SUPPORTING STATEMENT B 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: 4/31/2011

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

Yikyung Park, Sc.D. Staff Scientist Nutritional Epidemiology Branch Division of Cancer Epidemiology and Genetics National Cancer Institute/NIH Executive Plaza South, Room 3040 6120 Executive Boulevard, MSC 7242 Bethesda, MD 20892-7335 Voice: 301-594-2931 FAX: 301-496-6829 Email: parkyik@mail.nih.gov

TABLE OF CONTENTS

| В. | Colle | ctions of Information Employing Statistical Methods | 1 |
|----|-------|--|---|
| | 1. | Respondent Universe and Sampling Methods | 1 |
| | 2. | Procedures for the Collection of Information | 1 |
| | 3. | Methods to Maximize Response Rates and Deal with Non-response | 2 |
| | 4. | Tests of Procedures or Methods to be Undertaken | 3 |
| | 5. | Individuals Consulted on Statistical Aspects & Individuals Collecting and/or Analyzing | |
| | | Data | 3 |

LIST OF ATTACHMENTS

| Attachment 1 | NIH-AARP Diet and Health Study Original Study Summary | | |
|-----------------|---|--|--|
| Attachment 2 | Short Questionnaire | | |
| Attachment 3 | Bibliography of Manuscripts Published in Peer-Reviewed Scientific | | |
| | Journals | | |
| Attachment 4 | List of NIH-AARP Diet and Health Steering Committee Members | | |
| Attachment 5 | List of NIH-AARP Diet and Health External Working Group Members | | |
| Attachment 6 | NIH Privacy Act Officer's Letter | | |
| Attachment 7 | Westat's Procedures for Assuring Confidentiality | | |
| Attachment 8 | National Cancer Institute Institutional Review Board Approval, Short | | |
| | Questionniare | | |
| Attachment 9 | National Cancer Institute Institutional Review Board Approval, Diet and | | |
| | Health Study | | |
| Attachments 10: | | | |
| | | | |

| Attachment 10-A | Cover Letter for Short Questionnaire for Wave 1 Mailing |
|-----------------|---|
| Attachment 10-B | Cover Letter for Short Questionnaire for Wave 2 Mailing |
| Attachment 10-C | Cover Letter for Short Questionnaire for Wave 3 Mailing |
| Attachment 10-D | Cover Letter for Short Questionnaire for Wave 4 Mailing |

Attachment 11 NIH Confidentiality Certificate

B. Collections of Information Employing Statistical Methods

B.1. <u>Respondent Universe and Sampling Methods</u>

A total of 485,909 live, eligible participants for the questionnaire will be asked to complete the

questionnaire. No sampling will be performed: 100% of the live cohort members will be asked to respond to the Short Questionnaire. Collection of data from the complete cohort is desired so that longitudinal analyses can be performed, using data from more than one time point for each individual. Based on the pilot mailing, it is expected that response rates to this questionnaire should be approximately 63% completion and return of the questionnaires from respondents.

The current cohort consists of approximately 60% males and 40% females. Approximately 2% of respondents self-report Hispanic or Latino ethnicity. Also, 94.5% report being White, 4% Black, 1.2% Asian, less than 1% American Indian/Alaska Native, and less than 1% Native Hawaiian or Other Pacific Islander. The numbers of participants of varying racial and ethnic identities have allowed the analysis of sub-populations for a variety of analyses.

B.2. Procedures for the Collection of Information

a. Survey Procedures.

This study will use this brief two-page questionnaire one time (Attachment 2). Each participant in the study will be mailed a cover letter (Attachments 10-A through 10-D), adjusted as appropriate for each mailing wave of the questionnaire as appropriate. 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-D). The third and fourth mailings will be sent out to non-respondents three weeks following the previous mailing.

b. Rationale for Sample Size.

In 1995, the Nutritional Epidemiology Branch fielded the Prospective Study of Diet and Cancer in members of the American Association of Retired Persons (AARP) (OMB# 0925-0423). The objective of this research effort was to carry out a very large prospective cohort study of diet in relation to several major cancers, especially breast, prostate and colorectal malignancies. The cohort consisted of men and women members of AARP. A questionnaire was 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 eligible cohort that is still alive now consists of 485,909 persons (of 566,402 still followed for cancer ascertainment and mortality in the cohort). Actual incidence rates for breast, colorectal, prostate, and non-Hodgkin's lymphoma obtained from this cohort after 5 years of follow up suggest that moderate relative risk can be detected at 90 percent power for four major dietary factors (fat, fiber, fruits, and vegetables, and red meat). As a result, we plan to conduct the proposed study with all current live cohort participants composed of 485,909 persons.

c. Quality Control. The contractor chosen for this study will establish and maintain quality control procedures to ensure standardization and a high level of quality of data collection and processing. The contractor will maintain a written log of all decisions that affect study design, conduct or analysis. The contractor will monitor performance of the data monitoring activities, especially with regard to response rates and completeness of acquired data.

B.3. <u>Methods to Maximize Response Rates and Deal With Nonresponse</u>

Our experience with the 1995 Baseline Questionnaire showed that better response and retention rates can be achieved through establishing a good rapport with the respondents by showing appreciation for their participation and by clearly describing what is being asked of each respondent as they move through the various stages of the study. Contact will include a comment expressing our sincere appreciation for the respondent's contribution of time and effort to the study. Participants will continue to receive an annual newsletter called "Diet and Health Study News" that thanks participants for being part of the study and informs participants about the research findings that are published based on the data they provided. The newsletter also provides a link to the NIH-AARP Diet and Health Study website and information for receiving email updates. Additionally, overall response rates improve through up to four mailing waves which all include a different cover letter, and the Short Questionnaire. We project that 50-70% of the eligible 485,909 respondents will participate in this questionnaire.

B.4. Tests of Procedures or Methods to be Undertaken

Previous contact with study participants indicates that they are willing to answer questions regarding their health conditions and behaviors, in addition, the Short Questionnaire pilot mailing resulted in a response rate of 63% among participants known to be alive and who received questionnaires.

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

National Cancer Institute investigators, statisticians, and Steering Committee members have reviewed the data collection plan **(Attachments 4 and 5)**. The data collected will be available for use in analyses that are proposed and approved in the future. No additional consultation is planned.