

NINDS Human Genetics Repository Material Transfer Agreement for Biospecimens

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MISSION

The mission of the **NINDS Human Genetics Repository (NINDS Repository)** is to provide, develop, and manage research resources in order to advance discoveries into the causes and treatments of neurological diseases while concurrently protecting the rights of subjects providing human material resources.

PURCHASE PROCESS

This **Material Transfer Agreement (MTA)** must be submitted by each investigator requesting **cell lines, DNA samples or other biological material along with any correlating data (NINDS Materials)** from the NINDS Repository. Both the **recipient principal investigator (Principal Investigator)** and the institutional official who is authorized to make *legally binding* agreements for the **institution that employs the Principal Investigator (Institution)** must sign this MTA.

In addition to this MTA, the Principal Investigator must complete a **Statement of Research Intent (SRI)** (electronically for on-line orders or in hard copy for special requests for secondary distribution) describing the purpose of the research to be done using the NINDS Materials.

All fully executed MTAs will be kept on file at the NINDS Repository and considered applicable to subsequent purchases made by the Principal Investigator if at the same institution named in the originally signed MTA. If the NINDS Repository substantially revises this form in the future, the NINDS Repository reserves the right to require the Principal Investigator to execute the latest version of the MTA. A new SRI describing the intended research is required for all purchases.

HUMAN SUBJECTS ISSUES

Principal Investigator and Institution acknowledge that the conditions for use of the NINDS Materials are governed by the **Coriell Institute for Medical Research Institutional Review Board (IRB)** and must be in compliance with the Office of Human Research Protections (OHRP), Department of Health and Human Services (DHHS), regulations for the protection of human subjects found at 45 CFR Part 46. Under these regulations, research activities involving publicly available, existing specimens and data or research with existing specimens and data from which human subjects cannot be identified, either directly or through linked identifiers, may be exempt from the DHHS policy for protection of human research subjects. (45 CFR §46.101(b)(4)). Recipient Principal Investigator and Institution remains subject to all state and local laws or regulations and institutional policies which may provide additional protections for human subjects.

When applicable to research described in the SRI, Principal Investigator should adhere to ethical standards established by the International Society for Stem Cell Research (ISSCR).

NINDS Repository will under no circumstances provide information that will allow identification of individual subjects. Further, the Principal Investigator agrees not to try to identify or contact the submitter of the NINDS Materials or the donor subject from whom the sample was derived.

HUMAN EXPERIMENTATION

Principal Investigator and Institution agree that human experimentation utilizing the NINDS Materials or their derivatives is strictly prohibited.

DETERMINATION OF OWNERSHIP

NINDS Repository retains ownership of the NINDS Materials and any functional subunits thereof contained or incorporated in derivatives. Inventions and ownership of intellectual property resulting from the research will be determined by U.S. patent law.

COMMERCIAL USE

There is no restriction on development of commercial products resulting from the knowledge gained from research using the NINDS Materials. NINDS Materials may be used for internal research purposes by commercial entities. NINDS Materials or material isolated from them, such as RNA, DNA, or protein, may not themselves be used in the manufacture of commercial products or sold or distributed as commercial products themselves. The NINDS Repository disclaims any knowledge relating to third-party property interest in the NINDS Materials.

RESEARCH USE

Principal Investigator and Institution understand that the NINDS Materials provided under this MTA are experimental and are for use in research, in teaching and as standards in clinical genetics laboratories. Principal Investigators using NINDS Materials as research standards or controls are responsible for complying with all applicable laws and regulations specific to that intended use, including any requirements for FDA approval.

SHARED USE AND SECONDARY DISTRIBUTION

Secondary distribution, or the sharing of NINDS Materials with members of laboratories other than the Recipient Principal Investigator's, is not permitted except under certain clearly defined circumstances as described below and only with prior written authorization from the NINDS Repository. Principal Investigator should read the restrictions under this section very carefully and contact the NINDS Repository Principal Investigator before distributing NINDS Materials or their derivatives.

NINDS established an NINDS Repository Group consisting of program directors and staff with relevant scientific knowledge to review and authorize secondary distribution requests for NINDS Materials. Consistent with its mission to facilitate genetic research, the NINDS Repository and NINDS Repository Group will permit secondary distribution if such requests are supported under the mission of the NINDS Repository, if it can be established that protection of human subjects is ensured as necessary, if quality control of the NINDS Materials is ensured, and if an appropriate process for secondary distribution (as outlined in this MTA) is followed.

Permitted Uses:

1. *Single-use, multi-investigator collaboration.* Two or more investigators initiate a collaborative project that requires the use by each laboratory of identical NINDS Materials. At the time the order is placed, Principal Investigator explains in the SRI that the NINDS Materials will be shared with specific, named collaborator(s) for a common research project. Secondary distribution to named collaborator(s) may be permitted when the SRI is identical for all the named collaborator(s). Each collaborating investigator must have a current, executed MTA on file with NINDS Repository.
2. *Multi-user core facility.* A core facility (for high-throughput genotyping, for example) obtains NINDS Materials for use by investigators within the facility to perform assays for use at that facility or for a consortium. The SRI should describe the ranges of studies that will be conducted using the NINDS Materials. In this situation, use of these materials in the core facility may be permitted if the NINDS

Repository Review Group is assured that the use of the NINDS Materials is consistent with the research subject's informed consent. Since the NINDS Materials will be used in the same facility for multiple investigators, quality can be ensured.

3. *Distribution of samples for use as reference materials.* Principal Investigator may place an order for one or more NINDS Materials and describes in the SRI that the NINDS Materials will be distributed, either with or without modification, for use as a reference material. The SRI may not be able to specify which laboratories will receive NINDS Materials. The NINDS Repository Review Group will decide this type of request on a case-by-case basis with the advice of the NINDS Repository's Project Officer. Principal Investigator will be required to maintain records of where the NINDS Materials are sent. NINDS Materials must be distributed under a written agreement which includes: (i) a disclaimer of the NINDS Repository's responsibility regarding safety and quality; (ii) a requirement that the NINDS Materials be returned to the Principal Investigator or destroyed within a certain time frame or at the conclusion of the research; (iii) a restriction that the NINDS Materials or their derivatives are never transferred to a third party; and (iv) a notification that the NINDS Repository was the source of the materials.

4. *Development of a Unique Resource.* This permitted use involves the development of NINDS Materials into **substances comprising or containing an unmodified subunit of NINDS Materials (Unique Resource)**. Consistent with the NIH Research Tools Policy (64 FR 72,090), a Unique Resource encompasses a range of research tools, including but not limited to: subclones of unmodified cell lines, purified or fractionated subsets of the NINDS Materials, proteins expressed by DNA/RNA supplied by Principal Investigator, induced pluripotent cell lines, and monoclonal antibodies secreted by a hybridoma cell line. A Unique Resource is substantially different from the NINDS Materials. Simply modifying NINDS Materials through the introduction of a marker gene (*e.g.*, hTERT or green fluorescent protein) would not qualify as a Unique Resource. The Principal Investigator may distribute the Unique Resource by using an appropriate agreement between the Institution and the **entity receiving the Unique Resource (Secondary Recipient)**. The transfer agreement for the Unique Resource must include:
 - (i) a statement listing the identification number(s) of the NINDS Materials from which the Unique Resource was derived;
 - (ii) a statement that the Secondary Recipient must acknowledge the NINDS Repository and the NINDS Materials identification number in any publications or presentations based on the utilization of the Unique Resource;
 - (iii) a statement prohibiting the use of the unmodified Unique Resource for human experimentation or commercialization;
 - (iv) a disclaimer that the Unique Resource has not undergone the standard quality control of the NINDS Repository; and
 - (v) a statement that the Unique Resource may not be used for commercial purposes except for internal research purposes.

In addition to the above statements (i) – (v), the transfer agreement for the Unique Resource must be consistent with NIH's Simple Letter Agreement for the Transfer of Materials or the UBMTA (Uniform Biological Material Transfer Agreement). Both of these agreements are found under the MTA section at: http://www.ott.nih.gov/forms_model_agreements/forms_model_agreements.aspx.

Institution is encouraged to provide the NINDS Repository with the Unique Resource and protocols for its care, if appropriate.

Prohibited Uses:

1. *Multi-purpose use.* At some point after obtaining the NINDS Materials, Principal Investigator wishes to give a portion of the NINDS Materials or a culture derived from the NINDS Materials to another investigator who is working on a different project. In this case, secondary distribution of the NINDS Materials is prohibited because use of the NINDS Materials by the other investigator may not be consistent with the terms of this MTA and the Principal Investigator's SRI.
2. **The secondary distribution or sale of NINDS Materials for any purpose not specifically authorized above is PROHIBITED unless otherwise noted by NINDS Program staff.** If NINDS Materials are requested from Principal Investigator, he/she should direct the requester to the NINDS Repository.

DESTRUCTION AND FINAL REPORT

Principal Investigator must destroy the NINDS Materials within five (5) years of receipt of the NINDS Materials or upon completion of research described under the SRI, whichever is shorter. Within six (6) months after destruction of the NINDS Materials, Principal Investigator must email ninds@coriell.org a final report including: (i) a brief summary of the research results or outcome of the project; (ii) a list of related publications or presentations; and (iii) a statement attesting destruction of the NINDS Materials. Principal Investigator should include his/her current contact information in the final report should follow up be required.

PUBLICATION

Principal Investigator must acknowledge the NINDS Repository and the NINDS Materials identification number in any publications or presentations based on research utilizing the NINDS Materials.

BIOHAZARD

All cultured animal and human cells as well as other human biological have the potential for carrying viruses, latent viral genomes, and other infectious agents in a latent or inactive state. NINDS Materials should therefore NOT be treated as if they are free of contamination. NINDS Materials 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 the NINDS Materials, the undersigned assumes full responsibility for their safe and appropriate handling. Principal Investigator agrees to provide notice to the NINDS Repository of any containment or quality issues related to the NINDS Materials.

WARRANTY AND LIABILITY

Warranty: THE NINDS REPOSITORY MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. IN ADDITION, 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.

Liability Statement for State Institutions Receiving NINDS Materials: 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 NINDS Materials to the extent permitted under the laws of the Institution's state. This provision shall also apply to any derivatives of the NINDS Materials.

Liability Statement for U.S. Government Laboratories Receiving NINDS Materials: The United States assumes the liability for any claims, damages, injuries, or expenses arising from the use of NINDS

Materials or derivatives, but only to the extent provided under the Federal Tort Claims Act (28 U.S.C. Chapter 171).

Liability Statement for All Other Institutions Receiving NINDS Materials: Institution agrees to hold harmless the United States Government, Coriell Institute for Medical Research and the contributor of the NINDS Materials from any claims, costs, damages, or expenses resulting from any injury (including death), damage, or loss that may arise from its use. This provision shall also apply to any derivatives of the NINDS Materials.

SIGNATURES

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

Name of Recipient Institution: _____

Name of Recipient Principal Investigator: _____

Signature of Recipient Principal Investigator: _____

Date: _____

Name of Institutional Official who can make legal commitments on behalf of the Institution: _____
[Please see the document regarding the Institutional Official]

Title of Institutional Official: _____

Signature of Institutional Official: _____

Date: _____

The signed MTA and the SRI may be submitted to the NINDS Repository by FAX, mail or email (pdf).

To contact the NINDS REPOSITORY AT 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: ninds@coriell.org