Canadian Institutes of Health Research | Instituts de recherche en santé du Canada

Canada

APPLICATION FOR STEM CELL OVERSIGHT COMMITTEE REVIEW FOR RESEARCH PROPOSALS USING APPROVED CELL LINES

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

Researchers should consult the current version of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans or TCPS 2, Chapter 12, section F* and Frequently Asked Questions to determine whether or not the research requires review by the Stem Cell Oversight Committee (SCOC). There are links to these documents on the CIHR website. Any questions can be directed to StemCell-Cellulesouche@cihr-irsc.gc.ca.

NOTE: If your application proposes to derive human embryonic stem cells and/or use human embryonic stem cells that have not yet been approved

PLEASE CONTACT

StemCell-Cellulesouche@cihr-irsc.gc.ca.

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 or their derivatives to SCOC. 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, and/or the use of hESC lines not yet approved by SCOC).

Please send completed form to:
Stemcell-cellulesouche@cihr-irsc.gc.ca

FOR INTERNAL USE ONLY
Date Received by CIHR:

APPLICATION FOR STEM CELL OVERSIGHT COMMITTEE REVIEW FOR RESEARCH PROPOSALS USING APPROVED CELL LINES

A. GENERAL INFORMATION

APPLICATION DETAILS:

Select one - The nominated principal applicant is a:
☐ **FACULTY MEMBER**
☐ **TRAINEE, please list supervisor(s):** _____
Please ensure that the supervisor(s) sign(s) section B, below.

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:
Type of application:
☐ New funded grant ☐ Substantial changes to research proposed in grant ☐ Pilot project with no corresponding grant
Peer reviewed:
☐ Yes, by institution (provide details) ☐ 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 funding
☐ Other (please describe) _____

Funding start and end date: _____ to _____ (dd/mm/yyyy to dd/mm/yyyy)

Is this application subsidiary to a SCOC-approved project? That is, has the research that will be conducted been reviewed by SCOC as part of a previous application?
☐ Yes, wholly subsidiary ☐ Yes, subsidiary including revisions to the research project
☐ No
If 'Yes', please indicate which SCOC-approved project this proposal is subsidiary to:
Title:
Led by:
Funded by:
Date approved by SCOC:

OVERVIEW:

1. **Does this research propose the use of human induced pluripotent stem cells?**
   ☐ Yes (see below)
   ☐ 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.

OVERVIEW:

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 contact Stemcell-cellulesouche@cihr-irsc.gc.ca**

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

☐ Yes (see below)
☐ No

If 'Yes':

- **Will any embryonic or fetal non-human animals be engrafted with human pluripotent or human totipotent stem cells or cells derived from human pluripotent stem cells in this project?**
  ☐ Yes
  ☐ No
- **Will any non-human animals engrafted with human pluripotent or human totipotent 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 or human totipotent stem cell lines, or cells derived from them into human subjects?

☐ Yes (see below)
☐ No

If 'Yes', the research must also be in compliance with the *Food and Drugs Act* and all its applicable *Regulations*, including the Canadian Safety of Human Cells, Tissues and Organs for Transplantation Regulation, which must be confirmed by Health Canada. Has the application been submitted to Health Canada?

☐ Yes
☐ No

5. Describe the potential benefits of this research:

OVERVIEW:

6. **Describe how each of the human pluripotent or human totipotent stem cell lines will be used.** Please list each experiment that involves the use of human pluripotent or human totipotent stem cells and briefly (5-10 lines) describe specifically how the cells will be used in each. For engraftment into non-human animals or into human subjects, describe the cells, the site of the graft, the species and age of the animal (for non-human animals). SCOC has a diverse composition, so the description should be written in non-technical, jargon-free language, with sufficient detail for SCOC to understand exactly what will be done with the human pluripotent or human totipotent stem cells, to assess whether the use conforms to the provisions of the current edition of TCPS 2. If this is a program grant application, please include detail on the protocol and methods to be used. As needed, subsequent SCOC applications may be submitted in future years as the project evolves. This will ensure that SCOC has a clear understanding of which experiments proposed in the application for funding involve the use of human pluripotent or human totipotent stem cells, as the grant itself often does not provide sufficient detail and the experiments involving pluripotent cells may be included in different sections throughout the grant.

APPENDICES:
You must check a box in each section

Appendix 1 Funding application (mandatory)

For new funded grant: attach one complete copy of the original application for funding.
For substantial changes to grant or pilot project: attach a **2-page proposal** containing the research plan, including introduction, rationale, planned experiments/procedures and timeline.
Mandatory: 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 where these are not part of the application for funding.

☐ I have attached the complete application for funding.

Appendix 2 Financial interest

Please see Article 12.19 of TCPS 2: In some instances, disclosure may not be a sufficient response to concerns about actual, perceived or potential conflicts of interests and researchers and/or their institutions may be asked by SCOC to remedy any possible distortion of proper procedures attributable to such conflicts.

Do you or your co-applicants have any financial interest in the outcome of the research described in this application?

☐ Yes (see below)
☐ No, neither I nor my co-applicants have any financial interest

If 'Yes', please describe in detail any financial interest you may have in the outcome of the research described in this application and explain any commercial plan in a few short sentences and provide relevant documentation, and attach these as Appendix 2.

If 'No', then Appendix 2 is not required.

Appendix 3 Agreements and contracts

Are there agreements that may:

- **limit the ability to share tissues that may be derived from hESC in the course of the research; or**
- **restrict the right to publish the results of the research using hESC** (see 'Frequently Asked Questions' for interpretation of what constitutes a reasonable delay, generally submission for publication within approximately 90 days); or
- **impose commercial or other obligations that are related to the use of hESC?**

☐ Yes (see below)
☐ No, there are no relevant contracts

If 'Yes', please list and append the agreements, specifying the relevant provisions of each, with a brief explanation. Failure to append relevant contracts may delay research approval, please see Article 12.20 of TCPS 2.

If 'No', then Appendix 3 is not required.

Appendix 4 Other conflicts of interest

Do you have any other conflicts of interest in the outcome of the research described in this application?

☐ Yes (see below)
☐ No

If 'Yes', please append a description as Appendix 4.

If 'No', then Appendix 4 is not required.

ATTESTATIONS: **You <u>must</u> check each box below.**
I) An amended application will be submitted to SCOC for review and approval if any changes in direction of the research involving human pluripotent or human totipotent stem cells are planned and/or if cell lines that have not yet been approved by SCOC are to be used before such work commence. ☐ Yes
II) An amended application will be submitted to SCOC for review and approval if the principal applicant receives new and/or additional funding, and/or if a Trainee receives separate funding for related research. ☐ Yes
III) 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
IV) I understand my research institution's conflict of interest policy and will comply with that policy. ☐ Yes
V) SCOC will be notified of relevant contracts and/or potential conflicts of interest as they arise. ☐ Yes

B. 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**
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