



DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Institute of Environmental
Health Sciences
Building 31, Room 5A33
31 Center Drive, MSC 2490
Bethesda, Maryland 20892-2490

November 12, 2002

Dale P. Sandler, Ph.D.
Principal Investigator
Acting Chief, Epidemiology Branch, DIR, NIEHS
PO Box 12233
Research Triangle Park, North Carolina 27709

Dear Dr. Sandler:

Enclosed is the Confidentiality Certificate protecting the identity of research subjects in your project entitled, "The Sister Study: Environmental and Genetic Risk Factors for Breast Cancer." Please note that the Certificate expires on December 31, 2017.

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, December 31, 2017, 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 my attention at: National Institutes of Health, National Heart, Lung, and Blood Institute, Building 31, Room 5A33, 9000 Rockville Pike, Bethesda, Maryland, 20892-2486, phone number 301-496-5931 and fax number 301-402-0299.

Sincerely,

David L. Whitmer
NIEHS Certificate of Confidentiality Coordinator

Enclosure

CC: Dr. Kimberly Gray
Dr. Lutz Birnbaumer

CONFIDENTIALITY CERTIFICATE

NIEHS 02-07

Issued to

National Institute of Environmental Health Sciences (NIEHS)

conducting research known as

“The Sister Study: Environmental and Genetic Risk Factors for Breast Cancer”

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, Dale P. Sandler, Ph.D., to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Sandler is primarily responsible for the conduct of this research, which is funded by the National Institute of Environmental Health Sciences.

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 Institute of Environmental Health Sciences (NIEHS) and its contractors or cooperating agencies; and
2. have in the course of their employment or association access to information that would identify individuals who are the subjects of the research pertaining to the project known as “The Sister Study: Environmental and Genetic Risk Factors for Breast Cancer.”

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 Sister Study will examine environmental and genetic risk factors for breast cancer in a cohort of 50,000 sisters of women who have had breast cancer. A nationwide publicity campaign, coupled with an outreach program that takes advantage of the large networks of breast cancer advocates, will be used to recruit the sisters. Focus groups and preliminary study contacts suggest a high level of interest in the study among these advocacy groups and women with family histories of breast cancer. By focusing on a genetically susceptible group, more precise estimates of the contribution of environmental and other non-genetic factors to disease risk may be possible. The Sister Study will also enroll approximately 1,500 women with incident breast cancer, whose sisters have enrolled in the cohort, to participate in a parallel case-control study of breast cancer cases and sister controls that will be used to test current hypotheses and to generate hypotheses for future testing in the cohort study. Nested case-control or case-cohort analyses will be carried out among sisters who subsequently develop cancer and a sample of those who do not, to assess specific gene-environment interactions. Once assembled, the cohort also will provide the structure for assessing gene-environment interactions in risk for other diseases, and will provide

opportunities for add-on studies such as comparing tumor characteristics and risk factors in affected sister-pairs. In addition, by following incident cases over time, the researchers will have the opportunity to study the influence of environmental and genetic factors on breast cancer survival.

A Certificate of Confidentiality is needed because sensitive information about the genotype of the patients will be collected during the course of the study. The certificate will help researchers avoid involuntary disclosure that could expose subjects or their families to adverse economic, legal, psychological and social consequences. Followup questionnaires will update exposure and medical histories, as well as provide an opportunity to collect new data and environmental samples to evaluate emerging hypotheses. Tumor tissue and medical records will be sought for incident breast cancer cases. Data and sample collection is expected.

Confidentiality of each subject's information will be maintained according to standard clinical and research practice. Specifically, robust electronic security precautions will be enacted. Participants will be informed that their identity and all data collected will be kept confidential through the use of a unique identification number which will allow all data to be entered into the database in a confidential fashion, such that the information cannot be linked or traced to any person or family. Biological and environmental specimens will also be labeled solely with an ID number. All information gathered from participants will be used only for group statistical analyses, not individual results. Consent forms and medical abstract forms that contain names will not be stored with data forms, but will be secured in locked cabinets.

This research will begin in January 2003 and is expected to end on December 31, 2017.

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 December 31, 2017. The protection afforded by this Confidentiality Certificate 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:

11/5/02

Kenn Olden

Kenneth Olden, Ph.D.
Director, NIEHS