



CONFIDENTIALITY CERTIFICATE

AMENDMENT (NEW PRINCIPAL INVESTIGATOR)

Number: IC-2002-07

Issued to

Marshfield Medical Research Foundation

conducting research known as

“Marshfield Clinic Personalized Medicine Research Project”

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, Murray H. Brilliant, Ph.D., to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Brilliant is primarily responsible for the conduct of this research, which is supported by the Health Resources Services Administration (Grant #1D1ARH00025); a State of Wisconsin Technology Development Fund award; and the Marshfield Clinic.

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 Marshfield Clinic 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 “Marshfield Clinic Personalized Medicine Research Project,”

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 goal of this project is to make major advances in the application of genetic science to human health by translating genetic data into specific knowledge about disease and into clinically relevant information that will enhance patient care. The project will attempt to

accomplish this in part by creating a Personalized Medicine Research Database that will be used for multiple studies in population genetics, genetic epidemiology, medical genetics and pharmacogenetics.

A Certificate of Confidentiality is needed because sensitive information such as genetic information, comprehensive medical information and environmental 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 confidentiality and privacy, all information entered into the research database will be coded. The genetic information will be encrypted when entered into the research database. Information entered from the medical records and questionnaires will not contain personally identifiable information. Project staff having access to medical information will not have access to genetic information. The research database will be kept on a separate computer system that will not be connected with other Marshfield Clinic information systems or to any external network, such as the Internet. The computer will be housed in a highly secure location and only a limited number of authorized staff will have access to the research database.

This research began on August 19, 2002 and is expected to end in about 20 years. This certificate will expire on August 1, 2017, at which time the certificate will need to be renewed.

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

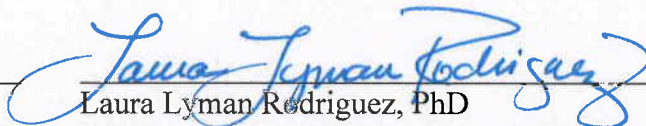
“Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.”

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 August 1, 2017. 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:

9-7-12



Laura Lyman Rodriguez, PhD

September 7, 2012

Director, Office of Policy, Communications and Education
National Human Genome Research Institute