



Stem Cell Research Oversight Committee (SCRO) Application Form

A. Demographic Information			
Date of Submission:			
Reason for Submission:			
<input type="checkbox"/> New Project	<input type="checkbox"/> Response to Comments	<input type="checkbox"/> Reconsideration	<input type="checkbox"/> Disapproval resubmission
<input type="checkbox"/> Modification	<input type="checkbox"/> Renewal	<input type="checkbox"/> Renewal with mods.	<input type="checkbox"/> Response to Audit
Project Title:			
Principal Investigator			
First Name	Last Name	Degree(s)	Title
Institution	School	Department	Division
Southern IL University Carbondale			
Phone	Fax	Email	
Office Address		Mailing Address (if different from office address)	
Alternative Contact with Knowledge of this Protocol			
First Name		Last Name	
Alternate Contact's Phone	Fax	Email	
Co-investigators:			
Source of Support (Please check all that apply)			
<input type="checkbox"/> Federal <input type="checkbox"/> State <input type="checkbox"/> Commercial <input type="checkbox"/> Foundation <input type="checkbox"/> Internal <input type="checkbox"/> Other: Please Specify:		Name of Sponsor(s) Grant #: Grant Title:	

B. Qualifications of Listed Investigators - Please describe the qualifications of the principal investigator and each of the listed co-investigators. This description should be limited to 3- 4 sentences describing the qualifications of each person to conduct the proposed research. An NIH bio-sketch should also be included for each individual.

C. Description of Facilities

On Campus (i.e. University owned or rented)

List Building(s) & Room Number(s):

Off Campus (non University owned or rented)

Address:

D. Specific Aim (s) and Experimental Design

Please provide a brief **non-technical** description of your research proposal. This description should also include a brief summary as to how the research is intended to benefit human health and/or advance science and medical knowledge. This description should not exceed 4 pages.

E. Category of research that best describes this project (Note more than one category may apply)

Research proposals should be submitted to the SCRO Committee AFTER review and approval by other relevant review committees, e.g. the IRB, IACUC, IBC. See SIUC Stem Cell Research Policy.

<p>1 <input type="checkbox"/> In vitro research involving human <i>non-embryonic</i> stem cells, where</p> <p>(a) IRB review has occurred, i.e. The cells were obtained by a process approved by an institutional review board to ensure that donor(s) provided voluntary informed consent in accordance with then current federal and state law, regulations, and guidelines, and</p> <p>(b) The cell lines have been de-identified, i.e. The cell lines and any corresponding information are anonymous or are coded in such a manner that the donor(s) cannot be identified (by the investigators or others) directly or indirectly through identifiers linked to the donor(s), pursuant to a written agreement obtained from the source of the cell lines stating that the identity of the donor(s) will not be released to the investigator under any circumstances.</p> <p><i>Non-embryonic stem cells include adult stem cells, fetal stem cells, placental stem cells, and umbilical cord stem cells.</i></p>
<p>2 <input type="checkbox"/> In vivo autologous or allogenic adult stem cell research. Research involving the transplantation into human subjects of autologous or allogenic adult stem cells derived from human <u>somatic</u> tissue</p>
<p>3 <input type="checkbox"/> NIH-listed human embryonic stem cells. In vitro research involving hES cell lines that are listed on the NIH Human Embryonic Stem Cell Registry.</p>
<p>4 <input type="checkbox"/> Transplantation of human stem cells into animals. Research involving human stem cells (whether adult, embryonic, umbilical, placental, or fetal) transplanted into animals except transplantation into an animal embryo or an animal's germline or brain.</p>
<p>5 <input type="checkbox"/> In vivo research involving the transplantation of stem cells derived from human <u>gonadal</u> tissue, fetal tissue or placental tissue</p>
<p>6 <input type="checkbox"/> The transplantation of any type of human stem cells into an animal embryo or an animal's germline or brain- For research of this nature, please contact the SCRO Office at escro@siu.edu first.</p>
<p>7 <input type="checkbox"/> *Human embryonic stem cells NOT on the NIH registry - For research of this nature, please contact the SCRO Office at escro@siu.edu first.</p>
<p>8 <input type="checkbox"/> *Other (please describe)</p>

F. Additional Questions for Research Involving Human Embryonic Stem Cells

NA – Go to Section G

1. Why are human embryonic stem cells, rather than non-human embryonic stem cells, necessary for use in this research?
2. Why is the use of human embryonic stem cells preferable to the use of adult stem cells in this research?
3. What type of animal work has preceded the proposed work involving human stem cells?

G. For research involving the introduction of human stem cells into non-human animals, each of the following questions should be addressed:

NA - Go to Section H

1. Why are human stem cells required for this project instead of cells from other primates or animals?
2. What is the anticipated effect of the human stem cells on the animal's anatomy, physiology, and species-specific behavior and the proposed methods for handling adverse events should they occur?
3. Is there a possibility that the animal will exhibit human-like traits (physical or behavioral), and if so, what are the procedures that will be implemented for management, documentation, and reporting of such occurrences to the IACUC and the SCRO Committee?
4. No animal into which hES cells have been introduced should be allowed to breed. Please describe the mechanisms that will be utilized to prevent breeding of the involved animals.

H. Privacy/Confidentiality of Donor

Are the human stem cells being used in this research linked to any information whereby it would be possible for you to identify the donors of the original blastocyst? Yes No NA

Are the human stem cells linked to any information whereby it would be possible for the source institution to identify the donors of the original blastocyst? Yes No NA

I. Approvals from other committees *within* Southern Illinois University

Please indicate approvals obtained from other committees within the University. **Copies of approval must be submitted for each applicable committee review and approval.**

- Institutional Review Board (Please indicate if approval was exempt, expedited or full board)
- Institutional Biosafety Committee – recombinant DNA or hazardous biomaterials (IBC)
- Institutional Animal Care and Use Committee (IACUC)

J. Approvals from IRB committees *outside* Southern Illinois University

Please indicate approvals obtained from IRB committees outside the University. **Copies of approval letters should be submitted for each respective committee review and approval.**

K. Materials Transfer Agreement

Southern Illinois University researchers must execute, with the SIUC Office of Research Development and Administration, a Material Transfer Agreement prior to obtaining any human stem cell lines from an external entity.

Is there a Materials Transfer Agreement for this study? Yes No NA

If yes, a copy of this agreement must be submitted.

L. Conflict of Interest

Does the principal investigator or any co-investigator or research coordinator involved in this study (or in aggregate with his/her spouse, dependents or members of his/her household):

a. possess an equity interest in the entity that either sponsors this research or owns the technology being evaluated that exceeds 5% ownership interest or a current value of \$10,000? Yes No

b. receive salary, royalty, or other payments from the entity that either sponsors this research or owns the technology being evaluated that is expected to exceed \$10,000 per year? Yes No

c. have an agreement with the University or an external entity that would entitle sharing of current or future commercial proceeds related to the technology being evaluated (e.g., royalties through a license agreement)?
 Yes No

d. have a financial relationship with a start-up company that has an option or license to Southern Illinois University technology being evaluated in this study?
 Yes No

If yes to any of the above, please submit detailed information including who has this involvement or conflict.

M. Investigator's Certification

- I have reviewed this protocol submission in its entirety and I am fully cognizant of and in agreement with all submitted statements.
- I have adequate resources and facilities to carry out the proposed research.
- I will comply with the current state and federal regulations and Southern Illinois University SCRO Committee requirements governing this research.
- I will ensure that all individuals associated with this project have the appropriate credentials to conduct the portion of the study in which they are involved.
- I will ensure that all co-investigators, and other personnel assisting in the conduct of this research study have been provided a copy of the entire current version of the research protocol and are fully informed of (a) the current study procedures (including procedure modifications); (b) potential risks associated with the conduct of this study and the steps to be taken to prevent or minimize these potential risks; (c) data and record-keeping requirements; and (d) the current approval status of the research study.
- I will respond promptly to all requests for information or materials solicited by the SCRO Committee.
- I will maintain adequate, current, and accurate records of research data, outcomes, and adverse events (if applicable) to permit an ongoing assessment of this research project.

Signature of Investigator:

Date:

I certify that I have read and will comply with the responsibilities outlined in Section M. The actual signature of the investigator is required. Please contact the SCRO Office to obtain a protocol number for this application and submit the signed form to the SCRO Office.

The SCRO Application Form must be submitted electronically to escro@siu.edu. If attachments cannot be converted to an electronic format, they may be faxed to 618-453-8038 or delivered to Woody Hall C214, Mail Code 4709, 900 S. Normal, Carbondale, IL 62901.

This application form is adapted from that of the University of Pittsburgh, by permission (6/26/2007), with modifications specifically for SIUC. See <http://www.rcco.pitt.edu/escro>