

U-M Human Pluripotent Stem Cell Research Oversight (HPSCRO) Committee Charge

Based upon the recommendations of the [National Academy of Sciences' Committee on Guidelines for Human Embryonic Stem Cell Research](#) (2005, with 2007, 2008, and 2010 amendments), the University of Michigan will establish a **Human Pluripotent Stem Cell Research Oversight (HPSCRO) Committee**. The purpose of this Committee is to provide local oversight of all issues related to derivation and research use of human embryonic stem cell (hESC) lines and human induced pluripotent stem cells (iPSC). The Committee will also facilitate the education of investigators involved in hESC and iPSC research.

The Committee complements existing compliance review functions (e.g., IRBs, UCUCA) by providing an additional level of review and scrutiny warranted by the complex issues raised by hESC research (including basic hESC research using pre-existing anonymous cell lines that does not require consideration by an IRB) and iPSC research.

Appeals of Committee decisions can be submitted to the Vice President for Research.

HPSCRO Committee Functions

The functions of the U-M HPSCRO Committee are guided by the specific recommendations in the [Final Report of The National Academies' Human Embryonic Stem Cell Research Advisory Committee and 2010 Amendments to The National Academies' Guidelines for Human Embryonic Stem Cell Research](#). Washington, DC: The National Academies Press, 2010.

HPSCRO Functions

- Serve as a clearinghouse for hESC and iPSC research proposals and assist investigators in identifying the types and levels of review required for a given protocol.
- Ensure that the provenance of hESC and iPSC lines is documented. This includes confirming evidence that an IRB approved the procurement, informed consent, and confidentiality protection processes and that the processes adhere to basic ethical and legal principles associated with human pluripotent stem cell research.
- Divide research proposals into two categories and set limits on research per the requisite level of oversight:
 - Research that is permissible after HPSCRO Committee review and approval:
 - In vitro hESC research with lines on the [NIH Stem Cell Registry](#)
 - In vitro iPSC research where appropriate provenance, de-identification, and, if applicable, informed consent is verified

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- All research involving the introduction of hES cells or iPS cells into non-human animals at any stage of embryonic, fetal, or postnatal development
- Research in which personally identifiable information about the donors of the blastocysts, gametes, or somatic cells from which the hES or iPS cells were derived is linked to the cell lines
- Research using non-federally approved hES cell lines
- Derivation of new hESC lines from donated blastocysts from in vitro fertilized oocytes.
- Derivation of iPSC lines from donated somatic cells
- Research that is unallowable at this time:
 - Derivation of new hES cell lines by somatic cell nuclear transfer. (SCNT).
 - Research involving in vitro culture of any intact human embryo beyond formation of the primitive streak (i.e., 14 days or older).
 - Research in which hES cells are introduced into non-human primate blastocysts or in which any embryonic stem cells are introduced into human blastocysts.
 - Research that involves breeding of any animal into which hES cells have been introduced (at any stage of development).
 - Research in which iPS cells have been introduced into animals such that the cells could contribute to the animal's germline.
- Establish and maintain standard operating procedures for the HPSCRO Committee that outline application, amendment, and renewal processes.
- Maintain an internal registry of HPSCRO Committee approvals, including amendments, renewals, and terminations.

Composition of U-M HPSCRO Committee

The U-M HPSCRO Committee should be composed of individuals with knowledge and expertise in hES and/or iPS cell science, bioethics, medicine, and law, with representation from the lay community. The Committee may consult with content experts as necessary.

Accordingly, the Committee will be composed of at least six voting members with the following characteristics:

- A community member not affiliated with the U-M

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- U-M faculty member with bioethics expertise
- U-M faculty member with legal and/or regulatory expertise
- U-M faculty member who is a practicing physician (M.D. or D.O.)
- Two U-M faculty members with expertise in the life sciences including one individual with scientific expertise in hES cell research.

The Committee will also include two non-voting ex officio members:

- An Associate or Assistant Vice President for Research
- A member of the Office of the General Counsel

The Committee shall be chartered under the auspices of the Vice President for Research. Nominees for membership to the U-M HPSCRO Committee will be made to the Vice President for Research who will extend formal invitations to serve renewable terms of three years (initially staggered such that three founding members will serve terms of two years, and three will serve terms of three years).

Operation of UM HPSCRO Committee

The U-M HPSCRO Committee will meet on an ad hoc basis so as to review proposals to conduct hESC and iPSC research within 30 days of their receipt, or to assist in U-M hESC and iPSC research policy development. A quorum shall consist of a simple majority with telephone or video participation permitted. Members of the Committee who have a conflict of interest (e.g., proposing to perform hESC or iPSC research themselves) will be excused from the review process for that proposal. At the time of the Committee meeting, the Committee will vote to approve, disapprove, or table proposals. Proposals may be tabled to obtain additional information from the applicant or to allow a resubmission based upon the advice of the Committee.

HPSCRO Committee Staff

Proposals and supporting materials will be submitted to a designated member of the *U-M Office of Research – Regulatory and Compliance Oversight* staff who will provide administrative support to the Committee. HPSCRO Committee staff will:

- Distribute the submitted materials to the members of the Committee prior to the scheduled meeting
- Record minutes of the Committee deliberations to be kept on file
- Notify the applicant within seven days of the Committee's review decision (approval, approval with contingency, disapproval, or request for modifications)