SUPPORTING STATEMENT A FOR:

SHORT FOLLOW-UP QUESTIONNAIRE FOR THE NATIONAL INSTITUTES OF HEALTH (NIH)-AARP DIET AND HEALTH STUDY (NCI)

February 2011

Extension Request for OMB No.: 0925-0587

Expiry Date: 4/30/2011

Yellow highlights indicate changes since the approval of the 2008 submission.

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A.1. Circumstances Making the Collection of Information Necessary

Justification and Background. 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 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. This scope of work includes research examining the relationship between nutrition and cancer; nutritional exposures are among the most modifiable risk factors for several major cancers. Therefore 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 members of the American Association of Retired Persons (AARP). Screening questionnaires (food frequency questionnaires) were initially sent 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 able to prospectively examine the relation 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. 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. After the first 5 years follow-up, the actual incidence rates for breast, colorectal, prostate, and non-Hodgkin's lymphoma in this cohort suggest that moderate relative risk can be detected at 90 percent power for four major dietary factors (fat, fiber, red meat, and fruits/vegetables).

Numerous analyses have been performed using the data collected to date. 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. However, rapidly growing public health problems, especially obesity, physical inactivity, and several medical conditions, demand more research on the associations between these health problems and cancer. We propose building on this successful research effort to continue to examine prospectively the relation between diet and major cancers in early- to late-middle aged men and women in the U.S. The Short Questionnaire is a two-page short questionnaire that will be sent to all surviving participants in the NIH-AARP Diet and Health Study. This brief questionnaire was recommended by the study's advisory board as a means of obtaining information on selected medical conditions, medical procedures, and physical status and lifestyle questions. The secondary objective of the short questionnaire is to maintain active follow-up with our participants. Collection of this information will allow the ongoing examination of health and lifestyle behaviors and contact with our study participants.

Statutory Authority. The Public Health Service Act outlines the mission of the National Cancer Institute. 42 USC 285a states, "The National Cancer Program shall consist of (1) an expanded, intensified, and coordinated cancer research program encompassing the research programs conducted and supported by the Institute and the related research programs of the other national research institutes, including an expanded and intensified research program for the prevention of cancer caused by occupational or environmental exposure to carcinogens, and (2) the other programs and activities of the Institute." 42 USC 285a-1 states, "The Director of the Institute shall establish and support demonstration, education, and other programs for the detection, diagnosis, prevention, and treatment of cancer...." This submission is a request for an extension to OMB No. 0925-0587 which is currently scheduled to expire on 4/30/2011. Full-scale launch of the project was delayed due to funding priorities at NCI (explained more fully in Section A.2).

A.2. Purpose and Use of Information Collection

The objectives of the Short Questionnaire are to:

1. Obtain information on certain medical conditions (18 conditions referenced) and several medical procedures;
2. Collect information on lifestyle characteristics that are of general public health interest and change over time;
3. Maintain active follow-up of the current participants by asking them to provide information on health conditions and lifestyle characteristics in the Short Questionnaire.

The NIH-AARP Diet and Health Study **Short Questionnaire (Attachment 2)** will collect the following information:

a. Physical status and lifestyle questions: current weight; body type at age 20, 30, 40, 50, 60 and at the current time; current cigarette smoking and frequency; frequency of moderate physical activity; and frequency of vigorous physical activity.

b. Eighteen (18) medical conditions: high blood pressure; diabetes; high cholesterol; heart attack; angina; or coronary artery disease; transient ischemic attack (TIA); stroke, pulmonary embolus; emphysema or chronic bronchitis; hip fracture; macular degeneration of the eye; kidney stones; colon or rectal polyps; stomach or duodenal ulcer; Parkinson's disease; multiple sclerosis; amyotrophic lateral sclerosis (ALS) Lou Gehrig's Disease; depression; and, cancer of any type.

c. Medical procedures and screening: coronary artery bypass or angioplasty; gallbladder removal; PSA testing; removal of uterus or ovaries).

Continued follow-up with the study cohort and collection of cancer and non-cancer endpoints, as well as self-reported lifestyle information extends non-cancer endpoint ascertainment first collected in the Baseline Questionnaire. The inclusion of questions directed at updating key covariates, such as smoking, body size and physical activity, prostate cancer screening, and hysterectomy/oophorectomy, is particularly valuable for analyses of nutrition and other lifestyle factors in relation to incident cancers. The Baseline Questionnaire (1995-96) also asked

questions about non-cancer endpoints; such information has been used in a number of analyses to date (e.g., history of diabetes versus colorectal cancer, and BMI versus mortality, with exclusions for pre-existing disease).

Additionally, frequent study contact with participants has been strongly recommended by the study's External Advisory Group. Frequent contact assures study participants that they are part of the ongoing prospective cohort study and providing useful health information for scientific research. Response to a brief questionnaire also provides information to the study about the participants' willingness and ability to respond in this aging cohort. Finally, participant addresses, and any updates to such addresses, are used when conducting cancer case ascertainment with state cancer registries and in mortality status review. Accurate information on cancer and mortality outcomes depend heavily on matching address information, along with other self-reported information from the respondent.

As stated in section A.1., data collected to date have been used in numerous analyses and reported in scientific journals. These reports have been published in well-known medical and public health peer-reviewed journals. Please see the bibliography in **Attachment 3**. Investigators from the National Cancer Institute have conducted these analyses using data from the study. A process has also been established that allows investigators from other National Institutes of Health institutes, as well as other public and private agencies and universities, to submit proposals for analysis of the data. If the analysis plan is approved by the study's steering committee, the investigator is provided access to the data and is assigned a senior researcher from the steering committee to oversee the analysis. Proposals, analyses, reports, and published papers are recorded in a computerized tracking system to monitor the overall contribution of the study to issues of public health concern.

Following OMB approval of the Short Questionnaire on April 24, 2008 (OMB No 0925-0587), NCI leadership determined that funding priorities prohibited the immediate full-scale launch of the project. To comply with the advisory board's recommendation to continue follow-up with the cohort and collect data using the Short Questionnaire, a pilot study was proposed to assess the likelihood that participants would be willing to complete the Short Questionnaire as well as the feasibility of receipt and return of the Short Questionnaire via the US Postal Service. Traditional mailings using hard copy questionnaires on the scale of the entire cohort are costly, and given the advancing age of the cohort from baseline contact in 1995-1996, the increased potential for declining physical health and cognition, as well as the concomitant expansion of Web-based surveys, it was essential to confirm that a

sufficient response rate could be obtained in order to justify the use of funds. Thus, in May, July, and August, 2010, the Short Questionnaire was mailed using the US Postal Service to 1,600 randomly selected participants of the original cohort. The pilot mailing demonstrated that, in general, the cohort remains willing to provide information on health history, diet, and medical conditions. The results from the pilot mailing found a response rate of 63% among participants known to be alive and who received the questionnaires. Thus, a 3-year extension is requested to complete the full-scale investigation.

A.3. Use of Improved Information Technology and Burden Reduction

This study will use this brief two-page questionnaire one time. The questionnaire **(Attachment 2)** is accompanied by a cover letter **(Attachment 10-A)** requesting a response from the cohort participant and will be sent to the participant in a hard copy format. Up to four waves of the questionnaire will be sent to participants, meaning that participants who do not respond to the first mailing of the questionnaire become eligible for a second mailing. The second mailing will be sent to participants one month following the first mailing **(Attachment 10-B)**. Likewise, a third mailing will be sent to participants who do not respond to the first or second mailing **(Attachment 10-C)**. A final mailing of the same questionnaire will be sent to participants who do not respond to any of the previous mailings **(Attachment 10-C)**. The third and fourth mailings will be sent out to non-respondents three weeks following the previous mailing. Overall response rate improvements are achieved with each additional mailing of a questionnaire.

No electronic media will be used to obtain responses to this brief questionnaire. The NCI Privacy Act Coordinator determined on 11/23/2010 that a Privacy Information Assessment (PIA) was not required since an IT system is not involved.

A bar code of the participant's study identification number, included on the survey, will allow for quicker processing of returned surveys and facilitate linking the newly collected data with previously collected information stored in the NIH-AARP Diet and Health Study database in a de-identified manner.

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

The Short Questionnaire has not previously been used in this population. While some questions similar in nature may be included in questionnaires in other study populations, these questions either have not been asked in this study cohort previously or are asked again in this questionnaire as a means of updating previous information (e.g., current weight). No other questionnaire or data could provide the information required for the prospective analyses being conducted for this study.

A.5. Impact on Small Businesses or 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

The proposed follow-up study is a single-time research effort. Participants will complete the Short Questionnaire one time. The participants are being re-contacted at this time in an effort to provide ongoing information updates for key covariates and some additional information on health and medical conditions as described in section A.2.

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

No special circumstances are anticipated.

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

The 60-Day Federal Register notice soliciting comments on this study prior to initial submission to OMB was published on February 4, 2011 (76 FR 6485) and there were no public comments. The NIH-AARP Diet and Health Study was developed with consultation from a number of scientists throughout the development period and throughout the course of the study. The study maintains a Steering Committee that meets monthly to discuss the design, conduct, and analyses for the study. The committee provides overall scientific direction for the study and serves as the major decision-making body for operations (list of members in **Attachment 4**). 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 (list of members found in **Attachment 5**). The

External Working Group, which typically met every six months, last met in October, 2009; however, it has not convened since that time due to the illness and death of one of the members. It is expected to resume its regular meeting schedule upon identification of a replacement member.

A.9. Explanation of Any Payment or Gift to Respondents

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

A.10. Assurance of Confidentiality Provided to Respondents

The information collected in this study is covered by NIH Privacy Act Systems of Record Notice (SORN) #09-25-0156, "Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD" published in the Federal Register on 9/26/2002 (Vol. 67, page 60743) (see **Attachment 6 for NIH Privacy Act Officer's Letter**). Respondent's contact information will be collected and retained throughout the active study period because this information is necessary for maintaining long term contact. The respondent's Social Security Number will not be collected. At the completion of the incorporation of the study data into study datasets and when or before the study results have been analyzed, hard-copy records will be destroyed. Updated contact information will be noted in study databases to aid in future contact on continuing study participants. Study data will be identified and retrieved by a study number only.

The initial OMB submission of the NIH-AARP Diet and Health Study included plans only for the specific study activities planned at that time. However, because the study is ongoing, respondent identifiers (name, address, and telephone numbers) have not been destroyed. Respondents' identity to the initial study questionnaire will be kept private under the Privacy Act. This information will be maintained for the respondents in the proposed studies. One of the contractors for this study, Westat Inc. of Rockville, MD, 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. Westat will provide the personal identifiers used in mailing the questionnaire to the participants of another NCI subcontractor, yet to be selected by NCI. A complete list of the procedures Westat will take to assure confidentiality of study data are found in **Attachment 7**.

While a separate consent form will not be included in the mailings to the study participants, the cover letter describes the purpose of the questions for ongoing data analysis and the privacy of the data, and participants imply consent in the completion and return of their questionnaires. The data from each questionnaire will be transferred to another NCI subcontractor for use in analysis. A Confidentiality Certificate was issued in 2005 that covers research subjects in the "NIH-AARP Diet Health Study" that is valid through 12/31/2013 (Attachment 11). 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 personal identifiers.

All contract staff working on the study are required to sign a statement pledging to maintain the confidentiality of all data. Access to study data is limited to the staff working on the study. All cover letters state that the information they provide will be kept private, in accordance with the Privacy Act. The data from this study will be maintained until the completion of the study or until no longer required for the research. Data will be destroyed as required by NIH Manual 1743 - Keeping and Destroying Records.

The National Cancer Institutes Special Studies Institutional Review Board (IRB) reviewed and approved the Short Questionnaire on July 24, 2007, in accordance with 45 CFR 46 (**Attachment 8).** Additionally, a copy of the National Cancer Institute Special Studies IRB's 2010 approval of the Diet and Health Study, in **Attachment 9.**

A.11. Justification for Sensitive Questions

When conducting epidemiologic studies, it is important to be able to capture data on medical conditions, medical procedures, health behaviors and physical characteristics. As a result, the Short Questionnaire includes these types of questions, although no questions usually considered of greater sensitivity (e.g., religious, cultural or sexual practices or selected health conditions) are asked. All respondents have the right to not answer particular questions without any consequence.

The current questionnaire does not collect personally identifying information (PII). The original NIH-AARP participant list originated from AARP and was provided to Westat, a contractor to NCI, in 1995. Only respondents to that questionnaire joined the study as participants and only their information is stored in a secure database separate from all questionnaire data. In addition to names, Westat also received addresses, phone numbers,

and birth date information for all participants. Other PII such as medical and health-related data collected in NIH-AARP Diet and Health Study baseline and follow up questionnaires are stored in separate databases and can only be linked to PII by study IDs. The PII (name and address information only) necessary to mail the Short Form Questionnaires to study participants will be downloaded from the separate address database at Westat. The addresses have been updated over time through notices from the USPS; information received from study participants via email or phone; USPS National Change of Address searches required by the USPS prior to all bulk mailings; and from MaxCoA, a change of address database provided by Anchor Inc. using USPS information, but extending 60 months prior to the date of search.

A.12. Estimates of Hour Burden Including Annualized Hourly Costs

The instrument is very brief, printed in large type appropriate for a study population of this age (currently age 62-81), and requires very little time on the part of the respondent.

a. Hour Burden Estimates. Table A.12-1 describes the estimates of the respondent burden for completion of the Short Questionnaire. The burden to complete the questionnaire is 4 minutes. The total requested number of respondents for this submission is less than in 2008 (513,225 respondents were originally requested). The annual burden is estimated to be 32,394 hours and over a three-year period, approximately 97,182 hours.

Table A.12-1 and A.12-2: Estimates of Respondent Hour Burden and Annualized Cost to Respondents

Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Response (Minutes/Hour)	Annual Hour Burden	Hourly Wage Rate	Respondent Cost
Senior Adults (Attachment 2)	485,909	1	4/60 (.067)	32,394	$20.90	$677,033

b. Annualized Hourly Costs. Based on an hourly wage rate for "all occupations" from the US Bureau of Labor Statistics (www.bls.gov/oes/current/oes_nat.htm#00-0000) of $20.90 per hour, the total estimated annualized cost to respondents is $677,033 (Table A.12-2). All annualized costs have been adjusted with an inflation factor of 5.2% according to the average change rates from 2007 to 2010 as presented on www.usinflationcalculator.com. The estimated annual cost for respondents is $677,033, and over a three-year period approximately $2,031,099.

A.13. Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers

There are no Capital Costs, Operating Costs, or Maintenance Costs to report.

A.14. Annualized Cost to the Federal Government

The estimated total cost to the government for the services of the study contractor(s) over the duration of the one-time survey is $89,392 (annualized cost of $89,392). These costs include formatting, printing, and mailing four waves of the Short Questionnaire, as well as 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 .05 FTE for scientific staff over the 12-month study period. These figures correspond to a total of $5,258 over 12 months, or an average annualized cost of $5,258. Finally, there are costs associated with data analysis, which total $.1,578 The total annualized cost to the government is $96,228. All annualized costs have been adjusted with an inflation factor of 5.2% according to the average change rates from 2007 to 2010 as presented on www.usinflationcalculator.com . The overall government distribution is summarized in Table A.14-1:

Table A.14-1 Estimated Government Cost Distribution

	ANNUAL AVERAGE	TOTAL OVER 3 YEARS
Contractor Costs	$89,392	$268,176
NCI Personnel Subtotal	$5,258	$15,774
Analysis	$1,578	$4,734
Grand Total	$96,228	$288,684

Thus, average annual cost to the government over the 12-month period is estimated to be $96,228. Over the three-year study period this amounts to $288,684.

A.15. Explanation for Program Changes or Adjustments

This is a request for an extension for an additional three years which is considered an adjustment due to agency estimate. This submission represents a reduction in total burden that was requested from the 2008 submission to OMB. Burden is reduced solely as a result of a reduction in respondents in this request. There are no changes to the questionnaire or proposed methodology.

A delayed start in information collection was due to NCI funding priorities. Once data was collected in 2010, it was as a pilot study to assess the response rate which involved the approved Short Questionnaire and methodology but fewer respondents than were requested in the 2008 OMB submission. The satisfactory response rate in the pilot mailing provides the basis for implementation of data collection using the Short Questionnaire in the entire cohort as outlined in previous sections. Because the conduct and analysis of the pilot mailing used the three-year period granted in the original OMB clearance, a time extension is necessary to conduct the full scale Short Questionnaire project.

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

The project schedule for completing data collection, processing, and analysis is presented in Table A.16-1.

Table A.16-1. Project Time Schedule

MILESTONE	COMPLETION SCHEDULE
OMB Approval	June 2011
Mail Short Questionnaire	January – May 2013
Receipt Short Questionnaire	January – June2013
Complete Data Processing and Analysis	June 2013 – August 2013
Report Results	September 2013 and forward
Estimated Publication Date	Incorporated into publications in 2014

Following OMB approval, other study tasks related to the NIH-Diet and Health Study are scheduled for completion that are currently ahead of the Short Questionnaire on the study timeline. These include vital status and cancer outcome analyses that are essential to the broader NIH-AARP Diet and Health Study objectives, before

obtaining additional self-reported information using the Short Questionnaire, as this would require dipping into limited funding and resources currently planned for use on other study tasks in 2011 and into 2012. The vital status and cancer outcome data will eventually be analyzed for associations with the data collected in the Short Questionnaire effort. Though data collection for the Short Questionnaire is anticipated to take less than one year, unexpected delays can result from any number of reasons, as was the case in the previous approval. In addition, given the costly nature of large mailings such as this, study leadership wishes to assure the optimal timing of questionnaire collection for this longitudinal study: the first part of the calendar year is generally more successful in reaching participants, thus, it would be most beneficial to wait until January 2013.

One analytic file will be built to contain the responses to the 10 questions and sub-questions and the following analytic variable will be created; 1) current medical condition for selected diseases; 2) current weight and body mass index (kg/m2); 3) body shape at various ages; 4) moderate and vigorous physical activity; 5) smoking status; and 6) cancer screening practice. The results from this questionnaire will be added to the overall cohort analytic file for use in analysis.

The following analyses will be performed resulting in a data table:

1) frequencies to all questions and sub-questions

2) changes in body weight and body mass index over time in relation to self-reported medical condition

3) moderate and vigorous physical activity in relation to self-reported medical condition

4) weight changes over life time and risk of cancer and death

5) moderate and vigorous physical activity in relation to risk of cancer and death

6) the effect of prostate cancer screening on risk of prostate cancer

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.