

USIDNET DNA and Cell Repository

Assurance Form

The mission of this USIDNET DNA and Cell Repository is to develop a sample resource that can be shared by the research community, while protecting the rights of subjects, in order to expedite discoveries into the causes and treatments of Primary Immunodeficiency.

There is no restriction on development of commercial products resulting from the knowledge gained from studies using Repository cell lines or DNA samples. However, use of the cell lines and DNA samples, and products derived from them, are subject to the prohibitions and restrictions below, to which the undersigned agree.

The undersigned agree that:

RESTRICTIONS ON REDISTRIBUTION AND USE AND PROHIBITIONS ON RESALE

- Cell cultures and DNA samples obtained from the USIDNET Repository may not be employed as human therapeutics.
- Repository materials may not be sold to third parties.
- Repository materials may be used as standards or controls by the original recipient laboratory, including fee-for-service diagnostic laboratories and quality control or quality assurance programs. Recipients of cell cultures or DNA samples for this use are responsible for complying with all laws and regulations applicable to the intended use of the materials including any requirements for FDA approval.
- Secondary distribution and shared use of cell cultures and DNA samples or the distribution of products derived from cell cultures or DNA samples obtained from the USIDNET Repository, with or without charge, is prohibited. Recipients of materials from the Repository agree not to provide these materials to other laboratories outside the direct control of the principal investigator to whom the samples are shipped. The fees charged for samples obtained from the Repository are modest specifically to encourage each potential user to obtain their own samples.

USE AND WARRANTY

The requesting investigator and the legally binding, authorized institutional official at the investigator's institution must sign an Assurance agreeing to adhere to the conditions for use stipulated by Coriell.

The investigator who receives the cell lines or DNA samples acknowledges that the conditions for use of the research materials (cell cultures and DNA samples) are governed by Coriell. The recipient agrees to comply fully with all such conditions. The recipient remains subject to applicable state and local laws or regulations and institutional policies.

Cell cultures and DNA samples are provided as a service to the research community. They are provided without warranty of merchantability or fitness for a particular purpose and without any other warranty, expressed or implied.

For State Institutions: The recipient institution agrees to be responsible for any claims, costs, damages, or expenses resulting from any injury (including death), damage, or loss that may arise solely from the use of the cell culture or DNA sample to the extent permitted under the laws of this state. This provision shall also apply to any byproducts or derivative of the cell cultures or DNA samples.

For U.S. Government Laboratories: The United States assumes the liability for any claims, damages, injury, or expenses arising from the use of material or any byproduct or derivative, but only to the extent provided under the Federal Tort Claims Act (28 U.S.C. Chapter 171).

For All Other Institutions: The recipient institution agrees to indemnify and hold harmless the United States Government, Coriell Institute for Medical Research, and the contributor from any claims, costs, damages, or expenses resulting from any injury (including death), damage, or loss that may arise from the use of the cell culture or DNA sample. This provision shall also apply to any byproducts or derivatives of the cell culture or DNA sample.

BIOHAZARD

All cultured human cells have the potential for carrying viruses, latent viral genomes, and other infectious agents in an unapparent state. The cell cultures shipped by the Repository should therefore not be treated as if they are free of contamination. These cells should always be handled carefully by trained persons under laboratory conditions that afford adequate biohazard containment following MINIMUM SAFETY GUIDELINES RECOMMENDED FOR WORKING WITH HUMAN CELL CULTURES.

By accepting these cells, the undersigned assume full responsibility for their safe and appropriate handling.

ASSURANCE

We, the undersigned, have read and understand this document and agree to adhere to the restrictions and warnings stated therein.

Name of Institution: _____

Principal Investigator (typed or printed): _____

Title: _____

Signature of Principal Investigator: _____

Institutional Official who can make legal commitments on behalf of the Institution

(typed or printed): _____

Title: _____

Signature of Institutional Official: _____

Date: _____