

## **MATERIAL TRANSFER AGREEMENT FOR TRANSFER OF HUMAN EMBRYONIC STEM CELL MATERIAL FOR CANADIAN UNIVERSITIES AND NON-PROFIT INSTITUTIONS**

THIS DOCUMENT CONSTITUTES AN AGREEMENT BETWEEN MOUNT SINAI HOSPITAL (“MSH”) AND THE RECIPIENT SCIENTIST AND INSTITUTION (COLLECTIVELY “RECIPIENT”) FOR THE DISTRIBUTION OF RESEARCH MATERIALS.

MSH is pleased to be able to provide research materials produced in the laboratory of Dr Andras Nagy subject to the following terms and conditions:

### 1. Definitions

For the purposes of this Agreement, the following terms have the respective meanings set out below:

”Material” includes:

- (i) *human embryonic stem cell lines designated CA1 and CA2*, derived in a manner that conforms with the Canadian Institutes of Health Research (CIHR) Guidelines for Human Pluripotent Stem Cell Research; and
- (ii) progeny, modifications or derivatives thereof, but only if such progeny, modifications or derivatives retain the ability to replicate themselves, to differentiate into cell types from all three germ layers, and to remain unspecialized (such ability hereafter referred to as “*stemness*”). By way of example, and not of limitation, the Material includes genetically modified or cloned cell lines produced by Recipient which retain these qualities.

“Derivative Material” means any materials or products that are physically derived from the Material, including, without limitation, differentiated cell lines or populations derived from the Material provided that such cell lines or populations do not possess *stemness*.

“Derived Somatic Stem Cell Lines” means somatic stem cell lines derived from the Material.

2. The Material is the property of MSH and is being provided as a service to the academic research community. Ownership of the Material shall remain with MSH and transfer of the Material to Recipient shall not affect MSH’s ownership of the Material. Derived Somatic Stem Cell Lines shall be owned by the Recipient, but MSH retains ownership of the Material contained therein.
3. As material conditions to effect transfer of the Material to the Recipient, the Recipient shall:
  - a) restrict use of the Material solely to the Recipient Scientist or individuals working under the direct supervision of the Recipient Scientist at the Institution, who are aware of and agree to be bound by the terms of this Agreement for academic, non-commercial research purposes as described in the research plan attached as Appendix A (the “Research Plan”) and for no other purpose;
  - b) have the formal written approval of the Research Plan by a properly constituted Recipient Research Ethics Board (REB), a copy of which shall be provided to MSH, and use the Material only in accordance with the Recipient REB’s approval;
  - c) have the formal written approval of the Research Plan by CIHR’s Stem Cell Oversight Committee (SCOC), a copy of which shall be provided to MSH, and use the Material only in accordance with SCOC’s approval;

- d) use the Material, Derived Somatic Stem Cell Lines and Derivative Material in compliance with this Agreement and all applicable laws, rules, regulations, guidelines, and policies relating to their handling, use or disposal and not for any diagnostic or therapeutic purposes or research involving human subjects;
- e) not transfer the Material to any other party or remove the Material from the Institution. The Recipient shall refer any request for the Material to MSH. To the extent supplies are available, MSH agrees to make the Material available to other scientists for teaching or non-commercial research use only, under a separate material transfer agreement under terms similar to those set forth herein. Recipient may distribute Derived Somatic Stem Cell Lines to researchers at other non-profit organizations only for academic, non-commercial research purposes under the terms of Recipient's customary material transfer agreement provided that the terms of such agreement are at least as protective of MSH's rights as those set out herein and subject to all applicable laws, rules, regulations, guidelines, and policies relating to their handling, use or disposal.
4. The contribution of Dr. Andras Nagy, Dr. Janet Rossant, Marina Gertsenstein, Kristina Vinterstein, Masha Mileikovsky and Jonathan Draper will be acknowledged in accordance with scientific custom in all published or oral communications concerning the research using the Materials.
  5. Upon request, the Recipient Scientist agrees to inform Dr. Andras Nagy about the results of the research using the Material.
  6. If the research using the Material results in a commercially useful Derived Somatic Stem Cell Line or a commercially useful product or process employing either the Material or a Derived Somatic Stem Cell Line, the Institution will promptly so notify MSH. MSH agrees to give due consideration to a request for a non-exclusive, royalty-bearing license to its property rights in the Material to enable such commercial use but shall not be obligated to grant any such license except at its sole discretion. Any such grant of MSH rights to the Material that may be needed by Recipient shall be the subject of a separate written agreement with MSH under terms no less favourable than other similar commercial licenses to the extent such rights are available.
  7. The Material is experimental in nature, may have hazardous properties, and must be used with prudence and appropriate caution, since not all of its characteristics are known. The Material must be used under containment conditions appropriate for the use of human tissue samples. THE MATERIAL IS PROVIDED WITHOUT ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PURPOSE, OR ANY OTHER WARRANTY EXPRESS OR IMPLIED. MSH MAKES NO REPRESENTATION THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT OR OTHER PROPRIETARY RIGHTS.
  8. To the extent permitted by law, the Recipient agrees to assume all liability for any loss, claim or damages which may arise from their use, storage, transfer or disposal of the Material, Derived Somatic Stem Cell Line or Derivative Material. MSH shall not be liable to the Recipient for any loss, claim or demand made by Recipient, or made against Recipient by any other party, due to or arising from the use, storage, transfer or disposal of the Material, Derived Somatic Stem Cell Line or Derivative Material by the Recipient or any other party.
  9. This Agreement shall become effective upon the date of the signature on behalf of MSH, (the "Effective Date") and shall continue in effect until one (1) year from the Effective Date ("Expiration Date") unless sooner terminated in accordance with the provisions of Section 10. This Agreement may be extended for a further one year term provided prior to the Expiration Date: (a) MSH receives an Amendment to extend the Agreement signed by Recipient in the form attached hereto as Appendix B, and b) MSH, in its discretion, signs and returns the request to

Recipient. In the absence of an Amendment signed by Recipient and MSH or early termination in accordance with Section 10, this Agreement will expire on the Expiration Date.

10. This Agreement shall terminate immediately upon (i) withdrawal or expiry of Recipient's REB or SCOC approval to conduct the research contemplated in this Agreement;(ii) upon Recipient's failure to comply with one or more material conditions set forth in Subsection 3 a) through e); (iii) upon any other breach of this Agreement by Recipient; or (iv) upon withdrawal or expiry of MSH's REB approval of the transfer of the Material hereunder. MSH may terminate this Agreement by 20 days written notice for any reason.
11. Upon expiration or termination of this Agreement for any reason, Recipient shall forthwith cease all use of the Material, destroy all Material on hand and provide written notice to MSH that it has done so. The provisions of Sections 3 through 8 shall survive expiration or any termination of this Agreement.
12. Material is provided with a transmittal fee of \$ 500 CDN to reimburse MSH solely for preparation and handling costs. Recipient shall be responsible for shipping costs.

[Signature Page Follows]

If you agree to accept this Material under the above conditions, two copies of this Agreement should be signed and dated by the Recipient Scientist and an authorized representative of the Institution and returned to:

Tessie Tacorda  
Office of Technology Transfer & Industrial Liaison, Suite 843  
Mount Sinai Hospital &  
the Samuel Lunenfeld Research Institute  
600 University Avenue, Toronto, ON  
Canada M5G 1X5  
Telephone: (416) 586-4800 ext. 3117  
Fax: (416) 586-8844  
E-mail: tacorda@mshri.on.ca

ACCEPTED AND AGREED:

FOR RECIPIENT SCIENTIST:

FOR INSTITUTION:

\_\_\_\_\_  
Name (Printed)

\_\_\_\_\_  
Name of Institution

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of Authorized Representative

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

\_\_\_\_\_  
Title

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

FOR MOUNT SINAI HOSPITAL:

Mr. Terry Donaghue  
Director, Technology Transfer & Industrial Liaison

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

## **Appendix A**

### Research Plan

**Appendix B**

**Amendment to extend the term of the Material Transfer Agreement for Transfer of Embryonic Stem Cell Material between Mount Sinai Hospital, \_\_\_\_\_ (Insert name of recipient scientist) and \_\_\_\_\_ (Insert name of Institution) effective \_\_\_\_\_ (Insert Effective Date) [the Material Transfer Agreement is hereinafter referred to as “Agreement”]**

The Agreement has a one year term and expires on \_\_\_\_\_. Recipient wishes to continue to use the Material for an additional one year term so that the terms and obligations of the Agreement continue, and remain in full force and effect to \_\_\_\_\_ (**insert date Agreement extended to**), unless terminated earlier as provided in the Agreement. As a condition of the grant of an extension to the term of the Agreement by MSH, Recipient has signed and is simultaneously delivering to MSH a Certification Statement.

Recipient hereby certifies, warrants and represents that the Recipient continues to have in full force and effect approval from the Recipient’s REB and SCOC to conduct the research contemplated in the Agreement, a copy of which is appended hereto, and shall comply with all conditions set forth in the Agreement.

All capitalized terms used but not otherwise defined herein shall have their meanings in the Agreement.

By signing and dating a copy of this Amendment, Recipient acknowledges acceptance of this Amendment to extend the term of the Agreement one year, and that all the terms and obligations of the Agreement continue and remain in full force and effect to \_\_\_\_\_. (**insert date Agreement extended to**)

ACCEPTED AND AGREED:

FOR [Insert name of recipient scientist]

FOR [Insert name of recipient Institution]

\_\_\_\_\_  
Signature

\_\_\_\_\_

\_\_\_\_\_  
Date

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

\_\_\_\_\_  
Date

MSH agrees to a one year extension to the term of the Agreement to \_\_\_\_\_, by signing and dating a copy of this Amendment.

FOR MOUNT SINAI HOSPITAL:

\_\_\_\_\_  
Name: Terry Donaghue  
Title: Director, Technology Transfer & Industrial Liaison  
Date: