SUPPORTING STATEMENT A FOR:

THE NIH-AARP *interactive* COMPREHENSIVE LIFESTYLE INTERVIEW BY COMPUTER STUDY (*i*CLIC) (NCI)

OMB #0925-0594
Expiry Date: 12/31/2010

NATIONAL CANCER INSTITUTE (NCI)

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This is a request for an extension. Yellow highlights in this document indicate changes from the final version of the SSA submitted in November, 2008 and the two non-substantive change approvals (March and November, 2009).

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A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

The Public Health Service Act, Section 412 (42 USC § 285a-1) and Section 413 (42 USC § 285a-2) authorizes the Division of Cancer Epidemiology and Genetics (DCEG) of the National Cancer Institute (NCI) to establish and support programs for the detection, diagnosis, prevention and treatment of cancer; and to collect, identify, analyze and disseminate information on cancer research, diagnosis, prevention, and treatment. The goal of the Nutritional Epidemiology Branch (NEB) within the DCEG is to clarify the nutritional etiology of cancer by conducting independent and collaborative research intended to raise the level of evidence of the association between nutritional factors and cancer. More recently, researchers have included investigations on the relationship of cancer to total energy expenditure to more completely assess the impact of nutritional factors on the development of cancer.

In 1995, the Nutritional Epidemiology Branch of NCI fielded the Prospective Study of Diet and Cancer in members of the American Association of Retired Persons (AARP) (OMB# 0925-0423). The "public friendly" name of this study is the National Institutes of Health (NIH)-AARP Diet and Health Study. The study cohort consisted of men and women who were members of the American Association of Retired Persons (AARP). Screening questionnaires (food frequency questionnaires) were initially mailed to 3.5 million AARP members who were 50 to 69 years of age, and who resided in the eight geographic areas selected for this study. The eight states or areas that were selected for this study were chosen on the basis of: 1) having a population-based cancer registry with adequate coverage and quality, and 2) having a sizeable minority population.

The current cohort consists of 566,402 persons, (60% men and 40% women), including both live and deceased cohort members. This study is the largest cohort study capable of prospectively examining the relationship between diet and major cancers in a cohort of early-to late-middle aged men and women in the U.S. In the early stages of the study, recruited cohort members completed and mailed back a food frequency questionnaire (FFQ) and a follow-up endpoint and exposure assessment questionnaire. More recently, another mailed follow-up questionnaire obtained information on disease outcomes and lifestyle factors. Cancer diagnosis and cause-of-death follow-up has been conducted over time by obtaining data from established population-based cancer registries and the National Death Index.

The study's original summary (**Attachment 1**) addressed three methodological problems impeding epidemiologic investigations of diet and cancer: 1) the prospective cohort eliminated recall bias by assessing diet prior to cancer diagnosis; 2) the large size of the cohort compensated for dietary measurement error; and 3) a two-stage cohort construction strategy allowed for enrichment of study population with persons at the extremes of intake to reduce the potential problem of homogeneity of dietary intake. In fact, enrichment was not necessary as both men and women in this cohort were found to have the desired wide distributions of intake of foods groups and nutrients of interest.

The NEB has planned the current *i*CLIC study (**Attachment 5**) to evaluate the feasibility of using these three computerized questionnaires and the DHQ in a population of early-to-late-middle-aged men and women as described above. The specific objectives of this evaluation study are:

- to determine response rates to an email invitation to participate in a study evaluating the four computerized questionnaires;

- to determine eligibility rates of those responding to the invitation to participate in the evaluation study;
- to evaluate the performance and configuration of the technical design of the computerized questionnaires;
- to evaluate the range of dietary intake, especially the extreme categories of dietary intake (in terms of fat, fiber, and other nutrients), using the ASA24 and to compare it to the dietary information collected using the DHQ;
- to identify the range of physical activity using the ACT-24 to ensure adequate reporting of daily physical activities; and
- to evaluate lifestyle and behavioral issues, medical conditions, and health practices, and the range of dietary intake and physical activity reporting associated with them.

This evaluation study comprises the necessary performance and feasibility tests for the new computerized questionnaires, which will provide an opportunity to assess the possibility of administering computerized questionnaires in future large prospective cohort studies. This evaluation study will also provide an opportunity to characterize participants' diet, physical activity, and lifestyle factors by using more detailed diet and health questionnaires.

A.2 Purpose and Use of Information

Numerous analyses have been performed using the data collected. The data collected at the beginning (1995-96) of the NIH-AARP Diet and Health Study has been used to examine the diet and cancer relationship, and scientific papers with important public health messages have been published. To date, over 100 papers describing the study's findings have been published in

scientific journals; many more are currently in press or have been submitted for review (**Attachment 2**). However, rapidly growing public health problems, especially obesity, physical inactivity, and several medical conditions, demand more research on the associations between diet, physical activity, and lifestyle and cancer as well as other health problems.

We propose building upon this research by utilizing developments in computer technology to conduct a feasibility study of four web-based instruments to better assess dietary intake, physical activity, lifestyle and behavioral factors, and self-reported health conditions. Early in 2009, we mailed invitations (**Attachments 3-1 to 3-6**) to 5,000 members of the current cohort, along with 10,000 current AARP members ages 50 and older from the same eight states as well as sixteen additional states known to have high-quality cancer registries. The response rate to two hard-copy invitations was less than 10% and very few of the original 15,000 invited had an email address and access to high-speed internet. However, a greater number of incoming AARP members appear to have email addresses as indicated by their selection of the AARP membership option to provide email addresses as a means of personal contact, thus expanding the absolute universe from which we are recruiting. Moreover, it highlights the importance of validating email as a successful mechanism for study contact.

Use of an email invitation also permits greater flexibility in customizing reasonable, repeated email invitations to a potential participant and provides an interested respondent with easy, direct access to the study website by clicking on an imbedded link in the email invitation. We wish to test if these electronic functions will aid in boosting response rates. An increased sample size will support the full evaluation of completion rates for the various instruments and will allow the assessment of the range of dietary intake, physical activity and lifestyle behaviors

among those responding, information that cannot be assessed without adequate completion of the instruments.

OMB approved an additional 50,000 AARP members aged 50 and older who have opted-in to receiving emails from AARP and who are not part of the current cohort to be invited by email to participate in the feasibility study **(Attachments 3-7 and 3-8)**. Based on data analysis conducted to date, the four pathway strategy did not improve the odds of a respondent completing the questionnaires and thus for this submission, it has been decided that all respondents will only follow a simplified questionnaire pathway, which is outlined in the SSB, p.3.

The four questionnaires used in the study are described below. Additional information and references about the questionnaires is discussed in the Background and References section of this document.

1. The Automated Self-Administered 24-hour Dietary Recall (ASA24) is a newly-developed computerized questionnaire that assesses an individual's diet during the previous 24-hour time-interval at multiple time points. This instrument has been developed in order to measure diet more accurately and in more detail than the traditional paper-based methods that assess an individual's diet during the previous year. The most commonly used existing self-administered questionnaires that assess diet are only based on a relatively small set of questions (e.g. 124 food items consumed), which is likely contributing to measurement error. Investigators are concerned that error in the measurement of diet using food intake over the past year may be compromising the ability to detect important but modest associations between nutrition and cancer.

The ASA24 will ask participants to identify specific food items they ate in the past 24-hour time period by selecting various items from a list. Participants will identify the portion size of each food item

by choosing a photograph that most closely resembles it. The test version of the ASA24 can be viewed online at the following URL: https://asa24.westat.com. If you have a pop-up blocker you will need to turn it off, or "accept pop-ups", for this website to work. The burden statement (**Attachment 4-1A**) and screenshots of the ASA24 instrument have also been provided (**Attachment 4-1B**). The food items reported in the screenshots are only examples of what a participant might report. The actual food items reported will be unique for each participant given the instrument uses a calendar or diary format. Additional information about the ASA24 instrument can be found at the National Cancer Institute's Risk Factor Monitoring and Management website: http://riskfactor.cancer.gov/tools/instruments/asa24.html

2. The Activities Completed by Time in 24 hours (ACT-24), assesses common daily physical activities or categories of physical activities performed on the day before the questionnaire is completed. This instrument addresses the need to obtain more detailed reports of physical activity in order to detect the potential associations between physical activity and cancer. Participants will enter the type of physical activity, the duration, and the time of day the physical activity was performed during the past 24-hour time period by choosing from a list of either daily activities performed (e.g. showering, cooking and preparing meals, driving a vehicle, working, using the computer, shopping, etc) or general activities (e.g. exercise and sports, routine chores, home/yard maintenance, quiet/leisure activities, etc). Depending on which activity is selected, the participant will enter more detail about the activity.

The test version of the ACT-24 can be viewed online at the following URL: http://act24demo.westat.com. The username for this questionnaire is "john" and the password is "bagelbites". The burden statement (**Attachment 4-2A**) and screenshots of the ACT-24 instrument have also been provided (**Attachment 4-2B**). The activities reported in the screenshots are only examples of what a participant might report. The actual activities reported will be unique for each participant given the instrument uses a calendar or diary format.

3. It is also important to consider how lifestyle and behavioral issues, medical conditions, and health practices influence or confound the associations observed between diet and physical activity exposure and cancer. Some questions regarding lifestyle factors have been included in previous NIH-AARP Diet and Health Study questionnaires; however they do not represent a comprehensive assessment of lifestyle and behavioral issues, medical conditions, and health practices. To measure these in a comprehensive and accurate way, we will use the computerized questionnaire called the Lifestyle and Health History Questionnaire (LHQ) to assess an individual's lifestyle factors through their entire lifespan. The questionnaire is divided into sections including general health, family health history, smoking and alcohol use, reproductive health, body shape, oral health, vitamin use and medications, sleeping habits, and demographic information. This questionnaire is designed as a traditional online instrument with imbedded skip patterns and edits checks that allow the presentation of questions based on previous responses or information.

The burden statement (**Attachment 4-3A**) and the screenshots of the LHQ instrument have also been provided (**Attachment 4-3B – Partial LHQ**). The website link is available to the respondents through the Web Survey Management System (WSMS) when they complete enrollment. There is no demo site available however, the paper version of the LHQ was only used for developing the computer-based LHQ questionnaire and will not be viewed by participants. The questions contained in the paper version of the LHQ are identical to the questions found in the computer-based version (**Attachment 4-3B – Full Paper LHQ)**.

4. The DHQ (Diet and Health History Questionnaire) is a food frequency questionnaire developed by NCI and is widely used in the assessment of dietary intake over the year prior to

the questionnaire completion date. The initial baseline questionnaire for the NIH-AARP Diet and Health Study used these questions, with additional questions added. This study will use the web-based version of the questionnaire that has been available to researchers online for a number of years. The DHQ ask participants about what they ate over the past 12 months versus the past 24-hours and will be used to compare dietary intake responses from ASA24.

The demo version of the DHQ can be viewed online at the following URL: http://riskfactor.cancer.gov/DHQ/. You will need to click on the DHQ*Web Demo link found on the right-hand side of the screen in order to access the demo version of the questionnaire. The burden statement (**Attachment 4-4A**) and the paper version of the DHQ instrument have also been provided (**Attachment 4-4B**). The Web-based version is identical in content to the original DHQ.

A.3 Use of Improved Information Technology and Burden Reduction

The diet, physical activity, and lifestyle information obtained in the computerized questionnaires will be an improvement over traditional paper-based questionnaires. The format of the questions in the computerized questionnaires will eliminate potentially confusing skip patterns by presenting to the participant only those questions that pertain to them, since skip patterns will automatically run behind the scenes (for example men will not need to skip through questions pertaining to women's health because they will not be presented with those questions). Data collection time and data entry errors will be diminished since the information collected from computerized questionnaires will be stored directly into a database and not transferred from paper to electronic format. This

process will be more efficient and cost-effective compared to using traditional paper-based questionnaires.

Information will also be collected from a comprehensive Web Survey Management System (WSMS). WSMS will be used to consent and enroll participants in the study, assign and manage questionnaire schedules, and route participants to each questionnaire. The test version of WSMS can be viewed online at the following URL: http://aarpwsmsdemo.westat.com. In addition to the URL, screenshots are provided of the pre-enrollment (**Attachment 6**) and enrollment activities (**Attachment 7**) that display how information will be collected by WSMS.

Developments in computerized questionnaire technology provide an opportunity to collect diet, physical activity, and lifestyle information using computerized questionnaires, which are fast, cost-effective, non-intrusive, and convenient. The 24 hour-recall instruments (ASA24 and ACT-24) will help reduce the burden to the participants by allowing them to log only the food items they ate or the physical activities they performed the day before the questionnaire completion. The LHQ computerized questionnaire will help reduce the burden to participants by improving the flow of the questions. The instrument is designed to follow a traditional skip pattern without the participant having to scroll through questions that do not apply. This will make it easier for the participant to understand which questions need to be answered as well as reduce the amount of time required to complete the questionnaire. A participant will experience no burden if he/she chooses not to respond to the questionnaire.

This data collection will be associated with an IT system, titled "NIH NCI AARP Phase I Pilot Study (APS)," to collect, use, store, maintain, disclose and possibly transmit

data if necessary. The Privacy Impact Assessment (PIA) was approved by DHHS on April 1, 2010 **(Attachment 16)**.

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

This evaluation study is unique in that it will be used in a population including younger AARP members who are more likely to have greater access to and knowledge of the internet. This study will be using newly designed computerized questionnaires to collect more detailed, targeted information about dietary intake, physical activity, and lifestyle factors. The dietary intake and physical activity instruments are based on a 24-hour recall, which has not been conducted before in this population or any other large scale cohort study.

The computerized questionnaires and accompanying Web Survey Management System represent a novel approach to conducting diet, physical activity, and lifestyle factor research. The computerized 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. This study will evaluate the use of computerized questionnaires in a sample of participants in order to assess the feasibility of using these computerized questionnaires in a large cohort study.

A.5 Impact on Small Businesses and Other Small Entities

No small businesses or other small entities will be involved in this study.

A.6 Consequences of Collecting the Information Less Frequently

Participants will be asked to complete the computerized questionnaires at different time-points during a three month period. Participants are being asked to complete the 24-hour recall instruments (ASA24 or ACT-24) more than once because evidence suggests that alternative data collection methods, such as 24-hour recalls or multi-day diet records, are 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 past year (such as the DHQ).

A.7 Special Circumstances Relating to 5 CFR 1320.5

There are special circumstances that require respondents to complete the information collection more than once every three months. The formative information collected in this evaluation study will be used to improve the accuracy of the data collected, reduce respondent burden, and decrease the costs of administration. Collecting the information less frequently would result in measurement error for diet, physical activity, and lifestyle factors that may compromise the ability to detect important albeit modest associations between diet, physical activity, and lifestyle factors with cancer.

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 October 18, 2010 (75 FR 63833). There was one public comment received on October 18, 2010 which questioned the use of "spending American tax dollars on this study." A response was sent on December 14, 2010.

The NIH-AARP *interactive* Comprehensive Lifestyle Interview by Computer (*i*CLIC) evaluation study was developed with consultation from a number of scientists throughout the development period. The study maintains a Steering Committee that meets monthly to discuss the design, conduct, and analyses for the study (**Attachment 10**). The committee provides overall scientific direction for the study and serves as the major decision-making body for operations. Additionally, NCI maintains an External Working Group advisory committee composed of external scientists well-prepared to advise NCI regarding the overall benefit of the study and its future direction (**Attachment 10**). The most recent External Working Group meeting was by teleconference on October 30th, 2009.

The data collected in this evaluation study will be reviewed by the Principal Investigator, External Working Group, and the Steering Committee members (**Attachment 10**).

A.9 Explanation of Any Payment of Gift to Respondents

Participants responding to this evaluation study will not receive remuneration for their participation.

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 11**).

The data required for linking to cancer registries, such as date of birth and social security number will be collected only to evaluate the participants' willingness to provide the information, which is important for future large-scale prospective studies that will rely on linkages to state cancer registries. Providing SSN will not be a requirement for participation. Participants in this study will not be passively followed for cancer outcomes.

Study data will be identified and retrieved by a study number only. Investigators will not have access to personal identifiers such as SSN, name, or address. All data collected in this study will be captured electronically, therefore avoiding concerns of hard-copy storage of materials that contain PII. Updated contact information will be noted in study databases to aid in future contact on continuing study participants.

Westat Inc. of Rockville, MD, a contractor for this evaluation study, is responsible for storing the 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 data files will contain PII. A complete list of the procedures Westat will take to keep the study data private are found in **Attachment 12**.

Furthermore, all contract staff members working on the study are required to sign a statement pledging to keep confidential all study data **(Attachment 17)**. 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. The data collected will be maintained until the completion of the study or until it is no longer required for research purposes.

The National Cancer Institute's Special Studies Institutional Review Board (IRB) reviewed and approved the NIH-AARP *interactive* Comprehensive Lifestyle Interview by Computer (*i*CLIC) study in March 2010, in accordance with 45 CFR 46. A copy of the IRB approvals are found in **Attachments 13A and 13B.**

A.11 Justification of Sensitive Questions

The participant's name, home address, and email address will be collected and retained throughout the active study period in order to maintain contact with the respondent. Personally identifiable information (PII) such as Social Security Number and date of birth will also be collected, although passive follow-up of participants' cancer outcomes will not be conducted in this study. Participants will be asked to provide their date of birth, gender, and social security number solely for the purpose of evaluating the participants' willingness to provide the information, which will be important for planning future large-scale studies will rely on linkages to state cancer registries. Participants will not be followed for cancer outcomes in this evaluation study. The purpose of evaluating the computerized questionnaires is to determine the best possible way for fashioning sensitive questions so that the respondent's comfort level is maximized and the responses are valid.

A.12 Estimates of Annualized Burden Hours and Costs

The study invitation letters and enrollment instruction card **(Attachments 3-1 to 3-6)** were mailed to 15,000 potential participants, as described earlier. The response rate to two hard-copy invitations was less than 10% and very few of the original 15,000 invited had an email address and access to high-speed internet.

Although an additional 50,000 potential participants will be invited, we do not expect that all email invitations **(Attachments 3-7 to 3-8)** will reach the potential participant; email is sometimes filtered or placed in junk or spam boxes and not received by the intended recipient. When this happens, the overall sample size is reduced in effect because the intended recipient never has the opportunity to read the invitation, and therefore has no associated burden. Given that at this time we do not have an accurate assessment of the extent to which recipients will open and read the email invitation, we will calculate the opening of email invitations in order to determine actual contact with potential participants. Such information will provide a much better determination of initial sample size needed to achieve desired response rates in a large future study.

In keeping with OMB requirements, Table A.12-1 documents the burden associated with the recruitment of the additional 50,000 persons who proceed to study enrollment and completion over a three-year recruiting period. A participant will be considered enrolled in the study if they agree to consent to participate in the study (**Attachments 6 and 14**), answer the required eligibility questions, and create a user identification code and password for accessing the study website that contains their assigned questionnaire schedule (**Attachment 7**).

It is estimated that approximately 16,667 participants will spend 1 minute each to read the email invitation letter **(Attachments 3-1 to 3-5 and 3-7, 3-8)**. Of those participants, 2,312 will continue to pre-enrollment following the steps on the enrollment instruction card **(Attachment 3-6),** which will account for the amount of time it will take a participant to access the study website, and read and agree to the consent statement. Answering the eligibility questions is considered part of the enrollment process. An hour burden has also been estimated for completing an optional evaluation survey, which will assess the participants' experiences during the study.

The annualized hour burden listed in Table 12-1 is estimated at 6886, which amounts to a total burden of 20,658 hours over the course of three years. However, it must be noted that this is truly an estimate for this feasibility study. A goal of this study is to determine how long it will take participants to complete the questionnaires given the participants' age, internet access and connection, and willingness to complete all surveys.

Similarly, the potential annualized cost to respondents will vary based on their level of participation. The estimated annualized costs are listed in Table 12-2. At $17.68 per hour, the total estimated annualized cost to respondents that complete all components of the study is approximately $121,743.

An additional annualized cost for re-entry (**Attachment 8**) into the study website has been accounted for based on the frequency of questionnaire assignments. Also, an annualized cost for completing the optional evaluation survey has been included (**Attachment 9**).

Table 12-1. Estimates of Annual Burden Hours				
Instrument(s) Tested	**Frequency of Response**	**Average Time per Response (Minutes/Hour)**	**Number of Respondents**	**Annual Hour Burden**
Read Invitation (Attachments 3)	1.00	1/60 (0.017)	16,667.00	278
Pre-Enrollment (Attachment 6)	1.00	10/60 (0.167)	2,312.00	385
Enrollment Process (Attachment 7)	1.00	5/60 (0.083)	2,288.00	191
ASA24 (Attachments 4-1)	2.00	30/60 (0.500)	1,944.00	1,944
ACT-24 (Attachments 4-2)	2.00	15/60 (0.250)	1,944.00	972
LHQ (Attachments 4-3)	1.00	20/60 (0.333)	1,944.00	648
DHQ (Attachments 4-4)	1.00	45/60 (0.750)	1,944.00	1,458
Web Re-entry (Attachment 8)	6.00	5/60 (0.083)	1,944.00	972
Evaluation Survey (Attachment 9)	1.00	1/60 (0.017)	2,288.00	38
Totals			33,275.00	6,886

Table 12-2. Annualized Cost to Respondents				
Type of Respondents	**Instrument(s) Tested**	**Annual Hour Burden**	**Hourly Wage Rate**	**Annual Respondent Cost**
Adults aged 50 and over	**Read Invitation**	278	$17.68	$4,911.15
	Pre-Enrollment	385	$17.68	$6,812.63
	Enrollment Process	191	$17.68	$3,371.05
	ASA24	1944	$17.68	$34,369.92
	ACT-24	972	$17.68	$17,184.96
	LHQ	648	$17.68	$11,456.64
	DHQ	1458	$17.68	$25,777.44
	Web Re-entry	972	$17.68	$17,184.96
	Evaluation Survey	38	$17.68	$674.14
Totals		6886		$121,743.01

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

There are no capital costs, operating costs, or maintenance costs to report.

A.14 Annualized Costs to the Federal Government

The estimated total cost to the government for the services of the study contractor(s) over the duration of the remainder of the study will be $154,500 with an annualized cost of $51,500. These costs include all management of the pilot study including response tracking, coding and processing the data, 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 0.05 FTE for scientific staff over the remaining 36-month study period. This figure corresponds to a total of $10,000 over 36 months, or an average annualized cost of $3333. Finally, there are costs associated with data analysis, which total $7500. The average annual cost to the government over the 12-month period is approximately $2500. The overall government distribution is summarized in the following table:

Table 14-1 Annual Cost to the Federal Government

	TOTAL	ANNUAL AVERAGE
Contractor Costs	$137,000	$45,667
NCI Personnel Subtotal	$10,000	$3,333
Analysis	$7,500	$2,500
Grand Total	$154,500	$51,500

A.15 Explanation for Program Changes or Adjustments

This is a request for a three year extension to the previously approved collection of information so that efforts can be made to increase response rates and instrument completion rates by using improved email invitations and communication and by soliciting participation from those with known email addresses. This is considered a change due to adjustment in agency estimate. The currently requested respondents and burden hours have decreased because some of the respondents have already been surveyed. The formerly approved respondents and hours included the original request in 2008, in addition to two change requests in 2009, both of which received an increase in respondents and burden.

Additionally, changes to the design are based on data analysis conducted to date which demonstrated that the four pathway strategy did not improve the odds of a respondent completing the questionnaires. Thus for this submission, it has been decided that all respondents will only follow a simplified questionnaire pathway which is outlined in the SSB, p.3.

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

MILESTONE	MONTHS AFTER OMB APPROVAL
Email Invitations	3 Month
Completion of Pilot Study Questionnaires	18 Months
Data Processing and Analysis	15+ Months

Initially this feasibility study was planned for a one year data collection time frame (i.e., an estimated 2 year approval from OMB). However due to the very low response rate and the extended time it took for respondents to answer the questionnaires,

we are requesting an additional 36 months. We have requested and been approved for an additional 50,000 contacts in order to more fully evaluate to goals of this feasibility study using invitations by email only.

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.

Background Information and References

ASA24: Researchers have determined that greater accuracy in assessment of dietary intake is possible using 24-hour dietary recall interviews administered at multiple time periods over a year.[1-3] This method of data collection allows for reports on variation in a respondent's diet through different seasons of the year and demands less estimation and recall by the respondent regarding his or her diet. However, this instrument has required the use of highly trained interviewers to conduct the interview, and subsequent complex coding of dietary and nutritional components, resulting in an extremely high cost per instrument completion. ASA24 translates this successful means of dietary data collection into a self-administered, low-cost dietary intake collection instrument. It also enhances the interviewer-led administration of the 24-hour dietary recall by providing pictures of foods reported as being consumed and associated portion sizes, permitting the respondent to visualize and more accurately indicate the food consumed.

ACT-24: While research has demonstrated an association between energy expenditure and health conditions such as cardiovascular disease and all-cause mortality,[4] associations between physical activity and cancer are less clear. Some questions in each of the NIH-AARP Diet and Health Study questionnaires have a physical activity component; however they are limited to 5-10 broad questions about an individual's physical activity over the past year or over the course of their life. Other epidemiologic studies include 2-4 questions regarding the amount of time spent in moderate or vigorous physical activities over the period of a week.[5] No other instrument is known to us as having been developed to measure physical activity over the past 24 hours at multiple time points throughout a year.

Other measurement devices such as doubly labeled water, considered the gold standard measure of free-living activity energy expenditure,[6-7] or motion sensor devices such as accelerometers and heart rate monitors, used to measure the movement of a person over time, have been employed in studies. However, measurement by these means requires physical supplies, direct respondent contact in many cases, and sufficient funding associated with the cost of the supplies and labor involved. Such methods are not feasible at this time in large prospective cohort studies. In order to obtain self-reported responses of physical activity, we have developed a simple instrument that will measure physical activity on the day before the questionnaire is completed. The questionnaire will be completed online and will allow the respondent to report specific activities or categories of activities over a 24 hour time period. Like the ASA24, this instrument is designed to obtain measurements at multiple time points over a year in order to account for seasonal variation in activity and to obtain the most complete report of activities over time.

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[2] Kristal AR, Peters U, Potter JD. Is it time to abandon the food frequency questionnaire? *Cancer Epidemiol Biomarkers Prev* 14:2826-8, 2005.

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[4] Manini TM, Everhart JE, Patel KV et al., Daily Activity Energy Expenditure and Mortality Among Older Adults. *JAMA*, Vol 296, No. 2, July 12, 2006.

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