

## CONFIDENTIALITY CERTIFICATE

NHLBI 05-31

Issued to

Johns Hopkins University

conducting research known as

**"Genetic Modifiers of Cystic Fibrosis: Sibling Study"**

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, Garry R. Cutting, M.D., to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Cutting is primarily responsible for the conduct of this research, which is funded by the National Heart, Lung, and Blood Institute (NHLBI).

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 Johns Hopkins University, et al, (see attached list) 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 " Genetic Modifiers of Cystic Fibrosis: Sibling 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 purpose of this study is to: 1) identify heritable cystic fibrosis (CF) phenotypes by twin study; 2) determine the contribution of genetic and other factors to CF phenotype variability by analysis of affected sibs; 3) identify biologic phenotypes that correlate with heritable CF phenotypes by clinical study of twins and sibs; and 4) identify modifier genes and loci responsible for heritable CF phenotypes by linkage and linkage disequilibrium approaches. Blood will drawn from each of the immediate family members (parents and affected offsprings). Families complete a family medical history questionnaire and each CF patient will fill out a personal questionnaire.

A certificate of confidentiality is needed to protect research subjects because DNA and both personal and family medical history information are collected. The certificate will help researchers avoid involuntary disclosure that could expose subjects or their families to adverse economic, legal, psychological, and social consequences.

Identifying information will be removed from all collected materials and replaced with a Johns Hopkins study ID number. Information will be kept in a database and will not contain any identifiers. Participant information will be kept in a locked cabinet and accessed only by the principal investigator.

This research began on September 30, 2001, and is expected to end on August 30, 2011.

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 30, 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: 2.23.06



Elizabeth G. Nabel, M.D.

Director