

**Memorandum of Understanding**

between

**BresaGen, Inc.**

and

**Public Health Service**

U.S. Department of Health and Human Services

This Memorandum Of Understanding (hereinafter "Agreement"), effective April 24, 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 BresaGen, Inc. having an address at The Georgia BioBusiness Center, 111 Riverbend Road, Athens, GA 30605-2613 ("BresaGen"). PHS and BresaGen are referred to herein as the "Parties".

WHEREAS BresaGen investigators have derived specific human embryonic stem cell line materials, their unmodified and undifferentiated progeny or derivatives ("BresaGen Materials") consistent with the Presidential Statement of August 9, 2001; 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 BresaGen Materials were made using solely private funds and are the proprietary, tangible property of BresaGen and, as such, their ownership is not subject to any rights and obligations previously granted to PHS; and

WHEREAS BresaGen desires to serve the public interest by making the BresaGen Materials widely available to PHS and other academic researchers either directly from BresaGen or through an affiliate, such as Cellsaurus of Athens, Georgia; 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 therefore the Government has certain use and other rights to the intellectual property granted by law and regulation; and

WHEREAS WiCell entered into a Memorandum of Understanding with

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the PHS on September 5, 2001 ("MOU") governing the use of certain technologies and materials concerning primate embryonic stem cells and their cultivation claimed in US Patents 5,843,780 and 6,200,806 and US Patent Application 09/522,030 and corresponding U.S. or foreign patent rights ("Wisconsin Patent Rights"); and

WHEREAS in this MOU WiCell permits Wisconsin Patent Rights to be used in PHS research programs involving materials other than those obtained from WiCell that may be within the scope of issued claims of Wisconsin Patent Rights ("Third Party Materials"), and WiCell granted suppliers of such Third Party Materials a limited, revocable, non-commercial, research license under the Wisconsin Patent Rights to provide such Third Party Materials to PHS research programs under terms "no more onerous" than those in the WiCell-PHS MOU; and

WHEREAS BresaGen desires to distribute BresaGen 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 BresaGen Materials for research conducted either by PHS or on behalf of PHS by its contractors:

- (1) The Parties agree that BresaGen Materials are to be made available by BresaGen or its affiliates for use in specified PHS biomedical research programs, either by PHS or on behalf of PHS by its specified contractors. For purposes of transferring BresaGen Materials to specified PHS scientists or contractors, BresaGen agrees to utilize the Simple Letter Agreement For The Transfer of Materials including the following conditions:
  - (a) BresaGen Materials are the property of BresaGen and are being made available to investigators in the PHS research community as a service by BresaGen. Ownership of BresaGen Materials shall remain with BresaGen.
  - (b) BresaGen Materials are not to be used for diagnostic or therapeutic purposes.
  - (c) BresaGen Materials may only be used in compliance with all applicable statutes, regulations and guidelines relating to their handling or use.
  - (d) The use of BresaGen Materials shall be for teaching or non-commercial research purposes only. As used herein, non-commercial research purposes specifically includes research funded by the US Government but excludes (i) research sponsored by a for-profit entity wherein the

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sponsor receives rights whether actual or contingent to the results of the sponsored research, and (ii) research sponsored by a non-profit entity 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 BresaGen Materials may not be used for commercial purposes or the direct benefit of research sponsor, except as such research sponsor is permitted to use BresaGen Materials under a separate written agreement with BresaGen. Specifically, BresaGen 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 BresaGen permitting such commercial use of BresaGen Materials.

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

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available for development and commercialization by industry. PHS agrees to notify BresaGen 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 BresaGen Materials delivered pursuant to this Agreement are understood to be experimental in nature and may have hazardous properties. BresaGen 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 BresaGen Materials will not infringe any patent, copyright, trademark or other proprietary rights. Unless prohibited by law, PHS assumes all liability for claims for damages that may arise from the use, storage, handling or disposal of BresaGen Materials except that, to the extent permitted by law, BresaGen shall be liable to PHS when the damage is caused by the gross negligence or willful misconduct of BresaGen.
  - (j) A transmittal fee will be requested by BresaGen to cover its preparation and distribution costs for samples of BresaGen Materials requested by PHS. Such fees will be the responsibility of the requesting PHS laboratory and are not expected to exceed Five Thousand Dollars (\$5,000 USD) per sample for domestic 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. This fee does not include any costs associated with training recipient scientist to grow or use BresaGen Materials. Any arrangements for training will be negotiated under a separate agreement.
- (2) Upon BresaGen'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 BresaGen 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.
  - (3) BresaGen agrees that it shall use reasonable efforts to make BresaGen Materials available for use by non-profit Recipient Institutions and in doing so shall offer to



provide BresaGen Materials under separate written agreements in accordance with the terms and conditions outlined herein.

BresaGen agrees that any non-profit Recipient Institutions currently granted rights to use BresaGen Materials may amend its agreement, in a separate written agreement, in accordance with the terms and conditions outlined above.

- (4) 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 BresaGen Materials shall continue as long as BresaGen Materials, their derivatives or progeny continue to be used by PHS or its Contractors.
- (5) Nothing contained herein shall be considered to be the grant of a commercial license or right under the BresaGen Materials. Furthermore, nothing contained herein shall be construed to be a waiver of BresaGen's property rights in BresaGen Materials.
- (6) The term of this Agreement will be three years from the effective date. The Parties agree to give serious good faith consideration to extending the term of the Agreement at that time.

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

**BresaGen, Inc.**

By: 

Name: JOHN R. SMEATON

Title: PRESIDENT & CEO

**Public Health Service**

By: 

Name: Mark L. Rohrbaugh, Ph.D., JD

Title: Acting Director, Office of Technology Transfer, NIH

**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, BresaGen Ref: \_\_\_\_\_, and its unmodified and undifferentiated progeny or derivatives) for a research program entitled \_\_\_\_\_.

BresaGen, 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. As used herein, non-commercial research purposes specifically includes research funded by the US Government but excludes (i) research sponsored by a for-profit entity wherein the sponsor receives rights whether actual or contingent to the results of the sponsored research, and (ii) research sponsored by a non-profit entity 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 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 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 PROVIDER permitting such use of MATERIAL.
3. 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.

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4. 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.
5. 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.
6. 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.
7. 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: \_\_\_\_\_ (\$5,000 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: \_\_\_\_\_

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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: \_\_\_\_\_

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