

**Harvard University
Embryonic Stem Cell Research Oversight (ESCRO) Committee**

Standard Operating Procedure

**Title: ESCRO Membership
("Membership SOP")**

Control #	Version	Written by	Approved by	Approval date
S-002	v.1.0	Laura Kandziolka, ESCRO Administrator	ESCRO Committee	3/10/2009

1.0 Summary

This Standard Operating Procedure covers all aspects of Harvard University ESCRO membership.

1.1 Applies to

- ESCRO Administrator/ESCRO Committee

1.2 Related Documents

- Protocol Review SOP
- Meetings SOP

2.0 Composition of Committee

2.1 Voting Members

The Committee is composed of at least six (6) voting members, including a Chair, with varying backgrounds to promote complete, adequate, and balanced review of research activities. In addition to possessing the professional competence necessary for balanced review of specific research activities, the voting membership as a whole must include:

- at least one representative of the public;
- at least one person with expertise in developmental biology;
- at least one person with expertise in stem cell research;
- at least one person with expertise in molecular biology;
- at least one person with expertise in assisted reproduction; and
- at least one person with expertise in ethical and legal issues in hES cell research.

Voting members are chosen to be representative of the community with the goal of including both men and women and members of minority groups.

For the purpose of protocol review, voting members are also determined to be either a "technical" (those with expertise in hES cell research) or "non-technical" member. In order to provide a broad perspective, one of each type is assigned to review each protocol on the meeting agenda. (See the Protocol Review SOP for more details.)

2.2 Members *Ex Officio*

The Committee may also include members *ex officio*, who will serve the Committee in an advisory capacity. Members *ex officio* will be chosen with the goal of incorporating relevant administrative expertise from central administration and the various schools, and shall include at least one representative of the Office of the General Counsel, serving as counsel to the committee and one member of the Office of the Vice Provost for Research. Members *ex officio* can take part in review and discussions, but do not vote, and do not count toward establishment of a quorum.

3.0 Responsibilities of Members

3.1 Review of Meeting Materials

Members are expected to review carefully all materials provided in connection with Committee activities and to participate actively in convened meetings. Reviewers assigned to particular protocols or other agenda items should come prepared to present and discuss any assigned materials.

3.2 Confidentiality

Committee members are expected to keep confidential the technical or scientific details of protocols submitted to it for consideration and review, and refrain from attribution of views expressed to the Committee by participants in the discussion.

3.3 Conflicts of Interest

No member may participate in the review or approval of a research project in which the member is personally involved or has any other conflict of interest pursuant to the University's or the research sponsor's conflict of interest policies, except to provide information requested by the Committee. A member who has a real or perceived conflict of interest must disclose it prior to the start of discussion and may not contribute to the constitution of a quorum. A member who has been assigned to review materials with which s/he has a conflict of interest should notify the ESCRO Administrator as soon as possible so that a new reviewer can be assigned.

3.4 Chair's Responsibilities

The Chair (and Associate Chair, if applicable) shall be experienced voting members of the Committee who are familiar with regulatory requirements, the design and conduct of hESC research, and biomedical research ethics. Their duties shall include presiding at meetings of the Committee and any other duties identified in the Committee's established procedures. The Chair (and Associate Chair, if applicable) may, from time to time, delegate certain duties to other members of the Committee in accordance with established Committee procedures.

5.0 New Members

Members are appointed by the Institutional Official (IO). The ESCRO Office generates an

appointment letter that is signed by the IO and delivered to the new member, with a copy to the ESCRO membership file.

5.1 Term of Appointment

Members, including the Chair and Associate Chair, are appointed for a three-year renewable term. The Chairs' terms are based on the date appointed as a regular member, even if the appointment as Chair/Associate Chair does not coincide with the three-year date.

5.2 New Member Training

New members can choose to meet with the ESCRO Administrator and/or ESCRO Chair for an overview of the Committee and review of the materials below. Whether or not they meet, new members receive the following materials:

Administrative:

- ESCRO administrator's contact information with instructions to ask lots of questions
- Current year's meeting schedule/calendar
- Harvard University ESCRO Committee Member Handbook
- Committee roster, including members' areas of expertise
- Members are shown the ESCRO isite

Policies/Regulations/Guidelines:

- Current approved versions of ESCRO policies and procedures
- *NAS Guidelines for Human Embryonic Stem Cell Research (2005)* ("NAS Guidelines")
- Subsequent Amendments to the NAS Guidelines
- *ISSCR Guidelines for the Conduct of Human Embryonic Stem Cell Research*

Reference Materials:

- *Human Embryonic Stem Cells* (Kiessling and Anderson) (optional)
- Non-technical members may also receive a copy of the NAS publication *Understanding Stem Cells*

5.2 Protocol Review

Generally, no protocol reviews will be assigned for the member's first two meetings.

6.0 Continuing Education

The Committee will offer continuing education to its members and staff with particular attention to changes in regulation and agency guidance. When possible, ESCRO Committee members are provided with materials that are related to the protocols, policies and other documents submitted for review. Members are also notified of upcoming seminars, conferences and other educational opportunities.