WAYNE STATE UNIVERSITY

Human Pluripotent Stem Cell Research Oversight (HPSCRO) Committee

Policy

I. Purpose

This policy ensures that all research involving the use of human stem cells at Wayne State University (WSU) is in compliance with all State and Federal regulations, University policies, and requirements developed by other relevant University committees. WSU's establishment of a Human Pluripotent Stem Cell Research Oversight (HPSCRO) Committee is responsive both to ongoing public concerns about the ethics and oversight of human embryonic stem cell research, and to the recommendations of the National Research Council and the National Academies of Science.

II. Definition

Stem Cell Research: For the purpose of compliance with this Policy, the term "human stem cell research" includes research involving the derivation and use of human pluripotent stem cells (hPSC), including human embryonic stem cells (hESC), human embryonic germ cells and pluripotent stem cells derived from other human tissues by reprogramming (human induced Pluripotent Stem Cells: hiPSC). Human somatic cell nuclear transplantation and use of stem cells derived from nuclear transfer are also considered "human stem cell research." The WSU SCRO Committee will not review research with cells extracted from cord blood, testes or bone marrow.

III. Charges to the HPSCRO Committee

This Committee serves as an advisory body to the WSU Vice President for Research on the ethical and scientific aspects of human stem cell research. The Committee's charge for the oversight of human stem cell research is complementary to, and not duplicative of, the missions of the Institutional Review Board (IRB), the Institutional Animal Care and Use Committee (IACUC), and the Institutional Biosafety Committee (IBC). It is responsible for:

A. Developing guidelines for researchers at WSU and its research affiliates with respect to all human oocyte, embryo and stem cell research. In particular, in accordance with the recommendations of the National Academies of Science, the committee will develop guidelines that:

1. Establish categories of research that require different levels of oversight such as research that is:
   - permissible after appropriate review only by the IRB, IACUC, and/or IBC;
   - permissible only after additional review by the HP SCRO committee; and
   - not permitted at WSU at this time.
2. Address the ethical issues resulting from human stem cell research, including intellectual property, commercialization, ownership, privacy, confidentiality, and uses of human stem cells.
3. Address the derivation of new hESC and hiPSC lines, including the confidentiality of the donors of the biological materials used to derive the lines.
4. Establish and maintain a registry of hPSC investigators, the types of research being carried out, and the hPSC lines in use (including the provenance of the hPSC).

B. Reviewing research protocols as required or needed.

C. Reviewing cases of collaborative research with investigators in other states or other countries to determine if procedures for deriving and using human stem cells as prescribed by collaborating institutions afford equivalent protections to those required by United States, the state of Michigan, and

WSU guidelines. The Committee will address research conducted by a WSU investigator in other states or countries as well as WSU investigators who collaborate with researchers from other states or countries and who are deriving human stem cells for research collaborations.

D. Reviewing and making recommendations on ethical issues regarding human oocyte, embryo, and stem cell research when requested by the Vice President for Research, University committees, or individual researchers.

E. Providing advice, as needed, on other ethical issues relating to human stem cell research projects.

F. Ensure that investigators involved in human stem cell research have received appropriate ethical and scientific training in this area of research.

G. Facilitate community outreach and education in order to enhance the public's trust in the ethical conduct of human stem cell research at WSU and its research affiliates.

IV. Policy and Procedures

A. WSU activities involving any human embryonic or adult stem cell research shall be conducted in accordance with the applicable State and Federal laws governing such research.

B. All individuals conducting human pluripotent stem cell research involving primary human tissue or human cultured cells to create pluripotent stem cells must submit a protocol to the IRB for review and approval prior to initiation of the study. This must be done even if there are no plans to put such cells into human subjects.

C. Additional approvals must be obtained from the IBC or the IACUC as appropriate.

D. Research that is not permitted at this time:

1. Derivation of new hESC lines by nuclear transfer.
2. Research involving *in vitro* culture of any intact human embryo beyond formation of the primitive streak.
3. Research in which hPSC are introduced into non-human primate blastocysts or in which any embryonic stem cells are introduced into human blastocysts.
4. Research that involves breeding of any animal into which hPSC have been introduced (at any stage of development)

IV. Composition of the HPSCRO Committee

The Committee shall have no fewer than 7 voting members. The Committee shall include at least: 3 members from relevant scientific disciplines; 1 scientific member who is also a member of the IRB; 1 member whose primary interest is medical or research ethics; 1 non-scientific member; 1 unaffiliated member (no affiliation with WSU). The Assistant Vice President for Research Compliance and a representative from the Office of General Counsel shall serve as ex-officio members.

V. Responsibility

A. Vice President for Research

The Vice President for Research appoints the members and the Chair(s) of the HPSCRO Committee, and also may convene ad hoc committees as necessary to resolve disagreements regarding stem cell matters.

B. Assistant Vice President for Research
The Vice President for Research delegates the operational oversight of this policy to the Assistant Vice President for Research Compliance.

C. Investigator
In conducting human stem cell research the investigators must conduct their research in compliance with applicable State and Federal laws and any conditions of approval required by the IRB, IACUC or IBC. "Investigator" includes all key personnel (e.g. co-investigators, technicians, trainees) involved in the research covered by this policy. Enforcement and sanctions shall be in accordance with the relevant policies of each committee and applicable laws.

D. Membership of HPSCRO Committee
Members, including Chairs, shall serve terms of up to 3 years each, and may be reappointed for additional terms of service as determined by the Vice President for Research. The appointments of members will be staggered so that the entire membership does not change every 3 years.

VI. State Regulation of human embryo and embryonic stem cell research

The Constitution of the State of Michigan directly regulates human stem cell research. The relevant provision of the Constitution is reproduced below:

Article 1 § 27 of the Constitution of the State of Michigan of 1963

(1) Nothing in this section shall alter Michigan's current prohibition on human cloning.

(2) To ensure that Michigan citizens have access to stem cell therapies and cures, and to ensure that physicians and researchers can conduct the most promising forms of medical research in this state, and that all such research is conducted safely and ethically, any research permitted under federal law on human embryos may be conducted in Michigan, subject to the requirements of federal law and only the following additional limitations and requirements:

(a) No stem cells may be taken from a human embryo more than fourteen days after cell division begins; provided, however, that time during which an embryo is frozen does not count against this fourteen day limit.

(b) The human embryos were created for the purpose of fertility treatment and, with voluntary and informed consent, documented in writing, the person seeking fertility treatment chose to donate the embryos for research; and

(i) the embryos were in excess of the clinical need of the person(s) seeking the fertility treatment and would otherwise be discarded unless they are used for research; or

(*ii*) the embryos were not suitable for implantation and would otherwise be discarded unless they are used for research.

(c) No person may, for valuable consideration, purchase or sell human embryos for stem cell research or stem cell therapies and cures.

(d) All stem cell research and all stem cell therapies and cures must be conducted and provided in accordance with state and local laws of general applicability, including but not limited to laws

concerning scientific and medical practices and patient safety and privacy, to the extent that any such laws do not:

(*i*) prevent, restrict, obstruct, or discourage any stem cell research or stem cell therapies and cures that are permitted by the provisions of this section; or

(*ii*) create disincentives for any person to engage in or otherwise associate with such research or therapies or cures.

(3) Any provision of this section held unconstitutional shall be severable from the remaining portions of this section.

VII. Other Relevant Policies and Regulations

- Institutional Review Board
- Institutional Animal Care and Use Policies
- OEHS Biosafety
- Title-42, Chapter 6A, Part H, Section 289g-2, Prohibitions regarding human fetal tissue
- Title-21, Food and Drugs, Part 600 Biological Products
- Title-45, Code of Federal Regulations, Part 46, Protection of Human Subjects
- Stem Cell Federal Policy

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