

SUPPORTING STATEMENT A FOR:

Interactive Diet and Activity Tracking in AARP (iDATA):

Biomarker Based Validation Study (NCI)

NATIONAL CANCER INSTITUTE (NCI)

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A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

Statutory Authority. Section 410 of the Public Health Service Act (42 USC § 285) authorizes the National Cancer Institute (NCI) to, “support research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients.” The mission of the Applied Research Program (ARP) in the Division of Cancer Control and Population Sciences within NCI is to understand how and why cancer-care and control activities in the United States influence patterns of care and trends in cancer incidence, morbidity, mortality and survival. The ARP accomplishes this by supporting methodological research to improve survey data collection and clinical databases, developing assessment tools for use in clinical trials and observational studies, and analyzing existing cancer control data. The goal of the Risk Factor Monitoring and Methods Branch within the ARP is to contribute to reducing cancer in the US population by serving as a critical link between etiologic research on cancer risk factors and the translation of such research into targeted and effective interventions for prevention. One way this mission is carried out is to develop and improve the methods of assessing cancer risk factors.

Pursuant to the mission of the Risk Factor Monitoring and Methods Branch, this information collection request is necessary to determine the optimum approach for minimizing measurement error in dietary and physical activity instruments including the internet-based Automated Self-Administered 24-Hour Dietary Recall instrument (ASA24) and the Activities Completed over Time in 24 Hours (ACT24). The Interactive Diet and Activity Tracking in AARP (iDATA) Study is a cross-divisional project involving three different NCI Divisions.

This project is collaboration with investigators from the ARP in the Division of Cancer Control and Population Sciences, the Nutritional Epidemiology Branch of the Division of Cancer Epidemiology and Genetics, and the Biometry Research Group in the Division of Cancer Prevention. The iDATA Study will utilize biological markers and wearable motion detection devices as criterion measures against which internet-based and conventional self-report instruments for assessing diet and physical activity will be evaluated in a population of free-living older adults.

Justification and Background. Conflicting results have emerged from large cohort studies and pooled analyses of cohort studies that attempted to explain the nutritional determinants of cancer. These epidemiologic studies all included commonly used self-report instruments to assess diet, such as food frequency questionnaires (FFQ), 24-hour dietary recalls, and food records. Measurement error inherent in these instruments is likely a contributing factor for these conflicting results and raises the possibility that even when associations between dietary factors and cancer are observed the strength of the associations may be underestimated. Previous studies, including NCI's Observing Protein and Energy Nutrition (OPEN) study (OMB No. 0925-0465, exp.10/31/2006) and the Women's Health Initiative (WHI) study (OMB No. 0925-0414, exp. 7/31/2013, <http://www.nhlbi.nih.gov/whi/background.htm>) have provided critical information on the extent and structure of the measurement error in these commonly used dietary instruments. Results from these studies also indicated that multiple 24-hour dietary recalls over the course of one year provide more accurate information about usual dietary exposure and create less bias in estimated risk compared with the typical FFQ that asks participants to remember dietary information over the entire past year. An obstacle to the 24-hour recall method is that it is typically administered by interviewers, and is prohibitively

expensive to use in large studies, especially multiple administrations. In response, NCI has developed a self-administered internet-based version, ASA24, which allows multiple recalls to be collected at very limited study expense and relatively low participant burden.

The OPEN and WHI studies yielded significant advances in the field of dietary assessment and nutritional epidemiology; however, to date there has not been a comparable effort to understand the properties and measurement error structure of self-report physical activity instruments. The burgeoning epidemic of obesity highlights the need to explore measurement error in both aspects of energy balance - dietary intake and energy expenditure through physical activity.

Concern persists among researchers that the true risks for disease associated with low physical activity levels are understated due to the imprecision of self-reported assessment instruments that rely on the respondent's long-term memory of activities. Emerging evidence suggests that sedentary behaviors may influence the risk for disease, independent of one's participation in moderate to vigorous exercise. However, the methods for measuring sedentary behaviors are not well developed. The 2003-06 National Health and Nutrition Examination Survey (NHANES) (OMB No. 0920-0237, exp. 11/30/2012) indicated significant disagreement between typical, long-term memory-based self-reported activity and objective wearable motion detection devices. To address this, NCI has developed a new internet-based instrument, ACT24, which measures the participant's past 24-hour activities in order to improve the accuracy of self-reported physical activity.

The measurement error structure of the new internet-based 24-hour assessment tools for diet and physical activity, ASA24 and ACT24, needs to be evaluated using biological markers and wearable motion detection devices to determine methods for adjusting estimates of risk in

disease etiology studies. The iDATA Study is designed to validate the ASA24 and ACT24, and compare them to other commonly administered self-reported diet and physical activity questionnaires in a free-living population aged 50 to 74 years and residing in the Pittsburgh, Pennsylvania area. The sampling frame will include current participants in the NIH-AARP Diet and Health Study cohort and current members of AARP. Further details about the iDATA Study are described in Supporting Statement B.

A.2 Purpose and Use of the Information

The iDATA Study will compare objectively measured energy expenditure, protein, nutrients, and physical activity with the self-reported intakes of energy, protein, nutrients, and physical activity using the newly developed internet-based diet and physical activity assessment tools, ASA24 and ACT24, as well as conventional self-report instruments for assessing diet and physical activity.

The specific objectives of the iDATA Study are:

- 1) To evaluate the measurement error in self-reported dietary assessment instruments, including the ASA24, against objectively measured intakes of energy, protein, and other nutrients.
- 2) To investigate the measurement error in self-reported physical activity instruments, including ACT24, against objectively measured energy expenditure and motion.
- 3) To evaluate analytic approaches for combining different types of self-reported data on diet and physical activity as well as combining self-reported and objective data.
- 4) To evaluate the potential for ‘energy adjustment’ of diet and disease associations that incorporates physical activity and body size.

The following information will be collected to meet the objectives of the iDATA Study:

- A Pre-Screening Telephone Interview (**Attachment 1**) with questions about general health and medication use will be conducted to determine whether participants meet the study eligibility criteria. Participants who meet the initial eligibility requirements will receive an iDATA Brochure (**Attachment 2**) in the mail prior to their first clinic visit.
- A Clinic Eligibility Screening Interview (**Attachment 3**) will be conducted at the first clinic visit to confirm eligibility for the study. Participant contact information, demographic information, emergency contact information, health conditions, and medication use will be collected. Once eligibility is confirmed, the participant will review the informed consent form (**Attachments 4A-4B**) and will be able to ask questions prior to signing it.
- A fasting blood will be interviewer-administered to determine baseline values of nutrients, including folate, vitamin E, vitamin A, carotenoids, vitamin C, lipids, and fatty acids (**Attachment 5**).
- The participants' resting metabolic rate (RMR) will be measured using indirect calorimetry to determine the amount of daily energy expended while at rest. To objectively measure total free-living energy expenditure, participants will be asked to drink one dose of doubly-labelled water (DLW) and collect a series of eight urine samples (**Attachments 6 and 7**) once. However, a subset of 100 participants will be randomly selected to complete both protocols a second time at the clinic six months later.

- The same subset of participants completing the additional DLW and RMR will also be asked to wear a heart rate monitor for seven consecutive days to measure cardiovascular response to physical activity. Participants will be asked to complete a daily log reporting the times they put-on and take-off the heart rate monitor **(Attachment 8)**. Participants in the subsample will be asked to sign a separate informed consent **(Attachment 9)** agreeing to the additional administrations of the DLW and RMR procedures as well as the heart rate monitor protocol.
- The Modified Canadian Aerobic Fitness Test will be conducted to determine functional capacity and perceived exertion **(Attachment 10)**. Eligibility for fitness testing will be determined with a Physical Activity Readiness Questionnaire (PAR-Q or PARmed-X) **(Attachments 11A-11B)**. Fitness data will be used in the analytic models to correct differentially reported physical activity for aerobic capacity in the whole sample and to calibrate the heart rate monitors in the subsample.
- To assess actual physical activity behaviors, both sedentary and active, and to estimate physical activity energy expenditure, participants will be asked to wear two physical activity monitors during their waking hours for a seven day period. The monitors are small, wearable devices. One monitor will be worn on the hip attached to an adjustable fabric belt (accelerometers); the other will be worn on the thigh attached to an adhesive pad (inclinometers). Participants will record the times they put on and take off the monitors during the seven day period **(Attachment 12)**.
- Participants' height, weight, and circumferences of waist and hip will be measured at each clinic visit. Height will be measured once with a fixed stadiometer at the first clinic visit. Weight will be measured using a standardized procedure to allow

evaluation of any weight change over time. Circumferences of waist and hip will be measured using the same standardized protocol described in the NHANES III Anthropometric Procedures (**Attachment 13**).

- Participants will be asked to collect two at-home 24-hour urines, six months apart, and urines will be analysed for nitrogen and potassium and metabolic profiles. Participants will complete a brief log recording the start and stop times of the 24-hour urine collection and times when para-amino benzoic acid (PABA) tablets were taken (benign markers that indicate protocol compliance) (**Attachment 14**).
- Participants will be asked to collect saliva at home using a saliva collection kit containing all the necessary materials and instructions for providing the sample. Each collection will consist of one morning and one evening sample (**Attachment 15**). Saliva samples will be analyzed for oral bacteria and microbioms and will also be used to evaluate the metabolic profiles of participants.
- To assess self-reported dietary intake, a combination of commonly used self-reported dietary instruments and the ASA24 (**Attachment 32**) will be administered. The web-based Diet History Questionnaire-II (DHQ*Web-II) will be administered twice, 12 months apart (<https://riskfactor.cancer.gov/cgi-bin/dhq2.pl?module=2&method=1>). The DHQ*Web-II (**Attachment 33**) is a food frequency questionnaire that consists of 134 food items and eight dietary supplement questions and asks the frequency and portion sizes of foods participants consumed over the past 12 months. A 7-Day Food Checklist will be collected (**Attachment 16**) with the DHQ*Web-II. The checklist consists of food groups and a response area for the respondent to check when the food was consumed. A 4-Day Food Record will also be collected (**Attachment 17**) in

which participants will be asked to write all foods, beverages, and dietary supplements consumed for four consecutive days. The newly-developed internet-based ASA24 will be administered six times, to assess participants' diets throughout the year. The ASA24 will ask participants to identify from a list specific foods they ate in the past 24-hour time period and the portion size of each food item. A demo version of the ASA24 can be viewed at <https://asa24.westat.com>.

- To assess self-reported physical activity, participants will be asked to complete five questionnaires including the Harvard Lifestyle Validation Study Physical Activity Questionnaire (**Attachment 18**), the Community Healthy Activities Model Program for Seniors (CHAMPS) Questionnaire (**Attachment 19**), the NIH-AARP Diet and Health Study Physical Activity Questions (**Attachment 20**), a Sedentary Behaviors Questionnaire (**Attachment 21**), and the Stanford Brief Physical Activity Survey (**Attachment 22**). The ACT24 (**Attachment 34**) is a newly developed internet-based instrument for reporting time spent in physical activity and sedentary behaviors during the previous day. The ACT24 will ask participants to select a specific activity from a list of activity categories and answer a set of follow-up questions for each activity to assess the participants' physical activity throughout the year. A demo version of the ACT24 can be found at <http://act24demo.westat.com/>.

Refer to the Supporting Statement B, Section B2 for a table that outlines the number of times an instrument is administered annually or over the course of the study.

Achievement of the proposed objectives for the iDATA Study using the above described information will allow researchers to determine the optimum approach for minimizing diet and

physical activity measurement error. This new capacity will resolve uncertainty in other research efforts to investigate links between energy balance, diet, physical activity, and cancer.

A.3 Use of Improved Information Technology and Burden Reduction

The iDATA Study will use internet-based self-administered 24-hour recalls and questionnaires, computer-assisted telephone interviews (CATI), and self-administered paper instruments for data collection. Developments in information technology provide the capability to collect diet and physical activity 24-hour recalls using the automated and self-administered ASA24 and ACT24, which are fast, cost-effective, non-intrusive, and convenient. The DHQ*Web-II, an internet-based FFQ, allows respondents to follow automated skip patterns, to be queried to complete all questions before proceeding to the next, to navigate within the instrument to correct or modify responses, and to log in at any time to complete the questionnaire, starting where they left off. DHQ*Web-II provides efficiency with respect to data quality because respondents cannot complete the questionnaire with missing or inconsistent responses. Collections performed using CATI instruments will also offer reduced respondent time and cognitive burden, lower administration cost, and facilitate greater accuracy. The CATI system will be used to conduct the initial telephone pre-screening interview. Data collection time and data entry errors will be diminished since the information collected from computerized questionnaires and CATI will be stored directly into a database and not transferred from paper to electronic format. For certain collections, such as daily logs, paper questionnaires have been chosen for the sake of participant convenience.

A Web Survey Management System (WSMS) will be used to assign and track questionnaire administration schedules. This type of management system will also allow

participants to view and manage their progression through the study, thereby improving participant understanding, communication, and completion of tasks.

The Privacy Impact Assessment (PIA) is in the process of being approved at the NCI level and will ultimately be reviewed and approved by NIH and HHS (**Attachment 23**). The data collected in this study will be associated with an IT system, titled “NIH NCI Interactive Diet and Activity Tracking in AARP (iDATA)”.

A.4 Efforts to Identify Duplication and Use of Similar Information

The iDATA Study is unique in that it will collect biomarker and physical activity monitor data, in addition to self-reported diet and physical activity information, from current participants in the NIH-AARP Diet and Health Study, in which pre-existing data about dietary intake and physical activity is available. The internet-based questionnaires and accompanying WSMS represent a novel approach to conducting diet and physical activity research. The internet-based questionnaires can be applied to observational studies (whether small or large in scope), case-control studies, cohort studies, as well as randomized controlled trials that are evaluating the effects of diet, physical activity, and lifestyle factors with cancer outcomes.

A.5 Impact on Small Businesses or Other Small Entities

Small business entities will be used for services such as printing and mailing. Personnel required to staff the clinic site in Pittsburgh, Pennsylvania, will likely be hired through a local temp agency.

A.6 Consequences of Collecting the Information Less Frequently

Participants are asked to complete certain instruments at different time-points throughout the year. Participants are asked to complete some questionnaires twice in order to assess within-individual variation. Because of weekend versus weekday differences in diet and physical

activity, it is preferable to have respondents complete the questionnaires for as many days of the week as possible. Participants are also asked to complete the 24-hour recall instruments (ASA24 or ACT24) six times throughout the year because evidence suggests this method is more accurate compared to data collection methods that are administered once and require participants to recall their diet or physical activities over the course of the entire past year. Collecting the information less frequently would result in an incomplete assessment of diet and physical activity.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are special circumstances that require respondents to complete some of the data collection instruments more than once every three months. Participants are being asked to complete a 24-hour recall instrument each month of the study, alternating between the ASA24 and ACT24. A participant will only have until the end of the day that they are assigned either the ASA24 or ACT24 to complete the recall since these are 24-hour recall instruments. Two additional scheduling attempts will be made within the month if the participant is not able to complete the ASA24 or ACT24 on their scheduled day.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

The 60-Day Federal Register notice soliciting comments on this evaluation study prior to initial submission to OMB was published on March 14, 2011 (76 FR 13647). There were no public comments in response to the notice.

The iDATA Study was developed with consultation from a number of scientists throughout the development period. The study maintains an advisory group that provides overall scientific direction for the study and serves as the major decision-making body for operations.

The data collected in this study will be reviewed by the Co-Principal Investigators, as well as members of the iDATA advisory group (**Attachment 24**).

This study was developed with consultation from scientists within and outside the agency. The study maintains relationships with two external scientists: Dale Schoeller, whose expertise is in developing stable isotope analysis techniques for measuring macronutrient metabolism, such as the DLW, and Patty Freedson, whose expertise is in wearable motion detection device calibration and validation for physical activity assessment. Affiliations and contact information for the external scientific consultants can be found in (**Attachment 25**).

A.9 Explanation of Any Payment or Gift to Respondents

Participants who complete the entire year-long study including all biospecimen collections and dietary and physical activity self-report instruments will receive \$450 as an incentive to complete the study. To help reduce the drop-out rate, participants will receive the incentive throughout the year with the hope that participants will remain committed to the study. Participants will receive \$175 at the end of the first clinic visit; \$150 after the second clinic visit; and \$125 at the end of the third clinic visit. Participants that are selected for the additional RMR, DLW, and heart rate monitor protocol will receive an extra \$100 as a thank you for their participation. The incentive amount for iDATA is based on the length of the study and the number/length of clinic visits, the types of procedures and the discomfort associated with them, and the number and frequency of questionnaires to be complete. For example, it is estimated that participants will spend between 4-6 hours at the first clinic visit in order to complete a battery of health and fitness tests in addition to the questionnaires. Participants will also be asked to collect two 24-hour urine specimens during the year-long study; this type of collection can be very difficult for participants to do because of their work schedule or other commitments.

The incentive is also based on past studies such as OPEN in which participants were asked to ingest doubly-labeled water, to undergo health and fitness tests, to have blood drawn, and to complete questionnaires. The amount for iDATA is considered to be the minimum adequate payment for participants in consideration of their time spent completing the information collection materials and performing the at-home and in-clinic procedures associated with the study.

A.10 Assurance of Confidentiality Provided to Respondents

The information collected in this evaluation study is covered by NIH Privacy Act System of Records 09-25-0200, “Clinical, Basic, and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD” published in the Federal Register on 9/26/2002 (67 FR 60776) (**Attachment 26**).

Study data will be identified and retrieved by a study number only. Investigators will not have access to personal identifying information (PII). The majority of data collected in this study will be captured electronically, therefore avoiding concerns of hard-copy storage of materials that contain PII. Hard-copy data forms will be identified only by a study identification number and will be stored in locked files at the contractor’s facilities. Hard-copy records provided by the respondents will be destroyed once the study data has been incorporated into the study datasets. The datasets collected will be maintained until the completion of the study or until it is no longer required for research purposes.

Westat of Rockville, MD, the contractor for the iDATA Study, is responsible for storing identifiers in a secure, password protected, and locked file according to Department of Health and Human Services, ADP Systems Security Policy as described in DHHS ADP Systems Manual, Chapters 6-30 and 6-35. All computerized data is maintained in a manner that is

consistent with the Department of Health and Human Services ADP Systems Security Policy as described in DHHS ADP Systems Manual, Chapters 6-30 and 6-35. No reports or analysis files will contain PII. A complete list of the procedures Westat will take to keep the study data private are found in **Attachment 27**.

Furthermore, all contract staff members working on the study are required to sign a statement pledging to keep confidential all study data (**Attachment 28**). Access to study data is limited to the staff working on the study.

All respondents are made aware in writing that the information they provide will be kept private under the Privacy Act. All participants have the right to not answer particular questions without any consequence. An informed consent form, which includes descriptions of risks, benefits, and privacy protections, will be reviewed with each potential participant and will be signed by all those choosing to participate in the study.

The National Cancer Institute's Special Studies Institutional Review Board (IRB) reviewed and approved the iDATA Study on April 20, 2011, in accordance with 45 CFR 46. Westat's IRB has reviewed this study on May 13, 2011 and approved the iDATA Study. A copy of the IRB approvals is found in **Attachment 29**.

A.11 Justification for Sensitive Questions

PII is being collected in this study. In conducting this study it is important to capture data on medical conditions, medical procedures, health behaviors and physical characteristics. Additionally, name, home address, email address, and phone number will be collected and retained throughout the active study period because this information is necessary for maintaining contact with the participant. Updated contact information will be noted in study databases to aid

in future contact on continuing study participants. The data sets created will contain no means of identifying individual participants.

A.12 Estimates of Annualized Burden Hours and Costs

Table A.12-1 estimates the annualized respondent burden for the iDATA Study and includes the time that an individual participant will spend reading and understanding the request for information, as well as the time the participant spends developing, compiling, recording, reviewing, and providing the information. The annualized respondent burden for the iDATA Study includes not only questionnaires but also clinic procedures and biospecimen collections.

The total annual burden is estimated to be 15,060 hours which amounts to a total of 45,180 hours over the course of three years. This is a conservative estimate since the iDATA Study includes a number of clinic procedures and biospecimen collections that have either a few or no questions associated with the protocol. In addition, we have estimated the burden for the maximum number of participants needed to attend the first clinic visit (n=2227) in order for 1,500 participants to complete the study over a three-year period. Reductions in estimated burden for participant drop-out have not been made given it is difficult to determine when and for what reason a participant may decide to leave the study.

A.12 - 1 Estimates of Annual Burden Hours					
Type of Respondents for All Instruments: Adult Participants, 50-74 Years of Age					
Study Component	Instrument	Number of Respondents	Frequency of Response	Average Time per Response (Minutes/Hour)	Annual Burden Hours
Screening	Pre-Screening Telephone Interview (Attachment 1)	1,334	1	15/60 (.25)	334
	Clinic Eligibility Screening Interview (Attachment 3)	742	1	10/60 (.167)	124
Clinical Components	NHANES III Anthropometry (Attachment 13)	742	3	10/60 (.167)	371
	Resting Metabolic rate – Main (Attachment 7)	742	1	30/60 (.50)	371

A.12 - 1 Estimates of Annual Burden Hours					
Type of Respondents for All Instruments: Adult Participants, 50-74 Years of Age					
Study Component	Instrument	Number of Respondents	Frequency of Response	Average Time per Response (Minutes/Hour)	Annual Burden Hours
	Resting Metabolic Rate – Subsample (Attachment 7)	34	1	30/60 (.50)	17
	Fasting Blood Protocol and Form (Attachment 5)	742	2	10/60 (.167)	247
	Fitness test Protocol and Form (Attachment 10)	742	1	15/60 (.25)	186
	Physical Activity Readiness Questionnaires – PAR-Q or PARmed-X (Attachments 11A-11B)	742	1	5/60 (.083)	62
	Doubly Labelled Water – Main (Attachment 6)	742	1	40/60 (.667)	495
	Doubly Labelled Water – Subsample (Attachment 6)	34	1	40/60 (.667)	23
Dietary Questionnaires	Automated Self-Administered 24-hour Dietary Recall (ASA24) (Attachment 32)	742	6	30/60 (.50)	2,227
	4-Day Food Record (Attachment 17)	742	2	60/60 (1.0)	1,485
	Diet History Questionnaire (DHQ*Web-II) (Attachment 33)	742	2	45/60 (.75)	1,114
	7-Day Food Checklist (Attachment 16)	742	2	60/60 (1.0)	1,485
Physical Activity Questionnaires	Activities Completed over Time in 24 Hours (ACT24) (Attachment 34)	742	6	30/60 (.50)	2,227
	Community Healthy Activities Model Program for Seniors (CHAMPS) (Attachment 19)	742	2	15/60 (.25)	371
	Harvard Lifestyle Validation Study Physical Activity Questionnaire (Attachment 18)	742	2	10/60 (.167)	247
	Sedentary Behaviors Questionnaire (Attachment 21)	742	2	20/60 (.33)	495
	Stanford physical activity Survey (Attachment 22)	742	2	8/60 (.133)	198

A.12 - 1 Estimates of Annual Burden Hours					
Type of Respondents for All Instruments: Adult Participants, 50-74 Years of Age					
Study Component	Instrument	Number of Respondents	Frequency of Response	Average Time per Response (Minutes/Hour)	Annual Burden Hours
	NIH-AARP physical activity questions (Attachment 20)	742	2	10/60 (.167)	247
Home Collections	24 Hour Urine Collection Log (Attachment 14)	742	2	60/60 (1.0)	1,485
	Saliva Protocol and Form (Attachment 15)	742	3	10/60 (.167)	371
	Heart Rate Monitor Log (Attachment 8)	34	1	35/60 (.583)	20
	Physical Activity Monitor Log (Accelerometer/ Inclinometer) (Attachment 12)	742	2	35/60 (.583)	866
TOTAL					5,060

Table A.12-2 shows the total estimated annualized cost to respondents is \$233,461 at \$15.50 per hour, which is the 2009 median wage in the Pittsburgh metropolitan area according to the Bureau of Labor Statistics. This amounts to a total cost of \$700,383 over the course of three years.

Table A.12-2: Annualized Cost to Respondents				
Type of Respondents for All Instruments: Adult Participants, 50-74 Years of Age				
Study Component	Instrument	Annual Burden Hours	Hourly Wage Rate (\$)	Total Respondent Cost
Screening	Pre-Screening Telephone Interview (Attachment 1)	334	\$15.50	\$5,171
	Clinic Eligibility Screening Interview (Attachment 3)	124	\$15.50	\$1,918
Clinical Component	NHANES III Anthropometry (Attachment 13)	371	\$15.50	\$5,753
	Resting Metabolic rate – Main (Attachment 7)	371	\$15.50	\$5,753
	Resting Metabolic Rate – Subsample (Attachment 7)	17	\$15.50	\$264
	Fasting Blood Protocol and Form (Attachment 5)	247	\$15.50	\$3,835
	Fitness test Protocol and Form (Attachment 10)	186	\$15.50	\$8,630

Table A.12-2: Annualized Cost to Respondents				
Type of Respondents for All Instruments: Adult Participants, 50-74 Years of Age				
Study Component	Instrument	Annual Burden Hours	Hourly Wage Rate (\$)	Total Respondent Cost
	Physical Activity Readiness Questionnaires – PAR-Q or PARmed-X (Attachments 11A-11B)	6 2	\$15.50	\$2, 877
	Doubly Labelled Water – Main (Attachment 6)	4 95	\$15.50	\$7, 671
	Doubly Labelled Water – Subsample (Attachment 6)	2 3	\$15.50	\$35 1
Dietary Questionnaires	Automated Self-Administered 24-hour Dietary Recall (ASA24) (Attachment 32)	2 ,227	\$15.50	\$34 ,519
	4-Day Food Record (Attachment 17)	1 ,485	\$15.50	\$23 ,012
	Diet History Questionnaire (DHQ*Web-II) (Attachment 33)	1 ,114	\$15.50	\$17 ,259
	7-Day Food Checklist (Attachment 16)	1 ,485	\$15.50	\$23 ,012
Physical Activity Questionnaires	Activities Completed over Time in 24 Hours (ACT24) (Attachment 34)	2 ,227	\$15.50	\$34 ,519
	Community Healthy Activities Model Program for Seniors (CHAMPS) (Attachment 19)	3 71	\$15.50	\$5, 753
	Harvard Lifestyle Validation Study Physical Activity Questionnaire (Attachment 18)	2 47	\$15.50	\$3, 835
	Sedentary Behaviors Questionnaire (Attachment 21)	4 95	\$15.50	\$7, 671
	Stanford physical activity Survey (Attachment 22)	1 98	\$15.50	\$3, 068
	NIH-AARP physical activity questions (Attachment 20)	2 47	\$15.50	\$3, 835
Home Collections	24 Hour Urine Collection Log (Attachment 14)	1 ,485	\$15.50	\$23 ,012
	Saliva Protocol and Form (Attachment 15)	3 71	\$15.50	\$5, 753
	Heart Rate Monitor Log (Attachment 8)	2 0	\$15.50	\$30 7
	Physical Activity Monitor Log (Accelerometer/ Inclinometer) (Attachment 12)	8 66	\$15.50	\$13 ,424
Total				\$ 233,461

A.13 Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no direct costs to respondents other than their time to participate in the study.

A.14 Annualized Cost to the Federal Government

The estimated total cost to the government for the services of the study contractor over the duration of the study will be \$4,000,000 with an annualized cost of \$1,333,333. These costs include all management of the study including development of materials, establishment of the study clinic site, recruitment, data collection, response tracking, coding and processing the data, analysis of DLW and urine, and delivery of final data files.

NCI staff time required to participate in planning and design activities, monitoring the study, and in analysis of this data is estimated to average 0.3 FTE for scientific staff over the 36-month study period. This figure corresponds to a total of \$90,000 over 36 months, or an average annualized cost of \$30,000. Finally, there are costs associated with data analysis, which total \$51,000. The average annual cost to the government over the 12-month period is approximately \$1,380,333.

The overall government distribution is summarized in Table A.14-1.

Table A.14-1 Annual Cost to the Federal Government		
	Total	Annual Average
Contractor Costs	\$4,000,000	\$1,333,333
NCI Personnel Subtotal	\$90,000	\$30,000
Analysis	\$51,000	\$17,000
Grand Total	\$4,141,000	\$1,380,333

A.15 Explanation for Program Changes or Adjustments

This is a new collection of information.

A.16 Plans for Tabulation and Publication and Project Time Schedule

To evaluate the measurement error in self-reported dietary assessment instruments using objectively measured reference biomarkers, latent-variable (measurement error) models described in Kipnis et al. (2003) and Carroll et al. (2006a) will be used. The models allow self-reported dietary intake to have intake-related and person-specific biases, but assume that reference biomarkers (doubly-labelled water, urinary nitrogen, urinary potassium) provide unbiased estimates of true usual intake at the individual level. Such models allow researchers to estimate the joint distribution of true and reported intake, and to estimate parameters of interest such as the correlation of true and reported intake and the “attenuation factor”, or slope in the regression of true intake on reported intake. The attenuation factor is an important measure of the bias one can expect in estimated diet-disease relationships in epidemiologic studies due to measurement error in self-reported intake.

The same latent-variable models can be used to evaluate the measurement error in self-reported total physical activity (measured in energy expenditure), or the error in estimated total energy expenditure derived from a physical activity monitor, using doubly-labelled water as a reference instrument. Researchers can also use such models to develop algorithms for estimating total energy expenditure from the measurements of wearable motion detection devices. For other physical activity measures of interest, such as minutes of vigorous activity or minutes of sedentary time per day, the physical activity monitors can be used to derive approximately unbiased estimates that can be used as reference instruments.

To evaluate alternative analytic approaches for combining different types of self-report data on diet and physical activity-related behaviors as well as self-reported and objective data, the method described in Kipnis et al. (2009) will be employed, which uses a measurement error model to estimate the conditional expectation of true intake given the self-reported measures. If

an unbiased reference measurement is available, one can estimate an r-square value (proportion of the variance of true intake explained by the self-report measures). The r-square represents the relative efficiency of using that predictor in a diet-disease analysis, and can be used to assess different combinations of instruments, and the effect of additional applications of the ASA24 per person. The same approach can be used to combine self-reported physical activity measures, or self-reported measures with wearable motion detection devices and/or heart rate monitors. Another possibility is to combine self-reported diet (or physical activity) measures with biomarkers such as serum carotenoids. The problem with this strategy is that most biomarkers are not unbiased measures of intake, so that other statistical approaches are needed. We will examine one approach that has been suggested by Freedman et al. (2010), and another approach that is currently being developed.

Nutritional epidemiologists studying the effects of changes in diet composition use “energy-adjustment” models to assess associations between nutrient intake and disease when total energy intake is held constant. Typically, “energy-adjusted” intake is calculated as the residual in the regression of nutrient intake on total energy intake. In addition to their intrinsic interest, energy-adjustment models can reduce the effect of measurement error in reported intake (Kipnis et al. 2003). In this study, researchers will be able to assess whether additional adjustments for physical activity and body size can further reduce measurement error, and whether adjusting specific physical activity measures (e.g., minutes of vigorous activity or sedentary time) for total energy expenditure can reduce the effects of measurement error in reported physical activity.

To evaluate whether ‘energy adjustment’ that incorporates physical activity and body size can reduce measurement error, we will use multivariate measurement error models similar to

those described in Carroll et al. (2006a) to estimate the joint distribution of true and reported values (nutrient intake, total energy, physical activity, body size). We can then calculate residual reported intake (given reported total energy, physical activity and body size) and residual true intake (given true total energy, physical activity and body size), and assess the measurement error properties of reported residual intake as a measure of true residual intake. Specifically, researchers will calculate the correlation of true and reported residual intake and the attenuation factor for residual reported intake and compare them to the same measures calculated for the simpler model that adjusts only for energy.

The following planned reports will be generated:

- Characteristics of the study sample
- Nutrient intakes based on ASA24, DHQ*Web-II, 4-day food diary and biomarkers
- Nutrient intakes based on biomarkers: for example total energy expenditure using doubly labelled water method and protein intake based on urinary nitrogen excretion.
- Physical activity based on ACT24 and other self-reported physical activity questionnaires
- Estimated physical activity based on wearable motion detection devices
- Estimate ratio of energy intake from ASA24 to total energy expenditure
- Estimate ratio of energy intake from DHQ*Web-II and 4-day food diary to total energy expenditure
- Estimate ratio of protein intake from ASA24 to urinary nitrogen concentration
- Estimate ratio of protein intake from DHQ*Web-II and 4-day food diary to urinary nitrogen

- Percentage of respondents classified as under-reporters of dietary intake by age, sex, body mass index, and other characteristics
- Percentage of respondents classified as over-reporters of dietary intake by age, sex, body mass index, and other characteristics
- Percentage of respondents classified as over-reporters of physical activity by age, body mass index, and other characteristics
- Estimated attenuation factor and correlation of nutrient intakes from ASA24 and other self-reported diet questionnaires and true intake from biomarkers
- Variance of true intake and parameters of dietary measurement error in ASA24 and other self-reported diet questionnaires
- Medians and quartiles for energy, protein, and protein density assessed by biomarker, ASA24 and other diet questionnaires
- Estimated between-person variation of true intake, slopes in the regressions of reported on true intake, variances of person-specific bias, and within-person variation for energy, protein, and protein density assessed by ASA24 and other diet questionnaires
- Estimated attenuation factors and correlations for energy, protein, and protein density assessed by ASA24 and other diet questionnaires for different numbers of repeats of the instrument

References to publications cited in this section are located on the last page of this document.

Table A.16-1. Project schedule for completing data collection, processing, and analysis.

Table A.16-1. Project Time Schedule	
Milestone	Completion Schedule

OMB Approval	OMB Approval
Study population selection and invitation mailing	One month after OMB approval
Recruitment phone calls and study enrolment	2-8 months after OMB approval
Data collection	2-34 months after OMB approval
Completion of data processing and analysis	36-42 months after OMB approval
Results reporting	36-42 months after OMB approval
Publication of results	45 months after OMB approval

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

All instruments will display the OMB expiration date.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to the Certification for Paperwork Reduction Act Submissions are requested.

References for Section A.16

Carroll RJ, Midthune D, Freedman LS, Kipnis V (2006a). Seemingly unrelated measurement error models, with application to nutritional epidemiology. *Biometrics* 62, 75-84.

Carroll RJ, Ruppert D, Stefanski LA, Crainiceanu CM (2006b). *Measurement error in nonlinear models: a modern perspective* (2nd edition). Chapman Hall/CRC: Boca Raton, FL.

Freedman LS, Kipnis V, Schatzkin A, Tasevska N, Potischman N (2010). Can we use biomarkers in combination with self-reports to strengthen the analysis of nutritional epidemiologic studies? *Epidemiologic Perspectives & Innovations* 7, 2-9.

Kipnis V, Subar AF, Midthune D, Freedman LS, Ballard-Barbash R, Troiano R, Bingham S, Schoeller DA, Schatzkin A, Carroll RJ (2003). The structure of measurement error: results of the OPEN biomarker study. *American Journal of Epidemiology* 158, 14-21.

Kipnis V, Midthune D, Buckman DW, Dodd KW, Guenther PM, Krebs-Smith SM, Subar AF, Tooze JA, Carroll RJ, Freedman LS (2009). Modeling data with excess zeroes and measurement error: application to evaluating relationships between episodically-consumed foods and health outcomes. *Biometrics* 65, 1003-1010.

Schatzkin A, Kipnis V, Carroll RJ, Midthune D, Subar AF, Bingham S, Schoeller DA, Troiano RP, Freedman LS (2003). A comparison of a food frequency questionnaire with a 24-hour recall for use in an epidemiological cohort study: results from the biomarker-based Observing Protein and Energy Nutrition (OPEN) study. *International Journal of Epidemiology* 32, 1054-1062.