



# Policy

## **Title: Embryonic Stem Cell Research Oversight Committee (“ESCRO Policy”)**

<b>Control #</b>	<b>Version</b>	<b>Written by</b>	<b>Approved by</b>	<b>Approval date</b>
P-001	v.2.1	ESCRO Administrator	ESCRO Committee	3/9/2010

### **1.0 Summary**

This is the guiding Policy for the Embryonic Stem Cell Research Oversight (ESCRO) Committee.

### **1.1 Applies to**

- **Covered Materials:** human pluripotent stem cells (hPSC) and materials related to their derivation and use, as detailed in “ESCRO Scope”
- **Covered Activities:** Research, training and/or education with Covered Materials. These activities, which are detailed further in “ESCRO Scope,” include any of the following:
  - activities paid for with funds administered by Harvard, regardless of where the work is performed; or
  - activities performed in University space, on University property or in University facilities, regardless of funding source; or
  - activities using Harvard’s Covered Materials, regardless of location or funding source<sup>1</sup>.
- **Covered Persons:** All persons, whether paid or unpaid, who conduct Covered Activities that:
  - use Harvard facilities, and/or
  - are paid for with funds administered by Harvard

Covered Persons include individuals working for Harvard on a temporary or term basis, such as collaborators, visiting scholars, post-doctoral fellows, interns and summer students. Note that students conducting Covered Activities as part of their coursework are *not* considered Covered Persons; however, course instructors are.

### **1.2 Related Documents**

- All ESCRO policies and SOPs

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<sup>1</sup> As noted in “ESCRO Scope,” Covered Materials do not include materials that have been provided to another institution under a duly executed MTA.

## **2.0 Definitions**

**2.1 Covered Materials:** see above description

**2.2 Covered Activities:** see above description

**2.3 Covered Persons:** see above description

**2.4 Harvard University, Harvard, and University** refer to the University-area and Longwood campuses, as well as any locations that are considered part of those campuses, whether owned, rented or borrowed. These terms explicitly exclude all legally independent Harvard affiliates, including hospitals and other clinical centers.

## **3.0 Committee Charge**

Harvard University's Embryonic Stem Cell Research Oversight Committee (hereafter "Committee" or "ESCRO Committee") provides oversight of all Covered Activities. This includes use of anonymous materials that may not require consideration by an Institutional Review Board (IRB).

The ESCRO Committee conducts itself in consideration of the *Guidelines for Human Embryonic Stem Cell Research* of the National Academy of Sciences (The National Academies Press, 2005), and any subsequent updates of those guidelines, as well as in compliance with federal, state, and local requirements. The ESCRO Committee ensures that sensitive activities are well justified and subject to the appropriate scientific and ethical oversight and that inappropriate activities are not conducted. Any departures from NAS *Guidelines* will be identified and explained.

## **4.0 Governance and Administration of the ESCRO Committee**

### **4.1 Governance**

The Provost has appointed the Vice Provost for Research (VPR) as the Institutional Official (IO). The IO has ultimate oversight of the ESCRO Committee, and the IO, the Committee Chair, and the Associate Chair (if applicable) maintain responsibility for administering the activities of the Committee in compliance with University policy and applicable law.

### **4.2 Operating Procedures**

The Committee establishes and maintains operating procedures consistent with this policy.

## **5.0 ESCRO Committee Authority and Responsibility**

### **5.1 Oversight of Covered Activities**

The ESCRO Committee has the authority to review all Covered Activities. Review and approval by the ESCRO Committee is required regardless of the applicability of state or federal law. It is required in addition to other approvals that may be required by law or institutional policy, including but not limited to (1) Institutional Review Board (IRB) approval, (2) Institutional Animal Care and Use Committee (IACUC) approval, (3) Institutional Biosafety Committee approval (at Harvard, the Committee on Microbiological Safety [COMS]), and (4) administrative approval at the school level.

The ESCRO Committee has final approval authority, and its approval will be contingent on the satisfaction of all other required approvals. No University official has the authority to approve Covered Activities that have not been approved by the Committee.

## **5.2 On-Campus Banking of Human Embryonic Stem Cells**

The ESCRO helps to establish, maintain and monitor compliance with institutional policies and procedures for on-campus banking of human embryonic stem cells (hESC).

## **5.3 Restrictions, Suspension, and Termination of Covered Activities**

- 5.3.1 The ESCRO Committee may place restrictions on activities that fall under its jurisdiction.
  
- 5.3.2 The ESCRO Committee may recommend suspension or termination of activities that fall under its jurisdiction and that are not being performed in compliance with the terms of its approval, its policies, or applicable law or regulation. Such recommendation shall be made in writing to the Institutional Official, who will take appropriate action.
  
- 5.3.3 If a sponsor or an institutional committee initiates an inquiry into human subjects, animal subjects, or ethical concerns, or suspends or terminates a study, the Principal Investigator must immediately notify the ESCRO Committee in writing.

## **5.4 Post-Approval Monitoring of Covered Activities**

The ESCRO Committee may observe or have a third party observe the conduct of any activities under its jurisdiction. This function includes the authority to review all records associated with the conduct of the activity.

## **5.5 ESCRO Registry**

- 5.5.1 The ESCRO Committee maintains a University-wide registry of persons conducting Covered Activities and descriptions of the activities being performed.
- 5.5.2 The ESCRO Committee documents the provenance of lines derived from or used in any Covered Activities and maintains this information in the registry.

## **5.6 Education and Training**

The ESCRO Committee oversees the provision of education and training of its members and all Covered Persons in the ethical and policy issues surrounding Covered Activities.

## **6.0 Amendment of this Policy**

Given the rapid pace of change in the area of hPSC research and approaches to ethical oversight of such research, it may be necessary to amend this policy from time to time. Such amendments will be made with the approval of a majority of voting members at a convened meeting of the

Committee, and the subsequent approval of the Institutional Official and, where necessary, other University officials.

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**Revision History**

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<b>Date</b>	<b>Purpose</b>	<b>Supersedes</b>
3/1/2010	Removed the need to document compliance with cost allocation methodology	v. 2, 3/10/2009
3/10/2009	Updated to reflect 2008 NAS amendments; moved procedural details into separate SOPs	v. 1, April 10, 2007