**** Columbia University**

***College of Physicians and Surgeons***

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**Material Transfer Agreement**

FOR THE TRANSFER OF NYSCF/COLUMBIA MATERIALS

TO A COMMERCIAL OR FOR-PROFIT ENTITY FOR INTERNAL RESEARCH USE

This Material Transfer Agreement (“Agreement”) is entered into on **[insert date]** (*“*Effective Date*”*) between New York Stem Cell Foundation, Inc. (“NYSCF”), a 501(c)(3) organization having its principal place of business at 1995 Broadway, Suite 600, New York, NY 10023 (“NYSCF”), and **The Trustees of Columbia University in the City of New York**, a non-profit corporation organized and existing under the laws of the State of New York (***“*Columbia*”***), collectively ***“*NYSCF/Columbia*”*** and **[insert name of recipient organization]**, having its principal place of business at **[insert recipient’s address]** (“Recipient”); each a “Party” and together the “Parties.”

Whereas, NYSCF/Columbia have developed and own certain materials; and

Whereas, Recipient, specifically the Recipient Scientist(s) **[insert Recipient Scientist(s) name(s)]**, wishes to obtain, and NYSCF/Columbia are willing to provide, such materials for internal research use on the terms and conditions set forth in this Agreement;

Now, therefore, the Parties agree as follows:

1. **Definitions.**
	1. **“Material”** shall mean Original Material, Progeny, and Unmodified Derivatives.
	2. **“Original Material”** shall meanthe material provided by NYSCF/Columbia to the Recipient as described in Attachment A.
	3. **“Progeny”** shall mean unmodified descendant(s) from the Material, such as cell from cell.
	4. **“Unmodified Derivatives”** shall mean substances, including cells, created or obtained by the Recipient that constitute an unmodified functional subunit or product expressed by or obtained from the Original Material or Progeny. Unmodified Derivatives include, without limitation, subclones of the Original Material or Progeny, purified or fractionated subsets of the Original Material or Progeny, and substances that Recipient either: (a) isolated or derived from Original Material, Progeny or other Unmodified Derivatives, or (b) isolated or derived from Modifications, and that are indistinguishable from substances that could have been isolated or derived from Original Material, Progeny or other Unmodified Derivatives.
	5. **“Modifications”** shall mean substances, including cells, created by the Recipient that are not Original Material, Progeny, or Unmodified Derivatives, but that either contain or incorporate Original Material, Progeny, or Unmodified Derivatives, or are cells derived from Original Material, Progeny, or Unmodified Derivatives. Modifications include, without limitation, Pluripotent Modifications, Non-Pluripotent Modifications, and genetically altered cells derived from Original Material, Progeny, or Unmodified Derivatives.
	6. **“Pluripotent Modifications”** shall mean pluripotent cells created by the Recipient from Original Material, Progeny, or Unmodified Derivatives, where such Original Material, Progeny, or Unmodified Derivatives is or was non-pluripotent.
	7. **“Non-Pluripotent Modifications”** shall mean non-pluripotent cells created by the Recipient from Original Material, Progeny, or Unmodified Derivatives, where such Original Material, Progeny, or Unmodified Derivatives is or was pluripotent.
	8. **“Recipient Scientist”** shall mean Dr. **[insert name]**, an employee of the Recipient.
	9. **“Third Party”** shall mean any person or entity that is not a Party to this Agreement.
	10. **“Non-Profit Entity”** shall mean 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 USC §501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 USC §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.
	11. **“Commercial Purposes”** shall mean the sale, lease, license, or transfer of Material or Modifications for profit or to a for-profit entity. Commercial Purposes shall also include uses of Material or Modifications by any person or entity 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 Material or Modifications to a for-profit organization. For clarity, use of Material or Modifications in industrially-sponsored research performed by a Non-Profit Entity in such entity's own laboratories shall not be considered use for Commercial Purposes.
2. **Ownership.**
	1. **Material.** NYSCF/Columbia retain ownership of Material, including any Material contained or incorporated in Modifications.
	2. **Modifications.** Recipient retains ownership of (i) Modifications (except that NYSCF/Columbia retain ownership of Material contained or incorporated therein), provided, however, that any Modifications created jointly by NYSCF/Columbia and Recipient working together in collaboration shall be jointly owned by NYSCF/Columbia and Recipient, in which case the rights and obligations of the Parties relating to such joint ownership shall be negotiated by the Parties in good faith and agreed in writing.
	3. **Substances That Are not Material or Modifications.** Recipient retains ownership of substances created by Recipient through the use of Material or Modifications, but that are not, and/or do not incorporate, Materials or Modifications.
3. **Use and Transfer of Material and Modifications.**

Recipient agrees:

* 1. to use Material and Modifications in accordance with any applicable Institutional Review Board (IRB) approval or patient consent forms under which the Material was obtained, as provided by NYSCF/Columbia hereunder, and to obtain IRB approval, if and as appropriate for Recipient’s use of Material and Modifications.
	2. to use the Material and Modifications only in compliance with applicable laws and regulations, and in compliance with Recipient’s applicable policies on human subject research;
	3. to use the Material and Modifications in accordance with any additional restrictions set forth in Attachment A, for example any additional restrictions on use provided in any patient consent form under which Material was obtained;
	4. in the case of entities receiving funding from agencies of the United States, to use the Material and Modifications only in compliance with applicable National Institutes of Health Guidelines on Human Stem Cell Research: http://stemcells.nih.gov/policy;
	5. not to use Material or Modifications in human subjects, in clinical trials, or for diagnostic purposes involving human subjects, without the written consent of NYSCF/Columbia;
	6. not to transfer Material or Modifications to any Third Party, except to the extent permitted in Section 4(b) below; and
	7. that NYSCF/Columbia will not provide Recipient with personally identifiable information, or the key code to personally identifiable information that is coded, related to the Material, and that Recipient will not to attempt to identify or contact any human donor from whom the Material was or may have been derived.
1. **Third Party Requests for Material and Modifications.**
	1. **Material.** Recipient shall not transfer or provide Material to any Third Party without written consent from NYSCF/Columbia.
	2. **Modifications.**
		1. Recipient may transfer Modifications to Third Parties that are Non-Profit Entities for use in non-Commercial Purposes, provided, however, that any such transfer shall be made under a separate written agreement, which agreement shall set forth NYSCF/Columbia’s ownership interest in any Material that is incorporated in the Modifications, or from which the Modifications were derived, and shall contain terms and conditions at least as restrictive, and at least as protective of NYSCF/Columbia’s rights, as those provided herein, including, but not limited to, those terms and conditions provided in sections 2-10, and 13of this Agreement.
		2. Recipient may not transfer Modifications to any Third Party (including Non-Profit Entities) for use in Commercial Purposes, without the written consent of NYSCF/Columbia. Recipient acknowledges that, to the extent that any Modifications which Recipient wishes to transfer to a Third Party for use in Commercial Purposes incorporate Material, NYSCF/Columbia may, at its discretion, require a license to NYSCF/Columbia’s ownership interest in the Material incorporated in the Modification, and Recipient also acknowledges that NYSCF/Columbia are under no obligation to grant such a license. Nothing in this paragraph, however, shall prevent Recipient from granting commercial licenses under the Recipient’s intellectual property rights claiming such Modifications, or methods of their manufacture or their use.
2. **No Implied License.** Recipient acknowledges that Material is or may be the subject of a patent application or issued patent or other proprietary rights in one or more countries. Except for the rights expressly granted in this Agreement, no express or implied licenses or other rights are provided to Recipient under any patents, patent applications, trade secrets or other proprietary rights of NYSCF/Columbia or of any Third Party. Unless specifically indicated, no license or right to use any third party patent, technology or intellectual property is conveyed to Recipient under this agreement. It is the sole responsibility of Recipient to obtain from Third Parties that may have a proprietary interest in the Material or Modifications, any permissions necessary for Recipients use or intended use of the Material or Modifications.
3. **Disclaimer.** The Recipient acknowledges that Material is experimental in nature and may have hazardous or other unpredictable and unknown properties, that it is to be used with caution, that it is not to be used for testing in or treatment of humans, and that its use may require acquisition or rights from Third Parties. NYSCF/COLUMBIA MAKE NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF THE MATERIAL, ITS SOURCE, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY.
4. **Limitation of Liability.** Except to the extent prohibited by law, Recipient assumes all liability for damages which may arise from Recipient’s use, storage or disposal of Material, Modifications, and any other substance created through the use of Material or Modifications. NYSCF/Columbia will not be liable to Recipient for any loss, claim or demand made by Recipient, or made against Recipient by any third party, due to or arising from Recipient’s use of Material, Modifications, or any other substance created through the use of Material or Modifications, including patent infringement.
5. **Indemnification.** Recipient agrees to hold harmless and indemnify NYSCF/Columbia, and its trustees, directors, officers, employees and agents, from and against any and all third party claims, liability, loss, damage, cost or expenses (including reasonable attorney’s fees) arising out of or otherwise related to Recipient’s obligations under this Agreement or Recipient’s use, handling storage or disposal of Material or Modifications, including patent infringement.
6. **Publication.** This Agreement shall not be interpreted to prevent or delay publication of research findings resulting from Recipient’s use of Material or Modifications. Recipient agrees to acknowledgment NYSCF/Columbia as the source of Material in any publications involving the Material, unless otherwise requested by NYSCF/Columbia.
7. **Compliance.** Recipient agrees to use and handle Material and Modifications in compliance with all applicable statutes and regulations, including, without limitation, Public Health service and National Institutes of Health regulations and guidelines, and any IRB approvals or patient consent forms under which Material was obtained, as provided by NYSCF/Columbia hereunder, or otherwise required for Recipient’s use of Material or Modifications.
8. **Termination.** This Agreement will become effective on the Effective Date and will remain in effect for as long as Recipient has possession of Material or Modifications, or until terminated by either Party upon sixty (60) days written notice to the other Party, whichever is the earlier. Upon termination of this Agreement for any reason, any unused Material (and any related confidential information provided by NYSCF/Columbia hereunder) will either be destroyed in compliance with all applicable statutes and regulations or will be returned to NYSCF/Columbia, as requested by NYSCF/Columbia, and, at the Recipient’s election, Recipient will either destroy Modifications or remain bound by the terms of this Agreement as they apply to Modifications.

Termination of this Agreement will not relieve either Party of any obligation accruing prior to termination. The following Sections of this Agreement shall survive any termination of this Agreement: 6, 7, 8, 9, 10, 11, 12 13, 15 and 17; and, additionally, Sections 2, 3, 4 and 14 as applied to any Modifications retained by Recipient after termination.

1. **Transmittal Fee.** Recipient agrees to pay **[amount in words]** dollars **($XXX)** within thirty (30) days of the Effective Date to cover costs, which are solely intended to reimburse for reasonable expenses incurred in production, maintenance, storing and transferring of the Material.
2. **Use of Name.** Except to the extent provided in Section 13 (Publication), Recipient shall not use NYSCF/Columbia’s name, logo, symbol, trademarks or service marks, or any abbreviation or variant thereof, in any publication, press release, or any advertisement or similar material used to promote or sell products or services, without the prior written consent of NYSCF/Columbia.
3. **Governing Law.** This Agreement shall be construed in accordance with the laws of the State of New York, without regard to conflicts of laws provisions available in such jurisdiction.
4. **Entire Agreement and Severability.** This Agreement (including the attachments hereto) contains the final, complete and exclusive agreement of the Parties relative to the subject matter hereof and supersedes all prior and contemporaneous understandings and agreements relating to said subject matter. This Agreement may not be amended or supplemented except by a written instrument signed by the Parties. No waiver of any provision of this Agreement or of any of a Party’s rights hereunder shall be effective unless in writing and signed by the waiving Party. If any provision of this Agreement shall be declared invalid, illegal or unenforceable, such provision shall be severed and all remaining provisions shall continue in full force and effect.
5. **Assignment.** The Recipient shall not assign or otherwise transfer this Agreement, or any rights or obligations hereunder, without NYSCF/Columbia’s prior written consent.
6. **Counterparts.** This Agreement may be executed in any number of counterparts, each of which, when executed, shall be deemed to be an original and all of which together shall constitute one and the same instrument.

**IN WITNESS WHEREOF,** the duly authorized representatives of each Party acknowledge that they have read and understood and agree to the terms and conditions set forth in this Agreement, as evidenced by their Signatures below:

|  |  |
| --- | --- |
| **For NYSCF** | **For Recipient** |
| By: Name: Title:  | By: Name: Title:  |

**For The Trustees of Columbia University**

By:

Name:

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_(TT#\_\_\_\_\_\_\_\_\_)

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Certification of Recipient Scientist:** I have read and understood the terms and conditions of this Agreement as they apply to my receipt and handling of Materials.

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Signature of Recipient Scientist Date

ATTACHMENT A

**Original Materials**

[Insert a description of the Original Materials transferred by NYSCF/Columbia to Recipient, including, in the case where the Original Materials are pluripotent stem cells, a description of the technology used to induce pluripotency, and any information regarding any restrictions on use (for example from any patient consents) over and above those provided in the body of the Agreement.]

List of Material transferred under this Agreement:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **#** | **Name or Designation** | **Description** | **If Applicable: iPSC****Reprogramming Method** | **Starting Material and IRB Protocol Number** |
| **1** |  | **iPSC line** |  | **Fibroblasts****PI Name:** **IRB:** **Consent Form:**  |
| **2** |  | **Fibroblast**  |  | **PI Name:** **IRB:** **Consent Form:**  |