SUPPORTING STATEMENT B FOR:

THE NIH-AARP COMPREHENSIVE LIFESTYLE INTERVIEW BY COMPUTER STUDY (CLIC)

NATIONAL CANCER INSTITUTE (NCI)

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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 for this study. The sample will comprise a random selection of 5,000 current cohort participants (aged 62-83) and a random selection of 10,000 current AARP members (aged 50 and over), who are not current cohort participants. These 15,000 people will be asked to participate in this evaluation study of computerized questionnaires. A simple random sample method without replacement will be used to select the sample of potential participants.

B.2. Procedures for the Collection of Information

a. Survey Procedures.

The AARP organization and investigators from the NCI will jointly sponsor the invitation letter, printed on letterhead containing both the NCI and AARP logos, (**Attachments 3-1 to 3-2**), which will be mailed through the U.S. Postal Service over a period of five days to ensure that all letters are received within a one week time period. A second letter reminding participants of the invitation will be mailed 30 days following the mailing of the initial letter (**Attachments 3-3 to 3-4**). Invitation letters will contain one of the two special study codes that will be used to distinguish new cohort participants from current cohort participants. Interested respondents will navigate to the secure study

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

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, email address, and social security number will be collected. Participants in this evaluation study will not be followed for cancer outcomes. However, the data required for linking to cancer registries, such as date of birth, gender, and social security number will be collected in this study, but only to evaluate the participants' willingness to provide the information, which will be important for planning large-scale studies in the future that will rely on linkages to state cancer registries. 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.

The type of questionnaire assigned to each participant will be determined by systematically assigning them to one of four pathways at the time of enrollment. Pathways will have been assigned in advance to ensure that participants are 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 enrolls in the study is assigned the next pathway in the assignment sequence. The participant will not know ahead of time which pathway they will be assigned.

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, 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 conservative response rates have been estimated for this evaluation study of computerized questionnaires because the results from surveys conducted among seniors to evaluate their familiarity with computers and their access to the internet vary greatly. For this study, it is expected that only 55% (n = 8252) of those invited will have access to the internet. Of these 2072 (~25%) are expected to enroll. Of those that enroll, it is estimated that 1082

(~52%) will complete the entire study. This overall response rate will reflect completion by 150 to 200 participants in each of the four pathways.

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.

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.

Furthermore, 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.

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.

Reference

[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.