# 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 Contact with Knowledge of this Protocol**

First Name Last Name

**School** **Department** **Division**

**Phone** **Fax** **Email**

**Office Address** **Mailing Address (if different from office address)**

**Project Title:**

**Source of Support (Please check all that apply)**

☐ Federal
☐ State
☐ Commercial
☐ Foundation
☐ Internal
☐ Other: Please Specify:

Name of Sponsor(s)

Grant #:

Grant title:

Please use additional pages if necessary to list relevant grants support or external sponsorship.

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.

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. Experimental Background and Design

Please provide a brief non-technical description of the background, aims and design 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 be brief; please limit it to this page, and one additional page if needed.

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. Provenance of Federally Approved Cell Lines**

1. Please provide the requested information regarding the source of the cell lines:
(see http://stemcells.nih.gov/research/registry/for information)

| Vendor | NIH Registry & Vendor Number | UCLA MTA Number | Number of lines |
|---|---|---|---|
| 1. | | | |
| 2. | | | |
| 3. | | | |
| 4. | | | |

## G. Additional Questions for Research Involving Human Embryonic Stem Cells

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 tissue-derived stem cells in this research?**

## H. For research involving the introduction of human stem cells into animals, each of the following animal research questions should be addressed:

**If not applicable got to section I**

1. Please list the animals and include the age and quantity of each animal necessary to accomplish the research goals.

| Animal/Age | Number of animals |
|---|---|
| 1. | |
| 2. | |
| 3. | |

2. Please briefly outline any animal experiments involving human stem cell implantation. Include specific information as to the species, sites and ages at xenograft.

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 you 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 source institution to link the cells to the donors of the original blastocyst? ☐Yes ☐No ☐NA

## J. Approvals from other committees within the University of Rochester

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

☐ RSRB Review Board (Please indicate if approval was ☐exempt, ☐expedited, or ☐ full board)

☐ Institutional Biosafety Committee-recombinant DNA (IBC-rDNA)

☐ Institutional Animal Care and Use Committee (UCAR)

☐ Dean's Office, prior Scientific Review and Approval

**K. External Collaborations**

Guidelines: Describe any arrangement with or procedures conducted by non-University investigators. If there are more than two, please list and describe on separate page.

1. [Name of collaborating institution]
   [Name of collaborator, degree]
   [Title]
   [Mailing address]

2. [Name of collaborating institution]
   [Name of collaborator, degree]
   [Title]
   [Mailing address]

## L. Approvals from IRB and ESCRO committees outside the University of Rochester

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

## M. Materials Transfer Agreement

University of Rochester researchers must execute, with the University Office of Research Project 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.

## N. 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 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 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 ESCRO 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.

## P. Signature of Investigator: Date:

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

The ESCRO Application Form must be submitted electronically to (Katie_Scoville@urmc.rochester.edu). Please, do not hesitate to contact me with questions, by email or cell phone: 585-329-3394.