



ESCRO - Embryonic Stem Cell Research Oversight
438 Whitney Road, Ext., U-1039, University of Connecticut, Storrs, CT 06269
Phone: (860) 486-2215 Fax: (860) 486-5381, email: escro@uconn.edu

Instructions for Amending an ESCRO Protocol

Revised 8-27-08

When do you need to amend your protocol?

When you:

- 1) Change personnel (including graduate students and post docs)
- 2) Need to get additional cell lines from the UConn CORE
- 3) Change the location of research or storage of hES cells
- 4) Change PI
- 5) Change your scientific experiments
- 6) Need to get additional cell lines not from the UConn CORE
- 7) Change the source, procurement procedure, or privacy protections for the donation of embryos or gametes

Some amendments are eligible for administrative or expedited approval and some require full committee or stringent review for approval. These are noted in the instructions below.

***Note - All amendments** are made using the ESCRO Amendment form found on the ESCRO web site at <http://www.escro.uconn.edu/>. The PI is also responsible for notifying other research administration offices (e.g. ORSP/OSP, IBC, ACC/IACUC/ IRB) of revisions in his/her protocols as required by the policies and procedures of those offices.

Please submit a completed and signed ESCRO Amendment Application Form and other documentation as described below to the ESCRO office either electronically or by mail:
ESCRO

University of Connecticut
438 Whitney Rd, Extension, U-1039,
Storrs, CT 06269.

escro@uconn.edu

For assistance please call the office at (860) 486-1725 or Dr. Hiskes at (860) 486-2215 or e-mail Dr. Hiskes at Anne.Hiskes@uconn.edu or Dana Howard, the Administrative Assistant, at Dana.Howard@uconn.edu



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Please use the ESCRO Amendment form for both types of amendments described below and submit with the appropriate information or documentation:

A. Amendments eligible for administrative review and approval.

1. Changes in Project Personnel (excluding PI; this includes any co-PI, post-doc, student, or technician).

Provide the information required on the ESCRO Amendment Form regarding personnel to be added or leaving the project

For a new or additional **Co-PI**, please also supply a Bio-sketch.

Each new person must complete the ESCRO Compliance Tutorial which can be found on the ESCRO website at <http://www.escro.uconn.edu> and be sure to indicate the associated PI and ESCRO protocol number in your communication.

2. Additional hESC lines to be obtained from the UConn-Wesleyan Core
provide the information required on the ESCRO Amendment Form

3. Change in location of rooms used for hESC research or hESC storage

Note any changes in room location on the ESCRO amendment form

***Notify** ORSP at the Health Center or the Office of Plant Funds at Storrs (contact Robin Graves-Hoagland) of any room/equipment changes

4. Change in PI

Provide the information required on the ESCRO Amendment Form

Submit a revised and signed ESCRO protocol application form and include a Bio-sketch

The PI must complete the stem cell research compliance tutorial

B. Amendments requiring expedited or full committee review:

The ESCRO chair determines whether the amendment is eligible for expedited or full committee review using the same criteria and procedures as used for the review of initial ESCRO protocol applications.

For the changes listed below, submit the ESCRO Amendment form as well as the following documentation:

A completed, signed, revised ESCRO protocol application form, with revisions indicated by using bold or upper case lettering

Documentation that any relevant amendments in the IBC, animal use and care, or IRB protocols have been approved by the appropriate committee(s).

1. **Addition of hESC lines** or derivatives **not** obtained from the UConn-Wesleyan Core

2. **Procurement of human embryos, gametes, or somatic cells** - Changes in source, procurement procedures, or privacy protections

3. **Changes in scientific experiments** using hES cells or derivatives, human embryos or gametes.