



# Rensselaer

## Institutional Stem Cell Research Oversight Committee (ISCRO)

ISCRO Reg. NO.: _____ Approval period: _____
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**GENERAL INSTRUCTIONS:** ALL human and non-human stem cell use at Rensselaer Polytechnic Institute requires completion of this form. For other Institutions using the RPI ISCRO, only compliance in regard to human stem cells requires use of this form. Approval is for one year, with re-evaluation at the end of each year for longer duration grants. An approval letter will be provided for the Protocol Director/PI after review. For NYSTEM grant proposals ISCRO review must be pending at time of grant submission.

**Statement of Confidentiality:** All of the information provided in this document is considered confidential and will be treated as such. However, it may be provided to the New York State Department of Health upon their request.

**\*\* PROTOCOL PERSONNEL \*\***

**Protocol Director/PI**

Name and Degree: \_\_\_\_\_ University \_\_\_\_\_

Title/Department \_\_\_\_\_

Email: \_\_\_\_\_

Phone : \_\_\_\_\_ Fax: \_\_\_\_\_

**RPI Administrative Contact**

Name: \_\_\_\_\_

Title/Department \_\_\_\_\_

Email: \_\_\_\_\_

Phone : \_\_\_\_\_ Fax: \_\_\_\_\_

**Co-Protocol Director/PI**

Name and Degree: \_\_\_\_\_ University \_\_\_\_\_

Title/Department \_\_\_\_\_

Email: \_\_\_\_\_

Phone : \_\_\_\_\_ Fax: \_\_\_\_\_

**Other Contact**

Name: \_\_\_\_\_ University \_\_\_\_\_

Title/Department: \_\_\_\_\_

Email: \_\_\_\_\_

Phone : \_\_\_\_\_ Fax: \_\_\_\_\_

**\*\* STEM CELL CHECKLIST\*\***

Please check all that apply:

- Registered Human Embryonic Stem Cell Lines  
(those included on the National Institutes of Health (NIH) Human Embryonic Stem Cell Registry at <http://escr.nih.gov>)
- Non-registered Human Embryonic Stem Cell Lines or human Pluripotent Stem Cells (IPS, ANT, etc.)  
(those excluded from the NIH Human Embryonic Stem Cell Registry at <http://escr.nih.gov>)
- Research involving Human Oocytes, Embryos or Embryo-like Structures
- Research involving derivatives of non-registered hESC or Pluripotent Stem Cells
- Research involving derivatives of human Embryos or Embryo-like structures
- hESC or human Pluripotent cells used in animals
- hESC or human Pluripotent cells used in humans
- Human Adult Stem Cells (Neuronal or Gonadal, circle each that apply)
- Human Adult Stem Cells that are not Neuronal or Gonadal
- Other non-human Stem Cells:  
Organism: \_\_\_\_\_  
Type: \_\_\_\_\_

**\*\* PROJECT LOCATIONS\*\***

A separate ISCRO form must be completed for each grant being submitted since the experimental questions, protocols and cell sources will vary. Space is provided below for co-PI and collaborators involved with this proposal.

Type of grant	Location/Dept Name	Address	Contact Information

**Other Institutional Committee Actions:** Please provide documentation of compliance with any required reviews (IRB, IACUC/APLAC, IBC and/or biosafety). This information will expedite approval of your project by the RPI ISCRO.

- |                            |                              |                             |
|----------------------------|------------------------------|-----------------------------|
| i. IACUC approval required | YES <input type="checkbox"/> | NO <input type="checkbox"/> |
| a. IACUC tracking #:       |                              |                             |
| ii. IRB approval required  | YES <input type="checkbox"/> | NO <input type="checkbox"/> |
| iii. IBC approval required | YES <input type="checkbox"/> | NO <input type="checkbox"/> |
| a. IBC pending             | YES <input type="checkbox"/> | NO <input type="checkbox"/> |
| b. IBC approved            | YES <input type="checkbox"/> | NO <input type="checkbox"/> |

**\*\* 1. PROJECT SUMMARY AND CELL LINE INFORMATION\*\***

GENERAL INSTRUCTIONS: ALL human and non-human stem cell use at Rensselaer Polytechnic Institute requires completion of this form. For other Institutions using the RPI ISCRO, only compliance in regard to human stem cell use requires completion of this form.

The intent of this form is to ensure compliance with current New York State and US Government guidelines for the ethical use of stem cells. The NYSTEM guidelines are stated in its Strategic Plan and are available on the NYSTEM website. These guidelines were constructed using guidance from the International Society for Stem Cell Research (ISSCR) and National Academy of Sciences (NAS) guidelines for stem cell and pluripotent cell research. In completing this form you state that you understand the ethical concerns related to the proposed research and that you have designed the experiments accordingly. All stem cell use regardless of funding source requires completion of this form for ISCRO review.

Relevant Websites: NYSTEM: [http://stemcell.ny.gov/about\\_nystem.html](http://stemcell.ny.gov/about_nystem.html)  
 ISSCR: <http://www.isscr.org>  
 NAS: <http://dels.nas.edu/bls/stemcells/>

Human Stem Cell lines and Sources:

Please list all Human Stem Cell Lines being used in your research along with their sources according to the Table below. You can list this below or provide it as an attachment if more room is needed. If you use several stem cell lines from a common derivation (ex. Neuronal) you can simply list these as derived or modified neuronal stem cell lines from the organ source. Please indicate 'To be determined' or TBD if the cell line does not yet exist but will be derived.

Name of stem cell line	Type of cell line	Current characterizations of each line: Ex. For potency, karyotype or safety (eg. Presence of human pathogens)	How did the provider(s) obtain the stem cell line or the tissue to derive the line?	Provider(s) contact

Project Goals Bullets/Summary of main goals or aims: *Please fill this out even if you are using non-human SCs*

Brief description of proposed research (please include enough information to describe project's specific aims, scientific rationale and methods used. Similar to a Project Summary). If full ISCRO review is required based on your description and stem cell sources, then more detailed information can be requested by the ISCRO committee.

Lay description of proposed research :

Brief description in lay terms of the research you will be doing with stem cells geared for non-scientists, ethicists.

**Ethical and Safety Consideration of Research:**

- (1) I have read the following ethical guideline documents for stem cell research:
- a. National Academies of Science (NAS) guidelines for human embryonic stem cell research  
[http://www.nap.edu/catalog.php?record\\_id=11278](http://www.nap.edu/catalog.php?record_id=11278)
  - b. International Society of Stem Cell Research (ISSCR) guidelines  
<http://www.isscr.org/guidelines/>
  - c. Conducted my own literature review for stem cell issues relevant to my stem cell field of interest.
  - d. I understand that under current NIH guidelines, that non-NIH approved hESC lines cannot be used in NIH-funded facilities. <http://stemcells.nih.gov/policy/guidelines.asp>
- (2) Please state in a few sentences what you understand to be the possible ethical impact of your stem cell research based on readings or database searches that you have done.
- (3) Describe your expertise, experience or training in the culture and use of human or non-human stem cells.
- (4) Does your research involve use of biohazard agents or recombinant DNA? YES \_\_\_\_ or NO \_\_\_\_.  
If YES, please describe your expertise, experience or training in the use of biohazard agents, rDNA.
- (5) If the stem cell line is a new hESC line or other pluripotent cell line derived from gametes, please provide the following information as an attachment to this protocol.
- (i) Was the consent of both gamete donors obtained to use the embryos for research?
  - (ii) Was that under an IRB research consent form or just a clinical consent form?
  - (iii) Was monetary or other compensation given to the donor(s)? If yes, please provide the details of donor compensation.
  - (iv) Has the maintenance and use of the stem cell line been performed under an approved IRB research protocol?
  - (v) Please provide a copy of the provider's IRB approval letter and a sample donor consent.

**Project Personnel:** Use the following table to list all personnel (including any students) in your laboratory who handle/will handle stem cell lines in your protocol/research under review. Please attach additional sheets if necessary.

Name/degree	Title	Role on Project involving stem cells

**\*\* 2. MATERIAL TRANSFER AGREEMENT\*\***

Please provide a copy of any signed MTA agreement.

**\*\* 3. HUMAN SOMATIC STEM CELLS, HUMAN OOCYTES, INDUCED PLURIPOTENT (IPS) OR MULTIPOTENT (MPS) CELLS, or NEW DERIVATIONS\*\***

**(1) The research involves the derivation of new human stem cell lines.** YES \_\_\_\_\_ or NO \_\_\_\_\_.

If YES, please complete the following questions (i) and (ii).

(i) Type of cell lines: examples might include hESC, fetal tissue-derived stem cells, adult tissue-derived stem cells, bone marrow stem cells, cord blood stem cells, iPSC, cancer stem cells or any other type of human stem cell.

(ii). Describe your expertise, experience or training in the handling and use of human or non-human stem cells, oocytes or embryos, including Somatic Cell Nuclear Transfer (SCNT) or other stem cell derivation and culture methods.

**(2) Will the research involve human oocytes, embryos or embryo-like structures created by SCNT or similar methods, including use of cellular or other material derivatives of the above?** YES \_\_\_\_\_ or NO \_\_\_\_\_.

If YES, please complete the following questions (i), (ii), (iii).

(i) Describe the rationale for the need to use human oocytes or embryos.

(ii) Is SCNT or any other method to create embryos or embryo-like structures going to take place with human cells or nuclei?

(iii) Provide a justification for use of human rather than non-human materials.

**(3) For new derivations of human stem cells, is there readily identifiable information available on the donors of human embryos, somatic cells or gametes?** YES \_\_\_\_\_ or NO \_\_\_\_\_.

If YES, please complete the following questions (i), (ii) and (iii).

(i) How will you maintain confidentiality of records?

(ii) Will donors be recontacted?

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(iii) Is there any payment or reimbursement to any donors of gametes, blastocysts or somatic cells?

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**(4) If your research involves the use of human oocytes, embryos or embryo-like structures created by SCNT or similar methods, please complete the following (i- iv).**

(i) How many human oocytes or embryos will be used?

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(ii) Please provide a justification for how this number was derived.

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(iii) How long will blastocysts be kept developing in culture? (State Laws limit culture to 12 days)?

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(iv) Please provide a copy of the IRB approved consent forms that were or will be used to obtain any gametes, blastocysts, or somatic cells.

**(5) Describe your expertise, experience or training in the handling and use of human or non-human oocytes or embryos- including SCNT and derivation or culture of human or non-human stem cells if applicable.**

If appropriate, you may state “refer to response from (1) ii”.

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**\*\* 4. STEM CELL USE IN ANIMALS \*\***

Please address the following questions if the research involves animal subjects in an attachment. That is if the research involves the introduction of either (a) embryonic or (b) human pluripotent or multipotent or (c) any human stem cell or (d) cellular derivatives of human stem cells, into nonhuman animals.

- (i) Will human pluripotent, multipotent or adult stem cells be placed in nonhuman primates?
- (ii) What animal species will be used?
- (iii) What is the developmental stage of the animal when human cells will be introduced?
- (iv) What type of human cell will be introduced?
- (v) Where will cells be placed (anatomical location)?
- (vi) Evaluate the probable pattern and effects of differentiation and integration of the human cells into the animal CNS.
- (vii) Evaluate the probable pattern and effects of differentiation and integration of the human cells into other animal tissues.
- (viii) If any human pluripotent or multipotent cells are introduced into a non-human animal, how are you guaranteeing that the animals will not breed? Please include plans for any accidental pregnancies.
- (ix) Describe your expertise, experience or training in the use of human or non-human stem cells in animal models.

**\*\* 5. STEM CELL USE IN HUMANS \*\***

Will the research involve introduction of embryonic stem cells, pluripotent stem cells or their cellular derivatives, or adult stem cells into humans? If so, provide as a separate attachment (1) the scientific rationale for the introduction of these stem cells into humans, (2) an evaluation of the probable pattern and effects of differentiation and integration of the human cells into human tissues and (3) a copy of the IRB approved informed consent forms.

**\*\* 6. CONFLICT OF INTEREST\*\***

Does anyone who (1) recruits, selects, consents or treats participants or (2) plans to analyze data or (3) plans to serve as an author on any papers originating from the research or (4) is an immediate family member (spouse, dependent child as defined by the IRS, domestic partner of any of the above) have any relationship listed in the table below? Check left box if NO.

___ NO	Have consulting arrangements, responsibilities or equity holdings in the Sponsoring company, vendor(s), provider(s) of goods or subcontractors(s)?
___ NO	Have a financial relationship with the sponsoring company, vendor(s), providers(s) of goods, or the subcontractor(s) including the receipt of honoraria, income or stock/stock options as payment?
___ NO	Serve as a member of an advisory board with the Sponsoring company, vendor(s), provider(s) of goods or subcontractor(s).

NO	Receive any gift funds from the Sponsoring company, vendor(s), provider(s) of goods or subcontractor(s).
NO	Have an ownership or royalty interest in any intellectual property utilized in this protocol?
NO	To your knowledge, does anyone in a supervisory role to the Protocol Director/PI have a conflict of interest related to this study?

If one or more of the above relationships exist, please include a statement in the consent form to disclose this relationship, ie. a paid consultant, a paid member of the Scientific Advisory Board, has stock or stock options, or receives payment for lectures given on behalf of the sponsor. The consent form should disclose what Institution(s) or Companies are involved in the study through funding, cooperative research, or by providing study drugs or equipment. If you answer yes to any of the questions above, you must file a conflict of interest disclosure with the Office of Research at RPI.

**\*\* 7. ATTACHMENTS PROVIDED TO ISCRO \*\***

If you needed to provide attachments for any of the sections of the ISCRO, please list the items provided below.

Page 3	Additional Stem Cell lines/Sources
Page 4	Ethics and Safety, part v, new stem cell lines
Page 5	Personnel working with stem cells
Page 2	Copy of IACUC approval/tracking no:
Page 2, 6	Copy of IRB approval, part (4)iv, or stem cell use in humans
Page 2	Copy of IBC approval
Pages 6,7	Conflict of Interest
Other	Please state:

**\*\* 8. Opportunity for comments \*\***

If you have any concerns or comments please use the space provided below.

**AFFIRMATION:** *By signing this document, I indicate that the information provided on this form is complete, accurate and true to the best of my knowledge. I agree to abide by the responsibilities under Federal, State and relevant University policies, including MTAs, purchase agreements, or other contracts with respect to my use of human or other stem cells. I also understand that research involving non-registered hESC, human embryos, or their derivatives must only be performed using space and equipment that has been pre-approved by the University and that I will ensure that all project personnel abide by these guidelines. I also understand the ethical issues related to the stem cells in use. I accept responsibility for ensuring that all personnel associated with this work have received the appropriate training on the hazards and level of containment required to perform this research safely with the proposed materials and that all personnel understand the ethical issues related to the stem cells in use.*

Protocol Director / Principle Investigator (print) \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Grant Agency Submitting to: \_\_\_\_\_



ISCRO COMMITTEE USE

Approval:  Yes  Yes, approved with modifications \*(see notes below)  No

Signatures:

ISCRO Chair or Representative (print/sign): \_\_\_\_\_ Date: \_\_\_\_\_

Modification(s) needed: