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

Study Summary
April 2008

Introduction
The purpose of the CLIC study is to examine the feasibility of using newly developed computerized questionnaires to update and expand upon dietary, physical activity, and lifestyle exposure data. A subset of participants (aged 62 to 83) in the current NIH-AARP Diet and Health Study, as well as younger AARP members (aged 50 and older) not currently affiliated with the NIH-AARP Diet and Health Study, will be recruited to participate in the CLIC study.

The CLIC study will use three new computerized questionnaires for assessing diet, physical activity, and lifestyle factors more accurately. They are the Automated Self-Administered 24-Hour Dietary Recall (ASA24), the Physical Activity 24-Hour Recall (ACT-24), and the Lifestyle and Medical History Questionnaire (LHQ). Additionally, the Diet and Health Questionnaire (DHQ), a well-established food frequency questionnaire developed by NCI, will also be included in the CLIC study for comparison purposes.

Objectives
The NIH-AARP CLIC Study will serve as a feasibility and formative evaluation of the quality and completeness of all the computerized questionnaires. The specific objectives of this study are to determine response rates to an 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 assess the completion rates for each pathway assignment, which is based on four different combinations of questionnaire ordering and timing; 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 PA24 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.

Study Design
The AARP organization and investigators from the NCI will jointly sponsor and mail an invitation letter to 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, asking them to participate in the CLIC study. Potential participants must reside in one of the eight states, including two metropolitan areas, that comprise the current cohort, or one of 16 new states (Arizona, Colorado, Connecticut, Illinois, Iowa,

Kentucky, Massachusetts, Nevada, New York, Oklahoma, Oregon, South Carolina, Texas, Utah, Washington, and Wisconsin) that will supplement the current cohort.

The invitation letter will contain the study website link to be entered by the participant into his or her internet browser. The letter of invitation will be sent to potential participants during a period of five days, so that all invitation letters are mailed within a one-week period. A second letter reminding participants of the invitation to participate in the study, combined with a thank you to participants who have already enrolled in the study, will be mailed to participants 30 days following the mailing of the initial letter.

Interested respondents will log on to the secure study website and will enter a special study code to gain entry to the site (each code set separately for existing cohort members and new cohort members). The respondent will be asked to consent to participation by reading the information provided to them and indicating their agreement by checking an "I agree" box. The participant will then complete a brief set of screening questions (name, age or date of birth, residential address, email address and social security number), and if eligible will be asked to create a unique username and password. The respondent will be systematically assigned to one of four different combinations of computerized questionnaires as indicated in the table below. Pathway assignments will be determined in advance to ensure that participants are distributed to pathways one or two 15% of the time, and to pathways three and four 35% of the time. Once assigned to a pathway, the respondent will be routed to their first computerized questionnaire.

Assignments	Baseline Questionnaires	30 Day Follow-Up	60 Day Follow-Up	90 Day Follow-Up
Pathway 1	ACT-24, LHQ	----	ACT-24, DHQ	----
Pathway 2	ASA24, DHQ	----	ASA24, LHQ	----
Pathway 3	ACT-24, ASA24, LHQ	----	ACT-24, ASA24, DHQ	----
Pathway 4	ACT-24, DHQ	ASA24, LHQ	ACT-24	ASA24

After completing an instrument, the respondent will either be forwarded to the next instrument to be completed at that time period or thanked for his or her time and effort when completed. The respondent will be reminded that they will receive an email and phone call notification requesting completion of the next series of questionnaires according to the pathway to which they are assigned.

If a participant wishes to end an instrument without fully completing the questions, 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 will be asked to being a new report of activities beginning the day prior to the new login date. However, for the LHQ or DHQ, the participant who leaves the instrument without fully

completing it 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. Even if the participant only partially completed any prior instrument, he or she will be asked to continue participation by completing the next instrument. Up to two email reminders and two automated telephone messages will be sent to a participant to remind him or her to complete the next instrument(s).

Subject Recruitment and Response Rates

An invitation to participate in the CLIC study will be extended to a random selection of 5,000 current cohort participants. Approximately 10,000 current AARP members age 50 and over who are not NIH-AARP Diet and Health Study cohort members will also be asked to join the CLIC study. Out of the 15,000 participants that receive the invitation letter, we expect 2,070 individuals will enroll in the study and 1,082 individuals will complete the study.

Significance of the Study

The CLIC study comprises necessary performance tests for the newly developed computerized questionnaires. The study will provide an opportunity to assess the possibility of constructing large web-based cohort studies as well as characterizing (in terms of diet, physical activity, and other demographic-lifestyle factors) individuals who successfully complete multiple 24-hour recall questionnaires.

Human Subjects Protection

Subjects will be eligible to participate in the CLIC study only after they have read and signed the informed consent statement. Children will not be eligible to participate in this study. Men and women 50 years of age or older will be eligible. No selection will be made based on gender or ethnicity of the participants. Biological samples will not be collected.