

Title: Stem Cell Research Policy	Policy Category: Research
Issuing Authority: Office of the Vice President for Research	Responsibility: Office of Research Compliance
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Policy Statement/Background:

None

Policy:

It is the policy of Stony Brook University (SBU) that Covered Research (identified below) involving human pluripotent stem cells (hPSCs) being conducted by SBU faculty, staff or students or involving the use of SBU facilities or resources shall be subject to oversight by the SBU Stem Cell Research Oversight (SCRO) Committee. Human Pluripotent Stem Cells (hPSCs) as defined here, include: any human pluripotent or totipotent stem cell line (e.g. human embryonic stem cell (hESC), human induced pluripotent stem cell (hiPSC), human extended pluripotent stem cell (hEPSC), and human embryonic germ cell (hEGC)). Covered research includes:

- All research using NIH approved established hESCs;
- All research involving establishment of new hPSCs;
- Research using established hPSCs where the research involves:
 - In vitro culture and/or differentiation of hPSCs.
 - Introduction/transplantation of hPSCs or their derivatives into any nonhuman recipient or animal at any stage of embryonic, fetal or postnatal development.
 - Introduction of hPSCs or their derivatives into humans.

In accordance with prevailing ethical and policy guidance and applicable law, the following categories of research are currently prohibited at SBU:

- 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
- Research in which hPSCs are introduced into human or non-human primate preimplantation embryos
- Research in which any products of research involving human totipotent or pluripotent stem cells are implanted into a human or non-human primate uterus
- Breeding of animals that had hPSCs introduced into the germ line
- Research on a stem cell line derived from human embryos created for research purposes rather than reproductive purposes
- Research on a stem cell line derived from human somatic cell nuclear transfer (SCNT)
- Research on a line derived from human parthenogenesis

This list may be revised to reflect changes in prevailing ethical and policy guidance and applicable law.

Stem Cell Research Oversight Committee

The SCRO Committee is a campus committee appointed by the Vice President for Research and charged with review and approval of human stem cell research performed at SBU.

The primary purpose of the SCRO Committee is to provide ethical oversight for all research conducted at SBU using hESCs or other hPSCs under the limited circumstances identified above. The SCRO Committee also requires compliance with other applicable governmental regulations and institutional policies. The SCRO Committee has the authority to approve, require modifications of, or withhold approval of all research activities that fall under its jurisdiction. Approved research shall be reviewed by the SCRO Committee every year, or more frequently, as determined by the SCRO Committee on a case-by-case basis. No modifications to the SCRO Committee approved research shall be implemented prior to SCRO Committee approval of the modifications.

The SCRO Committee serves as an educational resource and also provides consultation for researchers engaged in this type of research. Referrals to the SCRO Committee will also be made by the Institutional Animal Care and Use Committee (IACUC), the Institutional Biosafety Committee (IBC), or the Institutional Review Board (IRB). The SCRO Committee reviews research protocols that these referring committees believe would benefit from such a review.

The SCRO Committee has adopted operating procedures to implement this policy (see link below). These procedures shall serve as the governing procedures for the conduct and review of all stem cell research conducted under the auspices of the University, in conjunction with all other federal, state, and Institutional policies, as applicable.

Definitions:

Human Pluripotent Stem Cells (hPSC): refers to human stem cells that can develop into cells of all three germ layers (endoderm, ectoderm, mesoderm). hPSC include human embryonic stem cells (hESC) and induced pluripotent stem (iPS) cells.

Human Embryonic Stem Cells (hESC): are a subset of human pluripotent stem cells derived from pre-implantation embryos.

Induced Pluripotent Stem Cells: are adult *cells* that have been **genetically reprogrammed** to an embryonic *stem cell*-like state by being forced to express genes and factors important for maintaining the defining properties of embryonic *stem cells*.

Contact:

Additional information about this policy is available here:

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<https://www.stonybrook.edu/commcms/research-compliance/index.php>

Relevant Standards, Codes, Rules, Regulations, Statutes and Policies:

- [NIH Stem Cell Research Policy & FAQs](#)
- [SBU Stem Cell Research Oversight Standard Operating Procedures](#)