University of Rochester

Embryonic Stem Cell Research Oversight Committee (ESCRO) Application Form

A. General Information

Reason for Submission to ESCRO:

☐ New Project	☐ Response to Comments	☐ Reconsideration	☐ Disapproval resubmission
☐ Modification	☐ Renewal	☐ Renewal with mods.	☐ Response to Audit

Principal Investigator

First Name	
Last Name	
Degree(s)	
Experience/Number of Years	

Alternative mative

B. Qualifications of Listed Investigators-Please list the names, titles, department and qualifications of the principal Investigator and each of the listed co-investigators. An NIH bio-sketch should also be included for each individual.

E. Categories of research that best describes this project (Note more than one category may apply)
If your research proposal falls into categories 1 through 5, then it should be submitted to the ESCRO Committee AFTER review and approval by other relevant review committees. E.g. the IRB, IACUC, rDNA. Include a copy of each of these approvals. (See J.)

1. ☐ Research limited to in vitro procedures involving de-identified human stem cell lines, other than hES cells whereby:

   (i) 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 regulations and guidelines), and

   (ii) the cell lines and any corresponding information are anonymous or are coded in such a manner that the donor(s) cannot be identified (i.e. by the investigators or others) directly or indirectly through identifiers linked to the donor(s), and

   (iii) a written agreement has been obtained from the source of the cell lines and any corresponding confidential (e.g. medical record) information station that the identity of the donor(s) will not be released to the investigator under any circumstances.

2. ☐ Research limited to in vitro procedures involving hES cell lines that are listed on the NIH human Embryonic Stem Cell Registry

3. ☐ Human subject research involving autologous or allogenic non-embryonic stem cell transplantation intended for a hematopoietic indication.

4. ☐ Human subject research involving autologous or allogenic non-embryonic stem cell transplantation intended for a non-hematopoietic indication.

5. ☐ Research testing the function and character of human embryonic stem cells or their derivatives by transplant into non USDA regulated species (cold blooded animals, rats, mice and birds)

6. ☐ Research testing the function and character of human tissue stem cells by transplant into non USDA regulated species (cold blooded animals, rats, mice and birds)

7. ☐ Research testing the function and character of human embryonic stem cells or their derivatives or research testing the function and character of human adult tissue stem cells by transplant into non USDA regulated species (larger animals including primates)

8. ☐ Research involving human stem cells derived from umbilical cord blood, placenta or fetal tissue.

9. Human embryonic stem cells NOT on the NIH registry – **For research of this nature, please contact the ESCRO Office at (escro@urmc.rochester.edu)**

10. ☐ Other (please describe)

For research falling into category 8 or 9, the investigator must submit the proposal to the ESCRO Committee first for review by the convened ESCRO Committee. This submission should be done electronically and be accompanied by the proposed IRB research protocol and consent form document(s), if applicable (i.e., the proposed research involves human subjects); proposed IACUC research protocol, if applicable (i.e. the proposed research involves animal subjects); Materials

Transfer Agreement, if applicable (i.e., for human stem cell lines imported into the University) and if applicable the external sponsor's clinical protocol and investigator's brochure.

F.

3. Will cells be implanted into non-human fetuses? ☐Yes ☐No If yes, please answer the following:

   A. ☐Yes ☐No: Will hESC derivatives, HESC cells, or other pluripotent cells be introduced into non-human fetuses and allowed to develop into adult chimeras? If so, please explain the extent of human contribution to the resulting animal.

   B. ☐Yes ☐No: Will this protocol include the introduction of hESCs into non-human primate blastocysts?

   C. ☐Yes ☐No: Will this protocol include the introduction of hESCs into human blastocysts?

   D. Please outline anticipated potential consequences of the human contributions to the resulting chimeras. What is the anticipated effect of the human stem cells on the animal's anatomy, physiology and species-specific behavior? Consideration of any major functional contributions to the brain should be addressed specifically.

4. Will the animals be allowed to breed? If so, please explain and provide a scientific justification for allowing the animals to breed.
   ☐ Yes ☐No

5. Why are human stem cells required for this project instead of cells from other primates or animals?

6. How will any unanticipated results be handled, identified, managed, documented and reported to the IACUC and the ESCRO?

I. Privacy/Confidentiality of Donor

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

Are the stem cells linked to any information whereby it would be possible for the <u>source institution</u> to link the cells to the donors of the original blastocyst?

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 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 University of Rochester 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 and affirm that disclosure has been made to the Conflicts Committee.

O. 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 University of Rochester ESCRO 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 the current (a) 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