Interactive Comprehensive Lifestyle Interview by Computer (*i*CLIC)

Consent Form

Full Study Title: *Interactive* Comprehensive Lifestyle Interview by Computer or *i*CLIC

Conducted by: United States National Institutes of Health, National Cancer Institute, Division of Cancer Epidemiology and Genetics, Nutritional Epidemiology Branch

Principal Investigator: Arthur Schatzkin, M.D., Dr. PH

Funded by: United States National Cancer Institute

Why is this study being done?

The purpose of the *Interactive* Comprehensive Lifestyle Interview by Computer (*i*CLIC) is to collect information about diet, health, and lifestyle factors using computerized questionnaires. This study adds onto the National Institutes of Health (NIH)-AARP Diet and Health Study that began in 1995 and has approximately 500,000 persons still participating in follow-up. The original NIH-AARP Diet and Health Study collects information on diet and health using paper-based questionnaires sent in the mail. Answers from the questionnaires are combined with information on cancer and death in participants that comes from state and national statistics. As a result, researchers have learned more about how health behaviors are related to cancer and other diseases and over 50 articles have been published in scientific journals.

This new study will invite 5,000 current participants in the NIH-AARP Diet and Health Study and 10,000 newly invited persons who are AARP members age 50 and over. The *i*CLIC study will evaluate how much participation there is in a web-based study and whether participants complete the computerized questionnaires when they are asked to do them at different times over a few months. The study will also assess participant responses about diet, daily activities, and overall health and lifestyle. Information from this study will help researchers determine the best ways to use computerized questionnaires for research on diet and health.

What does it mean to participate?

If you are willing to participate, you will be asked a few initial questions about who you are and some identifying information such as your address, telephone number, email address, and sometimes social security number. Your answers are confidential and securely encrypted so that no access to this information is possible except for study purposes. Identifying information is separated from your responses so that your questionnaire responses cannot be linked to you. You may be contacted regarding this study or other health studies in the future, and you have the right to choose to participate or not participate in those studies.

Once you agree to participate, you will be linked to a separate secure internet site where you will create your own username and password in order to begin the

questionnaires. Each time you are scheduled to complete a new set of questionnaires, you will be sent an email message from the study. If you agree to be contacted by telephone or by text message, we will also contact you by these means to send you notification about completing a new set of questionnaires. For each set of questionnaires, participants may be asked to complete information about foods they've eaten the day before, their daily activities the day before, a lifestyle and health history survey, and/or a dietary questionnaire about foods eaten over the past year. Exactly how long it takes you to complete the questionnaires will depend on the questionnaires you are asked to do at that time and the answers you give in the questionnaires. We estimate that it will take 20 minutes to 1 hour each time you are asked to complete a set of questionnaires.

How long is this study?

Most participants will be asked to complete computerized questionnaires at the beginning of the study and two months later. Some participants will also be asked to complete a questionnaire one month after they start the study and then again, at two months and three months after they start the study (four times altogether). Participants selected to participate in the study are being asked to complete questionnaires at different time periods in order to see the best pattern for completing questionnaires. The iCLIC study will end in seven months, but most participants will be finished with all questionnaires in less than four months.

What are the risks and benefits of participating in this study?

Your participation in this research study is completely voluntary. This research project involves no more than minimal risk and does not affect your health care benefits or any other benefits you may receive.

There are no direct benefits to you for participating in this study. The information you provide may benefit society by increasing researchers understanding of how to best collect information for research on the role of diet, daily activities, and health and lifestyle factors.

Will the information I give be kept confidential?

The personal information you provide in this study will be kept confidential and secure. All personal identifying information will be securely encrypted and stored separately from the responses you give on the study questionnaires. Personal identifying information will be stored in a secure, password protected, and locked data file and only identified by a study number. In order to protect the confidentiality of the information you give us, only a study number will be used to identify you and the information you provide.

The study staff is required to keep your identity confidential and your name will never be used in any publications or presentations about this study. All staff working on the study will be required to sign a statement pledging to maintain the confidentiality of all data. Access to study data will be limited to the staff working on the study. When the study is complete or until the data is no longer required for research, the data will be archived and/or destroyed.

In becoming a study volunteer, the information you provide to the study comes under the NIH confidentiality policy for research participants. This policy is summarized in the previous two paragraphs. As a study participant, the information you provide will be covered under the NIH confidentiality policy and not the AARP's privacy policy. This means that if you give us your consent to participate in the study by checking the box below, NIH will not share with AARP any identifiable study information, and AARP will not share with NIH any identifiable information other than contact information and current AARP membership status.

What else do I need to know about the study?

Your participation in this study is completely voluntary. If you decide to participate, you may decide not to answer specific questions or leave the study at any time. The study investigators will use the information collected from you during the study up until the time you leave the study. There will be no penalty or loss of benefits to you if you decline to participate in the study or if you decide to leave the study at any time.

What if I have questions, comments, or concerns?

This consent form explains the research study. If you have any questions, comments, or concerns about the study or the informed consent process, you may telephone (301) 594-2931 or email the Principal Investigator, Arthur Schatzkin, M.D., Dr. P.H. at schatzka@mail.nih.gov .

If you have any questions about being a research participant, you may contact the study by email at iCLICcontactUs@westat.com or call us toll-free at 1-888-302-6672.

Approvals

This study protocol and this informed consent form have been reviewed by the institutional review boards of the United States National Cancer Institute and other organizations participating in monitoring the research data. These review committees monitor the safety and the rights of individuals participating in this research study.

Legal Rights

You are not waiving any of your legal rights by reading this consent form and agreeing to participate in the study.

This part will be outside the box and on the screen itself.

☐ I have read this informed consent information and agree to participate in the study.

☐ I have read the informed consent information above and do not want to participate in the study.