University of California, Santa Barbara

Embryonic Stem Cell Research Oversight (ESCRO) Committee

Policies and Procedures

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1.0 PURPOSE

The purpose of the UCSB Embryonic Stem Cell Research Oversight (ESCRO) committee is to provide oversight of human embryonic stem cell (hESC) research and other stem cell research covered by the California Institute for Regenerative Medicine (CIRM) regulations in order to ensure that UCSB research meets scientific and ethical standards. The goals are achieved in collaboration with the UCSB Administration, the UCSB Institutional Review Boards (IRBs), other applicable compliance committees, and the participation of the research community. ESCRO may also review the use of any human stem cells not covered by CIRM, at its discretion, in order to ensure UCSB research meets scientific and ethical standards.

2.0 AUTHORITY

UCSB policy and California law requires the creation of an ESCRO to oversee hESC research. The policy is based in part on the recommendations of the National Bioethics Advisory Commission[1], the National Academies of Science-Institute of Medicine[2] guidelines, and standards created by CIRM[3].

3.0 FUNCTION

The ESCRO reviews new protocols, modifications to currently approved research, and continuing research using hESCs, hESC lines, any proposed collection and use of germ cells designed to generate hESCs, and any "covered cells"[4] as required by State or Federal law.

4.0 Review

The ESCRO is one of several committees that may be required to review hESC research. The other committees include but are not limited to the IRB – Human Subjects Committee http://research.ucsb.edu/compliance/human-subjects, the Institutional Animal Care and Use Committee (IACUC) http://research.ucsb.edu/compliance/animal-subjects, the Institutional Biosafety Committee (IBC) http://research.ucsb.edu/compliance/biosafety, or other committees required by laws, regulations, or institutional policy.

4.1 Review Procedures

The ESCRO will assess protocols according to the hESC Review Standard Operating Procedures.

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[1] National Bioethics Advisory Commission, Ethical Issues in Human Stem Cell Research, 1999: http://www.georgetown.edu/research/nrcbl/nbac/pubs.html .

[2] National Academies of Science-Institute of Medicine, Guidelines for Human Embryonic Stem Cell Research, National Academies Press: 2005, http://fermat.nap.edu/books/0309096537/html/ .

[3] California Institute for Regenerative Medicine, Standards Working Group: http://www.cirm.ca.gov/ .

[4] The CIRM defines "covered cells" as "culture derived, human stem cell population that is capable of : 1) sustained propagation in culture; 2) differentiation along multiple cell lineages; and 3) self-renewing to produce daughter cells with equivalent developmental potential. This definition includes both embryonic and non-embryonic human stem cell lines regardless of the tissue of origin." Therefore, ESCRO review would be required for research with human embryonic stem cells and populations, regardless of their origin, capable of differentiation into multiple tissue types. Adult precursors that differentiate into cells of a single tissue type do not meet all three CIRM criteria and would not be subject to ESCRO review.

4.2 *Scope of review and responsibilities*

- **4.2.1** All issues related to derivation, use, procurement, and disposal of hESCs
- **4.2.2** Scientific merit, including whether the cells are well-characterized and screened for safety
- **4.2.3** Ensure the conditions under which cells are maintained and stored meet current scientific standards
- **4.2.4** For research that does not involve human subjects as defined by Federal regulations or State law, ensure the cells were obtained ethically and with informed consent as required by law or policy
- **4.2.5** Compliance with relevant regulations and guidelines
- **4.2.6** Consultation and collaboration with the IRBs and other relevant compliance committees
- **4.2.7** Maintain registry of hESC cells and lines derived or obtained by investigators
- **4.2.8** Maintain registry of hESC research
- **4.2.9** Adverse Events
- **4.2.10** Monitoring
- **4.2.11** Suspension and Termination
- **4.2.12** Maintenance of records
- **4.2.13** Education

4.3 *Continuing Review*

The ESCRO will review on-going research at a minimum of once every year.

4.4 *Modifications to Approved Protocols*

All modifications to approved protocols must be submitted prospectively to the ESCRO. No modifications may be implemented without prospective review and approval by the ESCRO and other applicable committees.

4.5 Approval

The ESCRO has the authority to approve, require modifications in a protocol in order to approve, or disapprove submitted research. The ESCRO will notify investigators in writing of its decision. An ESCRO decision to require modifications or disapprove a submission will include a written statement to the investigator of the reasons for its decision and give the investigator an opportunity to respond in writing and if requested, in-person. UCSB researchers shall not use any stem cells which require ESCRO approval unless and until ESCRO has approved the applicable protocol.

4.6 Appeals

Appeals of ESCRO decisions must return to the ESCRO for additional review. Investigators may request to present responses to ESCRO decisions during a convened meeting. Appeals must be in writing and submitted directly to the ESCRO prior to an investigator's personal presentation to the ESCRO.

4.7 *Expedited Review*

The ESCRO may conduct an expedited review of modifications to currently approved protocols and other protocols as approved by the Chair. Expedited review means the Chair, or other qualified member of the committee appointed by the Chair, to conduct the expedited review including the review and approval of the protocol or request modifications in order to approve a protocol without convening a quorum of the committee when the proposed changes are minor and do not modify the scientific design of the protocol, such as, changes in investigators, replacement of equivalent proven laboratory techniques, laboratory relocation, etc.

4.7.1 *Limits to Expedited Review Decisions*

The ESCRO member conducting expedited review will only have the authority to approve or recommend modifications to the submission in order to achieve approval. Expedited review may not be used to disapprove a modification. Only the convened ESCRO may disapprove a submission.

4.7.2 *Reporting Expedited Review to the ESCRO*

The ESCRO will be notified of all expedited approvals with a short description of the approved modification.

4.8 *Monitoring*

The ESCRO has the authority to observe or have a third party observe the research, monitor, and audit research under its jurisdiction or take any other measures considered by the ESCRO committee as appropriate to manage the use of stem cells in research.

4.9 *Adverse Events*

Adverse events may occur with human subjects, employees, or cellular material. Any adverse events that occur with human subjects that by UCSB policy require reporting to the IRB must also be reported to the ESCRO.

4.9.1 *Required Reporting of Events with Employees*

Any adverse events to employees that would be reported to the IBC/Environmental, Health, and Safety, will also be reported to the ESCRO.

4.9.2 *Required Reporting of Adverse Laboratory Events*

The investigator is responsible for documenting and reporting laboratory events to the ESCRO cells, such as but not limited to, the inability to expand cells due to contamination or contamination with pathogens. Such reports should include the reason for the contamination, the disposition of the cells, and any corrective actions.

4.10 *Collaboration with the IRBs*

The ESCRO will collaborate with the IRBs in order to ensure approved research meets scientific and ethical standards. ESCRO approvals will be contingent upon IRB approval of proposed research. ESCRO review will occur prior to IRB review and serve to inform the IRB review. ESCRO members are available to attend IRB meetings to discuss

proposed research, as requested by the IRBs. The IRBs and ESCRO will freely exchange information in order to facilitate and coordinate the review of proposed research.

4.11 *Suspension and Termination of ESCRO Approval*

The ESCRO has the authority to suspend or terminate its approval of research that is not being conducted in accordance with the ESCRO's requirements, regulatory agency requirements, or that has been associated with unexpected serious harm to subjects, or others. Suspension or termination will be promptly reported to other applicable campus compliance committees, the hESC Research Policy Board, and the chair of the investigator's department.

5.0 STRUCTURE

The ESCRO shall consist of a minimum of 5 members, including the Chair, appointed by the Vice Chancellor-Research after consultation with the *UCSB research community.* A majority of the voting members must have expertise in relevant scientific and/or medical fields, e.g., molecular biology, developmental biology, stem cell research, assisted reproduction, legal and/or ethical issues in hESC research as well as a non-scientific member who is also not affiliated with UCSB. There may be alternates and non-voting members.

5.1 *Consultants*

The ESCRO may, at its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the ESCRO. These individuals may not vote with the ESCRO.

5.2 *Ad Hoc Committees*

The ESCRO may, as necessary, create standing ad hoc subcommittees, composed of members of the parent Committee and, as appropriate, consultants with relevant expertise to perform specific functions within the ESCRO's jurisdiction. Subcommittee members may serve as a voting member on more than one subcommittee.

5.3 *Membership Terms*

Members shall be invited to serve for overlapping terms of **2** years, with terms of no more than **2** years contingent upon renewal of the Committee's Charter by appropriate action prior to its expiration. A member's participation on the ESCRO committee may be renewed for subsequent two year terms.

5.4 *Support*

Management and support services will be provided by the UCSB Office of Research.

6.0 MEETINGS

Meetings shall be held as often as necessary to provide timely review of submitted research. Meetings shall be conducted, and records of the proceedings kept, as indicated in other sections of this policy.

6.1 *Quorum*

Except in the case of expedited reviews, the ESCRO may only review and act upon proposed research during a convened meeting with a majority of the members present. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

6.2 *Conflict of Interest*

No member may participate in the ESCRO's initial or continuing review of any project in which the member has a significant conflict, or the appearance of a significant conflicting interest, except to provide information requested by the ESCRO. Members with a conflict of interest must be recused from the discussion and the vote of the protocol except to answer questions of the Committee about the proposed research.

7.0 ESCRO DOCUMENTATION

The ESCRO shall maintain documentation sufficient to meet the requirements of this policy.

7.1 *Research and Cell Registries*

The ESCRO will maintain an auditable database of:

a. hESC research conducted by UCSB investigators
b. hESCs and cell lines derived or obtained by UCSB investigators.

7.2 *Meeting Documentation*

The ESCRO will maintain minutes of the meetings and relevant correspondence with investigators, including approvals and disapprovals.

7.3 *Documentation Maintenance*

The ESCRO will maintain copies of reviewed proposals, reports of adverse events, progress reports, continuing review applications, correspondence with investigators, IRB and other applicable compliance committee approvals, and a list of ESCRO members.

7.4 *Documentation Retention*

The ESCRO will maintain related hESC records for at least 3 years, and records relating to research, which is conducted, shall be retained for at least 3 years after completion of the research.