

MASTER MATERIAL TRANSFER AGREEMENT FOR THE TRANSFER OF MATERIALS FROM NCRAD

This Master Material Transfer Agreement for the transfer of Materials from NCRAD (“Master Agreement”) is made and entered into by and between The Trustees of Indiana University having offices at 509 E. 3rd St., Bloomington, IN 47401, 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 National Centralized Repository for Alzheimer’s Disease and Related Dementias (“NCRAD”), a biorepository located within Indiana University and which was 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 biological material from humans and Associated Phenotypic Data (as defined below) submitted by Alzheimer’s Disease Centers, and public and private sector investigators; and

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

WHEREAS, IU desires to distribute this biological material, Biospecimen Data, 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 Biospecimen Data and/or isolation of Derived Materials (as defined below); and

WHEREAS, NIA has designated certain sites for the deposit of all Biospecimen Data determined or identified by investigators using the NCRAD Research Material and such sites include, but are not limited to (i) National Institute on Aging Genetics of Alzheimer’s Disease Data Storage Site (NIAGADS) at University of Pennsylvania, funded by NIA; and (ii) other NIA approved sites including but not limited to the **database of Genotype and Phenotype (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>) using the NCRAD Research Materials; and

WHEREAS, Recipient Institution, contingent upon Recipient Investigator being found to be a qualified investigator as determined by an approved advisory committee, desires to obtain NCRAD 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 NCRAD 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;

“Biospecimen Data” shall mean de-identified data derived from all analyses of the NCRAD 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;

“NCRAD Research Material” shall mean the biological material from humans including the biological samples and the Associated Phenotypic Data transferred from IU’s NCRAD 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 NCRAD Research Material, such as cell from cell, or organism from organism.

“Induced pluripotent stem cells (iPSCs)” shall mean a type of pluripotent stem cell derived from adult somatic cells that have been genetically reprogrammed to an embryonic stem (ES) cell-like state through the forced expression of genes and factors important for maintaining the defining properties of ES cells.

“Terminally Differentiated Cells” are specialized cells that have reached their final stage of differentiation and no longer have the capacity for further propagation and include cell types such as neurons, microglia, astrocytes, organoids, etc.

“Commercial Purposes” shall mean the sale, lease, license or other exploitation including but not limited to use, in whole or in part of the NCRAD Research Material, directly or indirectly, including any NCRAD Research Material contained or incorporated in Modifications, to a party for potential product development or profit-generating purpose, including, but not limited to, use of the NCRAD Research Material by Recipient Institution to perform contract research, to screen compound libraries, to develop, produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license or transfer of the NCRAD Research Material to any other party. Notwithstanding the foregoing, the sale, lease, license or other exploitation or other profit-generating activities developed using non-tangible scientific discoveries and/or knowledge gained through the use of NCRAD Research Material is not considered Commercial Purposes and is permissible provided neither the NCRAD Research Material nor Derived Materials are incorporated into such new products or profit-generating activities.

Terms and Conditions of Agreement:

1. The control and distribution of NCRAD Research Material is the responsibility of IU through the NCRAD facility and is made available as a service to qualified individuals in the research community to further research of Alzheimer’s Disease and related neurological diseases and aging.
2. IU and Recipient Institution agree that all NCRAD 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: NCRAD 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 NCRAD 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 NCRAD Investigator and will be subject to the terms and conditions of this Master Agreement. IU shall provide Recipient Institution with NCRAD 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. NCRAD Research Material represents a significant investment on the part of those who deposited the material with NCRAD and others, including the NIA and NIH. The NCRAD 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 as approved by Recipient Investigator in furtherance of research related to Alzheimer's Disease and related neurological 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 NCRAD Investigator shall list NCRAD 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. NCRAD 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 NCRAD Research Material.
5. Research Institution agrees to use the NCRAD Research Material, including the Original Research Material, Progeny, and Derived Materials, for Research Project purposes only. NCRAD Research Material shall not be used for Commercial Purposes. No right, title or interest in and to the NCRAD Research Material shall transfer to the Recipient Institution.
6. Subject to paragraph 3 of this Master Agreement, the NCRAD 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 NCRAD's prior written consent. The Recipient Institution or Recipient Investigator agrees to refer any such request for the NCRAD Research Material to NCRAD. For the avoidance of doubt, this transfer restriction shall not apply to transfer of Terminally Differentiated Cells derived from iPSCs materials that no longer contain the original iPSC material..
7. Recipient Investigator using NCRAD Research Material under this Master Agreement shall share Biospecimen Data derived from the Research Project by placing these Biospecimen Data and Associated Phenotypic Data in NIAGADS, or another NIA approved site, or all such sites. All approved sites will make these Biospecimen Data and Associated Phenotypic Data available to qualified investigators in the scientific community for secondary analysis in accordance with standards established by the NIA. The Recipient Investigator agrees to provide such Biospecimen 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 genome wide association study or next generation sequencing 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 NCRAD. 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 NCRAD under the terms and conditions of the MATERIAL TRANSFER AGREEMENT FOR THE TRANSFER OF DERIVED MATERIALS TO NCRAD, attached hereto and included herein as Appendix F. The Recipient Investigator agrees to provide NCRAD 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 NCRAD will consist of at least two vials of Derived Materials accompanied by documentation adequate to enable NCRAD investigators to culture and/or maintain Derived Material. Derived Material does not need to be transferred to NCRAD under this Section if, and only if, (i) the biological sample transferred from IU's NCRAD facility to the Recipient Institution, from which the Derived Material was created or isolated, was DNA, or (ii) Recipient has obtained NCRAD's prior written consent to not transfer the Derived Materials. Recipient Investigator shall not provide Derived Material to any other party.

9. Transfer of Biospecimen Data from NCRAD. The de-identified Biospecimen Data will be transferred from NCRAD to the Recipient Investigator. NCRAD will retain a copy of the de-identified Biospecimen Data in its data repository. Recipient Institution will endeavor not to re-associate the de-identified Biospecimen Data with any of the Recipient Institution's raw data and will promptly report any event in which re-identified data has been unlawfully or inappropriately disclosed to any third party.
10. Recipient Investigator will acknowledge the contribution of NCRAD, all institutions contributing to NCRAD, and the NIA in any and all oral and written presentations, disclosures, and publications resulting from any and all use and analyses of the NCRAD Research Material, as well as any data received from NCRAD. 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. 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.
11. Any NCRAD 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 NCRAD Research Material, the undersigned Recipient Institution assumes full responsibility for the safe and appropriate handling of the NCRAD Research Material. THE PARTY WHO ORIGINALLY DEPOSITED THE NCRAD RESEARCH MATERIAL WITH NCRAD, NCRAD, 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 IU.
12. The Recipient Institution and Recipient Investigator agree that the NCRAD Research Material including the biological samples 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 NCRAD Research Material was derived. In addition, should Recipient Institution or Recipient Investigator receive information that could result in identification of any subject from which the NCRAD Research Material was derived, then Recipient Institution and Recipient Investigator agree to refrain from providing such individual(s) with any NCRAD related Research Material data or results.
13. 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 NCRAD Research Material,

including accompanying Associated Phenotypic Data, Progeny and Derived Materials, and Recipient Investigator shall provide NCRAD with written certification of their destruction, unless permission to retain NCRAD Research Material is specifically provided in writing by IU to Recipient Institution. Obligations of Recipient Institution under clauses 5-11 shall survive termination. Subjects from whom NCRAD Research Material has been derived and provided to NCRAD may decide to withdraw consent for use of NCRAD Research Material. In the event NCRAD is notified that consent for use of NCRAD Research Material has been withdrawn, NCRAD may notify all recipients of that particular NCRAD Research Material and then the Recipient Institution shall immediately destroy the applicable NCRAD Research Material, including the Original Material, Progeny, Derived Material and Associated Phenotypic Data. Upon NCRAD's request Research Institution shall provide NCRAD with a written certification of destruction.

14. The NCRAD Research Material identified in each Appendix C is provided with a transmittal fee for Research Institution to reimburse NCRAD 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 NCRAD 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 Master Agreement and any attachments hereto/thereto may not be amended 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.

RECIPIENT INSTITUTION

Business Address of Recipient Institution:

Name of Recipient Institution:

By: _____

Authorized Official of Recipient Institution

Name:

Title:

Date:

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 NCRAD Research Material including the Progeny, Derived Materials and Associated Phenotypic Data.

RECIPIENT INVESTIGATOR

Shipping Address:

Read and Understood

By: _____

Name:

Title:

Date:

THE TRUSTEES OF INDIANA UNIVERSITY

By: _____

Authorized Official of Recipient Institution

Name:

Title:

Date:

NR _____

Read and Understood

By: _____

NCRAD Investigator

Name:

Title:

Date:

LEGAL ADDRESS:

Office for Research Administration

509 E. 3rd St.

Bloomington, IN 47401

oraresco@iu.edu

NCRAD ADDRESS

(Programmatic Correspondence)

Division of Hereditary Genomics

Indiana University

410 West 10th Street, HS 4000

Indianapolis, IN 46202-3002



APPENDIX C

ADDENDUM TO THE MASTER MATERIAL TRANSFER AGREEMENT: NCRAD 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 NCRAD” 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 terms and conditions of the Master Agreement shall govern this Appendix C.
3. Recipient Institution desires to obtain and IU agrees to provide the materials listed below (using specific identifiers for each material) to be included in NCRAD Research Material.
4. In consideration for the NCRAD Research Material, Recipient Institution agrees to pay per Table 1 a maximum amount of _____ samples for a maximum amount of \$ _____ which is to be paid by the IU with 30 days from when the invoice has been received. This per sample fee covers the material and effort to prepare and distribute the requested material, shipping, and handling. The overhead fee is determined by Indiana University.

Table 1: Fee Structure

	Year 1
# of Samples	
Per Sample Fee	
Overhead Fee	
Yearly Total	

5. If either party needs revisions to Appendix C regarding sample quantity or costs; an amended Appendix C can be reissued for signatures.

RECIPIENT INVESTIGATOR and RECIPIENT INSTITUTION INFORMATION

Recipient Investigator Name (Printed):

Phone:

Fax:

E-mail address:

Recipient Institution Name:

Shipping Address for receipt of the Research Materials:

Please list the NCRAD Research Material(s) being requested by the Recipient Institution (using specific identifiers for each Research Material) (attach separate page(s) as necessary):

Please describe the non-commercial research to be conducted by the Recipient Investigator ("Research Project") using the NCRAD Research Material(s) listed above (attach separate page(s) as necessary):

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

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 NCRAD Research Material described in this Appendix C, including the Progeny, Derived Material, and Associated Phenotypic Data.*

Recipient Investigator Signature

Date

NCRAD INVESTIGATOR INFORMATION and SIGNATURE

Name & Title of NCRAD Investigator:

Signature of NCRAD Investigator

Date

APPENDIX F

MATERIAL TRANSFER AGREEMENT FOR THE TRANSFER OF DERIVED MATERIALS TO NCRAD

This Material Transfer Agreement for the Transfer of Derived Materials to NCRAD (“Appendix F”) is made and entered into by and between the Trustees of Indiana University having offices at 509 East 3rd Street Bloomington IN 47401-3654, USA (hereinafter “IU”) and the Providing Institution identified on the signature page below (“Provider”) jointly referred to as the parties. This Appendix F is effective as of date of the last signature below (“Appendix F Effective Date”) and results from the terms and conditions of the “Master Material Transfer Agreement for the Transfer of Materials from NCRAD” between the parties with an **Effective Date of** _____ (hereinafter “Master Agreement”).

Whereas IU operates the National Centralized Repository for Alzheimer’s Disease and Related Dementias (NCRAD), a biorepository located within Indiana University, and which was 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 IU provided Original Research Material to Provider;

Whereas Provider generated Derived Materials (as defined in Master Agreement) under the terms and conditions of the Master Agreement;

Whereas Provider agreed in the Master Agreement to transfer Derived Materials (defined in Master Agreement) to IU at their NCRAD facility for distribution by NCRAD to nonprofit and for-profit organizations for furthering non-commercial research concerning Alzheimer’s Disease and related neurological diseases and aging;

Whereas Provider has obtained and generated Derived Material in compliance with all applicable statutes, rules, and regulations; and

Whereas Provider desires NCRAD, after consultation with the NIA and the relevant NCRAD advisory committee, to distribute Derived Material to qualified investigators in the research community.

Now Therefore, Provider and IU enter into this Appendix F governing the transfer and use of Derived Material.

1. The parties to this Appendix F are parties to the Master Agreement identified above and desire to execute this Appendix F as a result of the terms and conditions of the Master Agreement. Except as defined herein, all other capitalized terms shall be as defined in the Master Agreement.
2. The terms and conditions of this Appendix F shall be consistent with the Master Agreement.
3. Provider agrees, at its own expense, to transfer to IU (at the NCRAD facility) at least two vials of

the Derived Material(s) listed below as well as documentation adequate to enable NCRAD investigators to culture and/or maintain Derived Material. At any time, with the consent of IU, Provider may transfer additional vials of the same listed Derived Materials to IU under this Appendix F.

List Derived Materials: (Attach additional sheet if needed).

4. DERIVED MATERIAL MAY NOT BE USED IN EXPERIMENTS INVOLVING HUMAN SUBJECTS. IU agrees to comply with all Federal rules and regulations applicable to the use and handling of the Derived Material.
5. Derived Material will be used by NCRAD solely for teaching, noncommercial research purposes, and for subsequent distribution restricted to not be for Commercial Use. NCRAD will prepare and maintain Derived Material as appropriate in its facility, and will ship Derived Material to third party requesters under the terms and conditions of MASTER MATERIAL TRANSFER AGREEMENT FOR THE TRANSFER OF MATERIALS FROM NCRAD.
6. Derived Material transferred from Provider to IU pursuant to this Appendix F is understood to be experimental in nature and may have hazardous properties. PROVIDER 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 DERIVED 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 Derived 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.
7. This Appendix F 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.

[Signatures on following page]

IN WITNESS WHEREOF, the parties have executed Appendix F as of the Effective Date by their authorized representatives.

PROVIDER:

By: _____

Authorized Official of Provider
Name:

Date

Title:

THE TRUSTEES OF INDIANA UNIVERSITY

By: _____

Authorized Official
Name:

Date

Title:

Read and Understood

Signature of NCRAD Investigator

Date

Name:

Title:



LEGAL ADDRESS:

Office for Research Administration

509 East 3rd Street

Bloomington, IN 47401-3654

oraresco@iu.edu

NCRAD ADDRESS (Programmatic Correspondence)

Division of Hereditary Genomics

Indiana University

410 West 10th Street, HS 4000

Indianapolis, IN 46202-3002



APPENDIX G

Acknowledgement of Grant Support

According to Section 9 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 NCRAD Research Material using the following language:

NCRAD grant acknowledgement for all samples obtained from NCRAD repository: Samples from the National Centralized Repository for Alzheimer's Disease and Related Dementias (NCRAD), which receives government support under a cooperative agreement grant (U24 AG21886) awarded by the National Institute on Aging (NIA), 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:

- ☐ 4RTNI/4RTNI2: The Four Repeat Tauopathy Neuroimaging Initiative (4RTNI) study was made possible by National Institute on Aging grant 2R01AG038791. We thank the staff and investigators of the study as well as the participants and their families, whose help and participation made this work possible.
- ☐ 90+ STUDY: The 90+ Study receives support through a National Institute on Aging (NIA) grant R01AG21055. We thank the staff and investigators of the study as well as the participants and their families, whose help and participation made this work possible.
- ☐ AA Genetics: The AA Genetics Study was made possible by Grant Number R01 AG028786 from the National Institute on Aging (NIA). We thank the staff and investigators of the study as well as the participants and their families, whose help and participation made this work possible.
- ☐ ABC-DS: The Alzheimer's Biomarkers Consortium – Down Syndrome (ABC-DS) project is a longitudinal study of cognition and blood based, genetic and imaging biomarkers of Alzheimer's Disease. This study is funded by the National Institute on Aging (NIA) grants U01AG051406 and U01AG051412 and the National Institute for Child Health and Human Development (NICHD). We thank the ABC-DS study participants and the ABC-DS research and support staff for their contributions to this study.
- ☐ ADRC: Samples are contributed by the NIA-funded ADRCs: P30 AG066506 (PI Glenn Smith, PhD/David Loewenstein, PhD), P30 AG072980 (PI Eric Reiman, MD), P30 AG072978 (PI Ann McKee, MD), P30 AG072959 (PI James Leverenz, MD), P20 AG068053 (PI Justin Miller, PhD), P30 AG066462 (PI Scott Small, MD), P30 AG072958 (PI Heather Whitson, MD/Gwenn Garden, MD, PhD), P30 AG066511 (PI Allan Levey, MD, PhD), P30 AG072976 (PI Andrew Saykin, PsyD), P30 AG066507 (PI Marilyn Albert, PhD), P30 AG062421 (PI Bradley Hyman, MD, PhD), P30 AG062677 (PI Ronald Petersen, MD, PhD), P30 AG066514 (PI Mary Sano, PhD), P30 AG066512 (PI Thomas Wisniewski, MD), P30 AG072977 (PI Robert Vassar, PhD), P30 AG066518 (PI Lisa Silbert, MD, MCR/Miranda Lim, MD), P30 AG072975 (PI Julie Schneider, MD, MS), P30 AG066546 (PI Sudha Seshadri, MD, DM/Gladys Maestra, MD, PhD), P30 AG066515 (PI Victor Henderson, MD, MS/Kati Andreasson, MD), P20 AG068024 (PI Erik Roberson, MD, PhD), P30 AG072972 (PI Charles DeCarli, MD), P30 AG066519 (PI Frank LaFerla, PhD/Joshua Grill, PhD), P30 AG062429 (PI James Brewer, MD, PhD), P30 AG062422 (PI Gil Rabinovici, MD), P30 AG072973 (PI Russell Swerdlow, MD), P30 AG072946 (PI Linda Van Eldik, PhD), P30 AG072931 (PI Henry Paulson, MD, PhD), P30 AG072979 (PI David A Wolk, MD), P30 AG066468 (PI Oscar Lopez, MD/Julia Kofler, MD), P30 AG066530 (PI Helena Chui, MD/Arthur Toga, PhD), P30 AG012300 (PI Roger Rosenberg, MD), P30 AG066509 (PI Thomas Grabowski, MD), P30 AG062715 (PI Sanjay Asthana, MD, FRCP), P20 AG068077 (PI Gary Rosenberg, MD), P20 AG068082 (PI Angela Jefferson, PhD), P30 AG072947 (PI Suzanne Craft, PhD), P30 AG066444 (PI John Morris, MD), P30 AG066508 (PI Christopher van Dyck, MD/Stephen Strittmatter, MD, PhD).



- ADGC: The Alzheimer's Disease Genetics Consortium supported the collection of samples used in this study through National Institute on Aging (NIA) grants U01AG032984 and RC2AG036528.
- AGMP: Samples collected by the Alzheimer Gut Microbiome Project (AGMP) were supported by the National Institute On Aging of the National Institutes of Health under Award Number U19AG063744. (mPIs - Drs. Rima Kaddurah-Daouk, Rob Knight, and Sarkis Mazmanian).
- ALLFTD: The ARTFL-LEFFTDS Longitudinal Frontotemporal Lobar Degeneration (ALLFTD) study receives support through a National Institute of Aging (NIA) and National Institute of Neurological Disorders and Stroke (NINDS) grant U19AG063911. We thank the staff and investigators of the study as well as the participants and their families, whose help and participation made this work possible.
- API-ADAD: The API Colombia trial was supported by funding from the National Institute on Aging (1RF1AG041705, 5R01AG055444), part of the National Institutes of Health, Banner Alzheimer's Foundation and Genentech/Roche.
- ARTFL/LEFFTDS iPSCs: The Advancing Research and Treatment for Frontotemporal Lobar Degeneration (ARTFL) and Longitudinal Evaluation of Familial Frontotemporal Dementia Subjects (LEFFTDS) Studies were made possible through the support of the U.S Department of Health and Human Services (DHHS), the National Institute on Aging (NIA), the National Institute of Neurological Disorders and Stroke (NINDS) and the National Center for Advancing Translational Sciences (NCATS) grants: U54NS092089 and U01AG045390. We thank the staff and investigators of the study as well as the participants and their families, whose help and participation made this work possible. In addition, we acknowledge Drs. Kathryn Bowles and Alison Goate at the Icahn School of Medicine at Mount Sinai for their work in generating the CRISPR-edited iPSC lines. This work was funded by the Rainwater Charitable Foundation, the Association for Frontotemporal Dementia and the BrightFocus Foundation (#A2107144F).
- ANGI: The collection of the Amyloid Neuroimaging and Genetics Initiative (ANGI) samples was supported by a grant from the Alzheimer's Association (ANGI/IDEAS-17-497186). We thank the Alzheimer's Association for their support and the ANGI study participants for their contribution to the study. We would also like to acknowledge the Imaging Dementia – Evidence for Amyloid Scanning Study (iDEAS) from whom amyloid imaging and other clinical data were obtained.
- DIAN: The DIAN Study receives support through a National Institute on Aging (NIA) grant U19AG032438. We thank the staff and investigators of the study as well as the participants and their families, whose help and participation made this work possible.
- DMDC: The Duke Memory Disorders Clinic Biorepository is a one-time collection of blood and patient data donated by the patient population in the Duke Memory Disorders Clinic with a variety of neurodegenerative conditions.
- GEMS: This publication was made possible by Grant Number U01 AT000162 from the National Center for Complementary and Alternative Medicine, National Institutes of Health.
- GENERATION STUDY: The Generation Program was supported by Novartis Pharma AG, Basel, Switzerland and Amgen, Thousand Oaks, CA, USA, in collaboration with the Banner Alzheimer's Institute located in Phoenix, AZ, USA. Generation Study 1 was supported by funding from the National Institute on Aging (U19 AG046150), part of the National Institutes of Health, as well as the Alzheimer's Association, FBRI, GHR Foundation and Banner Alzheimer's Foundation. We thank the staff and investigators of the studies as well as the participants and their study partners, whose help and participation made this work possible.
- GIFT: Samples from the Genetic Investigation of Frontotemporal Dementia (GIFT) study, which were collected as a collaborative effort of 6 ADRCs (UCSF, UCLA, UCD, UCI, USC, Emory University) funded by the NIA (R01AG26938; PIs Geschwind/Coppola) and banked with the National Centralized Repository for Alzheimer's Disease and Related Dementias (NCRAD), which receives government support under a cooperative agreement grant (U24 AG21886) awarded by the National Institute on Aging (NIA), were used in this study. We thank



contributors, including the Alzheimer's Disease Centers who collected samples used in this study, as well as patients and their families, whose help and participation made this work possible

- ☐ HALS: Funding for this work was provided by NIH grant: R01 AG069265.
- ☐ INDIANAPOLIS-IBADAN STUDY: The Indianapolis-Ibadan dementia project is a 20 year comparative community based epidemiological study of the prevalence, incidence and risk factors for AD and dementia in populations of African origin, elderly African Americans in Indianapolis, Indiana and Yoruba in Ibadan, Nigeria. It was supported from 1991-2012 by NIH grants RO1 AG09956 and P30 AG 10133. We would like to take this opportunity to thank the many faculty and staff of the Universities of Ibadan and Indiana Medical School for their involvement as well as the 4000 plus elderly participants at each of the sites.
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 - ☐ P30 AG062715 (Sanjay Asthana, MD)

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- ☐ LEADS: The Longitudinal Early-onset Alzheimer's Disease Study is a longitudinal multi-site study designed to look at disease progression in adults with early-onset AD. Recruitment includes cognitively impaired and cognitively normal participants. This study is funded by NIA grants (R56 AG057195) and (U01 AG057195). We would like to thank the LEADS study participants and the LEADS research and support staff for their contributions to this study.
- ☐ LIFE-DSR: The Down Syndrome Clinical Trials Network (DS-CTN) Study of Alzheimer's Disease in Down Syndrome, Longitudinal Investigation for Enhancing Down Syndrome Research (LIFE-DSR) was a longitudinal study, collecting measures of change in cognition, function, behavior, and health status in adults with Down syndrome. Imaging and blood samples were collected for the development of plasma AD biomarkers useful in the DS population. This study was funded by LuMind IDSC Foundation with support from philanthropy, Alana Foundation, Merck, Eli Lilly, AbbVie and Alkermes. We are tremendously grateful to the study participants and their families, and the LIFE-DSR research and support staff for their contributions to LIFE-DSR.
- ☐ NIA-LOAD/NIA-AD-FBS: The NIA-LOAD National Institute on Aging Alzheimer's Disease Family Based Study (NIA-AD FBS) supported the collection of samples used in this study through National Institute on Aging (NIA) grants U24AG026395 and R01AG041797. We thank contributors, including the Alzheimer's Disease Centers who collected samples used in this study, as well as patients and their families, whose help and participation made this work possible.
- ☐ NAPS/NAPS2: The North American Prodromal Synucleinopathy Consortium for REM Sleep Behavior Disorder and North American Prodromal Synucleinopathy Consortium for RBD, Stage 2 (NAPS2) receives support through the National Institute of Health (NIH) grants R34 AG056639 and U19AG071754. We thank the participants in the NAPS/NAPS2 Consortium for their invaluable contributions as well as the support staff at each of the member sites for their assistance.

- ☐ NCRAD only as stated above.



- ☐ SAL-AD: A Phase 1b, 12-Month, Randomized, Double Blind, Placebo-Controlled Study of the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Preliminary Efficacy of Salsalate in Patients with Mild to Moderate Alzheimer’s Disease (UC-SAL-AD-001); NCT03277573. We thank the staff and investigators of the study as well as the participants and their families, whose help and participation made this work possible.
- ☐ T2 Protect AD: A Phase 2 Randomized Double-Blind Placebo-Controlled Trial to Evaluate the Efficacy and Safety of BHV-4157 in Patients with Mild to Moderate Alzheimer’s Disease receives support through Biohaven Pharmaceuticals, Inc. We thank the staff and investigators of the study as well as the participants and their families, whose help and participation made this work possible.
- ☐ VIVAMIND STUDY: The Seamless Phase 2A-B Randomized Double Blind Placebo Controlled Trial to Evaluate the Efficacy and Safety of PQ 912 in Patients with Early Alzheimer’s Disease (VIVA-MIND Study) was made possible through the support of the National Institute on Aging (NIA) under grant R01AG061146 and Vivoryan Therapeutics, N.V. We appreciate the staff, investigators, participants and their families for helping the VIVA-MIND trial meet milestones in Alzheimer’s disease research.
- ☐ WRAP: This research was supported by National Institutes of Health awards RF1 AG027161, and Clinical and Translational Science Award (CTSA) program, through the NIH National Center for Advancing Translational Sciences (NCATS), grant UL1TR002373; Portions of this research were supported by resources at the Wisconsin Alzheimer’s Institute and the Geriatric Research Education and Clinical Center of the William S. Middleton Memorial Veterans Hospital, Madison, WI. We gratefully acknowledge the WRAP study team who have carefully acquired the longitudinal data, and the WRAP participants who make this research possible.



APPENDIX I

INTELLECTUAL PROPERTY RIGHTS, USE RESTRICTIONS, AND LIMITED LICENSE FOR IPSCS FROM NCRAD

This Appendix I 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 OF MATERIALS FROM NCRAD between the Trustees of Indiana University and the Recipient Institution, with an Effective Date of _____ (hereinafter “Master Agreement From NCRAD”).

The parties agree as follows:

1. OWNERSHIP: IU grants Recipient Investigator a limited, non-transferable license to use the IU hiPSCs solely for Recipient Investigator’s internal life science research purposes in accordance with the terms of the IU Master Material Transfer Agreement under which the IU hiPSCs were delivered to Recipient Investigator and subject to the use restrictions in subsection 2 of this Appendix I and any applicable third party license restrictions or requirements included in subsection 3 of this Appendix I. No other license or right, express or implied, in or to the IU hiPSCs or the methods used to create them or any intellectual property owned by or licensed to IU including the intellectual property embodied in the IU hiPSCs is conveyed by the delivery of the IU hiPSCs or the parties’ performance under such IU Master Material Transfer Agreement. Recipient Investigator is solely responsible for obtaining any licenses it may require for Recipient Investigator’s specific research use(s) of the IU hiPSCs. Neither IU nor NCRAD makes any warranty or representation as to the validity, scope, or enforceability of the patents owned by or licensed to IU or NCRAD.

2. USE RESTRICTIONS: Recipient Investigator may differentiate the IU hiPSCs using publicly available or its own or licensed differentiation methods. No right to make, have made, offer to sell, or sell the IU hiPSCs is implied by the sale or delivery of the IU hiPSCs. Recipient Investigator shall not reverse engineer the IU hiPSCs.

The IU hiPSCs, and any cell directly or indirectly derived or made from the IU hiPSCs, must be used in accordance with all applicable laws and any applicable institutional review board protocol. Recipient Investigator shall not use the IU hiPSCs, or any cell directly or indirectly derived or made from the IU hiPSCs, in humans, in clinical trials, for diagnostic purposes involving human subjects, or for any therapeutic purposes. Recipient Investigator shall not use the IU hiPSCs, or any cell directly or indirectly derived or made from the IU hiPSCs, directly or indirectly to derive or make any human gamete or gamete precursor cell. The IU hiPSCs, and any cell directly or indirectly derived or made from the IU hiPSCs, may not be used for services for any third party; nor may they be used in the manufacture of any products. Recipient Investigator shall not deposit IU hiPSCs, or any cell directly or indirectly derived or made from the IU hiPSCs, into any biorepository or any other entity that intends to distribute the IU hiPSCs, or any cell directly or indirectly derived or made from the IU hiPSCs.

3. ADDITIONAL TERMS: IU to indicate any additional relevant terms described by Recipient indicated during transfer of samples to NCRAD. [Indicate “N/A” when not applicable.]

Signatures on the following page



READ AND ACKNOWLEDGED

Recipient Investigator

NCRAD Investigator

By: _____

By: _____

Name:

Name:

Title:

Title:

Date:

Date:

