



DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Heart, Lung, and Blood Institute
Management Policy Admin Services Branch
Building 31, Room 5A33
31 Center Drive, MSC 2490
Bethesda, Maryland 20892-2490

November 23, 2006

Philip A. Wolf, M.D.
Principal Investigator
The Framingham Study
Boston University School of Medicine
715 Albany Street, B-608
Boston, MA 02118-2526

P. A. WOLF, M.D.

FEB 1 2007

RECEIVED

Dear Dr. Wolf:

Enclosed is the Certificate of Confidentiality that will protect the identity of research subjects in your project entitled, "The Framingham Heart Study: Physical Examination, Testing, and Surveillance". Please note that the Certificate expires on August 31, 2011.

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, August 31, 2011, 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 either myself or Alesha Hopkins 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 either Alesha Hopkins or myself at: the National Institutes of Health, the 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,

Donna Jones

NHLBI Certificate of Confidentiality Coordinator

CONFIDENTIALITY CERTIFICATE

NHLBI 99-02 Extension 11-06

Issued to

Boston University School of Medicine

Conducting research known as

“The Framingham Heart Study: Physical Examination, Testing, and Surveillance”

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, Philip A. Wolf, M.D., to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Wolf is primarily responsible for the conduct of this research, which is funded by the National Heart, Lung, and Blood 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 Boston University School of Medicine, Neurological Epidemiology and Genetics and their contractors or cooperating field centers; 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 Framingham Heart Study: Physical Examination, Testing, and Surveillance,”

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 Framingham Heart Study has recruited participants for the Third Generation and New Offspring Spouse Cohorts since August 2001:

- ✓ The Third Generation participants are children of participants from the Offspring Cohort. Recruitment of the Third Generation (Gen3) Cohort began in November 2001 and ended in June 2005. Overall 4,095 individuals were recruited and enrolled in the Framingham Heart Study Gen3 Cohort.
- ✓ The New Offspring Spouse (NOS) Cohort consists of volunteers who are biological parents of at least two Gen3 participants. These subjects are in addition to Offspring Study subjects who were already enrolled in the Offspring Study in October 2003, when recruitment was initiated for the NOS Cohort. Recruitment ended in June 2005, with 103 people recruited.

The data collection activities are similar to those in previous examinations. Consent forms now include check boxes by which participants may opt in or out of specific aspects of the study. Participants/volunteers from each cohort partake in examinations at the Framingham Heart Study clinic, in their homes or at nursing homes at intervals of two to four years.

The Framingham Heart Study understands the value of sharing scientific knowledge and information with others. The study is playing an integral role in the FHS SHARe and NHLBI CARE initiatives. The Framingham Heart Study SNP Health Association Resource (SHARe) Project was initiated as a joint project between Boston University, NHLBI and NCBI to provide qualified investigators extensive phenotypic information and genotypes from the Framingham Heart Study, including about 550K genotypes from Affymetrix chips. These data have been collected from the Framingham Original, Offspring, and Gen3 Cohorts. In addition, the Framingham Heart Study will be involved with the NHLBI sponsored Candidate Gene Association Resource (CARE) initiative. The study will provide all phenotypes related to heart, lung, blood, and sleep to a central site for gene association studies.

Protecting the identity of Framingham Heart Study research subjects is critical due to the numerous genetic studies being conducted using Framingham DNA. Genetic research on Framingham DNA samples can occur outside the Framingham Genotyping Laboratory and outside the Framingham facility by researchers at other institutions. Hence, with so many projects involving Framingham DNA, it is especially important that the identity of these individuals remain confidential.

A Certificate of Confidentiality is needed to provide study subjects reassurance that certain sensitive information they provide will be protected.

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 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 August 31, 2011. 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: 1/25/2007

A handwritten signature in dark ink, appearing to read "Elizabeth G. Nabel for EGN".

Elizabeth G. Nabel, M.D.
Director