Women's Health Initiative

NUTRITIONAL BIOMARKERS STUDY

Telephone Screening Questionnaire/Script

Hello, my name is <your name> and I'm calling from the WHI Clinical Center. May I please speak with _____?

QX1. Is this _____? VERIFY PARTICIPANT NAME ON NBS TRACKING REPORT.

IF YES, GO TO QX2.

IF NO, AND PARTICIPANT IS NOT AVAILABLE, ASK: When would be a good time for me to call again? Thank you. Goodbye.

RECORD DATE AND TIME TO CALL ON A CALL ATTEMPTS LOG.

IF YOU REACH VOICE MAIL OR AN ANSWERING MACHINE SAY: This is <your name>. I'm calling from the WHI Clinical Center. Please call me at xxx-xxx-xxxx. I will also try to call you again later. Thank You.

QX2. Recently we sent you a letter describing a special nutrition study to learn better ways to measure dietary intake of energy, protein, vitamins and minerals. Did you receive the letter?

IF YES, GO TO QX3 ON PAGE 2.

IF NO, READ TEXT BELOW.

INFORMATION FOR WOMEN WHO DID NOT RECEIVE THE NBS INVITATION LETTER

Is <READ ADDRESS> your current address?

The letter explains that scientists involved in the Women's Health Initiative are conducting a special nutrition study to learn more about measuring dietary energy, protein, vitamins and minerals. The study will help the scientists understand the final results from the WHI Dietary Study. We are inviting women who are part of the Dietary Study to attend two visits at the WHI clinic. The visits will be two weeks apart. May I take a few minutes to describe the study to you? This call will take about 20 minutes. Is this a good time to talk?

GO TO QX3A ON PAGE 2.

INFORMATION FOR WOMEN WHO RECEIVED THE NBS INVITATION LETTER

QX3. I'm calling to tell you more about the study and to answer any questions you might have. If you are interested in participating, I need to ask you some questions to make sure that you meet the study criteria. This call will take about 20 minutes. Is this a good time to talk? GO TO QX3A**.**

QX3A.

IF YES, GO TO STUDY DESIGN.

IF NO, ASK: Is there a more convenient time for me to call you today? Thank you, I will call you again at _____. Good bye.

RECORD TIME TO CALL ON A CALL ATTEMPTS LOG.

IF NO CONVENIENT TIME THAT DAY CAN BE ARRANGED, ASK: Is there a more convenient time for me to call tomorrow? Thank you. I'll call you tomorrow at _____. Goodbye.

RECORD TIME TO CALL ON A CALL ATTEMPTS LOG.

IF PARTICIPANT IS NOT INTERESTED IN THE STUDY SAY: I understand that you do not want to participate in this study. Thank you. Goodbye.

COMPLETE QX5, FINAL DISPOSITION ON FORM 74 -NBS SCREENING RESULT.

STUDY DESIGN:

I would first like to describe the study to you and answer any questions you might have.

We would like to invite you to participate in a special nutrition study. The study involves measuring how many calories your body uses each day and measuring nutrients in your blood and urine. The testing procedures are not painful and cannot harm you. If you are interested in participating in this study, you will need to come to the clinic two times. Some women schedule the first visit to be the same day as their regularly scheduled annual visit. The second visit is two weeks later.

You will be given a special kind of water to drink that will allow us to measure how many calories your body uses during the next two weeks. The special water is tasteless and harmless and contains a type of oxygen and hydrogen that we can measure in your urine. There are no known hazards other than a few minutes of dizziness that affects about 1 person out of a hundred. Do you have any questions before I continue?

During your first visit you will be asked to give four urine samples over a period of four hours, complete a food questionnaire, and answer questions about your usual physical activity and any dietary supplements you may use. We will also measure your height and weight. If you are 60 years of age or over, we will also take a blood sample. During this visit we will complete the tasks for your WHI annual visit, if necessary.

(GO TO NEXT PAGE.)

We will ask you to return to the clinic two weeks later. The day before your second visit we will ask you to collect all of your urine for one full day in a special container that we will provide. The second visit will last about 1 ½ hours. We will ask you to give a fasting blood sample, two more urine samples, and measure your weight again. You will receive $100.00 upon completion of all of the study procedures. Do you have any questions?

Does this sound like something you would be interested in being part of?

IF NO: Thank you for taking the time to hear more about the study. We appreciate your interest. Goodbye.

IF YES: There are some questions about your medical history, weight, usual diet, and daily activities I need to ask you. These questions will help us determine whether you are eligible for the study. Your participation in this phone interview is voluntary and all information collected will be kept confidential. If there is any question you prefer not to answer, you are free to do so. Shall we begin?

NBS SCREENING ELIGIBILITY CHECKLIST

First I will ask about your medical history and any medications you may be taking.

1. Do you take insulin or oral hypoglycemic agents for diabetes?

IF NO: PARTICIPANT IS ELIGIBLE. GO TO QX2.

IF YES: PARTICIPANT IS INELIGIBLE. I'm sorry, we are not able to include women who have diabetes that must be controlled with insulin or oral agents. Unfortunately, diabetes can have an effect on the tests we will be doing. Thank you very much for your time and interest. Goodbye.

2. Do you routinely receive supplemental oxygen?

IF NO: PARTICIPANT IS ELIGIBLE. GO TO QX3.

IF YES: PARTICIPANT IS INELIGIBLE. I'm sorry, we are not able to include women who use supplemental oxygen as this may affect the study measurements. Thank you very much for your time and interest. Goodbye.

(GO TO NEXT PAGE.)

3. Are you expecting to receive blood transfusions or intravenous fluids within two weeks of your upcoming annual visit?

IF NO: PARTICIPANT IS ELIGIBLE. GO TO QX4.

IF YES: PARTICIPANT IS INELIGIBLE. I'm sorry, we are not able to include women who will receive blood transfusions or intravenous fluids during this time period because they will affect the study measurements. Thank you very much for your time and interest. Goodbye.

4. Do you have problems with bladder control that may make it difficult for you to collect urine?

IF NO: PARTICIPANT IS ELIGIBLE. GO TO QX5.

IF YES, ASK: Do you need or wear special undergarments for bladder control?

IF NO: PARTICIPANT IS ELIGIBLE. GO TO QX5.

IF YES: PARTICIPANT IS INELIGIBLE. I'm sorry, we are not able to include women who use special undergarments for bladder control because a complete urine collection is important for accurate tests. Thank you very much for your time and interest. Goodbye.

5. Have you tried to lose or gain weight during the past four weeks, by decreasing your food intake and/or increasing physical activity?

IF NO: PARTICIPANT IS ELIGIBLE. GO TO QX6.

IF YES, ASK: Have you lost more than 15 pounds during the past four weeks?

IF NO: PARTICIPANT IS ELIGIBLE. GO TO QX6.

IF YES: PARTICIPANT IS INELIGIBLE. I'm sorry, we cannot include women who are gaining or losing weight since changes in weight affect energy measurements.

6. Have you gained or lost weight <u>without trying</u> during the past four weeks?

IF NO: PARTICIPANT IS ELIGIBLE. GO TO QX7.

IF YES, ASK: Have you lost more than 15 pounds during the past four weeks?

IF NO: PARTICIPANT IS ELIGIBLE. GO TO QX7.

IF YES: PARTICIPANT IS INELIGIBLE. I'm sorry, we cannot include women with a recent weight change since changes in weight affect energy measurements.

(GO TO NEXT PAGE.)

7. Will you be traveling 200 or more miles from home during the two weeks before your Annual Visit?

IF NO: PARTICIPANT IS ELIGIBLE.

IF YES: Would you be willing to reschedule your annual visit to participate in this study?

> **IF NO:** I'm sorry, we are not able to include participants who will be this far away from home during this time period since differences in the content of local drinking water will affect study measurements.
> Thank you very much for your time and interest. Goodbye.
>
> **IF YES:** Thank you. We appreciate your willingness to change your annual visit so that you can participate in this special study.

Congratulations, you are eligible to participate in the Nutritional Biomarkers Study. Are you interested in participating in this study?

IF NO: Thank you very much for your time and interest in this study.

IF YES: I'd like to briefly review what we've talked about today. You will need to come to your WHI Clinical Center for two visits. The first visit may be combined with your annual visit (if necessary) and last between 5-6 hours. The second visit will be two weeks later and will last about 1 ½ hours [3 hours if Madison, Pittsburgh or Chicago-Northwestern]. You will need to arrive at the first visit having had nothing to eat for at least 4 hours prior to your arrival. We will provide you with a complimentary meal at the end of each clinic visit and you will receive $100.00 upon completion of all of the study procedures. Let's schedule your appointments now.

Your first visit is on <DATE AND TIME>. Please bring any dietary supplements you currently use with you and remember to fast for at least 4 hours prior to your arrival.

Your second visit is on <DATE AND TIME>. You will need to fast for 6 hours [12 hours if Madison, Pittsburgh or Chicago-Northwestern] prior to your arrival.

Thank you for your willingness to participate in this study. Good-bye.

COMPLETE QX5 FINAL DISPOSITION ON FORM 74 – NBS SCREENING RESULT.