



CONFIDENTIALITY CERTIFICATE

Number: DA-04-049

issued to

UNIVERSITY OF COLORADO

conducting research known as

"HERITABLE EARLY INDICATORS OF RISK FOR DRUG DEPENDENCE"

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, John K. Hewitt, Ph.D., Institute for Behavioral Genetics, University of Colorado, Boulder, CO 80309-0447, to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Hewitt is primarily responsible for the conduct of this research, which is supported by the National Institute on Drug Abuse grant number P60 DA11015.

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 University of Colorado, and its research sites, 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 "Heritable Early Indicators of Risk for Drug Dependence,"

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 twin study component of the center grant provides crucial information on the heritability of the phenotypes being studied. This study will extend the augmented twin study to understand how genes and environmental risks contribute to vulnerability to drug use, abuse and dependence as they develop in adolescence. The following will be looked at: (1) vulnerability to drug dependence in adolescence is predominantly a generalized phenomenon; (2) persistent drug use that progresses to regular use, abuse, and dependence is a more heritable phenotype than transient drug use; (3) individuals with persistent drug use, abuse, and symptoms of dependence are more likely to have comorbid symptoms of other psychiatric disorders; and (4) the genetic link between antisocial behavior and persistent generalized drug use, abuse, and dependence is mediated through a constellation of individual attributes that have been characterized as behavioral inhibition.

A Certificate of Confidentiality is needed because sensitive information about substance abuse and other illicit behaviors as well as DNA samples 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 subject identities, no names appear on any of the interviews or questionnaires. All of the information is stored in password-protected computer files with code numbers only. Any information, which does have names is kept locked up and separate from both the DNA and interview responses.

This research began on August 15, 2003, and is expected to end on April 30, 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 at the end of April 2008. 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: 11/19/07



Nora D. Volkow, M.D.
Director