NINDS Human Genetics Repository
Material Transfer Agreement
For Biospecimens
Version Date: June, 2012

MISSION

The National Institute of Neurological Disorders and Stroke ("NINDS"), which manages via contract a genetic resource center for human gene discovery in neurological disorders (the "NINDS Repository"), and the Michael J. Fox Foundation for Parkinson's Research ("MJFF"), a non-profit tax exempt charitable organization, have entered into a collaborative agreement to advance PD research through the collection of human biospecimens and data for biomarkers discovery and validation.

As per the agreement, the NINDS Repository ("Provider") has received coded human samples including blood, serum and cerebrospinal fluid ("CSF") samples which are collected and owned by MJFF;

Whereas, the Provider has the right to disperse coded human samples, including blood, serum, CSF, and/or other MJFF collected biological material to qualified researchers through a mechanism supported by MJFF and NINDS;

Whereas, Recipient Principal Investigator (as defined in **Appendix A,** "Research Project"), contingent upon being found to be a qualified investigator as determined by a joint review conducted MJFF and NINDS, desires to obtain from the Provider, some or all of the following: coded blood, serum, CSF and/or other MJFF collected biological material;

Whereas, the Provider will distribute coded blood, serum, CSF, and/or other MJFF collected biological material to qualified investigators for the development of data; and

Whereas, MJFF as owners of the coded blood, serum, CSF, and/or other biological material samples, require the reporting of any results obtained from the coded blood, serum and CSF samples and any corresponding data set and a copy of any analysis done on the data set developed by the Recipient Principal Investigator using the coded blood, serum and CSF samples; and

Whereas, data derived from biomaterial studies conducted by the Recipient Principal Investigator and other scientists will be stripped of all personal identifiers and thus unable to be linked to the individuals from whom they were obtained;

Therefore, Recipient Principal Investigator (as defined in **Appendix A**) and the Provider enter into the following Material Transfer Agreement ("MTA") governing the transfer and use of such coded blood, serum, CSF, and other biological material as well as any resultant data.

In response to Recipient Principal Investigator's request for **Repository Material** (defined as the specific coded blood, serum, CSF, and other biological material requested by Recipient Principal Investigator, including the biological samples, their progeny, and/or unmodified derivatives thereof, but excluding, without limitation, any modified derivatives, discoveries, results, and inventions) as listed in **Appendix A**, the institution that employs the Recipient Principal Investigator ("Recipient Institution"), having the authority to enter into this MTA, hereby agrees to the following terms and conditions on behalf of the Recipient Principal Investigator.

MATERIALS REQUEST PROCESS

This **MTA** must be submitted by each investigator requesting **CSF, coded blood, serum and/or other MJFF collected and owned biological material** along with any correlating data from the NINDS Repository.

In addition to this MTA, the Recipient Principal Investigator must complete a **Statement of Research Intent (SRI)** describing the purpose of the research to be done using the Repository Materials.

The Provider and Recipient Institution agree that additional transfers of the Repository Materials from the Provider to Recipient Principal Investigator and any changes to the Research Project will be made using an ADDENDUM TO THE MATERIAL TRANSFER AGREEMENT. This Addendum document will be signed by a NINDS Repository representative and MJFF.

HUMAN SUBJECTS ISSUES

Recipient Principal Investigator and Recipient Institution acknowledge that the conditions for use of the Repository 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 Recipient 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, Recipient Principal Investigator should adhere to ethical standards established by the International Society for Stem Cell Research (ISSCR).

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

HUMAN EXPERIMENTATION

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

DETERMINATION OF OWNERSHIP

MJFF retains ownership of the Repository Materials described in this agreement 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 Repository Materials. Repository Materials may be used for internal research purposes by commercial entities. Repository 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 Repository Materials.

RESEARCH USE

Recipient Principal Investigator and Recipient Institution understand that the Repository Materials provided under this MTA are experimental and are for use in research, in teaching and as standards in clinical genetics laboratories. Recipient Principal Investigators using Repository 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 Repository 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 Provider and MJFF. Recipient Principal Investigator should read the restrictions under this section very carefully and contact the NINDS Repository Principal Investigator before distributing Repository 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 Repository 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 Repository 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 Repository Materials. At the time the order is placed, Recipient Principal Investigator explains in the SRI that the Repository 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 Repository 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 Repository 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 Repository Materials is consistent with the research subject's informed consent. Since the Repository Materials will be used in the same facility for multiple investigators, quality can be ensured.

3. *Distribution of samples for use as reference materials*. Recipient Principal Investigator may request additional Repository Materials and describe in the SRI that the Repository 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 Repository 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. Recipient Principal Investigator will be required to maintain records of where the Repository Materials are sent. Repository 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 Repository Materials be returned to the Recipient Principal Investigator or destroyed within a certain time frame or at the conclusion of the research; (iii) a restriction that the Repository 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 Repository Materials into **substances comprising or containing an unmodified subunit of Repository 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 Repository Materials, proteins expressed by DNA/RNA supplied by Recipient Principal Investigator, induced pluripotent cell lines, and monoclonal antibodies secreted by a hybridoma cell line. A Unique Resource is substantially different from the Repository Materials. Simply modifying Repository 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 Repository Materials from which the Unique Resource was derived;
ii. a statement that the Secondary Recipient must acknowledge the NINDS Repository and the Repository 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 Repository Materials, Recipient Principal Investigator wishes to give a portion of the Repository Materials or a culture derived from the Repository Materials to another investigator who is working on a different project. In this case, secondary distribution of the Repository Materials is prohibited because use of the Repository Materials by the other investigator may not be consistent with the terms of this MTA and the Recipients Principal Investigator's SRI and Research Project.

2. **The secondary distribution or sale of Repository Materials for any purpose not specifically authorized above is PROHIBITED unless otherwise noted by NINDS Program staff**. If Repository Materials are requested from Recipient Principal Investigator, he/she should direct the requester to the NINDS Repository.

DESTRUCTION AND FINAL REPORT

Recipient Principal Investigator must destroy the Repository Materials within five (5) years of receipt of the Repository Materials or upon completion of research described under the SRI and **Appendix A**, whichever is shorter. Within six (6) months after destruction of the Repository Materials, Recipient 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 Repository Materials. Recipient Principal Investigator should include his/her current contact information in the final report should follow up be required.

PUBLICATION

Recipient Principal Investigator must acknowledge MJFF, the NINDS Repository, and the Repository Materials identification number in any publications or presentations based on research utilizing the Repository Materials described in this MTA.

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. Repository Materials should therefore NOT be treated as if they are free of contamination. Repository 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 Repository Materials, the undersigned assumes full responsibility for their safe and appropriate handling. Recipient Principal Investigator agrees to provide notice to the NINDS Repository of any containment or quality issues related to the Repository Materials.

WARRANTY AND LIABILITY

Warranty: THE NINDS REPOSITORY AND MJFF MAKE 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 Repository 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 Repository Materials to the extent permitted under the laws of the Institution's state. This provision shall also apply to any derivatives of the Repository Materials.

Liability Statement for U.S. Government Laboratories Receiving Repository Materials: The United States assumes the liability for any claims, damages, injuries, or expenses arising from the use of Repository 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 Repository Materials: Institution agrees to hold harmless the United States Government, Coriell Institute for Medical Research, MJFF, and the contributor of the Repository 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 Repository 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 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**