Harvard University
Embryonic Stem Cell Research Oversight (ESCRO) Committee

Policy

Title: Documenting the Provenance of Human Embryonic Stem Cell (hESC) Lines

Control #	Version:	Written by:	Approved by:	Approval date:
P-002	v.1.0	Laura Kandziolka, ESCRO Administrator ESCRO Subcommittee for Banking, Provenance, and Registration	ESCRO Committee	5/13/2008 (effective 8/4/2008; retroactive)

1.0 Definitions

1.1 Examination and Acceptance: In order to avoid confusion and the possibility of work being performed without ESCRO approval, the words "review" and "approve" are limited to protocols. The ESCRO "examines" and "accepts" the provenance of cell lines.

2.0 Introduction

Investigators must provide the ESCRO with documentation of the provenance of all human embryonic stem cell (hESC) lines derived at or proposed for use within the University. This includes lines derived within Harvard as well as those an investigator may wish to import from other institutions. No investigator may use a line until the ESCRO has accepted the provenance and added the line to its Human Embryonic Stem Cell Registry (the Registry), i.e., until the line has been registered.

3.0 Required Materials

The ESCRO Committee requires the following to conduct its examination of provenance:

1. Attestation from the supplying institution's ESCRO or Institutional Official[1] that:
    a. the donation and derivation were performed using an acceptable informed consent process that was approved by an Institutional Review Board (IRB) or foreign equivalent, and
    b. both gamete donors signed the consent form (or, if not applicable, explain why), and
    c. donors were not paid (beyond reimbursement for direct expenses) for their donation, and

[1] Note: An attestation from the principal investigator is not an appropriate substitute.

d. the donation and derivation processes complied with any additional required review by an Institutional Animal Care and Use Committee (IACUC), Institutional Biosafety Committee (IBC), or other institutionally mandated review, and
e. the donation and derivation processes complied with the extant legal requirements of the relevant jurisdiction.

2. A blank copy of the IRB-approved consent form(s) used to consent donors (all names and contact information for study contacts should be redacted).

Once a line has been registered, no further documentation of provenance is required, regardless of the investigator who wishes to use it; however, further review may be required from the ESCRO, IRB and/or IACUC, as well as COMS and individual schools prior to the use of the line in research.

4.0 NIH-approved Cell Lines

Per section 1.4(c) of the 2007 Amendments to the National Academies' *Guidelines for Human Embryonic Stem Cell Research*, "Presence on the list of NIH-approved cell lines constitutes adequate documentation of provenance…". Thus, these hESC lines do not require submission of the materials above; however, the investigator must register these lines with the ESCRO to document their existence within the University. Use of these lines in research may require additional ESCRO and other committee approval.

5.0 Information Harvard Provides to Other ESCROs

When distributing a cell line, Harvard provides the same materials that it requires for its own examination of provenance[2]. The lab that derived the line may choose to supply additional information to the receiving institution about the technical aspects of the line or about the clinical background of the donors consistent with the parameters of the consent form. The ESCRO, however, will not collect or supply this information.

[2] Harvard does not provide a copy of the consent form with HUES lines 1-28, in accordance with the Committee on the Use of Human Subjects (IRB).