The University of Connecticut

Human Embryonic Stem Cell Research Laboratory Policy

Addendum to UCHC Policies 2006-16 and 2006-17

Last revised: February 21, 2008

PURPOSE:

To ensure that all laboratories at all campuses and research arms of the University of Connecticut in which human embryonic stem cell research is conducted or in which human cells and tissues used in this research are stored comply with specified standards for laboratory safety, security, and cell and tissue tracking. This policy is supplemental to any other policies for the conduct of human embryonic stem cell research at the Institution.

SCOPE:

This policy applies to all who conduct or are involved with human embryonic stem cell research at any campus or research arm of the University of Connecticut, and to all laboratories at the Institution in which human embryonic stem cells or their live derivatives, human gametes, or human embryos are stored or used for the purposes of stem cell research.

DEFINITIONS:

- **BSL2 Standards:** Laboratory Biosafety Level 2 (BSL-2) containment and the OSHA Bloodborne Pathogen Standards (BPS) apply for the use of agents that pose moderate risks to the environment or personnel, and are required for laboratories using live human cells.
  For BSL-2 information see:
  http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm
  specifically Sections II, III, IV up to and including BSL-2, Table 1 of Sec. IV, Section V up to ABSL-2, Table 1 of Sec V, and Appendix H.
  For BPS information see:
  http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051 and
  http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=21519

- **Covered equipment**: Equipment with a useful life of more than one year and an acquisition cost of $1,000 or more.

- **ESCRO:** The Embryonic Stem Cell Research Oversight (ESCRO) is charged with the responsibility of reviewing all hESC research protocols and ensuring to the best of its power that all hESC research at the University is conducted in compliance with the highest ethical standards and with all relevant federal, state, and institutional laws and policies. See http//www.escro.uconn.edu

- **hESC**: Human embryonic stem cells, which are pluripotent cells that are self-replicating, derived from human embryos, and capable of developing into cells and tissues of the three primary germ layers

- **Human gametes:** human sperm or eggs

- **Human embryo:** Includes human embryos resulting from fertilization or parthenogenesis, and from nuclear transfer of human nuclear DNA into enucleated oocytes.

- **Non-recoverable hESC products:** Non-living products of hES cells such as nucleic acids, fixed cells, proteins, or lysates.

POLICY STATEMENT:

1. **Laboratory Safety**. All laboratories in which hESC research is conducted using hESC or hESC derivatives, human gametes, or human embryos must comply at a minimum with BSL2 and the Bloodborne Pathogen Standards.

2. **Laboratory Space and Equipment.**

   a. Space. The PI has responsibility for seeking approval for facilities to be used in the conduct of hESC research, and for notifying the appropriate campus offices and the ESCRO of any additions or deletions.
   At UCHC: Contact ORSP.
   At Storrs: Contact the Accounting Office, Plant Funds Manager.

   b. Equipment. The PI has the responsibility for initiating approval and tagging of any covered equipment prior to its use with hESC or hESC derivatives, and for complying with federal law concerning the use of federal funds in support of hESC research.
   At UCHC: Contact the Office of Research Administration and Finance.
   See http://researchfinance.uchc.edu
   At Storrs: Contact the Accounting Office, Plant Funds Manager.
   Phone (860) 486-3780.

3. **Laboratory Security**. PIs are responsible for implementing a system to ensure that only authorized and appropriately trained persons handle hESC or human embryos and gametes used for hESC research (individuals authorized to use hESC must be listed on an approved ESCRO protocol and also have completed appropriate scientific and compliance training). The following are required for laboratory security.

   a. For all hESC research labs:
   - Outside laboratory doors are locked when the laboratory is unoccupied
   - Freezers in which hESC, or human embryos or gametes are stored are kept locked. A separate freezer for hESC only is not required.
   - A list of all research personnel authorized to work in the lab is posted inside each laboratory, along with an indication of those who are authorized for hESC research.
   - PIs designate an individual to be responsible for lab security during their absences (e.g. when traveling for meetings, etc.)

   b. Additional security requirements for hESC research labs in which human embryos or gametes are stored or used:
   - Visiting researchers sign a lab use form or log book for those days when they will be in the lab.
   - All authorized personnel display ID badges.
   - Outside entrances to the lab or lab suite use a code-entry system.

4. **Sharing and transfer of hESC and derivatives between PIs and labs**.

   a. For internal sharing or transfer of hESC and derivatives between University of Connecticut laboratories and principle investigators:
      - Transfer must be approved in advance by the ESCRO Committee or included in an approved ESCRO protocol.
      - Non-recoverable hESC products may be transferred without ESCRO approval
      - The UConn-Wesleyan Stem Cell Core must be notified by the PI who intends to share frozen vials or live cultures of hESC or derivative lines originally obtained from the Core prior to the transfer of any materials.
      - Each individual who is involved with shipping/transporting the above items, even between campuses, needs to attend a Department of Transportation (DOT)/International Air Transport Association (IATA) Hazardous Material Shipping training session.

   b. For transfer of hESC and derivatives *to* a University of Connecticut PI or lab *from* a source external to the institution:
      - Contact UConn OSP/ORSP regarding the need for an SLA or MTA
      - Recipients of hESC or derivatives must have an approved ESCRO protocol or protocol amendment for use of the materials

- A TSCA import form must be completed and accompany each import from outside the US

c. For transfer of hESC and derivatives *from* a University of Connecticut PI or lab *to* a recipient external to the institution:
   - PIs are required to contact the UConn Center for Science and Technology Commercialization regarding the need for an outgoing MTA or SLA.
   - Each individual who is involved with shipping/transporting the above items needs to attend a DOT/IATA Hazardous Material Shipping training session.

5. Tracking of hESC and derivative lines, human gametes, and human embryos.

a. For hESC lines or human gametes approved for use by the ESCRO but not obtained from the Core, PIs should notify the ESCRO office once they receive these materials and also provide the ESCRO office with a copy of any simple letter of agreement or material transfer agreement which covers use of the materials. (This information is communicated to the ESCRO by the Core for any materials supplied by the Core.)

b. Each laboratory must keep a separate freezer log for hESC and derivatives. The hESC freezer log must include a) Cell line names, passage numbers, sources of the line, and the numbers and locations of vials for each line b) Date of each action and name of handler.

c. Any laboratory authorized to derive new cell lines from human gametes or embryos must follow the same policies and procedures as the Core for tracking and storing gametes, embryos, and cell lines. For example, there must be a separate Embryo/Gamete Log to record the numbers, deidentified sources, storage locations, usage of embryos and gametes, and date and name of handler.

d. All PIs who have received hESC, modified hESC lines, or human gametes or embryos for use in hESC research are required to submit an annual report to the ESCRO between May 15 and June 1 of each year showing their cryogenic storage inventory. The report will include information on the cell lines and numbers of vials in cryogenic storage, and also quantities and characteristics of any stored human gametes and embryos. Reports must be submitted annually as long as the PI maintains an inventory of hESC or recoverable hESC derivatives, or human gametes and human embryos for hESC research. This information will be used to maintain the mandated hESC Research Institutional Registry.