



CONFIDENTIALITY CERTIFICATE

CC-HG-16-006

issued to

University of Michigan

conducting research known as

"University of Michigan ("U-M") Medical School Central Biorepository ("CBR"). "

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. Victoria Blanc, to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Victoria Blanc is primarily responsible for the conduct of this research, which is funded by:

1. Internal Institution funding

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 Michigan 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 "University of Michigan ("U-M") Medical School Central Biorepository ("CBR"). "
3. 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 CBR is a repository of human biospecimens that serves as central storage facility, point of research access, and administrative hub for research using these biospecimens and data associated with or derived from them.

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.

The CBR operates subject to initial and continuing review by the University of Michigan Medical School Institutional Review Boards (IRBMED), which monitor CBR policies and procedures regarding intake, storage, and distribution of research materials. ILD are coded whenever possible, and viewing of ILD is restricted to a minimum-necessary standard via role- and field-specific restrictions in the LIMS. Research access to CBR materials is controlled by the CBR Governance Committee, which is comprised of, and/or ensures consultation of, individuals with appropriate scientific and bioethics expertise for review of each research project that utilizes CBR resources. Through committee oversight and decisions, CBR materials are provided to requestors for uses that are consistent with participant informed consent and all applicable regulatory and ethical requirements. Approved users must agree to documented terms of use for the CBR materials provided to them.

This research began on 06/17/2014, and is expected to end on 12/31/2026.

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 12/31/2026. 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,



Signed Date: 2/02/2016

Laura Lyman Rodriguez, Ph.D.
National Human Genome Research Institute