



APPLICATION FOR STEM CELL OVERSIGHT COMMITTEE REVIEW FOR GRANTS USING APPROVED CELL LINES

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

Researchers should consult the 2nd Edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans or TCPS 2 (2014), 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 (<http://www.cihr-irsc.gc.ca/e/15255.html>). Any questions can be directed to StemCell-Cellulesouche@cihr-irsc.gc.ca.

IF YOUR APPLICATION:	COMPLETE SECTIONS
<ul style="list-style-type: none"> Proposes to derive human embryonic stem cells and/or use human embryonic stem cells that have not yet been approved 	<p>PLEASE CONTACT StemCell-Cellulesouche@cihr-irsc.gc.ca.</p>
<ul style="list-style-type: none"> Is for Trainee or student funding 	<p>APPLICATION FORM FOR TRAINEES</p>

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, the use of hESC lines not yet approved by SCOC).

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

APPLICATION FOR STEM CELL OVERSIGHT COMMITTEE REVIEW FOR GRANTS USING APPROVED CELL LINES

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: <input type="checkbox"/> Yes, by institution <input type="checkbox"/> Yes, by funding organization <input type="checkbox"/> Not peer reviewed Approved for funding: <input type="checkbox"/> Yes, date of approval: _____ (dd/mm/yyyy) <input type="checkbox"/> Submitted to funding opportunity, awaiting decision <input type="checkbox"/> Pilot project using existing grant funding <input type="checkbox"/> Other (please describe):		

OVERVIEW:
<p>1. Does this research propose the use of human induced pluripotent stem cells?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If 'Yes':</p> <ul style="list-style-type: none">and the answers to 2, 3 and 4 are all 'No', then the research does not require SCOC reviewand 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.
<p>2. Does this research propose the use of human embryonic stem cells?</p> <p><input type="checkbox"/> Yes (see below) <input type="checkbox"/> No</p> <p>If 'Yes':</p> <ul style="list-style-type: none">Please list all lines that will be used: <ul style="list-style-type: none">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 stem cells or cells derived from human pluripotent stem cells in this project?

- Yes (see below)
 No

If 'Yes':

- 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, 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:

6. Describe 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 specifically how the cells will be used in each. SCOC has a diverse composition, so the description should be written in non-technical, jargon-free language, with sufficient detail for SCOC to assess whether the use conforms to the provisions of TCPS 2 (2014). 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 projects evolve. 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, 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 <u>must</u> check a box in each section
<p>Appendix 1 Funding application</p> <p>Attach one complete copy of the original application for funding as Appendix 1 (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.</p> <p><input type="checkbox"/> I have attached the complete application for funding.</p>
<p>Appendix 2 Agreements and contracts</p> <p>Are there agreements that may:</p> <ul style="list-style-type: none"> • 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 the hESC? <p><input type="checkbox"/> Yes <input type="checkbox"/> No, there are no relevant contracts</p> <p>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 grant approval, please see Article 12.20 of TCPS 2 (2014).</p>
<p>Appendix 3 Financial interest</p> <p>Please see Article 12.19 of TCPS 2 (2014): 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.</p> <p>Do you or your co-applicants have any financial interest in the outcome of the research described in this application?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No, neither I nor my co-applicants have any financial interest</p> <p>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 3.</p>
<p>Appendix 4 Other conflicts of interest</p> <p>Do you have any other conflicts of interest in the outcome of the research described in this application?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, please append a description as Appendix 4. If no, then Appendix 4 is not required.</p>

ATTESTATIONS: You <u>must</u> check each box below
<p>i) An amended application will be submitted to SCOC for review and approval if any changes in direction of the research involving human pluripotent stem cells are planned, before such work commences</p> <p><input type="checkbox"/> Yes</p>
<p>ii) An amended application will be submitted to SCOC for review and approval if a Trainee receives separate funding for related research.</p> <p><input type="checkbox"/> Yes</p>
<p>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).</p> <p><input type="checkbox"/> Yes</p>
<p>iv) I understand my research institution's conflict of interest policy and will comply with that policy.</p> <p><input type="checkbox"/> Yes</p>
<p>v) SCOC will be notified of relevant contracts and/or potential conflicts of interest as they arise.</p> <p><input type="checkbox"/> Yes</p>

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