Youth

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

Manual 1

Field Center Procedures

February 20, 2013- Version 3.1

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

Field Center Procedures
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1. FOREWORD

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

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

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

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

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

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

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

2. RECRUITMENT

2.1 Overview

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

2.2 SOL Youth Study Sample

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

2.3 Recruitment Plan

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

2.3.1 Monitoring and Mid-course Corrections

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

2.3.2 Recruitment List

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

2.4 Recruitment Steps

2.4.1 Initial Mailing

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

2.4.2 Screening

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

2.4.3 Number of Phone Calls

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

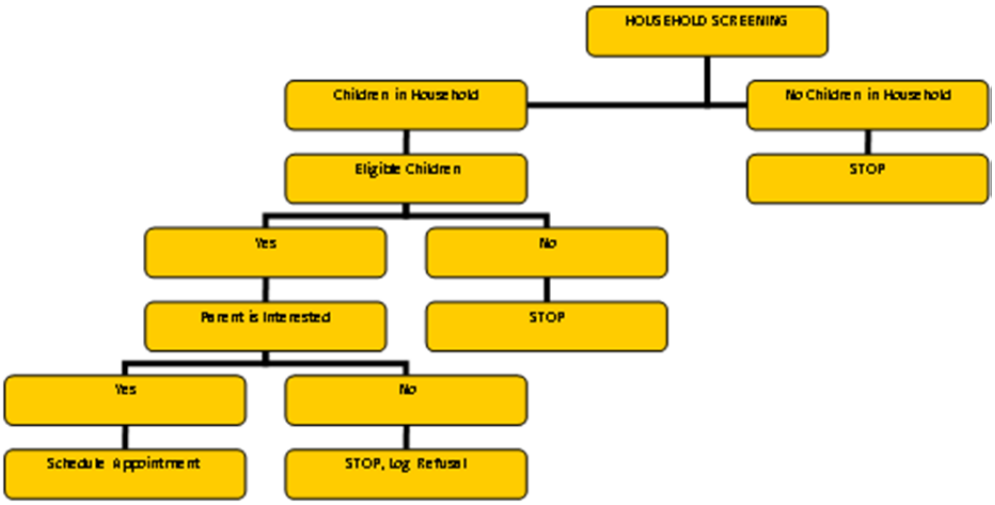
2.4.4 Reporting Screening Outcomes

Recruitment staff is responsible for completing the following forms:

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

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

2.4.5 Recruitment Flow Chart



2.5 Forms

2.5.1 Household Screening Roster Form (HSR)

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

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

2.5.2 Screening Call Tracking Form (SCT)

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

2.5.3 Individual Eligibility Checklist (ELE)

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

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

2.5.4 Participant Safety Screening Safety Form (PSE)

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

2.6 Eligibility Criteria

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

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

Inclusion

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

Exclusion

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

Temporary Exclusions

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

2.7 Recruiters

2.7.1 Overview

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

2.7.2 Training

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

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

2.7.3 Privacy and Confidentiality

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

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

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

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

2.7.4 Professional Ethics and Participants' Rights

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

2.7.5 Using Scripts/Guidelines for Probing

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

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

2.8 Collaborations

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

3. CONTACTING PARTICIPANTS / MAKING THE FIELD CENTER EXAMINATION APPOINTMENT

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

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

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

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

3.1. Participant Safety Screening

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

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

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

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

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

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

3.3. Appointment Reminders and Instructions for the Field Center Examinations

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

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

1. Appointment date and time.

2. Preparations:
   a) Instructions on how to complete the 10-hour fast;
   b) Instructions on proper hydration while maintaining the fast;
   c) Instructions concerning restrictions on the use of tobacco and vigorous physical activity the morning prior to the visit;
   d) Instructions on appropriate clothing to wear for the examinations.

3. Items to bring to the field center:
   a) Eyeglasses and hearing aid for parent/legal guardian and/or child, if needed;
   b) Name and address of the child's primary care physician;
   c) Name, address, and phone number of contact persons of the parent/legal guardian;
   d) Medication Instruction Sheet: Instructions to bring all the prescription and over-the-counter medications the child takes, including vitamins and mineral supplements, taken within one month prior to the examination. This includes pills, liquid medications, skin patches, inhalers, and injections. A bag for parents/legal guardians to bring their children's medications and supplements to the field center is enclosed.

4. Overview of Field Center Operations:
   a) A listing of the interviews and procedures for the examination (optional);
   b) A reminder that a snack for the child is provided during the exam;
   c) Field Center Examination hours and phone number for questions or rescheduling appointment.

5. Directions to the Field Center (e.g., a map) and to parking facilities:
   a) A reminder of the arrangements for parking and/or reimbursement.

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

3.4. Split Baseline Examinations

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

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

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

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

4. RECEPTION

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

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

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

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

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

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

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

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

5. INFORMED CONSENT AND ASSENT

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

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

5.1. Administration

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

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

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

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

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

5.2. Training and Certification

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

5.3. Data Collection

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

5.4. Ability to Comprehend the Informed Consent and Assent

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

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

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

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

5.5. Consent and Assent Tracking Forms

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

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

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

6. TRACKING

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

6.1 Procedure to remove a Participant from the Study

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

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

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

6.2 Procedures to Document Changes to Participant's Informed Consent

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

7. PARTICPANT FLOW AND ITINERARY

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

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

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

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

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

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

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

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

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

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

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

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

8. RECORDING MEDICATIONS AND SUPPLEMENTS

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

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

8.1. Administration of the MUE

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

8.1.1. Reception

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

8.2. Medication Record

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

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

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

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

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

8.3. Training

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

8.4. Certification

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

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

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

8.5. Quality Assurance

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

8.6. Data Collection

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

9. ANTHROPOMETRY

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

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

9.1. Equipment and Supplies

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

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

9.2. Staff

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

9.2.1. Anthropometry Form (ANT)

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

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

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

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

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

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

9.3. Examination Procedures

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

9.3.1. Standing Height

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

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

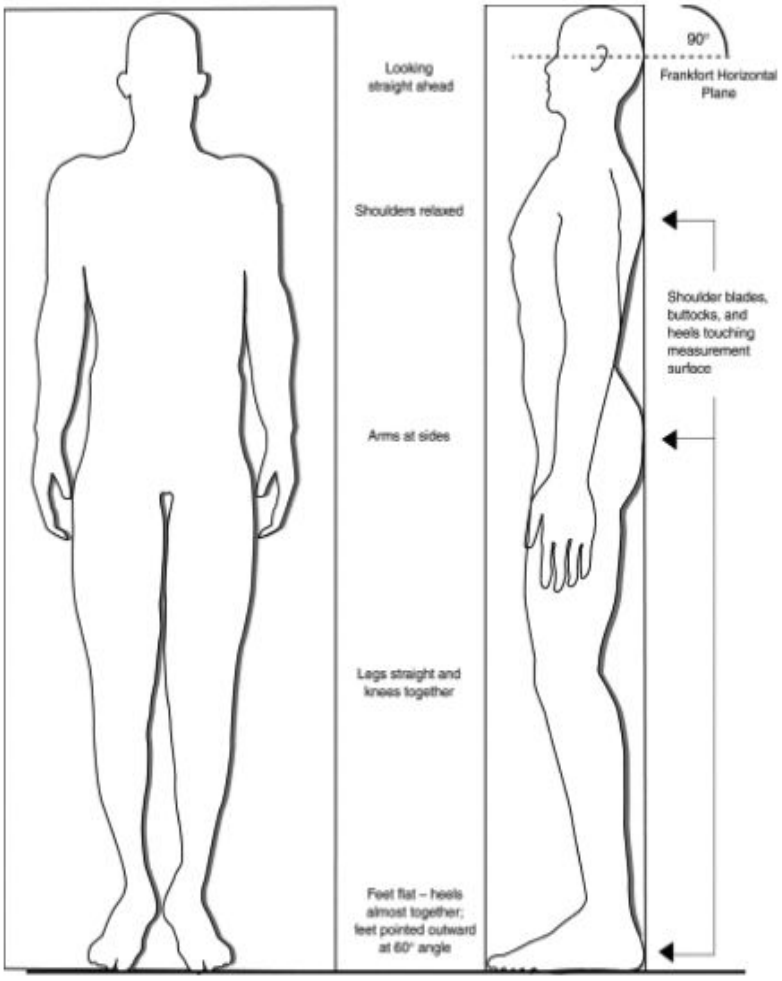
shoulder blades, and the back of the head for contact with the vertical backboard. **Make sure the child is not standing on his/her tiptoes; that shoulders are not shrugged and buttocks are not pushed out.**
Depending on the overall body conformation of the individual, all points may not touch. In such case, make sure the participant's trunk is vertical above the waist, and the arms and shoulders are relaxed.

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

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

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

Figure 1. Position for Standing Height



9.3.2. Inflexible hairdo:

There may be occasions when a participant's hairdo is inflexible, cannot be "taken down," and interferes with the measurement of standing height. If the hairdo appears to be less than 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."

9.3.3. Weight and Body Composition

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

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

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

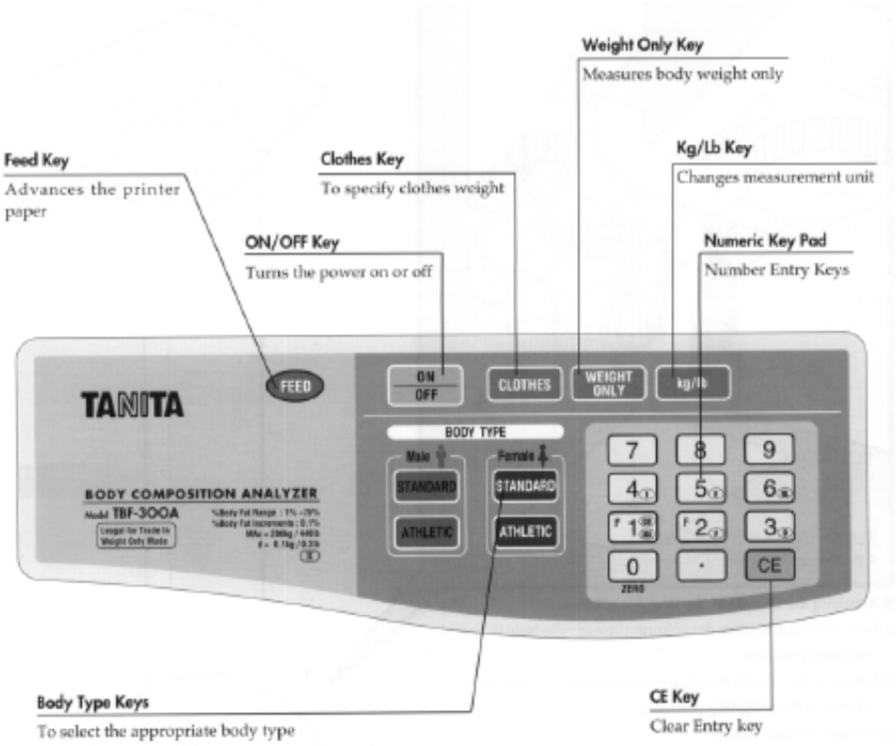


Figure 2. Control Panel of Tanita Body Composition Analyzer, TBF-300A

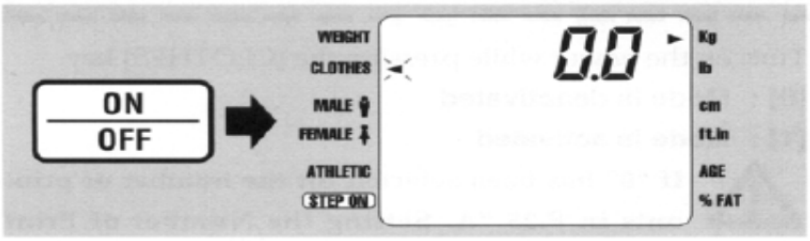
a. Initial set up

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

b. Setting the number of print outs and printing language

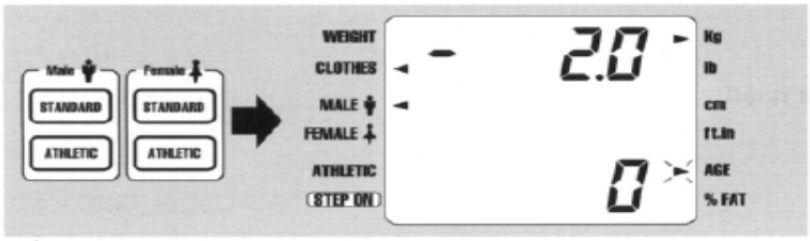
Press and hold the 0 key, and press the ON/OFF key once. Release the 0 key after "Prt-1" is displayed on the screen. Select 0 (no print out). When no print out is selected there is no need to select the printing language. The panel will switch to the measurement screen.

Operating instructions

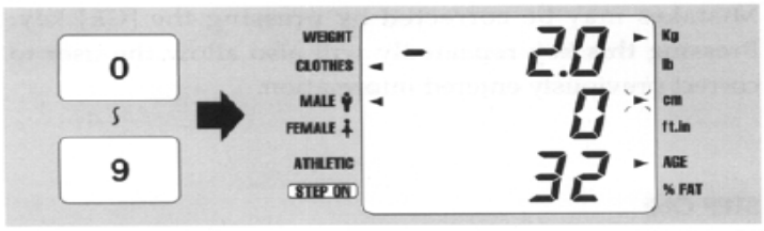


Press ON/OFF key to turn the machine on. Wait until 0.0 and an arrow appear on the screen. Check that the arrow points to "Kg". If arrow point to "lb", press the Kg/Lb key on the control panel and the arrow will shift to "Kg"

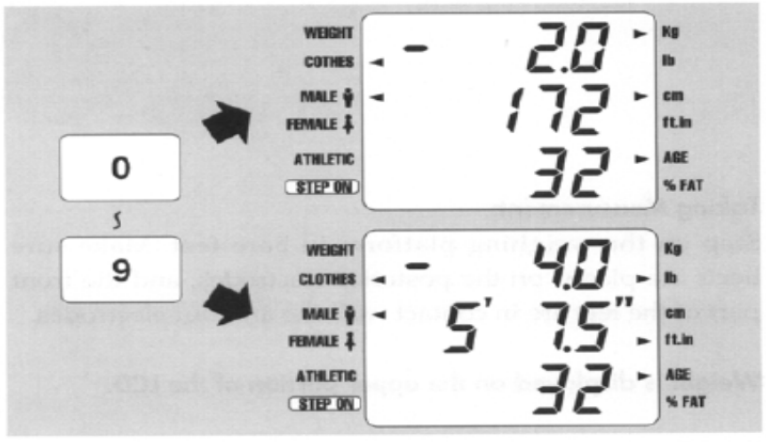
Enter Clothes weight: 1.0 kg using the numeric pad on the control panel



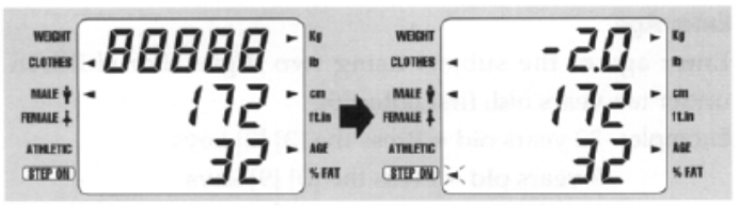
Select Gender and Body type: Standard Female or Standard Male



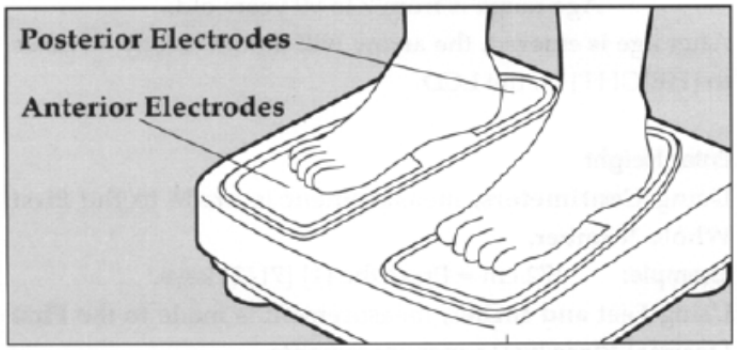
Enter age of participant using the numeric pad of the control panel. After age is entered, the arrow will direct you automatically to enter the height.



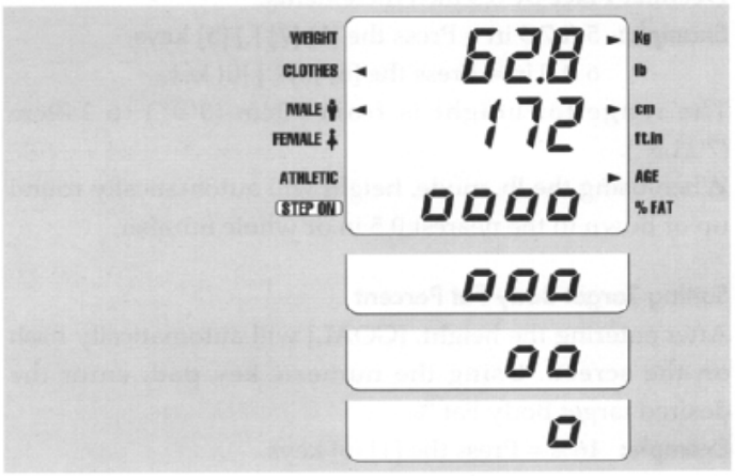
Enter height in cm. For example, for 172 cm, press the [1] [7] [2] keys. The height entered should be the repeated height (of the 3 measures) from the standing height measures (section 9.3.1).



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



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



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

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

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

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

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

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

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

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

9.3.4. Waist Circumference

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

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

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

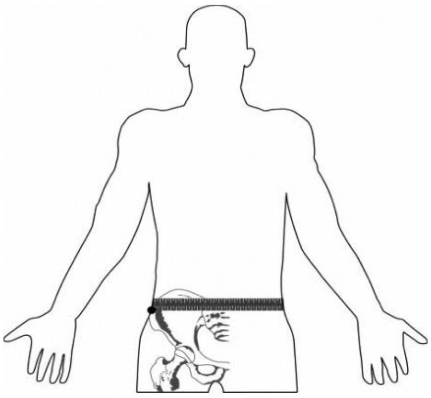
Hold the zero end below the measurement value. Make sure that the tape is parallel to the floor and that the tape is snug, but does not compress the skin. Use the wall mirror to ensure correct horizontal alignment of the measuring tape.

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

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

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

Figure 3. Measuring tape position for waist circumference



9.3.5. Hip Circumference

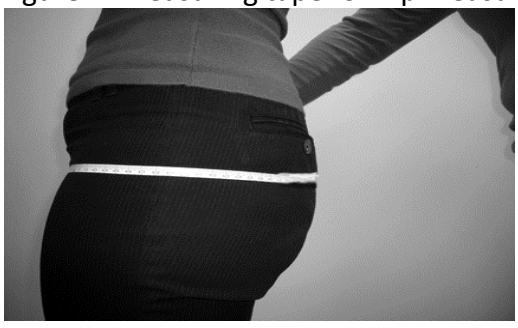
Instruct the participant to stand erect but relaxed, with weight distributed equally over both feet. The hip girth is measured at the level of maximal posterior protrusion of the gluteal muscles (buttocks). Keep the anthropometric tape horizontal at this level and record the measurement to the nearest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

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

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

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

Figure 4. Measuring tape for hip measurement



9.4. Quality Assurance/Quality Control

9.4.1. Calibration Procedures and Equipment Check

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

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

Wipe off plates on scale with antiseptic wipes.

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

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

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

9.4.2. Training, Certification and Quality Control

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

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

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

References

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

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

Q x Q ANTHROPOMETRY FORM (ANT) AND SCRIPTS

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

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

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

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

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

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

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

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

A. SAFETY QUESTIONS

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

If you are taking measures on the parent, ask:

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

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

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

If a participants answer YES, then use the Tanita Scale in weight only setting.

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

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

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

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

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

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

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

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

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

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

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

B.2. HEIGHT MEASUREMENT

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

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

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

Now, I am going to position your head so you can be the tallest you can be. I will tell you to move it up or down, just move it a little at a time.
[Position head in the Frankfurt horizontal plane so an imaginary horizontal line can be drawn between the bottom of the eye socket and the center of the opening of the ear.]

Please keep your head just like that until we finish. Now, hold your head still, keep your feet flat on the floor, and take a deep breath and hold it. Stand up nice and tall.
[Verify body is properly aligned and head position did not shift with deep breath. Move the headboard down onto the head with sufficient pressure to compress hair. Record the height on the form.]
Now let your breath out and you can step off the board.

C. WEIGHT MEASUREMENT

Now, I'm going to measure your weight. Please do not step on the scale until I ask you to.
[Follow procedures for starting the scale described in section 9.3.3 of Mop #1]

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

Great! Now you may step off the scale.

D. WAIST MEASUREMENT

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

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

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

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

Great, now I need to take your hip.

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

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

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

10. SITTING BLOOD PRESSURE

10.1. Introduction, Equipment and Supplies

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

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

Figure 4 OMRON sphygmomanometer and 4 cuffs

OMRON HEM907XL – with four cuffs

10.1.1. The Sitting Blood Pressure (SBP) form

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

10.2. Blood Pressure Measurement Procedures

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

10.2.1. Selection of the Arm

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

10.2.2. Cuff Size Selection and Application

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

10.2.3. Measurement of Arm Circumference

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

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

10.2.4. Choosing the Correct Cuff Size

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

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

Table 3.

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

10.2.5. Positioning the SOL Youth Participant and Placing the Cuff

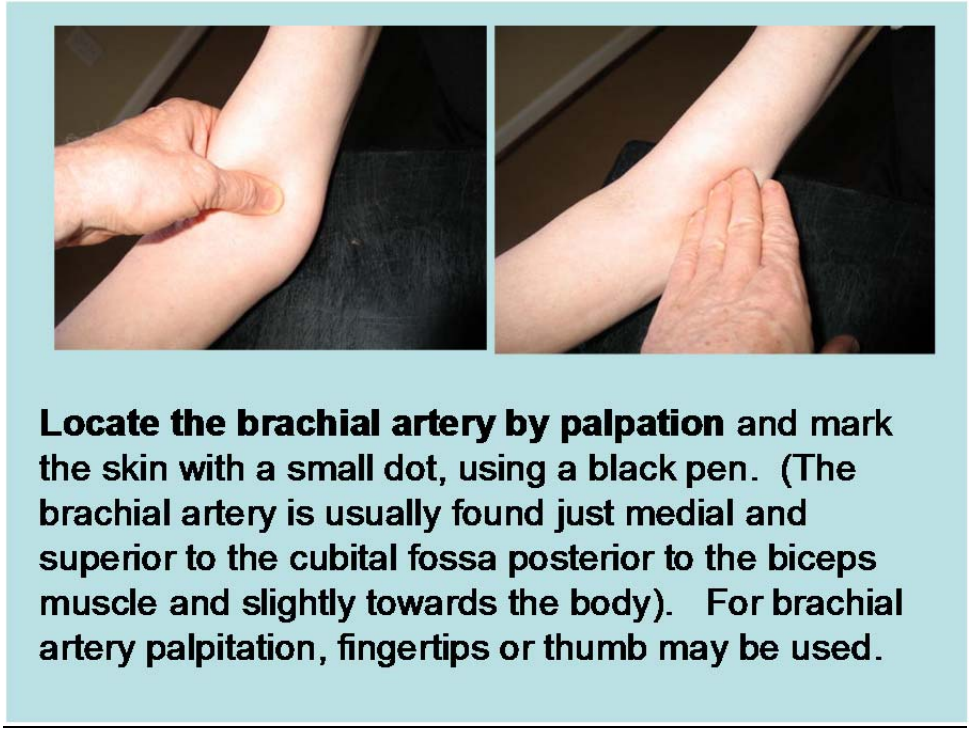
Ask the participant to sit and rest quietly in the chair after adjusting it, if necessary, to allow participant's feet to rest flat on the floor when legs are in the uncrossed position. The technician then explains the next steps using the following script: "Before taking your first blood pressure reading,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

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

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

10.2.6. Locating the Pulse Points

Figure 5: Locating the brachial pulse



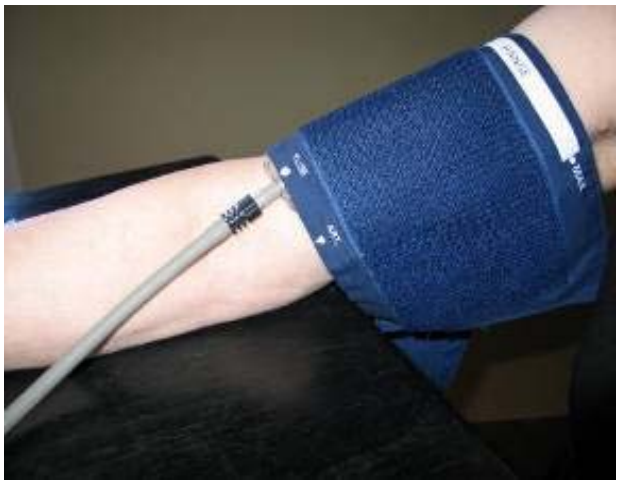
10.2.7. Wrapping the Blood Pressure Cuff around the Arm

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

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

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

Figure 6



10.3. Procedure for the OMRON HEM-907XL

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

10.3.1. Setting up the OMRON

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

Figure 7

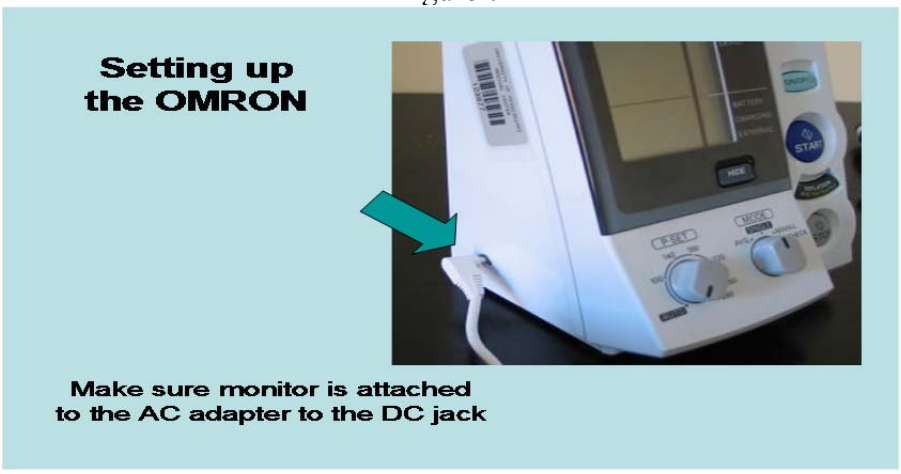
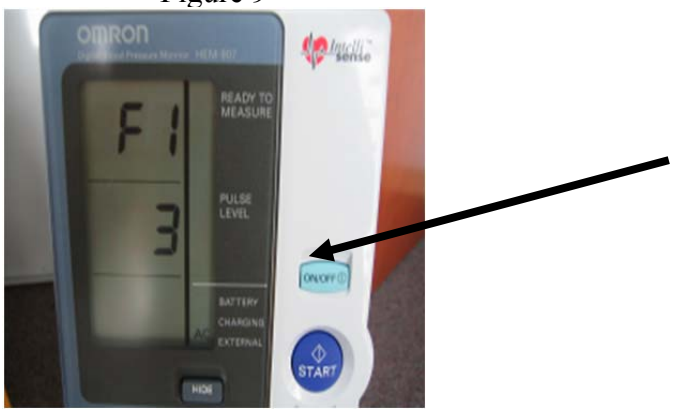


Figure 8

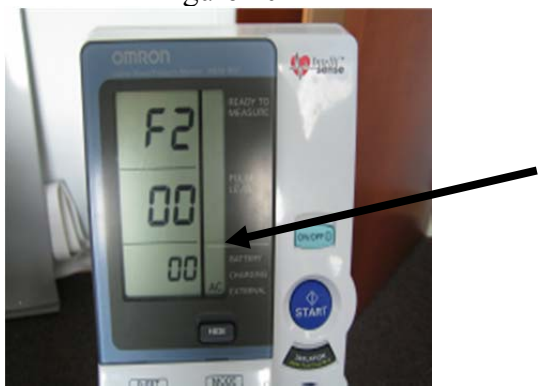
When the power is OFF, push the ON/OFF (power) button for more then three seconds while holding the START button simultaneously: F1 is displayed in the first window and three inflation (3) is displayed in the middle window (Figure 9). If needed push the DEFLATION (deflation control)/Measurement Result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

Figure 9



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

Figure 10



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

Figure 11

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

Table 4 summarizes the needed setting for the exam

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

10.3.2. Measuring the Blood Pressure

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

Figure 12

AUTO AVG

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

Figure 13

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

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

Figure 14

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

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

Figure 15

10.4. Recording the OMRON Results

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

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

10.5. Reporting the Blood Pressure Values

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

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

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

10.6. Equipment Maintenance

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

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

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

10.7. Inspection and Validation of the OMRON Sphygmomanometer

10.7.1. Daily Check points

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

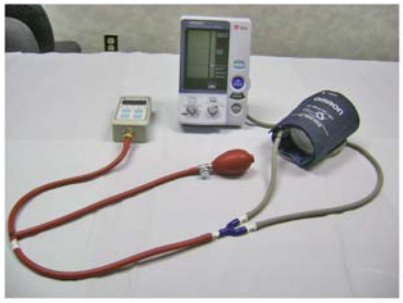
10.7.2. Quarterly Validation of the OMRON Sphygmomanometer

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

10.7.3 Equipment Required for Accuracy Check

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

Figure 16



10.7.4 Testing protocol

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

1. Inspect the OMRON sphygmomanometer for signs of damage to the case, and wall mount bracket if applicable.

2. Inspect the tubing for holes or cracks, which would allow air to leak out. Cracking is commonly found around the connection points to the sphygmomanometer, and cuff. If cracking

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

3. Inspect the cuff(s) for signs of wear and tear to the outer cloth casing and Velcro fabric. Also, inflate the unit (with the cuff connected to the OMRON and wrapped around a rigid cylinder and the OMRON MODE knob set on CHECK) enough to determine if the bladder within the cuff is leak- proof. If leaks or damage are noted to the cuff or bladder, it should be replaced.

4. Disconnect the cuff from the long adaptor tubing that stays connected to the OMRON sphygmomanometer.

5. Connect one upper arm of the Y adaptor to the short tubing from the cuff and attach the other upper arm to the long tubing attached to the OMRON.

6. Connect the bottom arm of the Y **adapte**r to one arm of the Y **tubing.**.

7. Connect other end of the Y **tubing** to the pressure-vacuum meter.

8. Turn the pressure-vacuum meter on. Use the accompanying AC adapter if necessary.

9. Following manufacturer's instructions, select "mm Hg" as the type of unit to be tested.

10. Zero the pressure-vacuum meter per manufacturer's instruction.

11. Pump up the aneroid unit to 280 mm Hg. Release the pressure slowly and observe the changing OMRON LED mm Hg for a smooth descent along the range to 20 mm Hg

12. Again, pump the aneroid unit to above 250 mm Hg (but less than 300 mmHg) using the bulb and tighten the valve as tightly as possible

13. Check to see if the aneroid unit is within $\pm$ 3 mm Hg of the readout on the pressure-vacuum meter.

14. Continue to compare the readout of the OMRON unit to the pressure-vacuum meter approximately every 20 mm Hg along the entire range – down to 30mm Hg. Variations greater than $\pm$ 3 mm Hg requires the OMRON unit be removed from service and repaired or replaced.

15. Record the results of the calibration checks on the OMRON calibration log (together with the unit number, the date and the technician ID) and send the log to the HCHS Coordinating Center. A copy of the calibration log is found in Appendix 4.

10.8. Glossary and References

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

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

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

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

11. BIOSPECIMEN COLLECTION AND PROCESSING

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

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

12. 24-HOUR DIETARY AND SUPPLEMENT INTERVIEW

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

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

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

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

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

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

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

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

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

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

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

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

13. PHYSICAL ACTIVITY MONITORING (ACCELEROMETRY)

13. PHYSICAL ACTIVITY MONITORING (ACCELEROMETRY)

13.1 Rationale

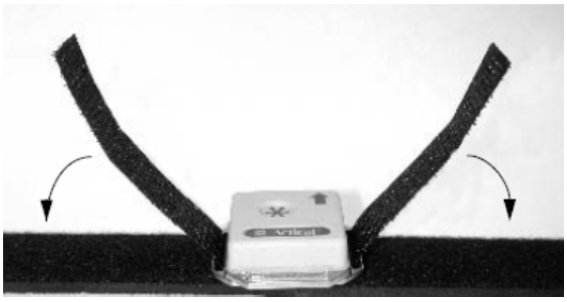
Study participants will wear a portable motion sensor (i.e., accelerometer) to measure the frequency, duration, and intensity of physical activity over 7 days. The accelerometer provides an objective measure of physical activity that will supplement the interviews for self-reported regular physical activity.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

13.2 Technical Information about the ActiCal Accelerometer

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

13.3 Protocol

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



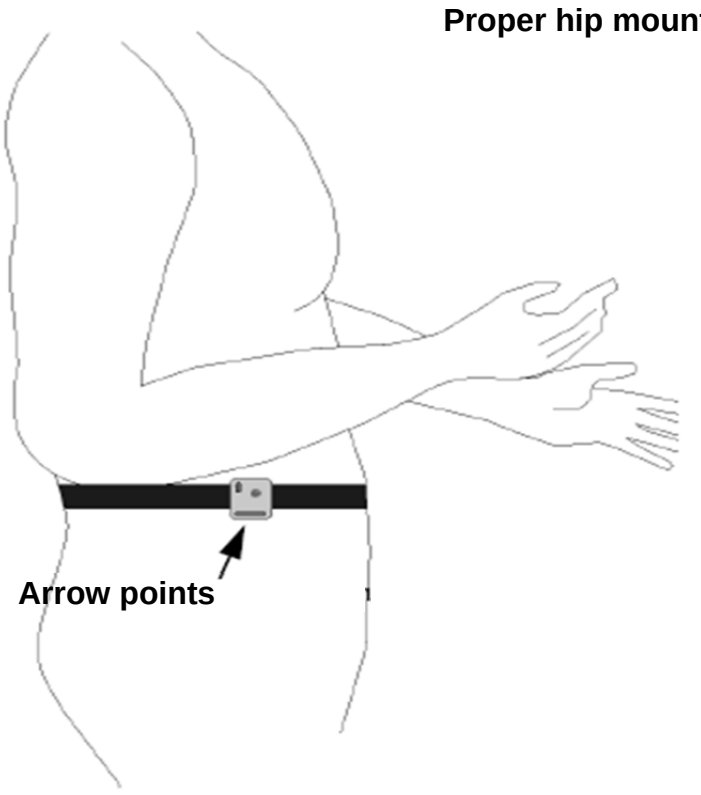
Study staff will briefly describe the purpose of physical activity monitoring and ask participants to undertake their normal activities for the week while wearing the monitor. Staff will

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

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

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

Figure 1: Proper placement of the Actical



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

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

13.4 Equipment and Supplies

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

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

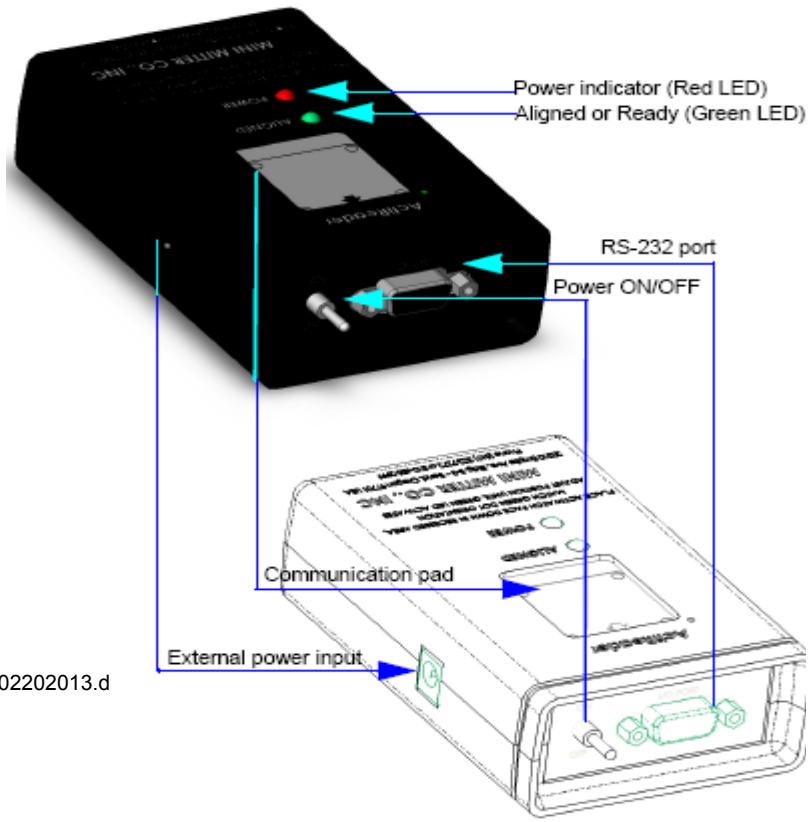
The ActiReader will be connected to the study computer. The computer do not need to be dedicated to collecting the accelerometry data; however, they should be available whenever units are returned so that data can be downloaded and stored when the units are received.

13.5 Initial Hardware and Software Set up

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

Figure 2: The ActiReader Device



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

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

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

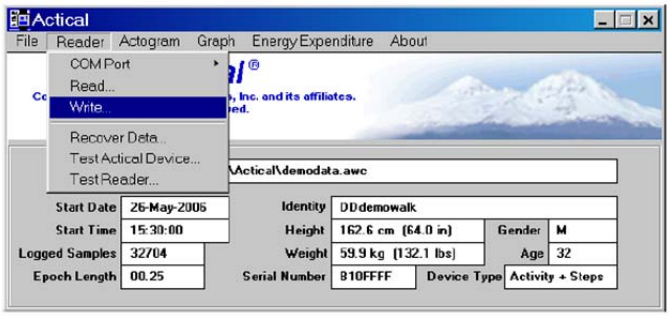
13.6 Initializing the Actical device

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

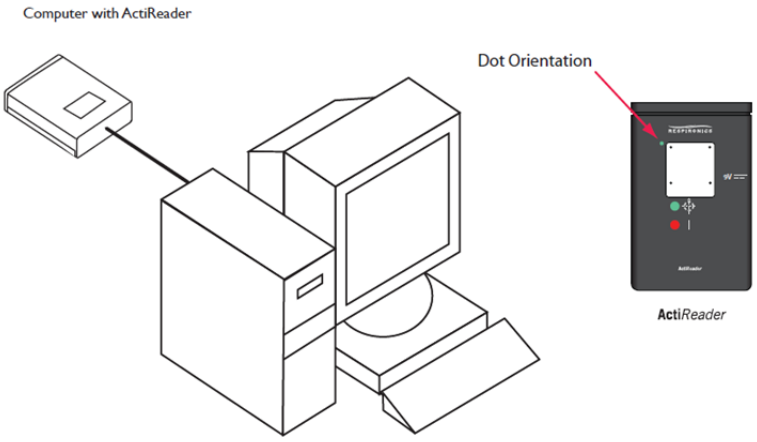
1. Select an Actical and record the monitor serial number, participant ID (ID) and participant name into the accelerometry tracking system.
2. Initialization should not take place before the participant arrives.
3. Initialize the accelerometer using the following steps:

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

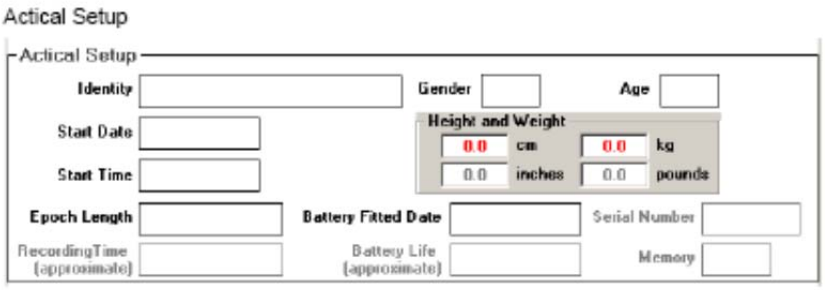
1. Open the Actical main window and select Reader > Write and follow the prompts that alert you that setting up a device will erase previously stored data.



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



4. The following setup screen will appear:



5. Check the battery life displayed under the battery fitted date. If the value is less than5 days, then replace the battery even if the battery was not scheduled to be replaced.
6. Under "Identity" enter the participant ID number. Enter gender and age as appropriate and enter the start date as the day of the scheduled visit and start time as 05:00 (5AM) on the day of the visit. Epoch length should be set to 15 seconds by entering 00.25. Enter 1.0 for height and weight because these values will not be used for the SOL/Youth Study.
7. When all information has been entered, click "Send". The Information will be sent to the Actical device.
8. The initialization progress will be shown by the red bar at the bottom of the window.
9. Remove the device from the reader and place it in the belt for use.

13.7 Instructions for using Accelerometer

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

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

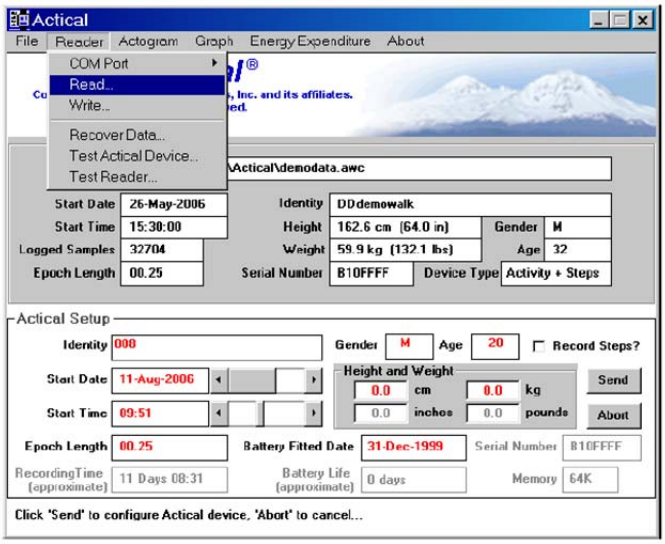
6. Expect telephone call to check up on the return of the accelerometer if it is not received back within two weeks of completing the protocol.

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

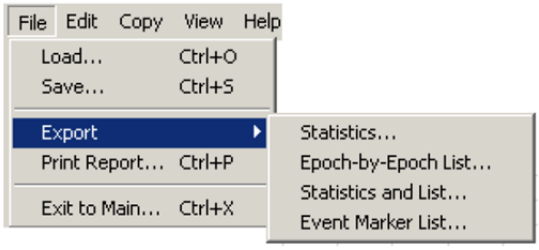
13.8 Downloading the data

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

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



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



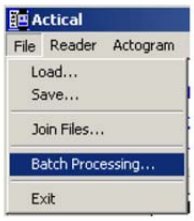
5. Select the default file name, but remove the "_list" part. Therefore, the file name is the participant ID and will have extension awc.

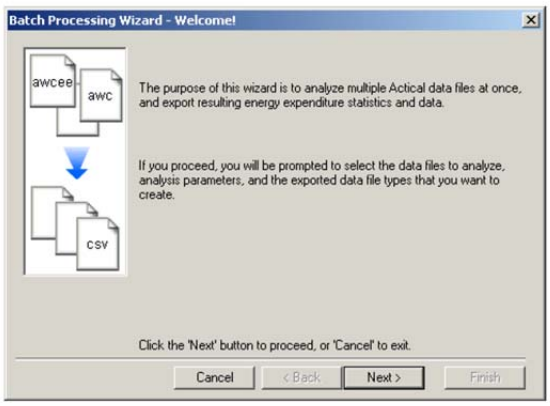
13.9 Transmitting data to the Coordinating Center

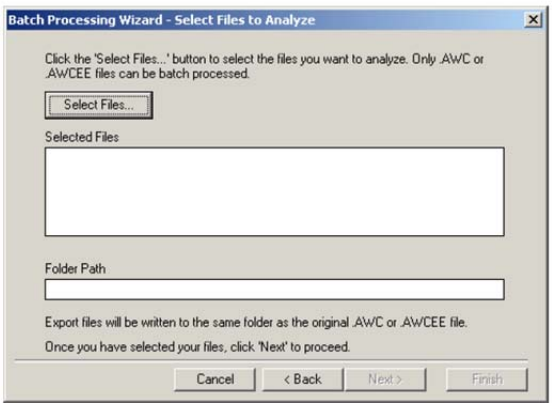
There are three steps: 1) convert data to csv format, 2) zip file and 3) upload to DMS.

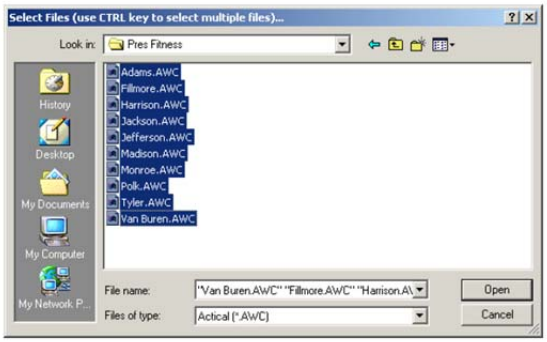
Please see "Appendix 4.1" of the Data Management MOP (MOP 5) for step-by-step instructions on how to upload the Actical data to the CDART.

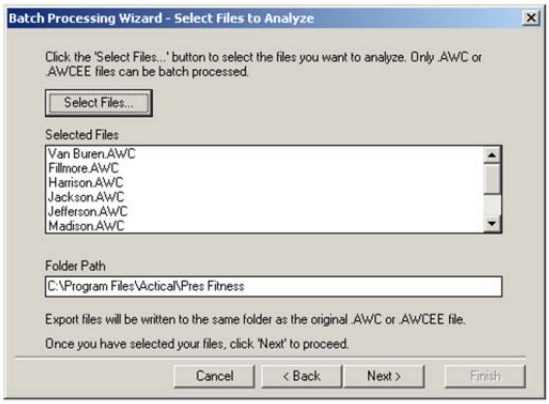
1. Convert data to csv format with batch processing:
   Batch processing is a function that allows processing simultaneously multiple files with similar characteristics. This will still work if you have only one file (*.awc).
   From the Main window, select File->batch processing and follow the wizard











2. ZIP file
3. Upload to DMS

13.10 Equipment Maintenance

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

on-line for download at the study website
http://www.healthcare.philips.com/us_en/homehealth/sleep/actical/

13.10.1 Cleaning

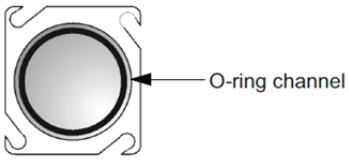
The Actical devices should be disinfected after each participant use by wiping the surface with a non-alcohol based germicide such as Lysol disinfectant wipes. Cleaning should only be carried when the battery cover is in place and fully sealed.

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

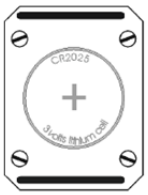
13.10.2 Battery Replacement

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

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

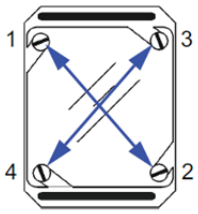


5. Place the clean O-ring into the channel on the back cover by pre-stretching the O-ring by gently flexing it in several directions. Be sure that it is properly sealed in the channel and is not twisted or deformed.
6. Place a new battery into the Actical case, positive (+) side up.



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

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



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

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

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

13.11 Quality Control

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

Appendix A
Instructions for Wearing Accelerometer (sample script)

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

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

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

After waiting for participants to ask questions, continue:

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

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

Appendix B
ActiCal check-up call

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

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

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

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

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

Optional script:

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

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

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

Optional script:

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

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

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

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

If you reach an answering machine:

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

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

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

How do I wear the physical activity monitor?
The physical activity device will be worn as a belt. Simply put the belt on your body so that the unit rests on the top of the right hip with the "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 our clinic *(Field Center address)* from 7:30am – 3pm to return the monitor.

What if I have any questions or problems with the physical activity monitor?
We will gladly answer any questions or help you through any issues. Feel free to contact us at *(Field Center number)* for physical activity monitoring.

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

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

¿Cómo debo ponerme el monitor de actividad física?
El aparato de actividad física se coloca como un cinturón. Simplemente colóquese el cinturón en el cuerpo y acomode el dispositivo arriba de su cadera derecha con el logotipo de "Respironics" (la estrellita) en la parte superior y el logotipo de "Actical" en la parte inferior.

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

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

¿Por cuánto tiempo debo ponerme el monitor de actividad física?
Debe colocarse el aparato continuamente por 7 días por lo menos 10 horas cada día.

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

¿Ya me puse el monitor de actividad física por 7 días. ¿Cómo lo devuelvo a la clínica?
Antes de entregarle el monitor le daremos instrucciones acerca de como devolverlo. Puede visitar la clínica *(Field Center address)* entre 7:30am a 3:00pm para devolver el dispositivo.

¿Qué puedo hacer si tengo preguntas o problemas con el monitor de actividad física?
Con gusto contestaremos cualquier pregunta y lo ayudaremos con problemas técnicos. Comuníquese con nuestra clínica llamando al *(Field Center number)*.

14. STEP TEST

14.1 Overview

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

14.2. Equipment

Stop watch
A black, blue, red or green non-permanent felt marker
Metronome to set step cadence
A one inch thick piece of plywood, approximately 30 inches by 24 inches
One, 18 inch ruler
Step benches: Steck Autobody 20350 Pro Step Heavy Duty Adjustable Work Platform
This bench allows for 2 inch changes in step height. The one-inch piece of wood is used to provide the smaller changes in height required by the step-test protocol.
Available from "the toolwarehouse.net" $114.50
http://www.thetoolwarehouse.net/p-6553-steck-autobody-20350.aspx
A chair. If a chair is not available the step-bench can be used.

14.3. Procedures

1. Ensure that bench is properly set up and that there is a chair nearby for child to sit on at the end of the test. Procedures for setting up the bench are as follows (also found in the Steck Autobody 20350 manual):

    1. Lay step-bench on the floor with the non-slip strips facing up.
    2. Slide the foam collars up the legs and set both legs into the platform. Set the platform in place using the quick-release pins on the four corners.
    3. With the Step-bench on its side, bolt caster rails to the second hole up.
    4. Do not attach the casters to the rails. Using the casters can make the base unstable during the step test.

2. Be sure that the floor under the bench is fairly level and free of obstruction. The bench can be placed facing the wall and if so, should be about 12 inches from the wall, with adequate space behind the bench for the participant to freely move and a space very nearby for a chair.

3.. Set the metronome for 88 counts or 22 assents per minute.
At 88 counts, each click represents a foot movement (up with one foot, up with the other; down with the first foot down with the other)

4. Verify that the child is in good health by administering Participant Safety Checklist (see appendix). Also, verify the proper footwear (no flip-flops) and any shoe laces are tied. If the child is pregnant and has indicated the parent/legal guardian is unaware of the pregnancy, then the Step Test will be rescheduled, 10-12 weeks after giving birth or when the child is no longer pregnant. If the parent questions why the procedure is not completed, personnel can inform the parent this test is a "random selection" and will not be done this day. Refer to Participant Safety MOP for guidelines to follow to ensure participant confidentiality in such cases.

5. Measure the height of the child in centimeters without shoes.

6. Adjust the bench height based on the child's height using the 18 inch ruler. If the desired height is between the 2 inch setting on the platform, slip the plywood sheet under the feet of the platform. Check to be sure the entire platform and plywood are not slipping. The table below presents the correct bench height for the height of the child:

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

7. Show the child how to perform the test and then let the child practice for 15-30 seconds.
Script at this point: **"During this next test I will be measuring your aerobic fitness. I will ask you to step up and down on this bench to the sound of the beat for a total of three minutes. I am going to show you how you will do the test. You will step up with one foot then, step up with the other, step down with the first foot and then step down with the second foot. *You do this to each beat you'll hear. Let me show you how to do it. Then I'll let you practice."***
Turn on the metronome and demonstrate, while saying Up, Up, Down, Down, repeat a few times. Emphasize that the person must straighten both legs when at the top of the step. If you need to change feet at any time during the test take an extra step in place (DEMONSTRATE). Let the child practice for about 15 to 30 seconds.
Script: **"When you are done you will sit down immediately on the chair and put your hands on your thighs and sit quietly for the next minute while I record your heart rate. I'll ask that you do not talk during this one minute so we can accurately measure your heart rate. For a few seconds after you sit down you can gently raise and lower your heels alternately keeping your toes on the floor (DEMONSTRATE), to prevent dizziness. If at any time**

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

8. Have the child sit for approximately 5 minutes after practicing.
9. During the rest period find the child's radial pulse. Place the child's palm of the dominant arm facing up. Feel between the tendon on the thumb side and the bone near the wrist. Do not use your thumb to find the pulse; use the sides of your fingers. Be sure not to press too hard or the pulse will be occluded – not felt. If no radial pulse is found, check for a carotid pulse. This can be found by gently palpating between the Trachea (throat) and the sternocleidomastoid muscle on the outside of the neck with the sides of the fingers. Once again, **do not press too hard**. Some individual are very sensitive to the pressure and may pass out.
10. Once a pulse is found mark the location with the felt pen. Then take a resting heart rate for 15 seconds and record on the data form.
11. Check to be sure the metronome is set for 88 counts or 22 assents per minute.
12. On the "**go**" SIGNAL the child starts stepping, the stopwatch is started and continues for three minutes. Provide verbal instructions and encouragement to be sure the child is stepping at the desired rate throughout the three minutes.
13. As the child nears the end of the exercise period. Instruct them as to what you want them to do at the end of the test. **"You are about finished. I will count down your last for steps. The please immediately sit down in the chair so that I can get an accurate pulse rate. Here we go, up, up down, down, stop and sit down in the chair."**
14. At the end of assessment the child immediately sits down on the bench or a chair with his hands on his thighs.
15. Wait exactly 5 seconds and then count the number of pulse beats for the next fifteen (15) seconds. Do not try to reset the watch at the end of the 5 seconds. There is not sufficient time. Simply start the count at the 5 second mark and measure to the 20 second mark. Count the total number of beats for the 15 seconds not the heart rate.
    Use the initial 5 seconds to find the pulse.
    Remind the child not to talk and keep his/her hands on the thighs.
16. Record the total number of heart beats on the data form.
17. For your information, aerobic fitness (VO_2max) can be estimated using that 15 second heart beat count by the following formula: VO_2max = 105.4 – 1.64(HR). However, the CC will make the calculation.
18. **NOTE: If the child does not finish all three minutes of the exercise test, the test is invalid. If the child could only finish one minute (or less) of the exercise, then they probably could not complete the test if given a second try, so do not ask them to repeat the test. If the child completes more than two minutes of the exercise, there is a likelihood that they could repeat the test and complete it. For such children, it is appropriate to ask if they would be willing to try the test again. If the child agrees, they can repeat the test once, but only after their heart rate has recovered to below 100 beats. This may take an additional 10 minutes for recovery.**

14.4 Quality Assurance

14.4.1 Training & Certification

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

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

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

14.4.2 Quality Control

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

14.5. Safety Procedures

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

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

14.6 References

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

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

Appendix 2:
Participant Safety Checklist for Step Test

Youth

SOL Youth Safety Checklist for Fitness Step Test

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

Administrative Information

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) 0b. Staff ID: ☐☐☐

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

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

   No……0 ☐
   Yes…..1 ☐ **INELIGIBLE**

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

   No……0 ☐ **GO TO QUESTION 3**
   Yes…..1 ☐

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

   No……0 ☐ **GO TO QUESTION 3**
   Yes…..1 ☐

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

   0-2 Times a Week… .....…0 ☐
   3 or More Times a Week……..1 ☐ **INELIGIBLE**

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

   a. Time of day: ..... ☐☐:☐☐ (H H M M)

   b. AM or PM

   AM .....A
   PM .....P

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

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

No……0 ☐
Yes…..1 ☐ **INELIGIBLE**

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

No……0 ☐
Yes…..1 ☐ **INELIGIBLE**

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

No……0 ☐
Yes…..1 ☐ **INELIGIBLE**

Appendix 3:
Step Test Data Form

Youth

SOL-Youth Fitness Step Test

ID NUMBER:									FORM CODE: FST VERSION: 1 11/10/11	Contact Occasion		SEQ #	

Administrative Information

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) 0b. Staff ID: ☐☐☐

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

6. Standing height: ..... ☐☐☐ cm

7. Bench height used: ..... ☐☐

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

8. Find radial pulse rate before exercise

No……0 ☐
Yes…..1 ☐

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

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

11. Heart Rate at discharge: Total counts for 15 seconds..... ☐☐ total beats
(Count should be ≤ 25 at the time of release)

12. Was this procedure completed?

No……0 ☐
Yes…..1 ☐ **GO TO END**

7a. If no, please explain

_____

15. Tanner Assessment

15.1 Overview

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

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

15.2 Equipment and Supplies

Hospital gown
Tanner Assessment Forms (see Appendix)

15.3 Procedures

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

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

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

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

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

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

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

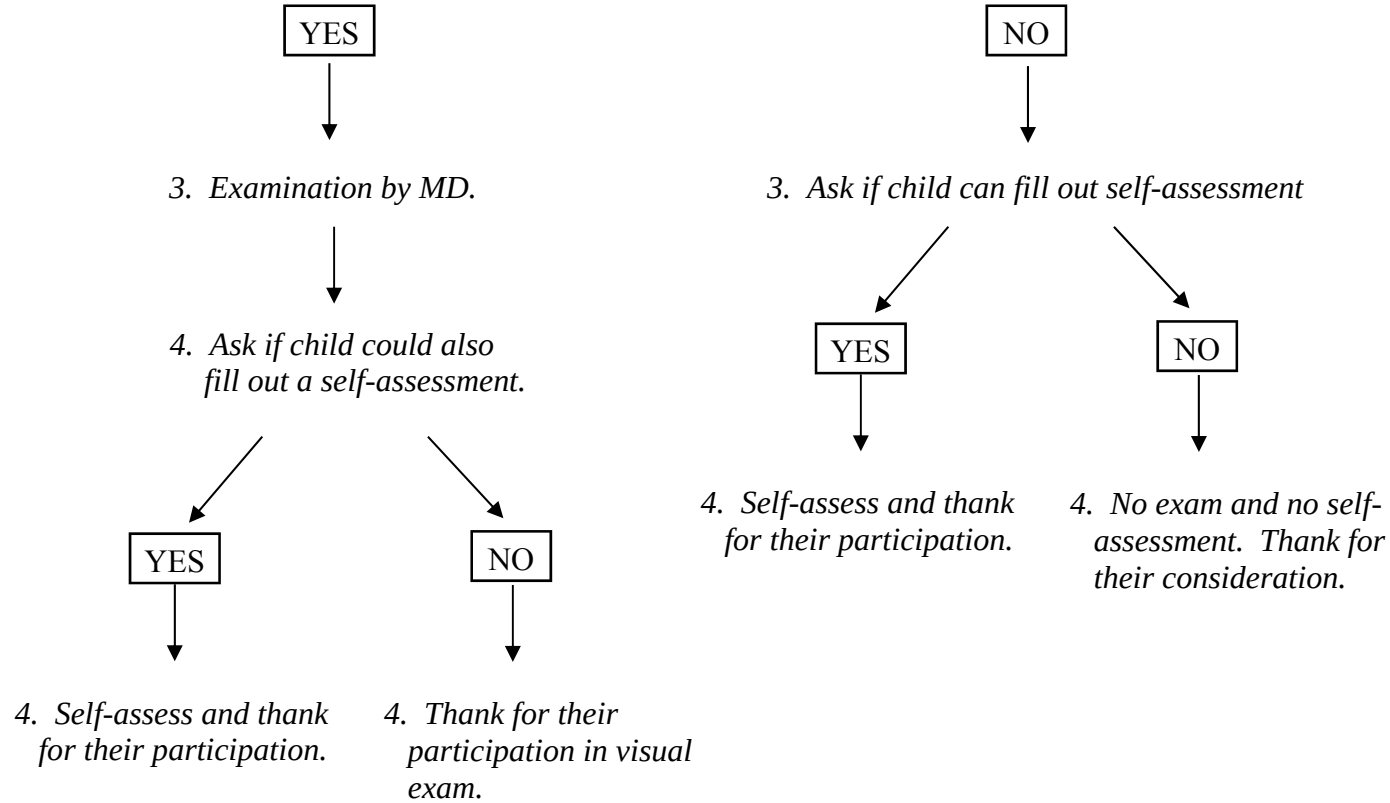
   If the parent and child AGREE to the self-assessment, then the physician will administer the Self-Assessment form (see Appendix 1 for males, 2 for females). The physician will read the text to the child and ask the child to cross the box that is closest to their current stage of development.

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

A summary overview of the protocol steps is shown below:

1. *Introduce self and read script.*

2. *Ask permission for visual examination.*



15.4 Quality Assurance

15.4.1 Training & Certification

Visual examinations will only be conducted by a physician.

15.4.2 Quality Control Procedures

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

15.5 Safety Procedures

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

15.6 References

August, G. P., Grümbach, M. M., & Kaplan, S. L. (1972). Hormonal changes in puberty. 3. Correlation of plasma testosterone, LH, FSH, testicular size, and bone age with male pubertal development. *Journal of Clinical Endocrinology and Metabolism, 34*(2), 319-326.

Burr, I. M., Sizonenko, P. C., Kaplan, S. L., &Grümbach, M. M. (1970). Hormonal changes in puberty. I. Correlation of serum luteinizing hormone and follicle stimulating hormone with stages of puberty, testicular size, and bone age in normal boys *Pediatr Research, 4*(1), 25-35.

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Sizonenko, P. C., Burr, I. M., Kaplan, S. L., &Grümbach, M. M. (1970). Hormonal changes in puberty. II. Correlation of serum luteinizing hormone and follicle stimulating hormone with stages of puberty and bone age in normal girls. *Pediatric Research, 4*(1), 35-45.

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

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

Part A. Instructions

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

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

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

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

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

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

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

Part B. Instructions

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

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

1) ☐ There is no hair at all.

2) ☐ There is a little soft, long, lightly colored hair at the base of the penis. It may be straight or a little curly.

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

4) ☐ The hair is as dark and curly as that of a man, but it hasn't spread out to the legs.

5) ☐ The hair is like that of a man. It has spread out to the legs.

**Source:*

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

Participant from Source: Males aged 6-20 years

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

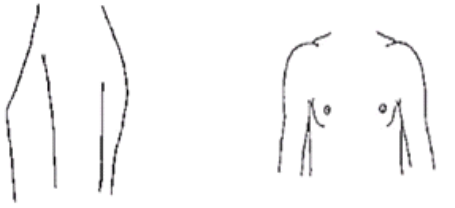
We would like to assess the stage of your physical development using the drawings on the next pages. These show various stages commonly used by doctors to assess the growth and development of girls. We need to know which drawings most closely match your stage of development at the moment. Not all teenagers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

Part A. Instructions

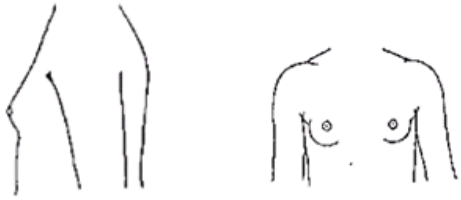
The drawings below show stages of the way the **breasts** develop. A teenager can go through each of the five stages shown, although some teenagers skip some stages. **Please look at each of the drawings.** It is also important to read the descriptions.

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

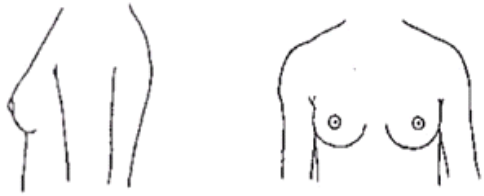
1) ☐ The nipple is raised a little in this stage. The rest of the breast is still flat.



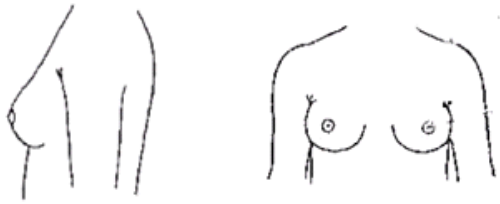
2) ☐ This is the breast bud stage. In this stage the nipple is raised more than in stage 1. The breast is a small mound. The dark area around the nipple (areola) is larger than in stage 1.



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



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

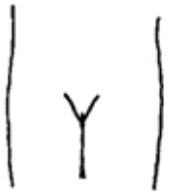


5) ☐ This is the mature adult stage. The breasts are fully developed. Only the nipple sticks out in this stage. The areola has moved back in the general shape of the breast.

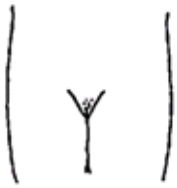
Part B. Instructions

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

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



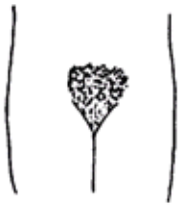
1) ☐ There is no pubic hair



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

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

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



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

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

**Source:*

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

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

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

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

Have you shaved or trimmed your pubic hair recently?

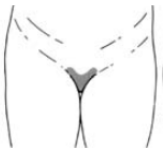
□ Yes → Have participant fill out a self-administration form for pubic hair development.Only conduct breast development assessment.

□ No → Continue with pubic hair development assessment and breast development assessment.

Part A: Pubic Hair Development

1) **Stage I (Preadolescent)**
Vellos hair develops over the pubes in a manner not greater than that over the anterior wall. There is no sexual hair. ☐

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

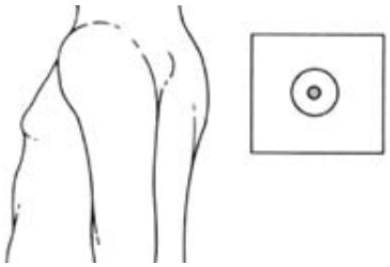


3) **Stage III**
Considerably darker, coarser, and curlier sexual hair appears. The hair has now spread sparsely over the junction of the pubes. ☐

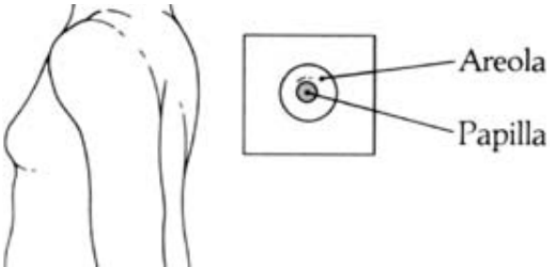
4) **Stage IV**
The hair distribution is adult in type but decreased in total quantity. There is no spread to the medial surface of the thighs. ☐

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

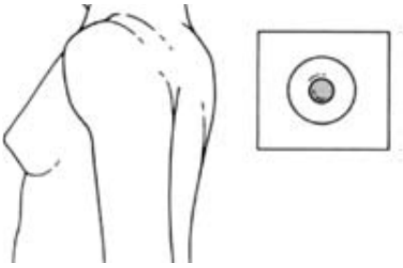
Part B: Breast Development



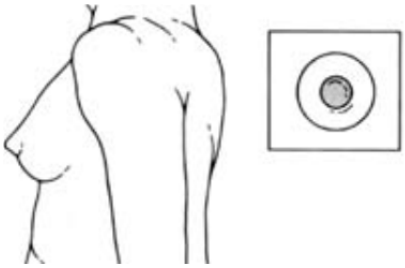
1) **Stage I (Preadolescent)**
Only the papilla is elevated above the level of the chest wall. ☐



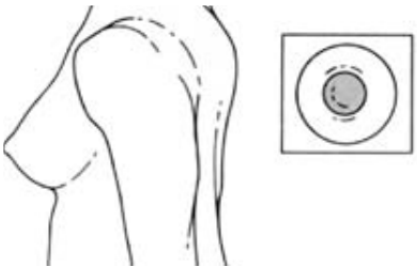
2) **Stage II (Breast Budding)**
Elevation of the breasts and papillae may occur as small mounds along with some increased diameter of the areolae. ☐



3) **Stage III**
The breasts and areolae continue to enlarge, although they show no separation of contour. ☐



4) **Stage IV**
The areolae and papillae elevate above the level of the breasts and form secondary mounds with further development of the overall breast tissue. ☐



5) **Stage V**
Mature female breasts have developed. The papillae may extend slightly above the contour of the breasts as the result of the recession of the areolae. ☐

Appendix 4.
HCHS SOL Youth, Tanner Stage Physician Assessment for Male

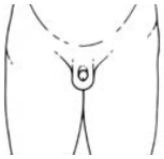
If the participant has no pubic hair or seems to shave, ask:

Have you shaved or trimmed your pubic hair recently?

□ Yes → Have participant fill out a self-administration form for pubic hair development. Only conduct genitalia development assessment.

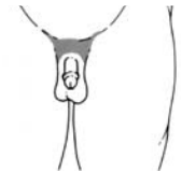
□ No → Continue with pubic hair development and genitalia development assessment.

Part A: Pubic Hair Development

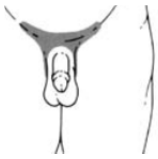


1) **Stage I (Preadolescent)**
Vellos hair appears over the pubes with a degree of development similar to that over the abdominal wall. There is no androgen-sensitive pubic hair. ☐

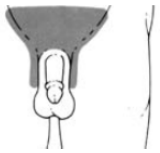
2) **Stage II**
There is sparse development of long pigmented downy hair, which is only slightly curled or straight. The hair is seen chiefly at the base of penis. This stage may be difficult to evaluate on a photograph, especially if the subject has fair hair. ☐



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



4) **Stage IV**
The hair distribution is now adult in type but still is considerably less that seen in adults. There is no spread to the medial surface of the thighs. ☐



5) **Stage V**
Hair distribution is adult in quantity and type and is described in the inverse triangle. There can be spread to the medial surface of the thighs. ☐

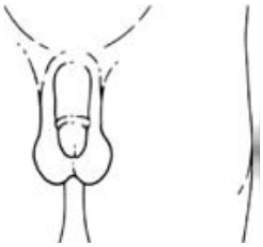
Part B: Male Genitalia Development

1) **Stage I (Preadolescent)**
The testes, scrotal sac, and penis have a size and proportion similar to those seen in early childhood. ☐

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

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

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



5) **Stage V**
The genitalia are adult with regard to size and shape. ☐

16. INTERVIEWS

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

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

16.1. Characteristics of a Good Interview

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

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

16.2. Characteristics of a Good Interviewer

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

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

16.3. Communication Traps and Obstacles to Standardization

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

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

16.4. Interviewer Bias

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

16.5. Conducting the Interview

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

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

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

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

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

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

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

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

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

"Can you tell me more about this?"

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

"How are you using that term?"

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

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

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

16.6. Administration of the Interviews

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

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

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

16.7. Quality Assurance of Interviews

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

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

(1) Knowledge of the substantive matter in the interview;

(2) Use of an even pace and conversational tone;

(3) Demonstration of a professional and nonjudgmental demeanor;

(4) Use of appropriate probing techniques;

(5) Ability to accurately record the participant's response.

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

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

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

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

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

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

(1) one check list for each interviewer; and

(2) three interviews recorded on tape(s) and three paper forms per interviewer.

17. DATA ENTRY SYSTEM (CDART)

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

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

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

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

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

18. DATA INVENTORY AND REPORT PREPARATION

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

19. EXIT INTERVIEW

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

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

20. PARTICIPANT SAFETY

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

20.1 Safe Clinic Environment

Overview

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

Child care

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

Food

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

20.2 Participant Safety Screening Form (PSE)

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

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

Modifying and verifying the PSE

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

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

20.3 Pregnancy

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

20.4 Cancelling/Rescheduling Clinical Components

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

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

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

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

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

20.5 Procedures for Handling Emergencies

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

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

Major emergencies

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

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

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

Minor emergencies

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

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

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

1. Have the person remain in the chair and sit with head between the knees or recline if the appropriate chair is used at the field center.

2. Provide the participant with a basin and a towel if he/she feels nauseous;

3. Have the participant stay in the chair until he/she feels better and the color returns.

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

2. Minor abrasions from a stumble during the step test

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

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

Emergency Equipment

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

20.6 Procedures to Document Adverse Events and Emergencies

Adverse Event Definition and Reporting in SOL Youth

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

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

AE Classification in SOL Youth

Serious (vs. minor or not serious)

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

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

Expected (vs. unexpected)

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

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

- **Related AE** – An adverse event which is related to the use of a device, procedure or an ingested substance in a way that supports a reasonable possibility (such as strong temporal relationship) that the adverse event may have been caused by the device, procedure or intervention used in SOL Youth.

- **Possibly Related AE** – An adverse event which is possibly study-related is one that may have been caused by a procedure, device, or ingested substance, with insufficient information to determine the likelihood of this possibility.

- **Unrelated AE** – An adverse event that has no apparent relationship to the study.

Reporting of Adverse Events and Information Flow

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

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

20.7 Participant Safety/Alert Thresholds on Study Measurements

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

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

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

Fatigue/Discomfort

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

20.8 Mental Health Emergency Procedures

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

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

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

a. Suicidal Ideation

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20.9 Procedure for Reporting Child Maltreatment

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

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

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

Second, if you and your supervisor feel the information warrants a report, a report must be made to the state's abuse hotline; research staff at each center should have that phone number available in the clinic.
Third, it is in the best interest of the child and the family if the family does the reporting. If appropriate, the Field Center supervisor can determine how to talk with the family about the need for reporting, and the family can be offered the following options.

- The best is for the family to call. Staff is responsible for making sure that they do so, however. Therefore, staff may offer to be in the room with them.

- Most families find it very difficult to self-report. Therefore, another very good option is for staff to call the hotline with the family in the room.

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

Other important issues when calling in an abuse report:

1. Call in the morning if that is when the child is in the clinic – DCF has strict timelines for investigations; a call in the morning makes it more likely that the case is addressed at a time when staff can be reached.

2. Ask to be either the "first point of contact" or "a point of contact." If you are the first point of contact, they will contact you first, before contacting the family or child. This may be important if you are worried about retribution to the child or other issues. Asking to be a point of contact allows you to give the information you would like to make sure that DCF has. This is an important step to remember.

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

Appendix 1.
Safety Script to Confirm/Update PSE

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

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

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

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

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

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

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

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

21. REPORT OF STUDY RESULTS, MEDICAL REFERRALS AND NOTIFICATIONS

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

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

21.1. Procedures for Medical Referrals and Notification of Results

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

21.2. Reporting of Results to SOL Youth Participants

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

21.3. Medically Relevant Information

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

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

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

Medical information is provided to participants at the following points:

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

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

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

21.4. Study Results Reporting Schedule

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

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

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

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

21.5. Thresholds for Referral and Reference Ranges for Study Results

21.5.1. Seated Blood Pressure

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

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

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

SBP= systolic blood pressure. DBP= diastolic blood pressure.
* Source: The 2004 NHBPEP Report. Pediatrics, 2004; 114: 555-576.
** Diagnosis of hypertension must be based on two or more readings taken at each of two or more visits following an initial screening.

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

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

21.5.2. Blood Chemistries

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

21.6 Conveying the Report of results to the study participant

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

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

21.7 Quality Assurance

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

22. SOL YOUTH RECRUITMENT SCRIPT

HCHS/SOL Youth Study
Recruitment Screening Script

A. No answer - Leave a message:

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

B. On the phone:

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

1. **Not available:**

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

a. Even if (**Main study participant name**) is not available at the moment. May I speak with (**Name of other participant/s**) or (**Name of other participant/s**).
If multiple study participants are recorded for this HSR.

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

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

2. **HCHS/SOL study participant is available:**

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

b. Hello, Mr/Ms ___(**main study participant name**)_____, my name is___(**recruiter name**)___. I work with the Hispanic Community Health Study/Study of Latinos (SOL), the study you participated in back in (**insert date).** We can't thank you enough for having participated in this study. *Continue with the following script.*
We recently mailed you a letter describing a new study designed to learn more about the health of Hispanic/Latino youth in the United States. This study is available to children of SOL participants. Before I tell you more about the study, let me verify your address. Are you still living at **[participant's address]**?

*If **yes**, continue with script*

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

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

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

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

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

*If **yes and given a reason**, **record answer in [Form XX].***
*If **no, document "No reason given" in Form XX →*** Ok no problem, thank you for your time.

3. Review of Data Collected.

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

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

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

b. *If Q2 of Household screening form = 1 or more (child in the household) – Go to question 3 in the HSR form.*

c. *If Q3 of Household screening form = 0 (no children between 8-16 in the household) –* *read the script below after rostering the children:*

If there are NO children younger than 8:
Thank you for answering all my questions. At this time we are only inviting children between the ages of 8 to 16to participate in the SOL Youth study. Once again, thank you for your time and for your participation in SOL.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

HCHS/SOL Youth Study
HOUSEHOLD SCREENING Spanish SCRIPT

B. No answer - Leave a message:

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

C. On the phone:

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

4. **Not available:**

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

a. Aunque (**Main study participant name)** no está disponible en este momento, puedo hablar con, (**Name of other participant/s**) o con (**Name of other participant/s**).
If multiple study participants are recorded for this HSR

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

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

5. **HCHS/SOL study participant is available:**

c. Trabajo con el Estudio de la Salud de la Comunidad Hispana/Estudio de los Latinos (HCHS/SOL), el estudio en el que usted participó en el pasado (en **insert date)** *Continue with script*

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

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

*If **yes**, continue with script*

*If **no**, collect the participant's information and assign new household ID.*
¿Podría decirme su nueva dirección para mantener nuestros archivos actualizados?

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

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

If participant refuses to be screened → ¿Podríamos saber porque usted/su niño no quiere participar?
*If **yes and given a reason**, **record answer in [Form XX].***
*If **no, document "No reason given" in Form XX** →* Ok no hay problema, muchas gracias por su tiempo.

6. Review of Data Collected.

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

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

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

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

b. *If Q2 of Household screening form = 1 or more (child in the household)* *– Go to question 3 in the HSR form.*

c. *If Q3 of Household screening form = 0 (no children between 8-16 in the household) –* *read the script below after rostering the children:*

If there are NO children younger than 8:
Gracias por haber contestado todas mis preguntas. En este momento estamos invitando solamente a niños de 8 a 16 años de edad para participar en el estudio de Juventud-SOL. De nuevo, gracias por su tiempo y participación en SOL.

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

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

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

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

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

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

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

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

4. ¿Quiere participar en el estudio Juventud SOL?

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

*If **yes and given a reason**, **record answer in [Form XX].***
*If **no, document "No reason given" in Form XX** →* Ok no hay problema. Gracias por su tiempo.

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

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

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

Date: _____Time_____ am/pm

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

If ELE Q. 12=4 (Eligible, Parent or child refuses to participate)→
¿Podríamos saber porque usted/su niño no quiere participar?

*If **yes and given a reason**, **record answer in [Form XX].***
*If **no, document "No reason given" in Form XX** →* Ok no hay problema. Gracias por su tiempo.

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

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

Su visita está programada para: **Date____** at **Time___** am

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

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

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

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