MASTER MATERIAL TRANSFER AGREEMENT
FOR THE TRANSFER OF MATERIALS FROM NINDS BioSEND

This Master Material Transfer Agreement for the Transfer of Materials from NINDS BioSEND ("Master Agreement") is made and entered into by and between The Trustees of Indiana University having offices at Office of Research Administration, 509 E. 3rd St., Bloomington, IN 47401-3654, USA (hereinafter "IU") and the Recipient Institution identified on the signature page below ("Recipient Institution") in the interest of the Recipient Investigator identified on the signature page below ("Recipient Investigator"). This Agreement is effective as of date of the last signature below ("Effective Date").

WHEREAS, IU operates the NINDS BioSEND, a biorepository located within Indiana University and which was originally established through funding from the National Institute of Neurological Disorders and Stroke (NINDS) of the National Institutes of Health (NIH), an agency of the Public Health Service (PHS) and the U.S. Department of Health & Human Services (HHS), to help address the public health needs for continued research concerning Parkinson's disease (PD), Huntington's disease (HD), traumatic brain injury (TBI) and other neurological and neuropsychiatric diseases; and

WHEREAS, NINDS BioSEND receives biological material from humans and Associated Phenotypic Data (as defined below) submitted by public and private sector investigators; and

WHEREAS, IU desires to distribute this biological material and Associated Phenotypic Data to Recipient Institution solely for use under the direction and supervision of Recipient Investigator for research which may include determination of Genetic Data and/or isolation of Derived Materials (as defined below); and

WHEREAS, NINDS has designated certain sites for the deposit of all Genetic Data determined or identified by investigators using the NINDS BioSEND Research Material and such sites include, but are not limited to NINDS approved sites including, but not limited to, the **d**ata**b**ase of **G**enotype **a**nd **P**henotype (dbGaP) (developed through NIH to archive and distribute the results of studies that have performed Genome Wide Association Studies (GWAS) and Genomic Data] http://www.ncbi.nlm.nih.gov/sites/entrez?db=gap) and the Data Management Resource (DMR; http://pdbp.ninds.nih.gov/) using the NINDS BioSEND Research Materials; and

WHEREAS, Recipient Institution, contingent upon Recipient Investigator being found to be a qualified investigator as determined by an approved NINDS process, desires to obtain NINDS BioSEND Research Material for use in Recipient Investigator's research;

NOW, THEREFORE, in consideration of the mutual promises contained herein, and other valuable consideration, the receipt and sufficiency of which is hereby acknowledged, IU will provide Recipient Institution with the agreed upon NINDS BioSEND Research Materials subject to the following terms and conditions:

Definitions:

"Associated Phenotypic Data" shall mean deidentified data on family structure, age, sex, vital status, psychopathology, diagnosis, and other clinically relevant associated phenotypic information, stripped of all personal identifiers and thus unlinkable to the individuals from whom they were obtained;

"Genetic Data" shall mean de-identified data derived from genotyping, mutation analysis, single nucleotide polymorphisms (SNPs) and any and all other analyses of the NINDS BioSEND Research Material as obtained or determined by Recipient Investigator and other scientists under his/her direction and supervision, stripped of all personal identifiers and thus unlinkable to the individuals from whom they were obtained;

"NINDS BioSEND Research Material" shall mean the biological material from humans including the biological samples and the Associated Phenotypic Data transferred from IU's NINDS BioSEND facility to Recipient Institution (jointly referred to herein as "Original Research Material") as well as Progeny and/or Unmodified Derivatives thereof, including stem cells derived therefrom. Unmodified Derivatives may also be referred to herein as "Derived Materials."

"Derived Material" (also referred to herein as Unmodified Derivatives) shall mean substances created or isolated by the Recipient Institution which constitute an unmodified functional subunit or product of the Original Research Material. Some examples include but are not limited to: stem cells, subclones of unmodified cell lines, purified or fractionated subsets of the biological samples of the Original Material, any and all genetically unmodified cells or cell lines created by or isolated from use of the biological samples of the Original Research Material.

"Progeny" shall mean unmodified descendant from the NINDS BioSEND Research Material, such as cell from cell, or organism from organism.

"Commercial Purposes" shall mean the sale, lease, license or other exploitation of the NINDS BioSEND Research Material to a party for profit-generating purpose, including, but not limited to, use of the NINDS BioSEND Research Material by Recipient Institution to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license or transfer of the NINDS BioSEND Research Material to any other party. However, industrially sponsored academic research shall not be considered a use of the NINDS BioSEND Research Material for Commercial Purposes unless any of the above conditions of this definition are met.

Terms and Conditions of Agreement:

1. The control and distribution of NINDS BioSEND Research Material is the responsibility of IU through the NINDS BioSEND facility and is made available as a service to qualified individuals in the research community to further research of Parkinson's disease (PD), Huntington's disease (HD), and traumatic brain injury (TBI) and other neurological and neuropsychiatric diseases.

2. IU and Recipient Institution agree that all NINDS BioSEND Research Materials that transfer from IU to Recipient Institution under this Master Agreement will be described specifically on an ADDENDUM TO THE MASTER MATERIAL TRANSFER AGREEMENT: NINDS BioSEND RESEARCH MATERIAL TO BE PROVIDED BY IU TO RECIPIENT INSTITUTION FOR THE BENEFIT OF RECIPIENT INVESTIGATOR, attached hereto and incorporated herein as an Appendix C. Subsequent requests for additional NINDS BioSEND Research Material under this Master Agreement shall require submission of an additional Appendix C. Therefore, there may be multiple Appendix C documents attached to the Master Agreement; each will be signed by the same Recipient Investigator and a NINDS BioSEND Investigator and will be subject to the terms and conditions of this Master Agreement. IU shall provide Recipient Institution with

NINDS BioSEND Research Material described on a signed Appendix C. IU shall have sole discretion whether or not to add a new Appendix C under this Master Agreement.

3. NINDS BioSEND Research Material represents a significant investment on the part of those who deposited the material with NINDS BioSEND and others, including the NINDS and NIH. The NINDS BioSEND Research Material is provided to Recipient Institution under this Master Agreement solely for use by Recipient Investigator, identified on the signature page below, or others at Recipient Institution under the direction and supervision of Recipient Investigator in furtherance of research related to Parkinson's disease (PD), Huntington's disease (HD), and traumatic brain injury (TBI) and related neurological and neuropsychiatric diseases and aging, such research as specifically described in an Appendix C ("Research Project"), attached hereto and incorporated herein. To be clear, each Appendix C signed by Recipient Investigator and NINDS BioSEND Investigator shall list NINDS BioSEND Research Materials that will transfer from IU to Recipient Institution and the Research Project for which they will be used by the Research Investigator and those under his/her direction and supervision under the terms and conditions of this Master Agreement.

4. NINDS BioSEND Research Material may not be used in experiments involving human subjects. The Recipient Institution agrees to comply with all Federal and state rules and regulations applicable to the use and handling of the NINDS BioSEND Research Material.

5. Research Institution agrees to use the NINDS BioSEND Research Material, including the Original Research Material, Progeny, and Derived Materials, for Research Project purposes only. NINDS BioSEND Research Material shall not be used for Commercial Purposes. No right, title or interest in and to the NINDS BioSEND Research Material shall transfer to the Recipient Institution.

6. The NINDS BioSEND Research Material, including the Original Material as well as their Progeny and Unmodified Derivatives thereof, including stem cells derived therefrom, shall not be further distributed to any other person or entity by the Recipient Institution or Recipient Investigator without NINDS BioSEND's prior written consent. The Recipient Institution or Recipient Investigator agrees to refer any such request for the NINDS BioSEND Research Material to NINDS BioSEND.

7. Recipient Investigator using NINDS BioSEND Research Material under this Master Agreement shall share Genetic Data derived from the Research Project by placing these Data and Associated Phenotypic Data in an NINDS approved site. All approved sites will make these Data and Associated Phenotypic Data available to qualified investigators in the scientific community for secondary analysis in accordance with standards established by the NINDS. The Recipient Investigator agrees to provide such Data as soon as reasonably possible, but no later than immediately upon acceptance of a subset of data for publication or public disclosure of a submitted patent application, whichever is earlier. When a genomic study has been performed, the Recipient Investigator agrees to abide by any current NIH-adopted policy concerning sharing of genetic data obtained in NIH supported studies.

8. Transfer of Derived Material to NINDS BioSEND. If Recipient Institution, Recipient Investigator, or those under the direction and supervision of the Recipient Investigator at the Recipient Institution, develops Derived Material (including, but not limited to, stem cells)

under this Master Agreement including any Appendix C attached hereto, then Recipient Institution and Recipient Investigator agree to transfer said Derived Material to NINDS BioSEND under the terms and conditions of the MATERIAL TRANSFER AGREEMENT FOR THE TRANSFER OF DERIVED MATERIALS TO NINDS BioSEND, attached hereto and included herein as Appendix F. The Recipient Investigator agrees to provide NINDS BioSEND samples of such Derived Material as soon as possible, but no later than one year after publication or oral presentation describing Derived Material. The Derived Material transferred from Recipient Institution to NINDS BioSEND will consist of at least two vials of Derived Materials accompanied by documentation adequate to enable NINDS BioSEND investigators to culture and/or maintain Derived Material. Derived Material does not need to be transferred to NINDS BioSEND under this Section if, and only if, (i) the biological sample transferred from IU's NINDS BioSEND facility to the Recipient Institution, from which the Derived Material was created or isolated, was DNA, or (ii) Recipient has obtained NINDS BioSEND's prior written consent to not transfer the Derived Materials. Recipient Investigator shall not provide Derived Material to any other party.

9. Recipient Investigator will acknowledge the contribution of NINDS BioSEND, all institutions contributing to NINDS BioSEND**,** and the NINDS in any and all oral and written presentations, disclosures, and publications resulting from any and all use and analyses of the NINDS BioSEND Research Material, as well as any data received from NINDS BioSEND. Acknowledgement language to be used is that set forth in Appendix G attached hereto and incorporated herein. From time-to-time, the language of Appendix G may be modified and such modification shall have no effect on the remaining provisions of this Master Agreement which shall continue in full force and effect.

10. Any NINDS BioSEND Research Material delivered pursuant to this Master Agreement is understood by Recipient Institution to be experimental in nature and may have hazardous properties. All cultured animal and human tissue cells have the potential for carrying viruses, latent viral genomes, and other infectious agents in a non-apparent state. By accepting NINDS BioSEND Research Material, the undersigned Recipient Institution assumes full responsibility for the safe and appropriate handling of the NINDS BioSEND Research Material. THE PARTY WHO ORIGINALLY DEPOSITED THE NINDS BioSEND RESEARCH MATERIAL WITH NINDS BioSEND, NINDS BioSEND, AND THE TRUSTEES OF INDIANA UNIVERSITY MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED INCLUDING, BUT NOT LIMITED TO MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE RESEARCH MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Unless prohibited by law, Recipient Institution assumes all liability for claims for damages against it by third parties which may arise from Recipient Institution's use, storage or disposal of the Research Material except that, to the extent permitted by law, IU shall be liable to the Recipient Institution when the damage is caused by the gross negligence or willful misconduct of the Provider.

11. The Recipient Institution and Recipient Investigator agree that the NINDS BioSEND Research Material including the biological sample and the Associated Phenotypic Data shall not be used either alone or in conjunction with any other information, in any effort whatsoever to establish the individual identities of any subjects from which the NINDS BioSEND Research Material was derived.

12. IU may terminate a particular Appendix C or the Master Agreement if the Recipient Institution is in default of any of the terms specified herein and if the deficit has not been remedied within thirty (30) days after Recipient Institution's receipt of written notice by IU of such deficit. Upon termination under this clause, the Recipient Institution agrees to destroy all unused NINDS BioSEND Research Material, including accompanying Associated Phenotypic Data, Progeny and Derived Materials, and Recipient Investigator shall provide NINDS BioSEND with written certification of their destruction, unless permission to retain NINDS BioSEND Research Material is specifically provided in writing by IU to Recipient Institution. Obligations of Recipient Institution under clauses 5-11 shall survive termination.

13. Subjects from whom NINDS BioSEND Research Material has been derived and provided to NINDS BIOSEND may decide to withdraw consent for use of NINDS BioSEND Research Material. In the event NINDS BioSEND is notified that consent for use of NINDS BioSEND Research Material has been withdrawn, NINDS BioSEND may notify all recipients of that particular NINDS BioSEND Research Material and then the Recipient Institution shall immediately destroy the applicable NINDS BioSEND Research Material, including the Original Material, Progeny, Derived Material and Associated Phenotypic Data. Upon NINDS BioSEND's request Research Institution shall provide NINDS BioSEND with a written certification of destruction.

14. The NINDS BioSEND Research Material identified in each Appendix C is provided with a transmittal fee for Research Institution to reimburse NINDS BioSEND in a cost-recovery model for preparation and distribution of samples. Each transmittal fee, one for each Appendix C, shall be mutually agreed to by the parties to this Master Agreement in order for NINDS BioSEND Research Material identified in each Appendix C to be shipped.

15. This Master Agreement and attached Appendices constitutes the entire agreement and understanding of the parties and supersedes any prior agreements, promises or understandings, written or verbal, relating to the subject matter hereof. This agreement and any attachments hereto/thereto may not be altered, modified, or waived in whole or in part, except in writing signed by both parties.

16. This Master Agreement is intended to be severable, and the invalidity and/or unenforceability of any clause of this Master Agreement, or part thereof shall not affect the validity and/or enforceability of any other clause or part thereof to the extent not invalidated or held unenforceable.

17. This Master Agreement or attachments thereto may be executed in counterparts, each of which shall be deemed to be an original, and all of such counterparts shall together constitute one and the same agreement.

18. This Master Agreement is not assignable, whether by operation of law or otherwise, without the consent of the other party hereto (which shall not be unreasonably withheld, or denied).

Signatures on Following Page

IN WITNESS WHEREOF, the parties have executed this Master Agreement as of the Effective Date by their authorized representatives.

Agreed:

RECIPIENT INSTITUTION
Name of Recipient Institution:
Business Address of Recipient Institution:

By:_____ _____
Authorized Official of Recipient Institution Date
Name:
Title:

Certification of Recipient Investigator: I have read and understood the conditions outlined in this Master Agreement and I agree to abide by them in the receipt and use of the NINDS BioSEND Research Material including the Progeny, Derived Materials and Associated Phenotypic Data

_____ _____
Recipient Investigator Signature Date
Name:
Title:

Shipping Address:

The Trustees of Indiana University

By: _____ _____
Authorized Official Date
Name:
Title:
IU Ref:

_____ _____
Signature of NINDS BioSEND Investigator Date
Name:
Title:

LEGAL ADDRESS:
Office of Research Administration
509 E. 3rd St.
Bloomington, IN 47401-3654

NINDS BioSEND ADDRESS (Correspondence)
Division of Hereditary Genomics
Indiana University
410 West 10th Street, HS 4000
Indianapolis, IN 46202-3002

Appendix C: *To be used each time Recipient Investigator requests NINDS* BioSEND *Research Material under the terms and conditions of the Master Agreement.*

APPENDIX C

ADDENDUM TO THE MASTER MATERIAL TRANSFER AGREEMENT: NINDS BioSEND **RESEARCH MATERIAL TO BE PROVIDED BY IU TO RECIPIENT INSTITUTION FOR THE BENEFIT OF RECIPIENT INVESTIGATOR**

This Appendix C is effective as of the date of the last signature below ("Appendix C Effective Date") and is governed by terms and conditions of the "Master Material Transfer Agreement for the Transfer of Materials From NINDS BioSEND" with an Effective Date of _____ (hereinafter "Master Agreement") between The Trustees of Indiana University (herein, "IU") and Recipient Institution identified in the signature block (jointly referred to as parties) in the interest of the Recipient Investigator identified on the signature page below. The parties agree as follows:

1. The parties to this Appendix C are parties to the Master Agreement identified above and desire to execute this Appendix C under the terms and conditions of said Master Agreement. Except as defined in this Appendix C, all other capitalized terms shall be as defined in the Master Agreement.

2. The materials to be provided by BioSEND are non-toxic and non-hazardous. These samples were collected from willing research study participants according to the principles of the ICH guidelines on Good Clinical Practice. To the best of our knowledge, the specimens were only taken from persons with no signs or symptoms of the following diseases: Cholera, Highly pathogenic avian influenza in humans (HPAIH), Human swine influenza with pandemic potential, Plague, Rabies, Severe acute respiratory syndrome (SARS), Small pox, Viral haemorrhagic fever in humans, Yellow fever, or any disease that is exotic to the country of destination.

3. **The terms and conditions of the Master Agreement shall govern this Appendix C.**

4. Recipient Institution desires to obtain and IU agrees to provide the materials listed below (using specific identifiers for each material) to be included in NINDS BioSEND Research Material.

5. In consideration for the Research Material, Recipient Institution agrees that there will be a transmittal fee mutually agreed upon by the parties to be paid by the Research Institution.

6. Recipient Investigator shall provide the following information:

a) Recipient Investigator's shipping address for receipt of the NINDS BioSEND Research Material(s):

b) List the NINDS BioSEND Research Material(s) being requested by Recipient Institution from NINDS BioSEND (using specific identifiers for each Research Material) (attach separate page(s) as necessary):

c) Describe the non-commercial research to be conducted by Recipient Investigator ("Research Project") using the NINDS BioSEND Research Material(s) listed above (attach separate page(s) as necessary):

d) Describe the specific Data that will be sought in the Research Project described above (attach separate page(s) as necessary):

RECIPIENT INVESTIGATOR and RECIPIENT INSTITUTION INFORMATION

Recipient Investigator Name (Printed):
Phone:
Fax:
E-mail address:

Recipient Institution Name:
Address:

SIGNATURES

Certification of Recipient Investigator: I have read and understood the conditions outlined in the Master Agreement to which this Appendix C is attached and incorporated and I agree to abide by the terms and conditions of the Master Agreement in the receipt and use of the NINDS BioSEND Research Material described in this Appendix C, including the Progeny, Derived Material, and Associated Phenotypic Data.

_____ _____
Recipient Investigator Signature Date
Recipient Investigator Name and Title:

NINDS BioSEND INVESTIGATOR INFORMATION and SIGNATURE

Name & Title of NINDS BioSEND Investigator:

_____ _____
Signature of NINDS BioSEND Investigator Date

APPENDIX G

Acknowledgement of Grant Support

According to Section 8 of the Master Agreement, Recipient Investigator will acknowledge the contribution of various parties in any and all oral and written presentations, disclosures, and publications resulting from use of the NINDS BioSEND Research Material using the following language:

NINDS BioSEND *grant acknowledgement for all samples obtained from NINDS* BioSEND*: Samples from the NINDS* BioSEND*, which receives government support under a cooperative agreement grant (U24 NS095871) awarded by the National Institute of Neurological Disorders and Stroke (NINDS), were used in this study. We thank contributors who collected samples used in this study, as well as patients and their families, whose help and participation made this work possible.*

The following grants, as checked, which supported the collection of samples included in Research Material shall also be acknowledged.

Check all that apply:

☐ The NINDS Parkinsons Disease Biomarkers Program (NINDS PDBP): Data and biospecimens used in preparation of this manuscript were obtained from the Parkinson's Disease Biomarkers Program (PDBP) Consortium, part of the National Institute of Neurological Disorders and Stroke at the National Institutes of Health. Investigators include: (please add the names of all investigators found at the following link – https://pdbp.ninds.nih.gov/sites/default/files/assets/policy/PDBP_publication_policy.pdf). The PDBP Investigators have not participated in reviewing the data analysis or content of the manuscript.

Prior to Journal publication the manuscript must be submitted to the PDBP Steering Committee (via PD-Pubs@ninds.nih.gov) who will verify within 5 days that the PDBP is appropriately acknowledged. If this time elapses without notice from the PDBP Steering Committee Representatives, authors may proceed with the paper.

☐ The BioFIND Project: Per the BioFIND project Data Use Agreement (see https://www.michaeljfox.org/files/NEWBioFIND%20Data%20Use%20Agreement.pdf): BioFIND is funded by The Michael J. Fox Foundation for Parkinson's Research and the National Institute Neurological Disorders and Stroke.

☐ The NINDS Udall Centers: Data and samples used in this study were collected in part via the National Institute of Neurological Disorders and Stroke Udall Centers of Excellence in Parkinson's Disease Program.

☐ PREDICT-HD: Samples used in this study were in part collected via the PREDICT-HD study (U01 NS082089). All manuscripts submitted, in addition to the appropriate authors, will acknowledge the Predict HD study investigators followed by an asterisk. The asterisk will point to a printed and/or, in a case of an electronic publication, web site https://neurology.wisc.edu/wp-content/uploads/2023/05/PREDICT-HD_2020_Acknowledgments.pdf (if allowed by the journal) listing the names of Predict HD study investigators.

☐ 2-CARE: Research reported in this publication was supported by the National Institute of Neurological Disorders and Stroke of the National Institutes of Health under Award Numbers NS052592 and NS052619 [(Cudkowicz, Mass General Hospital) and (McDermott; Rochester, Coordinating and Biostatistics), respectively.

☐ FTD-TAU Cohort: These samples were collected, in part, via the Early Symptoms of FTLD Study (R01 NS076837).

☐ READISCA: The READISCA study supported the collection of samples used in this study through National Institute of Neurological Disorders and Stroke (NINDS) grant NS104326. We thank contributors who collected samples used in this study, as well as patients and their families, whose help and participation made this work possible. The READISCA collection is currently housed at the NINDS BioSEND repository at Indiana University under grant U24NS095871.

☐ CRC-SCA: The CRC-SCA Research Consortium: Data and biospecimens used in this study were collected via The National Ataxia Foundation funded CRC-SCA consortium (https://www.ataxia.org/crc-sca/). We kindly acknowledge the patients involved in this consortium for their generous contributions to this work.

☐ LETBI: National Institutes of Health (NIH) National Institute of Neurological Disorders and Stroke (NINDS) (1RF1NS115268-01), Clinical & Biological Signatures of post-traumatic neurodegeneration: Toward in-vivo diagnosis of the Late Effects of TBI (LETBI).

☐ NINDS BioSEND only as stated above.