SUPPORTING STATEMENT B FOR:

THE NIH-AARP *interactive* COMPREHENSIVE LIFESTYLE INTERVIEW BY COMPUTER STUDY (*i*CLIC) (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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B. Collections of Information Employing Statistical Methods

B.1. Respondent Universe and Sampling Methods

All living participants in the current NIH-AARP Diet and Health Study cohort and AARP members residing in the eight states including two metropolitan areas that comprise the current cohort, as well as 16 new states (Arizona, Colorado, Connecticut, Illinois, Iowa, Kentucky, Massachusetts, Nevada, New York, Oklahoma, Oregon, South Carolina, Texas, Utah, Washington, and Wisconsin) will be the population from which a sample will be chosen. A random selection of 5,000 current cohort participants (aged 62-83) and 10,000 current AARP members (aged 50 and over), who are not current cohort participants, were asked in early 2009 to participate in the study. An additional 50,000 current AARP members (aged 50 and over), who are not current cohort participants and who have opted-in to receiving emails from AARP, will be asked to participate in this evaluation study using only email invitations.

B.2. Procedures for the Collection of Information

a. Survey Procedures.

The AARP organization and investigators from the NCI are jointly sponsoring the invitation letter, containing both the NCI and AARP logos (**Attachments 3-1 to 3-2**). For the 15,000 participants invited in early 2009, an invitation was mailed through the U.S. Postal Service over a period of five days to ensure that all letters were received within a one week time period. A second letter reminding participants of the invitation was mailed 30 days following the mailing of the initial letter (**Attachments 3-3 to 3-4**). Invitation letters contained one of the two special study codes that were used to distinguish new cohort participants from current cohort participants. Interested respondents navigated to the

secure study website using the URL provided in the invitation letter. Participants entered their special study code to gain further entry into the website.

For the remaining 50,000 current AARP members (aged 50 and over), an email invitation will be sent **(Attachment 3-7)**. A second email reminder will be sent to those that do not enroll five to seven days following the initial email invitation **(Attachment 3-8)**.

Prior to collecting any information, the respondent will be shown the consent form **(Attachment 12)**. Respondents will be asked to consent to participate in the study by reading the information provided to them and indicating their agreement by checking the "I agree" box. Once a respondent has consented to participating in the study, their name, date of birth, residential address, and email address will be collected. Each participant will pick a unique username and password in order to re-enter the study website at future times. Each participant will then be informed of their questionnaire schedule and will be able to start the first assigned questionnaire immediately.

For the 15,000 participants invited in early 2009, the type of questionnaire assigned to each participant was determined by systematically assigning them to one of four pathways at the time of enrollment. Pathways were assigned in advance to ensure that participants were distributed 15% of the time to Pathway 1 or Pathway 2 and 35% of the time to Pathway 3 or Pathway 4. Each new participant that enrolled in the study was assigned the next pathway in the assignment sequence. The participant did not know ahead of time which pathway they will be assigned. The response rate to this approach was less than 10% and very few of the original 15,000 invited had an email address and access to high-speed internet.

In order to better understand factors related to response and completion rates in this study, the remaining 50,000 current AARP members (aged 50 and over) will be assigned to one pathway, whereby all enrolled participants will follow the same schedule of questionnaire assignments. The 24-hour recall questionnaires will be assigned at baseline and again in approximately 60 days. The LHQ will be assigned at baseline and will be available for the duration of the study. The DHQ will be assigned at approximately 60 days and will be available for the remainder of the study.

If a participant wishes to end a session without fully completing the questions for any instrument, the information recorded to that point will be saved. If a participant wishes to return and resume completion of any of the 24-hour recall instruments (ASA24 and ACT-24) on the same day, the participant will be able to access and use the responses already recorded. If the participant returns to the ASA24 or ACT-24 instrument on another day, he or she will be asked to begin a new report of activities beginning the day prior to the new login date. However, for the LHQ or DHQ, if the participant leaves the instrument without fully completing it, he or she may return to complete the instrument within two weeks without any loss of information. Respondents will be prompted to fully complete the instrument when ending a session, but no email reminders will be sent separately to prompt full completion of an individual instrument. The respondent will be thanked when logging out of a session after the completion of any information provided.

Participants will receive notification by email when it is time to complete the next questionnaire. Even if the participant only partially completed any prior questionnaire, they will be asked to continue their participation by completing the next instrument. A

maximum of three emails will be sent to a participant to notify them to complete the next assigned questionnaire (**Attachments 15-1 to 15-5**).

b. Rationale for Sample Size.

Rather low response rates were observed for the first 15,000 invited to participate in this evaluation study of computerized questionnaires. Reasons for this include that 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 among the remaining 50,000 participants. This 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.

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. Methods to Maximize Response Rates and Deal With Non-response

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. In this evaluation study, email messages will be used to communicate with participants regarding their questionnaire schedule and completion of questionnaires. Frequently asked questions (FAQs) as well as an email help link will be available at all times.

Email will be the primary means of communicating with study participants. Through the use of email notifications, reasonable attempts will be made to increase participant response rates. An excessive use of email messages and reminders could result in the opposite desired affect and lead to a poorer response rate.

Invitees that login to the study website and decline to consent to participate will be given the opportunity to indicate why they have chosen not to participate, including whether internet connection speed was a factor in their ability to consent. Participants will also have the opportunity to voice their experiences about the feasibility study by completing an optional short evaluation survey, which will include a question about technical and/or other computer requirements.

For this study, the expected response rate is not expected to reach 80%. Given this is a feasibility study, each and every response will provide valuable information. Response rates

will be estimated for each step of the study, including navigation to the study website, consent and enrollment, completion of each computerized questionnaire, and the level of completeness.

Additionally, collected data will be used to determine the response rates to the email invitation to participate in the evaluation study, the eligibility rates of those responding to the invitation, the completion rates for each questionnaire and the performance and configuration of the technical design of the computerized questionnaires. If this were a large prospective cohort study and not an evaluation study, the information collected for each instrument would be used by researchers to examine the relationship between diet, physical activity, and lifestyle factors with major cancers in a population of early to late middle-aged men and women.

Lower response rates for internet-based studies are not uncommon. They offer substantial cost-savings compared to traditional paper-based methods. For example, the Department of Defense Millennium Cohort Study[1] administered an internet-based questionnaire of more than 450 questions to 77,047 military personnel during a 2-year period, which had an estimated cost savings as high as two million dollars compared to a paper-based study.

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 this study we are evaluating the performance and configuration of the technical design of the web-based instruments that will

be used by study participants. We are also evaluating the response rates, eligibility rates, and completion rates of the study participants.

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

National Cancer Institute investigators, statisticians, and the Steering Committee members have reviewed the data collection plan. The data collected will be available for use in analyses that are proposed and approved in the future. No additional consultation is planned for this feasibility study at this time.

References

[1] Smith B, Smith TC, Gray GC, Ryan MAK for the Millennium Cohort Study Team. When Epidemiology Meets the Internet: Web-based Surveys in the Millennium Cohort Study. *Am J Epidemiol* 166:1345-1354, 2007.