



**CIRM hPSC REPOSITORY
MATERIALS TRANSFER AGREEMENT
FOR HUMAN PLURIPOTENT CELL LINES**

This Agreement (the “**Agreement**”) is made by and between Coriell Institute for Medical Research (“**Coriell**”), having a place of business at 403 Haddon Avenue, Camden, New Jersey 08103, USA, and _____ (“**Institution**”), with an address at _____, on behalf of itself and _____ (“**Principal Investigator**”). This Agreement is made effective as of the ___ day of _____, 20__ (hereinafter referred to as the “**Effective Date**”).

WHEREAS, Coriell administers the CIRM Pluripotent Stem Cell (hPSC) Repository (the “**Repository**”) pursuant to a Repository Agreement by and between Coriell and the California Institute for Regenerative Medicine (“**CIRM**”), an agency of the state of California, having its address at 210 King Street, 3d Floor, San Francisco, California, which such agreement is effective as of December 1, 2013 (the “**Repository Agreement**”);

WHEREAS, the Repository has possession of materials referenced in Coriell’s catalog (as may be changed from time to time by Coriell, the “**Catalog**”), certain of which materials Principal Investigator and Institution desire to purchase (for the price listed in the then current Catalog), as set forth in one or more orders submitted by Principal Investigator and Institution to the Repository (each, an “**Order**”); and

WHEREAS, upon Coriell’s confirmation that: (i) the materials set forth in an Order are available for delivery, (ii) the price referenced in the Order is Coriell’s price for such materials listed in its then current Catalog, (iii) Institution has properly executed and delivered this Agreement, and (iv) Institution has acquired from Cellular Dynamics International, Inc. (“**CDI**”) or its successor any license(s) referenced in the Catalog as required for the purchase of those materials, Coriell will issue to Institution an order confirmation confirming such information (each, an “**Order Confirmation**”); and

WHEREAS, the Repository is willing to provide such Materials (defined below) to Institution, and Institution is willing to accept such Materials, subject to the terms and conditions of this Agreement.

NOW, THEREFORE, for and in consideration of the foregoing premises and the mutual covenants and obligations contained herein, the Parties agree as follows:

1. DEFINITIONS

a. “**Affiliate**” means, with respect to a Party, any corporation, company, partnership, joint venture, or other business entity controlled by, controlling, or under common control with such Party. For purposes of this definition, “control” means the direct or indirect

beneficial ownership of fifty percent (50%) or more of the voting interest in an entity, or such other relationship as, in fact, constitutes actual control.

b. **“CDI License”** means a license obtained from CDI or its successor governing the use of Materials.

c. **“Highly Unique Resource”** means material derived from, but substantially different than, Materials, that requires significant modification or specialized expertise to grow, characterize, and maintain.

d. **“Institutional Official”** means the legal representative of the Institution who is authorized to enter into legally binding agreements on behalf of the Institution.

e. **“Materials”** means the materials listed in the Catalog and referenced in an Order that is confirmed by Coriell in an Order Confirmation.

f. **“Modifications”** means substances created by Institution and/or Principal Investigator which contain or incorporate the Materials.

g. **“Party”** means Coriell or Institution, as applicable, and **“Parties”** means, collectively, Coriell and Institution.

h. **“Progeny”** means an unmodified descendant from the Materials, such as virus from virus, cell from cell, or organism from organism.

i. **“Secondary Distribution”** means delivering or providing access to Materials to: (i) any individual or entity not providing services to Institution in connection with the research being conducted by the Principal Investigator that is the subject of the Statement of Research Intent; or (ii) any individual or entity providing services to Institution in connection with the research being conducted by the Principal Investigator that is the subject of the Statement of Research Intent, for use in connection with any research or other activity not specified in the Statement of Research Intent.

j. **“Statement of Research Intent”** means the written description of the research to be performed by the Principal Investigator and the Institution using the Materials, and the purpose for such research.

k. **“Unmodified Derivatives”** means substances created by the Principal Investigator or Institution which constitute an unmodified functional subunit or product expressed by the Materials. Some examples include: subclones of unmodified cell lines, purified or fractionated subsets of the Materials, proteins expressed by DNA/RNA supplied by Coriell, or monoclonal antibodies secreted by a hybridoma cell line.

2. **PROCESS FOR PURCHASING MATERIALS.** This Agreement must be submitted by Institution on behalf of itself and the Principal Investigator requesting Materials from the Repository, and signed by the Institutional Official on behalf of Institution and the

Principal Investigator. By so signing the Agreement, Institution agrees to be liable for any non-compliance with any provision of this Agreement by the Principal Investigator. In addition, Institution must cause the Principal Investigator to complete and deliver to Coriell a Statement of Research Intent. If a new project, not covered by the original Statement of Research Intent is initiated, another Statement of Research Intent must be submitted to Coriell. All fully executed Agreements will be kept on file with Coriell and considered applicable to subsequent purchases made by Institution. If this form of Agreement is substantially revised in the future, Institution shall be required to execute Coriell's then current form of Agreement for any purchases after the revision. A new Statement of Research Intent describing the intended research is required for all purchases.

3. PROTECTION OF HUMAN RESEARCH PARTICIPANTS.

a. Institution acknowledges and agrees on behalf of itself and the Principal Investigator that all use of the Materials is governed by Coriell's Institutional 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)). Principal Investigator and Institution remain subject to all state and local laws or regulations and institutional policies which may provide additional protections for human subjects.

b. When applicable to research described in the Statement of Research Intent, Institution shall adhere, and shall cause the Principal Investigator to adhere, to ethical standards established by the International Society for Stem Cell Research (ISSCR), and to all applicable law.

c. Coriell will under no circumstances provide information that will allow identification of individual subjects. Further, Institution agrees on behalf of itself and the Principal Investigator not to try to identify or contact the submitter of the Materials or the donor subject from whom any Material was derived. Without in any way limiting the foregoing: (i) posting or making available through access to websites or databases data that could be used to identify an individual is strictly prohibited; (ii) Institution shall encourage investigators including the Principal Investigator to submit any datasets that could be used to identify an individual to the Database of Genotypes and Phenotypes (dbGaP), pursuant to its then current Code of Conduct; and (iii) the sharing with collaborators of genetic data that could be used to identify an individual may only occur after such collaborators have been informed of, and agree in writing, to the applicable genetic data posting rules.

d. Institution agrees on behalf of itself and the Principal Investigator that human experimentation utilizing the Materials or their derivatives is strictly prohibited.

4. USE OF MATERIALS.

a. Commercial Use. The Materials and any material derived or isolated from them, such as RNA, DNA, or protein, may be used in the development of commercial products unless restricted or prohibited by the applicable CDI License.

b. Research Use. The Materials are provided as a service to the research community. It is expressly understood that the Materials delivered pursuant to this Agreement are experimental in nature. The Repository number(s) of the cell line(s) must be cited as follows in publications or presentations that are based on the use of these Materials: "The following cell lines were obtained from the CIRM hPSC Repository at the Coriell Institute for Medical Research: [list Repository ID numbers here]."

c. Shared Use and Secondary Distribution. Secondary Distribution is **NOT** permitted except under certain clearly defined circumstances as described below and only with prior written authorization from Coriell. Coriell will permit Secondary Distribution if such requests are supported under the mission of the Repository, if it can be established that protection of human subjects is ensured as necessary, if quality control of the Materials is ensured, and if an appropriate process for secondary distribution (as outlined in this Agreement) is followed, all as determined by Coriell in its sole discretion.

i. *Permitted Uses.* Notwithstanding the preceding, the following shall be considered to be permitted uses of the Materials:

A. Single Purpose Collaboration: These collaborations are defined as projects in which two or more investigators, including the Principal Investigator, work together with the intent to jointly publish their findings. In single purpose collaborations that require the use by each laboratory of the same Materials, secondary distribution to named collaborator(s) is permitted. The following applies to secondary distribution of such Materials:

1. The Statement of Research Intent must be identical for all the named collaborator(s) and consistent with this Agreement. Each collaborating investigator and his or her Institutional Official must sign and submit a copy of this Agreement.

2. If collaborators who need to use the Materials are identified after the initial acquisition of the Materials, an amendment to the Statement of Research Intent for the existing project or a new Statement of Research Intent for a new project must be submitted to Coriell, naming the additional collaborator(s). Each additional collaborating investigator and his or her Institutional Official must sign and submit a copy of this Agreement.

B. Multi-User Core Facility: A core facility (for modeling a specific disease, for example) purchases Materials for use by the investigators within the facility to perform assays for investigators at his or her Institution or at a consortium of institutions. The Statement of Research Intent describes the range of studies that will be

conducted using the Materials. In this situation, use of the Materials in the core facility may be permitted after the Coriell IRB assures that the use of these Materials is consistent with the research subject's informed consent.

C. Development of a Highly Unique Resource: Institution through the Principal Investigator may distribute aliquots of the Highly Unique Resource material by using an appropriate agreement between Institution and the secondary institution receiving the Highly Unique Resource (“**Secondary Recipient**”). Often a material transfer agreement is used for transfers of research materials for this purpose. The agreement to transfer a Highly Unique Resource to a Secondary Recipient must include, and Institution shall be obligated to comply with, the following:

1. a statement naming the Repository and the Repository ID number of the cell line from which the Highly Unique Resource was derived;
2. a requirement that the Secondary Recipient must acknowledge the Repository and the cell line number(s) in any publications or presentations based on the utilization of the Materials as follows: "[Name of Highly Unique Resource] was derived from cell line [list CIRM Repository ID number] from the CIRM Repository at the Coriell Institute for Medical Research";
3. a prohibition on the use of the unmodified Highly Unique Resource for human experimentation;
4. a statement that the Highly Unique Resource obtained from different sources will not have undergone the standard quality control of the Repository; and
5. a prohibition on the redistribution or sale of the Highly Unique Resource or materials derived from it unless stated otherwise in a CDI License.

ii. *Prohibited Uses*. Notwithstanding the preceding, the following shall apply to use of the Materials:

A. Multi-Purpose Use: In the event an investigator who obtained Materials wishes to give a portion of the Materials or a culture derived from the Materials to an investigator who is working on a project outside the applicable Statement of Research Intent(s), secondary distribution is prohibited.

B. Sharing Within an Institution. Except as permitted by Section 4(c)(i) above, Institution may only share the Materials with the Principal Investigator

and individuals named in the applicable Statement of Research Intent, and only for use for the research purposes set forth in the applicable Statement of Research Intent.

C. Other Use: The secondary distribution or sale of Materials for any purpose not permitted by Section 4(c)(i) is prohibited.

5. **DISCLAIMER; LIABILITY.**

a. BIOHAZARD: Cultured human cells have the potential for carrying viruses, latent viral genomes, and other infectious agents in a latent or inactive state. Materials should therefore NOT be treated as if they are free of contamination. Materials should always be handled carefully by trained persons under laboratory conditions that afford adequate biohazard containment following MINIMUM SAFETY GUIDELINES RECOMMENDED FOR WORKING WITH HUMAN CELL CULTURES, which guidelines can be obtained from Coriell upon request. By accepting the Materials, Institution assumes full responsibility for their safe and appropriate handling. Institution agrees to provide notice to the Coriell and the Repository of any containment or quality issues related to the Materials.

b. DISCLAIMER: THE REPOSITORY, CIRM, AND CORIELL MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED, CONCERNING THE MATERIALS. ALL IMPLIED WARRANTIES WITH RESPECT TO THE MATERIALS INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, OR NON-INFRINGEMENT, ARE EXPRESSLY DISCLAIMED. IN ADDITION TO THE PROVISIONS OF THIS AGREEMENT, USE OF SOME OF THE MATERIALS MAY BE SUBJECT TO CERTAIN RESTRICTIONS AND/OR LICENSE REQUIREMENTS. IF REQUIRED, PRIOR TO DISTRIBUTION OF ANY OF THE MATERIALS, CORIELL MUST RECEIVE FROM CDI CONFIRMATION THAT EITHER (i) THE INSTITUTION HAS OBTAIN FROM CDI ANY REQUIRED CDI LICENSE; OR (ii) NO CDI LICENSE IS REQUIRED. THERE MAY EXIST ADDITIONAL RESTRICTIONS OR PROPRIETARY RIGHTS OF WHICH THE REPOSITORY IS UNAWARE; THE INSTITUTION IS RESPONSIBLE FOR COMPLIANCE WITH ALL CONDITIONS OF USE OF THE MATERIALS.

c. Liability Statement for State Institutions: The 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 the use of the Materials to the extent permitted under the laws of the Institution's state. This provision shall also apply to any byproducts or derivatives of the Materials.

d. Liability Statement for U.S. Government Laboratories: The United States assumes the liability for any claims, damages, injuries, or expenses arising from the use of Materials or any byproduct or derivative, but only to the extent provided under the Federal Tort Claims Act (28 U.S.C. Chapter 171).

e. Liability Statement for All Other Institutions: Institution agrees to indemnify and hold harmless Coriell, CIRM and the submitter of the Materials from any claims, costs, damages, or expenses resulting from any injury (including death), damage, or loss that may arise from the use of the Materials. This provision shall also apply to any byproducts or derivatives of the Materials.

6. TITLE; INTELLECTUAL PROPERTY RIGHTS.

a. Neither Principal Investigator nor Institution shall obtain any rights of ownership in or to the Materials, including any Materials contained or incorporated in Modifications. Institution acknowledges and agrees on behalf of itself and the Principal Investigator that all such ownership rights reside with CIRM.

b. Institution shall retain ownership of: (a) Modifications (except for ownership to the Materials included therein), and (b) those substances created through the use of the Materials or Modifications, but which are not Progeny, Unmodified Derivatives or Modifications (i.e., do not contain the Original Material, Progeny or Unmodified Derivatives). If either (a) or (b) above results from the collaborative efforts of the Parties hereto, joint ownership may be negotiated.

c. Institution acknowledges and shall inform the Principal Investigator that the Materials are or may be the subject of a patent or patent application. Except as provided in this Agreement, no express or implied licenses or other rights are provided to Principal Investigator or Institution under any patents, patent applications, trade secrets or other proprietary rights, including any altered forms of the Materials.

7. TERMINATION. This Agreement will terminate on the earliest of the following dates: (i) on completion of Principal Investigator's current research with the Materials, or (ii) delivery of written notice by Coriell to Institution in the event of material breach of this Agreement by Institution, including any non-compliance with any provision of this Agreement by the Principal Investigator. In the event of termination, Institution will discontinue its use of the Materials and will, upon direction of Coriell, return or destroy any remaining Materials. In the event of termination pursuant to Section 7(i) above, **Institution** shall also destroy the Modifications or remain bound by the terms of this Agreement as it applies to Modifications. In the event of termination pursuant to Section 7(ii) above, **Institution** shall destroy the Modifications.

Sections 1, 3 and 5 through 15 of this Agreement shall survive its termination.

8. INDEMNIFICATION. To the maximum extent permissible under applicable law, Institution agrees to defend, indemnify and hold harmless Coriell, CIRM and the Repository and their respective directors, officers, employees, agents and representatives (each an "Indemnified Party") from any losses, claims, damages, liabilities, costs, expenses and fees (including, without limitation, reasonable attorneys' fees) (each a "Liability"), which may arise from or in connection with: (i) the use, handling, or storage of the Materials by Principal Investigator, Institution, or any employee, agent or representatives of either; or (ii) any non-

compliance with any provision of this Agreement by the Principal Investigator; except, in the event of either (i) or (ii) above, if any such Liability arises from a negligent act or omission or the intentional misconduct of an Indemnified Party. These indemnification obligations are conditioned upon the Indemnified Party providing prompt notice of any such Liability and reasonable assistance in defending against such Liability.

9. **COMPLIANCE.** Institution agrees that upon the reasonable request of Coriell, Institution shall execute a certification under oath (in such form as is reasonably required by Coriell) confirming Principal Investigator's and Institution's compliance with the provisions of this Agreement.

10. **NO ASSIGNMENT.** Neither Party shall assign this Agreement to any third party or entity without the prior written consent of the other Party, nor any purported assignment without such consent shall be void.

11. **SEVERABILITY.** If a court or other tribunal of competent jurisdiction should hold any term or provision of this Agreement to be excessive, invalid, void or unenforceable, the offending term or provision shall be deleted, and if possible, replaced by a term or provision which, so far as practicable achieves the legitimate aims of the Parties.

12. **RELATIONSHIP BETWEEN THE PARTIES.** Both Parties, for all purposes related to this Agreement, shall be deemed as independent contractors. Nothing in this Agreement shall be deemed to create a relationship of employment or agency or to constitute the Parties as partners or joint ventures.

13. **NO WAIVER.** The failure of either Party to require performance by the other Party of any of that other Party's obligations hereunder shall in no manner affect the right of such Party to enforce the same at a later time. No waiver by any Party hereto of any condition, or of the breach of any provision, term, representation or warranty contained in this Agreement, shall be deemed to be or construed as a further or continuing waiver of any such condition or breach, or of any other condition or of the breach of any other provision, term, representation, or warranty hereof.

14. **ENTIRE AGREEMENT.** This Agreement, which the parties agree is entered into in the State of California, constitutes the entire agreement between the Parties with respect to the subject matter hereof, and supersedes all prior discussions and understandings regarding its subject matter.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement by their duly authorized officers or representatives.

INSTITUTION:

By: _____

Name: _____

Title: _____

Date: _____

Read and acknowledged by
the PRINCIPAL INVESTIGATOR:

Name: _____

Title: _____

Date: _____