac{1}{2}$ inch layer of plasma above the buffy coat/red blood cells. Distribute the plasma equally into each of four 2 mL vials in positions A6 through D6 of the sample aliquot tray. (Use the "0.5 mL template" vial and the 0.5 mL indicator notch on the plastic pipette as a guide for an approximate 0.5 mL volume.) Place a blue screw cap on each vial. Replace the blue stopper on both of the collection tubes and discard them in a biohazard waste container.

4.3. Stage Three: Processing of Serum

Stage three begins approximately 30 minutes after venipuncture.

1. As close to 30 minutes after venipuncture as possible, and no longer than 45 minutes after venipuncture, spin the red stoppered tubes #1 and #2 at 3,000 x g for 10 minutes. Record the time when centrifugation begins on the Biospecimen Collection form. (Stage 2 processing can be done while these tubes are centrifuging.)
2. When the centrifuge has come to a complete stop, remove tubes and place them in a wire rack in front of the sample aliquot tray. Remove the stopper.
3. Using a plastic transfer pipet and being careful not to disturb the red or white blood cell layers, remove the clear serum supernatant from tube #1. Aspirate slowly starting at the top of the serum (or just below the lipid layer if one is present on the top). The pipet tip does not get any closer than $\frac{1}{4}$ inch from the cell layer. Leave $\frac{1}{4}$ to $\frac{1}{2}$ inch layer of serum above the buffy coat/red blood cells. Place approximately 0.250 mL of serum into the 2 mL vial in position A8 of the sample aliquot tray. (Use the "0.250 mL template" vial and 0.250 indicator notch on the plastic pipette as a guide for an approximate 0.250 mL volume). Distribute the remaining serum equally into one amber vial in position B8 and

two 2 mL clear vials in positions C8 and D8 of the sample aliquot tray. Remember to withdraw only the clear serum; if lipids are present on top begin aspirating from below that layer. For tube #2, distribute the serum equally into the five 2 mL vials in positions A9, B9, C9, D9, and E9 of the sample aliquot tray. (Use the “0.5 mL template” vial and the 0.5 mL indicator notch on the plastic pipette as a guide for an approximate 0.5 mL volume. Fasten the red screw caps onto these vials.

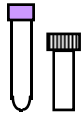
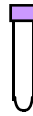
4. Re-stopper tubes #1 and #2 and discard them in a biohazard waste container.

Remove the purple-capped vials from the cup with ice slush, dry them with a paper towel, and place them into positions in columns 1 and 2 of the sample aliquot tray. Immediately place the aliquot tray in the -70° C freezer. The aliquots should freeze in an upright position so that the material does not freeze in the cap. Record the time these aliquots are placed in the freezer on the Biospecimen Collection form.

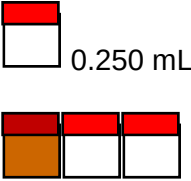
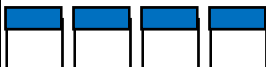
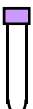
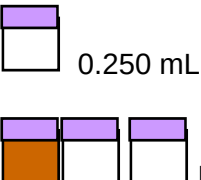
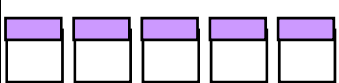
4.4. Overview of Specimen Collection

A summary overview of the protocol steps for the collection and processing of blood specimens is presented in Figure 2 and 3. (Specimen Processing Charts)

SOL Youth Blood Collection/Centrifuging Chart (Stage 1 Immediate Processing) Figure 2

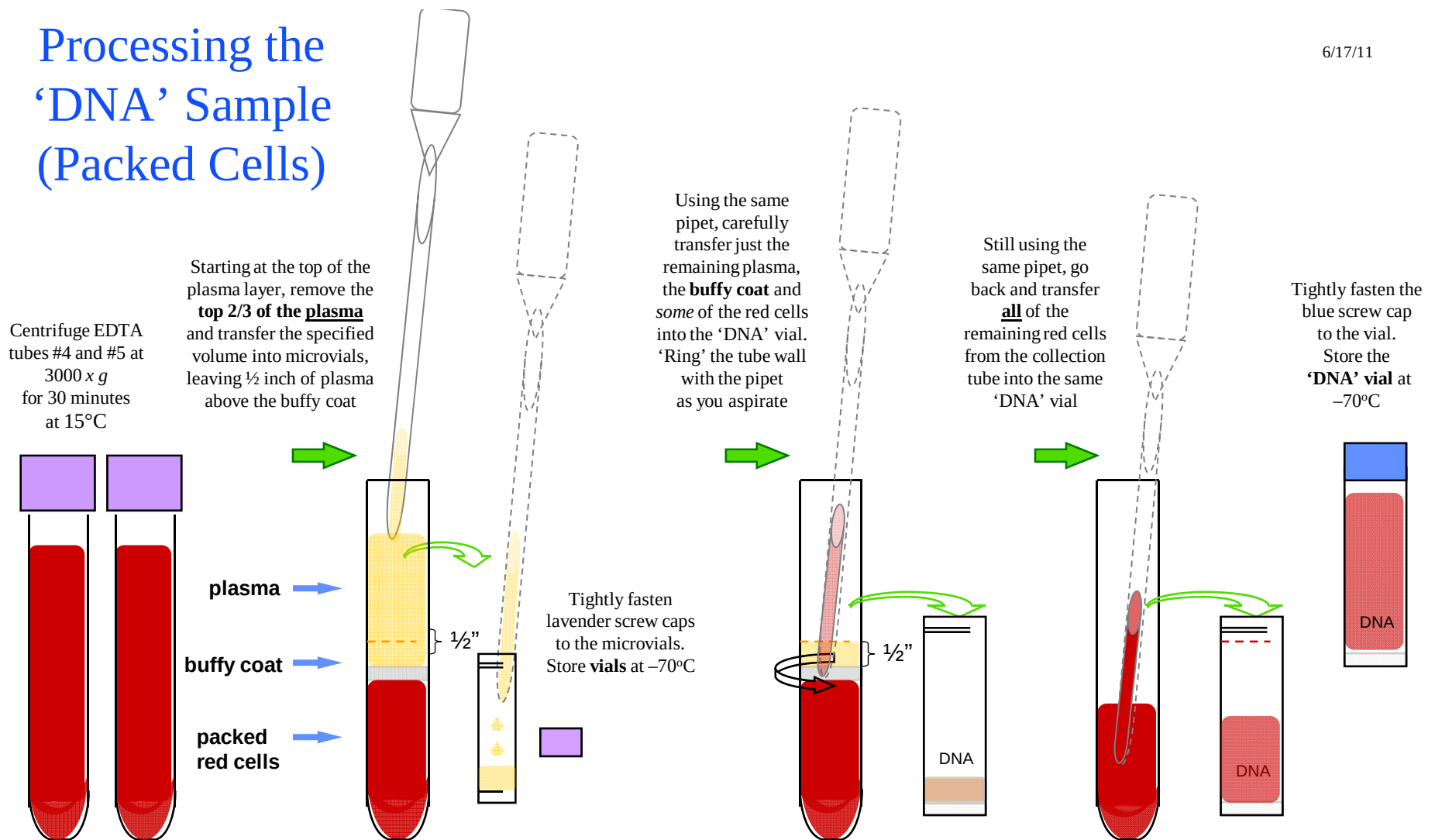
Test	Tube Name	Fasting Condition	Blood Collection Tube	Visual Reference	Collection/Centrifuging
Lipid Profile hsCRP	Red Top Tube #1	Fasting	5.0 mL red-top	Label Tube 	• Fill labeled tube completely with blood • Invert tube 8 times/Cover with Box • Tube must sit 30-45 min at Room Temp • Blood will clot • Centrifuge 15°C for 10 min at 3000 x g (Tubes #1 & #2) • Remove collection tube from centrifuge • Proceed to Specimen Aliquot Procedure
Adipocytokines Serum Storage	Red Top Tube #2	Fasting	5.0 mL red-top	Label Tube 	• Fill labeled tube completely with blood • Invert tube 8 times/Cover with Box • Tube must sit for 30-45 min at Room Temp • Blood will clot • Centrifuge 15°C for 10 min at 3000 x g (Tubes #1 & #2) • Remove collection tube from centrifuge • Proceed to Specimen Aliquot Procedure
vWF & PAI-1 Na Citrate Plasma Storage	Blue Top Tube #3	Fasting	4.5 mL blue top (Na Citrate)	Label Tube 	• Fill labeled tube completely with blood • Invert tube 8 times. • Centrifuge Immediately at 15°C for 30 min at 3000 x g • <i>Centrifuge tubes #3, #4, and #5 at same time</i> • <i>Will need to balance tube #3 with a water balance tube</i> • Remove collection tube from centrifuge • Proceed to Specimen Aliquot Procedure
Hemoglobin A1c Glucose Insulin	Purple Top Tube #4	Fasting	5.0 mL purple-top (EDTA)	Label Tubes 	• Fill labeled tube completely with blood • Invert tube 8 times/Place in Ice Water Bath/Cover with Box • Remove collection tube stopper • Transfer 1.0 mL of whole blood into clear capped 5.0 mL vial • Place labeled 5.0 mL vial of whole blood in -70°C freezer • Re-stopper collection tube tightly • Centrifuge Immediately at 15°C for 30 min at 3000 x g • <i>Centrifuge tubes #3, #4, and #5 at same time</i> • Remove collection tube from centrifuge • Proceed to Specimen Aliquot Procedure
EDTA Plasma Storage DNA	Purple Top Tube #5	Fasting	5.0 mL purple-top (EDTA)	Label Tube 	• Fill labeled tube completely with blood • Invert tube 8 times/Place tube in Ice Water Bath/Cover with Box • Centrifuge immediately at 15°C for 30 min at 3000 x g • <i>Centrifuge tubes #3, #4, #5 at same time</i> • Remove collection tube from centrifuge • Proceed to Specimen Aliquot Procedure

SOL Youth Specimen Aliquot Chart (Stage 2 Plasma Processing and Stage 3 Serum Processing)

Aliquot Instructions	Tube Name	Blood Collection Tube	Visual Reference	Aliquot Diagram
- From #1 transfer 0.250 mL into one clear 2-mL vial with red cap - Distribute remaining serum equally into one amber and two clear 2-mL vials with red caps	Red Top Tube #1	5.0 mL red-top	Centrifuged Tube 	Room Temp/Cover with Box until Freezer Placement  0.250 mL  Distribute remaining serum equally (0.500 mL minimum volume)
- From #2 distribute serum equally into five clear 2-mL vials with red caps - Keep all vials covered with Box - Place all nine serum vials into -70 ° C freezer until shipment	Red Top Tube #2	5.0 mL red-top	Centrifuged Tube 	*Room Temp/Cover with Box until Freezer Placement  Distribute remaining serum equally (0.500 minimum volume)
- From #3 distribute plasma equally into four clear 2-mL vials with blue caps - Place all four Na Citrate plasma vials into -70 ° C freezer until shipment	Blue Top Tube #3	4.5 mL blue top (Na Citrate)	Centrifuged Tube 	*Room Temp until Freezer Placement  Distribute plasma equally (0.500 mL minimum volume)
- From #4 transfer 0.250 mL into one clear 2-mL vial with purple cap - Distribute remaining EDTA plasma equally into one amber and two clear 2-mL vials with purple caps	Purple Top Tube #4	5.0 mL purple-top (EDTA)	Centrifuged Tube 	*Ice Water Bath/Cover with Box until Freezer Placement  0.250 mL  Distribute remaining plasma equally (0.500 mL minimum volume)
- From #5 distribute EDTA plasma equally into five clear 2-mL vials with purple caps - Keep all vials covered with box - Keep all vials in ice water bath - Place all nine plasma vials into -70 ° C freezer until shipment - Transfer Packed Cells from tubes #4 and #5 into one 5-mL vial	Purple Top Tube #5	5.0 mL purple-top (EDTA)	Centrifuged Tube 	*Ice Water Bath/Cover with Box until Freezer Placement  Distribute remaining plasma equally (0.500 mL minimum volume) *Packed Cells (From tubes #4 and #5); Room Temp until freezer placement  See Lab MOP for specific instructions

Processing the 'DNA' Sample (Packed Cells)

6/17/11



Processing the EDTA tube collected for DNA isolation: Follow steps for tubes #4 and #5 (Be sure to process only one participant's samples at a time)

Centrifuge the EDTA tubes #4 and #5 promptly at 3000 x g for 30 minutes at 15°C. From tube #4, being careful not to disturb the buffy coat and packed red cell layers, use a plastic transfer pipet to remove the top 2/3 of the clear plasma supernatant and transfer the specified volume into labeled microvials. Aspirate slowly starting at the top of the plasma. The pipet tip should not get any closer than one-half inch from the buffy coat. It is important to withdraw only the plasma and *none* of the buffy coat (containing white cells and platelets) that forms at the cell-plasma interface following centrifugation. Leave a ½-inch layer of plasma above the buffy coat-red blood cell layers.

Using the same plastic transfer pipet, slowly aspirate the remaining ½" layer of plasma, the buffy coat and *some* of the red cells from the tube. Take care not to aspirate the buffy coat into the bulb of the pipet! 'Ring' the tube with the pipet by carefully aspirating along the wall at the buffy coat layer to ensure maximum transfer. Dispense into the 5-mL vial labeled 'DNA'. Still using the same pipet, go back and transfer all of the remaining packed red cells from the tube #4 into the same 5-mL 'DNA' vial. This step will ensure that all of the buffy coat is adequately rinsed from the pipet. **Repeat steps for tube #5, placing packed cells in same DNA vial as tube #4.** Tightly fasten the blue screw cap on the DNA vial and place it in the -70°C freezer in aliquot tray until shipment to the Central Laboratory.

4.4.1 Freezing

When all of the blood specimens have been aliquotted into their respective vials and the vials have been replaced in the sponge rack, the entire rack is placed upright in the -70° C freezer for a minimum of 30 minutes. Samples must be placed into the freezer within 90 minutes from venipuncture time. Samples must be thoroughly frozen before packaging them for storage and shipping. Record the time that the aliquots are placed in the freezer on the Biospecimen Collection form.

5. PACKAGING AND SHIPPING

5.1. Storage, Packaging and Shipping (For Frozen Specimens)

Remove the sample aliquot tray from the -70° C freezer. Package quickly after this point to avoid thawing of the specimens and exposure to light. Each participant's serum and plasma vials are packaged in freezer storage bags according to their specimen type.

5.1.1 Packaging Frozen Specimens

Place eight of the red-capped serum vials into one 4" x 6" storage bag, eight of the purple-capped plasma vials into another 4" x 6" storage bag, and the four blue-capped plasma vials into a third 4" x 6" storage bag. Place the clear-capped whole blood into a fourth 4" x 6" storage bag and the blue-capped vial of packed cells (5 mL vial) into a fifth 4" x 6" storage bag. Place the 0.250 mL red-capped serum vial and the 0.250 mL purple-capped vials into a sixth 4" x 6" storage bag. Check again to make sure all vials/tubes are labeled as they are placed into the storage bags. Add an absorbent pad to each bag of samples. Press the air out of each bag and seal. Place all six of the sealed 4" x 6" bags into one 12" x 12" bag. Place the Lab ID# label for that set of aliquots on a piece of paper and insert it into the 12 x 12 bag so that it shows through. Expel the air from the bag and seal it. Place this bag in the Central Laboratory Styrofoam box in the -70° C freezer and do not remove it until the time of shipment. Complete the shipping log with appropriate information for these samples.

The bags of frozen sera, plasma, whole blood, and packed cells are packed and shipped in Styrofoam boxes. Packaging instructions (See Figure 4) are as follows:

1. Place a layer of dry ice on the bottom of the Styrofoam box.
2. Put one-half of the 12"x 12" bags of sample vial/tubes into the Styrofoam box on top of the dry ice.
3. Layer more dry ice on top of and around the sample bags.
4. Put the remaining sample bags into the Styrofoam box on top of the dry ice.
5. Layer more dry ice on top of and around the sample bags. The amount of dry ice in the shipping should total at least 5 pounds.

6. Place packing material on top of the dry ice to fill the box. Replace the Styrofoam cover. **DO NOT** tape the Styrofoam cover to the Styrofoam container; this damages the shipping containers making them unable to be reused.
7. Insert the paper shipping forms (**original** Face sheet, Contents sheet, and Biospecimen Collection forms; keep a copy of all forms at field center) into a 12" x 12" bag and place inside the shipping box. The shipping forms with instructions are shown in Appendix 4.
8. Seal the outer cardboard box tightly with strapping tape. Affix "Category B UN 3373" label and a Fed-Ex dry ice label to outside of box. These labels are provided by the Central Laboratory.
9. Affix the FedEx airbill to the outside of the box. Record the site address and telephone number in section 1. (Do NOT use FedEx billable stamps on dry ice shipments.) Contact Federal Express (1-800-GO-FEDEX) for pickup.
10. If necessary, more than one box may have to be shipped per week.
11. It is the clinical site's responsibility to ensure that the package is picked up by FedEx and delivered to the Central Laboratory. Follow these steps to track your package: Go to the FedEx website www.fedex.com/us/, click on <Track> drop-down menu, click on <Track by Tracking Number>, enter tracking number, and click on <Track>. The tracking information will be displayed on the <Summary> screen. If the <Summary Results> state "Not Found"; this means your package has not been picked up and FedEx should be contacted. Check to see if your package has been delivered to the Central Laboratory the morning following shipment using the same tracking procedure.
12. The Central Laboratory will check the "FedEx Insight Tracking Log" daily to view what SOL Youth packages should be arriving. However, only those packages actually picked up and scanned into the FedEx system will appear on this log.
13. See Figure 1-4 below for shipping diagram.

5.1.2 Shipping

The samples remain in their Styrofoam box at -70° C until they are shipped. All frozen plasma, sera, and packed cells tubes collected and stored within the last work week are shipped to the Central Laboratory on **Monday** with the exception of Quality Control aliquots, as discussed in the Quality Control section below. Samples can be shipped on Tuesday if the Field Center is closed on Monday, but the contact person at the Central Laboratory must be notified that the shipment will arrive one day later than usual. If very few participants were seen in the field center during a week, two or three weeks of specimens can be combined into one shipment. Notify the Central Laboratory if the weekly shipment is being held. Weigh all packages before shipping, if possible. It is important to record an accurate weight on the Federal Express Airbill. Do not over-estimate the package weight.

Remember to track your package the day following shipment to ensure that it was picked up. The Central Laboratory will check the "FedEx Insight Tracking Log" daily to view what SOL Youth packages should be arriving. However, only those packages actually picked up and scanned into the FedEx system will appear on this log.

Note: All shipping containers are sent to the SOL Youth Central Laboratory by overnight courier to ensure receipt within 24 hours. The empty Styrofoam containers are recycled by returning them to the Clinical Centers via FedEx Express Service. Shipping containers to the Central Laboratory are addressed as follows:

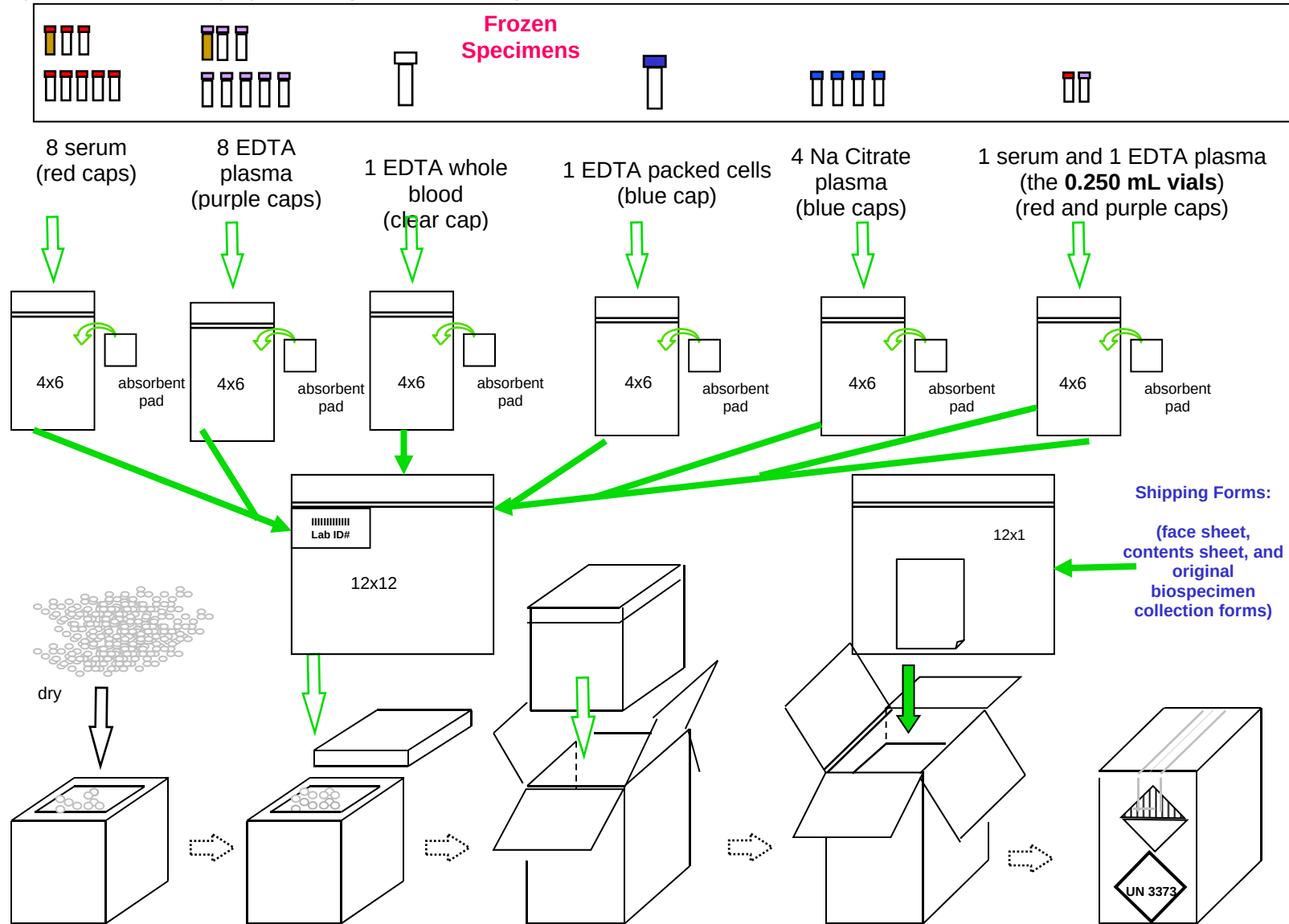
Annie Lukkari/ SOL Youth Central Laboratory
University of Minnesota, Advanced Research and Diagnostic Laboratory (ARDL)
Room L275 Mayo Memorial Building
420 Delaware Street S.E.
Minneapolis, MN 55455
Telephone: (612) 273-3645
Fax: (612) 273-3489

SOL Youth Central Laboratory Hours:

Monday-Friday	7:00 am-3:30pm
Saturdays	Open; hours vary
Sundays	Closed

*A holiday schedule will be emailed to all SOL Youth Clinical Sites in advance of upcoming holidays.

Figure 4. Packaging Frozen Specimens for Shipment



6. QUALITY CONTROL

There are two different aspects of quality control. One is the daily or monthly record of the performance of the refrigeration equipment, and centrifuge. Daily and monthly measurements (e.g., temperatures) are recorded on a log, as described below. The other aspect of quality control is documentation of problems with blood collection and processing which is part of each participant's record. (See Appendix 3, Items 10, 11, 18, and 19, Biospecimen Collection form.)

- all or some blood samples not drawn
- tourniquet reapplied
- fist clenching
- needle movement
- incomplete blood collection causing missing tubes
- broken tubes
- clotted tubes
- hemolyzed serum or plasma
- lipemic serum or plasma
- other processing problems

This record provides documentation that blood was drawn in a standardized manner and that the equipment was functioning properly. This quality control documentation is the best evidence that samples in each of the four Field Centers are being drawn and processed identically. Differences in the way the samples are collected or processed could potentially create a significant difference in assay results, which could seriously compromise the laboratory test data. It is very important that the quality control records of the procedures and the equipment be properly maintained.

Daily, log the temperatures of the laboratory, all refrigerators, freezers, and refrigerated centrifuges (Appendix 5). In addition, check and record the actual speed of the centrifuge annually with a tachometer. (This is usually performed by a biomedical engineer.)

6.1. Quality Control Duplicate Blood Samples

As part of the overall quality control program for laboratory determinations from blood samples, duplicate specimens are sent to the laboratory, with one half of each specimen pair sent under the participant's regular HCHS-SOL-Youth laboratory ID number, and the other half under a Quality Control Phantom Participant (QC) laboratory ID number. The QC laboratory ID numbers are not distinguishable from other laboratory ID numbers so that this forms a blinded external quality control program monitoring measurement variability.

To reduce the burden on any single participant, extra blood is drawn from three participants and sent out under the same QC ID number. For data analysis, results on each laboratory measurement are matched to the appropriate participant results at the Coordinating Center from the QC Phantom ID Form (Appendix 6) that is completed by Field Center technicians.

If extra QC blood is drawn for a tube that is processed for weekly shipment (Tubes #1, 2, 3, 4, and 5), the aliquots are stored at the Field Center for extra week/weeks until the entire QC set is complete and then the complete QC set is sent to the Central Laboratory with a regular shipment. **Two complete QC sample sets per month** should be sent to the Central Lab for the **first six months** of the study and then for the remaining months of the study only **one complete QC sample set per month** should be sent to the Central Lab.

The QC blood samples are collected in sequential order (cycling back to Tube #1 after QC Tube #5 has been collected). Over the entire study, each Field Center will collect QC samples from approximately 7% of all specimens (n=28). Three participants will be needed to provide three QC replicate specimens to form one phantom ID. Thus, one-fifth of participants (n=84=3x28) per field center will contribute to the pool of replicate specimens. Two QC sample sets should be sent to the Central Lab monthly for the first 6 months of the study. One QC sample set should be sent to the Central Lab monthly for the remaining months of the study. Choose older children with a larger body weight as QC sample candidates.

An example plan for collecting the QC samples: **First six months** of the study: Week one of the month; draw tubes #1 and #2 (day 1 of week); draw tube #3 (day 2 of week); draw tubes #4, and #5 (day 3 of the week). Week two of the month; draw tubes #1 and #2 (day 1 of week); draw tube #3 (day 2 of week); draw tubes #4, and #5 (day 3 of the week). Week three of the month can be used to collect QC samples if not enough can be collected in the week one and two of the month. On week four of the month; send the **two completed QC sample sets** to the Central Laboratory. **After the first six months of the study:** Week one of the month; draw tubes #1 and #2. Week two of the month; draw tube #3. Week three of the month draw tubes #4, and #5. On week four of the month; send the **one completed QC sample set** to the Central Laboratory. The plan for collecting QC samples will vary depending on the availability of appropriate candidates for the QC samples.

6.2. Blood Sample Checklist

The venipuncture technicians maintain a daily checklist posted in their work area of the QC samples to be drawn. As each sample is drawn and processing completed, it is checked off. An example of the checklist is given below.

Blood QC Sample Checklist

Date: _____

<u>Participant</u>	<u>Tubes</u>	<u>Aliquot Type</u>	<u>Sample collected? (Y/N)</u>
Participant 1	1 & 2	Serum	_____
Participant 2	3	Plasma, sodium citrate	_____
Participant 3	4, & 5	EDTA Whole Blood & Plasma	_____

6.3. Preparation for Drawing and Processing QC Samples

Blood Drawing Tubes: Each morning (or the afternoon before) the blood drawing technician(s) prepares the extra blood collection tube(s) for the QC sample(s) to be drawn that day. Each tube is labeled with the QC ID number to be used that day. In addition, the technicians may wish to mark QC blood drawing tubes "QC" in a clearly visible fashion, to reduce the chance that these tubes might be mixed up with the regular blood collection tubes during processing. The QC tubes are set in the same rack used to hold the regular blood collection tubes, in a separate row from the other tubes.

Sample Aliquot Tubes: Each morning (or the afternoon before) a separate sample aliquot tray is prepared for the QC blood vials that the technician will process that day. The tray contains all the aliquot vials needed to process the day's quality control sample. The tubes in each block are labeled in advance with the QC ID number being used that day. Care must be taken during

processing that the labels on the sample aliquot tubes match the label on the QC blood collection tubes.

6.4. Collecting and Processing QC Blood

Selecting Participants for QC Blood Draw: A QC sample will be collected from a total of six participants each month (two complete QC sample sets) for the first 6 months of the study. After the first 6 months of the study, then only three participants (one complete QC sample set) will be needed. Choose older children with a larger body weight as QC candidates. Based upon the size of their veins, the difficulty of drawing the blood, and the apprehension a participant shows about the blood draw, the venipuncture technician may forego the drawing of the QC tube from certain participants. (After a specific number of QC sample sets are collected from each field center as determined by the Coordinating Center, the frequency of participant QC collections may decrease.)

Order of QC Tubes in Relation to Regular Blood Collection: Draw the QC tubes after the other tubes have been collected. This procedure is followed to cause the least disruption of the collection of the regular blood samples. If the blood flow falls off at the end of the draw, so that it would be difficult to obtain the extra QC tubes, a different participant is used to get this blood. DO NOT PERFORM A NEW NEEDLE STICK JUST TO GET MORE BLOOD FOR A QC SPECIMEN. DO NOT REAPPLY THE TOURNIQUET AFTER INITIAL RELEASE.

Processing and Freezing QC Blood: Process the QC blood samples along with the regular blood samples. After processing is completed for each QC blood collection tube, the sample aliquot tubes are put into the -70° C freezer (for a minimum of 30 minutes) After the samples are thoroughly frozen, they are put into a freezer storage bag and put into the freezer box. Keep the QC specimens separate from the other specimens collected during the week so they are not shipped along with them.

Biospecimen Collection form: This form is completed for the QC phantom set of samples. However, it is not possible to complete this form truthfully since the set is collected from multiple participants. It is suggested that the information from the participant to donate tubes #1 and #2 is used to complete the form for the QC set.

Logging the Match between QC and Regular SOL Youth ID's and Reporting these to the Coordinating Center: The QC Phantom Participant's folder is kept in the blood drawing area. In the folder is the SOL Youth Quality Control Phantom Participant Form (see example in Appendix 6), which is used to keep track of the match between the QC and regular SOL Youth specimens. At the top of the log sheet is a space for the QC Phantom Participant's laboratory ID number. As participants donate blood to make up a QC set, labels with their participant ID numbers (not their Lab ID#) are added to the line corresponding to the tubes donated. This step must be done immediately after completion of drawing blood for that participant, to minimize the chance of recording the wrong ID number. One such form is recorded for each QC ID number used. As soon as the full set of tubes is completed for each phantom participant, the QC phantom participants' folder with this form is given to the receptionist (or other person designated by the Study Coordinator). The folder is processed like other participants' folders, with the QC phantom participant form transferred to the Coordinating Center by keying the Phantom form (PHT) into the data management system. Do not send a hardcopy of the Phantom form (PHT) to the Central Laboratory because it will unblind the masked QC analysis of the samples. A Biospecimen Collection form is also completed for the phantom duplicate.

6.5. Internal Laboratory Control

Internal quality control procedures monitor analytical performance of the test relative to medical goals and alert analysts to unsatisfactory analytical performance. Quality control statistics are used to make judgments about the quality of analytical results, whether system correction is necessary, whether patient data should be accepted or rejected, and for estimating performance parameters which can be compared to analytical and medical goals. Testing is monitored by two control samples analyzed daily in each batch of samples. A permanent standard deviation (SD) and coefficient of variation (CV) is determined by analyzing the material on 50 – 100 separate days. The mean for new lots of material is established by analyzing the material on 20 separate days. The SD and CV from the data collected over 20 days is used to monitor the permanently established SD. Quality control results are plotted on Levy-Jennings plots and acceptability (i.e. in statistical control) is determined using three Westgard rules (1-2s, 1-3s, and 2-2s). Documentation is made on the control charts when there is a change in reagent lot numbers, any action is taken due to unacceptable control results, and when other pertinent information is observed.

6.6. Reporting Results

The Central Laboratory has the responsibility for reporting results to the Coordinating Center. All test results are transmitted to the Coordinating Center through file transfer protocol (FTP) or use of a Coordinating Center upload facility that is accessed through the web based DMS. This transmission will occur weekly on Mondays. In order to see if the Coordinating Center has received and processed the lab results for a participant, the field center can run the “End of Study Availability Report” using the SOL Youth data management system. The availability report summarizes the receipt of information from the Central Laboratory and reading centers. Tests reported to the participants will be available to the field centers via a report in the DMS called the “End of Study Report”. Any tests included in this report whose results exceed their alert range will be flagged appropriately. In addition, any alert result on a test not normally reported to the participants will be included in a separate upload. Reference ranges and alert values can be found in Appendix 1. Note that test results will be available in approximately 3-4 weeks after the sample is collected.

7. TRAINING PROCEDURES

Technicians will be trained in actual procedure of phlebotomy by their respective institutions. The study does not provide phlebotomy training.

A check list of the venipuncture and processing procedures that SOL Youth technicians must know and be prepared to demonstrate is listed in Appendix 7. The technician must study the SOL Youth Specimen Collection and Processing Manual and watch a few participant samples being processed. Then the technician may proceed to a mock drawing and mock processing of samples, without performing any actual venipuncture. Mock venipuncture is performed with the Vacutainer system. A piece of latex tubing with a knot in one end leading to a glass of water is used as a target vein. Practice tubes are collected in the correct order, and then placed at their proper positions. The sample is processed from start to finish exactly as if real blood were being used. Each technician performs a minimum of two mock draws from beginning to end. Although the mock draws take time, they provide hands-on experience and allow the technician to become comfortable with the procedures before proceeding to live participants.

At this point the technicians are ready to practice on live volunteers. The technicians practice at least once with just one volunteer at a time and again process the blood entirely by themselves from start to finish. If the technicians do not feel comfortable, they can always go back and repeat the process with dummy tubes. If volunteers are available, it may be beneficial to repeat this several times. Any questions or problems that the technicians have must be solved before the technicians actually proceed to drawing the SOL Youth participants. Before the technicians draw blood from any SOL Youth participant, they must take and pass the practical and written tests included at the end of this manual (Appendix 8). After passing the test and depending on the written evaluation of their instructor, they may proceed either to drawing blood from the SOL Youth participants as part of a team, or do more practice on live volunteers.

8. SNACK

A light snack for the participant is scheduled as soon as possible after venipuncture. Menus are locally determined.

Appendix 1A. SOL Youth laboratory tests' reference ranges

Test Names	Reference Ranges		Age Ranges	Units
	Males	Females		
hs C-reactive protein	none/NR ^a	none/NR ^a	all	mg/L
e-Selectin	none/NR ^a	none/NR ^a	all	ng/mL
TNF-alpha	none/NR ^a	none/NR ^a	all	pg/mL
IL-6	none/NR ^a	none/NR ^a	all	pg/mL
Adiponectin	none/NR ^a	none/NR ^a	all	ng/mL
VWF (antigen)	none/NR ^a	none/NR ^a	all	%
PAI-1	none/NR ^a	none/NR ^a	all	U/mL
Insulin, fasting	none/NR ^a	none/NR ^a	all	pmol/L
Glucose, fasting ^b	60 – 99	60 – 99	all	mg/dL
Hemoglobin A1c	4.3 – 5.6	4.3 – 5.6	all	%
Total cholesterol ^c	<168	<177	5 – 9 years	mg/dL
	<173	<171	10 – 14 years	mg/dL
	<168	<176	15 – 19 years	mg/dL
Triglycerides ^c	<58	<74	5 – 9 years	mg/dL
	<74	<85	10 – 14 years	mg/dL
	<88	<85	15 – 19 years	mg/dL
LDL-cholesterol ^c	<103	<115	5 – 9 years	mg/dL
	<109	<110	10 – 14 years	mg/dL
	<109	<110	15 – 19 years	mg/dL
HDL-cholesterol ^d	>49	>48	5 – 9 years	mg/dL
	>46	>45	10 – 14 years	mg/dL
	>39	>43	15 – 19 years	mg/dL

^a Non-reported test result so no reference range is necessary.

^b Based on American Diabetes Association guidelines as reported in American Diabetes Association: Diagnosis and Classification of Diabetes Mellitus. Diabetes Care 2011;34 (Suppl. 1): S11–S61.

^c Based on 75th percentile for children and adolescents as reported in Daniels SR, Greer, FR et al. Lipid Screening and cardiovascular health in childhood. Pediatrics 2008;122:198-208.

^d Based on 25th percentile for children and adolescents as reported in Daniels SR, Greer, FR et al. Lipid Screening and cardiovascular health in childhood. Pediatrics 2008;122:198-208.

Appendix 1B. SOL Youth alert values and actions to be taken

Test name	Alert value	Script for result report
hs C-reactive protein	none/NR ^a	
e-Selectin	none/NR ^a	
TNF-alpha	none/NR ^a	
IL-6	none/NR ^a	
Adiponectin	none/NR ^a	
VWF (antigen)	none/NR ^a	
PAI-1	none/NR ^a	
Insulin, fasting	none/NR ^a	
Glucose, fasting	100 – 125 mg/dL	“Your child’s glucose is borderline high which is associated with an increased long-term risk of developing diabetes. <i>You should consult with your child’s healthcare provider to discuss these results and options within the next month.</i> ”
	126 – 299 mg/dL	“Your child’s glucose is high which if repeatedly high is diagnostic of diabetes. <i>You should consult with your child’s healthcare provider to discuss these results and options within the next week.</i> ”
	≥300 mg/dL	“Your child’s glucose is very high which suggests uncontrolled diabetes. <i>You should consult with your child’s healthcare provider to discuss these results and options as soon as possible.</i> ”
Hemoglobin A1c	5.7 – 6.4	“Your child’s hemoglobin A1c is borderline high which is associated with an increased long-term risk of developing diabetes in the future. <i>You should consult with your child’s healthcare provider to discuss these results and options within the next month.</i> ”
	≥6.5	“Your child’s hemoglobin A1c is very high which suggests your child has

		diabetes. <i>You should consult with your child's healthcare provider to discuss these results and options as soon as possible.</i>
Total cholesterol	ULRR ^b - 199 mg/dL	"Your child's total cholesterol is borderline high which is associated with an increased long-term risk of cardiovascular disease. <i>You should consult with your child's healthcare provider to discuss these results and options within the next month.</i> "
	≥ 200 mg/dL	"Your child's total cholesterol is high which is associated with an increased risk of cardiovascular disease. <i>You should consult with your child's healthcare provider to discuss these results and options within the next month.</i> "
Triglycerides	ULRR ^b – 199 mg/dL	"Your child's triglycerides are borderline high which is associated with an increased risk of cardiovascular disease. <i>You should consult with your child's healthcare provider to discuss these results and options within the next month.</i> "
	200 – 499 mg/dL	"Your child's triglycerides are high which is associated with an increased long-term risk of cardiovascular disease. <i>You should consult with your child's healthcare provider to discuss these results and options within the next few weeks.</i> "
	≥500	"Your child's triglycerides are very high which is associated with an increased long-term risk of cardiovascular disease and an immediate risk of other serious disorders such as acute pancreatitis. <i>You should consult with your child's healthcare provider to discuss these results and options as soon as possible.</i> "
LDL-cholesterol	ULRR ^b to 129 mg/dL	"Your child's LDL-cholesterol is borderline high which is associated with an increased long-term risk of

		cardiovascular disease. <i>You should consult with your child's healthcare provider to discuss these results and options within the next month.</i> "
	≥ 130 mg/dL	"Your child's LDL-cholesterol is elevated which is associated with a significantly increased long-term risk of cardiovascular disease. <i>You should consult with your child's healthcare provider to discuss these results and options within the next month.</i> "
HDL-cholesterol	$< \text{LLRR}^c$ mg/dL	"Your child's HDL-cholesterol is low which is associated with a significantly increased long-term risk of cardiovascular disease. <i>You should consult with your child's healthcare provider to discuss these results and options within the next month.</i> "

^a None/NR = no alert value and test result is not reported to study participants.

^b ULRR = upper limit of gender- and age-specific reference range

^c LLRR = lower limit of gender- and age-specific reference range

Appendix 2. Equipment and Supplies

Supplies to be supplied by the Central Laboratory:

Description

FedEX pre-printed shipping labels (Airbills)

Dry ice shipping labels

Category B UN 3373 labels

Supplies to be obtained by the Field Center:

Supplier	Catalogue No	Description
Cardinal Health	B3036-15A	Butterfly Needles, 23G x ¾", #367297
Cardinal Health	B3036-14	Butterfly Needles, 21G x ¾", #367296
Cardinal Health	B3036-16A	Butterfly Needles, 25G x ¾", #367298
Cardinal Health	B3035-12	Luer Adapters, #367290
Cardinal Health	40000-110	Alcohol Swabs 2,000/cs
Cardinal Health	KC9132A	Gauze Sponges 200/pk
Cardinal Health	JJ5644	Band Aids 100/pk
Cardinal Health	367203	Tourniquets, Latex free, 50/pk
Cardinal Health	F0882-30	LMX4 (4% lidocaine anesthetic cream); #0882-30
Cardinal Health	M1634	Tegaderm Clear Dressing (used to cover LMX4)
Cardinal Health	364815	Vacutainer Tube Holders 1000/cs BD #364815
Cardinal Health or Fischer Scientific	B2953-36 or 02-687-94	Serum, Red top tubes (no gel), 5mL; 100/pk (BD Manufacturer number: #367814)
Cardinal Health	81-310448 or	EDTA plasma, Purple Top, 5mL; 50/pk
Fischer Scientific	22-310-448	
Cardinal Health	B2994-91 or B2952-3 or 02-685-6B	Sodium Citrate, Blue Top, 4.5 mL; 100/pk
Fischer Scientific	02-685-6B	
Cardinal Health	C1300-82	Microvials, clear (2mL) 500/pk
Cardinal Health	C1300-83	Microvials, amber (2 mL) 500/pk
Cardinal Health	C1310-15	Red Screw Caps 1000/pk
Cardinal Health	C1310-20	Purple Screw Caps 1000/pk
Cardinal Health	C1310-13	Blue Screw Caps 1000/pk
Cardinal Health	T1234-3	Screw Top Vials w blue cap (5 mL) 1000/pk
Cardinal Health	T4136-315	Screw Top NUNC Vials w cap (4.5 mL) 1200/pk
Cardinal Health	P5214-12	Transfer Pipettes 500/pk
Cardinal Health	SBE2R46	Ziplock Freezer Bags 4" x 6" 1000/pk, 5000/cs
Cardinal Health	MGRL2P1212	Ziplock Freezer Bags 12" x 12" 5000/cs
Heathrow Scientific	HS21645A	Polyester Foam Tube Rack, 50 wells, 6/pk
Cardinal Health	C3521-01	Polyester Foam Tube Rack, 50 wells, 6/pk, #0010
Cardinal Health	B3062-40	PDI Ammonia Inhalant
Cardinal Health	B2922-1A	Blood Collection Trays
Cardinal Health	T2941-3 or T2960-4	Thermometers -20 C-+70 C
Cardinal Health	M1050-7	50 mL Absorbent Pads for shipping
Cardinal Health	C6510-1	Timer- 3 channel digital
Cardinal Health	M1066-15A	Styrofoam shipping box w/outer cardboard (Thermosafe Mfr. 355) (11x 11x 11 5/8; Styrofoam shipper) (14 ¼ x 14 ¼ x 14 5/8; outer cardboard) (Fits 5-8 sample sets)

Polyfoam Packers/ samples sets) ThermoSafe	398	Styrofoam shipping box, (Est. 25-30 frozen
Polyfoam Packers/ samples sets) ThermoSafe	352	Styrofoam shipping box, (Est. 28-30 frozen
		Dry Ice (approximately 5-10 lbs. per shipment)
		Packing Material
		3M, Scotch brand 3750 clear packaging tape

Note: Three different sizes of shipping boxes are listed in order to accommodate various recruitment levels.

Equipment purchased and maintained by Field Centers:

Table-top centrifuge with swinging buckets, refrigerated, and capable of producing 3,000 x g
Freezer capable of maintaining -70° C with a minimum of 5 cu ft storage

Refrigerator 4° C for storing centrifuged serum or plasma (in emergency situations when the samples cannot be aliquoted immediately).

Appendix 3



BIOSPECIMEN COLLECTION FORM

PARTICIPANT ID NUMBER:							
FORM CODE: BIO VERSION: 1 2/1/2012	Contact Occasion	0	1	SEQ #	0	1	

LAB ID#	Place sticker here:

Instructions: This form should be completed during the participant's visit. Affix the SOL-Youth participant ID label and the Lab ID label above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes.

A. Safety Questions:

- Has [CHILD's NAME] ever had a surgery where lymph nodes were removed from his/her armpits?
☐¹ Yes ☐⁰ No **If Yes, specify in Q11 and follow precautions per QxQ instructions**
- Does [CHILD's NAME] have any bleeding disorders? ☐¹ Yes ☐⁰ No **If Yes, specify in Q11; follow precautions per QxQ instructions**
- Has [CHILD's NAME] ever had a graft or shunt for kidney dialysis?
☐¹ Yes ☐⁰ No **If Yes, specify in Q11; follow precautions per QxQ instructions**

B. Fasting Blood Collection Information:

- On which day did [CHILD's NAME] last eat or drink anything except water: today, yesterday, or the day before yesterday?
☐¹ Today..... ☐² Yesterday ☐³ Before Yesterday
- And at what time was that? : A.M / P.M.
 h h : m m **(Circle One)**

C. Blood Collection: *Note: Remove LMX4 cream if used prior to blood collection; indicate LMX4 use in item 11.

- Date of blood collection: / / 7.Collection time: : A.M / P.M.
 m m/ d d / y y y y h h : m m **(Circle One)**
- Number of venipuncture attempts:
- Any blood drawing incidents or problems?..... ☐¹ Yes ☐⁰ No **If Yes, specify in Q10 and/or Q11**

10. Blood drawing incidents: Document problems with venipuncture in this table. Place an "X" in box(es) corresponding to the tubes in which the blood drawing problem(s) occurred. If a problem other than those listed occurred, use Item 11.

	Tube Number				
	1	2	3	4	5
a. Sample not drawn	☐	☐	☐	☐	☐
b. Partial sample drawn	☐	☐	☐	☐	☐
c. Tourniquet reapplied	☐	☐	☐	☐	☐
d. Fist clenching	☐	☐	☐	☐	☐
e. Needle movement	☐	☐	☐	☐	☐
f. Participant reclining	☐	☐	☐	☐	☐

11. If any other blood drawing problems/comments not listed above (e.g., fasting status, etc.), describe incident or problem here: (*also list LMX4 cream use here)

12. Phlebotomist's code number:

D. Blood Processing:

13. Time at which tubes 3 - 5 were centrifuged: : A.M / P.M.
h h : m m (Circle One)

14. Time at which tubes 1-2 were centrifuged: : A.M / P.M.
h h : m m (Circle One)

15. Time at which aliquot tray 1 vials were placed in freezer: : A.M / P.M.
h h : m m (Circle One)

16. Blood Processor's code number:

17. Any blood processing incidents or problems? ☐¹ Yes ☐⁰ No **If yes, specify in Q18 and/or Q19**

18. Blood processing incidents: Document problems with the processing of specimens in this table. Place an "X" in box(es) corresponding to tubes in which the processing problem(s) occurred. If a problem other than those listed occurred, use Item 19.

	Tube Number				
	1	2	3	4	5
a. Broken tube	☐	☐	☐	☐	☐
b. Sample re-centrifuged	☐	☐	☐	☐	☐
c. Clotted	☐	☐	☐	☐	☐
d. Hemolyzed	☐	☐	☐	☐	☐
e. Lipemic	☐	☐	☐	☐	☐

19. Comments on blood processing:

Appendix 4. Shipping forms

SHIPPING FORMS INSTRUCTIONS

There are two types of shipping forms: (1) the face sheet and (2) the contents sheet. Both forms are included in every frozen shipment. The **original** Biospecimen Collection form from each participant is also sent with every frozen shipment; keep a copy of the Biospecimen Collection forms at the field center.

FACE SHEET

The FACE SHEET is a two part form. Part One, on the top of the page, is completed by the Field Center. Part Two, on the bottom of the page, is completed by the Central Laboratory. The original form is sent to the Central Laboratory with the specimen shipment, and a copy is filed at the Field Center.

The NAME AND ADDRESS of the SHIPPER (Field Center) and the RECIPIENT (central laboratory) is printed on each shipping form.

The date and time the SHIPMENT was PACKED AND SEALED is recorded.

The STARTING and ENDING DATE of the REPORTING PERIOD is recorded.

The TOTAL NUMBER OF SPECIMENS ENCLOSED in the shipping container is confirmed by the Field Center technician by counting specimen bags and the total number of specimens within them.

The NUMBER OF CONTENTS PAGES ATTACHED is recorded. This varies depending on the number of samples in the shipment.

Remarks (peculiarities) about the shipment are written in COMMENTS CONCERNING SHIPMENT CONTENTS.

The INITIALS OF THE PERSON COMPLETING PART ONE OF THE SHIPMENT FORM are recorded.

Part Two of the SHIPPING FORM is completed by the receiver (e.g. the Central Laboratory).

The date and time the SHIPMENT ARRIVED at the Central Agency is recorded.

COMMENTS on the CONDITION of the SHIPMENT upon ARRIVAL are recorded, such as "shipment totally thawed."

The INITIALS OF THE PERSON COMPLETING PART TWO OF THE SHIPMENT form are recorded.

CONTENTS SHEET

The contents sheet lists the complete inventory of tubes in a given shipment. The original form is sent to the Central Laboratory with the specimen shipment, and a copy is filed at the Field Center. More than one contents sheet may be used in each shipment, depending on the

number of specimens enclosed. The number of pages attached and each page number are filled in at the top of the contents page (e.g. "page 1 of 5"). This form is filled out at the Field Center as the specimens are collected and stored. This form must be checked against the specimens when packed for shipment.

The SPECIMEN ID number is entered in the left hand column of the contents sheet. This is most easily done by attaching one of the adhesive specimen ID number labels in the space provided. This is done at the time of collection. It is suggested that a second person check these IDs against the IDs on the vials to correct any errors.

The tubes comprising a complete sample are listed in the upper left hand corner of the sheet. Under the category SPECIMEN COMPLETE?, YES or NO is marked for each participant to indicate whether the correct number of tubes has been shipped. If there is some deviation from the correct count, "NO" is marked, and a description of the problem follows in the column headed MISSING VIALS. The number of missing tubes and the color of their caps is recorded here.

COMMENTS on the quality of the specimens upon receipt are recorded at the agency receiving the specimens. These are optional, but are Participant ID number specific, such as tube broken, thawed, etc.

Face Sheet
SOL Youth SHIPPING FORM
PART ONE (To be completed at Field Center)

TO: SOL Youth Central Laboratory
University of Minnesota Advanced Research and Diagnostic Laboratory
Room L275 Mayo Memorial Building
420 Delaware Street S.E.
Minneapolis, MN 55455

FROM: Name and address of Field Center printed here.

SHIPMENT PACKED AND SEALED:

TIME: __ : __ AM
PM DATE: __ / __ / __.

REPORTING PERIOD: STARTING DATE: __ / __ / __

ENDING DATE: __ / __ / __

TOTAL NUMBER OF SPECIMENS ENCLOSED: _____

NUMBER OF CONTENTS PAGES ATTACHED: _____

COMMENTS CONCERNING SHIPMENT CONTENTS:

INITIALS OF PERSON PACKING AND COMPLETING SHIPPING FORMS: __ __

PART TWO (To be completed at Central Laboratory)

SHIPMENT ARRIVED AT CENTRAL LABORATORY:

TIME: __ : __ AM
PM DATE: __ / __ / __.

COMMENTS ON CONDITION OF SHIPMENT ON ARRIVAL:

INITIALS OF PERSON UNPACKING SPECIMENS: __ __

Frozen Contents Sheet

SOL YOUTH SHIPPING FORM

Page ____ of ____

SOL Youth Central Laboratory
University of Minnesota Advanced Research and Diagnostic Laboratory
Room L275 Mayo Memorial Building
420 Delaware Street S.E.
Minneapolis, MN 55455

Complete frozen sample for each participant includes 6 bags containing:

4-blue top microvials	8-red top microvials
8-purple top microvials	1- 5 mL clear top (EDTA whole blood)
1-5 mL blue top (packed cells)	2- (1) 0.250 mL red top and (1) 0.250 mL purple top

SPECIMEN ID	SAMPLE COMPLETE?		MISSING VIALS		COMMENTS
	YES	NO	#	COLOR	

[Place Lab ID
label here]

[illegible]

Appendix 6. SOL Youth Quality Control Phantom Participant ID Form



SOL Youth Phantom Form

PHANTOM ID NUMBER:								

Contact
Occasion:

01	SEQ #	00

FORM CODE: PHT
VERSION: A 8/19/2011

Instructions: This form should be completed during participants' visit. Affix the PHANTOM SOL-Youth ID label above. Affix the matching PARTICIPANT SOL-Youth ID labels for the corresponding QC blood sample below. Note: Lab IDs will be linked through the corresponding Laboratory Collection form for each Participant ID, including the Phantom ID.

1. Date phantom ID assigned:

 /

 /

M M D D Y Y Y Y

1a. LAB ID#: **Affix Spec.Label**

2. Code number of person assigning phantom ID:.....

PROCEDURE	MATCHING PARTICIPANT ID#	DATE COLLECTED (MM / DD / YYYY)	TECHNICIAN ID
Blood Samples			
1. Tubes 1 & 2 - 5 mL red-stoppered (serum)			
2. Tube 3 - 4.5 mL blue-stoppered (Citrate)			
3. Tubes 4 & 5 - 5 mL lavender-stoppered (EDTA)			

Appendix 7. Venipuncture and Processing Procedures Certification Checklist

VENIPUNCTURE	Satisfactory/ Unsatisfactory	Comments
1. Labels checked	_____	_____
2. Participant prepared and procedure explained	_____	_____
3. Venipuncture Form completed.	_____	_____
4. Tourniquet application and release	_____	_____
5. Venipuncture technique	_____	_____
6. Tube collection sequence	_____	_____
7. Inversion technique	_____	_____
8. Tube incubation location	_____	_____
9. Stasis obtained	_____	_____
10. Needle disposal	_____	_____
PROCESSING		
1. Knowledge of centrifuge operation	_____	_____
2. Aliquotting supply set-up	_____	_____
3. Stage 1 tube spin	_____	_____
4. Stage 2 aliquotting	_____	_____
5. Stage 3 tube spin and processing	_____	_____
6. Vials sealed	_____	_____
7. Freezer organization	_____	_____
8. Time constraints	_____	_____
9. Disposal of contaminated supplies	_____	_____
PACKAGING AND SHIPPING		
1. Specimens bagged	_____	_____
2. Adequate dry ice used in frozen shipping	_____	_____
3. Refrigerated shipping properly packaged shipping	_____	_____
4. Shipping paperwork	_____	_____
MISCELLANEOUS		
1. Quality Control temps and documentation	_____	_____
2. Phantom QC Procedure	_____	_____
3. Containers correctly labeled for shipping	_____	_____

Appendix 8. Sample Exams for Certification

PRACTICAL EXAM FOR SOL YOUTH BLOOD DRAWING TECHNICIAN

1. Place the following blood collection tubes in the correct set-up order and location for the venipuncture: 2-5 mL red top, 1-4.5 mL blue top, and 2-5 mL lavender top tubes.
2. Specify which tube(s) remain at room temperature after collection, and which are put into a cup with ice slush.
3. Remove the appropriate tubes from the tray and place them in the centrifuge in balanced positions. How long do they spin? At what speed?
4. Set up a sponge tray with the appropriate number and order of specimen storage tubes. Indicate the colors of screw caps and the types of specimen put into these tubes.
5. Place the collection tubes in front of their respective sample tubes. Describe what further processing is required of each collection tube before it is aliquotted into its respective sample tube.
6. Organize the color-capped sample tubes and prepare them for shipment.
7. Describe the quality control for each piece of equipment.

WRITTEN EXAM FOR SOL YOUTH BIOSPECIMEN COLLECTION AND PROCESSING TECHNICIAN

Name: (please print) _____ Field Center: _____ DATE: _____

1. When handling biological specimens, which of the following protective apparel must **ALWAYS** be worn?
 - a) gloves
 - b) sterile shoe covers
 - c) sterile head covers
 - d) lab coat and gloves
2. For the first six months of the study, how many HCHS-Youth participants at each field center will be asked to donate additional blood specimens collected to be used as part of the phantom duplicate?
 - a) Six per month
 - b) Six per week
 - c) Everyone
 - d) Eight per week
3. From which tubes are the packed cells used?
 - a) #1 and #2
 - b) #4 and #5
 - c) #3
 - d) none of the above
4. How long should tubes #1 and #2 sit at room temperature before centrifugation?
 - a) 5 minutes
 - b) 30 minutes
 - c) 2 hours
 - d) No waiting time required
5. Why is this step (un)necessary? _____
6. For what type of tests will the 4.5-mL blue-stoppered tubes be used?
 - a) Chemistry
 - b) Lipid
 - c) Coagulation
 - d) DNA testing
7. Which of the following labels must be affixed to the outside of a frozen shipping box?
 - a) biohazardous specimens
 - b) dry ice
 - c) Category B UN3373
 - d) dry ice and Category B UN3373
8. What is the minimum amount of dry ice that must be used for frozen shipments?
 - a) 2 lbs
 - b) 5 lbs
 - c) 10 lbs
 - d) 12 lbs

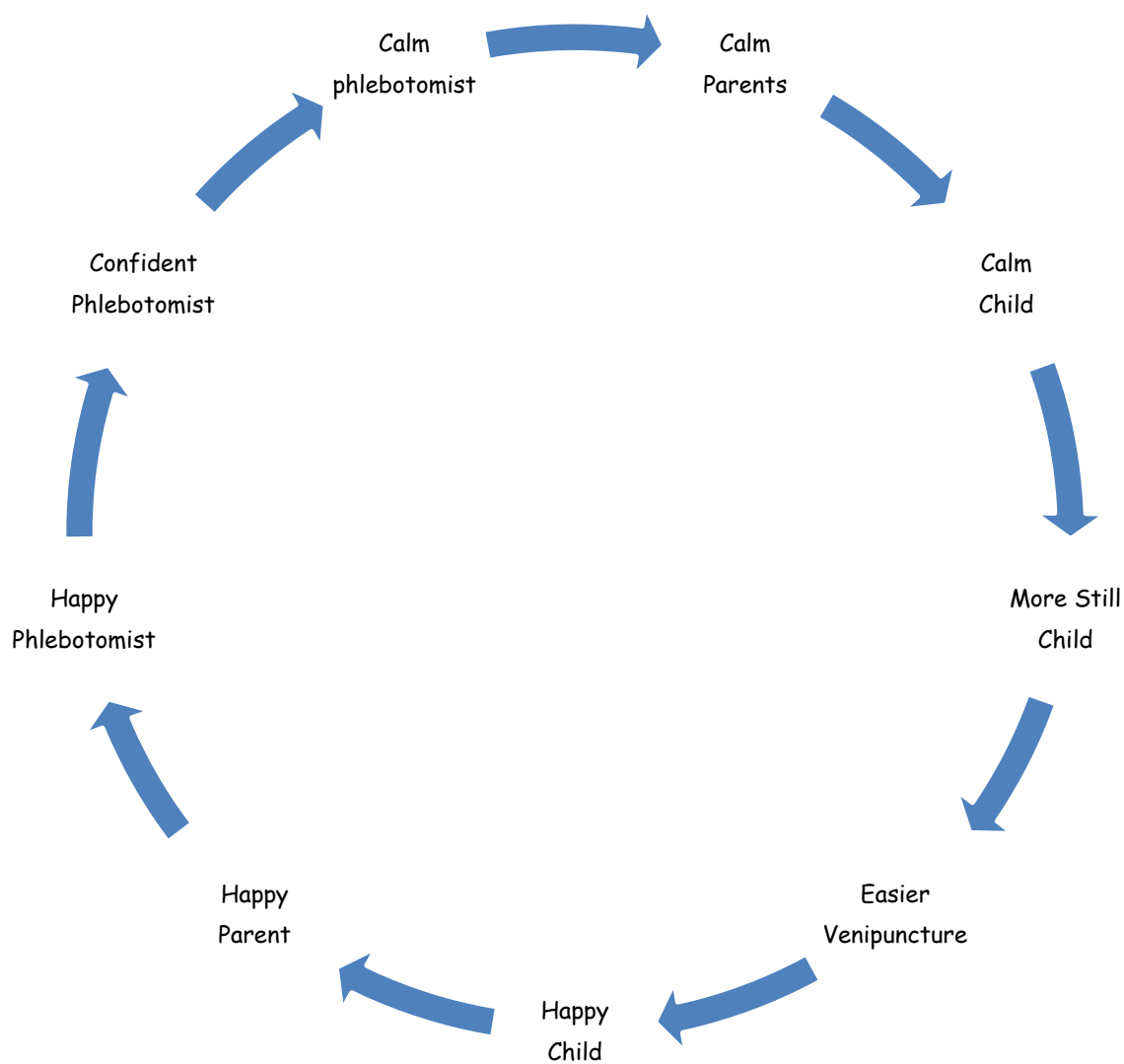
9. When transferring plasma to the microvials, how much plasma is left above the cells in the tubes?
- a) $\frac{1}{4}$ - $\frac{1}{2}$ inch
 - b) $\frac{1}{2}$ - $\frac{3}{4}$ inch
 - c) $\frac{3}{4}$ - 1 inch
 - d) none, all the plasma is removed
10. In what manner is the buffy coat from tubes #4 and #5 initially pipetted?
- a) Using slow aspiration avoiding plasma and red cells.
 - b) Using slow aspiration and include the remaining plasma and some red cells.
 - c) Using quick aspiration avoiding plasma and red cells.
 - d) Using quick aspiration and include the remaining plasma and some red cells.
11. What paperwork is completed and sent with each weekly frozen shipment?
- a) Copy of the Biospecimen Collection form
 - b) Original of the Biospecimen Collection form
 - c) Shipping Form Contents Sheet(s)
 - d) Original Shipping Form Face Sheet, Original Contents Sheet(s), and Original of all Biospecimen Collection forms
12. The LMX4 anesthetic cream needs to be applied 30-45 minutes prior to the blood collection to adequately numb the skin?
- a) True
 - b) False
13. The inner Styrofoam shipper needs to be taped shut?
- a) True
 - b) False
14. During the phlebotomy procedure it is important to always maintain a soft, quiet voice with the child?
- a) True
 - b) False
15. What choice below includes positive reinforcement techniques for a "happy child" following the phlebotomy procedure?
- a) Use general positives such as "good girl" or "good boy"
 - b) Positive reinforcement is not needed after the phlebotomy procedure
 - c) Say specific positive things that the child did; holding still, being brave
 - d) None of the above

Appendix 9. Pediatric Phlebotomy Techniques

Pediatric Phlebotomy Techniques:

Information provided by Jina Forys, MT ASCP, Pediatric Supervisor, Acute Care Lab, University of MN Medical Center- Fairview; Minneapolis, MN

Follow the Circle of Calm & Happiness



Calm Phlebotomist

Know Participant Background:

- 1) Each child has a variation of experiences that contribute to how they will handle this draw
- 2) Consider age, patient's reaction, parent reaction
- 3) Ask parent about previous draws and tips on what helps this participant best: "Has your child had a blood draw before?" "Is there anything specific that would help to make this easier?"
- 4) First time experience? Introduce new ideas to participant/parents: "Would you like me to explain what I am doing?"
- 5) PREPARE a plan of action for this unique child

Preparation=Confidence:

- 1) #1 Rule: Be confident that you can assess the situation and look for a vein
- 2) The more time you spend preparing out of the child's view, the less time they have to get anxious
- 3) Get equipment ready outside of the participant's view (needles, tubes)
- 4) Know your minimum volumes (tube priority if it is a difficult draw)
- 5) Wish for the best, plan for the worst- when you run into problems you will be glad you had everything ready to go

Extra Safety:

- 1) Pediatric guidelines suggest the first phlebotomist try twice, the second once, then contact the nurse or physician for further instructions

Calm Parent/Child

Phlebotomist Rapport:

- 1) A child left to their own thoughts can easily become scared and anxious
- 2) Your attitude can decrease stress
- 3) Introduce yourself: "My name is Jina, and I will be checking your blood today."
- 4) Ask questions about their day or things that they may have with them
- 5) Both participant and parent may see you as a real person and feel more comfortable
- 6) Parents appreciate common courtesy
- 7) Simple manners and a friendly tone can ease a parent's worry: "Thank you for coming to the lab today."

One Voice:

- 1) Be aware of lab environment; too many people talking at the same time can be over-stimulating, confusing, and lead to high anxiety for the child.
- 2) As the phlebotomist you can: If you notice the parent is talking to the child during the draw, be quiet to let the parent provide comfort.
- 3) As the phlebotomist you can: Allow the participant to engage in distraction activity without interrupting.
- 4) As the phlebotomist you can: Be aware that when a child's voice gets louder, adults often talk louder too. Always maintain a soft, quiet voice with the child.

Explanations:

- 1) Children can have misconceptions or fears about what is going to happen
- 2) Quite a bit of detail may be necessary
- 3) Do NOT tell children things that you don't know such as "this won't hurt" or "this is the last time"
- 4) If a child asks if it will hurt, be honest and say "some people think it feels like a bug bite or a little pinch"

- 5) Sometimes it may be necessary to give just as much explanation to parents as young children

Show Comfort and Concern for the Participant:

- 1) Wrap tourniquet over their sleeve so it doesn't pinch their arm (explain you do not want to hurt them)
- 2) Kindly ask to move things in your way
- 3) Let the child know it is okay to cry; sometimes it is reassuring to know that pokes are not fun for anyone. Crying is a coping strategy: "I know this is hard. You are doing great." Do NOT say "I'm almost done."

Choices:

- 1) Children need choices to be comfortable; provides a sense of control
- 2) Giving the child choices can decrease anxiety
- 3) Which arm can I look at first?
- 4) Would you like me to count to three before the poke?
- 5) What kind of bandage would you like?
- 6) Would you like to watch the blood draw or look away?
- 7) Some children may take advantage of choices and continually change their mind as a way to delay a poke
- 8) If the child cannot make a choice, or uses choices to stall, be confident to move forward with the procedure: "I'm going to look at your arm now."
- 9) Limit options, as too many could be overwhelming: "Would you like to look at an eye spy book? Or a light wand?"
- 10) Do NOT give the child options that they don't have: "Can I poke you now?"

Distraction:

- 1) Offer tools for participants and/or parents when appropriate: "It may help to have something fun to look at while I check your blood. Or it may help to count to 10."
- 2) Books, TV, stuffed animals, questions about their day
- 3) Ask parent to be a part of the distraction (reading a book, etc)
- 4) Giving jobs to take their mind off of the poke: Holding the gauze, counting or singing while the tubes fill, concentrating on staying very still

Comfort Positioning:

- 1) A child is going to be most trusting and comfortable with a parent or other comfort person/caregiver
- 2) Ask parent about their level of comfort in participation: "Are you comfortable holding your child's arm still?"
- 3) Give parent clear instructions on their role
- 4) Gives a parent a positive way to support their child
- 5) Having this person help hold the child can be beneficial in certain cases
- 6) Using comfort holds the child may be more relaxed and resist less, making the collection easier
- 7) You may still need another staff member to help stabilize the child
- 8) Seated positions are less scary than lying positions: promotes sense of control

Still Child: Role of Holder

- 1) Antecubital draw: one hand at wrist and one at elbow to minimize twisting
- 2) Hand draw: one hand at forearm and one holding fingers in fist

- 3) Holding too tightly can stop blood flow
- 4) While drawer is working holder can calm child
- 5) Never be afraid to ask for extra help from other medical staff or parents to hold child
- 6) Two or three people in a room are usually enough. Too many people can be scary!

Extra Measures for Comfort:

- 1) LMX4 anesthetic cream
- 2) Numbs the surface of the skin
- 3) Cream must be placed over the site for 30-45 minutes prior to phlebotomy (longer=better)
- 4) Takes away the initial sting of poke

Happy Child

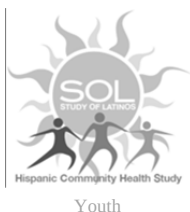
Reinforcement after the blood collection:

- 1) Trying to rebuild trust after the poke can be beneficial for the next time
- 2) Say specific positive things that the child did: holding still, being brave
- 3) Do NOT use general positives such as "good girl" or "good boy"
- 4) Small treasures or stickers can also reinforce the experience
- 5) Leaving them with a positive attitude may bring them back with one at a later time

Appendix 10. Aliquot Tray (sponge rack) Cleaning Procedure

NOTE: Wear safety glasses and gloves for this procedure.

1. Perform this procedure weekly or sooner if there is noticeable contamination.
2. Make a solution of 10% bleach by adding 1 part of household bleach to 9 parts of tap water in a bucket. Make this fresh each week.
3. Submerge the racks in the bleach solution and squeeze in and out 5 times.
4. Rinse under running tap water. Squeeze the racks under running tap water 10-20 times.
5. Squeeze out any remaining liquid and air dry overnight.



Appendix 11. Partial Biospecimen Collection Procedure

Participant Sample Set

1. If a full set of biospecimen collection tubes cannot be obtained after 2-3 attempts, determine if the SOL Youth participant is willing to return for a (fasting) re-collection appointment. Insert a comment on item #11 of the Biospecimen Collection Form that the participant will be coming back for a re-collection at another date. If the participant is unwilling to come back for a re-collection then state on item #11 of the Biospecimen Collection Form that the biospecimen set on this participant is a partial collection and no other specimens will be obtained and proceed to shipping.
2. If the participant is scheduled for a re-collection appointment, process all of the collection tubes that were obtained as directed in the Biospecimen Collection and Processing Manual and save them in a designated location in the freezer. DO NOT send the incomplete frozen biospecimen set to the Central Laboratory if the participant is coming back for a re-collection appointment.
3. Assign a new Lab ID to the SOL Youth participant for the re-collection appointment. Attempt to re-collect the entire sequence of biospecimen collection tubes.
4. Choose the most complete biospecimen set; either the biospecimen set that was obtained at the first visit or the biospecimen set that was obtained at the re-collection appointment. DO NOT combine biospecimens from both sets to make a full set.
5. If the biospecimen set from the first visit is the most complete, then send this set to the Central Laboratory and indicate on the Frozen Contents Sheet that this biospecimen set is incomplete and no other specimens will be obtained. Discard the other incomplete biospecimen set from the re-collection appointment. For the Field Center records, save the Biospecimen Collection Form from the re-collection appointment but insert a comment on item #11 that the biospecimens were discarded and the biospecimens from the first visit were sent to the Central Laboratory.
6. If the biospecimen set from the re-collection appointment is the most complete, then ship this set to the Central Laboratory and send the new Biospecimen Collection Form to the laboratory. Insert a comment on item #11 of the Biospecimen Collection Form that this participant had a re-collection. The new Lab ID number will be entered in place of the old Lab ID number from the first incomplete visit into the field center's data management system. Discard the incomplete biospecimen set from the first visit. For the Field Center records, save the Biospecimen Collection Form from the first visit but insert a comment on item #11 that the participant was re-collected and assigned a new Lab ID number and the first set of biospecimens were discarded.
7. The time limit for re-collection appointments is one month. If the participant cannot be re-collected within one month, then send the first set of incomplete biospecimens to the Central Laboratory. Indicate on the Frozen Contents Sheet that this biospecimen set is incomplete and no other specimens will be obtained.
8. Once a set of frozen biospecimens from a SOL Youth participant is sent to the Central Laboratory, no other biospecimens from this participant can be sent on another date.

9. Contact the Central Laboratory if any unusual circumstances or questions arise with any biospecimen collections.

Phantom QC Sample Set

1. If a full Phantom QC sample set cannot be obtained, a partial Phantom QC sample set is acceptable. The following guidelines should be observed.
2. One of Tube #1 or Tube #2 must be completely (100%) full. A partially filled second tube is acceptable to provide as much serum as possible.
3. Tube #3 must be completely (100%) full in order to maintain the proper ratio of blood to liquid anticoagulant.
4. One of Tube #4 or Tube #5 must be completely (100%) full. A partially filled second tube is acceptable to provide as much plasma as possible.

Hispanic Community Children's Health Study of Latino Youth

SOL-Youth

Manual Diet and Supplement August 2012

Study website - <http://www.csc.unc.edu/hchs/>

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DIETARY INTAKE, SUPPLEMENTS, AND BOTANICALS ASSESSMENT

1 Introduction

This manual of procedures has been developed for the Hispanic Community Children's Health – Study of Latino Youth (SOL Youth). The manual of procedures was adapted from that developed for the Hispanic Community Health Study/Study of Latinos (HCHS/SOL) by the Nutrition Coordinating Center (NCC) at the University of Minnesota. NCC has been designated as the Nutrition Reading Center (NRC) for SOL-Youth and works in collaboration with the Collaborative Studies Coordinating Center (CSCC) at the University of North Carolina to direct overall dietary assessment activities for the field centers. The purpose of the manual is to describe the data collection and quality assurance procedures for the dietary and supplement intake assessment. It is essential that any person who is involved in the dietary and supplement data collection fully reads and understands this manual.

2 Dietary Data Collection Staff

At least two dietary interviewers are needed at each field center to collect the dietary and supplement intakes. A lead interviewer is designated to provide supervision to the dietary data collection team. The lead interviewer may also be a regular data collector or may not, depending upon local personnel arrangements. All must complete the training and certification program conducted by the NRC staff.

2.1 Characteristics and Responsibilities of the Lead Interviewer

The lead interviewer has training in dietetics, food science, human nutrition, or home economics. He/she ideally is fluent in both Spanish and English and has skills to anticipate or detect possible problems that may affect the overall dietary data quality. He/she is responsible for supervising the collection and management of the dietary data and conducts local quality assurance of the dietary recalls, reviewing each intake record for completeness, data entry decisions, and identifies and corrects errors. He/she ensures the correct flow of data collection in each visit, and contacts the NRC SOL-Youth coordinator as needed with questions about the Nutrition Data System for Research (NDSR) database or program. The lead interviewer at each field center is responsible for submitting NDSR-back up files (electronic copies of the dietary intake records) to the NRC on a weekly basis.

2.2 Characteristics and Responsibilities of the Dietary Interviewers

The dietary interviewers at all field centers should be bilingual (in written and spoken Spanish and English). He/she has knowledge of the different names of the Hispanic foods and preparations in the Latin American countries represented in the SOL-Youth. Dietary interviewers are responsible for conducting the dietary and supplement recalls according to the SOL-Youth dietary and supplement data collection protocols. They welcome the participant and have all materials ready for each interview. It is essential that the interviewer is comfortable with the NDSR software, and able to locate foods within the system with ease. On a regular basis, they review the Hispanic Foods Glossary and are aware of the language translations, because the same food may be referred to using different words. Dietary interviewers review the information collected immediately after finishing each dietary recall. They will also print the Record Properties Report, Foods Report, and Dietary Supplements Report for future reference.

3 NDSR Training and Certification

3.1 Overview of Training Program

All individuals involved in the dietary collection are required to be trained and certified by the NRC prior to using NDSR dietary data collection software to collect dietary and supplement recalls. Training includes: use of the NDSR software, conducting the research interview, protocol for dealing with Hispanic foods and use of the SOL-Youth glossary, data review and documentation, data back-up, record management, and quality-control procedures. Interviewers trained for the HCHS/SOL study who have been collecting dietary data regularly, and who will be retained for the SOL-Youth study will not require face-to-face training on NDSR procedures but will participate in a training webinar/conference call with NRC staff to review protocols particular to SOL-Youth..

3.2 Certification Requirements

All dietary interviewers must be certified by the NRC prior to collecting dietary data from participants. The certification process evaluates the trainee in the following areas: ability to conduct the dietary and supplements recalls according to set standards, ability to use the software appropriately and to locate hard-to-find foods, identify and enter missing foods and supplements, use notes appropriately, probe for details of ingredients added to foods, and handle difficult data entry problems such as a food with two different amount units or two different added fats. Certification of the dietary interviewers includes practice data collection for a minimum of ten study-appropriate participants, with review by the NRC SOL-Youth coordinator in-person or by telephone. All dietary interviewers need to complete the following requirements:

3.2.1 Attend a NCC-Sponsored NDSR Training Workshop. Initial centralized training will be organized with the Coordinating Center and the NRC. Subsequent trainings are provided at the University of Minnesota as needed. All dietary interviewers who did not attend central training must be trained by personnel from the NRC.

3.2.2 Conduct a Baseline Recall with the NRC SOL-Youth Coordinator. The baseline recall provides an opportunity as part of the training to receive individualized instructions for using NDSR: navigating the software and database and conducting the research interview. The baseline recall may be conducted in-person on the last day of training or by the telephone following the training. The NRC trainer observes this interview and provides immediate feedback.

3.2.3 Conduct at Least Ten Practice Recalls. Dietary interviewers complete at least ten practice recalls with volunteer Hispanic participants who are similar to potential participants in the study. This provides an opportunity for practice using the NDSR software to conduct dietary and supplement interviews and related data management activities. Backup files of the practice NDSR projects are sent to NRC for review and feedback. At least five practice interviews should be conducted in Spanish and five in English. At least one of the practice interviews must be completed in Spanish with the NRC SOL-Youth coordinator.

3.2.4 Conduct a Final Recall with an NRC Trainer. The final recall allows the dietary interviewers to demonstrate the skills mastered and provides yet another opportunity to ask questions about the software, database, and other issues encountered to date. The final recall is

conducted in Spanish and/or English by telephone. The NRC trainer and the NRC SOL-Youth coordinator participate in the final recall.

3.3 Continuing Education

After completing the certification, dietary interviewers must continue to practice using the NDSR program to feel comfortable conducting the actual interviews.

3.4 Daily Usage of the NDSR Program

Daily usage of the NDSR program is highly encouraged to maintain NDSR skills learned during the training and certification process. Prior to study start-up, dietary interviewers (including the lead interviewers) will use the NDSR program to conduct at least one practice interview each day they work at the field center for the SOL-Youth. Backup files of practice recalls are sent to the NRC SOL-Youth coordinator every week until the SOL-Youth data collection starts. The SOL-Youth coordinator reviews and provides feedback as needed. This regular use of the software maintains familiarity with the software in case of prolonged time between training and examination of the first participants.

3.4.1 Monthly Updates from NRC. Regular written communications from NRC are distributed by email to each field center throughout the study, with information on data collection and management, common data-entry problems, and updates for new foods and dietary supplements not currently found in NDSR.

3.4.2 Dietary Inquiries. Field centers are contacted on a regular basis regarding questionable items noted during the NRC quality-control review. The queries address immediate questions and alert the dietary interviewers to the type of issues that are questioned and require confirmation and documentation on the NDSR dietary intake record.

3.4.3 Visits to the Field Centers. During the first year of data collection, the Nutrition Reading Center staff visit each field center to provide an opportunity to observe the dietary and supplement data collection and answer questions from local field center staff. Dietary interviewers are encouraged to review the Manual of Procedures throughout the project period to remain knowledgeable concerning dietary- and supplement-specific protocols.

4 Space, Hardware, NDSR Software and Materials

Each field center is responsible for providing the dietary interviewers with a location that is free from distractions and that includes the tools necessary to complete the dietary and supplement assessments for the SOL-Youth. Requirements include adequate computers, telephones, and secure storage for participant files and materials related to the dietary interviews. A participant file with information relevant to the dietary assessment must be available to the dietary interviewer until after the completion of the telephone recall. Access to a photocopy machine and printer is necessary for routine data collection activities.

4.1 NDSR Software

Copies of the NDSR are provided by NCC. Each field center has at least two copies of the software with use limited to SOL-Youth. Copies of NDSR are returned to NCC at the completion of the study. The Coordinating Center receives one copy of the software to be

retained throughout the study. Updates of NDSR are provided with each new release of the software, which occurs annually.

4.2 Computers

At least two computers are available for the dietary data collection at each field center. Portable storage devices or network backup systems should be in place to ensure that copies of the dietary and supplement recall interviews are protected from loss.

4.3 Computer Printers

At least one printer should be available at each field center. At the end of each dietary and supplement recall, the dietary interviewer prints NDSR reports that are used for local quality assurance and that serve as a secondary backup of the dietary and supplement recall.

4.4 Headset for the Telephone Interview

Each dietary interviewer should have his/her own headset for use in conducting the telephone dietary and supplement recall.

4.5 Calendar

A calendar should be available for each dietary interviewer. This can be used at the beginning of each dietary interview to assist the participant in recalling yesterday's dietary intake and in looking at the month ahead when completing the Telephone Recall Availability form.

4.6 Amount Estimation Tools

NRC provides each field center with two sets of amount estimation tools which are used during the in-person interview. Included in this set are an assortment of household cups, glasses, spoons, bowls, a ruler, replicas of select foods (Nasco models), and a laminated copy of the Food Amounts Booklet. Accurate quantification of foods and beverages is essential for obtaining useful dietary data. Some participants are much more adept than others in accurately estimating amounts of foods and beverages. To promote participant understanding of how to use the amount estimation tools, the dietary interviewers describe the use of each amount estimation tool at the clinic visit before proceeding to collect the 24-hour recall. No other food models or measuring devices are used for SOL-Youth dietary and supplement recalls. If one or more of the food models are damaged throughout the study, the lead interviewer contacts the NRC for replacement.

4.7 Food Amounts Booklet

NRC provides each field center with copies of the Food Amounts Booklet for distribution to each participant for use in the telephone recall. During the in-person interview, orientation to the Food Amounts Booklet occurs in conjunction with other amount estimation tools to help the participant understand how to recall and estimate the quantities of foods consumed. At the end of the in-person interview, the dietary interviewer provides a Food Amounts Booklet to each participant with a reminder to keep it until the telephone recall has been completed.

4.8 Dietary Recall Forms

Dietary recall forms have been developed to assist the dietary interviewers in the data-collection process. The Dietary and Supplement Recall Checklist (**Appendix 1**) documents each step in the process of dietary data collection and local quality assurance. The Telephone Recall Availability

Form (**Appendix 2**) and the Telephone Contact Log (**Appendix 3**) are used to facilitate contacting the participant to conduct the telephone recall.

SOL-Youth Dietary and Supplement Recall Checklist: The Dietary and Supplement Recall Checklist is initiated with each dietary recall and serves to document each step of local quality control. (One per dietary and supplement recall collected).

Telephone Recall Availability Form: At the end of each dietary recall a Telephone Recall Availability form is completed for each participant listing several possible days and times to receive the telephone recall. The participant must identify several best days and times since the telephone recall is unannounced. Instructions for completing this form are provided in Spanish and English.

Telephone Contact Log: A telephone contact log is kept for each participant to record all attempts to contact him/her. Detailed notes should be made about special situations including difficult-to-reach participants. If the dietary interviewer is not able to collect the telephone recall in the designated time window, the Telephone Contact Log serves as a record of his/her attempts.

5 General Guidelines for Working with SOL-Youth Participants

Since the SOL-Youth involves Hispanic participants with heritages from different Latin American countries, dietary interviewers need to be familiar with the traditions and dietary practices of the local Hispanic community and aware of the different names of foods, and plates in the different countries. Dietary interviewers should be enthusiastic about their job and have the ability to motivate the participant throughout the dietary interview, being sensitive to the overall length of the visit at the field center and the importance of the contribution from each participant.

5.1 Establishing Rapport

Because each participant is the primary respondent for the dietary and supplement recall, it is important for the dietary interviewer to be able to motivate him/her to provide complete and accurate information. He/she must always remain neutral and not let anything in words or manner express criticism, surprise, approval, or disapproval related to the participant's responses during the recall interview. Dietary interviewers should be sensitive by adapting a style and approach to make the participant comfortable. Every effort should be made to keep the dietary and supplement data collection as objective and non-judgmental as possible. He/she should avoid congratulating participants for eating certain foods or reacting with dismay to reports of other foods. The dietary interviewer should stress that he/she wants to know what the participant really ate and took as supplements and that honesty is appreciated. He/she should look for both verbal and non-verbal responses, be a good listener, and thank the participant for the information provided.

5.2 Privacy and Confidentiality

The dietary interviewer gains trust by assuring, before the recall begins, that everything the participant says is all right, and that there are no correct or wrong answers. Dietary intakes will not be discussed with other participants. Any necessary discussion between the dietary and lead interviewers about a specific dietary and supplement recall should be conducted in private and

not in the presence of others. Furthermore, the participant's personal information, such as contact information, is kept in folders in a secure location at the field center.

6 Field Center Procedures and Standardization of the Recalls

Dietary data collection takes place at each of the four sites across the U.S. (Bronx, Chicago, Miami, and San Diego). The first dietary recall is conducted in person at the field center, and the second interview is conducted over the telephone. Interviews may be conducted in Spanish and/or English at the discretion of the participant. It is essential to conduct the interviews in a space that is quiet and free from distractions. Dietary interviewers at all field centers follow the procedures provided by this manual, including the use of the food models, prompts and scripts to promote standardization and accuracy of the dietary and supplement data at all field centers.

6.1 The Visit 1 Dietary and Supplement Recall Interview

The Visit 1, in-person interview takes place at each field center. The dietary data collection includes both the dietary and supplement recalls. The combined interview may last approximately 45 minutes. The dietary interviewer conducts the interview using direct data entry into NDSR software, and refers to the amount estimation tools to aid in quantifying amounts of foods and beverages. Due to the need to fast prior to the clinic visit, the interval covered by the in-person dietary interview is that 24-hour period preceding 10:00 pm of the night before the interview. At the end of the interview the dietary interviewer provides the participant with the Food Amounts Booklet and explains what to expect during the follow up telephone interview. The importance of their participation in the phone interview should be stressed. The interviewer then completes the Telephone Recall Availability form to identify available days and times for the second interview. The interviewer should get as much information as possible about the participant availability, as this will help to minimize the number of follow up calls that are needed before the participant is successfully reached.

6.2 The Visit 2 Dietary and Supplement Recall Interview

The second interview is collected at least five days and ideally within 45 days, following the initial examination interview, most typically by telephone. When 45 days have passed after the first recall, interviewers may continue calling the participant if needed. The collection of complete study data should take priority over the 45-day time line. Up to 10 calls can be made to try and reach the participant. These calls should be made at different times of the day and week, in order to maximize the chances of making contact. If after several attempts a participant can still not be contacted, interviewers should consult other staff members who may know the participant to develop another strategy. An unannounced second recall is preferred but a scheduled interview may need to be set up and this is acceptable. The type of interview (scheduled or unscheduled) should be recorded on the NDSR recall header.

The 24-hour interval covered by the second recall is the 24 hours preceding 12:00 midnight of the previous night. The telephone interview lasts approximately 20 to 35 minutes. The exact day of the week for the telephone recall is chosen by field center staff from available participant times, with an aim that the distribution of days across participants includes all days of the week possible given clinic schedules. The second recall is ideally collected over the phone, but if the participant comes back to the clinic to return the SOL-Youth equipment or to complete an unfinished exam and he/she agrees to complete the interview at that time, the interviewer may complete the recall in-person, provided that at least 5 days has passed since the last interview.

The type of interview conducted (telephone or in-person) should be recorded in the NDSR header, using the field for Site ID. The first interview will always be scheduled and in-person. For the in-person interview record 1, in-person. The second interview is usually unscheduled but may be scheduled for the convenience of the participant. For the second interview, record 2U, phone unscheduled, 1U, in-person unscheduled or 2S, phone scheduled, 1S, in-person scheduled. The 24-hour dietary recall should not be collected without the Food Amounts Booklet. If at the time of the call the participant no longer has the Food Amount Booklet, a replacement should be mailed to him/her and the telephone recall should be attempted a few days later.

6.3 Prior to Conducting the Dietary Interview

On the day of the interview, before the participant arrives for the dietary interview, the dietary interviewer completes the NDSR Header tab using information from the participant file. Yesterday's date is recorded on the Header tab as the date of intake. The interviewer checks the interview station to ensure that the amount estimation tools are appropriately organized, that all necessary forms are in place, and that a current calendar is available for use in the in-person dietary recall and in planning for the telephone recall. When the participant arrives, the dietary interviewer welcomes the participants to the dietary and supplement recall portion of the visit. He/she introduces himself/herself in a friendly but professional manner and gives basic information about the dietary and supplement interview to the participant and responds to any questions the participant may have.

6.4 Setting the Language

Before starting the interview, the dietary interviewer sets the language with the participant. This process facilitates the flow of the interview. The dietary interviewer must be aware that it may be necessary to change the language to either Spanish or English at any time depending on the specific foods or supplements reported by the participant. In the event the participant chooses to have the interview in Spanish, the dietary interviewer may ask him/her if he/she prefers to be addressed as "tú" or "usted."

6.5 Introduction of the Interview

The dietary interviewer explains the importance of collecting complete and accurate information and how the interview will be conducted. Because the participant arrives at the examination centers fasting since 10:00 pm the night before the interview, the dietary interviewer explains that the focus of the interview is to recall everything he/she has to eat or drink during the 24 hours preceding the last meal (from 10:00 pm two days before the interview until 10:00 pm the night before the interview). The interviewer explains that after the dietary recall, he/she will ask about the dietary supplements taken. Dietary interviewers reassure participants that all information they collect is private and confidential.

6.6 Demonstrating the Amount Estimation Tools

Briefly, the dietary interviewer demonstrates how to use the amount estimation tools, including the Food Amounts Booklet, which is used during the interview. The dietary interviewer shows the food models, measuring cups, spoons, grid, geometric shapes, and rulers, and explains that they can also be used to estimate fractions or multiple amounts such as half amounts or twice the amount. The dietary interviewer explains that many of the items he/she has shown can be used to describe the same amount and the participant can use whatever item best describes the amount eaten or drunk. The dietary interviewer also emphasizes that these items are not always needed

to estimate amounts as many foods can be easily quantified as 1 can (soda), 1 small apple, or 1 MacDonald's hamburger. The dietary interviewer should reassure the participant that they do not need to worry about this part of the interview as they will help to guide them when the computer program is ready for the information.

7 General Guidelines for Conducting the Dietary and Supplement Interview

Procedures for administering the dietary and supplement interview have been established to help ensure standardization across field centers and to facilitate gathering of the data. Many of these procedures are imbedded in the NDSR program and documented in the NDSR User Manual. SOL-Youth-specific procedures to ensure consistency of data collection among field centers are highlighted at the NDSR training workshop.

7.1 Using a Script

A standard script is used to introduce the dietary and supplement interview and to start the recall process. The dietary interviewer explains that the interview will last approximately 45 minutes and that all information he/she collects is confidential. The scripts provide consistency between dietary interviewers. The remainder of the dietary recall is guided by the NDSR on-line interview prompts which help to standardize the dietary interviewer questions.

7.2 Special Procedures for Interviewing Members of the Same Household

In situations where the dietary interviews are collected the same day for multiple participant children of the same household who may have consumed similar foods and beverages, the dietary interviewer collects information only from the participant he/she is interviewing. While a parent may be consulted for clarification of a specific child's intake, no dietary and supplement data are collected for one child from another child, nor should the intake of a child be modified based on another's report. Each dietary recall is a record of what the participant reported and for the most part should not be changed after the interview to reflect information in another dietary recall.

7.3 Guidelines for Probing

Probing is the technique used by the dietary interviewer to stimulate discussion and to obtain more information about foods, beverages, and supplements reported. He/she probes when a participant's response is not meaningful or is incomplete, i.e., when it does not adequately answer the question or provide the information required by NDSR. Probing can be used to gather information about additional meals and snacks as well as additions to reported foods. The quality of the interview depends a great deal on the interviewer's ability to probe meaningfully and successfully. Probing techniques are covered extensively in the training workshop.

7.3.1 Unconsumed Portions. The amount the participant actually consumed is what should be entered, not what he/she was served or cooked for the entire family. Double check to ensure that the amount reported is what was consumed. Asking "Were you able to finish that?" ¿Pudiste terminarte todo? or "Did you eat all of it?" ¿Comiste todo? help to identify the unconsumed portions.

7.3.2 Unusual Portions. If something sounds unusual, the dietary interviewer should question it and not blindly accept the initial response. Redirecting questions and presenting appropriate alternatives from the amount estimation tools permit the participant to restate his/her

initial response and allow the interviewer to verify, confirm, or correct an unusual portion. Confirmation of any unusual intake or portions should be documented using the NDSR Notes field by stating which amount estimation tool or picture in the Food Amounts Booklet was used. Specific information about confirming portions and documenting unusual portions is provided at the training workshop.

7.4 NDSR Food Search

The NDSR database is extensive, detailed and complex, with more than 18,000 foods and recipes, and it includes over 8,000 brand-name products. NDSR uses the food search text on information provided during the initial part of the interview when the participant first mentions the food. For example, if a participant reported “tacos” the food search results would include a number of items with “taco” in the name such as filled tacos, Taco Bell, taco meat, taco salad, taco sauce, and many others. The dietary interviewer selects the appropriate food from the available choices. If the NDSR food search cannot match the search text with a database food, NDSR returns a “no foods found” message suggesting that the dietary interviewer needs to check the spelling of the word, revise the search text, select “search all”, or select the hierarchy button and begin the food search at a general level.

7.4.1 Hispanic Foods. Many Hispanic foods are included in NDSR. Most of them are mixed dishes and have been included with their Spanish names and their description in English. To locate Hispanic mixed dishes in NDSR, the dietary interviewer may write the name of the dish either in Spanish or in English depending on the situation. For example, if a participant reports “arroz con pollo” the dietary interviewer types “arroz” and all mixed dishes that contain the text arroz appear on the Food Search window. In the event the dietary interviewer types “rice” he/she must select the option for “rice...” and in the next Food Search window an option for “Hispanic...” will appear. The dietary interviewer selects this option and he/she is able to choose “arroz con pollo.” NDSR 2011 includes over 300 Hispanic foods, and additional Hispanic foods will be added as needed during the study.

7.4.2 Missing Foods. The dietary interviewer uses the Missing Food window to describe food details and to specify amounts of a food not found in NDSR. The lead interviewer uses the NCC New Food Request Form (**Appendix 4**) to submit a missing commercial, packaged and any food other than prepared dishes to NRC for resolution. The form is available online at <http://www.ncc.umn.edu/services/newfoodrequestform.php>. The lead interviewer includes all possible information about the missing food including the client number for the SOL-Youth. NRC will resolve the missing food using the information provided in this form. For all mixed dishes (home- or restaurant-prepared dishes) not found in NDSR, the dietary interviewer collects as much information as possible from the participant regarding name of the dish or food, country of origin, ingredients, amount eaten, method of preparation, and others and uses the Missing Food window to include those details. After performing quality control tasks for the dietary recall, the lead interviewer submits the weekly project including recalls that contains missing foods (mixed dishes) through the FTP program. Each month NDSR backup files of User Recipe projects with new food resolution for commercial products and mixed dishes, and User Product projects with new dietary supplement products are posted on the ftp site to make them available for all field centers.

7.5 Dietary Supplement Search in NDSR

The dietary interviewer uses the Product Search window to locate and describe dietary supplements in NDSR. NDSR prompts help the dietary interviewer obtain the complete name of the product. The dietary interviewer types the name of the dietary supplement and selects it or enters it as a Missing Product.

7.5.1 Missing Dietary Supplements. The dietary interviewer uses the Missing Product Detail window to add ingredient information for products not found in the Dietary Supplement Assessment Module (DSAM) database. The dietary interviewer completes the fields with information provided from the product label. It is important to enter as much information as possible from the product label during the in-person interview because this is the only opportunity to positively identify the exact supplement taken. The dietary interviewer selects “Add Ingredients” to insert all the ingredients listed on the label of the container, including the amounts and units. If the product has a long list of ingredients, the dietary interviewer includes at least the first three ingredients. He/she must always write a note specifying if all the ingredients listed on the container were entered or if the complete list was not entered due to time or other constraints. After performing local quality control of the dietary and supplement interview, missing products are resolved at NRC. Periodically, backup NDSR User Product projects are provided to the field centers to facilitate the entry of supplement products missing from the database.

7.6 Use of the Amount Estimation Tools

Participants are allowed to freely select any items from the amount estimation tools. Assistance is provided as needed during each interview to make sure that usage is appropriate. Participants may select a cup, bowl, replica food model, or specific page in the Food Amounts Booklet to quantify a food. Interviewers may need to suggest alternative options if the participant needs assistance or specifies an amount option that is not reasonable for the specific food. Notes should be made to indicate how the amount was estimated in the NDSR Notes field.

7.6.1 Standard Measuring Cups: ¼ cup, ⅓ cup, ½ cup, 1 cup. These four cup sizes may be used to describe amounts of any liquid or non-liquid food, including mixed dishes that can be easily visualized in a cup (e.g., cooked vegetables, soup, rice, sauce, ice cream). The dietary interviewer asks the participant whether or not the container was filled to the top. If not, he/she asks what proportion of the cup was filled. For example, the participant might indicate that the amount eaten was about a half of the ¼ measuring cup. This would be entered into NDSR as ⅛ cup. Measuring cups may also be turned over for estimating the volume of mound shapes for some foods, e.g. mashed potatoes.

7.6.2 Standard Measuring Spoons: ⅛ TS, ¼ TS, ½ TS, 1 TS, ½ TB, 1 TB. When using the measuring spoons, express the amount in terms of level spoonfuls. The amount contained in a rounded spoonful can vary considerably depending on the consistency of the food and how the spoon was lifted or shaken. If the participant specifies a rounded spoonful, the dietary interviewer asks him or her to quantify the rounded part of the spoonful separately. For example, the participant says he/she sprinkled a tablespoon of powder sugar on his fruit. The dietary interviewer asks him if the tablespoon was about level. If he/she indicates that it was rounded or heaping tablespoon, the dietary interviewer asks the participant to estimate how much more than a level tablespoon this was. His answer might be an additional one-half of a level tablespoon. If the measuring spoon was not filled to the top, the interviewer asks the participant to estimate the

proportion that was filled or to use a smaller measuring spoon. Measuring spoons may also be turned over for measuring small mounds or “dollops” of foods such as sour cream.

7.6.3 Representative Household Eating Bowls. Bowls have been selected to correspond with the pictures of bowls in the Food Amounts Booklet including: ½-cup bowl (small) (marked at ⅛ cup, ¼ cup, and ⅜ cup); 1 ½-cup bowl (medium) (marked at ⅜ cup, ¾ cup, and 1 ¼ cup); 3-cup bowl (large) (marked at ¾ cup, 1 ½ cup, and 2 ¼ cup); and 8-cup bowl (extra large) (marked at 2 cups, 4 cups, and 6 cups). Bowls may be used for quantification of any food that was eaten in a bowl of similar size to one of the bowls available for amount estimation. The dietary interviewer asks the participant to carefully estimate how full the bowl was. If the amount was between two of the markings, the dietary interviewer estimates the amount appropriately. For example, if the amount was between the 1 cup marking and the 1 ½ cup marking, calculate the difference and enter 1 ¼ cups.

7.6.4 Representative Household Drinking Glasses and Mugs. Glasses and mugs/cups have been selected to correspond to the pictures of glasses in the Food Amounts Booklet including: 5 fluid ounce glass (marked at 1 ¼ FO, 2 ½ FO and 3 ¾ FO,); 10 fluid ounce glass (marked at 2 ½ FO, 5 FO, and 7 ½ FO); 12 fluid ounce glass (marked at 3 FO, 6 FO, and 9 FO); 32 fluid ounce glass (marked at 8 FO, 16 FO, and 24 FO); 11 fluid ounce mug (marked at 2 ½ FO, 5FO, and 7 ½ FO); and 8.5 fluid ounce wine glass (marked at 2 FO, 4FO, and 6 FO). The dietary interviewer asks the participant to estimate at what level the selected container was filled and how much of that amount was actually consumed. Then the dietary interviewer estimates the number of fluid ounces based on the markings. For example, if the participant indicates that the 12 fluid ounce glass was filled to about half way between the 9 and 12 FO markings, and that about half of this amount was consumed, the dietary interviewer enters 5 ¼ FO (half of 10 ½ FO). Three paper cups have been added for SOL-Youth to aid in quantifying beverages obtained at restaurants that are not included in the NDSR database. These include: 12 fluid ounce cup (marked at 3 FO, 6 FO, 9 FO and 12 FO), 16 fluid ounce cup (marked at 4 FO, 8 FO, 12 FO and 16 FO), and 20 fluid ounces (marked at 5FO, 10 FO, 15 FO, and 20 FO). A single 45 FO beverage cup has been provided to each field center with along with instructions to obtain 2-3 additional cups from local convenience stores/gas stations where these are commonly used for self-service beverages.

7.6.5 Geometric Shapes. Geometric shapes, circles (1 ¾”, 2”, 3”, 4”, and 5” diameters), wedges (4” radius x 4.2” arc, 4.5” radius x 4.7” arc, 5” radius x 3.9” arc, 6” radius x 4.7” arc, and 8”radius x 4.2” arc), and squares (1 ¾”, 2”, 3”, 4”, and 5” square) are not intended to represent any one food. They are to be used to estimate portion size for any food that may be accurately described by a specific geometric shape. NDSR allows entering many solid foods using geometric shapes. Examples of foods that may be entered by shape include cornbread, pizza, and meatballs.

7.6.6 Container of Loose Dried Beans. One pound of navy beans is provided in a bowl-shape plastic container with lid. The purpose of the container of dried beans is to estimate the amount eaten when a participant expresses the amount in one or more handfuls (e.g. peanuts, sunflowers seeds, dry cereals, or raisins). The dietary interviewer asks the participant to grab a handful of beans of about the same amount that he/she grabbed a handful of that particular food.

The beans are transferred from the hand of the participant to one of the measuring cups or spoons to estimate the approximate amount eaten.

7.6.7 Ruler. The ruler is used to estimate dimensions in inches or centimeters. For example, the ruler may be used to describe the length, width, and height of a piece of cornbread.

7.6.8 Nasco Food Models. Replica models of foods are used for foods that are difficult to quantify and to help the participants learn to estimate amounts for foods using the 2-dimensional Food Amounts Booklet. Each dietary interviewer has available a set of the following Nasco food models:

- 1 Bolillo (Mexican bread) 5 ½" x 3", 2 ¼ oz;
- 1 set of two beef enchiladas, 3 ¾ oz;
- 1 broiled hamburger, 3 oz;
- 1 brownie, 2" square;
- 1 yellow frosted cake, 2" x 2" x 1 ¾" ;
- 1 refried beans, ½ cup;
- 1 roast beef, 3 oz;
- 1 boneless, skinless chicken breast, 3 oz;
- 1 roasted spareribs, 2 ½ oz.
- 1 French fries, 1 medium order

7.6.9 Representative Dinner Plate. The dinner plate is used for displaying food models; it is not to be used for estimating amounts.

7.6.10 Bags of Rice. Three bags of rice are provided. These are not meant to represent rice or another specific food but to help realize the amounts that the pictures in the FAB represent. Two bags contain one cup of rice to use for comparison with Mound 1 in the FAB to help interviewers and participants realize the quantity of Mound 1 and both may be placed in the bowls to help realize the volume that those contain. The third bag contains the amount equal to Mound 3 and would be used in the same way.

7.7 Guidelines for Amount Probing

After introducing the SOL-Youth amount estimation tools, the dietary interviewer emphasizes that these tools are not always needed for estimating amounts, he/she gives examples of amounts that can be expressed using food-specific unit such as a "large" apple, a "thin slice" of tomato.

Interviewers should not specify to the participant a particular method to use to estimate the amount of food or beverage. First, he/she asks a completely open-ended question such as, "how much juice did you drink?" "¿Cuánto jugo tomó?" the dietary interviewer encourages the participant to express the amount in his/her own words. If the participant appears to be having difficulty answering the question, the dietary interviewer may then suggest that he/she try to visualize the juice container and compare the amount with one of the amount estimation tools. If the participant continues having difficulty expressing the amount, the dietary interviewer might mention one or more of the options listed on the NDSR "Amounts Screen." The choice of available food specific unit options varies depending on the specific food item.)

The dietary interviewer reminds the participant that he/she needs to know the amount actually eaten or drunk, not the total amount on the plate or in the glass, or the amount that was prepared for the entire family. When an amount is given by the participant, the dietary interviewer asks if he/she ate all or only a part of that amount.

When using measuring cups or the bowls or beverage containers with markings, dietary interviewers do not assume that the container was full. Always, ask “To what line?” or “¿Hasta qué línea?” before entering the amount information.

If the participant reports eating more than one of an item that could be different sizes, the dietary interviewer needs to remember to ask if they were the same size.

When a participant reports drinking a beverage that may have contained ice, the dietary interviewer needs to remember to ask if ice was included in the amount reported. When the beverage is with ice and this is an option in NDSR, the interviewer specifies the amount with ice and NDSR calculates the amount without ice. If an automatic calculation is not available in NDSR, the participant is asked to specify the amount of beverage without ice. If he/she is unable to do this, a note is entered for subsequent resolution at NRC using the NDSR Data Entry Rules.

For many foods, the food-specific units such as small, medium, and large are further described using dimensions. It is not necessary to probe further for dimensions once the participant has specified a size because the dimensions are meant to be guidelines and do not need to be exact. However, if participants ask what is meant by small, medium, or large, the dietary interviewer may share this information with them. He/she must ask if the participant ate the entire piece, if not, indicate the proportion of the small, medium, or large piece that was consumed.

8 Conducting the Interview Using the Multiple-Pass Approach

The NDSR program automatically guides the dietary and supplement interview through the standard passes for collecting the dietary data.

8.1 PASS 1: Using the NDSR Quick List

The Quick List is used to collect an outline of the previous day’s intake. It is designed to get participants to begin thinking about what and when they ate. Foods and beverages as reported by the participant are entered on the Quick List window along with the time eaten and meal name if provided by the participant at this time. If the participant does not volunteer the time of the meal or give a specific meal name during the Quick List, the dietary interviewer does not interrupt to ask for this information. NDSR will prompt for this information during the third pass.

8.2 PASS 2: Reviewing the Quick List

A review of the Quick List permits the dietary interviewer to obtain an overview of the day’s intake and to note if there are large gaps in time, missed meals or missing beverages, and to insert the additional meals, snacks and foods or beverages recalled during this pass.

8.3 PASS 3: Collecting Complete Meal, Food, and Amount Detail

Pass 3 helps the participant remember specific details about what they ate. Information about the time, name, and location of the meal are provided in the Meal Information window. The dietary interviewer completes descriptive details for foods and beverages obtained during the first pass.

At this point, the participant is asked about additions to foods and beverages entered on the Quick List. The dietary interviewer asks probing questions based on the information displayed in the NDSR window and utilizes the NDSR food search feature to locate foods, and to obtain complete details for food descriptions, preparation methods, and variable ingredients. After specifying the food, an open-ended question “How much did you eat (drink)?” “¿Cuánto comió ó (tomó)?” is asked to obtain the amount eaten. The participant may use any of the food amount estimation tools for the in-person interview, and he/she will be referred to the Food Amounts Booklet during the telephone interview, to describe the amount consumed. The dietary interviewer should allow the participant to freely select from the available amount estimation tools. If they have any difficulty or select an inappropriate item, they should be encouraged to use a more appropriate item for the food eaten. The dietary interviewer should always refer the participant to the ruler when the participant gives dimensions in inches or centimeters. After entering the amount specified by the participant, NDSR displays a conversion to a common unit. The dietary interviewer needs to be able to visualize the amount reported and subsequently confirm with the participant any questionable amounts by using the amount estimation tools (e.g., 1 fluid ounce of juice or 4 cups of ice cream). The NDSR Note field is used to enter information to confirm atypical amounts as well as other unusual information (e.g., no beverage with a meal or any condiments and/or bread for sandwiches).

8.4 PASS 4: Reviewing the Recall

The fourth and final pass of the NDSR multiple-pass approach occurs after entering all of the food detail. During this review, the dietary interviewer probes for missed meals, beverages, and snacks and any other information that may have been overlooked earlier. Edits are made as needed and notes are provided. Foods not found in NDSR are flagged as missing and complete details are collected from the participant and recorded on the NDSR Missing Food window. Information recorded includes detailed descriptions of what the food looks like as well as ingredients and the amount eaten.

8.5 Documentation Using NDSR Note Field

NDSR notes are used to clarify contradictory, questionable, or unusual food items or amounts, or to document cases where typical companion foods are not consumed. Notes serve as communication between the dietary interviewers and the NRC SOL-Youth coordinator. NDSR forces a note when the amount reported exceeds what has been established in the database as more than the usual amount consumed at one time; such amounts should be confirmed with the participant. Small amounts are also flagged to alert the interviewer to potential data entry errors. In this case, the amount is corrected or a meaningful note is added to explain how the very large or very small amount was determined. NDSR food notes should match the information in the data entry. For example, if the dietary interviewer enters 6 cups of ice cream, the note should describe how the participant determined that he/she ate 6 cups and the number 6 should be re-typed in the note field to ensure that a typographical error did not occur. Further probing might reveal that the ice cream was scooped into the bowl and consequently a reduction in the 6 cups to account for the air space between the scoops needs to be factored in. Redirecting the participant to the mounds or measuring cups might result in a more realistic amount for the ice cream. Important information to be included in notes might concern missing meals or beverages, reference to the specific amount estimation tools picture and size used to estimate unusually large or small portions, missing condiments, and modifications of foods such as a McDonald's cheeseburger, when only half of the bun was eaten. Notes that warrant the attention of the lead

interviewer and/or the quality assurance staff at the NRC should be identified as priority by selecting the Priority Note field on the Food tab or the Dietary Supplement tab. Notes allow the lead interviewer and the NRC to make appropriate changes to the recall to reflect what was actually eaten as well as confirming that the interviewer entered what the participant reported.

8.6 Consulting Parent to Clarify Child Intake

The SOL-Youth study has children 8-14 years of age as participants. [**Note:** Protocol revision for increasing the eligible age range from 8-14 to 8-16 years old for SOL Youth was unanimously approved by the HCHS/SOL Ancillary Study Subcommittee and HCHS/SOL Steering Committee on August 8, 2012. All subsequent reference to the eligible age range in the remainder of this MOP will indicate the approved protocol change to 8-16 years old.]

Available data indicate that children at these ages can reliably report what they ate the previous day. Nevertheless, for SOL-Youth the protocol allows that a parent may be consulted after the diet interview to clarify gaps in the child's report or further details on what was eaten.

Interviewers should complete the dietary interview without the parent present, and then determine if a parental consultation is required based on the completeness of the child's record. This may be particularly useful for the younger children. The basic data are what the child reports. The purpose of the parental consultation is to help complete the child record not to change it to be what the parent thinks is "more healthy."

8.7 Printing or Saving NDSR Reports

As soon as possible following the dietary interview, the Record Properties Report (**Appendix 5**), the Foods Report (**Appendix 6**), and the Dietary Supplements Report (**Appendix 7**) should be printed, attached to the Dietary and Supplement Recall Checklist and placed in the respective participant folders. Alternatively these reports may be saved as Pdf and archived electronically for future reference.

9 Instructions for Conducting the 24-Hour Dietary Recall

9.1 Entering Meal Time

In general, the approach to collecting the 24-hour dietary recall is to find out when people eat and what they eat, versus asking what they ate for specific meals. The NDSR program does require a time for each eating occasion. Exact eating times are not important. A general time frame may be given with approximate times. When participants are not able to provide the time of meals and snacks, dietary interviewers may use the following times for a general framework, using additional times as needed for other meals or snacks reported:

Morning Meal: 7 am

Noon Meal: 12 pm

Afternoon Meal: 5 pm

Evening Snack: 8 pm

9.2 Entering the Meal Name

NDSR meal names include Breakfast, Lunch, Dinner/Supper, Snack, School Lunch, and Other (Desayuno, Almuerzo, Cena, Merienda o Colación, Almuerzo en el Colegio, y Otros). If the meal name is not stated by the participant, the dietary interviewer may ask the participant the meal name saying: "Was this your (insert most obvious meal name)?" Or "What would you call

this meal? “¿Fue este/esta tu (insert most obvious meal name)?” or ¿Cómo llamarías a esta comida? A meal name may be repeated several times in the context of a 24-hour intake. For example, the participant may report snacks several times throughout the day. If the name of the meal is obvious to the dietary interviewer, it is not necessary to ask the participant this question. For example, the first meal of the day may be labeled as breakfast and between-meal items may be labeled as snacks without probing.

9.3 Entering the Meal Location

NDSR meal locations include Home, Work, Friend’s Home, School, Day Care, Restaurant/Cafeteria/Fast Food, Deli/Take-out/Store, Community Meal Program, Party/Reception/Sporting Event, and Other (Casa, Trabajo, Casa de un amigo, Escuela, Guardería, Restaurante/Cafetería/Comida Rápida, Deli/Para Llevar/Tienda, Programa de Alimentación Comunitaria, Fiesta/Recepción/Eventos Deportivos, y Otros). The meal location helps to determine which food variables to enter during the 24-hour dietary recall. For example, many foods in NDSR differentiate between home prepared and restaurant prepared foods. Collecting information on the source of the meal aids in the food description process. Meal name and locations also identify the source of the food.

9.4 Entering the Visit Number

Visit 1 is used for the in-person interview. Visit 2 is used for the second interview (in-person or telephone) interview.

9.5 Entering the Site ID

Site ID refers to the location for the diet and supplement interview. 1, in-person is used for the interview completed in-person. 2, phone is used for the interview completed by telephone. This field is also used to record the type of interview, scheduled (S) or unscheduled (U).

9.6 Minimize the Response Burden by Knowing When and How to Probe

It is important to be sensitive to responses of the participant in terms of the overall length of the interview and to be able to determine the level of information that the participant can reasonably provide. The following lists a number of ways in which the response burden can be minimized for the participant without compromising the overall quality of the dietary data.

9.6.1 Selecting NDSR Default Foods. As a general rule, the dietary interviewer should accept the participant’s level of detail or opinion about the foods and beverages eaten. When it becomes clear that the participant is unable to provide the level of detail that the NDSR requires, an NDSR unknown should be selected. For example, if the participant had a meat empanada from a restaurant, the percent of fat will be unknown. In the event that the child eats meals at home but does not know the level of detail about home-prepared foods, defaults should be selected during the interview. Following the interview, the parent may be consulted to provide information if they are at the field center for the in-person interview or available at home for the phone interview. Defaults selected for foods prepared at home should be flagged with a Priority Note to serve as a reminder to ask the parents. Priority Notes can be de-selected after obtaining the information.

9.6.2 Preparation Methods and Details. When participants would not be expected to be able to provide the answers to the NDSR prompts, especially regarding preparation methods or

other details as part of a restaurant meal, interviewers should select the “unknown” defaults provided in NDSR. For example, asking too many questions that cannot possibly be answered may lead the participant to respond inappropriately just to provide an answer to the question.

9.6.3 Unknown Brand Name Products and Fast Food Items. If a category of foods within the NDSR database includes a brand-name or fast food listing and the specific item reported is not available, it should be entered as NDSR missing food and submitted to NCC.

9.6.4 Entering Assembled Foods. While NDSR contains many default sandwiches, tacos, and similar assembled foods, it is important for the dietary interviewer to probe to find out if the participant can describe the item eaten in terms of the ingredients and the amounts of each ingredient. If the participant can report each component of the sandwich, it is entered using the NDSR Assembled Food feature, entering each ingredient and amount. If the sandwich or taco is reported to be from a national fast food restaurant chain, the corresponding NDSR entry is selected. Any modifications made to national fast food restaurant meals, such as not eating the bun for a McDonald’s hamburger or ordering a Subway sandwich with only ham and lettuce should be recorded in the Note field for later adjustment by the lead interviewer or the dietary interviewer.

9.6.5 Entering Tossed Salads, Mixed Dishes, Soups, and Similar Foods. If a participant reports a tossed salad, mixed dish, or soup, the dietary interviewer will select the closest database match, based on the description of the food. As a rule, amounts of the individual ingredients in these foods should not be entered. The dietary interviewer will have the participant estimate the total amount consumed and the NDSR standard recipe will determine the amounts of the individual ingredients. For most food combinations, generic entries based on the types of ingredients are available. When unable to find a database food that is a good fit, the dietary interviewer should collect as much detail as possible from the participant, including the amount eaten. This detail is entered as an NDSR Missing Food. It is critical that with the written description, other reviewers can visualize the food and the amount eaten. Vague descriptions and incomplete amounts are unlikely to be interpreted correctly during data cleaning and quality assurance.

9.6.6 Become Familiar with Foods that Hispanics Frequently Report. Since Hispanic foods may be an important part of the diet of the SOL-Youth participants, it is recommended that dietary interviewers visit the local supermarkets and fast food restaurants to become familiar with the Hispanic foods available at their location, especially if dietary interviewers do not normally have exposure to these types of foods.

9.6.7 Supplements Reported During the 24-Hour Recall. The dietary interviewer should NOT enter any dietary supplements when recording the 24-hour dietary recall. If a participant reports a supplement during the 24-hour dietary interview, the dietary interviewer should thank the participant and tell him/her, that he/she will be asked about the use of dietary supplements later in the interview.

9.7 Entering Amounts

There are four types of units provided by NDSR for describing foods amounts. These include: food-specific units, geometric food shapes, weight, and volume. The availability of units

depends on the particular food item. Weight is always an option, and volume is an available option for nearly all foods and beverages in NDSR. Each of the four unit types is described below.

9.7.1 Food-Specific Units. Food-Specific Units (FSU) (e.g., slice, each, small, single serving bag, piece) are available for many foods in NDSR. FSU are most frequently available for packaged items such as one piece of hard candy or an ice cream bar. However, foods that may seem “standard” can come in several sizes (e.g., nugget, regular, extra large). These units are all options in NDSR. In general, it is preferable to have the participant describe the portion consumed using the amount estimation tools and amount unit options in NDSR as a guide to help quantify the food. Because the use of the Food Amounts Booklet often results in using dimensions and suggesting the food shapes, the dietary interviewer should look at the dimensions associated with the FSU to get a sense of how realistic the dimensions reported might be. In general, it is better to use the “small”, “medium” or “large” FSU to describe pieces of chicken and fruit. These foods tend to be overestimated when dimensions are used because the visual image includes refuse (e.g., bone, core, peel). FSU should also be considered for many baked goods when dimensions result in unrealistic amounts as compared with the standard amounts in NDSR.

9.7.2 Geometric Food Shapes. Shapes (e.g., circle, rectangle, wedge, cube) allow the participant to use two or three dimensions to describe the amount of food eaten. Food shapes in NDSR are measured using inches to describe the length, width, height or diameter depending on the food. In the event a participant reports the food shape in centimeters, the dietary interviewer refers him/her to the ruler that has inches and centimeters. Notes should be used for any unusual dimensions, making clear that the dietary interviewer has visualized the food and is aware of any unusual dimensions and has probed sufficiently to be sure the participant has given the best description for the amount consumed. Shapes are not permitted for describing liquid and in many situations the FSU is a better way to quantify the food item because few foods have true geometric shapes.

9.7.3 Weight Measures. Weight measurements (e.g., ounce, pound, gram) should only be used if the exact weight is available from a package label or if the participant reports an amount using an amount estimation tool that represents weight for that specific food. Pictures or meat replicas can be used to assist participants in describing their portion sizes of cooked meat including roast, steak, pork chop, and ham. (Note: chicken parts/pieces in the Food Amounts Booklet do not have weights associated with them and are considered food-specific units.) The meat replica pictures (page 16 of the Food Amounts Booklet) should not be used to represent cold cuts, sausage, meat loaf, or fish because the same volume for these items (meat replicas) will have different weight. NDSR will require the dietary interviewer to determine if the meat portions include either bones or fat, and if the fat was eaten. Consequently, the dietary interviewer should clarify with the participant if the amount of meat or fish envisioned by looking at the picture or the replica includes bone or other refuse.

9.7.4 Volume Measures. Volume measures (e.g., cup, fluid ounce, tablespoon, pint) are used to describe amounts for all liquid items, beverages, and non-liquid foods served or quantified in bowls, cups, or glasses. Examples in the Food Amounts Booklet include pictures of measuring cups and spoons, bowls, and glasses. When volume measurements are being used to

describe non-liquid foods, NDSR will first prompt the interviewer to select an amount unit (e.g., cup, teaspoon, tablespoon), and then the quantity and form in which the food was eaten (e.g., sliced, diced, solid). The form determines the amount that can be placed in a particular container and factors in the density of the food item. For most beverages, NDSR will prompt the dietary interviewer to ask if the amount included ice, consequently he/she should clarify if the amount the participant reports includes ice.

9.8 Entering Quantity

Once the unit is selected, the NDSR prompts for the quantity which may be entered as whole numbers, fractions or decimals. A “common unit” is assigned to each food item in NDSR. If the unit entered is not the common unit for that particular food, the amount displayed will include the common unit in parentheses. This information helps the dietary interviewer judge the appropriateness of the amount entered. Also, every food in NDSR is associated with a “maximum serving” amount, if the amount exceeds the established maximum serving size, the system will flag the amount and require a note.

9.9 Confirming the Amount

When the dietary interviewer is recording the intake of each food, it is important to confirm that the participant is describing the amount eaten, not the amount served. Additional probes to confirm amounts include: “Did you eat/drink all of the milk on your cereal?” “Were you able to finish that sandwich?” ¿Tomaste toda la leche asi como el cereal? “¿Terminaste todo el sandwich?”

10 Instructions for Conducting the Dietary Supplement Recall

10.1 Overview

The goal of the dietary supplement recall is to assess use of all types of dietary supplements and over-the-counter antacids. Over-the-counter antacids are included in this assessment because many of these products contain calcium. For the in-person interview, the period covered for dietary supplement intake is the same time period covered by the 24-hour dietary recall and the past 30 days. For the telephone (or second interview) this will be limited to the same time period as covered by the 24-hour dietary recall but will not include past 30 days. First, seven questions are asked to assess whether any dietary supplement or over-the-counter antacids were taken during the recall period (Tier 1). If one or more products are reported in response to these questions the interviewer enters the full product name into a search window in NDSR to identify a matching product in the database. Information from the product container is useful in conducting this search. After the product is entered, the participant is asked how many times they used the product during the recall period and how many pills/tablets he/she took each time they used the product (Tier 2). The final step (Tier 3) involves reviewing the information collected to allow for corrections and additions.

10.2 Pre-interview Activities for In-Person Interviews

Participants are asked to bring to the interview the bottles/containers for all of the dietary supplements and over-the-counter antacids they use. They are also asked to bring the bottles/containers for any over-the-counter and prescription medications they use (for the medication inventory which is conducted separate from the dietary recall and supplement assessment). To encourage compliance with these requests, participants are mailed a letter that

includes a listing of the types of products they should bring to the interview, with a bag provided for transporting the bottles/containers. As part of a reminder telephone call made to participants the day prior to the in-person interview, participants are reminded to bring product containers/bottles to the clinic visit.

10.3 Period of Dietary Supplement Recall

For the first in-person interview, the dietary supplement recall covers the same period of time as the 24-hour dietary recall and the past 30 days. For the telephone interview (or second interview) it covers only the 24-hour dietary recall period. In the event the participant brings a dietary supplement container to the in-person interview that was not taken during the past 24 hours or the past 30 days, it is NOT to be recorded during the recall, even when the participant reports he/she typically takes it but just forgot to take it yesterday (the day previous to the interview). Conversely, if a participant forgets to bring the bottle/container for a supplement used during the recall period, the product should still be recorded.

10.4 Completing Tier 1

Once the 24-hour dietary recall has been completed, the dietary interviewer tells the participant that they will now be asked about their use of dietary supplements and non-prescription antacids. Then, a series of seven questions are asked to screen for use of dietary supplements during the recall period. All screening questions must be asked even if the participant reports that he/she did not take any supplements. If this situation arises the dietary interviewer should say: “Although you didn’t take any supplements over the past 24 hours and/or 30 days, I still need to ask each of these questions” “A pesar de que usted no consumió ningún suplemento dietético en las últimas 24 horas y/o 30 días, yo necesito que (me) responda cada una de las siguientes preguntas” All questions must be asked because some products, such as fiber supplements, may not be perceived as dietary supplements by some people.

If the participant answers ‘no’ to each of the seven screening questions, the dietary and supplement interview is completed. If one or more products are reported in Tier 1, the next stage of questioning (Tier 2) is initiated.

10.5 Completing Tier 2

During the second tier of the supplement recall, the dietary interviewer refers to the containers the participant brought for the in-person interview for use in the selecting the supplement products from the DSAM database. For interviews conducted over the telephone, the participant must be asked to gather the bottles/containers for the products he/she reported in Tier 1. If the participant did not bring the container (in-person interview) or cannot find the container (telephone interview) for a product, the dietary interviewer should first try to find a matching product in the database based on the descriptive information the participant is able to provide. If the participant cannot recall enough detail about the product to allow for finding a match in the database, a generic or default supplement available in the database should be selected, and a note should be provided in the “notes” field to indicate that this was done. A generic supplement is selected when the participant knows the composition of the supplement (e.g., a calcium tablet with 1,200 mg of calcium). A default supplement should be selected when the participant does not know the composition of the supplement (e.g., a calcium tablet of unknown composition). If a generic or default product cannot be located in the database, the interviewer should enter the supplement as a missing product.

After a matching product in the database has been selected or the Missing Product window has been completed, the participant is asked how many times he/she took the product during the recall period and how many pills/tablets they took each time they used the product.

10.6 Completing Tier 3

The final Tier of the DSAM database occurs after entering all of the product details. During Tier 3, the dietary interviewer reviews with the participant the name and details about all products reported during the supplement recall. During Tier 3, the dietary interviewer can add a product and make any correction.

10.7 Including the Ingredients of a Missing Product

The dietary interviewer enters a Missing Product when a reported supplement cannot be found in the Dietary Supplement Assessment Module (DSAM) database. He/she uses the product label to include all possible information about the missing supplement, including a list of the ingredients. The dietary interviewer should list at least the first three ingredients found in the container and a note should be made specifying if all the ingredients were added or not in the Missing Product window. The list of ingredients should include amounts and units of each ingredient. If the unit cannot be selected because is not available, the dietary interviewer makes a note of the unit on the product label.

11 Conducting the 24-Hour Dietary Recall

11.1 Introduction

The dietary interviewer introduces him/herself to the participant. He/she should be friendly and calm. The dietary interviewer should always give neutral responses to whatever the participant tells them. He/she starts the interview by saying: “Hi (insert participant’s name). My name is (insert your name). How are things going today?” “Buenos días/tardes (insert participant’s name). Mi nombre es (insert your name). ¿Cómo ha estado?”

Pause, wait for their response, spend a minute or so to establish rapport, and proceed: “I’m going to be asking you about what you ate and drank. I’ll enter the information on a computer to get what we need. This is easy because it’s just about what you ate yesterday. There are no right or wrong answers. Whatever you ate is okay. Do you have any questions for me? Are you ready? I’m sure you’ll do a great job of helping me!” “Yo le voy a preguntar sobre todo lo que comió y bebió ayer. Voy a ingresar la información en la computadora para obtener lo que necesitamos. Esto es fácil porque es sólo sobre lo que usted comió ayer. No hay respuestas correctas o incorrectas. Lo que sea que haya comido está bien. ¿Tiene alguna pregunta? ¿Está listo/a? ¿Estoy segura de que usted hará un buen trabajo ayudándome!”

11.2 Entering the NDSR Quick List

The dietary interviewer proceeds by asking the participant to make a list of all the foods and beverages he/she had yesterday. He/she says: “First, we’ll make a list in the computer of what you ate and drank. Then I will ask you some more questions and we’ll figure out how much you had to eat. Do you have any questions?” “Primero, vamos a listar en la computadora todo lo que comió y bebió ayer empezando desde que se levantó. Luego le haré otras preguntas y determinaremos cuánto comió. ¿Tiene alguna pregunta?”

Pause, wait for and respond to questions, and proceed: “What was the first time you had something to eat or drink?” “¿Cuándo fue la primera vez que comió o bebió algo?” Enter the response then as needed say: “What did you have at that time?” “¿Qué comió a esa hora?” The interviewer enters the information reported by the participant on the NDSR Quick List screen, not requiring the participant to give time, meal name, or meal location. A slash must be used for each eating occasion but no further detail is needed because NDSR will prompt later for the time and meal name. Above all, the interviewer should let the participant think and say whatever comes to mind about the previous day’s intake, avoiding interruptions that may be distracting to the participant.

11.3 Reviewing the NDSR Quick List

During the review of the Quick List, it is important that the dietary interviewer try to visualize the entire 24-hour period in terms of what has been reported so far. This is a good opportunity to identify and ask about gaps of time when nothing has been reported and to check for frequently forgotten foods, such as beverages and snacks throughout the day. The dietary interviewer verifies all of the entries on the Quick List and probes for missed items by reading the list back to the participant and asking as appropriate: “I am going to read back what you have told me. Let me know if you want to add or change anything. Can you think of anything else you ate or drank yesterday that we haven’t put on the list? Do you remember if you got up during the night (after 10:00 pm or midnight) and had anything to eat or drink? Did you have any snacks after school or before bed?” “Le voy a leer lo que me ha dicho. Avíseme si quiere cambiar o añadir algo. ¿Puedes pensar en algo mas de lo que comiste o bebiste ayer que no hayamos listado? ¿Recuerdas si te levantaste durante la noche (después de las 10 de la noche o la medianoche) y comiste o bebiste algo? ¿Comió alguna merienda/bocado/colación después de la escuela o antes de ir a dormir?” Any errors should be corrected, and any additional foods the participant may report are added at this time.

11.4 Collecting Meal Information Detail

The dietary interviewer begins by saying: “Next we’ll go over our list and I will ask you some questions about each food. You can use the amounts estimation tools at any time to let me know how much you had.” “Ahora vamos a repasar nuestra lista y le haré algunas preguntas sobre cada uno de los alimentos listados. Puedes usar los modelos de alimentos en cualquier momento para decirme cuanto comió.” NDSR brings up the Meal Information window. The dietary interviewer uses this opportunity to ask questions about meal time, meal name, and meal location if this information was not provided earlier during the Quick List.

11.5 Asking About Additions

The dietary interviewer asks about additions to every food. An on-line prompt reminds him/her to say: “The first thing on your list is (NDSR inserts the name of each food).” “Lo primero en su lista es (NDSR inserts the name of each food):” Then, reading from the NDSR screen the dietary interviewer says: “Did you add anything to the (NDSR inserts the name of the food)?” “¿Le añadió algo a (NDSR inserts name of the food)?” The dietary interviewer continues asking the additions question for each food until a “no” response is received.

11.6 Collecting Complete Food and Amount Detail

The NDSR Food Search window prompts the dietary interviewer for each available level of detail during this third pass. An on-line prompt reminds him/her to begin by saying: “What type of (insert name of food) was it?” “¿Qué tipo de (insert name of the food) era?” The dietary interviewer continues defining the food, selecting food variables as required on each screen. “Unknown” should be entered if the participant cannot describe the food in detail (e.g., if it was prepared at a restaurant).

An on-line prompt for the amount reminds the dietary interviewer to say: “How much did you eat (drink)?” “¿Cuánto comió? o tomó?” Some foods require additional quantity details, with required fields indicated in yellow. After entering the amount provided by the participant, the NDSR displays a conversion to a common unit. At this time, the dietary interviewer must be able to visualize the amount reported and confirm as needed any questionable amounts using the amount estimation tools or by making reference to other familiar items or recognizable standards. For example, 1/16 of a hamburger should have a note saying, “ate only one bite” or 8 cups of popcorn should have a note saying, “ate entire box.” The dietary interviewer should ask if the entire amount described was eaten: “Were you able to finish that? or the (insert name of food)?” “¿Se terminó todo el/la (insert name of the food)?”

Note: Foods that do not have complete descriptive and/or complete amount information are indicated on the screen with a blue question mark to the left of the food. When the dietary interviewer has completely described a food, NDSR replaces the question mark with a green check mark to the left of each completed item. As the dietary interviewer conducts the 24-hour dietary recall, he/she provides positive reinforcement by stating things like “you are doing a good job” as appropriate. “Estas haciendo un muy buen trabajo” The dietary interviewer should maintain a pleasant tone of voice and avoid responding to the participant in any negative ways. If it is necessary to ask the participant to repeat what he/she said, the dietary interviewer should ask him/her to do so in a gentle way and take ownership by saying: “Sometimes it’s hard for me to hear things. Could you please tell me that again?” “A veces se me hace difícil escuchar. ¿Podría repetirme eso otra vez?”

11.7 Reviewing the Recall

During the fourth and final pass, the dietary interviewer probes for missed meals, beverages, and snacks, making sure no information was inadvertently overlooked. He/she tries to get a mental picture of the day, looking especially for time gaps of more than four hours between eating. Notes should be made to indicate skipped meals or to explain large time gaps. Notes are also used to record the absence of foods, beverages or typical condiments served with food. During the review, the dietary interviewer reads back each food and amount, asking for confirmation from the participant. For example: “Now we’ll go over what I’ve put in the computer one last time. The first thing that I have is at (insert meal name and time) when you had (insert food name).” “Ahora, vamos a revisar lo que escribí en la computadora por última vez. Lo primero que tengo en mi lista es (insert meal name and time) cuando comiste (insert food name).”

When the dietary interviewer notices a large time gap he/she should ask: “Did you have anything to eat or drink after the last meal? Anything before your (insert time e.g., evening meal) and (before bed)?” “Comiste o bebiste algo antes de (insert time e.g., evening meal) o (antes de ir a dormir)?” “¿Comió o bebió algo antes de (insert time e.g., evening meal) o (antes de ir a dormir)?” Additional foods and meals are inserted at any time. If the participant hesitates and

can't remember eating anything for a long period of time, the dietary interviewer may say: "Can you think of what you were doing (after school at dinner/supper time, etc.)? Sometimes if we think about what we were doing, where we were or whom we were with, it helps to remember what we ate." "¿Puedes pensar que hiciste (después de ir a la escuela, durante la cena, etc)? A veces si pensamos que estábamos haciendo, dónde estábamos o con quién estábamos, nos ayuda a recordar lo que comimos." The process continues until each meal and food has been reviewed and documented as needed in the NDSR notes.

11.8 Completing the Trailer Tab

When the 24-hour dietary interview is completed, the system presents the Trailer tab and the dietary interviewer ends the recall saying: "Next (insert name of participant), in terms of the amount of food you ate, would you say this was close to the amount that you usually eat, a lot more than you usually eat, or a lot less than you usually eat?" "¿En relación a la cantidad de alimentos que comió, dirías que la cantidad de hoy es parecida a lo que usualmente come, fue mucho más de lo que comúnmente come, o fue mucho menos de lo que usted comúnmente come?" This question refers to the overall amount of food for the day, not the type of food. The dietary interviewer records the participant response to the last question on the Trailer tab. If the participant reports a lot more, check "considerably more than usual" or a lot less than usual, check "considerably less than usual." In either case, NDSR requires the dietary interviewer to provide a note that briefly states why the intake was not usual. For example, a celebration meal with a lot of foods or a participant not feeling well and not eating much can result in eating a lot more or a lot less than usual. If needed the dietary interviewer can say: "What makes you say it's (a lot more or a lot less than usual)?" "¿Qué le hace decir que (lo que comió fue mucho más o mucho menos de lo usual)?"

The dietary interviewer will determine the reliability of the data. If the dietary recall is unreliable because the participant was unable to recall one or more meals or for some other reason, he/she clicks the appropriate NDSR button and adds the required NDSR Note. Dietary interviewers do not ask the participant this question, nor share their selection with him/her.

12 Conducting the Dietary Supplement Recall

The NDSR provides for an automated interview which prompts for the direct entry of the dietary supplements and their frequency of use. Collection of the dietary supplement takes place immediately following the entry of a 24-hour dietary recall and covers the same period. The in-person interview also includes the past 30 days. The dietary interviewer asks the participant about all dietary supplements and over-the-counter antacids he/she took during the recall period.

12.1 Introduction

The dietary interviewer explains the next questions are about all of the dietary supplements and over-the-counter antacids the participant took during the recall period. The dietary interviewer says: "Now I have questions about dietary supplements." In the case, the participant says he/she is not taken any supplement or vitamin, the dietary interviewer says: "Although you didn't take any supplements over the past 24 hours / 30 days, I still need to ask each of these questions" "A pesar de que usted no consumió ningún suplemento dietético en las ultimas 24 horas/ 30 días, yo necesito que usted responda cada una de las siguientes preguntas."

12.2 Tier 1 - Screening for Dietary Supplements

Tier 1 involves a series of questions to screen for use of dietary supplements and non-prescription antacids. The dietary interviewer asks about each of the dietary supplements the participant may have taken. He/she also explains that during Tier 1 he/she will record only the name of the products, later he/she will include the details for each dietary supplement. The dietary interviewer begins the recall by saying: “Now I have questions about dietary supplements you took over the past 30 days” “Ahora, le voy a hacer preguntas acerca de los suplementos dietéticos que usted ha consumido durante los últimos 30 días.” For each of the seven screening questions, examples are given. It is only necessary to list the examples if the participant does not understand the question and listing the examples would help them know how to respond.

The dietary interviewer proceeds by asking the participant: “Did you take any vitamins or minerals?” (Like One-A-Day, calcium, vitamin C or Centrum.) “¿Usted consumió alguna vitamina o mineral?” (Como One-A-Day, calcio, vitamina C o Centrum.) If the participant answers “No”, the dietary interviewer clicks “continue” and goes to the next question. In the case the participant has taken more than one multivitamin, the dietary interviewer asks for the complete name of the each product and lists each on a separate line. The dietary interviewer does this for all the questions in Tier 1.

The next question is about amino acid supplements, the dietary interviewer asks: “Did you take any amino acids? (Like glutamine, arginine or lysine.) “¿Usted consumió algún aminoácido?” (Como glutamina, arginina o lisina.)

Next, the dietary interviewer asks: “Did you take any supplements containing oils or omega-3 fatty acids? (Like fish oil, flaxseed oil, EPA or DHA.) “¿Usted consumió algún suplemento que contenía aceites o ácidos grasos Omega-3?” (Como aceite de pescado, aceite de linaza, EPA or DHA.)

“Over the past 30 days did you take any herbal or botanical products? (Like Echinacea, ginseng, ginkgo or St. John’s Wort.) “¿En los últimos 30 días, consumió usted algún producto herbal o botánico?” (Como equinácea, ginseng, ginko o hierba de San Juan [St. John’s Wort].)

The next question is about fiber supplements, the dietary interviewer asks: “Did you take any fiber supplements?” (Like Metamucil, Benefiber or Fibercon.) “¿Usted consumió algún suplemento de fibra?” (Como Metamucil, Benefiber o Fibercon.)

The next question records any supplement that has not been mentioned by the participant. The dietary interviewer asks: “Did you take any other dietary supplements that you haven’t told me about? (Like garlic extract, brewer’s yeast, coenzyme Q-10, glucosamine chondroitin, or weight loss supplements.) or “¿Usted consumió algún otro suplemento dietético que no me haya dicho? (Como extracto de ajo, levadura de cerveza, coenzima Q-10, glucosamina condroitina o un suplemento para bajar de peso.)

The last question is about antacids. The dietary interviewer asks the participant: “Did you take any over-the-counter antacids?” (Like Tums, Roloids or Mylanta)” “¿Usted consumió algún antiácido que compra en la tienda” (Como Tums, Roloids o Mylanta.) These over-the-counter

antacids provide a source of calcium but many people do not perceive antacids as dietary supplements

12.3 Tier 2 - Requesting the Dietary Supplement Containers

If a participant reports using one or more products in response to Tier 1 screening questions, Tier 2 is initiated. Tier 2 requires information to be obtained from the product bottle or containers. For the in-person interview, the dietary interviewer has the containers available in a labeled bag for completing Tier 2. For the in-person interview, the dietary interviewer says: “Now I’ll ask for detail about each of the products you reported. It will be helpful to have the containers for as many of these products as possible.” If the participant has not already removed the containers from the bag, they do so at this time. “Ahora le voy a hacer preguntas acerca de los detalles de los productos que usted reportó. Nos va a ayudar tener los botes de la mayoría de estos productos si le es posible.”

For the telephone interview, the dietary interviewer needs to wait until the participant gathers the containers for the interview. The dietary interviewer asks: “Now I’ll ask for detail about each of the products you reported. It will be helpful for you to have the containers for as many of these products as possible. I can wait while you gather them.” “Ahora le voy a hacer preguntas acerca de los detalles de los productos que usted reportó. Nos va a ayudar tener los botes de los productos de la mayoría de estos productos si le es posible. Yo esperaré mientras usted los va a buscar.”

12.4 Entering Complete Information of Dietary Supplements in Tier 2

NDSR Product Search window is used to locate and describe dietary supplements products. Prompts that appear are specific to the Dietary Supplement preferences set for the NDSR project. During the first interview (visit 1, in-person) the dietary interviewer reads the information of the products and records it in NDSR. A prompt assists the dietary interviewer to begin by saying: “You said that you took (insert dietary supplement name) in the past 24 hours / 30 days. I’ll take a look of the product label to know the complete name.” “Usted dijo que consumió (insert supplement name) en las últimas 24 horas/ 30 días. Voy a mirar la etiqueta del envase para saber el nombre completo del producto.” The dietary interviewer enters the name of the dietary supplement in the Find field and proceeds to select the appropriate supplement product.

After the product is found in NDSR, the Product Detail Windows prompts for additional information about product consumption. The dietary interviewer asks: “In the past 30 days, on how many days did you take this product?” “¿Cuántos días tomó este producto en los últimos 30 días?” “On average about how many (insert the unit, e.g. tablets, capsules, etc.) did you take each day you used the product over the past 30 days?”. “¿En promedio, cuántas (insert the unit, e.g. tablets, capsules, etc.) tomó cada vez que usted tomó este producto en los últimos 30 días?”

The next question is: “For how long have you been taking this product or a similar type of product?” “¿Por cuánto tiempo ha estado usted tomando este producto o uno similar a este?”

The next question is: “Did you take this product yesterday?” “¿Ayer tomó este producto?”

The next question is an open-ended question, so the dietary interviewer needs to collect accurate and complete information from the participant. The dietary interviewer asks: “Why do you take this product?” “¿Por qué toma usted este producto?”

During the second interview (visit 2, telephone interview) the participant has to report the information on the label of the product. The dietary interviewer says: “You said that you took (insert dietary supplement name) in the past 24 hours . Do you have the container for this product?” “Usted dijo que consumió (insert supplement name) en las últimas 24 horas. ¿Tiene el envase de este producto?”

Next, the dietary interviewer asks: “Please provide the complete name.” “Por favor dígame el nombre completo del producto.” The dietary interviewer enters the name of the dietary supplement in the Find field and proceeds to select the appropriate supplement product.

After the product is found in NDSR, the Product Detail window prompts for additional information about product consumption. The dietary interviewer asks: “In the past 24 hours, how many times did you take this product?” “¿En las últimas 24 horas, cuántas veces usted tomó este producto?” The dietary interviewer records the number on the box and clicks “continue.”

The next question is: “On average about how many (insert the unit, e.g. tablets, capsules, etc.) did you take each day you used the product over the past 24 hours?” “¿En promedio, cuántas (insert the unit, e.g. tablets, capsules, etc) tomó cada vez que usted usó este producto en las últimas 24 horas?”

The next question is: “For how long have you been taken this product or a similar type of product?” “¿Por cuánto tiempo usted ha estado tomando este producto o uno similar a este?”

The next question is an open-ended question, so the dietary interviewer needs to collect accurate and complete information from the participant. The dietary interviewer asks: “Why do you take this product?” “¿Por qué toma usted este producto?”

12.5 Tier 3 - Reviewing the Information Collected

Tier 3 is the final step during supplement data collection and includes reviewing the information collected in tier 2 to make corrections or additions. The dietary interviewer says: “Now we will review the products you have taken. Tell me if I have missed anything.” “Ahora revisaremos los productos que usted ha consumido. Dígame si no he registrado algún producto.” After reviewing the list with the participant, the dietary interviewer says: “This completes the interview. Thanks for your participation!” “Con esto hemos terminado la entrevista. ¡Muchas gracias por su participación!”

13 Ending the Dietary Interview

After finishing the interview, the dietary interviewer explains to the participant she/he will have a second dietary and supplement interview by telephone. The dietary interviewer identifies the days generally available for the telephone interview with the participant or parent (Telephone Recall Availability Form) and provides a copy of the participant Food Amounts Booklet. The dietary interviewer explains that the telephone interview is similar to this interview and that the

Food Amounts Booklet is used during the telephone interview for estimating amounts. The dietary interviewer thanks the participant and ends the dietary recall: “Thank you so much for your help. Do you have any questions for me?” “Muchísimas gracias por su ayuda. ¿Tienes alguna pregunta?” Pause, wait for and respond to questions, and proceed: “You did a great job and I really enjoyed talking with you. Remember to keep the Food Amounts Booklet in a safe place because we will use it when we do this again by telephone.” “Usted hizo un excelente trabajo, fue un placer hablar con usted. Recuerde mantener el Folleto de las Cantidades de Alimentos en un lugar seguro porque lo vamos a necesitar cuando hagamos esta entrevista otra vez por teléfono.”

“Thanks. Bye.” “Muchas gracias. Adiós.”

13.1 Obtaining Additional Information from the Parent

After the in-person interview with the child, use screening questions to determine if a parent is available to provide additional information about things the child didn’t know. For example ask: “Who brought you to the clinic today?” Quien te trajo a la clinica el dia de hoy? “Will he know about the foods and drinks you had yesterday?” El conoce acerca de los alimentos y bebidas consumidas el dia anterior? If the child responds yes, arrange to have the parent come to the diet interview room. Ask for clarification for the foods and drinks that the child reported where they did not know the details. During the phone interview, the child may offer to ask Mom or Dad during the recall, if so, you may say “it’s okay to ask your Mom or Dad for help.” “Esta bien si preguntas a tu Mami o Papi por ayuda”

13.2 Recording the Language Used during the Interview

After completion of the dietary and supplement recalls, the dietary interviewer determines and registers the language used during the interview. The decision is made by the dietary interviewer based on the predominant language the interviewer utilized to ask questions during the recall. There are three categories to specify the language:

- 1, Mainly Spanish
- 2, Mainly English
- 3, Combination of English and Spanish

The dietary interviewer selects one of the three options listed above and registers the information on the Record Information window on the Header Tab under Notes. The following is an example of an entry into the note field after interview completed: “3, combination of English and Spanish.” Include both the number and the language so there will not be misunderstanding.

Header	Food	Trailer	Dietary Supplements
Participant ID:	NRC008		
Date of intake: (mm/dd/yyyy)	07/19/2009	Day: Sunday	
Participant name:			
Date of birth: (mm/dd/yyyy)	10/10/1946		
Gender:	Female		
Life Stage Group:	Females, age 51-70 y		
Interviewer ID:	001		
Visit number:	1		
Site ID:	1, in-person		
Notes:	3, combination of English and Spanish		
Date of entry: (mm/dd/yyyy)	07/20/2009	Day: Monday	
Database Version:	2009		

13.3 Checking and Editing Recalls

The dietary interviewer should review and edit the dietary and supplement recall as soon as possible after its administration. During editing, special attention is paid to NDSR Missing Foods, Missing Products and NDSR Notes. Foods not found in the database are indicated by NDSR as missing with red capital M. Complete detail about the missing food should be reviewed and edited to ensure that adequate information has been provided by the dietary interviewers for future resolution. The dietary interviewer must remember that another person should be able to picture the reported food, so information about the color, size, shape, ingredients and preparations should be included in the note field.

The dietary supplements not found in the database are indicated as missing dietary supplements and all ingredients listed in the Supplements Facts panel on the product containers should be included. The NDSR Note field provides on-line documentation to clarify or confirm contradictory, questionable, or unusual food items. Notes serve as communication among the dietary interviewer, the lead interviewer, and the NRC SOL-Youth coordinator. Notes should be made to clarify unusual portion sizes, modifications to foods (e.g., not eating the crust of a piece of pizza), and eating foods without anticipated companion foods (e.g., hamburger without a bun or ketchup).

13.4 Special Considerations for Telephone Interview

Because the exact day for the telephone interview is not scheduled in advance, the Telephone Recall Availability Form is used to identify best potential days and times for the participant to be reached within the next month, beginning five days from the in-person interview. After the completion of the in-person dietary interview, the participant is asked to confirm their availability in the upcoming weeks. Notes should be made of any special plans, trips, or activities. The dietary interviewer can attempt to obtain another telephone number if the participant indicates that he/she will be at another location.

The Telephone Introduction Script for the Telephone Recall is used to start the recall and serves to remind the dietary interviewer that the participant must have the copy of the Food Amounts Booklet for use in estimating food amounts during the this recall. If the participant does not have the Food Amounts Booklet, the dietary interviewer says that he/she will send another one and will call back in a few days. The telephone interview should not be collected without the Food Amounts Booklet. The Telephone Contact Log is completed each time the dietary interviewer attempts to contact the participant. The lead interviewer reviews the Telephone Contact Logs daily or consults daily with the dietary interviewers to monitor the progress toward collection of the dietary and supplement recall for each eligible participant within the time window. He/she may need to confirm that a recall was not collected because yesterday was atypical, e.g. the participant was ill and did not eat. Sometimes it is not clear until completion of the recall that the day was atypical. The dietary interviewer should consult with the lead interviewer regarding the possible need to collect an additional recall if the intake reported represents extreme under-reporting and an additional day should be collected.

14 Data Management Procedures

Since the dietary and supplement recalls collected for SOL-Youth should flow from the field centers to the NRC on a regular, recurring basis, NDSR projects are set up to facilitate and direct that process. Each dietary interviewer should have two NDSR projects (one for Visit 1, in-person recalls, one for Visit 2, telephone recalls). All of the recalls collected by that interviewer within that week reside in those projects. Projects are backed-up on a daily basis and stored in a secure location, separate from the hard drive of the computer on which the NDSR program resides.

Each week, the lead interviewer restores all projects of data for the week and combines the recalls to begin preparing them for shipment to the NRC. The backup of the original data collected remains in archive storage. After cleaning and local quality assurance tasks have been completed by the lead interviewer, a backup of these new projects with the merged data are made and forwarded to NRC. A backup of these projects also remain in archive storage at the field center. NDSR backup files are password protected compressed files that cannot be read without first restoring them to the NDSR program.

14.1 Create the Dietary Interviewer NDSR Projects

Before beginning data collection each week, two new projects are created for each interviewer. One project contains the Visit 1, in-person recalls and another is for the Visit 2, telephone or in-person recalls (this is necessary because different NDSR preferences are specified for the supplement in-person and telephone recalls).

The requirements for the Project Information are as follows:

Folder: *Interviewer Name Recalls*

Project Name: *Interviewer Name SOL-Youth Recalls MM/DD/YY* (e.g., Alejandra's SOL-Youth In-person Recalls 09/06/09)

Project Abbreviation: Interviewer ID (3 digits) Data Collection Week (e.g., NNN083109V1)

Record Type: Recall

Dietary Supplement Assessment Module: 24-hour and past 30 days intake

Note: Recalls at the Nutrition Reading Center week beginning August 31, 2009.

See the following Project Information window:

Project Information

Folder: Mary's Recalls

Project Name: Visit One recalls

Project Abbreviation: N001083109

Record Type: Recall

Dietary Supplement Assessment Module:

- ☐ None
- ☐ 24-hour intake
- ☒ 24-hour and past 30 days intake

Notes: Recalls at the Nutrition Reading Center week beginning August 31, 2009

Help Preferences OK Cancel

15.2 Set the Preferences

Preferences are set when creating each project. The SOL-Youth preferences are described below.

15.2.1 Method Preferences. Deselect the Participant name and the Site ID per the following screen shot. The dietary interviewer enters the first name only for use during the collection of the dietary and supplement recall. After local quality assurance tasks are completed and before sending the data to NRC, the name of the participant must be deleted. The first name of the participant provides a valuable cross check against the participant identification number. In addition, when conducting the telephone recall the participant's name ensures the data is being collected correspond to the right participant. Select Display Spanish prompts to view prompts in Spanish along with English.

Preferences

Method Preferences Dietary Supplements User Preferences

Require on record header

☐ Participant name ☒ Interviewer ID

☒ Date of birth ☒ Visit number

☒ Gender ☐ Site ID

☒ Life Stage Group

Display

☒ Show non-required fields in record header

Meal time format: ☒ Standard ☐ 24-hour clock (military time)

☒ Display Spanish prompts

Food entry

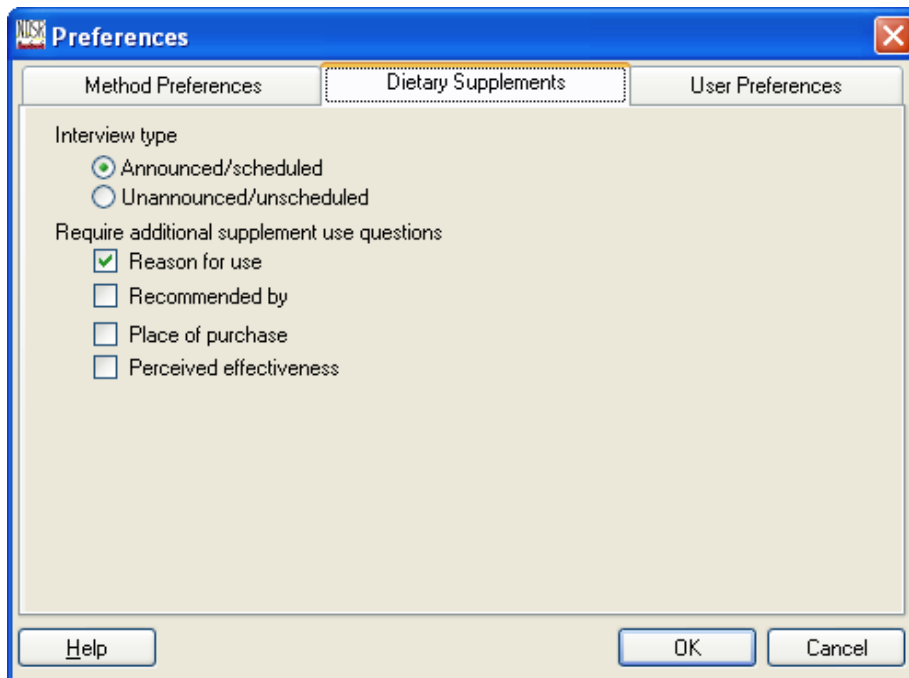
☒ Use Quick List ☒ Require meal name

☒ Require note if amount exceeds max ☒ Require meal location

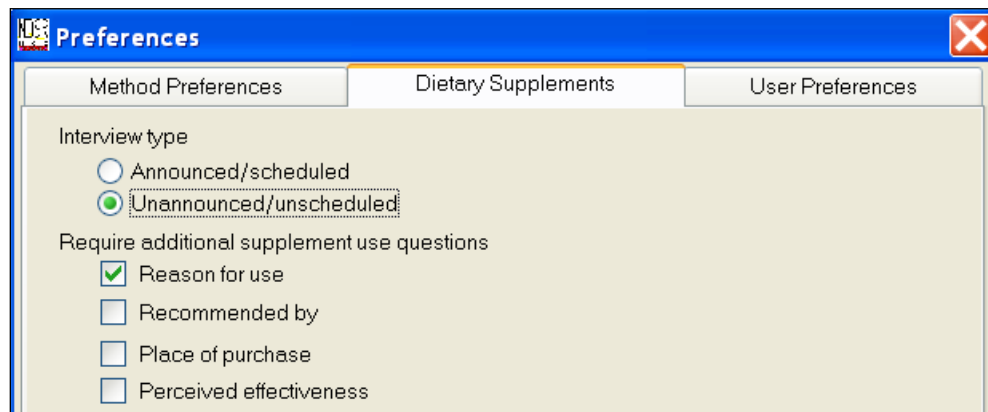
☒ Require note if amount is less than min ☐ Use Food Portion Visual

15.2.2 Dietary Supplements Preferences. For the Visit 1, in-person interview select Announced/scheduled for the Interview type. The Interview type determines the prompts for the dietary supplement interview and differs for the in-person interview and the telephone interview. Announced/scheduled is the interview type selected for the in-person interview or if the second recall is scheduled rather than unannounced. Unannounced/ unscheduled is selected for the interview type for the second or telephone recall. The additional supplement use question “Reason for use” should be selected. See the following Dietary Supplement Preferences window for the in-person interview:

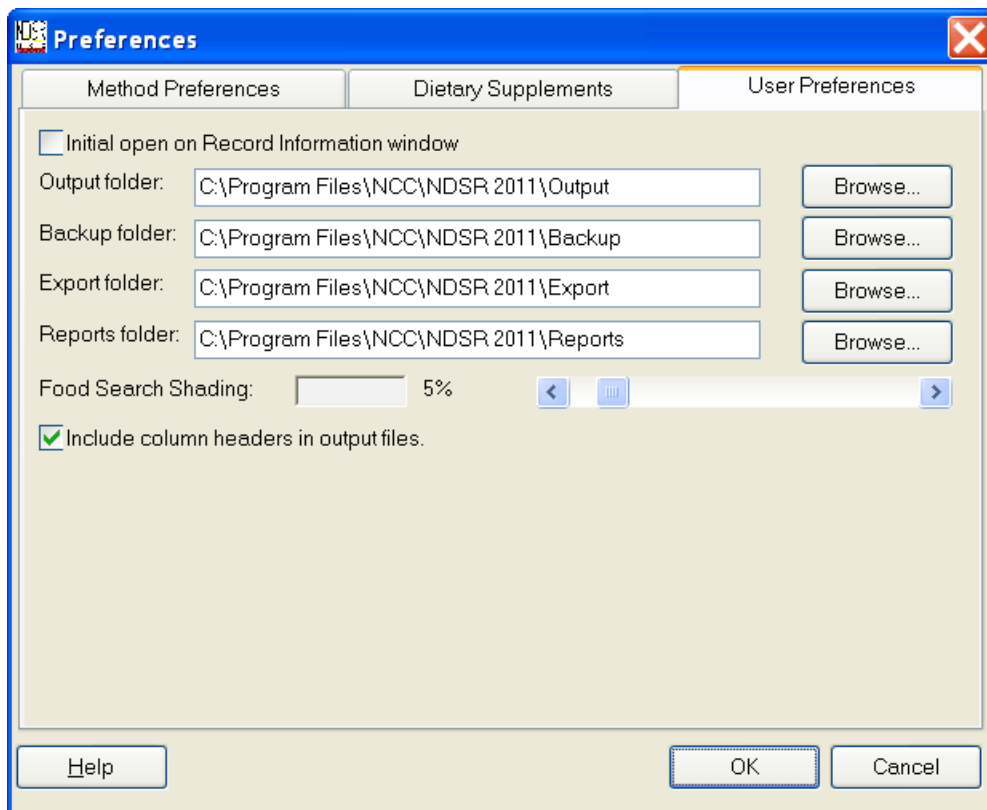
Visit 1, In-Person Interview Dietary Supplements Preferences



Visit 2, Phone Interview Dietary Supplements Preferences



15.2.2 User Preferences. The User Preferences designate the location for the backup files. If the computer used to collect SOL-Youth recalls is on a network server, it may be desirable to designate that as the backup folder location. In this example, backup files are stored in C:\Program Files\NCC\NDSR 2011\Backup. If this backup location is used, the backup files should be copied to a second secure storage location.



14.3 Create an Intake Record

Using the information obtained about the participant during the screening and recruitment process, the dietary interviewer completes the record header on the day of the visit. Because the NDSR automatically generates the date of entry, if the participant does not complete the dietary recall on the date the header is entered, the record is deleted and a new record is inserted the next time the participant is scheduled for an interview. All information set in the header preferences is required and the recall cannot continue until the header is complete. The requirements to complete the header preferences are as follows:

Participant ID: Centrally assigned by the CSCC. 8 characters beginning with the first letter of the field center (B=Bronx, C=Chicago, M=Miami, S=San Diego), a sequential number (NNNNNN) and a check digit based on the preceding sequential number.

Date of intake: mm/dd/yyyy

Date of birth: mm/dd/yyyy

Gender: Male or Female

Life Stage Group: NDSR automatically completes this field.

Interviewer ID: 3 digits designated by the CSCC.

Visit number: 1 for in-person interview; 2 for second interview (usually conducted by telephone)

Site ID: location and interview type, scheduled or unscheduled

Notes: Use to record the language of the interview

14.4 Backup of Dietary and Supplement Recall Data

Backup of the dietary and supplement recall data is routinely conducted by the dietary interviewer to ensure the security of the data. Ideally, a backup of the project is made after each recall is completed. At a minimum, daily backup copies of the data are made to a field-center-designated location per the NDSR preferences set. Each daily backup overwrites the backup from the day before. At the end of the week, the backup copy of each project is turned over to the lead interviewer for local quality assurance activities. Upon completion of those activities, another backup is made and sent off to NRC for final quality assurance tasks.

14.5 Printing NDSR Reports

Three NDSR reports are printed immediately following the dietary interview. These reports serve two purposes: first, in the event that there is computer system failure, and the file is corrupt or lost, the recall can be re-entered using the NDSR Foods Report, the Record Properties Report, and the Dietary Supplements Report. The second use is for the field center quality assurance activities.

14.6 Restoring Dietary and Supplement Recall Data

The lead interviewer restores the individual dietary recall projects to a computer with NDSR program installed. Recalls from individual dietary recall projects are merged and checked prior to submission to NRC.

14.7 Creating the Lead Interviewer NDSR Projects

Two projects are created for the lead interviewer. One project contains all Visit 1 recalls and the second contains all Visit 2 recalls ready for submission to NRC.

The requirements for the Project Information for the completed Visit 1, in-person recalls are as follows:

Project Name: *Field Center MM/DD/YY Visit 1 Recalls* (e.g., Bronx 12/07/09)

Project Abbreviation: *First letter of field center Date V1* (e.g., B120709V1)

Record Type: Recall

Dietary Supplement Assessment Module: 24-hour and 30-day intake

The requirements for the Project Information for the completed Visit 2, phone recalls are as follows:

Project Name: *Field Center MM/DD/YY Visit 2 recalls* (e.g., Bronx 12/07/09)

Project Abbreviation: *First letter of field center Date V2* (e.g., B120709V2)

Record Type: Recall

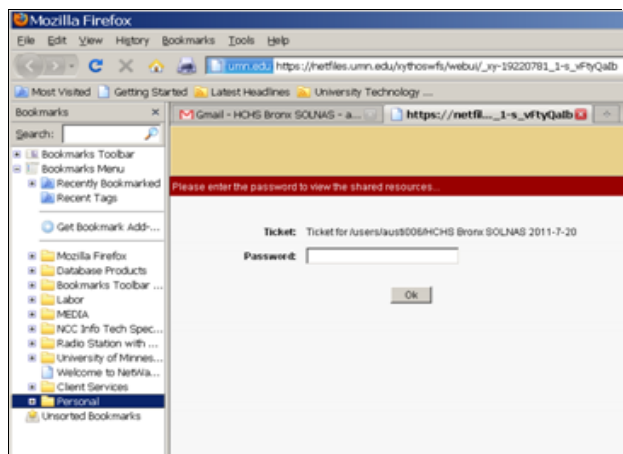
Dietary Supplement Assessment Module: 24-hour intake

14.8 Transmission of the Dietary and Supplement Recall Data to NRC

The completed recalls are transmitted to the NRC. NetFiles, an online file storage tool will be used to transfer the NDSR backup files to the NRC. NetFiles enables secure storage and sharing of files on a University server that has been approved for storing private and protected data. NetFiles can be accessed using most web browsers and allows sharing of content with people outside the University of Minnesota.

The NRC data manager will initiate NetFiles sharing by creating a ticket for each field center and will email the link to each lead interviewer. Upon receipt of the link, the lead interviewer will

click on the link and follow prompts insert the password and upload weekly NDSR backup files or download NDSR User Recipes and User Product projects. The following screen shot shows a sample ticket:



If a password appears, replace it with the password provided by the NRC in the email you received notifying you that User Recipe and User Product projects are ready to download.

Select the checkbox to the left of the file name(s) and then select Download from the banner at the top. If you select multiple projects, they will be downloaded a single zip file. Save to the desired location, extract and then restore the backup file in NDSR2011.

14.8.1 Send Backup Files to NRC. After local quality assurance activities have been completed the lead interviewer moves the completed recalls to a single project. Next, the project is backed up to: C:\Program files\NCC\NDSR2011\Backup, and submitted to NRC via NetFiles. Immediately after sending the backup file to the NRC, the interviewer sends an email to the NRC SOL-Youth coordinator. The subject of the email should state: “(month-day-year) backup file from (name of field center)” and the message should include the following:

- Project abbreviation
- Number of recalls in a project
- NDSR version (the current version is NDSR 2011)

14.8.2 Receive Backup Files from NRC. The NRC provides backup files of User Recipes and User Products to the field centers using NetFiles. The NRC SOL-Youth coordinator posts the backup file on the ftp site and sends an email to the lead interviewer stating that a new backup file has been posted on the ftp site. The lead interviewer accesses the site, obtains the backup file, and confirms receipt with the NRC by email (**Appendix 10**).

14.9 Archive Dietary Recall Data at the Field Center

Upon receipt of recalls at NRC, the field center is notified as to which projects can be removed from within the NDSR program and locally archived. An archived copy of all data should be kept until the study is complete. Frequent archiving keeps the number of stored recalls at a minimum, increasing the efficiency of the NDSR and the dietary interview.

14.10 Site Storage of Paper Documentation

The lead interviewer files copies of the all materials related to the dietary interview. The participant ID number is used for record retrieval in the event of questions.

14.11 Computer Failure

NDSR automatically saves all data as entered. In the event of a temporary interruption in operating NDSR, recovery likely goes unnoticed by the participant. Field centers should make provisions for long-term power failure problems. In the event of computer hardware or software problems, dietary interviewers notify the lead interviewer or information technology support staff at the field center immediately.

15 Dietary and Supplement Quality Assurance at the Field Center

The lead interviewer at each field center is responsible for ensuring the overall local quality of the dietary data collection. The dietary interviewers review the interviews, document unusual foods and amounts, and flag unreliable recalls.

On-site quality control includes two steps: Review and editing of each dietary recall by dietary interviewers within one or two days of collection, and review and editing of dietary recalls by lead interviewers within one week, with feedback provided to the respective dietary interviewer.

15.1 Daily Review of Dietary Recalls

With the collection of each recall, the dietary interviewer initiates the Dietary and Supplement Recall Checklist and upon completion of the recall, proceeds to review the data on the computer screen. Obvious errors may be corrected on the spot (e.g., entry of 10 hamburgers consumed when the dietary interviewer recalls that is was only one or entry a cup of instant coffee powder instead a cup of coffee prepared with instant powder). When the dietary interviewers have questions, they should discuss these with the lead interviewer to reach a consensus. Lead interviewers may consult with the NRC SOL-Youth coordinator for more information about the NDSR database entries that would help in making a decision. The following steps are taken during the daily review by the dietary interviewers:

- Check the Header tab. The Header tab is reviewed for complete and correct information including participant ID, date of intake, interviewer ID, visit number, interview type, and the language used during the interview.
- Check the Food tab. Each food and amount is carefully reviewed and confirmed. Unusually small or large portions are verified and any justification or rationale is documented in the Note field. Missing food information is checked for completeness.
- Check the Trailer tab. Ensure that notes provided for atypical intakes are complete.
- Check the Dietary Supplements tab. Entry of each dietary supplement and amount is carefully reviewed and confirmed. Missing product information is checked for completeness.
- Edit the dietary recall. The dietary interviewer conducts edits for each intake record within one to two days of initial data collection or after input from the lead interviewer.

15.2 Weekly Review of Dietary Recall Data

At least once per week, the lead interviewer reviews all dietary and supplement recalls collected at the field center. The lead interviewer may make or recommend changes in the dietary and supplement recalls only after discussing the proposed change(s) with the dietary interviewer. It is the responsibility of the lead interviewer to document and communicate site-specific consensus decisions to the NRC SOL-Youth coordinator and to the dietary interviewers within his/her field center. NDSR Quality Assurance Reports to be generated for these weekly checks include:

15.2.1 Check the Record Properties. The Records QA Report is used to check information entered in the header and trailer fields. It is important that the participant ID and date of intake are correctly entered. After reviewing the Records QA Report, anything unusual about the dietary and supplement recall should be recorded in the NDSR notes field. Outliers for target nutrients are flagged to identify potential data entry problems related to the intake.

15.2.2 Check the Foods QA Report. The Foods QA Report lists each food and amount. Priority notes are flagged. All notes should be reviewed and information clarified as needed with the dietary interviewer. Key nutrients are listed for each food and may indicate problems with selecting the wrong food or entering an incorrect amount.

15.2.4 Check the Dietary Supplements using the DSAM Product QA Report. The DSAM Product QA Report lists each dietary supplement reported. Priority notes are flagged and should be reviewed and adjustments made as necessary. It is important to verify the product and amounts are correctly selected and the answer to the question “why taken” and notes are meaningful.

15.3 Submitting a New Food Request

If any food other than mixed dishes is not in NDSR, the lead interviewer accesses the NCC New Foods Request form on the NCC website and completes the necessary information. If a mixed dish is missing in NDSR, the dietary interviewer enters all the information for the dish on the Missing Foods window. NRC resolves the New Food Request and edits the recall with the new information. At the end of each month, the field centers will receive an updated User Recipe project to be used for conducting the recalls.

15.4 Submitting the NDSR Recalls to NRC

On a weekly basis, after quality assurance activities have been completed, the lead interviewer combines the recalls collected in two projects, creates a new backup file for each with the following information:

- Project name: Name of the field center and the date of the week intended to submit the backup file. For example: San Diego 01/11/2008 Visit 1 Recalls
- Project abbreviation: The first letter of the field center and the date. For example: S011108V1

The lead interviewer transmits the backup file to the NRC via the website. The NRC SOL-Youth receives the backup file and confirms receipt with the lead interviewer by email.

16 Annual NDSR Updates

With each new release of NDSR, the field centers installs and transitions to the new database to take advantage of the more current, market reflective database and the added Hispanic foods. The timing for this transition is directed by the NRC SOL-Youth coordinator.

NUTRITION READING CENTER

17 Introduction

The Manual of Procedures has been developed by the Nutrition Coordinating Center (NCC) at the University of Minnesota. This manual contains the procedures for the dietary data management of the Hispanic Community Children's Health Study of Latino Youth (SOL-Youth) at the Nutrition Reading Center (NRC). The purpose of this manual is to document the NRC responsibilities for the dietary and supplement data collected at the four field centers (Bronx, Chicago, Miami and San Diego) including the standardization of the quality assurance review of data. All at NCC who are involved in the processing of SOL-Youth dietary and supplement data should be familiar with the contents of this manual and know their responsibilities for the study.

19 Nutrition Reading Center Personnel and Responsibilities

19.1 John Himes, Principal Investigator and Project Director

Dr. Himes is responsible for the overall coordination of the SOL-Youth, NRC. He is on the ASOL-Youth Steering Committee, and is responsible for all communications with the University of North Carolina's Collaborative Studies Coordinating Center (CSCC) and financial officials at the University of Minnesota. He works closely with the dietary and supplement group to identify Hispanic foods and recipes to be added to the NDSR Food and Nutrient Database. Dr. Himes meets regularly with the NCC Service Center manager, SOL-Youth project nutritionist and database scientist to review work priorities, assess work progress, and overview timelines.

19.2 Mary Stevens, Service Center Manager

Ms. Stevens is responsible for the general oversight of the NRC activities related to dietary and supplement recall data collection for the SOL-Youth. She works with NRC staff to develop the data collection and quality assurance procedures. She supervises the NRC development of all related data collection forms and materials for the SOL-Youth. She also provides oversight for the quality-control procedures specific to the study. She customizes the NDSR training to meet the needs of the SOL-Youth protocol and leads the training and certification of the dietary interviewers. She edits the study Manual of Procedures with each NDSR version. Ms. Stevens manages the efforts of and works closely with the project nutritionist to ensure the quality of the dietary and supplement data collection.

19.5 Alejandro Peralta, Project Nutritionist

Mr. Peralta is responsible for the external quality control for the dietary and supplement data collected by the dietary interviewers at each field center. He provides expertise for the identification of the Hispanic foods and recipes to be added in NDSR Food and Nutrient Database. He maintains close communication with the SOL-Youth field centers and is involved in the implementation of the dietary and supplement data collection and processing. Mr. Peralta assists in the training and certification of the dietary interviewers. He coordinates the monthly calls with the lead interviewers and writes the monthly newsletter for dietary interviewers.

19.6 Janet Pettit, Database Scientist

Ms. Pettit leads the effort to update the NDSR to accommodate Hispanic foods. She coordinates the addition of new foods to the NDSR database. She contributes to the process of selecting

foods for addition to the database and ensures that the new recipe information meets NCC criteria for addition to the NDSR database.

19.7 Susan Seftick, Database/Quality Control Nutritionist

Ms. Seftick is responsible for the resolution of new and missing database food requests for the SOL-Youth. She also researches food composition tables, websites, and other sources to obtain ingredient and nutrient information for foods not found and submitted for resolution by the field centers. She uses the NCC FoodCalc software to enter nutrient label and/or ingredient information for brand-name foods and for missing Hispanic foods and recipes. She provides expert guidance for the project nutritionist in conducting the NRC review of dietary and supplement recalls. Ms Seftick assists with the NDSR training and certification.

19.8 Mary Austin, Data Manager

Ms. Austin is responsible for the overall flow of data for the SOL-Youth at NCC. She communicates with the field centers, ships all study materials and provides clerical support as needed. Ms. Austin will receive the NDSR dietary and supplement recalls from the field centers and prepare them for quality control processing. She ensures that the dietary and supplement data receive appropriate security and privacy protection during the processing at NCC. She prepares monthly data processing status reports for the CSCC and is responsible for transmission of data, NDSR backup and output files to the CSCC after NRC processing.

20 Communication and Data Transmission

The NRC personnel maintain regular and close communication internally and with both the lead interviewers at each field center and with the CSCC. Information, study materials, forms and data are transmitted on a regular and ad hoc basis.

20.1 SOL-Youth Website

Routine updates of the Diet and Supplement Manual of Procedures and related forms will be uploaded to the SOL-Youth website to make them available for all field centers.

20.2 Email and Telephone

The lead interviewers call or send email messages to the SOL-Youth Project Nutritionist at NCC when he/she has questions or concerns regarding the dietary and supplement data collection. If the questions or concerns apply to all field centers, the Project Nutritionist addresses the issues on the monthly newsletter, so all interviewers receive the same information. The monthly newsletter will be sent via email to each dietary interviewer at the field centers.

20.3 Courier and US Mail

Courier services will be used to ship study materials to the field centers. Shipments will be tracked to ensure delivery to the appropriate personnel at the field centers. Materials to be sent include the Food Amounts Booklets for the participants and amount estimation tools for the in-person interview.

20.4 NCC Website

The NCC website (www.ncc.umn.edu) is used by the field centers to report a missing commercial, packaged and any food other than prepared dishes. The New Food Request Form is

completed with the information about the food or beverage and submitted to NCC for resolution. The New Food Request Form is filled out with the following information:

- Client Name: Name of the lead interviewer
- Client Number: 10801
- Institution: Name of the field center (Bronx, Chicago, Miami or San Diego)
- E-mail: sefti001@umn.edu
- Phone Number: Phone number of the lead interviewer

20.5 NRC FTP Site

NetFiles, an online file storage tool utilized by the University of Minnesota Office of Information Technology, will be used to transfer the NDSR backup files to the NRC. NetFiles enables secure storage and sharing of files on a University server that has been approved for storing private and protected data. NetFiles can be accessed using most web browsers and allows sharing of content with people outside the University of Minnesota.

20.6 Meetings at NRC

NRC personnel meet at least once a week to discuss the materials that are developed and improved for the data collection, the standardization of procedures, and the identification of challenges before the study starts. They also discuss timelines and any issues related to the NDSR software and database. During active data collection, weekly meetings are held to discuss the status of processing of incoming dietary and supplement recalls and to note any issues that need to be communicated to the field sites or to the CSCC.

21 Forms and Databases Utilized at the NRC

A number of forms are used to record information and to track data, monitor progress, and to ensure the overall quality and security of the dietary and supplement data received from the field centers. Information is recorded electronically in a Dietary Recall database for easy retrieval and reporting purposes.

21.1 SOL-Youth Dietary and Supplement Recall Interview Assessment Form

This form (**Appendix 11**) is completed for the baseline and final recalls and is used to evaluate each interviewer during the certification process. It also is used during the field site visits when interviews are observed. Copies of the completed Interview Assessment Forms are maintained on file by interviewer at NRC for the duration of the study.

21.2 SOL-Youth Dietary Inquiry Form

The SOL-Youth Dietary Inquiry Form (**Appendix 12**) is used by the NRC personnel during routine review of the dietary and supplement recalls during data collection. Questionable items found in the recalls are recorded on this form which is sent to the field center as email attachments. The lead interviewer at each site follows up in obtaining the needed information and returns the completed form via email to the NRC for inclusion in the dietary and supplement data as warranted.

21.3 SOL-Youth Field Center Visit Checklist

This form (**Appendix 13**) is completed by the NRC personnel at the time of the field center visit. It provides information about the use of the materials and forms as well as the adherence to overall dietary and supplement procedures as noted in the Field Center Manual of Procedures.

21.4 SOL-Youth Recall Database

The SOL-Youth Recall Database includes information about the dietary and supplement recalls received at NRC and is used to track the incoming recalls and to generate the monthly status report for the CSCC. The information provided in the SOL-Youth Recall Database includes: participant ID, date of intake, visit number, interviewer ID, and number of inquiries, number of missing foods and missing dietary supplement products for each dietary and supplement recall collected.

21.5 SOL-Youth Monthly Processing Status Report

Every month the Data Manager generates a report to be sent to the CSCC. The purpose of this report is to inform the CSCC about NRC activities for the study. This report includes a summary of the information that is kept in the Recall Database, including the number of recalls received at NRC and the status of NRC processing of dietary and supplement recall data.

21.6 NCC Service Center Quality Assurance Reports

A number of customized NDSR reports are used to facilitate the review of the recalls received at NRC in a standardized manner, and to allow NRC staff to generate dietary inquiries to detect possible data-entry errors, missing foods and missing dietary supplements. These reports include:

21.6.1 Records QA Report. The Records QA Report lists all intake records; includes header and trailer notes. Nutrients that exceed nutrient maximum values (95% of NHANES 2005-06 intake distributions) and/or do not meet nutrient minimum values (5% of NHANES 2005-06 intake distributions) are flagged. Recalls are subsequently checked for accuracy of food selection or amount entry.

21.6.2 Foods QA Report. The Foods QA Report lists all foods and identifies foods with Notes and Priority Notes. Displays database amount maximum and minimum values for all foods and calculates percent of each, flagging food amounts that are > 100% of maximum value or < 100% of minimum value. Priority notes are reviewed and the dietary recall is edited as appropriate.

21.6.3 Quick List Report. The Quick List Report is printed and reviewed for diet and supplement recalls identified as part of the 10% quality assurance sample. The Quick List Report is compared to the Food Report to ensure that the foods listed during the first pass of the interview are accounted for either by food selection or notes that describe why a food reported on the Quick List has not been entered.

21.6.4 Missing Food Report. The Missing Food Report identifies all recalls with foods flagged by NDSR as missing during the diet and supplement interview. The recalls submitted to the NRC may have missing mixed dishes that cannot be found in NDSR. This report will be

used to identify frequently reported missing foods which should be considered for inclusion in the upcoming NDSR release.

21.6.5 Missing DSAM Product Report. The Missing DSAM Product Report identifies all recalls with dietary supplement products flagged by NDSR as missing during the diet and supplement interview.

21.6.6 Meal QA Report. The Meal QA includes all notes reported on the meal information window. Dietary interviewers use this field to document additional information reported by the participant such as the name specific name of the restaurant, other meal location or the eating occasion. Information in the meal note is reviewed used as warranted.

21.7 SOL-Youth New Food Request Form

The NCC New Food Request Form (**Appendix 4**) is used to submit a missing commercial food to NCC for resolution. The form is available on-line at the NCC website which can be accessed from within the NDSR program or at www.ncc.umn.edu. NCC will resolve the missing commercial food using the information provided on this form.

22 Annual Updates of the NDSR Program

Every year, NCC releases a new version of the NDSR software including a new version of the NDSR food and nutrient database to more currently reflect the food marketplace. NCC makes adjustments and changes to improve the NDSR database, e.g. new foods and mixed dishes will be added, obsolete foods are deactivated, foods are reformulated and nutrient values are updated with improved information. Each year, with the release of the updated NDSR database, NCC provides the new version of the NDSR software to the field centers and communicate to the field centers as to the exact day that the new version should be installed and used for dietary and supplement collection.

23 NRC Training, Monitoring and Continuing Education of Field Staff

Central training of the dietary interviewers ensures the standardization and quality of the dietary and supplement data collection at the four field centers. NRC staff develops and maintain the dietary and supplement training materials for the field centers. Prior to the start of the study, NRC staff trains all dietary interviewers at a central training workshop. All dietary interviewers must be certified by NRC staff following the training. Ad hoc training workshops for new field staff are conducted as needed by NRC staff. With each new release of the NDSR software, the SOL-Youth training materials are updated to reflect any changes in the new version.

23.1 NRC Training and Certification Process

The training and certification includes the all aspects of the dietary and supplement interview; using the multiple-pass approach, dietary interview techniques, the use of the amount-estimation tools, use of scripts and interview prompts, and reviewing, making edits and corrections after each recall. It is intended that the dietary interviewers complete their baseline recall at the end of the last day of training. This allows the dietary interviewer to use all dietary and supplement materials to simulate an actual interview in a setting with the trainer. If some dietary interviewers do not complete the baseline certification recall the last day of training, they will

schedule the baseline recall with an NRC trainer for another day and this will be conducted by telephone.

23.2 Evaluating the Certification Baseline Recall

Before the baseline recall is conducted, the NRC trainer prepares the SOL-Youth Dietary and Supplement Recall Interview Assessment Form with the appropriate information for the dietary interviewer. A copy of the Baseline Certification Script and the Participant Food Amounts Booklet are ready to be used during the interview. To standardize the certification process, the NRC trainer uses the same baseline and final scripts for all dietary interviewers. The scripts are available in English as well as in Spanish. The Recall Interview Assessment Form is used to assess the overall skills of the dietary interviewer in using the NDSR software and database, interviewing techniques, use of the amount estimation tools, and establishing rapport with the participant. After the completion of the baseline recall, the NRC trainer reviews the interview with the dietary interviewer and provides feedback about interviewing, finding foods and dietary supplements in NDSR, and adherence to the SOL-Youth protocols. This is also an opportunity to answer any additional questions the interviewer may have. Certification records for dietary interviewers will remain on file at NRC for the duration of the study.

23.3 Management and Assessment of the Certification Recalls

Backup files containing at least ten practice recalls are submitted via the ftp site. Email notification is sent to the NRC data manager who retrieves the NDSR backup file from the ftp site. The backup file is restored to NDSR and receipt is confirmed via email to the lead interviewer and the dietary interviewer. Next, the final recall session is scheduled with the dietary interviewer. After restoring the backup file with the ten recalls, the data manager prints the Quick List, Record Properties Report, Foods Report, and the Dietary Supplements Report. She will also generate the Quality Assurance Reports as listed above. Each report is reviewed and evaluated by the NRC trainer and the project nutritionist. The NRC staff provides feedback in the form of written comments, as needed, on each of the above mentioned reports and discusses issues as needed before proceeding to the final recall with the dietary interviewer. Once the dietary interviewers are certified the lead interviewer and the CSCC are notified. An ad hoc report is provided to the CSCC with the names and interviewer identification numbers for interviewers as each group is trained and certified.

23.4 Conducting the Final Certification Recall

In preparation for the final recall the NRC trainer gathers the materials including the SOL-Youth Recall Interview Assessment Form, the Final Certification Script, and the Participant Food Amounts Booklet. Before the dietary interviewer starts the interview, the NRC trainer provides feedback about the ten practice recalls and responds to any questions from the dietary interviewer. After completing the final interview, the NRC trainer highlights the important issues identified during the interview, provides recommendations for improvement, as needed, and reinforces the good practices noted.

23.5 Monitoring

NRC personnel visit each field center during the first year of the data collection to evaluate adherence to the SOL-Youth Field Center Manual of Procedures, observe dietary and supplement interviews, evaluate local quality control procedures, understand field center challenges, check for confidentiality of dietary and supplement data and respond to questions

about overall NDSR data management and collection issues. Following the visit to the field center, the NRC staff will submit a detailed report to the CSCC about the progress and issues noted during the site visit. The SOL-Youth Field Center Checklist (**Appendix 13**) is used to document dietary and supplement data collection procedures.

23.6 Continuing Education

At all times during the SOL-Youth, it is imperative that the dietary and lead interviewer practice the skills learned at training and use the NDSR program on a regular basis. During the study, the NRC will have an opportunity to provide information about general issues that will be useful for all dietary and lead interviewers. Specific problems identified during the review of recalls will be communicated directly to the dietary and lead interviewers so that they can learn from their experiences.

23.6.1 Additional Practice Diet and Supplement Recalls. Prior to the start of the full-scale study each dietary interviewer is required to collect one recall per day he/she is working for the diet and supplement section of the SOL-Youth and submit at the end of each week the recalls via the ftp site during the time period before the startup of data collection.

23.6.2 Monthly Newsletter. General issues noted during the review of recalls and during site visits are documented and communicated to the dietary interviewers on an ongoing basis in the form of a newsletter. This is sent monthly via email to all the field centers.

24 Preparing Materials for the Field Centers

NRC staff has developed materials to be used by the dietary interviewers and participants to ensure the standardization and quality of the diet and supplement data collection at the four field centers.

24.1 Dietary Interviewer Training Manual

The Training Manual has been generated as a guide to be used during diet and supplement workshop. Each dietary interviewer receives a Training Manual that includes information regarding the use of NDSR, procedures for conducting the diet and supplement recall, the use of interview materials, practice with NDSR, and quality assurance of the interviews. The Training Manual should be available at the field center to be consulted by the dietary interviewer when necessary.

24.2 Dietary Interview Notebook

A Dietary Interview Notebook is provided to each dietary interviewer. Pages of the notebook are protected in plastic so that they may be used with each participant. Included in the notebook are the Participant Food Amounts Booklet, pictures of foods from the Hispanic Food Glossary, and calendar pages for discussing the upcoming telephone recall. The Interview Notebook is used during the in-person interview and should be kept at the field center.

24.3 Food Amounts Booklet

The Food Amounts Booklet is used during the in-person and telephone dietary and supplement recalls. This booklet was developed for use in the Dietary Intervention Study in Children in 1993 and has been modified by the NRC staff for the SOL-Youth. The graphics are converted to volume or weight amounts to be entered into NDSR amounts. Each interviewer receives a copy

of the booklet with labels on the pictures and a conversion chart to facilitate the amount data entry. On a quarterly basis, the NRC provides copies of the Participant Food Amounts Booklet to each field center for distribution to the participants.

24.4 Food Models

The NRC has provided each field center with two sets of 3-dimensional food models to be used during the in-person interview to aid in estimating amounts and to educate the participant in the use of the Food Amounts Booklet. The household food models have been selected to reflect the 2-dimensional pictures of the Food Amounts Booklet and include cups, bowls, glasses and replica foods for items that are not easily measured using cubic volumes or dimensions. A small container with a cover is provided by the NRC. This is to be filled with loose dried beans which are purchased locally.

24.4.1 Labeling of Food Models. Each 3-dimensional food model is measured and labeled with the same markings as the 2-dimensional pictures. The amount to enter in NDSR is marked on the bottom of each model. These markings are intended to be used only by the dietary interviewer.

24.4.2 Additional Food Model Sets. Each field center has been provided with two sets of food models and an inventory list to keep track of the sets. If any items are damaged throughout the study, the lead interviewer contacts the NRC staff for replacement. No other food models or measuring devices will be used to conduct the diet and supplement recalls.

24.5 Hispanic Food Glossary

A Hispanic Food Glossary has been developed for the SOL-Youth to guide and facilitate the process of data collection for the dietary interviewers. The glossary lists 208 foods including many fruits, vegetables, and Hispanic dishes. The Hispanic Food Glossary is not intended to be an exhaustive listing of Hispanic foods. Rather, the intent is to have a tool that will help the dietary interviewers to consistently choose the correct food when entering dietary data into the NDSR. The glossary should be reviewed frequently by the dietary interviewers so the dietary interviewers will become familiar with the Hispanic foods, NDSR data entry, and uncommon names of foods. There are two types of listing available for the interviewers: the PDF file that is organized by alphabetical order (Spanish), does not contain accent marks, and includes hyperlinks. The purpose of this glossary is to be a searchable document available for the dietary interviewer. The other type of glossary is organized by alphabetical order in Spanish with accent marks. A hard copy of the glossary is provided to each dietary interviewer during training.

24 Nutrition Reading Center Procedures for Dietary and Supplement Data

24.1 Receipt of NDSR Backup Files at NRC

On a weekly basis, after quality control is conducted at each field center, the lead interviewers send the backup files of completed records to NRC via the ftp site. If no backup files are received from a field center, NRC personnel contacts the lead interviewer regarding the status of the expected dietary and supplement recalls shipment to identify any possible problems that have been encountered with completing and submitting the recalls.

24.1.1 Restoring Data Sent from the Field Centers. The backup files are downloaded from the ftp site and restored to NDSR. The NRC data manager generates the NDSR Record Listing and confirms receipt.

24.1.2 Confirmation of the Data Received at NRC. The NRC data manager sends an email confirming receipt with the field center. The email contains information regarding the name of the project, the date of receipt and the number of records included in the project.

24.2 Quality Assurance and Editing of Dietary and Supplement Recalls

NRC quality assurance reports are generated for incoming recalls. Reports identify recalls that need further examination, may require editing and/or further information from the field center. A random sample of 10% of recalls is identified for a detailed review. During the quality assurance review, the NRC generates Dietary Inquiries for the field center about questioned items. Therefore, dietary interviewers learn from their own experience to improve the quality of future dietary and supplement data collected. Missing foods and missing dietary supplement products are resolved and recalls are edited as needed. All edits made to the diet and supplement recalls are documented at NRC with the date and identification number of the person who made the change.

24.2.1 Missing Foods and Dietary Supplement Products. Foods and dietary supplements may be identified as missing during the diet and supplement recall. These missing items include new brand name food products that are submitted by the lead interviewer using the NCC website to transfer information required for resolution. NCC generate a resolution for these missing foods and the recall is edited accordingly at the NRC. Hispanic foods, mixed dishes and dietary supplement products reported and not included in the database are flagged by the NDSR program during data entry and resolved during the quality assurance review at the NRC. Editing of these missing items is completed at the NRC and the information is available for all field centers at the end of each month for use potential use in future recalls.

24.2.2 Resolving New Brand Name Foods. NCC resolves each new-food request using nutrient and ingredient information provided by the field centers and matching to foods in NDSR. Primary nutrients for comparison include: calories, protein, fat, carbohydrate and sodium. Fortification nutrients are also matched. When complete nutrient and ingredient information is available, new-food requests are resolved using a calculation. In this calculation, amounts of the major ingredients are adjusted so that the nutrient values of the ingredients best match the nutrient information and fall within NCC established nutrient tolerances. When complete nutrient and ingredient information is not provided, new-food requests are resolved using a variety of resources, including the most current (unreleased) database version, manufacturer information, and previously resolved requests. When information is not available, NCC judgment is used to resolve the missing item.

24.2.3 Resolving New Hispanic Foods. Before the study starts, the NRC will provide the field centers with User Recipes for the most common Hispanic dishes not in NDSR 2011. Each month of the study when new dishes are reported, additional User Recipes will be provided. The recipes not in NDSR 2011 will be submitted for possible inclusion in NDSR 2011. NRC staff use a variety of Hispanic/Latino cook books located at NCC serve as primary sources of information to generate user recipes. The lead interviewers may be consulted prior to final

selection of a recipe to determine if the one selected at the NRC is the most representative for the food in question. Since a recipe may widely vary in preparation, ingredients and preferences, NCC uses the most representative recipe to generate the user recipe. However, this rule may not apply to all cases because there are Hispanic dishes that have the same name in two countries or regions but the preparation and ingredients are different in this case, the country name would be included in the recipe name to differentiate between these two types of foods.

24.2.4 Missing Dietary Supplement Products. Missing dietary supplement are resolved at the NRC by checking information entered by the dietary interviewer against product information sources whenever possible. NRC staff save the Missing Product as a DSAM User Product, verify the information by checking against available resources including dietary supplement product websites. The diet and supplement recall is edited to include the validated User Product. If the information entered for a product cannot be validated by the NRC, information collected during the recall is used; however this product is used only in the resolution of the dietary supplement recall for this particular participant and is not included in the NDSR User Product backup file for the other field centers because it has not been validated.

24.2.5 Data-Entry Rules. NCC has developed rules about food entry which are essential to maintain consistency in data entry among the dietary interviewers over time. These rules are used when a participant is no longer available for clarification, or after all probing during the dietary recall fails to elicit the required information. Since NRC data-entry rules may not cover every data-entry situation, NRC staff will regularly provide updates of the data-entry rules for the field centers.

24.3 Providing Missing Food and Missing Product Resolutions to the Field Centers
Each month NDSR backup files of User Recipe projects with new food resolution and Hispanic Recipes and User Product projects with new dietary supplement products are posted on the ftp site to make them available for all field centers.

24.4 Archive of the Final Dietary and Supplement Data Files at NRC

Electronic copies of the final dietary and supplement recalls are stored in a computer with access only for the personnel working for the SOL-Youth at NRC. Backup copies are stored on a secure server at the University of Minnesota, Division of Epidemiology and Community Health. All printed reports and forms are kept in folders at the NRC in a locked file cabinet until such time that the CSCC advises the NRC of the disposition of these files.

25 Transmission of the Final Dietary and Supplement Data Files to the CSCC

Each month NRC submits a backup file and an output file with the final dietary and supplement data to the CSCC via the ftp. The Status Report informs the CSCC of the number of recalls that are in process either at NRC. Those recalls are not sent to the CSCC until they are completed. Therefore, any outstanding recalls are sent with a subsequent batch, usually at the end of the following month.

Appendices

Appendix 1: SOL-Youth Dietary and Supplement Recall Checklist

Participant ID: _____

In-Person Recall (check): _____

Telephone Recall (check): _____

Dietary Interviewer	Complete review on the day the recall is collected	Check (✓)	Date	ID**
Header tab reviewed (see instructions on the back of checklist).				
Food tab reviewed.				
Trailer tab reviewed.				
Dietary Supplement tab reviewed.				
Missing foods and notes edited. Questions noted.*				
Unusual portions verified and documented. Questions noted.*				
Daily backup copy made and copied to the site designated location.				
Reports are printed				
Dietary and Supplement Recall Checklist forwarded to the lead interviewer				
Lead Interviewer	Completes review within 1 week of collection			
NDSR QA Reports generated. Lead Interviewer notes made on electronic copies of reports. Reports saved at field center.				
Record QA Report reviewed. Participant ID and date of intake confirmed. Documentation for atypical or unreliable recall is checked.				
Foods QA Report reviewed. Documentation for unusual foods/amounts and notes is checked.				
Missing Foods submitted through NCC website.*				
Dietary Supplements QA Report reviewed. Check (✓) each supplement as reviewed. NDSR Notes are checked.				
Sign off (bottom right hand corner) on each report and attach to this form.				
Dietary Interviewer	Complete edits within 1 week of data collection			
Edits made as noted from the lead interviewer.*				
Backup copy made and copied to the site designated storage location.				
Lead Interviewer	Prepares for submission to NCC			
Check edits.				
Move the completed record to designated project.				
NDSR Backup file submitted to NCC through the NetFiles Program				

*Use NA if not applicable.

** Dietary or Lead interviewer identification number (3 digits)

Instructions for SOL-Youth Dietary and Supplement Recall Checklist

Note: Remember to check (✓) as you verify each item checked.

Header Tab (Record Properties Report) (For more information see MOP Section 11.17.1)

✓ Check the following:

- ☐ Participant ID is correctly entered as four digits as assigned: *First letter of the field center following by a sequential number and a check digit. Participant ID assigned by the CC.*
- ☐ Date of Intake is correctly entered as the day before the recall is conducted.
- ☐ Interviewer ID is correctly entered as: **3 digits given at the diet and supplement training.**
- ☐ Visit Number is correctly entered as: **1 (in-person interview) or 2 (telephone interview).**
- ☐ Language of the interview is correctly entered. **Include number and language separated by a comma.**

Food Tab (Foods Report)

- ☐ **READ** each food and beverage name aloud to yourself so that you don't start looking over the information without actually seeing it.
- ☐ Read each food amount aloud and **VISUALIZE** what was entered.
- ☐ Read **notes** for completeness and accuracy.
- ☐ Check Servings Made and Servings Eaten for Assembled Foods.
- ☐ Use the study approved amount estimation tools and a ruler to "re-create" the portions.
- ☐ Study approved amount estimation tools used correctly for all foods or beverages.
- ☐ Portion sizes of meat, poultry, fish and cheese are described appropriately and are reasonable.
- ☐ Unusually small or large portions verified and rationale documented.
- ☐ Missing foods include a complete description of the food and amount eaten.

Trailer Tab (Record Properties Report)

- ☐ Read notes for completeness and accuracy.

Nutrients Per Food Report

- ☐ Check the gram weight for unusual amounts. Reference points include:
- ☐ 28g cheese = 1 oz; 454g steak = 1 pound; 250 g chili = 1 cup
- ☐ Check individual food items that are >400 kcal, >25 grams of fat, or >500 grams.

Dietary Supplement Tab

- ☐ Check the Dietary Supplement Report.
- ☐ Read notes for completeness and accuracy.
- ☐ Check the missing products for entire description of the product and list of ingredients.
- ☐ Verify the days, times, and amounts the product has been taken.
- ☐ Read and check the "Why taken" field for a meaningful answer.

Appendix 2: SOL-Youth Telephone Recall Availability Form

Participant Name: _____
 (English Version) Participant ID: _____

SOL-Youth Telephone Recall Availability Form

Instructions: In the space below, indicate the best days and times you would be available to receive a call for the 24-hour dietary recall. Because this call is unannounced, it is necessary that you list multiple days and times. This call may take 30-45 minutes of your time to complete. The dietary interviewer can call you from ____am to ____pm. Please keep your Food Amounts Booklet near your telephone for use during the telephone interview. A second copy of the Food Amounts Booklet can be provided to keep at work if you can be interviewed at work as well as at home.

Days	Best times of day to call	Check best times	Phone number (Include area code)
Monday	Morning (8AM-12N)		Day: _____
	Mid day (12N-5PM)		Evening: _____
	Evening (5PM-8PM)		Other: _____
Tuesday	Morning (8AM-12N)		Day: _____
	Mid day (12N-5PM)		Evening: _____
	Evening (5PM-8PM)		Other: _____
Wednesday	Morning (8AM-12N)		Day: _____
	Mid day (12N-5PM)		Evening: _____
	Evening (5PM-8PM)		Other: _____
Thursday	Morning (8AM-12N)		Day: _____
	Mid day (12N-5PM)		Evening: _____
	Evening (5PM-8PM)		Other: _____
Friday	Morning (8AM-12N)		Day: _____
	Mid day (12N-5PM)		Evening: _____
	Evening (5PM-8PM)		Other: _____
Saturday	Morning (8AM-12N)		Day: _____
	Mid day (12N-5PM)		Evening: _____
	Evening (5PM-8PM)		Other: _____
Sunday	Morning (8AM-12N)		Day: _____
	Mid day (12N-5PM)		Evening: _____
	Evening (5PM-8PM)		Other: _____

Please don't call before _____ am or after _____ pm.

Participant Name: _____
Participant ID: _____

(Spanish Version)

SOL-Youth Forma de Disponibilidad de Horario para el Recordatorio Telefónico

Instrucciones: Por favor, indique los mejores días y horas en los que usted estaría disponible para recibir un llamado para completar el recordatorio de 24-horas. Debido a que este llamado no es anunciado, es necesario que usted liste múltiples días y horas. Este llamado puede tomar unos 30-45 minutos de su tiempo en ser completado. El entrevistador puede llamarlo desde la(s) ____ a.m. hasta la(s) ____ p.m. Por favor mantenga el Folleto de las Cantidades de los Alimentos cerca de su teléfono para usarlo durante la entrevista telefónica. Usted puede recibir una segunda copia del Folleto de las Cantidades de los Alimentos para que lo mantenga en su trabajo, en el caso que usted sea entrevistado en su lugar de trabajo así como también en su casa.

Días	Mejores horarios para llamar	Seleccione Horarios	Numero telefónico (Incluya código de área)
Lunes	Mañana (8AM-12N)		Día: _____
	Mediodía (12N-5PM)		Tarde: _____
	Tarde (5PM-8PM)		Otro: _____
Martes	Mañana (8AM-12N)		Día: _____
	Mediodía (12N-5PM)		Tarde: _____
	Tarde (5PM-8PM)		Otro: _____
Miércoles	Mañana (8AM-12N)		Día: _____
	Mediodía (12N-5PM)		Tarde: _____
	Tarde (5PM-8PM)		Otro: _____
Jueves	Mañana (8AM-12N)		Día: _____
	Mediodía (12N-5PM)		Tarde: _____
	Tarde (5PM-8PM)		Otro: _____
Viernes	Mañana (8AM-12N)		Día: _____
	Mediodía (12N-5PM)		Tarde: _____
	Tarde (5PM-8PM)		Otro: _____
Sábado	Mañana (8AM-12N)		Día: _____
	Mediodía (12N-5PM)		Tarde: _____
	Tarde (5PM-8PM)		Otro: _____
Domingo	Mañana (8AM-12N)		Día: _____
	Mediodía (12N-5PM)		Tarde: _____
	Tarde (5PM-8PM)		Otro: _____

Por favor no llame antes de _____ a.m. o después de _____ p.m.

Appendix 3: SOL-Youth Telephone Contact Log

Primary Day(s) to Call: M T W Th F Sa Su

Collect Recalls from:

Primary Time(s) to Call: am (8a-12p) mid day (12p-5p) pm (5p-8p)

Participant ID:

Primary Phone Number: _____

Alternative Phone Number: _____

Line #	Date (mm/dd)	Time (am/pm)	Comments	Phone Contact Code	End Time (am/pm)	Interviewer ID
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

PENDING telephone contact codes

1- No answer/message left	5- Call back another day
2- No answer/no message left	6- Participant refusal/wants to drop
3- Busy signal	7- Needs new Food Amount Booklet
4- Call back later today	8- Other (add a note)

FINAL telephone contact codes

- 9- Recall completed (record end time for recall)
10- Other (add a note)

Appendix 4: New Food Request Form

Fields marked with an asterisk (*) are required.

Client Name*		
Client Number*		
Institution		
E-mail*		Resolution returned to this address.
Phone Number		
NDSR Version*		
New Food Name*		
Web Page		
Amount Consumed		
Serving Size		from label
Weight per Serving		from label
Calories		kcal
Fat		g
Saturated Fat		g
Trans Fat		g
Cholesterol		mg
Sodium		mg
Potassium		mg
Carbohydrate		g
Dietary Fiber		g
Sugars		g
Protein		g
Ingredients		
Vitamin A		%DV IU
Vitamin C		%DV mg

Calcium		%DV		mg
Iron		%DV		mg
Vitamin D		%DV		mcg
Vitamin E		%DV		mg
Vitamin K		%DV		mcg
Thiamin		%DV		mg
Riboflavin		%DV		mg
Niacin		%DV		mg
Vitamin B6		%DV		mg
Folic Acid		%DV		mcg
Vitamin B12		%DV		mcg
Pantothenic Acid		%DV		mg
Phosphorus		%DV		mg
Magnesium		%DV		mg
Zinc		%DV		mg
Selenium		%DV		mcg
Manganese		%DV		mg
Copper		%DV		mg
Other Information				

Appendix 5: Record Properties Report

Record Properties Report

Nutrition Data System for Research 2007

Project Abbreviation: 09W001

Participant ID: TBD

Date of intake: 05/14/2007

Project Name: Alejandra's HCHS In-Person Recalls 10/01/07

Project Abbreviation: 09W001

Record Type: Recall

Data collected in NCC database version: 2007

Data collected in software version: 2007

Dietary Supplement Assessment Module: Yes

NHANES Dietary Supplement Database Version:2003-2004

Participant ID: TBD

Participant Name:

Date of Birth: 03/01/1954

Gender: Male

Life Stage Group: Males, age 51-70 y

Date of Intake: 05/14/2007

Day of Intake: Monday

Date of Entry: 05/15/2007

Interviewer ID: TBD

Visit Number: TBE

Site ID: TBD

Notes: Week 1 of data collection October 1-7-2007. In-person recalls TBD: To be determined

Amount of Intake Was: Usual

Information Was: Reliable

Notes:

Appendix 6: Food Report

Foods Report

Nutrition Data System for Research 2007

Project Abbreviation: 09W001

Participant ID: TBD

Date of Intake: 05/14/2007

✓ 8:00a BREAKFAST HOME

- ✓ 1. orange, fresh

1 medium - 2 5/8" diameter

- ✓ 2. milk, 1% fat or lowfat

1 1/2 CP

- ✓ 3. Poptart, other toaster pastry, regular, regular

1 each

✓ 10:30a SNACK WORK

- ✓ 4. chips - snack type, Doritos Tortilla Chips - Salsa Verde!

1 bag - single serving - each 1 OZ (1.00 OZ)

- ✓ 5. cola, diet, with caffeine, sweetened with aspartame

1 can - each 12 FO (12.00 FO)

✓ 1:00p LUNCH WORK

- ✓ 6. burrito, bean (meatless), with cheese

1 each - 6" long, 8" diameter tortilla folded

Food Variables:

6.v1 I: tortilla, white flour, commercial type - plain

6.v2 I: refried beans - unknown

6.v3 I: cheese - unknown

- ✓ 7. banana, fresh or ripe

1/2 small - 6" to 6 7/8" long (0.43 medium - 7" to 7 7/8" long)

- ✓ 8. water - tap

8 FO, without ice (1.00 CP)

✓ 4:30p SNACK WORK

- ✓ 9. corn flakes, presweetened (frosted)

Foods Report

Nutrition Data System for Research 2007

Project Abbreviation: 09W001

Participant ID: TBD

Date of Intake: 05/14/2007

1/2 CP

Additions:

✓ 9.a1 milk, 2% fat or reduced fat

3/4 CP

Confirmed 2% fat milk purchased at work.

✓ 8:00p SNACK HOME

✓ 10. tea, spearmint

2 CP, without ice (16.00 FO)

no sugar or sweetener was added

✓ 11. cookies and bars, chocolate chip; without nuts, commercial package, regular

2 small (1.00 medium - approx 2 1/4" diameter)

✓ 9:00p DINNER/SUPPER HOME

✓ 12. salad, lettuce, tossed, with dressing, with tomatoes and/or carrots, without avocado, cheese or egg

1 1/2 CP

Food Variables:

12.v1 I: salad greens - mixed greens

12.v2 I: dressing for salads - oil and vinegar, homemade

12.v2v1 I: fat used in recipe - oil, Mazola Vegetable

12.v2v2 I: salt - regular

✓ 13. spaghetti - main dish (noodles and sauce), with tomato sauce, with meat, from recipe

1 CP

Food Variables:

13.v1 I: spaghetti sauce, with meat - homemade, unknown preparation

✓ 14. water - tap

12 FO, without ice (1.50 CP)

Foods Report

Nutrition Data System for Research 2007

Project Abbreviation: 09W001

Participant ID: TBD

Date of Intake: 05/14/2007

✓ 10:00p SNACK HOME

✓ 15. tea, camomile

1 CP, without ice (8.00 FO)

Additions:

✓ 15.a1 brown sugar

1 TS, unpacked

[End of Record]

Legend: a = addition; i = component/ingredient; v = variable; check = complete; ? = incomplete; m = missing food

Appendix 7: Dietary Supplements Report

Dietary Supplements Report

Nutrition Data System for Research 2007

Project Abbreviation: 09W001

Participant ID: TBD

Date of Intake: 05/14/2007

✓ 1. NATURE'S WAY ALIVE! WHOLE FOOD ENERGIZER MULTI-VITAMIN TABLETS

Taken 30 times in the last 30 days, 1 tablet/day, and 1 time (1 tablet) yesterday

Taken for: 2 Months

Why taken: Health purposes, to prevent cold

✓ 2. TUMS REGULAR STRENGTH ANTACID / CALCIUM 200 MG

Taken 10 times in the last 30 days, 2 tablets/day, and 1 time (2 tablets) yesterday

Taken for: 3 Months

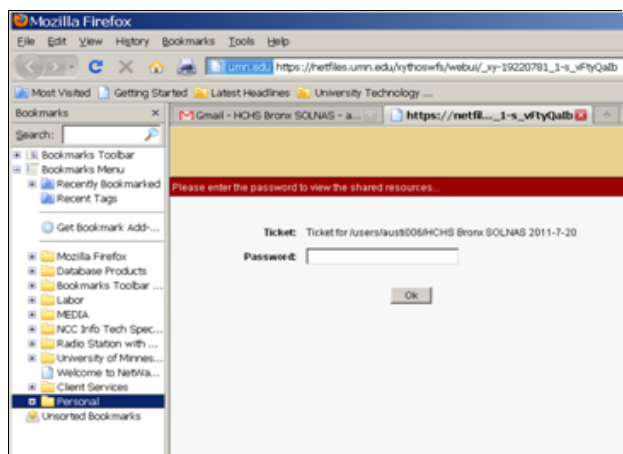
Why taken: heartburn

Legend: check = complete; ? = incomplete; m = missing product

Appendix 8: Send NDSR Backup Files to NRC and Receive NDSR Backup Files from NRC

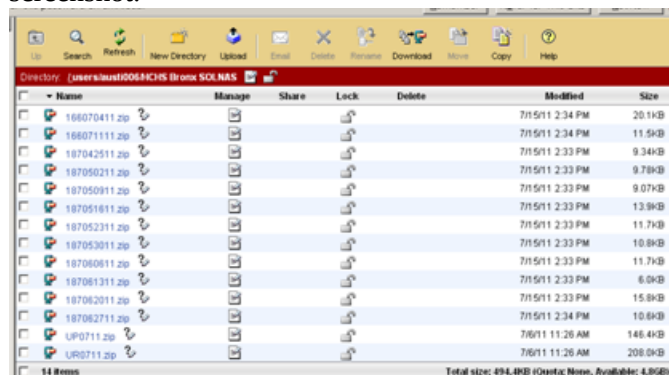
The following steps describe how to transfer NDSR backup files from the Field Centers or Coordinating Center to the Nutrition Reading Center (NRC).

The NRC data manager will initiate NetFiles sharing by creating a ticket for each field center and will email the link to each lead interviewer. Upon receipt of the link, the lead interviewer will click on the link and follow prompts insert the password and upload weekly NDSR backup files. The following screen shot shows a sample ticket:



If a password appears, replace it with the password provided by the NRC via email.

Select Upload and search/browse your computer for the NDSR backup file(s) to send. See the following screenshot:



After uploading files, a notification email should be sent to the NRC data manager, Mary Austin and the Project Nutritionist, Alex Peralta. The notification email should state the names of the backup files and the number of recalls in each backup file. Select the checkbox to the left of the file name(s) and then select

Download from the banner at the top. If you select multiple projects, they will be downloaded a single zip file. Save to the desired location, extract and then restore the backup file in NDSR2011.

When uploading files from the field center to the NRC, logon to NetFiles following the process described above.

Send an email with the subject line “(month-year) Backup file from (name of field center)” to Mary Austin at austi006@umn.edu and Alex (Alejandro Peralta Reyes) reyes067@umn.edu and include the following information:

- a. Project Abbreviation
- b. Dates of recalls (collected from – to)
- c. Number of recalls in the project
- d. NSDR version (in NDSR click on Help → About NDSR)

You will receive a confirmation email from NRC.

The same process is used to receive backup files for User Recipe and User Product Projects. Use the Checkbox to the left to select the monthly User Recipe and User Product Projects. Select the Download from from the banner at the top of the window. If you select multiple projects, the download will occur as a single zip file. Save this to a location on the hard drive of your computer and extract the projects from the zip file. Restore to the NDSR program.

Appendix 9: SOL-Youth Dietary and Supplement Recall Interview Assessment Form

Dietary Interviewer ID: _____	Field Center: _____
NRC Staff participant: _____	Date of Observation: _____
Language: _____	
1. Baseline or 2. Final (<i>circle</i>) 1. In-person or 2. Telephone recall (<i>circle</i>)	

Set-up and Introduction	Satisfactory (S) Needs Improvement (NI) Not Applicable (NA)
1. Computer set-up and NDSR program loaded and ready-to-go	
2. Forms and materials available	
3. Introduces himself/herself, establishes rapport	
4. Explains task and set the language	
5. Shows or references participant to the amount estimation tools	
6. Thanks the participant	
Comments or Concerns on Set-up and Introduction	

Quick List	Satisfactory (S) Needs Improvement (NI) Not Applicable (NA)
1. Follows interviewer prompts on quick list	
2. Prompts for additional food and beverage items with meals	
3. Prompts for items or snacks where there are time gaps	
4. Conducts review of Quick list, probing for omissions	
Comments or Concerns on the Quick List	

SOL-Youth Dietary and Supplement Recall Interview Assessment Form

Meal Information Window	Satisfactory (S) Needs Improvement (NI) Not Applicable (NA)
1. State back appropriate time given during quick list (am, pm)	
2. Uses appropriate questions for meal name and location	
Comments or Concerns on the Meal Information Window	
Food Additions and Food Search/Variable Windows	Satisfactory (S) Needs Improvement (NI) Not Applicable (NA)
1. Asks about additions until they receive a “no” response	
2. Collects complete food detail per NDSR prompts	
3. Asks appropriate variable and ingredient questions	
Comments or Concerns on the Food Additions and Search/Variable Windows	

Food Detail Window	Satisfactory (S) Needs Improvement (NI) Not Applicable (NA)
1. Collects complete food detail per NDSR prompts	
2. Collects amount detail per NDSR prompts	
3. Uses NDSR units and types appropriately	
4. Uses amount estimation tools appropriately	
5. Confirms unusual amounts with the participant	
6. Leaves appropriate and clear notes as necessary	
Comments or Concerns on the Food Detail Window	

SOL-Youth Dietary and Supplement Recall Interview Assessment Form

Review of Record and Trailer Tab	Satisfactory (S) Needs Improvement (NI) Not Applicable (NA)
1. Uses the interviewer prompts to review the record	
2. Asks for missing foods/beverages with each eating occasion	
3. Asks for missing items between meals	
4. Reviews the record reading back items, amounts, and details	
5. Asks the trailer tab questions appropriately	
Comments or Concerns on the Review of the Record or Trailer Tab	

Dietary Supplement Assessment Module	Satisfactory (S) Needs Improvement (NI) Not Applicable (NA)
1. Uses prompt to continue the recall with the DSAM	
2. Explains the next 10 questions need to be answer	
3. Collects product information per NDSR prompt	
4. Collects details of the product appropriately	
5. Collects a meaningful answer for the question “Reason for Use”	
6. Collects complete information of the missing products	
Comments or Concerns of the Dietary Supplement Assessment Module	

Interviewing Technique and Overall Assessment	Satisfactory (S) Needs Improvement (NI) Not Applicable (NA)
1. Motivates the participant and leads the interview	
2. Uses open-ended questions	
3. Maintains a comfortable pace	
4. Remains neutral throughout the interview	
5. Uses NDSR notes to document questionable foods and amounts	
6. Understands the NDSR database and can find foods quickly	
General Comments or Concerns of Overall Assessment and Interviewing	

Dietary Behavior Questionnaire	Satisfactory (S) Needs Improvement (NI) Not Applicable (NA)
1. Asks questions properly	
2. Reads all the choices for each question	
3. Records the answer the participant selected	
General Comments or Concerns on the administration of the Dietary behavior Questionnaire	

Appendix 10: SOL-Youth Dietary and Supplement Inquiry Form

NRC Staff Name:
Field center:
Project abbreviation:

Date of inquiry:
Lead interviewer:

Instructions: Review the following and provide a response if warranted. Return this form by e-mail to **reyes067@umn.edu** or by fax to 612-626-9444 to Alex Peralta within one week of receipt.

Participant ID	Date of intake	Food number	Supplement number	Inquiry/Reminder	Response

For use by NRC only
Date of Receipt:

Appendix 11: SOL-Youth Field Center Visit Checklist

NRC observer name: _____ Mode (*circle*): 1 In-person interview

Date (mm/dd/yyyy): _____ 2 Telephone Interview

Interviewer ID: _____ Field Center: _____

Instructions: Check the following fields using one of the three key letters listed below that best describe the observations during the dietary and supplement recall. Any additional observation, please use the notes field.

S: Satisfactory **U:** Unsatisfactory **NA:** Not Applicable

1.

The dietary interviewer has all the material ready for the dietary and supplement recall

Please check:

____ SOL-Youth Dietary and Supplement Recall Checklist

____ SOL-Youth Telephone Recall Availability Form

____ SOL-Youth Telephone Contact Log

____ Nasco and household food models

____ Computer set with the participant's information

____ Bag with the dietary supplements

____ Headset for the telephone interview

____ Food Amount Booklet

____ SOL-Youth Food Glossary

____ Comfortable and private environment

NOTES:

2. Establishing Rapport

____ Establishes and maintains a friendly and trusting atmosphere

____ Sets the language with the participant

____ Presents questions appropriately without biasing the interview

____ Remains objective during the interview and accepts information in a non-judgmental manner

____ Encourages active participation

3. Providing Clear and Simple Instructions

____ The dietary interviewer provides an overview about the dietary and supplement recall and also explains how the food models and the Food Amounts Booklet will be used during the interview.

Opportunity for questions is provided

____ Dietary interviewer does not get bogged down with details

4. General Interview Skills

____ Develops a natural conversational flow and talks at a good pace

- ___ Uses prompts and probes effectively to get accurate answers from the participant
- ___ Uses transitions as necessary
- ___ Is prepared and knows the materials
- ___ Repeats or rephrases question if participant did not hear or is confused
- ___ Ask every question and option on the Dietary Behavior Questionnaire...does not assume he/she knows the answer the question
- ___ Remains patient

5. Fill out the Forms

- ___ Completes the Telephone Recall Availability Form and explains the purpose of it
- ___ Registers each attempt to contact the participant during the second interview on the Telephone Contact Log

6. Quality Control

- ___ Takes time to edit and review the interview immediately after its administration
- ___ Prints the Record Properties, Foods and Dietary Supplement Reports and place them on the participant's folder

7. Confidentiality of the Information

- ___ Printed reports are stored in a secure location
- ___ The dietary interviewer does not discuss information collected with other participants
- ___ Any discussion between interviewers is conducted in private
- ___ The name of the participant is not included on the recalls

NOTES:



Hispanic Community Children's Health Study of Latino Youth (SOL Youth) Manual 4 Quality Assurance and Quality Control

August 21, 2012 - Version 2.0

Study website - <http://www.csc.unc.edu/hchs/>

Quality Assurance and Quality Control
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1. INTRODUCTION

1.1. Quality Assurance and Control Procedures

The distinction between quality assurance and quality control is both arbitrary and philosophical. The former is considered here as relating to activities to assure quality of data which take place prior to collection of data, while the latter relates more to efforts during the study to monitor the quality of data at identified points during data collection and processing. It is quality control on which this manual focuses, whereas quality assurance is the essence of the entire Manual of Operations, and includes the following activities:

- 1) Detailed protocol development. A clear description of the study design, training, certification, and the various data collection activities provides the blueprint for the study. Each protocol is a written reference for staff and researchers. Procedures for handling the routine, as well as the exceptional, are given. Those protocols constitute the SOL Youth Manuals of Operation.
- 2) Training. Training is the transfer of the study plans in the protocol to the research staff. The process has resulted in clarification and revision of the protocol. Special materials for this purpose have been developed for SOL Youth and are the basis for continuing education during the study.
- 3) Certification. Criteria to examine the adequacy of an individual's training have been established. Individuals meeting these criteria are qualified to execute a protocol or a segment of it. Certification indicates that an acceptable performance standard has been mastered or an adequate knowledge of material has been achieved. The Coordinating Center (CC) monitors the study to ensure that the research staff performs only those functions for which they are certified.

Quality control procedures involve monitoring data collection by observation (directly and by tape recording) and quantitative assessment (using repeated measurements and statistical analysis of study data). Monitoring is performed both by personnel within the field centers and by monitoring visits from the CC. A summary of selected aspects of SOL Youth Study quality control follows.

- 1) Observation monitoring. Over-the-shoulder observations of staff by supervisors are made to identify techniques that need improvement and points where the protocol is not being followed. Also, periodic monitoring visits by CC staff are made to observe clinic activities. Immediate feedback is given on issues related to protocol adherence, and recommendations for improvements are given to the field center Principal Investigator for action.
- 2) Quantitative monitoring. Repeat measurements taken by the same and different technicians are used as quality control tools. Randomly re-doing a fraction of an individual's work may not only stimulate better overall quality of data, but also allows estimation of measurement reliability. At the time of reporting the results of the study, it is important to establish that the "error" in the data is not so large as to threaten the validity of conclusions.

Mean and standard deviations of study variables, by technician, are monitored for differences among technicians or trends over time. Digit preference in anthropometry is monitored with study data.

- 3) Reporting results. Two aspects of the reporting of quality control monitoring should be emphasized. First, the results must be timely. When remedial action is required, reporting must be prompt so that a return to an acceptable level of performance is not unnecessarily delayed. Second, the reporting format must be easily understood. Tabular presentations are accompanied by clear graphical displays.
- 4) Action on results. With conscientious and trained staff, quality control reports provide an opportunity to praise a job well done. On the other hand, a poor performance is the basis for some remedial action. Depending upon past performance, the amount of error, and the appropriate action may be a simple discussion to encourage a better performance. Re-training may also be appropriate at times.

1.2. Monitoring of Data Quality and Implementing Corrective Action

The subsequent sections of this Manual describe the reports used to monitor quality control. These reports are designed to be clearly understandable and to lead to corrective actions. A Quality Control Committee (QCC) is designated by the SOL Youth Investigator Committee (PIs can choose representatives to participate) to coordinate and direct the quality control activities. This committee will have regular monthly conference calls to discuss issues that arise and review QC reports.

The QCC is charged with establishing the content of the quality control reports and reviewing them with specific attention given to deviation from protocol, and trends or shifts in data over time. The QCC prepares recommendations to the SOL Youth Investigator Committee in matters of quality assurance, and contacts field centers, reading centers, or laboratories as needed, to advise them of a problem and to discuss the mechanism for correction. The QCC has representation from the CC, field centers, reading centers, the Central Laboratory, and NHLBI.

As the repository for SOL Youth Study data, the CC is responsible for preparation and dissemination of QC reports. These reports consist of tabulated data and summary statistics, and identify protocol deviations, recurrent problems, or temporal trends. Each field center and reading center is asked to respond to the reports and to implement corrective action. The distribution of periodic QC reports is as follows:

- 1) QC reports on technician-specific performance are sent to the respective field center principal investigators, to study coordinators and to the QCC.
- 2) QC reports on laboratories/reading centers' performance are sent to the respective principal investigators and to the QCC.
- 3) Summary QC reports without technician-specific data are sent to the SOL Youth Investigator Committee after review by the QCC.

The following individuals should respond to the reports as follows:

- 1) Field center PIs, study coordinators: Review each QC report including technician-specific performance measures for their field center; identify a solution to each problem; implement corrective action; report corrective action to Coordinating Center QC Committee representative.
- 2) Central laboratory and reading center directors: Review each QC report for their laboratory/center; identify a solution to each problem; implement corrective action; report corrective action to QCC.
- 3) Quality Control Committee: Review each QC report with attention to deviation from protocol, recurrent technician or field center problems, and temporal trends; contact field center, reading center, or laboratory investigators to review data quality problems and ensure solutions are proposed; monitor the implementation of corrective action.
- 4) Investigator Committee: Review QC summary reports; monitor data quality trends; direct the QCC in areas needing special attention; propose changes to protocol when necessary.

1.3. Organization of the Quality Control Manual

What follows is a detailed list of quality assurance or quality control measures addressing each data transfer point or possible source of error. Section 2 describes certification procedures for field center staff. Section 3 describes the procedures for the Repeatability Study in which 120 participants (or individuals screened but not enrolled) repeat a portion of the clinic examination. The SOL Youth study's system of making (blinded) repeated measurements for quality control purposes is used in so many areas of the study that a separate section is devoted to description of this topic (Section 4). Section 5 discusses the types and schedules of quality control reports and describes the analysis of study data for quality control purposes. Sections 6 to 15 describe the quality control procedures for the various components of the data collection protocol.

2. CERTIFICATION PROCEDURES

Certification of study personnel is an essential aspect of effective quality assurance as well as quality control in clinical research. In order to maintain proper collection of data despite potential for personnel changes over the study period, the CC is responsible for establishing and providing the requisite minimum criteria and training and ensuring continued adherence to standards.

Although all SOL Youth staff members are expected to be familiar with the entire study protocol, the complexity of the design requires that study coordinators and staff designated to participate in certain areas of data collection for the study each be instructed and certified on specific data collection instruments and tasks.

Study coordinators are responsible for providing continuity from participant recruitment through exiting the study. Coordinators should be routinely involved in all aspects of the study with regard to participant and staff involvement as well as data collection. This includes recruitment and scheduling of participant visits as well as the performance (or supervision) of many segments of the clinic examination. Coordinators also serve as the liaison between their clinical site, the Central Laboratory, reading centers, and the CC. They communicate with participants' physicians when necessary with regard to study procedures and examination results. The study coordinator is responsible for accurate collection of data and oversight of the shipment of blood samples to the Central Laboratory, and pertinent materials to the reading centers.

The responsibilities of study technicians can vary between field centers and with staff qualifications. The study coordinator is responsible for periodically monitoring the accuracy of the work done by auxiliary personnel. However, it should be noted that the Principal Investigator is ultimately responsible for the clinical behavior and ethical standards of all staff at his/her study center.

All study coordinators must attend a Central Training Session. This training consists of a 3- day session involving all aspects of the study presented by personnel from the CC as well as clinical specialists from other academic institutions including SOL Youth field center staff.

In addition, staff must be certified on any of the following areas of the study in order to collect such data. Specific criteria and requirements for training in these areas are described in detail in the following sections of Manual 1, the field center manual (unless otherwise specified):

- A. Informed Consent – Manual 1
- B. Anthropometry – Manual 1
- C. Seated Blood Pressure – Manual 1
- D. Biospecimen Collection & Processing – Manual 2
- E. Physical Activity Monitoring – Manual 1
- F. Data Management – Manual 5
- G. Interviewing techniques – Manual 1
- H. Diet and Supplements – Manual 3

Additional specialized trainings and certifications are held for technicians/examiners responsible for sampling and recruitment (Manual 1).

Study technicians may train and be certified in any of the areas they have been assigned to by their Principal Investigator (PI) or Study Coordinator. Certified Study Coordinators or lead personnel may train and certify new personnel on site after initiation of the study by following the guidelines specified in Manual 1 and certification procedures described below. It should be noted that the Study Coordinator remains responsible for all data collection, data entry, and other procedures that may be delegated to staff. Study Coordinators should frequently monitor staff members to ensure the high quality performance of all procedures.

Study Coordinators will submit a **Certification Request Form** (Appendix 11) to the CC to document that a staff member has completed the necessary requirement for certification. The **Certification Request Form** documents how, when and which procedures/interviews were certified. The CC will assign a code number upon receipt of this form to staff who gains a certification in areas requested. Should staff learn more procedures and interviews for certification since the initial certification request, a re-submission of the form is needed to update those new areas of certification.

The CC will continually update records of all certifications at each study site, and staff code numbers will be compared against the data collection forms to ensure that only certified staff performs data collection on the specific procedures/interviews to which they have been assigned. Additional training and supervision will be carried out as individually needed at the field centers. Continued supervision will be the responsibility of the Study Coordinator. If at any time a center is found to be lacking in certification requirements, or the quality of data collection is found to be less than optimal by the Quality Control Committee, the center will be notified. If the center does not institute corrective action in the time allotted, further follow-up will take place by staff charged with study administration in an attempt to resolve the issues.

3. REPEATABILITY STUDY

3.1. Participant Selection

A portion of the clinic visit will be repeated on 120 volunteers to determine reliability of measurement procedures. The following interviews will be re-administered:

- Acculturative Stress (ASE) – administer to child only
- ARSMA (BAE) – administer to child only
- Ethnic Affirmation and Belonging (EAE) – administer to child only
- Familism (FAE) - – administer to parent
- Social Support (SSE) – administer to child
- Family Relationships –closeness/monitoring (RCE) – administer to child
- AHISMA (UNE) – administer to child

Each site will recruit 30 volunteers at a uniform rate over the study period to participate in the Repeatability Study. Given that the measurement period will last 21 months, and the repeatability study will start approximately 6-8 months after study clinic start-up, two volunteers per center per week is needed. Selection of participants need not be determined in a random fashion. However, representation from all subgroups (e.g., gender, age) is advised and will be monitored by the CC.

3.2. Data Collection Procedures

Field centers will use repeat visit ID numbers for data collected as part of the Repeatability Study. The repeat visit ID numbers are indistinguishable from other ID numbers, and forms belonging to Repeatability Study participants are entered just as regular study data. The Repeat Visit ID Form is used to match the repeat visit ID to the original SOL Youth ID of those participating in the Repeatability Study. This process is described in more detail as follows:

- 1) The day before the participant is schedule to have their repeat visit, one of the measurement staff completes the required fields on the **Repeat Visit ID Form** (affix the SOL Youth child participant ID label, the repeat visit ID, staff ID, and the date of the repeat visit).
- 2) Data collected on the repeat visit is entered into the DMS using the repeat visit ID.
- 3) The repeat clinic visit should be done no sooner than 1 week, and no later than 3 weeks after the original clinic visit.
- 4) The same or different technician may be used to collect the data, but he/she should refrain from accessing data from the participant's original visit (i.e., the technician should be blinded to the original measurement values).

Data from the original and repeat visit will be analyzed to estimate the reliability of all data collection procedures. Methods for computing reliability coefficients, within-person standard deviations, coefficients of variation, and systematic differences are similar to those outlined in section 5.2 of this manual.

4. QUALITY CONTROL SYSTEM FOR REPEATED MEASUREMENTS

To estimate the reliability of laboratory and body composition measures, some participants will provide an additional sample of blood, or will have anthropometric measurements repeated by a second technician on the same visit. The repeated anthropometric measurements are recorded on the “Anthropometry QC” (AQC) form. The additional QC laboratory specimens are labeled with a *phantom* participant ID that is indistinguishable from other ID numbers, so that the laboratory is blinded to the QC process. Forms belonging to the phantom participant are entered into the DMS just as regular study data. The **Phantom Form** (PHT) is used to match the phantom ID to the SOL Youth child’s participant IDs contributing repeat measurements. The QC phantom participant folders are created as follows:

- 1) Affix a phantom ID label to the **Phantom Form**; place these in a folder.
- 2) Every time a child participant contributes replicate data, his/her SOL Youth participant ID is affixed to the **Phantom Form** next to the type of data that was contributed. Multiple individuals will contribute the QC specimens under a single phantom ID.
- 3) After completing the **Phantom Form** for the phantom, the folder is processed along with the regular stream of participant folders as if the Exit Interview had just finished.

5. ANALYSIS OF STUDY DATA FOR QUALITY CONTROL PURPOSES

The methods to monitor the quality of the SOL Youth data collection process include analyses of the study data itself, overall, by center, and by technician. There will be periodic reporting by field center on:

- 1) status of variables in the database (no problem, skipped due to skip rule, problem with the entry), to assess the prevalence of data entry problems,
- 2) distribution of categorical (frequencies) and continuous variables (means, standard deviations, percentiles),
- 3) digit preference analysis for variables with high degree of subjective judgment by technicians, such as anthropometry data,
- 4) distribution of variables that give information on protocol adherence and the validity of data (e.g., fasting time before blood drawing).

5.1. Quality Control Reports

For a report to be of use in correcting problems, it must appear frequently and reflect as much of the collected data as possible. The frequency of reports is determined by balancing the study's need for prompt and frequent monitoring with the available resources to generate such reports and the need to accumulate enough data to have an adequate sample size. For example, analysis of adjusted means by technician is not feasible on a monthly basis, but can usefully be done each quarter. The standard monthly QC reports will contain the following information:

- 1) Digit Preference
 - a. Anthropometry
- 2) Repeated measures
 - a. Anthropometry
 - b. Biospecimens
- 3) Protocol Compliance
 - a. Fasting time
- 4) Descriptive statistics
- 5) Timeliness and completeness of data entry

5.2. Replicate Data Analysis

The following modeling process will be used to analyze replicate QC data. The total variance of the study data (σ_T^2) can be partitioned into two components: the measurement error component (σ_e^2) and the true variation between and within individuals in the study population (σ_b^2), so that $\sigma_T^2 = \sigma_b^2 + \sigma_e^2$. One quantity of interest for assessing data quality is the reliability coefficient, $R = \sigma_b^2 / (\sigma_b^2 + \sigma_e^2)$, which is one minus the proportion of total variance due to error variation.

The components of variance will be estimated from the replicate data using maximum likelihood (ML) or restricted maximum likelihood (REML) methods.

The estimates of reliability and error variance will be closely watched. In monitoring biospecimen data, $\hat{\sigma}_e$ for each assay is compared with the target standard deviation (SD) which the laboratory has set based on analyses of internal quality control pools. Blind replicate estimates which are more than twice the target SD are considered cause for concern. In addition,

if the coefficient of variation (CV) is greater than 10% corrective action should be requested from the laboratory.

To monitor for systematic differences between original and replicate measurements, the proportion of non-zero differences which are positive is monitored. With no systematic trend, this proportion should be one-half. A sign test is done to test for significant differences, and significant differences which persist over several months are pointed out to the laboratory. Means and percentiles of these differences are also presented.

Before any analysis is done on the QC replicate pairs, the data are screened for possible mismatches or "strange" observations. For each biospecimen, the mean and standard deviation of the difference between repeat and original pairs are used to determine acceptable intervals.

5.3. Monitoring for Digit Preference

Monitoring for digit preference is done by the Coordinating Center for standing height, hip and waist circumferences. Summary reports are sent to the QCC, and reports on individual technicians are sent to the Field Center. The actual technician-specific frequencies of final digits recorded are not revealed to the Field Center, to prevent technicians from overcompensating to avoid digits that they had preferred in previous reports.

Final digits 0,1,2,... 9 are possible. Let k be the number of possible final digits, so $k = 10$. For a technician with no digit preference, in a large number N of studies the expected frequency of each final digit is N/k . A Pearson chi-square goodness-of-fit test is done to test the null hypothesis that all possible final digits are observed with frequency N/k . The statistic is calculated as

$$\chi^2 = \frac{\sum_{i=1}^k \left(O_i - \frac{N}{k} \right)^2}{N/k}, \text{ where } N = \sum_{i=1}^k O_i.$$

O_i is the observed frequency of the i^{th} possible digit. For large N , this statistic is distributed approximately as a chi-square distribution with $k-1$ degrees of freedom. Note that Chi-square = 0 when the observed number for each possible digit is N/k . For each calculated value of Chi-square, the p-value is calculated as the probability upon repeated sampling (N fixed) of getting a value as extreme as that actually observed. For the validity of this test, $N \geq 25$ for blood pressure and $N \geq 50$ for anthropometry are required. A cut point of $p < .05$ is used to determine if the divergence from a uniform distribution of digits is statistically significant. However, with large enough N , even small deviations from uniformity are declared statistically significant. Thus a "digit preference score" was developed:

$DPS = 100\sqrt{\chi^2 / Nk}$. This score can be shown to have values between 0 and 100. (It is 0 when all observed digit frequencies are N/k and is 100 when all observed counts are in one cell.) Arbitrarily, a cut point used in the HCHS/SOL study for marked digit preferences was $DPS \geq 20$. A technician is judged to show "strong evidence of digit preference" if all of the following are true: (1) $N \geq$ minimum N required (25 for blood pressure, 50 for anthropometry); (2) $p < .05$; and (3) the $DPS \geq 20$. If digit preference is indicated, the technician will be required to undergo re-training.

6. ANTHROPOMETRY

6.1. Anthropometry Procedures

Anthropometry is performed with the participants wearing light clothing but no shoes (thin socks or pillow slippers are OK). The participants are asked to empty their pockets and remove their belt, jacket, heavy sweater, watches and jewelry or accessories (e.g. hair piece) that could affect weight measurement. The measurements include standing height, body weight, and abdominal and hip girth. Weight and height are measured without shoes. Important quality assurance/control measures include clear and detailed protocols for each measure, training and certification, instrument checks, replicate measurements, observation of technicians by a supervisor, and a periodic quality review of study data by the QCC.

6.2. Training and Certification

All data collectors taking anthropometric measurements must be certified by successfully completing training requirements. Training and practice sessions will be conducted prior to certification. An examiner who attends the central training and passes certification criteria can be train and certify other examiners at the field center. Certification testing requires a minimum of 3 practice subjects be measured by both the expert trainer and the trainee. Agreement between the expert and the trainer must be within 0.5 cm for height, 0.5 kg for weight, and 2 cm for the waist measurement among 2 of the 3 subjects.

6.3. Observation of Anthropometry Measurement

Technicians are observed by the clinic coordinator twice monthly for the first month and then quarterly to ensure standardization. The Checklist for Observation of Anthropometry Measurements (Appendix 3) is used to document these observations and deviations from the protocol are reviewed with the technicians. The observations are also summarized quarterly on the Summary of Observation and Equipment Checklists (Appendix 1). A minimum of 3 procedures every month is required in order to maintain certification. Local re-training sessions are scheduled when a lack of standardization (e.g., technicians who fail to meet the certification criteria described above) is observed among the technicians.

6.4. Maintenance of Equipment

Anthropometry equipment is calibrated frequently and results are recorded on an Anthropometry Equipment Calibration Log (Appendix 8). Scales are zero balanced daily and calibrated weekly, or when moved. Place the 10 kg calibrated weights on the scale and read the result when the digital display has stabilized. The values should be within 1.5 kg of the expected weight. If it weighs outside this range, notify the clinic coordinator to have the scale recalibrated by the manufacturer or by the appropriate institution personnel. Measuring tapes are checked monthly for wear or stretching by comparing them with the height stadiometer. If the measure falls outside the 119.5 - 120.5 cm the tape should be replaced. Each day the headboard of the stadiometer should be checked to ensure it moves up and down the track smoothly. These equipment checks may be done by any certified anthropometry technician. Quarterly, the equipment logs are summarized onto the Summary of Observation and Equipment Checklist (Appendix 1), which is then sent to the Coordinating Center. Copies of the equipment logs may be requested by the Coordinating Center.

6.5. Random Replicate Measurements

Five percent of child participants will be randomly selected to have anthropometry measurements repeated by a different technician. The steps in the random selection and repeat measurement process are:

- 1) Once the last item on the Anthropometry form (ANT) has been keyed into the DMS, the technician will be notified with a pop-up message if the participant has been selected for repeat measurements.
- 2) The repeat measurements should be done as soon as they can be fit in to the participant's and technician's schedules. When more than one trained technician is available, the repeat measurements should be assignment randomly to one of the certified technicians, say, by coin toss.
- 3) The technician who repeats the measurements completes the Anthropometry Quality Control (AQC) form, identical to the Anthropometry form, without looking at the measurement determined by the first technician.

Inter-technician agreement is analyzed by the QCC and serves as a criterion for recertification. Retraining sessions are scheduled at the request of the Quality Control Committee when a lack of standardization is observed among the technicians.

7. SITTING BLOOD PRESSURE

The OMRON HEM-907XL sphygmomanometer is used to measure seated blood pressure. The technician explains the procedure to the participant, measures arm circumference, wraps the arm with the correct cuff, the participant sits quietly for 5 minutes, and then records the average of the three readings. Important elements in quality assurance are training and certification programs, observation of data collection by the study coordinator, quarterly simultaneous blood pressure measurements by the technician and the study coordinator, and standard equipment maintenance procedures performed and summarized quarterly onto the **Summary of Observation and Equipment Checklist** (Appendix 1) and sent to the Coordinating Center. We will also monitor the distribution of readings from the OMRON to look for any irregularities.

7.1. Training and Certification

Blood pressure technicians are trained and certified at a central training session or at local field centers by a certified technician prior to participant recruitment. Certification results from training of new staff at the field centers are submitted using a **Certification Request Form** to the CC to document certification status.

Certification for sitting blood pressure requires the trainer to observe the trainee performing blood pressure measurements on 3 volunteers (not SOL Youth participants) to look for adherence to protocol procedures. Results are summarized onto the **Checklist for Observation of Blood Pressure and ABI Measurement** (Appendix 4).

7.2. Observation of Blood Pressure Measurement

Quarterly, the blood pressure supervisor observes each technician responsible for taking blood pressure and ABI measurements using the checklist given in Appendix 4.

7.3. Maintenance of Equipment

- 1) Availability of all sizes of cuffs: The blood pressure and ABI supervisor(s) makes certain that the field center always has the full range of blood pressure cuffs available at each blood pressure and ABI stations. Field center staff report immediately to the supervisor if they cannot find all cuff sizes at the station.
- 2) OMRON sphygmomanometer: Each OMRON unit is checked every 3 months as described in Manual 2. The results of the calibration checks are recorded on the OMRON calibration log (together with the unit number, the date and the technician ID) and sent to the HCHS Coordinating Center for inclusion in the quality control reports. A sample copy of the maintenance and calibration log is found in Appendix 15.

8. FITNESS STEP TEST

The Steck Autobody 20350 Pro Step Heavy Duty Adjustable Work Platform is used to estimating aerobic fitness or maximal oxygen uptake (VO₂max). The technician explains the procedure to the participant, checks for medication or safety checklist issues, measures standing height (or obtains the measurement from the anthropometry form (ANT)), adjusts the height of the bench, measures the resting heart rate, has the participant conduct the 3 minute step test, and then records the post-exercise and discharge heart rates. Important elements in quality assurance are training and certification programs, observation of data collection by the study coordinator, quarterly simultaneous step test measurements by the technician and the study coordinator, and standard equipment maintenance procedures performed and summarized quarterly onto the **Summary of Observation and Equipment Checklist** (Appendix 1) and sent to the Coordinating Center. We will also monitor the distribution of heart rates from the procedure to look for any irregularities.

8.1. Training and Certification

Step test technicians are trained and certified at a central training session or at local field centers by a certified technician prior to participant recruitment. Certification results from training of new staff at the field centers are submitted using a **Certification Request Form** to the CC to document certification status.

Certification for fitness step test requires the trainer to observe the trainee performing the procedure on 3 volunteers to look for adherence to protocol procedures. Results are summarized onto the **Checklist for Observation of Fitness Step Test** (Appendix 5).

8.2. Observation of Measurement

Quarterly, the study coordinator observes each technician responsible for conducting the fitness step test using the checklist given in Appendix 5.

8.3. Maintenance of Equipment

The step bench construction will need to be checked daily to ensure no components of the bench have been damaged. The metronome will need to be checked for calibration issues monthly as follows:

Equipment needed: Metronome and stopwatch.

- 1) Set the metronome at 88 counts per minute
- 2) Turn on metronome.
- 3) Start the stop watch on one “click”.
- 4) Count the number of “clicks” for 30 seconds. There should be 44 clicks.
- 5) If the count is accurate (± 1 click) then the metronome is calibrated.
- 6) If the count beyond acceptable limits:

- A. If lower than 43, set the metronome to the next greater count and redo the 30 second test. Repeat if necessary until the correct count is obtained.
- B. If greater than 45, set the metronome to the next lower count and redo the 30 second test. Repeat if necessary until the correct count is obtained.

When the correct count is obtained then that should be the correct setting. Note on metronome for future use.

9. TANNER STAGING

Children go through many biological changes during puberty. Some of these changes include maturation of their bodies. We would like to determine the stage of maturation of SOL Youth participants. In order to accurately assess the stage of maturation, 80 participants will briefly be visually examined. This examination will be similar to how a doctor periodically assesses a child, except this assessment will only be visual and there will be no touching involved. For girls, we will view their breasts and genitalia and for boys we will only view their genitalia. This visual inspection will take less than 1-2 minutes. Parents may stay in the room with the child during this part of the visual examination.

Because the onset and progression of puberty are so variable, Tanner has proposed a scale, which is now uniformly accepted, to describe the onset and progression of pubertal changes (see Manual 1, Section 15: Appendix 3 for females, 4 for males). Boys and girls are rated on a 5 point scale. Boys are rated for genital development and pubic hair growth, and girls are rated for breast development and pubic hair growth.

9.1. Training and Certification

Technicians are trained and certified at local field centers by a certified technician prior to participation in the Tanner staging assessment. Certification results from training of new staff at the field centers are submitted using a **Certification Request Form** to the CC to document certification status.

Each examiner will assess five standardized photographs for breast and pubic hair development using a practice sheet. The practice sheet includes their name, date, site, email and marked for certification.

Instructions for the examiners:

1. Open the envelope and list the breast photographs in numerical order in the left column, and the pubic hair photographs on the right-hand column.
2. Make your assessment of each photo using B for breast stage and PH for pubic hair. Stage 2 of breast development would be marked B2. Stage 4 of pubic hair development would be marked PH4. The sheet that lists and describes the maturity stages for breast and pubic hair development may be used as a reference for this certification.
3. Fax the certification sheets to Virginia Bishop at 773-269-2663 to be graded.
4. To be certified, examiners must agree with the exact stages assigned by Dr. Bishop for at least four out of five for each set and be no more than 1 stage off for the fifth.
5. Examiners, Principal Investigators and the coordinating Center will be notified of who is certified for the sexual maturity ratings.

6. Examiners who have not been initially certified can participate in a follow-up and review call (date to be determined).
7. After every examiner at each site is certified, the correct stages for all certification photographs will be available for reference and practice.

10. BIOSPECIMEN COLLECTION AND PROCESSING

10.1. Blood Collection and Processing

At the time of the telephone contact, participants are requested to fast for 12 hours before field center visit unless they are diabetics taking insulin or have other medical reasons that make fasting inadvisable. The specific steps to be taken in blood drawing and processing are described in Manual 2 (sections 3 and 4). Blood samples are either shipped refrigerated on the same day as collection or frozen at -70°C for weekly shipment to the Central Laboratory. All shipments to the Central Laboratory are made by courier or overnight delivery services. These steps are performed by technicians trained in the SOL Youth protocol and certified to have adequately mastered its details.

The first step in quality assurance for blood drawing consists in the training and certification process. Other steps include maintaining logs of equipment checks, observation of technicians (by other technicians and by CC staff on monitoring visits) as they go through the sequence of steps in blood drawing and processing; review of the condition of samples received at central laboratories for problems in shipment; and periodic analysis of the study data for participant compliance with fasting and for signs of problems in drawing or processing, such as hemolysis or delays in completing processing.

Quarterly, the field center supervisor observes each technician responsible for collection, processing, and shipping of the bio-specimens using the checklist given in Appendix 6. These observations are summarized quarterly on the Summary of Observation and Equipment Checklists (Appendix 1).

10.2. Training and Certification

To be certified, technicians complete a central training taught by certified laboratory staff which includes bio-specimen (blood, urine) collection, processing, packaging and shipping as well as quality control measures such as phantom specimens and blind replicate matching. Each technician must complete the training and pass both written and practical exams before becoming certified for the SOL Youth study. Certification requirements for personnel who do not attend the centralized training are:

- Collection, processing, and shipping bio-specimens for 3 volunteers under the supervision of the certified lead bio-specimen technician at the field center, and
- Completion and submission to the CC of the written exam (Appendix 10)

Those learning phlebotomy must also conform to their own institution's requirements for certification in this area. Once certified, each technician should draw and process at least once per week to maintain their certification status.

10.3. Maintenance of Equipment

Each field center performs daily temperature checks on the refrigerators, freezers and the refrigerated centrifuge as well as the rooms in which these are located. The actual speed of the centrifuge is checked and recorded annually with a tachometer. The results of these checks are recorded on the **Daily Centrifuge, Freezer, Refrigerator and Room Temperature Log**

(Appendix 9) kept at the blood processing station, and are summarized onto the **Summary of Observation and Equipment Checklist** (Appendix 1) quarterly and sent to the Coordinating Center.

In addition, each technician is responsible for maintaining his/her pipettes for blood processing. Certificates should be purchased with each pipette and filed. Pipettes should be calibrated and cleaned professionally on an annual basis. Monthly calibrations can also be done professionally.

10.4. Monitoring by the Central Laboratory

The Central Laboratory reviews the drawing and processing time, as recorded on the **Laboratory Collection Form** (LAB). If there are extreme values that raise questions about the validity of laboratory results, the field center is alerted to the problems.

10.5. Packing Samples for Shipment to the Central Laboratory

All vials of blood samples as well as the plastic bags in which the samples for a given participant are packed for shipment to the laboratories are labeled with the laboratory ID. To avoid delays in transit to the laboratories which might cause samples to be warmed or thawed in shipping, all samples are shipped by an overnight delivery service. One tube is shipped to the Central Laboratory the same day as it is collected. All frozen plasma, sera, and packed cells collected and stored within the last work week are shipped to the Central Laboratory on Monday with the exception of Quality Control aliquots, as discussed in the Quality Control section below. Samples can be shipped on Tuesday if the Field Center is closed on Monday, but the contact person at the Central Laboratory must be notified that the shipment will arrive one day later than usual.

A shipping list is enclosed with each shipment to the Central Laboratory giving the IDs for all sets of samples that are enclosed (see **Biospecimen Shipping** Form in SOL Youth Laboratory & Biospecimens Manual 2). The person unpacking these samples at the Central Laboratory verifies that the IDs on the vials match the ID on the plastic bag and checks both against the shipping list. If any discrepancies are detected, the Central Laboratory contacts the field center to resolve the problem.

For samples that are shipped weekly to the Central Laboratory, the staff receiving the shipment will monitor that the shipment was delivered overnight. If delays are found, the Laboratory notifies the field center to alert them. If the problem persists, and fault lies with the delivery service, the field center will change to an alternate delivery service. If delays are due to protocol violations at the field center, the Coordinating Center is contacted in addition to the field center.

Blood vials shipped to the Central Laboratory must be packed securely to avoid both breakage and warming. Full instructions for packing samples are specified in the **Biospecimen Collection and Processing** manual. The laboratories monitor the arrival condition of the samples sent from each field center on the **Biospecimen Shipping Form**. If problems are encountered, the laboratories notify the Field Centers involved. If a pattern of sample damage becomes apparent that suggests a need to modify the materials used to ship samples (e.g., excessive leakage of a certain type of vial) or how samples are packed, the QCC should be alerted to ensure appropriate action is taken.

10.6. Replicate Blood Specimens

As part of the overall quality control program for laboratory determinations from blood samples, duplicate specimens are sent to the laboratory, with one half of each specimen pair sent under the participant's regular HCHS-SOL-Youth laboratory ID number, and the other half under a Quality Control Phantom Participant (QC) laboratory ID number. The QC laboratory ID numbers are not distinguishable from other laboratory ID numbers so that this forms a blinded external quality control program monitoring measurement variability.

To reduce the burden on any single participant, extra blood is drawn from three participants and sent out under the same QC ID number. For data analysis, results on each laboratory measurement are matched to the appropriate participant results at the Coordinating Center from the QC Phantom ID Form (Appendix 6) that is completed by Field Center technicians.

If extra QC blood is drawn for a tube that is processed for weekly shipment (Tubes #1, 2, 3, 4, and 5), the aliquots are stored at the Field Center for extra week/weeks until the entire QC set is complete and then the complete QC set is sent to the Central Laboratory with a regular shipment. **Two complete QC sample sets per month** should be sent to the Central Lab for the **first six months** of the study and then for the remaining months of the study only **one complete QC sample set per month** should be sent to the Central Lab.

The QC blood samples are collected in sequential order (cycling back to Tube #1 after QC Tube #5 has been collected). Over the entire study, each Field Center will collect QC samples from approximately 7% of all specimens ($n=28$). Three participants will be needed to provide three QC replicate specimens to form one phantom ID. Thus, one-fifth of participants ($n=84=3 \times 28$) per field center will contribute to the pool of replicate specimens. Two QC sample sets should be sent to the Central Lab monthly for the first 6 months of the study. One QC sample set should be sent to the Central Lab monthly for the remaining months of the study. Choose older children with a larger body weight as QC sample candidates.

See the **Biospecimen Collection and Processing Manual** (Manual 2) for details. To reduce the chance of error in linking the real participant ID with the phantom ID, as soon as replicate sample is obtained the real participant ID label is affixed to the appropriate space on the **Phantom Form**.

11. BIOSPECIMEN PROCESSING AT THE CENTRAL LABORATORY

11.1. Procedures for Central Laboratory Analyte Determinations

Blood samples are collected and processed at the field centers for shipment to a single central laboratory for analysis of several analytical tests. In the present section, the emphasis is on quality assurance in the central laboratories, beginning with the receipt of samples. This section differs from other chapters of this manual in being more of a general overview and summary of quality assurance measures. These matters receive careful and detailed discussion in the central laboratory manual, which covers procedures for: receiving samples and storing them at a proper temperature until analysis; schedules of equipment maintenance; storage and handling of reagents, calibration standards, and quality control materials; internal and external quality control programs; and transcription and reporting of measurement results. This section of the manual supplements the laboratory manual by its discussion of reporting on the effectiveness of laboratory quality assurance procedures and of the utilization for quality control of (1) analyses of study data and (2) blind replicate samples from participants sent to the laboratory.

11.2. Receiving Samples at Laboratory

At the Central Laboratory, a record in the local data base is created using the laboratory ID number for each specimen when it arrives. It is important in handling SOL Youth frozen blood samples to avoid any unnecessary exposure to room temperature. Clear procedures for unpacking specimens upon arrival are set out in the Central Laboratory's protocol to minimize such exposure. While awaiting analysis, specimens are to be kept in storage at -70°C . The laboratory has provisions for (1) prompt detection of power failure or of failure of freezer to maintain the proper temperature, including both local alarms and alarm signals to a central security office that will notify appropriate laboratory personnel if a problem develops after hours; (2) back-up power supplies in the event of power failure; (3) plans for the use of dry ice to maintain the sample temperature until any problems with the freezer can be repaired.

The probable stability of different analytes in frozen storage has been assessed and standards set for how soon analyses will be performed after the arrival of specimens at the laboratory.

11.3. Maintenance Procedures at the Central Laboratory

Maintenance procedures for laboratory equipment are fully specified in the laboratory protocols or in manufacturers' manuals referenced in the protocols. Technicians are fully instructed in these procedures.

A regular schedule is set up for routine maintenance procedures, with logbooks kept on their performance. The laboratory supervisors review these logs on a regular basis to verify that proper maintenance procedures are being carried out according to the schedule set and that any special maintenance procedures needed are carried out.

The laboratory protocol fully specifies the reagents used, the sources from which they are procured, and the procedures used to prepare and store reagents to guarantee the stability of the reagent and the accuracy of the assay. The laboratory protocol also fully specifies the sources of calibration standards and quality control materials, the procedures used to prepare and store calibration standards and quality control materials, to guarantee the stability of the material and the accuracy of the assay. To maintain the comparability of measurements using new and old

calibration standards and controls, an overlap period is carried out, during which concentration values for the new standard are determined using the standard which is being replaced.

11.4. Internal Quality Control Pools

The Central Laboratory maintains an internal quality control program involving the analysis of multiple samples from quality control pools in each analysis run in which SOL Youth study samples are analyzed. Results on these samples are used to decide whether the measurement process is in control and whether the results on the study samples will be accepted or whether the measurements should be repeated after taking corrective action. Quarterly, the Central Laboratory provides a summary of the internal quality control results to the Coordinating Center, including the following information for each assay: (1) monthly summary statistics (n, mean, and standard deviation) on all quality control pools, including new pools being overlapped to replace established QC pools; (2) summaries of any unusual problems or conditions noted. The Coordinating Center reviews these reports for evidence of trends with time in results on these pools.

Results on analyses of quality control pools are analyzed by the Coordinating Center for trends over time that may represent either (1) shifts in measurement or (2) changes over time in the concentration of the analyte in a given pool. To determine which of these is the case, trends in a given pool can be compared with (1) trends in other pools (if any) used to control analyses of a given analyte; (2) trends in differences on measurements of samples from quality control phantom participant duplicates which are repeated several months apart; (3) trends in the study data. If there is evidence of changes in the concentration of a control pool over time, it should be replaced.

11.5. External Quality Control

For many of the assays performed in the SOL Youth study, the Central Laboratory participates in various standardization or certification programs run by outside agencies, such as the College of American Pathologists or the CDC Lipid Standardization Program. The Central Laboratory should continue to maintain acceptable results in these programs and promptly provide the Coordinating Center with copies of any reports on their performance generated by these programs. Should any of the results achieved in these programs appear problematic, they are reviewed by the Coordinating Center and the Laboratory Committee together with other quality control information on the assay in question to determine what action is appropriate.

12. PHYSICAL ACTIVITY

The physical activity assessment includes an administration of a questionnaire by a trained interviewer and data collected from having the participant wear an activity monitor over a 1-week period.

12.1. Training and Certification

Training topics include proper coding of various physical activities and knowledge of when and how to probe. Training for the activity monitor will involve instruction on the proper method of wearing the monitor. Certification is achieved either at the successful completion of central training or at the field center (local certification). These are trained by the lead certified interviewer at the corresponding field site and must demonstrate 3 successfully administered interviews observed by the lead interviewer in addition to be certified on Interviewing Techniques.

12.2. Practice Initialization, Download, and Transfer

Following central training, staff persons trained on procedures for initializing accelerometers and downloading data will transfer two new data files per week to the Coordinating Center until the start of data collection. The monitor should be initialized and worn by a staff volunteer for at least 24 hours before the data is downloaded and transferred. This regular use of the software will maintain familiarity with the software during the time between training and study start.

12.3. Adherence Report

The goal of this study is to obtain valid physical activity data on at least 80% of participants in the study. By “valid” data we mean that a participant has worn the monitor for a reasonable fraction of the expected wearing time. In many studies, that is defined as 4 days of at least 10 hours of data. In order to monitor compliance with wearing the monitor, an “Adherence Monitoring” report will be produced periodically by the Coordinating Center to indicate whether the transferred accelerometer files meet the minimum criteria for defining adherence. If a participant was found to be non-adherent, he/she could be asked to wear the monitor for another week in order to obtain more complete data.

The technician responsible for physical activity monitor processing should check the Adherence Monitoring report on the SOL Youth periodically to determine which participants could be invited for re-measuring.

13. PARTICIPANT INTERVIEW

Establishing quality control for interviews is critical in ascertaining whether interviews are conducted according to protocol. If all interviews are not conducted according to protocol, then the information that one interviewer obtains from a participant may be different from the information another interviewer might have obtained from the same participant. Audio recording and observation are used to monitor the quality of the data that interviewers collected as described below.

13.1. Certification on Interviewing Technique

Requirements for certification or re-certification on interviewing techniques include:

- Attending central training, or reviewing a presentation on Interviewing Techniques (request from the CC), for initial certification.
- Successfully completing a short written exam on material, for initial certification.
- Round-robin (explained below) or Reading Center review of taped interviews, covering all questionnaires.
- Adequate frequency of interviews with each instrument, with acceptable level of missing data.
- There are additional requirements for certification for Medications Transcription, handled by the Coordinating Center
- Certification and audiotape review is handled separately for the neurocognitive instruments and for dietary recall, by the respective reading centers.

Completed written exams are sent to the CC for evaluation.

13.2. Observation of Interviewing Technique

Quarterly, the field center supervisor will observe each interviewer twice while the interview is in progress. Interviewers will not know in advance which interviews will be monitored for quality control purposes. The study coordinator will rate the interviewer's performance using standard criteria from a checklist (Appendix 2) and give the interviewer immediate feedback. These interviews should be summarized quarterly on the Summary of Observation and Equipment Checklists (Appendix 1).

13.3. Recording of Interview

For a one week period every month, interview-administered questionnaire components will be audio recorded with a handheld digital recorder and recordings tracked on an inventory list. Prior to recording, participants should be reminded that interviews are used for quality control purposes and the information on the audiotape would be kept confidential and destroyed after review. (*Interview components not to be recorded are: the 24-h dietary recall.*)

Each digital recording for a single participant visit should contain recordings for interview components. Recordings will be labeled and organized by staff-ID, participant-ID, date and content. If the same staff member is administering multiple questionnaires consecutively to the same participant, he/she does not need to make a separate recording for each questionnaire, but can make one continuous recording.

The label/name of the recorded file(s) should look like:

One recorded participant interview file will be randomly selected and reviewed by the interview supervisor each month, checking for adherence to protocol, using the observation checklist. These reviews should be summarized on the Checklist for Review of Audio Recorded Interviews (Appendix 13).

Round-robin review: Quarterly, the CC will randomly select three participant interview recordings from each field center for review using the observation checklist. These reviews will be documented on the Quarterly Checklist for Interviews (Appendix 14). Notes about any inconsistencies in implementing the interview protocol will be documented and sent to the CC. The CC will distribute to the QC Committee a summary of the comments, protocol violations and discrepancies in interview methods and the summary will be discussed on a QC conference call with interview coordinators.

The CC will run periodic reports to see if there are staff who have not been part of the monthly recording and quarterly reviews. In this case, the CC and the Field Center will work together in order to insure that all staff are recorded during the next quarterly review.

Table 13.3.1 -Schedule for exchange of audio tapes between field centers:

Exchange	Originating Field Center	Reviewing Field Center
#1	Chicago	Bronx
	Bronx	Chicago
	Miami	San Diego
	San Diego	Miami
#2	Chicago	Miami
	Bronx	San Diego
	Miami	Chicago
	San Diego	Bronx
#3	Chicago	San Diego
	Bronx	Miami
	Miami	Bronx
	San Diego	Chicago
#4	Chicago	San Diego
	Bronx	Chicago
	Miami	Bronx
	San Diego	Miami

13.4. Analysis of Study Data

Study data will be analyzed periodically to assess frequency of interviews for each interviewer, for each questionnaire. Minimum levels will be set to allow for continued certification. Levels of missing data will also be assessed by interviewer, and maximum acceptable levels set.

13.5. Analysis of CDART Data Entry from Forms Administered on Paper

Study data collected on paper first and subsequently entered into the CDART data management system will be analyzed periodically to access proper keying of collected data. There are two main instances where this quality control check must occur:

- a. Examinations at the start of the study where ALL exam forms (questionnaires, procedures, administrative, recruitment) were collected on paper and later entered into the CDART system.
- b. Exam forms that are continually collected on paper throughout the SOL Youth Study even after the CDART system is fully operational:
 - Self-administered questionnaires to children (CDE, MAE, PDE, TUE, AUE, LSE, TSF/TSM)
 - Other SOL Youth forms collected on paper based on field center-specific clinic operations (ex. Clinic Exam Checklist forms (CKC and CKP), procedure forms, etc.)

The step-by-step procedure for the CDART data entry QC will be as follows:

1. CC to select a random sample of 10% of IDs for the QC of data entry based on a cutoff date of clinic visits.
2. FCs will compare the paper forms to the online data for those selected IDs.
3. Focus will not be on 100% of the forms for those IDs, but on key variables from selected key forms which will be outlined in the selection process and communicated to the FCs as the study progresses to allow for adjustments based on QCC findings.
4. Tolerance of 0.5 % or less, by data entry operator (staff ID); if above, must re-train and re-enter all forms of that data entry operator.

14. DIET AND SUPPLEMENTS

14.1. Training and Certification

Following central training on the use of the Nutrition Data System for Research (NDSR) software package, dietary interviewers will conduct one practice recall per day they work for the Diet and Supplement section and submit results to the Nutrition Reading Center coordinator until the start of data collection. The SOL Youth coordinator will review and provide feedback as needed. This regular use of the software will maintain familiarity with the software during the time between training and study start.

The dietary interviewer will review and edit the diet and supplement recall as soon as possible after its administration, using the 24-hour Recall Checklist (Appendix 7). Obvious errors should be corrected on the spot. When the dietary interviewers have questions, they may discuss these with the lead interviewer to reach a consensus. Lead interviewers may consult with the Nutrition Reading Center coordinator for more information. Once per week, the lead interviewer will review all dietary and supplement recalls collected at the field center. The lead interviewer may make or recommend changes to the diet and supplement recall only after discussing the proposed change(s) with the dietary interviewer.

14.2. Observation of Diet and Supplement Component of Interview

In addition to regular monitoring visits by the Coordinating Center, during the first year of data collection, NRC personnel visit each field center to evaluate adherence to the SOL Youth Field Center Manual of Procedures, observe dietary and supplement interviews, evaluate local quality control procedures, understand field center challenges, check for confidentiality of dietary and supplement data and respond to questions about overall NDSR data management and collection issues. Following the visit to the field center, the NRC staff will submit a detailed report to the CSCC about the progress and issues noted during the site visit. The SOL Youth Field Center Checklist (Appendix 7) is used to document dietary and supplement data collection procedures.

14.3. Replicate Measurements of Diet and Supplement Component of Interview

To quantitatively evaluate reliability of the dietary and supplement interviews, each dietary interviewer conducts an interview with staff from the NRC six times per year after the start of regular data collection. The NRC staff person follows an exact script for this telephone interview. The script is changed three times each year of the data collection. This approach provides replicate measurements for analysis and helps identify possible problem issues in data collection.

One method of assessing quality control for interviews is to ask a subset of participants to provide duplicate dietary recalls to different interviewers and then to compare the nutrient profiles of each individual subject's two recalls. Rather than burden participants with having to provide two dietary recalls in a row, repeated dietary recalls will be conducted on someone from the Nutrition Reading Center.

Bimonthly, each dietary interviewer will interview the same person from the Nutrition Reading Center and these interviews will be summarized on the Bimonthly Checklist for Interviews (Appendix 14). This volunteer will report on the same 24 hour period for each interviewer, and results compared. Even with only two dietary interviewers per center, over 3 years this would

provide around 150 pairs of repeat measurements for comparison. In order to acquire an early look at repeatability the frequency of these repeat measurements will be increased to monthly for the first 3 months.

15. MEDICATION TRANSCRIPTION

15.1. Training and Certification

The **Medication Use Questionnaire** (MUE) records all prescription and over-the-counter medications, including cold and allergy medications, vitamins, herbals or supplements used by participants in the four weeks preceding their interviews. The survey ascertains usage of up to 10 medications. Ascertainment includes scanning of twelve-digit Universal Product Code (UPC) bar code symbols when available. Medical Therapeutic Classification (coding) is automated where possible. Otherwise, manual coding is centralized (performed only in the Coordinating Center).

Interviewers are centrally trained and when certified, assume responsibility for providing local staff training in medication scanning / transcription.

Interviewers are certified to administer the MUE by attending the central training, completing the scanning / transcription exercise designed by the central trainer, and passing with a score of $\geq 80\%$. New staff unable to attend central training are eligible for remote certification when:

- The candidate is trained by the lead certified interviewer at the corresponding Field Center.
- The Coordinating Center has sent to the Study Coordinator a mock medication bag with detailed instructions for the candidate's certification.
- The candidate independently completes an MUE and enters it into the Data Entry System.
- The Study Coordinator returns the medication bag with all of its contents, the instructions, and printouts of the MUE screens to the Coordinating Center for evaluation.
- The candidate passes with a score of $\geq 80\%$.



Appendix 1. Summary of Observation and Equipment Checklists

Instructions: This form should be completed quarterly and sent to the Coordinating Center.

Field Center: _____ Date: ____ / ____ / ____
(mm dd yyyy)

Quarterly Reporting period:

Jan - Mar 20 ____ Apr - Jun 20 ____ July - Sep 20 ____ Oct - Dec 20 ____

A. Observation Checklist

	Technician ID	Supervisor ID	Date (mm/dd/yy)
General interview techniques	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
Anthropometry observation	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
Blood pressure observation	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
Biospecimen collection	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
Tanner Staging	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____

	Technician ID	Supervisor ID	Date (mm/dd/yy)
Fitness Step Test	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____

B. Equipment Checklist

	Frequency	No. times assessed	No. times within calibration
Anthropometry			
(1) Scale read zero	Daily	_____	_____
(2) Headboard of stadiometer	Daily	_____	_____
(3) Weight scales	Weekly	_____	_____
(4) Measuring tape	Monthly	_____	_____
Blood Pressure			
(1) Sphygmomanometer inspection	Quarterly	_____	_____
(2) Calibration checks of sphygmomanometer	Quarterly	_____	_____
Biospecimen collection			
(1) Refrigerators, freezers, room temp	Daily	_____	_____
(2) Speed of centrifuge	Annually	_____	_____
(3) Pipettes	Annually	_____	_____
Fitness Step Test			
(1) Step bench construction	Daily	_____	_____
(2) Metronome calibration	Monthly	_____	_____

Comments: _____



Appendix 2. Checklist for Observation of General Interviewing Techniques

Field Center: _____ Tech ID: _____ Supervisor ID: _____ Date: ____/____/____

Interviews Observed (Check all that apply)

To Children Only			To Parent Only		☐
After School Environment - Child	AEE	☐	Barriers to Activity in Neighborhood - Parent	BNE	☐
Away from Home Foods - Child	AFE	☐	Demographics - Parent	DPE	☐
Alcohol Susceptibility - Child	AUE	☐	Demographics - Partner/Spouse - Parent	DSE	☐
Body Image - Child	BIE	☐	Equipment Checklist in Home - Parent	ECE	☐
Child Depression Inventory - Child	CDE	☐	Familism - Parent	FAE	☐
Demographics - Child	DCE	☐	Foods in the Home - Parent	FHE	☐
Eating Disorders - Child	EDE	☐	Family Meals - Parent	FME	☐
Dietary/PA Family Support - Child	FSE	☐	Food and Neighborhood Environment - Parent	FNE	☐
How I Feel (Lie) Scale - Child	LSE	☐	Food Security - Parent	FOE	☐
MASC-10 - Child	MAE	☐	Health Insurance - Parent	HPE	☐
Physical Activity - Child	PAE	☐	Neighborhood SES - Parent	NSE	☐
Parenting for Eating and PA - Child	PCE	☐	Parenting for Eating and PA - Parent	PPE	☐
Family Relationship - Child	RCE	☐	SES - Parent	SPE	☐
Social Attitudes Towards Weight - Child	SAE	☐	To Parent About Each Child		☐
School Food Environment - Child	SFE	☐	Authoritative Parenting Index - Parent (each child)	APE	☐
Sleep Duration - Child	SLE	☐	Health Insurance - Parent (each child)	HCE	☐
Social Support - Child	SSE	☐	Medical History - Parent (each child)	MHE	☐
Tobacco Susceptibility - Child	TUE	☐	Medication Use - Parent (each child)	MUE	☐
Food Practices with TV/Video viewing - Child	TVE	☐	Pre-Migration of Child- Parent (each child)	PME	☐
AHISMA Scale - Child	UNE	☐	Family Relationship - Parent (each child)	RPE	☐
Workout Equipment in Home - Child	WEE	☐	School Type - Parent (each child)	STE	☐
To Both Parent and Child			Procedures/Exams	Code	
Acculturative Stress - Both	ASE	☐	Safety Check for Fitness Step Test	SST	☐
ARSMA Scale - Both	BAE	☐	Tanner Staging - Female - Child	TSF	☐
Ethnic Affirmation and Belonging - Both	EAE	☐	Tanner Staging - Male - Child	TSM	☐
Family Function - Both	FFE	☐	Pubertal Assessment - Child	PDE	☐

Item	Yes	No	Comments
1. Introduces her/himself at beginning of the interview; thanks participant at the end.	_____	_____	_____
2. Verifies participant's name.	_____	_____	_____
3. Explains purpose of interview when appropriate, e.g., reads introductions or transition statements when included on form.	_____	_____	_____
4. Reads questions exactly as written, stressing time frame and key elements.	_____	_____	_____
5. Demonstrates familiarity with content, flow, definitions, and skip patterns.	_____	_____	_____
6. Uses standardized tone of voice with supportive, non-judgmental statements.	_____	_____	_____
7. Paces interview in response to participant's level of comprehension/comfort.	_____	_____	_____
8. Trains participant in response patterns when appropriate.	_____	_____	_____
9. Refrains from probing except to clarify ambiguous, unclear, untrue, or inconsistent, responses.	_____	_____	_____
10. Uses standardized definitions when asked for clarification.	_____	_____	_____
11. Repeats questions stressing portions of question which were misunderstood.	_____	_____	_____
12. Selects appropriate type of probe.	_____	_____	_____
13. Accurately records participants' responses.	_____	_____	_____

Comments: _____



Appendix 3. Checklist for Observation of Anthropometry Measurement

Instructions: This checklist documents observation of anthropometry technicians by supervisors. Quarterly, checklists and logs are summarized onto the Summary of Observation and Equipment Checklists (Appendix 1). Copies of this log may be requested by the CC.

Field Center: _____ Tech ID: _____ Supervisor ID: _____ Date: ____/____/____

	Yes	No	Comments
1. Anthropometry is done BEFORE the snack.	_____	_____	_____
2. If the participant is wearing any nylon hose other than knee highs, the participant is instructed to remove hose.	_____	_____	_____
3. Participant is wearing light-weight, non-constricting underwear.	_____	_____	_____
4. Participant is wearing light clothes or scrub suit.	_____	_____	_____
5. Participant has removed shoes.	_____	_____	_____

Standing Height Measurement

1. Procedure is explained to participant.	_____	_____	_____
2. Participant's spine and heels are placed against the wall.	_____	_____	_____
3. Participant's eye to ear plane is horizontal [i.e., Frankfort plane].	_____	_____	_____
4. Subject takes a normal breath, holding breath in a <u>relaxed</u> manner, and then <u>gently</u> exhales,	_____	_____	_____
5. Measurement is taken with triangle or measuring block.	_____	_____	_____
6. Data recorded accurately in cm	_____	_____	_____

Technician's measurement of participant height: _____ cm _____ cm _____ cm

Supervisor's measurement of participant height: _____ cm _____ cm _____ cm

Waist Measurement	Yes	No	Comments
1. Procedure is explained to participant.	_____	_____	_____
2. Subject stands erect, yet relaxed, with weight equally distributed on both feet, and feet together.	_____	_____	_____
3. Measuring tape is placed around subject's waist using lateral border of ilium as bony landmark.	_____	_____	_____

4. Subject takes a normal breath and <u>gently</u> exhales, holding breath in a <u>relaxed</u> manner at the end of exhalation.	_____	_____	_____
5. Tape is horizontal and snug, but not tight enough to compress tissue. [Invert tape, <u>if needed</u> , to insure reading edge of tape is snug to skin for measurement.]	_____	_____	_____
6. Reading is recorded to the nearest centimeter, rounding down.	_____	_____	_____

Technician's measurement of participant waist: _____ cm _____ cm _____ cm

Supervisor's measurement of participant waist: _____ cm _____ cm _____ cm

Hip Measurement

Yes **No** **Comments**

1. Procedure is explained to participant.	_____	_____	_____
2. Subject stands erect, yet relaxed, with weight equally distributed on both feet, and feet together.	_____	_____	_____
3. Measuring tape is placed around subject's hip using maximal posterior protrusion of the gluteal muscles (buttocks) as landmark.	_____	_____	_____
4. Tape is horizontal and snug, but not tight enough to compress tissue. [Invert tape, <u>if needed</u> , to insure reading edge of tape is snug to skin for measurement.]	_____	_____	_____
5. Reading is recorded to the nearest centimeter, rounding down.	_____	_____	_____

Technician's measurement of participant hip: _____ cm _____ cm _____ cm

Supervisor's measurement of participant hip: _____ cm _____ cm _____ cm

Weight Measurement

Yes **No** **Comments**

A. Equipment

1. Scale firm on floor.	_____	_____	_____
2. 10 kg standard weight available.	_____	_____	_____
3. Anthropometry Equipment Calibration log up-to-date.	_____	_____	_____

B. Procedure

1. Participant prepared and procedure explained.	_____	_____	_____
2. Participant is bare-foot.	_____	_____	_____
3. Position of participant on center of scale.	_____	_____	_____
4. Balance achieved.	_____	_____	_____
5. Recordings completed.	_____	_____	_____

6. Data recorded accurately in kg _____

Technician's measurement of participant weight: _____ kg

Supervisor's measurement of participant weight: _____ kg

Comments: _____

Appendix 4. Checklist for Observation of Blood Pressure Measurement

Instructions: This checklist documents observation of blood pressure and ankle brachial index (ABI) technicians by supervisors. Quarterly, checklists and logs are summarized onto the **Summary of Observation and Equipment Checklists** (Appendix 1). Copies of this log may be requested by the CC.

Field Center: _____ Tech ID: _____ Supervisor ID: _____ Date: ____/____/____

Blood Pressure Measurement	Yes	No	Comments
1. Checks function settings on OMRON unit (ENTER, 3 inflations, 30)	_____	_____	_____
2. Checks Mode and P-setting on OMRON unit	_____	_____	_____
3. Makes sure AC adapter for OMRON unit is securely connected (tends disconnect from unit)	_____	_____	_____
4. Checks AC adapter cord and tubing for cracks	_____	_____	_____
5. Cleans all the equipment	_____	_____	_____
6. Allows subject to rest for five full minutes	_____	_____	_____
7. Performs arm measurement and cuff selection properly	_____	_____	_____
8. Identified brachial pulse location properly	_____	_____	_____
9. Proper cuff placement	_____	_____	_____
10. Attaches cuff to monitor	_____	_____	_____
11. Uses proper settings on OMRON unit	_____	_____	_____
12. Turns monitor on with ON/OFF button	_____	_____	_____
13. Sets MODE selector to AVG	_____	_____	_____
14. Sets P-SET knob to AUTO	_____	_____	_____
15. Position arm at heart level, legs uncrossed with both feet flat on the floor/step stool	_____	_____	_____
16. Pushes START button	_____	_____	_____
17. Records average, 1 st , 2 nd , 3 rd systolic and diastolic BP readings and average heart rate	_____	_____	_____
18. Instructions to participant are clear	_____	_____	_____
19. Holds arm vertically for 5 seconds between readings	_____	_____	_____

Comments: _____

Appendix 5. Checklist for Observation of Fitness Step Test Measurement

Instructions: This checklist documents observation of fitness step test measurement technicians by supervisors. Quarterly, checklists and logs are summarized onto the **Summary of Observation and Equipment Checklists** (Appendix 1). Copies of this log may be requested by the CC.

Field Center: _____ Tech ID: _____ Supervisor ID: _____ Date: ____/____/____

Fitness Measurement	Yes	No	Comments
1. Checks to be sure step-bench construction is sturdy	_____	_____	_____
2. Checks to be sure wood platform is immediately available	_____	_____	_____
3. Checks to be sure chair, metronome & stopwatch is immediately available	_____	_____	_____
4. Checks to be sure data form is available	_____	_____	_____
5. Asks the child's pre-testing screening questions	_____	_____	_____
6. Explains step-test procedures to child	_____	_____	_____
7. Measures the child's height (if needed) and sets correct bench height	_____	_____	_____
8. Identifies the child's pulse (radial or carotid)	_____	_____	_____
9. Set the proper metronome cadence (88 bts/min)	_____	_____	_____
10. Allows the child time to practice	_____	_____	_____
11. Allows child to recover before administering step-test Heart rate $\leq$ 100 bts/min	_____	_____	_____
12. Verbally assist the child in keeping proper cadence during test	_____	_____	_____
13. Provide verbal encouragement and monitoring during test	_____	_____	_____
14. At the end of the test, quickly seats child and finds pulse	_____	_____	_____
15. Counts pulse for 15 seconds and records on data form	_____	_____	_____
16. Monitors child until heart rate below 100 bts/minute	_____	_____	_____

Comments:



Appendix 6. Checklist for Observation of Biospecimen Collection and Processing

Instructions: This checklist documents observation of technicians responsible for biospecimen collection, processing, and shipping by supervisors. Quarterly, checklists and logs are summarized onto the Summary of Observation and Equipment Checklists (Appendix 1). Copies of this log may be requested by the CC.

Field Center: _____ Tech ID: _____ Supervisor ID: _____ Date: ____/____/____

Biospecimen Collection	Satisfactory/ Unsatisfactory	Comments
1. Labels checked	_____	_____
2. Participant prepared and procedure explained	_____	_____
3. Tourniquet application and release	_____	_____
4. Venipuncture technique	_____	_____
5. Tube collection sequence	_____	_____
6. Inversion technique	_____	_____
7. Tube incubation location	_____	_____
8. Stasis obtained	_____	_____
9. Needle disposal	_____	_____
10. Laboratory Collection form completion	_____	_____
 Biospecimen Processing		
1. Knowledge of centrifuge operation	_____	_____
2. Aliquotting supply set-up	_____	_____
3. Stage 1 tube spin	_____	_____
4. Stage 2 aliquotting	_____	_____
5. Stage 3 tube spin and processing	_____	_____
6. Stage 4 tube spin and processing	_____	_____
7. Vials sealed	_____	_____
8. V-Form completed	_____	_____
19. Freezer organization	_____	_____
10. Time constraints	_____	_____
11. Disposal of contaminated supplies	_____	_____
12. Paxgene tube freezing	_____	_____
 Biospecimen packing and shipping		
1. Specimens bagged	_____	_____
2. Adequate dry ice used in shipping	_____	_____
3. Shipping paperwork	_____	_____
 Miscellaneous		
1. Incident Form	_____	_____
2. QC Procedure	_____	_____
3. Containers correctly labeled for shipping	_____	_____

Comments: _____



Appendix 7. Checklist for Observation of Dietary Interview

Instructions: This checklist documents observation of technicians responsible for administration of the dietary interview. Items are circled below to indicate strengths and weaknesses in the administration of the Dietary Intake Form. A"=Acceptable "NA"=Not Acceptable. Quarterly, checklists and logs are summarized onto the Summary of Observation and Equipment Checklists (Appendix 1). Copies of this log may be requested by the CC.

Field Center: _____ Tech ID: _____ Supervisor ID: _____ Date: ____/____/____

1. Establishes Rapport

- A NA Establishes and maintain a friendly and trusting atmosphere
- A NA Presents questions appropriately
- A NA Remains objective during interview; accepts information in a non-judgmental manner
- A NA Encourages active participation

2. Provides Simple and Clear Instructions

- A NA Basic instructions included as text on the interview form were presented conversationally and participant's understanding ensured; instructions were provided, opportunity for questions was provided
- A NA Participant was oriented to cups/glasses, response cards; response card was read at least once when first given to participant
- A NA Interviewer does not get bogged down with details
- A NA Interviewer does not become preoccupied with serving sizes

3. Uses Good General Interview Skills

- A NA Reads in a natural and conversational rhythm, as if speaking; reads items conversationally (e.g. "2% milk", not "milk, 2%")
- A NA Uses transitions as necessary
- A NA Is prepared and knows the material. Reads at a good pace...not too fast...not too slow....
- A NA Responds to participant's comments (confused, bored, fatigued, frustrated, amused)
- A NA Repeats or rephrases question if answered inappropriately
- A NA Asks every question on the FFQ...does not assume that he/she knows the answer to the question
- A NA Remains patient

4. Uses Probing Techniques Appropriately

- A NA Uses silence to get a response
- A NA Does not accept a “Don’t know” answer
- A NA Watches for irrelevant answers: realizes importance of acknowledging responses and makes it clear that participant’s responses were heard, but probes for the appropriate information
- A NA Watches for vague, incomplete answers
- A NA Repeats the question or answers categories or uses paraphrasing: Acknowledges what the participant said, then goes on to solicit the necessary information
- A NA Lets the participant know that 100% accuracy is not required
- A NA Uses neutral probes that do not suggest answers or imply judgments
- A NA Stays on track and keeps participant focused on interview
- A NA Avoids "Depends” or other qualified answers by the participant

5. Cultural Sensitivity

- A NA Presents all lines of the FFQ, no matter what
- A NA If the participant is unfamiliar with a particular food, it is unlikely to be an important source of nutrients. Time is minimized on these items.
- A NA Is aware and familiar with the variety of foods on the FFQ
- A NA If participant gives an unfamiliar food (as an open-ended response), the participant is asked to describe it. Writes this information down.

Quarterly Checks

Quarter (circle one): Q1/Q2/Q3/Q4 Year: _____ Tech ID: _____

A. Submit Summary of Observation and Equipment Checklists to CSCC	Yes	Y	No	N



Appendix 9. Daily Centrifuge, Freezer, Refrigerator and Room Temperature Log

Tech ID	Date	Centrifuge	Freezer	Refrigerator	Room																								
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Appendix 10. Sample Written Exams for Certification

PRACTICAL EXAM FOR SOL YOUTH BLOOD DRAWING TECHNICIAN

1. Place the following blood collection tubes in the correct set-up order and location for the venipuncture: 2-5 mL red top, 1-4.5 mL blue top, and 2-5 mL lavender top tubes.
2. Specify which tube(s) remain at room temperature after collection, and which are put into a cup with ice slush.
3. Remove the appropriate tubes from the tray and place them in the centrifuge in balanced positions. How long do they spin? At what speed?
4. Set up a sponge tray with the appropriate number and order of specimen storage tubes. Indicate the colors of screw caps and the types of specimen put into these tubes.
5. Place the collection tubes in front of their respective sample tubes. Describe what further processing is required of each collection tube before it is aliquotted into its respective sample tube.
6. Organize the color-capped sample tubes and prepare them for shipment.
7. Describe the quality control for each piece of equipment.



WRITTEN EXAM FOR SOL YOUTH BIOSPECIMEN COLLECTION AND PROCESSING TECHNICIAN

Name: (please print) _____
DATE: _____

Field Center: _____

1. When handling biological specimens, which of the following protective apparel must **ALWAYS** be worn?
 - a) gloves
 - b) sterile shoe covers
 - c) sterile head covers
 - d) lab coat and gloves
2. For the first six months of the study, how many HCHS-Youth participants at each field center will be asked to donate additional blood specimens collected to be used as part of the phantom duplicate?
 - a) Six per month
 - b) Six per week
 - c) Everyone
 - d) Eight per week
3. From which tubes are the packed cells used?
 - a) #1 and #2
 - b) #4 and #5
 - c) #3
 - d) none of the above
4. How long should tubes #1 and #2 sit at room temperature before centrifugation?
 - a) 5 minutes
 - b) 30 minutes
 - c) 2 hours
 - d) No waiting time required
5. Why is this step (un)necessary? _____
6. For what type of tests will the 4.5-mL blue-stoppered tubes be used?
 - a) Chemistry
 - b) Lipid
 - c) Coagulation
 - d) DNA testing
7. Which of the following labels must be affixed to the outside of a frozen shipping box?
 - a) biohazardous specimens
 - b) dry ice
 - c) Category B UN3373
 - d) dry ice and Category B UN3373

8. What is the minimum amount of dry ice that must be used for frozen shipments?
- a) 2 lbs
 - b) 5 lbs
 - c) 10 lbs
 - d) 12 lbs
9. When transferring plasma to the microvials, how much plasma is left above the cells in the tubes?
- a) $\frac{1}{4}$ - $\frac{1}{2}$ inch
 - b) $\frac{1}{2}$ - $\frac{3}{4}$ inch
 - c) $\frac{3}{4}$ - 1 inch
 - d) none, all the plasma is removed
10. In what manner is the buffy coat from tubes #4 and #5 initially pipetted?
- a) Using slow aspiration avoiding plasma and red cells.
 - b) Using slow aspiration and include the remaining plasma and some red cells.
 - c) Using quick aspiration avoiding plasma and red cells.
 - d) Using quick aspiration and include the remaining plasma and some red cells.
11. What paperwork is completed and sent with each weekly frozen shipment?
- a) Copy of the Biospecimen Collection form
 - b) Original of the Biospecimen Collection form
 - c) Shipping Form Contents Sheet(s)
 - d) Original Shipping Form Face Sheet, Original Contents Sheet(s), and Original of all Biospecimen Collection forms
12. The LMX4 anesthetic cream needs to be applied 30-45 minutes prior to the blood collection to adequately numb the skin?
- a) True
 - b) False
13. The inner Styrofoam shipper needs to be taped shut?
- a) True
 - b) False
14. During the phlebotomy procedure it is important to always maintain a soft, quiet voice with the child?
- a) True
 - b) False
15. What choice below includes positive reinforcement techniques for a "happy child" following the phlebotomy procedure?
- a) Use general positives such as "good girl" or "good boy"
 - b) Positive reinforcement is not needed after the phlebotomy procedure
 - c) Say specific positive things that the child did; holding still, being brave
 - d) None of the above



Appendix 11. SOL Youth Certification Request Form

Instructions: This form documents which procedures/interviews a staff member is certified for and how they received certification. It is submitted by the **trainer** or **Study Coordinator** (SC) to Franklyn Gonzalez II at the Coordinating Center (CC) to receive a code number once a staff member is certified. A new form is submitted to the CC for additional procedures/interviews a staff member is trained and certified on after the original submission.

1. Submitted by _____ at the _____ field center on _____
(name of /manager or trainer) (date)

2. Requesting a staff code number for _____
(name of the staff)

3. Assigned staff code number by Coordinating Center (3-digit number)
(Leave this field blank if the staff does not have an existing code number)

4. Specify for which procedure/interviews the staff member has completed certification or quality control requirements and describe specific actions that were taken to achieve these steps (including supervisors or certified staff members who observed the process).

Procedure & Interview	Date Certified	Certification Method (select ALL that applies) 1 = Attended central training presentation 2 = Certified by central trainer 3 = Direct observation by the local certified lead staff member in specified area 4 = Completed written exam 5 = Completed practice. Specify how many sets of practice were performed, and the differences of the measurements compared to the local trainer's for local certification. 6 = Other (specify) 7 = N/A (not applicable to the staff member)
A. Anthropometry		
B. Sitting BP		
C. Fitness Step Test		
D. Data Management		
E. Biospecimen collection, processing		
F. Physical Activity		
G. General Interviewing Techniques		
H. Medication and Supplements		
I. Recruitment		

Coordinating Center Use Only

Assigned staff code number: _____

Certified for procedures/interviews (circle ALL that apply): A, B, C, D, E, F, G, H, I

Date Received: _____, Processed by _____ (Staff initial) _____



Appendix 14. Bimonthly Checklist for Interviews

Instructions: This checklist documents the bimonthly checks of the interviews. There should be one such log done every two months.

Month/Year	____/____ and ____/____		
	Technician ID	Supervisor ID	Date (mm/dd/yy)
Two interviews randomly selected and sent to another field center (Excluding 24 Hour Dietary Recall Neurocognitive Interview)	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
Dietary interviewer interviews the same person from the Nutrition Reading Center	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
_____	_____	_____	

Appendix 15. OMRON Maintenance and Calibration Log

Instructions: This checklist documents the quarterly checks for the OMRON. There should be one such log done every quarter. If there is more than one sphygmomanometer used, indicate the checks with a separate log for each sphygmomanometer.

Tech ID: _____ Field Center: _____ Date: _____ OMRON unit #: _____

Cracking?	Yes	Y	No	N	Action: _____
Holes?	Yes	Y	No	N	Action: _____
Worn outer cloth of Velcro?	Yes	Y	No	N	Action: _____
Leakage of cuff bladder?	Yes	Y	No	N	Action: _____

Calibration Check with Pressure-Vacuum Meter (see Manual 2, section 12.7.2)

Smooth descent of OMRON LED mm Hg from 280 to 20 mm Hg? Yes Y No N

Observed pressure values on the Pressure-Vacuum Meter and the OMRON from 250 to 20 mmHg, in approximant decrements of 20 mm Hg:

Measurement Number	Pressure-Vacuum Meter					OMRON				
1					mmHg					mmHg
2					mmHg					mmHg
3					mmHg					mmHg
4					mmHg					mmHg
5					mmHg					mmHg
6					mmHg					mmHg
7					mmHg					mmHg
8					mmHg					mmHg
9					mmHg					mmHg
10					mmHg					mmHg
11					mmHg					mmHg
12					mmHg					mmHg

Appendix 16. Timeline for Supervisor Checking of Technicians

Table 1: Frequency of Regular Checks and Observations (with section number where task description can be found)	
Daily	Anthropometry scales balanced to read zero (Appendix 8) – 6.4 Headboard of the stadiometer checked (Appendix 8) – 6.4 Construction of step bench checked (Appendix 5) – 7.3 Temperature check in refrigerators, freezers, etc. (Appendix 9) – 10.3
Weekly	Anthropometry scales calibrated or when scaled moved (Appendix 8) – 6.4
Monthly	Measuring tapes checked for wear or stretching (Appendix 8) – 6.4 One audio recorded interview selected and reviewed by coordinator (Appendix 2), recorded (Appendix 13) – 14.3 Calibration of metronome (Appendix 5) – 7.3
Bimonthly	Each dietary interviewer will interview the same person from Nutrition Reading Center (Appendix 14) – 14.3 Coordinator selects two audiotapes per interviewer to be mailed to another center (Appendix 14) – 13.3
Quarterly	Anthropometry technicians observed (Appendix 3), recorded (Appendix 1) – 6.3 Anthropometry equipment checks summarized, info sent to CC (Appendix 1) – 6.4 Calibration and inspection of the OMRON (Appendix 15), recorded (Appendix 1) – 7.3 Biospecimen technicians collecting, processing and shipping observed (Appendix 6), recorded (Appendix 1) – 10.1 Biospecimen equipment checks summarized, info sent to CC (Appendix 1) – 10.3 Supervisor observes interviewer twice (Appendix 2), recorded (Appendix 1) – 13.2 Supervisor observes dietary interview (Appendix 7), recorded (Appendix 1) – 14.2
Annually	Checking of the actual speed of the centrifuge (Appendix 1) – 10.3 Calibration and professional cleaning of pipettes (Appendix 1) – 10.3

Table 2: Frequency of Additional Checks and Observations During the First Three Months of Study	
Twice during the first month	Anthropometry technicians observed (Appendix 3) – 6.3
Monthly for the first three months	Each dietary interviewer will interview the same person from Nutrition Reading Center – 14.3



SOL Youth Manual 05 Data Management

August 22, 2012 - Version 3

Study website - <http://www.csc.unc.edu/hchs/>

SOL Youth Manual 5 - Data Management

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1. SOL YOUTH Field Center Data Management

This data management manual focuses on SOL Youth data collection and processing procedures at the field centers, at the central agencies and at the Coordinating Center (CC.) Topics include identification of participants, data collection forms and procedures, instructions for completion of paper and electronic forms (including corrections), data transfer and naming conventions, revisions to manuals and forms, and general guidelines to ensure data security, accuracy, and accessibility at field centers and central agencies.

1.1. Web-Based Data Management

The SOL Youth data management software Carolina Data Acquisition and Reporting Tool (CDART) is a system created to manage data collected in the SOL Youth study. The field centers and reading centers will be using this system to collect SOL Youth data. CDART runs over the Internet from any computer with a high speed internet connection, using Firefox or Google-Chrome web browser (do not use Internet Explorer.) By design, CDART supports data entry either interactively “on screen” during data collection, or from paper forms. However with the exceptions noted below, the data collection protocol specifies direct entry into the CDART as the mode of data collection. Work station configuration at the field centers should be arranged accordingly. In all circumstances when information is collected on paper form, transcription into the CDART should occur before the participant leaves the field center, to allow for clarification and collection of missing items. The forms that may be collected on paper first are:

Recruitment/Administrative

- Household Screening Roster Form (HSR)
- Screening Call Tracking Form (SCT)
- Individual Eligibility Checklist Form (ELE)
- Participant Safety Screening Safety Form (PSE)

Self-Administered

- CDE - Child Depression Inventory
- MASC-10 (MAE)
- Pubertal Development (PDE)
- Tobacco Susceptibility (TUE)
- Alcohol Susceptibility (AUE)
- How I feel scale (LIE)

The separate CDART User’s Guide provides specific instructions on using CDART. Usernames and passwords for the system are provided by the CC in a secure and confidential manner to each site’s project and data managers.

CDART provides several major functions that are fundamental for data management:

Data Entry: Allows data collection of forms to be keyed, edited and updated.

Reports: Provides customized reporting based on study need. The CDART will generate participant lists, form inventories, bar-coded form labels, etc. to help the field centers with any data management-related tasks. Requests for reports or lists not provided by the CDART can be made by the field centers to the CC. Participant recruitment, scheduling, and other managing of participant flow is the responsibility of the field center.

Data Transfer: Allows field center and/or central agency data to be sent to the SOL Youth Coordinating Center for inclusion into the consolidated study database.

1.2. CDART Data Entry URL

<https://cdart.cscs.unc.edu/SYOUTH>

Copy and paste the link into the address bar in your Firefox or Google-Chrome web browser. Remember; **DO NOT** use Internet Explorer (IE.)

1.3. SOL Youth Participant ID Numbers

Study ID numbers for participants enrolled in the SOL Youth study are created and assigned to each field center by the CC as part of the recruitment process (see section “Eligibility Criteria”, of manual 1 for more details.) Bar coded study ID labels for use on data collection forms can be generated using the CDART by selecting the study ID for which you want to print a sheet of label stock.

SOL Youth participant ID’s are 8 characters long with the following format:

- Character 1: Site Identifier (B, C, M, S for Bronx, Chicago, Miami, San Diego, respectively)
- Characters 2-7: Participant ID number
- Character 8: Check Digit (based on published algorithm, used for input validation of ID)

1.4. Identification Information on Data Collection Forms

The information that identifies each form as a unique record in the CDART is the key field information contained in the “header” box at the top of the first page on all forms (see example below.) The following guidelines should be observed in filling out the "header" information located at the top of the first page on all forms.



SOL Youth Personal Information Questionnaire

ID NUMBER:								FORM CODE: AEE	Contact	0	1	SEQ #		
								VERSION: 1 1/10/12	Occasion					

When paper forms are used, preprinted, bar-coded participant ID labels should be used in the header of the form whenever possible. Study ID labels can be generated using the CDART “Report” interface. Detail information on “Reports” can be found in the CDART manual. If the 8-digit ID number is handwritten, care must be taken to make sure the number is accurate and legible for data entry.

1.4.1. Form Code and Version

The form code is unique for each data collection form in the SOL Youth study. Form codes and versions are preprinted on all forms. If form content changes during the study, those changes will result in the version being updated from the initial version, “1”, to the next whole number.

It is the sites responsibility to ensure that the appropriate versions of the forms are being used at all times. Note that the CDART will load the current version of a form automatically. The sites will be informed via email of any form changes. The new version of the paper form will be uploaded to the study website.

1.4.1.1. Selection of Form Version in CDART

Sometimes form versions have to be selected during data entry when the current version is not the version being keyed in. When different versions are available CDART will provide a column titled Version that will allow form version selection. The screen looks as follows:

TCRDMS

<< Back To Subject Selection

Subject ID: S9000004

Event Name	Form Name	Version	Occurrence
Recruitment			
Administrative			
	(PSE) SOL Youth Participant Safety Screening	1.0	
	(CKC) HCHS/SOL: SOL-Youth Clinic Check List (CKC vers. A)	1.0	
	(CKP) HCHS/SOL: SOL-Youth Clinic Check List-Parent (vers. A)	1.0	
	(ICT) SOL Youth Informed Consent Tracking	1.0	
	(IAT) SOL Youth Informed Assent Tracking	1.0	
	(ICU) SOL Youth Informed Consent Update Tracking	1.0	
	(IAU) SOL Youth Informed Assent Update Tracking	1.0	
	(IYT) SOL Youth Informed Assent Young Adult Tracking	4.0	
	(PHT) SOL Youth Phantom Form	1.0	
	(IYU) SOL Youth Informed Assent Young Adult Update Tracking	4.0	
	(MEE) SOL Youth Minor Adverse Event Form	1.0	
	(SEE) SOL Youth Serious Adverse Event Form	1.0	

Version selection column

Left sidebar menu:

- Name: sy_test1
- Username: sy_test1
- Study: SYouth
- Site: San Diego
- [Change Study/Site](#)
- Island Administration
- User Administration
- Study Administration
- Data Capture
- Data Extraction

1.4.2. Contact Occasion

The Contact number will be used to differentiate a participant 'contact occasion' or visit over time. The contact occasion is pre-printed on forms. Given that this is the first contact time for data collection for SOL Youth participants, all interview forms and procedures are collected at contact occasion "01." As the study participant follow-up schedule is defined over time, contact occasion will be incremented.

1.4.3. Sequence Number

The sequence number (Seq #) enumerates and distinguishes multiple forms collected during a specific (i.e. the same) visit number. For all forms at the regularly scheduled contact the sequence number is simply "01." Where appropriate, the sequence number has been pre-coded on the form. Any forms that are repeated for use in quality control purposes will have a different sequence number (such as "02", "03") to distinguish them from regularly scheduled contact forms.

1.5. Administrative Information

1.5.1. Code Number IDs

Certified site staff will be assigned a 3-digit code number by the CC. The staff member must use this number on data collection screens that ask for a staff code number ID. This number is assigned by the CC. Contact the CC to obtain numbers for new staff members.

1.5.2. Date

The date to be recorded onto a data collection form header is the date of the participant contact or specimen collection (i.e. clinic visit examination date), or the date the form is completed. The date must conform to the month / day / year format as specified and be within the bounds of the time line. Pre-dating and post-dating of forms should not be done.

1.6. Data Collection

1.6.1. Background

SOL Youth uses a combination of data collection methods: direct data entry, recording on paper forms followed by data entry, and forms collected on paper only (with no data entry.) The purpose of this section is to provide instructions for completing forms. Prior to working with the forms, both this section and the specific question-by-question set of instructions for each form (QxQ) should be read carefully. (The QxQ instructions will follow the paper form in the corresponding MOP. They are also posted in the study website, following corresponding paper form.)

1.6.2. Form Structure

The CDART data entry screens are designed to parallel the data collection paper forms. The general layout of the paper forms is as follows:

First Page of Form:

- Form Title
- "Header" Information
- Participant's ID Number
- Form Code and Version
- Contact Occasion
- Sequence Number
- Data collection questions

In the CDART, the Form code, contact occasion, and version are displayed in the left-pane of the form entry screen. The form name is displayed in the heading of the form entry screen and in the form grid.

Form entry Screen
Form Grid

Event Name	Form Name
Recruitment	(SCT) SOL Youth Screening Call Tracking Form
Administrative	(ICT) SOL Youth Informed Consent Tracking
	(IAT) SOL Youth Informed Assent Tracking
	(ICU) SOL Youth Informed Consent Update Tracking
	(IAU) SOL Youth Informed Assent Update Tracking
Procedures	(ANT) SOL Youth Anthropometry
	(SBP) SOL-Youth Sitting Blood Pressure
	(BIO) BIOSPECIMEN COLLECTION FORM
	(FST) SOL-Youth Fitness Step Test
	(CHM) Chemistry Import
	ACT
Questionnaires-Child	(DCE) SOL-Youth Demographics - Child
	(CDE) SOL-Youth Child Depression Inventory - Child
	(TUE) SOL-Youth Tobacco Susceptibility - Child
	(AUE) SOL-Youth Alcohol Susceptibility - Child
	(LSE) SOL-Youth How I Feel Scale - Child
Questionnaires-About Child	(MHE) SOL-Youth Medical History - Parent (each Child)

1.6.3. Recording Responses to Questions

Many of the questions in the SOL Youth forms have a set of pre-coded responses, with instructions to “enter the appropriate response” (code) or “check all that apply” (checkbox.) However, a few questions require a written response. Some questions request a textual response. Others request elaboration of an “other” or “specify” response from a previous question. Space is provided on the form for those unstructured written responses.

If a participant’s answer does not logically fit into one of the pre-coded answers, the interviewer must specify the response by recording it on the form beside the pre-coded answers. Data entry personnel are trained to enter the additional data into note logs.

The data collection practices below must be followed at all times to assure that the recorded response accurately reflects the participant's answers and that questionnaire data can be converted to a computer-readable format.

Guidelines for the interviewer include:

- Listen to what the participant says and record the appropriate answer if the response satisfies the objective of the question.
- In recording answers to open-ended questions or “other” categories, record the response in the participant's exact words.
- On paper, record in the white space (below the questions) any responses “that don't quite fit” in one of the response categories. The interviewer's notes will help the data analyst to understand points of confusion, difficulty, etc. Notes on paper forms can be entered as “note logs” in the CDART.

On paper, print or write legibly.

- If a participant refuses to answer a question, and “refused” is not a value in the response set, write “refused” in the left-hand margin beside the question and enter **equal signs** (“=”) in the response field to signify a double strikethrough.
- A single answer code must be circled / entered for each question to represent the participant's answer.
- A “select all that apply” answer pattern is indicated with a checkbox, or with instructions to “circle all responses that apply”.

Some of the questions in the SOL Youth study ask about recall of events over time. The interviewer may assist the participant without violating probing rules by working with him/her on converting dates to duration (e.g. “for how long did you...”) or pinpointing dates or events. Another way to help with the collection of more accurate information is to ask the participant to think about the time of year or season when an event occurred.

1.6.4. General Instructions for Completing and Correcting Items on the Forms

General guidelines for the interviewer regarding forms:

Review each form and its instructions prior to use. If you are collecting data on a paper form prior to data entry, verify that you are using the appropriate form by checking its 3 letter form code, version, and date, all located in the lower left-hand corner of the page. Each unique form type will have specific instructions for filling out that form in the Field Center Procedures Manual (MOP 1.) Be familiar with the instructions described in MOP 1 before attempting to complete a form. Print all text responses legibly; do not use cursive writing if collecting data on paper first.

All items fall into one of three main categories: (1) “fill ins”, (2) multiple-choice (circle or check), and (3) qualitative information (comments/short-answer questions.) Techniques for completing each of these types of items, as well as making corrections, are described below. A general rule is to record information only in the spaces provided (except for some error corrections.)

Corrections to paper forms should be made in the following manner:

- Cross out the original response with an ‘X’ in such a way that it is still legible.
- Write the correct response above or to the side of the original response.
- Date and initial the correct response.
- In cases where numerous corrections were made to the same response, the final corrected response should be circled.
- Major changes should be documented with a brief explanation in the margin.

Corrections to electronic forms are made using the CDART. The CDART records the date and time of the update and the user who makes the change. Many corrections will be made in response to queries sent to the field center from the CC.

Do not attempt to correct errors by using correction fluid or erasers at any time. Data collection forms need to maintain the history of data recorded in the event of an audit. The audit log in the CDART maintains this history for forms which have been entered and subsequently corrected (but does not track paper-only corrections.)

When a response is outside the normal limits or seems contradictory based on other data, confirm the data and, if using paper, write “confirmed” in the margin. This will decrease time-consuming queries and help the data entry staff.

Carefully proofread each page of data for legibility, accuracy, and completeness prior to transferring the form to the data entry staff.

1.6.5. “Fill Ins”: Recording Information

“Fill Ins” refers to items where the question is given a defined space for recording the answer. Questions asking for a date, participant study ID number, height, weight, etc. will have a limited amount of space for data entry and usually require the answer to be inputted in a certain format. In the event that the response contains more characters than there is room for in the space provided by the form, indicate the correct response in the form margin near the original response, and enter the value into a note log in the CDART.

Numeric fields may have a preprinted number of decimal places. In this case, the QxQ instructions will specify the number of decimal places to be recorded. Instructions on how to round values to the expected number of decimal places are found in the QxQ instructions.

When a date is recorded, slashes ("/") are used as the separator characters for month, day, and year. These are usually preprinted in the response field on the paper form but must be entered into the CDART manually. The format to be used to record dates is indicated below the boxes. SOL Youth uses the U.S. order for recording dates (month/day/year.)

SOL Youth usually records time using a 12-hour clock, indicating AM or PM. In most cases, colons (":") are used as the separator character for hours and minutes and are typically preprinted in the response field on the paper form but must be entered for questions where hours and minutes are not separate questions.

1.6.6. “Fill Ins”: Correcting Mistakes on Paper Forms

If a number or letter is entered incorrectly, the person making the correction should first mark through the incorrect entry with an "X". Then, he/she should clearly code the correct entry above the original (incorrect) entry and initialize the correction, using his/her 3 initials, and record the date of the correction.

If a mistake is made and corrected, and then it is discovered that the correction is incorrect, make a second correction using the same rules as above.

1.6.7. “Fill Ins”: Unknown or Inapplicable Information

If an item of this type (either alphabetic or numeric) does not apply to the participant being interviewed, leave it blank. For example, if the participant does not have an "other" phone number, that item is left blank. Similarly, if the form provides spaces for three measurements, but only two are taken, the third space left blank.

1.6.8. Multiple-choice: Recording Information

In this type of question several choices are given for the answer, each having a corresponding letter and/or word. Once it is decided which answer choice is most appropriate, circle the corresponding letter on the paper form. Always circle one letter/word only. Key the letter or word into the CDART when entering the data.

1.6.9. Multiple-choice: Correcting Mistakes on Paper Forms

If a response is coded incorrectly, mark through the incorrectly coded response with an "X" and circle the correct response. Initialize and date the correction.

1.6.10. Qualitative Information: Recording Information

Some forms contain a substantial amount of qualitative data. These short answer and comment questions will be handled differently than "fill in" type data. If these types of questions are filled out by hand on paper forms, write clearly. When keying these responses, any unreadable answers/comments should be answered to the best of the data entry personnel's ability with a note describing what was illegible.

1.6.11. Skip Patterns

Generally, questions are answered in the order presented, with none omitted.

However, a skip pattern will direct that one or more questions be omitted (skipped) when they are not pertinent to the participant's situation. (For example, if question 1 pertains to gender, and question 2 pertains to pregnancy, a male respondent would be directed to skip question 2.)

Skip patterns occur in some multiple-choice items. This may be indicated on the form by an "If _____, go to question #" statement. If response associated with the skip is selected, the next item to be asked is the one indicated in the "go to" statement.

If a skip pattern response is not selected, proceed to the next item in sequence as usual. Occasionally, a skip pattern will occur in a "fill-in" item (such as, "Other, specify".) If the skip criteria are not met, continue to the next item as usual.

1.6.12. Problem Clarification and Data Queries

The CDART is programmed to automatically query out-of-range values inputted during the data entry process. However there may be a need to send queries from the CC regarding data values within or across forms. All queries will be sent electronically to the data coordinator, participants will be identified by ID number, forms will be identified by header information, data items will be identified by question numbers, the original response will be indicated, and the reason for the query will be described. A cover memo will accompany the data queries describing the problem, with suggestions of ways to resolve the problem and a timeline.

1.6.13. Permanently Missing Forms

In the event that a participant is unable to complete an exam, all forms for the contact (or visit) which were not completed should be coded in the CKP/CKC CDART form as it applies, using the appropriate notelog window option to determine a status of the form. Selections available in the Notolog-Window are: "Missing, Not Applicable, Refused..." CDART does not require that you create an empty form as permanently missing. Indicating the Status on the CKP/CKC is sufficient.

1.6.14. Missing/Unresolvable Items

In the event there is no available answer to key in for a certain item (for any reason such as the participant refused to answer, the answer was not recorded on the paper form, the participant did

not know the answer, etc.) then users should open the notelog dialog box and select the appropriate choice from the drop-down menu located at the bottom.

1.7. Security of Paper Forms

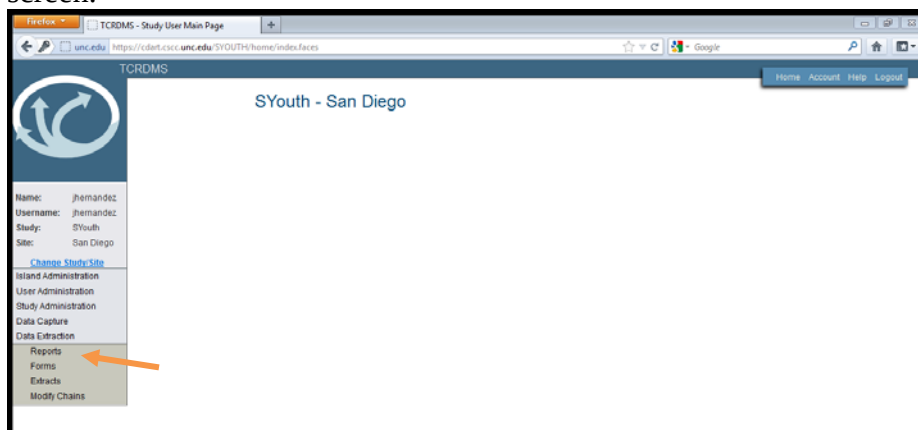
Each clinical site is responsible for assuring that participant study data is stored in a secure location that meets participant confidentiality requirements.

1.8. Data Management Reporting

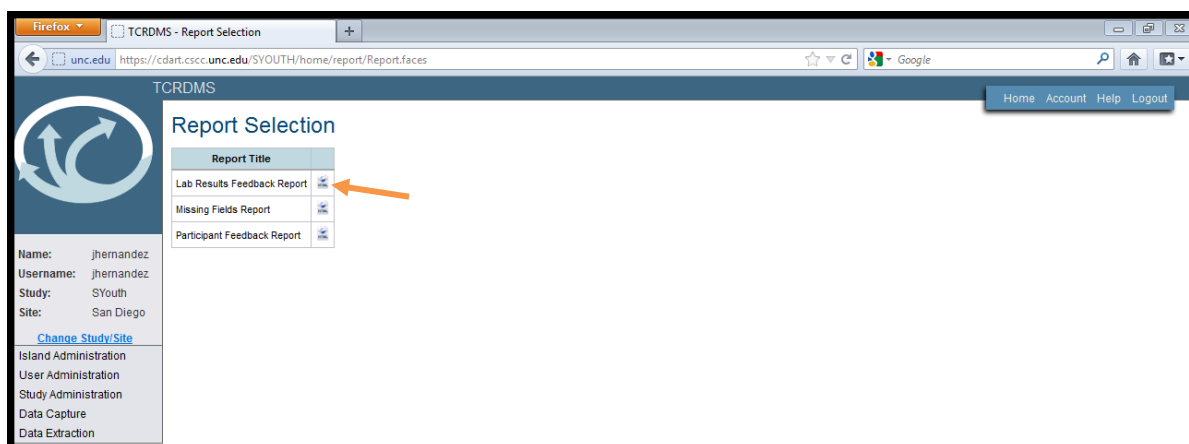
The CDART has numerous reporting programs to facilitate data management at the sites. The SOL Youth CDART User's Guide contains the documentation of the reports available in the CDART. Information on updates and changes to these reports will be provided through the Numbered Memo communication (Section 13.12.1) from the CC to the field centers. As these CDART reports are updated or changed, training conference calls with the field center data coordinators or project managers may also be scheduled.

1.8.1. Lab Results Feedback Report

To generate the lab results feedback report log onto the CDART system and select the appropriate site. Next select "Data Extraction" and then "Reports" from the left-hand side of the screen.



Click on the icon beside "Lab Results Feedback Report" on the next screen.



The following screen requires staff to enter the participant ID. After the ID has been entered, click “Ok”. The generated report can be printed and given to the participant. An example of the Lab Results Feedback Report is attached in Appendix 4.2.1.

1.8.2. Participant Feedback Report

The participant feedback report can be generated in a similar manner to the lab results feedback report. An example of a participant feedback report is attached in Appendix 4.2.2.

1.9. CDART Training and Certification

Central CDART training took place in May 2012 via conference call. Two members of each site are required to be present. Those attending may provide additional training to other staff members at their sites. Follow-up conference call training sessions will be scheduled as needed. Monitoring site visits by CC personnel are scheduled to take place throughout the study; some CDART training can occur during these visits as well (depending on the circumstances and the perceived need for such training.)

1.10. Official Study Documents

Current versions of all study documents, protocol, data collection forms, MOP, user’s guides, and other important documents are available on the study website at <http://www.cscs.unc.edu/hchs>. They are in the Study Members’ area under the “Protocols and Manuals”, and “Training Materials” pages. To access them the user must supply a username and password. Each document exists as an MS Word file and/or a PDF file. It is recommended that the PDF files be printed at the sites because formatting and special characters are retained. MS Word files are kept on the web site to facilitate working drafts as needed.

IMPORTANT: Versions of these documents that are designated as usable in the field (otherwise called “final”) were sent to each study site as hard copy in an official SOL Youth Study Documents Notebook. One notebook will be provided to each Project Coordinator and Steering Committee Member. Section 13.8.1 describes the process of communicating updates to documents and of verifying receipt of communication on modifications.

1.10.1. Numbered Memos

The CC will routinely send emails or memos that are numbered and identified as “Numbered Memos”. These memos are considered official documents and are to be stored at the back of the documents notebook. Updated information regarding the protocol, forms, MOP, QxQ’s, and other documents being used in the field will be sent to the centers as Numbered Memos. Numbered Memos will be sent to all SOL Youth Project Coordinators and Steering Committee members. It is the site’s responsibility to make sure this notification goes to all SOL Youth staff at each site that is affected. Each Project Coordinator must send email confirmation of receipt of a Numbered Memo to HCHSAdministration@unc.edu.

The numbered memo will instruct the recipient to print the updated version of the form, MOP, QxQ or other document from the Web and place this into the Site's Study Documents Notebook (Project Coordinator’s notebook), replacing the older version. Numbered memos should be stored at the back of each binder from back to front with the most recent memo on top. Each site should provide archival storage of previous versions of documents according to their Institutional requirements. The CC will also keep all versions of official documents archived. Only memos that say “CC Memo #” should be filed in the Numbered Memos section.

The Project Coordinator's notebook (not the PI’s notebook) is considered each site’s official version of the documentation. The status of this notebook is monitored during any site monitoring visits.

1.10.2. Instructions for New / Corrected Materials

Forms: Any new or corrected forms will be available to print from the website. Forms should be replaced and copied for immediate use. Email confirmation must be sent to the CC (HCHSAdministration@mail.csc.unc.edu) when the revised forms are downloaded from the Internet.

Manual: The revised pages/chapters of the SOL Youth MOP 1 should be printed from the website and filed immediately in the MOP notebook. Email confirmation must be sent to the CC (HCHSAdministration@mail.csc.unc.edu) when the revised pages/chapters are downloaded.

QxQ’s: Any new or corrected QXQ will be available to print from the website. They should be printed and filed immediately together with the appropriate form in the MOP binder. Email confirmation should be sent to the CC (HCHSAdministration@mail.csc.unc.edu) when the new QxQ’s are downloaded.

1.10.3. Instructions for Outdated Materials

All outdated pages of the MOP, forms or QxQ’s should be removed from the Documents Notebook as instructed in the Numbered Memo. Outdated materials should be archived according to each site’s institutional requirements. All study materials are archived at the CC.

1.10.4. General Filing Instructions

All participants should have either a binder or file folder filed in alphabetical order by participant ID. If the center prefers to file by last name, there should be a cross-referenced list available with the corresponding ID number. It is important for centers to be able to communicate effectively with the CC by the participant's ID number. Data queries sent to the sites from the CC will only identify a participant by ID number. Remember, before sending any forms to the CC; blind (or mask) all personal information pertaining to the participant.

The safety and confidentiality of the study data and equipment is the responsibility of each study site. There is no need for participant data to be stored on portable memory devices such as flash drives or CDs. File cabinets with locks should be used for the storage of paper forms as well as the rooms containing these file cabinets. Computers containing participant information should also be locked.

2. Central Agency Data Management

Data management at each of the six reading centers will vary. This section describes the practices at each agency and the standards for data transfer established for SOL Youth.

2.1. Central Laboratory

The University of Minnesota Fairview Hospital Clinical Laboratory will receive, store and analyze the blood chemistries for the specimens transferred from the field centers. The central laboratory will send the results to the CC who will then send files for the feedback letters to the sites..

Each transfer from the central laboratory to the CC will comprise a single Excel spreadsheet. These worksheet names should not change without notice. Variables for each data set are defined in the first line of the sheet and are different for each set of data. The names in the spreadsheet are mapped to standard CDART variable names through a table called LABNAMES. It is important that once these names are agreed upon, they do not change without notice. The files are named according to study, lab and transfer sequence.

Central laboratory analyses are sent incrementally as samples are analyzed by the University of Minnesota Fairview Hospital Clinical Laboratory. If a record needs corrections to result values, it is included in a later transfer. The new record overwrites the original one.

The Excel files are uploaded to the CC using the CDART web site. Files are processed into the SOL Youth consolidated database overnight and available for reports the following day.

Clinic visit results are added to the clinical laboratory CLAA data table. The variable mapping is HCHS-SOL Laboratory Tests, Reference Ranges, and Alert Values.

Test Names	Reference Ranges		Age Ranges	Units
	Males	Females		
hs C-reactive protein	none/NR ^a	none/NR ^a	all	mg/L
e-Selectin	none/NR ^a	none/NR ^a	all	ng/mL
TNF-alpha	none/NR ^a	none/NR ^a	all	pg/mL
IL-6	none/NR ^a	none/NR ^a	all	pg/mL
Adiponectin	none/NR ^a	none/NR ^a	all	ng/mL
VWF (antigen)	none/NR ^a	none/NR ^a	all	%
PAI-1	none/NR ^a	none/NR ^a	all	U/mL
Insulin, fasting	none/NR ^a	none/NR ^a	all	pmol/L
Glucose, fasting ^b	60 – 99	60 – 99	all	mg/dL
Hemoglobin A1c	4.3 – 6.0	4.3 – 6.0	all	%
Total cholesterol ^c	<168	<177	5 – 9 years	mg/dL
	<173	<171	10 – 14 years	mg/dL
	<168	<176	15 – 19 years	mg/dL
Triglycerides ^c	<58	<74	5 – 9 years	mg/dL
	<74	<85	10 – 14 years	mg/dL
	<88	<85	15 – 19 years	mg/dL
LDL-cholesterol ^c	<103	<115	5 – 9 years	mg/dL
	<109	<110	10 – 14 years	mg/dL
	<109	<110	15 – 19 years	mg/dL
HDL-cholesterol ^d	>49	>48	5 – 9 years	mg/dL
	>46	>45	10 – 14 years	mg/dL
	>39	>43	15 – 19 years	mg/dL

^a Non-reported test result so no reference range is necessary.

^b Based on American Diabetes Association guidelines as reported in American Diabetes Association: Diagnosis and Classification of Diabetes Mellitus. Diabetes Care 2011;34 (Suppl. 1): S11–S61.

^c Based on 75th percentile for children and adolescents as reported in Daniels SR, Greer, FR et al. Lipid Screening and cardiovascular health in childhood. Pediatrics 2008;122:198-208.

^d Based on 25th percentile for children and adolescents as reported in Daniels SR, Greer, FR et al. Lipid Screening and cardiovascular health in childhood. Pediatrics 2008;122:198-208.

*These tests will be reported to the participants.

2.2. Nutrition and Supplements Reading Center

The University of Minnesota Nutrition Coordinating Center (NCC) supported by grants from NIH developed the NDS-R and DSAM software used to collect the 24 hour diet and supplement recall. The NDS software generates one file per participant interview. It is the responsibility of the local lead interviewer at each field center to review, over-read, and update the weekly collection of diet recall interviews. Once a week, a zip archive of the raw backup files will be uploaded to the CC using the CDART web site. The transfer files are named according to study and weekly date. For example a file created at the Bronx on October 22, 2012 would be named B_HCHS_20121022.

Files are later downloaded by NCC for nutrient coding. Once a month the NCC will transfer coded dietary interview data to the SOL Youth consolidated database.

3. SOL YOUTH COORDINATING CENTER DATA MANAGEMENT

Computers at the CC are connected via a Local Area Network. The network includes clustered database servers running the Novell network operating system and is connected to a Storage Area Network (SAN.) Clustered servers running the Microsoft network operating system provide web services for the data management system. The web servers are isolated by a router from the servers holding study data.

The consolidated database will be stored in a SQL-server database. Standard transaction validity checks will be applied to all updates to the database (e.g., to prevent the addition of records with duplicate keys, etc..) Audit logs from the CDART provide complete documentation for changes to the consolidated database. Backups of the consolidated database as well as processing reports are made daily. Once a month, the current backup tape is permanently archived at an off-site data storage facility. Periodically the consolidated database goes through a series of closure checks to ensure the completeness and correctness of data collection and processing. These checks are performed on a 'frozen' version of the database defined by a specific time cut point. Typical closure checks include classifying the universe of IDs, assuring all expected forms were received and assuring all queries generated were resolved.

3.1. Central Agency Data

Data from central agencies will be processed into the consolidated database every night or the night after receipt (if not entered via the CDART.) An automated process will read the data, perform key field and record level integrity checks and add valid records to the database. Data from each agency is processed and results reports are generated. The report lists key fields of records which were not processed due to error. It also lists total number of records processed without error. The processing reports are available to the agencies, the field centers and CC SOL Youth staff.

3.2. Field Center Data

Field center data, entered via the CDART, will be copied from the web server to the local area network (LAN) every night. From the files on the LAN, data will be retrieved into statistical analysis files for use in study reports for the steering committee and NHLBI.

3.3. Reports

The CDART will provide each field center with the ability to generate a variety of reports. These include participants contacted and examined, indicators of data quality, completion status of participant result reports and specimen tracking reports, among others. Such reports make it easy for study coordinators to monitor their center's performance and the timely identification and resolution of problems in data collection. The reports for study participants and their dentists or physicians are described in the CDART Manual under the "Reports" section. .

The field center data quality reports are complementary to the monthly Steering Committee reports. The former can be run in real time by field center staff and access up-to-date data stored in the consolidated data base. The Steering Committee reports will be produced monthly (or a schedule defined by the Steering Committee) and thus reflect the status of the study at the time of the most recent retrieval. Their purpose is to provide the Steering Committee and center investigators with performance information at all sites.

3.4. Data Security and Confidentiality

Data confidentiality and security will be applied at all levels of data acquisition, transfer and storage, and applied to all study agencies, from field centers to the CC. The CDART developed by the CC meets exacting data management standards of confidentiality, as well as HIPAA requirements. Beyond the password controlled access to the study equipment and the CDART, data collected at the field centers and in hospital record rooms are encrypted by the system and can only be decrypted for display on-screen by authorized study personnel. Personal identifiers are collected on separate forms (and transferred as separate, encrypted records.) The CC will be responsive to data confidentiality requirements originating from providers of medical care or IRBs, as needed to enable the work of the field centers. When paper data collection forms are used they will be retained at secure locations at the field centers until the Steering Committee acts on recommendations from the CC to dispose of such records (e.g., incremental data closure.) The secure storage and disposition of hard copy records at field centers will follow institutional procedures at each site.

The CDART server will be housed at the CC and will be exclusively managed by CC personnel. Measures to ensure the security of the data include: restricting access to users with valid IDs and passwords; using a firewall to restrict access to the web server and to shield the CC LAN from web users; using the secure sockets layer standard to provide encryption and user authentication. In accordance with CC standard operating procedures, system security logs and event logs are monitored daily to detect unauthorized attempts to access the system. The UNC Information Technology Systems group publishes a guide called "ITS Security at UNC Chapel Hill – Securing IIS". The CC follows these guidelines, which include closing unused ports; requiring user passwords to be long and difficult to guess; deleting certain files and subdirectories; and managing file and folder privileges.

All data transferred to the CC will be stored, processed, and analyzed within the CC office suite. At the CC, all access to office space containing data is controlled through locked doors. Visitors may enter only when accompanied by a CC escort. All office space remains locked after working hours. Access to computer data files is controlled by passwords released only to the CC personnel who use such files. In addition, data files with personal identifiers (and sensitive information per designation by a study's Steering Committee) are encrypted.

As standard practice, output mailed to a field center identifies participants only by ID number. No individually identifiable information will be distributed by the CC to any study agency other than the originating field center. Printed material containing confidential information is discarded through supervised loading, transportation, and storage using a chain of custody control process, until the material can be recycled into paper pulp.

It is a requirement for all CC staff to complete a confidentiality certification procedure upon employment. Policies regarding the confidential nature of the data collected, processed, and stored at the CC are explained to all personnel, who must then sign a "confidentiality certification" to be allowed access to confidential information. The CC reinforces the confidential nature of all study data at its staff meetings.

3.5. Data Retrieval and Statistical Computing

Data will be retrieved from the study database and converted into SAS files on a regular schedule (e.g., monthly.) The retrieved files will be stored as SAS datasets within a SAS data library. Most statistical computing will be done using SAS software. All statistical computing will be performed by a dedicated statistical programming staff, using a well-established statistical computing request system that has proven itself through use with many long-term, multi-center research projects managed by the CC. This system includes thorough documentation of requested computing, programming standards, naming conventions for datasets, programs and program results, inventorying and tracking of computing requests, procedures for program review, and permanent archival of completed programs, results, and datasets.

3.6. Database Closure

Data queries will be generated on a monthly basis, immediately following data retrieval. Typical data checks include classifying the universe of enrolled IDs, assuring all expected forms were received, performing consistency checks between related data fields, assuring all queries generated are resolved, etc. If there are unexpectedly high error rates for a site or a user, we explore the causes of the error and take corrective action, such as retraining personnel or making changes to the data management system. Research indicates that this comprehensive data checking, in combination with extensive real-time edits, can substitute for double data entry for data entered from paper forms.

Periodically the study's consolidated database is subjected to closure checks for completeness and accuracy of data collection and processing. These checks are performed on a "frozen" version of the database defined by a specific time cut point, and precede the use of data for publication. Typical closure checks include classifying the universe of IDs, assuring that all

expected forms were received and all queries were resolved, examining the consistency of items across forms and visits, and checking distributions of key variables for possible errors. Current plans entail closing the database in waves, one per examination year so that investigators will have access to interim results for study monitoring, review, and publication.

4. APPENDIX

4.1. Actical Export

Sending Actical (activity monitor) data to the CSCC is a two step process.

- 1) Run the **Actical Export** program to create a zip file of all files downloaded onto the computer since the last export.
- 2) Run the DMS Utility **Actical Upload** to send the zip file to the CC.

Export

After downloading the Actical monitors to your computer (location: C:\HCHS\Programfiles\Actical\), click on the icon on the Windows Desktop called 'Actical Export'.

If there are files to send, you will see the following screen:



This screen tells you the name of the .zip file that was created – AB010006 – in the above example. The file name means this is Actical export (AB010006) for the Bronx (AB010006) computer number 1 (AB010006) export number 6 (AB0100006.) This is the file to upload to the CC.

If there are no files to send, you will get the message:

There are no files to export.

SOL-Youth Actical Data Upload

- 1) In a web browser (Chrome and Firefox work best) go to URL for study.
- 2) Login.

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TCRDMS

Please log in using the form to the right.

Username: hope

Password:

TCRDMS

Login

- 3) Select your site by clicking on the site name. (Here there is only one site because it is a test system.)

TCRDMS

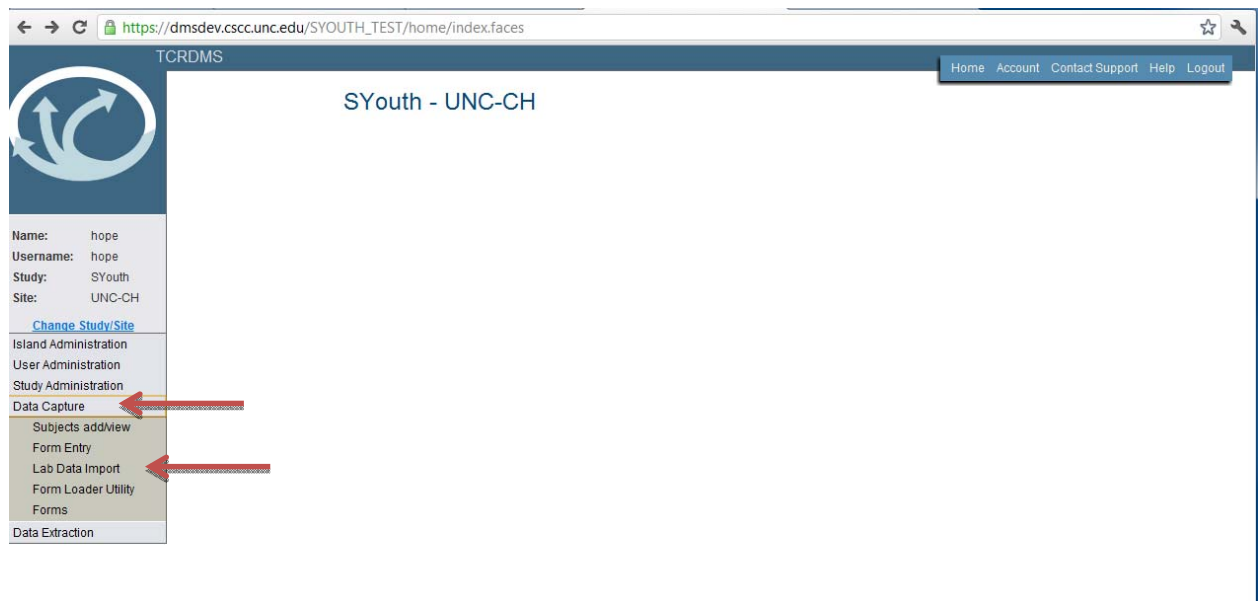
Home Account Contact Support Help Logout

Site Selection

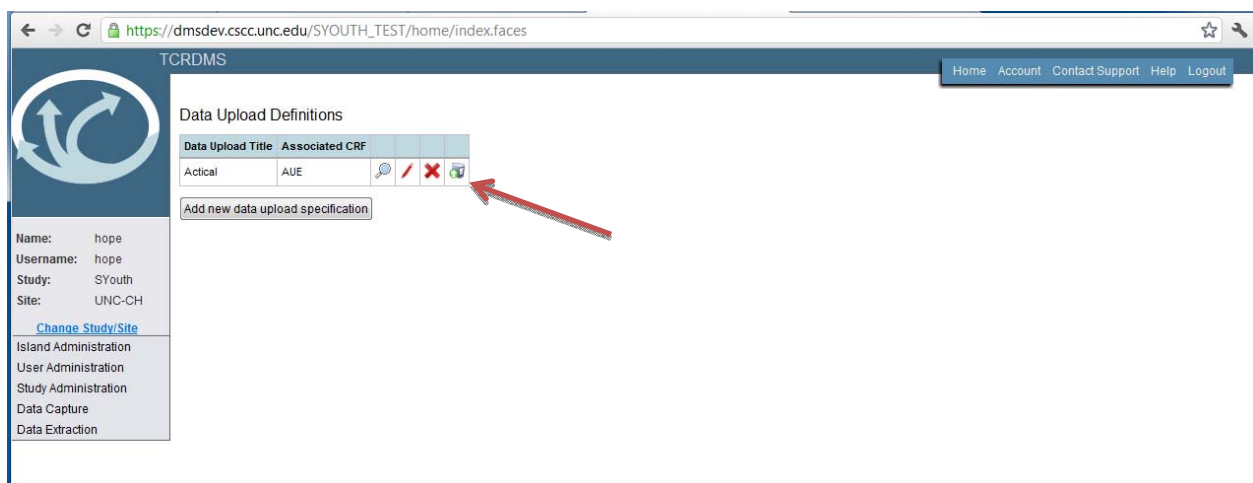
Site Name	Primary Contact	Total Subjects
UNC-CH		1

Name: hope
Username: hope
Study: SYouth
Site:
[Change Study/Site](#)
Island Administration
User Administration
Study Administration
Data Capture
Data Extraction

- 4) From left hand menu, click on 'Data Capture' to expand menu option.
- 5) Choose 'Lab Data Import'.



- 6) On the 'Actical' row, select the far right icon to upload files.



7) In the bottom panel, click 'Upload Data File'.

TCRDMS

Home Account Contact Support Help Logout

Lab Data Upload

Title: Actical Study: SYouth CRF Name: AUE

Transformation File Name:

Allow Automatic Subject Creation?: true

0 Data File(s) Previously Uploaded

File Name	Bytes	Records	File Upload Date	Delete File	Process File

Select a CSV Data File to upload

[Upload Data File](#)

[Done](#)

8) From Windows Explorer, select the zipped Actical file you want to upload (location: C:\HCHS\Export\send\.)

9) Once the file is uploaded, it will appear in the upper panel. In the screen below, the file S0001929_EE.csv shows.

TCRDMS

Home Account Contact Support Help Logout

Lab Data Upload

Title: Actical Study: SYouth CRF Name: AUE

Transformation File Name:

Allow Automatic Subject Creation?: true

0 Data File(s) Previously Uploaded

File Name	Bytes	Records	File Upload Date	Delete File	Process File
S0001929_EE.csv	534003	10719	12/06/2011 12:11 PM		

Select a CSV Data File to upload

[Upload Data File](#)

[Done](#)

10) You can upload as many files as you want. Click 'Done' when finished.

4.2. Examples of Feedback Reports

4.2.1. Lab Results Feedback Report



SOL Youth Study

ID NUMBER: X0000000

STUDY YEAR: 01 SEQ# 01

Report Version Date: 1/19/12

SUMMARY OF SOL YOUTH STUDY LAB RESULTS FOR PARENTS/CAREGIVERS OF CHILD PARTICIPANTS

Participant's Name: _____

Age: XX

Gender: X

Date of visit to the SOL Youth center: XX/XX/XXXX

Date/Time of Blood Collection: XX/XX/XXXX, XX:XX am

Date of Lab Report Release: XX/XX/XXXX

Requester's Name: FC PI Name goes here

Testing Laboratory: University of MN Advanced Research and Diagnostic Laboratory
420 Delaware St. SE
Room L275 Mayo Bldg.
Minneapolis, MN 55455
Ph. (612) 273-3645

Dear Parent/Caregiver of _____:

Thank you very much for your and your child's participation in the SOL Youth Study. This report contains a summary of evaluations conducted during your child's recent visit to the SOL Youth center. This report contains results from your child's blood tests, including cholesterol, high density lipid (HDL), low density lipid (LDL), triglycerides, glycosylated hemoglobin A1c, and fasting blood sugar.

Laboratory Test Results:

<u>Blood Tests</u>	<u>Reference Range</u>	<u>Test Result</u>	<u>Brief Interpretation</u>
Total Cholesterol (mg/dL)	Age/Gender dependent so values will be auto-pop. from DMS	XXX	Auto-populated from DMS

ID NUMBER: X00000000

Participant's Name: _____

Age: XX

Gender: X

Date of visit to the SOL Youth center: XX/XX/XXXX

Laboratory Test Results (cont.):

<u>Blood Tests</u>	<u>Reference Range</u>	<u>Test Result</u>	<u>Brief Interpretation</u>
LDL-Cholesterol (mg/dL)	Age/Gender dependent so values will be auto-pop. from DMS	XXX	Auto-populated from DMS
HDL-Cholesterol (mg/dL)	Age/Gender dependent so values will be auto-pop. from DMS	XXX	Auto-populated from DMS
Triglycerides (mg/dL)	Age/Gender dependent so values will be auto-pop. from DMS	XXX	Auto-populated from DMS
Glycosylated hemoglobin A1c (%)	4.3 – 5.6	XXX	Auto-populated from DMS
Fasting blood sugar (mg/dL)	60 - 99	XXX	Auto-populated from DMS

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We encourage you to share this report with your child's health care provider. Again, thank you very much for your and your child's participation in the SOL Youth study. Do not hesitate to contact us at _____ at your local SOL Youth center if you have any questions. We look forward to your continued participation in the Hispanic Community Children's Health/Study of Latino Youth (SOL Youth) and related projects in the future.

Sincerely,

FC PI Name goes here (Auto-populated from DMS)

BRIEF EXPLANATIONS OF THE TESTS WE PROVIDE

Total cholesterol, LDL-cholesterol and triglycerides are the major fats in your blood. For more information please see <http://www.americanheart.org/presenter.jhtml?identifier=1516>

High density lipoprotein (HDL) cholesterol is also a blood fat; it appears to protect against hardening of the arteries. You can learn more about total cholesterol, LDL-cholesterol, HDL-cholesterol and triglycerides, at <http://www.americanheart.org/presenter.jhtml?identifier=180>

Glucose is a type of blood sugar that is the body's main source of energy and the amount in the blood is elevated in conditions such as diabetes. You can find more information about glucose levels and diabetes at <http://www.diabetes.org/about-diabetes.jsp>

If glucose levels are usually high in the blood this can be measured with glycosylated hemoglobin. A buildup of hemoglobin that is glycosylated usually indicates poorly controlled blood sugar levels in diabetics or undetected diabetes. More information about this test can be found at http://en.wikipedia.org/wiki/Glycosylated_hemoglobin

4.2.2. Participant Feedback Report



SOL Youth Study

ID NUMBER: X0000000

STUDY YEAR: 01 SEQ# 01

Report Version Date: 1/19/12

SUMMARY OF SOL YOUTH STUDY EXAM RESULTS FOR PARENTS/CAREGIVERS OF CHILD PARTICIPANTS

Participant's Name: _____

Age: XX

Gender: X

Date of visit to the SOL Youth center: XX/XX/XXXX

Dear Parent/Caregiver of _____:

Thank you very much for your and your child's participation in the SOL Youth Study. This report contains a summary of evaluations conducted during your child's recent visit to the SOL Youth center. This report contains information on your child's weight and height, body mass index, and blood pressure.

Height, Weight, and Body Mass Index Results:

Weight: XXX kg (XXX lbs)

Height: XXX cm (X ft, XX in)

Body Mass Index: XX.X

BMI Percentile: XX

Body mass index (BMI) percentile is used to measure whether a child has a healthy weight compared with other youth of the same age and gender. Your child's BMI is normal if it is between the 6th and 84th percentile. If your child's BMI is below the 5th percentile, it is considered underweight. If your child's BMI is between the 85th and 94th percentile, it is considered overweight. If your child's BMI is above the 95th percentile, it is considered obese. If your child is underweight, overweight, or obese, you may want to discuss your child's results with your child's health care provider to consider options.

Blood Pressure Results:

Blood Pressure: XXX/XXX mm Hg (This is the average of three measurements taken after five minutes of rest)

Blood Pressure Percentile: XX/ XX percentile

Blood pressure (BP) percentile is used to measure how high the BP is compared to other youth of the same age, gender, and height. Blood pressure measures how hard the heart has to work to pump blood through the body. Your child's BP is considered normal if the BP is below the 90th percentile. If the BP is between the 90th and 95th percentile it may indicate pre-hypertension. If the BP is at or above the 95th percentile this may indicate hypertension. If your child's BP is not defined as normal, you may want to discuss your child's results with your child's health care provider to consider options.

We encourage you to share this report with your child's health care provider. Again, thank you very much for your and your child's participation in the SOL Youth study. Do not hesitate to contact us at _____ at your local SOL Youth center if you have any questions. We look forward to your continued participation in the Hispanic Community Children's Health/Study of Latino Youth (SOL Youth) and related projects in the future.

Sincerely,

FC PI Name goes here (Auto-populated from DMS)

BRIEF EXPLANATIONS OF THE TESTS WE PROVIDE

Obesity: The American Academy of Pediatrics recommends that health care providers to assess a child's risk for obesity and suggest weight control strategies for children who are overweight or obese. Because of the health consequences of being obese as a child, SOL Youth will report BMI categories per the American Academy of Pediatrics. You can find more information at <http://www2.aap.org/obesity/about.html>

Hypertension in children and adolescents continues to be defined as systolic BP and/or diastolic BP that is, on repeated measurement, at or above the 95th percentile. BP between the 90th and 95th percentile in childhood has been designated "high normal." To be consistent with the Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7), this level of BP will now be termed "prehypertensive." For more information, please see http://www.nhlbi.nih.gov/health/prof/heart/hbp/hbp_ped.pdf

4.2.3. Participant Depression Feedback Report



SOL Youth Study

ID NUMBER: X0000000

STUDY YEAR: 01 SEQ# 01

Report Version Date: 01/18/12

SUMMARY OF SOL YOUTH DEPRESSION RESULTS FOR PARENTS/CAREGIVERS OF CHILD PARTICIPANTS

Participant's Name: _____

Age: XX

Gender: X

Date of visit to the SOL Youth center: XX/XX/XXXX

Child Depression Inventory – Short Form (CDI-S)

CDI-S Score: XX

As part of today's assessment, your child reported a high number of symptoms associated with depression. On this screening measure, he/she reported symptoms greater than the 95% percentile. While this does not mean your child is depressed, it does suggest he/she has some concerns that should be evaluated by a health professional. We therefore recommend that you let your child's health care provider know of this result, and consider having a more formal assessment conducted by a mental health professional.

BRIEF EXPLANATIONS OF THE TESTS WE PROVIDE

The CDI-S form consists of 10 items each rated 0, 1, or 2; the range of scores for the scale is 0-20. Recent published reports indicate raw score cut-points of > 6 for boys and > 8 for girls exceeds the 95th percentile. These cut-points are used to identify children possibly at risk of depression, for whom additional evaluation by a health care provider may be indicated.

