NIGMS HUMAN GENETIC CELL REPOSITORY

Material Transfer Agreement (Assurance Form) for Human Cell Lines, Somatic Cell Hybrids, and DNA Samples

This Material Transfer Agreement ("MTA") pertains to the samples ("NIGMS Repository Sample(s)") that are part of the NIGMS Human Genetic Cell Repository ("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 NIGMS Repository Samples.

The Principal Investigator is the person receiving the NIGMS Repository Sample(s) and is responsible for the conduct of the Statement of Research Intent, defined below. The Principal Investigator's research team that is under the direct supervision of the Principal Investigator may have access to the NIGMS Repository Sample(s) only after they have been informed of and agreed to the provisions of this MTA.

To ensure compliance with the Office for Human Research Protections, Department of Health and Human Services ("DHHS") regulations for the protection of human subjects (45 CFR Part 46), before NIGMS Repository Sample(s) can be shipped from the Repository by Coriell, the Principal Investigator must provide to Coriell a written description of the purpose of the research to be done using the NIGMS Repository Sample(s) ("Statement of Research Intent"). The Statement of Research Intent and the signed MTA must be submitted to Coriell.

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 NIGMS Repository Sample(s) are governed by the Coriell Institutional Review Board ("Coriell IRB") in accordance with DHHS regulations (45 CFR Part 46). The Institution agrees to comply fully with all such conditions and to report promptly to the Coriell IRB any proposed changes in the Statement of Research Intent. 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 or DNA sample was derived. The Institution and the Principal Investigator agree not to name the population from whom the samples were obtained, if this information is not essential. (See Policy for the Responsible Collection, Storage, and Research Use of Samples from Named Populations for the NIGMS Human Genetic Cell Repository.)

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 MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

IN ADDITION TO THE TERMS CONTAINED IN THIS MTA, USE OF SOME OF THE NIGMS REPOSITORY SAMPLE(S) MAY BE SUBJECT TO CERTAIN RESTRICTIONS AND/OR LICENSE REQUIREMENTS. RESTRICTIONS AND/OR LICENSE REQUIREMENTS OF WHICH THE REPOSITORY IS AWARE HAVE BEEN NOTED IN THE REPOSITORY'S ONLINE CATALOG ON THE SAMPLE DETAIL PAGE IN THE "REMARKS" FIELD UNDER THE "OVERVIEW" TAB. LICENSE REQUIREMENTS RELEVANT TO NIGMS REPOSITORY SAMPLES MAY BE FOUND IN THE LIMITED USE LICENSES AVAILABLE HERE AND ARE INCORPORATED IN FULL INTO THIS AGREEMENT. THERE MAY EXIST ADDITIONAL RESTRICTIONS OR PROPRIETARY RIGHTS OF WHICH THE REPOSITORY IS UNAWARE; THE INSTITUTION IS RESPONSIBLE FOR COMPLIANCE WITH ALL CONDITIONS OF USE OF THE NIGMS REPOSITORY SAMPLE(S).

Liability Statement for State Institutions: The Institution agrees to be responsible for any claims, costs, damages, or expenses resulting from any injury (including death), damage, or loss that may arise from the use of the NIGMS Repository 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 NIGMS Repository Sample(s).

Liability Statement for U.S. Government Laboratories: The United States assumes the liability for any claims, damages, injuries, or expenses arising from the use of NIGMS Repository 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 the United States Government, Coriell, and the submitter of the sample from any claims, costs, damages, or expenses resulting from any injury (including death), damage, or loss that may arise from the use of the NIGMS Repository Sample(s). This provision shall also apply to any byproducts or derivatives of the NIGMS Repository Sample(s).

HUMAN EXPERIMENTATION

Human experimentation utilizing the NIGMS Repository 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 NIGMS Repository 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 NIGMS Repository 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 NIGMS Repository Sample(s), including any requirements for FDA approval.

The Repository number(s) of the cell line(s) or the DNA sample(s) must be cited as follows in publications or presentations that are based on the use of these materials: "The following cell lines/DNA samples were obtained from the NIGMS Human Genetic Cell Repository 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 NIGMS Repository Sample(s). However, with the exception of the NIGMS Repository Samples listed here, NIGMS Repository 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 NIGMS HUMAN GENETIC CELL REPOSITORY SAMPLES

NIGMS Repository 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. For a limited subset of NIGMS Repository samples for which the donor-subject provided explicit informed consent for public data posting, open-access public posting of potentially individually identifying data is permitted (click here for a list of these samples).

Prior to posting or sharing with a collaborator personally identifying genetic information derived using NIGMS Repository biospecimens, the Principal Investigator must request permission to do so from the NIGMS Repository by submitting a completed, signed Statement of Research Intent

Form describing the proposed data posting and/or sharing. The collaborator must also submit to the NIGMS Repository a completed and signed Statement of Research Intent Form.

SECONDARY DISTRIBUTION AND SHARED USE OF CELL CULTURES AND DNA SAMPLES FROM THE NIGMS HUMAN GENETIC CELL REPOSITORY

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 if it can be established that protection of human subjects and quality control of the samples can be ensured. Secondary distribution, defined as the sharing of NIGMS Repository Sample(s) from the Repository **with members of laboratories other than the Principal Investigator's**, is permitted only under certain clearly defined circumstances.

Principal investigators who might wish to share NIGMS Repository Sample(s) with other investigators should read the information below very carefully and must contact Coriell before proceeding with a secondary distribution.

Permitted Uses:

1. **Single purpose collaboration:** Two or more investigators initiate a collaborative project that requires the use by each laboratory of the same NIGMS Repository Sample(s). One Principal Investigator obtains NIGMS Repository Sample(s) and explains in the Statement of Research Intent that the sample will be shared with specific, named collaborator(s) for a common research project. Secondary distribution to named collaborator(s) is permitted when the Statement of Research Intent is identical for all the named collaborator(s) and is consistent with this MTA. 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 NIGMS Repository 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. The Statement of Research Intent describes the range of studies that will be conducted using the NIGMS Repository Sample(s). In this situation, the use of these NIGMS Repository Sample(s) in the core facility may be permitted after the Coriell IRB assures that the use of these samples is consistent with the research subject's informed consent. Since the NIGMS Repository Sample(s) will be used in the same facility by multiple investigators, quality can be ensured.

3. **Distribution of aliquots of samples for use as reference materials:** An Institution purchases a sample and describes in the Statement of Research Intent that the NIGMS Repository Sample(s) will be distributed for use as a reference material (for proficiency

testing, for example). The Statement of Research Intent may not be able to specify the laboratories that will receive the materials. Prior approval by the Coriell IRB for this use of the NIGMS Repository Sample(s) is required. The Coriell IRB will decide this type of request on a case-by-case basis with the advice of the NIGMS Repository's Project Officer. The NIGMS Repository Sample(s) that are distributed must be accompanied by a disclaimer of the Repository's responsibility regarding safety and quality. Furthermore, residual NIGMS Repository Sample(s) must be returned to the Principal Investigator or destroyed.

4. **Development of a Highly Unique Resource**: An Institution purchases a cell line from the Repository and develops it into a Highly Unique Resource that requires significant modification or specialized expertise to grow, characterize, and maintain (such as an induced pluripotent stem cell line). A Highly Unique Resource is substantially different from the original NIGMS Repository Sample obtained from the Repository. Simply modifying an NIGMS Repository Sample obtained from the Repository through the introduction of a gene (*e.g.*, hTERT or green fluorescent protein) would not qualify as creating a Highly Unique Resource. The Principal Investigator may distribute aliquots of the Highly Unique Resource material by using an appropriate agreement between the Principal Investigator and/or the Principal Investigator's Institution and the secondary institution receiving the Highly Unique Resource ("Secondary Recipient"). Often a material transfer agreement is used for transfers of research materials for this purpose. The agreement to transfer the Highly Unique Resource to a Secondary Recipient must include: (1) a statement naming the NIGMS Human Genetic Cell Repository and the Repository ID number of the cell line from which the Highly Unique Resource was derived; (2) a statement that the Secondary Recipient must acknowledge the Repository and the cell line number(s) in any publications or presentations based on the utilization of the NIGMS Repository Sample(s) as follows: "[Name of Highly Unique Resource] was derived from cell line [list NIGMS Repository ID number] from the NIGMS Human Genetic Cell Repository at the Coriell Institute for Medical Research"; and (3) a statement that the Highly Unique Resource obtained from different sources will not have undergone the standard quality control of the Repository.

   The terms of the agreement between the investigator who developed the Highly Unique Resource and the Secondary Recipient who obtains the Highly Unique Resource for research purposes must be consistent with NIH's Simple Letter of Agreement for the Transfer of Materials or the Uniform Biological Material Transfer Agreement. Both of these documents can be found at: http://www.ott.nih.gov/forms-model-agreements#MTACTA.

   An Institution that purchases the NIGMS Repository Sample(s) is encouraged to make available aliquots of the Highly Unique Resource derived from the NIGMS Repository Sample and appropriate protocols and training to the NIGMS Repository for the NIGMS Repository to expand, characterize and distribute the unique resource through the NIGMS Repository, should the NIGMS Repository wish to do so.

Prohibited Uses:

1. **Multi-purpose use** - An investigator working on a particular project submits a Statement of Research Intent describing that project and obtains NIGMS Repository Sample(s). At some time after obtaining the NIGMS Repository Sample(s), the Principal Investigator wishes to give a portion of the NIGMS Repository Sample(s) or a culture derived from the NIGMS Repository Sample(s) to an investigator who is working on another project. In this case, secondary distribution is prohibited because the use of the NIGMS Repository Sample(s) by the second investigator may not be consistent with this MTA and the Statement of Research Intent. In addition, errors in cell culture technique and identification of cultures or DNA samples can occur and could compromise the Repository's reputation.

2. **The Secondary Distribution or sale of NIGMS Repository Sample(s) for any purpose not specified above is prohibited.**

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. NIGMS Repository Samples shipped by the Repository should therefore not be treated as if they are free of contamination. These NIGMS Repository Sample(s) 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 NIGMS Repository Sample(s), the undersigned assume full responsibility for their safe and appropriate handling.

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**