

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

Standard Operating Procedure

Title: Registration of Human Embryonic Stem Cell Lines and Research Protocols Using Those Lines

Control #	Version:	Written by:	Approved by:	Approval date:
S-ESC-001	v.1.0	Laura Kandziolka, ESCRO Administrator	ESCRO Committee	7/8/2008

1.0 Summary

This Standard Operating Procedure defines the process for registering a human embryonic stem cell (hESC) line or protocol with the Harvard University Embryonic Stem Cell Research Oversight (ESCRO) Committee.

1.1 Applies to

- Investigators using hESC and staff responsible for hESC protocol administration
- ESCRO Committee/ESCRO Administrator

2.0 Definitions

2.1 Registered line: An hESC line listed in the Registry of Human Embryonic Stem Cell Lines Accepted for Use within Harvard (the Registry). Not to be confused with a line listed on the NIH registry. (A line included on NIH's registry may or may not be registered with Harvard.)

2.2 Registry: Refers to the Harvard Registry. When referring to the NIH registry, "NIH" will be explicitly stated.

3.0 Registration of Lines

All human embryonic stem cell lines derived at or proposed for use within Harvard must be registered with the ESCRO. Once registered, a line does not need to be re-registered regardless of the investigator who wishes to use it. Registration of lines consists of an examination of the provenance of the lines.

3.1 Registration of Cell Lines Derived at Harvard

Lines derived at Harvard generally undergo administrative examination and acceptance.

- 3.1.1 Once a cell line has been determined to be pluripotent, the investigator begins the registration process by submitting a Human Embryonic Stem Cell Line Registration Form (Registration Form) and all materials required per the Form.
- 3.1.2 The ESCRO Administrator examines the ESCRO files, consulting with the IRB and/or investigator when necessary, to confirm that the provenance of

the line meets Harvard's standards as described in the policy P-002: "Documenting the Provenance of Human Embryonic Stem Cell (hESC) Lines," i.e., is "acceptable."

- 3.1.3 If the provenance is acceptable, the ESCRO Administrator adds the line to the Registry and informs the investigator of the acceptance. Committee members are informed at regular monthly meetings of lines accepted administratively since the last meeting.
- 3.1.4 The ESCRO Administrator cannot reject the registration of a line. Any questionable lines must be forwarded to the full ESCRO.
- 3.1.5 Investigators with known plans for future use of the line may submit a use protocol for review at the same time they submit the Registration Form; however, the two are reviewed in separate parts of the ESCRO meeting.

3.2 Registration of Cell Lines Derived Outside Harvard (except NIH lines)

Lines derived outside of Harvard generally require full committee examination and acceptance.

- 3.2.1 An investigator who wishes to use an unregistered line derived outside of Harvard (except NIH lines; see below) should begin the registration process as early as possible by submitting a Registration Form and all materials required per the Form.
- 3.2.2 The ESCRO Administrator confirms receipt of all information required by the Provenance policy. The Administrator also compares the consent form to the checklist of ESCRO-preferred consent items and notes any items that are not included in the consent form.
- 3.2.3 The full ESCRO will examine the Registration form, any supporting materials, and copy of the consent form checklist. After the meeting the ESCRO Administrator informs the investigator of the status of the line (accepted/rejected) and adds accepted lines to the Registry.
- 3.2.4 Investigators with known plans for future use of the line may submit a use protocol for review at the same time they submit the Registration form; however, the two are reviewed in separate parts of the ESCRO meeting.

3.3 Registration of Cell Lines on the NIH Registry

NIH registry lines generally undergo administrative examination and acceptance.

- 3.3.1 An investigator who wishes to use an unregistered NIH registry line must submit the Registration Form.
- 3.3.2 The ESCRO Administrator confirms that the form is complete, adds the line to the Registry and informs the investigator of the acceptance. (Gamete donors for the lines listed on the NIH registry are unknown, so no provenance information is available. The Harvard ESCRO has accepted NAS' grandfathering of these lines.)
- 3.3.3 The ESCRO Administrator informs the ESCRO at regular monthly meetings of NIH lines accepted administratively since the last meeting.
- 3.3.4 The ESCRO Administrator cannot reject the registration of a line. Though

this is highly unlikely, any questionable NIH lines must be forwarded to the full ESCRO.

4.0 Communication of Restrictions on Use of the Lines

The material transfer agreement (MTA) includes information on any restrictions on the use of the cell lines. To facilitate the communication of restrictions, the ESCRO Administrator will make the details of any restrictions available to the Office of Technology Development (OTD).

5.0 Registration of Research Protocols

- 5.1 An investigator who wishes to either derive an hESC line or use an hESC line in experiments (*in vitro* or *in vivo*) must obtain the approval of the ESCRO Committee.
 - 5.1.1 Protocols for the use of hESC lines must list the specific lines to be used. Any lines not explicitly listed on the protocol may not be used. Vague terms such as “all HUES lines” are insufficient.
 - 5.1.2 Any new lines (including those proposed for use on the same protocol on which they were derived) must be added via an amendment.
 - 5.1.3 A use protocol (or amendment) cannot be approved until all lines proposed for use have been registered.
- 5.2 Once the ESCRO has approved the protocol (or amendment), the ESCRO Administrator will add the protocol to the Registry (or amend the existing registration). Investigators do not need to take any additional action to register the protocol.