



National Institutes of Health
National Human Genome
Research Institute
Ethical, Legal, and Social
Implications (ELSI) Research
5635 Fishers Lane, Suite 4076
Bethesda, MD 20892-9305
Telephone: (301) 402-4997
Fax: (301) 402-1950

CONFIDENTIALITY CERTIFICATE

Number: HG-2009-01

Issued to

**National Center for Biotechnology Information
National Library of Medicine
National Institutes of Health**

conducting research known as

“The database for Genotype and Phenotype (dbGaP).”

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, James Ostell, Ph.D., to protect the privacy of research subjects by withholding genotype and phenotype data from all persons not connected with this research. Dr. Ostell is primarily responsible for the conduct of this research, which is supported by the National Library of Medicine, National Institutes of Health.

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 Library of Medicine, National Institutes of Health and its contractors or cooperating agencies and
2. have in the course of their employment or association access to genotype or phenotype data from individuals who are the subjects of the research submitted to the project known as **“The database for Genotype and Phenotype (dbGaP).”**,

are hereby authorized to protect the privacy of the individuals who are the subjects of that research by withholding genotype and phenotype data from all persons not connected with the conduct of that research.

This database serves as a central point of research access for NIH-supported and other genotype-phenotype datasets, as well as some DNA sequence-based studies. dbGaP contains both public "open access" information about genetic studies as well as "controlled access" for research datasets with individual-level data. Individual-level data, as well as summary level statistics files of all genotype data, are included in the controlled access sections of dbGaP. Publicly available dbGaP information includes details of study design, participant selection, and aggregate outcomes. Controlled access data provides research access to the genotype and phenotype data for individual participants. The National Center for Biotechnology Information, National Library of Medicine has the linking code back to the identifiers located at the contributing site.

A Certificate of Confidentiality is needed because potentially sensitive genetic information 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.

To protect participants' confidentiality, there will be on-going assurance of participant protections pertaining to data held within dbGaP based on oversight by the NIH of data access to "secondary" data users. Research access to dbGaP data will be provided through a "Controlled Access" process implemented by NIH Data Access Committees (DACs). Data Access Committees will be constituted by the NIH Institutes with federal employees possessing the appropriate scientific and bioethics expertise, and through the oversight and actions of these committees access to dbGaP datasets will be provided based on the consistency of specific research uses (proposed by data requestors) with the data use limitations set by the institutions submitting the datasets to the NIH. Approved data users will agree, along with their home institutions, to follow specified principles and terms of use for the specific dataset provided. NIH will monitor data use practices over time to assure that policies and procedures for protecting participants and their interests remain robust.

This research began on December 14, 2006 expected to be ongoing. This Certificate will end on October 31, 2018 and is expected to be renewed at that time.

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 October 31, 2018. 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) in a study that is submitted to the dbGaP project during any time the Certificate is in effect.

Date: 10/31/2008

Elizabeth Thomson

Elizabeth J. Thomson, DNSc, RN, CGC, FAAN
Program Director
Ethical, Legal, and Social Implications Research