NINDS Human Cell and Data Repository
Material Transfer Agreement (Working Cell Bank)

This Materials Transfer Agreement (the "MTA") is made as of this _____, ___, 20__, (the "Effective Date") by and between **[NHCDR]**, with an office at **[145 Bevier Road, Piscataway, NJ 08854]** ("Provider"), and **[PLEASE INSERT FULL LEGAL NAME OF PRINCIPAL INVESTIGATOR ("Principal Investigator"), REPRESENTING _____("Institution"),** with an office at **[PLEASE INSERT PI ADDRESS]**.

MISSION

The mission of the **NINDS Human Cell and Data Repository (NHCDR)** is to provide, develop, and manage cell and data research resources in order to advance discoveries into the causes and treatments of neurological diseases while concurrently protecting the rights of subjects providing human material resources.

PURCHASE PROCESS

This **Material Transfer Agreement (MTA)** must be executed by each investigator requesting **cell lines, DNA samples or other biological material (NINDS Materials)** from the NHCDR. Both the **recipient principal investigator (Principal Investigator)** and the institutional official who is authorized to make *legally binding* agreements for the **institution that employs the Principal Investigator (Institution)** must sign this MTA. Please note that the Institution will also be provided with appropriate certificate of assurance on cell lines to include karyotype information, pluripotency markers, mycoplasma testing, etc.

In addition to this MTA, the Principal Investigator must complete a **Statement of Research Intent (SRI)** (electronically for on-line orders or in hard copy for special requests for secondary distribution) describing the purpose of the research to be done using the NINDS Materials.

All fully executed MTAs will be kept on file at the NHCDR and considered applicable to subsequent purchases made by the Principal Investigator if at the same institution named in the originally signed MTA. If the NHCDR substantially revises this form in the future, the NHCDR reserves the right to require the Principal Investigator to execute the latest version of the MTA. A new SRI describing the intended research is required for all purchases.

HUMAN SUBJECTS ISSUES

Principal Investigator and Institution acknowledge that the conditions for use of the NINDS Materials are governed by the Rutgers University Institution Review Board **(IRB)** and must be in compliance with the Office of Human Research Protections (OHRP), Department of Health and Human Services (DHHS), regulations for the protection of human subjects found at 45 CFR Part 46. Under these regulations, research activities involving publicly available, existing specimens and data or research with existing specimens and data from which human subjects cannot be identified, either directly or through linked identifiers, may be exempt from the DHHS policy for protection of human research subjects (45 CFR §46.101(b)(4)). Recipient Principal Investigator and Institution remains subject to all state and local laws or regulations and institutional policies which may provide additional protections for human subjects.

When applicable to research described in the SRI, Principal Investigator should adhere to ethical standards established by the International Society for Stem Cell Research (ISSCR).

NHCDR will under no circumstances provide information that will allow identification of individual subjects. Further, the Principal Investigator agrees not to try to identify or contact the donor subject from whom the sample was derived.

HUMAN EXPERIMENTATION

Principal Investigator and Institution agree that the introduction of NINDS Materials or their derivatives (any cell product where NINDS Materials were used for creation or modification of the product) in human subjects, their administration to human subjects as part of clinical trials, or for diagnostic purposes involving human subjects, is strictly prohibited without the written consent of NINDS.

DETERMINATION OF OWNERSHIP

NINDS retains ownership of the NINDS Materials and any functional subunits thereof contained or incorporated in derivatives. Inventions and ownership of intellectual property resulting from the research will be determined by U.S. patent law.

COMMERCIAL USE

NINDS Materials were developed by Lonza under contract for the NIH. NINDS places no restriction on development of commercial products resulting from the knowledge gained from research using the NINDS Materials. However, iPS Academia Japan, Inc. ("iPS AJ") owns patents that may cover certain of the NINDS Materials, and can be contacted at http://ips-cell.net/e/license/policy.html to discuss obtaining a commercial license. NINDS Materials or material isolated from them, such as RNA, DNA, or protein, may not themselves be used in the manufacture of commercial products or sold or distributed as commercial products themselves. The NHCDR cannot provide a warranty or any assurances whatsoever relating to third-party property interests that may exist in the NINDS Materials. The attached Appendix A, "Notification to Recipient," is incorporated fully into this MTA as required by Lonza's license with iPS AJ and cannot be further modified. The Principal Investigator and the Institution will be responsible for adhering to the terms and conditions in Appendix A as well as those in the MTA. The terms and conditions attached hereto as Appendix A shall take precedence over any contrary or inconsistent terms and conditions appearing or referred to in this MTA.

RESEARCH USE

Principal Investigator and Institution understand that the NINDS Materials provided under this MTA are experimental and are for use in research, in teaching and as standards in clinical genetics laboratories. Principal Investigators using NINDS Materials as research standards or controls are responsible for complying with all applicable laws and regulations specific to that intended use, including any requirements for FDA approval.

SHARED USE AND SECONDARY DISTRIBUTION

Secondary distribution, or the sharing of NINDS Materials with members of laboratories other than the Recipient Principal Investigator's, is not permitted except under certain clearly defined circumstances as described below and only with prior written authorization from the NHCDR. The Principal Investigator should read the restrictions under this section and Appendix A very carefully and contact the NHCDR Principal Investigator before distributing NINDS Materials or their derivatives. Any secondary distribution must include a copy of Appendix A, Notification to Recipient.

NINDS established an NINDS Repository Group consisting of program directors and staff with relevant scientific knowledge to review and authorize secondary distribution requests for NINDS Materials. Consistent with its mission to facilitate neuroscience research, the NHCDR and NINDS Repository Group will permit secondary distribution if such requests are supported under the mission of the NHCDR, if it can be established that protection of human subjects is ensured as necessary, if quality control of the NINDS Materials is ensured, and if an appropriate process for secondary distribution (as outlined in this MTA) is followed.

Permitted Uses as reviewed and approved by the NINDS Repository Group:

1. *Single-use, multi-investigator collaboration*. Two or more investigators initiate a collaborative project that requires the use by each laboratory of identical NINDS Materials. At the time the order is placed, Principal Investigator explains in the SRI that the NINDS Materials will be shared with specific, named collaborator(s) for a common research project. Secondary distribution to named collaborator(s) may be permitted when the SRI is identical for all the named collaborator(s). Each collaborating investigator must have a current, executed MTA on file with NINDS Repository.

2. *Multi-user core facility*. A core facility (for high-throughput screening, for example) obtains NINDS Materials for use by investigators within the facility to perform assays for use at that facility or for a consortium. The SRI should describe the ranges of studies that will be conducted using the NINDS Materials. In this situation, use of these materials in the core facility may be permitted if the NINDS Repository Review Group is assured that the use of the NINDS Materials is consistent with the research subject's informed consent. Since the NINDS Materials will be used in the same facility for multiple investigators, quality can be ensured.

3. *Distribution of samples for use as reference materials*. Principal Investigator may place an order for one or more NINDS Materials and describe in the SRI that the NINDS Materials will be distributed, either with or without modification, for use as a reference material. The SRI may not be able to specify which laboratories will receive NINDS Materials. The NINDS Repository Review Group will decide this type of request on a case-by-case basis with the advice of the NHCDR's Project Officer. Principal Investigator will be required to maintain records of where the NINDS Materials are sent. NINDS Materials must be distributed under a written agreement which includes: (i) a disclaimer of the NHCDR's responsibility regarding safety and quality; (ii) a requirement that the NINDS Materials be returned to the Principal Investigator or destroyed within a certain time frame or at the conclusion of the research; (iii) a restriction that the NINDS Materials or their derivatives are never transferred to a third party; and (iv) a notification that the NINDS Repository was the source of the materials.

4. *Development of a Unique Resource*. This permitted use involves the development of NINDS Materials into **substances comprising or containing an unmodified subunit of NINDS Materials (Unique Resource)**. Consistent with the NIH Research Tools Policy (64 FR 72,090), a Unique Resource encompasses a range of research tools, including but not limited to: subclones of unmodified cell lines, purified or fractionated subsets of the NINDS Materials, proteins expressed by DNA/RNA supplied by Principal Investigator, induced pluripotent cell lines, and monoclonal antibodies secreted by a hybridoma cell line. A Unique Resource is substantially different from the NINDS Materials. Simply modifying NINDS materials obtained from NHCDR through the introduction of a gene (e.g., hTERT or green fluorescent protein) would not qualify as creating a Unique Resource. The Principal Investigator's Institution may distribute the Unique Resource by using an appropriate agreement between the Institution and the **entity receiving the Unique Resource (Secondary Recipient)**. The transfer agreement for the Unique Resource must include:
   (i) a statement listing the identification number(s) of the NINDS Materials from which the Unique Resource was derived;
   (ii) a statement that the Secondary Recipient must acknowledge the NHCDR and the NINDS Materials identification number in any publications or presentations based on the utilization of the Unique Resource;
   (iii) a statement prohibiting the use of the unmodified Unique Resource for human experimentation or commercialization;
   (iv) a disclaimer that the Unique Resource has not undergone the standard quality control of the NHCDR; and

(v) a statement that the Unique Resource may not be used for commercial purposes except for internal research purposes.
(vi) A copy of Appendix A, Notification to Recipient.

In addition to the above statements (i) – (v), the transfer agreement for the Unique Resource must be consistent with NIH's Simple Letter Agreement for the Transfer of Materials or the UBMTA (Uniform Biological Material Transfer Agreement). Both of these agreements are found under the MTA section at: http://www.ott.nih.gov/forms-model-agreements#MTACTA

Institution is required to provide the NHCDR with the Unique Resource for distribution and protocols for its care, if appropriate, after an agreed upon embargo period.

Prohibited Uses:

1. *Multi-purpose use*. At some point after obtaining the NINDS Materials, Principal Investigator wishes to give a portion of the NINDS Materials or a culture derived from the NINDS Materials to another investigator who is working on a different project. In this case, secondary distribution of the NINDS Materials is prohibited because use of the NINDS Materials by the other investigator may not be consistent with the terms of this MTA and the Principal Investigator's SRI.

2. **The secondary distribution or sale of NINDS Materials for any purpose not specifically authorized above is PROHIBITED unless otherwise noted by NINDS Program staff**. If NINDS Materials are requested from Principal Investigator, he/she should direct the requester to the NHCDR.

DESTRUCTION AND FINAL REPORT

Unless instructed otherwise by NHCDR, Principal Investigator must destroy the NINDS Materials within five (5) years of receipt of the NINDS Materials or upon completion of research described under the SRI, whichever is shorter. Within six (6) months after destruction of the NINDS Materials, Principal Investigator must email NINDS@dls.rutgers.edu a final report including: (i) a brief summary of the research results or outcome of the project; (ii) a list of related publications or presentations; and (iii) a statement attesting destruction of the NINDS Materials. Principal Investigator should include his/her current contact information in the final report should follow up be required.

PUBLICATION

Principal Investigator must acknowledge the NHCDR and the NINDS Materials identification number in any publications or presentations based on research utilizing the NINDS Materials. Additionally, the following acknowledgement statement must be included in all publications, "*Generation of the GMP line LiPSC-GR1.1 was supported by the NIH Common Fund Regenerative Medicine Program, and reported in Stem Cell Reports. The NIH Common Fund and the National Center for Advancing Translational Sciences (NCATS) are joint stewards of the LiPSC-GR1.1 resource."*

BIOHAZARD

All cultured animal and human cells as well as other human biological have the potential for carrying viruses, latent viral genomes, and other infectious agents in a latent or inactive state. NINDS Materials should therefore NOT be treated as if they are free of contamination. NINDS Materials should always be handled carefully by trained persons under laboratory conditions which afford adequate biohazard containment following MINIMUM SAFETY GUIDELINES RECOMMENDED FOR WORKING WITH HUMAN CELL CULTURES. By

accepting the NINDS Materials, the undersigned assumes full responsibility for their safe and appropriate handling. Principal Investigator agrees to provide notice to the NHCDR of any containment or quality issues related to the NINDS Materials.

WARRANTY AND LIABILITY

THE NHCDR MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. IN ADDITION, 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.

IN ADDITION THE PRINCIPAL INVESTIGATOR'S INSTITUION ACKNOWLEDGES THAT THE MATERIAL MAY BE THE SUBJECT OF A PATENT APPLICATION OR COVERED BY PATENT RIGHTS IN ONE OR MORE COUNTRIES. EXCEPT AS PROVIDED IN THIS AGREEMENT, NO EXPRESS OR IMPLIED LICENSES TO SUCH PATENT RIGHTS ARE PROVIDED. UNLESS SPECIFICALLY STATED, NO LICENSE OR RIGHT TO USE ANY THIRD PARTY PATENT, TECHNOLOGY, OR INTELLECTUAL PROPERTY IS CONVEYED TO PRINCIPAL INVESTIGATOR'S INSTITUION UNDER THIS AGREEMENT. IT IS THE SOLE RESPONSIBILITY OF THE PRINCIPAL INVESTIGATOR TO OBTAIN FROM THIRD PARTIES THAT MAY HAVE A PROPRIETARY INTEREST IN THE MATERIAL, OR MODIFICATIONS (ADDITION OR DELETION OF BIOLOGICAL COMPONENTS) OR DERIVATIVES THEREOF, ANY PERMISSIONS NECESSARY THAT ARE CONSISTENT WITH PRINCIPAL INVESTIGATOR'S INSTITUION INTENDED USE OF THE MATERIAL, MODIFICATIONS, OR DERIVATIVES.

Liability Statement for Institutions Receiving NINDS Materials: Institution agrees to be responsible for any claims, costs, damages, or expenses resulting from any injury (including death), damage, or loss that may arise from its use or distribution of the NINDS Materials obtained under this agreement or any derivatives thereof to the extent permitted by law.

Liability Statement for U.S. Government Laboratories Receiving NINDS Materials: Institution assumes the liability for any claims, damages, injuries, or expenses arising from its use of NINDS Materials or derivatives, but only to the extent provided under the Federal Tort Claims Act (28 U.S.C. Chapter 171).

Indemnification: Unless Institution is a State Institution or federal agency or is otherwise prohibited by law, Institution agrees to hold harmless the United States Government, Rutgers University, the NINDS Human Cell and Data Repository and the contributor of the NINDS Materials from any claims, costs, damages, or expenses resulting from any injury (including death), damage, or loss that may arise from its use. This provision shall also apply to any derivatives of the NINDS Materials.

SIGNATURES

We, the undersigned, have read and understand this document and agree to adhere to the terms and conditions stated therein.

Name of Institution: _____

Name of Principal Investigator: _____

Signature of Principal Investigator: _____

Date: _____

Name of Institution Official who can make legal commitments on behalf of the Institution: _____

Title of Institution Official: _____

Signature of Institution Official: _____

Date: _____

The signed MTA and the SRI may be submitted to the NHCDR through the NHCDR online catalog

To contact the NHCDR
e-mail: NINDS@dls.rutgers.edu

or contact

Michael Sheldon, Ph.D.
RUCDR Infinite Biologics Director, Stem Cell Center
Associate Professor in Genetics
Rutgers, The State University of New Jersey
sheldon@dls.rutgers.edu

Appendix A

Notification to RECIPIENT

Definitions:

LONZA: Lonza Walkersville, Inc. and any of its affiliates.

CLIENT: The person or entity purchasing MATERIAL from LONZA.

RECIPIENT: CLIENT and/or any party receiving the MATERIAL or ALTERED CELLS either directly or indirectly from CLIENT.

MATERIAL: Pluripotent cells, derivatives of pluripotent cells, genetic modifications of pluripotent cells, partially-differentiated cells, and terminally-differentiated cells.

ALTERED CELLS: Changes made to the MATERIAL made only by a RECIPIENT.

COMMERCIAL PURPOSES: The sale, lease, license, or other transfer of MATERIAL or ALTERED CELLS to a for-profit organization. COMMERCIAL PURPOSES shall also include uses of MATERIAL or ALTERED CELLS by a for-profit organization, to perform contract research, to perform screening of compound libraries to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of MATERIAL or ALTERED CELLS. However, industrially sponsored academic research shall not be considered a use of MATERIAL or ALTERED CELLS for COMMERCIAL PURPOSES per se, unless any of the above conditions of this definition are met. NOR WILL SENDING THE MATERIAL OR ALTERED CELLS TO A FOR-PROFIT ORGANIZATION TO PERFORM SERVICES ON BEHALF OF THE RECIPIENT SUCH AS KARYOTYPING, HYBRIDIZATION, ARRAY AND GENOME ANALYSIS UNLESS THE ABOVE CONDITIONS ARE MET.

1. RECIPIENT shall have the right, without restriction, to distribute MATERIAL or ALTERED CELLS to academic organizations or to academic core laboratories for their internal non-commercial purpose only, which may include generation of data. RECIPIENT may also distribute MATERIAL or ALTERED CELLS to for-profit organizations under appropriate license from any third party(ies) required for such distribution.

2. RECIPIENT shall acknowledge that the MATERIAL and ALTERED CELLS is or may be the subject of an issued patent or pending patent application. Except as provided in this Notification, no express or implied licenses or other rights are provided to RECIPIENT under any patents, patent applications, trade secrets, licenses or other proprietary rights("INTELLECTUAL PROPERTY") of LONZA, or any third parties, including any altered forms of the MATERIAL made by LONZA. In particular, no express or implied licenses or other rights are provided to use the MATERIAL, or any related patents of LONZA, or any third parties, for COMMERCIAL PURPOSES.

3. If RECIPIENT desires to use or license the MATERIAL or ALTERED CELLS for COMMERCIAL PURPOSES, RECIPIENT agrees, in advance of such use, to negotiate in good faith with parties holding applicable intellectual property rights to establish the terms of a commercial license. It is understood by RECIPIENT that LONZA or any third party shall have no obligation to grant such a license to RECIPIENT, and may grant exclusive or non-exclusive commercial licenses to others, or sell or assign all or part of the rights in the MATERIAL or ALTERED CELLS to any third party(ies), subject to any pre-existing rights held by others and obligations to the Federal Government. For clarity, any terminally-differentiated cells made and sold by LONZA may be used by RECIPIENT for COMMERCIAL PURPOSES.

Nothing in this paragraph, however, shall prevent RECIPIENT from granting commercial licenses under RECIPIENT's intellectual property rights claiming ALTERED CELLS, or methods of their manufacture or their use.

4. Any MATERIAL and ALTERED CELLS delivered pursuant to this Notification is understood to be experimental in nature and may have hazardous properties. LONZA 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 ANDALTERED CELLS WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

5. Except to the extent prohibited by law, RECIPIENT assumes all liability for damages which may arise from its use, storage or disposal of the MATERIAL or ALTERED CELLS. LONZA will not be liable to RECIPIENT for any loss, claim or demand made by RECIPIENT, or made against RECIPIENT by any other party, due to or arising from the use of the MATERIAL or ALTERED CELLS by RECIPIENT, except to the extent permitted by law when caused by the gross negligence or willful misconduct of LONZA.

6. RECIPIENT agrees to use MATERIAL and ALTERED CELLS in compliance with all applicable statutes and regulations and agrees to notify RECIPIENT of same. For the removal of doubt, RECIPIENT shall not use MATERIAL and ALTERED CELLS for application and use for human/animal therapeutic, diagnostic and/or prophylactic purposes including but not limited to clinical applications, cell therapy, transplantation, and /or regenerative medicine without appropriate license.

7. RECIPIENT shall be required to convey a copy of this "Notification to RECIPIENT" to any person or party receiving MATERIAL or ALTERED CELLS from RECIPIENT.

8. LONZA has obtained its rights to manufacture the MATERIAL pursuant to a non-exclusive license agreement ("the AJ agreement") with iPS Academia Japan, Inc. ("AJ"). No rights, either express or implied, obtained by LONZA in the AJ agreement are provided to RECIPIENT to use the MATERIAL or ALTERED CELLS.

9. If RECIPIENT desires to use or license the MATERIAL or ALTERED CELLS for COMMERCIAL PURPOSES, RECIPIENT is not required to obtain further license or other rights from LONZA resulting from its manufacturing of the MATERIAL. Notwithstanding, the RECIPIENT is still required to meet the obligations of any other party (which may include AJ) provided for in this notification for use of the MATERIAL or ALTERED CELLS for COMMERCIAL PURPOSES.