

# National Stem Cell Bank

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Following is a check-list for submitting agreements from ES Cell International or WiCell Research Institute to the National Stem Cell Bank (NSCB) for human embryonic stem cells.

- Create an account on the NSCB Web site if you do not already have one. You may access this site by going to [www.nationalstemcellbank.org](http://www.nationalstemcellbank.org).
- Submit an online request for the stem cell(s) of your choice

## **Memorandum of Understanding (MOU) (pages 1-4 of the agreement)**

- \* If your institution already has an MOU in place you will not need to complete another one.
- \* Mail two original, signed MOU's.
- Leave the agreement number blank (page 1).
- Leave the effective date blank (page 1).
- Fill in the name of the institution, university, or organization (page 1).
- Fill in the address of the institution, university, or organization (page 1).
- An authorized official must sign under institution (page 4).
- This person might be from the technology transfer or legal department.
- Mail two original, signed MOU's.

## **Simple Letter Agreement (SLA) (pages 5-6 of the agreement)**

- \* Please complete two signed, original SLA's per cell line being requested.
- Fill in your order reference number from the NSCB Web site (page 5).
- Leave the agreement number blank (page 5).
- Fill in the name of the institution, university, or organization (page 5).
- Fill in the name of the provider (WiCell or authorized provider).
- Fill in the name of the principal investigator under "Recipient" (page 5).
- Fill in which cell line you are requesting (page 5).
- Fill in a descriptive research title (page 5). If you're listing "differentiation of stem cells," please indicate what you will be differentiating to.
- Leave the date for the Simple Letter Agreement and Memorandum of Understanding blank (page 5).
- Have the recipient scientist/principal investigator sign where indicated (page 5).
- Complete the shipping address where indicated (page 5).
- Have the authorized institution official sign where indicated (page 5).  
This person might be from the Tech Transfer or legal department.
- Save the Annual Certification, as you will need to submit it on June 1 of each year as referenced in Section 2 of the SLA (page 5).
- Mail two original, signed SLA's per cell line.

When the Contract Manager receives your agreements, the NSCB request created in Step 1 will be updated. Please direct any questions to the NSCB Contract Manager at "[info@wicell.org](mailto:info@wicell.org)."

Thank you.

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

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

Mailing address:

### **US Mail:**

National Stem Cell Bank  
c/o WiCell Research Institute  
Contract Manager  
PO Box 7365  
Madison, WI 53707

### **International or Express Mail:**

National Stem Cell Bank  
c/o WiCell Research Institute  
Contract Manager  
614 Walnut St.  
Madison, WI 53726 USA

## Memorandum of Understanding – Wisconsin Materials

This Memorandum of Understanding (hereinafter “Agreement”) is made effective as of the \_\_\_ of \_\_\_\_\_, 200\_\_, by and between \_\_\_\_\_ (“Institution”), having an address at \_\_\_\_\_, and **WiCell Research Institute, Inc.** (“WiCell”), a Wisconsin nonprofit corporation having an address at 614 Walnut Street, Madison, Wisconsin 53726.

**WHEREAS**, WiCell holds certain rights in human embryonic stem cell lines developed by James A. Thomson of the University of Wisconsin – Madison, working either alone or with other researchers at the University (the “Wisconsin Materials”);

**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 “Patent Rights”), and has afforded WiCell the right to grant sublicenses under the Patent Rights to non-profit and academic research institutions;

**WHEREAS**, WARF and WiCell have a mission to serve the public good and desire to provide Institution, and researchers who have entered into a Simple Letter Agreement with WiCell governing the transfer of Wisconsin Materials (“Recipients”), the opportunity to use the Wisconsin Materials for non-commercial research purposes in the Recipient’s laboratory at Institution; and

**WHEREAS**, Institution agrees that any such research conducted using the Wisconsin Materials shall be in accordance with the terms and conditions set forth below.

**NOW, THEREFORE**, in consideration of the above premises and the mutual covenants contained herein, the parties agree as follows:

1. Institution shall have the nontransferable right under the Patent Rights to maintain and use the Wisconsin Materials within the laboratories of its Recipients solely for non-commercial research purposes. As used herein, the “Wisconsin Materials” shall further include any progeny and modified version of the Wisconsin Materials, other than differentiated cells no longer capable of functioning as a stem cell. Any and all uses of the Wisconsin Materials must be in compliance with all applicable statutes, regulations, guidelines (including the NAS Guidelines) and any Institutional Review Board decisions. Specifically, Institution agrees that the research conducted by its Recipients will exclude:

- (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; and
- (c) attempting to make whole embryos with Wisconsin Materials by any method.

Institution agrees that each Recipient shall submit to WiCell an annual Certification Statement confirming compliance with the restrictions hereunder on the use of the Wisconsin Materials.

2. Institution agrees that it shall require each researcher at Institution who desires to receive and use the Wisconsin Materials, whether provided by WiCell hereunder or by a third party authorized by WiCell to provide Wisconsin Materials to Institution, to enter into and execute the Simple Letter

Agreement attached hereto as Appendix A. WiCell shall cause the requested Wisconsin Materials to be shipped to the Recipient upon receipt of both an executed Simple Letter Agreement requesting such Wisconsin Materials and the transmittal fee, if any, requested by WiCell pursuant to paragraph 3 below.

3. Institution acknowledges that a transmittal fee may be requested by WiCell to cover the preparation and distribution costs for each sample of Wisconsin Materials requested by each Recipient. Such fees will be the responsibility of the requesting Recipient laboratory. Despite the payment of any such fee, the transfer of the Wisconsin Materials shall not be considered a sale of the Wisconsin Materials to Recipient or Institution.

4. Wisconsin Materials are the property of WiCell and are being made available to Institution and its Recipients as a service by WiCell and the National Stem Cell Bank. 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 to any Recipient hereunder will be returned to WiCell or destroyed upon a material breach of any terms of the Simple Letter Agreement.

5. Institution and its Recipients shall have the right to transfer Wisconsin Materials to other Recipients, provided that:

(a) WiCell provides written confirmation that the receiving Recipient has entered into and executed a Simple Letter Agreement relating to the Wisconsin Materials to be transferred;

(b) the transfer of the Wisconsin Materials shall be made for no consideration (i.e., commercial grantback 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);

(c) 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 Recipient; and

(d) the Recipient provides written notice to the receiving Recipient that the Wisconsin Materials are not being provided by or on behalf of WiCell and have been maintained by the Recipient in conditions which may not be consistent with those utilized by WiCell.

6. WiCell recognizes that the technology of the Patent Rights may be used by Recipients in research to make patentable discoveries ("Institution Patent Rights") which may eventually provide commercial products that benefit the public health. Institution agrees to grant WiCell, the University of Wisconsin and other like non-profit and/or academic research institutions a license under the Institution Patent Rights to use the technology of the Institution Patent Rights for non-commercial research purposes.

7. The rights provided hereunder do not grant Institution the right to grant sublicenses under the Patent Rights, or the right to develop and/or use Wisconsin Materials for any therapeutic or commercial purpose, including the right to use the Wisconsin Materials to perform services (including diagnostic services) for consideration, or for the production or manufacture of products for sale or distribution to third parties. Any license needed by a third party under the Patent Rights for the manufacture, production, use or commercialization of any Institution Patent Rights shall be provided by a separate written agreement with WARF. Nothing herein shall be construed to require WARF to enter into any such agreement, or to hinder WiCell or WARF from entering into any other agreement with any third party which may limit the grant of any license under the Patent Rights necessary for the practice of the Institution Patent Rights.

8. Institution and its Recipients shall communicate to WiCell all publications and/or research results made public by Institution or its Recipients 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.

9. 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 ANY WARRANTY THAT THE USE OF THE WISCONSIN MATERIALS WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK OR OTHER PROPRIETARY RIGHTS. Institution assumes all liability for any claim for damages which may arise from the use, storage, handling or disposal of Wisconsin Materials by its Recipients, except to the extent caused by the gross negligence or willful misconduct of WiCell.

10. The provisions of this Agreement, and the obligations hereunder, shall continue as long as the Wisconsin Materials continue to be used by Institution or any of its Recipients. Nothing contained herein shall be construed to be a waiver by WiCell or WARF of any rights under the Patent Rights.

11. This Agreement shall be governed by and construed in all respects in accordance with the laws of the State of Wisconsin, without reference to its conflicts of laws principles. If the enforcement of any provisions of this Agreement are or shall come into conflict with the laws or regulations of any jurisdiction or any governmental entity having jurisdiction over the parties or this Agreement, those provisions shall be deemed automatically deleted, if such deletion is allowed by relevant law, and the remaining terms and conditions of this Agreement shall remain in full force and effect. If such a deletion is not so allowed or if such a deletion leaves terms thereby made clearly illogical or inappropriate in effect, the parties agree to substitute new terms as similar in effect to the present terms of this Agreement as may be allowed under the applicable laws and regulations.

12. This Agreement reflects a negotiated compromise between the parties. Neither party shall be considered to be the drafter of this Agreement, or any of its provisions, for the purpose of any statute, case law or rule of interpretation or construction that would or might cause any provision to be construed against the drafter. The Section headings contained herein are for reference purposes only and shall not in any way affect the meaning or interpretation of this Agreement.

13. This Agreement is not intended to be for the benefit of and shall not be enforceable by any third party. Nothing in this Agreement, express or implied, is intended to or shall confer on any third party any rights (including third-party beneficiary rights), remedies, obligations or liabilities under or by reason of this Agreement. This Agreement shall not provide third parties with any remedy, claim, reimbursement, cause of action or other right in excess of those existing without reference to the terms of this Agreement. No third party shall have any right, independent of any right that exists irrespective of this Agreement, to bring any suit at law or equity for any matter governed by or subject to the provisions of this Agreement.

14. This Agreement constitutes the full understanding between the parties with reference to the subject matter hereof, and no statements or agreements by or between the parties, whether orally or in writing, except as provided for elsewhere in this paragraph 14, made prior to or at the signing hereof,

shall vary or modify the written terms of this Agreement. Neither party shall claim any amendment, modification, or release from any provisions of this Agreement by mutual agreement, acknowledgment, or otherwise, unless such mutual agreement is in writing, signed by the other party, and specifically states that it is an amendment to this Agreement.

15. The persons signing on behalf of WiCell and Institution hereby warrant and represent that they have authority to execute this Agreement on behalf of the party for whom they have signed.

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**

**Institution**

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

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

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

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

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

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

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Reviewed by WiCell's Legal Counsel:

\_\_\_\_\_, \_\_\_\_\_  
David M. Kettner, Esq.

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

WiCell Ref: Thomson – P98222US

Order Reference No. \_\_\_\_\_

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

### 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 progeny or modified 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 Memorandum of Understanding between WiCell and Institution dated \_\_\_\_\_ (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: \_\_\_\_\_

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

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

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: \_\_\_\_\_