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**INTELLECTUAL PROPERTY MANAGERS  
CONTRACT AND GRANT OFFICERS  
VICE CHANCELLORS – RESEARCH/ADMINISTRATION**

SUBJECT: WiCell Memorandum of Understanding with the University of California

Background

The use of federal funds for human embryonic stem cell research was approved by the Bush Administration in 2001, but only for existing cell lines meeting strict criteria described in an August 9, 2001 Presidential Statement—a few dozen lines in all. Seeking to expand the scope of work in this field, California voters in November 2004 approved Proposition 71, the “California Stem Cell Research and Cures Act,” which, over the next ten years, will provide about \$3 billion in state support for stem cell research. As this is likely to result in increased stem cell research within the University, it is important that campuses and Laboratories be familiar with the terms of the Memorandum of Understanding executed on April 25, 2002 by the University and the WiCell Research Institute (“WiCell”), a key supplier of stem cell lines and technologies.

Much current research involving human embryonic stem cells relies on inventions made by James A Thomson and others at the University of Wisconsin-Madison (UW) and claimed in patents held by the Wisconsin Alumni Research Foundation (WARF). WiCell, a subsidiary of WARF, has been licensed to distribute human embryonic stem cells and related materials and technologies developed at UW. The UW patents claim certain primate and human embryonic stem cells, a method of isolating pluripotent primate and human embryonic stem cell lines, and the cell lines created by these methods. The relevant claims appear in U.S. Patent 5,843,780, U.S. Patent 6,200,806 and U.S. Patent Application 09/522,030, referred to in the MOU as the “Wisconsin Patent Rights”. WiCell also owns human embryonic stem cell lines, referred to in the MOU as the “Wisconsin Materials”, five of which meet the criteria for use with federal research funds.

The April 25, 2002 Memorandum of Understanding (MOU) between the University and WiCell serves two purposes: 1) it gives the University of California a license under the WiCell patents, and 2) it creates a framework for the physical transfer of UW stem cell line materials to University of California researchers. With this MOU in place, University researchers may receive these materials from WiCell by executing a pre-negotiated Simple Letter Agreement (SLA) and paying a transmittal fee. The MOU thus serves as a master Material Transfer Agreement between UC and WiCell, with individual transfers accomplished by means of the SLA.

The UC-WiCell MOU reflects changes to what was then the WiCell standard MOU, negotiated by UCOP’s Office of Technology Transfer. Some of these changes were driven by the fact that two of the lines that are consistent with the 2001 Presidential Statement were derived by UCSF, making it

necessary for the license portion of the MOU to specifically address UC's ability to make the UCSF lines available to other research institutions.

However, even with the changes that were negotiated with WiCell, the MOU, as noted in the discussion that follows, still presents several issues. In particular, the license under Wisconsin Patent Rights does not provide for the use of human embryonic stem cell lines that are outside the 2001 Presidential Statement, i.e., those developed after August 9, 2001. At the time the MOU was executed, WiCell and the University acknowledged this as an issue and committed to working together to address it in the form of an amendment to the MOU. However, the matter has not yet been resolved. Particularly in light of the passage of Proposition 71 and the likely increase in University stem cell research activities, OTT is in the process of reopening discussions with WiCell. Any such amendment will be communicated as a supplement to this Guidance Memo.

The following summarizes the significant points of the existing UC-WiCell MOU, and highlights its remaining issues, as well as the implementation concerns for University administrators and researchers considering the use of WiCell's stem cell materials.

### Agreement Summary

The following is a brief summary of the main points of the MOU:

- The MOU provides the University with a license to use the Wisconsin Patent Rights and to conduct research using the Wisconsin Materials.
- The Simple Letter Agreement (SLA) attached to the MOU functions as the instrument to transfer Wisconsin Materials to University campuses and Laboratories.
- The University must pay WiCell a \$5,000 transmittal fee for providing the Wisconsin Materials.
- The Wisconsin Materials may not be used for therapeutic or diagnostic purposes.
- The Wisconsin Materials may not be used in certain research involving viable embryos or other efforts that could lead to cloned life-forms.
- The Wisconsin Materials may only be used for non-commercial research and teaching purposes.
- The Wisconsin Materials may be used in research sponsored by a for-profit entity (through the supply of funding or materials), but only if it has its own license from WiCell or receives no rights to the results of the sponsored research.
- Research using Wisconsin Patent Rights may involve only cell lines that are on the list of those approved for use with federal funding, which may exclude any UC or third-party cell lines developed subsequent to the August 9, 2001 Presidential Statement.
- Materials that originate with a third party, that are consistent with the 2001 Presidential Statement, and that are within the scope of an issued claim of Wisconsin Patent Rights may be used in the proposed research, but the third party may not receive any rights to the research results.
- The Wisconsin Materials may not be transferred within the University or to any third parties without first obtaining WiCell's written consent.
- All materials supplied by WiCell must be destroyed or returned upon the University's material breach of the terms of the SLA.

- Recipient Scientists receiving Wisconsin Materials under the SLA must submit an Annual Certification form, reaffirming adherence to the conditions of the MOU, including no commercial research using these materials.

## Implementation Issues

The three documents governing the relationship between the University and WiCell—the executed MOU, the approved Simple Letter Agreement, and the Annual Certification form—are attached to this Guidance Memo as a single pdf file. In addition, to simplify implementation, the SLA and the Annual Certification form are provided together as a modifiable Microsoft Word document. Each of these documents raises its own set of issues regarding implementation.

### **I. The Memorandum of Understanding**

#### **A. Federally-Approved Lines Only**

The principal gap in the UC-WiCell MOU is that it addresses only research involving human embryonic stem cell line materials that are consistent with the August 9, 2001 Presidential Statement. Two of these approved lines were developed by UCSF and they are covered by the MOU. However, the license in the MOU does not provide for use of the Wisconsin Patent Rights in research involving any cell lines that do not meet the criteria for federal funding.

#### **B. Restrictions on Nature of Research Permitted by the MOU**

The WiCell MOU provides the University with rights under the Wisconsin Patents to use the Wisconsin Materials for non-commercial research purposes, but with certain key restrictions placed upon the kinds of research that may be conducted. Specifically excluded are research programs that involve mixing the materials with an intact embryo, implanting the materials in a uterus, or attempting to make whole embryos. Moreover, the Wisconsin Materials are not to be used for diagnostic or therapeutic purposes.

#### **C. Limitations on Sponsorship**

The research license under the MOU also limits the use of Wisconsin Patent Rights and Wisconsin Materials to non-commercial research and teaching activities. However, “non-commercial research” is defined in the MOU by what it excludes: specifically, any research sponsored by a for-profit entity (through the supply of funding or materials), unless the sponsor already has a separate license agreement with WiCell or agrees to receive no rights to the results of the sponsored research.

This approach to defining non-commercial vs. commercial research is somewhat ambiguous, and may limit research sponsorship opportunities. To be clear, if campus investigators working with WiCell lines want to enter into research arrangements with for-profit entities, the University must first ascertain whether the for-profit entity has an appropriate agreement with WiCell. If not, then to prevent the possibility of conflicting

legal obligations, investigators will need to keep the research programs completely separate.

**D. New Materials and Discoveries**

If the University discovers any new materials in the course of the research using the Wisconsin Materials, reasonable quantities must be provided upon request to WiCell or the University of Wisconsin for internal research purposes. This requirement does not come into play until the materials have been publicly disclosed or “reasonably characterized.” Similarly, if the University makes any patentable discoveries in research using the Wisconsin Patent Rights, the University agrees to grant research licenses to WiCell and the University of Wisconsin.

**E. Transfer of UCSF Cell Lines**

One of the key changes that the University negotiated to the standard WiCell MOU was the right to provide the University’s two federally-approved human embryonic stem cell lines (developed at UCSF) to non-profit third parties for non-commercial research purposes. Third parties receiving the cell lines must either have a standing MOU with WiCell, or enter into a WiCell-approved MTA with UC (<http://escells.ucsf.edu/ucsfMTA.pdf>).

**II. The Simple Letter Agreement for the Transfer of Materials to Recipient Scientists**

**A. The MOU and the SLA**

The MOU, which is the primary agreement between the parties, addresses both WiCell’s intellectual and physical property. The SLA serves as the implementing document for each physical transfer of Wisconsin Materials to a particular UC campus and researcher. The SLA recapitulates those provisions of the MOU that deal specifically with the University’s use of the Wisconsin Materials. It stipulates the uses that are not permitted (including therapeutic, diagnostic and cloning research), as well as the limitations placed on commercial research work sponsored by for-profit entities.

**B. Utilizing the SLA**

The SLA requests certain information, including the title of the proposed research program, along with the names of the recipient scientist and the recipient organization. Executing the SLA requires payment of a \$5,000 transmittal fee to WiCell, together with three signatures: the president of WiCell, an authorized official of the University, and the University scientist.

**III. Annual Certification Form**

**A. Terms of the Certification**

Attached to the Simple Letter Agreement is an Annual Certification form that the Recipient Scientist is required to submit to WiCell, commencing on the first anniversary of the execution of the SLA. The Annual Certification reaffirms that the Recipient Scientist understands and agrees to abide by the terms and conditions of the MOU and the SLA. The Recipient Scientist also asserts that “he or she is not engaged, and has not been

engaged, in commercial research using the Material or any Third Party Material which requires a license under the Wisconsin Patent Rights.”

**B. Certification Issues**

The Annual Certification raises a couple of issues for campuses operating under an executed SLA with WiCell.

- i. The annual requirement places an administrative burden on the investigator, which, if neglected, may place the University in breach of the SLA and subject to its termination provisions.
- ii. Because the Recipient Scientist certifies that he or she “has not been engaged” in commercial research requiring a WiCell license, the Annual Certification can reach to a time prior to the execution of the SLA or the MOU. If the Recipient Scientist has ever engaged in what WiCell would consider commercial research using these Materials, the Annual Certification cannot be signed. WiCell has indicated that it wants to address each such situation on a case-by-case basis.

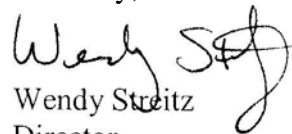
Informed Participation

It is important that individuals involved in research conducted under the MOU and the SLA understand the terms of these agreements and acknowledge the restrictions placed upon research using WiCell’s patent rights and materials. To assist in this process, a sample Informed Participation Notice is attached to this Guidance Memo, which campuses may use as a basis for the notice they provide to prospective recipient scientists.

If you have any questions concerning the WiCell Memorandum of Understanding or the Simple Letter Agreement for the Transfer of Materials to Recipient Scientists, please contact:

Charles Drucker  
(510) 587-6011  
charles.drucker@ucop.edu

Sincerely,



Wendy Streit  
Director

Policy, Analysis and Campus Services

- Attachment A: WiCell Memorandum of Understanding and Simple Letter Agreement (pdf)
- Attachment B: Simple Letter Agreement for the Transfer of Materials to Recipient Scientists and Annual Certification form (Word)
- Attachment C: Sample Important Notice Concerning Research Use of WiCell Stem Cell Materials and Technologies (Word)

## Memorandum of Understanding

This Memorandum Of Understanding (hereinafter "Agreement"), effective April 25, 2002, by and between The Regents of the University of California having an address at 1111 Franklin Street, 12<sup>th</sup> Floor, Oakland, California 94607-5200 ("Recipient") and the WiCell Research Institute, Inc., a Wisconsin nonprofit corporation having an address at 614 Walnut Street, Madison, Wisconsin 53705 ("WiCell"). Institute 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, U.S. Patent 6,200,806, 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 by Recipient as well as potential utility for commercial applications; and

**WHEREAS**, specific human embryonic stem cell line materials, their unmodified and undifferentiated progeny or unmodified and undifferentiated derivatives ("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; and

**WHEREAS**, 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 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 Recipient 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 by Recipient; and

**WHEREAS**, human embryonic stem cell line materials that are qualified for Federal funding under the President's announcement of August 9, 2001 have been derived from the research efforts of Recipient investigators ("UC Materials"); and

**WHEREAS**, UC Materials are the property of Recipient; and

**WHEREAS**, Recipient has a mission to serve the public good and desires to serve the public interest by making UC Materials and other research results of Recipient researchers using Wisconsin Materials and the Wisconsin Patent Rights widely available to other academic researchers;

**NOW, THEREFORE**, the Parties hereby agree to the following terms and conditions regarding use of Wisconsin Materials or Wisconsin Patent Rights for academic, non-commercial research conducted by

Recipient:

- (1) The Parties agree that Wisconsin Patent Rights are to be made available without cost for use in the Recipient 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. Specifically, Recipient agrees that its research programs will exclude: (i) the mixing of Wisconsin Materials with an intact embryo, either human or non-human; (ii) implanting Wisconsin Materials or products of Wisconsin Materials in a uterus; and (iii) attempting to make whole embryos with Wisconsin Materials by any method. An annual Certification Statement confirming compliance with the restrictions on the use of Wisconsin Materials shall be supplied to WiCell by Recipient and the scientists receiving Wisconsin Materials under the terms of the "Simple Letter Agreement For The Transfer of Materials" (Attachment A). Recipient agrees that Wisconsin Materials are to be returned to WiCell or destroyed upon Recipient's material breach of the terms of the Simple Letter Agreement for the Transfer of Materials Agreement.
  - (b) Wisconsin Patent Rights may also be used in Recipient research programs involving materials other than Wisconsin Materials that are within the scope of an issued claim of Wisconsin Patent Rights and that originate with a third party to this Agreement ("Third Party Materials"), or involving UC Materials. This research may be conducted only in Recipient research programs using UC Materials or Third Party Materials that are derived consistent with the Presidential Statement of August 9, 2001 and 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 Recipient 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 Recipient 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 research sponsored by a for-profit entity either through supply of materials or funding, except as such research sponsor i) is permitted to use Wisconsin Patent Rights under a separate written agreement with WiCell or WARF, or ii) receives no rights to the results of the sponsored research. Specifically, Third Party Materials shall not be used in a Recipient research program sponsored by a for-profit research sponsor who does not have a separate written agreement with WiCell permitting commercial use of Wisconsin Patent Rights unless such sponsor receives no rights, actual or contingent, to the results of the sponsored research. Recipient is granted a limited, revocable, non-commercial, research license by WiCell to provide UC Materials to non-profit third parties for non-commercial research purposes as defined herein. Such UC Materials may be provided by Recipient to a third party if such third party has 1) already entered into an MOU with WiCell, or 2) enters into an MTA with Recipient that has been approved in writing by WiCell (in which case Recipient will provide WiCell with a copy of the fully executed

MTA within thirty (30) days of signing by both parties).

- (d) The Parties recognize that Wisconsin Patent Rights may be used in Recipient research to make patentable discoveries (“Recipient 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 Recipient 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 Recipient’s biomedical research programs. For purposes of transferring Wisconsin Materials to Recipient investigators, WiCell agrees to utilize the Simple Letter Agreement For The Transfer of Materials in Appendix A, including the following conditions:
- (a) Wisconsin Materials are the property of WiCell and are being made available to investigators at Recipient institution 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. Specifically, Recipient agrees that its research program will exclude: (i) the mixing of Wisconsin Materials with an intact embryo, either human or non-human; (ii) implanting Wisconsin Materials or products of Materials in a uterus; and (iii) attempting to make whole embryos with Wisconsin Materials by any method. An annual Certification Statement confirming compliance with the restrictions on the use of Wisconsin Materials shall be supplied to WiCell by Recipient and the scientists receiving Wisconsin Materials under the terms of the Simple Letter Agreement For The Transfer of Materials. Recipient 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 Recipient or its investigators.
  - (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 research sponsored by a for-profit entity either through supply of materials or funding, except as such research sponsor i) is permitted to use Wisconsin Materials under a separate written agreement with WiCell or WARF, or ii) receives no rights to the results of the sponsored research. Specifically, Wisconsin Materials shall not be used in a Recipient research program sponsored by a for-profit research sponsor who does not have a separate written agreement with WiCell permitting such commercial use of Wisconsin Materials unless such sponsor receives no rights, actual or contingent, to the results of the sponsored research.
  - (e) Wisconsin Materials may not be transferred by Recipient to third parties without the written consent of WiCell.
  - (f) Recipient 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 Recipient and WiCell that may utilize Wisconsin Materials, Recipient 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 Recipient 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 Recipient's research program to make discoveries of different materials ("Recipient 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 Recipient 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. Recipient assumes all liability for claims for damages which may arise from Recipient's use, storage, handling or disposal of Wisconsin Materials except that, to the extent permitted by law, WiCell shall be liable to Recipient 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 Recipient. Such fees will be the responsibility of the requesting Recipient laboratory and are not expected to exceed Five Thousand Dollars (\$5,000) to accompany the Recipient Simple Letter Agreement for the Transfer of Materials.

(3) Upon WiCell's written request, Recipient agrees to provide without cost, other than payment of Recipient's actual out-of-pocket costs, reasonable quantities of any Recipient Materials that it makes in the course of its research program to WiCell for research purposes only at WiCell or the University of Wisconsin after Recipient has publicly disclosed or reasonably characterized such Recipient Materials. Recipient also agrees to grant under the Recipient Patent Rights internal research licenses to WiCell and the University of Wisconsin.

(4) 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 Recipient.

(5) 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.

(6) In the event of a disagreement between the terms of this Agreement and those of the Simple Letter Agreement for the Transfer of Materials in Appendix A, the terms of this Agreement shall control.

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: 4/25/02

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

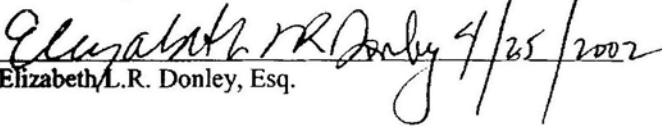
**Recipient**

By: 

Date: April 25, 2002

Title: Executive Director  
Research Admin. and  
Technology Transfer

Reviewed by WiCell's General Counsel:

  
Elizabeth L.R. Donley, Esq.

(WiCell's attorney shall not be deemed a signatory to this Agreement.)

WiCell Ref: Thomson - P98222US

## APPENDIX A

Agreement No. \_\_\_\_\_

### **Simple Letter Agreement for the Transfer of Materials to Recipient Scientists**

In response to RECIPIENT's request for MATERIAL (Human Embryonic Stem Cells, WiCell Ref: No. P98222US and its unmodified and undifferentiated progeny or derivatives) for a research program entitled \_\_\_\_\_

WiCell Research Foundation, Inc. ("PROVIDER") has entered into a Memorandum of Understanding dated \_\_\_\_\_ (the "MOU") with RECIPIENT which is hereby incorporated by reference and asks that the RECIPIENT and the RECIPIENT SCIENTIST agree to the following before the RECIPIENT SCIENTIST 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 research sponsored by a for-profit entity either through supply of materials or funding, except as such research sponsor i) is permitted to use MATERIAL under a separate written agreement with PROVIDER, or ii) receives no rights to the results of the sponsored research. Specifically, MATERIAL shall not be used in a research program sponsored by a for-profit research sponsor who does not have a separate written agreement with PROVIDER permitting such use of MATERIAL unless such sponsor receives no rights, actual or contingent, to the results of the sponsored research.
4. Nothing contained herein shall be considered to be the grant of a commercial license or right under U.S. Patent 5,843,780, U.S. Patent 6,200,806, 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, reissues and reexaminations ("WISCONSIN PATENT RIGHTS") or to the MATERIALS. Furthermore, nothing contained herein shall be construed to be a waiver of PROVIDER's patent rights under the WISCONSIN PATENT RIGHTS or PROVIDER's property rights in the MATERIALS.
5. 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.
6. The RECIPIENT agrees to acknowledge the source of the MATERIAL in any publications reporting use of it.
7. Upon PROVIDER's written request, RECIPIENT agrees to provide without cost, other than

payment of RECIPIENT's actual out-of-pocket costs, reasonable quantities of any RECIPIENT MATERIALS that it makes in the course of its research program to PROVIDER for research purposes only at PROVIDER or the University of Wisconsin after RECIPIENT has publicly disclosed or reasonably characterized such RECIPIENT MATERIALS. RECIPIENT also agrees to grant under the RECIPIENT Patent Rights internal research licenses to PROVIDER and the University of Wisconsin-Madison.

8. 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 RECIPIENT's 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.
9. The RECIPIENT agrees to use the MATERIAL only in compliance with all applicable statutes, regulations and guidelines relating to their handling, use or disposal. Specifically, RECIPIENT agrees that its research program will exclude: (i) the mixing of MATERIAL with an intact embryo, either human or non-human; (ii) implanting MATERIAL or products of MATERIAL in a uterus; and (iii) attempting to make whole embryos with MATERIAL by any method. RECIPIENT shall supply an Annual Certification Statement confirming compliance with the restrictions on the use of MATERIAL supplied by PROVIDER. RECIPIENT agrees that MATERIAL is to be returned to PROVIDER or destroyed upon a material breach of the terms of this Agreement by RECIPIENT.
10. 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 \$5000.

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.

WICELL RESEARCH INSTITUTE, INC.

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

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

RECIPIENT INFORMATION and AUTHORIZED SIGNATURE

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

Recipient Organization: \_\_\_\_\_

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

Signature of Recipient Scientist: \_\_\_\_\_

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

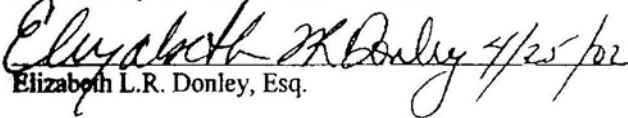
Name of Authorized Official: \_\_\_\_\_

Title of Authorized Official: \_\_\_\_\_

Signature of Authorized Official: \_\_\_\_\_

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

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**Reviewed by WiCell's General Counsel:**

  
**Elizabeth L.R. Donley, Esq.**

(WiCell's attorney shall not be deemed a signatory to this Agreement.)

WiCell Ref: Thomson – P98222US

ANNUAL CERTIFICATION

Annual Certification of Recipient Scientist: I have read and understood the conditions outlined in the Memorandum of Understanding executed by The Regents of the University of California and the WiCell Research Institute, and in the Simple Letter Agreement for the Transfer of Materials executed thereunder on <insert date> and I agree to abide by them in the receipt and use of the MATERIAL. I further certify that, consistent with those agreements, I am not engaged and have not been engaged in commercial research using the MATERIAL or any Third Party Material which requires a license under the WISCONSIN PATENT RIGHTS.

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

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

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

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

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

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

Agreement No. \_\_\_\_\_

## **Simple Letter Agreement for the Transfer of Materials to Recipient Scientists**

In response to RECIPIENT's request for MATERIAL (Human Embryonic Stem Cells, WiCell Ref: No. P98222US and its unmodified and undifferentiated progeny or derivatives) for a research \_\_\_\_\_ program \_\_\_\_\_ entitled \_\_\_\_\_

\_\_\_\_\_  
WiCell Research Foundation, Inc. ("PROVIDER") has entered into a Memorandum of Understanding dated \_\_\_\_\_ (the "MOU") with RECIPIENT which is hereby incorporated by reference and asks that the RECIPIENT and the RECIPIENT SCIENTIST agree to the following before the RECIPIENT SCIENTIST 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 research sponsored by a for-profit entity either through supply of materials or funding, except as such research sponsor i) is permitted to use MATERIAL under a separate written agreement with PROVIDER, or ii) receives no rights to the results of the sponsored research. Specifically, MATERIAL shall not be used in a research program sponsored by a for-profit research sponsor who does not have a separate written agreement with PROVIDER permitting such use of MATERIAL unless such sponsor receives no rights, actual or contingent, to the results of the sponsored research.
4. Nothing contained herein shall be considered to be the grant of a commercial license or right under U.S. Patent 5,843,780, U.S. Patent 6,200,806, 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, reissues and reexaminations ("WISCONSIN PATENT RIGHTS") or to the MATERIALS. Furthermore, nothing contained herein shall be construed to be a waiver of PROVIDER's patent rights under the WISCONSIN PATENT RIGHTS or PROVIDER's property rights in the MATERIALS.
5. 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.
6. The RECIPIENT agrees to acknowledge the source of the MATERIAL in any publications reporting use of it.

7. Upon PROVIDER's written request, RECIPIENT agrees to provide without cost, other than payment of RECIPIENT's actual out-of-pocket costs, reasonable quantities of any RECIPIENT MATERIALS that it makes in the course of its research program to PROVIDER for research purposes only at PROVIDER or the University of Wisconsin after RECIPIENT has publicly disclosed or reasonably characterized such RECIPIENT MATERIALS. RECIPIENT also agrees to grant under the RECIPIENT Patent Rights internal research licenses to PROVIDER and the University of Wisconsin-Madison.
8. 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 RECIPIENT's 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.
9. The RECIPIENT agrees to use the MATERIAL only in compliance with all applicable statutes, regulations and guidelines relating to their handling, use or disposal. Specifically, RECIPIENT agrees that its research program will exclude: (i) the mixing of MATERIAL with an intact embryo, either human or non-human; (ii) implanting MATERIAL or products of MATERIAL in a uterus; and (iii) attempting to make whole embryos with MATERIAL by any method. RECIPIENT shall supply an Annual Certification Statement confirming compliance with the restrictions on the use of MATERIAL supplied by PROVIDER. RECIPIENT agrees that MATERIAL is to be returned to PROVIDER or destroyed upon a material breach of the terms of this Agreement by RECIPIENT.
10. 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 \$5000.

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.

WICELL RESEARCH INSTITUTE, INC.

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

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

RECIPIENT INFORMATION and AUTHORIZED SIGNATURE

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

Recipient Organization: \_\_\_\_\_

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

Signature of Recipient Scientist: \_\_\_\_\_

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

Name of Authorized Official: \_\_\_\_\_

Title of Authorized Official: \_\_\_\_\_

Signature of Authorized Official: \_\_\_\_\_

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

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Reviewed by WiCell's General Counsel:

\_\_\_\_\_, \_\_\_\_\_  
Elizabeth L.R. Donley, Esq.

(WiCell's attorney shall not be deemed a signatory to this Agreement.)

ANNUAL CERTIFICATION

Annual Certification of Recipient Scientist: I have read and understood the conditions outlined in the Memorandum of Understanding executed by The Regents of the University of California and the WiCell Research Institute, and in the Simple Letter Agreement for the Transfer of Materials executed thereunder on <insert date> and I agree to abide by them in the receipt and use of the MATERIAL. I further certify that, consistent with those agreements, I am not engaged and have not been engaged in commercial research using the MATERIAL or any Third Party Material which requires a license under the WISCONSIN PATENT RIGHTS.

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

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

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

University Investigators, Researchers, Students, and Collaborators

# IMPORTANT NOTICE

concerning

## Research Using WiCell Stem Cell Materials and Technologies

The University's license to use stem cell materials and patented technologies from WiCell places limits on the kinds of research projects that you may conduct, and requires you to provide WiCell with certain research results and notifications. You must read and understand the full systemwide UC-WiCell **Memorandum of Understanding** as well as the **Simple Letter Agreement for the Transfer of Materials to Recipient Scientists** before using the WiCell Materials.

The University of California has entered into a systemwide Memorandum of Understanding (MOU) with the WiCell Research Institute to license the use, for research and teaching purposes only, of stem cell materials and patented technologies originally developed at the University of Wisconsin-Madison. The intellectual property and other terms of the MOU are more desirable to researchers and UC than are otherwise available directly from WiCell. However, there are still limitations on the kinds of research projects that may be conducted using the WiCell materials and technologies, some of which reflect current federal policy regarding funding for human embryonic stem cell research. In addition, the MOU obliges researchers to provide WiCell with certain research results and annual notifications.

### **BRIEF SUMMARY OF TERMS**

The following summary is intended to highlight certain terms of the systemwide UC-WiCell Memorandum of Understanding that may limit your ability to conduct certain types of research activities that utilize stem cells covered under the MOU.

***Obligation to Sign Agreement:*** Before receiving stem cell materials provided by WiCell, you are required to read the entire UC-WiCell MOU. You must also read and sign the Simple Letter Agreement for the Transfer of Materials to Recipient Scientists

(SLA) indicating your acceptance of its provisions. The SLA requires that you provide the name of the research project for which the WiCell materials are requested.

***Transmittal Fee:*** To receive materials for your research project, the campus is required to pay WiCell a \$5,000 transmittal fee at the time the signed SLA is sent to them.

***Rights Provided:*** The MOU and the SLA allow you to use WiCell materials and patented technologies for non-commercial research and teaching purposes, but with certain significant restrictions. Use is prohibited in research programs that involve mixing the materials with an intact embryo, implanting the materials in a uterus, or attempting to make whole embryos. Moreover, you may not use the materials for diagnostic or therapeutic purposes.

***Use With Federally-Approved Lines Only:*** Your research using the WiCell materials or patented technologies may involve other cell lines developed by UC or third parties only if they are among those cell lines approved for federal funding as of August 9, 2001. This restriction is consistent with current NIH policy regarding support for research that uses human embryos to derive new cell lines. Your use of the WiCell materials and patented technologies with any cell lines that do not meet the August 9, 2001 requirements for federal funding is not permitted under the terms of the MOU and the SLA. While two cell lines developed by UCSF are currently approved for use with federal research funds, other lines developed by UC and third parties since the execution of the MOU in 2002, as well as those that may be derived in the future, are not approved for use under the WiCell MOU.

***Research Involving Third-Party Materials:*** You may conduct research using WiCell patented technologies with stem cell materials developed and provided by third parties, but with several restrictions. The materials must meet the August 9, 2001 criteria for federal funding; the research must be for teaching or non-commercial purposes only; and the third party supplying the materials must agree to receive no rights to the research results.

***Limitations on Sponsorship:*** You may not use the WiCell materials or technologies in research projects sponsored by a for-profit entity, or for which a for-profit entity provides research materials, unless the project sponsor has a separate agreement with WiCell, or else agrees to receive no rights to the research results.

***Treatment of Materials:*** You may not transfer the WiCell materials to other researchers within the University or to any third parties without first obtaining WiCell's written consent. You must destroy or return to WiCell any materials supplied by them if there is a breach in any of the terms of the SLA.

***Annual Certification:*** Each year, you are required to submit to WiCell a signed form certifying that you are not engaged, and have not been engaged, in any commercial research that uses the WiCell materials, or any third party materials requiring a license to WiCell's patented technologies. Failure to submit this form annually is a breach of the SLA, and could result in its termination. Care must be exercised in submitting this form, as your certification that you "have not been engaged" in such research may apply to your participation in projects started before the execution of the SLA. If you have ever engaged in what WiCell would consider commercial research using these Materials, the Annual Certification cannot be signed as is.

***Intellectual Property Obligations:*** In brief, if your research with WiCell materials or patented technologies results in the discovery of new materials, reasonable quantities of such new materials must be provided upon request to WiCell or the University of Wisconsin, after the materials have been reasonably characterized or published. Similarly, if you make any patentable discovery research using the Wisconsin patent rights, the University must grant research license to WiCell and the University of Wisconsin.

May 10, 2005