



National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

04-17-2012

Dr. Michael Alavanja
National Cancer Institute
Executive Plaza South, Room 8000
6120 Executive Blvd., MSC 7240
Rockville, MD 20852

Dear Dr. Alavanja,

Enclosed is the amended Confidentiality Certificate protecting the identity of research subjects in your project entitled "Agricultural Health Study - A Prospective Study of Cancer and Other Diseases Among Men and Women in Agriculture." Please note that the Certificate expires on 9/22/2019.

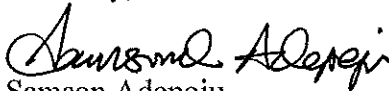
Please be sure that the consent form given to research participants accurately states the intended uses of personally identifiable information (including matters subject to reporting) and the confidentiality protections, including the protection provided by the Certificate of Confidentiality with its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

If you determine that the research project will not be completed by the expiration date, 9/22/2019, 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 220, 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-02-028A

issued to

National Cancer Institute

conducting research known as

N01-CP-21095

"Agricultural Health Study - A Prospective Study of Cancer and Other Diseases Among Men and Women in Agriculture"

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. Michael Alavanja, to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Alavanja 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 "Agricultural Health Study - A Prospective Study of Cancer and Other Diseases Among Men and Women in Agriculture"

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 "Agricultural Health Study" (AHS) is a collaborative effort between the National Cancer Institute and the National Institute of Environmental Health Sciences. The US Environment Protection Agency is providing support for a limited exposure assessment effort. The stimulus for this prospective investigation comes from the growing evidence that, despite a low mortality overall, farmers experience an excess of several cancers.

Participating institutions include: The National Cancer Institute, the National Institute of Environmental Health Sciences, the National Institute of Occupational Safety and Health, the US Environmental Protection Agency, University of Iowa, Battelle, Westat, Information Management Services, Social and Scientific Systems (SSS), and designated biospecimen repositories.

Initial data collection on a prospective cohort of 89,658 study subjects has been completed as of December 1997. Participants completed questionnaires that included items on pesticides used, other agriculture exposures, and work practices that modify exposure as well as on other activities that may affect either exposure or disease risks (e.g., diet, exercise, alcohol consumption, medical conditions, family history of cancer, other occupations and smoking history).

A Certificate is needed because sensitive genetic information will be collected during the course of this study. This Certificate will help researchers avoid involuntary disclosure, which could expose subjects and their families to adverse economic, legal, psychological, and social consequences.

Each subject is assigned a six-digit number; these IDs are used for any references to subjects on an individual basis. Names and other identifying information are kept in a separate database maintained by the Field Stations. Contact of subjects occurs only through designated contractors.

This research began on 9/1/2002 and ends on 9/22/2018.

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

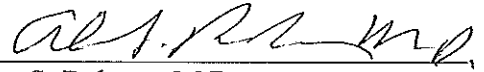
"Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

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 9/22/2019. The protection afforded by this Certificate of Confidentiality is permanent with respect to any individual who participates as a research subject (i.e., about whom the investigator maintains identifying information) during any time the Certificate is in effect.

Date

4/30/12.



Alan S. Rabson, M.D.
Deputy Director
National Cancer Institute
National Institutes of Health