Guidance for Research with Human Embryonic Stem Cells Ineligible for Federal Funding

While research with human embryonic stem cells (hESC) is allowed per federal guidelines (http://stemcells.nih.gov/policy/pages/2009guidelines.aspx), federal funds **cannot be used** for:

- The derivation of stem cells from human embryos
- Research with hESC lines that are **not** listed on the NIH Stem Cell Registry

This means:

- Direct and indirect **project expenses** must be paid using non-federal funds
- **Personnel effort** must be paid using non-federal funds
- **Laboratory space** must be excluded from the university's indirect cost recovery calculations
- **Laboratory equipment/supplies** must be purchased with non-federal funds*, tagged to identify restricted use, and excluded from indirect cost recovery calculations.

Investigators are expected to follow U-M compliance guidelines, jointly defined by *Human Pluripotent Stem Cell Research Oversight* (HPSCRO) *Committee* and the *Cost Reimbursement Office*, when proposing or conducting research (including derivation) with "ineligible" hESC lines.

Process

U-M Investigators/Project Team

- When applying for HPSCRO approval to obtain unregistered hESC lines or to derive new hESC lines, complete **Section D** of the application. This section documents:
 - a. The non-federal funding source(s) of the research project
 - b. The percent effort of project personnel that is supported by NIH funds
 - c. The location (building and room numbers) of the research with the hESC lines
 - d. If federally-funded equipment or supplies is housed in that location
 - e. Measures the project team will take to ensure federally funded equipment and supplies will not be used for the hESC work

Note: HPSCRO notifies the *Office of Cost Reimbursement* when approving research with "ineligible" hESC lines. HPSCRO approval is contingent upon facility and equipment accounting provisions being in place prior to the start of the work.

2. Prior to starting the approved research, coordinate with the *Office of Cost Reimbursement* and *Property Control* to tag the lab equipment that will that will touch live (including frozen) hES cells.

Note: The *Office of Cost Reimbursement* maintains documentation on the facility/lab equipment review.

University of Michigan Human Pluripotent Stem Cell Oversight (HPSCRO) Program Office of Cost Reimbursement

Issued: 07/01/2010 Last Updated: 03/25/2016

Guidance for Research with Human Embryonic Stem Cells Ineligible for Federal Funding

- 3. When amending or renewing your HPSCRO approval, list any facility or equipment changes.
- 4. Upon project completion, notify the *Office of Cost Reimbursement* so that appropriate accounting adjustments can be made.

* Depreciation of Equipment

Equipment purchased with federal funds that has been fully depreciated can be used for research with hESC lines that are not listed on the NIH registry. If using depreciated equipment, notify the *Office of Cost Reimbursement* to ensure proper accounting.

The table below shows the depreciation schedule of laboratory equipment commonly used for hES cell work (i.e., likely to touch live (including frozen) hES cells during the research). This equipment typically meets the university's capitalized equipment threshold (i.e., \$5,000 purchase price).

Asset	Profile	Life/Months	Life/Years
Nitrogen Gas Generator	GENERATORS	120	10
Waterjacketed CO2 incubators	INCUBATORS	120	10
Laminar flow hood	FUME HOODS	120	10
Dissecting microscope with lighted base	MICROSCOPE	120	10
Inverted microscope with or without fluorescence	MICROSCOPE	120	10
Vibration-free microscope system	MICROSCOPE	120	10
Plate microscope	MICROSCOPE	120	10
Micromanipulators	LAB EQUIP	120	10
Microinjectors	LAB EQUIP	120	10
Laser Dissection	LAB EQUIP	120	10
Heated stages	LAB EQUIP	120	10
Cryostorage Tank	LAB EQUIP	120	10
Fluorescent activated cell sorter	LAB EQUIP	120	10
Centrifuge	CENTERFUGE	120	10
Image capturing system/cameras/ computer	CAMERA	96	8
Live cell imaging systems	CAMERA	96	8

Contacts

- HPSCRO Program, 734-764-7545, <u>HPSCROquestions@umich.edu</u>
- Office of Cost Reimbursement, 734-647-3843, cost.reimbursement.office@umich.edu