NATIONAL INSTITUTES OF HEALTH – AARP DIET AND HEALTH STUDY

September 2007

STUDY OVERVIEW

This study is being conducted by the National Cancer Institute, Division of Epidemiology and Genetics, Nutritional Epidemiology Branch. Arthur Schatzkin, M.D., Dr. P.H., Chief of the Nutritional Epidemiology Branch, is the principal investigator. Westat serves as the coordinator for the study, under contract to the National Cancer Institute (NCI). The NIH-AARP Diet and Health Study is designed to prospectively examine the relationship between diet and major cancers (especially those of the breast, large bowel and prostate) in a sample of early to late middle-aged men and women in the United States. The study began in 1995. The sampling frame used for this study was the membership roll of the American Association of Retired Persons (AARP). The AARP is an ideal source of participants for this study because of the size and demographics of its membership, and its commitment to promoting the health of its members.

For this study, participants have been asked to provide three types of health information:

1) dietary history information,
2) cancer risk factor information, and
3) cancer diagnosis information.

Historically, observational epidemiologic studies of diet and cancer have suffered from the problem of dietary homogeneity among the study subjects. This study overcomes that problem by collecting dietary data from a very large number of persons, thereby including those persons in the extreme categories of dietary intake (in terms of fat, fiber and other nutrients). This process ensures that the cohort is heterogeneous in terms of dietary intake.

The primary method of information collection is mail questionnaires. Questionnaires are formatted for optical scanning which allows very rapid and accurate data entry, editing, and processing. Cancer information is collected from population-based cancer registries. Vital status information is collected from Westat's copy of the latest Social Security Administration (SSA) mortality database and from the National Death Index, a federally operated mortality database.

To collect the dietary data needed for the cohort selection process, a baseline questionnaire (primarily a dietary assessment questionnaire) was mailed to 3.5 million AARP members aged 50 to 69 years sampled from among those who, in 1995, resided in eight states or metropolitan areas selected for

the study. The states and metropolitan areas were selected based on the quality of the cancer registry, the number of minority residents, and the willingness of the registry to collaborate with us. The eight states/areas included in the study are: California, Florida, Louisiana, New Jersey, North Carolina, Pennsylvania, the Detroit metropolitan area, and the Atlanta metropolitan area.

Following the baseline questionnaire, a second questionnaire was mailed to those persons who agreed to participate in the study (i.e., who completed and returned the baseline questionnaire), and who met the study eligibility criteria. The second questionnaire collected dietary history and additional cancer risk factor information. Dietary and other data collected in the two questionnaires indicates that the study cohort of approximately 540,000 persons has a broad range of dietary intake. The cohort is being followed for outcome assessment in terms of cancer incidence and mortality. Linkages to mortality databases are performed to learn about mortality events and linkages to cancer registries are performed to collect outcome (i.e., cancer incidence) information.

A calibration study was also conducted. The calibration study involved 2,000 study participants and included 24-hour dietary recall telephone interviews conducted on two separate occasions with each subject, followed by another mailing of a dietary assessment questionnaire. The 24-hour dietary recall telephone interview data was compared to the mail questionnaire food frequency data to measure correlations between the two types of dietary data.

In 2004, an additional component of the study was launched. Collection of buccal cell DNA from approximately 80,000 participants in the NIH-AARP Diet and Health Study began. Collection proceeded according to a case-cohort design: cases comprised all surviving cohort members diagnosed with colorectal, breast, prostate cancer, or non-Hodgkin's lymphoma after baseline (1995-96); the comparison subcohort was randomly selected from the cohort as a whole. A total of 77,462 buccal cell kits were delivered to study participants. Collection was completed in December 2005 and samples sent to an NCI biorepository for permanent storage. However, the study continued to receipt any late incoming buccal cell samples through June 2006, and in July transferred these remaining samples to the NCI biorepository for storage. A total of 34,262 participants returned buccal cell samples and no further analyses of the samples have been conducted.

In 2004-2006, a follow-up questionnaire was mailed to participants to obtain information on daily physical activities; smoking; medication, vitamin and supplement use; family history of selected cancers, and personal history of cancers, other health conditions, and medical procedures. The total number of respondents to the questionnaire was 318,261. Data is currently being analyzed.

Westat has subcontracted with National Computer Systems (NCS) to perform the printing, mailing, receipt, optical scanning, and processing of the mail questionnaires.

DATA SECURITY

All work performed under this contract was reviewed and approved by Westat's Institutional Review Board (IRB) and the National Cancer Institute's Special Studies IRB (NCI SSIRB). Both IRBs have been monitoring, and will continue to monitor, the study activities on an annual basis. The NCI SSIRB, at the request of the NCI principal investigator, will determine if any other NIH institute, academic institution, or contractor may be involved in ancillary studies utilizing data for analysis or personal identifiers for contacting study participants.

All NCI and Westat employees who work with data must sign a pledge of confidentiality and complete annual human subjects training. Individual subject data is not disclosed to anyone except the researchers conducting the study, except as required by law. No information that would enable the identification of individuals is included on any data file used for analysis. Westat ensures the confidentiality of all data, as required by Section 308(d) of the Public Health Service Act and the U.S. Privacy Act of 1974. Paper records containing personal identifiers are kept in locked file rooms at both Westat. When the study is complete, all hard-copy records will be delivered to NCI, stored in a locked vault, or destroyed, depending upon the direction of NCI. Westat believes these procedures to be extremely effective in ensuring that risks to the subjects are minimized and that the confidentiality of the data is maintained.

INVESTIGATORS

NCI Principal Investigator:

Arthur Schatzkin, M.D., Dr.P.H.
Chief, Nutritional Epidemiology Branch
National Cancer Institute
Executive Plaza South, Room 7040
Rockville, MD 20892
Telephone: (301) 594-2931

Westat Project Director:

Kerry Grace Morrissey, M.P.H.
Westat
1650 Research Blvd., TB312
Rockville, MD 20850
Telephone: (240) 453-2742
Fax: (301) 294-2092