**MATERIAL TRANSFER AGREEMENT ASSURANCE FORM**

**For access to iPSC lines derived from patients with CDKL5 deficiency deposited at the Coriell Institute for Medical Research**

This Material Transfer Agreement Assurance Form ("Assurance Form") serves to provide a record of the below-described biological material transfer and to document the agreement between the PROVIDER, on behalf of the PROVIDER SCIENTIST, (identified below) and the RECIPIENT, on behalf of the RECIPIENT SCIENTIST (identified below) to abide by all terms and conditions of this Assurance Form and the Material Transfer Agreement ("MTA"), attached herein as EXHIBIT A, (collectively, the "Agreement").

The Coriell Institute for Medical Research ("CORIELL") is an independent, non-profit research center with a mission to accelerate scientific discovery by generating world-class biomaterials and conducting groundbreaking research in biobanking, personalized medicine, and stem cell biology.

The PROVIDER has engaged CORIELL to provide certain services related to the management of biological materials, including distribution and shipment. The ORIGINAL MATERIAL (identified below) has been deposited by the PROVIDER and is made available through CORIELL as a service to the scientific community.

| **ORIGINAL MATERIAL:** | |
|---|---|
| **PROVIDER (Organization providing the ORIGINAL MATERIAL)** | |
| Organization: | The Trustees of the University of Pennsylvania (also referred hereinafter as "PENN") |
| Address: | Office of Research Services, 3451 Walnut Street, Franklin Bldg., 5th Floor, Philadelphia, PA 19104-6205 |
| **PROVIDER SCIENTIST** | |
| Name: | Sheridan Carrington, Ph.D. |
| Title: | Program Manager |
| **RECIPIENT SCIENTIST** | |
| Name: | _____ |
| Title: | _____ |
| Address: | _____ |
| **RECIPIENT ORGANIZATION CERTIFICATION** (Organization receiving the **ORIGINAL MATERIAL**) | |
| Organization: | _____ |
| Address: | _____ |
| **RESEARCH** (provide summary of research): | |
| **EFFECTIVE DATE:** | |
| **TERMINATION DATE** (optional): | |

CORIELL will forward the ORIGINAL MATERIAL to the RECIPIENT SCIENTIST upon receipt of a completed Assurance Form signed by the RECIPIENT SCIENTIST and by an authorized representative of the RECIPIENT.

By signing below, the RECIPIENT agrees and the RECIPIENT SCIENTIST acknowledges to abide by and be bound by the terms and conditions of this Agreement, including its EXHIBITS and APPENDICES, as of the Effective Date specified above.

**RECIPIENT**

By:_____
Signature

_____
Name of Authorized Representative

_____
Title

_____
Date

**RECIPIENT SCIENTIST**

By:_____
Signature

_____
Name

_____
Title

_____
Date

**EXHIBIT A**

**MATERIAL TRANSFER AGREEMENT ("MTA")**

**I. Definitions:**

1. PROVIDER: Organization providing the ORIGINAL MATERIAL as specified in the Assurance Form.

2. PROVIDER SCIENTIST: The name and address is specified in the Assurance Form.

3. RECIPIENT: Organization receiving the ORIGINAL MATERIAL as specified in the Assurance Form.

4. RECIPIENT SCIENTIST: The name and address is specified in the Assurance Form.

5. ORIGINAL MATERIAL: The description of the material being transferred as specified in the Assurance Form.

6. MATERIAL: ORIGINAL MATERIAL, PROGENY, and UNMODIFIED DERIVATIVES. The MATERIAL shall not include: (a) MODIFICATIONS, or (b) other substances created by the RECIPIENT through the use of the MATERIAL which are not MODIFICATIONS, PROGENY, or UNMODIFIED DERIVATIVES.

7. PROGENY: Unmodified descendant from the MATERIAL, such as virus from virus, cell from cell, or organism from organism.

8. UNMODIFIED DERIVATIVES: Substances created by the RECIPIENT which constitute an unmodified functional subunit or product expressed by the ORIGINAL MATERIAL. Some examples include: subclones of unmodified cell lines, purified or fractionated subsets of the ORIGINAL MATERIAL, proteins expressed by DNA/RNA supplied by the PROVIDER, or monoclonal antibodies secreted by a hybridoma cell line.

9. MODIFICATIONS: Substances created by the RECIPIENT which contain/incorporate the MATERIAL.

10. COMMERCIAL PURPOSES: The sale, lease, license, or other transfer of the MATERIAL or MODIFICATIONS to a for-profit organization. COMMERCIAL PURPOSES shall also include uses of the MATERIAL or MODIFICATIONS by any organization, including RECIPIENT, to perform contract research, to screen 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 the MATERIAL or MODIFICATIONS to a for-profit organization. However, industrially sponsored academic research shall not be considered a use of the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSES per se, unless any of the above conditions of this definition are met.

11. NON-PROFIT ORGANIZATION(S): A university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any non-profit scientific or educational organization qualified under a state non-profit organization statute. As used herein, the term also includes government agencies.

12. CORIELL: The Coriell Institute for Medical Research serving as the repository for the ORIGINAL MATERIAL as specified in the Assurance Form.

**II. Terms and Conditions of this MTA**

RECIPIENT acknowledges that the ORIGINAL MATERIAL is developed under a collaboration between the PROVIDER and Boston Children's Hospital ("BCH") and originates from CDKL5-mutant patient fibroblasts collected at BCH under BCH's IRB protocol #P00016119 ("CDKL5 Material"). Consequently, the following terms and conditions shall apply:

1. BCH retains ownership of the CDKL5 Material and the MATERIAL, including any MATERIAL contained or incorporated in MODIFICATIONS. The transfer of the ORIGINAL MATERIAL to RECIPIENT hereunder shall not affect BCH's ownership of the CDKL5 Material and the ORIGINAL MATERIAL.

2. The RECIPIENT retains ownership of: (a) MODIFICATIONS (except that, BCH retains ownership rights to the MATERIAL included therein), and (b) those substances created through the use of the MATERIAL or MODIFICATIONS, but which are not PROGENY or UNMODIFIED DERIVATIVES or MODIFICATIONS (i.e., do not contain the ORIGINAL MATERIAL, PROGENY, UNMODIFIED DERIVATIVES).

3. The RECIPIENT and the RECIPIENT SCIENTIST agree that the MATERIAL:

(a) is to be used solely for any lawful internal research purposes related to CDKL5 in neurological disease ("Field of Use"). A summary of the specific research project within the Field of Use shall be listed under Research in the Assurance Form;

(b) will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects without the written consent of the PROVIDER;

(c) is to be used only at the RECIPIENT organization and only in the RECIPIENT SCIENTIST's laboratory under the direction of the RECIPIENT SCIENTIST or others working under his/her direct supervision; and

(d) will not be transferred to anyone else within the RECIPIENT organization or outside of the RECIPIENT organization without the prior written consent of the PROVIDER and that all such third parties who request the ORIGINAL MATERIAL have to obtain it from CORIELL.

4. The RECIPIENT and the RECIPIENT SCIENTIST agree to refer to the PROVIDER any request for the MATERIAL from anyone other than those persons working under the RECIPIENT SCIENTIST's direct supervision.

5.

(a) The RECIPIENT and/or the RECIPIENT SCIENTIST shall have the right, without restriction, to distribute substances created by the RECIPIENT through the use of the ORIGINAL MATERIAL only if those substances are not PROGENY, UNMODIFIED DERIVATIVES, or MODIFICATIONS.

(b) Under a separate agreement at least as protective of the PROVIDER's and BCH's rights, the RECIPIENT may distribute MODIFICATIONS to NONPROFIT ORGANIZATION(S) for research and teaching purposes only, with notification to the

PROVIDER. The RECIPIENT shall provide MODIFICATIONS to the PROVIDER upon request.

(c) Without written consent from BCH, the RECIPIENT and/or the RECIPIENT SCIENTIST may NOT provide MODIFICATIONS for COMMERCIAL PURPOSES. It is recognized by the RECIPIENT that such COMMERCIAL PURPOSES may require a commercial license from BCH and BCH has no obligation to grant a commercial license to its ownership interest in the MATERIAL incorporated in the MODIFICATIONS. Nothing in this paragraph, however, shall prevent the RECIPIENT from granting commercial licenses under the RECIPIENT's intellectual property rights claiming such MODIFICATIONS, or methods of their manufacture or their use.

6. The RECIPIENT acknowledges that the MATERIAL is or may be the subject of a patent application. Except as provided in this MTA, no express or implied licenses or other rights are provided to the RECIPIENT under any patents, patent applications, trade secrets or other proprietary rights of BCH, including any altered forms of the MATERIAL made by BCH. In particular, no express or implied licenses or other rights are provided to use the MATERIAL, MODIFICATIONS, or any related patents of BCH for COMMERCIAL PURPOSES.

7. If the RECIPIENT desires to use or license the MATERIAL or MODIFICATIONS for COMMERCIAL PURPOSES, the RECIPIENT agrees, in advance of such use, to negotiate in good faith with BCH to establish the terms of a commercial license. It is understood by the RECIPIENT that BCH shall have no obligation to grant such a license to the 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 to any third party(ies), subject to any pre-existing rights held by others and obligations to the Federal Government.

8. The RECIPIENT is free to file patent application(s) claiming inventions made by the RECIPIENT through the use of the MATERIAL but agrees to notify and consult with BCH prior to filing a patent application claiming MODIFICATIONS, or method(s) of manufacture, or use(s), or improvements of the MATERIAL. The RECIPIENT shall not file patent applications claiming the CDKL5 Material and/or the MATERIAL unless RECIPIENT receives prior written consent from BCH. The transfer of the ORIGINAL MATERIAL to the RECIPIENT hereunder shall not result in the grant of any rights in the CDKL5 Material and/or the ORIGINAL MATERIAL other than those specifically set forth in this MTA. This MTA does not affect the intellectual property rights of either party in effect before the MTA has been commenced or any intellectual property rights unrelated to the MTA.

9. Any MATERIAL delivered pursuant to this MTA is understood to be experimental in nature and may have hazardous properties. The PROVIDER AND BCH MAKE 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 OR MODIFICATIONS WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. TO THE MAXIMUM EXTENT PERMITTED BY LAW, IN NO EVENT SHALL A PARTY OR ITS TRUSTEES, DIRECTORS, OFFICERS AND EMPLOYEES, BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND, REGARDLESS OF WHETHER SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

10.

(a) Liability Statement for State Institutions and NON-PROFIT ORGANIZATIONS: RECIPIENT agrees to be responsible for any claims, costs, damages, or expenses resulting from breach of this Agreement and any injury (including death), damage, or loss that may arise from the use, handling, storage, transfer or disposal of the MATERIAL or MODIFICATIONS, provided that for State Institutions this shall be applicable to the extent permitted under the laws of the RECIPIENT's state.

(b) Liability Statement for U.S. Government Laboratories: The United States assumes the liability for any claims, damages, injuries, or expenses arising from breach of this Agreement and the use, handling, storage, transfer or disposal of the MATERIAL or MODIFICATIONS, but only to the extent provided under the Federal Tort Claims Act (28 U.S.C. Chapter 171).

(c) Liability Statement for All Other Institutions: The RECIPIENT agrees to indemnify and hold harmless the PROVIDER, BCH, and CORIELL from any claims, costs, damages, or expenses, including third party claims, resulting from breach of this Agreement and any injury (including death), damage, or loss that may arise from the use, handling, storage, transfer, or disposal of the MATERIAL or the MODIFICATIONS.

11. This MTA shall not be interpreted to prevent or delay publication of research findings resulting from the use of the MATERIAL or the MODIFICATIONS. The RECIPIENT SCIENTIST agrees to provide appropriate acknowledgement of the source of the MATERIAL in all publications.

12.

(a) The RECIPIENT agrees to use, handle, transfer, and dispose of the MATERIAL in compliance with all applicable statutes and regulations, including but not limited to, Public Health Service and National Institutes of Health regulations and guidelines such as, for example, those relating to research involving the use of animals or recombinant DNA as well as all export and re-export control laws and regulations, including the Export Administration Regulations maintained by the U.S. Department of Commerce, trade and economic sanctions maintained by the Treasury Department's Office of Foreign Assets Control, and the International Traffic in Arms Regulations maintained by the Department of State. The RECIPIENT agrees not to directly or indirectly sell, export, re-export, transfer, divert, or otherwise dispose of the MATERIAL and MODIFICATIONS, specifically to any destination, entity, or person prohibited by the laws or regulations of the United States, without obtaining prior authorization from the competent government authorities as required by those laws and regulations.

(b) It is understood that BCH and PROVIDER do not intend to provide to the RECIPIENT any protected health information ("PHI") as such term is defined in the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended from time to time, and regulations promulgated thereunder, including medical records and other individually identifiable health information (collectively "Information"). However, if in the performance of the Research, the RECIPIENT is inadvertently provided, obtains or has access to such Information, the RECIPIENT shall not use, publish or disclose such Information in any manner whatsoever. The RECIPIENT shall comply with applicable laws and regulations relating to the confidentiality and privacy of such Information. The RECIPIENT agrees to notify BCH and its investigators orally and in writing within twenty-four (24) hours of its discovery of any Information in its possession which is improperly used, copied, or removed by anyone except an authorized representative of the RECIPIENT or BCH. The RECIPIENT shall cooperate with BCH and BCH investigators in taking such steps as are deemed appropriate by BCH to enjoin the

misuse, regain possession of the Information, and otherwise protect BCH's rights and patients' privacy. The RECIPIENT shall not contact or make any effort to identify individuals who are or may be the source(s) of the MATERIAL.

(c) The RECIPIENT acknowledges that performance of/and obtaining whole genome or exome sequencing data may constitute PHI, and as such will treat any such information in accordance with HIPAA. The RECIPIENT shall not (a) perform whole genome sequencing, whole exome sequencing, genome-wide association studies, whole transcriptome analysis, or total RNA sequencing on the MATERIAL or MODIFICATIONS. The RECIPIENT shall limit genome analysis to that required for the performance of the Research, and agrees to publish only the minimum of such genome analysis results necessary.

(d) The RECIPIENT agrees to comply with RECIPIENT's internal institutional guidelines and policies applicable to the use, storage and handling of human stem cells with regard to the MATERIAL and MODIFICATIONS, and shall ensure that any third party to whom the MATERIAL and MODIFICATIONS are transferred shall be similarly advised to comply with its respective institutional guidelines and policies governing use of human stem cells.

13.

(a) If the RECIPIENT breaches the terms of this MTA, the PROVIDER may terminate the Agreement upon thirty (30) days' written notice to the RECIPIENT. If the RECIPIENT remedies the breach during this thirty (30) days' period, the Agreement shall not be terminated.

(b) Either party may terminate the Agreement immediately upon notice to the other party: (i) in the event the other party engages in criminal or fraudulent conduct, or is convicted or sanctioned by any governmental agency in connection with illegal or unethical conduct; (ii) in the event the other party breaches the terms of the Agreement and is unable to cure the breach in accordance with Section 13(a) in the MTA; or (iii) upon a judicial or administrative determination that this Agreement or any part of it, substantially jeopardizes its charitable characterization under state or federal law or the exemption of either party from taxation under the Internal Revenue Code. BCH may terminate the Agreement immediately upon notice to RECIPIENT, if the BCH institutional review board ("IRB") has determined that the use of the MATERIAL must terminate, or that conditions of IRB approval have not been met, or that the use of the MATERIAL is determined to be inappropriate or not covered under the relevant consent forms.

(c) Upon termination of the Agreement, the RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of the PROVIDER, return or destroy any remaining MATERIAL. The RECIPIENT, at its discretion, will also either destroy the MODIFICATIONS or remain bound by the terms of this MTA as they apply to MODIFICATIONS.

14. Paragraphs of this Agreement that are intended to survive, including but not limited to paragraphs 1, 2, 5, 6, 7, 8, 9,10, 12, 14, 15 and 16 shall survive termination.

15. Each party agrees that it will not use the names, logos or trademarks of the other party or any of its affiliates, nor the name or photograph or other depiction of any employee or member of the other party's staff or such affiliates, nor any adaptation of any of the foregoing, in any advertising, promotional, or sales literature without, in each case, prior written consent from the other party, as case may be, and from the individual staff member, employee, or student if such individual's name photograph or depiction is used, except that each party may use the name of the other party as necessary to comply with disclosure requirements of all applicable laws relating

to its business, including United States and state security laws. In addition, each party may refer to publication by employees of the other party in the scientific literature. In all publications, RECIPIENT shall acknowledge BCH as the source of the ORIGINAL MATERIAL and the CDKL5 Material.

16. RECIPIENT acknowledges that any use of the MATERIAL and MODIFICATIONS hereunder will be subject to the Limited Use Label License No: 518 Cyto Tune ™ Technology for Products from Thermo Fisher Scientific, Inc. ("Thermo Fisher") attached herein as APPENDIX A, including any subsequent updates posted by Thermo Fisher at: https://tools.thermofisher.com/search/index.cfm?fuseaction=search.lullsearch&lullid=518

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**APPENDIX A to MTA**

**Thermo Fisher Scientific Inc. Limited Use Label License No: 518 CytoTune™ Technology for Products**

ThermoFisher
SCIENTIFIC

## Limited Use Label Licenses

**Limited Use Label License No: 518 CytoTune™ Technology for Products**

Notice to Purchaser: This product is authorized for reprogramming methods that involve or pertain to the preparation of iPS cells or related cells. The purchase of this product conveys to the purchaser the limited, non-transferable right to use the purchased amount of product to perform internal research and for educational purposes. This product or any of its components, or iPS cells generated by use of the product, or progeny (including those genetically engineered)/modifications (partially or fully differentiated cells) thereof (hereafter "Materials") shall not be administered to - (a) human subjects, including for human clinical use and/or to (b) animals for veterinary use (i.e., not for research) – for therapeutic, diagnostic or prophylactic purposes including but not limited to clinical applications, cell therapy, transplantation and/or regenerative medicine, nor shall be used for the creation of human embryos, and/or admixed embryos with embryos of animals including humans for any purpose including for research. No right to resell the Materials is conveyed expressly, by implication, or by estoppel. For clarity, purchasers have the right to use third party service providers for generating iPS cells and modifications for the benefit of such purchasers, but not for screening using the Materials except when such a provider has appropriate licenses from ID Pharma Co., Ltd. and iPS Academia Japan, Inc. Purchasers can deposit the Materials with not-for- profit repositories ("Repositories") and transfer cells to not-for-profit research entities (not affiliated with a for-profit organization) for their internal research. Such recipient Repositories and not-for-profit research entities are allowed to distribute the Materials not-for financial gain to other users for their internal research, and in case the recipient user is a for-profit entity, such recipient Repositories and not-for-profit research entities shall notify the recipient user that such for-profit entity is required to contact iPS Academia Japan, Inc., which notification shall be fulfilled by transferring a copy of this Label License along with the transferred Materials. The limited right allowed in paragraph 1 above does not include the following commercial applications: (i) use of iPS cells and progeny (but not modifications) for manufacture or quality control of any product; (ii) use of the Materials to provide services including (a) generation of the Materials, information or data on behalf of a third party for financial gain and (b) screening on behalf of purchasers for financial gain; (iii) use of the Materials by purchasers for screening or later stage development of therapeutics, diagnostics, prophylactics (e.g., hit-to-lead, lead optimization), except when performed by or on behalf of a not-for-profit research entity for internal research and not for financial gain; (iv) sale of the Materials to third parties. To obtain commercial rights for above commercial applications (i) through (iv), purchasers are requested to contact ID Pharma Co., Ltd. at cytotune@dnavec-corp.com and Academia Japan, Inc. directly at license@ips-ac.co.jp or through ID Pharma Co., Ltd. Notwithstanding the foregoing, the following activities are not considered commercial applications for purposes of this label license: (a) basic research, including, without limitation, target discovery, target validation and assay development; (b) transfer of cells to not-for-profit research entity for its internal research not for financial gain; (c) compound screening and safety testing for development of therapeutics, diagnostics and prophylactics by academic and not-for-profit research entities for their non-commercial internal research; (d) license or commercialization of research results except where such results are drugs or drug candidates, iPS cells or modifications, or where such license or commercialization uses iPS cells or progeny; Other than rights granted herein, no other right, express or implied, is conveyed by the sale of this product. Notice: If the Materials are transferred to third parties including Repositories in accordance with the terms of this label license accompanying the Materials (hereafter "Label License"), the transferring party should notify recipients of such Materials of these terms by transferring a copy of the Label License to the recipients.