The Michael J. Fox Foundation for Parkinson’s Research (MJFF)

MATERIAL TRANSFER AGREEMENT:
For requesting cell lines from the Parkinson’s Progressions Marker Initiative
Biorepositories established by The Michael J. Fox Foundation for Parkinson’s
Research

This Material Transfer Agreement (MTA) has been adopted for use by The Michael J. Fox
Foundation for Parkinson’s Research (MJFF) specifically for transferring fibroblasts and/or
induced pluripotent stem cells (iPSC) from the Parkinson’s Progression Markers Initiative
(PPMI) Biorepository at MJFF and ADB Biorepositories at Indiana University
(“RESEARCH MATERIAL”) to researchers at for-profit and non-profit institutions who
wish to conduct scientific research using such material in accordance with the guidelines set
forth by MJFF for PPMI. This Agreement is effective as of date of the last signature below
(“Effective Date”).

Definitions:
PROVIDER: Scientist and Scientist’s organization contributing material(s) to the PPMI
Biorepository.
REPOSITORY: Biorepositories at Indiana University, a research institution contracted
by MJFF to processes, store and ship biomaterials on behalf of MJFF.
RECIPIENT: Includes Scientist (“RECIPIENT SCIENTIST”), including anyone
working directly under her or his direction or indirectly in collaboration as outlined in
Research Proposal, and Scientist’s organization (“RECIPIENT INSTITUTION”)
requesting and receiving PPMI’s biomaterial(s).
RESEARCH MATERIAL: The human fibroblasts and/or induced pluripotent stem cells
transferred to RECIPIENT under this Agreement, as well as Progeny and modified or
unmodified derivatives thereof. Unmodified and modified derivatives may also be
referred to herein as “DERIVED MATERIALS.” RESEARCH MATERIALS are
detailed specifically below.
DERIVED MATERIAL: Substances created from or isolated from the RESEARCH
MATERIAL transferred to RECIPIENT from REPOSITORY which constitute modified
or unmodified functional subunits or products of the RESEARCH MATERIAL.
Examples of DERIVED MATERIAL include, but are not limited to: stem cells,
subclones of unmodified or modified cell lines, differentiated cells that are not
pluripotent, purified or fractionated subsets of the RESEARCH MATERIAL, any and all
genetically unmodified cells or cell lines or nucleic acids created from or isolated from
the RESEARCH MATERIAL
PROGENY: Unmodified descendant from the RESEARCH MATERIAL, such as cell
from cell
CELL LINE MANUFACTURER: The organization that generated the cell lines from
the original biological material as identified in Appendix A.
In response to the RECIPIENT’S request for the following RESEARCH MATERIAL: (describe with specificity)

(hereinafter referred to as RESEARCH MATERIAL), MJFF requires that the RECIPIENT INSTITUTION and the RECIPIENT SCIENTIST agree to the following before the RECIPIENT receives the RESEARCH MATERIAL.

This RESEARCH MATERIAL will be used by RECIPIENT SCIENTIST solely in connection with the research project ("RESEARCH PROJECT"), which is described with specificity in RECIPIENT’S approved Research Proposal (MJFF sample request ID: __________) submitted to the PPMI Biospecimen Review Committee (BRC). In no event shall the RESEARCH MATERIAL be used for any purpose other than neurodegenerative disease research.

1. The above RESEARCH MATERIAL is made available by MJFF through the REPOSITORY to the RECIPIENT as a service to the research community.

2. RECIPIENT agrees to and the RESEARCH MATERIALS received by RECIPIENT are subject to the additional terms and conditions of Appendix B attached hereto for RESEARCH MATERIAL manufactured by FUJIFILM Cellular Dynamics, Inc. and/or Appendix C for RESEARCH MATERIAL manufactured by New York Stem Cell Foundation attached hereto, whichever is the applicable CELL LINE MANUFACTURER of the RESEARCH MATERIALS received by RECIPIENT from REPOSITORY (the “Applicable Appendix”), which Applicable Appendix is hereby incorporated in and made a part of this Agreement.

IN THE EVENT OF ANY INCONSISTENCY OR CONFLICT BETWEEN ANY PROVISION IN ANY OTHER SECTION OF THIS AGREEMENT OR ANY GUIDELINE, POLICY, OTHER AGREEMENT OR DOCUMENT ENTERED INTO OR SUBMITTED BY RECIPIENT, OR OTHERWISE APPLICABLE, IN CONNECTION HEREWITH AND THE APPLICABLE APPENDIX, THE PROVISION THAT IS MORE RESTRICTIVE SHALL APPLY AND WILL BE GIVEN EFFECT IN LIEU OF THE OTHER PROVISION. IN THE EVENT OF ANY AMBIGUITY REGARDING WHETHER ANY PROVISION IN ANY OTHER SECTION OF THIS AGREEMENT OR ANY GUIDELINE, POLICY, OTHER AGREEMENT OR DOCUMENT ENTERED INTO OR SUBMITTED BY RECIPIENT, OR OTHERWISE APPLICABLE, IN CONNECTION HEREWITH OR ANY PROVISION IN THE APPLICABLE APPENDIX IS THE MORE RESTRICTIVE PROVISION, THE PROVISION IN THE APPLICABLE APPENDIX SHALL APPLY AND WILL BE GIVEN EFFECT IN LIEU OF THE OTHER PROVISION.
3. RECIPIENT SCIENTIST agrees to retain control over the RESEARCH MATERIAL and not to transfer the RESEARCH MATERIAL or any part thereof to any individuals other than employees of RECIPIENT INSTITUTION under her or his direct supervision who, in the case of RESEARCH MATERIALS for which Appendix B is the Applicable Appendix, have agreed to such Applicable Appendix. The RECIPIENT shall refer any request for use of the RESEARCH MATERIAL by anyone other than the RECIPIENT SCIENTIST to MJFF.

4. RECIPIENT agrees to use the RESEARCH MATERIAL in compliance with all applicable laws and the guidelines associated with the PPMI PBMC and Cell Line Use Agreement, detailed at http://www.ppmi-info.org/study-design/research-documents-and-sops/.

5. RECIPIENT will comply with any rules and regulations imposed by RECIPIENT’s institution and its Institutional Review Board (IRB) in requesting these RESEARCH MATERIALS.

6. Any RESEARCH MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. PROVIDER, MJFF AND REPOSITORY MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OR 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. Unless prohibited by law, RECIPIENT assumes all liability and will indemnify, defend, and hold PROVIDER, MJFF and REPOSITORY harmless, for claims for damages against it by third parties which may arise from the use, storage or disposal of the RESEARCH MATERIAL and PROVIDER, MJFF and REPOSITORY disclaim any liability or responsibility for such claims or damages.

7. RECIPIENT agrees to receive coded, de-identified RESEARCH MATERIALS and will not attempt to establish the identity of or contact any of the PPMI subjects. RECIPIENT shall guarantee that all possible measures are taken to ensure the protection of subject anonymity, privacy, and medical confidentiality.

8. Unless prohibited by law from doing so, RECIPIENT agrees to defend, hold harmless and indemnify MJFF and REPOSITORY for all liabilities, demands, damages, expenses and losses arising out of RECIPIENT'S use for any purpose of the RESEARCH MATERIAL.
9. RECIPIENT acknowledges that researchers who receive approval to access RESEARCH MATERIAL will be granted an exception to the standard PPMI Intellectual Property (IP) Policy that prohibits claiming of new IP generated through use of PPMI samples. Further:
   i. Any user of RESEARCH MATERIAL may generate and claim proprietary IP rights on research tools developed therefrom (“Inventor”).
   ii. IP on compounds developed and/or tested with any research tool created through or from RESEARCH MATERIAL in conformity with PPMI IP policies may remain with the Inventor.
   iii. RECIPIENT hereby grants to MJFF a non-exclusive sublicensable license in and to any IP and results generated through use of RESEARCH MATERIAL or DERIVED MATERIAL at no charge only for internal non-commercial scientific research, which sublicensable license includes the right of MJFF to designate one or more third party researchers, whether or not such researchers are employed by or affiliated with for-profit or non-profit entities, to receive and use such IP and results at no charge only for non-commercial scientific research. “Non-commercial scientific research” shall include preclinical research and clinical research up to and including a phase 3 clinical trial, even if such preclinical or clinical research involves investigation of a product that may be commercialized.
   iv. RECIPIENT shall promptly report results and any claim of IP rights to MJFF in writing and shall promptly provide materials and/or access necessary to effectuate the license set forth in subsection iii. upon request of MJFF but may delay providing such materials and/or access only upon reasonably asserting that exercise of the license will materially compromise Inventor’s ability to obtain IP protection from a government agency or first publish the IP rights; in such event, MJFF will limit or refrain from exercising such license so that filing for IP protection and/or first publication, whichever is applicable, is not materially compromised.
   v. Nothing herein shall be construed to allow the Inventor or any RECIPIENT to claim any IP rights on the RESEARCH MATERIAL or DERIVED MATERIAL.

10. RECIPIENT will comply with all provisions described in the PPMI Publication Policy, including the following:
   i. If RECIPIENT publishes abstracts on analyses of RESEARCH MATERIAL, RECIPIENT agrees to the following:
      1. RECIPIENT will cite PPMI as the source of the RESEARCH MATERIAL and the PPMI funding sources in the abstract as space allows.
2. Unless the abstract is identified as a Primary Publication (see PPMI Publication Policy), group authorship of PPMI will not be cited in the authorship line of the abstract.

3. RECIPIENT will upload abstracts onto the PPMI website for registered users to see either as they are accepted or after they are presented.

ii. If RECIPIENT publishes manuscripts using RESEARCH MATERIAL, RECIPIENT agrees to the following:

1. Unless manuscript is identified as a Primary Publication (see PPMI Publication Policy), group authorship of PPMI will not be cited in the authorship line of the manuscript.

2. RECIPIENT will include language similar to the following in the methods section of the manuscripts in order to accurately acknowledge data gathering by the PPMI personnel. Depending upon the length and focus of the article, it may be appropriate to include more or less than the example below, however, inclusion of some variation of the language shown below is mandatory:

"Samples used in the analyses presented in this article were obtained from the Golub Capital iPSC Parkinson’s Progression Markers Initiative (PPMI) Sub-study (www.ppmi-info.org/cell-lines). As such, the investigators within PPMI contributed to the design and implementation of PPMI and/or provided data and collected samples but did not participate in the analysis or writing of this report. For up-to-date information on the study, visit www.ppmi-info.org."

iii. RECIPIENT will acknowledge funding by PPMI in the support acknowledgement section of the manuscript using language similar to the following:

“PPMI – a public-private partnership – is funded by The Michael J. Fox Foundation for Parkinson’s Research and corporate sponsors, including [list all PPMI Industry Partners found at http://www.ppmi-info.org/about-ppmi/who-we-are/study-sponsors/].”

iv. RECIPIENT will submit all abstracts and manuscripts to the PPMI Data and Publications Committee (DPC) prior to submitting to a journal. This review will not be a scientific review, but is intended to ensure that all items in this Section 9 above are correctly implemented. The DPC will maintain confidentiality of the
manuscript and will complete its review within two weeks.

v. Researchers who publish or present analyses of RESEARCH MATERIALS will make these freely available without charge to the research community through the PPMI website, when not prohibited by journal copyright terms and conditions.

11. RECIPIENT will submit a report of completed analyses using RESEARCH MATERIAL to the PPMI Biospecimen Review Committee (BRC). RECIPIENT understands that the BRC reserves the right to deposit these analyses in the PPMI study database for use by the research community 45 days after the report of completed analyses is submitted. RECIPIENT agrees to respond to annual requests for updates on analyses using RESEARCH MATERIAL from MJFF or the BRC.

12. RECIPIENT will ensure that other Investigators who utilize RESEARCH MATERIAL use appropriate administrative, physical and technical safeguards to prevent use of the RESEARCH MATERIAL other than as provided for by this Agreement and outlined in the application protocol.

13. MJFF may terminate this Agreement if the RECIPIENT is in breach of any of the terms specified herein and if the deficit has not been remedied within thirty (30) days of written notice by MJFF of such breach. Upon termination under this clause, the RECIPIENT agrees to, at the direction of MJFF, destroy or otherwise dispose of all unused RESEARCH MATERIAL, including accompanying PROGENY and DERIVED MATERIALS, and RECIPIENT shall provide MJFF with written certification of their return or destruction, unless permission to retain RESEARCH MATERIAL is specifically provided in writing by MJFF to RECIPIENT INSTITUTION. Section 2 and provisions of the Applicable Appendix will survive the expiration or termination of the Agreement.
NAME OF RECIPIENT INSTITUTION:

__________________________________________________________________

RECIPIENT SCIENTIST
Name: _____________________________________________________________
Signature: _______________________________________  Date: _____________

RECIPIENT INSTITUTIONAL OFFICIAL
Name: _____________________________________________________________
Title: ______________________________________________________________
Signature: _______________________________________  Date: _____________
Mailing Address: ____________________________________________________

REPOSITORY CORE LEADER
Name: Tatiana Foroud, PhD
Title: Professor and Chair, Department of Medical & Molecular Genetics
Signature: _______________________________________  Date: _____________
Mailing Address: Indiana University School of Medicine
Department of Medical & Molecular Genetics
Hereditary Genomics Division
410 West 10th Street, HS 4000
Indianapolis, IN 46202-3002

SIGNATURES CONTINUE ON NEXT PAGE:

REPOSITORY INSTITUTIONAL OFFICIAL
Name: _____________________________________________________________
Title: ______________________________________________________________
Signature: _______________________________________  Date: _____________
Mailing Address: Indiana University
Office of Research Administration  
980 Indiana Avenue, Second Floor  
Indianapolis, IN 46202

THE MICHAEL J. FOX FOUNDATION FOR PARKINSON’S RESEARCH

Name: _____________________________________________________________
Title: ______________________________________________________________
Signature: _______________________________________ Date: _____________

Mailing Address: The Michael J. Fox Foundation for Parkinson’s Research  
Grand Central Station  
P.O. Box 4777  
New York, NY 10163-4777  
USA
Appendix A – Cell Line Manufacturer
of RESEARCH MATERIALS comprising human induced pluripotent stem cells or
RESEARCH MATERIALS derived therefrom

RECIPIENT will receive RESEARCH MATERIALS generated by:

- FUJIFILM Cellular Dynamics, Inc. ("FCDI") [see Appendix B]
- New York Stem Cell Foundation (NYSCF) [see Appendix C]
- Both FCDI and NYSCF [see Appendices B and C]
Appendix B – Additional Terms and Conditions for
PPMI Cell Lines that were made by FUJIFILM Cellular Dynamics, Inc. (“FCDI”)

As provided in Section 2 of the Material Transfer Agreement of which this Appendix B is a part, RECIPIENT SCIENTIST and RECIPIENT INSTITUTION agree to the following terms and conditions in connection with the receipt of iPSCs that were made by FCDI:

I. CERTAIN DEFINITIONS.

1. As used herein, RESEARCH MATERIAL comprised of the induced pluripotent stem cells made by FCDI for The Parkinson’s Progression Markers Initiative (PPMI) are referred to as “iPSCs.” iPSCs include:
   a. any such RESEARCH MATERIAL received by RECIPIENT from REPOSITORY;
   b. any additional iPSCs propagated from iPSCs; and
   c. any components of or any modifications made to the iPSCs;
   d. including subclones of unmodified or modified iPSCs, substances extracted or isolated from unmodified or modified iPSCs by RECIPIENT, Progeny, and Derived Material that is not a derivative as defined below.

2. As used herein, RESEARCH MATERIAL comprised of cell types differentiated, derived, developed or expanded from the iPSCs are referred to as “derivatives.” Derivatives include:
   a. cells that are derived from iPSCs or other derivatives and that are not pluripotent; and
   b. substances extracted or isolated from such cells described in the immediately preceding clause 2a by RECIPIENT.

3. As used herein and notwithstanding any term or implication elsewhere herein, to receive, possess and/or use RESEARCH MATERIAL, RECIPIENT must be an academic or not-for-profit entity and be engaging in solely internal research permitted in accordance herewith.

4. To obtain information regarding additional rights that may be licensed from FCDI, contact fcdi-licensing@fujifilm.com.

II. RESTRICTIONS; INTELLECTUAL PROPERTY.

1. The iPSCs and their derivatives must be used for internal research purposes only. Accordingly:
   a. RECIPIENT shall not sell or transfer the iPSCs and their derivatives except the transfer of iPSCs or derivatives pursuant to a single purpose collaboration in accordance with Section III below.
   b. iPSCs and their derivatives may not be used in the manufacture of any products.
   c. RECIPIENT shall not propagate more than 120,000,000 live iPSCs at any one time (approximately the number of iPSCs in 10 conventional culture plates) at any of RECIPIENT’s facilities.
d. The iPSCs and their derivatives may not be used in services for any third party.

e. The iPSCs and their derivatives may not be used for sponsored research of any kind where intellectual property rights or options to intellectual property rights may be granted to the commercial sponsor of such research. However, nothing herein shall prevent RECIPIENT from claiming intellectual property rights from research utilizing the iPSCs or their derivatives that are independent of the rights or intellectual property embodied in the iPSCs owned or licensed to FCDI.

2. The iPSCs may not be used directly or indirectly to derive or make any human gamete or gamete precursor cell.

3. The iPSCs may not be reversed engineered.

4. RECIPIENT may not use the iPSCs or their derivatives in humans, in clinical trials, for diagnostic purposes involving human subjects or for any therapeutic use.

5. RECIPIENT acknowledges and agrees that the receipt of the iPSCs by RECIPIENT shall not be construed as a transfer of any title or the grant of any rights in or to the intellectual property embodied in the iPSCs owned or licensed by FCDI. The iPSCs made by FCDI are covered by pending patents and/or one or more of the following patents: U.S. Patent Nos. 8,058,065, 8,048,999, 7,892,830, and corresponding foreign patent claims. The iPSCs are also covered by a number of patents and pending patents licensed to FCDI from iPS Academia Japan Inc. Neither FCDI nor its licensor, iPS Academia Japan, Inc. makes any warranty or representation as to the validity, scope, or enforceability of the patents owned by or licensed to FCDI.

6. RECIPIENT shall not use FCDI’s patented and/or proprietary methods for differentiation of the iPSCs, and no license to use such methods is conveyed herein.

III. SINGLE PURPOSE COLLABORATION.

1. A “single purpose collaboration” is a project in which:

   a. two or more RESEARCH SCIENTISTS at different laboratories each of whom is a collaborator named in RECIPIENT’S Research Proposal (a “named collaborator”);

   b. each such named collaborator requires the use of the same iPSCs or derivatives; and

   c. all such named collaborators are working together with the intent to jointly or mutually publish their findings resulting from use of the iPSCs or derivatives.

2. In a single purpose collaboration, transfer by one such named collaborator to another such named collaborator is permitted subject to the following:

   a. RECIPIENT’S Research Proposal must be identical for all the named collaborator(s) and must describe research use that is permitted by this Agreement.
b. Each named collaborator and his or her RECIPIENT INSTITUTION must have signed and submitted, as RESEARCH SCIENTIST and RECIPIENT INSTITUTION (i.e., collectively, as RECIPIENT), to REPOSITORY a copy of this Agreement.

c. If after submission of RECIPIENT’S Research Proposal, there would be any change in the named collaborators (i.e., the addition of any additional named collaborator(s) or the removal of any named collaborator(s)), then prior to making such change, an amendment to RECIPIENT’S Research Proposal for such single purpose collaboration must be submitted to REPOSITORY, naming the additional collaborator(s) or removed collaborator(s), as applicable. Each additional named collaborator and his or her RECIPIENT INSTITUTION must have signed and submitted, as RESEARCH SCIENTIST and RECIPIENT INSTITUTION (i.e., collectively, as RECIPIENT) must have signed and submitted to REPOSITORY a copy of this Agreement and RECIPIENT’S Research Proposal described in Section III.2.a.

IV. NO WARRANTIES; INDEMNIFICATION.

THE IPSCS ARE PROVIDED TO RECIPIENT “AS IS”. TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, FCDI DISCLAIMS ALL REPRESENTATIONS, AND WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE IPSCS, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENTS. To the fullest extent permitted under applicable law, RECIPIENT shall be solely responsible for RECIPIENT’S receipt, use, storage, transfer or disposal of the iPSCs and their derivatives. Unless prohibited by law from doing so, RECIPIENT agrees to defend, hold harmless and indemnify FCDI for all liabilities, claims, demands, damages, costs, expenses and losses (including reasonable attorneys’ fees) arising out of RECIPIENT’S use for any purpose of the RESEARCH MATERIAL; provided, however, that, in the case of any claim alleging infringement of any third party’s intellectual property rights relating to any method or process by which the iPSCs were derived or made, FCDI shall have the right to elect, upon notice to Recipient and subject to RECIPIENT’s foregoing indemnity and hold harmless obligation, to conduct the defense of such claim.

V. FURTHER LIABILITY LIMITATION.

TO THE FULLEST EXTENT PERMITTED UNDER APPLICABLE LAW, FCDI SHALL NOT HAVE ANY LIABILITY FOR INCIDENTAL, COMPENSATORY, PUNITIVE, CONSEQUENTIAL, INDIRECT, SPECIAL OR OTHER SIMILAR DAMAGES, HOWEVER CAUSED AND REGARDLESS OF FORM OF ACTION WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT PROTOTYPE LIABILITY OR OTHERWISE, EVEN IF FCDI HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.
VI. MISCELLANEOUS.

Each person signing this Agreement represents and warrants that he or she is duly authorized and has legal capacity to execute and deliver this Agreement. RECIPIENT INSTITUTION represents and warrants that the execution and delivery of the Agreement and the performance of RECIPIENT INSTITUTION's obligations hereunder have been duly authorized and that the Agreement is a valid and legal agreement binding on such party and enforceable in accordance with its terms. For avoidance of doubt, (1) RECIPIENT may not transfer any of RECIPIENT'S rights or obligations hereunder, whether by assignment, delegation, or otherwise and (2) FCDI hereby is expressly made a third party beneficiary hereof. Section 2 of the Material Transfer Agreement of which this Appendix B is a part and the provisions of this Appendix B will survive the expiration or termination of the Agreement. With respect to PPMI Cell Lines that were made by FUJIFILM Cellular Dynamics, Inc. ("FCDI"), the Material Transfer Agreement of which this Appendix B is a part sets forth the exclusive terms and conditions relating to the subject matter of the receipt, use, storage, transfer or disposal of any and all such RESEARCH MATERIALS as licensed by FCDI, and all prior negotiations, representations, agreements including PPMI PBMC and Cell Lines Use Agreement by RECIPIENT as relates to such RESEARCH MATERIALS, and understandings related to such subject matter are merged into, extinguished by, and completely expressed by this Agreement.
Appendix C – Additional Terms and Conditions for PPMI Cell Lines that were made by New York Stem Cell Foundation (NYSCF)

As provided in Section 2 of the Material Transfer Agreement of which this Appendix C is a part, RECIPIENT SCIENTIST and RECIPIENT INSTITUTION agree to the following terms and conditions in connection with the receipt of iPSCs that were made by NYSCF:

RECIPIENT acknowledges and agrees that any and all of the systems and methodologies related to the New York Stem Cell Foundation Global Stem Cell Array™, and any improvements thereto, are proprietary to New York Stem Cell Foundation.