

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

Review and approval by the ESCRO Committee is required for all research involving the use of human embryos or the derivation or use of hES cell lines, regardless of the source of funding or 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 Institutional Review Boards (IRBs), Institutional Animal Care and Use Committees (IACUCs), the Committee on Microbiological Safety (COMS), and cost allocation approval at the school level. Approval from the ESCRO Committee will be contingent on the satisfaction of all other required approvals. ESCRO Committee policies, procedures, and resources may be found at <http://escro.harvard.edu>.

Type of Application: **New**
 Re-Approval **Amendment of ESCRO Protocol No. E _____**

PI: _____	Name: _____	
Co-I: _____	Admin. Contact: _____	Tel: _____ Fax: _____
	Email: _____	

PI Phone: _____	PI Email: _____
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PI School: _____	PI Dept.: _____
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Funding Source(s): _____

Project Title: _____

**Type of Research
(check all that apply)**

Purely in vitro human embryonic stem cell research with pre-existing coded or anonymous hES cell lines.

Human embryonic stem cell lines included on the NIH Human Embryonic Stem Cell Registry (<http://escr.nih.gov>)
 Cell Line No.: _____

Non-registered human embryonic stem cell lines
 Origin and designation of cell line: _____
 Has work with these cell lines previously been approved by the Harvard ESCRO Committee?
 No Yes: ESCRO Approval No.: E_____

Derivation of new human embryonic stem cell lines from:
 Donated human embryos. No. of embryos to be obtained: _____.
 In vitro fertilized human oocytes. No. of oocytes to be obtained: _____.
 Nuclear transfer. No. of oocytes to be obtained: _____.
 Other: _____

Research in which personally identifiable information about the donors of the blastocysts, gametes, or somatic cells from which the hES cells were derived is readily ascertainable by the Principal Investigator or any other researchers working on this project.

Research involving the introduction of hES cells into nonhuman recipients:
 at the embryonic or fetal stage
 at a postnatal stage

Other research involving the use of human embryos.

Required Approvals and Documentation (check all that apply)

Human Subjects (attach copy of IRB application or approval ltr. with protocol/consent forms)

Pending Approved Exempt Protocol No. _____ Date: _____

Vertebrate Animals (attach copy of IACUC application or approval letter with protocol)

Pending Approved Protocol No. _____ Date: _____

Committee on Microbiological Safety (COMS) (attach copy of approval letter)

Pending Approved Date: _____

Cost Allocation Protocol (attach copy of approval letter)

Pending Approved Date: _____

Material Transfer Agreement(s) (attach copies)

Pending Approved Date: _____

Other ESCRO Approval (attach copy)

Pending Approved Collab. Institution: _____ Date: _____

Other ESCRO Approval (attach copy)

Pending Approved Collab. Institution: _____ Date: _____

Biosketches and Research Plan

In addition to this form and documentation listed above, please submit the following for review:

1. Biosketches or CVs for all Key Personnel

2. Research Plan

A summary of your proposed research, including an explanation as to why it is necessary to use hESC. To aid the ESCRO Committee in evaluating potential benefits of the research in light of possible ethical concerns, the research summary should include specific discussion and justification of any of the following:

a. Research involving the attempted derivation of new hES cell lines from donated embryos, from in vitro fertilized oocytes, or by nuclear transfer. Particular attention should be given to the scientific rationale for the need to generate new hES cell lines, and the numbers of embryos or oocytes required for the project.

b. Research involving the introduction of hES cells into nonhuman animals at any stage of embryonic, fetal, or postnatal development. Particular attention should be given to the probable pattern and effects of differentiation and integration of the human cells into the nonhuman animal tissues.

c. Research in which personally-identifiable information about the donors of the embryos, gametes, or somatic cells from which the hES cells were derived is readily ascertainable by investigators. Particular attention should be given to the scientific and ethical rationale for maintaining the identifying link between donor and donated material.

Principal Investigator's Certification

I have read and understood the policies of the Harvard University ESCRO, and certify that the information in this application is accurate and complete.

X _____
Principal Investigator

Date