Summary of the Institutional Stem Cell Research Oversight (ISCRO) Committee Review Process and Guidelines
Office of Research, Rensselaer Polytechnic Institute

ISCRO Review Sequence

1. The current forms include an ISCRO Application Form and ISCRO Renewal/Update Form. Both are available from the ISCRO Chair or in the future from the ISCRO Website that is being developed. For non-RPI researchers the form is also available via your ISCRO Administrative contact person.
2. For initial review, RPI researchers should submit the ISCRO Application Form and if possible a copy of the proposal to the Chair of the committee. Non-RPI researchers will submit proposals to the ISCRO via its Chief Administrator.
3. You will be assigned an ISCRO registration number and Approval Period, leave these blank.
4. The ISCRO committee will determine the review type based on the criteria below.
5. Once review is completed by the ISCRO and the committee confirms with the Protocol Director/Principle Investigator that all requirements are met, an Approval Letter is issued along with the original signed and approved final page of the ISCRO Form. A copy of this page is also kept on file by the ISCRO committee.
6. Annual ISCRO review is currently required. An ISCRO Renewal/Update Form is used.

Protocols/Research requiring ISCRO Review

1. It is requested that all research on human pluripotent or adult stem cell types complete the ISCRO form. NYSTEM requires ISCRO approval for human embryonic stem cells regardless of their status as NIH approved lines.
2. Designated Administrative Review is suggested for non-human stem cells by criteria stated below.
3. Non-RPI Institutions that use the ISCRO need not undergo ISCRO review if their research does NOT involve human stem cells.
4. Non-RPI Institutions that use the ISCRO need not undergo ISCRO review if their research is described under Part1a or Part1b Designated Review.
5. Minor changes to a previously approved protocol must be submitted for review using the appropriate form that is signed by the proposal Principle Investigator.

ISCRO Review

1. **Designated Administrative Review:** The ISCRO Chair member may approve.
    a. Pluripotent human stem cells are not used or generated and no human neural or gonadal adult progenitor cells are being placed in humans or animals.
    b. Existing pluripotent cells are used *and all of the following are true*:
        i. Pluripotent cells are not put into animals
        ii. Pluripotent cells are not put into humans
        iii. Provenance of the cell line(s) has been previously documented:
            A. NIH registered lines
            B. Cells from the UK Stem Cell Bank
            C. Cells from the Canadian National Stem Cell Oversight Committee
            D. RPI or Institute has provenance documentation on file
    c. Minor changes to a previously approved IRB/ISCRO protocol by amendment but without changes to the protocol, scope or aims of the research. Minor changes include addition of personnel, source of approved cell lines.

2. **Designated Review with Committee Approval:** At least two ISCRO members review protocol.
    a. Existing pluripotent cells are used *and all of the following are true*:
        i. Pluripotent cells are not put into animals
        ii. Pluripotent cells are not put into humans
        iii. Provenance of the cell line(s) has NOT been documented:
            1. Investigator provides provenance information
            2. Provenance documentation is reviewed by ISCRO ethics member
            3. Ethics member and ISCRO member discuss review
            4. Full panel review not required but may be requested by two reviewers
    b. Other types of designated reviews may include:
        i. Requested review
            A. Purpose: to assist ISCRO member in determining correct review process.
            B. Science and/or ethics reviewers can be assigned as needed.
        ii. Confirmation review
            A. Purpose: to determine that protocol changes requested by ISCRO have been completed and satisfy ISCRO.
            B. ISCRO member assigns review
        iii. Amendment review
            A. Purpose: to assess protocol when minor changes are added to a previously approved IRB/ISCRO protocol by amendment and there is a change to the scope or aims of the research.

3. **Full Panel Review:** Quorum of ISCRO meetings to include at least 1 ethicist and 1 stem cell expert with related expertise. Required if any of the following are true:
    a. New pluripotent cells are derived or generated, including conversion of somatic cells into pluripotent or multipotent cells without the use of human embryos.
    b. Pluripotent cells are put into animals
    c. Pluripotent cells are put into humans
    d. Human gametes are donated for stem cell research
    e. Human embryos are donated for stem cell research
    f. Somatic cells are used in reprogramming (IPS cells)
    g. Placement of human neural progenitor cells into brains of non-human animals or humans
    h. Placement of human gonadal progenitor cells into non-human animals or humans
    i. Clinical trials involving transplantation of hESC or cells differentiated from hESC or IPS cells.
    j. SCNT or any method that generated human blastocyst-like structures are used.

    <u>Full Panel Review Sequence</u>:
    a. Protocols are read and evaluated by multiple committee members
    b. Protocols and review decisions are discussed by multiple committee members
    c. Panel generates a specific list of queries or recommendations
    d. Panel determines if the protocol is:
        i. Approved
        ii. Approved pending modifications; compliance to be confirmed by ISCRO
        iii. Not approved.
    e. Protocol Director/PI addresses any deficiencies or recommendations
    f. Protocols not approved are re-reviewed at the next committee meeting date.