Interactive Diet and Activity Tracking in AARP (iDATA)
Additional Procedures Component Consent Form

Full Study Title: Interactive Diet and Activity Tracking in AARP (iDATA): Biomarker based validation study of internet-based and conventional self-report instruments for assessing diet and physical activity within AARP – Additional Procedures Component

Conducted by: United States National Institutes of Health, National Cancer Institute, Division of Cancer Control and Population Sciences and Division of Cancer Epidemiology and Genetics

Principal Investigators: Heather Bowles, Ph.D and Yikyung Park, Sc.D.

Why am I being asked to do these additional procedures?

As part of the iDATA study we are randomly selecting participants who have completed the doubly labeled water (DLW) and resting metabolic rate (RMR) tests and asking them to complete these tests again. These second tests will assess if the tests consistently measure results from one time to another within one individual.

Who is eligible to participate in the additional procedures?

To be eligible for participation in the Additional Procedures Component, you need to have completed all activities that were part of the DLW procedure including providing a urine sample 10-14 days after the procedure and to be randomly selected to participate.

What do I have to do for the Additional Procedures Component?

You will need to come to the clinic in Pittsburgh to repeat these two (2) tests and will also complete one (1) activity at home. The activities that will be completed are listed below:

<u>Resting Metabolic Rate (RMR)</u>

Your RMR is the number of calories you burn while you are resting and not exerting yourself in any way, and is calculated from the oxygen you breathe. Your RMR represents the calories the body uses to maintain vital body functions such as heart rate, brain function, and breathing. In simple terms, it's the number of calories a person would burn if awake, but at rest, all day. We will use a device to measure your RMR at the clinic.

We will use a ventilated hood to measure your RMR. While you are resting quietly, a clear hood will be placed over your head to collect the oxygen you breathe in and the carbon dioxide you breathe out. The measurement should take about 5 – 10 minutes.

Doubly Labeled Water (DLW)

DLW is a special type of water with heavy atoms that are nonradioactive and naturally found in your body. The 4-ounce (1/2 cup) dose of DLW water you will drink will slightly raise your body's level of these atoms. We will use urine samples to measure the heavy atoms as they are eliminated from your body. The rate of elimination depends on how many calories your body uses.

Altogether, the DLW procedure will involve the collection of eight (8) urine samples. You will be given a dose of DLW to drink at the clinic. Prior to drinking the DLW dose, you will be asked to provide two (2) urine samples. You will then drink a small amount of the DLW. Later that day, you will provide four (4) more urine samples. We will provide you with the supplies and instructions for collecting your last two urine samples at home 10 to 14 days later. We will call you to remind you about the collection days. We will pick up samples from your home or you can drop them off at our clinic.

One week before and about two weeks after you drink the DLW (3 weeks total), you will need to stay within 100 miles of your home. Remaining in the same area is important because water you drink in other areas may have different levels of the naturally-occurring heavy atoms. Those different levels could affect our test results.

Heart Rate Monitor (HRM)

You will wear a heart rate monitor for seven (7) days that will record your heart rate and your activity during this period. The HRM will be attached to your chest using two (2) standard ECG pads. You will return the HRM at the end of the seven (7) day period. You will wear it all the time, except while swimming or showering. You will be asked to record the time you put the monitor on and took them off each day on a log sheet.

What are the benefits and risks of participating in the Additional Procedures Component?

Your participation in this component of the research study is completely voluntary. There are no direct benefits to you for participating in these procedures. By participating, you will help researchers learn more about the precision of the measurements in these tests.

There are no known risks associated with drinking 4 ounces (1/2 cup) of DLW. In a small number of people, this water can cause dizziness for up to 15 minutes after drinking. You will remain sitting in the clinic after drinking the water. We will assist you in obtaining appropriate medical treatment if for any reason you experience a research-related injury related to dizziness (e.g., fall or accident), but we cannot provide financial assistance for medical or other costs.

Will the information I give be kept private?

In becoming a study volunteer, the information you provide comes under the National Institutes of Health (NIH) privacy policy for research participants, and not the AARP's privacy policy. This means that if you give us your consent to participate in this additional component of the study by signing below, as with the main study, NIH will not share with AARP any identifiable information, and AARP will not share with NIH any identifiable information other than your contact information and current AARP membership status. This NIH privacy policy is summarized in the following two paragraphs:

The personal information you provide in this study will be kept private and secure. All personal identifying information will be securely encrypted and stored separately from the responses you give on the study questionnaires. Personal identifying information will be stored in a secure, password protected, and locked data file and only identified by a study number. In order to protect the privacy of the information you give us, only a study number will be used to identify you and the information you provide.

The results of the tests administered in this study will be kept private under the Privacy Act. Your name will not appear on the label of the urine samples or any of the study questionnaires. Results will be grouped and reported as summaries and will not contain any individual names. The study staff is required to keep your identity private and your name will never be used in any publications or presentations about this study. All staff working on the study will be required to sign a statement pledging to maintain the privacy of all data. Access to study data will be limited to the staff working on the study.

When the study is complete or until the data is no longer required for research, the data will be archived and/or destroyed.

What else do I need to know about the Additional Procedures Component of the study?

Your participation in this portion of the study is completely voluntary. If you decide to participate, you may decide not to answer specific questions or discontinue your participation at any time. When you agree to participate in the study, even if you later leave the study, all information collected from you will be securely stored and used in study analyses unless you indicate otherwise. There will be no penalty or loss of benefits to you if you decline to participate in the study or if you later decide to not participate further in the study. However, if you decide to participate, we hope that you will complete all study parts because we will need all of the information to draw correct conclusions.

What if I have questions, comments, or concerns?

This consent form explains this portion of the research study. If you have any questions, comments, or concerns about the Additional Procedures Component or the informed consent process, you may telephone or email the Principal Investigators, Dr. Heather Bowles (301-435-2845; heather.bowles@nih.gov) or Dr. Yikyung Park (301 594-6394; yikyung.park@nih.gov).
If you have any questions about being a research participant, you may contact the study by email at iDATAStudy@westat.com or call us toll-free at XXX-XXX-XXXX.
If you have any questions about any aspect of the study or your rights as a volunteer, a staff person will be on hand to answer them before you sign this consent form. Before you sign this form, please ask any questions on any aspects of this study that are unclear to you.

Approvals

This study protocol and this informed consent form have been reviewed by the Special Studies Institutional Review Boards of the United States National Cancer Institute and Westat in monitoring the research data. These review committees monitor the safety and the rights of individuals participating in this research study.

Legal rights

You are not waiving any of your legal rights by reading this consent form and agreeing to participate in the Additional Procedures Component of the study.

Remuneration

In appreciation of your contribution of time and effort to this study you will receive $100 at the completion of the final urine collection for this portion of the study.

Authorization:

The above Additional Procedures Component of the study has been explained to me, and I have read the information given. I voluntarily consent to be a part of this research. I have had a chance to ask questions and understand that future questions I may have about the research or about my rights will be answered by one of the investigators or staff listed below.

I understand the purpose of the additional procedures to be performed. I agree to participate with the understanding that I may withdraw at any time without any penalty.

_____ _____ _____

DATE PARTICIPANT'S NAME SIGNATURE

_____ _____ _____

DATE WITNESS NAME SIGNATURE

Project Coordinator's Statement:

I have provided an explanation of the above additional procedures for the research project. The participant was given an opportunity to discuss the procedures and to ask any additional questions. A signed copy of the consent form has been given to the participant.

_____ _____ _____

DATE PROJECT COORDINATOR SIGNATURE