MASTER 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 thedate 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 institutions, and public and private sector investigators for the purpose of storing and 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 in its own capacity desires to transfer to NCRAD, and NCRAD agrees to receive, certain human biological material or Research Material, Biospecimen Data, and Associated Phenotypic Data in furtherance of NCRAD's Purpose;

WHEREAS the Parties also desire to make clear their respective duties, responsibilities and assumption of associated liabilities arising out of or related to a decision regarding Return of Research Results ("Return of Research Results" or "Research Results") from Research Material to individuals from whom it collected human biological materials and associated phenotypic data, including results it receives from NCRAD that may be used by Providing Institution to return such results to individuals from whom human biological material and associated phenotypic data has been collected and consists of the research based genetic and/or biomarker assay results;

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 de-identified 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 or associated IU laboratories 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 ofunmodified 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 including but not limited to use, in whole or in part of the ResearchMaterial, directly or indirectly, including any NCRAD Research Material contained or incorporated in Modifications, to a Party for proof of concept, potential product development or 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 develop, produce or manufacture products for general sale, or to conduct research activities that result inany sale, lease, license or transfer of the Research Material to any other party. However, industry sponsored academic research shall not necessarily be considered a Commercial Purpose unless such research is contrary to the terms and conditions of this agreement.

1.7. "Non-Commercial Research" shall mean any research which is not for Commercial Purposes.

1.8. "Research Results" shall mean research based genetic and/or biomarker assay results.

2. Terms and Conditions.

2.1. Original Research Material is provided to IU's NCRAD facility from Providing Institution as a service to theresearch 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 partiesand to use it for its own purposes.

2.6. Providing Institution represents and certifies 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 certifies that is has complied with all applicable laws and regulations aspertains 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 certifies 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 andconsistent 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 IUand 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 Providing Institution/Providing Investigator. NCRAD will retain a copy of the de-identified Biospecimen Data in its data repository. Providing Institution/Providing Investigator may re-associate the de-identified Biospecimen Data if consented to by the participant for the purpose of the institutionally approved analyses for this research project and only to the extent permitted by applicable law. No further use of the de-identified Biospecimen Data is allowed.

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. It is expected that studies using biomarker assay data include scientists from the biomarker laboratory in drafting or revising of manuscripts for important intellectual content and each Party shall in good faith review and take a Party's comments into consideration. Providing Institution agrees that any proposed publication or presentation relating to the NCRAD Research Material conducted under this Agreement will be submitted to the biomarker laboratory scientists for review at least thirty (30) days prior to submission for publication or presentation to remove confidential information. As such, the scope of confidential information in this publication context does not include the results arising out of the performance of this Agreement.

2.17 Providing Institution/Investigator of certain human biological material and associated phenotypic data that Providing Institution/Investigator had collected and transferred to IU under this Master Agreement represents and warrants that it has in the past and will continue in the future to consult and comply with its Institutional Review Board (internal or external) in connection with their Return of Research Results. All decisions and actions taken by Providing Institution/Investigator regarding Return of Research Results will comply with 45 CFR 46.

2.18 In all instances in which Providing Institution/Investigator has in the past or will in the future engage in Return of Research results, Providing Institution/Investigator will:

- Advise any individual or authorized representative that receives from Providing Institution/Investigator the Return of Research Results that that the testing processes and results are, pursuant to Providing Institution/Investigator's requirements, research-grade only,

and therefore were not expected by Providing Institution/Investigator or intended by the Parties to be conducted in a CLIA-certified manner, and therefore, are not intended to be used or relied upon for diagnosis or clinical decision-making.

- Advise any individual or authorized representative that receives from Providing Institution/Investigator the Return of Research Results that the sample collection and accessioning process is research-grade only, and therefore, inaccuracies or errors in the process can and do occur with greater frequency than in a CLIA-certified process. Therefore, the Return of Research Results communicated to a given individual may be erroneous.
- Advise any individual or authorized representative that receives from Providing Institution/Investigator the Return of Research Results that their receipt of the Return of Research Results and any future testing may have an adverse impact on their insurance status.

2.19 Providing Institution acknowledges Research Material was processed under a research protocol which does not include chain of custody documentation and is not Clinical Laboratory Improvement Amendments (CLIA) certified. Additionally, Research Results were produced under a research protocol which does not include chain of custody documentation and are not CLIA certified. IU recommends all Research Results be reproduced in a CLIA setting.

2.20 Providing Institution will defend, indemnify, save and hold harmless IU and its parent, subsidiaries and affiliates and their respective trustees, directors, officers, employees and agents from and against any third-party claim(s), lawsuit(s) or demand(s) arising out of, related to, or attributable to the use of Research Results from Research Material or Providing Institution's Return of Research Results, provided Providing Institution is given written notice of the claim(s)/lawsuit(s)/demand(s) as soon as practical. The Parties agree, however, that failure to give such notice shall only relieve Providing Institution of its obligations if and to the extent Providing Institution has been substantially prejudiced by such delay. Providing Institution will be given information and reasonable assistance at Providing Institution's sole cost and expense, and the authority to defend and/or settle any claim, provided that Providing Institution may not settle any claim without IU's prior written consent that provides for anything other than a monetary remedy or does not contain an unconditional release of IU in form and substance reasonably satisfactory to IU.

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 [completedonly 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 definedin 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 mutuallyagreed 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. If either party needs revisions to Appendix A regarding sample quantity or costs, an amended Appendix A can be reissued for signatures. For multi-year collections, fees are subject to change.

6. 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

Signature on following page

READ AND ACKNOWLEDGED:

Providing Investigator	NCRAD Investigator
By:	By:
Name:	Name:
Title:	Title:
Date:	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. Providing Institution/Providing Investigator 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: _____

   Title:

   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? Yes

6. Providing Institution/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 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

READ AND ACKNOWLEDGED:

Provider Investigator	NCRAD Investigator
By: _____	By:_____
Name:	Name:
Title:	Title:
Date:_____	Date: _____