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## Research Requiring GESCR Review

### Definitions

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#### Adult Stem Cells

### Definitions

What are stem cells?

Stem cells are cells that have the potential to differentiate into specialized (tissue specific) cell types.

What are human embryonic stem cells (hESCs)?

hESCs typically come from the inner cell mass of embryos that have grown to the blastocyst stage, beyond 100 cells.

What are induced pluripotent stem (iPS) cells?

IPS cells are typically derived by the reprogramming of cells that are not pluripotent in order to create pluripotent cells.

What is a stem cell derivative?

Derivatives are the biological materials derived from pluripotent stem cells such as DNA, RNA, proteins, and any other products extracted from stem cells.

## Research Requiring GESCR Review

The research described below requires GESCR review and possibly review by the IRB or other committees. Click on the links for additional info or exceptions. Submission instructions are available on the Submission and Review Process <sup>[1]</sup> page.

Human embryonic stem cells (hESCs)

Any research use of hESCs:

- Use of commercially available, de-identified hESCs
- Use of existing hESC lines from prior studies approved by GESCR or IRB
- Use of newly derived hESCs from current studies approved by GESCR or IRB
- Banking of hESCs
- Derivation of new pluripotent hESC
- Development of hESCs into gametes (sperm/oocytes)
- Projects that involve animal reproductive function (IACUC approval also required)
- Injection/transplantation of hESCs or their derivatives into any non-human animals ( IACUC <sup>[2]</sup> approval also required)
- Injection/transplantation of hESCs or their derivatives into human subjects

Induced pluripotent stem (iPS) cells

Any research use of iPS cells:

- Use of commercially available, de-identified iPS cells
- Use of existing somatic cells from prior studies approved by GESCR or IRB
- Derivation of iPS cells from newly collected somatic cells (IRB approval also required)
- Derivation of iPS cells from de-identified existing somatic cells already collected
- Banking of iPS cells
- Development of iPS cells into gametes (sperm/oocytes)
- Projects that involve animal reproductive function (IACUC <sup>[2]</sup> approval also required)
- Injection/transplantation of iPS cells into non-human animals (IACUC <sup>[2]</sup> approval also required)
- Injection/transplantation of iPS cells into human subjects (IRB approval also required)

Human embryos

- Destruction of reproductive quality human embryos (capable of producing a pregnancy) in the course of research
- Donation and research use of embryos deemed unacceptable for assisted reproductive

technology care

- Banking of human embryos to be used for research purposes
- Creation of pluripotent human stem cells and lines and the downstream use of such cells and their derivatives
  - Derivation of human embryonic stem cell lines
  - Parthenogenesis
  - Somatic Cell Nuclear Transfer (SCNT)
- Any injection or transplantation of cells into non-human animals
  - Embryos
  - Derivatives of embryos
- Sensitive research projects involving human embryos that raise symbolic concerns or concerns about human dignity
- Any protocols for which the IRB requests formal GESCR review. In addition, the IRB may request that the GESCR Chair or Committee member assist in the IRB review.
- Generally, research whose goal is improving reproductive outcomes in infertility treatment does not require GESCR approval.

Human gametes (sperm and oocytes)

- Use of reproductive quality oocytes (capable of being fertilized) in research that is not directed towards improving reproductive outcomes in infertility treatment
- Donation and research use of oocytes deemed unacceptable for assisted reproductive technology care.
- Creation of pluripotent cells and stem cell lines from gametes and the downstream uses of these pluripotent cells and their derivatives, including:
  - Parthenogenesis
  - Somatic Cell Nuclear Transfer (SCNT)
  - Creation of embryos expressly for research
  - Androgenesis
- Any injection/ transplantation into non-human animals
  - Oocytes
  - Sperm
- Sensitive research projects involving human gametes that raise symbolic concerns or concerns about human dignity
- Procurement and banking of human gametes (oocytes, ovarian tissue, sperm, testicular tissue) for research purposes
- Any protocols for which the IRB requests formal GESCR review. In addition, the IRB may request that the GESCR Chair or Committee members assist in the IRB review.

Generally, research whose goal is improving reproductive outcomes in infertility treatment does **not** require GESCR approval.

Other pluripotent cells

Research involving cells that are, will, or could become pluripotent must undergo GESCR review.

## Adult Stem Cells

Adult stem cells include cord blood, mesenchymal, fetal, placental, hematopoietic or progenitor (does not include germ cells).

The GESCR Committee no longer reviews most adult stem cell protocols (see exceptions below). Studies that include the use of adult stem cells should apply to the IRB only.

The following EXCEPTIONS apply

- All CIRM funded research, regardless of tissue/cell type, must undergo a GESCR review
- Research involving processing of adult stem cells that significantly modifies/alters their capabilities
- A Phase I or Phase II clinical trial of a new, commercially manufactured stem cell product which has not previously undergone GESCR review. (Example: The early Prochymal studies underwent GESCR review. Further GESCR review of Prochymal studies is no longer required. IRB review is still required.)
- Injection/transplantation of neural progenitor cells into non-human animals
- Injection/transplantation of adult human stem cells into non-human animals that are expected to cause morphologic changes that are characteristically human
- Development of human stem cells into gametes (sperm/oocytes)
- Projects that involve human stem cells and animal reproductive function

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### Links

[1] <http://irb.ucsf.edu/review-process-gescr>

[2] <http://iacuc.ucsf.edu/>