



Rensselaer

ISCRO POLICY DOCUMENT

**CHARGE TO THE INSTITUTIONAL STEM CELL RESEARCH OVERSIGHT
COMMITTEE**

The Institutional Stem Cell Research Oversight (ISCRO) committee functions as the Rensselaer Polytechnic Institute (RPI) human embryonic stem cell, pluripotent stem cell and adult stem cell research oversight committee. It also serves in these roles as a multi-Institutional ISCRO in the Albany, NY area. The ISCRO reports to the Rensselaer Associate Vice President for Research (AVPR) on any issues that arise related to the conduct and use of human stem cells (embryonic, pluripotent or adult) in research. The ISCRO policy is based on the National Academy of Science (NAS) and International Society of Stem Cell Research (ISSCR) standards for human stem cell research that are the current guiding principles used in the United States as well as New York Empire State Stem Cell Board (ESSCB). RPI ISCRO Review Process Guidelines and Application Information are available.

The Rensselaer ISCRO committee is charged with:

- 1) Education of stem cell researchers at Rensselaer to include all primary investigators, technical staff and student trainees involved in stem cell research as well as the general public to understand the importance of stem cell research in advancing basic science and medical applications with these cells. This will include generation of a public website for access to stem cell information and documents.
- 2) Review of proposals for all human embryonic stem cells, human totipotent or pluripotent stem cells, and human pluripotent stem cell lines including induced pluripotent stem cell (IPS) lines, to ensure that all research that uses or derives new lines or products are in compliance with NAS or ISSCR guidelines and with New York Empire State Stem Cell Board (ESSCB) statutes. The ISCRO will confirm that procedures used in human pluripotent stem cell research meet ethical standards and are of scientific merit. In regard to the generation of new hESC lines using the inner cell mass of blastocysts, the New York ESSCB mandates in accordance with ISSCR 11.2 guidelines that consent to donate gametes or embryos in excess of reproductive need to research must be obtained at the time of donation and consent must be obtained from all gamete donors for use of embryos in research. Donors must also be informed that they retain the right to withdraw consent at any time until the materials are used in research. In regard to payment for donors who produced gametes originally for reproductive purposes, the ISCRO will review information where available for compliance with ISSCR 11.5 (a). Where no such information is reasonably available, the ISCRO need not ensure that payments complied with ISSCR guidelines. Consent to donation of biological materials (gametes, embryos, and somatic cells) and the procurement of such materials must comply with NAS or ISSCR (11.3, 11.6) guidelines modified for ESSCB to include: a dynamic process in informed consent that clarifies options for excess embryo disposition, accessibility to counseling services, clear separation of donation of embryos in excess of clinical need, no affect on medical care, ability to withdraw consent, information on intended initial use of biological materials, and financial disclosure discussion in consent form.
- 3) Review of proposals on human Neural and Gonadal progenitor stem cells. Human adult stem cell lines and nonhuman (animal) stem cells that remain restricted in tissue potential and are not known to

possess totipotent or pluripotent potential do not require ISCRO review but must meet requirements of other Institutional regulating agencies as well as being in compliance with national and state standards for research with these cells.

4) Review of ethics and protocols for the generation of chimeras by use of transplanted human stem cells into animal models.

5) Maintaining a record of all human stem cell research at Rensselaer to ensure that review, when appropriate has been done, and that education in stem cell research reaches those in the field. Any researcher at Rensselaer that uses human stem cells will be required to submit an ISCRO form for approval.

The Rensselaer ISCRO Committee will meet quarterly or as necessary to review stem cell proposals and monitor grant compliance with committee standards and will retain written records of its meetings and activities. One half of the committee, or three members minimum, must be present to generate a quorum for meeting and have any decisions be binding. The ISCRO will coordinate its activities with other research oversight committees, Rensselaer offices, and regulatory and advisory Institutional bodies at Rensselaer, including:

- 1) IACUC (Institutional Animal Care and Use Committee)
- 2) IRB (Institutional Review Board)
- 3) IBC (Institutional Biosafety Committee)
- 4) Office of the General Council
- 5) Office of the Vice President for Research
- 6) Research Administration and Finance

Any violations of approved protocols after review may be reported to the Institute Official. The committee will review current policies and recommend any future changes to internal policies based on external regulations. Any significant changes to internal policy will be presented to the Institute Official for approval. Additional duties of the ISCRO committee may be assigned from the Institute Official to meet future needs or guidelines in stem cell research.

INTER-INSTITUTIONAL USE OF THE RPI ISCRO

The RPI ISCRO currently serves as a multi-institutional ISCRO for Rensselaer Polytechnic Institute, New York Neural Stem Cell Institute, Ordway Research Institute and University at Albany, State University of New York, including the College of Nanoscale Science and Engineering. The RPI ISCRO will move to establish itself as a Albany Capital Region SCRO by Spring 2011.

CONFLICT OF INTEREST

In accordance with the policies of Rensselaer Polytechnic Institute, no member of the ISCRO committee may be involved in ISCRO review of any stem cell proposal that he/she is a participant on. Nor may an individual of the ISCRO committee participate in review of a proposal if they report by employment to an investigator on the proposal or hold any financial interests in the research. No member will participate in initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the SCRO committee.

MEMBERSHIP

Membership in the ISCRO committee is through appointment by the Institute Official with term of membership for 12 months and renewable. Calendar term of membership is February 1 to January 31 of the following year. The committee will be composed of at least five primary members with expertise in the areas of hESCs, human adult stem cells, developmental biology, and biomedical ethics. Additional areas of expertise may include assisted reproduction and external patient advocates. Administrative contacts for the committee at RPI include the VPR and General Council. External membership includes an Administrative Officer from that Institution using the RPI ISCRO. When more specific expertise is demanded, nonmembers that may be faculty or others with appropriate expertise may attend a meeting, but only upon invitation by the ISCRO Chair. ISCRO meetings are otherwise closed to the public, although meeting notes are available upon request and approval.

ISCRO Current Committee Members:

Janet L. Paluh, Chair	Associate Professor, CNSE	hESCs, pluripotent SCs
George Plopper	Associate Professor, Biology	hMSCs
Glenn Monastersky	Director of Operations CBIS	Dev. Biol. & Asst. Reprod.
Sally Temple	Scientific Director, NYNSCI	NSC Expert
Wayne Shelton	AMBI, Albany Medical College	Ethics Expert

ISCRO Current Administrative Contacts:

Wolf W. von Maltzhan	RPI Associate Vice President of Research
Charles F. Carletta	RPI Secretary of Institute and General Counsel
Tom Irwin	NYNSCI Chief Administrator
Sharon Boswell	Ordway Manager, Office Sponsored Research
Adrienne Bonilla	UAlbany-SUNY, CNSE Assistant Vice President Research, Director Office of Regulatory Research Compliance

DOCUMENTATION, REPORTING AND STAFF SUPPORT

The Rensselaer ISCRO committee will keep meeting minutes and documents for a period of six years in accordance with ESSCB requirements. The committee will generate an annual report to the VPR of its activities. Future requests for changes to ISCRO policy or recommendations on Institution policies on stem cell research will be made to the VPR as necessary. The Office of the VPR will provide necessary administrative support for the ISCRO committee.