

Memorandum of Understanding

between

ES Cell International Pte. Ltd.

and

Public Health Service

U.S. Department of Health and Human Services

This Memorandum Of Understanding (hereinafter "Agreement"), effective April 5, 2002 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, United States ("PHS") and the ES Cell International Pte. Ltd., having an address at PO Box 6492, St. Kilda Road Central, Melbourne, Victoria 8008, Australia ("ESI"). PHS and ESI are referred to herein as the "Parties".

WHEREAS certain technologies and materials concerning primate embryonic stem cells and their cultivation claimed in Patent Applications PCT/AU99/0090; PCT/AU01/00278; PCT AU01/00735 and corresponding U.S. or international 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 ("ESI Patent Rights") have usefulness in basic research conducted or funded by PHS as well as potential utility for commercial applications; and

WHEREAS specific human embryonic stem cell line materials, their unmodified and undifferentiated progeny or derivatives ("ESI Materials") have been derived consistent with the Presidential Statement of August 9, 2001 from the research efforts of Dr. Martin Pera, Professor Ariff Bongso, Dr. Alan Trounson and Dr. Benjamin Reubinoff working along 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 ESI Materials were made using solely private funds and are the proprietary, tangible property of ESI and, as such, their ownership is not subject to any rights and obligations previously granted to PHS; and

WHEREAS ESI desires to serve the public interest by making the ESI Materials and the ESI Patent Rights widely available to PHS and other academic researchers; and

WHEREAS ESI represents that it has been assigned all rights to ESI Patent Rights from Monash University, National University of Singapore and the Hadasit Medical Research Services and Development Company, Ltd. and that ESI also owns or otherwise has the right to distribute ESI Materials to third parties; and

WHEREAS PHS has received permission to use ESI Materials under the terms and conditions of its September 5, 2001 Memorandum of Understanding with the WiCell Research Institute concerning U.S. Patents 5,843,789, 6,200,806 and related patent rights as well as having certain use and other rights arising by law and regulation from its funding of primate research studies at the University of Wisconsin which may be applicable for the use of ESI Materials; and

WHEREAS PHS funded primate research studies at the University of Wisconsin - Madison that led to certain discoveries claimed in U.S. Patents 5,843,780, 6,200,806 and related 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 ESI desires to exercise ESI Patent Rights and distribute ESI 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 ESI Materials or ESI Patent Rights for research conducted either by PHS or on behalf of PHS by its contractors:

- (1) The Parties agree that ESI Patent Rights are to be made available without cost for use in specified PHS biomedical research program(s) subject to the following conditions:
 - (a) ESI Patent Rights may be used in research programs involving ESI Materials only in programs in compliance with all applicable statutes, regulations and guidelines for research of this type.

- (b) ESI Patent Rights may also be used in PHS research programs involving materials other than ESI Materials that may be within the scope of an issued claim of ESI Patent Rights ("Third Party Materials"). This research may be conducted only in PHS research programs using Third Party Materials that are derived consistent with the U.S. 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 ESI under the ESI 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 ESI 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 of rights to the sponsor such as those afforded the U.S. Government under the Bayh-Dole Act and similar rights retained by non-profit research sponsors. The ESI 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 ESI Patent Rights under a separate written agreement with ESI. 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 ESI permitting commercial use of ESI Patent Rights.

- (d) The Parties recognize that ESI 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 ESI 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 ESI permitting such use of ESI Patent Rights under terms not less favorable than other similar commercial licenses granted by ESI to the extent such rights are available.
- (2) The Parties agree that ESI Materials are to be made available by ESI for use in specified PHS biomedical research programs, either by PHS or on behalf of PHS by its specified contractors. For purposes of transferring ESI Materials to specified PHS scientists or contractors, ESI agrees to utilize the Simple Letter Agreement For The Transfer of Materials including the following conditions:
- (a) ESI Materials are the property of ESI and are being made available to investigators in the PHS research community as a service by ESI. Ownership of ESI Materials shall remain with ESI.
 - (b) ESI Materials are not to be used for diagnostic or therapeutic purposes.
 - (c) ESI Materials may only be used in compliance with all applicable statutes, regulations and guidelines relating to their handling or use.
 - (d) The use of ESI 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 ESI Materials may not be used for commercial purposes or the direct benefit of research sponsor, except as such research sponsor is permitted to use ESI Materials under a separate written agreement with ESI. Specifically, ESI 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 ESI permitting such commercial use of ESI Materials.

- (e) ESI Materials may not be transferred by PHS or its contractors to third parties without the written consent of ESI.
- (f) PHS agrees to acknowledge the source of ESI Materials in any publications or other disclosures reporting their use and provide a copy of any such disclosure to ESI upon its publication.
- (g) In order to facilitate potential novel collaborative research interactions between PHS and ESI that may utilize ESI Materials, PHS agrees to provide a descriptive research title of its planned research in its individual requests for samples of ESI Materials. This information is to be provided to facilitate new inter-disciplinary collaborations among individual scientists at PHS and ESI, but not to obligate either Party to a specific program of research utilizing ESI Materials.
- (h) The Parties recognize that ESI 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 ESI Materials or ESI Patent Rights that may be needed by a third party for commercialization of PHS Materials shall be done by a separate written agreement with ESI permitting such use of ESI Materials or ESI Patent Rights under terms not less favorable than other similar commercial licenses granted by ESI to the extent such rights are available. Furthermore, PHS acknowledges that it has a policy of making discoveries from its research program available for development and commercialization by industry. PHS agrees to notify ESI in accordance with federal regulations (37 CFR 404) concerning discoveries relating to PHS Materials that are available for licensing through its Office of Technology Transfer.

- (i) Any ESI Materials delivered pursuant to this Agreement are understood to be experimental in nature and may have hazardous properties. ESI 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 ESI 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 ESI Materials except that, to the extent permitted by law, ESI shall be liable to PHS when the damage is caused by the gross negligence or willful misconduct of ESI.

 - (j) A transmittal fee will be requested by ESI to cover its preparation and distribution costs for samples of ESI Materials requested by PHS. Such fees will be the responsibility of the requesting PHS laboratory and are not expected to exceed Six Thousand Dollars (\$6,000 USD) per sample for international transfers of a defined cell line or as specified in the appropriate schedule of a U.S. Government procurement accompanying the PHS Simple Letter Agreement for the Transfer of Materials.

 - (k) Any ESI Material provided will be for the sole use of the specified Recipient, who will have no right to transfer any ESI Material(s) to any other person not under their supervision or other entity without the prior written consent of ESI, which consent shall not be unreasonably withheld provided that the proposed transferee pays the described transmittal fee.
- (3) Upon ESI'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 ESI 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) ESI agrees that it shall make ESI Patent Rights and ESI Materials available for use by non-profit Recipient Institutions under separate written agreements in accordance with the terms and conditions outlined above. ESI agrees that any non-profit Recipient Institutions currently licensed under the ESI Patent Rights or ESI 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 ESI Patent Rights shall be in effect only during the term of the ESI Patent Rights. However, the provisions of this Agreement and the obligations hereunder with respect to the ESI Materials shall continue as long as ESI 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 ESI Patent Rights or to ESI Materials. Furthermore, nothing contained herein shall be construed to be a waiver of ESI's patent rights under the ESI Patent Rights or ESI's property rights in ESI Materials.

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

ES Cell International Pte. Ltd.

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 Human Embryonic Stem Cells, ESI Ref: _____, and its unmodified and undifferentiated progeny or derivatives) for a research program entitled _____ ES Cell International Pte. Ltd. ("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 and to provide PROVIDER a copy upon actual publication.

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. The RECIPIENT shall not use the MATERIAL in humans or in contact with any cells or other materials to be transferred into humans. Use of the MATERIALS to prepare somatic cell therapy products or gene therapy products is specifically prohibited. Specifically, where the MATERIALS are cells, the RECIPIENT will not reintroduce these cells alone or in combination with other cells into the reproductive tract of a female animal, nor use these cells for purposes of in-vitro culture with human or animal zygotes or embryos.

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: _____ (\$6,000 USD per sample of a defined cell line provided). This transmittal fee does not include any costs associated with training RECIPIENT in cell growth and maintenance.

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: _____