SUPPORTING STATEMENT B FOR:

Interactive Diet and Activity Tracking in AARP (iDATA):

Biomarker Based Validation Study

NATIONAL CANCER INSTITUTE (NCI)

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LIST OF ATTACHMENTS

* These attachments are considered instruments to be completed by the participant.

B. STATISTICAL METHODS

B.1 Respondent Universe and Sampling Methods

The iDATA Study will be conducted among current living members of the NIH-AARP Diet and Health Study and current AARP members between the ages of 50 and 74 who live in the Pittsburgh, Pennsylvania, area. Eligible participants must be comfortable using a computer and have high-speed internet in order to complete the majority of the questionnaires. Participants will also be asked to visit the Pittsburgh study clinic three times over the course of one year. Biological samples will be collected at the clinic and by participants at home.

Sample size and power calculations were made such that 1500 participants (750 men and 750 women) should be sufficient to test hypotheses of interest within each gender with at least 85% power.

Table B.1-1. The power of testing H_0: attenuation factor $\leq \lambda_0$ against H_1: attenuation factor = λ_1 using a one-sided test at 5% significance level.

Sample Size/gender(n)	Power for nutrient density H_0: $\lambda_0 \leq 0.4$ vs.H_1: $\lambda_1 = 0.5$	Power for physical activity energy expenditure H_0: $\lambda_0 \leq 0.1$ vs. H_1: $\lambda_1 = 0.3$
350	59%	73%
500	72%	85%
750	86%	95%

Sample size calculations are based on testing the following hypotheses:

1) For nutrient density, test the null hypothesis H_0: attenuation factor ≤ 0.4 against the alternative H_1: attenuation factor = 0.5.
2) For physical activity energy expenditure, test H_0: attenuation factor ≤ 0.1 against H_1: attenuation factor = 0.3.

The hypotheses are based on an analysis of the Observing Protein and Energy Nutrition (OPEN) study (OMB No. 0925-0465), which estimated that for protein density the attenuation factor for six 24-hour recalls was greater than 0.5 (both men and women), while the attenuation factor for an FFQ was between 0.35 (women) and 0.4 (men). For total energy intake, the attenuation factor for six 24-hour recalls was about 0.35 for men and 0.25 for women, while the attenuation factor for an FFQ was about 0.1 for both men and women. We assumed that physical activity energy expenditure as measured by questionnaires and 24-hour recalls would approximately lead to the same attenuation as those for energy intake.

In the sample size calculations, a one-sided test at 5% significance level was used. The power depends not only on the hypothesized values of the attenuation factors, but also on the unknown ratio of the variance of the reference measurement to the variance of the considered instrument (questionnaire or 24-hour recall). Should the participation in the iDATA Study result in fewer than 750 men and women completing the study, the power will remain close to those shown for n = 750 in Table B.1-1 if the measurement error models fit for men and women grouped together, but only under the provision that most of the parameters in the model are the same for men and women.

As stated previously, participants will be recruited from current living members of the NIH-AARP Diet and Health Study (OMB No. 0925-0423, 0925-0587, expiry date 4/30/2011) and current AARP members between the ages of 50 and 74 who reside in the Pittsburgh, Pennsylvania, area. It is estimated that 50,000 households overall will need to be contacted in order to reach the target of 1500 participants completing the study. The anticipated response, eligibility, and participation rates between the two groups are expected to differ greatly. Therefore, initial sample size estimates and recruitment strategies have been customized for each group in order to maximize these rates.

The NIH-AARP Diet and Health Study began in 1995 and is the largest prospective cohort study with over 566,000 living and deceased participants that continues to examine the relationship between diet and major cancers in early-to late-middle aged men and women in the U.S. In the early stages of the study, participants completed and mailed back a food frequency questionnaire (FFQ) and a follow-up endpoint and exposure assessment questionnaire. More recently, selected participants have been asked to complete multiple administrations of the internet-based ASA24 (https://asa24.westat.com) and ACT-24 (http://act24demo.westat.com/) as well as the DHQ*Web-II as part of interactive Comprehensive Lifestyle Interview by Computer Study or iCLIC (OMB #0925-0594) and to complete a mailed short follow-up questionnaire (OMB # 0925-0587) to obtain information on disease outcomes and lifestyle factors. As the cohort ages, NIH-AARP Diet and Health Study participants continue to respond consistently to new information requests, both paper-based and internet-based.

Nearly 13,000 current living participants in the NIH-AARP Diet and Health Study reside in the Pittsburgh area, the majority of who are between the ages of 66-74. From this sample, 6,500 will be selected for the iDATA Study, of which it is expected that approximately 500 will complete the study. Even though potential participants from this group may be more likely to respond to the invitation to participate compared to the current AARP members, it is expected that many will not be eligible due to existing medical conditions and medication use. Once eligible however, it is expected that retention and completion rates in the group will be relatively high.

Given recent experiences with the recruitment of current AARP members aged 50 and over to participate in iCLIC, it is expected that recruitment rates into the iDATA Study may be low. Although this population includes younger as well as older potential participants (aged 50 to 74), low recruitment rates are expected because potential participants are not already affiliated

with the NIH-AARP Diet and Health Study and at least for the younger participants, they are more likely to be employed full-time and cannot commit the time to participate. It is also expected that a higher proportion of eligible participants will be needed from this group since a greater drop-out rate is likely. Therefore, 43,000 will be selected from current AARP members for the iDATA Study, of which it is expected that approximately 1,500 will complete the study. AARP members that were asked previously to participate in the feasibility study of the online instruments ACT24, ASA24, and DHQ (OMB # 0925-0594, expiry date 2/28/2014) will be removed from the list of AARP members prior to selecting the sample for the iDATA Study.

Overall, it is estimated that 49,500 potential participants will need to be contacted in order to recruit 2,500 eligible persons to ensure that 2,227 attend the first clinic visit. Of those, it is expected that about 67% (500 NIH-AARP Diet and Health Study cohort members and 1,000 current AARP members) will complete the entire study, (i.e., completing all visits, questionnaires, and biospecimen collections).

B.2 Procedures for the Collection of Information

Two versions of a paper invitation letter **(Attachment 30A-30B)**, one tailored to the existing NIH-AARP Diet and Health Study cohort and another tailored to current AARP members, will be sent to the potential participant sample previously described. The invitation letter will contain information about the study requirements, the procedures and questionnaires, and the compensation offered for participation. Invited persons will be requested to call a toll-free number in order to determine if they are eligible for the study and will provide an opportunity for questions about the study to be answered. Invited participants will also be able to contact the iDATA Study by email and will be able to find out more about the study at the study website. Potential participants who do not express interest in the study within a month of the initial invitation letter will be sent a second invitation letter. An email reminder **(Attachment 31)**

will also be sent to those current AARP members who have opted-in to receiving email messages (approximately 25% of AARP households in the Pittsburgh area have provided AARP with email addresses and agreed to receive email contact from AARP).

Participants will be administered a telephone pre-screening interview **(Attachment 1)** to determine initial eligibility into the study. The inclusion criterion includes access to a high speed internet connection. Exclusion criteria include non-English speakers or readers, those currently on a weight loss diet, BMI ≥ 40 or ≤ 18.5 (calculated from height and weight questions), history of renal failure, congestive heart failure, conditions involving disturbances in fluid balance, use of supplemental oxygen, and known allergy to para-amino benzoic acid (PABA, used in the 24-hour urine collections). Those determined to be eligible at that point will be sent in the mail an iDATA Study Welcome Packet **(Attachment 2)**, which will include a copy of the informed consent in addition to written information about the purpose of the study, number of clinic visits, the clinic location, and compensation for completing the study. Participants will also be contacted by the clinic study coordinator to set-up their first clinic appointment.

At the first clinic visit, participant eligibility will be confirmed and contact and demographic information will be collected. The informed consent will be reviewed with the participant whereby any questions will be answered by the clinic coordinator and the form signed and witnessed by a member of the study staff. It is expected that 2,227 individuals will attend the first visit and enroll in the study.

A number of physiologic measures, such as the resting metabolic rate (RMR), fitness test, doubly labeled water (DLW), and fasting blood collection will be conducted during the first clinic visit. Participants will be asked to visit the study clinic two additional times (once midway and once at the end of the year-long study period) for repeat tests and biospecimen collections. Monthly at-home assignments will include a combination of internet-based diet and physical

activity questionnaires and paper-based logs and records, biospecimen collections such as saliva and urine, and wearable motion detection devices.

Throughout the course of the year-long study, all participants will be administered the:

Number of Times Adminstered and Intervals	**Once**	**Two times at least six months apart**	**Three times over 12 months**	**Six times over 12 months**
Instruments or Forms	Pre-Screening Telephone Interview (Attachment 1)	DHQ*Web-II (Attachment 33)	Saliva Collection (Attachment 15)	ASA24 (Attachment 32)
	Clinic Eligibility Screening Interview (Attachment 3)	Fasting Blood Collection (Attachment 5)	Anthropometric measurements (Attachment 13)	ACT24 (Attachment 34)
	Fitness Test (Attachment 10)	4-day Food Record (Attachment 17)		
	Resting Metabolic Rate (RMR) test (Attachment 7)	7-day Food Checklist (Attachment 16)		
	Doubly Labeled Water (DLW) protocol (Attachment 6)	Resting Metabolic Rate (RMR) test (Attachment 7)		
	Physical Activity Readiness Questionnaires – PAR-Q or PARmed-X (Attachments 11A-11B)	Doubly Labeled Water (DLW) protocol (Attachment 6)		
	Heart Rate Monitor Log (Attachment 8)	Physical Activity Monitor Log (Accelerometer/ Inclinometer) (Attachment 12)		
		24-hour Urine Protocol and Form (Attachment 14)		
		Harvard Lifestyle Validation Study Physical Activity Questionnaire (Attachment 18)		
		Community Healthy Activities Model Program for Seniors (CHAMPS) (Attachment 19)		
		Sedentary Behaviors Questionnaire (Attachment 21)		
		NIH-AARP Physical Activity Questionnaire (Attachment 20)		
		Stanford physical activity Survey (Attachment 22)		

For the DLW and RMR protocols, a random subsample of 100 respondents (50 men and 50 women) will be selected from iDATA Study participants to repeat both the protocols six months following their initial administration and to wear a heart rate monitor for a period of seven days. This will help assess within person random error in these variables and measure cardiovascular response to physical activity intensity.

Westat, the contractor for the study, will provide standardized training for both Telephone Research Center (TRC) interviewers and clinic personnel to ensure uniform data collection. Westat will manage all data collection systems including information collected during the telephone screening interview, information collected at the study clinic, and information collected from internet and paper-based questionnaires and real-time data collection monitors. To ensure data quality, data will be captured either directly from answers provided to internet-based questionnaires, downloaded from a wearable motion detection device (accelerometer, inclinometer, heart-rate monitor), or keyed from hard-copy forms into the same central data collection system. In all cases, data will be stored in the central office data systems. Study forms, materials, and supplies will be stored and used at the study clinic site located in Pittsburgh, Pennsylvania, which will also be operated by Westat staff.

B.3 Methods to Maximize Response Rates and Deal with Nonresponse

Given the length of the iDATA Study and the number of questionnaires, tests, and biospecimens collected, participants will be compensated $150 after completion of the first clinic visit, $100 after the second clinic visit (6-months later) and $150 after the third clinic visit for a total of $400. The subsample of 100 participants who complete the additional DLW, RMR, and wear a heart rate monitor will receive an additional $100.

As stated above, two versions of a paper invitation letter, one tailored to the existing NIH-AARP Diet and Health Study cohort and another tailored to current AARP members will be

sent to the potential participants. The invitation letter to existing NIH-AARP Diet and Health Study cohort participants will emphasize the long-standing success of the study and the important role their continued participation plays in the progress of health research. The invitation letter to current AARP members will introduce the important ongoing research evaluating diet, physical activity, and chronic disease and will state the need for their participation.

Potential participants who do not express interest in the study within one month of the first invitation letter will be mailed a second invitation letter. The tone of the letter will transmit a greater sense of urgency and will emphasize the compensation offered for participation to a greater degree. An email invitation will also be sent to those current AARP members who have opted-in to receiving email messages. The email invitation will include signatures from both NCI investigators and the AARP leadership in order to increase confidence in the trustworthiness of the message. An iDATA Study logo will be included on all participant correspondence and study materials to continue to encourage study recognition throughout the study period.

Several efforts will be undertaken throughout the study to encourage continued participation and completion of all the data collection components. Chauffeured transportation will be provided to participants to and from the study clinic if needed. A courier service will be used to pick up the self-collected biospecimens.

For each study activity to be completed by the participant, including clinic visits and at-home completion of data collection instruments and biospecimen collection, an email and phone reminder will be sent to participants, providing the time period in which the activity must be completed and the specific instructions on completing the activity. In each reminder, participants will be provided with the clinic number and study's toll-free telephone number, the study email address, and the study website.

At the first clinic visit, an iDATA Study refrigerator magnet will be provided to participants containing the study contact information for easy reference to communication channels for the study. Participants will be encouraged to contact study personnel whenever they have a question.

B.4 Test of Procedures or Methods to be Undertaken

Many aspects of the iDATA Study have been previously tested and improved upon in order to minimize burden and improve utility. The OPEN study was an NCI-sponsored study designed to assess dietary measurement error by comparing results from self-reported dietary intake data with four dietary biomarkers: DLW and urinary nitrogen, sodium, and potassium. The study was conducted from July 1999 to March 2000 and included 484 men and women, aged 40-69 years old. The Re-OPEN study contacted OPEN study participants to further assess measurement error issues related to food records and a combined food frequency questionnaire and a 7-day checklist. Protocols, procedures, and questionnaires used in the OPEN and Re-OPEN studies provide the basis for much of the dietary information collected in the iDATA Study. Additionally, accelerometers have been previously used to collect physical activity monitor data from the 2003-2004 National Health and Nutrition Examination Survey (NHANES).

Recently iCLIC has tested the feasibility of using a Web-based Survey Management System (WSMS) for administering internet-based questionnaires, such as the DHQ*Web-II, and 24-hour recalls, including the ASA24 and ACT24. The WSMS System has proven to be an efficient and successful way of tracking complex questionnaire schedules.

The iDATA Study will also incorporate a start-up phase in order to work out minor details related to logistics, especially during the first few clinic days, which will schedule fewer

participants than capacity in order to allow for extra time per participant per procedure that may be needed to efficiently carry out all tasks scheduled for the day.

B.5 Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The iDATA Study was developed with consultation from a number of scientists throughout the development period. The study maintains an advisory committee that provides overall scientific direction for the study and serves as the major decision-making body for operations. Members of the advisory committee have provided expertise with developing the research plan, the conceptual framework, survey questions, and sampling strategies underlying the iDATA Study. Members of the advisory group, specifically those in the Biometry Research Group of the NCI Division of Cancer Prevention, Victor Kipnis, Ph.D, Douglass Midthune, MS, and Kevin Dodd, Ph.D, will be involved with the analysis once the data are collected. A full listing of the members of the iDATA advisory committee is contained in **Attachment 24.**

Furthermore, the iDATA Study was developed with consultation from scientists outside the agency. The study maintains relationships with two external scientists: Dale Schoeller, Ph.D, whose expertise is in developing stable isotope analysis techniques for measuring macronutrient metabolism, such as the DLW, and Patty Freedson, Ph.D., whose expertise is in wearable motion detection device calibration and validation for physical activity assessment. Both will be involved with analysis of the data from this study. Affiliations and contact information for the external scientific consultants can be found in **Attachment 25**.