

Amended and Restated Memorandum of Understanding

between

WiCell Research Institute, Inc.

and

Public Health Service

U.S. Department of Health and Human Services

This Memorandum of Understanding (hereinafter "Agreement") is made effective as of the 15<sup>th</sup> day of February, 2008, by and between the Public Health Service of the U.S. Department of Health and Human Services as represented by the Office of Technology Transfer ("PHS"), having an address at National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852, and the WiCell Research Institute, Inc. ("WiCell"), a Wisconsin nonprofit corporation having an address at 614 Walnut Street, Madison, Wisconsin 53726. PHS and WiCell are referred to herein as "Parties."

**WHEREAS**, the Wisconsin Alumni Research Foundation ("WARF") holds certain intellectual property rights provided by U.S. Patent Nos. 5,843,780; 6,200,806; 7,005,252, and various patents or patent applications (foreign and domestic) claiming priority thereto (collectively the "Wisconsin Patent Rights"); and

**WHEREAS**, the Wisconsin Patent Rights have usefulness in basic research conducted or funded by PHS, as well as potential utility for commercial applications, and WARF has afforded WiCell the right to grant sublicenses under the Wisconsin Patent Rights to the PHS and other non-profit and academic research institutions; and

**WHEREAS**, specific human embryonic stem cell line materials, their unmodified and undifferentiated progeny and derivatives (the "Wisconsin Materials") have been derived consistent with the Presidential Statement of August 9, 2001 from the research efforts of James A. Thomson of the University of Wisconsin – Madison, working alone or with other investigators;

**WHEREAS**, PHS has a basic mission on behalf of the U.S. Government to conduct and provide support for health research performed at its own facilities and at facilities of other institutions through funding agreements ("Recipient Institutions"); and

**WHEREAS**, PHS funded primate research studies at the University of Wisconsin - Madison that led to certain discoveries claimed in the Wisconsin Patent Rights and, therefore, the U.S. Government has certain rights to the inventions of the Wisconsin Patent Rights by law and regulation; and

**WHEREAS**, the Wisconsin Materials were made using solely private funds and are the proprietary, tangible property of WiCell and, as such, their ownership is not subject to the rights and obligations granted to the U.S. Government in the Wisconsin Patent Rights; and

**WHEREAS**, WARF and WiCell have a mission to serve the public good and desire to serve the public

interest by making the Wisconsin Materials and the Wisconsin Patent Rights widely available to PHS and other researchers; and

**WHEREAS**, WiCell represents that it owns or otherwise has the right to distribute the Wisconsin Materials to third parties, and that it desires to exercise its rights under the Wisconsin Patent Rights and distribute Wisconsin Materials without placing undue restrictions or burdens upon health research conducted or funded by PHS; and

**WHEREAS**, WiCell and PHS previously entered into an agreement dated September 5, 2001, pertaining to the technology made a subject of this Agreement (the "2001 Agreement"), and now desire to amend and restate the 2001 Agreement in favor of the terms and conditions set forth below.

**NOW THEREFORE**, the Parties hereby agree that this Amended and Restated Memorandum and Understanding and its following terms and conditions shall supersede and replace the terms of the 2001 Agreement regarding the use of the Wisconsin Materials and/or Wisconsin Patent Rights for research conducted either by PHS or on behalf of PHS by its contractors:

1. The Parties agree that the Wisconsin Patent Rights are to be made available without cost for use in the PHS biomedical research program subject to the following conditions:
  - (a) The Wisconsin Patent Rights may be used only in research programs that are in compliance with all applicable statutes, regulations, and guidelines for research of this type.
  - (b) The Wisconsin Patent Rights may be used in PHS research programs involving materials, other than the Wisconsin Materials, which are (1) within the scope of an issued claim of the Wisconsin Patent Rights; and (2) derived consistent with the Presidential Statement of August 9, 2001, and in compliance with all applicable statutes, regulations and guidelines (hereinafter "Third Party Materials").
  - (c) Suppliers of Third Party Materials are hereby granted a limited, revocable, non-commercial, research license by WiCell under the Wisconsin Patent Rights to provide such Third Party Materials to PHS research programs, provided that such suppliers make the Third Party Materials available on terms no more onerous than those contained in this Agreement. Specifically, but without limitation, suppliers of Third Party Materials shall not receive rights, either directly or indirectly (either actual or contingent), for themselves or others under agreements or arrangements governing the supply or use of the Third Party Materials. The use of the Wisconsin Patent Rights in PHS research programs utilizing the Third Party Materials shall be for teaching or non-commercial research purposes only. The Wisconsin Patent Rights may not be used for commercial purposes.
  - (d) The Parties recognize that the Wisconsin Patent Rights may be used in PHS research to make patentable discoveries ("PHS Patent Rights"), which themselves may eventually be the basis of commercial products that benefit the public health. Any rights that may be needed by a third party under the Wisconsin Patent Rights for purposes of commercializing the PHS Patent Rights shall be the subject of a separate written agreement with WARF permitting such use of the Wisconsin Patent Rights under terms not less favorable than those of other similar commercial licenses, to the extent such rights are available.
2. The Parties agree that the Wisconsin Materials are to be made available by WiCell for use in PHS biomedical research programs, either by PHS or on behalf of PHS by its contractors. For purposes of

transferring the Wisconsin Materials to PHS or PHS contractors, WiCell agrees to utilize the Simple Letter Agreement for the Transfer of Materials attached hereto as Appendix A (the "Simple Letter Agreement"). Any such transfer shall be subject to following conditions:

- (a) The Wisconsin Materials are the property of WiCell and are being made available to investigators in the PHS research community as a service by WiCell. Ownership of the Wisconsin Materials shall remain with WiCell.
- (b) The Wisconsin Materials are not to be used for diagnostic or therapeutic purposes.
- (c) The Wisconsin Materials may only be used in compliance with all applicable statutes, regulations and guidelines relating to their handling or use. PHS agrees that its research program will exclude: (i) the mixing of Wisconsin Materials with an intact embryo, either human or non-human; (ii) the implanting of the Wisconsin Materials, or products of the Wisconsin Materials, in a uterus; and (iii) any attempt to make whole embryos with the Wisconsin Materials by any method. On or before June 1 of each year in which this Agreement is in effect, an Annual Certification Statement confirming compliance with the restrictions on the use of the Wisconsin Materials shall be supplied to WiCell by PHS and each scientist receiving the Wisconsin Materials under the terms of the Simple Letter Agreement. PHS agrees that the Wisconsin Materials are to be returned to WiCell or destroyed upon a material breach of the terms of the Simple Letter Agreement.
- (d) The use of the Wisconsin Materials shall be for teaching or non-commercial research purposes only.
- (e) PHS shall have the right to transfer the Wisconsin Materials to third parties, provided that:
  - (1) WiCell provides written confirmation that the receiving third party has entered into and executed a Simple Letter Agreement relating to the Wisconsin Materials to be transferred (Such confirmation shall not be unreasonably withheld and will be provided promptly and within five (5) business days if practicable);
  - (2) the transfer of the Wisconsin Materials shall be made for no economic consideration (i.e., commercial grant-back rights, ownership interest in inventions created by the recipient, or royalties from the recipient due to the commercialization of inventions created using the Wisconsin Materials);
  - (3) the transfer of the Wisconsin Materials shall be subject to the terms of this Agreement and the Simple Letter Agreement between WiCell and the receiving third party; and
  - (4) PHS and/or its contractors provide written notice to the receiving third party that the Wisconsin Materials are not being provided by or on behalf of WiCell and have been maintained by PHS and/or the contractor in conditions which may not be consistent with those utilized by WiCell.
- (f) PHS agrees that it and its Contractors shall acknowledge the source of the Wisconsin Materials in any publications or other disclosures reporting their use.
- (g) In order to facilitate potential novel collaborative research interactions between PHS and WiCell that may utilize Wisconsin Materials, PHS agrees to identify the titles of its planned research in its individual requests for samples of Wisconsin Materials. This information is to be provided to

facilitate new inter-disciplinary collaborations among individual scientists at PHS and WiCell, but not to oblige either Party to a specific program of research utilizing the Wisconsin Materials.

- (h) The Parties recognize that the Wisconsin Materials may be used in the PHS research program to make discoveries of different materials ("PHS Materials") which themselves may eventually be the basis of commercial products that benefit the public health. Any rights that may be needed by a third party under the Wisconsin Patent Rights or the Wisconsin Materials for purposes of commercializing the PHS Materials shall be the subject of a separate written agreement with WARF permitting the use of the Wisconsin Materials and/or Wisconsin Patent Rights. The terms of such agreement shall be no less favorable than other similar commercial licenses, to the extent such rights are available.
  - (i) The Parties recognize that Wisconsin Materials and Wisconsin Patent Rights may be used in research by PHS in collaboration with for-profit institutions, such as under a Cooperative Research and Development Agreement (CRADA), without the need for the for-profit institution to license the Wisconsin Patent Rights or rights to the Wisconsin Materials when only the PHS is using the Wisconsin Patent Rights and Wisconsin Materials in a direct manner with the collaborative research project.
  - (j) Any Wisconsin Materials delivered pursuant to this Agreement are understood to be experimental in nature and may have hazardous properties. WiCell makes no representations and extends no warranties of any kind, either expressed or implied. There are no express or implied warranties of merchantability for fitness for a particular purpose, or that the use of the Wisconsin Materials will not infringe any patent, copyright, trademark or other proprietary rights. Unless prohibited by law, PHS assumes all liability for claims for damages which may arise from the use, storage, handling or disposal of Wisconsin Materials except that, to the extent permitted by law, WiCell shall be liable to PHS when the damage is caused by the gross negligence or willful misconduct of WiCell.
  - (k) A transmittal fee may be requested by WiCell to cover, its preparation and distribution costs for samples of the Wisconsin Materials requested by PHS. Such fees will be the responsibility of the requesting PHS laboratory and are not expected to exceed Five Thousand Dollars (\$5,000), or as specified in the appropriate schedule of a U.S. Government procurement accompanying the PHS Simple Letter Agreement for the Transfer of Materials.
3. Upon WiCell's written request, PHS agrees to provide, without cost, reasonable quantities of any PHS Materials that it makes in the course of its research program to WiCell under a simple letter agreement, but only after PHS has publicly disclosed or reasonably characterized such PHS materials. WiCell agrees to use such PHS materials for research purposes only, after PHS has publicly disclosed or reasonably characterized such PHS Materials. With respect to the PHS Patent Rights, PHS also agrees to continue its current policy of retaining the right to grant research licenses to either non-profit or for-profit institutions.
4. WiCell agrees that it shall make the Wisconsin Patent Rights and Wisconsin Materials available for use by non-profit Recipient Institutions under separate written agreements in accordance with the terms and conditions outlined above. WiCell agrees that any non-profit Recipient Institutions currently licensed under the Wisconsin Patent Rights or Wisconsin Materials may amend its license, in a separate written agreement, in accordance with the terms and conditions outlined above.
5. Notwithstanding the terms of this Agreement, nothing herein shall be construed to diminish or

supersede any rights or authorities available to PHS as a U.S. government agency. The provisions of this Agreement and the obligations hereunder with respect to the Wisconsin Patent Rights shall be in effect only during the term of the Wisconsin Patent Rights. However, the provisions of this Agreement and the obligations hereunder with respect to the Wisconsin Materials shall continue as long as Wisconsin Materials, their derivatives or progeny continue to be used by PHS or its Contractors.

6. Nothing contained herein shall be considered to be the grant of a commercial license or right under the Wisconsin Patent Rights or the Wisconsin Materials. Furthermore, nothing contained herein shall be construed to be a waiver by WARF or WiCell of any patent rights under the Wisconsin Patent Rights or WiCell's property rights in the Wisconsin Materials.

IN WITNESS WHEREOF, the Parties agree to the foregoing and have caused this Agreement to be executed by their duly authorized representatives.

**WiCell Research Institute**

By: \_\_\_\_\_  
Carl E. Gulbrandsen, President  
Date: \_\_\_\_\_

**Public Health Service**

By: \_\_\_\_\_  
Mark L. Rohrbaugh, Ph.D.  
Director, Office of Technology Transfer  
National Institutes of Health  
Date: \_\_\_\_\_

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## Simple Letter Agreement

**INSTITUTION:** \_\_\_\_\_

**RECIPIENT:** \_\_\_\_\_

**PROVIDER:** \_\_\_\_\_  
(WiCell or Name of Authorized Provider)

**CELL LINE:** \_\_\_\_\_

**RESEARCH PROGRAM TITLE:** \_\_\_\_\_

This Simple Letter Agreement dated and effective \_\_\_\_\_, \_\_\_\_\_, is between the above Recipient, a researcher employed by the above Institution, and WiCell Research Institute, Inc. ("WiCell"), a Wisconsin nonprofit corporation having an address at 614 Walnut Street, Madison, Wisconsin 53726.

It is WiCell's understanding that the Recipient desires to obtain samples of the Cell Line listed above (hereinafter referred to, along with any unmodified and undifferentiated progeny or derivatives versions thereof, as the "Wisconsin Materials") for use as part of research to be conducted in Recipient's laboratory at Institution. In accordance with the terms and conditions of the Amended and Restated Memorandum of Understanding between WiCell and the Public Health Service dated February 15, 2008 (the "MOU"), which is incorporated herein by reference, Recipient hereby agrees and acknowledges the following:

1. Recipient hereby represents that he/she has read and acknowledges the terms and conditions of the MOU, and agrees to be bound by its terms and conditions. Specifically, Recipient acknowledges and agrees that the research conducted by Recipient will not include:

- (a) mixing of Wisconsin Materials with an intact embryo, either human or non-human;
- (b) implanting Wisconsin Materials or products of the Wisconsin Materials in a uterus;
- (c) attempting to make whole embryos with Wisconsin Materials by any method; or
- (d) using Wisconsin Materials for therapeutic or commercial purposes, including the performance of services (including diagnostic services) for consideration or the production or manufacture of products for sale or distribution.

2. Recipient agrees that on or before June 1 of each year in which this Simple Letter Agreement is in effect, he/she will submit to WiCell a signed Annual Certification Statement as set forth on Exhibit A confirming compliance with the above restrictions.

3. Wisconsin Materials are the property of WiCell and are being made available to Institution and Recipient as a service by WiCell. Ownership of all Wisconsin Materials, including any progeny or modified versions thereof, shall remain with WiCell, regardless of whether such Wisconsin Materials are received from WiCell or an authorized third party. Any Wisconsin Materials provided hereunder will be returned to WiCell or destroyed upon a material breach of any terms of this Simple Letter Agreement or the MOU.

4. Recipient agrees to communicate to WiCell all publications and/or research results made public by Institution or Recipient based on research using the Wisconsin Materials. In addition, any reports, publications, or other disclosure of results obtained with the Wisconsin Materials will acknowledge WiCell as the original source of the Wisconsin Materials and, in the event that the Wisconsin Materials were received from an authorized third party, the conditions in which such Wisconsin Materials were maintained prior to their transfer.

The Institution and Recipient must sign both copies of this letter and return both signed copies to WiCell, along with any fees if applicable, before the Wisconsin Materials may be provided to the Recipient.

**Recipient Scientist**

**Institution**

**WiCell Research Institute**

By: \_\_\_\_\_

By: \_\_\_\_\_

By: \_\_\_\_\_

Carl E. Gulbrandsen, President

Name: \_\_\_\_\_

Name: \_\_\_\_\_

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

Title: \_\_\_\_\_

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

Address: \_\_\_\_\_

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

\_\_\_\_\_

\_\_\_\_\_

**EXHIBIT A**

ANNUAL CERTIFICATION

Annual Certification of Recipient Scientist: I have read and understood the terms and conditions outlined in the Simple Letter Agreement and Memorandum of Understanding, and I agree to abide by such terms and conditions in the receipt and use of the Wisconsin Material. I further certify that the research that I am engaged in, and have been engaged in, does not include the following:

- (a) mixing of Wisconsin Materials with an intact embryo, either human or non-human;
- (b) implanting Wisconsin Materials or products of the Wisconsin Materials in a uterus;
- (c) attempting to make whole embryos with Wisconsin Materials by any method; or
- (d) using Wisconsin Materials for any therapeutic or commercial purpose, including the performance of services (including diagnostic services) for consideration or the production or manufacture of products for sale or distribution.

Recipient Scientist: \_\_\_\_\_

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

Recipient Scientist: \_\_\_\_\_

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

Recipient Scientist: \_\_\_\_\_

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