



National Institute of General
Medical Sciences
Division of Extramural Activities,
NIGMS
45 Center Drive
Rm. 2AN.24G, MSC 6200
Bethesda, MD 20892

CONFIDENTIALITY CERTIFICATE

CC-GM-15-004

issued to

Coriell Institute for Medical Research, Inc.

conducting research known as

"NIGMS Human Genetic Cell Repository (HGCR)"

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

Institution Center: NIGMS, Grant Number: 1U42GM115336-01

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 Coriell Institute for Medical Research, Inc. 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 "NIGMS Human Genetic Cell Repository (HGCR)".
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.

Project Narrative The NIGMS Human Genetic Cell Repository stimulates and facilitates biomedical research, teaching, and the diagnosis and prevention of human genetic diseases by providing well-characterized and high-quality cell lines and DNA for use in biomedical research. The NIGMS Repository, which currently contains more than 11,300 cell lines and 5,600 DNA samples in its online catalog, focuses on acquiring biological samples from individuals with inherited diseases, apparently healthy individuals, and individuals of diverse geographic origins. The NIGMS Repository also provides stem cell lines, including many that carry disease gene mutations, which can be used for purposes ranging from disease modeling to drug discovery.

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.

All subjects will be assigned a coded number and identifying information and records will be kept in locked files.

The NIGMS Repository has measures in place to protect the privacy of donors. The measures in place to protect privacy include: 1. Storage of direct-to-patient recruited donor contact information in a secure, password-protected database kept separate from databases containing de-identified sample information shared with NIGMS Repository users. 2. Assignment of a code number to each sample. 3. Removal from submitted materials of the donor's name and any personal identifying information, if present. 4. Strict guidelines that forbid the NIGMS Repository from distributing personal identifying information to recipients of samples. 5. A Certificate of Confidentiality which protects the NIGMS Repository from being forced to disclose information that may identify donors, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative or other proceedings.

This research begins on 12/31/2014, and is expected to end on 12/31/2019.

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 12/31/2019. 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:

7/23/2015



Jon Lorsch, Ph.D.
Director, National Institute of General Medical Sciences