

MATERIAL TRANSFER AGREEMENT FOR TRANSFER OF MATERIALS TO NCRAD

This Master Material Transfer Agreement for Transfer of Materials to NCRAD (“Master Agreement”) is made and entered into by and between the Trustees of Indiana University, an educational institution organized under the laws of the State of Indiana and having offices at 509 East 3rd Street Bloomington IN 47401-3654, USA (“IU”) and the Providing Institution identified on the signature page below (“Providing Institution”), each a “Party” and collectively the “Parties”. This Master Agreement is effective as of the date of the last signature below (“Effective Date”).

WHEREAS IU operates the National Centralized Repository for Alzheimer’s Disease and Related Dementias (“NCRAD”), a biorepository located within Indiana University and originally established through funding from the National Institute on Aging (NIA) 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 Alzheimer’s Disease and related neurological diseases and aging; and

WHEREAS NCRAD receives certain human biological material and Associated Phenotypic Data from Alzheimer Disease Centers, and public and private sector investigators for the purpose of distributing submitted human biological material along with Associated Phenotypic Data to qualified investigators, as determined by an approved advisory committee and who may meet qualifications established by a multi-institutional Sample Acquisition Committee, at nonprofit and for-profit organizations to further Non-Commercial Research of Alzheimer’s Disease and related neurological diseases and aging (“NCRAD’s Purpose”);

WHEREAS, NCRAD and associated IU laboratories will analyze the Research Material contemplated under this Agreement and its Appendices for purposes of producing and obtaining Biospecimen Data;

WHEREAS Providing Institution desires to transfer to NCRAD, and NCRAD agrees to receive, certain human biological material, Biospecimen Data, and Associated Phenotypic Data in furtherance of NCRAD’s Purpose;

NOW THEREFORE, in consideration of the foregoing and the covenants and promises contained in this Master Agreement, and other valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. **Definition of Terms.** As used herein, the following terms shall have the following meanings:
 - 1.1. “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.
 - 1.2. “Biospecimen Data” shall mean de-identified data derived from all analyses of the Research Material as obtained or determined by users of Research Material, stripped of all personal identifiers and thus unlinkable to the individuals from whom they were obtained.
 - 1.3. “Research Material” shall mean the biological material from humans, including the biological



samples and the Associated Phenotypic Data transferred to IU's NCRAD facility from Providing Institution (jointly referred to herein as "Original Research Material"), as well as Progeny and/or Unmodified Derivatives thereof. Unmodified Derivatives may also be referred to herein as "Derived Materials."

- 1.4. "Derived Material" (also referred to herein as Unmodified Derivatives) shall mean substances created from or isolated from the biological samples transferred to IU's NCRAD facility from Providing Institution which constitute an unmodified functional subunit or product of the Original Research Material. Examples of Derived Material 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 or nucleic acid created from or isolated from the biological samples of the Original Research Material.
- 1.5. "Progeny" shall mean unmodified descendant from the Research Material, such as cell from cell, or organism from organism.
- 1.6. "Commercial Purposes" shall mean the sale, lease, license or other exploitation of the Research Material to a Party for profit-generating purpose, including, but not limited to, use of the Research Material by a recipient 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 Research Material to any other party. However, industrially sponsored academic research shall not be considered a use of the Research Material for Commercial Purposes unless any of the above conditions of this definition are met.
- 1.7. "Non-Commercial Research" shall mean any research which is not for Commercial Purposes.

2. Terms and Conditions.

- 2.1. Original Research Material is provided to IU's NCRAD facility from Providing Institution as a service to the research community. IU and Providing Institution agree that all Research Material that transfers from Providing Institution to IU under this Master Agreement will be identified by the Study (e.g., Study Name) and the Principal Investigator of the Study at the Study Site ("Providing Investigator") on a Research Material Transfer Document, executed under and attached to this Master Agreement as Appendix A. An exemplary Research Material Transfer Document is attached hereto as Appendix A and is incorporated into this Master Agreement. There shall be a separate Appendix A completed for each different Study and for each different Providing Investigator transferring Research Materials under this Master Agreement. Each completed Appendix A shall be signed by the Providing Investigator and by the lead NCRAD Investigator and shall be governed by the terms of this Master Agreement. Each completed Appendix A is incorporated into this Master Agreement. IU shall have the sole discretion whether or not to accept Research Materials into IU's NCRAD facility.
- 2.2. RESEARCH MATERIAL MAY NOT BE USED IN EXPERIMENTS INVOLVING HUMAN SUBJECTS.
- 2.3. IU and Providing Institution agree to comply with all Federal, State and local rules and regulations applicable to their use and handling of the Research Material.
- 2.4. Research Material will be used by IU's NCRAD facility solely for teaching, noncommercial research purposes, and for subsequent distribution of Research Materials, including Derived Materials, to qualified third parties for Non-Commercial Research Purposes (collectively, the "NCRAD Purpose"). NCRAD will prepare and maintain Research Material as appropriate in its



facility, and has the authority to provide Research Material to qualified third party requesters (“Recipients”) under a Master Material Transfer Agreement for the Transfer of Materials From NCRAD. (A current exemplary copy of Master Material Transfer Agreement for the Transfer of Materials From NCRAD is available for Providing Institution to review upon request).

- 2.5. Providing Institution reserves the right to distribute the Research Material in its possession to third parties and to use it for its own purposes.
- 2.6. Providing Institution represents and warrants that it has the authority to provide the Research Material to IU, including all requisite approvals from the source of the Research Material, and to authorize NCRAD to use the Research Material in a manner consistent with the NCRAD Purpose. Providing Institution shall make informed consent data for the Research Material available to NCRAD upon request.
- 2.7. Providing Institution represents and warrants that it has complied with all applicable laws and regulations as pertains to its collection and transfer of the Research Material under this Master Agreement. If collection of the Research Material by Providing Institution was subject to informed consent and/or Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) authorization, Providing Institution represents and warrants that the scope of such informed consent and/or authorization is consistent with the supply of the Research Material to IU pursuant to this Master Agreement and consistent for use by IU under the NCRAD Purpose.
- 2.8. Any Research Material delivered pursuant to this Master Agreement is understood to be experimental in nature and may have hazardous properties. OTHER THAN THOSE EXPRESSLY STATED IN THIS MASTER AGREEMENT, THE PROVIDING INSTITUTION MAKES NO REPRESENTATIONS AND EXTENDS 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, IU assumes liability only for claims for damages which may arise from the use, storage, or disposal of the Research Material by IU to the extent permitted by law. 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. Accordingly, IU shall adhere to the applicable guidelines for appropriate laboratory procedure.
- 2.9. If Providing Institution is notified that consent to use any particular Research Material that has been transferred to IU under this Master Agreement has been withdrawn, the Providing Institution shall notify IU and IU shall destroy any Research Material in its possession. IU shall take additional steps to notify third party recipients of the Research Material if required to do so under the Providing Institution’s consent form with the source of the Research Material.
- 2.10 Providing Institution acknowledges that there is a transfer and maintenance fee (“Fee”) payable to IU for all Research Materials transferred under this Master Agreement. The amount of the fee and the identity of the Payor shall be agreed upon in writing by the Providing Investigator and NCRAD Investigator prior to signing an Appendix A. IU reserves the right to refuse transfer of Research Material under this Master Agreement or under a particular Appendix A attached to this Master Agreement if payment of a Fee for the study is in arrears.
- 2.11 Neither Party will assign this Master Agreement, in whole or in part, without the prior written consent of the other Party, whose consent shall not be unreasonably withheld.
- 2.12 This Master Agreement and all attached Appendix A documents represents the entire and



integrated agreement between the Parties with respect to the subject matter herein and supersedes all prior negotiations, representations or agreements, either written or oral, regarding the Research Material described herein.

- 2.13 If any provision of this Master Agreement is deemed to be invalid or unenforceable, it shall not affect the validity or enforceability of any of the remaining provisions.
- 2.14 This Agreement may be executed in two (2) or more counterparts, each of which is deemed an original, but all of which together constitutes one instrument. Electronically transmitted and facsimile transmitted signatures shall have the full force and effect of an original signature.
- 2.15 Transfer of Biospecimen Data from NCRAD. The de-identified Biospecimen Data will be transferred from NCRAD to the Provider. NCRAD will retain a copy of the de-identified Biospecimen Data in its data repository. Provider will endeavor not to re-associate the de-identified Biospecimen Data with any of the Provider's raw data and will promptly report any event in which re-identified data has been unlawfully or inappropriately disclosed to any third party.
- 2.16 Except as otherwise provided herein, authorship of any publications shall be determined by academic standards as set forth by the International Committee of Medical Journal Editors (ICMJE) guidelines and it is expected that studies using biomarker assay data include scientists from the NCRAD biomarker laboratory in drafting or revising of manuscripts for important intellectual content and providing final approval of the version to be published.

Signatures on following page



IN WITNESS WHEREOF, the Parties have caused this instrument to be executed by their respective duly authorized officers or representatives.

PROVIDING INSTITUTION

Business Address of Providing Institution:

Name of Providing Institution:

By: _____

Authorized Official of Providing Institution

Name:

Title:

Date:

THE TRUSTEES OF INDIANA UNIVERSITY

By: _____

Authorized Official of Recipient Institution

Name:

Title:

Date:

NR _____



APPENDIX A
RESEARCH MATERIAL TRANSFER DOCUMENT

(To be completed when it is intended that Research Materials from a Study are to transfer from Providing Institution to NCRAD [completed only with or prior to the first transfer] or when a Study already providing Research Materials to NCRAD has a new Principal Investigator)

This Appendix A is effective as of the date of the last signature below and is subject to the terms and conditions of the MASTER MATERIAL TRANSFER AGREEMENT FOR TRANSFER OF MATERIALS TO NCRAD between The Trustees of Indiana University and the Providing Institution.

The Parties agree as follows:

1. The Parties to this Appendix A are Parties to the Master Agreement to NCRAD identified above and desire to execute this Appendix A under the terms and conditions of said Master Agreement to NCRAD. Except as defined in this Appendix A, all other capitalized terms shall be as defined in the Master Agreement to NCRAD.
2. **The terms and conditions of the Master Agreement to NCRAD shall govern this Appendix A.**
3. Providing Institution desires to provide and IU agrees to accept at its NCRAD facility, certain mutually agreed upon Research Materials obtained from the following:

- A. Study Name (if any):
- B. Providing Investigator
 - i. Name
 - ii. Title:
 - iii. Phone:
 - iv. Email:

4. Providing Investigator and NCRAD Investigator agree that (i) a transfer and maintenance fee payable to IU, and (ii) the identity of the Payor has been agreed upon prior to signing this Appendix A.
5. Research Materials shall be shipped to:

National Centralized Repository for Alzheimer's Disease and Related Dementias (NCRAD)
Department of Molecular and Medical Genetics
Indiana University 351 West 10th Street TK-217
Indianapolis, IN 46202-5251
Phone: (800) 526-2839
Fax: (317) 278-1100
E-mail: alzstudy@iu.edu



READ AND ACKNOWLEDGED:

Providing Investigator

NCRAD Investigator

By:
Name:
Title:
Date:

By:
Name:
Title:
Date:



APPENDIX H
RESEARCH MATERIAL TRANSFER DOCUMENT

(To be completed when it is intended that Research Materials from a Study are to transfer from Provider to NCRAD [completed only with or prior to the first transfer] or when a Study already providing Research Materials to NCRAD has a new Principal Investigator)

This Appendix H is effective as of the date of the last signature below and is subject to the terms and conditions of the MASTER MATERIAL TRANSFER AGREEMENT FOR TRANSFER OF MATERIALS TO NCRAD between The Trustees of Indiana University and the Provider Institution, with an Effective Date of _____ (hereinafter “Master Agreement to NCRAD”).

The parties agree as follows:

1. The parties to this Appendix H are parties to the Master Agreement to NCRAD identified above and desire to execute this Appendix H under the terms and conditions of said Master Agreement to NCRAD. Except as defined in this Appendix H, all other capitalized terms shall be as defined in the Master Agreement to NCRAD.
2. The terms and conditions of the Master Agreement to NCRAD shall govern this Appendix H.
3. Provider desires to provide and IU agrees to accept at its NCRAD facility, certain mutually agreed upon Research Materials obtained from the following:

Sample Type(s): hiPSC

Provider Investigator (name and title printed): _____

Phone:

Email:

4. List any legal terms and conditions (if necessary) that were provided to you upon receipt of the cells and need to transfer to NCRAD with the samples.
5. Can cells be distributed with for-profit companies for non-commercial research?
6. Provider Investigator and NCRAD Investigator agree that (i) a transfer and maintenance fee payable to IU, and (ii) the identity of the Payor has been agreed upon prior to signing this Appendix H.
7. Research Materials shall be shipped to:

National Centralized Repository for Alzheimer’s Disease and Related Dementias (NCRAD)
Department of Molecular and Medical Genetics
Indiana University
351 West 10th Street
TK-217
Indianapolis, IN 46202-5251

Phone: (800) 526-2839
Fax: (317) 278-1100
E-mail: alzstudy@iu.edu

Signatures on following page



READ AND ACKNOWLEDGED:

Provider Investigator

By: _____

Name:

Title:

Date: _____

NCRAD Investigator

By: _____

Name:

Title:

Date: _____

