



National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

08-29-2005

Dr. Arthur Schatzkin
National Cancer Institute
Chief, Nutritional Epidemiology Branch
Executive Plaza South, Room 7040
6120 Executive Boulevard
Rockville, MD 20892

Dear Dr. Schatzkin,

Enclosed is the amended Confidentiality Certificate protecting the identity of research subjects in your project entitled "NIH-AARP Diet and Health Study." Please note that the Certificate expires on 12/31/2013.


Please be sure that the consent form given to research participants accurately states the intended uses of personally identifiable information (including matters subject to reporting) and the confidentiality protections, including the protection provided by the Certificate of Confidentiality with its limits and exceptions.

If you determine that the research project will not be completed by the expiration date, 12/31/2013, you must submit a written request for an extension of the Certificate three months prior to the expiration date. If you make any changes to the protocol for this study, you should contact me regarding modification of this Certificate. Any requests for modifications of this Certificate must include the reason for the request, documentation of the most recent IRB approval, and the expected date for completion of the research project.

Please advise me of any situation in which the certificate is employed to resist disclosure of information in legal proceedings. Should attorneys for the project wish to discuss the use of the Certificate, they may contact the Office of the NIH Legal Advisor, National Institutes of Health, at (301) 496-6043.

Correspondence should be sent to: Samson Adepoju, Institute Review Office, National Cancer Institute, 6116 Executive Blvd., Suite 212, MSC 8349, Bethesda, Maryland 20892-8349
Phone: (301)-496-7628, Fax: (301)-435-1832

Sincerely,


Samson Adepoju
Certificate Coordinator

Enclosures



National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

CONFIDENTIALITY CERTIFICATE

NCI-01-009A

issued to

National Cancer Institute

conducting research known as

OH95-C-N025

"NIH-AARP Diet and Health Study"

In accordance with the provisions of section 301(d) of the Public Health Service Act 42 U.S.C. 241(d), this amended Certificate is issued in response to the request of the Principal Investigator, Dr. Arthur Schatzkin, to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Schatzkin is primarily responsible for the conduct of this research which is supported by the National Cancer Institute.

Under the authority vested in the Secretary of Health and Human Services by section 301(d), all persons who:

1. are enrolled in, employed by, or associated with the National Cancer Institute and its contractors or cooperating agencies, and
2. have in the course of their employment or association access to information which would identify individuals who are the subjects of the research pertaining to the project known as "NIH-AARP Diet and Health Study"

are hereby authorized to protect the privacy of the individuals who are the subjects of that research by withholding their names and other identifying characteristics from all persons not connected with the conduct of that research.

The objective of this study is to carry out a prospective cohort study of diet in relation to several major cancers, especially breast, prostate and colorectal malignancies.

Approximately 540,000 members of the American Association of Retired Persons (AARP) between the ages of 50 and 69, 50% male and 50% female, are participants in this study. Questionnaires are obtained, and passive follow-up will be performed through state registries. Active follow-up with record retrieval will be conducted for the small percentage of cohort members who have moved out of the cancer registry areas. A recent protocol amendment allows for buccal cell collection from saliva samples; DNA will be collected and used to investigate the relation of certain genetic factors, in conjunction with dietary and other lifestyle characteristics, to the risk of developing cancer.

A Certificate of Confidentiality is needed because sensitive genetic and lifestyle information will be generated. The Certificate will help researchers avoid involuntary disclosures which could expose study participants and their families to adverse economic, psychological, and social consequences.

All study participants are assigned a coded number, and identifying information and records are kept in secured computer files maintained by project contractors.

This research began on 1/1/1994 and ends on 12/31/2012.

As provided in section 301(d) of the Public Health Service Act 42 U.S.C. 241 (d):

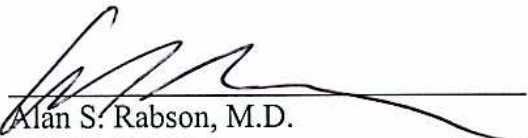
"Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

This Certificate does not protect you from being compelled to make disclosures that: (1) have been consented to in writing by the research subject or the subject's legally authorized representative; (2) are required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or regulations issued under that Act; or (3) have been requested from a research project funded by NIH or DHHS by authorized representatives of those agencies for the purpose of audit or program review.

This Certificate does not represent an endorsement of the research project by the Department of Health and Human Services. This Certificate is now in effect and will expire on 12/31/2013. The protection afforded by this Certificate of Confidentiality is permanent with respect to any individual who participate as a research subject (i.e., about whom the investigator maintains identifying information) during any time the Certificate is in effect.

Date

9/1/05


Alan S. Rabson, M.D.

Deputy Director
National Cancer Institute
National Institutes of Health