ISSCR SAMPLE FORM

**Uniform Human Embryonic Stem Cell-related Materials Transfer Agreement**

**I. Definitions**:

 1. PROVIDER:

 2. PROVIDER SCIENTIST:

 3. RECIPIENT:

 4. RECIPIENT SCIENTIST:

 5. ORIGINAL MATERIAL:

 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 restricted by third party rights that may govern the material, or unless it grants intellectual property rights in excess of a nonexclusive internal research license and the right to review (but not own) research data.

**II. Terms and Conditions of this Agreement:**

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

(a) is to be used solely for teaching and academic or other noncommercial internal research purposes;

(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;

(d) will not be transferred to anyone else within the RECIPIENT organization without the prior written consent of the PROVIDER.

(e) will be used only in compliance with applicable treaties, laws and regulations, as they are amended from time to time, and only after securing such review and approval as such

treaties, laws and regulations require;

(f) will be used ethically, in substantial compliance with the review procedures and ethical guidelines of the International Society for Stem Cell Research or, where those are superseded by authoritative, higher national standards, in substantial compliance with such standards; and

(g) recognizing that third parties may have contractual and intellectual property rights related to receipt and proposed use of the MATERIALS under the laws of diverse countries, will be used consistent with rights of such third parties;

2. (a) The RECIPIENT 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 or other rights are provided to the RECIPIENT under any patents, patent applications, trade secrets or other proprietary rights of the PROVIDER or any third party, including with respect to any altered forms of the MATERIAL made by the PROVIDER. In particular, but without limitation, no express or implied licenses or other rights are provided to use the MATERIAL, MODIFICATIONS, or any related patents of the PROVIDER for COMMERCIAL PURPOSES.

(b) RECIPIENT represents that, based on adequate exercise of due diligence, it has verified the extent to which third-party rights, treaties, laws and regulations may restrict its receipt of the MATERIALS or the use of the MATERIALS in research, including commercially sponsored research, and that it has satisfied all such requirements, including by entering into such third party agreements and licenses, and securing such regulatory and institutional approvals, as are required. RECIPIENT will provide adequate documentation of its compliance with this term upon PROVIDER request.

(c) RECIPIENT hereby agrees to indemnify and hold harmless PROVIDER, its trustees, officers, employees, agents and medical and research staff, including without limitation SCIENTIST, against any claim arising from RECIPIENT’s use of this Agreement, including without limitation any claim that RECIPIENT’s use of the MATERIAL violates any of intellectual property or other rights of the third party, or violates any provision of law, or arises from a breach of this Agreement.

3. The PROVIDER retains ownership of the MATERIAL, including any MATERIAL contained or incorporated in MODIFICATIONS.

4. Subject to any third-party rights, the RECIPIENT retains ownership of: (a) MODIFICATIONS (except that, the PROVIDER 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, UNMODIFIED DERIVATIVES or MODIFICATIONS (i.e., do not contain the ORIGINAL MATERIAL, PROGENY, or UNMODIFIED DERIVATIVES). If either 4 (a) or 4 (b) results from the collaborative efforts of the PROVIDER and the RECIPIENT, such material will be jointly owned.

5. 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. The RECIPIENT and/or the RECIPIENT SCIENTIST shall have the right to distribute, nonexclusively, substances and materials created by the RECIPIENT through the use of the ORIGINAL MATERIAL, provided that (a) those substances are not PROGENY or UNMODIFIED DERIVATIVES, (b) such transfer is not otherwise restricted by unlicensed third party rights or otherwise; (c) the RECIPIENT, in documents effecting such distribution, reserves the right to deposit the substances and materials in banks and depositories providing reasonable public and scientific access on ethical terms in accordance with guidelines and standards of the International Society for Stem Cell Research; (d) the RECIPIENT reserves all rights necessary to transfer nonexclusively such substances and materials, and sufficient rights to use them, to other academic and governmental research institutions for internal research purposes at nominal cost, and will implement arrangements to effect such transfers; (e) the RECIPIENT agrees that upon request it will also provide such materials to PROVIDER at nominal cost; and (f) the RECIPIENT conditions transfer of such materials to further recipients on terms substantially similar to the terms of this paragraph 5, and does not acquire commercial, monetary or other rights directly or indirectly for itself or others under such agreements or arrangements that are greater than the rights received by PROVIDER under this agreement.

 6. Without written consent from the PROVIDER, the RECIPIENT and/or the RECIPIENT SCIENTIST may NOT provide or license MODIFICATIONS for COMMERCIAL PURPOSES. It is recognized by the RECIPIENT that such COMMERCIAL PURPOSES may require a commercial license from the PROVIDER and/or third parties and the PROVIDER has no obligation to grant a commercial license to its ownership interest in the MATERIAL incorporated in the MODIFICATIONS. RECIPIENT may grant commercial licenses under the RECIPIENT's intellectual property rights claiming such MODIFICATIONS, or methods of their manufacture or their use, if not subject to third party rights and restrictions.

 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 the PROVIDER to establish the terms of a commercial license, subject to any pre-existing rights held by others. It is understood by the RECIPIENT that the PROVIDER 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 governmental authorities and funding agencies or bodies. RECIPIENT is responsible for timely procuring all necessary licenses from all third parties.

 8. Subject to third party rights or restrictions in the MATERIAL, 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 the PROVIDER upon filing a patent application claiming MODIFICATIONS or method(s) of manufacture or use(s) of the MATERIAL.

 9. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties and that its use may require acquisition of rights from third parties. The PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF THE MATERIAL, ITS SOURCE, MERCHANTABILITY, TRANSFER OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

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

 11. This agreement 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. This Agreement will terminate on the earliest of the following dates: (a) when the MATERIAL becomes generally available from third parties without restriction, for example, though reagent catalogs or public depositories or (b) on completion of the RECIPIENT's current research with the MATERIAL, or (c) on thirty (30) days written notice by either party to the other. Upon the effective date of termination, or if mutually agreed, any deferred effective date of termination, 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 agreement as they apply to MODIFICATIONS.

 14. Paragraphs 2, 3, 9, and 10 of Article II shall survive termination.

 15. The MATERIAL is provided at [no cost] [with a transmittal fee of \_\_\_\_ solely to reimburse the PROVIDER for its preparation and distribution costs].

16. This agreement will be construed so as to comply with the laws of both the PROVIDER and the RECIPIENT, except that to the extent they conflict and cannot be harmonized, the contractual provisions of this agreement shall be construed in accordance with the laws of the PROVIDER, and ethical restrictions and prohibitions on uses of the MATERIALS shall be construed in accordance with the laws of the location where research is being conducted.

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[PROVIDER Scientist]

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[PROVIDER Institution] Date

[Title – Authorized official]

ACCEPTED BY RECIPIENT:

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[RECIPIENT Scientist]

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[RECIPIENT Institution]

[Title - Authorized Official]

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Title Date

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Institution

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Address

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"This Material Transfer Agreement was adapted and modified from the uniform biological material transfer agreement published in the Federal Register, February 18, 1995."