

UNIVERSITY OF MICHIGAN
Embryonic Stem Cell Research Oversight (ESCRO) Committee

CHARGE

Based upon the recommendations of the Committee on Guidelines for Human Embryonic Stem Cell Research, National Research Council, National Academy of Sciences of April 26, 2005, the University of Michigan will establish an Embryonic Stem Cell Research Oversight (ESCRO) Committee. The purpose of this Committee is to provide local oversight of all issues related to derivation and research use of human embryonic stem (hES) cell lines and to facilitate education of investigators involved in hES cell research. This Committee will complement existing review functions (e.g., IRBs) by providing an additional level of review and scrutiny warranted by the complex issues raised by hES cell research (including the review of basic hES cell research using pre-existing anonymous cell lines that does not require consideration by an IRB).

Specific ESCRO Committee Functions

The function of the UM ESCRO Committee will be guided by the specific recommendations in the National Academy of Sciences Report including the following:

- ∞ Serve as a clearinghouse for hES cell research proposals and assist investigators in identifying the types and levels of review required for a given protocol.
- ∞ Ensure that the provenance of hES cells is documented. This includes confirming evidence that the procurement process was approved by an IRB to ensure adherence to the basic ethical and legal principles of informed consent and protection of confidentiality.
- ∞ Divide research proposals into three categories and set limits on research determining the requisite level of oversight:
 - Research that is permissible after notification of the ESCRO Committee and the completion of the reviews mandated by current requirements (e.g., purely in vitro hES cell research with pre-existing federally approved hES cell lines).
 - Research that is permissible only after additional review and approval:
 - All research involving the introduction of hES 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 cells were derived is linked to the cell lines.
 - Research that should not be permitted at this time:
 - Derivation of new hES cell lines from donated blastocysts from in vitro fertilized oocytes or by nuclear transfer.

- Research involving in vitro culture of any intact human embryo beyond formation of the primitive streak.
 - 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).
- ∞ Maintain a registry of hES cell lines in use and of investigators working in this field and descriptive information on the types of hES cell research in which they are engaged.

Composition of UM ESCRO Committee

The UM ESCRO Committee should be composed of individuals with knowledge and expertise in hES cell science, bioethics, medicine, and law, with representation of the lay community. Accordingly, the Committee will be composed of at least six voting members with the following characteristics:

- A community member not affiliated with the UM
- UM faculty member with bioethics expertise
- UM faculty member with legal and/or regulatory expertise
- UM faculty member who is a practicing physician (M.D. or D.O.)
- Two UM 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 Vice President for Research
- A member of the Office of the General Counsel

The Committee can consult with content experts as necessary.

Operation of UM ESCRO Committee

The UM ESCRO Committee will meet on an ad hoc basis so as to review proposals to conduct hES cell research within 30 days of their receipt, or to assist in hES cell research policy development. A quorum shall consist of a simple majority with telephone or video participation permitted. Proposals and supporting materials will be submitted to a designated member of the OVPR office staff who will provide administrative support to the Committee. ESCRO Committee staff will distribute the submitted materials to the members of the Committee at least seven days prior to the scheduled meeting.

Members of the Committee who have a conflict of interest (e.g., proposing to perform hES cell 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 for the use of hES cells in research (table for the purposes of obtaining additional information from the applicant or to allow a resubmission based upon the advice of the Committee). Committee staff will record minutes of the Committee deliberations to be kept on file. Notice of Committee review (approval, disapproval, or request for modifications) will be forwarded to the applicant within seven days of the Committee review.

The Committee shall be chartered under the auspices of the Office of the Vice President for Research. Appeals of Committee decisions can be submitted to the Vice President for Research.

Nominees for membership to the UM ESCRO 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).

RFT/jcr
10/21/05