

CONFIDENTIALITY CERTIFICATE

National Institutes of Health National Institute on Drug Abuse Bethesda, Maryland 20892

Number: DA-03-201

issued to

UNIVERSITY OF COLORADO AT BOULDER INSTITUTE FOR BEHAVIORAL GENETICS conducting research known as

"FAMILIAL AGGREGATION OF ANTISOCIAL SUBSTANCE DEPENDENCE COMPONENT 2 OF ANTISOCIAL DRUG DEPENDENCE: GENETICS"

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, Michael Stallings, 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. Stallings is primarily responsible for the conduct of this research, which is supported by NIDA grant P60 DA11015.

Under the authority vested in the Secretary of Health and Human Services by section 301(d), all persons who:

- are enrolled in, employed by, or associated with the Institute for Behavioral Genetics, University of Colorado and its contractors or cooperating agencies and sites, 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 "Familial Aggregation of Antisocial Substance Dependence Component 2 of Antisocial Drug Dependence: Genetics,"

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.

Antisocial Behavior and substance use disorders (SUD) develop over time. The purpose of this study is to conduct a 5-10 year follow-up of 485 families of subjects formerly in treatment for SUD and conduct disorder (CD) as adolescents and 400 unselected control families. This study will provide important information regarding: (1) family influences underlying vulnerability to SUD and CD; (2) the generality versus specificity of important familial influences on these behaviors; (3) whether influences on the expression of familial liability may be gender-specific; and (4) the identification of family factors that differentiate persistent versus adolescent-limited problem behavior.

A Certificate of Confidentiality is needed because sensitive information about substance use and other illicit behaviors 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 subjects' 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 are kept locked up and separate from the DNA and interview responses.

This research begins September 1, 2003 and is expected to end September 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 September 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: \$\(\sigma \frac{13}{0}\)

D. Volkow, M.D.

Director