



11/6/2015

University of Cincinnati
Dr. Judith Feinberg
College of Medicine
Division of Infectious Diseases/Holmes Bldg
200 Albert Sabin Way Room 3112 ML#0405
Cincinnati, OH 45267

Dear Dr. Feinberg,

Enclosed is the Confidentiality Certificate, protecting the identity of research subjects in your single-site/single-protocol project entitled "Southern Ohio Prevents Hepatitis (StOPHep)".

We are providing one more year of Certificate coverage than you requested because it has been our experience that many studies take longer to complete than initially projected. Providing an extra year will ensure coverage for subjects, and may spare you the need to formally submit a request for an extension. Please note that the Certificate expires on 05/06/2021.

Please be sure that the consent form given to research participants accurately states the intended uses of personally identifiable information 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, 05/06/2021, you must submit a written request for an extension of the Certificate three (3) 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 me 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:

Natisha Rowe
National Institute on Drug Abuse
NSC BG RM 4225
6001 EXECUTIVE BLVD
ROCKVILLE, MD 20852

Sincerely,



Nadine E. Rogers, Ph.D.
Confidentiality Certificate Coordinator

Approved Date: 11/06/2015

**CONFIDENTIALITY CERTIFICATE***CC-DA-15-170*

issued to

UNIVERSITY OF CINCINNATI

conducting research known as

"SOUTHERN OHIO PREVENTS HEPATITIS (STOPHEP)"

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, Dr. Judith Feinberg, to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Judith Feinberg is primarily responsible for the conduct of this research, which is funded by: Centers for Disease Control and Prevention (CDC).

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 University of Cincinnati and its 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 "Southern Ohio Prevents Hepatitis (StOPHep)".

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.

As the heroin epidemic continues to ravage non-urban areas in this region, young adults are at very high risk of HCV. There is an urgent need to better define this population in terms of demographics, risk behaviors, and social networks; to prevent infection with bloodborne chronic viral infections; and to link infected individuals to appropriate medical care. Eligible subjects are persons who: 1) are 18-30 years old, 2) reside in a target nonurban county, 3) report IDU within the prior 12 months, 4) are not likely to be sentenced to jail or prison within the next 90 days, and 5) are willing to provide written informed consent. This project will utilize Peer Navigators (PNs) to screen participants, obtain written informed consent and collect baseline epidemiological data and hepatitis and HIV serologies.

A Certificate of Confidentiality is needed because sensitive 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.

In order to protect subjects' identities, participants are assigned an ID code, by which they are identified on paper forms and database in which information is stored. (Documents requiring their full name (such as Informed Consent Forms and copies of medical records) are secured separately from other study documents, to prevent linkage of a given ID code with a full name). Linking information is held securely in a separate location. All records are maintained in a facility which is double locked to provide security, and will remain secure after study closure. Electronic files are password protected.

This research begins on 05/06/2015 , and is expected to end on 05/06/2021.

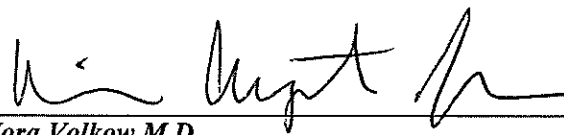
As provided in section 301 (d) of the Public Health Service Act 42 U.S.C. 241(d):

"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 05/06/2021. 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 the time the Certificate is in effect.

Sincerely,



Nora Volkow M.D.
Director
National Institute on Drug Abuse

Signed Date:

12/12/2015