WHEREAS, the National Institute on Aging (NIA), pursuant to its public health mission to identify and characterize the genetic basis of Alzheimer’s Disease (AD), supports research projects in which there is the generation of data resulting from the examination of Genetic Analysis Data and Associated Phenotypic Data by scientific investigators ("Submitters") studying affected and unaffected individuals;

WHEREAS, the NIA supports the National Institute on Aging Genetics of Alzheimer’s Disease Data Storage Site (NIAGADS https://www.niagads.org/) as operated under an NIA award to the University of Pennsylvania and NIAGADS maintains as a national resource both primary and secondary Genetic Analysis Data and Associated Phenotypic Data on the genetics of AD that are distributed for analysis by qualified scientific investigators conducting research specifically on the genetic bases of AD;

WHEREAS, the NIA supports the National Cell Repository for Alzheimer’s Disease (NCRAD http://ncrad.iu.edu/) as operated under an NIA award to Indiana University (www.ncrad.org);

WHEREAS the NIA supports the National Alzheimer's Coordinating Center (NACC https://www.alz.washington.edu/), as operated under an award to the University of Washington, which facilitates collaborative research among the NIA funded Alzheimer's Disease Centers (ADCs) and which maintains a database of information collected by the ADCs regarding affected and unaffected individuals;

WHEREAS, the NIA supports the Alzheimer’s Disease Sequencing Project (ADSP) https://www.niagads.org/adsp/content/home under awards funded to 1) identify new genes involved in AD, (2) identify gene alleles contributing to increased risk for or protection against the disease, (3) provide insight as to why individuals with known risk factor genes escape from developing AD, and (4) identify potential avenues for therapeutic approaches and prevention of the disease;

WHEREAS scientists funded by NIA for the study of the genetics of AD, the ADSP, scientists funded by NIA through NACC grants, and scientists who utilize NCRAD resources are expected to submit Genetic Analysis Data to NIAGADS;

WHEREAS scientists other than those funded by the NIA who are studying the genetics of AD may submit Genetic Analysis Data to NIAGADS;

WHEREAS, only deidentified data on family structure, age, sex, vital status, psychopathology, diagnosis, and other clinically relevant associated phenotypic information ("Associated Phenotypic Data") collected by Submitters, stripped of all personal identifiers and thus unlinkable to the individuals from whom they were obtained, are provided to NIAGADS by Submitters and by NCRAD;
WHEREAS, de-identified data derived from genotyping, mutation analysis, single nucleotide polymorphisms (SNPs) and other primary and secondary genetic analyses of Biomaterials and Associated Phenotypic Data conducted by Submitters and other scientists, stripped of all personal identifiers and thus unlinkable to the individuals from whom they were obtained, referred to as "Genetic Analysis Data", are provided to NIAGADS by Submitters;

Whereas Recipient Institution(s) is / are either individual Institutions or collaborating Institutions;

WHEREAS, ________________________________________________________________

desires to use Genetic Analysis Data and Associated Phenotypic Data at its sole risk and at no expense to NIAGADS

NOW THEREFORE, it is mutually agreed as follows:

1. NIAGADS agrees to transfer to Recipient(s) Genetic Analysis Data, Associated Phenotypic Data, and accompanying documentation for exclusive use by Recipient's (s’) principal investigator(s) ("Principal Investigator(s)") to conduct research on the genetic basis of AD.

2. Recipient(s) will submit to NIAGADS this signed and dated Distribution Agreement for which Genetic Analysis Data and Associated Phenotypic Data are requested.

3. Genetic Analysis Data, and Associated Phenotypic Data received from NIAGADS will be used exclusively by Principal Investigator(s) in connection with a specific genetic research project ("Research Project") for which Principal Investigator(s) has / have sole responsibility, and which is explicitly described on ATTACHMENT PAGES. This description will specify which Genetic Analysis Data are expected to be produced in the proposed Research Project.

4. This Distribution Agreement is not transferable to another recipient or to another facility. Principal Investigator cannot transfer the Research Project to a different institution unless NIAGADS agrees to a new Distribution Agreement with that institution. Recipient cannot appoint a new Principal Investigator, conduct the Research Project at a different facility under Recipient's control, or make other substantive changes, unless NIAGADS agrees to an appropriate amendment of this Distribution Agreement.

5. Recipient agrees to retain control over Genetic Analysis Data and Associated Phenotypic Data received from NIAGADS and further agrees not to provide them, with or without charge, to any other entity or any individual other than Principal Investigator(s).
6. No rights of Recipient(s) under this Distribution Agreement may be assigned or otherwise conveyed to any party, including a purchaser of Recipient(s), without the specific written agreement of NIAGADS.

7. NIAGADS agrees to make available upon individual requests of Principal Investigator(s) updates, if available, of family structure, Genetic Analysis Data and Associated Phenotypic Data on AD.

8. NIAGADS expects publication of secondary and meta-analysis data arising from Genetic Analysis Data. Principal Investigator(s) will acknowledge the contribution of Submitters who generated Genetic Analysis Data received from NIAGADS in any and all oral and written presentations, disclosures, publications, and patents resulting from any and all analyses of Genetic Analysis Data and Associated Phenotypic Data received from NIAGADS. Principal Investigator(s) will provide to NIA and NIAGADS yearly upon the anniversary of the signing of this document with a list of all such presentations, disclosures, publications, and patents. Principal Investigator(s) will use the following acknowledgement:

Acknowledgement for Alzheimer Disease Genetic Analysis Data
Biological samples and Associated Phenotypic Data used in primary data analyses were stored at Principal Investigators’ institutions, and at the National Cell Repository for Alzheimer’s Disease (NCRAD) at Indiana University funded by NIA. Associated Phenotypic Data used in primary and secondary data analyses were provided by Principal Investigators, the NIA funded Alzheimer’s Disease Centers (ADCs), and the National Alzheimer’s Coordinating Center (NACC) and stored at Principal Investigators’ institutions, NCRAD, and at the National Institute on Aging Alzheimer’s Disease Data Storage Site (NIAGADS) at the University of Pennsylvania, funded by NIA. Contributors to the Genetic Analysis Data included Principal Investigators on projects that were individually funded by NIA, other NIH institutes, private U.S. organizations, or foreign governmental or nongovernmental organizations.

Acknowledgement for the Alzheimer’s Disease Sequencing Project
Acknowledgment shall include the dbGaP accession number to the specific version of the dataset(s) analyzed.

The Alzheimer’s Disease Sequencing Project (ADSP) is comprised of: two Alzheimer’s Disease (AD) genetics consortia and three National Human Genome Research Institute (NHGRI) funded Large Scale Sequencing Centers (LSSC). The two AD genetics consortia are the Alzheimer’s Disease Genetics Consortium (ADGC) funded by NIA, and the Cohorts for Heart and Aging Research in Genomic Epidemiology (CHARGE) funded by NIA, NHLBI, other NIH institutes and other foreign governmental and non-governmental organizations. The ADGC cohorts include: Adult Changes in Thought (ACT), the Alzheimer’s Disease Centers (ADC), the Chicago Health and Aging Project (CHAP), the Memory and Aging Project (MAP), Mayo Clinic (MAYO), Mayo PD (MPD), Miami
University (MIA), the Multi-Institutional Research in Alzheimer’s Genetic Epidemiology (MIR), the National Cell Repository for Alzheimer’s Disease (NCRD), Religious Orders Study (ROS), the Texas Alzheimer’s Research and Care Consortium (TARC), Vanderbilt University (VAN), the Washington Heights-Inwood Columbia Aging Project (WHI) and the Washington University Sequencing Project (WUSP). The CHARGE cohorts include: the Atherosclerosis Risk in Communities Study (ARIC), the Austrian Stroke Prevention Study (ASPS), the Cardiovascular Health Study (CHS), the Erasmus Rucphen Family Study (ERF), the Framingham Heart Study (FHS), and the Rotterdam Study (RS). The three LSSC are: the Human Genome Sequencing Center at the Baylor College of Medicine, the Broad Institute Genome Center, and the Washington University Genome Institute. Biological samples and associated phenotypic data used in primary data analyses were stored at Study Investigators’ institutions, and at the National Cell Repository for Alzheimer’s Disease (NCRAD) at Indiana University funded by NIA. Associated Phenotypic Data used in primary and secondary data analyses were provided by Study Investigators, the NIA funded Alzheimer’s Disease Centers (ADCs), and the National Alzheimer’s Coordinating Center (NACC) and stored at Study Investigators’ institutions, NCRAD, National Institute on Aging Alzheimer’s Disease Data Storage Site (NIAGADS) at the University of Pennsylvania, funded by NIA, and at the Database for Genotypes and Phenotypes (dbGaP) funded by NIH. Contributors to the Genetic Analysis Data included Study Investigators on projects that were individually funded by NIA, and other NIH institutes, and by private U.S. organizations, or foreign governmental or nongovernmental organizations.

9. Recipient(s) agree(s) to provide NIAGADS with an electronic copy of any and all primary and secondary Genetic Analysis Data derived from Associated Phenotypic Data received under the conditions of this Distribution Agreement for both primary and secondary genetic data analysis, including meta-analysis. Recipient(s) will provide to NIAGADS this Genetic Analysis Data immediately upon acceptance of each journal publication or patent application submission, whichever is earlier. This will continue until the Research Project is completed and will include primary, secondary, and meta-analyses. NIAGADS may at any time distribute these Genetic Analysis Data to qualified scientific investigators in a time frame that is compliant with the NIH Genomics Data Sharing Policy http://gds.nih.gov/. Recipient(s) agree(s) to notify NIAGADS within 60 days of any patent applications that are filed or of any pending or awarded patent applications that are based on the Genetic Analysis Data. Such information will be provided to NIAGADS on an annual basis. This obligation will continue until the project is complete.

10. The Research Project shall be deemed completed for purposes of this agreement three (3) years after its effective date or when the project is completed and the data have been placed in the public domain. If the project will extend beyond the prescribed three years, the Recipient(s) will obtain NIAGADS’s agreement to an extension of the agreement. Any such extension must
be in writing and in accordance with the terms and conditions under which NIAGADS is
distributing data at that time.

11. Recipient(s) agree(s) that Genetic Analysis Data and Associated Phenotypic Data received
from NIAGADS will not be used, either alone or in conjunction with any other information, in
any effort whatsoever to establish the individual identities of any of the subjects from whom
Genetic Analysis Data and Associated Phenotypic Data were obtained.

12. NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE MERCHANTABILITY OR
FITNESS FOR ANY PURPOSE OF THE GENETIC ANALYSIS DATA AND ASSOCIATED PHENOTYPIC
DATA PROVIDED BY NIAGADS TO RECIPIENT(S) UNDER THIS AGREEMENT, OR THAT THE
GENETIC ANALYSIS DATA AND ASSOCIATED PHENOTYPIC DATA MAY BE EXPLOITED WITHOUT
INFRINGEMENT THE INTELLECTUAL PROPERTY OR PROPRIETARY RIGHTS OF ANY THIRD PARTIES.

13. The United States (US) Government and its funding recipient that operates NIAGADS are not
responsible for the accuracy of Genetic Analysis Data and Associated Phenotypic Data, provided
by Submitters and other Recipients, which are distributed by NIAGADS.

14. Recipient(s) agree(s) not to claim, infer, or imply endorsement by the US Government of the
Research Project, the institution, or personnel conducting the Research Project or any resulting
commercial product(s). To the extent permitted by law, non-US Government Recipients agree
to hold the US Government, its funding recipient that operates NIAGADS, Submitters, and other
Recipients providing Genetic Analysis Data to hold NIAGADS harmless and to indemnify all such
parties for all liabilities, demands, damages, expenses, and losses arising out of Recipient's use
for any purpose of Genetic Analysis Data and Associated Phenotypic Data received from
NIAGADS.

15. Execution of this Distribution Agreement is contingent upon Recipient's(s') compliance with
all terms and conditions of any existing Distribution Agreement.

16. NIAGADS may terminate this Distribution Agreement if Recipient(s) is/are in default of any
of the terms specified herein and if the deficit has not been remedied within 30 days after the
date of written notice by NIAGADS of such deficit.

17. Failure to comply with any of the terms specified herein may result in disqualification of
Recipient from receiving additional Genetic Analysis Data and Associated Phenotypic Data from
NIAGADS.

18. NIA reserves the right to distribute, through NIAGADS, any and all Genetic Analysis Data and
Associated Phenotypic Data to others and to use it for its own purposes. NIAGADS may also
make available upon request from NIA, genetic data to be deposited at an NIH database which
will continue to ensure the privacy and confidentiality of the individuals that participated in the
original genetic association studies.
NIAGADS Data Distribution Agreement

19. Amendments to this Distribution Agreement must be made in writing and agreed to by both parties.

20. Recipient(s) expressly certify/certifies that the contents of any statements made or reflected in this Distribution Agreement are truthful and accurate.

21. This Distribution Agreement shall be construed in accordance with Federal law as applied by the Federal courts in the Commonwealth of Pennsylvania.

__________________________________   __________________________
Signature of the Principal Investigator   Date

__________________________________   __________________________
Printed Name of the Principal Investigator   Date

__________________________________   __________________________
Signature of the Institutional Official   Date

__________________________________   __________________________
Printed name of the Institutional Official   Date

Additional signatures on next page.
NIAGADS Data Distribution Agreement

Additional Signatures

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