NeuroBioBank (NBB) Brain and Tissue Repositories
Material Transfer Agreement (MTA)

This Material Transfer Agreement (the "Agreement") is by and between the National Institutes of Health ("NIH" or "PROVIDER" or "PROVIDER ORGANIZATION") and _____ ("RECIPIENT" or "RECIPIENT ORGANIZATION"), as represented by investigator, _____, serving as RECIPIENT SCIENTIST, for purposes stated herein under the following conditions of this Agreement. Throughout this Agreement, PROVIDER and RECIPIENT ORGANIZATION are collectively referred to as the "Parties." This Agreement will become effective upon the date of the last signature below.

WHEREAS, the collection of biospecimens from deceased individuals is not legally classified as human subjects research under 45 CFR Part 46. However, donor recruitment sites typically will obtain written or telephonic authorization from next-of-kin for participation in the NBB in order to ensure that the wishes of the family and the deceased are respected. The written consent form typically includes statements covering the intention to perform genetic analyses, establish cell lines, and to share data with the scientific community (including academic and industry) for research (non-clinical) use. The NBB project obtains authorization for broad future research use.

WHEREAS, some NBB sites also enroll donors prospectively; this is considered human subjects research and as such requires approval from an institutional IRB and informed consent.

WHEREAS, the NBB Brain and Tissue Repositories (BTRs), as funded by NIH, serve as a resource of high-quality human biospecimens and associated data for the broader scientific community, including basic and clinical researchers and the biotechnology and pharmaceutical industries that rely on biospecimens for basic and translational neuroscience and drug development; and

WHEREAS the National Institute of Mental Health (NIMH), an NIH institute, has administrative oversight of the NBB and therefore the NIMH will handle the approval and tracking of all Material Transfer Agreements (MTAs) involving NBB biospecimens and data; and

WHEREAS, the NIMH has approved the request to transfer biospecimens and related data from one or more NBB BTRs to the RECIPIENT SCIENTIST for the research purposes identified herein.

NOW, THEREFORE, the PROVIDER and RECIPIENT ORGANIZATION, acting on behalf of the RECIPIENT SCIENTIST, agree as follows:

Definitions. The following definitions, taken from the Uniform Biological Materials Transfer Agreement (UBMTA), will apply to this Agreement:

a. Unmodified Derivatives: Substances created by the RECIPIENT which constitute an unmodified functional subunit or product expressed by the MATERIAL provided under this Agreement. Some examples include, without limitation: subclones of unmodified cell lines, purified or fractionated subsets of the MATERIAL, proteins expressed by DNA/RNA isolated

from MATERIAL, or monoclonal antibodies secreted by a hybridoma cell line created using MATERIAL.

b. Modifications: Substances created by the RECIPIENT which contain or incorporate all or part of the MATERIAL, including but not limited to induced pluripotent stem cells (iPSC) and their subsequently derived cell lines, and transfected cells.
c. MATERIAL: Original biospecimens being transferred.
d. DATA: data associated with MATERIAL and transferred to the RECIPIENT along with the MATERIAL.

1. The MATERIAL and any Unmodified Derivatives are the sole property of the PROVIDER and their use is subject to the terms of this MTA.

2. The requested MATERIAL and DATA are the property of the PROVIDER and are made available to RECIPIENT SCIENTIST and RECIPIENT ORGANIZATION as a service to the research community.

3. The RECIPIENT acknowledges that the MATERIAL and DATA provided are for research purposes and such MATERIAL, or any Unmodified Derivatives or Modifications may not be used in human subjects or for the treatment or diagnosis of human subjects or patients.

4. The MATERIAL and DATA provided by PROVIDER will be de-identified and will contain no Protected Health Information (PHI), as defined by the Federal Health Insurance Portability and Accountability Act (HIPAA, 45 C.F.R. 164).

5. The MATERIAL and/or DATA will not be further distributed to a third party without the PROVIDER's prior written consent. The RECIPIENT will refer any request for the MATERIAL and/or DATA to the PROVIDER. To the extent supplies of MATERIAL are available, the PROVIDER may make the MATERIAL available, under a separate Agreement.

6. The RECIPIENT agrees that the MATERIAL and DATA will only be used for the stated research purposes as described in the request for MATERIAL. Any changes to these research purposes and procedures must be reported to the PROVIDER.

7. The RECIPIENT agrees to acknowledge the source of the MATERIAL and/or DATA in any presentations, disclosures, or publications resulting from any analyses conducted on the MATERIALS, Modifications, or Unmodified Derivatives. Acknowledgement should refer to the “NIH NeuroBioBank” as the source of the tissue (see Appendix A for example statement).

8. The RECIPIENT agrees to send the PROVIDER the citation for any scientific publication resulting from research involving the MATERIAL, Modifications, or Unmodified Derivatives and/or DATA.

9. Any MATERIAL and DATA transferred pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties, contain infectious agents, or pose other health and safety risks. The PROVIDER makes no representations and extends no warranties of any kind, either expressed or implied. There are no express or implied warranties of merchantability or fitness for a particular purpose, or that the use of the MATERIAL will not infringe

any patent, copyright, trademark, or other proprietary rights. The RECIPIENT will use the MATERIAL with all due skill and care and with dignity, sensitivity and respect. Unless prohibited by law, RECIPIENT assumes all liability for claims for damages against it by third parties which may arise from the use, storage or disposal of the MATERIAL and DATA except that, to the extent permitted by law, the PROVIDER will be liable to the RECIPIENT when the damage is caused by the gross negligence or willful misconduct of the PROVIDER.

10. The RECIPIENT acknowledges that the diagnosis of disorders attributed to the MATERIAL is based on available clinical records and has not been verified by genetic testing. The PROVIDER is not liable for discrepant sequence data provided with the MATERIAL and DATA.

11. The RECIPIENT agrees to use the MATERIAL and DATA in compliance with all applicable statutes and regulations.

12. The RECIPIENT will not pursue information identifying the donors of the MATERIAL or their family members and will not attempt to contact the same.

13. The RECIPIENT agrees to place research results derived from the MATERIAL and DATA in the public domain, such as publication in a scientific journal or presentation at a scientific meeting. The details of the data sharing and reporting plans within the RECIPIENT request for MATERIAL should be consistent with NIH data sharing policies (see Appendix A).

14. The RECIPIENT agrees that no Intellectual Property (IP) rights are granted to any MATERIALS AND/OR DATA.

15. Subject to the PROVIDER'S rights in the MATERIAL, the RECIPIENT owns all right, title, and interest in and to any Modifications or any discoveries or inventions developed using the MATERIAL and/or DATA or from the knowledge generated by the research project. The RECIPIENT will not sell or seek to gain monetary profit from the MATERIAL or Unmodified Derivatives or DATA themselves.

16. Either Party may terminate this Agreement for any reason upon thirty (30) days written notice to the other Party.

17. The provisions of Paragraphs 3, 5, 6, 8, 11, 12, and 14 will survive the expiration or early termination of this Agreement.

The MTA will be valid for one year from the date it is executed and may be used for any future requests within that one year period.

Authorized signatories of the PROVIDER and RECIPIENT must sign this letter and return one signed copy to the PROVIDER by uploading the signed MTA to the designated NIH platform (e.g. NBB centralized tissue request website). Provided that the request is approved and MATERIAL is available, the PROVIDER will then electronically counter-sign the MTA and send the MATERIAL.

RECIPIENT INFORMATION

RECIPIENT ORGANIZATION Name: _____

RECIPIENT ORGANIZATION Authorized Official:

_____

Authorized Official Printed Name and Title

_____

Signature Authorized Official RECIPIENT ORGANIZATION Date

RECIPIENT SCIENTIST:

_____

Printed Name and Title

_____

Signature of RECIPIENT SCIENTIST Date

Address for Legal Notices sent to RECIPIENT ORGANIZATION:

_____

_____

Address for Notices sent to RECIPIENT SCIENTIST:

_____

_____

PROVIDER INFORMATION

Provider Authorized Signatory Name and Title:

Michelle Freund, Office of Technology Development and Coordination

_____

Signature of Authorized Official

Provider Organization:

Office of the Director, National Institute of Mental Health (NIMH), part of National Institutes of Health (NIH), component of United States Department of Health and Human Services (USDHHS)

Address for Provider for Notices Sent by U.S. Postal Service, FedEx, UPS, and Other Couriers

National Institute of Mental Health (NIMH)
National Institutes of Health (NIH)
6001 Executive Blvd., Room 7101
Rockville, MD 20852
T (301) 443-1815
E-mail: neurobiobank@mail.nih.gov

Appendix A

Acknowledgement Statement. All published scientific findings derived from tissues and/or data obtained through the NeuroBioBank must acknowledge the NIH NeuroBioBank as the source. NIH NeuroBioBank must be notified of any publications so that the publication can be linked to the tissues or data.

Data Release Principles and Standards. Data from NeuroBioBank tissues are expected to be shared in an easily accessible format so as to increase the value of the significant public investment. Consistent with achieving the goals of this program, the NIH expects that information such as data syntheses, associated data (e.g. phenotype and exposure data), any information necessary to interpret the submitted data, such as study protocols, data instruments, survey tools, and any other meta data collected will be widely shared with the scientific community for research and made publicly available through a data portal or data repositories. Such release of data will be shared with NeuroBioBank so that location of data can be linked to the tissues or data.

Data Sharing Plan. As of August 27, 2014, all NIH-funded research that generates large-scale human or non-human genomic data as well as the use of these data for subsequent research must follow the NIH Genomic Data Sharing (GDS) Policy (for complete details, refer to: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html; see also, http://gds.nih.gov). Large-scale data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomic, epigenomic, and gene expression data, irrespective of funding level and funding mechanism (e.g., grant, contract, cooperative agreement, or intramural support). NIH Institutes or Centers (ICs) may expect submission of data from smaller scale research projects based on the state of the science, the programmatic priorities of the IC funding the research, and the utility of the data for the research community.

This policy might be revised should further NIH-wide data sharing guidance become available.