



CONFIDENTIALITY CERTIFICATE

NCI-02-028

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 Certificate is issued in response to the request of the Principal Investigator, Michael Alavanja, Dr. P.H., 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, and McKesson HBOC Clinical and Biological Services.

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 the Field Stations.

This research begins on 9/1/2002 and ends on 12/31/2008.

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 12/31/2009. 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

2/3/02



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