

ORPHAN DISEASE CENTER BIOREPOSITORY

Material Transfer Agreement (Assurance Form) for Human Induced Pluripotent Stem Cells

This Material Transfer Agreement (“MTA”) pertains to the samples (“ODC BioRepository Sample(s)”) that are part of the University of Pennsylvania Orphan Disease Center BioRepository (“Repository”), and which are administered by the Coriell Institute for Medical Research, Camden, New Jersey (“Coriell”). The Institutional Official is the legal representative (“Institutional Official”) of the Institution (“Institution”) receiving the ODC BioRepository Samples.

The Principal Investigator is the person receiving the ODC BioRepository Sample(s). The Principal Investigator’s research team that is under the direct supervision of the Principal Investigator may have access to the ODC BioRepository Sample(s) only after they have been informed of and agreed to the provisions of this MTA.

The Principal Investigator must acknowledge on the signature page of this MTA that he/she has read and understands the terms and conditions of this MTA. The Principal Investigator’s Institutional Official must also sign this MTA agreeing to adhere to the terms and conditions of this MTA. The Institutional Official acknowledges that the conditions for use of the ODC BioRepository Sample(s) are governed by the University of Pennsylvania Institutional Review Board (“UPenn IRB”) in accordance with DHHS regulations (45 CFR Part 46). The Institution agrees to comply fully with all such conditions as further outlined in this MTA. The Institution remains subject to all applicable state and local laws or regulations and Institution policies that provide additional protections for human subjects.

Coriell will under no circumstances provide information that will allow investigators to identify human subjects. Furthermore, the Institution and the Principal Investigator agree not to try to identify or contact the submitter of the sample or the donor subject from whom the cell line was derived.

WARRANTY AND LIABILITY

Warranty: THE REPOSITORY AND CORIELL MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE ODC BIOREPOSITORY SAMPLE(S) WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

Liability Statement for State Institutions: The Institution agrees to be responsible for any claims, costs, damages, or expenses that may arise from their use of the ODC BioRepository Sample(s) to the extent permitted under the laws of the Institution’s state. This provision shall also apply to any byproducts or derivatives of the ODC BioRepository Sample(s).

Liability Statement for U.S. Government Laboratories: The United States assumes the liability for any claims, damages, injuries, or expenses arising from their use of ODC BioRepository Sample(s) or any byproduct or derivative, but only to the extent provided under the Federal Tort Claims Act (28 U.S.C. Chapter 171).

Liability Statement for All Other Institutions: The Institution agrees to indemnify and hold harmless Repository, Coriell, and the submitter of the sample from any claims, costs, damages, or expenses that may arise from the use of the ODC BioRepository Sample(s). This provision shall also apply to any byproducts or derivatives of the ODC BioRepository Sample(s).

HUMAN EXPERIMENTATION

Human experimentation utilizing the ODC BioRepository Sample(s) is strictly prohibited.

RESEARCH USE, COMMERCIAL USE, AND RESTRICTIONS ON REDISTRIBUTION AND PROHIBITIONS ON RESALE

The Repository provides biomaterials as a service to the research community. The purpose of the Repository is to stimulate and facilitate research in genetics and related fields, leading to a better understanding of normal genetic and cellular processes, to the identification and function of disease-related genes, and to the diagnosis and treatment of genetic disorders.

It is expressly understood that the ODC BioRepository Sample(s) delivered pursuant to this MTA are experimental in nature and are for use in research, in teaching, and as reference materials in clinical genetics laboratories. Institutions using ODC BioRepository Sample(s) for use as reference materials or controls are responsible for complying with all laws and regulations applicable to the intended use of the ODC BioRepository Sample(s), including any requirements for FDA approval.

The Repository number(s) of the cell line(s) must be cited as follows in publications or presentations that are based on the use of these materials: "The following cell lines were obtained from the Orphan Disease Center BioRepository at the Coriell Institute for Medical Research: [list Repository ID numbers here]."

There is no restriction on development of commercial products resulting from the knowledge gained from studies using the ODC BioRepository Sample(s). However, ODC BioRepository Samples, or material isolated from them, such as RNA, DNA, or protein, may not themselves be used in the manufacture of commercial products.

SHARED USE AND POSTING OF PERSONALLY IDENTIFYING GENETIC INFORMATION DERIVED USING ODC BIOREPOSITORY SAMPLES

ODC BioRepository samples, or material isolated from them, such as RNA, DNA, or protein, have the potential to generate data that could be used to identify an individual (e.g.: Combined DNA Index System (CODIS) reports, whole-genome microarray genotyping data, whole-exome or whole-genome DNA sequencing data). Investigators are strictly prohibited from posting or making available through open-access public websites and/or databases genetic data that might identify an individual. Investigators, however, are encouraged to submit such datasets to the Database of Genotypes and Phenotypes ([dbGaP](#)), which requires users of the data to abide by a [Code of Conduct](#).

SECONDARY DISTRIBUTION AND SHARED USE OF CELL CULTURES AND DNA SAMPLES FROM THE ORPHAN DISEASE CENTER BIOREPOSITORY

Genetic research often involves collaborations among several investigators or several laboratories that share materials toward a common goal. Also, as a result of new genomic technologies, data are often generated by multi-user core facilities. Many laboratories benefit from using common biological reference materials for research or clinical purposes. Thus, consistent with the mission to facilitate genetic research, the Repository will permit secondary distribution to accommodate certain situations, subject to the provisions below and in accordance with all applicable rules and regulations regarding protection of human subjects and quality control of the samples. Secondary distribution, defined as the sharing of ODC BioRepository Sample(s) from the Repository **with members of laboratories other than the Principal Investigator's**, is permitted only under the clearly defined circumstances and provisions specified below.

Principal investigators who might wish to share ODC BioRepository Sample(s) with other investigators should read the information below very carefully.

Permitted Uses:

1. **Single purpose collaboration:** Two or more investigators initiate a collaborative project that requires the use by each laboratory of the same ODC BioRepository Sample(s). Each collaborating investigator and his or her Institutional Official must sign and submit a copy of this MTA.
2. **Multi-user core facility:** A core facility (for high-throughput genotyping, for example) purchases ODC BioRepository Sample(s) for use by the investigators within the facility to perform assays for investigators at his or her Institution or at a consortium of institutions. In this situation, the use of these ODC BioRepository Sample(s) in the core facility may be permitted only if the use of these samples is consistent with the research subject's informed consent. Since the ODC BioRepository Sample(s) will be used in the same facility by multiple investigators, quality can be ensured.

BIOHAZARD

All cultured animal and human cells have the potential for carrying viruses, latent viral genomes, and other infectious agents in a latent or inactive state. ODC BioRepository Samples shipped by the Repository should therefore not be treated as if they are free of contamination. These ODC BioRepository Samples should always be handled carefully by trained persons under laboratory conditions which afford adequate biohazard containment following minimum safety guidelines recommended for working with human cell cultures. By accepting ODC BioRepository Sample(s), the undersigned assume full responsibility for their safe and appropriate handling and release Repository, Coriell and the submitter of the sample from any liability.

Signature page to follow

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

Name of Institution

Name of Institutional Official who can make legal commitments on behalf of the Institution
(typed or printed)

Title of Institutional Official

Signature of Institutional Official

Date

Read and Understood the terms and conditions of this Agreement:

Name of Principal Investigator (typed or printed)

Signature of Principal Investigator

Date

To contact the CORIELL CELL REPOSITORIES:

Write: 403 Haddon Avenue, Camden, New Jersey 08103 USA

Call: 800-752-3805 in the United States; 856-757-4848 from other countries

Fax: 856-757-9737

E-mail: ccr@coriell.org