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SOL FLOR

HCHS/SOL Ancillary Study
Family Lifestyle Outcomes Research (SOL FLOR)

Field Center Procedures

February 2021 - Version 3.0

Study website - http://www.cscc.unc.edu/hchs

Tracking of Revisions to SOL FLOR Manual of Procedures- Highlighted text is new to this version

Version	Who	Date	What changed
1.0	CSCC	12/17/2019, to v1.1	- Additional items to bring to FC have been added to the instructions to participants (added to section 3.1) - The informed consent including 2nd parent signature could be returned "in-person (mother may bring it in with her), or any other method that is allowed by the local field center's IRB." (added to section 5.6) - Anthropometry certification maintenance could also include anthropometry procedures conducted in other HCHS studies in order to ensure minimum number of procedures are conducted monthly to maintain certification. (added to section 8.3.2)
1.1	CSCC	2/5/2020, to v1.2	- Edit acronym for eligibility forms from ELEE to ELEB. - Addition of obtaining bioimpedance during anthropometry procedure (added to section 8.2.4) - Addition of safety questions for bioimpedence versus weight only mode (added to section 2.2 and in recruitment scripts in appendix, also in eligibility form) - Change eligibility requirement from "Visit 1 AND Visit 2" to "Visit 1 OR Visit 2" (changed in section 2.2 and in recruitment scripts) - Change to dietary recall window from 30 days to 90 days (edited in section 12)
1.2	CSCC	7/8/2020, to v2.0	Changes reflect implementation of remote interview mode 1: - Appendix 5. Remote Interview Administration of SOL FLOR Examination Questionnaires - Appendix 6: SOL FLOR Recruitment Script – Remote interview
2.0	CSCC	**2/10/2021, to v3.0**	Changes reflect implementation of in-person visit during Mode 2 and full in-person visit: 1. The DXA procedure will not be conducted. 2. Second parental consent will not be obtained (no DXA). 3. Saliva collection will be performed by the mother preferably at the clinic following directions from FLOR staff keeping social distance. However, if it is not possible it can be conducted at the children's home and shipped to the site on a prepaid envelope. See Appendix 8 (NEW) "Revised Saliva Swab Collection (Modifications to Chapter 11)" for changes in the protocol. 4. Questionnaires from mode 2 can be collected remotely and preferably within a month of the in-person clinic visit. Infection Prevention and Control Procedures due to COVID-19 pandemic will be in place to ensure staff and participant safety. See Appendix 7 (NEW) "In-Person Clinic Visit Infection Prevention and Control Procedures". 5. Recruitment scripts (full protocol and mode 2 only) edited to reflect above changes. See Appendix 9 (NEW) "SOL FLOR Recruitment Script – Mode 2 interview".

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1. FOREWORD

This manual, entitled **Field Center Procedures** is a series of protocols and manuals of operation for the study Family Lifestyle Outcomes Research (SOL FLOR) an Ancillary Study to the Hispanic Community Health Study/Study of Latinos (HCHS/SOL). This manual provides an overview of the interviews and clinical measurements conducted as part of the field center examination. **Table 1** lists the questionnaires (administrative, mom, child) and procedures referencing to the corresponding study form codes.

Because high quality of data and a strict standardization of the examination and interview techniques across all four field sites are essential it is important that SOL FLOR field center personnel be familiar with this manual of procedures. To meet our scientific goals and to make this study a success, all SOL FLOR 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 FLOR data can reflect differences between study participants and between subpopulations of Hispanic/Latino ancestry, as opposed to differences between study technicians or deviations from study protocol. Strict and sustained adherence to study protocol by all SOL FLOR 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.

1.1. Modifications to SOL FLOR procedures due COVID19.

Due to the coronavirus pandemic, infection prevention and control procedures will be in place to ensure staff and participant safety (**see Table 7.1 in Appendix 7**). Before scheduling participant's study visit, the field center will follow the same protocol and procedures to conduct a SOL Cohort Visit 3 Clinic (in person) during the COVID-19 Pandemic. Like all other HCHS/SOL ancillary studies, SOL FLOR staff will wear a surgical mask and other personal protective equipment (PPE) as described in **Appendix 7**. Wash hands or use hand sanitizer before and after any FLOR measurement. Participants will wear a surgical mask or other mask for the duration of the SOL FLOR clinic visit. **All procedures must follow institutional guidelines in addition to any other procedure and PPE requirements listed in the Appendix 7 protocol.**

Table 1. SOL FLOR procedures and questionnaires ordered by priority of administration (pre-COVID19)

Questionnaire or Procedure	Form code	Time of administration (min)
ADMINISTRATIVE		
Pre-visit screening (eligibility)	ELE	3
Reception, itinerary checklist form	CHK	15
Informed consent/assent tracking & HIPAA	ICT	10-25
Demographic Information	DEM	3
Child Wellness Visits (staff entry from charts only)	CWV	--
PROCEDURE		
Saliva Swab (child)	SSW	3-15
Delayed Gratification task (child)	MAT	10-25
Anthropometry (child)	ANT	5
DXA (child)	DXA	5-10
24-hr dietary recall (parent about child)	--	15-30
QUESTIONAIRES		
CHILD		
Assessment of Prepubertal Development Scale* (only for >=9 yrs old)	PDE	3
Health Questionnaire	CHQ	7
Hospitalizations	HSP	3
Feeding Habits	CFH	2
Eating Behavior	CEB	3
Child Care	CHC	3
Media Use & Sedentary Behavior	CMU	8
Physical Activity & Transportation to School	PAT	4
Sleep Habits	CSH	5
MOTHER		
Caregiver's Feeding Styles	CFS	4
Reward Based Eating Drive Scale	RED	1.5
Modified Yale Food Addiction Scale	MAF	3
Well Being (Depression and Anxiety)	WBQ	3
Acculturation Stress	MAS	3
Home Food Inventory/availability (completed at home)	HFI	20

* For children > =9, we will assess prepubescent stage through a questionnaire administered with the mom and child that quires about signs of pubertal development.

2. RECRUITMENT

2.1 Overview

SOL FLOR study builds on the research infrastructure and data collection protocols of the Hispanic Community Health Study/Study of Latinos (HCHS/SOL). Briefly, the HCHS/SOL is a population-based cohort study designed to identify risk factors and disease prevalence rates of Hispanic/Latino populations residing within four communities in the United States (Miami, Bronx, Chicago, and San Diego) and representing individuals with ancestry from Cuba, the Dominican Republic, Mexico, Puerto Rico, and Central and South America. The study enrolled 16,415 Hispanics/Latinos between March 2008 and June 2011.

HCHS/SOL clinic visit 2 (October 2014–December 2017) added assessments of reproductive history, including detailed information about pregnancies, related complications, and birth outcomes. For the women who gave birth and/or were hospitalized for any pregnancy complication after the baseline visit, medical record abstraction and review is being conducted by parent study HCHS/SOL. Adding data from the child assessments and maternal drivers of food reward planned in this ancillary study to the extensive data from baseline and visit 2 provides an efficient way of studying the association between preconception health and child's weight and adiposity status as well as understanding early modifiable psycho-social and behavioral aspects of Hispanic/Latino mother-child dyads associated with childhood obesity in this understudied population. This chapter contains information to help field centers manage recruitment for the SOL FLOR study.

2.2 SOL FLOR Study Sample

SOL FLOR study will enroll women participants in HCHS/SOL who completed the baseline or visit 2 and had a child since the baseline exam or visit 2. **We will hereafter refer to the biological mother who is an HCHS/SOL participant as the mom.** In December 2017 HCHS/SOL visit 2 ended data collection and among the 2,556 women 18-44y who participated, 544 had at least one singleton live born. Of these, 521 children will be ≤9 years old at the start of the study.

We anticipate an 85% participation rate (440 mother/child dyads or 880 total individuals) based on our experience with other ancillary studies such as SOL Youth and given that these women have already participated in two visits, making them the more adherent participants. There are an additional ~20 live births after visit 2 (identified from annual follow-up calls and confirmed from medical records) that could be included ensuring our numbers.

2.3 Recruitment

2.3.1 Recruitment List

The coordinating center will provide each field center with a list of eligible women and first live child after baseline or visit 2 including its age at start of SOL FLOR study. The information in this list will be used to prepare for recruitment and to call older children first before they turn 10 years old. We will start recruitment and data collection with the 9-year-old children, allowing the younger children to age up so that all assessments will be performed between the ages of 3 and 9. HCHS/SOL participants will also be encouraged (ex. through SOL FLOR initial mailing, HCHS/SOL AFU contact, etc.) to contact their field center to schedule an appointment.

HCHS/SOL recruiters need to have all names and contact information readily available prior to calling.

2.3.2 Initial Mailing

After receiving the participant recruitment list from the Coordinating Center, field centers will select moms off the top of the list (ordered by child's age in descending order) to create the first mailing. The invitation letter will be mailed in batches depending on the field center needs, response rates and preferences. The SOL FLOR invitation letter provides information about the SOL FLOR study to the HCHS/SOL participant (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.

2.3.3 Number of Phone Calls

Approximately 10 phone call attempts should be done before declaring the mom as unable to be contacted (code 1 in the ELEB 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 should be accomplished in approximately 4-6 weeks. Each call attempt will be tracked in the local tracking system at each field center for internal use.

2.3.4 Reporting Screening Outcomes

Recruitment staff is responsible for completing the form Eligibility Checklist (ELEB) and record the information into the SOL FLOR study data management system (C-DART) live or within 48-72 hours after collection depending on the field site. Data entry 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 Individual Eligibility Checklist (ELEB)

The Eligibility Checklist Form (ELEB) records the primary inclusion (e.g., legal guardianship, living in HH status, individual participation status), exclusion (e.g., developmental disabilities) criteria, and safety questions for anthropometry procedure (e.g. medical devices). Recruiters are responsible for verifying that all individuals meet the eligibility criteria for inclusion into the study. Refer to the ELEB QxQ for further instructions on how to complete the form.

2.5 Eligibility Criteria

Only the first live born after baseline or after visit 2 will be eligible to participate; the eligibility list from the Coordinating Center will have already identified these children. The biological mother (HCHS/SOL participant) will have to bring the child to his/her appointment. The full name of the child will be noted in the DEMB as well as whether the biological father is an HCHS/SOL participant.

Inclusion

- Biological mother is an HCHS/SOL participant (aka mom) and had a live birth after baseline or only after visit 2.
- First child born after the biological mother's baseline or visit 2 date, and being within the 3-9 years old age group at the time of SOL FLOR examination.

Exclusion

- Mother is not the legal guardian of the child.
- Child does NOT reside with the mom.
- Child has any disability (mental or physical).

Temporary Exclusions

- Child is currently suffering from a temporary physical injury preventing them being able to stand (ex. broken bone) or any mouth injuries. Schedule examination after recovery.

2.6 Recruiters

2.6.1 Overview

Recruiters must be HCHS/SOL parent study staff members who are organized, confident, and knowledgeable of the HCHS/SOL and the SOL FLOR 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 and follow HCHS/SOL procedures for human subjects' protection and interviewing techniques. They also need to review and understand the recruitment flow 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.

2.6.2 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 for the study.

Because of the risks involved with a breach of confidentiality, it is very important to maintain 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 the car as soon as possible to avoid loss, theft or damage.
- Do not discuss participant's information 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 purposes and analyses.

2.6.3 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.

2.6.4 Using Scripts/Guidelines for Probing

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 (e.g. confirming child's date of birth, gender). If a recruiter is having difficulty obtaining all the information needed to complete the recruitment phase of the study, s/he 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 FLOR study recruitment process.

2.7 Collaboration within research team

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 FLOR Study recruitment team will be in contact with the HCHS/SOL Annual Follow Up team and other ancillary studies staff 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 FLOR 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 could be invited to multiple ancillary studies in a calendar year. Other studies/ancillaries should be made aware once an HCHS/SOL participant becomes part of SOL FLOR.

3. CONTACTING PARTICIPANTS / MAKING THE FIELD CENTER EXAMINATION APPOINTMENT

SOL FLOR biological mothers who meet the eligibility criteria (see ELEB form) are scheduled along with their first live born after baseline and visit 2 to a field center examination. The field center recruitment personnel coordinate 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. Local tracking systems are used in managing recruitment flow and outcomes. The eligibility of each mother/child dyad is determined using the Eligibility Checklist (ELEB form) which is also used to record the date of the field center examination. Field centers schedule appointments taking into consideration the mother and child's availability. Each field center is responsible for entering information promptly into CDART. The coordinating center keeps updated records of recruited SOL FLOR participants and their child and sends periodic reports for tracking purposes.

Before calling the HCHS/SOL mother, field center personnel must have appropriate scheduling forms, worksheets, available examination appointment dates/times, and all relevant scripts. The SOL FLOR recruitment personnel makes the appropriate number of call attempts and is responsible for tracking them in their local field center's internal tracking system.

~~The staff member also needs to determine if there is a father, or other parent and if s/he has given permission, and a determination of "reasonable availability" of this parent is obtained. No data collection can take place before informed consent/assent has been obtained by the second parent. If the second parent is available then a procedure is set up to obtain their signature for the child's participation, if not already done so. If the second parent is NOT available then the staff member will need to determine why, especially for instances when the second parent is considered "not reasonable available." This must be done prior to the mother/child coming into the clinic to participate in SOL FLOR. See Chapter 5, section 6 for more information regarding obtaining father/2nd parent consent and also the individual eligibility (ELEB) form and the recruitment script (Appendix 2) for determination of "reasonable availability".~~

Key scheduling tasks are to explain where the field center examination is located; identify an appointment time (mother/child only, both parents/child, mother/child and second parent separately, as applicable); establish how the mother 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 child's mom with the specifics of the appointment just made 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.

3.1 Appointment Reminders and Instructions for Examinations

After a successful scheduling call, study personnel process the mom's ID and 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 mom of the child soon after the appointment is made. The instructions include:

1. Appointment date and time.
2. Instructions on appropriate child's clothing to wear for the examinations. ~~For the DXA scan loose clothing with no metal.~~
3. Items to bring to the field center:
    - Child's social security number (SSN);
    - Name and address of the child's primary care physician;
    - If child attends daycare/preschool or school, information from daycare provider or teacher on what was eaten the day before.
    - Child wellness visit growth charts that contains any weights and heights since birth.
    - Home Food Inventory Form
    - Food Record Letter/Instructions
    - Food Record Collection Form
    - Any other field center-specific documents (ex. brochure, consent packet for review, etc.)

4. Overview of field center operations:
    - A listing of the interviews and procedures for the examination (optional);
    - Field center examination hours of operations
    - Phone number for questions or rescheduling appointment.
    - Directions to the field center (e.g., a map) and to parking facilities

5. Transportation, if applicable (some centers provide transportation and arrange for participant pick-up).

3.2 Split Clinic Examination

Clinic examinations may be scheduled as split exams because ~~(1) the Dual Energy X-ray absorptiometry (DXA) procedure will be done at different locations from the SOL FLOR field center,~~ (1) the mother or child is unable to commit to a full examination on single day, or (2) 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 remote interviews (ex. phone) or 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.

4. RECEPTION

Reception is the first workstation for the mom/child dyad examination visit. At this station, mom and child are welcomed, informed consent and assent are obtained, ~~"reasonable availability "of the second parent is confirmed on the informed consent signature page~~, questions are answered, and demographic and tracking information are updated.

At the time of the mother/child dyad arrival at the reception station, display the Clinic Exam Checklist Form (CHK) on your computer and confirm the identifying information on the form with the mom. Staff confirms that special needs are documented on the participant's Clinic Exam Checklist Form (CHK). Mother's and child's language preference for the interviews to be conducted during the visit are also recorded on this form which is then printed and attached to the participants' labeled folder to accompany them throughout the examination visit.

As soon as the initial steps of welcome and reception mentioned above have been completed and participants are comfortable, they are given the opportunity to read and review the informed consent/ assent as described below.

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

Study personnel and Field Center Clinic Managers at each field center will initially be trained at a central training session. Future training for new staff may be conducted by Field Center Clinic Managers at each field center. The Certification requirements include the training on general interviewing techniques, procedures ~~(excluding DXA)~~, Human Subjects Protection, Informed Consent/Assent, the Informed Consent and Assent Tracking forms, and the Data Entry System. All study personnel must complete a formal certification process in interviewing techniques. Clinic Manager conducts direct observations of interviewing techniques for quality assurance and standardization.

During the interview, study personnel also inquire 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.

5. INFORMED CONSENT AND ASSENT

Informed consent and assent are the first data collection forms administered during the course of the exam. Their core content complies with guidelines from the National Health Institutes, and the content, format and consent/assent administration process are tailored to meet the specific requirements of each field center's Institutional Review Board which are coordinated by the UNC single IRB. Assent forms will only be administered to the 7-9 year-old children, per NIH guidelines.

The primary objective of administering informed consent and assent is to inform the parent(s) and the child of the SOL FLOR procedures, protect the rights of the study participants, meet any Institutional Review Board requirements, and to communicate with parent(s) and children the type of information to be collected, their long-term storage and disposition, and consent for child's medical record release. The medical record release is to obtain at the minimum weights and heights since birth if not already provided and if willing, other information concerning the health of the child which may be used for future studies. The informed consent and assent makes the parent(s) and children 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 parent(s) are asked for authorization for subsequent contacts by SOL FLOR personnel.

5.1. Administration of Surveys

The purpose of SOL FLOR measurements will be reviewed with the participants. Informational materials about SOL FLOR, 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 FLOR 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 (CHKE) for easy access during the remainder of the exam visit.

Before proceeding, assess whether the participants use corrective lenses or hearing aids. Record this information on the Clinic Exam Checklist Form (CHKE) and explain to the participants to have the hearing aid(s) /corrective lenses conveniently available throughout the field center examination visit.

After introducing the informed consent and assent forms to the participants in a private area ask whether they prefer to read the informed consent and assent forms or to have it read by the study personnel. Record this preference on the Clinic Exam Checklist Form (CHKE) 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 and assent with study participant and the second parent 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(s) and child to read and sign the informed consent and assent document in the presence of SOL FLOR personnel serving as witness.

5.2. Training and Certification

Clinic Mangers will participate in a webinar training hosted by the UNC Coordinating Center with delivery of content by subject matter experts. Clinic Managers are responsible for providing training to field center study personnel. Certification by the Clinic Manager is required. Quality Assurance is provided at each field center by means of observation by the local Clinic Manager.

5.3. Data Collection

The informed consent and assent are paper forms. When the parent(s) receives copies of the informed consent and assent, the field center has the option of providing a copy of the entire form packets, or signed consent/assent pages only. 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 FLOR 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 and single 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").

Unless an IRB specifies procedures for vulnerable individuals, there is no need for guidelines common to the SOL FLOR 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 FLOR 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 bring this to the attention of the field center Clinic Manager.

5.5. Consent and Assent Tracking Form

The informed consent and assent forms signed by the parent(s) and the child (7 year old or older) during the visit are used to complete the Informed Consent and Informed Assent Tracking form, which are NOT administered to participants. The purpose of this tracking form is to document the level of consent/assent and to track any changes (revisions) following the field center examination visit to a participants' consent/assent. 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(s) or the child requests that a change be made to his or her consent/assent status. Parent(s) approval is not necessary to make changes in the child's assent status.

~~5.6. Instances when second parent is not reasonably available to consent~~

Due to the COVI-19 pandemic the DEXA component will NOT be conducted under mode 2. Therefore, the study does not require the consent of the 2nd parent to participate in the study

~~The informed consent forms are expected to be signed by both parents of the child, when reasonably available. The UNC sIRB, using federal guidelines for research studies (HHS code of federal regulations: 45 CFR 46.406, 21 CFR 50.53), has determined that the DXA represents a greater than minimal risk for the children as they would be exposed to radiation that is greater than they would experience in everyday life. Additionally, since it is for research purposes only with no prospect of direct benefit to the children (non-intervention), the regulations indicate that permission must be obtained from both parents unless one parent determined as "not reasonably available" to give consent.~~

~~**"Not reasonably available"** is not intended to mean that a parent is temporarily unavailable, unless there are specific circumstances where time is of the essence. There are numerous specific situations that could support a determination that a parent is not reasonably available. In general, however, a parent who is not reasonably available is one whose whereabouts are unknown; who should not be contacted because of the nature of the relationship between the parent and child; whom there is no way to reach in-person or by phone, mail, email, fax or any type of videoconferencing; or who has not responded to multiple contact attempts. "Not reasonably available" does not apply to situations when a parent is at work, traveling, not immediately available by electronic means, or living in another state or country, without more to justify the investigator's inability to reach the parent and seek permission.~~

~~Examples of situations when one may reasonably conclude that a parent is not reasonably available could include the following situations:~~

~~• The parent is incarcerated and not contactable.~~
~~• The parent is on active military duty and not contactable.~~
~~• The parent's whereabouts are unknown.~~
~~• The parent is known and contactable but chooses not to be involved in the child's care.~~
~~• The parent is known but, upon inquiry, there is reason to believe that requesting permission would be inconsistent with the parent/child relationship, such as where there is reason to believe~~

~~there is or has been domestic violence or other situations involving harm to the health or welfare of the child.~~

~~The parent should be asked to provide the other parent's contact information, including address, home and work phone and fax numbers, email address, etc., and a concerted effort should be made to contact the absent parent in-person and/or by phone. Once contacted, a research investigator or other research staff who is eligible to obtain parental permission based on the approved protocol must be available to provide him or her with all the information required to make a fully informed decision about whether to permit the child's participation. Since written informed consent is required, the approved consent document should be mailed and/or faxed (if allowed by local IRB), along with a cover letter or note from the investigator explaining the circumstances. The executed consent can be returned via mail, email, fax, in-person (mother may bring it in with her), or any other method that is allowed by the local field center's IRB. In the event of a time sensitive consent, the local IRB (if allowed) may also permit the parent to take a picture of the signature page with a smart phone and send it via text messaging.~~

~~If the absent parent cannot be reached by telephone, email or fax after repeated attempts and no other contact information is available, the investigator may determine that the parent is "not reasonably available." Note that it is very important to retain dated copies of any letters, faxes or emails sent to the absent parent, and a log of all phone calls –attempted and answered – should be kept and documentation entered into the medical record.~~ **~~IMPORTANT NOTE:~~** ~~If the second parent subsequently responds and refuses to provide permission, the child's participation must end.~~

~~When the second parent is determined to be not reasonably available, the reason must be written in the informed consent signature page as well as the informed consent tracking form in CDART. The following reason codes to use are as follows:~~

- ~~Parent is deceased (1)~~
- ~~Incompetent (2)~~
- ~~Whereabouts unknown (3)~~
- ~~Only mother has legal responsibility for the care and custody of the child (4)~~
- ~~Not reasonably available (5)~~

~~Because this list is NOT included in the informed consent package, any IRB-approved changes or additions to the reason for not obtaining second parental consent may be conducted separately (ex. changes only made within response card, CDART form response, MOP) without changes to the original informed consent package.~~

6. PARTICIPANT TRACKING

To establish the ability of SOL FLOR personnel to maintain contact with its participants, during the field center examination visit the mom of the child is asked to confirm any 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. Follow HCHS/SOL procedures for local tracking mechanisms implemented to record new changes in mom's 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 mom's 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 mom, wishing a full withdrawal from the study and no further contact.
(3) Threatening / antisocial behavior by the child or his/her mom towards the staff or other study participants.

Administrative exclusion of an eligible participant recruited and/or examined by SOL FLOR 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.

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. The time of administration of each procedure and interview is recorded on the Clinic Exam Checklist Form (CHKE). The procedures and questionnaires are ordered by priority of data collection (Table 1) but in certain circumstances the order can be altered and this will be documented in the Clinic Exam Checklist Forms (CHKE). These are prepared one day in advance according to the number of study participants scheduled and the available personnel. Clinic Exam Checklist Forms (CHKE) 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 (CHKE) is desirable to accommodate last minute cancellations or delays that occur during the participant's progression through the sequence of examinations and interviews.

The primary use of the examination-visit checklist (CHKE) is to prevent inadvertent omissions in data collection. The Clinic Exam Checklist Form (CHKE) serves additional purposes: it reminds study personnel of a participant's special needs or medical conditions; it serves to monitor the completion of components 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 (CHKE).

8. ANTHROPOMETRY

Due to the coronavirus pandemic, infection prevention and control procedures will be in place to ensure staff and participant safety (**see Table 7.1 in Appendix 7**).

Anthropometric measures include height and weight of the child. These measures are used to assess body mass index (BMI) and the relationship between obesity and risk of disease.
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. For children > =9, we will assess prepubescent stage through a questionnaire administered with the mom and child that inquires about signs of pubertal development. This is needed to interpret body fat measurements.

8.1. Equipment and Supplies

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

- Tanita BF-689 Body Fat Monitor
- Wall mounted stadiometer
- Balance weight scale (available at all times as back up)
- Calibration weights (10 kg)
- Antiseptic wipes

8.2. 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 measurements; 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 s/he 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.

8.2.1. Anthropometry Form (ANTE)

The ANTE form records anthropometry measurements in two sections: (A) ability to stand and height, (C) and weight from the Tanita scale. If a participant cannot stand with both feet then no measurement will be taken. As the technician progress through the examination procedures, they will record results into the ANTE form. Ideally, data entry into the computer should be completed before the participant moves to the next stage.

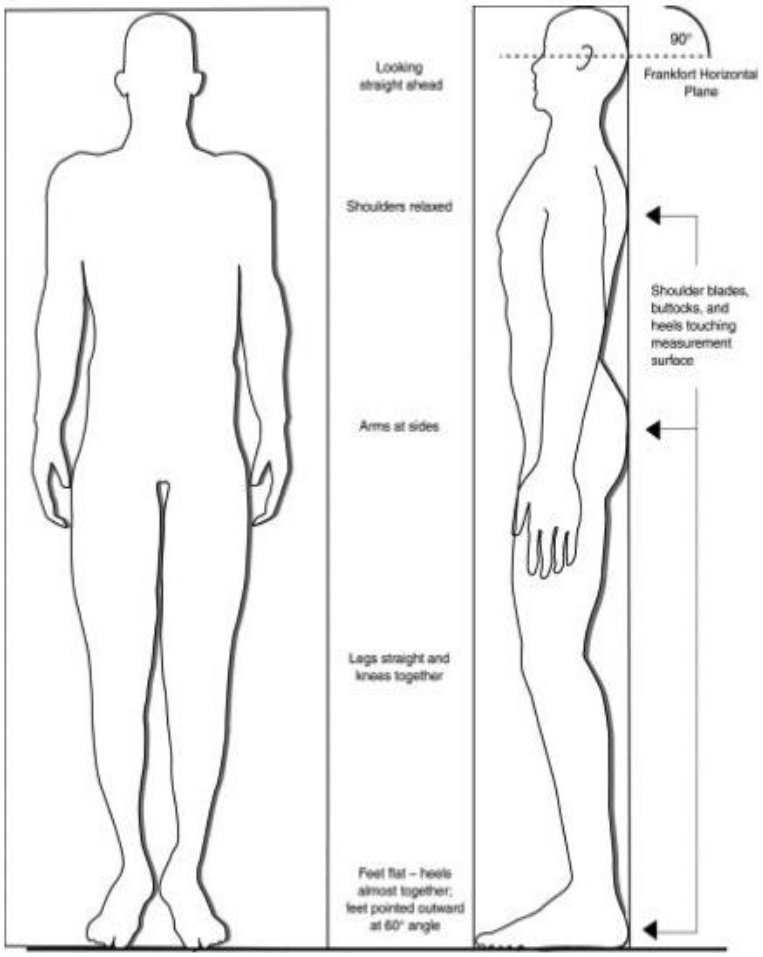
8.2.2. Standing Height

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. 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 a 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. Two measurements should be made. If the two measures vary by more than 2 centimeters, then collect a third measurement (see ANTA form for measure comparison results and prompts for third measure, when needed).

Figure 1. Position for Standing Height

The staff will take two measurements of height and enter them in the ANT form in CDART which will compare these two measurements. If these two measurements differ by more than 2 cm, then a third measurement must be taken. If the third measurement difference is less than 2cm with one of the first two measurements, then the procedure is finished. Otherwise, the clinic manager must perform two new measurements and enter them over the first measurements performed (replacing the values in the ANTE form).

8.2.3. 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 ½ 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 ½ cm and is inflexible, follow the modified procedure for measuring height outlined below:

a. Position the participant according to the standard protocol.
b. 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."

8.2.4. Weight

The participant's weight is measured using the Tanita scale and recorded on the SOL FLOR Anthropometry Form (ANTE). 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. 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. If a participant has a cast that cannot easily be removed, or that the participant is not comfortable removing, measure weight in the "Weight Only" mode, make a note in the comment section of the form.

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.

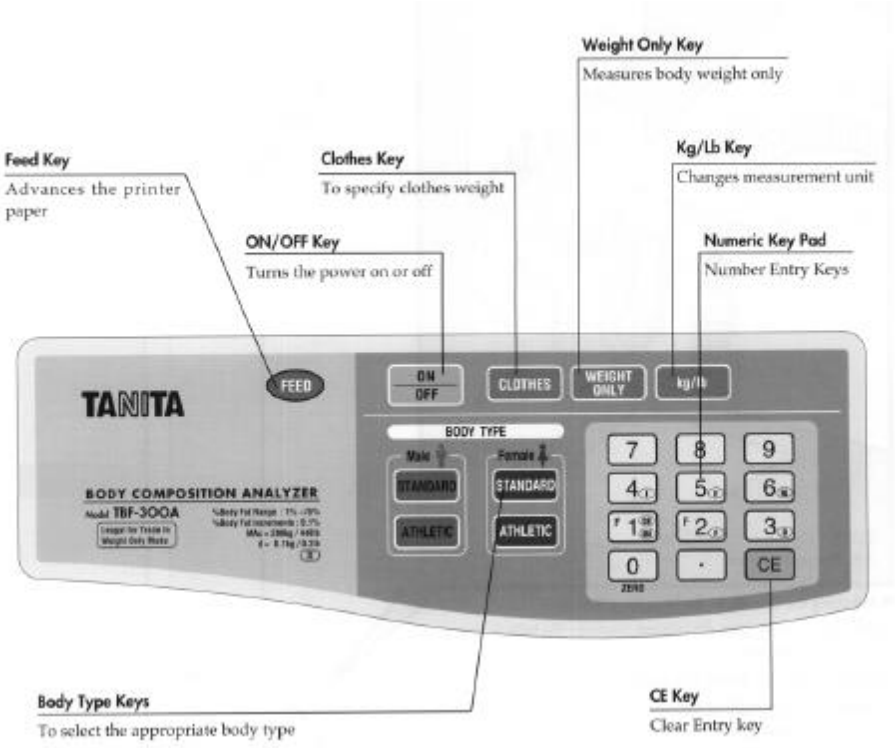


Figure 2. Control Panel of Tanita Body Composition Analyzer, TBF-300A

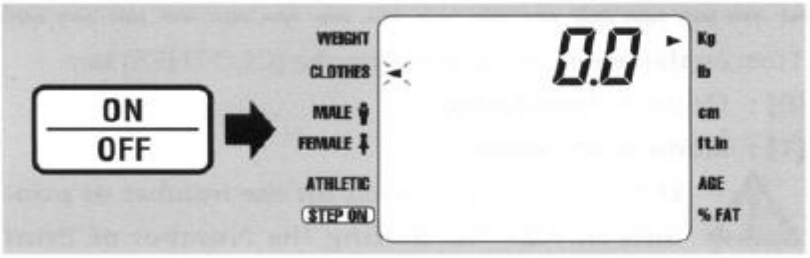
a. Initial set up

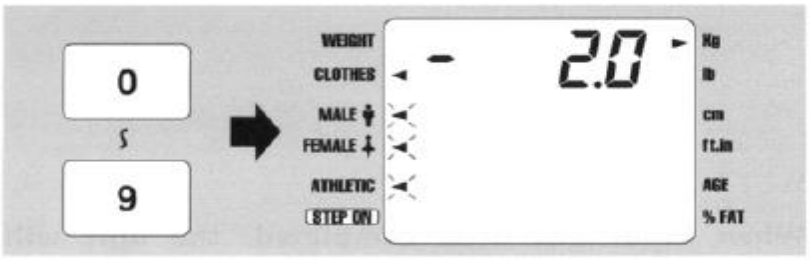
1. Place the scale platform on a flat and level surface as possible, preferably not on carpet. Don't worry if balance bubble indicates it is not exactly leveled.
2. Connect the keyboard to the scale with the gray cord attached to the scale and plug it into the back of the keyboard in the socket marked "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."

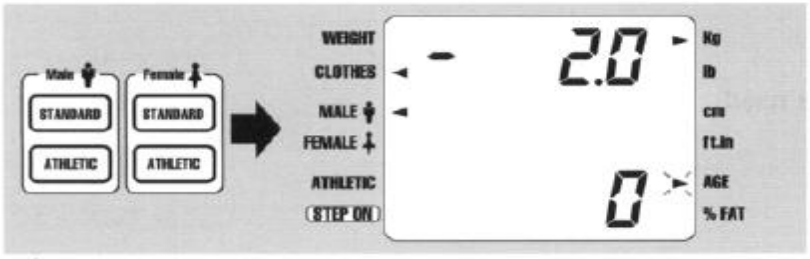
b. Setting the number of print outs and printing language

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 1 (print out) and select the printing language (LNG-1 = English). The panel will switch to the measurement screen.

<u>Operating instructions</u>







After turning on the unit, press the "weight only" key if WEIGHT ONLY mode required. After a momentary display check, "0.0" will appear on the LCD. If measuring units need to be changed, do so at this time by pressing the [kg/lb] key and select the "kg" option.

Enter Clothes weight: 1.0 kg

Select Gender and Body type: Standard Female or Standard Male

Enter age of participant (=7 if child is less than 7 yrs old)

Enter height in cm.

Mistakes may be corrected by pressing the [CE] key.

An arrow on the LCD will follow the selection of

2. Weight Measurement
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. Step on the weighing platform. Weight will be displayed on the LCD. 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.

3. When measuring is complete, press the [ON/OFF] key to turn off the power.

•No printer is available when measuring weight only.

Important Note: There is no automatic weight lock function.

If the screen returns to "----" for weight, the participant weighs more than 440 lb.

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

Once measurements are completed, the machine will automatically return to the initial set-up screen. Leave keyboard on. Wipe off plates on scale with antiseptic wipes. You can then measure the next participant.

In the event of a power outage or if the scale is not functioning properly, notify the Clinic Manager. Participants may have their weight measures using the back-up scale.

8.3. Quality Assurance/Quality Control

8.3.1. 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.

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

8.3.2. Training, Certification and Quality Control

Field technicians or examiners will be trained via a webinar in both anthropometric measures. Each technician will perform a minimum of 3 observed procedures to receive certification. Agreement between the expert and the trainer must be within 0.5 cm for height, and 0.5 kg for weight.

Technicians are observed by the Clinic Manager 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 (note: total per

month can be combined with anthropometry procedures conducted in any other HCHS/SOL study, main study or any ancillary study, following similar protocol).

A sample of 5% participants will be 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 (AQCE). Inter-technician agreement serves as a criterion for recertification. Retraining sessions are scheduled when a lack of standardization is observed among the technicians.

9 WHOLE-BODY DXA SCAN. Due to the coronavirus pandemic, the DXA procedure was dropped from the protocol and it will no longer be conducted.

~~9.1 Overview of the DXA~~

~~Dual energy X-ray absorptiometry (DXA) is becoming an increasingly popular technique to measure body composition, in particular "fat mass," "lean mass" or the "fat-free soft tissue". Prior to this timely technology, body fat was most frequently reported as body mass index (BMI) from a calculation including height and weight which has limitations. Furthermore, other anthropometry measurements such as skin folds and circumferences were also used to gather body composition but recent advances, such as the DXA, have brought a new and more accurate measure to body composition for research purposes.~~

~~The SOL FLOR study involves exposure to radiation from only one (1) DXA scan and only for three to five (3-5) minutes with an estimated exposure of only 1.5mrem. For comparison, this exposure is the same as one tenth of an X-ray. This radiation exposure involves a small risk and is necessary to obtain the body composition information desired.~~

~~For this study, we will measure body composition via a whole body DXA scan. The scan will provide values for total body weight, total fat mass and lean body mass (in grams) and as percentages of total body weight. Presently, there are two different types of DXA scanners being used with the field centers; GE Lunar (Model Prodigy) will be employed only in the Bronx, while the Hologic Discovery QDR series (Model 010-1549) will be employed in Chicago, Miami and San Diego. This manual provides the operating instructions for providing a whole body DXA scan on either machine to obtain body composition.~~

~~9.2 Personnel~~

~~A technician, who is a certified by the ISCD (International Society of Clinical Densitometry), will be conducting all of the scans. Technicians operating the densitometers are required to wear radiation badges for dosimetry processing if law mandates.~~

~~9.3 Measure Weight~~

~~All children will need a weight and height collected to be entered into the DXA machine. If the DXA scan is within a week of the clinic visit, then we will use that weight (ANTE form; CDART will convert it from kg to lb (see section 9.5)). If not, then the child needs to be weight again.~~

~~9.4 Procedure Script~~

~~The DXA script (Appendix 3) introduces the procedure to the participants, confirms the child's last meal, and ensures that the child is wearing proper attire. During this time, the study participant should be again asked about and examined for metal that could be in the scans path. Typical metal objects to look for are earrings, eyeglasses, wristwatches, coins, rings, buttons, buckles, zippers, body piercings, and support braces. The child should remove shoes, and it may be necessary to remove skirts, slacks, etc. If in doubt, it is best to remove the object in question. All items removed for the scan should be given to the study participants guardian, who must be present, for secure storage.~~

DXA technician (along with field center staff assistance) will then walk through the procedure instructions and the DXA technician will conduct the procedure.

9.5 DXAE form

This form will be collected in paper and then entered into CDART.

Section A of the DXAE Form include information needed to be entered in DXA machine:

- SOL FLOR clinic date
- Weight measured at SOL FLOR clinic converted to pounds (by CDART)
- Height measured at SOL FLOR clinic converted to inches (by CDART)
- Date of birth (for all children, day of birth will be removed and replaced with 01 for confidentiality purposes)
- Sex

Section B of the DXAE Form include general questions related to the procedure:

- DXA technician Number
- Date of DXA scan
- Weight measured on the day of scan procedure (because the difference between FLOR clinic visit and DXA visit is more than a week apart)
- Time when last meal was eaten and time when DXA procedure is done
- Use of bathroom before the scan
- Use of positioning aids
- Indicator whether the child moved during the scan

Section C of the *DXAE Form* has space to enter the measurements of total fat mass and lean body mass (in grams) and as percentages of total body weight. *Staple the printout into the DXA paper form and archive with child's records.*

~~HOLOGIC printout~~

DXA Results Summary:

Region	BMC (g)	Fat Mass (g)	Lean Mass (g)	Lean + BMC (g)	Total Mass (g)	% Fat
L Arm	32.75	306.1	592.5	625.3	931.4	32.9
R Arm	35.04	321.1	587.3	622.3	943.5	34.0
Trunk	157.93	1659.7	5050.0	5207.9	6867.5	24.2
L Leg	87.74	968.3	1699.5	1787.2	2755.5	35.1
R Leg	84.67	949.5	1630.6	1715.3	2664.8	35.6
Subtotal	398.13	4204.7	9559.9	9958.0	14162.7	29.7
Head	206.85	762.3	2121.5	2328.3	3090.6	24.7
Total	**604.97**	**4967.0**	**11681.3**	**12286.3**	**17253.3**	**28.8**

Body Composition Results

Region	Fat Mass (g)	Lean + BMC (g)	Total Mass (g)	% Fat	%Fat Percentile YN	%Fat Percentile AM
L Arm	216	734	949	22.7		
R Arm	360	736	1096	32.8		
Trunk	1554	6560	8114	19.2		
L Leg	1214	1901	3115	39.0		
R Leg	1226	2160	3385	36.2		
Subtotal	4569	12090	16659	27.4		
Head	861	2646	3508	24.6		
Total	**5430**	**14736**	**20167**	**26.9**		
Android (A)	239	1032	1271	18.8		
Gynoid (G)	1060	1815	2875	36.9		

~~GE Lunar printout~~

BODY COMPOSITION (Enhanced Analysis)

Region	Tissue (%Fat)	Region (%Fat)	Tissue (g)	Fat (g)	Lean (g)	BMC (g)	Total Mass (kg)
Arms	14.0	13.4	8,642	1,207	7,435	371.2	9.01
Arm Right	14.6	13.9	4,490	655	3,835	208.9	4.70
Arm Left	13.3	12.8	4,152	552	3,600	162.3	4.31
Legs	19.1	18.3	26,867	5,131	21,736	1,130.7	28.00
Leg Right	19.3	18.5	13,602	2,620	10,982	580.6	14.18
Leg Left	18.9	18.2	13,265	2,511	10,754	550.1	13.82
Trunk	14.0	13.6	32,288	4,516	27,772	873.1	33.16
Trunk Right	14.4	14.0	16,042	2,304	13,737	449.0	16.49
Trunk Left	13.6	13.3	16,247	2,212	14,035	424.1	16.67
Android	11.5	11.4	4,828	556	4,272	56.2	4.88
Gynoid	18.7	18.3	11,809	2,211	9,597	302.3	12.11
Total	16.3	15.7	72,003	11,739	60,264	2,841.5	74.84
Total Right	16.6	16.0	36,382	6,051	30,331	1,486.3	37.87
Total Left	16.0	15.4	35,621	5,688	29,933	1,355.1	36.98
TBLH	16.0	15.5	67,797	10,854	56,943	2,374.9	70.17

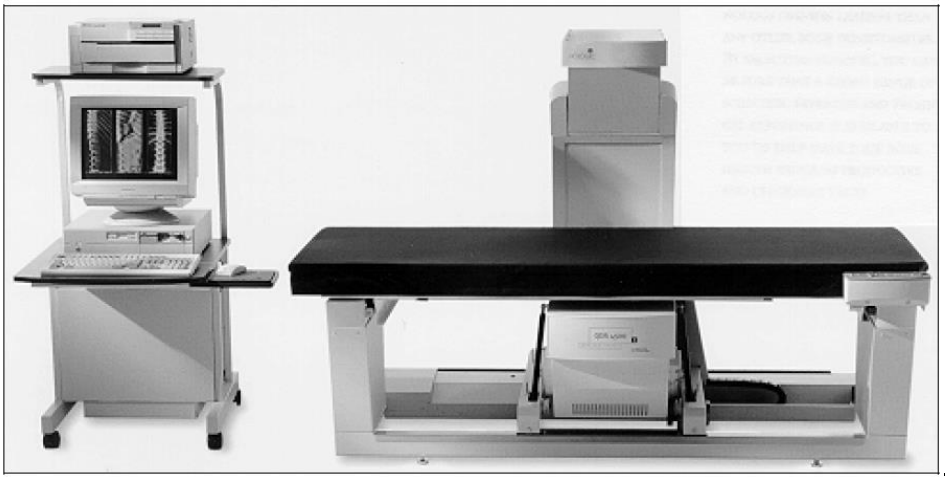
~~9.6 DXA Procedure~~

~~If the computer is left on overnight, it is necessary to reboot the computer first thing in the morning. This will set the system date and time to the computer's internal clock and will perform basic checks on the computer system memory.~~

~~This study will use either the ***GE Lunar*** or ***Hologic Discovery*** DXA scanners. Figure 4 shows the GE Lunar which is a fan beam X-ray bone densitometer which is designed to estimate the bone mineral density and body composition (lean and fat tissue mass) of patients. Figure 5 features the ***Hologic Discovery*** QDR 4500A which is also a fan beam X-ray bone densitometer, which uses two different energy levels produced by an energy tube to estimate bone mineral content (BMC) and bone mineral density (BMD). The QDR uses a low level of X-rays.~~

~~Figure 4 GE Lunar~~

~~Figure 5 Hologic Discovery QDR series (Model 010-1549)~~



For both machines:

To **turn on machine** press the ON/OFF button. The machine should be turned on at the beginning of the day and turned off after all scans are complete for the day.

The **Emergency Stop Button** should only be used in the case of an emergency, not to regularly abort a scan. It is located on the scan arm for the GE Lunar and is a round red button at the right end of the instrument control panel on the Hologic.

Laser Positioning. The Laser-On Lamp is an amber light above the Laser switch on the Instrument Control Panel. It alerts the user that the laser position indicator is active. The laser position indicator unit produces 1 mW laser emission. The examinee and technologist should avoid looking directly into the beam, or placing reflective objects in the path of the beam.

9.6.1 GE Lunar Systems

1. Every morning, before you start child measurements, complete the daily Quality Assurance procedure as described in the GE operator's manual. This will consist of a daily scan of the manufacturer's QA block; it will not let you proceed with patients until done (takes ~7 min). In addition, best to run a phantom (typically spine) once weekly to monitor possible machine drift.
2. Enter the scan type from the main menu (Whole Body).

3. Enter basic child information in the Lunar Mandatory Information screen:

- For First Name enter "FLOR";
- For Last Name enter the participating child's ID;
- Child's date of birth should be their actual month and year of birth, only. For DAY always enter 01.
- Height (inches), weight (lbs), sex, and ethnic type (always Hispanic). If the DXA procedure is the same day as the clinic visit, then use weight and height measured at the clinic (section A of DXAE form). If the DXA procedure is on a different day, then weight the child again but use the height measured at the clinic visit (section A of DXAE form).
- **Set the OUTPUT measures to be in grams.**

DO NOT ENTER THE CHILD'S ACTUAL NAME or FULL DOB IN ORDER TO PRESERVE CONFIDENTIALITY!

4. Position the child as discussed below and allow scan to complete itself.

5. Analyze and print results immediately after each child's measurement. Provide print out to HCHS/SOL staff.

NOTE: If the child is uncooperative or fearful then allow the mom (if not pregnant) to remain in the room and assist as needed in calming the child. Some states, including CA, do not permit other people in the room when scanning.

~~9.6.2 Hologic Systems~~

~~1. Hologic 'QA' is performed internally and automatically when the machine is turned on. It also prompts the technician to run a daily spine phantom scan. In addition, best to run a phantom (typically spine) once weekly to monitor possible machine drift. Make sure you save your printed results to provide to the SOL FLOR research team for any other future reference.~~

~~2. Go to "Patient" in the menu: enter "FLOR" for First Name; enter the child's ID for Last Name; enter weight in pounds from ANTE form or from weight measured on scanning day; then press Enter. DO NOT ENTER THE CHILD'S ACTUAL NAME or FULL DOB IN ORDER TO PRESERVE CONFIDENTIALITY!~~

~~3. Enter the child's month and year of birth and their sex. If a day is required always enter 01.~~

~~4. Press F10, and check that "FLOR" and ID appear at the top of the screen.~~

~~5. Position the child as discussed below, then in the "Scan Selection" screen, select the scan type by clicking on "Whole Body" with the mouse. The scan type is highlighted hit next to scan.~~

~~6. Let the scan complete itself. Never move the child off the table until the tabletop is centered over the base. The Scan window displays with the image appearing on the left side. Flashing X-rays On indicator at the top of the window continues until the scan stops.~~

~~9.7 Child Positioning Techniques and Scan Acquisition Whole Body~~

~~1. When prompted by the program, ask the child to lie down on the scan table.~~

~~2. The centerline on the table pad should divide the child's body in half. Use the lines on the table pad to assure the child is lying straight on the table. The child's head must be below (about 1-3") the horizontal line located along the top of the table pad (see figure 6).~~

~~3. In order to have the software correctly place the top horizontal line for the android region, the child's head should be in neutral position, neither tucked or hyperextended. This is because the software uses the chin line (which should be placed just one 'click' of the machine below the bony part of the chin) to calculate where to place the top of the android ROI line. This makes placement of the head region cut line easier to place.~~

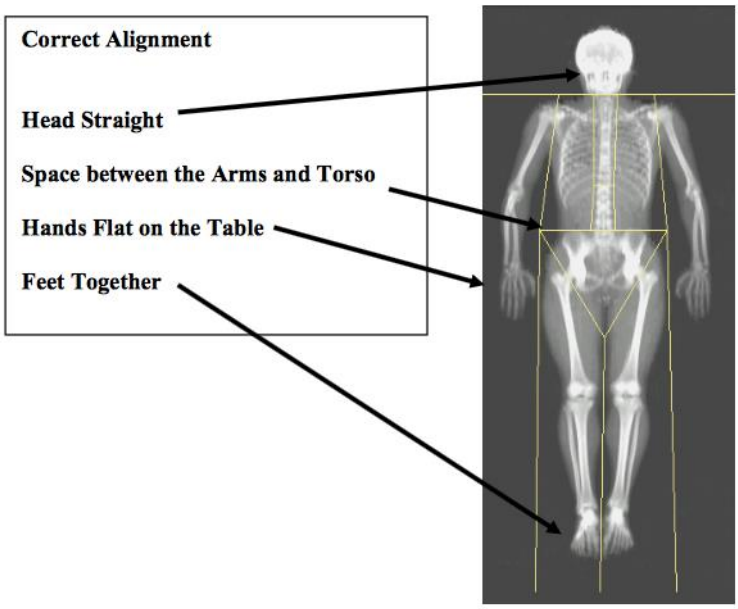
~~4. A foam wedge (or pillow) may not be used under the child's head as it will affect the body composition results.~~

~~5. Have the child place hands in a "palms down" position, i.e., heel of hand on the table with palms facing downward. DO NOT OVERLAP HANDS AND LEGS. The child's entire body must fit within the scan lines on the table pad (see figure 6). If the technician cannot get separation between hands and body, then do a hemi-scan. To conduct a hemi-scan (see figure 7), move the child off-center such that the LEFT arm is mostly off the table and out of the scan field (same on~~

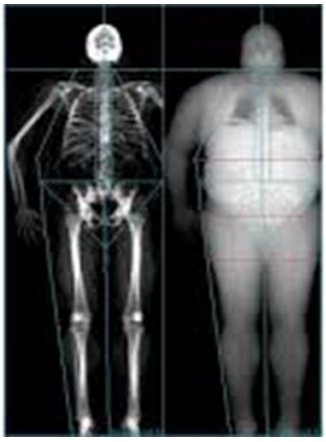
~~GE and Hologic). There's no measurement required as to how far off-center to move the child as long as about 3/4 of the child's arm is out of the scan field (so the software 'understands' a hemi-scan is being done and thus will not stop and tell you part of the body is outside the image area).~~

~~6. The child's feet should be together, heel and toes touching, and secured using a Velcro strap (see figure 6. Below). The child should be asked not to move until directed to do so.~~

~~There must be a space between the child's arms and sides whenever possible. Figure 6 illustrates a correctly positioned individual for the whole body scan:~~



~~Figure 6. Correctly positioned whole body scan~~



~~Figure 7. Correctly positioned hemi-scan~~

7. Continuing the scan will cause the x-ray tube to ramp up to the appropriate current and voltage. The operator should check to make sure the orange "X-Ray On" light is lit, and remain in the room to check the progress of the scan acquisition as it appears on the screen.

8. The child's head should appear with a few blank scan lines above it. As the scan proceeds, the total-body image should be in a straight line vertically on the screen. If these conditions are not met, the scan should be stopped. The scan arm will move to the original start position and the localizer light will come on. The child should be repositioned as needed. This should not be necessary if care is taken to position the child centered, straight, and not angled. In particular, with this age group we will want to avoid having to stop and re-scan.

9. When the detector moves past the child's feet, the auto stop feature then interrupts the scan and closes the shutter (**GE**). A message appears on the screen, allowing the operator to continue the scan or shut down the system. After the scan ends, the shutter closes, the voltage and current ramp down and a messages appears for the operator to wait. The scan arm moves to the home position and a screen message appears to inform the operator that the scan is over and to remove the child from the table. The technician should click to the Total-body Scan Options screen, then save the scan file. On **Hologic,** the entire table and the scan arm move during the scan. The computer monitor will indicate when the scan is finished. Wait for this before moving the child off the table.

9.8 DXA Scan Output Procedure

1. Scan printout (save as pdf) and archive print results before you leave for the day.
2. Enter printout into CDART form DXAE and attach pdf.

10. DELAYED GRATIFICATION TASK

Due to the coronavirus pandemic, infection prevention and control procedures will be in place to ensure staff and participant safety (**see Table 7.1 in Appendix 7**).

Child self-control will be assessed using a delayed discounting paradigm referred to as the 'marshmallow task'. This delay discounting task quantifies delay of gratification. Ability to delay is a stable construct and is associated with academic performance and ability to cope with frustration in adolescence, as well as ability to delay in the face of temptation over 40 years later (Caleza, Yañez-Vico, Mendoza, & Iglesias-Linares, *J Pediatr* 2016).

10.1 General Instructions

While their moms are waiting in an adjacent waiting area, children will be escorted to an adjoining room absent of any distractions (e.g., televisions, video games). Children will be seated at a table and given a treat of their choice (marshmallow, Oreo cookie, pretzel or a Hershey's kiss – whichever they initially indicate is the 'most yummy'). The selection of four food choices will be the same in all four field centers and taking into account allergies. They will be told that they can eat their selected treat now (i.e., "immediate gratification") or receive two treats if they can wait until the experimenter returns (i.e., 15 minutes, "delayed gratification"). Do no tell the child the amount of time (i.e. 15min) s/he will wait. Children must first make this choice. The child will be instructed wait patiently and when they are finished waiting they can ring a bell on the desk. If the child says s/he is not willing to wait, they are given just one treat. The research assistant will leave the room and start the stopwatch. Once the bell is rung, the child will be brought the smaller food portion by research staff who will first record the total wait time (minutes and seconds) using a stopwatch (Mischel et al, *Science* 1989). Thus, the outcome is duration wait time (minutes/seconds) the child is able to delay.

10.2. Equipment and Supplies

The equipment and supplies necessary for the delayed gratification task are as follows:

- Selection of treats (marshmallow, Oreo cookie, pretzel or a Hershey's kiss)
- Paper plates
- MROCO Big Call Desk Service Bell
- MARATHON Adanac 3000 Digital Sports Stopwatch Timer
- HelloBaby HB32 Wireless Video Baby Monitor (non-recording, observation only)

10.3 Script

The delayed gratification script (Appendix 4) introduces the procedure to the participants, determines the child's selected treat, and walks through the procedure instructions before conducting the procedure.

10.4 Form (MATE)

The form MATE will include details about food choice made, reason for stopping the watch, observed behavior while waiting the 15 minutes (minutes and seconds).

10.5 Operating Procedures

- Set up-Room with monitor, table, chair and bell. The room should be free of distraction with a child-sized table and chair.
- Show the child and parent the room where the “marshmallow test” will be administered.
- On the table, initially there should be only a bell.
- Practice the Bring-Me-Back Bell with the child. See script in appendix 4.
- Explain to the child that their mom/parent will go to another room for a few minutes while the child will play a game with the research assistant. Make sure the child is comfortable and reassure him/her that they will be taken back to their parent after they finish the game.
- After the parent has left, have the child sit down in front of the table where the bell is and then place four types of food treats on a tray. After child indicates preference, take the other three away and leave the preferred treat.
- Start the stopwatch timer and walk out.
- Go to the place where the baby monitor is located. The experimenter stops the stopwatch and returns if the child exhibits distress or has begun to eat the treat.
- **Once bell is rung or 15 minutes have passed**, record time and give the treat chosen. If bell was not rung and time expired, record on form and give two treats (the same chosen).
- Praise the child for playing the game, and bring them back to the parent.

11. SALIVA SWAB SAMPLE COLLECTION

Due to the coronavirus pandemic, infection prevention and control procedures will be in place to ensure staff and participant safety (**see Table 7.1 in Appendix 7**). Specifically, for the saliva assisted collection it will no longer be performed by SOL FLOR staff. Instead, the mom will assist the child. See **Appendix 8** for detailed specific changes to this procedure.

11.1 Overview/General Instructions

We will obtain DNA from children using the non-invasive Oragene•DISCOVER (OGR-600) by DNA Genotek Inc. (Ottawa, Ontario, Canada) which was designed to collect saliva from younger children (ages 6 mos-5 yrs) who might have difficulty spitting. Highly absorbent sponges on sticks will be placed in the child's mouth and the saliva obtained from the sponges will be squeezed into the collection tube. The collection process will be repeated until the desired amount of 2 mL is achieved, then the tubes will be capped (thereby releasing the stabilizing solution) and samples stored at ambient temperature until ready to ship to the Human Genetics Center (HGC) Laboratory at the University of Texas Health Science at Houston, for DNA isolation and genotyping. DNA will be isolated with the Gentra Puregene Blood Kit (Qiagen, N.V., Venlo, The Netherlands) and stored in accordance with the manufacturer's instructions.

Supplies Needed

- Oragene-DISCOVER (OGR-600) by DNA Genotek Inc. (Ottawa, Ontario, Canada) for unassisted collection
- Oragene-DISCOVER (OGR-675) by DNA Genotek Inc. (Ottawa, Ontario, Canada) for assisted collection
- Zebra Symbol DS2278-SR Wireless 2D/1D Bluetooth Barcode Scanner/Imager
- Preprinted barcode labels provided by HGC Laboratory to field centers
- Gloves
- 4 3/4" High White Cardboard Box w/Drainhole for 15/50ml Tubes (5 3/4"L x 5 3/4"D x 4 15/16"H), Phenix Research (FBK-4C)
- 36 Place Divider for 4" Boxes, Cell Opening: 0.87", For 15ml Tubes, Phenix Research (FDK-364)
- EPS Foam w/Corrugated Shipping Container, ThermoSafe (398) (for protection during shipping, not temperature regulation)
- Large rubber band to go around cardboard boxes
- Large envelopes

11.2 Collection Precautions

- Do NOT remove the plastic film from the funnel lid.
- Check sponge for damage each time before inserting into donor's mouth. Use second sponge if first sponge shows any signs of wear or tear.
- Do NOT substitute with other sponges or swabs.
- Ensure donor does NOT eat, drink, brush their teeth, or chew gum for 30 minutes before collecting a saliva sample.
- Ensure donor is in an upright position during sample collection.

- The small cap and plastic bag are considered choking hazards. Do not leave subject unattended with collection kit.
- Do not allow subjects to handle collection kit items.
- Wash with water if stabilizing liquid comes in contact with eyes or skin. Do not ingest.

11.3 Barcode Labels

IDs linking CHILD SUBJECT ID to LAB ID will be created by the coordinating center and a list will be sent to the HGC Laboratory for printing. The HGC Laboratory will pre-print all barcodes necessary for saliva collection and ship to the field centers prior to the start of the project. An additional 2D barcode, called a sample tag, are included on biological specimens for sample tracking of individual aliquots by the HGC Laboratory.

11.4 Forms

1. Complete the top part of the SOL ***FLOR Biospecimen Collection Form*** which includes the CHILD SUBJECT ID and affix a pre-printed barcode with the LAB ID.
2. Complete ***Section A. Saliva Collection Information***. If the parent answers yes to Q2, proceed with unassisted collection in an OGR-600 tube, section 11.5. If the parent answers no or don't know to Q2, proceed with assisted collection in an OGR-675 tube, section 11.6.

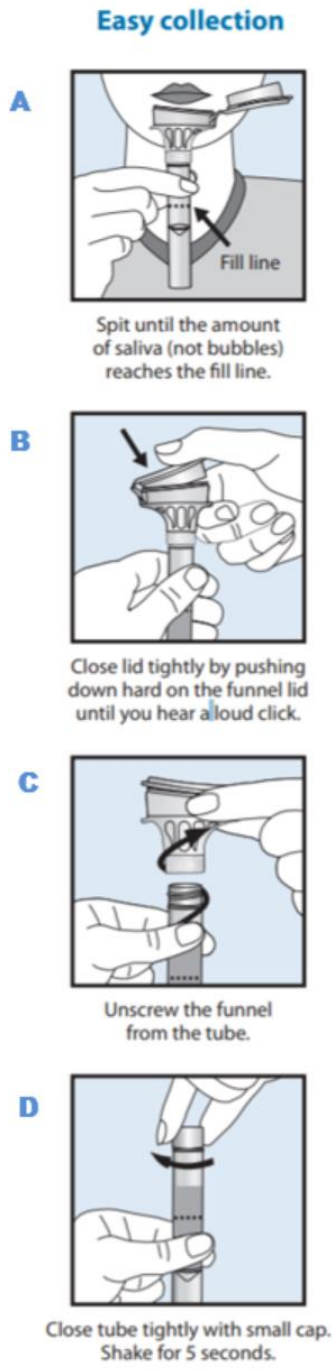
11.5 Operating Procedures for Unassisted Collection in an OGR-600 tube

1. It may take up to 5 minutes to collect a saliva sample when following the steps below.
2. Attach a preprinted ID label to the collection tube. Labels should be placed on the tubes so that the barcode is aligned vertically. The portion of the barcode to be scanned must not wrap around the tube, as the scanners can't read them. Compare and confirm that the barcode label on the saliva tube matches the barcode label on the ***FLOR Biospecimen Collection Form***.
3. Complete ***Section B. Saliva Collection Information*** Q3-5. Field center staff should use gloves to open the sterilized kit (**Figure 1**) and provide to the subject for self-collection.
4. Subject should spit into the funnel until 2 mL liquid saliva reaches the fill line. Bubbles will be present and are not considered liquid saliva. Tap the tube bottom against a hard surface to reduce the number of bubbles present (**Figure 2A**).
5. Once the fill line is reached, hold the container upright and close the lid tightly by pushing down until you hear a click. This will allow the enclosed liquid (in the cap) to mix with the saliva (**Figure 2B**).
6. Hold the container upright, and twist the funnel counter-clockwise to unscrew it from the tube (**Figure 2C**).

Figure 1. Unassisted Saliva Collection Kit Contents

7. Close the tube with the small cap and shake vigorously for 5 seconds (**Figure 2D**).
8. Discard the funnel in regular trash.
9. Complete ***Section B. Saliva Collection Information*** Q6-10.
10. If food particles or other contaminants are found, first have participant rinse their mouth with water then steps 1-9 may be repeated with a new label, new tube, and new SOL - ***FLOR Biospecimen Collection Form***. Extra labels will be provided in case a repeat sample is necessary.
11. Complete ***Saliva Sample Inventory*** Excel manifest (template provided by the HGC Laboratory) and store samples at room temperature (15°C–30°C) in an upright position in cardboard boxes until ready to ship.

Figure 2. Unassisted Saliva Collection Instructions

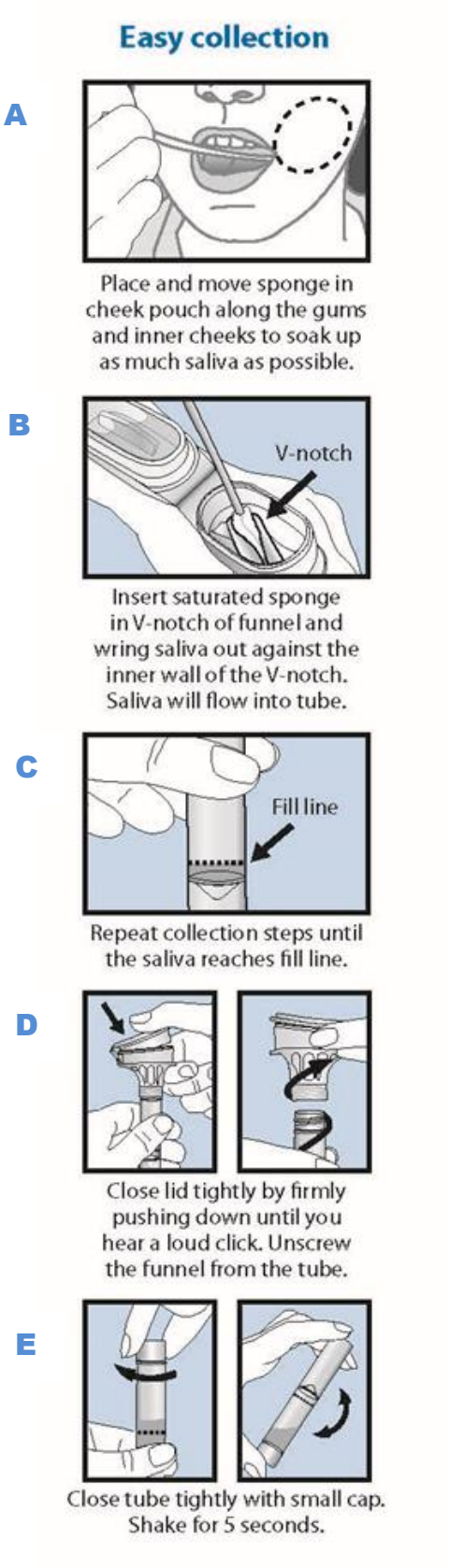


11.6 Operating Procedures for Assisted Collection in an OGR-675 tube

1. It may take up to 15 minutes to collect a saliva sample when following the steps below.
2. Attach a preprinted ID label to the collection tube. Labels should be placed on the tubes so that the barcode is aligned vertically. The portion of the barcode to be scanned must not wrap around the tube, as the scanners can't read them. Compare and confirm that the barcode label on the saliva tube matches the barcode label on the SOL ***FLOR Biospecimen Collection Form***.
3. Complete ***Section B. Saliva Collection Information*** Q3-5. Field center staff should use gloves to open the sterilized kit (**Figure 1**) and perform the collection.
4. Place one sponge along the cheek pouch. Gently move the sponge along the gums and inner checks for up to 30 seconds to soak up as much saliva as possible (**Figure 4A**). If the subject is having trouble salivating, stimulate production by rubbing the cheeks just behind the back teeth.
5. Insert the saturated sponge in the V-notch of the funnel and wring saliva out again the inner wall of the V-notch using a twisting and pushing motion. Saliva will flow into the tube (**Figure 4B**).
6. Repeat collection steps using the same sponge until liquid saliva reaches the fill line. Bubbles will be present and are not considered liquid saliva (**Figure 4C**). Tap the tube bottom against a hard surface to reduce the number of bubbles present.
7. Check the sponge for damage each time before inserting into the subject's mouth. Use the second sponge provided if the first sponge shows damage.
8. Once the 2 mL fill line is reached, hold the container upright and close the lid tightly by pushing down until you hear a click. This will allow the enclosed liquid (in the cap) to mix with the saliva (**Figure 4D**).
9. Hold the container upright, and twist the funnel counter-clockwise to unscrew it from the tube (**Figure 4D**).
10. Close the tube with the small cap and shake vigorously for 5 seconds (**Figure 4E**).
11. Discard the funnel and sponges in regular trash.
12. Complete ***Section B. Saliva Collection Information*** Q6-10.
13. If food particles or other contaminants are found, have participant rinse their mouth with water then steps 1-9 may be repeated with a new label, new tube, and new SOL ***FLOR Biospecimen Collection Form***. Extra labels will be provided in case a repeat sample is necessary.
14. Complete ***Saliva Sample Inventory*** Excel manifest (template provided by the HGC Laboratory) and store samples at room temperature (15°C–30°C) in an upright position in cardboard boxes until ready to ship.

Figure 3. Assisted Saliva Collection Kit Contents

Figure 4. Assisted Sample Collection Instructions



11.7 Preparing package for shipping to Houston

1. Complete SOL ***FLOR Biospecimen Collection Form*** Q11, if necessary, for each specimen that may have been compromised during storage (i.e., tube cracked).
2. Make copies of SOL ***FLOR Biospecimen Collection Form*** for all samples to be shipped. Place hard copies in large envelopes or plastic zip lock bags.
3. Ensure ***Saliva Sample Inventory*** Excel manifest has been completed.
4. Saliva samples will be shipped at ambient temperature and are not considered diagnostic specimens.
5. Place a rubber band around each box to keep the lid on during transit.
6. Place cardboard boxes inside Styrofoam shipping container.
7. Use brown paper or bubble wrap to fill air space so that the contents do not move during transit.
8. Place Styrofoam lid on box.
9. Please envelope with copies of SOL ***FLOR Biospecimen Collection Form*** on top of Styrofoam lid.
10. Seal outer container (cardboard box) with packing tape.
11. Ship only Monday to Wednesday. Generate a FedEx airway bill for shipment to the HGC Laboratory at the address below.
12. Schedule pick up with FedEx.
13. Email ***Saliva Sample Inventory*** Excel manifest and tracking number to HGC_lab@uth.tmc.edu.

Attn: **Human Genetics Center Laboratory**
University of Texas Health Science Center at Houston
School of Public Health
1200 Pressler St., RAS E453
Houston, TX 77030 USA
Phone: 713-500-9800

11.8 Processing at UT Houston

DNA will be isolated with the Gentra Puregene Blood Kit (Qiagen, N.V., Venlo, The Netherlands) in accordance with the manufacturer's instructions and stored at -80°C.
Genotyping will be performed using the Illumina Infinium® Multi-Ethnic Global-8 array (MEG array). The HGC Laboratory has two decades of DNA isolation and genotyping experience and is fully automated with liquid handling robotics which are integrated with a Laboratory Information Management System (LIMS) database. All sample handling occurs using uniquely 2D barcoded vials, thereby ensuring accurate tracking of individuals and merging with final genotypes. Laboratory best practices will be followed using established Illumina protocols (www.illumina.com) and as previously described in Grove et al. (Grove et al. 2013). In order to call rare variants, we will perform additional post processing steps which include using zCall v3.4_GenomeStudio to statistically determine genotypes of missing calls. A subset of rare variants will be manually reviewed for accuracy. The final genetic dataset will then be converted

to PLINK format and distributed to The University of North Carolina at Chapel Hill (UNC) for further quality assurance analyses.

11.9 Data Distribution to UNC

The HGC Laboratory Genetic data will be returned to UNC via secure file transfer protocol (sftp). Before transfer of the genetic data our data management team will use md5sum, a program designed to generate a text file of checksums, which are digital fingerprints of the files. The checksums text file will be sent along with the genetic data files. UNC can then use md5sum to confirm the integrity of the files and notify us if differences are seen or corruption occurs in transit. Problematic files will then be resent until integrity has been confirmed.

11.10 Training/Certification and Quality Control

Central training through webinar. No minimum to maintain certification. Some initial QC may be generated by Houston (shipping issues/counts, labeling issues, minimum mL fluid capture issues, etc.). UNC to track (along with Houston) shipped samples to ensure samples are being sent and to determine completed exams for project management reports. There will be 5% biospecimen replicates masked shipped to the HGC Lab as a measure of quality control.

12. 24-HOUR DIETARY

A 24-hour dietary recall is conducted on two occasions. Due to the COVID-19 pandemic, flexibility has been given to FC to complete dietary recalls. The first dietary recall may be conducted by telephone (mode 1) or in-person. The second recall may be conducted by telephone (mode 2) or in-person (mode 2) and it should conducted within one month (preferably 7-14 days) of the clinic visit. In rare instances due to issues scheduling recalls due to the COVID-19 pandemic, some recalls may be collected up to or beyond 90 days. The dietary interviewer conducts the recalls using direct data entry into NDSR software and refers to the food portion sizes for children to aid in quantifying amounts of foods and beverages.

Each field center installs the NDSR copy licensed to them on designated computer. Each bilingual dietary interviewer must have a headset or wireless earpiece for use in conducting the telephone dietary recall. **UNC Diet and Physical Activity Core (DPAC)** will supply each field center with a copy of the food portion sizes specifically for this age group (children 3-9 yrs of age).

The NDSR program automatically guides the dietary recall 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 24-hour interval covered by the in-person dietary recall begins with the first food or beverage the child had from midnight the day previous to the recall until midnight the night prior to the interview. During the in-person interview, the mother will be oriented to the process of the 24-hour recall and will learn how the food portion sizes are used to help estimate the quantities of foods consumed. The interviewer may also use food models as needed with participants to help them determine quantities of food or beverages consumed by their child. If a child is attending daycare or school, the mother will need to have the information readily available concerning what the child ate to facilitate the collection of dietary data; instructions and forms were provided at the time the visit was scheduled. If this information is not available, the recall should be rescheduled.

At the end of each in-person recall, ask the mother to identify several best days and times for the 2nd recall and attempts to schedule diet interview with the mother. The exact day of the week for the telephone recall is chosen by field center staff from available times, with an aim that the distribution of days across participants includes all days of the week possible, given clinic schedules. If the child is in school or day care, the dietary interviewer will remind the parent about how to use the SOL FLOR food record form to record the child's intake. In addition, a copy of the food portion sizes is given to keep for use in the subsequent telephone recall. The interviewer will provide instructions on how to use the portion size guide during the telephone call and stress the importance of having the portion size guide for reference during the call.

The telephone interview is collected at least five days, but preferably no more than 90 days, following the child's initial dietary recall interview. The 24-hour interval covered by the second recall is the 24 hours preceding 12:00 AM (midnight) of the previous night. If a child is attending

daycare or school, the mother will need to have the information readily available concerning what the child ate to facilitate the collection of dietary data. The telephone 24-hour dietary recall can be collected without the food portion sizes information, but interviewers should aim to have participants use the portion size guide whenever possible. If at the time of the call, the mom no longer has this and time allows, a replacement can be mailed to her and the telephone recall can be attempted a few days later. This will be left to the discretion of the interviewer and determined by time remaining to complete the second diet interview.

The dietary interviewer reviews the diet recalls, documents unusual foods and amounts, and flags unreliable recalls as soon as possible after administration. At the end of each dietary 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 recall. 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 monthly 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 transfers it to the UNC DPAC via UNC One Drive. A link to the appropriate One Drive will be sent to each Study Site Study Coordinator. The project name should include the field site, month, year, study name X, participant ID, and recall sequence (1-in person, 2-telephone) as done in previous HCHS studies that include dietary recall data.

UNC DPAC will upload projects into NDSR and check 20% of recalls within each project for quality of data entry. This includes but is not limited to: notes matching amounts, accuracy of amounts eaten, priority notes resolved, correct determinations for 'best match' of foods not found in NDSR, correct chronological order of meals, correct entry of supplements, and any other areas of specific interest as determined by study protocol. UNC DPAC will also check over all outliers in the dataset, and check all foods that are over 200 grams, 200 calories, and 10 grams of fat at the individual food level as well as all daily total intakes plus or minus one standard deviation from the mean of daily total calories. Any data found to be above or below the outlier range will be investigated further by UNC DPAC. Should sufficient information not be found in the notes of the recall, UNC DPAC will reach out to lead interviewer at field site for further clarification.

If you have any further questions, please contact:

Dina Lajoie
dplajoie@email.unc.edu, 919-966-7236

13. INTERVIEWS

Due to the coronavirus pandemic, infection prevention and control procedures will be in place to ensure staff and participant safety (**see Table 7.1 in Appendix 7**). Questionnaires, some or all, may be collected remotely.

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

Interviews in SOL FLOR study are administered in English or Spanish – at the preference of the study participant (child and mom 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 FLOR field center are administered using the SOL FLOR Data Entry System (CDART) 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 FLOR 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.

13.1. 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 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.

13.2. 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 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.

13.3. 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 of 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.

13.4. 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.

13.5. 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.

13.6. Administration of the Interviews

SOL FLOR questionnaires are interviewer-administered to the parent participants, using a specialized data entry and management system. The data entry and management system used by SOL FLOR 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 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 FLOR Steering 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, Dominican, and Central/South American). The final translations were certified prior to release for programming at the coordinating center.

13.7. 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 by HCHS/SOL staff in interviewing techniques, in the subject matter, terminology, and flow of each data collection form.

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.

14. DATA ENTRY SYSTEM (CDART)

Interviews and questionnaires will be entered into Carolina Data Acquisition and Reporting Tool (CDART). 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.

15. 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 mother 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 HCHS/SOL. The mother 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.

16. PARTICIPANT SAFETY

Due to the coronavirus pandemic, infection prevention and control procedures will be in place to ensure staff and participant safety (**see Appendix 7**).

The safety of the SOL FLOR 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.

16.1. Safe Clinic Environment

Due to the coronavirus pandemic, infection prevention and control procedures will be in place to ensure staff and participant safety (**see Appendix 7**).

Overview

Standard procedures pertaining to clinic cleanliness, professionalism and safety should be adhered to. When mothers are not accompanying their children, clinic staff members are

responsible for supervising the child. Children should be accompanied at all times by a staff member if mom 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. Children 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. SOL FLOR field centers should 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.

Food

Allergic reactions to certain foods are a potentially serious problem for some 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.

16.2. Procedures for Handling Emergencies

For persons with conditions which require emergency and immediate referrals to a physician, each field center should follow their specific HCHS/SOL procedures. If appropriate, the clinic exam should be terminated at the onset of emergency and field-center specific emergency procedures should be followed. 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 Clinic Manager identifies a person responsible for its maintenance.

16.3. 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. However, staff is responsible for making sure that they do so. 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 before to make the call without their presence, if there are specific things they want to make sure you inform Department of Child and Family Services (DCF) 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.

16.4 Infection prevention and control procedures after the participant has completed study measurements

Due to the coronavirus pandemic, infection prevention and control procedures will be in place to ensure staff and participant safety (**See Appendix 7**).

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Appendix 1: SOL FLOR Invitation Letter (English/Spanish)

Dear HCHS/SOL Participant,

Thank you for being a part of the ***Hispanic Community Health Study/Study of Latinos (HCHS/SOL)***. Your support to help us understand more about the health of all Latinos is so greatly appreciated. This is a special invitation to you and your child to participate in a new study called Family Lifestyle Outcomes Research or *SOL FLOR,* funded by the National Institutes of Health (NIH).

SOL FLOR will use information from HCHS/SOL visits 1 and 2 concerning a mother's diet, physical activity, life style behaviors and health status to see how they are associated with the health of her child born after visit 1. We will also study how parenting factors and children's lifestyle factors are associated with a child's weight.

We are inviting all HCHS/SOL women who have had a baby since visit 1, and their child, the first child born after visit 1 who is now between 3 and 9 years old to participate in SOL FLOR. Across all of HCHS/SOL field sites, we hope to enroll 440 mother/child pairs.

If you agree to participate in *SOL-FLOR,* the following will happen:

1. You and the father of your child will be asked permission for your child to participate in the study.
2. During the study visit, which may last 2 ½ to 3 hours, a trained *SOL FLOR* staff will measure your child's height, weight, and body fat, and collect a sample of his/her saliva. We will also assess the amount of time your child can wait for a food treat of his/her choice. You will be asked questions concerning your child's health, eating habits, food intake, media use, and physical activity habits, and a questionnaire about your mood and mental health as well as why you eat what you eat.
3. ~~We will perform a scan of your child's body, called a DXA scan for Dual-energy X-ray absorptiometry, to understand your child's body composition or how body weight is divided into fat, bone and lean muscle. This scan takes about 3-5 minutes and is not harmful.~~
4. Five to 10 days after your study visit, a research staff will call you to ask questions about your child's food intake. This call may last 30 minutes.
5. You will be asked to complete at home a check list of foods that you have in your home.

SOL FLOR researchers will use this information to find out how we can help Latino children eat, play and lead healthier lives. Your participation in *SOL FLOR* is voluntary and will not affect your participation in HCHS/SOL. If you decide to participate, you may receive up to $100 to reimburse you and your child for your time and transportation costs. You will receive a call from a SOL FLOR research staff in the next few days inviting you to participate or call us at [site's phone number].….

Thank you for your consideration. Your participation makes a difference!
Sincerely,

SOL FLOR and HCHS/SOL Principal Investigator
Estimado Participante de HCHS/SOL,

Gracias por formar parte del Estudio de Salud de la Comunidad Hispana/Estudio de los Latinos (HCHS/SOL). Apreciamos mucho su apoyo para ayudarnos a comprender más sobre la salud de todos los latinos. Esta es una invitación especial para que usted y su hijo/a para participen en un nuevo estudio llamado Estudio de Latinos-Estudio Complementario De los Resultados del Estilo de Vida Familiar (SOL-FLOR), patrocinado por los Institutos Nacionales de la Salud (NIH *por sus siglas en inglés*).

SOL FLOR utilizará información de las Visitas 1 y 2 de HCHS/SOL con respecto a la dieta, la actividad física, las conductas de estilo de vida y el estado de salud de una madre para ver cómo se relacionan con la salud de su hijo/a nacido/a después de la Visita 1. También estudiaremos cómo los factores de crianza y de estilo de vida de los niños se asocian con el peso de un niño/a.

Estamos invitando a todas las mujeres que participaron en HCHS/SOL que han tenido un bebé desde la Visita 1, y su niño/a, quien ahora tiene entre 3 y 9 años para participar en SOL FLOR. A través de los cuatro centros regionales de HCHS/SOL, esperamos inscribir 440 parejas de madres e hijos.

Si usted acepta participar en *SOL-FLOR*, sucederá lo siguiente:

1. Se le pedirá permiso a usted y al padre de su hijo/a para que participe en el estudio.
2. Durante la visita clínica en persona, cual podría durar 2 ½ y 3 horas, personal capacitado de *SOL FLOR* medirá la altura, el peso, y grasa corporal de su hijo/a y tomará una muestra de su saliva. También evaluaremos la cantidad de tiempo que su hijo/a puede esperar por un premio de comida de su elección. Se le harán preguntas sobre la salud de su hijo/a, los hábitos alimenticios, la ingesta de alimentos, el uso de los medios de comunicación y los hábitos de actividad física, y un cuestionario a usted sobre su estado de ánimo y salud mental, y también sobre por qué come lo que come.
3. ~~Haremos un escaneo al cuerpo de su niño/a, llamado una exploración DXA, para entender la composición corporal de su hijo/a o cómo se divide el peso corporal en grasa, hueso y musculo. La exploración dura unos 3-5 minutos y no es dañino.~~
4. Cinco a diez días después de su visita clínica en persona, un personal del estudio la llamara para hacerle preguntas sobre la ingesta de comida de su hijo/a. Esta llamada puede durar 30 minutos.
5. Se le pedirá que complete en su casa una lista de verificación de los alimentos que tiene en su hogar.

Los investigadores de *SOL FLOR* usarán esta información para descubrir cómo podemos ayudar a los niños/as latinos/as a comer, jugar y llevar vidas más saludables. Su participación en *SOL FLOR* es voluntaria y no afectará su participación en HCHS/SOL. Si decide participar, puede recibir hasta $100 para reembolsarle el tiempo y los costos de transporte.
Recibirá una llamada de una personal del estudio SOL FLOR en los próximos días para invitarle a participar, o nos puede llamar al [site's phone number].….

Gracias por la oportunidad brindada. ¡Su participación hace una gran diferencia!
Atentamente,
Investigador Principal de SOL-FLOR y HCHS/SOL

Appendix 2: SOL FLOR recruitment Script (English/Spanish)

A. No answer - Leave a message:

Option 1:
Hello, my name is [recruiter name], I am calling from the Hispanic Community Health Study/Study of Latinos, this message is for [name of participant]. I would like to talk to you about a new study, called SOL FLOR, designed to learn more about the health of Hispanic/Latino children in the United States. Our site is now opened to see participants in person with all infection prevention and control procedures in place to ensure our participants and staff safety. Please feel free to call us at [field center's phone number] if you are interested or we will call you back in a couple of days. Information from this new study will help us better understand the ways in which your health and your child's health are connected. Thank you very much, have a nice day.

Option 2:
"Hello, my name is [recruiter name], I am calling from the Hispanic Community Health Study/Study of Latinos, this message is for [name of participant]. We would like to talk to you about a new study, called SOL FLOR. Please feel free to call us back at [field center's phone number] or we will call you back in a couple of days. Thank you very much, have a nice day."

B. On the phone, initial welcome/confirmation of first-born child since HCHS/SOL V1:

Hello, my name is [recruiter name], I am calling from Hispanic Community Health Study/Study of Latinos. May I speak with [name of participant]?

Not Available:

When would be a good time to call her back? [Obtain date and time]
Thank you, I will call again. *Call is ended.*

HCHS/SOL Participant is available:

Hello, Ms ___[name of participant]_____, my name is___[recruiter name]___. I work with the Hispanic Community Health Study/Study of Latinos (SOL). We can't thank you enough for continuing to participate in this study. *Continue with the following script.*

We recently mailed you a letter describing the Family Lifestyle Outcomes Research Ancillary Study (SOL FLOR) a new study designed to learn more about the health of Latino children in the United States. Before I tell you more about the study, let me verify your address. Are you still living at [participant's address]?

*If **NO**, collect the participant's information.*
Could you please tell me your new address to keep our records updated?

*If **YES**, continue with script below.*

Thank you very much. Since you are an active SOL participant, we would like to invite you and your child to participate in SOL FLOR Study. Information from this new study will help us better understand the ways in which your health and your child's health are connected. You were selected from individuals who participated in SOL visit 2 because you gave birth to a child after your participation in SOL Visit 1 on [insert V1 date from eligibility list]**.**

Please answer the following questions.

Our records from SOL Visit 2 indicate that your first child born after SOL Visit 1 was a (insert sex, boy or girl, from eligibility list) born on (insert MM/DD/YYYY from eligibility list). Is this correct?

*If **YES**, continue to Section C.*

*If **NO**…*
If they are confirmed as the first-born child since SOL Visit 1 yet the information is incorrect, then ask for the child's correct date of birth and gender and update the CDIE form accordingly. Continue to Section C.

If not confirmed as first-born child, ask if/which child (if others) is the oldest who was born after the SOL Visit 1 on [insert V1 date from eligibility list]. Then ask for her/his date of birth and gender and update the CDIE form accordingly. Continue to Section C.

C. Eligibility Determination.

What is the name of your child?
Enter info into field center local tracking system and refer to the child by name below.

I have a couple of questions to ask to make sure you and your child are eligible to participate in SOL FLOR. May I ask them?

*If **NO**, i.e. participant refuses to be screened, complete Q#4 in ELEB form and ask* → May we know why you would not like to participate?

*If **yes and given a reason, record reason as notelog in ELEB form**.*
*If **no, document "No reason given" as notelog in ELEB*** → Ok no problem, thank you for your time and participation in SOL.

If participant agrees to be screened → Administer the Individual Eligibility (ELEB) form to determine eligibility status.

*If the child has been determined as **ineligible**, then record ineligible status in ELEB form →*
Thank you for answering all my questions. Unfortunately, you and your child are ineligible to participate in SOL FLOR. Once again, thank you for your time and for your continued participation in SOL.

*If the child has been determined as **eligible**, then continue to Section D below.*

D. Interest in Participation.

We expect that the entire examination will take between 2 to 2 ½ hours. If you and your child agree to participate, you may receive up to $100 for your time and/or transportation [*field center specific information]*.

During your visit to the SOL center, we will ask you about your child's health, eating habits, media use, and physical activity habits, and about your mood and mental health as well as why you eat what you eat. We will also measure your child's weight, height, and body fat percentage. We will also ask for him/her to spit in a tube to obtain DNA from the saliva, and assess the amount of time [insert CHILD's NAME] can wait for a food treat of their choice.

During your visit we will also ask about what food your child may have eaten over the past 24 hours. This 2nd Diet Recall can also be completed over the phone. To get a more accurate picture of her/his diet, we will repeat this procedure in a week. This process of asking what your child ate is similar to what you experienced in your first SOL visit and will take approximately 20 minutes.

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

Would you like to participate in this SOL FLOR study?

No, I'm not interested → *complete Q#4 in ELEB form and ask →* May we know why you/your child would not like to participate?

*If **yes and given a reason, record answer as notelog in ELEB form.***

*If **no, document "No reason given" as notelog in ELEB Form →*** Ok no problem, thank you for your time.

Not sure → Would you like me to send you more information about this study? I can send you some SOL FLOR study information and 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? *Track day/time locally and attempt again at that time.*

Yes, I am interested → *Complete Q#4 in ELEB*

E. Father/2nd Parent Availability.

Note: Since the DXA has been removed from the SOL FLOR study protocol, the Father/2nd parent availability is no longer needed. This section has been removed from the script and the ELEB questions will be deactivated.

F. Scheduling Visit.

Is your child able to stand and walk without the use of a **temporary** assisted movement devices (ex. crutches, wheelchair)?

If **NO** → OK, then we will need to re-contact you soon after your injury has healed in order to schedule your visit.

Determine an estimated date that the injury will likely be healed and re-contact the participant then. Once re-contacted, be sure to ask this question again. Record injury status in ELEB form

If **YES** → Does your child currently have any mouth injuries?

If **YES** → OK, then we will need to re-contact you soon after your injury has healed in order to schedule your visit.

Determine an estimated date that the injury will likely be healed and re-contact the participant then. Once re-contacted, be sure to ask this question again. Record injury status in ELEB form

If **NO** → When would be a good time for you and your child to come to the SOL FLOR research center? →enter scheduled day/time in ELEB form.

Your appointment is on _(date)____ at __(time)_____am

Let me remind you that the clinic is located at ___[field center address]_____. Our phone number is _[field center phone number]_____. Also, I'd like to inform you that neither you (mom) nor your child need to fast for this study.

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

G. Safety questions.

To ensure the visit is safe for (state child's name), I would like to ask you a couple of questions related to the weight and body fat measurements acquisition.

Does your child have either a heart pacemaker or defibrillator or any other internal electronic device inserted in the body that your child cannot remove?
(If yes, then use WEIGHT ONLY setting for Tanita Scale)

If **YES** → then use WEIGHT ONLY setting for Tanita Scale.

Does your child have a prosthetic limb or a non-removable cast that your child cannot remove or that your child may not be comfortable removing?
If **YES** → then use WEIGHT ONLY setting for Tanita Scale.

Record safety status information in the ELEB form

(Field center specific) Will you need a ride to our clinic? If so, we can arrange {field center specific on how the transportation will be accommodated].

(Field center specific) You should expect a package of instructions for your visit before your appointment date. **This package includes** a copy of the [***SOL FLOR informed consent forms***, instructions on how to ask your child's teacher or day care provider about what your child ate the day before the visit, list of items to bring to the research center, the type of clothes he/she should wear to make it more comfortable for them, and a map with directions to our research center. **Please be sure to share this information with the child's [father/other parent]. We will need for them to sign the consent form either before or at the visit. 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 information in the package, or your child's participation in the study, feel free to call ___[field center phone number]___ .

A. No answer - Leave a message:

Option 1:
Hola, mi nombre es [recruiter name], estoy llamando del Estudio de la Salud de la Comunidad Hispana/Estudio de Latinos, este mensaje es para [name of participant]. Me gustaría hablar con usted sobre un nuevo estudio, llamado SOL FLOR, diseñado para conocer más sobre la salud de los niños hispanos/latinos en los Estados Unidos. Nuestra clínica ahora está abierta para ver a participantes en persona con todos los procedimientos de prevención y control de infecciones implementados para garantizar la seguridad de nuestros participantes y personal. Por favor, si está interesada no dude en llamarnos al [field center's phone number] o nosotros le volveremos a llamar en un par de días. La información que obtengamos de este nuevo estudio nos ayudará a comprender mejor las formas en que su salud y la de su hijo están conectadas. Muchas gracias, que tenga un buen día.

Option 2:
Hola, mi nombre es [recruiter name], estoy llamando del Estudio de la Salud de la Comunidad Hispana/Estudio de Latinos, este mensaje es para [name of participant]. Me gustaría hablar con usted sobre un nuevo estudio, llamado SOL FLOR. Por favor, no dude en llamarnos al [field center's phone number] o nosotros le volveremos a llamar en un par de días. Muchas gracias, que tenga un buen día.

B. On the phone, initial welcome/confirmation of first-born child since HCHS/SOL V1:

Hola, mi nombre es [recruiter name], estoy llamando del Estudio de la Salud de la Comunidad Hispana/Estudio de Latinos. ¿Se encuentra [name of participant]?

Not Available:

¿Cuándo sería un buen momento para volverla a llamar? [Obtain date and time]
Gracias, volveré a llamar. *Call is ended.*

HCHS/SOL Participant is available:

Hola, Sra ___[name of participant]_____, mi nombre es___[recruiter name]___. Yo trabajo con el Estudio de la Salud de la Comunidad Hispana/Estudio de los Latinos. Estamos muy agradecidos por su continua participación en este estudio. *Continue with the following script.*

El Estudio Complementario de investigación sobre los Resultados del Estilo de Vida Familiar (SOL-FLOR) es un nuevo estudio diseñado para aprender más sobre la salud de los niños latinos en los Estados Unidos. Antes de hablar más sobre el estudio, permítame verificar su dirección. ¿Sigue viviendo en [participant's address]?

*If **NO**, collect the participant's information.*

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

*If **YES**, continue with script below.*

Muchas gracias. Como usted es una participante activa de SOL, queremos invitarla a usted y a su hijo/a a participar en el estudio de SOL FLOR. La información de este nuevo estudio nos ayudara a comprender mejor las formas en que su salud y la salud de su hijo están conectadas. Usted fue seleccionada entre las personas que participaron en la Visita 2 porque dio a luz a un bebé después de su participación en SOL Visita 1 en [insert V1 date from eligibility list]**.**

Por favor responda a las siguientes preguntas.

Nuestros registros de SOL Visita 2 indican que su primer hijo nacido después de SOL Visita 1 fue (insert sex, boy or girl, from eligibility list), nació en (insert MM/DD/YYYY from eligibility list). ¿Es esto correcto?

*If **YES**, continue to Section C.*

*If **NO**…*
If they are confirmed as the first-born child since SOL Visit 1 yet the information is incorrect, then ask for the child's correct date of birth and gender and update the CDIE form accordingly. Continue to Section C.

If not confirmed as first-born child, ask if/which child (if others) is the oldest who was born after the SOL Visit 1 on [insert V1 date from eligibility list]. Then ask for her/his date of birth and gender and update the CDIE form accordingly. Continue to Section C.

C. Eligibility Determination.

¿Cuál es el nombre de su hijo/a?

Enter info into field center local tracking system and refer to the child by name below.

Tengo un par de preguntas para asegurarme de que usted y su hijo/a sean elegibles para participar en SOL FLOR. ¿Puedo hacerlas?

*If **NO**, i.e. participant refuses to be screened, complete Q#4 in ELEB form and ask →*
¿Podemos saber por qué no le gustaría participar?
*If **yes and given a reason, record reason as notelog in ELEB form**.*

*If **no, document "No reason given" as notelog in ELEB*** → Ok no hay problema, gracias por su tiempo y participación en SOL.

If participant agrees to be screened → *Administer the Individual Eligibility (ELEB) form to determine eligibility status.*

*If the child has been determined as **ineligible**, then record ineligible status in ELEB form* → Gracias por responder a todas mis preguntas. Desafortunadamente, usted y su hijo/a no son elegibles para participar en SOL FLOR. Una vez más, gracias por su tiempo y su continua participación en SOL.

*If the child has been determined as **eligible**, then continue to Section D below.*

D. Interest in Participation.

Esperamos que la examinación en persona dure entre 2 y 2 ½ horas. Si usted y su hijo/a aceptan participar, puede recibir hasta $100 por su tiempo y/o transporte. [*field center specific information]*.

Durante su visita al centro de SOL, le preguntaremos sobre la salud, hábitos alimenticios, el uso de medios digitales, y hábitos de actividad física de su hijo/a, y sobre el estado de ánimo y salud mental suyos, así como el motivo por el que come lo que come. También tomaremos medidas de la estatura, el peso y el porcentaje de grasa corporal de su hijo/a. También le pediremos a él/ella que escupa en un tubo para obtener ADN de la saliva, y evaluaremos la cantidad de tiempo que [insert CHILD's NAME] puede esperar por un premio de comida de su elección.

Durante su visita también le preguntaremos sobre que alimentos su niño/a pudo haber comido en las últimas 24 horas. El segundo registro de dieta también se puede completar por teléfono. Para obtener una idea más precisa de su dieta, repetiremos este procedimiento en una semana. Este proceso de preguntar que comió su hijo es similar a lo experimento usted en su primera visita SOL y tomará aproximadamente 20 minutos.

La participación en este estudio es voluntaria. Si usted y/o su hijo/a eligen no participar, no afectara su relación con el estudio SOL. Aún será un participante de SOL y parte de todas las actividades de SOL.

¿Le gustaría participar en este estudio SOL FLOR?

No, I'm not interested → *complete Q#4 in ELEB form and ask* →¿Podemos saber por qué a usted o su niño/a no le gustaría participar?

*If **yes and given a reason, record answer as notelog in ELEB form.***

*If **no, document "No reason given" as notelog in ELEB Form*** → Ok no hay problema, gracias por su tiempo.

Not sure → ¿Quiere que le envíe más información sobre este estudio? Puedo enviarle información sobre el estudio SOL FLOR y volverla a llamar la semana que viene.

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

¿Cuándo sería un buen día y hora volver a llamarle? *Track day/time locally and attempt again at that time.*

Yes, I am interested → *Complete Q#4 in ELEB and Q#1 in ICRE forms.*

E. Father/2nd Parent Availability.

Note: Since the DXA has been removed from the SOL FLOR study protocol, the Father/2nd parent availability is no longer needed. This section has been removed from the script and the ELEB questions will be deactivated.

F. Scheduling/Conducting Remote Interview.

¿Puede su hijo/a pararse y caminar sin el uso dispositivos de movimiento asistido **temporario** (ej. muletas, silla de ruedas)?

If **NO** → OK, entonces tendremos que volver a ponernos en contacto con usted después de que su lesión haya sanado para programar su visita.

Determine an estimated date that the injury will likely be healed and re-contact the participant then. Once re-contacted, be sure to ask this question again. Record injury status in ELEE form

If **YES** → En este momento ¿Tiene su hijo/a tiene actualmente alguna lesión en la boca?

If **YES** → OK, entonces tendremos que volver a ponernos en contacto con usted después de que su lesión haya sanado para programar su visita.

Determine an estimated date that the injury will likely be healed and re-contact the participant then. Once re-contacted, be sure to ask this question again. Record injury status in ELEE form

If **NO** → ¿Cuándo sería un buen momento para que usted y su hijo/a vinieran al centro de investigación SOL FLOR? →enter scheduled day/time in ELEE form.

Su cita es el _(date)____ a las __(time)_____am

Le recuerdo que la clínica está ubicada en ___[field center address]_____. Nuestro número telefónico es _[field center phone number]_____. Además, me gustaría informarle que ni usted (mamá) ni su hijo/a necesitan ayunar para este estudio.

Un día antes de su cita, recibirá una llamada para recordarle a usted y a su hijo/a de su cita.

G. Safety questions.
Para asegurar que la visita sea segura para [insert CHILD's NAME], me gustaría hacerle unas preguntas relacionadas con la adquisición de las medidas de peso y grasa corporal.

¿Su niño tiene un marcapasos o desfibrilador cardiaco o cualquier otro dispositivo electrónico interno insertado en el cuerpo que su hijo no se puede quitar?

If **YES** → then use WEIGHT ONLY setting for Tanita Scale.

¿Su niño tiene una prótesis o un yeso no removible que su niño no se puede quitar o que quizás no se sienta cómodo quitándose?
If **YES** → then use WEIGHT ONLY setting for Tanita Scale.

Record safety status information in the ELEB form

(Field center specific) ¿Necesitará que la lleven a nuestra clínica? Si es así, podemos organizar {field center specific on how the transportation will be accommodated].

(Field center specific) Usted debe recibir un paquete de instrucciones para su visita antes de la fecha de su cita. **Este paquete incluye** una copia de los formularios de consentimiento informado de SOL FLOR, instrucciones sobre cómo preguntar al maestro de su hijo/a o al proveedor de guardería sobre lo que comió el día anterior a la visita, lista de artículos para llevar al centro de investigación, el tipo de ropa que él/ella debe usar para que sea más cómodo para ellos, un mapa con instrucciones para llegar a nuestro centro de investigación. **Asegúrese de compartir esta información con el padre de su hijo/a. Necesitaremos que firmen el formulario de consentimiento antes o en la visita. Esperamos que estos materiales expliquen lo que usted y su hijo deben esperar el día de su visita.** Si tiene alguna pregunta o inquietud sobre la información en el paquete, o la participación de su hijo en el estudio, no dude en llamar. ___[field center phone number]___ .

Appendix 3: DXA Procedure Script (English/Spanish)

All children will need a weight and height collected to be entered into the DXA machine. If the DXA scan is on the same day of the clinic visit, then we will use that weight and height (ANTE form) but converted from kg to lb. If not, then the child needs to be measured again following procedures described in the SOL FLOR Manual of Procedures.

During this time, the study participant should be again asked about and examined for metal that could be in the scans path. Typical metal objects to look for are earrings, eyeglasses, wristwatches, coins, rings, buttons, buckles, zippers, body piercings, and support braces. Dental braces are obviously not removable, and present no problem. The child should remove shoes, and it may be necessary to remove skirts, slacks, etc. If in doubt, it is best to remove the object in question. All items removed for the scan should be given to the study participants guardian, who must be present, for secure storage

A. Introduction to procedure:

Say to the mother: "Today we are going to perform a Dual-energy X-ray absorptiometry or DXA scan on your child. This whole-body scan will give us a detailed snapshot of how your child's body weight breaks down into fat, bone and lean tissue. The scan itself only takes about 3-4 minutes to complete. The amount of radiation exposure to your child is much less than going through the metal detector gate at an airport, or spending a day outdoors."

C. Preliminary Procedure Information and Safety Checks:

Say to the mother:
"Now let me ask you a few questions: When was the last time your child ate a meal?" Record the last meal time (HH:MM) in the DXA Bone Mineral Density (DXAE) form.

"Has your child used the bathroom in the last hour?"

If not ask them to do so. If yes or once bathroom is used, record bathroom used in the DXA Bone Mineral Density (DXAE) form.

"Please remove any earrings, eyeglasses, wristwatches, coins, rings, buttons, buckles, zippers, body piercings, and support braces."

"Finally, can we please have your child remove his/her shoes."

C. Begin Procedure

Say to the mother: "I will position (name of child) on the scan table. Before we get started, I want to caution you and [child's name] not to bump into or reach for the scan arm [show both the scan arm] because it could be easily damaged."

Say to the child: "[Name of child] now please lie down on the table and I will position you for the scan. I'm going to pull up on your shoulders to straighten you. I will position your arms and feet correctly for the scan and then wrap these Velcro straps loosely around your feet to hold them in place. In order to receive a good quality scan, it is important that you lie perfectly still during the scan and do not talk. Do you have any questions?"

Answer any questions the child and/or parent may have.

If any other positioning aids are used, record this and the type(s) used in the DXA Bone Mineral Density (DXAE) form.

D. End Procedure

Once the DXA technician completed the procedure, praise the child for completing the procedure.

Record any observed moving behaviors (ex. hand or foot movement, body shifting, etc.), in the DXA Bone Mineral Density (DXAE) form.

Obtain the DXA scan printout from the technician. Upon return to the field center clinic, be sure to scan the DXA printout into a PDF (name SBJECTID.pdf). Enter the specifically requested DXA measurements on the DXA Bone Mineral Density (DXAE) form per the SOL FLOR study MOP. Also upload the scanned PDF using the CDART file upload tool in the CDART version of the DXA Bone Mineral Density (DXAE) form.

All children will need a weight and height collected to be entered into the DXA machine. If the DXA scan is on the same day of the clinic visit, then we will use that weight and height (ANTE form) but converted from kg to lb. If not, then the child needs to be measured again following procedures described in the SOL FLOR Manual of Procedures.

During this time, the study participant should be again asked about and examined for metal that could be in the scans path. Typical metal objects to look for are earrings, eyeglasses, wristwatches, coins, rings, buttons, buckles, zippers, body piercings, and support braces. The child should remove shoes, and it may be necessary to remove skirts, slacks, etc. If in doubt, it is best to remove the object in question. All items removed for the scan should be given to the study participants guardian, who must be present, for secure storage

A. Introduction to procedure:

Say to the mother: "Hoy vamos a hacerle a su hijo(a) una absorciometría de rayos X de doble energía, o DXA. Esta exploración de todo el cuerpo nos permitirá ver el contenido de grasa, hueso y tejido magro del cuerpo de su hijo(a). La prueba en sí solo dura entre 3 y 4 minutos. La exposición a la radiación es mucho menor que cuando se pasa por el detector de metales en los aeropuertos".

B. Preliminary Procedure Information and Safety Checks:

Say to the mother:
"Ahora permítame que le haga unas preguntas: ¿Cuándo fue la última vez que su hijo(a) comió algo?"
Record the last meal time (HH:MM) in the DXA Bone Mineral Density (DXAE) form.

"¿Ha ido al baño el niño/la niña en la última hora?"

If not ask them to do so. If yes or once bathroom is used, record bathroom used in the DXA Bone Mineral Density (DXAE) form.

"Por favor, quítele los aretes, los anteojos, el reloj de pulsera, monedas, anillos, botones, hebillas, cremalleras, *piercings* y aparatos ortopédicos".

"Finalmente, ¿podemos por favor pedirle a su hijo(a) que se quite los zapatos?".

C. Begin Procedure

Say to the mother: "Voy a colocar a (nombre del niño) en la camilla de exploración".

Say to the child: "[Nombre del niño], ahora acuéstate en la camilla y yo te colocaré para hacerte la prueba. Voy a tirarte de los hombros para ponerte derecho(a). Voy a ponerte los brazos y los pies en la posición correcta para la prueba y luego voy a enrollar estas tiras de velcro sin apretarlas mucho alrededor de tus pies para mantenerlos en su lugar. Para que la

prueba salga bien, es importante que te quedes acostado sin moverte y que no hables durante toda la prueba. ¿Tienes alguna pregunta?"

Answer any questions the child and/or parent may have.

If any other positioning aids are used, record this and the type(s) used in the DXA Bone Mineral Density (DXAE) form.

D. End Procedure

Once the DXA technician completed the procedure, praise the child for completing the procedure.

Record any observed moving behaviors (ex. hand or foot movement, body shifting, etc.), in the DXA Bone Mineral Density (DXAE) form.

Obtain the DXA scan printout from the technician. Upon return to the field center clinic, be sure to scan the DXA printout into a PDF (name SBJECTID.pdf). Enter the specifically requested DXA measurements the DXA Bone Mineral Density (DXAE) form per the SOL FLOR study MOP. Also upload the scanned PDF using the CDART file upload tool in the CDART version of the DXA Bone Mineral Density (DXAE) form.

Appendix 4: Delayed Gratification Procedure Script (English/Spanish)

Prior to the start of the procedure (usually during informed consent/assent and again right before procedure), explain to the child (and mother /parent) that their mother will go to another room for a few minutes while the child will play a game with the research assistant.
Make sure the child is comfortable and reassure him/her that they will be taken back to their parent after they finish the game.

A. Introduction to procedure:

We are going to play a game today. But first I want to show you this. Look, a bell! See, this is how it works. *(Ring bell once.)*

Now you try it. *(Pause for child to ring bell.)*

Sometimes I have to go out of the room, but you can always make me come back by ringing this bell. This is called the bring-me-back bell. Every time you ring it you make me come back immediately. Let's try it now. I'll go out of the room, and you will make me come back by ringing this bell.

Experimenter goes out of the room and comes back immediately at the sound of the bell.

See, you made me come back! Let's try again.

The child and experimenter practice this scenario until the child is comfortable with the recall procedure.

B. Treat Selection:

After the parent has left, have the child sit down in front of the table where the bell is and then place four types of food treats on a tray, including one marshmallow, one Oreo cookie, one pretzel, and one Hershey Kiss, and then say:

First I want to ask you, which one do you think is yummiest?
Enter selection in Delayed Gratification (MATE) form.

In rare instances, a child and/or mother may not select any of the four treats (ex. diet restrictions, all are negative preferences, etc.). If so, try to reiterate the choices for the procedure in hopes that they agree to one of them. Otherwise, field center staff may offer other types of food products to use as a treat for this task (ex. fruit, other candy, etc.)

After child indicates preference, take the others away and leave the preferred treat. Enter selection in Delayed Gratification (MATE) form.

C. Begin Procedure

Okay, now we are going to play a game. I'm going to have to leave the room for a little while to do some work. You can get one treat now if you do not want to wait until I get back, but if you can wait until I get back, then you will get two of the treats.

Do you have any questions so far?

The experimenter explains then states the rules for waiting (i.e., child must not eat any of the treat), as well as reiterating the recall protocol and the associated rewards. To emphasize that the experimenter has no preference regarding the child's decision, s/he explicitly encourages the child to make his or her own choice.

If you wait without eating the _[chosen treat]__ until I come back, then you can have two of the _[chosen treat]__. If you don't want to wait, you can ring this bell any time you want to, and I'll come back right away. But if you ring the bell, you cannot have two treats, you can only have one _[chosen treat]__.

There is no right or wrong way to do this. Do whatever you prefer: you might want to wait and get two treats later or you might not want to wait and get one treat right now. Either way is OK. It is your decision and you can stop any time you want to by ringing this bell.

So remember, you can get one treat now or two later, ok?

If child indicates s/he understands, say:

Do you want one treat now or do you want to wait so you can have two treats later?

Keep one of the chosen treat on the tray on the table in front of the child along with the bell.

If answer is not to wait, record that child initially chose **not to wait** in the delayed gratification (MATE) form and give only one treat (the same chosen) to the child. Praise the child and returns the child to their parent.

If answer is to wait, record that child initially **chose to wait** in the delayed gratification (MATE) form. Staff then says:

Ok. I am going to leave the room now, but when you are done waiting, just ring this bell and I will come back in. If you do not ring the bell, then I will come back in a little while. You are not allowed to eat the treat. Any questions? Are you ready?

The experimenter then leaves the room and starts the stopwatch.

D. End Procedure

The experimenter stops the watch and returns to room if the child exhibits distress or has begun to eat the treat. If the bell is rung and watch stopped, record that the child **did not wait the full 15 minutes** and also record the total wait time in the delayed gratification (MATE) form. Give one treat to the child.

If the full 15 minutes have passed, record that the child **did wait the full 15 minutes** in the delayed gratification (MATE) form. Give two treats to the child.

Also record the first incidence of any observed behaviors (ex. sat in chair whole time, left chair and wandered around, etc.), while waiting the 15min in the delayed gratification (MATE) form.

Praise the child for playing the game, and bring them back to the parent.

Prior to the start of the procedure (usually during informed consent/assent and again right before procedure), explain to the child (and mother /parent) that their mother will go to another room for a few minutes while the child will play a game with the research assistant.
Make sure the child is comfortable and reassure him/her that they will be taken back to their parent after they finish the game.

A. Introduction to procedure:

Hoy vamos a jugar a un juego. Pero primero quiero enseñarte esto. ¡Mira, es un timbre! Fíjate cómo funciona. *(Ring bell once.)*

Ahora prueba tú. *(Pause for child to ring bell.)*

Algunas veces tendré que salir de la habitación, pero si necesitas que vuelva solo tienes que tocar el timbre. Le llamamos el timbre "vuelve ya". Siempre que la toques, volveré inmediatamente. Vamos a probar. Voy a salir de la habitación y tú harás que vuelva tocando este timbre.

Experimenter goes out of the room and comes back immediately at the sound of the bell.

¿Has visto? ¡Hiciste que regresara! Hagámoslo otra vez.

The child and experimenter practice this scenario until the child is comfortable with the recall procedure.

B. Treat Selection:

After the parent has left, have the child sit down in front of the table where the bell is and then place four types of food treats on a tray, including one marshmallow, one Oreo cookie, one pretzel, and one Hershey Kiss, and then say:

Primero quiero preguntarte cuál de estos dulces te parece más rico.
Enter selection in Delayed Gratification (MATE) form.

En raras ocasiones, ni el niño ni los padres elegirán ninguna de las opciones, por ejemplo por restricciones en la dieta, porque no les gusta ninguna, etc. Si eso ocurre, pruebe a repetir las opciones de este procedimiento para ver si así eligen alguna de ellas. Si siguen sin elegir, el personal de FC podrá ofrecer otras opciones para esta tarea, como puede ser fruta, otros dulces, etc.

After child indicates preference, take the others away and leave the preferred treat. Enter selection in Delayed Gratification (MATE) form.

C. Begin Procedure

Ahora vamos a jugar a un juego. Voy a salir de la habitación un ratito mientras tú haces un trabajo. Te puedo dar un dulce ahora si no quieres esperar hasta que regrese, pero si esperas, te daré dos cuando vuelva.

¿Quieres preguntarme algo?

The experimenter explains then states the rules for waiting (i.e., child must not eat any of the treat), as well as reiterating the recall protocol and the associated rewards. To emphasize that the experimenter has no preference regarding the child's decision, she explicitly encourages the child to make his or her own choice.

Si esperas sin comerte el/la_[chosen treat]__ hasta que yo vuelva, te daré dos _[chosen treat]__. Si no quieres esperar, puedes tocar la campanilla cuando quieras y volveré enseguida. Pero si tocas la campanilla, no te daré dos, sino solo un/una _[chosen treat]__.

Hagas lo que hagas no estará ni mal ni bien. Puedes hacer lo que prefieras: esperar y recibir dos dulces más tarde o no esperar y que te dé un dulce ahora mismo. Hagas lo que hagas estará bien. Es decisión tuya y puedes parar en cualquier momento tocando la campanilla.

Acuérdate: te puedo dar un dulce ahora o dos más tarde, ¿de acuerdo?

If child indicates s/he understands, say:

¿Quieres el dulce ahora o quieres esperar y te doy dos más tarde?

Keep one of the chosen treat on the tray on the table in front of the child along with the bell.

If answer is not to wait, record that child initially chose **not to wait** in the delayed gratification (MATE) form and give only one treat (the same chosen) to the child. Praise the child and returns the child to their parent.

If answer is to wait, record that child initially **chose to wait** in the delayed gratification (MATE) form. Staff then says:

Muy bien. Ahora voy a salir de la habitación, pero si te cansas de esperar, toca la campanilla y volveré. Si no la tocas, volveré dentro de un ratito. No puedes comerte el dulce. ¿Quieres preguntarme algo? ¿Estás listo(a)?

The experimenter then leaves the room and starts the stopwatch.

D. End Procedure

The experimenter stops the watch and returns to room if the child exhibits distress, or has touched or begun to eat the treat. If the bell is rung and watch stopped, record that the child **did not wait the full 15 minutes** and also record the total wait time in the delayed gratification (MATE) form. Give one treat to the child.

If the full 15 minutes have passed, record that the child **did wait the full 15 minutes** in the delayed gratification (MATE) form. Give two treats to the child.

Also record any observed behaviors (ex. sat in chair whole time, left chair and wandered around, etc.), while waiting the 15min in the delayed gratification (MATE) form.

Praise the child for playing the game, and bring them back to the parent.

Appendix 5: Remote Interview Administration (Mode 1) of SOL FLOR Examination Questionnaires

Core SOL FLOR Questionnaires conducted as a remote interview

Background. The steering committee approved conducting a portion of the interview battery from SOL FLOR via a remote interview (ex. telephone, videoconferencing, etc.) while the field centers are closed or open with limitations due to the COVID-19 pandemic. For the period of time that field center operations for SOL FLOR examinations have restricted (or no) physical contact with cohort study participants due to infectious disease control measures implemented for participant and staff safety, administration of select portions of the core questionnaire battery is permitted as outlined below.

a. Eligibility and Recruitment

Participants should be contacted for eligibility determination and verbal consent and administration of the SOL FLOR telephone battery in the order already presented by the SOL FLOR eligibility lists.

b. Assessment Priorities for SOL FLOR

The table below outlines the SOL FLOR questionnaires so that remote administration can occur in approximately 40-45 minutes contact time. Since participants may have limited time and be reluctant to engage in lengthy interviews remotely, participants may be recontacted back to complete the interview. Staff will also schedule a 24-hr dietary recall (15-30 minutes) to be completed in a separate call at a later time. Since some SOL FLOR measurements such as ~~DEXA,~~ anthropometry, and the saliva are closely associated in time with questionnaires such as the sleep habits, physical activity, and hospitalizations interviews (among several others), those are reserved for in-person administration, and are not be conducted remotely even if there is an expressed desire by the participant to complete.

Table 8 Questionnaire Interview Portion of SOL FLOR Examination

Questionnaire or Procedure	Form code	Time of administration in MOP (min)	Time observed in FLOR at SD English (min)	Time observed in FLOR at SD Spanish (min)
ADMINISTRATIVE				
Eligibility/Verbal Informed Consent	ELE/ICR	10-15	12	14
Demographic Information	DEM	3	3	3
QUESTIONAIRES (all administered to the mother)				
CHILD				
Health Questionnaire*(Q1-5 only)	CHQ	7	7	3
Feeding Habits	CFH	2	2	2.5
Eating Behavior	CEB	3	5	7
MOTHER				
Caregiver's Feeding Styles	CFS	4	5	5

Questionnaire or Procedure	Form code	Time of administration in MOP (min)	Time observed in FLOR at SD English (min)	Time observed in FLOR at SD Spanish (min)
Reward Based Eating Drive Scale	RED	1.5	2	2.5
Modified Yale Food Addiction Scale	MAF	3	3	2.5
Acculturation Stress	MAS	3	5	2

c. Verbal Consent Administration

In order to administer a subset of the SOL FLOR Exam Core questionnaires as a remote battery an abbreviated version of informed consent is administered first. See the SOL FLOR remote interview recruitment/consent script for the precise language to use in describing the remote interview and the compensation for the participant's time. Obtaining verbal consent for the SOL FLOR remote interview and documenting that is done using a new SOL FLOR remote consent tracking form (ICR) and the procedure and questionnaire administration checklist (CHK). Since the full SOL FLOR adult consent is not being administered at this time, only the new SOL FLOR remote consent tracking form (ICR) is completed and not the full SOL FLOR consent/assent tracking form (ICT). The full SOL FLOR consent/assent will be administered and this information will be updated at the time of a later in-person visit the field center. The CHK is used to document that SOL FLOR data collection began with the remote interview battery.

d. Data quality

The administrative tool known as the Procedure and Questionnaire Administration tracking form (CHK) will continue to serve as an inventory control record for both remote interview and in-person administration of questionnaires. There is a concern that quality of data collected remotely can be susceptible to incomplete or rushed responses as influenced by the length of individual calls. The recommendation from the study Retention and Follow-up committee is to keep total contact time to around 30 to 45 minutes to allow for the administration of an entire block of questionnaires with respect and consideration for the effort on the part of the participant. The CDART system has a missing field completeness report which should be run before stopping the interview session so that any missing items can be resolved and unnecessary call-backs avoided.

Appendix 6: SOL FLOR Recruitment Script – Remote interview (Mode 1) (English/Spanish)

A. No answer - Leave a message:

Hello, my name is [recruiter name] and I am calling from the Hispanic Community Health Study/Study of Latinos. I would like to talk to [name of participant] about a new study, called SOL FLOR, designed to learn more about the health of Hispanic/Latino children in the United States. Please feel free to call us at [field center's phone number] if you are interested or we will call you back in a couple of days. Information from this new study will help us better understand the ways in which your health and your child's health are connected. Thank you very much, have a nice day.

B. On the phone, initial welcome/confirmation of first-born child since HCHS/SOL V1:

Hello, my name is [recruiter name], I am calling from [field center name]. May I speak with [name of participant]?

Not Available:

When would be a good time to call her back? [Obtain date and time]
Thank you, I will call again. *Call is ended.*

HCHS/SOL Participant is available:

Hello, Ms ___[name of participant]_____, my name is___[recruiter name]___. I work with the Hispanic Community Health Study/Study of Latinos (SOL). We can't thank you enough for continuing to participate in this study. *Continue with the following script.*

The Family Lifestyle Outcomes Research Ancillary Study (SOL FLOR) is a new study designed to learn more about the health of Latino children in the United States. Before I tell you more about the study, let me verify your address. Are you still living at [participant's address]?

*If **NO**, collect the participant's information.*
Could you please tell me your new address to keep our records updated?

*If **YES**, continue with script below.*

Thank you very much. Since you are an active SOL participant, now it is my pleasure to invite you and your child to participate in SOL FLOR Study. You were selected from individuals who participated in SOL visit 2 because you gave birth to a child after your participation in SOL Visit 1 on [insert V1 date from eligibility list]. Information from this new study will help us better understand the ways in which your health and your child's health are connected.

Our records from SOL Visit 2 indicate that your first child born after SOL Visit 1 was a (insert sex, boy or girl, from eligibility list) born on (insert MM/DD/YYYY from eligibility list). Is this correct?

*If **YES**, continue to Section C.*

*If **NO**…*
If they are confirmed as the first-born child since SOL Visit 1 yet the information is incorrect, then ask for the child's correct date of birth and gender and update the CDIE form accordingly. Continue to Section C.

If not confirmed as first-born child, ask if/which child (if others) is the oldest who was born after the SOL Visit 1 on [insert V1 date from eligibility list]. Then ask for her/his date of birth and gender and update the CDIE form accordingly. Continue to Section C.

C. Eligibility Determination.

What is the name of your child?
Enter info into field center local tracking system and refer to the child by name below.

I have a couple of questions to ask to make sure you and your child are eligible to participate in SOL FLOR. May I ask them?

*If **NO**, i.e. participant refuses to be screened, complete Q#4 in ELEB form and ask* → May we know why you would not like to participate?

*If **yes and given a reason, record reason as notelog in ELEB form**.*
*If **no, document "No reason given" as notelog in ELEB*** → Ok no problem, thank you for your time and participation in SOL.

If participant agrees to be screened → *Administer the Individual Eligibility (ELEB) form to determine eligibility status.*

*If the child has been determined as **ineligible**, then record ineligible status in ELEB form* → Thank you for answering all my questions. Unfortunately, you and your child are ineligible to participate in SOL FLOR. Once again, thank you for your time and for your continued participation in SOL.

*If the child has been determined as **eligible**, then continue to Section D below.*

D. Interest in Participation.

Due to the COVID pandemic our protocols for this study are split into two parts. In the first part, you (the mom) will be contacted remotely (ex. telephone, videoconference) by SOL FLOR research staff. The research staff member will ask you questions about how you feed your child, how you think about food for yourself and your child, and how you have been able to adapt to living in this country. We will also ask you questions about your child's health, feeding habits, and eating behavior. During this or a separate call, we will also ask about what food your child may have eaten over the past 24 hours. This

process of asking what your child ate is similar to what you experienced in your first SOL visit and will take approximately 20 minutes.

In the second part, we will invite you and your child to an in-person visit to the SOL center to complete the examination. During your visit to the SOL field center, we will ask you about your child's health, eating habits, media use, physical activity habits, and about your mood and mental health as well as why you eat what you eat. We will also measure your child's weight and height, and will perform a body scan to see how much his/her weight is fat, bone, or lean muscle. This scan has much less radiation exposure than a typical chest x-ray. We will also ask for him/her to spit in a tube to obtain DNA from the saliva, and assess the amount of time [insert CHILD's NAME] can wait for a food treat of their choice. During your visit we will also ask about what food your child may have eaten over the past 24 hours.

We expect that the entire in-person examination will take between 1 ½ to 2 ½ hours. If you and your child agree to participate, you may receive up to $100 for your time to complete the questionnaires remotely and the in-person visit and/or transportation [*field center specific information]*.

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

Do you have any questions for me?

Would you like to participate in this first part of the SOL FLOR study?

No, I'm not interested → *complete Q#4 in ELEB form and ask* → May we know why you/your child would not like to participate?

*If **yes and given a reason, record answer as notelog in ELEB form.***

*If **no, document "No reason given" as notelog in ELEB Form*** → Ok no problem, thank you for your time.

Not sure → Would you like me to send you more information about this study? I can send you some SOL FLOR study information and 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? *Track day/time locally and attempt again at that time.*

Yes, I am interested → *Complete Q#4 in ELEB and Q#1 in ICRE forms.*

E. Father/2nd Parent Availability.

I am now going to ask some questions concerning the child's father/2nd parent. We are asking because our study will need to have their permission for your child to participate in the **second part** of the SOL FLOR study. We will need for them to sign the consent form either before or at the in-person visit.

Is the child's father/second parent currently living with you? *Complete Q#5 in ELEB*

Can we contact the [father/second parent] to request consent? *Complete Q#6 in ELEB*

If **YES** →
Ask the father/2nd parent contact information. Thank you, we will contact the father/2nd parent only once we contacted you again to complete the second part of this study, in-person.

Once father/2nd parent has been contacted, the consent can be obtained using options outlined in SOL FLOR MOP (in-person at clinic visit date, in-person prior to clinic visit date, by mail before clinic visit, or other mechanisms) as allowed at local FC yet must be PRIOR to clinic visit.

If **NO** →
Ask the reason(s) and try to determine whether the reason(s) indicate that the father/2nd parent is unavailable to obtain parental permission (ex. death), especially making efforts, if needed, to determine that the 2nd parent is "not reasonably available" per SOL FLOR MOP. Record the reason for father/2nd parental consent being unavailable to order to obtain parental permission in Q#6a of the ***ELEB***.

F. Scheduling/Conducting Remote Interview.

< **Remote Interview (mode 1): Continue with interview** >
Would you like to continue the first part of the FLOR study now?

If **NO** but wants to participate→ When would be a good time for us to schedule your remote interview? →enter scheduled day/time in ELEB form.

Your remote interview appointment is on _(date)____ at __(time)_____am

If NO and does NOT want to participate → *complete Q#1 in ICRE form and ask* → May we know why you would not like to participate?

*If **yes and given a reason, record answer as notelog in ICRE form.***
*If **no, document "No reason given" as notelog in ICRE Form*** → Ok no problem, thank you for your time.

If **YES** →
Administer FLOR remote interview portion only.

< **Remote Interview (mode 1): Schedule and recontact**>

We would like to send some information to you by mail to help with the interview. We will then contact you again to complete the first part of the FLOR study.

When would be a good time for us to schedule your remote interview? →enter scheduled day/time in ELEB form.

Your remote interview appointment is on _(date)____ at __(time)_____am

<Call Back>:
Hello, my name is [recruiter name], I am calling from [field center name]. May I speak with [name of participant]?

Not Available:

When would be a good time to call her back? [Obtain date and time]
Thank you, I will call again. *Call is ended.*

HCHS/SOL Participant is available:

Hello, Ms ___[name of participant]_____, my name is___[recruiter name]___. From the SOL FLOR study. We scheduled your interview for today and I am calling you back now to complete it. Would you like to continue the first part of the FLOR study now?

If **NO** but still wants to participate→ When would be a good time for us to reschedule your remote interview? →enter scheduled day/time in ELEB form.

Your remote interview appointment is on _(date)____ at __(time)_____am

If NO and does NOT want to participate → *complete Q#1 in ICRE form and ask* → May we know why you would not like to participate?

*If **yes and given a reason, record answer as notelog in ICRE form.***
*If **no, document "No reason given" as notelog in ICRE Form*** → Ok no problem, thank you for your time.

If **YES** →
Administer FLOR remote interview portion only.

Appendix 7: In-Person Clinic Visit Infection Prevention and Control Procedures

Due to the coronavirus pandemic, infection prevention and control procedures will be in place to ensure staff and participant safety (**Table 7.1**). Before scheduling participant's study visit, the field center will follow the same protocol and procedures to conduct a SOL Cohort Visit 3 Clinic (in person) during the COVID-19 Pandemic. Like all other HCHS/SOL ancillary studies, SOL FLOR staff will wear a surgical mask and other personal protective equipment (PPE) as described in the procedure below. Wash hands or use hand sanitizer before and after any FLOR measurement. Participants will wear a surgical mask or other mask for the duration of the SOL FLOR clinic visit. **All procedures must follow institutional guidelines in addition to any other procedure and PPE requirements listed in the protocol below.**

Table 7.1. SOL FLOR Infection Prevention and Control Procedures.

Component	Description of procedure	Frequency	Product(s)
Day of the visit	Symptom and temperature screening; follow institutional guidelines	Before the visit. Follow institutional guidelines.	Touchless thermometer
FLOR staff	- Wear surgical mask and other personal protective equipment (PPE) per field center protocol. - Wash hands/use hand sanitizer before and after measurement.	Wear PPE always and wash/sanitize hands before and after measurements	PPE and hand sanitizer per field center protocol
HCHS/SOL participants	- Wear surgical mask. - Wash hands/use of sanitizer. - Gloves available upon entrance to collection room.	Upon arrival and throughout FLOR visit	Mask, sink with soap, and hand sanitizer, gloves
Scale and stadiometer	- Wipe or spray with alcohol or disinfectant.	Before and after each participant	Alcohol or other disinfectant
Saliva collection	- See description below (pages 3-5 of Appendix)	As indicated below	As indicated below
Delayed Gratification Task	- Wipe or spray with alcohol or disinfectant the table, chair, bell, baby monitor and stopwatch. - In the presence of the mother, using gloves, pull from closed container the preferred treat (marshmallow, Oreo cookie, pretzels, or Hershey kisses). - Child will not wear mask while being alone.	After each participant	Alcohol or other disinfectant
Laptop, top of desk stand, pens, and all hard surfaces touched	- Wipe with alcohol wipe keyboard, top of desk stand, pens, pencils and all hard surfaces.	After each participant and use of room or if switching FLOR staff	Alcohol wipe or other disinfectant

*Please refer to the appendix of HCHS/SOL Manual 2 for additional information about COVID-19 related protocols that will be implemented in HCHS/SOL in-person clinic visit 3.

Table 7.2 summarizes SOL FLOR procedures and questionnaires (ordered by priority of administration), pre-COVID-19 and by modes 1 & 2 during COVID-19 pandemic. **The changes to SOL FLOR original protocol for the in-person visit are:**

6. **The DXA procedure will not be conducted.**
7. **Saliva collection will be performed by the mother** preferably at the clinic following directions from FLOR staff keeping social distance. However, if it is not possible it can be conducted at the children's home and shipped to the site on a prepaid envelope.
8. **Questionnaires from mode 2 can be collected remotely** and preferably within a month of the in-person clinic visit.

Table 7.2. SOL FLOR procedures and questionnaires, Pre-COVID-19 and by modes 1 and 2 during COVID-19 pandemic.

Questionnaire or Procedure	Form code	Time of administration	Pre-COVID-19 Clinic Visit	Mode 1 (Remote[a])	Mode 2 (Clinic Visit)
ADMINISTRATIVE					
Pre-visit screening (eligibility)	ELE	3	Yes	Yes	Yes
Reception, itinerary checklist form	CHK	15	Yes		Yes
Informed consent/assent tracking	ICT/ICR	3-10	Yes	ICR	ICT
Child Demographic Information	DEM	3	Yes	Yes	
Exit interview & Interviewer Assessment of Interview	IAI	2	Yes		Yes
PROCEDURE					
Saliva Swab (child)	SSW	3-15	In-person		In-person or remote (performed by mom)
Marshmallow task (child)	MAT	10-15	In-person		In-person
Anthropometry (child)	ANT	5	In-person		In-person
DXA (child)	DXA	5-10	In-person		WILL NOT BE DONE
24-hr dietary recall, supplements (parent about child)	--	15-30	In-person (1st) & phone (2nd)	Remote (1st)	Remote[b] (2nd)
QUESTIONAIRES					
CHILD (staff-administered to the mom)					
Assessment of Prepubertal Development Scale[c] (only for ≥9 yrs old)	PDE	3	In-person		In-person or remote[b]
Health Questionnaire	CHQ	7	In-person	Remote (Q1-Q5)	In-person or remote[b] (Q6-Q7)
Hospitalizations	HSP	3	In-person		In-person or remote[b]
Feeding Habits	CFH	2	In-person	Remote	
Eating Behavior	CEB	3	In-person	Remote	
Child Care	CHC	3	In-person		In-person or remote[b]
Media Use & Sedentary Behavior	CMU	8	In-person		In-person or remote[b]
Physical Activity & Transportation to School	PAT	4	In-person		In-person or remote[b]
Sleep Habits	CSH	5	In-person		In-person or remote[b]
MOTHER					
Caregiver's Feeding Styles	CFS	4	In-person	Remote	
Reward Based Eating Drive Scale	RED	1.5	In-person	Remote	
Modified Yale Food Addiction Scale	MAF	3	In-person	Remote	
Well Being (Depression and Anxiety)	WBQ	3	In-person		In-person or remote[b]
Acculturation Stress	MAS	3	In-person	Remote	
Home Food Inventory/availability (completed at home)	HFI	20	Self-administered		Self-administered

[a] Preferred order for Mode 1 (remote) questionnaires: CFH, CEB, CFS, RED, MAF, MAS, CHQ and DEM.

[b] Questionnaires for mode 2 should be administered within a month of in-person clinic-visit. It can be while scheduling the in person visit or after it.

[c] For children ≥9, we will assess prepubescent stage through a questionnaire administered with the mom and child that quires about signs of pubertal development.

Appendix 8: Revised Saliva Swab Collection (Modifications to Chapter 11)

We will continue to obtain DNA from children using the non-invasive Oragene-DISCOVER models OGR-600 or OGR-675 for unassisted (self-collection) and assisted, respectively. Additional procedures to protect from SARS-CoV-2 exposure are included in the directions below.

Collection Room Set Up

- Clean all surfaces with alcohol or other approved cleaner at the beginning of each day.
- The keyboard, mouse and any of items of high touch should be covered with clear disposable plastic barrier film and changed between each participant.
- A disposable paper or diaper should be placed on a surface for the participants to place any items they brought in with them such as a purse or phone.

PPE

- To be worn by researcher at all times when in the room where saliva collection is occurring:
    - Surgical mask or mask with higher air filter protection Face shield
    - Gloves
    - Disposable gown

- To be worn by parent and child when in collection room:
    - Disposable surgical face masks (child's removed during saliva collection).
    - Gloves. If children are unable to wear gloves, their hands should be washed with soap and water or hand sanitizer before and after collection.

Sample Handling Precautions

- During saliva collection researchers should attempt to stay 6 feet from the patient whenever possible.
- Upon collection of the saliva sample wipe the collection tube down with an alcohol wipe to remove any residual saliva before placing in the rack. Do not wipe the collection sticker as smearing may occur.
- Any writing utensils or other items should be cleaned with an alcohol wipe and not left the collection room.
- If collection personnel are leaving the collection area, the face shield doffing should be performed as described on page 7. Also, follow the direction in this document should the face shield become dirty.

Unassisted Collection (OGR-600)

To be done by researcher:

- Place barcode label on saliva collection tube.
- Compare barcode on tube to barcode on FLOR Biospecimen Collection Form to ensure they match.
- Provide gloves to parent and child (participant) to be worn.
- Show the parent and participant the pictures on the brochure or show self-collection video.
- Ask and observe the participant to swish with water and spit, or sip some water if child is too young to spit.
- Ask if they have any questions before beginning.
- Provide labeled saliva collection tube to parent.
- Provide verbal cues and advice to parent & child (participant) while they are performing the self-collection steps.
- After collection help participant place gloves & collection funnel into the appropriate biohazard waste container.

To be done by parent:

- Ensure gloves are always worn when handling the saliva specimen tube.
- Assist child in self collection by performing steps A to D (Figure 2 from Chapter 11).
- Return capped tube to researcher nurse or coordinator.
- Discard gloves and sample collection funnel into appropriate biohazard container held by the researcher accordance with infection control procedures.
- Wash hands with soap and water for 20 seconds or use alcohol-based hand sanitizer.

Assisted Collection (OGR-675)

To be done by researcher:

- Place barcode label on saliva collection tube.

- Compare barcode on tube to barcode on FLOR Biospecimen Collection Form to ensure they match.
- Provide gloves to parent (and child if possible) to be worn during collection.
- Show the parent the pictures on the brochure to demonstrate or show assisted collection video.
- Ask the parent if they have any questions before beginning.
- Provide labeled saliva collection tube and swabs to parent.
- Provide verbal cues and advice to parent while they are performing the assisted collection steps.

To be done by parent:

- Ensure gloves are always worn when handling the saliva specimen tube.
- Perform assisted collection as shown in steps A to E (Figure 4 from Chapter 11).
- Return capped tube to researcher nurse or coordinator.
- Discard gloves and collection funnel in appropriate biohazard waste Wash hands with soap and water or use hand sanitizer.

Collection Room Cleaning and Readiness Between Participants

- Remove gloves between patients & wash hands with soap and water or hand sanitizer. Put on new gloves.
- Remove the covering on keyboards, mouse, etc. with their collection gloves prior to ungloving. Discard paper or disposable diaper in appropriate biohazard waste.
- Clean plastic should be applied with clean gloves prior to the next study participant.
- Wipe down chairs, tables, desks or any other items in room with approved disinfectant. Replace paper or disposable diaper for participant's items.
- Remove gloves used during cleaning and wash hands with soap and water or hand sanitizer.
- Put on clean gloves to proceed with next participant.
- If at any point it appears that the gown appears to be dirty remove and replace with a clean gown. Discard all gloves, gowns and N95 masks at the end of the day in appropriate biohazard waste containers. Clean face shields as directed on the last page of this Appendix.

Storage Conditions

- Store samples at room temperature (15°C–30°C) in an upright position in cardboard boxes until ready to ship.
- Samples should be stored in locked laboratory with access by study personnel only.
- Depending on institution policies, samples should be treated as derived from potentially COVID positive participants and stored in a locked cabinet.

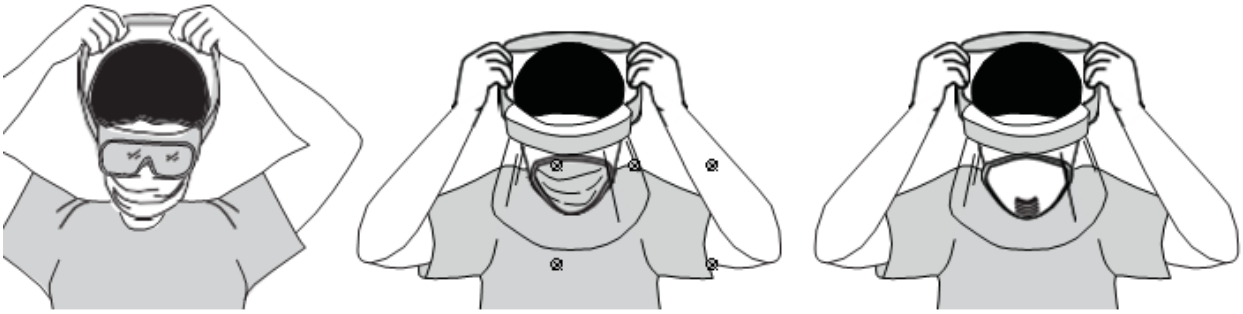
Sample Manifest/Inventory

- Add column "COVIDProtocol" to sample manifest.
- Mark with "1" if revised protocol collection due to COVID-19 was used.

DISINFECTING AND RESUSING EYE WEAR

1. GOGGLES OR FACE SHIELD DOFFING

- <u>Outside of goggles or face shield are contaminated!</u>



- Perform hand hygiene remove google/face shield by grabbing it from the back.
- If your hands get contaminated during goggle or face shield removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Remove goggles or face shield from the back by lifting head band and without touching the front of the goggles or face shield

2. REPROCESSING EYE WEAR

- While wearing gloves, carefully wipe the inside, followed by the outside of the face shield or goggles using a clean cloth saturated with neutral detergent solution (such as mild dish soap or enzymatic), a cleaner wipe, or alcohol.
- Wipe the inside of face shield or goggles with clean water or alcohol to remove residue.
- Carefully wipe the outside of the face shield or goggles using a wipe or clean cloth saturated with EPA-registered hospital disinfectant solution. Allow for full contact time.
- Wipe the outside of face shield or goggles with clean water or alcohol to remove residue.
- Fully dry (air dry or use clean absorbent towels).
- Remove gloves and perform hand hygiene.

Appendix 9: SOL FLOR Recruitment Script – In-person (Mode 2) (English/Spanish)

A. No answer - Leave a message:

Option 1:
Hello, my name is [recruiter name] and I am calling from the Hispanic Community Health Study/Study of Latinos. I would like to talk to [name of participant]. Thank you so much for having completed the phone initial questionaries for the SOL FLOR study. Our site is now opened to see participants in person with all infection prevention and control procedures in place to ensure our participants and staff safety. I am calling about scheduling 2nd part of the SOL FLOR study. Please feel free to call us at [field center's phone number] to schedule your appointment or we will call you back in a couple of days. Thank you very much, have a nice day.

Option 2:
Hello, my name is [recruiter name] and I am calling from the Hispanic Community Health Study/Study of Latinos. This message is for (name of participant) regarding SOL FLOR study. Please feel free to call us back at [field center's phone number] or we will call you back in a couple of days. Thank you very much, have a nice day.

B. On the phone, initial welcome/confirmation of first-born child since HCHS/SOL V1:

Hello, my name is [recruiter name], I am calling from Hispanic Community Health Study/Study of Latinos. May I speak with [name of participant]?

Not Available:

When would be a good time to call her back? [Obtain date and time]
Thank you, I will call again. *Call is ended.*

HCHS/SOL Participant is available:

Hello, Ms. ___[name of participant]_____, my name is___[recruiter name]___. I work with the Hispanic Community Health Study/Study of Latinos (SOL). We can't thank you enough for continuing to participate in this study. We are also very thankful that you completed the initial phone questionnaires of The Family Lifestyle Outcomes Research Ancillary Study (SOL FLOR) study. *Continue with the following script.*

We are now calling you back to schedule your visit to participate in 2nd part of the SOL FLOR study. Before I tell you more about that, let me verify your address. Are you still living at [participant's address]?

*If **NO**, collect the participant's information.*
Could you please tell me your new address to keep our records updated?

*If **YES**, continue with script below.*

Thank you very much.

C. Interest in Participation.

If you recall, due to the COVID19 pandemic our protocols for this study were split into two parts. In the first part, SOL FLOR research staff contacted you by phone and asked you questions about you and your child, including what your child eat over the past 24 hours.

In the second part, we would like to invite you and your child to an in-person visit to the SOL center to complete the FLOR study. During your visit to the SOL field center, we will ask you about your child's health, eating habits, media use, physical activity habits, and about your mood and mental health as well as why you eat what you eat. We will also measure your child's weight, height, and body fat percentage. We will also ask for him/her to spit in a tube to obtain DNA from the saliva, and assess the amount of time [insert CHILD's NAME] can wait for a food treat of their choice. During your visit we will also ask about what food your child may have eaten over the past 24 hours. This 2nd Diet Recall can also be completed over the phone.

We expect that the in-person examination will take between 1 and 1 ½ hours. You may receive up to $[*field center specific information]* for your time to complete the questionnaires and the in-person visit and/or transportation [*field center specific information]*.

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

Do you have any questions for me?

E. Father/2nd Parent Availability.

Note: Since the DXA has been removed from the SOL FLOR study protocol, the Father/2nd parent availability is no longer needed. This section has been removed from the script and the ELEB questions will be deactivated.

F. Scheduling Visit.

Is your child able to stand and walk without the use of a **temporary** assisted movement devices (ex. crutches, wheelchair)?

If **NO** → OK, then we will need to re-contact you soon after your injury has healed in order to schedule your visit.

Determine an estimated date that the injury will likely be healed and re-contact the participant then. Once re-contacted, be sure to ask this question again. Record injury status in ELEE form

If **YES** → Does your child currently have any mouth injuries?

If **YES** → OK, then we will need to re-contact you soon after your injury has healed in order to schedule your visit.

Determine an estimated date that the injury will likely be healed and re-contact the participant then. Once re-contacted, be sure to ask this question again. Record injury status in ELEE form

If **NO** → When would be a good time for you and your child to come to the SOL FLOR research center? →enter scheduled day/time in ELEE form.

Your appointment is on _(date)____ at __(time)_____am

Let me remind you that the clinic is located at ___[field center address]_____. Our phone number is _[field center phone number]_____. Also, I'd like to inform you that neither you (mom) nor your child need to fast for this study.

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

G. Safety questions.

To ensure the visit is safe for (state child's name), I would like to ask you a couple of questions related to the weight and body fat measurements acquisition.

Does your child have either a heart pacemaker or defibrillator or any other internal electronic device inserted in the body that your child cannot remove?
(If yes, then use WEIGHT ONLY setting for Tanita Scale)

If **YES** → then use WEIGHT ONLY setting for Tanita Scale.

Does your child have a prosthetic limb or a non-removable cast that your child cannot remove or that your child may not be comfortable removing?
If **YES** → then use WEIGHT ONLY setting for Tanita Scale.

Record safety status information in the ELEB form

(Field center specific) Will you need a ride to our clinic? If so, we can arrange {field center specific on how the transportation will be accommodated].

(Field center specific) You should expect a package of instructions for your visit before your appointment date. **This package includes** a copy of the [***SOL FLOR informed consent forms***, instructions on how to ask your child's teacher or day care provider about what your child ate the day before the visit, list of items to bring to the research center, the type of clothes he/she should wear to make it more comfortable for them, and a map with directions to our research center. **Please be sure to share this information with the child's [father/other parent]. We will need for them to sign the consent form either before or at the visit. 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 information in the package, or your child's participation in the study, feel free to call ___[field center phone number]___ .

A. No answer - Leave a message:

Option 1:
Hola, mi nombre es [recruiter name], estoy llamando del Estudio de la Salud de la Comunidad Hispana/Estudio de Latinos, este mensaje es para [name of participant]. Muchas gracias por completar a través de teléfono los cuestionarios iniciales para el estudio SOL FLOR. Nuestra clínica ahora está abierta para ver a participantes en persona con todos los procedimientos de prevención y control de infecciones implementados para garantizar la seguridad de nuestros participantes y personal. Estoy llamando para programar le segunda parte del estudio SOL FLOR. Por favor, si está interesada no dude en llamarnos al [field center's phone number] o nosotros le volveremos a llamar en un par de días. Muchas gracias, que tenga un buen día.

Option 2:
Hola, mi nombre es [recruiter name], estoy llamando del Estudio de la Salud de la Comunidad Hispana/Estudio de Latinos, este mensaje es para [name of participant]. Me gustaría hablar con usted sobre un nuevo estudio, llamado SOL FLOR. Por favor, no dude en llamarnos al [field center's phone number] o nosotros le volveremos a llamar en un par de días. Muchas gracias, que tenga un buen día.

B. On the phone, initial welcome/confirmation of first-born child since HCHS/SOL V1:

Hola, mi nombre es [recruiter name], estoy llamando del Estudio de la Salud de la Comunidad Hispana/Estudio de Latinos. ¿Se encuentra [name of participant]?

Not Available:

¿Cuándo sería un buen momento para volverla a llamar? [Obtain date and time]
Gracias, volveré a llamar. *Call is ended.*

HCHS/SOL Participant is available:

Hola, Sra ___[name of participant]_____, mi nombre es___[recruiter name]___. Yo trabajo con el Estudio de la Salud de la Comunidad Hispana/Estudio de los Latinos. Estamos muy agradecidos por su continua participación en este estudio. Estamos muy agradecidos de usted por completar por teléfono los cuestionarios iniciales de El Estudio Complementario de investigación sobre los Resultados del Estilo de Vida Familiar (SOL-FLOR). *Continue with the following script.*

Le estamos llamando para programar su visita para participar en la segunda parte del estudio SOL FLOR. Antes de hablar más sobre el estudio, permítame verificar su dirección. ¿Sigue viviendo en [participant's address]?

*If **NO**, collect the participant's information.*
¿Podría decirme su nueva dirección para mantener actualizados nuestros registros?

*If **YES**, continue with script below.*

Muchas gracias.

C. Interest in Participation.

Si recuerda, debido a la pandemia de COVID19, nuestros protocolos para este estudio se dividieron dos partes. En la primera parte, el personal de investigación de SOL FLOR se comunicó con usted por teléfono y le hizo preguntas sobre usted y su niño, incluyendo lo que comió su niño durante las últimas 24 horas.

En la segunda parte, queremos invitarla a usted y su hijo/a a una visita en persona al centro SOL para completar su examinación. Durante su visita al centro de SOL, le preguntaremos sobre la salud, hábitos alimenticios, el uso de medios digitales, y hábitos de actividad física de su hijo/a, y sobre el estado de ánimo y salud mental suyos, así como el motivo por el que come lo que come. También tomaremos medidas de la estatura y el peso de su hijo/a, y realizaremos un escaneo del cuerpo de su hijo/a para entender cómo se divide el peso corporal en grasa, hueso y músculo. Esta exploración tiene una exposición a la radiación mucho menor que una típica radiografía del pecho. También le pediremos a él/ella que escupa en un tubo para obtener ADN de la saliva, y evaluaremos la cantidad de tiempo que [insert CHILD's NAME] puede esperar por un premio de comida de su elección. Durante su visita también le preguntaremos sobre que alimentos su niño/a comió en las últimas 24 horas. El segundo registro de dieta también se puede completar por teléfono.

Anticipamos que la visita en persona tomara entre 1 hora y 1 hora y 30 minutos. Recibirá hasta $ *[field center specific information]* por su tiempo y/o transportación [*field center specific information]*

La participación en este estudio es voluntaria. Si usted y/o su hijo/a eligen no participar, no afectara su relación con el estudio SOL. Aún será un participante de SOL y parte de todas las actividades de SOL.

¿Tiene alguna pregunta para mí?

E. Father/2nd Parent Availability.

Note: Since the DXA has been removed from the SOL FLOR study protocol, the Father/2nd parent availability is no longer needed. This section has been removed from the script and the ELEB questions will be deactivated.

F. Scheduling Visit

¿Puede su hijo/a pararse y caminar sin el uso dispositivos de movimiento asistido **temporario** (ej. muletas, silla de ruedas)?

If **NO** → OK, entonces tendremos que volver a ponernos en contacto con usted después de que su lesión haya sanado para programar su visita.

Determine an estimated date that the injury will likely be healed and re-contact the participant then. Once re-contacted, be sure to ask this question again. Record injury status in ELEE form

If **YES** → En este momento ¿Tiene su hijo/a tiene actualmente alguna lesión en la boca?

If **YES** → OK, entonces tendremos que volver a ponernos en contacto con usted después de que su lesión haya sanado para programar su visita.

Determine an estimated date that the injury will likely be healed and re-contact the participant then. Once re-contacted, be sure to ask this question again. Record injury status in ELEE form

If **NO** → ¿Cuándo sería un buen momento para que usted y su hijo/a vinieran al centro de investigación SOL FLOR? →enter scheduled day/time in ELEE form.

Su cita es el _(date)____ a las __(time)_____am

Le recuerdo que la clínica está ubicada en ___[field center address]_____. Nuestro número telefónico es _[field center phone number]_____. Además, me gustaría informarle que ni usted (mamá) ni su hijo/a necesitan ayunar para este estudio.

Un día antes de su cita, recibirá una llamada para recordarle a usted y a su hijo/a de su cita.

G. Safety questions.

Para asegurar que la visita sea segura para [insert CHILD's NAME], me gustaría hacerle unas preguntas relacionadas con la adquisición de las medidas de peso y grasa corporal.

¿Su niño tiene un marcapasos o desfibrilador cardiaco o cualquier otro dispositivo electrónico interno insertado en el cuerpo que su hijo no se puede quitar?

If **YES** → then use WEIGHT ONLY setting for Tanita Scale.

¿Su niño tiene una prótesis o un yeso no removible que su niño no se puede quitar o que quizás no se sienta cómodo quitándose?

If **YES** → then use WEIGHT ONLY setting for Tanita Scale.

Record safety status information in the ELEB form

(Field center specific) ¿Necesitará que la lleven a nuestra clínica? Si es así, podemos organizar {field center specific on how the transportation will be accommodated].

(Field center specific) Usted debe recibir un paquete de instrucciones para su visita antes de la fecha de su cita. **Este paquete incluye** una copia de los formularios de consentimiento informado de SOL FLOR, instrucciones sobre cómo preguntar al maestro de su hijo/a o al proveedor de guardería sobre lo que comió el día anterior a la visita, lista de artículos para llevar al centro de investigación, el tipo de ropa que él/ella debe usar para que sea más cómodo para ellos, un mapa con instrucciones para llegar a nuestro centro de investigación. **Asegúrese de compartir esta información con el padre de su hijo/a. Necesitaremos que firmen el formulario de consentimiento antes o en la visita. Esperamos que estos materiales expliquen lo que usted y su hijo deben esperar el día de su visita.** Si tiene alguna pregunta o inquietud sobre la información en el paquete, o la participación de su hijo en el estudio, no dude en llamar. ___[field center phone number]___ .