



**Study of Latinos – Community and Surrounding Areas Study
SOL CASAS**

**Manual 1
Field Center Procedures**

September 20, 2016 - Version 1.2

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Field Center Procedures**

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1. FOREWORD

This manual is a series of protocols for the Study of Latinos – Community and Surrounding Areas Study (SOL CASAS). This manual provides an overview of the study and the interviews conducted as part of the field center study visit, including appendices of forms and question by question instructions for questionnaire administration. Table 1a lists the main components of the SOL CASAS study visit.

Because high quality of data and strict standardization of the study visit and interview techniques among each of the interviewers are essential, it is important that SOL CASAS personnel be familiar with this manual of procedures. To meet our scientific goals and to make this study a success, all SOL CASAS personnel must be fully trained and certified in the procedures described in this manual, and must remain standardized through the data collection phase.

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.

2. STUDY OVERVIEW

2.1 Objectives

The scientific aims of the SOL CASAS ancillary to the HCHS/SOL are to: (1) determine if HCHS/SOL Visit 1 macro-scale social and built neighborhood environments are associated with 6-year changes in metabolic health, physical activity, and depression, and whether changes in physical activity and depression mediate the association between the environment and metabolic health change; (2) determine if 6-year changes in macro-scale neighborhood environments between HCHS/SOL Visits 1 and 2 are associated with 6-year changes in metabolic health, physical activity, and depression, and whether changes in physical activity and depression mediate the association between neighborhood environment change and metabolic health change; and (3) using variables available at HCHS/SOL Visit 2 only, to investigate cross-sectional relations of macro- and *micro*- scale social and built neighborhood environments to metabolic health, physical activity, and multiple psychosocial factors (chronic stress, depression, and social support), and whether physical activity and psychosocial factors mediate the association between the environment and metabolic health.

2.2 Background

SOL CASAS is an ancillary study using only the San Diego HCHS/SOL cohort, rather than participants from all four sites (San Diego, CA, Chicago, IL, Miami, FL, and Bronx, NY). From March 2008 to June 2011 (Visit 1, “baseline”), the HCHS/SOL enrolled 16,425 (N = 4,097 at the San Diego site) male and female adult participants between the ages of 18 and 74 years from four field centers located across the U.S. The purpose of the parent study is to determine the prevalence and incidence of cardiovascular disease and other chronic conditions, and to identify risk factors playing a protective or harmful role in these conditions, in Hispanics/Latinos. Participants eligible for SOL CASAS include those who participated in the HCHS/SOL Visit 1 who are returning to complete the HCHS/SOL Visit 2 at the San Diego Field Center (N = 4,097).

Table 1. Outline of SOL CASAS Study Visit, with Reference to the Corresponding Study Form Codes

Visit Components	Form Code
Pre-visit screening (eligibility)	CEL-1
Reception, participation status	CEL-2
Informed consent	CEL-3
Interviews:	
Physical Activity	PAE
Neighborhood Selection	NSE
Accelerometry	CEL-6,7

3. RECRUITMENT

3.1 Overview

This section contains information to help the San Diego field center, the South Bay Latino Research Center (SBLRC), manage recruitment for SOL CASAS. SOL CASAS is a study of 1,750 Hispanic/Latino adults participating in HCHS/SOL in San Diego and is funded by the National Institute of Diabetes and Digestive and Kidney Diseases.

3.2 SOL CASAS Study Sample

The study aims to recruit 1,750 Hispanic/Latino adults aged 18-74 years at Visit 1 who completed the HCHS/SOL clinic Visit 1 and are completing Visit 2 at the San Diego South Bay Latino Research Center (SBLRC).

3.3 Recruitment Plan

Recruitment for SOL CASAS will coincide with recruitment for Visit 2 of the HCHS/SOL parent study starting in December of 2015 and ending when the HCHS/SOL parent study Visit 2 concludes in September of 2017. The recruitment plan consists of two basic steps -initial mailing and telephone contact- both of which are discussed further in the Recruitment Steps section.

3.3.1 Monitoring and Mid-course Corrections

The SOL CASAS recruitment period is 22 months in duration. The SBLRC will monitor the recruitment rates on an ongoing basis. Adjustments to the recruitment procedures may occur as a result of this monitoring and are referred to as mid-course corrections.

3.4 Recruitment Steps

3.4.1 Initial Mailing

For the first two months of recruitment, the SOL CASAS invitation letter will be included with the clinic instructions for Visit 2 of the HCHS/SOL parent study. After this, the SOL CASAS invitation letter will be included with the invitation letter for Visit 2 of the HCHS/SOL parent study, which is mailed in batches one to two months before the participant's recruitment window for the HCHS/SOL Visit 2 is open. The SOL CASAS invitation letter provides information about the SOL CASAS study to the HCHS/SOL participant, including the study site address and phone number to visit or call if they are interested in participating.

3.4.2 Screening

Screening potential SOL CASAS participants will be done via telephone when the participant is called to schedule their HCHS/SOL Visit 2. Once the participant is screened and scheduled for their Visit 2, the recruiter will proceed with the SOL CASAS Phone Script (Appendix 1). Interested participants will be administered Section 1 of the Eligibility/Participation Checklist (Appendix 2) to determine eligibility. Once it is determined that an individual is eligible to participate in SOL CASAS, he/she will be invited to participate. Eligible participants who agree to participate will be given the option of completing the SOL CASAS study visit concurrently with their HCHS/SOL Visit 2 or at a separate visit.

3.4.3 Number of Phone Calls

Phone call attempts will be made in conjunction with HCHS/SOL Visit 2 scheduling phone call attempts. Each call attempt should be noted in the SBLRC SOL CASAS access database for internal use. If a HCHS/SOL participant wishes to be contacted about SOL CASAS at a later

time, the recruiter should note the best day and time to reach him/her. The individual should be contacted again on the day and time specified. If the individual does not respond at that time, it should be noted so that a SOL CASAS research assistant could follow up with him/her during the Visit 2.

3.4.4 Reporting Screening Outcomes

Recruitment staff is responsible for completing page one of the Eligibility/Participant Checklist (CEL) prior to when the individual arrives at the SBLRC for their HCHS/SOL Visit 2. If a HCHS/SOL participant is undecided about participation in SOL CASAS, a note should be made in the notes section of the CEL and a SOL CASAS staff member should follow up with the participant the day they complete their HCHS/SOL Visit 2.

The information on the CEL form should be entered into the SOL CASAS CDART 2 data management system live or within 48-72 hours after data collection. Data entry for this form is important for coordination between the SBLRC and the Coordinating Center; the latter will use these data to monitor the recruitment process.

3.5 Forms

3.5.1 Eligibility/Participation Checklist (CEL)

The Individual Eligibility/Participation Checklist (CEL) includes the script for determining a participant's eligibility. The participant's eligibility and participation status are recorded in sections 1 and 2 of the form. Sections 3 and 4 are completed the day of the SOL CASAS study visit. Recruiters are responsible for verifying that all individuals meet the eligibility criteria for inclusion in the study. Refer to the CEL QxQ (Appendix 3) for further instructions on how to complete the form.

3.6 Eligibility Criteria

A HCHS/SOL participant is considered eligible to participate in SOL CASAS if they have completed their HCHS/SOL Visit 1, are completing their HCHS/SOL Visit 2, and can walk one block without help. Refer to the CEL QxQ for further clarification on the type of assistance that would determine an individual ineligible for participation in SOL CASAS.

3.7 Recruiters

3.7.1 Overview

Recruiters will be knowledgeable of the HCHS/SOL and the SOL CASAS ancillary 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 materials. They also need to review and understand the recruitment flow chart and understand the reasons for ineligibility. In addition, recruiters will be expected to maintain their IRB certificate current and be able to demonstrate knowledge of the IRB regulations.

3.7.2 Training

All recruitment staff will be provided with adequate training prior to their first contact with potential SOL CASAS study participants. The following are the certifications that the SOL CASAS study recruitment staff needs to complete.

- Human Subjects Protection

- Overview of principles, regulations, and policies which affect research involving human subjects in research
- General Interview Techniques
 - Overview of questionnaire administration and interviewing techniques
- Recruitment and Screening
 - Overview of recruitment and screening process for the SOL CASAS study
- Web-based Data Management System
 - Overview of the CDART2, data entry, and training on the use of SOL CASAS study forms

3.7.3 Privacy and Confidentiality

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

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

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

3.7.4 Professional Ethics and Participants' Rights

As a recruiter, there is a professional responsibility to adhere to the highest possible standards of ethical practices and to protect the rights of the participant. Each recruiter is responsible for taking and passing the required Human Subjects Protection course through their institution.

As a professional it is important for the recruiter to make sure that individuals understand what is involved when participating in a study and are able to ask questions before and during their voluntary participation. Any study participant has the right to autonomy, privacy, and the freedom of action.

3.7.5 Using Scripts

A script is provided for uniformity and standardization during the screening process. The script needs to be followed in order to maintain consistency. Deviations to the script may occur when potential participants ask questions about the study.

4. RECEPTION

All participants will be received in the main HCHS/SOL Visit 2 reception area. Participants will be received according to the procedures outlined for the HCHS/SOL Visit 2. If a HCHS/SOL participant expressed an interest in participating in SOL CASAS or expressed uncertainty towards participating in SOL CASAS, their information will be transferred to the Eligibility-Participation Checklist (Appendix 2). Throughout the participant's HCHS/SOL Visit 2 examination, they will be presented with opportunities to hear more about SOL CASAS and talk to a SOL CASAS research assistant about any questions they may have. If the participant agrees to participate, the HCHS/SOL Visit 2 staff will work together with the SOL CASAS staff to coordinate the completion of the SOL CASAS informed consent and study visit components. If a participant is uncertain about participating in SOL CASAS, they will be provided with a copy of the informed consent and a follow up phone call will be made to see if the participant has additional questions about participating in SOL CASAS.

5. INFORMED CONSENT

Informed Consent is the first data collection form administered during the SOL CASAS visit. The informed consent and its content meet the requirements of both the SDSU and UCSD Institutional Review Boards.

The primary objective of administering informed consent is to inform the individual of the SOL CASAS visit procedures, protect the rights of the study participants, and meet local Institutional Review Board requirements. The informed consent makes the study participants aware of their right to withdraw from the study or to decline to answer question(s) without penalty.

5.1. Administration

The purpose of SOL CASAS measurements is to be reviewed with the participants. Informed consent forms are available in Spanish and English, and bilingual SOL CASAS personnel will be available to review and administer.

After introducing the informed consent form to the participant in a private area, the SOL CASAS study personnel will ask whether the participant prefers to read the informed consent form or to have it read by SOL CASAS study personnel. Study personnel will review the informed consent with the study participant in great detail. Questions are encouraged and time will be allowed for the participant to read and sign the informed consent document in the presence of SOL CASAS personnel serving as witness. Informed consent must be obtained before all other SOL CASAS study visit components can take place.

The original informed consent document is filed in the participant's study folder. A copy of the informed consent is given to the participant before they leave the SBLRC.

6. INTERVIEWS

Interviewing is a collaboration between the SOL CASAS staff and the study participant to collect study data using standardized techniques. This section presents a general description of interviewing for SOL CASAS.

Interviews in SOL CASAS are administered in English or Spanish, at the preference of the study participant, by trained and certified personnel who are bilingual. Interviewers are administered using the SOL CASAS CDART 2 Data Management System, which provides quality assurance features such as missing fields checks. The most important factor influencing the study participants' satisfaction and the quality of the interview data is the interviewer, his/her skills and adherence to the study protocol.

6.1 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 session. Interview areas should be as quiet and private as 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 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 that was not understood when the question is repeated is often more efficacious than re-reading it in exactly the same manner.

6.2 Characteristics of a Good Interviewer

Interviewers are responsible for being fully familiar with the questions, response categories, and skip patterns of each interview. At the beginning of an interview the study participants may wish to be reassured that of the confidentiality of each response/measurement. Interviewers use a conversational tone and establish a pace consistent with the engagement and comprehension 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) that indicates positive feedback is inappropriate.

6.3 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. Questions thought to be "sensitive" should be asked in a neutral manner that 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.

6.4 Interviewer Bias

The use of standardized interviewing techniques is employed to reduce one of the many potential sources of misclassification; i.e., interview 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.

6.5 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 presented on the monitor screen (or printed on the form).

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, uh-uh") 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; do not change the question; and do not suggest an answer.

6.6 Quality Assurance

6.6.1 Interview Observations

All SOL CASAS interviewers will be observed two times during each quarter to ensure interviewing techniques are in accordance with the study protocol. The SOL CASAS interviewer will ask the participant for permission before the observation, being sure to stress that the observation is for quality control purposes only. After the second observation, the interviewer will be given feedback that includes strengths and improvement areas for the next quarter.

6.6.2 Audio-recordings

All SOL CASAS assessments, including informed consent, will be audio-recorded monthly. The SOL CASAS interviewer will ask the participant for permission before starting to record, also stressing that the recording is for quality control purposes only.

7. PHYSICAL ACTIVITY MONITORING (ACCELEROMETRY)

7.1 Rationale

Study participants will wear a portable motion sensor (i.e., accelerometer) to measure the frequency, duration, and intensity of physical activity over 7 days. The accelerometer provides an objective measure of physical activity that will supplement the interviews for self-reported regular physical activity. SOL CASAS staff will give each participant the instructions for wearing the device near the end of the SOL CASAS study visit and provide each participant with instructions on how the device should be returned to the SBLRC.

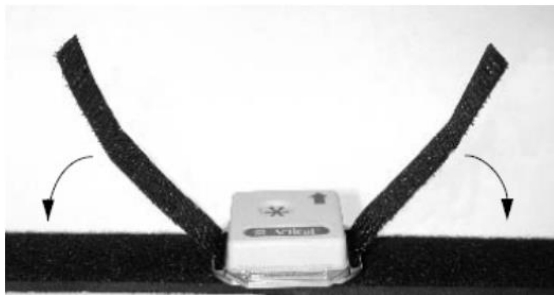
7.2 Technical Information about the ActiCal Accelerometer

The ActiCal™ (MiniMiter Respironics®, Bend, OR) accelerometer (model 198-0302-00) is a small, lightweight motion sensor that is attached to a belt and worn on the body. The Actical device measures the occurrence and intensity of motion in all directions by generating an electrical signal proportional to the force of the displacement. A microprocessor inside the accelerometer digitizes the signals, sums and stores them as “activity counts” over a user-defined time interval that can be as short as 1 second. Data can be collected and stored for approximately 6 weeks before being downloaded for data analysis. In addition to the activity counts per unit of time, the average time spent in light, moderate, and vigorous activity can be estimated.

7.3 Protocol

SOL CASAS staff will give the participant an accelerometer following the administration of study visit questionnaires. Study staff will select the appropriate size waist strap for the participant. The waist strap should be about 2-3 inches greater than the participant’s waist.

Thread the Actical unit onto the waist strap as pictured below. With the belt loop on the right, the orientation of the arrow on the monitor should be facing up.



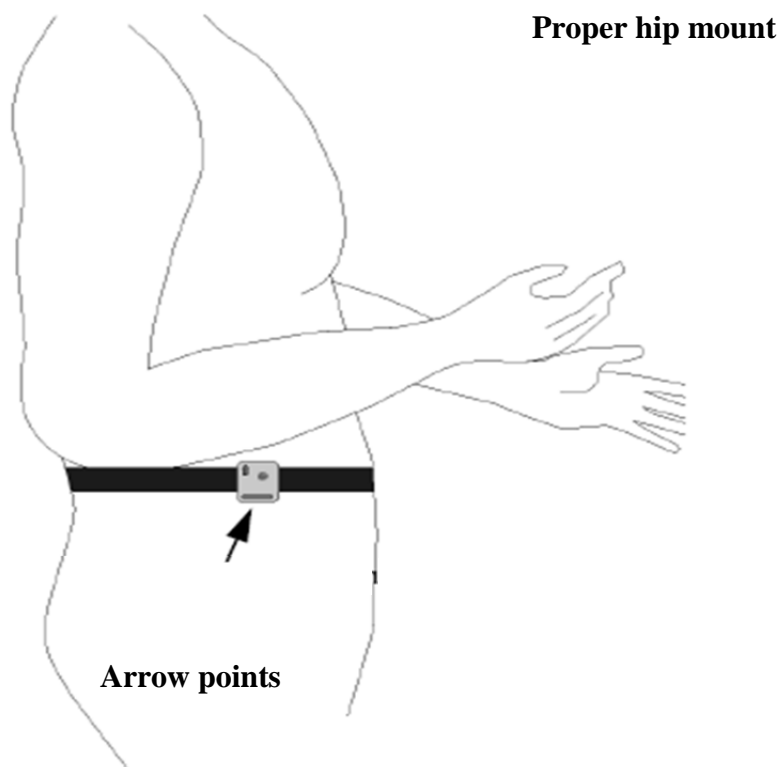
Study staff will briefly describe the purpose of physical activity monitoring (please Appendix 5 for a sample script) and ask participants to undertake their normal activities for the week while wearing the monitor. Staff will emphasize that participants should not engage in activities that they ordinarily would not engage in, specifically because they are wearing activity monitors.

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

present to provide feedback.

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

Figure 1: Proper placement of the Actical



Participants are told that a staff member will call them two times during the week to answer any questions or concerns about the device and to make sure that the instructions are clear. The phone call also provides staff with the opportunity to remind participants to wear the monitor continuously. Before leaving the SOL CASAS study visit, staff will give participants a brochure (Appendix 4) with instructions for using the Actical. This pamphlet will also include the date indicating when the participant should stop wearing the device. Participants will be given the option of returning the Actical device to the SBLRC or having a staff pick up the device from their home. Staff will call participants again two weeks after completion of the recording period if their accelerometer has not been returned to the examination clinic.

Please see Appendix 7 frequently asked questions about the accelerometer device.

A sample Actogram will be showed to participants the day of the study visit when they are being fitted with the device. This sample Actogram will help research staff convey to the participants the type of data the device will be collecting as well as the importance of adherence. During the study visit, participants are told that they can request a copy of the actogram when they return the device after the seven days.

7.4 Equipment and Supplies

The following items are needed to conduct the accelerometry portion of SOL CASAS:

- Actical devices
- Waist straps of varying sizes
- 2 ActiReader units
- Cables with USB adapter for connecting the ActiReaders to the computer
- Actical software v3.10 to load onto the study computer
- User's manual for the Actical
- "O-rings" (to be checked when replacing batters)
- CR2025 lithium coin cell ion batteries

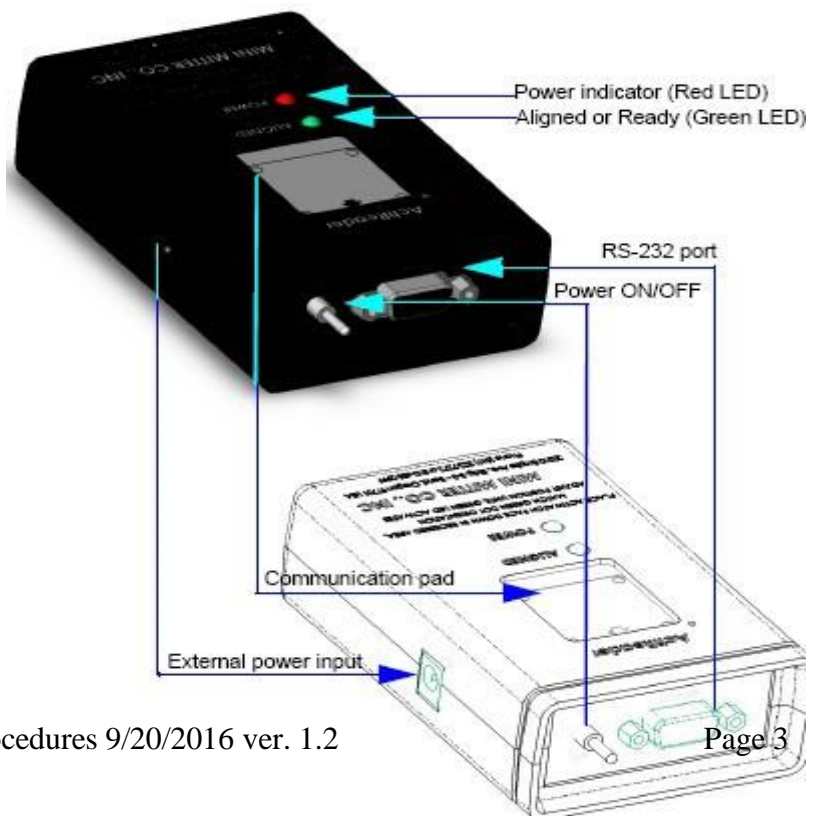
The ActiReader will be connected to the study computer. The computer does not need to be dedicated to collecting the accelerometry data; however, it should be available whenever units are returned so that data can be downloaded and stored when the units are received.

7.5 Initial Hardware and Software Set-up

Actical software must be installed on each PC (laptop or desktop) that will be used for initializing and reading Actical data. Detailed installation instructions are provided in the Actical User's Manual found online. A hard copy should be present at each field center and the coordinating center.

1. Install the Actical software by loading the installation CD into your drive and follow software installation instructions.
2. Connect one end of the serial communication cable to a USB COM Port on the PC and the other end to the ActiReader (Figure 2). As soon as the reader is plugged into the PC, a window should pop up saying which COM Port you are connected to (e.g., COM 2).
3. When you first open the Actical 3.10 software, go to Reader > COM Port and select the appropriate port number (e.g., COM 2)

Figure 2: The ActiReader Device



4. Test the ActiReader set by selecting: Reader > Test Reader. Follow the prompts through the test procedure. If the test fails, follow the prompts to correct the problem.
5. If the Belkin adapter cable is not recognized and you are using a 64-bit Windows 7 system, you may need to download a special driver ([contact Jordan Carlson jacarlson@cmh.edu](mailto:jacarlson@cmh.edu)).

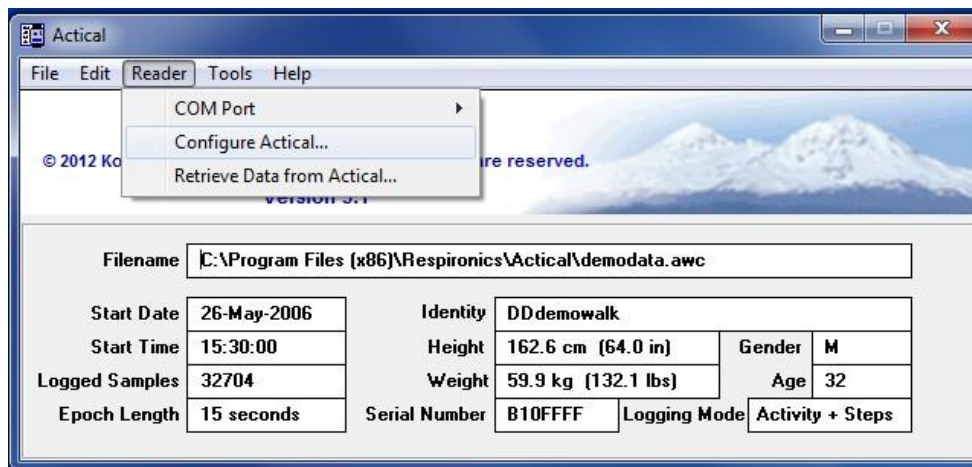
This procedure should be repeated for each computer/ActiReader used in the study.

7.6 Initializing the Actical Device

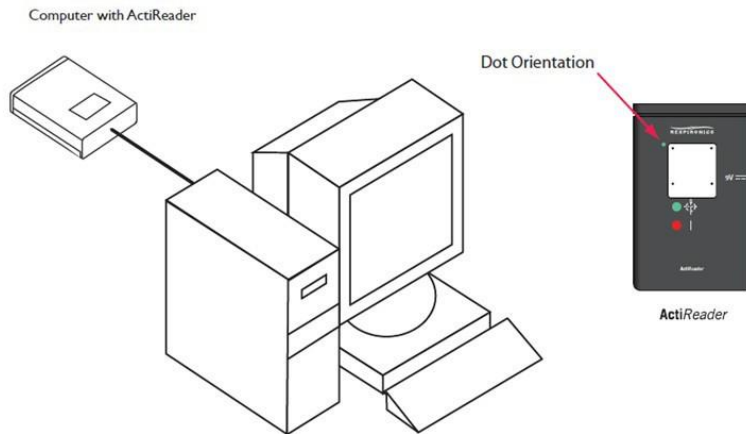
Initialization of the Actical device should not take place before the participant arrives to the South Bay Latino Research Center (SBLRC). Once the participant arrives, the study staff should select an Actical and record the monitor serial number and participant ID in the accelerometry tracking log. Then the study staff should initialize the accelerometer using the following steps:

Each Actical device must be uploaded with set-up information (initialization) prior to collecting data. This is done within the Actical 3.10 software and then loaded onto the Actical device using the ActiReader.

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



2. Click “Yes” in response to the question “Do you want to continue?”
3. Place the Actical device on the ActiReader by aligning the green dot in the metal back of the communication pad, the green LED will light up. The “communication” bar at the bottom of the screen will demonstrate a connection.



4. Click “Okay”.
5. Check the battery life displayed under the battery fitted date. If the value is less than 5 days, then replace the battery even if the battery was not scheduled to be replaced.
6. Under “Identify” enter the participant ID number. Enter gender and age as appropriate. The start date should be the next day’s date and the start time should be entered as 00:00 (midnight). Epoch length should be set to 15 seconds using the drop down menu. Enter 1.1 for height and weight because these values will not be used for SOL CASAS.
 - The participant should leave the study visit wearing the actual device even though the device won’t be recording any data until midnight of the next day. This is so that staff can observe that the participant is wearing the device correctly and to ensure that data will be collected in the event that the participant is still awake and moving about when midnight approaches. The participant should not be told that the device is not collecting data when they put it on.
 - For example, if a participant arrives and completes the study visit on 1/12/2016, the start date and time would be set as follows:

Actical Configuration															
Identity	<input type="text" value="1234567"/>	Gender	<input type="text" value="M"/>												
		Age	<input type="text" value="59"/>												
Start Date	<input type="text" value="13-Jan-2016"/>	<input type="checkbox"/> Raw Mode?	<table border="1"> <thead> <tr> <th colspan="4">Height and Weight</th> </tr> </thead> <tbody> <tr> <td><input type="text" value="1.0"/></td> <td><input type="text" value="cm"/></td> <td><input type="text" value="1.0"/></td> <td><input type="text" value="kg"/></td> </tr> <tr> <td><input type="text" value="0.4"/></td> <td><input type="text" value="inches"/></td> <td><input type="text" value="2.2"/></td> <td><input type="text" value="pounds"/></td> </tr> </tbody> </table>	Height and Weight				<input type="text" value="1.0"/>	<input type="text" value="cm"/>	<input type="text" value="1.0"/>	<input type="text" value="kg"/>	<input type="text" value="0.4"/>	<input type="text" value="inches"/>	<input type="text" value="2.2"/>	<input type="text" value="pounds"/>
Height and Weight															
<input type="text" value="1.0"/>	<input type="text" value="cm"/>	<input type="text" value="1.0"/>	<input type="text" value="kg"/>												
<input type="text" value="0.4"/>	<input type="text" value="inches"/>	<input type="text" value="2.2"/>	<input type="text" value="pounds"/>												
Start Time	<input type="text" value="00:00"/>	<input type="checkbox"/> Record Steps?	<input type="button" value="Send"/> <input type="button" value="Abort"/>												
Epoch Length	<input type="text" value="15 seconds"/>	Battery Installed	<input type="text" value="12-Oct-2015"/>												
Serial Number	<input type="text" value="B105470"/>														
RecordingTime (approximate)	<input type="text" value="11.4 days"/>	Battery Life (approximate)	<input type="text" value="88 days"/>												
Memory	<input type="text" value="64 KB"/>														

7. When all the information has been entered, click “Send”. The information will be sent to the Actical device.
8. The initialization progress will be shown by the red bar at the bottom of the window.
9. Remove the device from the reader, put it back in the plastic case, and label the case with the participant ID number. The case should then be stored with the participant chart until

the time of the CASAS study visit.

10. During the study visit, staff will place the Actical device on a belt for the participant to wear. The participant should start wearing the device during the visit. The staff should demonstrate to the participant how to put on, wear, and remove the belt as outlined in the brochure (Appendix 4).
11. Arrangements for the return of the accelerometer should be established at this time.

7.7 Instructions for using the Accelerometer

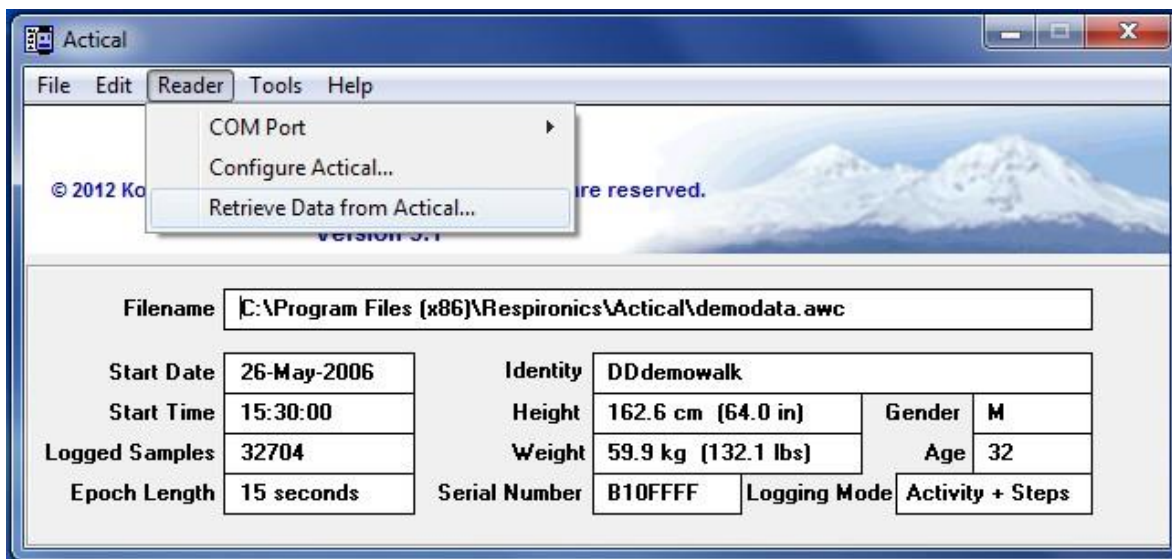
A brochure (Appendix 4) with instructions for the use and return of the accelerometer should be given to the participant before he or she leaves the SBLRC and should include the following points:

1. What the accelerometer is and what it records;
2. Importance of wearing it every day, all day;
3. Proper placement of the accelerometer;
4. Importance of returning the accelerometer promptly;
5. Expect telephone calls two times during the week following the clinic visit to make sure the participant is wearing the accelerometer and understands the instructions;
6. Expect telephone call to check up on the return of the accelerometer if it is not received back within two weeks of completing the protocol.

7.8 Downloading the Data

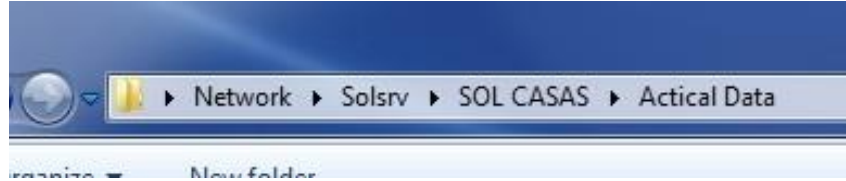
As soon as the accelerometer is returned, download the data. This should be done on the same computer on which the accelerometer was initialized.

1. Place the device into the ActiReader and open the Actical 3.10 software.
2. Click on Reader > Retrieve Data from Actical. The data download will be shown by the red progress bars at the bottom of the window. A prompt will tell you when the download is complete.

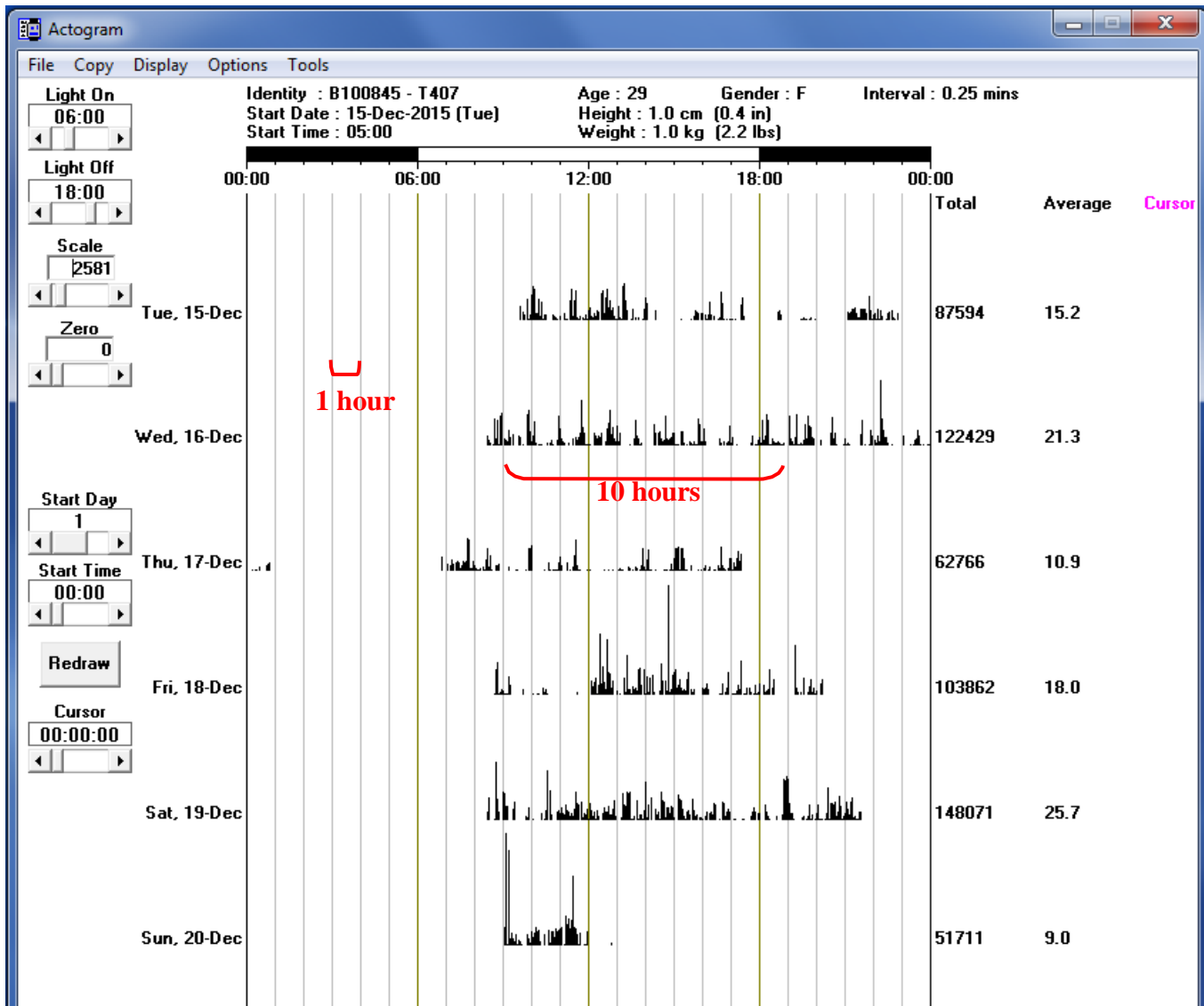


3. Once the download is complete, a window will appear stating "Actical Data Retrieved Successfully". Click "Save Data Now", assure that the file name is appropriate (select the default name, but remove the "list" part. Therefore, the file name is the participant ID and will have the extension awc). Select the appropriate location (shown below) to

save the file to. After saving, navigate to the folder to assure the .AWC file was saved appropriately. Path to folder:



4. Next, check to assure that the participant wore the device for the required minimum wear time of at least 4 days with at least 10 hours per day.
 - a. Click on Tools > Actogram.
 - b. Count how many days have at least 10 hours of wear time. Each vertical grey line that extends from the top to the bottom of the window represents 1 hour. The vertical black lines within each day show movement and indicate the times when the device was worn. When there are no vertical black lines, it means the participant was not wearing the device. In general, you should identify, for each day, where the black lines start and end, and calculate the time frame (i.e., number of hours) between those start and end points. The only exception to this method of calculating wear time is that gaps of over 120 minutes of non-wear (i.e., no lines) in the middle of the day should be excluded from the total wear time calculation.
 - c. If the participant has not worn the device for at least 10 hours per day on at least 4 days, they should be asked to rewear the device for 7 more days. Note that a new device will need to be initialized to collect data again. So you will need to initialize another device and give it to the participant before he or she leaves the field center..



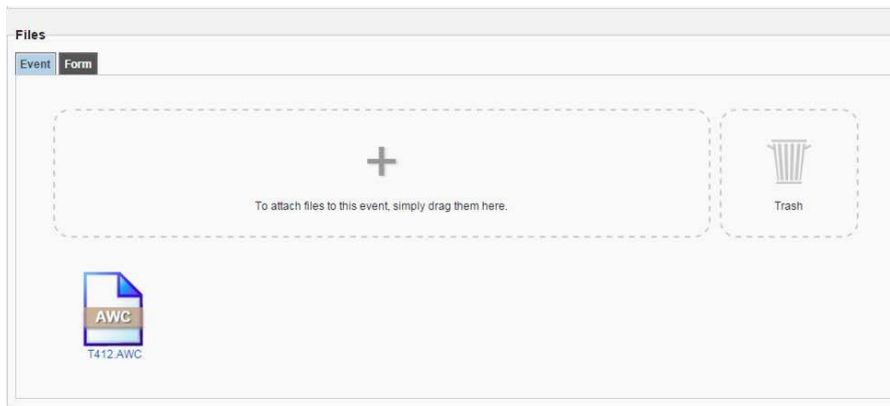
7.9 Quality Control

It is important that each Actical unit not be worn more than 4 times since the quality of data collected can diminish after 5+ uses. The number of times an Actical unit is used will also be tracked in the Inventory log to ensure it does not exceed 4 uses. After 4 wears, remove the Actical from circulation by placing it in the box labeled “Acticals used 4 times in SOL CASAS”.

7.10 Transmitting Data to the Coordinating Center

Actical files will be sent to the Coordinating Center by uploading the files to CDART.

1. Go to the CDART website and log in: <https://cdart2.csc.unc.edu/CDART2/login.jsp>.
2. Use the search box to find Subject’s ID. Click on the subject’s ID to open the forms.
3. Click on “edit form” (the red pencil icon) for the (CEL) CASAS Eligibility form.
4. Click and drag your chosen file from the Actical Data folder to the event area.
 - a. Once the file is uploaded, it will appear below this area.
 - b. To discard this attached file, simply drag it to the defined “Trash” area.
5. Click on save when the chosen file is uploaded to the appropriate subject’s CASAS Eligibility form.



7.11 Equipment Maintenance

7.11.1 Cleaning

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

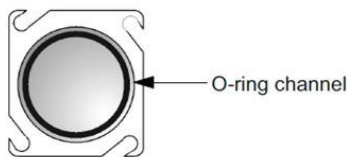
Waist straps should be rinsed in a cleansing solution such as Tide and hang to dry after each use.

7.11.2 Battery Replacement

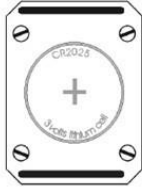
The Actical unit runs on a CR2025, 3-volt, 220-m-Amp-hour Lithium Manganese cell battery. The battery is required for data collection, reading, and writing. Although stored data are not lost after the battery has run down, it is important to change the batteries after every other use. A battery indicator light on the reading device will display a green light when the battery is charged. A log of battery changes should be kept for each Actical device.

The steps are as follows:

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

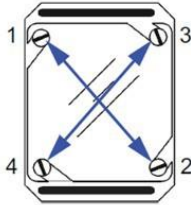


5. Place the clean O-ring into the channel on the back cover by pre-stretching the O-ring by gently flexing it in several directions. Be sure that it is properly sealed in the channel and is not twisted or deformed.
6. Place a new battery into the Actical case, positive (+) side up.



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

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



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

For any technical questions or product support, please contact Philips Respironics at 1-800-685-2999.

7.12 Quality Control

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

8. EXIT INTERVIEW

The end of visit debriefing provides an opportunity to ask for feedback about the visit and to identify aspects that the participant may have perceived as stressful or unpleasant. It also provides an opportunity to further develop rapport with the study participant and to seek commitment for a long-term association with SOL. The participant is reminded of the follow-up call (about 3 day) and the call can be scheduled at that time. The participant will also be asked if they prefer to bring the device back to the SBLRC or have a staff pick up the device at the end of the 7 days.

Appendix 1:
SOL CASAS Phone Script (English and Spanish)

SOL CASAS Phone Script

1. After scheduling HCHS/SOL V2: You also received a letter in the mail about a new HCHS/SOL study called SOL CASAS. May I take a few minutes to tell you about this new study?
 - **No:** May we call you another time?
 - **No:** No problem. We can check in with you when you come for your second HCHS/SOL examination on (date of scheduled V2). Please feel free to call us at (619) 205-1926 if you have any questions before then. Thank you. [Call is ended- Go to 2 in SOL CASAS ELE and check 2nd box, Update SOL CASAS database]
 - **Yes:** When would be a good time to call you back? Date/Time: _____ Thank you. We look forward to talking to you then. [Call is ended- Update SOL CASAS database]
 - **Yes:** Thank you. [Go to ELE]
2. After completing ELE: Now I will tell you more about SOL CASAS:
 - a. If you decide to participate in SOL CASAS, you will be asked to complete a 30-40 minute visit. During the visit, we will ask you questions about your physical activity and reasons for moving to your current neighborhood. You can complete the SOL CASAS visit when you come for your second HCHS/SOL examination or you can schedule the visit for another day.
 - b. You will also be asked to wear a physical activity measurement device for 7 days. This is the same device you wore at your first HCHS/SOL examination. After the 7 days, you can return the device to the clinic or our staff can pick it up at your home.
 - c. After your visit, HCHS/SOL researchers will use information from your HCHS/SOL examinations, including your home address, to learn about how neighborhoods and physical activity are related to health. HCHS/SOL researchers will combine this with public information about your neighborhood to better understand the health of your community.
 - d. If you choose to participate, you will receive \$40 to reimburse you for your time and transportation costs. You will receive the first \$20 the day of your SOL CASAS visit and the second \$20 after the physical activity measurement device is returned.
 - e. Your participation in SOL CASAS is voluntary. If you choose not to participate, your relationship with the HCHS/SOL study will not change. You will still be a HCHS/SOL participant and part of all HCHS/SOL activities.
3. Would you like to participate in SOL CASAS?
 - **No:** No problem. Could you please tell me the reasons you are not interested in participating in SOL CASAS? Thank you for your time. We look forward to seeing you on (date of scheduled V2) when you come for your second HCHS/SOL examination. [Call is ended- Go to 2 in SOL CASAS ELE and check 4th box, Update SOL CASAS database]

- **Not sure:** Would you like us to call you again next week or check in with you when you come for your second HCHS/SOL examination on (date of scheduled V2)?
- Call back: When would be a good time to call you back? Date/Time: - _____ Okay, thank you. We look forward to talking to you then. [Call is ended- Update SOL CASAS database]
 - Check in at V2: We will check in with you when you come for your second HCHS/SOL examination on (date of scheduled V2). Please feel free to call us at (619) 205-1926 if you have any questions before then. Thank you. [Call is ended- Update SOL CASAS database]
- **Yes:** Thank you for agreeing to participate in SOL CASAS. Your participation makes a difference. Would you like to complete the SOL CASAS visit when you come for your second HCHS/SOL examination on (date of scheduled V2) or schedule the visit for another day?
- With parent study V2: Thank you. We look forward to seeing you then. Please feel free to call us at (619) 205-1926 if you have any questions about your visit. [Call is ended- Go to 2 in SOL CASAS ELE and check 5th box, Go to 3 in SOL CASAS ELE and check 1st box, Update SOL CASAS database]
 - Separate appointment: When would you like to come for your SOL CASAS visit? [Record date and time on SOL CASAS ELE]
- Thank you. We look forward to seeing you then. Please feel free to call us at (619) 205-1926 if you have any questions about your visits. [Call is ended- Go to 2 in SOL CASAS ELE and check 5th box, Go to 3 in SOL CASAS ELE and check 2nd box, Update SOL CASAS database]

SOL CASAS Phone Script

4. After scheduling HCHS/SOL V2: Usted también recibió una carta sobre un nuevo estudio de HCHS/SOL llamado SOL CASAS. ¿Me permite unos minutos para informarle sobre este nuevo estudio?
- **No:** ¿Podemos llamarle en otro momento?
 - **No:** No hay problema. Podemos consultarlo con usted cuando venga a su segundo examen de HCHS/SOL el (date of scheduled V2). Por favor, siéntase con libertad de llamarnos al (619) 205-1926 si tiene alguna pregunta antes de esa fecha. Gracias. [Call is ended- Go to 2 in SOL CASAS ELE and check 2nd box, Update SOL CASAS database]
 - **Sí:** ¿Cuándo sería un buen momento para llamarle de nuevo? Date/Time: - _____ Gracias. Esperamos poder hablar con usted entonces. [Call is ended- Update SOL CASAS database]
 - **Sí:** Gracias. [Go to ELE]
5. After completing ELE: Ahora le voy a hablar más sobre SOL CASAS:
- f. Si usted decide participar en SOL CASAS, se le pedirá que complete una visita de 30-40 minutos. Durante esta visita, le haremos preguntas sobre su actividad física y sus razones para mudarse a su vecindario actual. Usted puede completar la visita de SOL CASAS cuando venga a su segundo examen de HCHS/SOL o se le puede programar la cita en otro día.
 - g. Se le pedirá que lleve un dispositivo de medición de la actividad física por 7 días. Este dispositivo es el mismo que usted llevo en su primer examen de HCHS/SOL. Después de los 7 días, puede devolverlo a la clínica o nuestro personal puede recogerlo en su casa.
 - h. Después de su visita, los investigadores de HCHS/SOL utilizarán la información de sus exámenes de HCHS/SOL, incluyendo su domicilio, para aprender acerca de cómo los vecindarios y la actividad física están relacionados con la salud. Los investigadores de HCHS/SOL combinarán esto con la información pública sobre su vecindario para entender mejor la salud de su comunidad.
 - i. Si usted decide participar, recibirá \$40 como reembolso por su tiempo y costos de transportación. Usted recibirá los primeros \$20 el día de su visita de SOL CASAS y los segundos \$20 después de que devuelva el dispositivo de medición de la actividad física.
 - j. Su participación en SOL CASAS es voluntaria. Si usted decide no participar, su relación con HCHS/SOL no cambiará. Usted seguirá siendo un participante de HCHS/SOL y parte de todas las actividades de HCHS/SOL.
6. ¿Le gustaría participar en SOL CASAS?
- **No:** No hay problema. ¿Por favor, me podría dar las razones por la que no está interesado/a en participar en SOL CASAS? Gracias por su tiempo. Esperamos verlo/a el (date of scheduled V2) cuando venga a su segundo examen del HCHS/SOL. [Call is ended- Go to 2 in SOL CASAS ELE and check 4th box, Update SOL CASAS database]

- **Not sure:** ¿Le gustaría que le llamemos de nuevo la próxima semana o consultemos con usted cuando venga a su segundo examen de HCHS/SOL el (date of scheduled V2)?
- Call back: ¿Cuándo sería un buen momento para llamarle de nuevo?
Date/Time: _____ Bueno, gracias. Esperamos poder hablar con usted entonces. [Call is ended- Update SOL CASAS database]
 - Check in at V2: Le consultaremos con usted cuando venga a su segundo examen del HCHS/SOL el (date of scheduled V2). Por favor, siéntase con libertad de llamarnos al (619) 205-1926 si tiene alguna pregunta antes de esa fecha. Gracias. [Call is ended- Update SOL CASAS database]
- **Yes:** Gracias por aceptar participar en SOL CASAS. Su participación hace la diferencia. ¿Le gustaría completar la visita de SOL CASAS cuando venga a su segundo examen de HCHS/SOL el (date of scheduled V2) o programar la cita en otro día?
- With parent study V2: Gracias. Esperamos verlo/a en esa fecha. Por favor, siéntase con libertad de llamarnos al (619) 205-1926 si tiene alguna pregunta sobre su visita. [Call is ended- Go to 2 in SOL CASAS ELE and check 5th box, Go to 3 in SOL CASAS ELE and check 1st box, Update SOL CASAS database]
 - Separate appointment: ¿Cuándo le gustaría venir a su visita de SOL CASAS?
[Record date and time on SOL CASAS ELE]
Gracias. Esperamos verlo/a entonces. Por favor, siéntase con libertad de llamarnos al (619) 205-1926 si tiene alguna pregunta sobre sus visitas. [Call is ended- Go to 2 in SOL CASAS ELE and check 5th box, Go to 3 in SOL CASAS ELE and check 2nd box, Update SOL CASAS database]

Appendix 2:
Eligibility-Participation Checklist (CEL)



HCHS/SOL CASAS Eligibility/Participation Checklist

ID NUMBER:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
------------	----------------------	----------------------	----------------------	----------------------	----------------------	----------------------	----------------------	----------------------	----------------------

FORM CODE: CEL
VERSION: 1,
9/23/2015

Contact Occasion

0	1
---	---

 SEQ #

<input type="text"/>	<input type="text"/>
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ADMINISTRATIVE INFORMATION

0a. Completion Date (mm/dd/yyyy):

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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 0b. Staff ID:

<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------

0c. Language Administered: English Spanish

Instructions: Transition to this form after the HCHS/SOL AFU interview is completed and the participant has been scheduled for their Visit 2. This eligibility screening form must be completed before the participant can be scheduled for their SOL CASAS visit.

Eligibility Screening Status for Individual:

1. SOL CASAS is a study about how neighborhoods and physical activity affect health in the Hispanic/Latino community. We would like to ask you a question to see if you are eligible to participate in SOL CASAS. Can you walk one block without help?

SOL CASAS es un estudio acerca de cómo los vecindarios y la actividad física afectan la salud de la comunidad Hispana/Latina. Nos gustaría hacerle una pregunta para ver si usted es elegible para participar en SOL CASAS. ¿Puede usted caminar una cuadra sin ayuda?

No (0): We appreciate your interest but unfortunately you are not eligible to participate in SOL CASAS. We will let you know of any new HCHS/SOL studies that you may be eligible for in the future. We look forward to seeing you on (date of scheduled V2) when you come for your second HCHS/SOL examination. Thank you.

Apreciamos su interés pero desafortunadamente usted no es elegible para participar en SOL CASAS. Le avisaremos sobre nuevos estudios de HCHS/SOL en los que usted pueda ser elegible en el futuro. Esperamos verlo(a) el (date of scheduled V2) cuando venga a su segundo examen de HCHS/SOL. Gracias.

Ineligible- Go to 1 and check 3rd box, end script

Yes (1): Great. You are eligible to participate in SOL CASAS.

Excelente. Usted es elegible para participar en SOL CASAS.

Continue with phone script

2. Individual Participation Status:

- Unable to contact, status unknown (1)
- Refuses to participate, status unknown (2)
- Ineligible (3)
- Eligible but refuses to participate (4)
- Eligible and agrees to participate (5)**

2a. Date (mm/dd/yyyy):

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	---	----------------------	----------------------	---	----------------------	----------------------	----------------------	----------------------

 2b. Time:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------	----------------------

 (24hr.)

3. Appointment Information:

- With parent study V2 (1)
- Separate visit (2)

ID NUMBER:									
------------	--	--	--	--	--	--	--	--	--

FORM CODE: ELE
 VERSION: 1,
 9/23/2015

Contact Occasion	0	1	SEQ #		
------------------	---	---	-------	--	--

Consent Status for Individual:

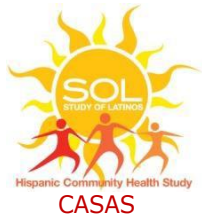
4. Agrees to participate in SOL CASAS:
 Δ No (0)
 Yes (1)

Visit Checklist:

Form/Procedure for CDART data entry			Staff ID	
5. Physical Activity (PAE)	a. <input type="checkbox"/>		b.	
6. Neighborhood Selection (NSE)	a. <input type="checkbox"/>		b.	
7. a. Actical issued: <input type="checkbox"/> b. Serial # _____	c. Date out: ____/____/____	d. Date in: ____/____/____	e.	
8. a. Actical reissued: <input type="checkbox"/> b. Serial # _____	c. Date out: ____/____/____	d. Date in: ____/____/____	e.	

9. Additional Comments/Notes:

Appendix 3:
Eligibility Participation Checklist (CEL) QxQ



HCHS/SOL CASAS Eligibility/Participation Checklist CEL – QxQ

General Instructions

The first three sections on page one of the Eligibility/Participation Checklist (CES) are completed at the time of initial contact with potential SOL CASAS participants or on subsequent contact occasions if eligibility is not obtained at the time of initial contact.

The fourth section is to track the consent status for an individual after eligibility is determined.

Sections 5 through 8 are completed the day of the study visit. The purpose of these sections is to track each study visit component and to ensure completeness of each component.

QxQ Instructions

Q0a-c This section is administrative information that should not be read aloud to the potential SOL CASAS participant.

Q1 Eligibility Screening Status for Individual: “Can you walk one block without help?”

This question is used to determine if the individual is eligible to participate in SOL CASAS. If the individual answers, “No”, he/she is ineligible. The definition of “help” may be interpreted differently by each participant.

If the individual states that he/she requires the help of a wheelchair for mobility, he/she is considered ineligible. Record “No” for Q1 and read the closing script.

If the individual states that he/she requires the help of another mobility device, such as a walker or crutches, to walk one block, he/she is considered eligible. Record “Yes” for Q1 and continue with the script.

Q2 Individual Participation Status:

This section is for administrative purposes only. It is a status code for the individual level eligibility.

- (1) Unable to contact, status unknown- NO contact has been made and his/her individual eligibility status is unknown. Further attempts may be made by phone when the recruiter calls back to schedule the HCHS/SOL Visit 2 and/or a CASAS staff will follow up with the individual when they complete the HCHS/SOL Visit 2.
- (2) Refuses to participate, status unknown- The individual refuses to participate before section 1 is completed.
- (3) Ineligible- Section 1 is completed and the individual is ineligible due to a “No” response to Q1.

(4) Eligible but refuses to participate- Section 1 is completed. The individual is eligible due to a “Yes” response to Q1 but he/she refuses to participate.

(5) Eligible and agrees to participate- Section 1 is completed. The individual is eligible due to a “yes” response to Q1 and he/she agrees to participate. Continue with the script and go to sections 2a, 2b, and 3 to record the appointment information.

Q2a Appointment Date (mm/dd/yyyy):

Set appointment date and record with two digit month, two digit day, and four digit year.

Q2b Appointment Time:

Set appointment time and record with two digit hour and two digit minute. Record in 24 hour time.

Q3 Appointment Information:

(1) With parent study V2- The SOL CASAS study visit will be completed the same day as the HCHS/SOL Visit 2.

(2) Separate Visit- The SOL CASAS study visit will be completed at a separate visit.

Q4 Consent Status for Individual:

This section is completed the day of the study visit after the individual has reviewed the informed consent form with a SOL CASAS staff. After the individual consents to participate and a CASAS staff obtains the participant’s witnessed signature on the informed consent document, “yes” should be recorded.

Q5-6 Physical Activity (PAE) and Neighborhood Selection (NSE):

(a) The box should be checked indicating that the questionnaire is complete.

(b) The staff ID of the interviewer who administered the questionnaire should be recorded.

If a questionnaire is not completed, a note should be made in section 9 explaining why and what kind of follow up is needed.

Q7 Actical issued:

(a) The box should be checked to indicate that the participant is being issued an actical.

(b) Serial #: Record the serial number of the actical being issued to the participant.

(c) Date out: Record the date that the actical is assigned to the participant.

(d) Date in: Record the date that the actical is returned

(e) Record the Staff ID of the person who is giving the actical to the participant and the Staff ID of the person who is collecting the actical from the participant at the end of the 7 days.

If the participant returns the actical and it is determined that the data collected is unusable, he/she will be reissued an actical and asked to repeat the 7 days of wear time.

Q8 Actical reissued:

This section is completed only in the event that an actical is reissued.

- (a) The box should be checked to indicate that the participant is being reissued an actical.
- (b) Serial #: Record the serial number of the actical being reissued to the participant.
- (c) Date out: Record the date that the actical is issued to the participant.
- (d) Date in: Record the date that the actical is returned
- (e) Record the Staff ID of the person who is giving the actical to the participant and the Staff ID of the person who is collecting the actical from the participant at the end of the 7 days.

Q9 Additional Comments/Notes:

This section should be used to clarify reasons for an incomplete study visit and/or to provide additional information needed to facilitate follow-up with the participant.

Appendix 4:
Actical Brochure



SOL CASAS Physical Activity Monitor

What is a Physical Activity Monitor?



- ◆ It is a device that measures your physical activity levels. We also call this device an Actical.
- ◆ The monitor tells us how often you are active, for how long, and how intense your physical activities are during the day.
- ◆ The monitor does not tell us where you are or where you have been.
- ◆ The monitor does not tell us what type of activities you took part of.
- ◆ The monitor does not count your steps and will not show you any information being recorded.

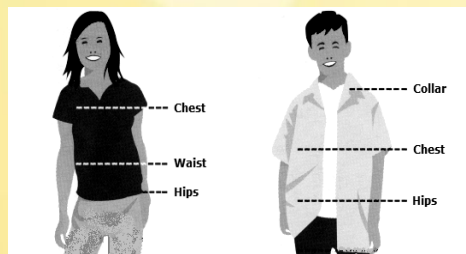
Tracking your physical activity will help us understand the effects of physical activity on your health.

How to wear the Physical Activity Monitor



Wearing the monitor is simple! You do not have to worry about turning it on or off because it is automatic. All you have to do is make sure you wear it!

- ◆ Always wear the monitor under your clothes or over a thin t-shirt.
- ◆ Make sure the monitor belt is snug around the waist so it does not jiggle when you move.
- ◆ Always wear the monitor on your right hip bone with the sticker facing up.



IMPORTANT!

Make sure your monitor is within your reach when you wake up in the morning to help you remember to wear it. Please take good care of the monitor so others have the opportunity to use it.

The Dos and Don'ts

Do...

- ✓ Do wear the monitor everyday from the day you come for your study visit and for the following 7 days...
...from when you wake up until you go to bed.



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- ✓ Do take part in your usual activities.

Don't...

- ⊘ Don't let others wear your monitor.
- ⊘ Don't wear it while sleeping, taking a shower, or swimming.



Stop wearing the monitor on:

Please return the monitor on:

If you have any questions, please call (619) 205-1923.



Thank you!



SOL CASAS Monitor de Actividad Física

¿Qué es el monitor de actividad física?



- ◆ Es un aparato que mide sus niveles de actividad física. También le llamamos Actical.
- ◆ El monitor nos dice qué tan activo es, por cuánto tiempo y qué tan intensas son sus actividades durante el día.
- ◆ El monitor no nos dice dónde está o dónde ha estado.
- ◆ El monitor no nos dice qué tipo de actividades ha realizado.
- ◆ El monitor no cuenta sus pasos y no le mostrará la información que ha sido grabada.

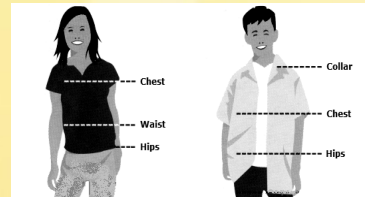
El monitoreo de su actividad física nos ayudará a entender sus efectos en su salud.

¿Cómo usar el monitor de actividad física?



¡Usar el monitor es simple! No tiene que preocuparse de prenderlo o apagarlo porque es automático. ¡Todo lo que tiene que hacer es usarlo!

- ◆ Siempre use el monitor bajo su ropa o sobre una camiseta delgada.
- ◆ Asegúrese de que el cinturón del monitor se ajuste alrededor de su cintura de modo que no se mueva.
- ◆ Siempre use el monitor del lado derecho de la cadera con la calcomanía/sticker voltenado hacia arriba.



¡IMPORTANTE!

Asegúrese que su monitor esté cerca de usted cuando se levante para que recuerde usarlo.

Por favor cuide el monitor para que otros tengan la oportunidad de usarlo.

Los "Sí" y los "No"

Sí...

- ✓ Use el monitor cada día, desde el día de su visita y por los siguientes 7 días...



...desde que se levanta hasta que se acueste.

- ✓ Use el monitor como parte de sus actividades cotidianas.

No...

- ⊘ No permita que otros usen su monitor.
- ⊘ No lo use mientras esté durmiendo, bañando o nadando.



Dejar de usar el monitor el día:

Regresar el monitor el día:

Si tiene alguna pregunta, por favor llame al (619) 205-1923.



¡Gracias!

Appendix 5:
Instructions for Wearing Accelerometer – Sample Script

Instructions for Wearing Accelerometer (sample script)

Initial script for distributing the accelerometer to SOL CASAS participants:

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

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

After waiting for participants to ask questions, continue:

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

If any questions arise during this next week, please call us at (619) 205-1923. We’ll also be calling you in the next day or so to see if you have any questions or problems. Do you have any questions?”

Appendix 6:
Actical Check-up Call – Phone Script

Actical Check-up Call – Phone Script

Participants should be contacted on the 3rd day after leaving the SBLRC. This call is to ensure that participants are wearing the monitor correctly and to answer any questions that the participant has. The call is meant to be brief.

“Hello, I am (full name), from the SOL CASAS Study at the South Bay Latino Research Center. Can I speak to _____?”

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

“I am calling to make sure that the directions for wearing the activity monitor made sense and to ask if questions about wearing the activity monitor.”

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

Optional script:

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

Also, remind the participant of the pick-up or drop-off arrangement to return the ActiCal to the SBLRC.

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

Optional script:

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

- You do not need to wear the monitor while showering, bathing or swimming, but don't worry about getting it wet. It will still work and record your movements.
- You don't need to wear it while you're sleeping. If you fall asleep with the monitor on it won't hurt you or the data; it may just be a bit uncomfortable. In the morning if you're the type of person to go directly from bed to the shower, put it on after your shower. But if you're going to be up for 15 minutes or more before getting into the shower, go ahead and put it on, then take it off prior to your shower and then put it back on when you've finished showering.
- Please do wear the monitor until you actually go to sleep at night, even if you're just sitting reading or watching TV. If you just get up to answer the phone or go to the bathroom, the monitor will collect these movements as you walk through the house.
- I will call again on DATE (day 3) to make sure you are wearing it right, but feel free to call me at (619) 205-1923 if you have any questions or problems with the monitor.

Ask the participant if he/she has any questions. Then reschedule the pick-up or drop-off return date and time of the ActiCal monitor.

If the participant does not want to participate in this procedure, thank the participant for his/her time and confirm the pick-up or drop-off date and time to return the ActiCal (you may want to reschedule for an earlier return date). Follow procedures for marking this examination as a partial examination in CDART as well as in the SOL CASAS database.

If you reach an answering machine:

“Hello, I am (full name) calling from the SOL CASAS Study at the South Bay Latino Research Center. I am calling because I want to make sure that the directions for wearing the activity monitor make sense. I will try to call back tomorrow or the day afterwards, but you can also call me at (619) 205-1923 if you have any questions about wearing the monitor.”

Appendix 7:
Frequently Asked Questions about the Physical Activity Monitor

Frequently Asked Questions about the Physical Activity Monitor

What is a portable motion sensor?

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

How do I wear the physical activity monitor?

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

Can I wear the physical activity monitor underneath my clothes?

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

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

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

How long should I wear the physical activity monitor?

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

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

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

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

Before you take home the unit, instructions on how to return the device will be given to you. You can always stop by the SOL clinic (450 4th Avenue, Chula Vista, Ste. 311, Chula Vista, CA 91910) from 8:00am – 3pm to return the monitor. We can also schedule a time for a staff to pick up the monitor from your house.

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

We will gladly answer any questions or help you through any issues. Feel free to contact us at (619) 205-1923.

Preguntas Frecuentes Sobre el Monitor de Actividad Física

¿Qué es un sensor de movimiento portátil?

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

¿Cómo debo ponerme el monitor de actividad física?

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

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

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

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

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

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

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

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

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

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

Antes de entregarle el monitor le daremos instrucciones acerca de cómo devolverlo. Puede visitar la clínica (450 4th Avenue, Chula Vista, Ste. 311, Chula Vista, CA 91910) entre 8:00am a 3:00pm para devolver el dispositivo.

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

Con gusto contestaremos cualquier pregunta y lo ayudaremos con problemas técnicos. Comuníquese con nuestra clínica llamando al (619) 205-1923.