Study Orientation for Sub Study Participants

Telephone 24-hour Dietary Recall and Urine and Duplicate Salt Collection

Public reporting burden of this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road, NE, M/S D74, Atlanta, GA 30333, ATTN: PRA 0920-0982.

"Over the next 11 days we need to talk to you over the telephone 4 times to ask you to report everything you ate and drank the previous day and all dietary supplements and non-prescription antacids you may have taken. Each telephone call will take about 30 minutes. The day before the telephone call we'll need you to collect samples of all the salt you add to food in cooking at home and at the table- like salt from a salt shaker you may add to your food. One day must be a weekend day; the other three will be weekdays. Also, the day of each telephone call you'll need to collect all your urine. The urine samples must be returned to the clinic the day after they are collected. You'll receive \$10 for each completed duplicate salt collection and telephone interview, which is \$40 total for completing all 4 days. For each completed urine collection you'll receive \$20 for a total of \$80 for collecting urine for 4 days."

Salt Collection Instructions

"First let's talk about the salt collection you'll need to do. On each of the four days we will schedule for salt collection you'll need to use the salt collection kit we are providing you with. On each of these days we want you to collect duplicate samples of all the salt you add to food at the table. Also, all salt added in preparing foods at home that day needs to be collected."

"Here is what is in the kit and what you'll need to do [OPEN THE COLLECTION KIT]. For collecting duplicate samples of the salt you add to your food **at the table** each day a single plastic bag with a neon label is provided. [SHOW PARTICIPANT THE 'TABLE SALT' PLASTIC BAG]. Each time you shake salt onto a food at the table, shake the same amount into the plastic bag. Do this throughout the day and wherever you add salt to food including at work and restaurants. On the bag is a spot for providing information about the type of salt in the salt shaker you use at home. Please be sure to fill in this information. If you did not add salt to your food at the table on your collection day please check the box 'I did not add salt at the table today'."

"For collecting duplicate samples of all the salt added to food in **home cooking** on the day the collection is to be done there are several plastic bags in the collection kit. For each food prepared with salt added, put the same amount of salt added to the food in the plastic bag. On the plastic bag is a label where you need to provide some information such as a description of the food the salt was added to in preparation, the date, and the type of salt used. If someone

else in your home is preparing a food that includes salt, make sure they do this collection or you do it with them."

"When you drop off your first 24-hour urine sample, the clinic manager will give you two salt shakers containing study salt. Once you have received the study salt please use it whenever you add salt to food at the table; even when eating meals outside the home like at work or a restaurant. Please also use the study salt whenever you add salt to food prepared at home. You'll use this study salt until you complete your fourth and final 24-hour urine collection. You will also collect duplicate salt samples using the study salt."

"We have a couple tips for you. First, please make sure the plastic bag is completely sealed shut after you have collected the duplicate salt sample. Second, remember to take the table salt collection bag and study salt with you wherever you go so that you're able to collect duplicate samples of salt added at the table at work, restaurants, and other places you may eat away from home. Please bring the duplicate salt samples to us on the day you return your final urine collection and study salt shakers. We cannot begin to process your payment until we have received your duplicate samples so it is important that you remember to return them to the clinic."

Food Record Form and Instructions (4 each)

"On each of the four days you are collecting salt we need you to write down everything you eat and drink from midnight to midnight that day. You don't need to record how much you eat. You'll be asked that during the telephone interview."

"This record does not get turned in to the study. We're asking you to complete it because it will help you remember what you ate when it comes time for the telephone recall." [SHOW PARTICIPANT FOOD RECORD FORM AND FOOD RECORD FORM INSTRUCTION WITH THE EXAMPLES.]

"You'll see that we want you to write in the total amount of food made for any food you ate that was prepared at home with salt added in preparation. For example, if you or another family member made a batch of banana nut muffins that included salt in the recipe, we'd like you to describe the total amount made (e.g. made 1 dozen muffins). Write in the amount in whatever way it makes sense for a food. For example, 3 cups of salsa."

"Be sure to have this record by the phone when it is time for your scheduled dietary recall."

"Do you have any questions about the food record form?"

Telephone Interview Instructions

"Now let's talk about the telephone interviews we will schedule. During the interview you'll be asked to report everything you ate and drank the previous day. To help you in reporting the amount of foods eaten you will need to have this Food Amount Booklet with you for the call [SHOW PARTICIPANT THE BOOKLET]. You'll also be asked some questions about the duplicate salt samples you collected the previous day, so have those with you also for the call. Finally, you'll be asked about any dietary supplements and non-prescription antacids you may have taken the day before the call. We'd like you to have the bottles and containers for any of

these products with you during the call since the interviewer may ask you some questions about the product that is found on the label."

"Do you have any questions about the telephone interviews at this time? If you think of a question later feel free to call the number included in the instruction sheet in your information packet [POINT OUT THE INSTRUCTION SHEET]". Also, if you need to reschedule the telephone call please let us know as soon as possible. We need to have each telephone interview done the day after you have collected the salt samples. So, if you need to change the date of the telephone interview we'll also need to change the day you're scheduled to collect salt samples. If you forget to collect the samples please call this number also to reschedule your telephone interview."

Urine Collection Instructions

"You will collect all your urine for four 24 hours periods. Each urine collection will occur on the same day as your telephone interview. The night before each collection have the urine kit near the toilet to be ready for use the next morning. When you wake up, urinate in the toilet as usual. DO NOT collect this urine but be sure to write down the date and time of this first urine on the label on the storage container and the '24-hour Urine Collection Form' on the line 'Start Time'." [SHOW PARTICIPANT 24-HOUR COLLECTION CONTAINER WITH LABEL AND 24-HOUR URINE COLLECTION FORM.]

"Begin to collect your urine in the bottle the second time you urinate that day. Make sure to screw the lid on tightly and keep the bottle stored in a cool place such as the basement of your home, in a cooler with ice, or in the large drawstring bag in your refrigerator. Continue to collect all your urine in the bottle each time you urinate during the 24-hour period. If you need to pass stool, urinate and collect your urine first."

"On the next morning plan to wake up about the same time you did the day before. This time you WILL collect the urine the first time you urinate. This is the last urine you will collect for the 24-hour period. Write down the time of this last urine on the label on the storage container and on the 24-Hour Urine Collection Form. Ensure the container is sealed tightly and attach the form to the container with a rubber band. Return the storage container and form to the clinic in the drawstring bag. You will be asked to answer some questions about the urine collection when you return your sample. When you return your final urine collection we ask that you also return your study salt shakers and your duplicate salt samples."

"Do you have any questions about the urine collections at this time?"

"Great. Now let's schedule the dates and times for the salt and urine collections and telephone interviews."

[DISPLAY CALENDAR SO THAT PARTICIPANT CAN SEE THE POSSIBLE DATES OVER THE NEXT 11 DAYS. ONE OF THE DAYS SCHEDULED FOR SALT COLLECTION MUST BE A WEEKEND DAY AND THREE MUST BE WEEKDAYS. RECORD THE DATES AND TIMES CHOSEN ON THE CALENDAR AND GIVE THE CALENDAR TO THE PARTICIPANT.]

[PULL OUT THE PREASSEMBLED SALT COLLECTION KIT FOR THE PARTICIPANT AND WRITE IN THE SCHEDULED SALT COLLECTION DATE ON THE NEON LABEL FOR EACH TABLE SALT COLLECTION BAG]