

Binghamton University

Human Stem Cell Research Policy

I. Purpose

This policy is intended to ensure that all research involving the derivation or use of human pluripotent stem cells at Binghamton University is conducted with the highest ethical and scientific research standards, and in compliance with all applicable federal and state regulations, Binghamton University policies, and the requirements of extramural research sponsors.

II. Authority

These policies are issued by the Office of Research Compliance, on behalf of the Vice President for Research.

III. Definitions

- A. Human Pluripotent Stem Cells (hPSC): 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.
- B. Human Embryonic Stem Cells (hESC): a subset of human pluripotent stem cells derived from pre-implantation embryos.
- C. Non-embryonic hPSC: the subset of human pluripotent stem cells that are not hESC, e.g., iPS cells.
- D. Human adult stem cell: a human cell capable of differentiation into one or more adult cell types.
- E. Human stem cell: refers to both human pluripotent and human adult stem cell.
- F. Somatic cell nuclear transfer (SCNT): The transfer of a somatic cell nucleus into an oocyte.
- G. Stem Cell Research Oversight Committee (SCRO): A campus committee appointed by the Vice President for Research and charged with review and approval of human stem cell research performed at Binghamton University.

IV. Policy

- A. Research using human stem cells may be conducted at Binghamton University, subject to the terms, conditions, and requirements of this Policy, and in conformance with all applicable federal and state regulations, as well as those of the University, and extramural research sponsors.

B. The following types of research on or with human stem cells are prohibited at Binghamton University as of the effective date of this policy:

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.
2. Research in which hESCs are introduced into nonhuman primate blastocysts or in which any embryonic stem cells are introduced into human blastocysts.
3. Research in which any products of research involving human totipotent or pluripotent cells are implanted into a human or non-human primate uterus. No animal into which hESCs have been introduced at any stage of development are permitted to breed - no contribution to the germ line is permitted.
4. Research on a stem cell line derived from human embryos created for research purposes rather than reproductive purposes.
5. Research on a stem cell line derived from human somatic cell nuclear transfer.
6. Research on a line derived from human parthenogenesis.

C. Prior to commencing research using human embryonic stem cells/cell lines or other pluripotent stem cells/cell lines regardless of source (not limited to embryos, adult tissues, amniotic fluid or fetal tissue) Binghamton University investigators must have their research protocol approved by the campus Stem Cell Research Oversight Committee (SCRO).

1. SCRO approval will remain in effect for a maximum of one year.
2. SCRO review does not preclude the necessity of review by other research oversight Committees as applicable such as Human Subject Research Review Board, (HSRRB), the Institutional Animal Care and Use Committee (IACUC), Institutional Biosafety Committee (IBC), etc. Such reviews may take place simultaneously with review by the SCRO committee. However, SCRO approval will not be granted until these other approvals are obtained, as applicable.
3. Annual protocol renewal reviews will confirm compliance with all applicable rules and regulations.
4. The SCRO committee has established guidelines indicating when a convened meeting is required for application review, when a review can be done electronically with quorum approval and when a subcommittee electronic review is sufficient. In addition, the SCRO may establish guidelines and procedures for expedited review of renewal applications with no alterations in stem cell procedures such that review by the entire SCRO committee is not required.

D. SCRO Committee Membership and Functions

1. The SCRO Committee shall be composed of persons with expertise including, but not limited to, stem cell research, developmental biology, molecular biology, assisted reproduction, and ethical issues in research. The SCRO Committee shall include at least one member who is not employed by, appointed to or remunerated by Binghamton University and is not in the immediate family of a person employed by Binghamton University.
2. The SCRO meetings shall be convened at a frequency to ensure timely review of applications. A quorum, consisting of more than 50% of the total membership must be present in order for the meeting to be held. A simple majority of those members present is required in order for a decision (e.g., approval, modifications required, etc.) regarding study status to be passed.
3. No SCRO member shall have a financial conflict of interest in the research under review. SCRO Committee members who are involved in a research project that is being considered by the Committee must recuse themselves from the review and approval of that research project.
4. The SCRO shall provide scientific and ethical review and approval of Binghamton University research on human pluripotent stem cell lines as described in section E of this policy. The SCRO shall ensure that human pluripotent stem cell research protocols conform to the research and ethics guidelines and regulations of the organization(s) funding the research.
5. In instances of multi-institutional collaboration, Binghamton may enter into Memoranda of Understanding, permitting the Binghamton SCRO Committee to accept the review and approval of the SCRO Committee at another research institution. Likewise, such collaborations and Memoranda of Understanding can permit review and approval by the Binghamton SCRO Committee of research conducted at another research institution.
6. The SCRO Committee shall facilitate the education of investigators with requirements of this policy, as well as the ethical issues surrounding stem cell research. Each investigator who is required to submit a SCRO application will be required to complete the CITI Stem Cell Oversight Modules located at: <https://www.citiprogram.org/Default.asp?>
7. The SCRO shall be responsible for maintaining records (e.g., SCRO applications and committee determinations, registry of embryonic cell lines, etc.) pertaining to all human pluripotent stem cell research conducted at Binghamton University. All records related to the SCRO committee and the research conducted will be retained for a minimum of six years.

8. The SCRO shall investigate and report as necessary to the Institution, sponsoring agency, and other entities as required, any instance of serious investigator noncompliance with the requirements or determinations of the SCRO committee.

E. SCRO Committee Review & Notification

1. Binghamton University stem cell research of the types described below must be reviewed and approved by the SCRO Committee. Research may not commence without documented SCRO Committee approval. In all cases, the investigator must provide to the SCRO Committee documentation of compliance with any required review of the proposed research by HSRRC, IACUC, IBC, or other mandated review. In cases where SCRO Committee review and approval are required, the committee shall notify investigators in writing of its decision to approve, require modifications, defer, or disapprove, the research activity. For decisions other than approval, SCRO Committee will include in its written notification a statement of the reasons for its decision. Research that may be conducted at Binghamton University, following review and approval by the SCRO Committee:

Note: Work with human embryonic stem cells/lines, only NIH-Approved human embryonic stem cell lines, listed on the NIH Human Pluripotent Stem Cell Registry, <http://stemcells.nih.gov/research/registry/>, may be used at Binghamton University.

2. Research involving human embryonic stem cells.
3. Research involving introduction/transplantation of human pluripotent cells from any source (not limited to embryos, adult tissues, amniotic fluid or fetal tissue) into any nonhuman recipient or animal at any stage of embryonic, fetal or postnatal development. Transplantation into an animal embryo or an animal's germline or brain is not permitted.
4. Introduction of human pluripotent cells or embryonic stem cells into humans

F. Informed Consent Requirements

1. The Binghamton University Human Subjects Research Review Committee is responsible for managing the informed consent approval process. Review of informed consent documents can take place simultaneously with review of the research protocol by the SCRO Committee. When HSRRC approves the consent process for a given project, it will notify both the principal investigator and the SCRO Committee.
2. With regard to the special requirements for informed consent involving stem cell research (Section F.3 of this policy), the SCRO committee or HSRRC can grant exceptions on the basis of inapplicability to the current or potential future uses of donated materials.

3. Research may not violate the documented preferences of subjects with regard to the use of their donated materials. In addition to the general requirements for informed consent, to ensure that subjects are fully informed of the potential uses of donated materials:
 - (a) Researchers must inform the subject that derived cells or cell products may be kept for many years.
 - (b) Researchers must disclose in the consent document whether the identity of the subject will be ascertainable to those who work with the resulting cells or cell products. If the identity of the subject is retained (even coded), the consent document must address plans for re-contacting subjects (for purposes of, e.g., providing information about research findings, obtaining additional health information, etc.), and must obtain specific consent for re-contact. Subjects may be re-contacted in the future only if they consent to re-contact at the time of donation.
 - (c) Researchers must inform subjects that cell lines may be used for future studies, some of which may not be predicted at this time, that will undergo further ethics review to assess need for further consent and to ensure that the subjects' research rights remain protected.
 - (d) Researchers must inform subjects that derived cells or cell products may be used in research involving genetic manipulation.
 - (e) Researchers must inform subjects that derived cells or cell products may be transplanted into humans or animals.
 - (f) Researchers must inform subjects that derived cells or cell products are not intended to provide direct medical benefit to the subject(s), except in the case of autologous donation.
 - (g) Researchers must inform subjects that the donation is being made without restriction regarding who may be the recipient of transplanted cells, except in the case of autologous donations.
 - (h) Researchers must inform subjects that neither consenting nor refusing to donate materials for research will affect the quality of any future care provided to potential subjects.
 - (i) Researchers must inform subjects that the results of research may be patentable or have commercial potential, and that the subject will not receive patent rights and will not receive financial or any other benefits from future commercial development.

4. Researchers shall offer subjects an opportunity to document their preferences regarding future uses of their donated materials. Researchers may choose to use materials only from subjects who agree to all future uses.
5. For research involving the donation of the umbilical cord, cord blood or the placenta, consent shall be obtained from the birth mother.