

**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"), effective October 1, 2001, 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, having an address at National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852 ("PHS") and the WiCell Research Institute, Inc., a Wisconsin nonprofit corporation having an address at 614 Walnut Street, Madison, Wisconsin 53705 ("WiCell"). PHS and WiCell are referred to herein as the "Parties".

WHEREAS certain technologies and materials concerning primate embryonic stem cells and their cultivation claimed in U.S. Patent 5,843,780 and U.S. Patent Application 09/522,030 and corresponding U.S. or foreign patent rights and any patents granted on any divisional and continuation applications of any type but only to the extent it claims an invention claimed in a patent application listed herein ("Wisconsin Patent Rights") have usefulness in basic research conducted or funded by PHS as well as potential utility for commercial applications; and

WHEREAS specific nonhuman, primate embryonic stem cell line materials, their unmodified and undifferentiated progeny or derivatives ("Wisconsin Materials") have been derived from the research efforts of James A. Thomson of the University of Wisconsin - Madison working alone or with other investigators; and

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

WHEREAS PHS funded primate research studies at the University of Wisconsin - Madison that led to certain discoveries claimed in Wisconsin Patent Rights and therefore the Government has certain use and other rights to the intellectual property comprising the Wisconsin Patent Rights granted by law and regulation; and

WHEREAS Wisconsin Materials are the proprietary, tangible property of WiCell and, as such, their ownership is not subject to the rights and obligations granted the Government in the Wisconsin Patent Rights; and

WHEREAS the Wisconsin Alumni Research Foundation of the University of Wisconsin - Madison ("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 academic researchers; and

WHEREAS WiCell represents that it has received a license, with the right to grant sublicenses, to Wisconsin Patent Rights from WARF and that WiCell also owns or otherwise has the right to distribute Wisconsin Materials to third parties; and

WHEREAS WiCell desires to exercise Wisconsin Patent Rights and distribute Wisconsin Materials without placing undue restrictions or burdens upon health research conducted or funded by PHS;

NOW, THEREFORE, the Parties hereby agree to the following terms and conditions regarding use of Wisconsin Materials or Wisconsin Patent Rights for research conducted either by PHS or on behalf of PHS by its contractors:

- (1) The Parties agree that Wisconsin Patent Rights are to be made available without cost for use in the PHS biomedical research program subject to the following conditions:
  - (a) Wisconsin Patent Rights may be used in research programs involving Wisconsin Materials only in programs in compliance with all applicable statutes, regulations and guidelines for research of this type. PHS agrees that Wisconsin Materials are to be returned to WiCell or destroyed upon a material breach of the terms of the Simple Letter Agreement for the Transfer of Materials Agreement by PHS.
  - (b) Wisconsin Patent Rights may also be used in PHS research programs involving materials other than Wisconsin Materials that may be within the scope of an issued claim of Wisconsin Patent Rights ("Third Party Materials"). This research may be conducted only in PHS research programs using Third Party in compliance with all applicable statutes, regulations and guidelines.
  - (c) Suppliers of Third Party Materials are 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 such 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 be permitted to directly or indirectly receive rights (either actual or contingent) for themselves or others under agreements or arrangements governing the supply or use of Third Party Materials. The use of Wisconsin Patent Rights in PHS research programs utilizing Third Party Materials shall be for teaching or non-commercial research purposes only. As used herein, non-commercial research purposes specifically excludes sponsored research wherein the sponsor receives a right whether actual or contingent to the results of the sponsored research, other than a grant for non-commercial research purposes to the sponsor. The Wisconsin Patent Rights may not be used with Third Party Materials for commercial purposes or the direct benefit of research sponsor, except as such research sponsor is permitted to use Wisconsin Patent Rights under a separate written agreement with WiCell or WARF. Specifically, Third Party Materials shall not be used in a PHS research program where rights (either actual or contingent) have already been granted to a research sponsor who does not have a separate written agreement with WiCell permitting commercial use of Wisconsin Patent Rights.

- (d) The Parties recognize that 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 public health. Any grant of Wisconsin Patent Rights that may be needed by a third party for commercialization of PHS Patent Rights shall be done by a separate written agreement with WiCell permitting such use of Wisconsin Patent Rights under terms not less favorable than other similar commercial licenses to the extent such rights are available.
- (2) The Parties agree that 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 Wisconsin Materials to PHS or PHS contractors, WiCell agrees to utilize the Simple Letter Agreement For The Transfer of Materials including the following conditions:
  - (a) 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 Wisconsin Materials shall remain with WiCell.

- (b) Wisconsin Materials are not to be used for diagnostic or therapeutic purposes.
- (c) Wisconsin Materials may only be used in compliance with all applicable statutes, regulations and guidelines relating to their handling or use. PHS agrees that Wisconsin Materials are to be returned to WiCell or destroyed upon a material breach of the terms of the Simple Letter Agreement for the Transfer of Materials by PHS.
- (d) The use of Wisconsin Materials shall be for teaching or non-commercial research purposes only. As used herein, non-commercial research purposes specifically excludes sponsored research wherein the sponsor receives a right whether actual or contingent to the results of the sponsored research, other than a grant for non-commercial research purposes to the sponsor. The Wisconsin Materials may not be used for commercial purposes or the direct benefit of research sponsor, except as such research sponsor is permitted to use Wisconsin Materials under a separate written agreement with WiCell or WARF. Specifically, Wisconsin Materials shall not be used in a PHS research program where rights (either actual or contingent) have already been granted to a research sponsor who does not have a separate written agreement with WiCell permitting such commercial use of Wisconsin Materials.
- (e) Wisconsin Materials may not be transferred by PHS or its contractors to third parties without the written consent of WiCell.
- (f) PHS agrees to acknowledge the source of 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 interdisciplinary collaborations among individual scientists at PHS and WiCell, but not to obligate either Party to a specific program of research utilizing Wisconsin Materials.

- (h) The Parties recognize that 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 public health. Any grant of rights to Wisconsin Materials or Wisconsin Patent Rights that may be needed by a third party for commercialization of PHS Materials shall be done by a separate written agreement with WiCell permitting such use of Wisconsin Materials or Wisconsin Patent Rights under terms not less favorable than other similar commercial licenses to the extent such rights are available.
  - (i) 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.
  - (j) A transmittal fee may be requested by WiCell to cover its preparation and distribution costs for samples of Wisconsin Materials requested by PHS. Such fees will be the responsibility of the requesting PHS laboratory and are not expected to exceed Two Thousand Five Hundred Dollars (\$2,500) 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 for research purposes only after PHS has publicly disclosed or reasonably characterized such PHS Materials. For 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 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 any terms of this Agreement, nothing herein shall be construed to diminish or supercede 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 to Wisconsin Materials. Furthermore, nothing contained herein shall be construed to be a waiver of WiCell's patent rights under the Wisconsin Patent Rights or WiCell's property rights in 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**

**Public Health Service**

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

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

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

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

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

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

**Sample Simple Letter Agreement for the Transfer of Materials to  
PHS Scientists and PHS Contractors**

In response to RECIPIENT's request for MATERIAL (\_\_\_\_ sample of nonhuman primate embryonic stem cells, WiCell Ref: \_\_\_\_\_, and its unmodified and undifferentiated progeny or derivatives) for a research program entitled \_\_\_\_\_

WiCell Research Foundation, Inc. ("PROVIDER") asks that the RECIPIENT and the RECIPIENT SCIENTIST agree to the following before the RECIPIENT receives the MATERIAL:

1. The above MATERIAL is the property of the PROVIDER and is made available as a service to the research community. Ownership of the MATERIAL shall remain with PROVIDER and transfer of the MATERIAL to the RECIPIENT shall not affect PROVIDER's ownership of the MATERIAL.
2. This MATERIAL is not to be used for diagnostic or therapeutic purposes.
3. The MATERIAL will be used for teaching or non-commercial research purposes. As used herein, non-commercial research purposes specifically excludes sponsored research wherein the sponsor receives a right whether actual or contingent to the results of the sponsored research. The MATERIAL may not be used for commercial purposes or the direct benefit of research sponsor, except as such research sponsor is permitted to use MATERIAL under a separate written agreement with PROVIDER. Specifically, MATERIAL shall not be used in a research program where rights (either actual or contingent) have already been granted to a research sponsor who does not have a separate written agreement with PROVIDER permitting such use of MATERIAL.
4. The MATERIAL will not be further distributed to others without the PROVIDER's written consent. The RECIPIENT shall refer any request for the MATERIAL to the PROVIDER. To the extent supplies are available, the PROVIDER or the PROVIDER SCIENTIST agree to make the MATERIAL available, under a separate Simple Letter Agreement to other scientists for teaching or non-commercial research purposes only.
5. The RECIPIENT agrees to acknowledge the source of the MATERIAL in any publications reporting use of it.

6. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. THE PROVIDER MAKES 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 WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Unless prohibited by law, RECIPIENT assumes all liability for claims for damages which may arise from the use, storage, handling or disposal of MATERIAL except that, to the extent permitted by law, PROVIDER shall be liable to the RECIPIENT when the damage is caused by the gross negligence or willful misconduct of the PROVIDER.
  
7. The RECIPIENT agrees to use the MATERIAL only in compliance with all applicable statutes, regulations and guidelines relating to their handling, use or disposal. RECIPIENT agrees that MATERIAL is to be returned to PROVIDER or destroyed upon a material breach of the terms of this Agreement by RECIPIENT.
  
8. The MATERIAL is provided with a transmittal fee solely to reimburse the PROVIDER for its preparation and distribution costs. The amount of the fee for this transfer of MATERIAL will be indicated here: \_\_\_\_\_

The PROVIDER, RECIPIENT and RECIPIENT SCIENTIST must sign both copies of this letter and return one signed copy to the PROVIDER. The PROVIDER will then send the MATERIAL.

PROVIDER INFORMATION and AUTHORIZED SIGNATURE

Provider Scientist: \_\_\_\_\_  
Provider Organization: \_\_\_\_\_  
Address: \_\_\_\_\_  
Name of Authorized Official: \_\_\_\_\_  
Title of Authorized Official: \_\_\_\_\_  
Signature of Authorized Official: \_\_\_\_\_  
Date: \_\_\_\_\_



RECIPIENT INFORMATION and AUTHORIZED SIGNATURE

Recipient Scientist: \_\_\_\_\_  
Recipient Organization: \_\_\_\_\_  
Address: \_\_\_\_\_  
Name of Authorized Official: \_\_\_\_\_  
Title of Authorized Official: \_\_\_\_\_  
Signature of Authorized Official: \_\_\_\_\_  
Date: \_\_\_\_\_

CERTIFICATION

Certification of Recipient Scientist: I have read and understood the conditions outlined in this Agreement and I agree to abide by them in the receipt and use of the MATERIAL.

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