APPLICATION FOR STEM CELL OVERSIGHT COMMITTEE REVIEW

INFORMATION SHEET **(do not submit this page with completed application form)**

Researchers should consult the *Guidelines for Human Pluripotent Stem Cell Research* ("the Guidelines") and Frequently Asked Questions posted on the CIHR website http://www.cihr-irsc.gc.ca/e/15255.html to determine whether or not the research requires review by the Stem Cell Oversight Committee (SCOC). Any questions can be directed to stemcell@cihr-irsc.gc.ca.

IF YOUR APPLICATION:	COMPLETE SECTIONS
• Will use existing SCOC-approved human embryonic stem cells	**A,D**
• Includes experiments involving the engraftment of induced human pluripotent stem cells into human and/or non-human animals	**A,D**
• Is for Trainee or student funding	**A,B,D**
• Is to derive human pluripotent stem cells from human embryos, fetal tissue, or amniotic fluid	**A,C,D**
• Will use existing human pluripotent stem cells that have been derived from human embryos, fetal tissue, or amniotic fluid, and have not yet been approved by SCOC	**A,C,D**

Additional information may be requested from the researcher if SCOC has concerns that are not addressed in the documentation provided.

Governing Council has delegated its authority to approve research using existing SCOC-approved human embryonic stem cell (hESC) lines and/or human induced pluripotent stem (iPS) cells to SCOC, unless the research involves the engraftment of those cells into humans. SCOC will respond to research proposals within its delegated authority within 30 business days of receipt of a complete application.

Governing Council's approval is required on all other types of research proposals (e.g., research involving the derivation of hESC from human embryos, the use of hESC lines not yet approved by SCOC, and/or the engraftment of human pluripotent stem cells into human beings).

Please send completed form to:
Stem Cell Oversight Committee
Canadian Institutes of Health Research
160 Elgin St., 9th Floor
Address Locator 4809A
Ottawa, Ontario K1A 0W9

FOR INTERNAL USE ONLY

Date Received by CIHR:

APPLICATION FOR STEM CELL OVERSIGHT COMMITTEE REVIEW

A. GENERAL INFORMATION

APPLICATION DETAILS:		
Nominated Principal Applicant:		
Mailing address of Principal Applicant:		
E-mail address of Principal Applicant:		
All Other Applicants:		
Title of application for funding:		
Funding Agency:	**Funding competition:**	**Application Number:**

Application status:

Peer reviewed: Yes, by institution ☐ Yes, by funding organization ☐ Not peer reviewed ☐

Approved for funding:

- ☐ Yes, date of approval: (dd/mm/yyyy)
- ☐ Submitted to funding opportunity, awaiting decision
- ☐ Pilot project using existing grant funding
- ☐ Other (please describe):

OVERVIEW:

1. Does this research propose the use of human induced pluripotent stem cells?

- ☐ Yes
- ☐ No

If 'Yes':

- and the answers to **2**, **3 and 4** are all 'No', then the research does not require SCOC review
- and the answers to **2 and 4** are 'No' and the answer to **3** is 'Yes', but limited to teratoma formation, then the research does not require SCOC review. Do not submit this form. However, you must inform SCOC in writing (at address above) that human pluripotent stem cells will be used for teratoma formation only and include a statement that the animals will not be used for reproductive purposes.

2. Does this research propose the use of human embryonic stem cells?

- ☐ Yes (see below)
- ☐ No

If 'Yes':

- **Please list all lines that will be used:**
- **If any of these lines have not been approved by SCOC, please complete section C**

3. Will any non-human animals be engrafted with human pluripotent stem cells or cells derived from human pluripotent stem cells in this project?

- ☐ Yes (see below)
- ☐ No

If 'Yes':

- **If the engraftment experiments are not described in detail in the application for funding, please provide a description of these experiments**
- **Will any non-human animals engrafted with human pluripotent stem cells or cells derived from human pluripotent stem cells in the course of this research be used for reproductive purposes?**
  - ☐ Yes
  - ☐ No

4. Does the research involve grafting human pluripotent stem cell lines into human subjects?

- ☐ Yes (see below)
- ☐ No

If 'Yes':

- **Append copies of consent and information forms to be used**
- **Ensure that the proposal describes evidence from preclinical models for safety and efficacy, and that the research is carried out in well-designed clinical trials. You may append additional information if needed to provide more details than contained in the application.**

OVERVIEW:

5. Describe the potential benefits of this research:

APPENDICES:

☐ **Description of how each of the human pluripotent stem cell lines will be used.** Please list each experiment that involves the use of human pluripotent stem cells and briefly (5-10 lines) describe how the cells will be used in each. This will ensure that SCOC has a clear understanding of which experiments proposed in the application for funding involve the use of human pluripotent stem cells.

☐ **One copy of the original application for funding. Please include the budget, the list of patents held by the principal applicant, and the list of the funds requested and the funds held by all applicants.**

☐ **Copies of any contracts relevant to this application, and any relevant budgetary information. Failure to append relevant contracts may delay grant approval (please see Section 8.4.2 of the Guidelines):** Copies of contracts between researchers, institutions and industry sponsors and any relevant budgetary information must be provided to the Stem Cell Oversight Committee and the local REB, to examine and evaluate any potential or actual conflict of interest and to ensure the right to publish freely after a modest interval. Should any potential conflicts of interest arise following approval of an application, the Stem Cell Oversight Committee must be advised.

Please list all contracts that are appended:

☐ **There are no relevant contracts**

☐ **Description of any financial interest you may have in the outcome of the research described in this application (please see Section 8.4.1 of the Guidelines):** In some instances, disclosure may not be a sufficient response to concerns about actual, perceived or potential conflicts of interest and researchers and/or their institutions may be asked by SCOC to remedy any possible distortion of proper procedures attributable to such conflicts. Should any potential conflicts of interest arise following approval of an application, the Stem Cell Oversight Committee should be advised.

Please explain the commercial plan in a few short sentences:

☐ **I have no financial interest in the outcome of the research described in this application**

ATTESTATIONS:

i) An amended application will be submitted to SCOC for review and approval if:

a. any changes in direction of the research involving human pluripotent stem cells are planned, before such work commences

b. a Trainee receives separate funding for related research.

☐ Yes
☐ No

ii) SCOC will be provided with written notification should the use of additional SCOC-approved stem cell lines not described in the original research application be planned (this notification would include the title of the original application, the name of the PI and indicate which cell lines would be used).

☐ Yes
☐ No

iii) I understand my research institution's conflict of interest policy and will comply with that policy.

☐ Yes
☐ No

B. APPLICATIONS FOR TRAINEE OR STUDENT

RESEACH SUPPORTED BY TRAINEE OR STUDENT FUNDING:
Is this application for Trainee or student funding wholly subsidiary to a SCOC-approved project? ☐ Yes (see "Attestations" below) ☐ No
ATTESTATIONS:
☐ Yes, **the Trainee or student proposal is wholly subsidiary to the SCOC-approved project:**
Title:
Led By:
Funded By:
Date approved by SCOC:
Supervisor's signature:

C. APPLICATIONS TO:

- ***DERIVE HUMAN PLURIPOTENT STEM CELLS FROM HUMAN EMBRYOS, FETAL TISSUE, OR AMNIOTIC FLUID; AND/OR***
- ***USE EXISTING HUMAN PLURIPOTENT STEM CELLS THAT HAVE BEEN DERIVED FROM HUMAN EMBRYOS, FETAL TISSUE, OR AMNIOTIC FLUID, WHICH HAVE NOT YET BEEN APPROVED BY SCOC.***

DESCRIPTIONS:
If this application is being submitted to use human embryos to derive human embryonic stem cells, please describe the need for human embryos: ☐ This is not an application to derive human embryonic stem cells
APPENDICES:
☐ **Copies of consent and information forms used** a) unsigned research consent (see section 8.3.2 of the Guidelines); and/or b) unsigned embryo donor or research subject consent; and c) information forms SCOC will review these documents to ensure that the consent provisions of the Guidelines (see 8.1, 8.3) and the Final Report of the ad hoc Working Group on Stem Cell Research have been met.
☐ **Attestation(s) that the embryos have been created for reproductive purposes and are no longer required for such purposes**
☐ **Attestation(s) that neither the ova nor the sperm from which the embryos were created, nor the embryos themselves, have been obtained through commercial transactions**
☐ **Attestation(s) that the researchers did not/will not ask, encourage, induce or coerce members of the fertility treatment team to generate more embryos than necessary for the optimum chance of reproductive success**
☐ **Attestation(s) that the embryos have not/will not be grown in vitro for more than 14 days**
ATTESTATIONS:
Any human embryonic stem cell lines generated under the auspices of federal funding agencies (CIHR, NSERC, SSHRC) will be listed with the registry and made available to other researchers, subject to reasonable cost-recovery charges. ☐ Yes ☐ Not applicable

D: SIGNATURES

I certify that all information provided above is correct to the best of my knowledge:		
Name	**Signature**	**Date**
Name	**Signature**	**Date**
Name	**Signature**	**Date**
Name	**Signature**	**Date**