

**MANUAL OF OPERATIONS FOR THE STUDY OF LATINOS: NUTRITION &
PHYSICAL ACTIVITY ASSESSMENT STUDY (SOLNAS)**

**VERSION 1.0
March 9, 2012**

We thank the Women's Health Initiative Extension Nutrition & Physical Activity Assessment Study (NPAAS) investigators for permission to adapt portions of the NPAAS Procedure Manual to SOLNAS.

HCHS-SOL NUTRITION AND PHYSICAL ACTIVITY ASSESSMENT STUDY (SOLNAS) PROCEDURE MANUAL

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SOLNAS recalls will be submitted to the UNC-CC as projects separate from the Main/Parent study recalls.

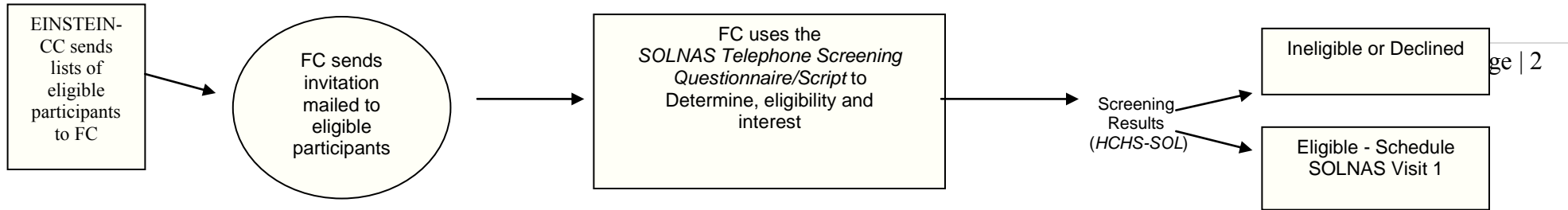
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SECTION 1:
**STUDY OF LATINOS: NUTRITION AND PHYSICAL ACTIVITY ASSESSMENT
STUDY OVERVIEW**

1.1 Overview of the Study of Latinos: Nutrition and Physical Activity Assessment Study (SOLNAS)

- The Study of Latinos: Nutrition and Physical Activity Assessment Study (SOLNAS) is a sub-study of the Hispanic Community Health Study-Study of Latinos (HCHS-SOL). It is sponsored by the Albert Einstein College of Medicine Coordinating Center (EINSTEIN-CC) and data are managed via the University of North Carolina Coordinating Center of the parent study (UNC-CC) hereby known as UNC-Data CC. The objective of the SOLNAS is to collect biological markers of dietary intake (energy, protein, fatty acids, and micronutrients) and physical activity for use in regression calibration models that will correct the random and systematic bias of dietary and physical activity self-report and better estimate associations of dietary intake and physical activity with disease outcomes. The calibrated nutrient intake data will be used for a broad range of nutrient-disease and physical activity-disease analyses from the HCHS-SOL.
- SOLNAS will be implemented in a subset of 476 participants in the HCHS-SOL who have consented to participate in SOLNAS. Participants will be mailed an invitation letter prior to being contacted for a telephone screening. Willing participants will be consented at the first SOLNAS clinic visit which lasts about 5 hours. Following consent, they will complete a 24 hr dietary recall, provide information about current dietary supplements and sedentary activity, receive a single oral dose of doubly labeled water (DLW), and provide three spot urines. Participants aged 60 years and older will also provide a blood specimen. Between clinic visits participants will collect a 24-hour urine specimen. Participants will return to their Field Center for a 3-hour visit on about Day 13, at which time they will return the 24-hour urine specimen (collected at home), be weighed, provide a fasting blood specimen, complete an indirect calorimetry protocol and give two spot urines. At the Bronx site they will also complete the Tufts Food Frequency Questionnaire aka Multicultural Food Frequency Questionnaire. For a subset of 96 participants (the reliability subsample), the full protocol will be repeated approximately 6 months later. The Nutrition and Physical Activity Assessment Study implementation at the FCs begins January 2011 and continues through June 2012. Figure 1.1 – *HCHS-SOL (HCHS-SOL) Nutrition and Physical Activity Assessment Study Overview* provides an overview of SOLNAS.

Recruitment/Screening



Field Center Visits

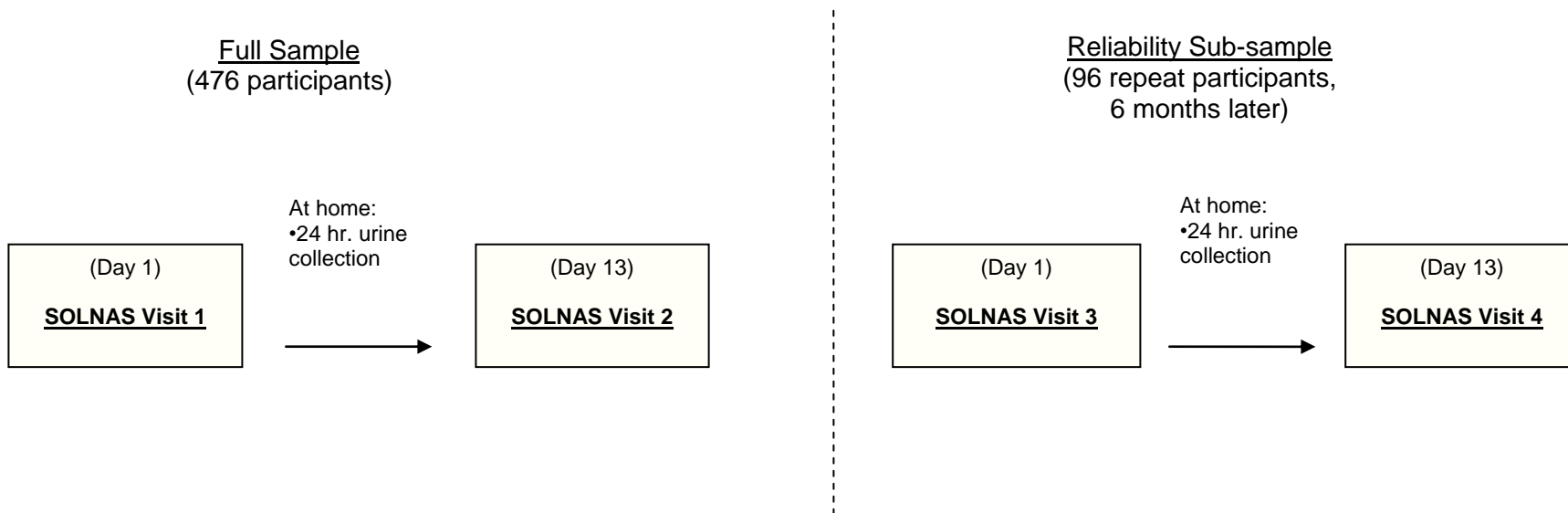


Figure 1.1: Study of Latinos Nutrition and Physical Activity Assessment Study (SOLNAS) Overview

SECTION 2: Guidelines

2.1 Overview

- This section contains information to help Field Centers (FCs) manage SOLNAS. Guidelines for staffing, training and communication, and supplies are provided. This section may be helpful for staff training and can be used as a checklist to ensure that essential elements are in place to conduct the study.

2.2 Staffing

- Each FC has the following staff positions covered in their initial SOLNAS budget projections: Project Coordinator, Nutritionist, Medical Assistant, Research Assistant, and Lab Technician, or similar configurations to support implementation of the SOLNAS at each FC.

2.2.1 SOLNAS Lead-Ops

- Each FC identifies an SOLNAS Lead-Ops person to oversee SOLNAS operations and be the SOLNAS point person. This person may be the FC Principal Investigator, the investigator with local oversight for the SOLNAS, or a separate person. The SOLNAS Lead-Ops person needs to:
 - Be in the clinic and involved in the SOLNAS visits so that he/she can supervise what is happening and respond to questions that staff may ask.
 - Train other non-lead SOLNAS staff.
 - Ensure that the SOLNAS protocol is followed, supplies are available, specimens and completed forms are shipped according to the schedule provided by EINSTEIN-CC and any procedural problems or adverse events are reported to both EINSTEIN-CC and the UNC-Data CC.
 - Oversee management of the following SOLNAS operations:
 - Recruitment
 - SOLNAS visits and tasks
 - FC-SOLNAS budget oversight
 - FC IRB submissions and renewals
 - Other duties as required

2.3 Training

- The purpose of training within SOLNAS is to teach staff the SOLNAS protocol and procedures for implementation at the Field Center (FC). To facilitate the implementation of SOLNAS uses a train-the-trainer model similar to the one used in HCHS-SOL. One SOLNAS Lead-Ops person per FC receives training for all SOLNAS-specific tasks and is then responsible for training his/her staff for SOLNAS tasks. Staff who are responsible for administering the doubly-labeled water, indirect calorimetry,

and phlebotomy tasks are strongly encouraged to attend the appropriate training components provided on-site by the EINSTEIN-CC SOLNAS Study Coordinator. EINSTEIN-CC provides one time FC on-site training, conference call training, and the *SOLNAS Manual*. The FC SOLNAS Lead-Op is responsible for training of staff who are unable to attend the on-site training. Additional or follow-up training may occur through conference calls.

2.3.1 SOLNAS Staff

SOLNAS Lead-Ops

- The SOLNAS Lead-Ops person attends the on-site FC SOLNAS training conducted by the EINSTEIN-CC SOLNAS Study Coordinator at his/her FC and reads the *SOLNAS Manual*.
- Non-lead SOLNAS staff attend pertinent sections of the FC on-site training conducted by the EINSTEIN-CC SOLNAS Study Coordinator, read relevant sections of the *SOLNAS Manual* and discuss relevant training topics with the SOLNAS Lead-Ops person.
- FC staff will be trained by the EINSTEIN-CC SOLNAS Study Coordinator or FC Lead-Ops on implementing the SOLNAS protocol.
- For training on SOLNAS forms collection and visit implementation, including blood and urine collection, the SOLNAS Lead-Ops person attends the SOLNAS training and reads the *SOLNAS Manual*. The Lead-Ops person trains the designated FC staff. FCs must also follow the pertinent safety precautions found in the *SOLNAS Manual*, as well as their local regulations for bio-specimen handling (blood and urine).

2.3.2 Training Resources

2.3.2.1 SOLNAS Training at Field Centers

- The EINSTEIN-CC Study Coordinator conducts one on-site SOLNAS training for each FC at the time of SOLNAS start-up.
- *SOLNAS Training Materials* includes the agenda and relevant materials.

2.3.2.2 SOLNAS Procedure Manual (referred to as the *SOLNAS Manual*)

- The *SOLNAS Manual* describes the study design (as outlined in the study protocol), procedures, and data management. The primary function of the manual is to provide common training and reference materials across all participating SOLNAS FCs as a way of assuring uniform application of the protocol.

2.3.2.3 SOLNAS Conference calls

- Conference calls will be used to supplement or follow-up the FC on-site training.

2.4 Communication

- Communication will occur via bi-weekly conference calls between the Coordinating Center and EINSTEIN-CC; monthly or as needed with all investigators and

monthly with lead ops and EINSTEIN-CC Study Coordinator during pre-enrollment/training and study enrollment period.

2.5 Print Materials and Supplies

- This section provides information about print materials and supplies for SOLNAS.

2.5.1 Print Materials

2.5.1.1 Materials Printed by Field Centers (FCs)

- FCs print several of the SOLNAS forms and materials locally from masters provided by EINSTEIN-CC. Electronic copies of the masters are provided to the FCs. The SOLNAS forms and materials that FCs print locally are outlined below. *Forms that are included in Data Management System (DMS) need not be printed, except for back-up copies in case DMS is experiencing difficulties:*
 - Letter of Invitation to Participants (to be printed on local institutional stationary)
 - Script – Telephone Screening
 - Telephone Screening Questionnaire Visit 1 and 3 (DMS): TSE/TSS
 - Letter confirming appointment for two visits
 - Frequently Asked Questions (for staff)
 - SOLNAS Informed Consent
 - Visit 1 and Visit 3 Eligibility Worksheet (DMS): VEE/VES
 - Visit 1 and Visit 3 (DMS): VSE
 - Sedentary Behavior (DMS): SDE/SDS
 - Body Image (DMS): BIE/BIS
 - Instructions for 24-hour Urine Collection
 - Record sheet for 24-Hour Urine Collection (DMS) UCE/UCS
 - 24-Hour Urine Collection Worksheet for Staff (DMS): SUC
 - Between Visits at a Glance
 - Visit 2 and Visit 4 Participant Update Worksheet (DMS): VUE/VUS
 - Visit 2 and Visit 4 (DMS): VTE
 - Reliability Telephone Script
 - SOLNAS Reliability Consent Form
 - Mailing Labels
 - Return Address Labels
 - Participant Member ID Labels
 - Resting Energy Expenditure Results Letter to Participants
 - Consent for Future Contact

2.5.1.2 Print Materials Supplied by Central Lab

Central Lab provides each FC with the print materials outlined below.

- SOLNAS label set for lab specimens, and indirect calorimetry.

Supplies and Guidelines for Ordering Supplies

The list below includes the list of SOLNAS supplies and guidelines for ordering them. FCs may choose to use a different vendor than the one recommended for supplies obtained locally.

<u>Supplies</u>	<u>Recommended Vendor/Part Number:</u>	<u>Source</u>
Doubly labeled water (DLW) protocol		
• Pre-mixed DLW- to be weighed out at individual sites based on participant weight	William Wong; Baylor College of Medicine	
• Top-loading digital scales with capacity up to 500 grams and accuracy to three decimal places for weighing out the DLW dose based on participant weight	Bronx will provide	Bronx
• Cups with capacity to hold up to 200 grams of the DLW mixture	Bronx will provide	Bronx
<u>Miscellaneous</u>		
• Participant meal replacement beverage (8 ounce) for 1 hour after DLW dose at Visit 1 1 per SOLNAS participant	Local medical supply or store Suggested brand: Boost	FC
• Participant lunch at the end of Visit 1 1 per SOLNAS participant	FC option	FC
• Participant snack at the end of Visit 2 1 per SOLNAS participant	FC option	FC
• Straws (for drinking DLW) 2 per SOLNAS participant	Local medical supply or store (a straight size as opposed to one that is bent)	FC
• Pre-weighed tissue in Ziplock baggies (in case of DLW spillage)	Bronx will provide	Bronx
• Forceps to handle pre-weighed tissue	Bronx will provide	Bronx
• Office supplies, e.g., envelopes, mailing labels, member ID labels, postage	Local store	FC

Blood and Urine Collection Supplies

- | | | |
|---|-------------------------------|-------|
| <ul style="list-style-type: none"> • Urine collection hats (Specipans)

3 per SOLNAS participant – 1 to use at each of two clinic visits, 1 to send home with participant for 24-hour urine collection | Bronx will order and provide | Bronx |
| <ul style="list-style-type: none"> • 24-hour urine collection containers
two (3 liter) per SOLNAS participant | Bronx will order and provide | Bronx |
| <ul style="list-style-type: none"> • Plastic funnels for 24-hour urine collection and processing--
1 per SOLNAS participant for at-home collection

Extras as needed for pouring contents of two collection bottles together for mixing; Needed for large collections (i.e. > 3L) | Bronx will order and provide | Bronx |
| <ul style="list-style-type: none"> • Plastic carry bag for 24-hour urine collection kit
1 per SOLNAS participant | Bronx will order and provide | Bronx |
| <ul style="list-style-type: none"> • Plastic container (with lid) for mixing large urine collections (2.5 gallon) | Bronx will order and provide | Bronx |
| <ul style="list-style-type: none"> • Safety pins (large size) for participants to pin to their undergarments as a reminder for 24-hour urine collection
1 per SOLNAS participant (1 box of ~100 per FC) | Local store | FC |
| <ul style="list-style-type: none"> • Gel ice packs for participants to transport their 24-hour urine collections to the Field Center
20 per FC (~6 ounce; 4” x 6”) | Local medical supply or store | FC |
| <ul style="list-style-type: none"> • PABA (B-vitamin) tablets, 3 per participant | Bronx will order and provide | Bronx |
| <ul style="list-style-type: none"> • Boric acid powder, one 500 gram jar, for urine collection preservative | Bronx will order and provide | Bronx |
| <ul style="list-style-type: none"> • Stickers for 24-hour urine collection containers | Bronx will order and provide | Bronx |

<ul style="list-style-type: none"> • Royal blue-stoppered (serum) tubes with Hemogard closure and clot activator, 6 mL 1 per SOLNAS participant 	BD Vacutainer Labware No.: 368380	FC
<ul style="list-style-type: none"> • Lavender-stoppered plasma 10 mL tube, with powdered Sodium (Na₂ EDTA) 1 per SOLNAS participant under the age of 60 years 2 per SOLNAS participant 60 years of age and older 	Central Lab or Monoject 310745 Terumo Venoject T200SQ (Baxter B3042-54 or Laboratory Supply)	FC
<ul style="list-style-type: none"> • Needles, 21 gauge, 1 to 1½” multiple sample Vacutainer® 	Local medical supply	FC
<ul style="list-style-type: none"> • 23-gauge butterfly with 12” tubing with multiple sample Luer adapter 	Local medical supply	FC
<ul style="list-style-type: none"> • Syringes 	Local medical supply	FC
<ul style="list-style-type: none"> • Monoject hypodermic needle (21-23 gauge, 1 ½”) 	Local medical supply	FC
<ul style="list-style-type: none"> • Blood draw workstation 	Recommended Baxter S9267-1	FC
<ul style="list-style-type: none"> • Vacutainer® holder 	Local medical supply	FC
<ul style="list-style-type: none"> • Test tube racks 	Local medical supply	FC
<ul style="list-style-type: none"> • Alcohol swabs or cotton balls, alcohol, and alcohol dispenser or gauze swabs 	Local medical supply	FC
<ul style="list-style-type: none"> • Bandages (“Band-Aids”) or surgical tape 	Local medical supply	FC
<ul style="list-style-type: none"> • Biohazard container for needles (“sharps” container) 	Local medical supply	FC
<ul style="list-style-type: none"> • Biohazard container for waste 	Local medical supply	FC
<ul style="list-style-type: none"> • Wash bottle 	Local medical supply	FC
<ul style="list-style-type: none"> • Lab coat 	Local medical supply	FC
<ul style="list-style-type: none"> • Disposable latex gloves (or substitute) 	Local medical supply	FC
<ul style="list-style-type: none"> • Anti-bacterial hand soap 	Local store	FC

- | | | |
|---|-------------|----|
| <ul style="list-style-type: none"> Aluminum foil or yellow plastic sleeves to protect the blood drawn in all of the fasting blood collection tubes from light (SOLNAS Visit 2 & SOLNAS Visit 4) | Local store | FC |
|---|-------------|----|

Blood and Urine Processing Supplies

Recommended Vendor/Part Number:

- | | | |
|--|------------------------------|-------|
| <ul style="list-style-type: none"> 2 mL Corning cryovial tubes with rubber O-ring (yellow caps for spot urine samples, purple for plasma, red for serum and green for 24-hr urine collection) | Bronx will order and provide | Bronx |
|--|------------------------------|-------|

15 per SOLNAS participant. For QC sample: 5 additional per participant for spot urine (5% of sample) and 10 additional per participant for 24 hr urine, plasma and serum (10% of sample)

Visit 1

3 for spot urine (yellow cap)

1 for Lavender tube 3-hour post-DLW blood draw (for participants 60 years and older) (purple cap)

Visit 2

2 for spot urine (yellow cap)

4 for Royal Blue fasting blood (red cap)

3 for Lavender fasting blood (4 if participant is 60 years and older) (purple cap)

3 for 24-hour urine (green cap)

- | | | |
|--|------------------------------|-------|
| <ul style="list-style-type: none"> 10 mL tube for centrifuging 24-hour urine collection samples | Bronx will order and provide | Bronx |
|--|------------------------------|-------|
- 1 per participant per FC plus 1 per participant for QC (10% of sample)

<ul style="list-style-type: none"> • Disposable transfer 7.5 ml pipettes (for transferring urine from DLW spot urine collection to 2 mL cryovial, and for transferring the centrifuged 24-hour urine sample into the three 2 mL cryovials) 6 per participant 	Bronx will order and provide; note only three spot urines are collected at visit one; two at visit two.	Bronx
<ul style="list-style-type: none"> • Top loading Digital Scale (for measuring weight of 24-hour urine collections) 	Bronx will order and provide for sites that do not have the scales	Bronx
<ul style="list-style-type: none"> • Acticals: four for each field site 	Bronx will order and provide	Bronx
<ul style="list-style-type: none"> • Labels, 0.75" x 0.75" latex saturated, cold temp adhesive 	Bronx will order and provide	Bronx
<ul style="list-style-type: none"> • Refrigerated centrifuge with swinging buckets (able to reach relative centrifugal force of 1,300 xg) 	Local medical supply	FC
<ul style="list-style-type: none"> • Large and small test tube racks for holding Vacutainer® tubes and cryovials 	Local medical supply	FC
<ul style="list-style-type: none"> • Chlorine bleach 	Local medical supply	FC
<ul style="list-style-type: none"> • Goggles or glasses or mask with face shield or barrier shield behind HCHS-SOL to process blood samples 	Local medical supply	FC
<ul style="list-style-type: none"> • Tape 	Local store	FC
<ul style="list-style-type: none"> • 1 mL adjustable automatic pipettor 	Local medical supply	FC
<ul style="list-style-type: none"> • Disposable pipette tips (for blood processing) 	Local medical supply	FC

Blood and Urine Storage and Shipment

<ul style="list-style-type: none"> • Freezer boxes for 2 ml Corning cryovial tubes 	Bronx will order and provide	Bronx
<ul style="list-style-type: none"> • Freezer at -70°C or colder, with CO₂ back-up system and temperature recorder 		FC
<ul style="list-style-type: none"> • Suggested shipping supplies: (Please refer to your local institution's shipping guidelines) <ul style="list-style-type: none"> ○ Insulated Shippers 	FCentral Lab Catalog # 03-530-17 (SCA THERMOSAFE No.:355) or Central Lab Catalog #03-530-32 (SCA THERMOSAFE No.:398)	FC

- Freezer alarm for each -70°C freezer FC
- Waterproof packing tape (strapping tape) FC
- Dry ice nuggets FC
- Indelible ink pen FC
- Shipping tape FC
- Scale for weighing shipment FC
- Bubble wrap (to cushion cryovials inside freezer box) FC
- Paper towels (for freezer box exterior; to absorb condensation) FC
- Leak-proof plastic bag FC
- Maps for freezer boxes FC
- Notification of SOLNAS Shipment Form FC
- Frozen Specimen Shipping Labels FC
- Other supplies as needed for safe handling of biospecimens FC

SECTION 3: RECRUITMENT

3.1 Overview

- This section contains information to help FCs manage SOLNAS recruitment. The materials describe the SOLNAS study sample, recruitment goals, recruitment plan, recruitment list, invitation letter, and resources for recruitment.

3.2 SOLNAS Study Sample

- SOLNAS will be implemented in a subset of 476 HCHS-SOL participants who have consented to participate in the HCHS-SOL.

3.3 Recruitment Goals

- The recruitment goals for each FC are 119 at each of the four sites: Bronx, Chicago, Miami and San Diego

3.4 Recruitment Plan

- Each FC receives a SOLNAS recruitment plan from UNC-Data CC based on weighted sampling for age, body mass index and ethnicity, in addition to recruitment criteria specified in the protocol.
- FCs will explicitly follow the SOLNAS recruitment plan. The UNC-Data CC will monitor recruitment rates.

3.5 Recruitment List

- The UNC-Data CC provides each FC with a list of eligible participants. The report includes HCHS-SOL participants who have consented to participate in and are active in the HCHS-SOL and who meet the eligibility criteria outlined in the SOLNAS protocol. The list includes participants who have completed the second 24 hr dietary recall in the parent study, are within six months of baseline parent study visits and the criteria below. Telephone screening will further determine eligibility based on the following:
 - Do not take insulin or other medications to manage diabetes.*
 - Do not require supplemental oxygen.*
 - Have not had blood transfusions, administration of blood products or administration of intravenous fluids in excess of 500mL in the week prior to the first clinic visit for this study or an expectation of the same during the

period between visits 1 and 2 (including IV fluids administered as part of any administered anesthesia such as during a screening colonoscopy).*

- Will remain within 200 miles of their home during the week prior to the study and throughout the two week study period. *
- Have not lost or gained more than 10% of their body weight in the previous month. (Note: The telephone screening questionnaire states 15 lbs of weight loss or gain in previous month to simplify ascertainment of weight loss/gain)
- Do not have bladder control problems that would make collection of a 24-hour urine specimen difficult.
- Do not take medication for bladder control such as Detrol™.
- Have not **recently** started medications that can affect energy expenditure (e.g. thyroid medication) or energy intake (e.g. weight loss medication or chemotherapy.). A participant who has a history of taking thyroid medication and is weight stable, however, is eligible for the study.
- Do not take diuretics in an irregular manner that results in weight swings of more than 5% during the DLW period.
- Not on methadone treatment.
- Do not have self-reported claustrophobia, HCHS-SOL could cause the participant to become anxious when the plastic hood is placed over their head for the indirect calorimetry procedures. These procedures require that the participant lie quietly for at least 30 minutes, as anxiety caused by claustrophobia would produce inaccurate test results.

* These factors interfere with the doubly labeled water measurements of energy expenditure, indirect calorimetry measures, or other study procedures.

- **Invitation Letter**
- After receiving the participant recruitment list from UNC-CC, FCs begin to mail the SOLNAS invitation letter to participants. It would be helpful to alert parent study staff of the upcoming letters and to share ideas with other ancillary study coordinators on how best to optimize recruitment to all studies.
- It is important to mail the SOLNAS invitation letter separate from other HCHS-SOL mailings. This provides an opportunity to:
 - Ensure that the invitation letter is not lost in the HCHS-SOL materials.
 - Send the invitation letter in a timely manner.
- It is important to mail the invitation letter in small batches (i.e., do not to mail to the entire SOLNAS recruitment list all at once). In the early stages of recruitment, use of batches is recommended. If FCs mail too far in advance, the participant's strata status may change before a FC can contact the participant.
- To avoid any potential of selection bias (subjectively selecting participants), FCs should mail an invitation letter to only the eligible participants on the list and continue to invite participants sequentially as appearing on the report unless:
 - The stratum closes before the FC approaches them.

-
- The participant is known *a priori* to be ineligible (e.g., lives greater than 200 miles from the FC).
 - To track the SOLNAS mailings and screening calls, FC uses SOLNAS tracking system to track the following pieces of recruitment information:
 - Who has been sent the SOLNAS invitation letter.
 - Date letter sent.
 - Date to call participant (one week after invitation letter sent).
 - Number of phone attempts

SECTION 4: SCREENING

4.1 Overview of Screening Process

- The SOLNAS screening process determines the eligibility and interest of potential HCHS-SOL participants. Below is a summary overview of the screening process:
 - Contact each participant by phone within one week of mailing the invitation letter.
 - Use the *Telephone Screening Questionnaire/Script* to determine the participant's eligibility and interest.
 - Schedule SOLNAS Visit 1 and Visit 2 for eligible and interested participants. Consider participant's ability to collect urine before Visit 2 when scheduling.

4.2 Screening Activities

4.2.1 Telephone Contact and the SOLNAS tracking system

- FCs telephone all participants who are mailed an invitation letter within one week of the SOLNAS mailing. The SOLNAS interviewer uses the SOLNAS tracking system to record the dates when a participant is contacted by phone.
 - the SOLNAS tracking system contains the following information: date, time of day, day of the week, and a place for interviewer's comments.
- If the SOLNAS interviewer is unable to reach the participant by telephone, after at least five attempts at different times of the day and days of the week the participant is marked '4 – Unable to contact' on SOLNAS local tracking.
- **Determine Eligibility and Interest**
- During the screening phone call, the SOLNAS interviewer uses the *Telephone Screening Questionnaire/Script* to explain the SOLNAS study and determine the participant's eligibility and interest. If needed, the interviewer may refer to *Frequently Asked Questions* document when answering participants' questions about the doubly labeled water (DLW) protocol.

4.2.2 Schedule SOLNAS Visit 1 and Visit 2

- If a participant is eligible and interested, the SOLNAS interviewer schedules the SOLNAS Visit 1 and Visit 2. Visit 2 should be scheduled to occur **twelve** days after Visit 1.

SECTION 5: SOLNAS Tracking System

5.1 INTRODUCTION

The SOLNAS Database System was designed to simplify administering the SOLNAS Ancillary Study. This system will:

- Supply contact information about Participants in the original study who are potential Participants in the Ancillary Study
- Facilitate automatic printing of Ancillary Study Introduction letters to potential Participants
- Allow each site to record all phone contacts with potential Participants in a phone contact log
- Allow each site to track visits and scheduled appointments for actual Ancillary Study Participants
- Provide real-time reports to assist in accomplishing these tasks and monitoring Participant progress.

5.2 BASIC PRINCIPLES:

POTENTIAL PARTICIPANTS

The DMS supplies a file with a list of potential Participants without any identifying contact information such as name, phone number etc.

CONTACT INFORMATION MERGE

Each Center uses the Tracking System's UPLOAD DATA FILE function to merge the DMS-supplied potential Participant file with the Center's local data in order to produce a file with Participant contact data to be used as input in the Tracking System.

MAILINGS TO POTENTIAL PARTICIPANTS

The Tracking System provides a function to produce initial Ancillary Study invitation letters in batches to potential Participants. This function allows a Center to indicate how many Potential Participants receive invitations in each invitation creation batch. The system will prioritize mailings to participants who are closest to their 7 month expiration date.

PARTICIPANT STATUS TREE

The Tracking System provides the user with the Participant Status Tree screen for an overview of the status of all Potential and Active Participants in the Ancillary Study. The Participant Status Tree screen is organized to reflect the "flow" of Potential and Active Participants through the Ancillary Study process (e.g. from Eligible → Invitation Sent → Phone Contact → Visits). The screen is composed of a series of "nodes" with each node representing a particular Participant State (e.g. Sent Invitation, Phone Contact Attempted, Ineligible, Visit Scheduled). By click on a node, the user is able to review all Participants in that Participant State.

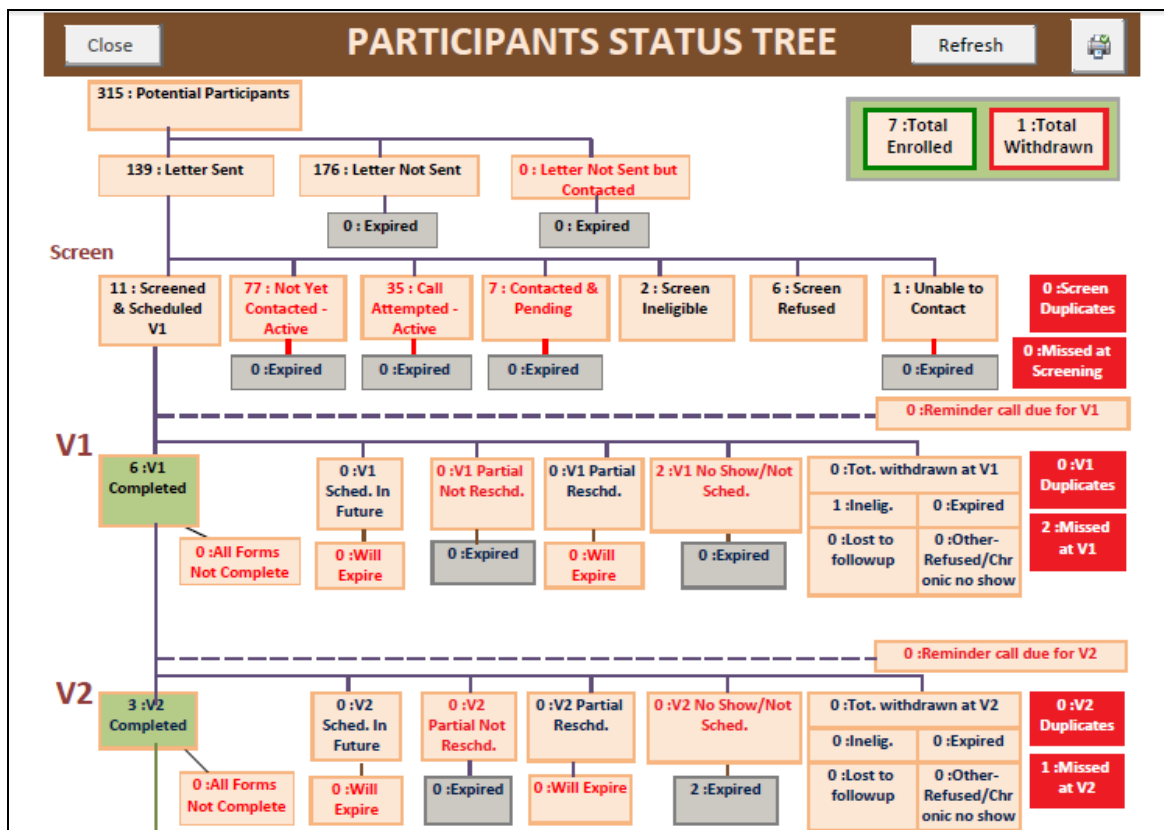


Figure 5.1 Participant Status Tree – Partial View

PHONE CONTACT LOG

The Tracking System provides the user with functions that allow for tracking of phone contacts with Participants and the result of each contact (i.e. refused, ineligible, scheduled etc.) .

VISIT TRACKING

Once a Participant becomes an Active Participant, the Tracking System provides the user with functions for managing Active Participant activities. This includes logging their visits, scheduling subsequent visits and providing reports to users to indicate when Active Participants should be called to remind them of scheduled visits.

5.3 Installing the Tracking System

In order to use the Tracking System, you must first prepare several file directories and associated files. The steps are as follows. If you have any problems with any of these install steps please contact AECOM/EISMU.

5.3.1 Create the SOLNAS User and Data directory

SOLNAS files are stored either in the SOLNAS “User” Directory or the SOLNAS “Data” Directory. If only one user will be running the SOLNAS system (or if several users are all using the same system and only one at time) then the SOLNAS “User” and “Data” Directory may be the same directory on your computer. However, if you wish multiple users from their own PCs to be able to use SOLNAS on a common group of Participants, then you must set up a local “User” Directory for each user, accessible to that user and a single “Data” Directory that is *available to all* users.

In order for SOLNAS to run correctly, you must also configure each “User” Directory to be a “Trusted Location” for the corresponding user’s MS-Access’s Trust Center. Please see the article [http://msdn.microsoft.com/en-us/library/bb421308\(v=office.12\).aspx](http://msdn.microsoft.com/en-us/library/bb421308(v=office.12).aspx) for information on using Access’ Trust Center. (Alternately you may Google “*using the access trust center*” for this and other links relevant to the Trust Center facilities.) (*This step should be performed by your system administrator if you are unfamiliar with using MS-Access directly.*)

5.3.2 Copy the System Files

Into the directories you created in the prior step, copy the following files that we will have provided you:

In to each “User” Directory you have created, you should place a copy of:

- SOLNAS_CD.accdb¹
- SOLNAS_ConfigInfo.accdb

In to the single “Data” Directory you have created, you should place the following files:

- SOLNAS_DT.accdb
- English Letter Template.doc
- Spanish Letter Template.doc
- SOLNAS INPUT DATA.xls
- SOLNAS CONTACT INFO.xls

5.3.3 Configure your SOLNAS_ConfigInfo file

This step should be performed for each instance of SOLNAS_ConfigInfo.accdb you created in the previous step. There should be one such instance for each SOLNAS “User” directory you created.

¹ In general, if we send you a software upgrade, it will be in the form of a new SOLNAS_CD.accdb file. You will need to load the new, upgraded copy of this file into each “User” Directory. Any additional steps you will need to take as part of any upgrade will be in the upgrade instructions distributed with the upgrade.

This step should be performed by your system administrator if you are unfamiliar with using MS-Access directly.

1. Open SOLNAS_ConfigInfo.accdb file in MS-Access
2. Open the table “tbl_ConfigInfo”
3. Update the following records in the table:

In the record where the ConfigValueName is	Set the corresponding ConfigValue to
CD_Path	the full path of this “User” directory
DT_Path	the full path of the common “Data” directory ²
Letters_Path	the full path of the common “Data” directory (this is the same directory as for DT_Path).

4. Close the SOLNAS_ConfigInfo database.

5.3.4 Password Protect your SOLNAS_DT and SOLNAS_ConfigInfo file

It is suggested that you password protect your SOLNAS_DT.accdb database using MS-Access encryption. Refer to the following link for instructions on how to perform this action: <http://office.microsoft.com/en-us/access-help/encrypt-a-database-by-using-a-database-password-HA010096299.aspx>. (You may Google “*encrypting access databases*” to obtain this and other related links.)

If you choose to password protect your SOLNAS_DT.accdb database, then you should also password protect each copy of your SOLNAS_ConfigInfo.accdb database as this file will contain the password of the SOLNAS_DT file. You may make the passwords for each of these files different.

5.3.5 Configure the Invitational Letters

The files “English Letter Template.doc” and “Spanish Letter Template.doc” that were placed in your SOLNAS “Data” directory in step 5.3.2 *Copy the System Files* are MS-Word Mail Merge documents. A one-time configuration process must be performed on each of these files so that they are correctly configured to obtain their Mail Merge data from SOLNAS_DT.accdb where it is located on your system (the SOLNAS “Data” directory). If you are unsure how to perform this step you may wish to consult <http://office.microsoft.com/en-us/publisher-help/change-the-data-source-for-a-mail-merge-or-a-catalog-merge-HP005114433.aspx>. (You may Google “*changing a mail merge data source*” to obtain this and other related links.)

5.3.6 First Time Startup of SOLNAS_CD

Every time you start SOLNAS_CD.accdb, you will be prompted for the password of the SOLNAS_CD.accdb file. Ask your system administrator of this application for this password.

The first time you start SOLNAS_CD.accdb, it will ask you for the password (if any) of your SOLNAS_ConfigInfo file and then for the location and then password (if any) of your SOLNAS_DT file. After the first start up, this information will be remembered by the system. *However*, if a new version of SOLNAS_CD.accdb is installed, then the first time the new version is started you will be prompted again for the password (if any) of the SOLNAS_ConfigInfo file. Note that these first time start up behaviors occur for each instance of SOLNAS_CD.accdb that you have installed.

² Note that if the common “Data” directory maps to a different path on different computers, you want to use the path as it is known from the computer where the particular instance of the SOLNAS_ConfigInfo.accdb resides.

5.3.7 Add the Coordinating Center Provided Information

The Coordinating Center will provide all clinics with a file of potentially eligible Participants for this study. They will do this in one of two ways. They will either allow users to run a report in DMS to download this list³ or they may email this file to you on a regular basis. In either case, you should copy the Participant information in this file into the “SOLNAS input data.xls” you installed into the SOLNAS “Data” directory in **Step 5.3.2.** above.

5.3.8 Create the Patient Contact File

Since the list from the Coordinating Center will not contain the identifying information of participants, you will need to create a file with this information (i.e. name, address, phone etc.). This file must be in Excel “97-2003” (.xls) format. The file’s name must be “SOLNAS Contact Info.xls”. The file’s contents must be organized as follows:

Column	Column Name	Column Description
A	ID	This is the Potential Participant’s (patient’s) identification which must match that in the “SOLNAS input data.xls” file provided by DMS.
B	First Name	Potential Participant’s first name
C	Last Name	Potential Participant’s last name
D	Street 1	First line of the Potential Participant’s mailing address
E	Street 2	Second line of the Potential Participant’s mailing address – this value may be blank
F	City	The city of the Potential Participant’s mailing address
G	State	The state of the Potential Participant’s mailing address
H	Zip	The zip code of the Potential Participant’s mailing address
I	Home Phone	A home phone number, including area code, for the Potential Participant
J	Work Phone	A work phone number, including area code, for the Potential Participant
K	Cell Phone1	A cell phone number, including area code, for the Potential Participant
L	Cell Phone2	A second cell phone number, including area code, for the Potential Participant
M	Other Phone	An additional phone number, including area code, at which the Potential Participant may be reached.

³ If the Coordinating Center creates this functionality in DMS, they will provide you with instructions of where and how to download this file.

Column	Column Name	Column Description
N	Email	An e-mail address for the Potential Participant. This value may be left blank.
O	Best Phone To try	This column's value should be set to "Work", "Home", "Cell 1", "Cell 2" or "Other".
P	Best Time To Phone	This column's value can be any information felt helpful in successfully contacting the Potential Participant

Table 5.1: SOLNAS Contact Info.xls Column Layout

5.4 NAVIGATING THE SOLNAS TRACKING SYSTEM

The user starts the SOLNAS Tracking System, by double-clicking the SOLNAS_cd.mdb file in the SOLNAS directory created during the installation of the system.

Once the system starts, it will prompt you for a password. Use the password provided to you by the SOLNAS Coordinating Center. Once the correct password is entered, the following screen, the SOLNAS Main Menu, will be presented:



Figure 5.2: SOLNAS Tracking System Main Menu Screen

5.4.1 Main Menu

The Main Menu has four buttons:

- **Participant Status Tree**
- **Update Contact Log & Appointment Schedule**
- **Update Visit Checklist**
- **Utilities**

The functionality of each button is discussed below.



Figure 5.6: Main Menu Tasks

5.4.2 Participant Status Tree

If you click the **Participant Status Tree** button on the Main Menu causes the system to display the Participant Status Tree screen. This screen (Figure 2) graphically depicts the flow of interactions with Participants and each Participant's current status in SOLNAS. The main focus of operations of the SOLNAS system is monitoring and tracking each Participant for this study and moving Participants through the study flow until study completion. This screen provides an interactive environment for monitoring Participant flow through each stage of the study and for recording all contacts that accomplish this.

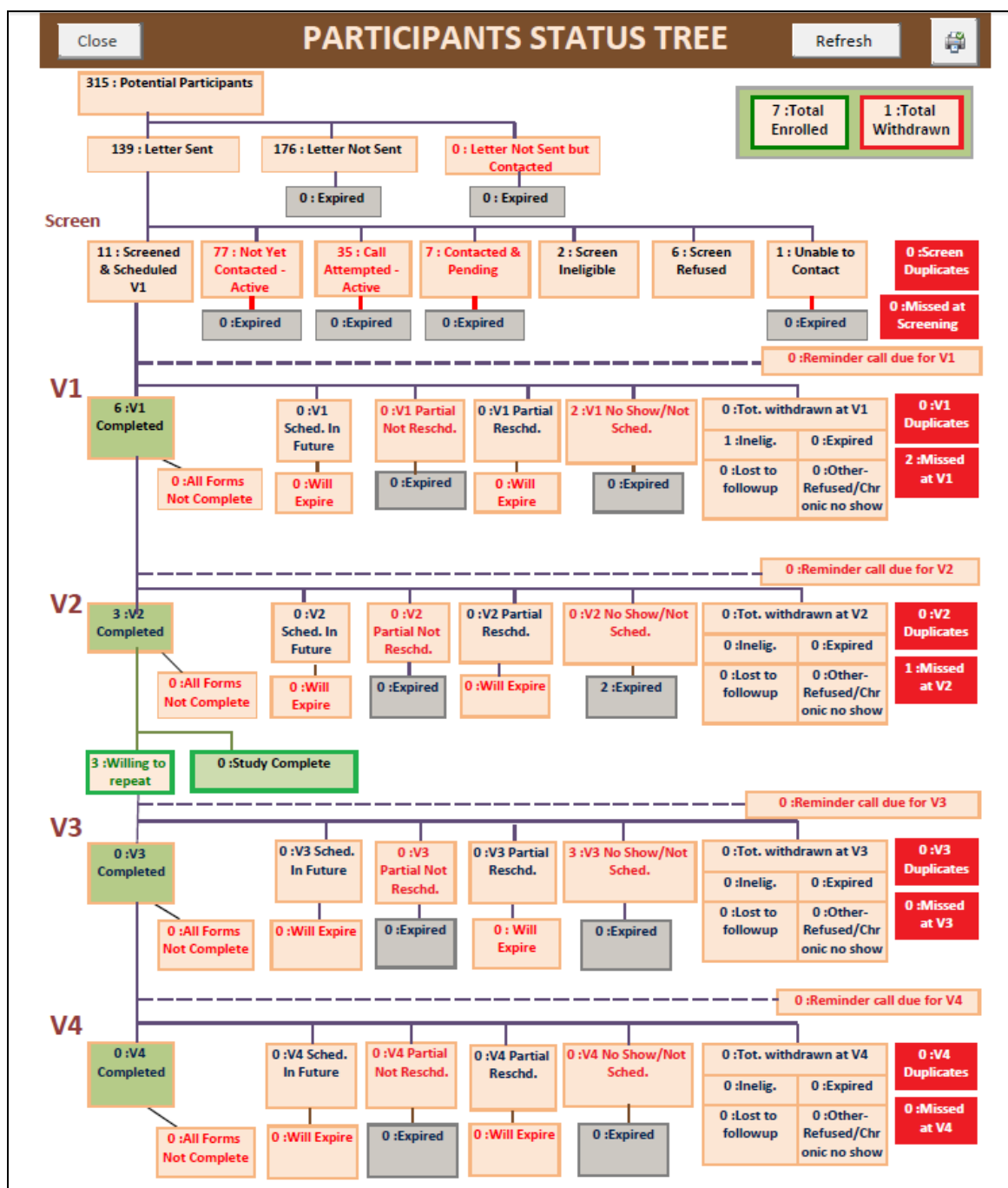


Figure 2: Participant Status Tree Screen – Full View

5.4.2.1 Participant Status Flow:

Each Participant has three types of Status:

- 1) Contact Status⁴,
- 2) Eligibility Status
- 3) Visit Status (a Participant has a Visit Status for each visit)

⁴ A Participant actually has a Contact Status for each entry in the Contact Log. The Contact Status of a Participant’s most recent Contact Log entry is considered the Participant’s current Contact Status.

As a Participant “flows” through the study, his/her various statuses change. The SOLNAS Tracking System will allow you to log all phone contacts with Participants and assign new statuses based on the most recent contact, thereby moving the Participant along in the study flow. The three types of Status that we track correspond to the three main tasks of this study. The following table lists these tasks, statuses and various allowed status values.

Task	Status type	Possible statuses	When/Where to update
Contact a potential Participant by phone	Contact Status	<ul style="list-style-type: none"> • Call attempted, left message • Call attempted, not available • Call attempted, wrong number • Contacted, pending • Refused • Unable to contact after repeated attempts • Ineligible • Scheduled 	After every phone contact with a Participant using the Contact Log
Enroll a Participant or deem ineligible	Eligibility Status	<ul style="list-style-type: none"> • Screened Eligible • Screened, Ineligible • Enrolled • Ineligible at Visit • Screen Refused • Withdrew: Participant Choice • Withdrew: Lost to follow-up • Withdrew: Chronic No Show • Withdrew: Past Expiry Date • Withdrew: Eligibility Criteria • Withdrew: Other Reason 	When a Participant’s eligibility changes using the Visit Checklist
Conduct a Visit	Visit Status	<ul style="list-style-type: none"> • Completed • Scheduled • No Show • Expired, incomplete • Chronic no show • Partial, rescheduled • Partial, not rescheduled 	After a scheduled visit using the Visit Checklist

Table 1: System Tasks and Associated Participant Statuses

As previously mentioned, each node in the Participant Status Tree lists the number of Participants that fall into that category (status). For example, in the Participant Status Tree image above (Figure 2), of the 139 Participants who received letters, only 77 Participants have not yet been contacted and are still active (potentially eligible) for the study.

5.4.2.2 Status Tree Secondary Screens

Clicking on any node in the Status Tree will cause the Tracking System to display an appropriate secondary screen listing all Participants who match the appropriate status(es). For

example, clicking on the NOT YET CONTACTED box will bring up the following secondary screen:

The screenshot shows a web-based form titled "NOT YET CONTACTED". At the top left is a "Close Form" button. The main area is divided into two columns of input fields. The left column contains: PPT_ID, FirstName, LastName, Eligibility (dropdown), BaselineDate, EndOfElig (with a value of 1), Gender (F), PrefLang (E), Age (45), HispanicBackground (Puerto-Rican), and Race. The right column contains: Street1, Street2, City, State, Zip, HomePhone, WorkPhone, CellPhone1, CellPhone2, OtherPhone, Email, and BestPhoneToTry. To the right of these fields is a "Contact Log /Schedule Appt." button and a "Notes:" text area. Below the form is a table listing participants with columns for PPT_ID, FirstName, LastName, Eligibility, BaselineDate, EndOfElig, Gender, and PrefLang.

PPT_ID	FirstName	LastName	Eligibility	BaselineDate	EndOfElig	Gender	PrefLang
001		8/1/2010	2/1/2011	F	E
002		8/1/2010	2/1/2011	F	S
003		8/1/2010	2/1/2011	F	S
004		8/1/2010	2/1/2011	F	E
005		8/1/2010	2/1/2011	F	S
006		8/1/2010	2/1/2011	F	S

Figure 3: Not Yet Contacted screen

The bottom of the screen has the complete listing of Participants in the selected category (Not Yet Contacted). Clicking on any name in the list at the bottom will bring up all information for that Participant to the top of the screen. The top part of the screen lists all of the specific information for the selected Participant (so that you do not need to scroll to the right to see all fields for this Participant).

If you wish to attempt to contact the Participant to schedule a first or subsequent visit, you click the **Contact Log/Schedule Appt.** button at the top right side of the screen to begin the contact attempt. After clicking the button, the following Contact Log screen appears:

Close Form
Contact Log
Visit Checklist

AREA 1: Lists all contact and Visit Summary information for selected Participant

AREA 2 : Enter the results of the phone contact here

AREA 3: If Participant gets scheduled, enter the Appointment information here

Close Form
Contact Log
Visit Checklist

PPT_ID: [text] Street1: [text] Email: none Eligibility: Screen Eligible

FirstName: C Street2: [text] HomePhone: [text] V1 Appt. Date: [text]

LastName: LO City: Bronx WorkPhone: [text] V1 Visit Status: Scheduled

Race: [text] State: NY CellPhone1: [text] V2 Appt. Date: [text]

Gender: F Zip: 10460 CellPhone2: [text] V2 Visit Status: [text]

ImportDate: [text] Willing to Repeat? [text] OtherPhone: [text] V3 Appt. Date: [text]

BaselineDate: [text] Initial Letter Date: 4/20/2011 BestPhoneToTry: [text] V3 VisitStatus: [text]

DaysLeft: [text] BestTimeToPhone: [text] V4 Appt. Date: [text]

View Clinic Schedule

Visit Type	Contact Date (MM/DD/YYYY)	Contact Time (HH:MM AM/PM)	Contact Duration	Contact Status	Contacting Staff
V1	5/5/2011	11:03 AM		Scheduled	

Records: 1 of 1

Schedule/Reschedule an appointment :					
VisitType	ApptDate (MM/DD/YYYY)	ApptTime (HH:MM AM/PM)	# Times Rescheduled	Reminder Call Done?	CalNotes
V1	5/5/2011	11:03 AM	1	NO	

Figure 4: Contact Log screen

The Participant’s contact information and visit summary information appears at the top of the screen (AREA 1). For EACH Phone Contact attempt (successful or not), fill out the Contact Log row (AREA 2) with the appropriate information:

<p><i>Visit Type</i></p>	<p>The Visit type for which you are attempting to schedule a visit. Choices are:</p> <ul style="list-style-type: none"> • Screening • Visit 1 • Visit 2 • Visit 3 • Visit 4 <p>Note that all initial contacts before the initial visit is scheduled should be coded as a SCREENING visit type.</p>
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<i>Contact Date and Time</i>	This will default to today's date and time. It can be modified if the contact happened at an earlier time.
<i>Contact Duration</i>	Please enter this in minutes
Contact Status	<p>This is the most crucial field in the Contact Log. It is the Contact Status that determines where in study tracking flow a Participant is moved next. Possible choices are:</p> <ul style="list-style-type: none"> • Call attempted, Left Message • Call attempted, Not available • Call attempted, Wrong Number • Contacted, Pending • Refused • Unable to contact after repeat attempts • Ineligible • Scheduled <p><u>Important Notes:</u></p> <p>If a Contact Status of <i>Refused</i> is entered when you have selected a <i>Visit Type</i> of SCREENING, the system will prompt you to confirm that you want to change the Participant's Eligibility Status to <i>Screen Ineligible</i> and will display a dialog box to inform you of this change.</p> <p>If a Contact Status of <i>Ineligible</i> is entered when you have selected a <i>Visit Type</i> of V1, V2, V3 or V4, the system will prompt you to confirm that you want to change the Participant's Eligibility Status to change to <i>Withdrawn: Eligibility Criteria</i>.</p> <p>If a Contact Status of <i>Scheduled</i> is entered when you have selected a <i>Visit Type</i> of Screening, the Visit Status of the Participant for Visit 1 will be set to SCHEDULED as well.</p>
<i>Contacting Staff</i>	Select your name here.

Table 2: Contact Log Field Descriptions

If, during the contact, you wish to schedule a visit, you may click on the **VIEW CLINIC SCHEDULE** button to see available time slots. After determining an appropriate appointment date and time, return to the Contact Log Screen and enter the information in AREA 3 of the screen. Be sure to indicate the correct **Visit Type** (V1, V2, V3 or V4) for the appointment you are scheduling.

To work on the next Participant, click **CLOSE** button at the top of the Contact Log screen and you will be back to the Secondary Screen from which you had opened the Contact Log with the list of Participants.

5.4.2.3 Status Tree Refresh Button

When you update information about Participants on one of the Secondary Screens (e.g. the Contact Log or Visit Checklist screens), this will usually change one or more of the Participants' statuses. When you initially return to the Participant Status Tree screen from a Secondary Screen, the Status Tree will not reflect these changes. In order to have the screen reflect the changes, you may click on the **Refresh** button in the upper right of the Participant Status Tree screen. Whenever you return to the Participant Status Tree, the system will display a dialog box to remind you that the display may not be up-to-date.

5.4.2.4 Participants Contacted without Invitational Letter

On the Participant Status Tree screen, in the first line of boxes, you will note a box indicating Participants for whom a "Letter Not Sent but Contacted." Participants in this "flow state" will not be properly tracked by the system if such Participants are left as is. In order to correct this situation, the user first clicks on the "Letter Not Sent but Contacted" box. The Tracking System will bring up a Secondary Screen for these Participants. For each Participant listed, the user should enter an Invitation Letter Date. The actual date to use is up to the User, but the initial contact date is suggested. By providing an Invitation Letter Date, the Tracking System will put the Participant back into the correct Participant flow state. (Note that the **Refresh** button on the Participant Status Tree screen needs to be clicked to see the changes on this screen.)

5.4.3 Update Contact Log & Appointment Schedule

As a rule, you will use the Participant Status Tree screen to identify Participants to contact and to document the contact. However, in the case where a Participant initiates a call to your center and you need to document the contact and /or reschedule the Participant's appointment(s), use **Update Contact Log & Appointment Schedule** button on the Main Menu to more directly access this Participant's Contact Log and Appointment information. When you click on the **Update Contact Log & Appointment Schedule** button, the system will prompt you to enter either the Participant's ID or name. Select the Participant by the method you prefer and click the **GO** button. The system will then display the Contact Log screen (see **Figure 4: Contact Log screen**, above) for the selected Participant.

5.4.4 Update Visit Checklist

The Visit Checklist form contains a full accounting of a Participant's status in the study and what happened to the Participant at each visit. It is on this screen that you can document what happened at a visit or if they change their eligibility status.

The Visit Checklist should be printed out and brought to each visit and used as a checklist to ensure that all scheduled tasks are performed at the visit. After the visit, the staff may use the **Update Visit Checklist** button on the Main Menu to retrieve and modify the Participant's visit information as recorded on the printed checklist. When you click on the **Update Visit Checklist** button, the system will prompt you to enter either the Participant's ID or name. Select the Participant by the method you prefer and click the **GO** button. The system will then display the Visit Checklist for this person (see Figure 6, below).

The sub-sections below further describe selected fields of the Visit Checklist screen.

Close Form

Visit Checklist

Contact Log/Schedule Appt.

Search For Participant By ID: Or Search For Participant By Name:

Participant's ID	Participant's Name	Participant's Eligibility	Baseline Date	Willing to Repeat?	Initial Letter Dt.	Confirmation Letter Dt.
<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>

V1

V1 Expiration Date:

V1 Appt. Date:

V1 Complete Date:

V1 Status:

Completed?

Informed Consent:

Weight:

Pre-DLW Spot Urine:

DLW dosing:

2 Post DLW urines:

Blood draw for ppts 60+ yrs old:

In-Person 24 hours Diet Call:

Body Image Sed. Beh. Q:

24 Hr Urine Instructions:

DLW QC?:

Schedule V2 Appointment

V2

V2 Appt. Date:

V2 Complete Date:

V2 Status:

Completed?

Collected 24 Hr Urine:

24 Hr Urine Date:

Weight:

Fasting Blood:

Fasting Blood Date:

Fasting Urine:

Fasting Urine Date:

One Spot Urine:

One Spot Urine Date:

Indirect Calorimetry:

Indirect Calorimetry Date:

Tufts FFQ (Bronx site only N=119):

DLW QC?:

Central Lab QC?:

Schedule V3 Appointment

V3

V3 Appt. Date:

V3 Complete Date:

V3 Status:

Completed?

Weight:

Pre-DLW Spot Urine:

DLW dosing:

2 Post DLW urines:

Blood draw for ppts 60+ yrs old:

In-Person 24 hours Diet Call:

Body Image assessment:

24 Hr Urine Instructions:

Physical Activity:

Actual Questions:

Schedule V4 Appointment

V4

V4 Appt. Date:

V4 Complete Date:

V4 Status:

Completed?

Collected 24 Hr Urine:

Weight:

Fasting Blood:

Fasting Urine:

Fasting Urine Date:

One Spot Urine:

One Spot Urine Date:

Indirect Calorimetry:

Indirect Calorimetry Date:

Tufts FFQ (Bronx site only N=119):

General Participant Info

Visit SPECIFIC Info

Notes:

Figure 6: Visit Checklist screen

5.4.4.1 Participant's Eligibility Status

If a Participant's Eligibility changes, it must be updated on the Visit Checklist screen. The possible Participant Eligibility Statuses are:

Eligibility Status	Meaning

Eligibility Status	Meaning
-none-	The eligibility of the Participant has not yet been determined. All Participants start with this status. Note that the status field is actually blank, it does not say ‘-none-’.
Screen Refused	The potential Participant was contacted refused to participate in the study.
Screened, Ineligible	The potential Participant was contacted and deemed ineligible for the study during the contact phone call.
Screened, Eligible	The potential Participant was deemed eligible for the study and has either scheduled a V1 appointment or is planning to schedule one.
Enrolled	The Participant has shown up for at least a partial V1 visit and has signed their informed consent ⁵ .
Withdrawn: Participant Choice	After enrolling in the study, the Participant subsequently declined to continue through the planned visits.
Withdrawn: Eligibility Criteria	After enrolling in the study, the Participant was subsequently deemed no longer eligible for continuation in the study. If their ineligibility was due to passing of an expiration date, then use “Withdraw: Past Expiry Date” for their Eligibility Status.
Withdrawn: Lost to Follow-up	After enrolling in the study, the Participant became impossible to contact in order to complete the necessary visits.
Withdrawn: Chronic No Show	After enrolling in the study, the Participant either chronically failed to reschedule or did not show up for scheduled appointments.
Withdrawn: Past Expiry Date	After enrolling in the study, the Participant was unable or choose not to show for appointments, such that their window of eligibility ended before they completed the necessary visits.
Withdrawn: Other Reason	After enrolling in the study, the Participant was discontinued before completing the study for a reason other than those given above.

⁵ The system expects the Participant to sign their Informed Consent at their first visit if they are to continue in the study.

Note that a Participant's Eligibility Status is for a Participant and not for any specific visit. For example, initially a Participant's Eligibility Status is deemed unknown (the Eligibility field is blank). After the phone screen, if the Participant is scheduled, the system will set the Participant's Eligibility Status to 'Screen Eligible' when you set the Contact Status to **Scheduled**.

When a person completes Visit 1 and signs their Letter of Informed Consent, the Participant Eligibility Status should be set to Enrolled. If he becomes ineligible at any subsequent point, the Eligibility Status should be changed to one of the "Withdrawn" statuses according to the study protocol.

5.4.4.2 Visit Status

As previously mentioned, each visit (V1, V2, V3 and V4) has its own Visit Status. If a Visit Status changes (as the result of a visit or phone contact) you must change the Visit Status on this screen. (If a Participant's Eligibility changes, you must update it on the Visit Checklist screen as well.) The possible Visit Statuses are:

Visit Status	Meaning
-none-	The Visit Status for this Visit has not yet been determined. All Visit Statuses start with this status. Note that the status field is actually blank, it does not say '-none-'.
Scheduled	The Participant is scheduled for this visit.
NoShow	The Participant was scheduled for a visit, but did not show, but may still be scheduled before their eligibility period expires.
Expired_Incomplete	The Participant's did not complete this visit before their eligibility period for this visit expired.
Partial_NotRescheduled	The Participant appeared and performed some of the activities for this Visit ⁶ . However, the Participant has not rescheduled to finish the remaining tasks of this Visit.
Partial_Rescheduled	The Participant appeared and performed some of the activities for this Visit and has rescheduled to finish the remaining tasks of this Visit.
Complete	The Participant has completed all tasks of this visit.

⁶ Note that for Visit V1, the Participant must complete their informed consent as part of the initial appearance for the Visit.

5.4.4.3 Utilities

The **Utilities** button provides access to the remaining functions of the SOLNAS system. See **Section 5.5 - Utility Menu** for details on these functions.

5.5 Utility Menu

From the **Utilities** button on the Main Menu screen (Figure 2) you can access the Utilities Menu (Figure 5). The Utilities Menu provides access to the remaining functions of SOLNAS. This section details those functions.

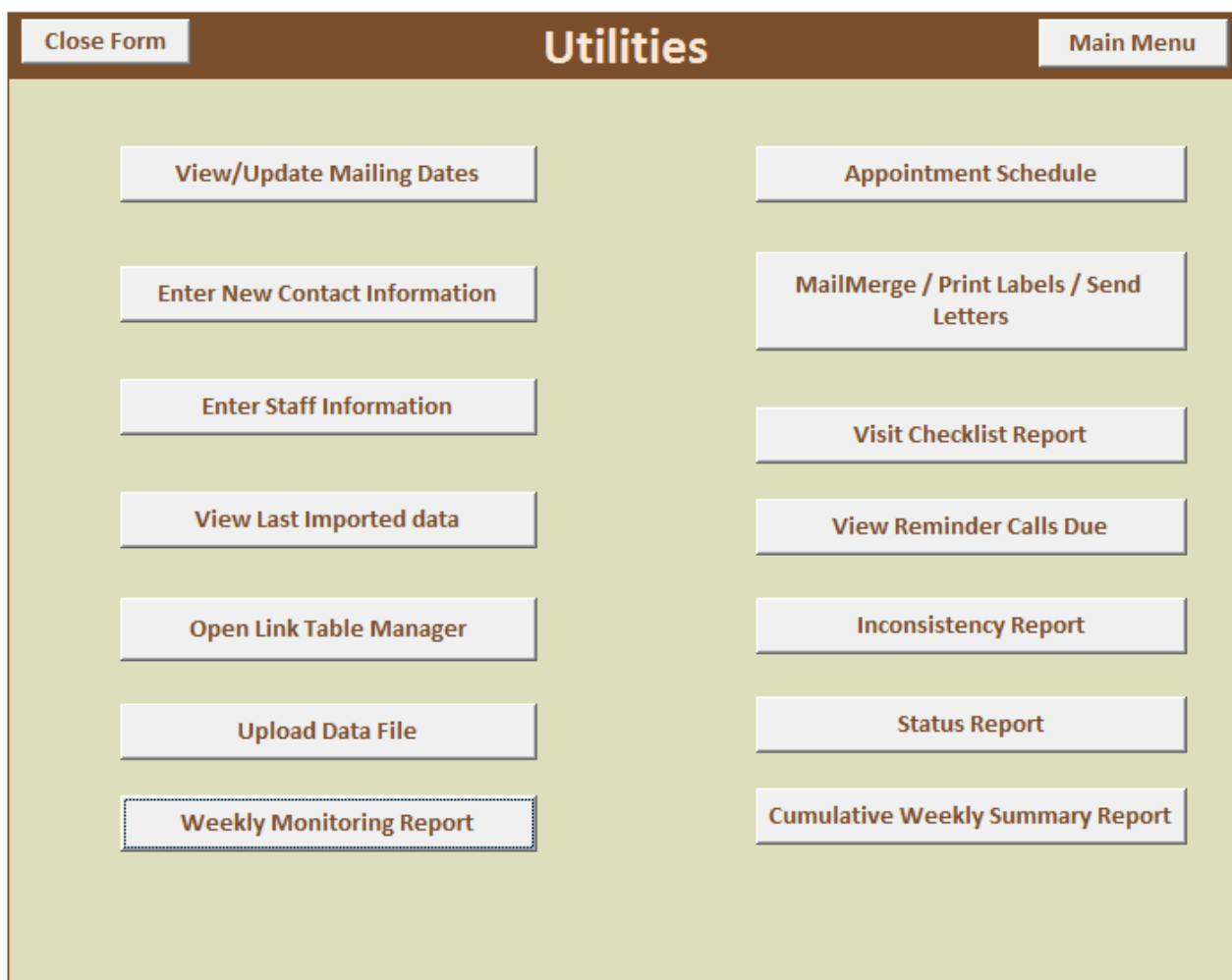


Figure 5: Utilities screen

5.5.1 View/Update Mailing Dates

If you click the **View/Update Mailing Dates** button the system will display the Mailing Dates screen (Figure 6). The Mailing Dates screen lists all Participants and the date their mailing was sent out. If the system believes that no mailing went out yet for a Participant then their mailing date will be blank. In the event that you send a Participant a mailing without using the system (or contact them without sending an Invitational Letter), you can enter that mailing date into the system using this screen so that the system can reflect that the Participant actually was

contacted. Additionally, if there is a need to reflect that a Participant did not get a mailing that was recorded for them, then you can delete the Participant’s mailing date to reflect this situation.

Close Form		View / Update Mailing Dates			
Participant's ID	First Name	Last Name	Initial Letter Date	Confirmation Letter Date	Notes
B5110001	KEVIN	██████			
B5110001	HEATHER	██████	7/7/2011	7/7/2011	
B5110001	CLARA	██████			
B5110001	CHRISTOPHER	██████	7/7/2011		
B5110001	SARAH	██████	7/7/2011		
B5110001	CHRISTOPHER	██████	7/7/2011		
B5110001	CHRISTOPHER	██████	7/7/2011		
B5110001	TIMOTHY	██████	7/7/2011		
B5110001	ANTHONY	██████	7/7/2011		
B5110001	FRANCISCO	██████	7/7/2011		

Figure 6: Mailing Dates screen

5.5.2 Enter New Contact Information

If you click the **Enter New Contact Information** button the system will display the New Contact Information – Participant Select screen (Figure 7). From this screen you select the Participant by Participant ID for whom you wish to update contact information and press the **Go** button.

Close Form

New Contact Information

Search For Participant By ID : ▼ Go

Figure 7: New Contact Information - Participant Select screen

You will then be shown the New Contact Information - New Information screen (Figure 8). In the top portion of the screen you may enter new or edit existing contact information in all but the grayed boxes. By pressing the Submit button, you will commit the new information to the SOLNAS database. Note that the changes you make to contact information within SOLNAS are only stored in SOLNAS. However, you may use the “Is this contact updated in parent study (SOL)?” dropdown to keep track as to whether any other system has been updated with this information. This dropdown can be left blank or set to YES or NO.

Close Form

New Contact Information

Search For Participant By ID:

Go

Participant's ID:

First Name:

Last Name:

Street1:

Street2:

City:

State:

Zip:

Notes:

Home Phone:

Work Phone:

Cell Phone1:

Cell Phone2:

Other Phone:

Email:

Best Phone To Try:

Best Time To Phone:

Is this contact updated In parent study (SOL)?

Submit

Updated Contact Information:

Updated In parent study?	Participant's ID	Street1	Street2	City	State	Zip	Home Phone	Work Phone
▶	E-123456	100 WEST 167TH ST		Bronx	NY	10475-0800	347-212-0070	

Figure 8: New Contact Information - New Information screen

5.5.3 Enter Staff Information

If you click the **Enter Staff Information** button the system will display the Staff Information screen (Figure 9). This screen allows you to enter all staff names from your Center so that they will appear automatically in drop down boxes that allow entry the staff member who did a task (e.g. made an entry in the Contact Log).

StaffID:	Staff Name
100	M. Ginsberg
101	M. Martello
102	E. Senior
103	Y. Rahmani

Figure 9: Staff Information screen

5.5.4 View Last Imported Data

If you click the **View Last Imported Data** button the system will display the Last Imported Data screen. This screen displays the information combined and added to the database in the **last Upload Data File** action. The displayed data is the result of the Upload (a.k.a. merge) of the “SOLNAS input data.xls” and “SOLNAS Contact Info.xls” files prior to the merged data’s inclusion in the main SOLNAS database. See section *Upload Data file* below, for more information about the merge and upload process.

5.5.5 Open Link Table Manager

If you click the **Open Link Table Manager** button, the system will open MS-Access’s Linked Table Manager. As a general rule, this function is not longer needed by end-users. If necessary, it can be used to change the expected location of the SOLNAS_DT and SOLNAS_ConfigInfo files for this copy of the SOLNAS_CD.accdb. **Improper use of the Linked Table Manager can seriously impair the proper behavior of SOLNAS. Do not use this function unless you are absolutely sure of its effects.**

5.5.6 Upload Data file

If you click the **Upload Data File** button the system will display the Upload Data File screen (Figure 10). From this screen you can perform a merge of the latest Coordinating Center-provided Participant information with your locally provided contact information for these participants. *Note: Be sure that both files are in the SOLNAS “Data” directory created during the installation in Step II, 5.3.1 Create the SOLNAS User and Data directory. Also insure that the “SOLNAS Contact Info.xls” file is in the required format (see Step 5.3.7 Add the Coordinating Center Provided Information*

The Coordinating Center will provide all clinics with a file of potentially eligible Participants for this study. They will do this in one of two ways. They will either allow users to run a report in DMS to download this list or they may email this file to you on a regular basis. In either case, you should copy the Participant information in this file into the “SOLNAS input data.xls” you installed into the SOLNAS “Data” directory in **Step 5.3.2.** above.

Create the Patient Contact File.

Close Form

Upload data file procedure

Step 1: Please place the file you have received from the Coordinating Center in the same directory as your SOLNAS_DT.accdb database is located. The file should be renamed to SOLNAS INPUT DATA.xls. You may use the link below to check that the file is correctly placed and named. The file displayed from this link is the one that will be used by the upload process.

[SOLNAS INPUT DATA.xls](#)

Step 2: Prepare the contact information in an Excel file named SOLNAS CONTACT INFO.xls for those participants in Step 1. The format of this file is detailed in the SOLNAS User Guide. This file also must be in the same directory as your SOLNAS_DT.accdb is located in. You may use the link below to check that the file is correctly placed and named. The file displayed from this link is the one that will be used by the upload process.

[SOLNAS CONTACT INFO.xls](#)

Note: Required "Import Date" is the date you retrieved new participants

Import Date:

Before you proceed to the Last Step, please close any open Access tables that you might have.

Last Step: Append New Participants

Figure 10: Upload Data File screen

Each month, when new Participant data is obtained from the Coordinating Center, you should copy and paste it into the "SOLNAS input data.xls" file in your SOLNAS "Data" directory. You should first remove the prior month's data from this file before pasting in the new data. **You should take care not to remove the first ("header") row of this file as it is expected to be there by the SOLNAS Upload procedure.** Then replace your "SOLNAS Contact Info.xls" file in the same directory with the most updated version of your contact information. Next, provide the Import Date. This should be the "as of" date for the data you received from the Coordinating Center. Finally click on the **Last Step: Append New Participants** button. This will update SOLNAS with new Participant information while retaining the information on Participants that you have already uploaded.

5.5.7 Updating the Mailing Date

After entering the Mailing Date, the user clicks the “**Step 1: Update Mailing Date**” button to confirm to the Tracking System that it should use the Mailing Date specified. Until this button is clicked, the user may change the Mailing Date value. After clicking this button, the Tracking System will respond with a dialog box indicating that the Mailing Date has been accepted.

5.5.8 Gathering Address Information

Next, the user clicks the “**Step 2: Gather addresses for mail merge**” button. This causes the Tracking System to collect and prepare the selected Potential Participants’ address information needed for the next two steps. The user will see a dialog box indicating that the step has completed and should click the “OK” button to move on to the next step.

5.5.9 Creating the English Language Letter

After the addresses have been gathered, the user presses the **Step 3: Open English letter** button⁷. The Tracking System will first present a warning window on which the user should press the **Yes** button to continue. Next, the Tracking System will present a MS-Word “Mail Merge” document of the English language Invitational Letters for all Potential Participants selected in the previous steps. (See note below about the letter templates.) It is beyond the scope of this User Guide to explain the “Mail Merge” document and its use in detail⁸.

However, in brief, use the following instructions (these instructions are for Word 2007, for earlier versions of Word, please consult the on-line help by pressing the F1 key while in Word):

- i. Once the template document opens, look for the “Mailings” menu at the top of the screen and select it.
- ii. On the far right, there will be a button “Finish & Merge”, click it and the individual letters will be generated.
- iii. Once the letters are generated, select “Print Documents” to print the letters.

In steps i and ii the user can further modify the Invitational Letters. Changes to the letter in step i will affect all of the letters, changes can be made in step ii to individual letters. Once the English language Invitational Letters have been printed, the user may close the “Mail Merge” document and move on to step 4.

5.5.10 Creating the Spanish Language Letter

If you click on the **Step 4: Open Spanish letter** button, the system starts the same series of actions as for “**Step 3**”, except the Spanish language Invitational Letters are generated in the “Mail Merge” document. You should follow essentially the same steps as you did for the production of the English language Invitational letters.

5.5.11 Creating the Mailing Labels

⁷ Before the first use of this feature, someone at your site must correctly configure the English and Spanish letters. See Section 5.3.5 - Configure the Invitational Letters (page 6) for more information.

⁸ Readers are referred to office.microsoft.com for more information about Mail Merge. The keywords “word mail merge training” can be put in the search box that will be displayed to see articles and training videos from Microsoft about this feature.

The final step in preparing the Invitational Letters is to produce the mailing labels for the envelopes into which the Invitation Letters will be placed. To do this, the you click the **Step 5: Print labels** button. The Tracking System will display a new MS-Word Print Preview screen with the address labels. The user should use Avery 5160 or 5260 Label stock paper in order to correctly print labels.

A note about the Letter Templates.

The English and Spanish language Invitational Letters are generated using the “English Letter Template.doc” and “Spanish Letter Template.doc” MS-Word Mail Merge Template documents, respectively. These documents are placed in the SOLNAS “Data” directory as part of the installation of the SOLNAS system (see section 5.3.5 - *Configure the Invitational Letters*). If you are familiar with Mail Merge Template documents you may edit these documents yourself to match your specific needs for the Invitational Letters. If you are uncomfortable with performing modification of these documents, you may contact the Einstein SMU team (see section *Contact Information*: and have us modify these documents to your requirements. We will then e-mail you the modified versions which you will then place in the SOLNAS “data” directory, overwriting the older versions of these documents.

5.5.12 View Reminder Calls Due

If you click the **View Reminder Calls Due** button the system will display the Reminder Call Date Range screen (Figure 11). This screen will prompt you for a date range. When the Start Date and End Date have been entered and the **Submit** button is pressed, the system will list all Participants who are due for a reminder phone call within that date range (Figure 12). Reminder phone calls are due 3 days before a scheduled visit. The list of Participants will be displayed in a format similar to that displayed on all previously discussed secondary screens with a list of the Participants at the bottom of the screen and more specific information for the selected Participant at the top of the screen.

Close Form		Reminder call due	
<div style="background-color: #4b4b4b; color: white; padding: 2px; margin-bottom: 5px;">Start Date</div> <input style="width: 100%; border: 1px solid #ccc;" type="text" value="2/9/2011"/>	TO	<div style="background-color: #4b4b4b; color: white; padding: 2px; margin-bottom: 5px;">End Date</div> <input style="width: 100%; border: 1px solid #ccc;" type="text" value="2/16/2011"/>	
<input style="border: 1px dashed #ccc; padding: 5px 15px;" type="button" value="Submit"/>			

Figure 11: Reminder Call Date Range screen

When you make a reminder phone call, do not forget to click on the **Contact Log/Schedule Appt.** button on the top right of the screen to document the contact in the Contact Log (and adjust appointments if necessary).

PPT_ID	FirstName	LastName	Eligibility	BaselineDat	EndOfElig	Gender	PrefLang
PPT_ID	SANCHEZ	SANCHEZ	Screen Eligible	8/2/2010	2/2/2011	M	S

Figure 12: Reminder Call screen

5.5.13 Inconsistency Report

If you click the **Inconsistency Report** button the system will display the Inconsistency Report screen (Figure 13). The SOLNAS Tracking System relies on consistent data entry in order to correctly determine a Participant’s status. All data in the Participant Status Tree assumes consistent data entry. For example, if a Participant is deemed **Ineligible** in the Contact Log and in the Visit Checklist the Participant’s eligibility status equals **Enrolled**, that would be considered inconsistent data and the system will not be able to determine where the Participant belongs in the Participant Status Tree. This report should be run regularly to ensure that all information in the system is accurate. In particular, if the Participant Status Tree boxes labeled “Missed at Vx” or “Vx Duplicates” have counts other than zero it indicates that there are Participants which have been determined to have inconsistent data. In such cases the Inconsistency Report should be run to determine and rectify the inconsistent information.

0 :V1 Duplicates

1 :Missed at V1

The Inconsistency Report is shown below (Figure 13). The Inconsistency Report is broken into two sections. The top half of the report lists all Participants for whom inconsistencies have been found. To help with the resolution of the inconsistencies, information about the Participant including Contact, Eligibility and Visit statuses and relevant dates are shown. At the bottom of the report in the section titled “Cause and Resolution” are the various reasons that one or more of the Participants were found to be inconsistent. This information should help you understand what needs to be done to resolve the inconsistencies.

Close Report		SOLNAS - Inconsistency Report							Print
Participant's ID	Name	Consent Signed at V1?	Invitation Letter Date	Eligibility	V1ApptDate	V2ApptDate	V3ApptDate	V4ApptDate	
			Last Contact Status		V1status	V2status	V3status	V4status	
B511007	CHINA	YES	1/1/2011	Screen Eligible	1/1/2011				
	CHINA		Scheduled		Partial_NotRescheduled				
B511008	CHINA		1/1/2011	Screen Eligible	1/1/2011				
	CHINA		Scheduled		Scheduled				
B511009	CHINA	YES	1/1/2011	Enrolled	1/1/2011	1/1/2011			
	CHINA		Scheduled		Completed	Scheduled			
B511010	CHINA		1/1/2011	Withdrawn: Eligibility Criteria	1/1/2011				
	CHINA		Ineligible		Scheduled				
B511011	CHINA		1/1/2011	Enrolled	1/1/2011	1/1/2011			
	CHINA		Scheduled		Partial_NotRescheduled				
E511012	CHINA	YES	1/1/2011	Enrolled	1/1/2011	1/1/2011			
	CHINA		Contacted_Pending		Completed	Scheduled			
B511013	CHINA	YES	1/1/2011	Screen Eligible	1/1/2011				
	CHINA		Scheduled		Scheduled				
B511014	CHINA	YES	1/1/2011	Enrolled	1/1/2011	1/1/2011			
	CHINA		Scheduled		Completed	Partial_Rescheduled			

Total : 8

Cause and resolution

Consent is not signed and eligibility is set to Enrolled or Withdrawn
 Visit1 status is Complete or Partial_rescheduled or Partial_Not reshcedled but eligibility is not Enrolled yet.
 V1 Visit status is Scheduled / Partial_Rescheduled but V1 Appointment date is in past or not yet set.
 V2 Visit status is Scheduled / Partial_Rescheduled but V2 Appointment date is in past or not yet set.
 V1 complete date is earlier than the V1 appointment date

Figure 13: Inconsistency Report screen

5.5.14 Status Report

If you click the **Status Report** button the system will display the Status Report screen (Figure 14). The Status Report screen displays various in aggregate information relevant to analyzing enrollment and visit completion rates for Participants in this study. This report can be printed, if desired.

SOLNAS STATUS REPORT			
	Potential Participants		Denominator
	N	%	
<u>Letter Sent</u>	298	54.88 %	Potential Participants
<u>Screened</u>	78	26.17 %	Letter Sent
<u>Refused V1</u>	21	26.92 %	Screened
<u>Scheduled V1</u>	47	60.26 %	Screened
<u>Enrolled</u>	31	65.96 %	Scheduled V1
<u>Withdrawn before Consent</u>	0	0 %	Screened
<u>Overall V1 Resched. Rate</u>	31		# of Appts. Scheduled for V1
<u>V1 Completed</u>	31	100 %	Enrolled
<u>In 1 to 3 Months</u>	0	0 %	V1 Completed
<u>In 4 to 7 Months</u>	31	100 %	V1 Completed
<u>After 7 + Months</u>	0	0 %	V1 Completed
<u>Withdrawn at V1</u>	0	0 %	Enrolled
<u>V2 Completed</u>	26	83.87 %	V1 Completed
<u>Urine done <=13 from V1</u>	27	103.85 %	V2 Completed
<u>Calom. done <=21 from V1</u>	25	96.15 %	V2 Completed
<u>Withdrawn at V2</u>	1	3.23 %	V1 Completed
<u>Willing to repeat</u>	26	100 %	V2 Completed
<u>V3 Completed</u>	0	0 %	Willing to repeat
<u><=213 days from V1</u>	0	0 %	V3 Completed
<u>>213 days from V1</u>	0	0 %	V3 Completed
<u>Withdrawn at V3</u>	0	0 %	Willing to repeat
<u>V4 Completed</u>	0	0 %	V3 Completed
<u>Urine done <=13 from V3</u>	0	0 %	V4 Completed
<u>Calom. done <=21 from V3</u>	0	0 %	V4 Completed
<u>Withdrawn at V4</u>	0	0 %	V3 Completed

		Enrolled N	% Goal
RACE	Race1 : Puerto-Rican (Goal=60)	13	21.67 %
	Race2 : Dominican (Goal=59)	17	28.81 %
	Race3 :		
GENDER	Male (Goal 54)	14	25.93 %
	Female (Goal 65)	16	24.62 %
AGE GROUP	18 to 44 (Goal 48)	8	16.67 %
	45+ (Goal 71)	22	30.99 %
BMI	<18.5 (Goal 1)	1	100 %
	18.5 to 25 (Goal 35)	2	5.71 %
	25 to < 30 (Goal 42)	15	34.88 %
	>=30 (Goal 41)	12	29.27 %
Sent for QC	DLW QC (Goal=6)	2	33.33 %
	Central Lab QC (Goal =12)	2	16.67 %

Figure 14: Status Report screen

5.5.15 Weekly Monitoring Report

If you click the **Weekly Monitoring Report** button the system will display the Weekly Monitoring Report screen (Figure 15). For this report, you are prompted for a Start and End Date. For the report to work as intended, the Start Date should be a Monday and the End Date should be the next following Sunday. After you enter these dates, click on the **Get Report** button and the system will generate and display the Weekly Monitoring Report results. The Weekly Monitoring Report screen displays information relevant to Study activity in the selected week (e.g. number of Participants seen, number scheduled for appointments, number of No Shows). If you click on the **Save this weekly data** button, the displayed information will be stored for future, further analysis along with the results from other weeks.

Cumulative Weekly Summary Report. This function should be performed as early as possible after the week in question has completed as further actions within the SOLNAS System may affect the results shown in this report. This report may also be printed.

Figure 15: Weekly Monitoring Report

5.5.16 Cumulative Weekly Summary Report

If you click the **Cumulative Weekly Summary Report** button the system will display the Cumulative Weekly Summary Report screen. This report is a listing of all Weekly Monitoring Report data that was stored by a user clicking the **Save this weekly data button** on the Weekly Monitoring Report screen (Figure 15).

5.6 Contact Information:

For specific questions pertaining to the SOLNAS system please contact:

Mindy Ginsberg
mindy.ginsberg@einstein.yu.edu
(718) 430-3559.

Jatin Solanki
Jatin.solanki@einstein.yu.edu
(718)430-2279

SECTION 6: SOLNAS VISITS

6.1 Overview of SOLNAS Visits

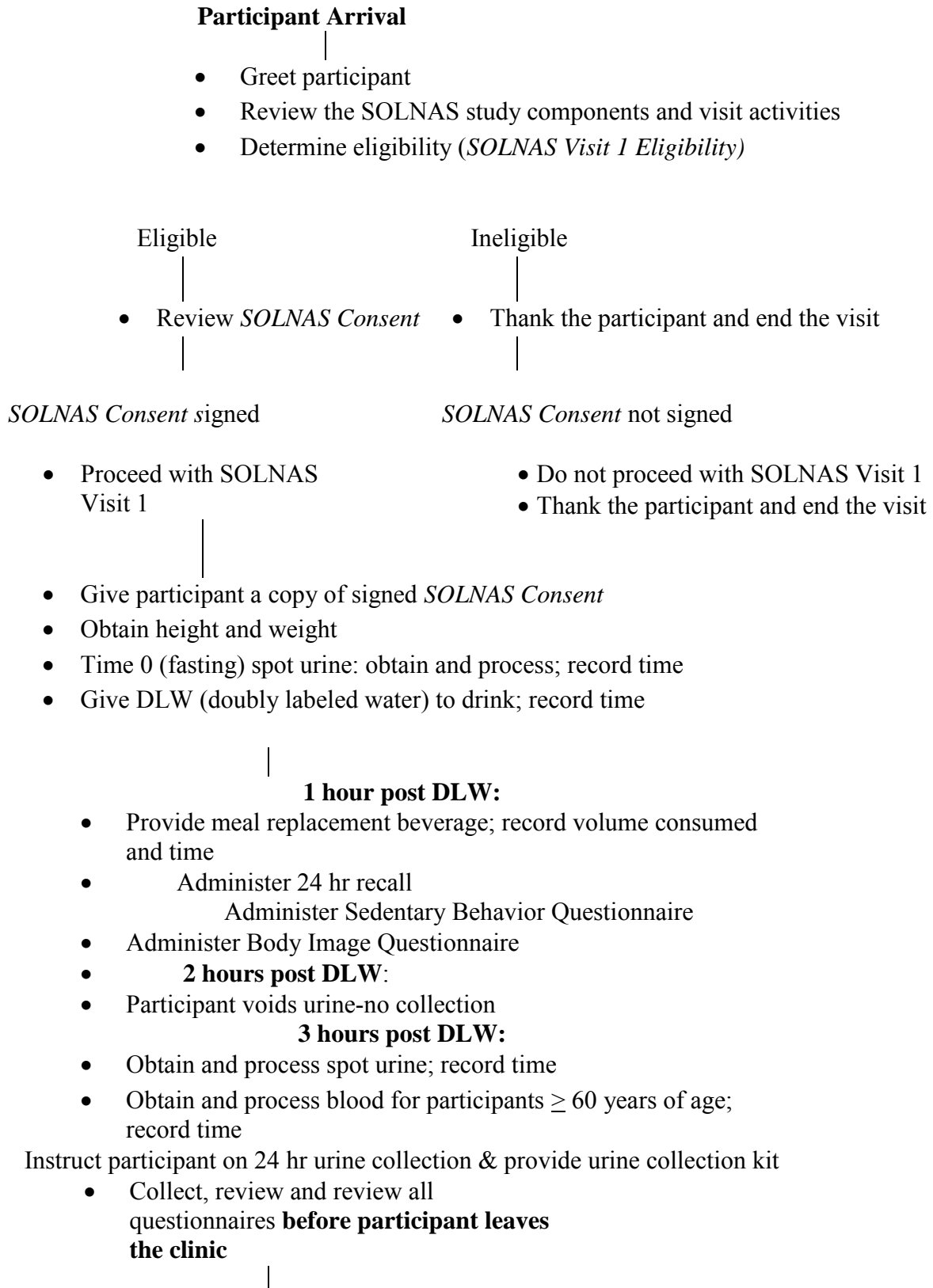
- Phase I (Primary Sample) includes two SOLNAS visits (SOLNAS Visit 1 and SOLNAS Visit 2). *Figure 6.2 –SOLNAS Visit 1 (Day 1)* and *Figure 6.3–SOLNAS Visit 2 (Day 13)* highlights the specific tasks for SOLNAS Visit 1 and SOLNAS Visit 2. *Sections SOLNAS Visit 1 (Day 1)* and *SOLNAS Visit 2 (Day 13)* describe the activities of the two primary visits in detail and follow the flow depicted in *Figure 6.2* and *Figure 6.3*.
- Phase II (Reliability Subsample) will include two additional visits (SOLNAS Visit 3 and SOLNAS Visit 4) for a subset of participants. Procedures for SOLNAS Visit 3 and SOLNAS Visit 4 will be similar to Visits 1 and 2, respectively. The purpose of the additional visits among the subset of participants is to obtain measures of reliability. Refer to *SOLNAS Manual for specific information about the Reliability Subsample, p. 81*.
- In general, all visits contain similar activities in terms of preparation for the visit, greeting the participant, performing various visit activities, reviewing forms, providing the participant with appropriate materials before he/she leaves, scheduling or confirming the next visit, and shipment of specimens to Central Lab. Because the visits contain many different activities and the participant will most likely be seen by several different FC staff, it is critical to designate an SOLNAS staff person (SOLNAS Lead-Ops) to oversee the SOLNAS visits (including pre- and post-visit activities).

6.2 SOLNAS Visit 1 (Day 1)

6.2.1 Overview of Activities

- *Figure 6.1 – Overview of SOLNAS Visit 1 (Day 1)* provides an overview of SOLNAS Visit 1.

Figure 6.1
Overview of SOLNAS Visit 1 (Day 1)



4 hours post DLW:

- Obtain and process spot urine; record time
- Provide participant with meal/snack
- Give participant the *Between Visits at a Glance* sheet
- Answer any questions about between visit tasks or indirect calorimetry to be completed at Visit 2.
- Schedule or confirm participant for SOLNAS Visit 2 twelve days later- (range is 11-13 days later.)
- Thank participant and escort him/ her to the exit.
- Complete blood and urine processing and storage; ensure correct labels are on each specimen; complete specimen storage box position spreadsheet.
- Collate all SOLNAS forms into participant's SOLNAS folder for use at SOLNAS Visit 2.
- Complete SOLNAS Status Update in HCHS-SOL to indicate completion of Visit 1.

6.2.2 Timing and Sequence of SOLNAS Visit 1 Tasks

- It is important to maintain the sequence of SOLNAS activities throughout the visit. This is important because:
 - The length of time a participant is in the clinic depends on when the SOLNAS activities begin.
 - The sooner the SOLNAS activities begin, the sooner the participant completes his/her clinic visit.
 - The sequence of the SOLNAS activities related to the doubly labeled water dosing and urine/blood collections is critical to the protocol and should not be changed.
- The SOLNAS protocol will take approximately 5 hours for participants to complete at Visit 1. Participants will be busy answering questions, but they may have some free time between tasks. Therefore, when scheduling participants, encourage them to bring something to keep busy (e.g., crossword puzzles, a book, knitting etc.)
- The sequence of the SOLNAS activities related to the doubly labeled water and specimen collection may not be changed. It is critical to keep track of the time for SOLNAS tasks. Consider using a stop watch or other reminder to document the first fasting urine sample, doubly labeled water dosing, and tasks scheduled at specific intervals thereafter (i.e., meal replacement beverage, spot urine collections, and blood draw for participants ≥ 60 years of age).
- It is also important to have a designated SOLNAS staff person oversee the pre and post SOLNAS visit activities. This includes ensuring that all forms administered by the SOLNAS protocol are collected and reviewed, before the participant leaves the clinic.

Figure 6.2 – SOLNAS Visit 1 Sequence of Tasks

* The sequence of the tasks in the starred columns may be modified to best meet your clinic's needs.

	Estimated Times	SOLNAS Visit Tasks
45 min	5 min	Reception
	5 min	Complete <i>SOLNAS Visit 1 Eligibility</i>
	20 min	Complete <i>SOLNAS Consent</i>
	5 min	Obtain- height and weight
	10 min	Time 0 - Fasting spot urine collection and processing
	~90 min	5 min
30 min		Sedentary Behavior & Body Image forms administered
5 min		Time 1 - Meal replacement beverage consumed: 1 hour after DLW
45 min		24 hr dietary recall and supplements questionnaire
5 min	5 min	Time 2- Void urine-2 hrs after DLW-do not collect
~ 40 min	5 min	Time 3 – Spot urine collection and processing: 3 hours after DLW
	5 min	Time 3 - Blood collection sample (non-fasting) - age 60 or older
	20 min	Provide instructions and kit for 24-hour urine collection. Give participant <i>Between Visits At A Glance</i> sheet.
	10 min	Time 4 – Spot urine collection and processing - 4 hours after DLW
~ 30 min	10 min	Review all questionnaires. Clarify missing information with participant.
	5 min	Confirm appt. for next visit. Provide complimentary meal and \$25.00 incentive (e.g., box lunch).

6.2.3 Pre-SOLNAS Visit 1 Activities

6.2.3.1 Supplies and Forms

- SOLNAS staff confirm that all supplies and forms needed for SOLNAS Visit 1 are available for the participant's visit.

Supplies:

- Folder (for participant handouts)
- SOLNAS label set (for forms and specimens)
- Urine collection hats (2)
- Bounty® paper towels
- Doubly labeled water (DLW)
- Digital toploading scale to weigh DLW
- *FAQ & Answers* Sheet
- Syringes, needles, & gloves
- Lavender (**dry EDTA**) blood collection tubes (for participants \geq 60 years of age) (1)
- Corning cryovials with rubber O-ring, 2 mL (3 with yellow caps for spot urine collections) (1 with a purple cap for plasma if participant is 60 years or older)
- Disposable transfer pipettes
- Ziplock bag with pre-weighed tissue
- Meal replacement beverage (e.g, Boost, Ensure Sustacal, 8 oz).
- 24-hour urine collection kit (*Instructions for 24-hour Urine Collection, Record Sheet for 24-hour Urine Collection*, urine collection hat, 2 [3-liter] containers, plastic funnel, large safety pin, and 2 gel ice packs in a plastic carrying bag)
 - The urine collection kit contains:
 - A highlighted copy of the *Instructions for 24-hour Urine Collection* where there is a reminder to “take one PABA (B-vitamin) tablet with each meal” on the day of the urine collection (use a Hi-Liter® marker to call attention to this text). **NOTE:** Participants who indicate an allergy or sensitivity to PABA will not receive PABA in their urine collection kits.
 - 3 sealed PABA (B-vitamin) tablets
 - 2 [3-liter] urine collection bottles in each of which you place 2.0 gram (**0.5 level measuring teaspoon**) boric acid * and on each of which you place four stickers, that read “Bottle #1” (or #2), “Leave powder preservative inside bottle”, “Remember...take the PABA (B-vitamin) tablets” and “Keep bottles refrigerated.” Each collection bottle should also be labeled with the participant's Study ID and/or use a lab label to identify the bottles. See *Instructions for the 24-hour Urine Collection*.

Be sure to have recorded the weight of each urine collection bottle per instructions on the *SOLNAS 24-Hour Urine Collection Worksheet for Staff* before giving the collection bottles to the participant.

* The boric acid may be weighed or measured using household measuring spoons labeled, “For boric acid use only.” When handling the boric acid, wear disposable gloves and preferably a disposable mask. Even though boric acid is a safe preservative, take precautions to avoid skin contact or inhalation.

- Complementary meal

Forms & Print Materials:

- *SOLNAS Informed Consent Document*
- *Between Visits At A Glance Sheet*
- *SOLNAS 24-Hour Urine Collection Work/sheet for Staff*

6.2.3.2 Pre-Visit 1 Reminder Call

- An SOLNAS staff person calls each participant one day prior to his/her SOLNAS Visit 1. If a participant is scheduled for Monday, the call may be made on the preceding Friday. During the call, complete the following:
 - Confirm the participant’s SOLNAS Visit 1 appointment.
 - Remind the participant to refrain from eating any food or drinking any calorie-containing beverages for **4 hours** prior to his/her clinic appointment time. This includes chewing gum, sugar in tea, etc.
 - Let participant know that during the 4-hour fast he/she should take all his/her regular medications (including diuretics) with water and he/she may drink decaffeinated black coffee or herbal tea (without milk, cream or sugar). **Regular (caffeinated) coffee or tea should be avoided.** Encourage the participant to drink water liberally during the fast; otherwise, he/she may become dehydrated which can be uncomfortable for the participant and result in difficulties collecting urine and blood samples.
 - Ask the participant to bring all his/ her dietary supplement bottles to the visit
 - Ask the participant to wear clothing which allows the sleeve to be easily raised above the elbow without constricting the blood flow to the forearm and hands, and allows for ease of multiple urine collections.
 - Optional: FCs may choose to use the Visit 1 Eligibility during the pre-Visit reminder call, **in addition to** its administration during Visit 1. This may help FCs to avoid having a participant travel unnecessarily to the visit if he/she is ineligible. Please note, however, that completion of the Visit 1 Eligibility during the pre-Visit 1 reminder call does not eliminate the need to complete this task in-person at Visit 1.

6.2.4 SOLNAS Visit 1 Activities

6.2.4.1 Reception

- When a participant first arrives at the FC for SOLNAS Visit 1, have participant check-in at the reception desk. The Receptionist should:
 - Locate the participant's file.
 - Indicate a comfortable place where the participant may wait until he/she can be seen.
 - Immediately notify the SOLNAS Lead-Ops (or designee) that the participant is waiting.

6.2.4.2 Eligibility

- Some of the SOLNAS eligibility questions asked during the telephone screening call are repeated at SOLNAS Visit 1 to ensure that the participant remains eligible. Begin the participant's visit by using the *SOLNAS Visit 1 Eligibility* to update a participant's continuing eligibility.
 - If a participant reports any change in the information previously provided on the *SOLNAS Telephone Screening Questionnaire/Script* that now make him/her ineligible (e.g., began taking insulin or medications for diabetes), mark him/her "Ineligible" on *SOLNAS Visit 1*. Thank the participant and inform him//her that he/she is not eligible to participate. Escort participant to the facility exit.
 - If a participant reports a change that would make him/her 'temporarily ineligible' (e.g., traveled more than 200 miles in past 2 weeks) for SOLNAS Visit 1 and he/she is not willing to reschedule SOLNAS Visit 1, mark him/her "Ineligible"– *SOLNAS Visit 1 Eligibility*. Thank the participant.
 - If a participant reports a change that would make him/her 'temporarily ineligible' (e.g., traveled more than 200 miles in past 2 weeks) for SOLNAS Visit 1, but he/she is willing to reschedule *SOLNAS Visit 1 Eligibility 1*, thank the participant, reschedule the SOLNAS Visit 1 for another day.
- If a participant remains eligible, mark "Eligible" on *SOLNAS Visit 1 Eligibility* and begin the *SOLNAS Consent* procedures.

6.2.4.3 SOLNAS Consent

- Mailing the *SOLNAS Consent* Before SOLNAS Visit 1. It is recommended that the *SOLNAS Consent* not be sent with the SOLNAS invitation letter. It could be overwhelming to the participant to read the *SOLNAS Consent* without having had the opportunity to discuss the SOLNAS protocol with staff. If a FC wants to send the *SOLNAS Consent* to interested participants, the FC could mail the consent to the participant after he/she has completed the SOLNAS phone screening contact and is scheduled for SOLNAS Visit 1.

- Reviewing the SOLNAS Consent. Provide the participant with a copy of the *SOLNAS Consent*. Review the consent with the participant after he/she has had ample time to read it. Ask whether he/she has any questions and answer questions thoroughly. The following key points must be covered with the participant:
 - Participation in SOLNAS is voluntary and does not affect his/her participation in the HCHS-SOL Study. He/she may withdraw from SOLNAS at any time.
 - Any information given will be kept completely confidential and will be released to no one except HCHS-SOL personnel and, if appropriate, authorized NHLBI staff.
 - Responses will be added to those of other participants and only grouped information will be released. Neither participant's name nor any other identifying information will be released in SOLNAS reports or publications.
 - A description of the SOLNAS procedures during Visit 1 and Visit 2 (e.g., height, weight, administration of DLW, spot urines, blood draws, and indirect calorimetry).
 - A description of each procedure and any risks associated.
 - The loading dose of doubly labeled water may cause temporary vertigo. This is rare at the small tracer dose used for this study. As a precaution, however, participants should sit down when drinking the loading dose and should remain seated for 15 minutes after drinking the loading dose.
 - The blood draw may cause discomfort and a bruise at the site of the needle puncture. All efforts will be made to minimize this risk.
 - People with known allergies to PABA may get a slight rash if they take the PABA vitamin. Participants who know they are allergic to PABA will not be asked to take it.
 - The participant may find it inconvenient to collect urine for a 24-hour period.
 - The participant will receive \$25.00 after the first visit and \$75.00 after the second visit for time and additional travel expenses. Participants who do not return for the second visit procedures will not receive the remainder of the incentive or \$75.00.
 - The potential of repeating the entire study about six months later to help us learn about the reliability of the measurements.
- Each FC must also follow the requirements imposed by their own Institutional Review Board (IRB) in carrying out the informed consent procedures.
- Signing the SOLNAS Consent:
 - Once the participant's questions have been answered, ask him/her to sign and date two copies of the *SOLNAS Consent* in the appropriate places. Sign two copies of the form yourself, as a SOLNAS representative, and date the form. Give one copy of the *SOLNAS Consent* to the participant and file the other copy in his/her file. Record on *SOLNAS Visit 1 and Visit 3 (VSE)* that the participant has signed the *SOLNAS Consent*.

- If a participant declines to sign the *SOLNAS Consent*, do not continue further SOLNAS activities. Record on *SOLNAS Visit 1 and Visit 3 (VSE)* that the participant did not sign the *SOLNAS Consent*. Thank the participant and end the SOLNAS visit.
- Provide a folder: Provide each participant with a folder to hold the SOLNAS study materials provided at SOLNAS Visit 1 (i.e., copy of *SOLNAS Consent*, *Between Visits At A Glance*, and *Instructions for 24-hour Urine Collection*).

6.2.4.4 Provide Study at a Glance Handout

- Give participants, who consent to participate in SOLNAS, a copy of *Between Visits At A Glance* (copy available in *SOLNAS website*).

6.2.4.5 Physical Measurements (height and weight)

- Collect the height and weight on the day of the SOLNAS Visit 1. Use a measured height and weight (not an estimate). If possible, a stadiometer should be used to measure participant height. If a stadiometer is not available, then the preferred method would be to measure height from a stationary tape measure that is affixed to the wall. A measured height and weight are critical to correctly estimate total energy expenditure from the doubly labeled water and for the statistical modeling planned for the SOLNAS study.
- Height and weight are recorded in centimeters and kilograms, respectively, on *SOLNAS Visit 1 and Visit 3 (VSE) form*.
- To avoid any measurement errors, particularly in administering the DLW, collect the participant's height and weight twice. Ask participants how much they normally weight in pounds and multiply this number by 2.2 for an estimate in kilograms.

6.2.4.6 Spot Urine Collection – SOLNAS Visit 1

6.2.4.6.1 General Information

- There are three spot urine samples collected at SOLNAS Visit 1: a fasting sample (before the doubly labeled water [DLW] is administered) and two samples post DLW administration at approximately 3, and 4 hours.
- Refer to *SOLNAS Manual, Section 8.3.2.2.2—DLW Spot Urine Collection Steps* for information about the collection and processing of the spot urine samples at SOLNAS Visit 1.
- **Thoroughly Rinse and Dry Collection Devices**
The spot urine collections will be done using a urine collection hat (the hat is placed on the toilet, under the toilet seat). Each participant will have one urine collection hat for all his/her spot urine collections at SOLNAS Visit 1. However,

if more than one SOLNAS participant is in the FC in a single day, do not share urine collection hats (mark each hat with the participant's initials for identification purposes). The urine hat will need to be rinsed and thoroughly dried with a Bounty® paper towel between each spot urine. It is critical that the collection device be DRY before each urine collection because any water that contaminates the urine either during collection or processing will dilute the isotopic concentration of the DLW tracers. After each collection, the urine collection hat should be rinsed thoroughly and dried according to the following procedures:

1. While wearing protective gloves, use a clean Bounty® paper towel to thoroughly dry the collection hat. Dispose of the used towel by placing it in a biohazard container.
2. Obtain a second, clean Bounty® paper towel. Dry the collection hat a second time to remove additional droplets that may remain. Dispose of the second used towel by placing it in a biohazard container.
3. Obtain a third, clean Bounty® paper towel. Dry the collection hat a third time to remove additional droplets that may remain. Dispose of the third used towel by placing it in a biohazard container.

- **Prevent Evaporation**

Do not leave the urine open to the air so that it can either evaporate or exchange with the moisture of the air. A minute or two is okay, but do not leave the urine sitting around for 15 minutes without being capped. Ideally, have the participant's SOLNAS specimen label on the cryovial; transfer the urine to the 2 mL cryovial, cap and store within 10 minutes.

6.2.4.6.2 Time 0 (Fasting) Urine Collection

- The Time 0 (fasting) spot urine needs to be collected, as soon as possible, after the participant's height and weight measurements have been taken. The fasting urine should not have to be the participant's first urine of the day BUT the urine must be collected BEFORE the participant drinks the DLW because the tracer gets in the urine very quickly (within 30 seconds). If it is the first urine of the day, please ask participant to void before starting informed consent form. When the sample is collected, record staff ID (staff collecting urine) and time of collection on *SOLNAS Visit 1*.
- Use the procedures described in the *SOLNAS Manual Section 8.3.2.2.1— Timing of the Spot Urine Collections* and 8.3.2.2.2 DLW Spot Urine Collection Steps for information about the collection and processing of the spot urine samples at SOLNAS Visit 1.

6.2.4.7 Administration of Doubly Labeled Water (DLW) – Fasting

6.2.4.7.1 DLW Doses

The pre-mixed DLW doses will be shipped to the study sites directly from the Central DLW Laboratory at Baylor College of Medicine.

6.2.4.7.2 Ordering and Storage of DLW

When ordering an additional supply of DLW, FCs should place orders preferably two weeks (one week at a minimum) in advance of the date that the DLW is needed. For DLW mixture, please contact Lucinda Clarke at lucindac@bcm.edu with copy to William Wong at wwong@bcm.edu, William Liu at chunl@bcm.edu, Lejuana Himes at lhimes@bcm.edu and Maria Martello at maria.martello@einstein.yu.edu. In case of emergency, please call Lucinda Clarke at 713-798-7122 or William Wong at 713-798-7168. Although the DLW mixture can be shipped out quickly via Federal Express for overnight delivery, it is recommended that the site staff to give notice at least one week in advance. Also to allow for sufficient time to track the shipment, the DLW mixture is shipped early in the week such as Monday and Tuesday. Try to avoid submitting request immediately before or after a major holiday such as Thanksgiving, Christmas and New Year.

Once at the site, the DLW bottles should be refrigerated. The plastic bottles tend to give the water a bit of a ‘plastic’ taste, but chilling the water tends to make it a little more palatable.

DLW Administration

- Contact Central DLW Laboratory if the FC is running low on the DLW tracers. Please alert Lucinda Clarke at Baylor College of Medicine when you are down to two bottles of the DLW tracers. For DLW mixture, please contact Lucinda Clarke at lucindac@bcm.edu with copy to William Wong at wwong@bcm.edu, William Liu at chunl@bcm.edu, and Lejuana Himes at lhimes@bcm.edu –see instructions in next section below.
- Ordering and Storage of DLW. Usually 5-10 one Liter bottles of DLW mixture are sent to each site to get started. Ten bottles of DLW will take up half a shelf in a “regular” size refrigerator. The refrigerator can be set between 35 and 41 degrees Fahrenheit or between 2 and 4 degrees Celsius.
 - Record HCHS-SOL staff ID (staff administering DLW), the dose weight of the bottle and the lot number of the bottle on *SOLNAS Visit 1 and Visit 3* form (VSE). It is critical to get the correct information recorded on the form.

6.3 Conducting a DLW Study

6.3.1 DLW Dose Preparation

The local Lead Op or Study Coordinator notifies the DLW tech of a scheduled DLW study. Then, the DLW tech performs the following procedures.

- Prior to the arrival of the study subject, pulls out a bottle of DLW dose mixture from the dose refrigerator.
- Records the DLW lot number and bottle number on the DLW dose mixture bottle on the *SOLNAS Visit 1 and Visit 3* form (VSE)
- Obtains the participant’s weight as measured on the official clinic scale.

- Based on the participant's official clinic weight, calculate the weight of DLW needed by multiplying the body weight of the study subject in kilograms by 1.4 grams / kilogram body weight, i.e.,

$$\text{Amt DLW needed (gm)} = 1.4 \times \text{subject weight (kg)}.$$

- **Don't guess or perform mental arithmetic! Use a calculator to perform the multiplication. Confirm the DLW weight by re-performing the multiplication on the calculator.**
- Record the amount on the *SOLNAS Visit 1 and Visit 3* form (VSE).
- Put a wide-mouth, clean drinking container on a digital scale with accuracy up to at least two decimal places. Record the weight of the drinking container with cap and tare the scale to zero.
- While the cap of the bottle containing the DLW dose mixture is still closed, whirl the DLW mixture in the bottle several times to make sure the mixture is uniformly mixed.
- Carefully, pour an approximate amount of DLW dose mixture needed into the drinking container. **Be careful not to spill the dose mixture on the side of the drinking container or onto the digital scale or weighing pan.**
- **It is best to pour a little more (but no greater than 5 gm more) of the DLW mixture into the drinking container. Do not use less than the calculated amount.**
- **If an accident occurs and more than 10 grams of DLW mixture is poured, proceed to administer the dose to the participant and contact EINSTEIN—CC. It is important, however, to be extremely careful to minimize overdosing.**
- **If spillage occurs, dry out the spillage completely especially if the spillage occurs on the digital scale.**
 - Use a new drinking container to weigh out the dose mixture for the study subject. **Repeat the steps outlined above.**
 - Add the DLW dose mixture that is already poured into the first drinking container to the new drinking container.
 - **However, do not return any DLW dose mixture that is already poured out back into the DLW dose mixture bottle.**
 - **Save the leftover DLW mixture in a separate bottle and label it "LEFTOVER DLW MIXTURE".**
- Cap and return the DLW dose mixture bottle to the dose refrigerator.
- Record the exact weight of the DLW mixture to the nearest 0.01 gm on the *SOLNAS Visit 1 and Visit 3* form (VSE). Note that If the container and the cap have already been tared to zero above, this weight will represent the weight of the DLW dose mixture in the container.

6.3.2 DLW Dose Administration

To administer the DLW dose, the DLW tech performs the following procedures.

- **First, make sure you have collected the one pre-dose urine sample from the study subject.**
- Pre-weigh a tissue and put it in a Zip-lock bag. Record the weight of the tissue on the *SOLNAS Visit 1 and Visit 3* form (VSE).
- Then, ask the subject to drink the DLW water. **It is critical that the entire solution is consumed without any loss.**

- **Encourage participants to drink the DLW right away (i.e. within a few minutes, and not over the course of ½ hour.)**
- If there is a small spillage, use the pre-weighed tissue to pick up the spill. Re-weigh the tissue and record the weight on the *SOLNAS Visit 1 and Visit 3* form (VSE).
- Record the date and time of dose administration on *SOLNAS Visit 1 and Visit 3* form (VSE).
- Rinse the DLW drinking container with about 20 ml of drinking water. It is best to keep the drinking water in a plastic squeeze bottle in order to control the rinsing
- Add the drinking water to the container, replace and tighten the lid or cap, and shake the water inside to make sure that any DLW that adheres to the wall of the container or the bottom of the lid or cap is captured by the rinse water.
- Ask the subject to drink the entire amount of the rinse water. Use a straw without flexible tip.
- Repeat the rinsing procedure one more time.
 - Record the time the participant begins drinking the DLW dose on *SOLNAS Visit 1 form*.
 - Ask the participant to remain seated for about 15 minutes after drinking the DLW to minimize the small chance of dizziness that may occur upon drinking the loading dose.

6.3.2.1 Provide Meal Replacement Beverage (MRB)

One hour after administration of the doubly labeled water (DLW), provide the participant with an 8-ounce (240 mL) meal replacement beverage (e.g., Boost, Ensure, Sustacal etc.). Record “Yes” on *visit one form – MRB Consumed* and then record the amount (mL) and time the participant begins drinking the MRB. Encourage the participant to drink the beverage in a timely manner, rather than sipping.

If a participant refuses to drink the MRB and is hungry, you may give him/her 8 ounces of apple juice to drink. Record “Yes” on *visit one form – MRB Consumed* and then record the amount (mL) and time the participant begins drinking the MRB. Try to avoid orange juice since the acidity of the juice slows gastric emptying.

6.3.2.1.1 Handling Collection Problems

- **Participant Produces No Urine**

If a participant is unable to produce urine for the 3rd or 4th spot urine collection, give him/her a little something to drink (i.e., ½ cup of water) and then have him/her try again in about half an hour. Record the amount and time of fluid intake on *SOLNAS Visit 1, (Other Beverages Consumed)*.

 - After a half-hour, if a participant is still unable to provide a spot urine sample, run warm water over the inner part of the participant’s wrists. If still unable to provide a spot urine sample, leave the appropriate urine collection question blank and indicate in the “Notes” section at the end of *-SOLNAS Visit 1* that the participant was unable to provide a Time X urine specimen. Follow the procedures outlined in the *SOLNAS Manual Section 8.6.7.1—Using the “Notes”*

Box' on the SOLNAS Forms and notify Maria Martello Study Coordinator (718-430-3189 – 347-491-8704) or Yasmin Mossavar-Rahmani, Ph.D. (718-430-2136) at EINSTEIN-CC.

- **Participant Produces Very Little Urine**

If a participant produces very little urine for the 3rd or 4th spot urine collection (less than 10 mL of urine), toss out the urine collection, give him/her a little something to drink and have him/her try again in about a half-hour. Record the amount and time of fluid intake on *SOLNAS Visit 1, (Other Beverages Consumed)*. If still unable to produce a urine sample, run warm water over the inner part of the participant's wrists. Note: Do not combine urine collections together to create a larger volume (i.e. combining first attempt with second attempt).

6.3.2.2 Three Hour Urine Collection

- Three hours post DLW dose, have the participant provide a third spot urine sample. Use the procedures described in the *SOLNAS Manual, Section 8.3.2.2.1—Timing of the Spot Urine Collections* and 8.3.2.2.2 DLW Spot Urine Collection Steps for information about the collection and processing of the spot urine samples at SOLNAS Visit 1.
- Record SOLNAS staff ID (staff collecting the urine) and time of collection on *SOLNAS Visit 1 and Visit 3 (VSE)*.
- If a participant has problems with the void, follow the procedures for handling collection problems, described in the *SOLNAS Manual, Section 6.3.2.1.1—Handling Collection Problems*.

6.3.2.3 Three Hour Blood Draw (for participants \geq 60)

- For participants 60 years of age and older, there is often an increase in the prevalence of post-void residual volume in the bladder. This means that the bladder does not totally empty out and this indirectly creates a problem in calculating energy expenditure. To help resolve this problem, a blood sample is used to check against the urine volume to detect if there was post-void residual volume.
- Three hours post DLW dose, draw a blood sample from participants who are 60 years of age or older. The 3-hour blood draw must occur just after the 3-hour spot urine collection. If the 3-hour spot urine is slightly delayed, the 3-hour blood draw should also be delayed to immediately after that urine collection. Record the blood draw on *SOLNAS Visit 1 and Visit 3 (VSE)*. Use standard HCHS-SOL blood handling and processing procedures described in the *SOLNAS Manual, –Time 3 Blood Draw (3 hours after DLW ingestion, for participants 60 years of age or older) Section 8.3.2.2.6, Time 3 Blood Draw (3 hours after DLW ingestion, for participants 60 years of age or older)*.

- If a participant has problems with the blood draw, follow the procedures for blood collection problems, described in the *SOLNAS Manual, Section 8.5.4, p. 122 Blood Collection Problems*.

6.3.2.4 Four Hour Urine Collection

- Four hours post DLW dose, have the participant provide a fourth spot urine sample. Use the procedures described in the *SOLNAS Manual, Section 8.3.2.2.2 DLW Spot Urine Collection Steps* for information about the collection and processing of the spot urine samples at SOLNAS Visit 1.
- Record HCHS-SOL staff ID (staff collecting the urine) and time of collection on the *SOLNAS Visit 1 and Visit 3 (VSE)* form.
- If a participant has problems with the void, follow the procedures for handling collection problems, described in the *SOLNAS Manual, 6.3.2.1.1 Handling Collection Problems*.

6.3.2.5 Other Beverages between hours two and four after DLW administration:

- It is important to record all the fluids that a participant drinks. Participants should not have free access to fluids – intake needs to be controlled. Record all fluid intake between the time of the DLW dose and the last spot urine sample at SOLNAS Visit 1. Strongly encourage participants to drink fluids in a timely manner, rather than sipping.
- Participants should preferably have no more than 250 mL of fluids in addition to the 250 mL in the meal replacement beverage (MRB) for a total of 500 mL. But, it is important to get the urine specimens, so if a participant needs to go slightly above this 500 mL total to get the 3 or 4 - hour spot urine (e.g., the participant is dried out), staff may go ahead and provide a small amount of fluid. However, one liter is the upper limit; do not go above the one liter limit.
- **Participant may have either caloric or non-caloric beverages, such as coffee, tea, or juice between two and four hours after DLW administration. These beverages do not interfere with the collection of the post-DLW protocol. However it is important that the participant not drink any calorie-containing or caffeinated beverages prior to the two hours post –DLW period other than the meal replacement beverage one hour after administration of the DLW.**
- When measuring the amount of other beverages, it is not necessary to measure the beverage in a graduated cylinder. A measurement within 10-20 mL of actual volume is close enough. Record the amount and time of beverage consumption on the *SOLNAS Visit 1 and Visit 3 (VSE)* form. (*Other Beverages Consumed*)

- If a participant does not drink any other beverages between hours 2-4 after the DLW, record '0' for (*Beverage 1 Amount*) and (*Beverage 1 Time*) on- SOLNAS Visit 1.

6.3.2.6 Explain and Provide Materials for 24-hour Urine Collection

- Near the end of SOLNAS Visit 1, explain to the participant that he/she will need to collect all of his/her urine for 24 hours. He/she will begin his/her 24-hour urine collection on the day before SOLNAS Visit 2 (Day 11) and bring it back to his/her SOLNAS Visit 2 appointment (Day 13). The 24-hour urine collection will be used to determine urinary nitrogen (a marker of protein intake).
- The 24-hour urine collection is preferably scheduled to coincide with the collection being completed for SOLNAS Visit 2 on Day 13. However, for participant convenience, SOLNAS Visit 2 may be scheduled between Day 11 and Day 13.
- Review the information provided on the *Instructions for 24-hour Urine Collection* with the participant. Provide clarification as needed.
- To ensure a balanced concentration of boric acid in each urine collection (which may affect laboratory procedures), FC staff are asked to instruct participants on filling each collection bottle as follows:
 1. Transfer all collections from the hat to Bottle #1, until the contents measures approximately 2000 mL. **Note: FC staff should darken the 2000 mL graduation on each bottle with a Sharpie® pen, so as to assist participants in this process.**
 2. Bottle #2 should be used only if Bottle #1 has been filled with 2000 mL of urine.
 3. If Bottle #2 becomes filled to the 2000 mL line (marked fill line), the participant may alternate transferring additional urine collections from the hat into each of the two bottles. This will allow for approximating equal volumes in each container, thus maintaining a greater balance in the boric acid concentration.
- PABA
The PABA procedure helps to determine completeness of the 24-hour urine collections. PABA is a type of B-vitamin that is absorbed but not metabolized by humans. A few participants may be allergic or hypersensitive to PABA and should not receive it.
 - Ask participants if they ever had hypersensitivity reactions to PABA-containing sunscreens or are allergic to PABA.
 - If yes (allergic to PABA):
 - Remove the PABA (B-vitamin) tablets from the urine collection kit and contact EINSTEIN-CC.

- Complete questions on the *SOLNAS Visit 1 and Visit 3 (VSE)* form that the participant was not given the PABA (B-vitamin) tablets because he/she has had past hypersensitivity to PABA.
- If no (not allergic to PABA):
 - Instruct participants to take one PABA (B-vitamin) tablet with each meal (or one after the first urine is flushed, one mid-day, and one in the evening). Point participants to the text on the *Instructions for 24-hour Urine Collection* where there is a reminder to “take one PABA (B-vitamin) tablet with each meal” on the day of the urine collection (use a Hi-Liter® marker to call attention to this text).
 - Instruct participants to refrain from taking acetaminophen (e.g., Tylenol®) or any vitamins **the day before AND the day** when collecting the 24-hour urine sample.
 - Ask participants to bring back the PABA tablet packaging with him/her to SOLNAS Visit 2.
 - Complete questions on *SOLNAS Visit 1 and Visit 3 (VSE)* form.
 - Note: There is no need to restrict the use of PABA-containing sunscreen surrounding the 24-hour urine collection period (unless, of course, the participant is allergic to PABA.)
- Provide the participant with a carrying bag containing the following 24-hour urine collection supplies:
 - *Instructions for 24-hour Urine Collection*, includes a *Record sheet for 24-hour Urine Collection* (last page of instructions). There is a reminder to “take one PABA (B-vitamin) tablet with each meal” on the day of the urine collection (use a Hi-Liter® marker to call attention to this text).
 - 2 [3-liter] containers that have 2.0 gram (**0.5 level measuring teaspoon**) boric acid inside each bottle and are labeled with two stickers that read “Leave powder preservative inside bottle” and “Remember...take the PABA (B-vitamin) tablets”. Remember to record the weight of each collection bottle per instructions on the *SOLNAS 24-Hour Urine Collection Worksheet for Staff* before giving the collection bottles to the participant.
 - One urine collection hat
 - One plastic funnel
 - One large safety pin
 - Two gel ice packs
 - One plastic carrying bag
 - 3 sealed PABA (B-vitamin) tablets.
- Inform the participant that a SOLNAS staff person will call to remind him/her when to begin his/her 24-hour urine collection. Explain to the participant that he/she will need to bring his/her 24-hour urine collection, the *Record sheet for 24-hour Urine Collection* and the gel ice packs to his/her SOLNAS Visit 2. Also explain that he/she will also be asked to bring the PABA tablet packaging with

him/her to SOLNAS Visit 2. Provide participant with \$25.00 for participation in visit #1.

6.3.2.7 Confirm Appointment for SOLNAS Visit 2

- The SOLNAS Visit 2 occurs on Day 13, twelve days after SOLNAS Visit 1.
- Confirm that the participant has a SOLNAS Visit 2 appointment scheduled for a date that is 12 days after the first SOLNAS visit (Days 13). Schedule a SOLNAS Visit 2 appointment, if necessary. If needed, SOLNAS Visit 2 could be scheduled one day before or after Day 13.
- Give participant the *Between Visits At A Glance* sheet.

6.3.2.8 Provide Complimentary Meal

- Thank the participant for his/her participation and provide a complimentary meal (e.g., box lunch). The meal can be offered anytime after his/her last spot urine sample (i.e., 4-hour spot urine).
- Escort participant to exit.

6.3.2.9 Check Visit 1 Completeness

Use the *local tracking system* to check that all SOLNAS Visit 1 activities have been completed. Complete any remaining tasks, if required. The staff member who reviews *SOLNAS Visit 1* and checks completion of SOLNAS Visit 1 tasks, designates completion by recording his/her SOLNAS Staff ID on *SOLNAS Visit 1*. Place all completed forms and questionnaires in participant's SOLNAS folder

6.3.2.10 5.1.4.20. Urgent Visit Questions – Contacting EINSTEIN-CC:

- FCs should direct on-the-spot visit questions in the following manner:
Primary Contact: Maria Martello, cell: 917-576-1746; off: 718-430-3189
Alternate Contact numbers, off: 718-430-3324; cell: 347-491-8704
Yasmin Mossavar-Rahmani, Ph.D. cell: 203-918-3898; off: 718-430-2136.
- For urgent situations during which the above SOLNAS contact persons at EINSTEIN-CC cannot be reached directly, FC staff should call the Einstein Clinical Research Center: 718-430-8800.
- FCs are advised to consider scheduling the first few SOLNAS visits during hours when SOLNAS staff at EINSTEIN-CC are likely be available for questions (i.e. no later than 5 pm EST).

6.3.3 Post-SOLNAS Visit 1 Activities

6.3.3.1 Follow-up on Missing Forms

- If a participant leaves the clinic and SOLNAS staff discovers that any of the tasks are missing or have incomplete data, assign a SOLNAS staff person to follow-up with the participant within **1-2 days** of SOLNAS Visit 1.
- Place all completed SOLNAS Visit 1 forms in the participant's SOLNAS file.

6.4 SOLNAS Visit 2 (Day 13)

6.4.1 Overview of Activities

- *Figure 5.3 – Overview of SOLNAS Visit 2 (Day 13)* provides an overview of SOLNAS Visit 2.

Figure 6.3
Overview of SOLNAS Visit 2 (Day 13)

Participant Arrival

- Greet participant
- Complete *SOLNAS Visit 2 Screening Form (VUE, VUS)*
- Receive and process 24-hour urine collection
 - Obtain weight
 - Obtain and process Time 0 (fasting) spot urine sample
 - Obtain and process Time 0 (fasting) blood draw
 - Conduct Indirect Calorimetry
 - Provide snack/meal
 - Obtain and process Time 1 spot urine (1-hour post fasting urine)
- Provide Resting Energy Expenditure Results Letter
- Discuss repeat of SOLNAS protocol in about 6 months. Complete *Consent for Future Contact and Continued Participation in this Study*
 - Schedule SOLNAS Visit 3 appointment, if participant consents to repeat
- Begin necessary institutional paperwork for participant's \$75.00 for time and travel
- Thank participant for completing the SOLNAS protocol
- Complete – Enter into local tracking system

6.4.2 Pre-SOLNAS Visit 2 Activities

6.4.2.1 Supplies and Forms

- SOLNAS staff confirms that all supplies and forms needed for SOLNAS Visit 2 are available for the participant's visit.

Supplies:

- SOLNAS specimen label set (**must be** the remainder of the label set started at SOLNAS Visit 1 for the specific participant)
- Royal blue and lavender (dry EDTA) blood collection tubes
- Corning cryovials with rubber O-Ring , 2mL (for spot urine aliquots) (2)
- 2.0 mL cryovials (for blood and 24-hour urine aliquots) (10 < 60 yr; 11 >=60 yr)
- Toploading digital scale to measure 24-hour urine collections
- Urine collection hat
- Disposable transfer pipettes
- 2.5 gallon plastic container (for mixing bottle contents of large urine collections)
- Snack
- Participant member ID labels
- Resting Energy Expenditure Results Letter

Forms:

- *SOLNAS 24-Hour Urine Collection Worksheet for Staff*
- *SOLNAS Consent for Future Contact and Continued Participation in this Study*
- Tufts Food Frequency Questionnaire (Bronx only)

6.4.2.2 Pre-Visit 2 Reminder Call

- **Three days prior** to the participant's scheduled SOLNAS Visit 2, call the participant. Remind him/her of the following:
 - Avoid consumption of vitamins (other than the study PABA pills) and acetaminophen-containing medications on the day *before* and the day *of* collection. Remind participants not to engage in vigorous or intense activities the 2 days before the visit. These include activities that make a person breathe much harder than normal. Examples: intense energy training.
 - Start the 24-hour urine collection by collecting all of his/her urine beginning at 8 AM on the day before his/her Visit 2 using the specially provided urine collection kit.
 - Take one PABA pill at each meal on the day of urine collection for all SOLNAS participants excluding those who reported known allergies or hypersensitivities to PABA.
 - Fast for 12 hours prior to SOLNAS Visit 2. That means no morning coffee. **No caffeine before visit 2.**

6.4.2.2.1 Review Instructions for 24-hour Urine Collection (Day 13)

- Review the steps the participant needs to take to complete his/her 24-hour urine collection. Ask him/her if he/she has any questions and answer his/her questions thoroughly. The following key points must be covered with the participant:
 - The collection period begins at 8:00 AM on the morning of the *DAY BEFORE* the participant's SOLNAS Visit 2. The collection ends at 8:00 AM on the morning of the *DAY OF* his/her appointment. The time can vary slightly as long as the collection time is 24 hours. If his/her appointment is scheduled early in the morning, he/she may start and end earlier than 8:00 AM.
 - During the at-home collection, containers containing urine should be tightly capped and stored in a refrigerator on the bottom shelf at least 6 inches away from food. It may also be stored in a cooler with ice if preferred.
 - During the urine collection period:
 1. The participant begins by emptying his/her bladder at 8:00 AM.
 2. He/she is to flush this urine. He/she will collect all urine *after* this point but record this time as "Start of collection" on the attached record sheet (*Record sheet for 24-hour Urine Collection*).
 3. He/she should take one PABA (B-vitamin) tablet with each meal (or one after the first urine is flushed, one mid-day, and one in the evening). He/she is not to take acetaminophen (e.g., Tylenol®) or vitamins on the day before or the day of the collection period. If he/she has had hypersensitivity reactions to PABA in sunscreens, he/she should not have PABA (B-vitamin) tablets in his/her urine kit. Omit this instruction if participant is allergic or hypersensitive to PABA.
 4. He/she is to attach the large safety pin to his/her underclothing to serve as a reminder that he/she is collecting urine. It should be in a place that he/she can easily see when he/she goes to the restroom.
 5. The next time he/she goes to the restroom, he/she is to place the urine collection hat in the toilet (under the toilet seat) before urinating. It is important that he/she collects all of the urine. If he/she needs to have a bowel movement, he/she should collect the urine separately.
 6. After urinating, he/she is to use the plastic funnel to pour the urine from the urine collection hat into the collection container. Let the participant know that he/she should completely fill one urine bottle before starting to fill a second container.
 7. He/she is to continue collecting all urine for 24 hours (all day and night).
 8. At 8:00 AM (or 24 hours from his/her START time) the following day, the SOLNAS participant is to empty his/her bladder into the urine collection hat and add this final urine to the collection container. The exact time of this last collection should be recorded on the "End of Collection" line on the *Record sheet for 24-hour Urine Collection*.
 9. The participant is to note any problems with the urine collections on the *Record sheet for 24-hour Urine Collection* (last page of *Instructions for 24-hour Urine Collection*).

10. The participant is to bring all urine collected, the *Record sheet for 24-hour Urine Collection* and the gel ice packs with him/her to SOLNAS Visit 2. In addition, he/she is to bring back the PABA tablet packaging with him/her to SOLNAS Visit 2.

6.4.2.2.2 Confirm Appointment and Fasting Time

- Confirm the participant's SOLNAS Visit 2 appointment. If the participant needs to re-schedule his/her clinic appointment (e.g., emergency situations), try to reschedule the appointment within \pm one day. **Do not go longer than 13 days post SOLNAS Visit 1 (Day 14). For special situations, please contact EINSTEIN-CC Study Coordinator.**
- Remind the participant to:
 - Refrain from eating any food for **12 hours** prior to his/her clinic appointment. Encourage the participant to drink water liberally during the fast; otherwise, he/she may become dehydrated which can be uncomfortable for the participant and result in difficulties collecting urine and blood samples. Black coffee or tea, without milk, cream or sugar (caffeinated or decaffeinated) is okay at SOLNAS Visit 2 **after fasting urine and indirect calorimetry have been completed.**
 - Take all his/her regular medications with water on the day of SOLNAS Visit 2.
 - Wear clothing which allows the sleeve to be easily raised above the elbow without constricting the blood flow to the forearm and hands and allows for ease of multiple urine collections.
 - **Possible Script:** "You are scheduled for a clinic visit at (time and date). During this visit, you will undergo a test to measure the number of calories that you burn at rest. In order to obtain accurate test results, you must not eat after 8 PM the night before the visit or on the morning before the visit. You may not drink any calorie containing beverages on the morning of your visit. It is also important that you do not smoke or take any nicotine products (chew, nicotine gums or patches), any caffeine containing products (coffee, tea, or diet sodas, or drugs to stay awake) for **12 hours** before the visit."
- Ask the participant if he/she has questions and provide information as needed.
- Remind him/her to bring his/her completed 24-hour urine sample to Visit 2.

6.4.3 SOLNAS Visit 2 Activities

6.4.3.1 Reception – Welcome

- When the participant first arrives for SOLNAS Visit 2, have him/her check in at the reception desk. The receptionist should:
 - Locate the participant's file.

- Indicate a comfortable place where the participant may wait until he/she can be seen.
- Notify the SOLNAS Lead-Ops (or designee) that the participant is waiting.

6.4.3.2 Complete SOLNAS Visit 2 Participant Update

Complete *SOLNAS Visit 2 Participant Update Worksheet* to monitor and note potential changes that might influence the spot urine samples collected at SOLNAS Visit 2. None of the questions on this update will make a participant ineligible unless the use of supplemental oxygen is permanent (i.e., travel, use of IV fluids, etc.). The SOLNAS Lead-ops (or designee) reviews the *SOLNAS Visit 2 Participant Update* and takes the appropriate actions outlined below.

- If a participant marks ‘No’ to questions 1-4 on the *SOLNAS Visit 2 Participant Update Worksheet*, SOLNAS staff should begin SOLNAS Visit 2 activities.
- If a participant marks ‘Yes’ to question 1, 2, 3 or 4 on the *SOLNAS Visit 2 Participant Update* SOLNAS staff should:
 - Note the participant’s response on the line next to the appropriate question.
 - Reschedule Visit 1 & 2 as indicated on the questionnaire.
 - At the end of SOLNAS Visit 2, follow the procedures outlined in the *SOLNAS Manual*, notify EINSTEIN-CC Study Coordinator.
- If a participant marks ‘No’ to questions 1, 2 and 3, but ‘Yes’ to question 4 on the *SOLNAS Visit 2 Participant Update* (indicating that he/she has not fasted for 12 hours), SOLNAS staff should:
 - Refer to the procedures in the *SOLNAS Manual, Section 6.4.3.7.1 Handling Non-Fasting Participants-Caffeine and Indirect Calorimetry and Directions for Staff When Participants Are Not Fasted* to manage the blood draw for non-fasting participants.
 - Begin SOLNAS Visit 2 activities.

Rescheduling of the Indirect Calorimetry procedures.

If the participant is only unable to complete the indirect calorimetry, this procedure can be conducted within 20 days post- visit 1. Note that the two spot urine collections, however, must occur on Day 13 plus or minus one day. Be sure to weigh participants before starting the indirect calorimetry.

If participants who are unable to attend visit 2 twelve days after visit 1, he/she will be asked to collect a spot sample on Day 13 at home.

6.4.3.3 Receive 24-hour Urine Collection

- Follow procedures outlined in the *SOLNAS Manual, Section 8.4.3.2.1, Receive the 24-hour Urine Collection From Participant*—to receive the participant’s 24-hour urine

collection, review his/her *Record sheet for 24-hour Urine Collection*, and complete the relevant sections of the *SOLNAS Visit 2 and Visit 4 (VTE)* form.

Handling 24-hour Urine Collection Problems:

- If a participant arrives at the FC with an incomplete or contaminated 24-hour urine collection, the Lead-ops (or designee) be sure that problems are noted on the *SOLNAS 24-hour Urine Collection Record sheet*
- If a participant arrives at the FC without a 24-hour urine collection, the Lead-ops (or designee) decides how to handle the missing 24-hour urine collection using the scenarios provided below:
 - **Participant Forgot to Collect:** If a participant forgot to collect his/her 24-hour urine sample, reassign a day for the collection within **3 working** days. Continue with the remaining SOLNAS Visit 2 activities.
 - **Participant Forgot Collection at Home:** If a participant completed his/her 24-hour urine collection but forgot the container(s) at home, ask him/her to return his/her 24-hour collection to the clinic as soon as possible, within **2 working** days. Continue with the remaining SOLNAS Visit 2 activities.
 - **Participant Refuses to Collect 24-hour Urine:** If a participant refuses to complete his/her 24-hour urine collection, the SOLNAS Lead-ops (or designee) continues with the remaining SOLNAS Visit 2 activities and at the end of the visit, follows the procedures outlined in the *SOLNAS Manual, 8.6.7.1 Using the “Notes” Box’ on the SOLNAS Forms* and notify the EINSTEIN-CC Study Coordinator.

6.4.3.4 Physical Measurements (weight)

- Measure the participant’s weight in kilograms and record on *SOLNAS Visit 2*. The same scale should be used at Visit 2 as was used for measuring the participant’s weight at Visit 1.

6.4.3.5 Spot Urine Collection - SOLNAS Visit 2

6.4.3.6 General Information

- There are two spot urine samples collected at SOLNAS Visit 2: a fasting sample and a sample one hour later. Use the procedures described in the *SOLNAS Manual, 8.3.2.2.1 Timing of the Spot Urine Collections* and *8.3.2.2.2 DLW Spot Urine Collection Steps* for information about the collection and processing of the spot urine samples at SOLNAS Visit 2.
- Use the guidelines provided in the *SOLNAS Manual, General Information* to thoroughly dry collection devices and avoid leaving the urine sample open to evaporation.

6.4.3.6.1 Time 0 (Fasting) Urine Collection

- The Time 0 (fasting) spot urine sample needs to be collected, as soon as possible, after completing *SOLNAS Visit 2 Participant Update Worksheet* and obtaining the participant's weight. Use the procedures described in the *SOLNAS Manual*, 8.3.2.2.1 *Timing of the Spot Urine Collections* and 8.3.2.2.2 *DLW Spot Urine Collection Steps* for information about the collection and processing of the spot urine sample at SOLNAS Visit 2.
- When the sample is collected, record staff ID (for staff collecting the urine) and time of collection on - *SOLNAS Visit 2 and Visit 4 (VTE)*.

6.4.3.7 Fasting Blood

- A fasting blood sample is required for all participants at SOLNAS Visit 2. Draw the participant's blood if he/she has been fasting for at least **12 hours**. Use standard blood handling and processing procedures described in the *SOLNAS Manual*, Section 8.4.3.2.3, Time 0 (Fasting) Blood Draw
- Be sure to protect all the blood samples collected at SOLNAS Visit 2 from natural and fluorescent light. For example, cover vacutainers with foil until processing is completed (refer to *SOLNAS Manual*, *Time 0 (Fasting) Blood Draw*).

6.4.3.7.1 Handling Non-Fasting Participants-Caffeine and Indirect Calorimetry

- For managing participants who arrive at SOLNAS Visit 2 non-fasting, refer to *SOLNAS Manual*, *Directions for Staff When Participants Are Not Fasted*.
- Note: If a participant fasted for twelve hours, but had caffeine within about 2-4 hours of the visit, then he/she should proceed with the rest of the visit, but reschedule the indirect calorimetry. **If it has been more than 2-4 hours since consumption of the caffeine, the participant should complete the indirect calorimetry procedures.**

6.4.3.8 Indirect Calorimetry

6.4.3.8.1 Overview of Indirect Calorimetry

- Indirect calorimetry is a measurement of resting energy expenditure. FCs will supply their own metabolic cart and train their own staff.
- Resting metabolic rate will be measured with a Deltatrac II Respiratory Gas Analyzer, a Sensormedics 29, or similar instrument. These are semi-portable units that measure the concentrations of oxygen and carbon dioxide in air streams entering and exiting a clear plastic hood placed over the participant's head. Oxygen consumption and carbon dioxide production are calculated from the change in concentration and flow rate. The

measurement must be made under standard conditions and requires about 30-40 minutes to complete. A 30-minute rest period is required prior to the start of the indirect calorimetry test to ensure that resting energy expenditure is measured.

- The resting energy expenditure measurements will serve the following purposes:
 - Identify the physiologic determinants of total energy expenditure
 - Provide a measure of physical activity by difference when used in conjunction with total energy expenditure

6.4.3.8.2 Eligibility

- Participants who have self-reported claustrophobia, which would cause them to become anxious when the plastic RMR hood is placed over their head should be excluded from taking part in the indirect calorimetry procedures. The procedures require that the participant lie quietly for 30 minutes and anxiety caused by claustrophobia would produce inaccurate test results. If participant fasted for twelve hours, but had caffeine within about 2-4 hours of the visit, then he/she should proceed with the rest of the visit, but **reschedule the Indirect Calorimetry**. If it has been more than 2-4 hours since consumption of the caffeine, the participant may complete the Indirect Calorimetry procedures because the caffeine has likely been metabolized. Please encourage participants at the pre-visit 2 reminder call not to have caffeinated coffee before visit 2.

6.4.3.8.3 Indirect Calorimetry Procedures

- The indirect calorimetry measurement may be conducted either before or after the rest of SOLNAS Visit 2 procedures, but the participant must remain fasted until the conclusion of the indirect calorimetry test and until the SOLNAS Visit 2 fasting blood has been drawn.
- Below is an overview of the steps taken to measure energy expenditure (indirect calorimetry). Note most of these measures may be conducted by local CRC staff, but whenever possible, we ask that this protocol be followed:
 1. Ensure that the equipment has been properly calibrated at the start of each day.
 2. Ensure that the equipment is turned on and warmed up for at least 30 minutes prior to using it with a participant.
 3. Ask the participant to lie down and rest quietly for about 30 minutes.
 4. If the participant feels cold, offer him/her a blanket. If the participant feels hot, alter the environment to insure that he/she does not sweat.
 5. Check that the monitor is in canopy mode. Change if needed (This may differ between instruments).
 6. Check that the monitor is in the artifact suppression mode with a 10 min start delay (This may differ between instruments).
 7. Check that the hoses from the hood to the metabolic monitor are connected and the unit is turned on.
 8. Perform a calibration of the metabolic monitor, as needed.

9. After the initial 30 minute rest period, measure the resting metabolic rate as per instrument instructions.
10. The printer should be reporting data on a minute by minute basis. If it is not printing, check the connections, printer power, or see the PRINTER SETUP.
11. Proceed with the measurement for 30-40 min.
 - The technician must remain with the participant - monitoring gas flow alarms and visually checking for labored breathing to insure that gas flow does not fail.
 - The participant must remain at rest but not sleep. We recommend that you speak to the participant if you feel it is necessary to keep him/her from falling asleep. If that approach is not effective, then a second attempt could be made by a gentle “nudge.” It is important that FC staff are careful not to startle participants in doing this; however as this could cause an increased heart rate, thereby affecting the test. Participant should always be warned verbally in advance of a physical contact.
 - Use of classical music and a relaxing poster over the bed are acceptable methods for keeping participants calm during the indirect calorimetry test. However, please do not use videos or any other strategies for relaxation unless approved by EINSTEIN-CC. It is important that we maintain consistency across SOLNAS FCs and some techniques (videos) may potentially affect a participant’s heart rate and respiration.
 - The participant must not talk, except when necessary to communicate a potential problem. If the participant does talk, lift their arms to scratch an itch, shift their weight to prevent stiffness etc, indicate the time and movement on the printout using a pen or pencil.
 - Confirm that the participant is still thermally comfortable.
 - If the participant has to get up because he/she needs to use the bathroom, then the measurement can be terminated, but the participant will need to start over. The measurement sequence (i.e., steps 3-13) needs to be repeated beginning with a 10 min rest in place of the 30 min called for in the basic protocol.
12. At 30 minutes, check the display data printout for a stable reading (steady state).
13. End the measurement.
14. Obtain the output data from the metabolic cart. Save the readings on a disk or other electronic format. If electronic output not available, FCs will enter output onto Excel spreadsheet (using the template provided by the EINSTEIN-CC).
15. Remove the hood from over the participant’s head.
16. Ask the participant to sit upright.
17. Help the participant to their feet and be sure that they steady. Remember that they have fasted and there is a small risk of hypoglycemia.

Give the participant his/her snack, if he/she has completed the SOLNAS Visit 2 fasting blood draw.

18. Transcribe the participant's resting energy expenditure results onto the Resting Energy Expenditure Results Letter and give it to the participant. Answer any questions, as needed.
 19. Sanitize the canopy per local procedures.
- **Note:** The primary safety concern is that airflow through the hood is maintained while the hood is in place over the participant's head. Loss of flow due to a rare failure of the fan in the metabolic cart or due to a loose hose will cause discomfort and in an extreme case may cause asphyxiation. Although an alarm will sound if the unit does not detect breathing, the EE technician should remain with the participant throughout the measurement. Care should also be exercised when the participant stands-up after the measurement should dizziness develop secondary to the fast.

6.4.3.8.4 Post- Indirect Calorimetry Quality Check

- After completion of the indirect calorimetry test, complete a quality check on the following:
 1. The printout/electronic record is legible. If not, correct problem and reprint.
 2. The average RQ is between 0.75 and 0.9. Values outside of this range may indicate that the participant fasted longer than 15 h (<0.75), ate within the last 6 h (>0.93), or hyperventilated during the measurement (>0.93). Other possible explanations are very high fat diets (<0.75), a weight loss diet (<0.75) or very high carbohydrate diets (>0.93). If the participant admits to a recent meal, reschedule the test.
 3. Check that the coefficient of variation is less than 10%. Possible explanations are excessive participant movement, irregular breathing pattern, failure to suppress the first 10 min of the measurement, or instrument maintenance problems. If the first 10 min of the measurement were not deleted, manually calculate the average and SD without the first 10 min. If the revised coefficient of variation is less than 10%, record these values. If not, repeat the measurement of resting metabolic rate.

6.4.3.8.5 Indirect Calorimetry Data Management

FCs should use the following template as follows to report the results of the Indirect Calorimetry:

1. Required fields:

Participant ID:

Date (mm/dd/yyyy):

Start Time:

Weight (kg):

Age:

Minute-by-minute values for the entire pre-test and testing period. This includes the 10-minute (or longer) resting period that occurs prior to the participant's "steady state." Additional rows may be added by FCs if this duration exceeds 30 minutes. Please note: Each of the (pre-test) resting period minutes should be indicated by an asterick (*):

---VCO₂ (cells B13 through B42)

---VO₂ (cells C13 through C42)

---RQ (cells D13 through D42)

---EE (cells E13 through E42) (Note: EE may be listed as BEE or RMR)

Summary information (mean, standard deviation, and coefficient of variation) for VCO₂, VO₂, RQ and EE.

Graphic representation of EE. Please note: After the minute-by-minute EE cells are populated (cells G13 through G42), the graphical representation of EE should occur automatically.

2. DESIRED FIELDS- FC that have the ability to obtain the following data are asked to enter (or import) it in the fields provided:

Corrected minute-by-minute values for VCO₂ (cells D13 through D42) and VO₂ (cells E13 through E42).

Minute-by-minute values for FIO₂ and FCO₂

Flow constant (L/min)

Calibration information (Ambient CO₂, CO₂ Meas./Set, O₂ Meas./Set)

3. Submission of electronic Indirect Calorimetry data to EINSTEIN-CC: Depending upon your FC's equipment capabilities, you may fulfill this electronic submission requirement by using either of the following options:

Option #1(for FCs with printing AND downloading capability):

1. Download the indirect calorimetry data from the metabolic cart's computer to a disk or other storage device.
2. Reformat the electronic data, using the format provided by EINSTEIN-CC.
3. Submit the reformatted data file to DMS. Please note that one file may contain data for multiple participants, but each participant's data should be contained on a separate worksheet within the file. For example, the template contains worksheets for participant X and participant Y.

Option #2 (for FCs with printing capability only):

From the IC printout, manually re-enter the data into Excel, using the template provided by EINSTEIN-CC directly into DMS.

Photocopy a hard copy of the printout (minute-by-minute and summary information) and staple as a back-up. Place the xeroxed copy of the indirect calorimetry printout in the participant's SOLNAS chart.

6.4.3.9 Snack/Meal

- After the fasting blood is drawn, give the participant a light snack (e.g., juice, fruit, or crackers) while he/she is sitting in a quiet, comfortable place, away from the blood-drawing area. Serve foods that will help to bring blood sugar back up quickly. Some examples include fruit juices, fruit, granola bars, crackers, English muffins, bagels or toast (offered with jelly, margarine or peanut butter).

6.4.3.10 One Hour Urine Collection

- A final spot urine sample is collected 1 hour after the Time 0 (fasting) sample. Use the procedures described in the *SOLNAS Manual*, 8.3.2.2.1 *Timing of the Spot Urine Collections* and 8.3.2.2.2 *DLW Spot Urine Collection Steps* for information about the collection and processing of the spot urine sample at SOLNAS Visit 2.
- When sample is collected, record staff ID (for staff collecting the urine) and time of collection on *SOLNAS Visit 2*.
- *Note that the Indirect Calorimetry may take 60 minutes, so plan the one-hour urine collection accordingly.*

6.4.3.11 —24 hr Dietary Recall Protocol—As per NDSR guidelines and Addendum.

6.4.3.12 Invite Repeat of SOLNAS - (Reliability Subsample)

- After the final spot urine, give the participant the *Consent for Future Contact and Continued Participation in this Study*. Explain that this consent is asking the participant if he/she would be interested in participating in a repeat of SOLNAS in about 6 months. **The Reliability Study Visit 3 occurs no earlier than five months after visit 1 and not later than seven months after visit 1.**
- Ensure that the participant understands that by checking the box “I am willing to participate in a repeat of the procedures in the HCHS-SOL Nutrition and Physical Activity Assessment Study in about six months” – it means that he/she is consenting to be part of the reliability subsample (90 participants).
- Explain that by agreeing to repeat the Nutrition and Physical Activity Assessment Study, he/she will be asked to repeat all of the study procedures he/she just

finished (i.e., drinking doubly labeled water, providing blood and urine specimens (spot urines at the clinic visits and 24-hour urine collection at home), being weighed, and completing questionnaires). There should be at least six months between SOLNAS Visit 2 and the first reliability subsample visit (SOLNAS Visit 3).

- **Note:** Each FC strives to recruit about 20% of their participants for the reliability subsample; oversampling helps to ensure that there is an adequate number of participants available for the reliability subsample. Some participants recruited at the end of SOLNAS Visit 2 may be unavailable in 6 months when the reliability subsample study begins. EINSTEIN-CC and UNC-Data CC will monitor response rates for the reliability subsample and let FCs know if they need to recruit more or fewer participants for the reliability subsample.

6.4.3.13 Make Arrangements for Time and Travel Costs and Provide Thank You for Participation

- **Time and Travel Cost Arrangements.** When the participant has completed his/her SOLNAS Visit 1 activities, initiate the paperwork required by the FCs local institution to process a check/provide cash for the participant. The costs are included in each FC's total budget.
- **Thank You.** Thank the participant for his/her participation in the SOLNAS study. If the participant has agreed to be part of the reliability subsample, let him/her know that SOLNAS staff will contact him/her within the next 6 months to schedule SOLNAS Visit 3.

SECTION 7: SOLNAS RELIABILITY SUBSAMPLE

7.1 Overview of SOLNAS Reliability Subsample

- For a subset of 96 participants (a 20% reliability sample), the SOLNAS protocol is repeated approximately six months after his/her SOLNAS Visit 2. The 96 participants in the SOLNAS Reliability Subsample are identified at the end of the SOLNAS Visit 2 when they sign the *Consent for Future Contact and Continued Participation in this Study* indicating that they are willing to participate in a repeat of the procedures in SOLNAS.

7.2 Sample Size

- Each FC strives to have **20% of their** participants repeat the procedures for the SOLNAS Reliability Subsample.

7.3 Approaching Participants for the SOLNAS Reliability Subsample

- Not all participants approached for the SOLNAS Reliability Subsample repeat the procedures. The reasons a participant does not repeat the procedures include:
 - The participant is no longer available or interested.
 - The participant is no longer eligible (e.g., now using insulin or other medication for diabetes).
 - The FC has already enrolled all the participants needed for the SOLNAS Reliability Subsample.
 - The participant was not able to complete all SOLNAS Visit 1 and Visit 2 activities.
- When approaching participants for the SOLNAS Reliability Subsample, keep the following in mind:
 - Approach and schedule participants for SOLNAS Visit 3 in the same order they complete SOLNAS Visit 2.
 - To start, limit the number of participants who complete SOLNAS Visit 3 and Visit 4 to 50 participants (24 for the study and 26 on wait-list.) To accomplish this, consider the following:
 - Schedule all recruited participants, but let participants with the latest SOLNAS Visit 3 dates know that they are on a waiting list and may not be needed.
 - Schedule participants on the waiting list so that their SOLNAS Visit 3 date is at least five weeks after the last SOLNAS Visit 4 has occurred for the first **12** participants. This ensures that participants on the waiting list will not begin repeating the procedures until the FC is sure the participant is needed.
- After **12** participants have completed SOLNAS Visit 3 and Visit 4, contact the participants on the waiting list. Thank these participants for their interest and willingness to participate and let them know that they are still on a waiting list.

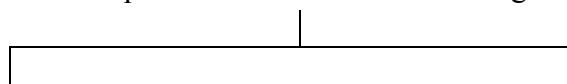
- Participants who meet the following criteria are eligible to participate in the SOLNAS Reliability Study:
 - Completed SOLNAS Visit 1 and Visit 2.
 - Do not take insulin or other medication to manage diabetes.*
 - Do not require supplemental oxygen.*
 - Have not had blood transfusions, administration of blood products or administration of intravenous fluids in excess of 500mL in the week prior to the first clinic visit for this study or an expectation of the same during the period between visits 3 and 4 (including IV fluids administered as part of any administered anesthesia such as during a screening colonoscopy).*
 - Will remain within 200 miles of their home during the week prior to the study and throughout the two week study period. **
 - Have not lost or gained more than 15 pounds since SOLNAS Visit 2. *
 - Do not have bladder control problems that would make collection of a 24-hour urine specimen difficult.
 - Do not take medication for bladder control such as Detrol™.
 - Have not **recently** started medications that can affect energy expenditure (e.g. thyroid medication) or energy intake (e.g. weight loss medication or chemotherapy). A participant who has a history of taking thyroid medication and is weight stable, however, is eligible for the study.
 - Do not take diuretics in an irregular manner that results in weight swings of more than 5% during the DLW period.
 - Do not have self-reported claustrophobia, which could cause the participant to become anxious when the plastic hood is placed over their head for the indirect calorimetry procedures. These procedures require that the participant lie quietly for at least 30 minutes, as anxiety caused by claustrophobia would produce inaccurate test results.
 - * These factors interfere with the doubly labeled water measurements of energy expenditure, indirect calorimetry measures, or other study procedures.
 - ** Note: Travel of 200 miles or more (one-way) away from home or receipt of blood transfusions or IV fluids in the two weeks prior to SOLNAS Visit 3 makes a participant temporarily ineligible. Ask the participant if he/she is willing to reschedule his/her SOLNAS Visit 3 to accommodate the 2-week waiting period.
- Complete *SOLNAS Pre-Visit 3 Eligibility*
 - If a participant is ineligible:
 - Thank him/her for his/her time and interest in repeating the SOLNAS Study.
 - If a participant is eligible:

- Schedule and/or confirm his/her SOLNAS Visit 3 appointment.
- Ask the participant to refrain from traveling more than 200 miles away from home (one-way) or receiving blood transfusions or IV fluids in the 2 weeks prior to his/her SOLNAS Visit 3 appointment.

Figure 7.1 - Reassessing Eligibility

Three to Four Weeks before SOLNAS Visit 3

- Conduct pre-SOLNAS Visit 3 call to reassess eligibility
- Complete SOLNAS Pre-Visit 3 Eligibility



‘Ineligible’

- Thank the participant

‘Eligible’ for SOLNAS Visit 3

- Schedule and/or confirm SOLNAS Visit 3

One Day before SOLNAS Visit 3:

- Conduct reminder call for SOLNAS Visit 3

7.4 Pre-SOLNAS Visit 3 Activities

7.4.1 Supplies and Forms

- SOLNAS staff confirms that all supplies and forms needed for SOLNAS Visit 3 are available for the pre-Visit 3 eligibility reassessment call.

Supplies:

None

7.4.2 Conduct SOLNAS Pre-Visit 3 Eligibility Reassessment Call / Complete *SOLNAS Pre-Visit 3 Eligibility Worksheet*

Figure 6.1 – Reassessing Eligibility provides an overview of SOLNAS pre-Visit 3 activities

- The SOLNAS staff completes the *SOLNAS Pre-Visit 3 Eligibility* for all participants receiving a pre-SOLNAS Visit 3 call to reassess eligibility. **Note: This differs from the *SOLNAS Visit 3 Eligibility* which will be completed in person when the participant arrives for SOLNAS Visit 3.**
- Record the participant’s eligibility summary on *SOLNAS Pre-Visit 3 Eligibility (SOLNAS Pre-Visit 3 Eligibility Summary)*. The eligibility summary represents the participant’s status at the end of the eligibility reassessment call:
 - **‘Eligible’**: Participant is eligible to participate in a repeat of the SOLNAS Study. Record ‘eligible’ if the participant meets the eligibility criteria, **regardless of**

whether or not he/she has accepted or declined participation in the Reliability Study.

- If the participant is eligible, but is not interested in participating in the Reliability Study, then a ‘declined’ result should be indicated by marking “No” to question 8.1.1.
- If the participant is eligible and is interested in participating in the Reliability Study, then an “accepted” result should be indicated by marking “Yes”
- ‘Ineligible’: Participant is not eligible to participate in a repeat of the SOLNAS Study.

7.4.3 Pre-Visit 3 Reminder (one day prior to SOLNAS Visit 3)

- SOLNAS staff calls each participant one day prior to his/her SOLNAS Visit 3. If a participant is scheduled for Monday, the call may be made on the preceding Friday. During the call, provide the same reminder information described in the *SOLNAS Manual, Section 6.2.3.2, Pre-Visit 1 Reminder Call*.

7.5 SOLNAS Visit 3 (Day 1)

7.5.1 Supplies and Forms

- SOLNAS staff confirms that all supplies and forms needed for SOLNAS Visit 3 are available for the participant’s visit.

Supplies:

None

Questionnaires & Print Materials:

- *SOLNAS Visit 3 Eligibility*
- *Consent for Future Contact and Continued Participation in this Study* (confirm that consent signed at SOLNAS Visit 2 is in participant’s chart)
- *SOLNAS Visit 3*
- *Between Visits At A Glance* sheet
- *SOLNAS 24-Hour Urine Collection Worksheet for Staff*
- *24-Hour Urine Collection Kit*

7.5.2 Overview of SOLNAS Visit 3 Activities

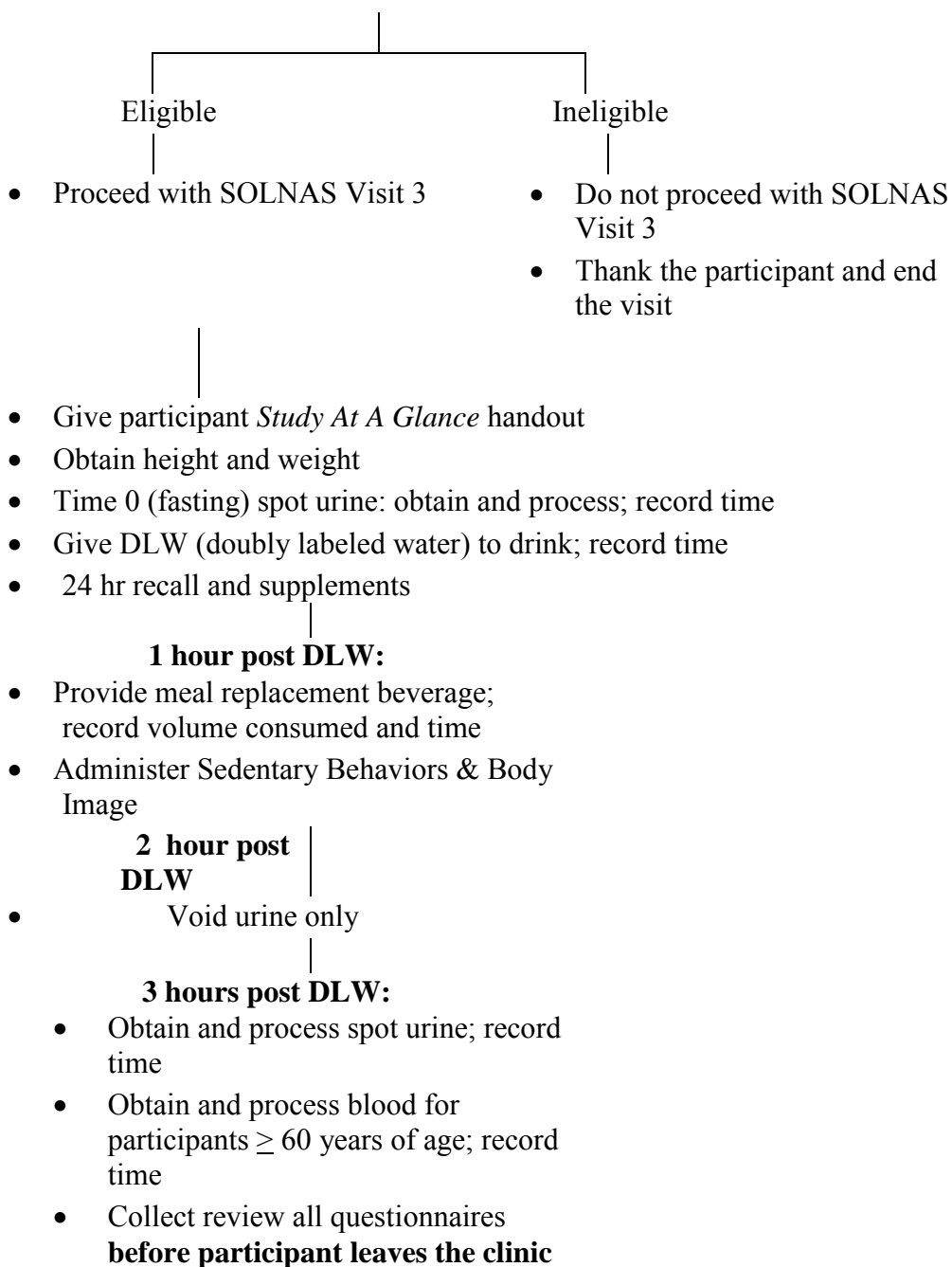
Figure 6.2 – Overview of SOLNAS Visit 3 provides an overview of SOLNAS Visit 3.

Figure 7.2

Overview of SOLNAS Visit 3 (Day 1)

Participant Arrival

- Greet participant
- Confirm *Consent for Future Contact and Continued Participation in this Study* signed at SOLNAS Visit 2 is in participant's file
- Review the SOLNAS study components and visit activities
- Determine eligibility (*SOLNAS Visit 3 Eligibility Worksheet*)



|
4 hours post DLW:

- Obtain and process spot urine; record time
 - Provide participant with meal/snack
 - Instruct participant on 24-hour urine collection and provide urine collection kit
 - Provide instructions on Actical to be used for seven days
 - Give participant the *Between Visits At A Glance* sheet.
 - Answer any questions about between visit tasks or indirect calorimetry to be completed at Visit 2.
 - Schedule or confirm participant for SOLNAS Visit 4 (12 days later)
 - Thank participant and escort his/her to the exit.
- |
- Complete blood and urine processing and storage; ensure correct labels are on each specimen
 - Collate all SOLNAS forms into participant's SOLNAS folder for use at SOLNAS Visit 2.
 - Complete local tracking system to indicate completion of Visit 3.

7.5.3 SOLNAS Visit 3 Activities

- SOLNAS Visit 3 activities are very similar to those described in the *SOLNAS Manual, SOLNAS Visit 1 (Day 1)*, with the exception of the following:
 - Staff confirms that the participant has a signed *Consent for Future Contact and Continued Participation in this Study* in his/her chart. A duplicate consent is not required.
- For a detailed description of SOLNAS Visit 3 activities, refer to the *SOLNAS Manual, SOLNAS Visit 1 Activities*.
- Staff use *SOLNAS Visit 3* to record information collected at SOLNAS Visit 3.

7.5.4 Post-SOLNAS Visit 3 Activities

- For a detailed description of post-SOLNAS Visit 3 activities, refer to the *SOLNAS Manual, Section 6.3.3, Post-SOLNAS Visit 1 Activities*.

7.6 SOLNAS Visit 4 (Day 13)

7.6.1 Pre-SOLNAS Visit 4 Activities

7.6.1.1 Pre-Visit 4 Reminder Call

- SOLNAS staff calls each participant two days prior to his/her SOLNAS Visit 4. During the call, provide the same reminder information described in the *SOLNAS Manual, Section 6.4.2.2, Pre-Visit 2 Reminder Call*.

7.6.1.2 Supplies and Forms

- SOLNAS staff confirms that all supplies and forms needed for SOLNAS Visit 4 are available for the participant's visit.

Supplies:

- Refer to the *SOLNAS Supplies and Forms*, for a list of the supplies to have available for SOLNAS Visit 4.

Forms and Print Materials:

- *SOLNAS Visit 4 Participant*
- *SOLNAS Visit 4*
- *SOLNAS 24-Hour Urine Collection Worksheet for Staff*
- *Resting Energy Expenditure Results Letter*

7.6.2 Overview of SOLNAS Visit 4 Activities

Figure 6.3 – Overview of SOLNAS Visit 4 provides an overview of SOLNAS Visit 4.

Figure 7.3
Overview of SOLNAS Visit 4 (Day 13)

Participant Arrival

- Greet participant
- Complete *SOLNAS Visit 4 Participant Update*
- Receive and process 24-hour urine collection
- Collect Actical and download data per protocol
- Obtain weight
- Obtain and process Time 0 (fasting) spot urine sample
- Obtain and process Time 0 (fasting) blood draw
- Conduct Indirect Calorimetry
- Provide snack/meal
- Obtain and process Time 1 spot urine (1-hour post fasting urine)
-
- Provide Resting Energy Expenditure Results Letter.
- Begin necessary institutional paperwork for participant's \$75.00 for time and travel costs as applicable.
- Thank participant for completing the repeat of the SOLNAS protocol.

7.6.3 SOLNAS Visit 4 Activities

- SOLNAS Visit 4 activities are very similar to those described in the *SOLNAS Manual, SOLNAS Visit 2 (Day 13)*, with the exception of the following:
 - Staff do not invite the participant to return and do not collect the *Consent for Future Contact and Continued Participation in this Study* at the end of the visit.
- For detailed descriptions of SOLNAS Visit 4 activities, refer to the *SOLNAS Manual, SOLNAS Visit 2 Activities* (omitting the invitation to repeat SOLNAS).
- Staff use *SOLNAS Visit 4* to record information collected at SOLNAS Visit 4.

7.6.4 Post-SOLNAS Visit 4 Activities

- For a detailed description of post-SOLNAS Visit 4 activities, refer to the *SOLNAS Manual – Post-SOLNAS Visit 2 Activities*.

SECTION 8: BLOOD AND URINE COLLECTION, PROCESSING, AND SHIPMENT

8.1 Introduction

This section of the manual for the HCHS-SOL Nutrition and Physical Activity Assessment Study (SOLNAS) describes procedures for collecting, processing, and shipping blood and urine samples for the HCHS-SOL SOLNAS.

The SOLNAS protocol calls for three types of specimen collection procedures:

1. Doubly labeled water (DLW) procedure of spot urine collections (and blood sample for participants ≥ 60 years of age) for the analysis of energy expenditure.
2. 24-hour urine collection procedure for analysis of (a) urinary nitrogen (UN) as an estimate of protein intake and (b) select minerals as biomarkers of intake.
3. Fasting blood draw procedure for analysis of plasma phospholipids fatty acids and biomarkers of micronutrient intake, e.g., total cholesterol, triglycerides, blood tocopherols, retinol, folate, carotenoids, B-vitamins, and selenium.

The three specimen collection procedures occur during two participant in-person clinic visits and one at-home 24-hour urine collection:

SOLNAS Visit 1

During SOLNAS Visit 1 (or SOLNAS Visit 3), participants provide three spot urine collections for the DLW procedure and, for participants ≥ 60 years of age, one non-fasting blood sample is taken three hours after ingesting the doubly labeled water. Participants receive instructions and a kit for the 24-hour urine collection procedure that is done one day before SOLNAS Visit 2.

24-hour Urine Collection

One day before SOLNAS Visit 2 (or SOLNAS Visit 4), participants begin a 24-hour urine collection.

SOLNAS Visit 2

During SOLNAS Visit 2 (or SOLNAS Visit 4), one fasting blood draw is taken and participants provide two spot urine collections for the DLW procedures. The participants bring in their 24-hour urine collection for processing.

Processing and shipping samples occurs as follows:

FC staff process and freeze samples from the blood and urine specimens in preparation for shipping.

FC staff ship specified serum, plasma, and urine samples to Central Lab in Minneapolis, MN and the DLW urine and plasma samples to Baylor University, Houston TX.

Laboratory quality control occurs as follows:

Five percent of DLW urine and 10% of biospecimen serum, plasma, and 24 hr urine samples will have blinded duplicate aliquots collected for laboratory quality control (QC).

8.2 General Guidelines

8.2.1 Safety Procedures - Precautions for Handling Blood

The SOLNAS has adopted the Universal Precautions for blood collection, as was used with the HCHS-SOL, processing and shipping. These precautions are intended as optimal "guidelines." These do not apply to urine unless there is visible blood in the urine. The term *Universal Precautions* refers to an approach to infectious disease control HCHS-SOL assumes that every direct contact with body fluids is infectious. Also refer to the Occupational Safety and Health Administration (OSHA) guidelines HCHS-SOL should be available from your institution for handling blood specimens.

Follow all local requirements for handling and disposing of blood and materials exposed to blood. Check with your institution's Health and Safety office for any additional requirements as this/here may be some local variation at each FC, procedures may be stricter or slightly less strict than those listed below.

The following are guidelines for all blood collection and processing procedures:

- Handle all blood specimens as potentially infectious material. Transmission of the infectious agents associated with hepatitis and acquired immunodeficiency syndrome (AIDS) via "needle stick" skin punctures have been documented.
- Wear disposable plastic latex gloves (or suitable substitute) when collecting and processing specimens. When drawing blood, change gloves between participants.
- Wear protective eye goggles, a face mask, a full face shield, or work behind a barrier shield at all times when processing blood. Regular glasses without splatter shields are not sufficient.
- Encourage staff having direct contact with blood specimens to get a Hepatitis B vaccination. Your local institution may provide Hepatitis B vaccinations for personnel handling blood specimens. The Hepatitis B vaccine provides immunity against Hepatitis B, an infectious, blood-borne disease causing inflammation of the liver with possibly serious or fatal consequences. The vaccination series involves three separate doses over six months. This protection is believed to last five to seven years at HCHS-SOL each time a booster dose may be needed.
- Wash your hands with soap and water:
 - Immediately after contact with blood or other infectious materials (even if you wore gloves).
 - Before and after using restroom facilities.
 - After you take off your gloves or other protective clothing.
 - Before and after each participant contact.
 - When you leave the work area where blood or other infectious materials are present.

- Do not use gloves if they are peeling, cracked or discolored, or if they have punctures, tears or other evidence of deterioration. Cover skin cuts or abrasions with a Band-Aid underneath the glove.
- Anyone performing a process where there is a potential for splashing of blood (e.g., the processing of blood) should wear a long-sleeved, buttoned-up, fluid-resistant lab coat.
- Use disposable lab coats, if available. Place disposable protective equipment in a labeled infectious waste container for disposal.
- Remove the disposable/non-disposable lab coat when leaving the blood draw area. The lab coat worn in the blood draw area should not be worn in other areas of the clinic.
- Tie back any long hair.
- If you accidentally sustain a contaminated (or used) needle stick, thoroughly cleanse the wound with soap and water. Notify the FC-affiliated physician to order an analysis of the participant's serum for possible hepatitis or HIV antibodies. Complete a local accident report, as needed, and follow all appropriate OSHA guidelines as dictated by your institution.
- Do not manipulate needles, scalpel blades, or other contaminated sharp objects by hand. Do not bend, break or remove needles from disposable syringes by hand. Store unused needles in a secure cabinet when the FC is closed.
- Do not recap or resheath needles or sharp instruments unless absolutely necessary. If you need to recap a needle, cover it immediately after use. To recap the needle, use a cap holder designed for this purpose (placed in close proximity); or use a hemostat. Do not use your hand to recap the needle since this is the most common cause of sustaining a contaminated needle stick.
- Use 0.1% sodium hypochlorite (10% household bleach) to clean up any spills of blood, serum or urine. Use this solution on all work surfaces at the end of each day. Dilute one part household bleach with nine parts water to get a 0.1% sodium hypochlorite solution. Apply with a paper towel. Do not use an aerosol spray to apply the solution.
- Deposit all used needles, blood collection tubes, transfer pipettes and pipette tips in puncture-resistant containers for safe disposal.
- Place all other used blood processing supplies and blood products in biohazard bags for disposal. Also dispose of other materials exposed to blood in biohazard bags.
- Never perform any pipetting by mouth, especially if any blood or serum is involved.
- Avoid formation of potentially infectious aerosols by carefully removing stoppers from the vacutainer tubes and by careful pipetting and centrifugation.
- Never allow food or drink in the blood drawing or processing rooms. Do not store food or drink in the same refrigerator or freezer as blood samples.
- Do not eat, drink, apply cosmetics or lip balm, or handle contact lenses in work areas where blood or potentially infectious materials are present.

- Assume all laundry to be contaminated. Wear protective gloves when handling laundry. Bag laundry at the location where it was used. Double bag if soaking through is likely.
- Label all containers of infectious waste (i.e., biohazardous and medical waste), refrigerators and freezers containing blood or other potentially infectious materials with the biohazard symbol. The biohazard symbol must be black on an orange background.
- Transport all specimens or containers of blood and other potentially infectious materials in a secondary container (e.g., plastic bag or other container having a liquid-tight seal).

8.2.2 Safety Procedures - Precautions for Handling Urine

Follow relevant safety precautions described in the *SOLNAS Manual, Precautions for Handling Blood*. Additionally, follow institutional, local, and state guidelines and requirements for safe handling of urine as a biological specimen.

8.2.3 Training

FC staff person may draw, process and ship the blood and urine specimens for the SOLNAS after completing the SOLNAS training activities (refer to *SOLNAS Manual, Non-Lead SOLNAS Staff*).

FC staff should also be familiar with local or state certification requirements. Keep a copy of any local and state requirements relating to the collection and processing of blood and urine products on file at the FC.

Because blood collection may involve a small amount of pain for the participant, it is important that phlebotomists review the techniques involved in the collection process. Phlebotomists should be highly experienced with vacutainer and butterfly blood collections, prepared to handle common problems such as fainting, and familiar with precautions to avoid exposing themselves to blood. Ideally they will be CPR certified. They should: 1) read "Collection and Handling of Laboratory Specimens: A Practical Guide" or similar phlebotomy manual; 2) wear clean HCHS-SOL lab coats (with no blood stains) and appear generally neat and tidy; 3) wear name tags and introduce themselves to the participants before the blood draw; and 4) not chew gum or have any food items in their mouths during blood draws.

Because the study depends on the voluntary return of participants, the phlebotomist should make every effort to make the entire procedure as easy and painless as possible. The phlebotomist should remain calm and project an attitude of competence even when faced with the most nervous or inquiring participant. The best way to achieve this is to be thoroughly knowledgeable about all aspects of the procedures. This includes knowledge about the participant contact, the handling of each tube and the purpose of each sample.

8.2.4 Facilities

Phlebotomy Room

Perform blood draws in a private area such as an isolated room (blood drawing room) or in an area separated by room dividers. Equip the room with all the necessary blood drawing supplies. Use a counter or work table for all of the blood handling equipment and supplies. The blood drawing room should be clean and tidy with no obvious evidence of a previous blood draw such as used needles, blood stains, etc. A phlebotomy chair should be available for 15 to 20 minute periods to allow participants to be seated for a few minutes before the blood draw. Ideally, only the participant and phlebotomist should be in the room during the procedure.

Blood Processing Room

Equip the blood processing room with a refrigerated centrifuge, a small refrigerator and sufficient counter space for the processing of blood specimens. A -70°C freezer should be in or near the room. The room must have a sink and running water available. Use one counter area for processing the blood samples and another counter area for completing paperwork. Safety regulations state food and drink should not be kept in refrigerators or freezers in which you put the blood samples. Food should not be kept in the blood processing room even if it is not in the same refrigerator as the blood samples. Food should not be eaten in the blood processing room.

8.2.5 Supplies

Refer to *SOLNAS Manual, Guidelines for Ordering Supplies* for information about supplies for blood and urine collection, processing and shipment.

8.2.6 Labels

8.2.6.1 Label Sets

The Central Laboratory provides the FCs with SOLNAS label sets. **There is one SOLNAS label set per participant.** This means that all the blood and urine specimens collected from a participant at SOLNAS Visit 1 and SOLNAS Visit 2 have the same specimen identification number. Each label set contains 30 labels, all of which are needed for the SOLNAS Visit 1 and SOLNAS Visit 2 forms, sample tubes, and sample aliquots. Refer to *Figure 7.1 SOLNAS Label Set (Visits 1 and 2)*.

- There are 9 labels for SOLNAS Visit 1:
 - 6 labels with bar codes to be used for the DLW spillage, and blood and urine aliquots.
 - 3 extra labels bar codes.
- There are 21 labels for SOLNAS Visit 2:
 - 18 labels with bar codes to be used for the indirect calorimetry, and blood and urine aliquots.

- 3 extra labels with bar codes.

SOLNAS Visits 3 and 4 have a similar label set and are labeled appropriately with Visit 3 and Visit 4 text.

Place the participant's SOLNAS label set in his /her chart. Write the participant's name or HCHS-SOL member ID label on the back of the SOLNAS Lab ID label set.

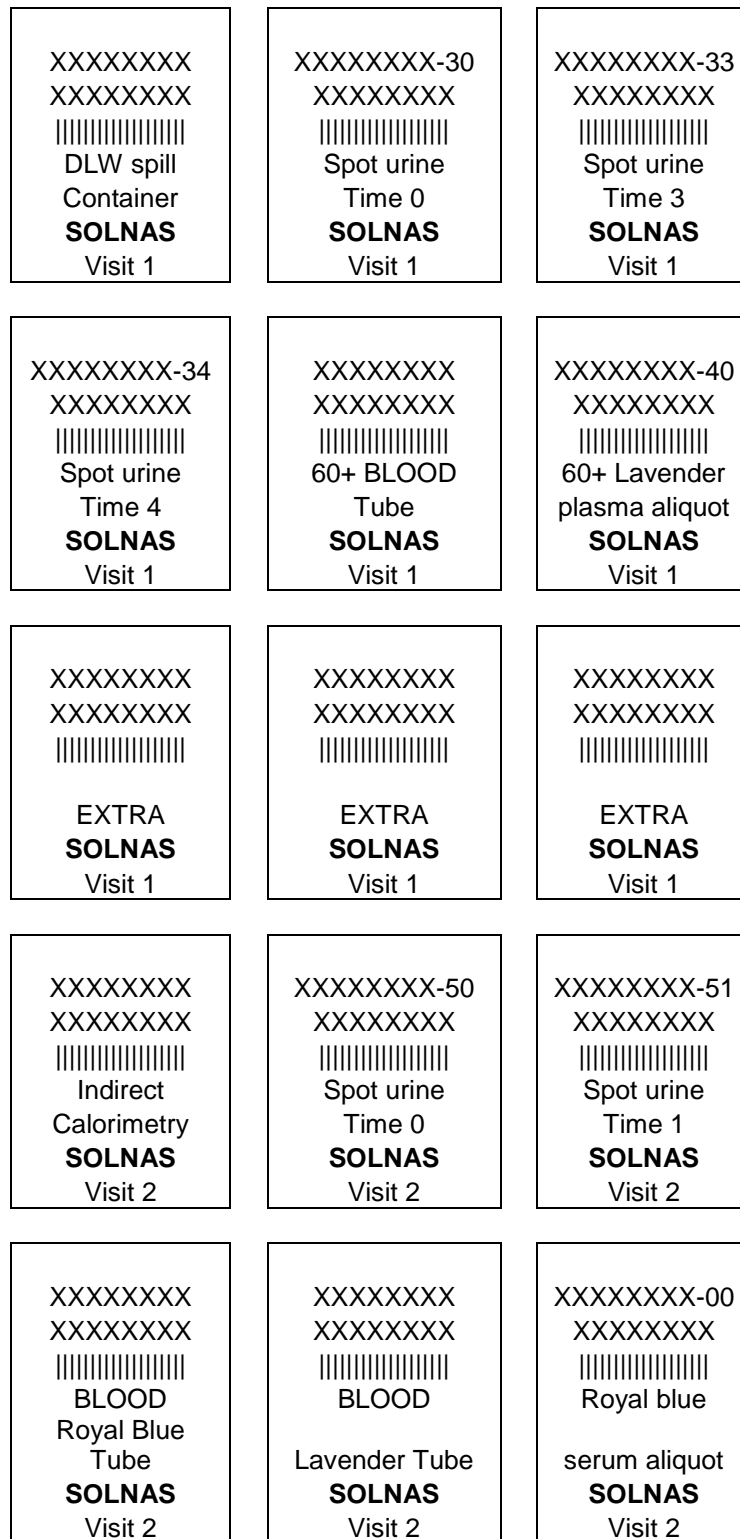
KEY POINTS (about the SOLNAS label set):

- Each participant is assigned their HCHS-SOL ID number. The label sets for the samples will have a different "Laboratory" identification number that is linked to the participant's study identification number on the visit 1 VSE form.
- Each laboratory label set has an identification number.
- Label all the specimens collected at SOLNAS Visits 1 and 2 with this identification number using the appropriate bar-coded SOLNAS label.
- Label *Form – SOLNAS Visit 1* and *SOLNAS Visit 2* with one label each. This will be a check on key-entry of *SOLNAS Visit 2* to ensure that the label set identification number matches the one entered on *Form – SOLNAS Visit 1*.
- When time points are involved in specimen collection, those times are explicitly displayed on the label and the last digit of the aliquot matches the time point. For example, the SOLNAS Visit 1 spot urine aliquots are as follows: 30=Time 0, 33=Time 3, 34=Time 4.
- The 2-digit aliquot identification numbers remain consistent across label sets for different participants. Only the label set identification number differs between participants.

The same key points about the SOLNAS label set apply to SOLNAS Visits 3 and 4.

Figure 8.1 – SOLNAS Label Set (Visits 1 and 2) provides a sample label set for SOLNAS Visits 1 and 2.

Figure 8.1 SOLNAS Label Set (Visit 1 and 2)



XXXXXXXX-01 XXXXXXXX Royal blue serum aliquot SOLNAS Visit 2	XXXXXXXX-02 XXXXXXXX Royal blue serum aliquot SOLNAS Visit 2	XXXXXXXX-03 XXXXXXXX Royal blue serum aliquot SOLNAS Visit 2
XXXXXXXX-10 XXXXXXXX Lavender plasma aliquot SOLNAS Visit 2	XXXXXXXX-11 XXXXXXXX Lavender plasma aliquot SOLNAS Visit 2	XXXXXXXX-12 XXXXXXXX Lavender plasma aliquot SOLNAS Visit 2
XXXXXXXX-20 XXXXXXXX 60+ Lavender plasma aliquot SOLNAS Visit 2	XXXXXXXX XXXXXXXX 24Hr Urine Container SOLNAS Visit 2	XXXXXXXX XXXXXXXX 24Hr Urine Centrifuge Tube SOLNAS Visit 2
XXXXXXXX-60 XXXXXXXX 24Hr Urine SOLNAS Visit 2	XXXXXXXX-61 XXXXXXXX 24Hr Urine SOLNAS Visit 2	XXXXXXXX-62 XXXXXXXX 24Hr Urine SOLNAS Visit 2
XXXXXXXX XXXXXXXX EXTRA SOLNAS	XXXXXXXX XXXXXXXX EXTRA SOLNAS	XXXXXXXX XXXXXXXX EXTRA SOLNAS

8.2.6.2 Placement of Specimen Labels

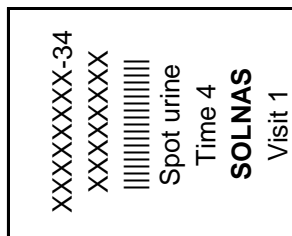
Specimen labels that have been incorrectly placed on the cryovials may prevent Central Lab from being able to scan the barcodes. To ensure data quality, it is imperative that the barcode on the cryovial be scannable.

Please be sure that all staff know to place the specimen label on the cryovial as follows:

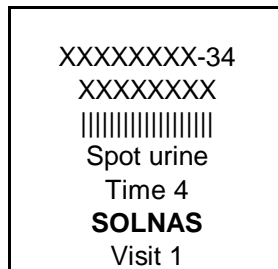
- Wrap the label around the circumference of the vial so that the short edge of the label is parallel with the long edge of the vial.
- Start with the non-barcode end of the label first so that when the label overlaps itself, the barcode is completely exposed.

Please see *Figure 7.2 – Placement of Specimen Labels*.

Figure 7.2 Placement of Specimen Labels



CORRECT ORIENTATION



INCORRECT ORIENTATION

8.2.7 Quality Control (QC) for Laboratory Analysis

Laboratory quality control will be assessed on a 5% subsample of SOLNAS DLW urine and 10% subsample of serum, plasma, and 24 hr urine specimens, i.e., specimens from 24 or 48 participants SOLNAS-wide for SOLNAS Visits 1 and 2 and from 6 or 12 participants SOLNAS-wide for SOLNAS Visits 3 and 4. The analytic laboratories will receive the QC samples as blinded duplicate aliquots.

Blood QC.

- 3-hour post-DLW plasma (for participants 60 years of age or older). For SOLNAS Visit 1 (or SOLNAS Visit 3), QC samples will not be collected.
- Fasting serum and plasma. For SOLNAS Visit 2 (or SOLNAS Visit 4), fasting serum and plasma samples will be collected from the first participant who volunteers during the first week of every month. .

Urine QC.

- DLW Spot Urine Collection. For the first participant the first week of each month, staff will prepare and label one additional 1.75 mL aliquot for QC.
- 24-hour Urine Collection. For the 24-hour urine collection processed at SOLNAS Visit 2 (or SOLNAS Visit 4), staff will prepare and label three additional 1.75 mL aliquots for QC.
- Participants will not need to provide additional urine collections for SOLNAS QC for the DLW spot urine collections

For QC details related to each SOLNAS Visit, refer to *SOLNAS Manual*, 8.3.1.2 *Quality Control (QC) Samples for SOLNAS Visit 1 (or SOLNAS Visit 3)* and 8.4.1.2 *Quality Control (QC) Samples for SOLNAS Visit 2 (or SOLNAS Visit 4)* -.

8.3 SOLNAS Visit 1 (or SOLNAS Visit 3)

8.3.1 General Blood and Urine Sampling and Aliquot Schedule and Quality Control (QC)

8.3.1.1 Sampling and Aliquot Schedule

SOLNAS Visit 1 (or 3) General Blood & Urine Sampling & Aliquot Schedule

TIME	SAMPLE	ALIQOT	QC
Time 0 (Fasting)	Spot urine Sample in hat	One, 1.75 mL (One 2 mL cryovial) DLW-Baylor	One, 1.75 mL (One 2 mL cryovial) DLW-Baylor
Time 1	One hour after DLW dosing	No specimen	No specimen
Time 2	Empty bladder	No specimen	No specimen
Time 3 (Three hours post- DLW),	Spot urine Sample in hat	One, 1.75 mL (One 2 mL cryovial) DLW-Baylor	One, 1.75 mL (One 2 mL cryovial) DLW-Baylor
Time 3 (Three hours post- DLW)	Blood Draw Lavender dry EDTA, one 10 mL <u>for participants 60 years of age or older</u>	One 1.75 mL plasma (One 2 mL cryovial) DLW-Baylor	No specimen
Time 4 (Four hours post-DLW)	Spot urine Sample in hat	One, 1.75 mL (One 2 mL cryovial) DLW-Baylor	One, 1.75 mL (One 2 mL cryovial) No QC for participants 60 yrs or older as bloods are collected DLW-Baylor

QC on one person per month at each site (first week of every month) = 5% of sample

shipped monthly to Baylor and 10% to Central Lab

8.3.1.2 Quality Control (QC) Samples for SOLNAS Visit 1 (or SOLNAS Visit 3)

Refer to *SOLNAS Manual*, section on 8.2.7 *Quality Control (QC) for Laboratory Analysis* for general blood and urine QC information.

One Visit 1 participant will be selected the first week of every month to provide urine for QC samples. All urine QC aliquots must be from the same participant.

Labels. For each QC participant, use a separate Lab ID label set for the SOLNAS Visit QC aliquots.

Forms: Fill out a Phantom Id Form (SPF) for each participant in the QC sample. Print a copy for your files and affix the corresponding Phantom ID Label. **DO NOT MAIL THIS FORM TO THE LABS.**

Blood. QC samples will NOT be collected from participant 60 years of age or older at Visit 1 (or SOLNAS Visit 3).

Urine. For the spot urine collections at SOLNAS Visit 1 (or SOLNAS Visit 3), collect one additional 1,75 mL aliquot at each time point. Label one of these additional aliquots from the Lab ID label set assigned for the QC samples.

8.3.2 Day of SOLNAS Visit 1 (or SOLNAS Visit 3) (Day 1)

8.3.2.1 Before the Participant Arrives

1. Obtain a *Form – SOLNAS Visit 1* (or *SOLNAS Visit 3*).
2. Obtain one SOLNAS Lab ID label set for the participant. (If this participant is also donating extra blood and urine for QC, select a second set of Lab ID labels.)
3. Insert the *Form – SOLNAS Visit 1* and the SOLNAS Lab ID label set(s) into the participant's file (or– *SOLNAS Visit 3* for the reliability subsample). Enter the participant's HCHS-SOL (SOLNAS) study ID the assigned Lab ID in the appropriate places on the visit one VSE form.
4. Using the appropriate labels from the Lab ID label set, label the lavender dry EDTA tube and arrange in a test tube rack (for participants 60 years of age and older). Label and arrange the corresponding 2 mL cryovial in rack.
5. Label three 2 mL cryovials for urine samples (with rubber O-ring seal for spot urine aliquots) and arrange in a rack.

8.3.2.2 During the Visit (Overview)

1. Verify that the participant is eligible and has signed the *SOLNAS Consent* by reviewing *SOLNAS Visit 1* (or *SOLNAS Visit 3*).
2. Enter the SOLNAS identification number on *SOLNAS Visit 1* (or *SOLNAS Visit 3*). For participants in the QC subsample, enter the assigned QC Lab ID number in the appropriate section of the SOLNAS form.
3. Review with the participant the blood and urine collection procedures for SOLNAS Visit 1 (or SOLNAS Visit 3).
4. Collect the spot urine samples for Time 0, Time 3, and Time 4.
5. For participants 60 years of age or older, draw a blood sample 3 hours after DLW ingestion, in conjunction with the 3-hour spot urine collection.
6. Collect the spot urine sample for Time 4.
7. Instruct the participant on the 24-hour urine collection and give his/her the 24-hour urine collection kit.

8.3.2.2.1 Timing of the Spot Urine Collections

The timing for each of the spot urine collections during the visit do not need to be precisely “on the hour,” but the exact times do need to be recorded on *SOLNAS Visit 1* (*SOLNAS Visit 3 form*). Subsequent collections may be collected at their scheduled times.

Example: SOLNAS Visit 1. A participant ingests the DLW at 9:00 AM. He/she is unable to produce a urine sample 3 hours after ingestion of the DLW (12:00 PM), but is able to 3-1/2 hours after (12:30 PM). On *SOLNAS Visit 1* (or *SOLNAS Visit 3*

Form), note 12:30 PM for the Time 3 Urine Collection. Obtain the Time 4 Urine Collection at 1:00 PM as scheduled.

Example 2: SOLNAS Visit 1. A participant ingests the DLW at 9:00 AM and he/she needs to void 2.5 hours later (11:30 AM). Discard the 2.5 hr samples and ask the participant to try to void again after 3 h postdose. On *SOLNAS Visit 1* (or *SOLNAS Visit 3*), note the 11:30 AM void, but enter the exact time of the 3-h void for the Time 3 Urine Collection. Obtain the Time 4 Urine Collection at 1:00 PM as scheduled.

Coordinate the timing of the 3-hour urine and blood collections for participants 60 years of age and older to occur together, i.e., if the urine collection needs be earlier or later than the scheduled Time 3 collection, collect the blood draw immediately after the urine collection.

For the DLW method, the following qualify control procedures will be implemented:

The analytical stability of the isotope ratio measurements will be monitored based on the results of (1) reference materials, (2) dose dilutions, and (3) test-retest samples.

(1) Reference materials

- The International Atomic Energy Agency (IAEA) reference materials (302A, 302B, 304A and 304B) will be analyzed at least semi-annually or when a new batch of zinc is used, a filament is replaced, or a major tune up of the mass spectrometer is required.
- The percentage difference of these measurements from the published values will be used to monitor the accuracy and precision of the isotope ratio measurements over time.

(2) Dose dilutions

- For each batch of DLW dose mixtures, two dose dilutions (~1:400 and ~1:1,500) that simulate the expected isotopic enrichments of the postdose samples to be collected on day 0 and Day 13 of the 12-day DLW study will be prepared.
- The dose dilutions and the water used in preparing the dose dilutions will be analyzed daily in duplicate over a period of 10 days.
- The logarithmic transformed isotopic enrichments of these measurements will be used to generate the hypothetical constants for the conversion of these enrichment values to produce theoretical fractional turnover rates of ^2H (k_{H} , 0.1) and ^{18}O (k_{O} , 0.13).
- Subsequent measurements of these dose dilutions will be converted to k_{H} and k_{O} using the hypothetical constants.
- The differences in the fractional turnover rates generated from the subsequent dose dilution measurements will be compared to the theoretical difference of 0.1 and 0.13, respectively.

(3) Test-retest samples

- The identities of these samples will be blinded to the mass spectrometry laboratory.
- The re-test values will be compared to the initial values.
 - DLW Spot Urine Collection. Five percent of the DLW spot urine collection will be tested for Quality Control using one additional 2 mL aliquot.
 - 24-hour Urine Collection. For the 24-hour urine collection processed at SOLNAS Visit 2 (or SOLNAS Visit 4), staff will prepare and label three additional 2 mL aliquots for QC.

- Participants will not need to provide additional urine collections for SOLNAS QC for blood draw (plasma) for participants 60 yrs of age or older at visits 1 or 3.

8.3.2.2.2 DLW Spot Urine Collection Steps

At each time point when collecting the spot urine samples for the doubly labeled water analysis, follow these six steps:

1. Place the urine collection hat on the toilet (under the toilet seat) and ask participant to void into the hat. If he/she needs to have a bowel movement, he/she should remove the hat, have the bowel movement, and then replace the hat for the urine collection.
 2. Complete the appropriate section of the SOLNAS Visit forms.
 3. Attach appropriate labels to cryovials. For participants in the QC subsample, label the extra cryovials.
 4. Using a disposable transfer pipette, fill the labeled 2 mL Corning cryovial with 1.75 mL of urine specimen, cap with o-ring containing yellow caps, and store in freezer. Do not fill the cryovial to the top in order to allow for volume expansion upon freezing. For participants in the QC subsample, fill one additional labeled 2 mL Corning cryovials with 1.75 mL of urine specimen. Urine samples for the DLW analyses do not need to be centrifuged.
 5. Discard remaining urine by flushing down the toilet.
 6. Rinse and **dry** hat. **It is critical that the hat be thoroughly dried.**
- Refer to *SOLNAS Manual, 6.3.2.1.1 Handling Collection Problems* for guidelines on handling problems with delayed or insufficient urine collection.

8.3.2.2.3 Time 0 (Fasting) Blood Draw and Urine Collection

Before starting the visit procedures and before administering the DLW tracers, verify that the participant is eligible and has signed the *SOLNAS Consent* by reviewing *SOLNAS Visit 1* (or *SOLNAS Visit 3*).

Collect the **fasting spot urine** sample by following steps in the *SOLNAS Manual, 8.3.2.2.2 DLW Spot Urine Collection Steps*. Note the exact collection time on *SOLNAS Visit 1* (or *SOLNAS Visit 3*). Collect the fasting blood sample by following steps in the *SOLNAS Manual*. Please consider using a catheter to minimize multiple venipunctures.

8.3.2.2.4 . Time 2-Urine-Discard only (2 hours after DLW ingestion.)

Ask participant to produce urine, but do not collect urine in the hat. Urine can be flushed.

8.3.2.2.5 Time 3 Urine Collection (3 hours after DLW ingestion)

Collect the **3-hour spot urine** sample by following steps in the *SOLNAS Manual, 8.3.2.2.2 DLW Spot Urine Collection Steps*. The time does not need to be exactly at

three hours; however, note the exact collection time on *SOLNAS Visit 1* (or *SOLNAS Visit 3*).

8.3.2.2.6 Time 3 Blood Draw (3 hours after DLW ingestion, *for participants 60 years of age or older*)

Collect the **3-hour blood draw** for participants 60 years of age or older, noting the exact time on *SOLNAS Visit 1* (or *SOLNAS Visit 3*). **Coordinate the time to occur just after the 3-hour spot urine collection.** Note the exact time on the SOLNAS Visit form.

1. Follow general preparation for the participant (refer to *SOLNAS Manual, Section 8.5.2—Preparation for the Participants*)
 2. Ensure the participant understands that you will draw 2 teaspoons of blood from his/her arm.
 3. Following HCHS-SOL venipuncture procedures (*SOLNAS Manual, Venipuncture*), draw a single 10 mL lavender-dry EDTA tube 3 hours after the DLW ingestion. Attempt to draw a full tube. If the venipuncture is not successful or if you do not draw enough sample on the first occasion to fill the tube at least halfway, ask the participant for permission to attempt a blood draw a second time. If on the second attempt, less than 10 mL is collected, process the total amount collected. Refer to *SOLNAS Manual, Section 8.5.4.7—Deficient Serum and Plasma Samples*. Note: If the 3-hour spot urine collection is slightly delayed, then delay the 3-hour blood draw to immediately after that urine collection.
 4. Note any missing collections in the “Notes” section of *SOLNAS Visit 1*. Follow the procedures outlined in the *SOLNAS Manual, 8.6.7.1 Using the “Notes” Box’ on the SOLNAS Forms* and notify EINSTEIN-CC Study Coordinator.
 5. Check the identifying information on the form and the labels to make sure the form is correctly labeled.
- The 3-hour post-DLW blood draw sample does not need to be protected from light.
 - Bring the lavender tube to the blood processing area. Process the blood according to *SOLNAS Manual, 8.6 Blood Processing*.

8.3.2.2.7 4 Urine Collection (4 hours after DLW ingestion)

Collect the **4-hour spot urine** sample by following steps in the *SOLNAS Manual, 8.3.2.2.2 DLW Spot Urine Collection Steps*. The time does not need to be exactly at four hours; however, note the exact collection time on *SOLNAS Visit 1* (or *SOLNAS Visit 3*).

8.3.2.2.8 Instructions for the 24-hour Urine Collection

General instructions for the 24-hour urine collection

- Refer to *SOLNAS Manual, Section on 6.3.2.6 Explain and Provide Materials for 24-hour Urine Collection* for instructing participants how to conduct the 24-hour urine collection.

For participants who receive PABA (B-vitamin) tablets:

- Add boric acid powder to the urine collection bottles (boric acid supplied by EINSTEIN-CC).
 - Before giving the urine collection bottles to participants, add 2.0 gram of boric acid powder to each urine collection bottle. Measure the boric acid powder using a gram scale. If a gram scale is not available, add **0.5 level measuring teaspoon** of boric acid powder to each bottle*. Use standard safe laboratory practices by wearing a mask and gloves when adding the boric acid powder to the urine collection bottles. Boric acid is a weak acid, although it can be slightly irritating if inhaled.

* The boric acid may be weighed or measured using household measuring spoons labeled, “for boric acid use only.” When handling the boric acid, wear disposable gloves and preferably a disposable mask. Even though boric acid is a safe preservative, take precautions to avoid skin contact or inhalation.
- Place two stickers on each urine collection bottle: one sticker that reads “Leave powder inside” and a second sticker that reads “Remember...take the PABA (B-vitamin) tablets” (stickers supplied by EINSTEIN-CC).
- Apply a “Bottle #1” sticker to one of the collection bottles, and apply a “Bottle #2” sticker to the other bottle (stickers supplied by EINSTEIN-CC). Alternatively, a Sharpie® pen may be used to write “#1” on one collection bottle and “#2” on the other collection bottle.
- Use SOLNAS labels to identify the collection bottles: 24-hr urine container label and an extra label from visit 1. Alternatively, write the participant’s name on each bottle with a Sharpie® pen.
- With a Sharpie® pen, mark the 2,000 mL mark on each bottle.
- Weigh each 24-hour urine collection bottle after adding the boric acid inside the bottle, after placing the three stickers on the outside of the bottle, and after labeling or writing on each bottle with the participant’s name.
 - Follow the scale manufacturer’s instructions for calibrating the scale.
 - Weigh each 24-hour urine collection bottle and transcribe the weight on the *SOLNAS 24-Hour Urine Collection Worksheet for Staff*. *Transcribe the weights to the nearest 2grams. For example, 28 grams and 26 grams.*

For participants who do not receive PABA (B-vitamin) tablets:

- **Contact :**
- **Maria Martello: 718-430-3189 (off), 347-491-8704 (cell);**
maria.martello@einstein.yu.edu;

- **Dr. Yasmin Mossavar-Rahmani: 718-430-2136: yasmin.mossavar-rahmani@einstein.yu.edu**

8.4 SOLNAS Visit 2 (or SOLNAS Visit 4) (Day 13)

8.4.1 General Blood and Urine Sampling and Aliquot Schedule and Quality Control (SOLNAS-modified)

8.4.1.1 Sampling and Aliquot Schedule

SOLNAS Visit 2 (Or SOLNAS Visit 4) General Blood & Urine Sampling & Aliquot Schedule

TIME	SAMPLE	ALIQUOT	QC
Time 0 (Fasting)	Spot urine Sample in hat	One, 1.75 mL (One, 2 mL cryovial) DLW-Baylor	One, 1.75 mL (One, 2 mL cryovial) DLW-Baylor
Time 0 (Fasting)	Blood Royal Blue, one 6 mL COLLECT <u>BEFORE</u> LAVENDER DRY EDTA	Four 0.5 mL (minimum) Serum (Four, 2 mL cryovials) Central Lab	Four 0.5 mL (minimum) Serum (Four, 2 mL cryovials) Central Lab
Time 0 (Fasting)	Blood Lavender (dry EDTA), one 10 mL COLLECT <u>AFTER</u> ROYAL BLUE SERUM	One 1.5 mL Plasma (DLW-Baylor) if participant is over 60 years old <u>and</u> Three 0.5 mL (minimum) Plasma for Central Labs (Four, 2 mL cryovials)	Baylor - No specimen Three 0.5 mL (minimum) Plasma for Central Labs (Three, 2 mL cryovials)
Received from participant	24-hour urine collection	Baylor – No specimen Three, 1.5 mL (Three, 2.0 mL cryovials) Central Lab (to send to Fred Hutch, Univ. of Mich. and Fairview)	Baylor - No specimen Three, 1.5 mL (Three, 2.0 mL cryovials) Central Lab (to send to Fred Hutch, Univ. of Mich. & Fairview)
Time 1 (One hour after Time 0)	Spot urine Sample in hat	One, 1.75 mL (One, 2 mL cryovial) DLW-Baylor	One, 1.75 mL (One, 2mL cryovial) DLW-Baylor

8.4.1.2 Quality Control (QC) Samples for SOLNAS Visit 2 (or SOLNAS Visit 4) -

Refer to *SOLNAS Manual*, Section on 8.2.7 *Quality Control (QC) for Laboratory Analysis* for general blood and urine QC information.

Each FC will collect QC aliquots by convenience sampling from the first participant in the first week of each month until the specified number of participants have had QC specimens collected. For an SOLNAS QC participant at SOLNAS Visit 2 (or SOLNAS Visit 4), all urine QC aliquots must be from the same participant, and the same participant must donate a second royal blue tube and have a full 10 mL EDTA tube collected.

Labels. For each QC participant, use one additional SOLNAS participant label set for the QC aliquots. For SOLNAS Visit 2 (or SOLNAS Visit 4) carry forward use of the label sets stored with the participant chart from SOLNAS Visit 1 (or SOLNAS Visit 3).

Blood. Collect one additional royal blue tube (and lavender tube if the first one collected is not full). Aliquot serum and plasma into 2 mL vials labeled with the Lab ID number reserved for the QC samples.

Urine:

- For spot urine collections at SOLNAS Visit 2 (or SOLNAS Visit 4), collect one additional 2 mL aliquot per SOLNAS QC participant at each time point. Open a second set of labels for the QC samples.
- For the 24-hour urine collection, Visit 2 (or SOLNAS Visit 4), centrifuge and collect three additional 2 mL aliquots per SOLNAS QC participant*.

8.4.2 One Day Before SOLNAS Visit 2 (or SOLNAS Visit 4) (Day 12)

Refer to *SOLNAS Manual*, Section 6.4.2.2 *Pre-Visit 2 Reminder Call* and Section 6.4.2.2.1 *Review Instructions for 24-hour Urine Collection (Day 13)*.

8.4.3 Day of SOLNAS Visit 2 (or SOLNAS Visit 4) (Day 13)

8.4.3.1 Before the Participant Arrives

1. Access *SOLNAS Visit 2* (or *SOLNAS Visit 4*) in DMS.
2. Enter the HCHS-SOL (SOLNAS) identification number on the SOLNAS Visit 2 form.
3. Insert the labeled *SOLNAS Visit 2* form and the label set carried forward from Visit 1 into the participant's file (or *SOLNAS Visit 4*). Enter the participant's Lab ID number in the appropriate place on the SOLNAS Visit 2 form.
4. Using the appropriate labels from the specimen label set, label one royal blue serum tube and one dry lavender EDTA tubes and arrange the tubes in a test tube rack.

5. Label seven 2 mL cryovials (eight if the participant is over 60 years of age) with the appropriate serum/plasma labels from the specimen label set.
6. Label the two 2 mL cryovial tubes (with rubber O-ring for spot urines collections)..
7. Label the three 2 mL cryovial tubes (for 24-hour urine collections).

8.4.3.2 During the Visit (Overview)

1. Verify that the *SOLNAS Visit 2 Eligibility Form* has been completed and that before the blood draw is taken that the participant has been fasting for twelve hours.
2. Review with the participant the blood and urine visit procedures for SOLNAS Visit 2 (or SOLNAS Visit 4).
3. Receive the 24-hour urine collection from participant (*SOLNAS Manual, 8.4.3.2.1, Receive the 24-hour Urine Collection From Participant*).
4. Collect the Time 0 (fasting) spot urine sample (*SOLNAS Manual, 8.4.3.2.2 Time 0 (Fasting) Urine Collection*).
5. Draw the Time 0 (fasting) blood sample (*SOLNAS Manual, 8.4.3.2.3 Time 0 (Fasting) Blood Draw*).
6. Collect the Time 1 (1-hour) spot urine sample (*SOLNAS Manual, 8.4.3.2.4 Time 1 Urine Collection (1 hour after Time 0 [fasting] urine collection)*).
7. Process the 24-hour urine collection (*SOLNAS Manual, 8.4.3.2.5 24-hour Urine Collection Processing*).

8.4.3.2.1 Receive the 24-hour Urine Collection From Participant

1. Verify that the participant's name on the bottle is the name of the participant. Place the collection container(s) in the refrigerator until after the Time 0 (Fasting) Urine Collection and Time 0 (Fasting) Blood Draw have been completed. Refer to *SOLNAS Manual, 8.4.3.2.5 24-hour Urine Collection Processing* for the specific steps for processing the 24-hour urine collection.
2. Attach a participant member ID label to *Record sheet for 24-hour Urine Collection (Instructions for 24-hour Urine Collection, given at SOLNAS Visit 1)*.
3. Review the *Record sheet for 24-hour Urine Collection* with the participant to ensure all pertinent questions have been answered. The goal is to gather information about missed or contaminated urine collections.
4. The following responses on the participant's *Record sheet for 24-hour Urine Collection* indicate the potential of a missed, spilled, or contaminated 24-hour urine collection:
 - 'Yes' response to Qx. 1: "Did you miss any urine collections?"
 - 'No' response to Qx. 4: "If you were away from home, were you able to collect your urine?"
 - 'No' response to Qx. 5: "Were you able to collect your urine during the night?"

- ‘Yes’ response to Qx. 6: “Did you have any diarrhea during the collection period.”
 - ‘Yes’ response to Qx. 7: “Did you spill any urine when pouring it into the bottle.”
5. If the participant indicates that he/she missed any urine collections, use Qx. 2 – “If you missed urine collections, how many did you miss?” on the *Record sheet for 24-hour Urine Collection* to note the total number of collections the participant missed.
 6. For participants who have indicated a missed, spilled, or contaminated 24-hour urine collection, follow the procedures described in the *SOLNAS Manual, Section 8.6.7.1 Using the “Notes” Box’ on the SOLNAS Forms* and notify EINSTEIN-CC.
 7. Place the *Record sheet for 24-hour Urine Collection* in the participant’s SOLNAS file. complete PABA-related questions on *SOLNAS Visit 2 (or SOLNAS Visit 4)*.

8.4.3.2.2 Time 0 (Fasting) Urine Collection

Collect the **fasting spot urine** sample following the steps outlined in *SOLNAS Manual, Section 8.3.2.2.2--DLW Spot Urine Collection Steps*. Note the exact time on *SOLNAS Visit 2 (or SOLNAS Visit 4)*.

8.4.3.2.3 Time 0 (Fasting) Blood Draw

Collect the **fasting blood draw**.

1. Verify that the participant has been fasting for twelve hours.
2. Follow general preparation for the participant (refer to *SOLNAS Manual, Section 8.5.2—Preparation for the Participants*).
3. Ensure the participant understands that you will draw 1-2 Tablespoons of blood from his/her arm.
4. Follow the WHI venipuncture procedures (refer to *SOLNAS Manual, Section 8.5.3—Venipuncture*).
 - Draw the royal blue tube(s) first, followed by the lavender tube.
The reason that the royal blue tubes are drawn first is because they are preservative-free for trace element analysis. By drawing them first, the risk is lessened for contamination from the lavender EDTA tube.
 - Attempt to draw the full set of blood collection tubes. If you do not draw enough sample on the first occasion, follow the procedures in *SOLNAS Manual, Section, 8.5.4.7—Deficient Serum and Plasma Samples*. The remainder of SOLNAS Visit 2 may continue without the blood draw.
 - All of these samples must be protected from heat and light. Prepare aluminum sleeves for all of the tubes. Samples from these tubes will be analyzed for carotenoids, folate, and other nutrients which break down in white light. The aluminum foil cover will help protect the blood from light and prevent deterioration of the carotenoids.

5. Check the identifying information on the form and the labels to make sure that all are correctly labeled.

8.4.3.2.4 Time 1 Urine Collection (1 hour after Time 0 [fasting] urine collection)

Collect the **1-hour spot urine** sample following the steps outlined in *SOLNAS Manual, Section 8.3.2.2.2—DLW Spot Urine Collection Steps*. The time does not need to be exactly at one hour; however, note the exact time on *SOLNAS Visit 2* (or *SOLNAS Visit 4*).

8.4.3.2.5 24-hour Urine Collection Processing

The 24-hour urine collection may be processed between other visit tasks, as time allows. The 24-hour urine collection is measured by weight by using a digital scale. Record weight in grams to the nearest 2 grams. Follow these steps for processing the 24-hour urine collection:

1. Weigh each urine collection bottle before removing any urine for processing. Be sure that the scale is calibrated according to the manufacturer's instructions. Transcribe the weight on the *SOLNAS 24-Hour Urine Collection Worksheet for Staff*. Complete the *SOLNAS 24-Hour Urine Collection Worksheet for Staff* to calculate the total weight of the 24-hour urine collection.
2. Document the total weight of the 24-hour urine collection on *SOLNAS Visit 2 and Visit 4 (VTE)*. Staff do not need to inspect the urine for color or degree of cloudiness. The lab will note any questionable samples.
3. Mix the 24-hour urine collection in its container thoroughly by inverting the tightly capped container ten times. If the participant brings in more than one 3-liter container, mix the contents of the containers together using the steps outlined below:
 - a. **If the total volume of the urine collection is less than 3 liters:**
Use a plastic funnel to transfer all contents to one bottle. Cap tightly and invert ten times.
 - b. **If the total volume of the urine collection is greater than 3 liters:**
Use a plastic funnel to carefully transfer the contents from both collection bottles to a 2.5 gallon container. Cap tightly and invert ten times. Pour a portion of the mixed urine back into one of the 3 liter collection bottles for aliquotting.
4. Pour (or use a disposable transfer pipette) and centrifuge two 9 mL urine samples of the well mixed collection using the 10 mL centrifuge tubes provided for urine centrifugation. Centrifuge the 24-hour urine for 5 minutes at 1,300 xg. Refer to *SOLNAS Manual Section 8.6.2—Operating the Refrigerated Centrifuge* for instructions on how to obtain 1,300xg.
 - The intent of 24-hour urine centrifugation is to exclude particulates, but a small amount of sediment in the sample is acceptable.

5. Attach the appropriate labels to each cryovial.
6. Use a disposable transfer pipette to aliquot the centrifuged urine by placing:
 - 1.75 mL of urine into each of three labeled 2 mL cryovials and cap with o-ring containing green caps.

For QC samples, prepare:

- 1.75 mL of urine into each of three additional 2 mL cryovials and cap with green caps.

Be careful not to overfill the cryovials because urine volume will increase upon freezing and the cryovials may crack.

7. Place labeled cryovials in the -70 degree Centigrade freezer.

8.5 Blood Draw Specifics

8.5.1 Preparation of the Blood Drawing and Processing Areas for All SOLNAS Visits

Ensure the blood drawing and blood processing areas are equipped with the proper supplies.

8.5.2 Preparation for the Participants

SOLNAS specifics:

- Each participant must have signed the SOLNAS Consent authorizing the FC to draw blood before you can draw his/her blood.
- Ensure the participant understands the general aspects of blood collection as detailed in the SOLNAS Consent.
- Verify with the participant that he/she has been fasting for 12 hours at SOLNAS Visit 2. If needed, refer to *SOLNAS Manual, Section 7.4.4.1 – Directions for Staff When Participants Not Fasted*.

Generalities

1. Blood drawing is standardized to the sitting position. Whenever possible, have the participant in the sitting position for five minutes immediately before venipuncture.
2. Review safety issues with the participant. Ask participant if he/she has had any problems with blood drawing in the past.
 - **If the participant reports that he/she bleeds or bruises easily.** If he/she has had any problems with excessive bleeding or bruising at a venipuncture site, draw his/her blood only if approved by a Clinic Manager, FC physician or Principal Investigator (PI).
 - **If the participant reports that he/she has ever been told he/she has a disorder related to blood clotting or coagulation or is taking any anticoagulants or**

aspirin. Continued bleeding may be a complication if the participant has any problems related to blood clotting or coagulation. To prevent bleeding and preserve the vein, you may need to apply pressure to the site for an extended period of time after you draw the blood. Stay with the participant to ensure the bleeding has stopped. Use Coban self-adhis/herent wrap, or the equivalent, to keep in place for 10-15 minutes over the blood draw site.

- **If the participant has ever experienced fainting spells while having blood drawn.** If he/she has experienced fainting spells during venipuncture, ask his/her the frequency of fainting spells. Proceed with the venipuncture if he/she has fainted only once before. If he/she advises that he/she frequently faints, consult the Clinic Manager, FC physician or PI before attempting the venipuncture. Provide smelling salts, amyl nitrate, basin, or cold cloth, if needed. Have orange juice or fruit juice available to offer to the participant. It is advisable to have the participant lie down initially. Note the condition in the participant's file, and perform future blood draws while he/she is lying down. It is also advisable to loosen any tight clothing before drawing the blood, especially clothing around the neck. (See also *Section 7.4.4.6. Fainting.*)
- **If the participant have had a radical mastectomy or other surgery where lymph nodes were removed from their armpits.** If they have, blood should not be collected from the arm where this has occurred.
- **If the participant have ever had a graft or shunt for kidney dialysis.** If they have, blood should not be collected from the arm where this has occurred.

8.5.3 Venipuncture

In general, refer to *WHI Manuals: Volume 2 – Procedures; Section 8.5.3 – Venipuncture.*

SOLNAS specifics:

- Refer to *SOLNAS Manual, Section 8.3—SOLNAS Visit 1 (or SOLNAS Visit 3)* and *SOLNAS Manual, Section 8.4—SOLNAS Visit 2 (or SOLNAS Visit 4) (Day 13)* for the SOLNAS sampling and aliquot schedule.
- Complete the remaining relevant sections of *Form – SOLNAS Visit 1* (for SOLNAS Visit 1),– *SOLNAS Visit 2* (for SOLNAS Visit 2),– *SOLNAS Visit 3* (for SOLNAS Visit 3), or– *SOLNAS Visit 4* (for SOLNAS Visit 4). **Note a missing blood draw in the “Notes” section of the SOLNAS Visit form.** Follow the procedures outlined in the *SOLNAS Manual, Section 8.6.7.1 Using the “Notes” Box’ on the SOLNAS Forms* and notify EINSTEIN-CC.
- Deliver the blood sample tube(s) and *SOLNAS Visit 1* (for SOLNAS Visit 1) or *SOLNAS Visit 2* (for SOLNAS Visit 2) to the blood processing area. Do the same for SOLNAS Visits 3 and 4 for the reliability subsample, using *SOLNAS Visit 3* or *SOLNAS Visit 4*, respectively.

8.5.3.1 Wash Hands and Put on Gloves

Wash your hands with soap and water before every blood draw and put on pair of disposable plastic latex gloves.

8.5.3.2 Assemble the Vacutainer Holder

1. Attach the needle to the vacutainer holder.
2. Place the royal blue-stoppered tube in the vacutainer holder being careful not to break the vacuum

8.5.3.3 Identify Venipuncture Site

1. Position the participant's arm on the drawing table. Extend the arm toward you, palm up. Use a padded cushion under his/her elbow for comfort, if appropriate.
2. Wrap the tourniquet around the arm three to four inches (7.5 to 10.0 cm) above the venipuncture site.

A tourniquet is used to increase venous filling. It makes the veins more prominent and easier to enter. **PRECAUTIONS WHEN USING A TOURNIQUET:** The tourniquet should be on the arm for the shortest time possible. **Never** leave the tourniquet on for longer than two (2) minutes at a time. To do so may result in hemoconcentration or a variation in blood test values. (It was documented [Clinical Chemistry, 20:1513-1519, 1974] that changes in venous occlusion from 1 to 3 minutes led to a change in various blood components including increase in total lipids (4.7%) and cholesterol (5.1%) and decrease in his/her other components.) If you must apply a tourniquet for the preliminary vein selection, release and reapply it after a wait of one minute. If the participant has a skin problem, put the tourniquet over the participant's shirt or use a piece of gauze or paper tissue so as not to pinch the skin.

3. DO NOT ask the participant to make a fist.
4. Identify a vein. Use the antecubital site of either arm as first choice. The median cubital vein is the one used most frequently. If the venipuncture of this vein is unsuccessful, use the cephalic and basilic veins as the next appropriate choices, followed by veins on the back of the hand. Palpate and trace the path of veins several times with the index or middle finger. Unlike veins, arteries pulsate, are more elastic and have a thick wall. Thrombosed veins lack resilience, feel cord-like and roll easily. If you cannot readily see superficial veins, ask the participant to open and close his/her fist. Lowering the lower arm over the arm of the chair will allow the veins to fill to capacity. Identify the best available vein.
5. Palpate the vein. If you do not feel a vein, try another arm or site (see *Section 8.5.4.4—Difficult-to-Identify Venipuncture Sites*).
6. Cleanse the vein site with the alcohol prep using a circular motion from the center to the periphery.

7. Allow the area to dry to prevent possible hemolysis of the specimen and a burning sensation to the participant when you perform the venipuncture.
8. If venipuncture becomes difficult, you may need to touch the vein again with your hand. If this happens, cleanse the site again with alcohol.

8.5.3.4 Perform Venipuncture

1. Explain the procedure to participant; for example, "I will be drawing a blood sample from your arm. You will probably feel a small prick when I insert the needle."
2. Grasp the participant's arm firmly, using your thumb to draw the skin taut. This anchors the vein. The thumb should be one or two inches (2.5 or 5.0 cm) below the venipuncture site.
3. Enter the vein in a smooth continuous motion with the needle bevel upward and parallel to the vein. Use a straight stab; do not poke around.
4. Make sure the participant's arm is in a flat and stable position and the hand is relaxed.
5. Grasp the flange of the vacutainer holder and push the tube forward until the butt end of the needle punctures the stopper, exposing the full lumen of the needle.
6. Remove the tourniquet after blood is flowing into the tube. If no blood enters the tube, the needle may not be positioned in the vein. See *Section 8.5.4—Blood Collection Problems* for possible action.
7. Keep a constant, slight forward pressure (in the direction of the needle) on the end of the tube. This prevents release of the shutoff valve from stopping blood flow. Do not vary pressure or reintroduce pressure after completion of the draw.
8. Draw each vacutainer tube in order specified. Fill each tube as completely as possible, that is, until the vacuum is exhausted and the blood flow stops. If a vacutainer tube fills only partially, remove the vacutainer tube and attach another without removing the needle from the vein.
9. When the blood flow ceases, remove the tube from the holder. The shutoff valve recovers the point, stopping blood flow until you insert the next tube (if necessary).
10. Draw the required blood tubes and place the lavender-stoppered tubes into sleeves of aluminum foil to protect from the light.
11. Gently invert the lavender -stopped vacutainer tube several times to ensure proper mixing of blood with the anticoagulants before placing the tubes in the rack. Do not invert the royal blue-stoppered tube.
12. If not already done, label the visit form and each tube with a blood sample label immediately after you complete the blood draw. (You can best do this while the participant is holding the gauze pad over the venipuncture site; see the steps below.)

8.5.3.5 Bandage the Arm

1. Under normal conditions:
 - To remove the needle, lightly place clean gauze over venipuncture site. Remove the needle quickly and immediately apply pressure to the site with a

- gauze pad. Discard needle with its cap into a needle box. If using a syringe with needle, dispose entire set-up into disposable container.
- Have the participant hold the gauze pad firmly for one to two minutes to prevent a hematoma. Ask the participant to keep his/her arm extended. Bending his/her arm at the elbow increases the risk of developing a hematoma.
 - Apply an adhesive or gauze bandage over the venipuncture site after making sure that blood flow has stopped.
2. If the participant continues to bleed:
 - Apply pressure to the site with a gauze pad. Keep the arm elevated until the bleeding stops.
 - Wrap a gauze bandage tightly around the arm over the pad.
 - Tell the participant to leave the bandage on for at least 15 minutes.
 3. Wash your hands.
 4. Complete the remainder of the “Blood Collection” section of *the visit form*.
 5. Deliver the blood sample tubes to the blood processing area.

8.5.4 Blood Collection Problems

8.5.4.1 Directions for Staff When Participants Are Not Fasted

For SOLNAS Visit 2, do not draw the blood sample if the participant has not been fasting for at least 12 hours (water, black coffee or tea is OK). Note: A participant is considered to be non-fasting if he/she has consumed food, or caloric beverages within the 12 hours before the blood draw.

If he/she is not fasting and is:

- Willing to wait at the FC until the required number of hours of fasting has occurred, proceed with the blood draw at that time.
- Not willing to wait at the FC until the required number of hours of fasting has occurred, ask him/her if he/she is willing to reschedule his/her appointment.

If he/she is:

- Willing to reschedule - reschedule an appointment for the fasting blood draw and indirect calorimetry, and then proceed with the remaining SOLNAS Visit 2 tasks. *Note: The Time 0 and Time 1 urine spot urine collection at SOLNAS Visit 2 **need not** be fasting.* Complete the appropriate section of the *SOLNAS Visit 2 Participant Update Note scheduling of indirect calorimetry must occur 20 days post- visit 1.*
- Not willing to reschedule - proceed with the remaining SOLNAS Visit 2 tasks. Complete the appropriate section of the *SOLNAS Visit 2 Participant*

Update and follow the procedures outlined in the SOLNAS Manual, Section 8.6.7.1—Using the “Notes” Box’ on the SOLNAS Forms and notify the EINSTEIN-CC Study Coordinator.

8.5.4.2 Handling Participants Who Are Extremely Apprehensive About Having Blood Drawn

- Even though blood drawing is standardized for the sitting position, you may ask an extremely apprehensive participant to lie down, if there is a bed available in the FC.
- Do not force the participant to have blood drawn under any circumstances. It may help to explain to the participant that the blood drawing is designed to be as painless as possible. Sometimes it helps to let the participant go on with another part of the visit. It may also be helpful to have the participant relax in the blood drawing chair just so that you can check the veins in his/her arms, without actually drawing blood. If the participant has "good veins" you can reassuringly say, "Oh, you have good veins; there should be no problem." You may also consider using a butterfly needle to perform the draw if the participant is apprehensive. The butterfly needle is a thinner, smaller needle and may be less painful to the participant.
- Have the participant sit upright with jacket or sweater removed and with the sleeves rolled up to expose the antecubital fossa (elbow).
- Give the participant enough time to feel comfortable both before and after the blood collection. In many cases the most memorable part of the experience for the participant is the blood collection process, the contact with the staff person who draws the blood, and the staff person's general attitude and competence.
- Reassure participants who are concerned about the volume of blood that the total amount of blood drawn is about two teaspoons at Visit 1 (for participants who are 60 years of age or older) and about 2 tablespoons of blood at Visit 2. Assure the participants that they donate up to 10 times as much blood (450 ml) when they donate a pint of blood.

8.5.4.3 Special Consideration for Drawing Blood in the Elderly

The elderly pose some special blood drawing problems due to fragile and small veins, especially if the samples are drawn during a fasting period. The system of drawing blood by using vacuum tubes can increase this problem, causing veins to collapse due to high pressure exerted by the vacuum tubes. Steps outlined in *Section 8.5.4.5—Difficult Venipuncture* below may help to lessen some of the problems.

An important point in drawing blood is that the tourniquet must not occlude arterial flow; otherwise the problem of veins collapsing during the venipuncture may be accentuated. By using a syringe rather than a vacuum tube, you can control the pressure and reduce this problem. When using a smaller needle (for example, 22 gauge 1"), there is less chance of blowing (hematoma formation) a fragile vein.

8.5.4.4 Difficult-to-Identify Venipuncture Sites

1. Determine if the vein is difficult to identify, which may occur, if:
 - The palpitated vein feels small or rolls.
 - The participant has been stuck once already.
2. If the vein is difficult to find, check the back of the hand and forearm for venipuncture sites with larger veins. You can also try one or more of the following vein-dilation methods:
 - Be sure the room is not too cool.
 - Hot pack the venipuncture site with warm, wet towels for 3-5 minutes.
 - Have the participant wash his/her hands in warm water for 3-5 minutes.
 - Have the participant dangle his/her arm at his/her side with the tourniquet in place for one minute.
 - Use the blood pressure cuff as a tourniquet by pumping the pressure to 60-80 mm Hg.
3. If the vein is small, try a disposable syringe and 22-gauge needle or a butterfly initially.
4. Finish the venipuncture following the procedures outlined above.

8.5.4.5 Difficult Venipuncture

In general, refer to *WHI Manuals: Volume 2 – Procedures; Section 11.2.6.3 – Difficult Venipuncture*.

SOLNAS specifics:

- The participants may be dehydrated having fasted for 12 hours (except water or black coffee or tea) in preparation for SOLNAS Visit 2. Encourage the participants to drink water liberally during the fast. If this is a particular problem at your FC, consider offering the participants water as they arrive at the visit.
- If venipuncture for SOLNAS Visit 1 (or SOLNAS Visit 3) fails with the second attempt or second technician, do not attempt again. Proceed with the remaining tasks for SOLNAS Visit 1 (or SOLNAS Visit 3). **Note the missing blood draw in the “Notes” section of the SOLNAS Visit form.** Follow the procedures outlined in the *SOLNAS Manual, Section 8.6.7.1 Using the “Notes” Box’ on the SOLNAS Forms* and notify EINSTEIN-CC.
- If venipuncture for SOLNAS Visit 2 (or SOLNAS Visit 4) fails with the second attempt or second technician, ask the participant if he/she is willing to return at another time for a venipuncture. (Refer to *SOLNAS Manual, Section 7.4.4.7 - Deficient Serum and Plasma Samples*). Then proceed with the remaining tasks for SOLNAS Visit 2 (or SOLNAS Visit 4).

Generalities

If you performed the venipuncture and a blood sample is not forthcoming, you may find the following manipulations helpful:

- If there is a sucking sound, turn the needle slightly or lift the holder to move the bevel away from the wall of the vein.
- If no blood appears, move the needle slightly in hopes of entering the vein. Do not probe. If unsuccessful, release the tourniquet and remove the needle. A second attempt can be made on his/her arm.
- If the vein rolls, withdraw the needle slightly without coming back through the skin and try a second thrust.
- If the vein collapses, remove the vacutainer tube, call another staff person to reapply the tourniquet, ask the participant to open and close fist, and then reinsert tube. If still no blood appears in the tube, stop the procedure and use techniques in *Section 8.5.4.4—Difficult-to-Identify Venipuncture Sites* above.

If this is a problem on a particular participant, try using a butterfly needle rather than a vacutainer needle to draw the blood.

The participants come to the FC visit fasting for 12 hours (nothing but water) and may be dehydrated. Encourage the participants to drink water liberally during the fast. If this is a particular problem at your FC, consider offering the participants water as they arrive at the visit.

- Loosen the tourniquet. You may have applied it too tightly, thereby stopping the blood flow. Reapply the tourniquet loosely. If the tourniquet is a Velcro type, quickly release and press back together. Be sure, however, that the tourniquet remains on for no longer than one minute at a time.
- Remove the tube and insert a second vacutainer tube. On rare occasions, the vacutainer tube may have lost its vacuum and thus may not draw blood into the tube even when the needle is positioned properly in the vein.
- If another technician is available, allow the other technician to attempt a venipuncture.
- If venipuncture fails with the second technician, request that the participant return at another time for a successful venipuncture. (See *Section 8.5.4.7—Deficient Serum and Plasma Samples*)
- Reassure the participant that the inability to obtain a clean venipuncture is not any sign of a medical problem on his/her part.
- No single staff member should attempt more than two venipunctures on the same participant at any single visit.

8.5.4.6 Fainting

If participant shows signs of fainting (loss of color in the face, unusual sweating on forehead) or reports feeling dizzy:

- Finish drawing blood if possible but do not proceed if participant is clearly in trouble.
- Have participant lay his/her head on a table.
- Continue talking to participant to assess level of consciousness.
- Have participant lie down for 5-10 minutes after removing the needle; apply pressure on vein to prevent injuries from possible fall or seizure.
- Apply cool compress to his/her forehead.
- Have participant put a pillow or cushion under his/her knees.

If the participant faints:

- Withdraw the needle immediately.
- Apply pressure at the venipuncture site.
- Call for help.
- Apply a cool compress to his/her forehead.
- Use an ammonia capsule, if needed, by crushing the ampule and waving it under his/her nose for a few seconds.
- Once recovered, have the participant lie down on an exam table until he/she feels better.
- Take blood pressure readings to assess his/her recovery, if necessary.
- Offer the participant water, juice and food.

Note: If you do not collect a blood sample, reschedule the blood draw for another day. Realize that the participant might be disoriented, embarrassed, or irritable and needs reassurance and attention. Recognize also that this incident may have an impact on future blood drawing and possibly on study adherence and must be handled well. Make a note of the difficulty in the participant's file for future reference.

8.5.4.7 Deficient Serum and Plasma Samples

Deficient blood from venipuncture:

- In general: If the venipuncture is not successful (no blood obtained) ask the participant for permission to attempt a second blood draw. Do not attempt a third time.
- Blue tube: If you do not get a full royal blue-stoppered vacutainer of blood (for serum), you should try to collect an additional half-tube immediately, with permission. After centrifuging the tubes, you can combine the serum from the half-tube with the serum from the first incompletely filled royal blue-stoppered tubes.
- Lavender tube: If you do not draw enough sample on the first occasion to fill the lavender tube at least halfway, attempt a blood draw a second time, with permission. If you have two partially filled lavender tubes, centrifuge each one and

aliquot the plasma per procedures described in the *SOLNAS Manual, Section 8.6.3.1—Preparation of Blood Cryovials*.

Deficient plasma or serum after centrifugation:

- Do not draw additional blood if plasma or serum is inadequate after centrifuging the blood samples.

8.6 Blood Processing

8.6.1 Blood Sample Handling and Processing: Time limits

Procedures and time limits for blood processing are listed below. See also *Figure 8.3 - Guidelines for Blood Processing*.

1. Stand time:
 - Allow the royal blue-stoppered tubes to stand for at least 30 minutes at room temperature. The 30-minute waiting time is necessary to allow an adequate clot to form. If you frequently find fibrin clots in the centrifuged serum samples, try letting the samples sit for 45 minutes before centrifugation.
 - **Always protect blood samples for carotenoids (in lavender-stoppered tubes) from natural and fluorescent white light. Store samples in covered containers or tubes.**
2. Refrigerate time:
 - Refrigerate the royal blue (after clotting) and 10 mL lavender tubes if it is not possible to centrifuge the samples within one hour after collection.
 - Set the samples in wet ice if a refrigerator is not available.
3. Centrifuge time:
 - Make every attempt to centrifuge the tubes between 30-45 minutes after collection. Set a timer, if necessary, as a reminder when the collected blood is ready for centrifugation.
 - Centrifuge the royal blue and lavender tubes within two hours of collection. These tubes may be centrifuged at the same time.
4. Aliquot time:
 - Aliquot the serum and plasma into the cryovials within 15 minutes after centrifugation.
5. Freeze time:
 - Freeze all aliquoted specimens within two hours of collection.

Figure 8.3
Guidelines for Blood Processing

Blood Collection Tube	Minimum Stand Time at Room Temp.	Maximum Stand Time at Room Temp. (before refrigeration)	Min. Time Post-blood Collection to Begin Centrifugation	Max. Time to Begin Centrifugation	Centrifuge Time	Post-Centrifugation Aliquot Time	Freeze Time Post Collection
Royal blue (6 ml)	30 min.	1 hr	≥ 30 min	2 hours post collection	10 minutes	15 minutes post-centrifugation	Within 2 hours post collection
Lavender (10 ml)	0 min	1 hr	Immediately post-collection	2 hours post-collection	10 minutes	15 minutes post-centrifugation	Within 2 hours post-collection

8.6.2 Operating the Refrigerated Centrifuge

1. Set the centrifuge temperature at 15°C.
2. Load the rotor, being careful to place balanced tubes in buckets directly opposite to each other. If necessary, fill an empty tube with water, insert stopper and use as a balance for a blood sample tube. Be sure there is enough clearance for the tube and stopper when the buckets are in horizontal position.
3. Close the centrifuge cover and lock.
4. Centrifuge for ten minutes with brake off at a speed setting that will yield a relative centrifugal force (RCF) of 1,300 x g.

You can obtain the desired RCF of 1,300 x g on various centrifuges by adjusting the revolutions per minute (RPM). You need to do this because the RPM setting of a centrifuge does not equal the RCF. The following equation shows the calculation of RCF:

$$RCF = (1.118)(10^{-5})(r)(n^2)$$

where r = rotating radius in centimeters (the distance from the center of the centrifuge rotor to the middle of the sample tube when the tubes in the swinging buckets are at the horizontal position) and n = revolutions per minute.

Alternately, use *Figure 7.4 – Nomogram for Calculating RCF* by lining up the radius in cm and RCF = 1,300 x g with a straight edge and reading the point at which the straight edge intersects the scale for RPM. For example, to achieve RCF of 1,300 x g with a centrifuge that has a radius of 10 cm, a straight line from these points on *Figure x.7.4* intersects the RPM scale at 3,400 RPM.

5. Note the time you started the centrifuge.

6. The centrifuge will stop automatically at the prescribed time. Allow the centrifuge to come to a complete stop before opening the cover. Do not use the brake to slow down the centrifuge. Using the brake may cause the RBCs to become resuspended in the plasma.
7. Remove the blood sample tubes one at a time and put in the test tube rack. Be careful not to tip the tubes and disturb the red cell layer. Re-centrifuge any tube containing red blood cells in the serum or plasma.
8. Consult the Centrifuge Service manual for other guidelines and for troubleshooting.

Equipment Quality Assurance

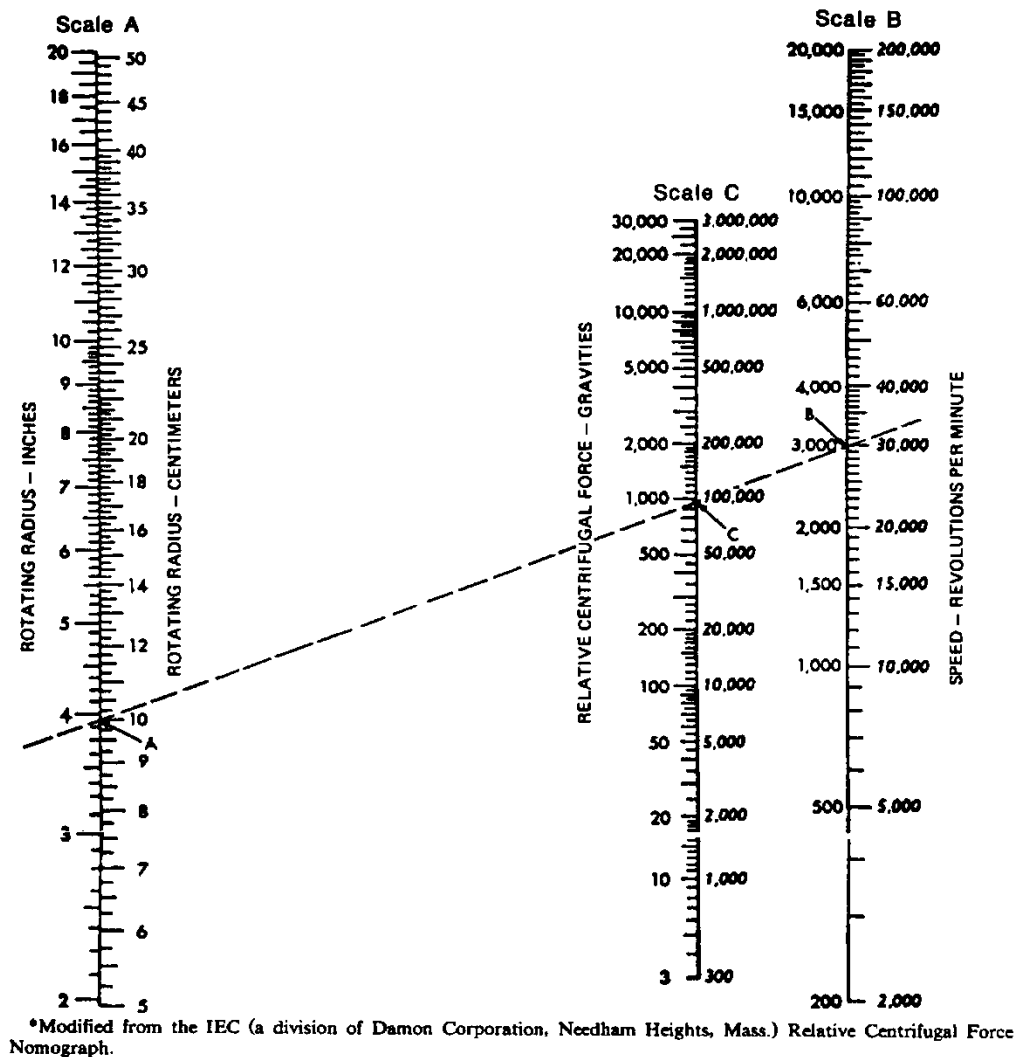
- **Centrifuge**

Monitor the temperature of the refrigerated centrifuge daily using the temperature gauge on the centrifuge. Measure the temperature before centrifugation. Recording each temperature check on a log sheet is optional.

Once each month, check the temperature of the centrifuge using a certified temperature thermometer in the 0°C to 20°C range. Do this even if you have an internal digital thermometer, as this will then also check the accuracy of the digital thermometer. You may do this by laying the thermometer on the bottom of the centrifuge.

Once each year, check the speed of the centrifuge using a tachometer. Perform routine maintenance as suggested by the centrifuge manufacturer. A centrifuge maintenance log can be used to record these routine equipment checks and maintenance at the FC's discretion and is optional.

Figure 8.4 – Nomogram for Calculating RCF



8.6.3 Processing Blood Samples

You can process several blood samples at a time as long as you follow the timing guidelines listed in *Section 8.6.1—Blood Sample Handling and Processing: Time limits* and in *Figure 8.3 - Guidelines for Blood Processing*. To keep the blood samples you are processing separate, keep the blood collection and cryovials from each participant in a separate rack. This will help you aliquot the samples into the correct corresponding cryovials.

The following is an example of how you can set up your work area and process several blood samples at one time. You may change the procedure as needed to make the processing more efficient at your FC.

- Set up a separate rack for each participant's set of blood samples. Because the cryovials fit better in a rack with smaller holes, you can use two racks for each blood sample: the one with smaller holes for the cryovials in front, and one with larger holes for the blood collection tubes directly behind the smaller rack.
 - When you first get the blood sample tubes, put the royal blue tubes in the appropriate racks to stand for 30 minutes and allow the blood to clot.
 - Centrifuge the 10 mL lavender tube for ten minutes.
 - While the samples are centrifuging, label the cryovials. Place the labeled cryovials in the smaller rack. Remove the lavender caps and lay them in front of the corresponding cryovials in the rack.
 - When the centrifuge stops, place the tubes from the centrifuge in the appropriate larger racks, placing the tubes directly behind the row of cryovials into which you will be placing the plasma.
 - When 30 minutes have passed, centrifuge the royal blue tubes. While the tubes are centrifuging, you can complete processing of the lavender tube, if you have not already done so.
 - Follow the procedure in *Section 8.6.3.1—Preparation of Blood Cryovials* for processing the serum from the royal blue tubes.
 - Alternately, wait for 30 -45 min until the royal blue tube has clotted and centrifuge both tubes together.

8.6.3.1 Preparation of Blood Cryovials

- Inspect each centrifuged tube for hemolysis. Re-centrifuge any specimen that appears to contain red cells suspended in the serum or plasma and then proceed with aliquotting, freezing and shipping. The analytic laboratory (ies) will make note of samples that may not be usable.
- Review *Form – SOLNAS Visit 1* (for SOLNAS Visit 1) or *SOLNAS Visit 2* (for SOLNAS Visit Two) to determine the number of cryovials to prepare. Do the same for SOLNAS Visits 3 and 4 with respective SOLNAS Visit forms.

When transferring the serum and plasma to the cryovials:

Lavender-stoppered tube (SOLNAS Visit 1 or SOLNAS Visit 3; SOLNAS Visit 2 or SOLNAS Visit 4):

- Remove the stopper from the Lavender-stoppered tube. **When you remove the stoppers from blood collection tubes that do not have hemoguards, remove them behind a work shield or wear a face shield to avoid potential exposure to the preservative.**
- For SOLNAS Visit 1 or 3, transfer 1.75 mL of plasma into one 2 mL cryovial and cap with an o-ring containing lavender cap.
- For SOLNAS Visit 2 or 4, transfer a minimum of 0.5 mL of plasma into each of three 2 mL cryovials. If the participant is over 60 years of age, a fourth cryovial

is filled with 1.75 mL of plasma. If only three cryovials are needed, first fill each of the vials with 0.5 mL of plasma and then dispense additional plasma up to 1.0 mL into each vial. If the fourth vial is needed, transfer 1.75 mL of plasma before transferring additional plasma into the first three vials. Screw the o-ring containing lavender caps onto the three or four cryovials. Place the three vials with minimum 0.5 mL of plasma in a freezer box dedicated to SOLNAS UMN Lab and cover with a lid to protect the plasma from light. Place the fourth plasma vial with 1.75 mL of plasma into a second freezer box dedicated to SOLNAS DLW Lab. Insert the lavender stopper back into the blood collection tube. Place the blood collection tube and the pipette tip in a biohazard container.

Royal Blue stoppered tubes (SOLNAS Visit 2 or SOLNAS Visit 4):

- Remove the stopper from the royal blue-stoppered tubes.
 - Transfer a minimum of 0.5 mL of serum into each of the four 2 mL cryovials. First fill each of the vials with 0.5 mL serum. Then dispense the remaining serum evenly into each vial until you run out of serum. Screw the red o-ring containing caps onto the four cryovials. Place the four serum vials next to the three plasma vials in a freezer box dedicated to SOLNAS UMN Lab and cover with a lid to protect the plasma and serum from light. Insert the royal blue stoppers back into the blood collection tubes. Place the blood collection tubes and the pipette tip in a biohazard container.
- Place the samples in the freezer box. Check that all cryovials are correctly labeled. Complete the *Blood Processing* portion of *Form--SOLNAS Visit 1 (or SOLNAS Visit 3) or SOLNAS Visit 2 (or SOLNAS Visit 4)* as you place the aliquots into the freezer box, marking the corresponding aliquot on the form.

8.6.4 Freezing, Storing, Inventorying, Packaging, and Shipping Blood and Urine Aliquots

8.6.4.1 Freeze SOLNAS aliquots at -70 degrees Celsius biological freezer.

Freeze SOLNAS samples in a -70 degree Celsius biological freezer. If you do not have a -70°C freezer immediately available, put the cryovials in a -20°C freezer immediately after aliquoting. Then transfer to a -70°C freezer as soon as possible but no longer than two days (over the weekend). Placing the samples on wet ice or dry ice does not sufficiently preserve the sample, so you must put the samples in at least a -20°C freezer. Do not thaw the samples after freezing. If frozen samples are thawed (i.e., the result of a freezer failure) contact Vicky Makky at Fairview Lab — ph: 612-273-3645 for instructions.

Equipment Quality Assurance

- Freezer

Work with the person at your institution who is responsible for freezers to be sure that biological freezer temperatures are monitored daily. Use a certified low temperature

thermometer in the -70°C range or a digit temperature display that may be on the freezer. If you use the digit display for the daily temperature checks, check the temperature of the freezer using a certified thermometer in the -80°C to -60°C range at least once each month. Recording each temperature check on a log sheet is optional.

Each month check the CO_2 tank to be sure it has not been emptied. Also test the alarm system to be sure it will sound should the freezer temperature rise above -50°C . An appropriate system must have the capacity to monitor the freezer and to call multiple phone numbers should malfunction occur. Perform routine maintenance as suggested by the freezer manufacturer such as routine freezer defrosting and record in freezer maintenance log. Make sure there are no samples in the freezer when you defrost it. You can coordinate the timing of the defrosting with the shipment of samples to Central Lab; or use temporary storage in another freezer during the defrosting.

8.6.4.2 Store SOLNAS aliquots in boxes dedicated to SOLNAS.

- Store the UMN Lab serum, plasma, and 24 hr urine cryovials in a separate box from the DLW spot urine and plasma cryovials.
- Using a black Sharpie® marker, mark SOLNAS UMN Lab or SOLNAS DLW Lab in large letters on the side of the top of the box and the side of the bottom of each box.
- Store aliquots in a way that facilitates shipping all samples from SOLNAS Visit 1 and SOLNAS Visit 2 together for a given participant in each of the boxes. (and similarly for SOLNAS Visit 3 and SOLNAS Visit 4 for the reliability subsample).

8.6.4.3 Inventory stored aliquots.

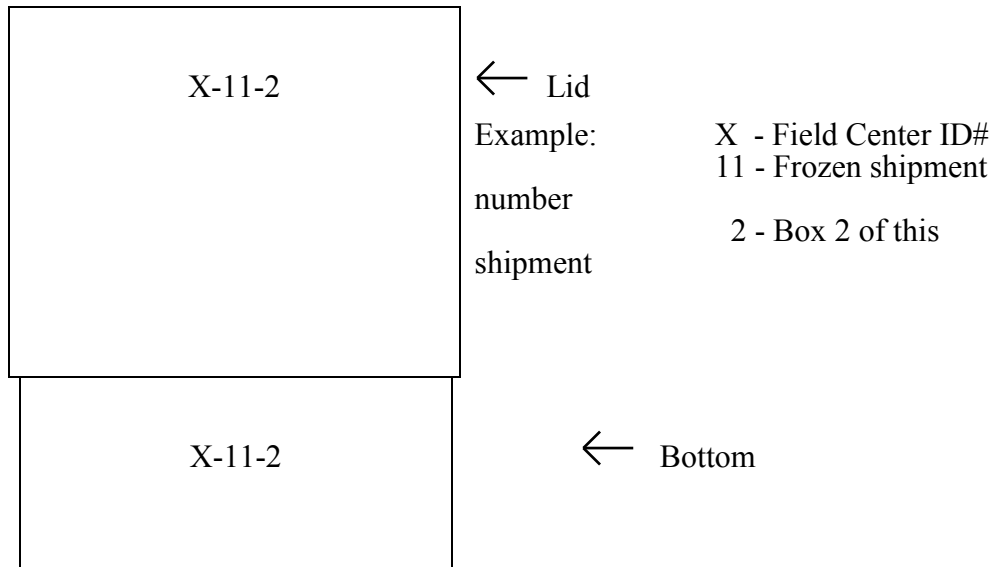
Inventory the processed cryovials in labeled freezer storage boxes as described below.

1. Assign a sequential frozen shipment number to each frozen shipment you send to the UMN lab and the DLW Lab, starting with number "1". Do not use duplicate numbers for two batches since Labs cannot track duplicate batch numbers. Do not skip numbers, since the skipped numbers indicate a missing or lost batch.
2. Label any side of both the freezer storage box and lid with your FC number, frozen shipment number, and a box sequence number. Start the box sequence number with "1" for each month's shipment. For example, use "X-011-2" for the FC with an ID number of X, frozen shipment number 11, and box number 2.
3. See *Figure 8.5 - Specimen Storage Box* for instructions how to map boxes to Central Lab and Baylor. Cryovials from multiple participants can be mapped to one box. The map can help you locate a sample if necessary.
4. Place the frozen cryovials in the freezer storage box according to the map you made.
5. Place the storage box with specimens in the -70°C freezer. If after freezing, you find a cryovial is broken, do not send it to the lab. Place it in the biohazard container. Record the information of the breakage on a log sheet and edit the corresponding SOLNAS Visit Form to indicate that you are not sending the broken sample to Central Lab. A

broken cryovial may indicate more than 1.8 mL of serum was added to the cryovial. Review the blood processing procedures to ensure blood processing staff do not overfill the vials.

**Figure 8.5
Specimen Storage Box**

Front view of box and lid



**Figure 8.5.1
Specimen Storage Box—UMN Lab**

Top View of Box

1 V10	2 V11	3 V12	4 V00	5 V01	6 V02	7 V03	8 V60	9 V61
10 V62	11 V10	12 V11	13 V12	14 V00	15 V01	16 V02	17 V03	18
19	20	21 V10	22	23	24	25	26	27
28	29	30	31 V10	32	33	34	35	36
37	38	39	40	41 V10	42	43	44	45
46	47	48	49	50	51 V10	52	53	54
55	56	57	58	59	60	61 V10	62	63
64	65	66	67	68	69	70	71 V10	72
73	74	75	76	77	78	79	80	81 Empty

Figure 8.5.1 detail:

This is the matrix that displays the order in which the samples need to be positioned in the specimen storage box. This layout is crucial as it is used by the Central Lab to identify which are the samples that they receive. Please make sure that the positioning of the samples is accurate. If a sample is missing, place a cotton ball in the position allocated for that specific sample. Every LabID will have 10 vials which will be ordered as indicated.

- The **V-number** indicates vial number assigned to that specific sample in Lab Labels. The single number is the position in the box for that sample. Plasma vials have purple caps, Serum vials have red caps, and Urine vials have green caps (colored scheme represented in **Figure1**.) The UMN form will have these numbers in the sample shipped indicators.
- The first sample for each LabID will be the first Plasma-purple-cap vial 10. The numbered positions for the first sample are: 1, 11, 21, 31, 41, 51, 61, and 71.
- Mention the order of V10, v11, v12, etc.
- The location 81 will not have any vials. Instead place a cotton ball in this location to indicate the last position of the box.

8.6.4.4 Shipping to Central Lab. –UMN Form

1. The UMN form (available in DMS) will be used to track shipment from the FC to the Central Lab. It is entered for each specimen storage box and it includes which vials are present for each of eight (8) LabID's. Each vial in the form has a number that corresponds to its position in the specimen storage box.
2. Heading of the UMN Form
 - a. **ID number** will be the ID for each Field Center as follows:
Bronx ID = B0000000; Chicago = C0000000; Miami = M0000000; San Diego = S0000000
 - b. **Styrofoam Box (contact occasion)** will contain the shipment number.
 - c. **Specimen Storage Box (seq #)** will contain the number of the box included in the shipment.
3. Once the shipment information is entered in the DMS, create a PDF of the form, print the form, and affix LabID labels (from the EXTRA LabID labels) in the location provided (right margin of the form). Send the original form with affixed labels to the Central Lab in the Styrofoam box with the samples. Make a copy for FC's records and send a copy of the PDF file to the Coordinating Center to mdla_abreu@unc.edu.

If you have any questions, please do not hesitate to contact Maria de los Angeles (Nana) Abreu at mdla_abreu@unc.edu or 919-962-6254.

Figure 8.5.2
Specimen Storage Box—DLW Lab

Top View of Box

	PD1	PD1	PD1	PD1	PD1	PD1	PD1	PD1
D1a	D1a	D1a	D1a	D1a	D1a	D1a	D1a	D1a
D1b	D1b	D1b	D1b	D1b	D1b	D1b	D1b	D1b
D13a	D13a	D13a	D13a	D13a	D13a	D13a	D13a	D13a
D13b	D13b	D13b	D13b	D13b	D13b	D13b	D13b	D13b
D1	D1	D1	D1	D1	D1	D1	D1	D1
D13	D13	D13	D13	D13	D13	D13	D13	D13

PD1: Visit 1—Time 0 Spot Urine

D1a: Visit 1—Time 3 Spot Urine

D1b: Visit 1—Time 4 Spot Urine

D13a: Visit 2—Time 0 Spot Urine

D13a: Visit 2—Time 1 Spot Urine

D1: Visit 1—Plasma for participants who are 60 years or older

D13: Visit 2—Plasma for participants who are 60 years or older

8.6.4.5 Shipping to Baylor—DLS Form

- All forms must be entered in DMS for those participants whose samples are being shipped. If a participant is in the QC sample, verify that the Phantom ID Form (SPF) has been filled out. Affix a Phantom ID label (provided by the Coordinating Center) to the SPF paper form to be kept in the participant's folder; enter information on DMS.
- Create a Shipment to DLW Lab form (DLS) for each freezer/specimen box being shipped.
 - ID Number: This form will have an ID for each field center in this field. Enter your field center ID information as follows:
 - Bronx: B0000000
 - Chicago: C0000000
 - Miami: M0000000
 - San Diego: S0000000
 - Contact Occasion: Enter shipment number. When more than one Styrofoam box is being shipped at a time, each box counts as a separate shipment.
 - SEQ#: Each freezer/specimen box should have a different sequence number. SEQ starts counting from "01" with each shipment.
 - Lab ID: With a barcode scanner, scan one Lab ID label from each set. If a participant is in the QC sample, both sets of labels need to be scanned. Lab IDs can be entered manually

in case there is a problem with the barcode scanner; however, in order to avoid errors use the barcode scanner.

- Study Sequence: Select “1” for the Primary Study and “3” for the Reliability Study.
- Mark the samples that will be shipped.
 - o *U30* for Visit 1 Spot Urine Time 0, Lab label “30”
 - o *U33* for Visit 1 Spot Urine Time 3, Lab label “33”
 - o *U34* for Visit 1 Spot Urine Time 4, Lab label “34”
 - o *U50* for Visit 2 Spot Urine Time 0, Lab label “50”
 - o *U51* for Visit 2 Spot Urine Time 1, Lab label “51”
 - o If participant is 60 years or older, mark:
 - *P40* for Visit 1 Plasma 60+, Lab label “40”
 - *P20* for Visit 2 Plasma 60+, Lab label “20”
- 3. Create a PDF file using the DMS-Print command. Print a copy of the DLS form and ship them with the samples. DLS PDF should be attached to the shipment email.
- 4. Send an email to Baylor and CC Einstein as per MOP instructions with an electronic copy of the DLS forms.

8.6.5 Packaging Instructions

Pack the freezer storage boxes of frozen blood and urine samples in the shipping boxes as follows:

(The shipping box is composed of an inner styrofoam insulating portion and an outer fiberboard he/shell). On the day before the shipment, notify each lab (via email) of the shipment.

1. Wrap the freezer storage boxes containing the SOLNAS samples in absorbent material (paper towels, wadding, etc.).
2. Place the freezer storage boxes in a plastic bag, either self-sealed zip-lock bag or secured with a waterproof seal. Remove as much of the air from the bag as possible and seal.
3. Place dry ice nuggets on the bottom. Place the freezer storage boxes on top of the dry ice layer and then scatter additional dry ice nuggets around the freezer storage boxes. The amount of dry ice used should be at least 5 lbs.
4. Stuff any empty space in the shipping box with newspaper or absorbent material.
5. Place the styrofoam cover on the insulating portion of the shipping box with a copy of the email notification of shipment taped to the top. **DO NOT TAPE** the styrofoam cover to allow the dry ice gas to escape. Close and tape the outer fiberboard shell of the shipping box by sealing the top and corners of the box with waterproof tape to keep as much cool air as possible from escaping. **Do not use scotch or masking tape.** Affix “Exempt Human Specimens” label and a Fed-Ex dry ice label to the outside of the box.
6. Attach the airbill holder to the front of the box.

See *Figure 8.6 Frozen Specimen Shipping Labels* to see sample labels and placement of the labels on top of the shipping box. You must follow the current federal regulations of labeling or face a possible fine of up to \$10,000 if proper labels are not in compliance.

7. Complete the airbill for your carrier. Enter:
 - The date of the shipment.
 - Weight of dry ice (in pounds or kilograms), as requested.
 - Number of packages and total weight of shipment.

As with the dry ice label, record the weight requested on the label. Insert the airbill in the airbill holder.

8. To delay thawing, place the box in the -70°C freezer to wait for pick up. You don't need to do this if you pack the box within 2-3 hours of pickup and you hold the box in a controlled temperature area (for example, at room temperature and not over 80°F).

9. Notify each lab via email (or phone if email is not possible) the day you ship the specimens. Please direct email correspondence to the contacts listed below. Retain a copy of the email notification memo for inclusion in the shipping box. In addition, retain a copy for your records.

Email Notification of SOLNAS Shipment to UMN Lab:

Primary Contact

Vicky Makky vmakky1@fairview.org

Secondary Contacts:

Mary Van Hale maryvan1@fairview.org

Elleni Kidanemariam ekidanel@Fairview.org

Email Notification of SOLNAS Shipment to DLW Lab:

For the DLW protocol:

Primary Contact: William W. Wong (wwong@bcm.edu)

Secondary Contacts: Lucinda Clarke (lucindac@bcm.edu) and Chun Liu (chunl@bcm.edu)

In the shipment notification (email) message, include:

- Study Title: HCHS-SOL SOLNAS
- The FC name.
- The date of the shipment.
- The date of expected arrival (same day or next day).
- Number of shippers being sent.
- Number of freezer boxes contained within the shipper(s).
- The airbill number from the carrier's label.
- Attach the corresponding shipping spread sheet (each lab has their own template)

Figure 8.6 Frozen Specimen Shipping Labels

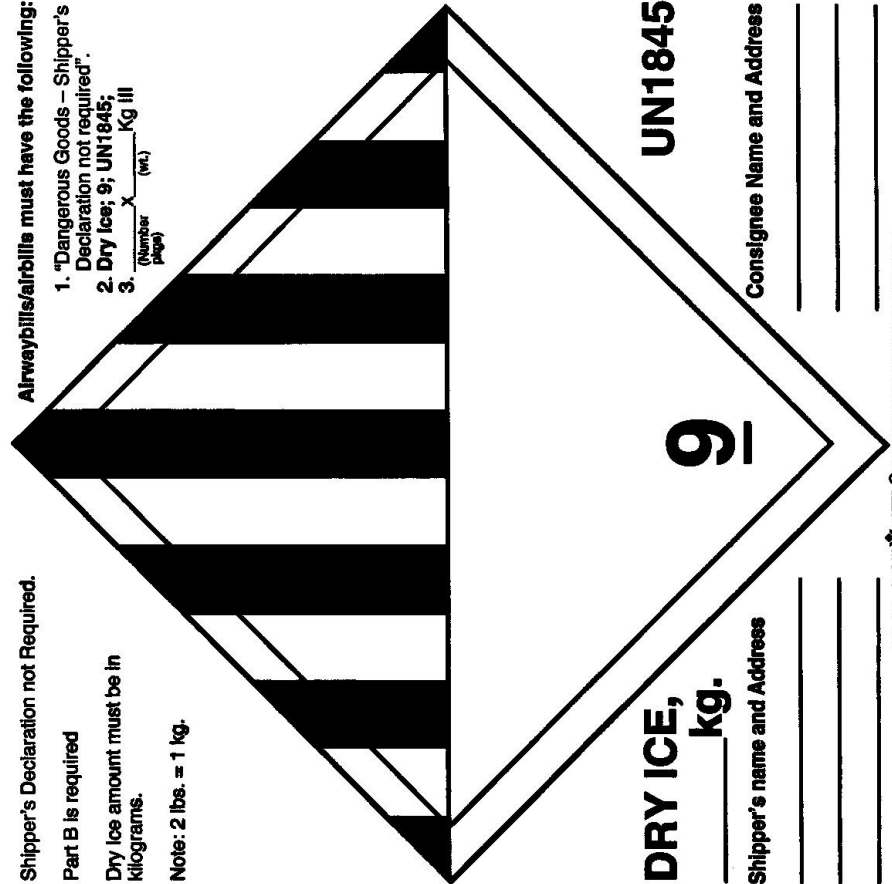


Chris Constantine
Fisher BioServices
625 Lofstrand Lane
Rockville, MD 20850

Shipper's Declaration not Required.
Part B is required
Dry ice amount must be in kilograms.
Note: 2 lbs. = 1 kg.

Airwaybills/airbills must have the following:

1. "Dangerous Goods – Shipper's Declaration not required".
2. Dry ice; 9; UN1845;
3. $\frac{\text{Number}}{\text{piece}} \times \text{Kg III}$



8.6.6 Shipment of Samples

Ship frozen SOLNAS aliquots to University of Minnesota every three months

**SOLNAS Central Laboratory
University of Minnesota Medical Center, Fairview
Room L275 Mayo Memorial Building
420 Delaware Street S.E.
Minneapolis, MN 55455
Telephone: (612) 273-3645
Fax: (612) 273-3489**

Ship frozen SOLNAS aliquots to the DLW Lab every three months.

**For the DLW protocol:
USDA/ARS Children's Nutrition Research Center
1100 Bates Street, Houston, TX 77030 (713-798-7122)**

Ship either Monday or Tuesday and not two days before any national holidays.

See address below. Packaging and shipping procedures are detailed in the sections that follow.

Ship samples every three months. Ship the first set of samples three months after your first participant has completed SOLNAS Visit 1 and SOLNAS Visit 2. Ship samples every three months after that regardless of the number of samples in the freezer. Be sure that all samples from SOLNAS Visit 1 and SOLNAS Visit 2 are shipped together for a given participant (and similarly for SOLNAS Visit 3 and SOLNAS Visit 4 for the reliability subsample).

Ship only on a Monday, Tuesday. Do not ship two days before a holiday. UMN Lab holidays are: New Year's Day, Memorial Day, Independence Day, Labor Day, Thanksgiving day, and Christmas day.

Samples must be frozen at least two hours at -70°C before packing them for shipment. If the blood samples were drawn on the same day you plan to ship them, to help with freezing, leave the lid off the freezer box until it is ready to be packed for shipment. If the insulated shipping container is not filled, stuff newspapers to stabilize the freezer boxes. Ship the fiberboard shipping box with frozen samples to labs by day or overnight courier to ensure receipt within 24 hours.

There is no minimum number of cryovials to include in a shipment; ship all frozen cryovials that complete a visit 1 AND visit 2 (or visit 3 AND visit 4) set regardless of the number of specimens that have been frozen and stored within the last collection period. However, FCs must follow current International Air Transport Association (IATA) regulations.

Notify each lab (via email) the day before an SOLNAS Shipment. Instructions for sending the email notification are provided in the *SOLNAS Manual, Section 8.6.5 Packaging Instructions*. Upon receiving the sample shipment, each lab will send an email to the FC confirming the receipt of the shipment. If the required email notification of SOLNAS shipment is not sent to either lab by the FC, then they cannot send a confirmation of receipt.

8.6.7 Receipt of Frozen Specimen Shipment at either lab

UMN and DLW Lab personnel will email a Confirmation of Receipt to the FC upon arrival of the shipment at the repository.

The e-mail will include:

- Date shipment arrived.
- Number of boxes received.
- Condition of the total shipment, for example, “thawed.”

If the shipment is not received on the expected day, they will trace the shipment using the air bill number.

For Data Management –please refer to parent study manuals:

<http://www.csc.c.unc.edu/hchs/public/UNLICOMMMManual13DataManagement01232008.pdf>

8.6.7.1 Using the “Notes” Box’ on the SOLNAS Forms

- Record notes/responses on SOLNAS Visit forms, worksheets and/or the participant’s *Record sheet for 24-hour Urine Collection* in the following situations:
 - There are missing tasks on the SOLNAS Visit forms
 - If a specific SOLNAS task is missed or cannot be completed (i.e., participant refuses a blood draw or is unable to provide a specific spot urine, even after having additional water), SOLNAS staff leave the appropriate question on the SOLNAS form ‘blank’ and indicate the problem in the “Notes” box at the end of the SOLNAS Visit form.
 - There are out-of-sequence tasks that prevent completion of the SOLNAS Visit form
 - The participant was not given PABA (B-vitamin) tablets because of past hypersensitivity
 - There are responses on *SOLNAS Visit 2 (or Visit 4) Participant Update Worksheet* indicating potential changes that could affect DLW results (questions 1-3).
 - There are responses on the *Record sheet for 24-hour Urine Collection* indicating missing or contaminated 24-hour urine collections (questions 1, 2, 4, 5, 6 and 7).

8.7 Acticals

For Actical Instruction: Please refer to the SOLNAS Actical User Guide located in the Ancillary Studies Hub in the SOL website:

http://www.csc.unc.edu/hchs/utilities/docfilter.php?study=hchs&filter_type=abstracts

Please send Acticals (note for Reliability Study only) separate from parent study Acticals in one batch once all are complete to Nana Abreu at the UNC-Data CC.

Email address: abreu@email.unc.edu

SECTION 9: SOLNAS DATA ENTRY FORMS AND WORKSHEETS

9.1 Overview

- This section provides copies of the SOLNAS study forms and worksheets. Accompanying each form is a detailed set of instructions describing who completes the form, when and how each data item should be coded, and what should happen to the form when it is completed. Copies of the following SOLNAS forms and worksheets are included in this section.

9.2 Printing SOLNAS Forms and Worksheets

- FCs will receive ‘PDF’ files of all SOLNAS Visit forms & Worksheets (i.e., *SOLNAS Visit 1 Eligibility Worksheet*, *SOLNAS Visit 2 Participant Update Worksheet*, *SOLNAS Visit 3 Eligibility Worksheet*, and *SOLNAS Visit 4 Participant Update Worksheet*). FCs use these electronic files or the hard copies available in the *SOLNAS website* to make copies of forms and worksheets, as needed. For information about SOLNAS printed materials, refer to *SOLNAS Manual, Section 2.5.1—Print Materials*.

Forms & Worksheets – SOLNAS Visit 1 and SOLNAS Visit 2:

- *SOLNAS Visit 1 and Visit 3 Eligibility Worksheet (VUE/VUS)*
- *Food Amounts Booklet*
- *Food models, cups, etc for 24 hr recall*
- *Sedentary Behavior Form*
- *Q by Q for Sedentary Behavior Form (SDE/SDS)*
- *Body Image Form (BIE/BIS)*
- *Q by Q for Body Image Form*
- *Staff 24-Hour Urine Collection (SUC)*
- *SOLNAS Visit 1 and Visit 3 Form (VSE)*
- *SOLNAS Phantom Form (SPF)*
- *SOLNAS Visit 2 and Visit 4 Participant Update Worksheet (VUE/VUS)*
- *SOLNAS Visit 2 and Visit 4 Form (VTE)*
- *SOLNAS Calorimetry Form (CSE)*
- *SOLNAS Shipment to Central Lab Form (University of Minnesota Form) (UMN)*
- *SOLNAS Shipment to DLW Lab Form (Baylor) (DLS)*

Forms & Worksheets – SOLNAS Visit 3 and SOLNAS Visit 4 (Reliability Subsample):

- *SOLNAS Visit 1 and Visit 3 Eligibility Worksheet (VUE/VUS)*
- *Food Amounts Booklet*
- *Food models, cups, etc for 24 hr recall*

- *Sedentary Behavior Form*
- *Q by Q for Sedentary Behavior Form (SDE/SDS)*
- *Body Image Form (BIE/BIS)*
- *Q by Q for Body Image Form*
- *Staff 24-Hour Urine Collection (SUC)*
- *SOLNAS Visit 1 and Visit 3 Form (VSE)*
- *SOLNAS Visit 2 and Visit 4 Participant Update Worksheet (VUE/VUS)*
- *SOLNAS Visit 2 and Visit 4 Form (VTE)*
- *SOLNAS Calorimetry Form (CSE)*
- *SOLNAS Shipment to Central Lab Form (University of Minnesota Form) (UMN)*
- *SOLNAS Shipment to DLW Lab Form (Baylor) (DLS)*

SECTION 10: ADDENDUMS**10.1 Diet and Supplement Addendum**

Manual 11
Diet and Supplement
Addendum for SOLNAS
June 2011

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

10.2 Introduction

This addendum covers specific procedures developed for SOLNAS, a reliability study ancillary to the Hispanic Community Health Study/Study of Latinos (HCHS/SOL). Procedures have developed in collaboration with the study PI, Yasmin Mossavar-Rahmani and her team at the Albert Einstein College of Medicine, Bronx NY and the UNC-CC. These procedures have been documented by the Nutrition Reading Center (NRC) at the University of Minnesota to serve as instructions for the field centers in collecting the 24-hour dietary and supplement recalls and transmitting the data to the NRC. Field centers should refer to Manual 11 which fully describe the data collection and quality assurance procedures for the dietary and supplement intake assessment. It is essential that any person who is involved in the dietary and supplement data collection fully read and understand this manual.

It important to note that the visit numbers assigned to the SOLNAS dietary recalls will be the same as the actual SOLNAS visit numbers. Dietary recalls are collected at visit 1, 3 and 4 (note that there are no dietary recalls performed at SOLNAS visit 2). To avoid confusion with Main Study/Parent Study recalls which are assigned Visit 1 and 2, SOLNAS Reliability Study recalls are collected in separate projects and will be submitted to the UNC-CC separate from the Main study/Parent Study recalls.

10.3 Data Management Procedures

As with the dietary and supplement recalls collected for HCHS/SOL SOLNAS data should flow from the field centers to the NRC on a regular, recurring basis, NDSR projects are set up to facilitate and direct that process. Each dietary interviewer should have one NDSR project for SOLNAS recalls. All of the recalls collected by that interviewer within that week reside in those projects. Projects are backed-up on a daily basis and stored in a secure location, separate from the hard drive of the computer on which the NDSR program resides.

Each week, the lead interviewer restores all projects of data for the week and combines the recalls to begin preparing them for shipment to the NRC. The backup of the original data collected remains in archive storage. After cleaning and local quality assurance tasks have been completed by the lead interviewer, a backup of these new projects with the merged data are made and forwarded to NRC. A backup of these projects also remain in archive storage at the field center. NDSR backup files are password protected compressed files that cannot be read without first restoring them to the NDSR program.

10.4 Create the Dietary Interviewer NDSR Projects

Before beginning data collection each week, one new project is created for each interviewer.

The requirements for the Project Information are as follows:

Folder: *SOLNAS Recalls*

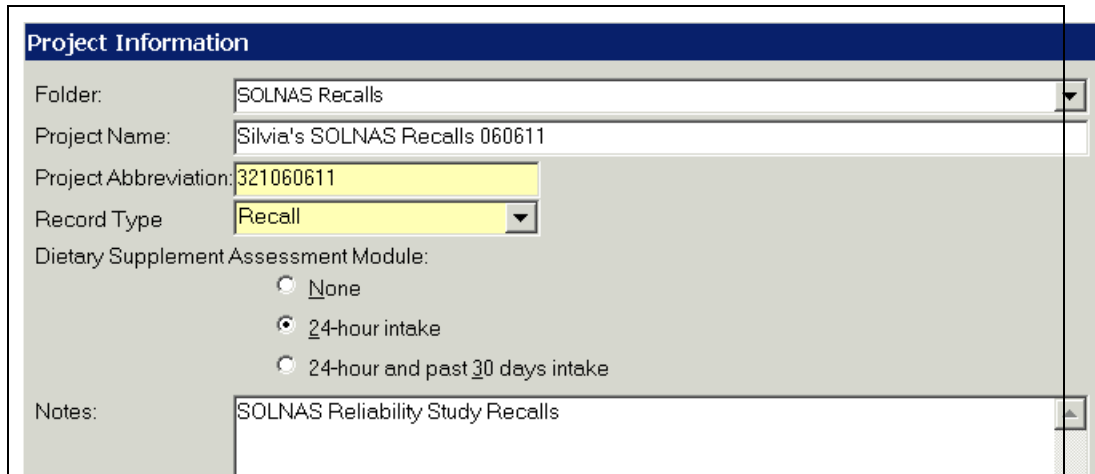
Project Name: *Interviewer Name SOLNAS Recalls MM/DD/YY* (e.g., Silvia's SOLNAS Recalls 06/06/11)

Project Abbreviation: Interviewer ID (3 digits) Data Collection Week (e.g., NNN060611SOLNAS)

Record Type: Recall

Dietary Supplement Assessment Module: 24-hour

Note: SOLNAS Reliability Study Recalls
See the following Project Information window:



The screenshot shows a 'Project Information' window with the following fields and values:

- Folder: SOLNAS Recalls
- Project Name: Silvia's SOLNAS Recalls 060611
- Project Abbreviation: 321060611
- Record Type: Recall
- Dietary Supplement Assessment Module:
 - None
 - 24-hour intake
 - 24-hour and past 30 days intake
- Notes: SOLNAS Reliability Study Recalls

10.5 Set the Preferences

Preferences are set when creating each project. The HCHS/SOL preferences are described below.

10.5.1 Method Preferences.

Deselect the Participant name and the Site ID per the following screen shot. The dietary interviewer enters the first name only for use during the collection of the dietary and supplement recall. After local quality assurance tasks are completed and before sending the data to NRC, the name of the participant must be deleted. The first name of the participant provides a valuable cross check against the participant identification number. In addition, when conducting the telephone recall the participant's name ensures the data is being collected correspond to the right participant.

The screenshot shows the 'Method Preferences' tab of the 'Preferences' dialog box. The 'Require on record header' section has the following settings: Participant name, Interviewer ID, Date of birth, Visit number, Gender, and Site ID. The 'Display' section has Show non-required fields in record header. The 'Meal time format' is set to Standard and 24-hour clock (military time). The 'Display Spanish prompts' checkbox is checked. The 'Food entry' section has Use Quick List, Require meal name, Require note if amount exceeds max, Require meal location, Require note if amount is less than min, and Use Food Portion Visual.

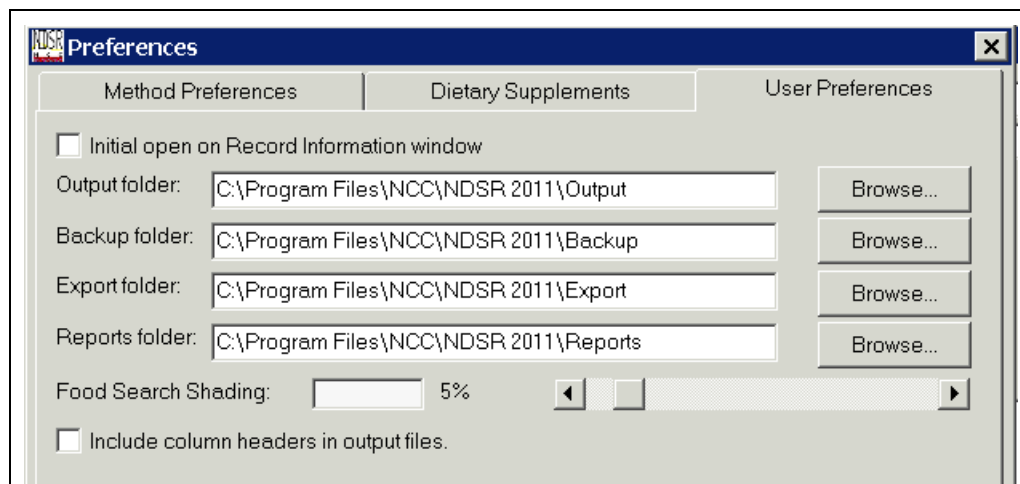
10.5.2 Dietary Supplements Preferences.

Announced/scheduled is selected for the interview type for Visit 1 and Visit 3 SOLNAS recalls. For visit 4 (Reliability Study) it would be unannounced/unscheduled. The additional supplement use question "Reason for use" should be selected. See the following Dietary Supplement Preferences window:

The screenshot shows the 'Dietary Supplements' tab of the 'Preferences' dialog box. The 'Interview type' section has Announced/scheduled and Unannounced/unscheduled. The 'Require additional supplement use questions' section has Reason for use, Recommended by, Place of purchase, and Perceived effectiveness.

10.5.3 User Preferences.

The User Preferences designate the location for the backup files. If the computer used to collect HCHS/SOL recalls is on a network server, it may be desirable to designate that as the backup folder location. In this example, backup files are stored in C:\Program Files\NCC\NDSR 2011\Backup. If this backup location is used, the backup files should be copied to a second secure storage location.



10.6 Create an Intake Record

Using the information obtained about the participant during the screening and recruitment process, the dietary interviewer completes the record header on the day of the visit. Because the NDSR automatically generates the date of entry, if the participant does not complete the dietary recall on the date the header is entered, the record is deleted and a new record is inserted the next time the participant is scheduled for an interview. All information set in the header preferences is required and the recall cannot continue until the header is complete. The requirements to complete the header preferences are as follows:

Participant ID: Centrally assigned by the CSCC. 8 characters beginning with the first letter of the field center (B=Bronx, C=Chicago, M=Miami, S=San Diego), a sequential number (NNNNNN) and a check digit based on the preceding sequential number.

Date of intake: mm/dd/yyyy

Date of birth: mm/dd/yyyy

Gender: Male or Female

Life Stage Group: NDSR automatically completes this field.

Interviewer ID: 3 digits designated by the CSCC.

Visit number: 1, 3 or 4 to coincide with SOLNAS visits

Site ID: location and interview type, scheduled or unscheduled

Notes: Use to record the language of the interview and to confirm that this is a SOLNAS recall.

10.7 Creating the Lead Interviewer NDSR SOLNAS Project

One project is created for the lead interviewer. One project contains all SOLNAS recalls ready for submission to the NRC.

The requirements for the Project Information for the completed SOLNAS recalls are as follows:

Project Name: *Field Center MM/DD/YY SOLNAS recalls* (e.g., Bronx SOLNAS 06/06/11)

Project Abbreviation: *First letter of field center Date V2* (e.g., B060611 SOLNAS)

Record Type: Recall

Dietary Supplement Assessment Module: 24-hour intake

Refer to Section 15 of the MOP for additional Data Management information for the field center.

Nutrition Reading Center Procedure for SOLNAS recalls

SOLNAS recalls will be submitted to the UNC-CC as projects separate from the Main/Parent study recalls.

SOLNAS Recalls will be submitted to the UNC