NIMH Center for Collaborative Genetic Studies

Distribution Agreement

WHEREAS, the National Institute of Mental Health ("NIMH"), pursuant to its public health mission to identify and characterize the genetic basis of Alzheimer disease, schizophrenia, bipolar disorder, autism spectrum disorders, and other mental disorders, supports research projects in which there is collection by scientific investigators ("Submitters") of blood and/or other cell samples and clinical data from affected individuals and their relatives;

WHEREAS, anonymous blood and/or other cell samples collected by Submitters, stripped of all personal identifiers and thus unlinkable to the individuals from whom they were obtained, are provided to the NIMH Center for Genetic Studies ("the Center"), as operated under an NIMH cooperative agreement to Rutgers University for the production of transformed or reprogrammed cell lines and extraction of DNA (cell lines and DNA samples are collectively known as "Biomaterials");

WHEREAS, anonymous data on family structure, age, sex, vital status, psychopathology, diagnosis, and other clinically relevant information ("Clinical Data") collected by Submitters, stripped of all personal identifiers and thus unlinkable to the individuals from whom they were obtained, are provided to the Center;

WHEREAS, anonymous data derived from genotyping, mutation analysis, and other genetic analyses of Biomaterials and Clinical Data ("Genetic Analysis Data") conducted by Submitters and other scientists, stripped of all personal identifiers and thus unlinkable to the individuals from whom they were obtained, are provided to the Center;

WHEREAS, the Center maintains as a national resource Biomaterials, Clinical Data, and Genetic Analysis Data on mental disorders that are distributed for analysis by qualified scientific investigators conducting research specifically on the genetic bases of those disorders. The disorders for which Biomaterials, Clinical Data, and Genetic Analysis Data are currently being distributed by the Center are listed on the NIMH Human Genetics Initiative World Wide Web site at https://www.nimhgenetics.org/nimh_human_genetics_initiative/index.php;

WHEREAS,

Receiving Institution ("Recipient") desires to use Biomaterials, Clinical Data, and Genetic Analysis Data at its sole risk and at no expense to NIMH.

NOW THEREFORE, it is mutually agreed as follows:

1. NIMH, through the Center, agrees to transfer to Recipient Biomaterials and/or Clinical Data for exclusive use by Recipient's principal investigator ("Principal Investigator") to conduct research on the genetic basis of

_____

(please list disorder(s) that is/are being researched).

2. Recipient will submit a signed and dated Distribution Agreement to NIMH for Biomaterials, Clinical Data, and Genetic Analysis Data that are being requested.

3. Biomaterials, Genetic Analysis Data, and Clinical Data received from the Center will be used exclusively by Principal Investigator and individuals working on the project under the direction and control of the Principal Investigator in connection with a specific genetic research project ("Research Project") for which Principal Investigator has 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 that is not under the control of Recipient. Principal Investigator cannot transfer the Research Project to a different institution unless NIMH 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 NIMH agrees to an appropriate amendment of this Distribution Agreement.

5. Recipient agrees to retain control over Biomaterials, Clinical Data and Genetic Analysis Data received from the Center and further agrees not to provide them, with or without charge, to any other entity or any individual other than Principal Investigator.

6. No rights of Recipient under this Distribution Agreement may be assigned or otherwise conveyed to any party, including a purchaser of Recipient, without the specific written agreement of NIMH.

7. NIMH, through the Center, agrees to provide Principal Investigator with Clinical Data and accompanying documentation, on the disorder specified above.

8. NIMH, through the Center, agrees to provide Principal Investigator with periodic updates of Clinical Data on the disorder specified above, including updates of family structure as determined from laboratory analysis of DNA samples, if available.

9. NIMH, through the Center, agrees to provide Principal Investigator with periodic updates of Genetic Analysis Data on the disorder specified above, if available, including the name and address of the scientists who generated such Genetic Analysis Data.

10. Biomaterials are provided at a cost of $100 per 25 micrograms of lymphoblastoid cell line DNA, $200 per lymphoblastoid cell line, $250 per fibroblast or olfactory cell line, and $500 per reprogrammed cell line such as induced pluripotent stem cells (iPSCs). Bulk orders will be provided at reduced cost. Where available, whole blood DNA is provided at a cost of $100 per 3 micrograms. Services for reprogramming source cells (e.g., fibroblasts) to iPSCs or other reprogrammed cell types will be provided at full cost to the Recipient, ranging from $6,400 to $11,000 per line, depending on source material and extent of validation; with the use of this service the $500 distribution cost will be waived. These fees are subject to change following written notification from NIMH. Recipient agrees to pay any and all fees to the Center. If Recipient is awarded a peer-reviewed NIMH research grant to specifically analyze Biomaterials for the disorder specified above, the fees for obtaining those Biomaterials will be waived (with the exception of reprogramming services). Shipping costs will be applied to all orders.

11. Recipients who propose to use Biomaterials in the Research Project described in this agreement must request those Biomaterials no later than four (4) months from the date on which Clinical Data and Genetic Analysis Data are made available by the Center. If Biomaterials are not requested within that time period, the proposed Research Project will be deemed terminated. At that time, Recipient will notify NIMH and provide written certification that any and all Clinical Data and Genetic Analysis Data were destroyed by Recipient, unless Recipient obtains NIMH'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 NIMH is distributing data and biomaterials at that time.

12. Recipient agrees to provide an electronic copy of all raw molecular data (genotyping, ChIP-Seq, RNA-seq, and other genomic, epigenetic and protective data) and Genetic Analysis Data derived from Clinical Data and Biomaterials received under the conditions of this Distribution Agreement. Recipient will submit such genetic data to dbGaP no later than the agreed-upon data submission date as stipulated in the Data/Resource Sharing Plan and dbGaP study registration, or upon publication of research in which such data were analyzed, whichever comes first. NIH may at any time distribute these Genetic Data to qualified scientific investigators, subject to any patents or pending patent applications of Recipient. Recipient will provide Genetic Data, indexed by NIMH subject ID number and cell-ID number, in the electronic format specified by dbGaP. When genotyping has been conducted, DNA marker names and allele sizes in base pairs will be provided for each individual subject, as indexed by NIMH subject ID number. Descriptive information about each typed marker, including marker name, allele sizes in base pairs and corresponding frequencies, relative distances in Megabases and in Centimorgans, marker heterozygosity, and the source of information used to determine map location, will also be provided. Recipient also agrees to submit to the Center all data relevant to the establishment of family structure as determined from laboratory analysis, at the time such determinations are made.

13. Principal Investigator will acknowledge the contribution of scientists who generated Genetic Analysis Data received from the Center, in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of

these Genetic Analysis Data. Principal Investigator will provide to NIMH a list of all such presentations, disclosures, and publications.

14. Principal Investigator will acknowledge the contribution of both the NIMH Repository & Genomics Resource and Submitters in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of Biomaterials and Clinical Data received from the Center. Principal Investigator will provide to NIMH a list of all such presentations, disclosures, and publications. Principal Investigator will use the following acknowledgment: "Bio-samples and/or data for this publication were obtained from NIMH Repository & Genomics Resource, a centralized national biorepository for genetic studies of psychiatric disorders." In addition to the above statement, Principal Investigator will use detailed collection-specific acknowledgements found at: https://www.nimhgenetics.org/acknowledgements.php, depending upon which disorder Biomaterials and Clinical Data were received and analyzed.

15. When the Research Project is completed, Recipient must notify NIMH and provide written certification of the destruction of Biomaterials, Clinical Data, and Genetic Analysis Data received from the Center in accordance with any applicable laws and/or accepted safety procedures. The Research Project shall be deemed completed for purposes of this agreement three (3) years after the effective date of this agreement, unless Recipient obtains NIMH'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 NIMH is distributing data and biomaterials at that time.

16. Recipient agrees that Biomaterials, Clinical Data, and Genetic Analysis Data received from the Center 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 Biomaterials, Clinical Data, and Genetic Analysis Data were obtained.

17. Recipient agrees that Biomaterials, their progeny, and unmodified or modified derivatives thereof will not be used in any experiments or procedures that are not disclosed and approved as part of the Research Project, and will not be used in human experimentation of any kind.

18. Recipient acknowledges that the Biomaterials may be the subject of a patent application or covered by patent rights in one or more countries. Except as provided in this Distribution Agreement, no express or implied licenses to such patent rights are provided. NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE MERCHANTABILITY OR FITNESS FOR ANY PURPOSE OF THE BIOMATERIALS, CLINICAL DATA, AND GENETIC ANALYSIS DATA PROVIDED BY THE CENTER TO RECIPIENT UNDER THIS AGREEMENT, OR THAT THE BIOMATERIALS, CLINICAL DATA, AND GENETIC ANALYSIS DATA MAY BE EXPLOITED WITHOUT INFRINGING THE INTELLECTUAL PROPERTY OR PROPRIETARY RIGHTS OF ANY THIRD PARTIES.

19. The United States (US) Government and its contractor and subcontractor that operate the Center are not responsible for the accuracy of Clinical Data and Genetic Analysis

Data, provided by Submitters and other Recipients, which are distributed by the Center.

20. Recipient acknowledges that Biomaterials have the potential for carrying viruses, latent viral genomes, and other infectious agents in an in apparent state. Recipient agrees to treat Biomaterials received from the Center as if they were not free of contaminations, and that Biomaterials will be handled by trained persons under laboratory conditions that afford adequate biohazard containment. By accepting Biomaterials from the Center, Recipient assumes full responsibility for their safe and appropriate handling.

21. Recipient agrees 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 contractor and subcontractor that operate the Center, Submitters, and other Recipients providing Genetic Analysis Data to the Center 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 Biomaterials, Clinical Data, and Genetic Analysis Data received from the Center.

22. Recipient acknowledges that the conditions for use of Biomaterials, Clinical Data, and Genetic Analysis Data are approved by the Institutional Review Board (IRB) of the NIMH contractor and subcontractor that operate the Center in accordance with Department of Health and Human Services regulations at 45 CFR Part 46. Recipient agrees to comply fully with all such conditions and to report promptly to NIMH any proposed changes in the Research Project and any unanticipated problems involving risks to subjects or others. Recipient remains subject to applicable State or local laws or regulations and institutional policies which provide additional protections for human subjects.

The following two paragraphs apply to Recipients that have entered into a previous Distribution Agreement.

23. Execution of this Distribution Agreement is contingent upon Recipient's compliance with all terms and conditions of any existing Distribution Agreement. This excludes the requirement stated in paragraph 6 of Distribution Agreements executed from January 1, 1996 through December 31, 1997, in which Recipient agreed to provide genotyping data one year after laboratory confirmation or upon publication of marker data, whichever came first.

24. The requirements set forth in this paragraph supersede the requirements set forth in paragraph 6 of Distribution Agreements executed from January 1, 1996 through December 31, 1997. If Recipient executed a Distribution Agreement more than twelve (12) months from the time of the current request for Biomaterials, Clinical Data, and Genetic Analysis Data, and has not provided to NIMH Genetic Analysis Data derived from any Biomaterials previously received from NIMH or its current or previous contractor(s), Recipient agrees that provision to NIMH, through the Center, of such Genetic Analysis Data is a condition for execution of the current Distribution Agreement. If Recipient executed a Distribution Agreement within twelve (12) months from the time of the current request for Biomaterials, Clinical Data and

Genetic Analysis Data, Recipient agrees to provide to NIMH, through the Center, any Genetic Analysis Data derived from such Biomaterials within twelve (12) months from the time that Biomaterials were previously received, or upon publication of research in which such data were analyzed, whichever comes first.

25. NIMH may terminate this Distribution Agreement if Recipient is 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 NIMH of such deficit. Upon termination of this Distribution Agreement, Recipient agrees to return all unused Biomaterials, Clinical Data, and Genetic Analysis Data to the Center, or provide NIMH with written certification of their destruction.

26. Failure to comply with any of the terms specified herein may result in disqualification of Recipient from receiving additional Biomaterials, Clinical Data, and Genetic Analysis Data from NIMH, as provided by the Center.

27. NIMH reserves the right to distribute, through the Center, any and all Biomaterials, Clinical Data, and Genetic Analysis Data to others and to use it for its own purposes.

28. Recipient expressly certifies that the contents of any statements made or reflected in this Distribution Agreement are truthful and accurate.

29. This Distribution Agreement shall be construed in accordance with Federal law as applied by the Federal courts in the District of Columbia.

NIMH Center for Collaborative Genetic Studies
Distribution Agreement

Please list disorder(s) that is/are being researched_____

_____

Name and Title, Principal Investigator **(PLEASE PRINT)**

Mailing Address, Principal Investigator

Telephone Number, Principal Investigator

Fax Number, Principal Investigator

E-Mail, Principal Investigator

Name and Title, Receiving Institution's Authorized Representative

Mailing Address, Receiving Institution's Authorized Representative

Telephone Number, Receiving Institution's Authorized Representative

Fax Number, Receiving Institution's Authorized Representative

E-Mail, Receiving Institution's Authorized Representative

DATED SIGNATURES

Signature, Principal Investigator Date

Signature, Receiving Institution's Authorized Representative Date

Signature, NIMH Center for Genetic Studies' Authorized Representative
Rutgers University Date

Signature, NIMH's Authorized Representative Date