**Stem Cell Research Oversight (SCRO) Committee:**

**Policy and Guidelines**

**I. OVERVIEW OF THE STEM CELL RESEARCH OVERSIGHT (SCRO)**

**PROGRAM**

The policies of the Upstate Stem Cell Research Oversight Program are based on the

National Academies' Guidelines for Human Embryonic Stem Cell Research (amended as

of September 2008) and the International Society for Stem Cell Research (ISSCR)'s

Guidelines for the Conduct of Human Embryonic Stem Cell Research.

The Vice President for Research has established an Institutional Stem Cell Research

Oversight (SCRO) Committee to provide oversight over all issues related to derivation

and use of human embryonic stem cell lines, for the purpose of implementing Upstate’s

Stem Cell Research Oversight Program and to facilitate education of investigators

involved in stem cell research.

**II. TYPES of RESEARCH THIS POLICY COVERS**

**A.** Research that uses human embryonic stem (hES) cells, including the derivation of

hES cell lines and all research that uses hES cells derived from:

• blastocysts made for reproductive purposes and later obtained for research

from *in vitro* fertilization (IVF) clinics;

• blastocysts made specifically for research using IVF;

• somatic cell nuclear transfer (NT) into oocytes.

**B.** Research that uses fetal stem cells or embryonic germ cells derived from fetal

tissue (federal statutory restrictions at 42 USC 289g-2(a) and federal regulations at 45

CFR 46.201 also apply).

**C.** Research that uses human pluripotent stem cells (hPS) derived from non-embryonic

sources, such as spermatogonial stem cells and ‘induced pluripotent’ stem cells

derived from somatic cells by introduction of genes or otherwise (i.e., iPS cells), and

other pluripotent cells yet to be developed.

**D**. The Committee does not review research that uses nonhuman stem cells.

**\*** SCRO Committee review does not replace other institutionally required reviews such

as reviews by the Institutional Review Board for the Protection of Human Subjects (IRB),

the Committee for the Humane Use of Animals (CHUA), or the Bio-Safety Committee

(IBC).

**III. SCRO COMMITTEE GUIDELINES:**

The Committee has the authority to approve, require modifications in, or disapprove all

research activities that fall within its jurisdiction. The SCRO Committee findings and

actions taken on proposals are communicated with the Upstate Administration through

the Vice President for Research who receives the minutes for each convened meeting.

Committee members are not permitted to review and/or approve (in the case of proposals

eligible for expedited review) proposals in which they are involved. Any member

involved in a proposal being reviewed by the Committee will be recused from discussion

and voting on any actions, but may provide the Committee with information. Any

member involved in the study will absent him/herself from the meeting during voting.

Committee members not scheduled to attend a meeting will receive a copy of the agenda

and minutes from the previous meeting.

Committee records shall be retained for at least 3 years.

The Committee members have adopted a Conflict of Interest Policy for SCRO

Committee Members (appendix 1). In addition, all Upstate faculty, staff and students are

required to adhere to the University *Policy on Relations with the Pharmaceutical,*

*Medical Device and Biotechnology Industries*, which is designed to address conflicts of

interest that arise when employees, faculty and students enter into relationships with

pharmaceutical, medical device, and biotechnology industries

<http://www.upstate.edu/policy/pdf/CAMP_A-24.pdf>

**IV. COMPOSITION OF SCRO COMMITTEE**

The SCRO Committee will be comprised of experts in the following areas**:**

1. independent representatives of the lay public;

2. persons with expertise in developmental biology;

3. persons with expertise in stem cell research;

4. persons with expertise in molecular biology;

5. persons with expertise in assisted reproduction;

6. persons with expertise in ethical and legal issues in human embryonic stem cell

research;

7. persons with expertise in animal research.

**V. UPSTATE REQUIRED TRAINING:**

Various Institutional requirements for research education must be satisfied prior to the

review and/or approval of any proposal being considered by the SCRO Committee.

These may include any or all of the following (refer to specific committees for

requirements):

• CITI Biomedical Human Subjects course (Basic or refresher) for those

conducting human subjects research;

• CITI Responsible Conduct of Research (RCR) course for all basic science investigators, graduate and undergraduate students, postdoctoral fellows and associates, and laboratory personnel. The RCR course is required for all people doing basic science research whether they be in a Basic Science or Clinical Department and independent of whether they are doing wet or dry lab research;

• CITI Lab Animal Welfare Course;

• Environmental Health and Safety Training programs

( <http://www.upstate.edu/ehs/ehs_training.php> ).

**VI. SCRO REVIEW OF PROPOSALS**

1. The Review of a proposal includes assessment of the:

1. Scientific merit of the proposal;

2. Relevant expertise of investigators;

3. Ethical permissibility and justification;

4. Compliance with relevant regulations and institutional policies.

**VII. LEVEL OF REVIEW REQUIRED**

The level of review required is determined by which category of research the experiment

is designated.

A. **Expedited Review:** Experiments listed in Category 1 may be exempt from full

SCRO Committee review. These experiments may be reviewed under expedited

procedures. Expedited review is performed by the SCRO Committee Chair and/or

another member of the committee as designated by the Chair.

B. **Full SCRO Committee Review:** Experiments listed in Category 2 require review

at a convened meeting of the SCRO Committee.

**VIII. CATEGORIES OF PERMISSIBLE RESEARCH**

Documentation of the provenance of all hES (human embryonic stem) cell lines is

required. Proposals may also require documentation of approval by other applicable

internal or external compliance committees (e.g., IRB, CHUA, IBC).

1. **Category 1:**

**1.** Purely *in vitro* hES cell research using previously and appropriately

derived hES cell lines.

**2.** Purely *in vitro* research using hPS cells, unless designed or expected to

yield gametes.

**3.** Experiments that involve only transplantation of hPS cells into postnatal

nonhuman animals with no likelihood of contributing to the central

nervous system or germ line.

1. **Category 2:**

**1.** Generation of new lines of hES cells by whatever means.

**2.** Research in which the identity of the donors of blastocysts, gametes, or

somatic cells from which hES cells were derived is readily ascertainable

or might become known to the investigator.

**3.** Research in which hES cells are mixed with pre-implantation human

embryos. In no case shall such experiments be allowed to progress for

more than 14 days of development in vitro, or past the point of primitive

streak formation, whichever is first.

**4.** Research in which cells of totipotent or pluripotent human origin are

transplanted into living human subjects.

**5.** Research involving the introduction of hES cells into nonhuman animals

at any stage of fetal or postnatal development.

**6.** Research involving transplantation of hPS cells into nonhuman animals at

any stage of fetal development.

**7.** Experiments that involve only transplantation of hPS cells into postnatal

nonhuman animals **with** likelihood of contributing to the central nervous

system or germ line.

**IX**. **CATEGORIES OF RESEARCH WHICH ARE NOT PERMISSIBLE**

1. **Category 3:**

**1.** *Research involving in vitro* culture of any intact human embryo, regardless

of derivation method, for longer than 14 days or until formation of the

primitive streak begins, whichever occurs first.

**2.** Research in which hES cells are introduced into nonhuman primate

blastocysts or in which any embryonic stem cells are introduced into

human blastocysts.

**3.** Experiments that involve transplantation of hPS cells into human

blastocysts.

**4.** Research in which hPS cells are introduced into nonhuman primate

embryos.

**5.** Research involving the breeding of nonhuman animals into which hPS or

hES cells.

**X. ASSESSING THE PROVENANCE OF STEM CELL LINES**

Investigators must provide the SCRO Committee with documentation of the provenance

of all stem cell lines proposed for use within the University. This includes lines derived

within Upstate as well as those an investigator may wish to import from other

institutions. No investigator may use a line until the SCRO committee has accepted the

provenance and added the line to its Human Embryonic Stem Cell Registry.

1. **Use of NIH-Approved hES Cell Lines**

Presence on the list of NIH-approved cell lines constitutes adequate documentation

of provenance.

**B. Use of hES Cell Lines and hPS Cell Lines (derived from non-embryonic sources)**

**Imported from Other Institutions or Jurisdictions**

The following information is required in order for the SCRO Committee to assess

whether cell lines have been acceptably derived.

 **1**. Attestation from the supplying institution’s SCRO Committee or

Institutional Official that:

 **a)** the donation protocol was reviewed and approved by an Institutional

Review Board (IRB) or foreign equivalent;

**b)** consent to donate was voluntary and informed;

**c)** donation was made with reimbursement policies consistent with NAS

and/or ISSCR guidelines; and

**d)** donation and derivation complied with the extant legal requirements of

the relevant jurisdiction.

**XI. STEM CELL REGISTRY**

The SCRO Committee tracks the existence and use of human embryonic stem cell lines

within the University via its Human Stem Cell Registry.