

## **GUIDANCE RELATED TO FISCAL MANAGEMENT OF STEM CELL RESEARCH AT UC DAVIS**

### **I. Purpose**

The UC Davis campus is issuing this interim guidance to investigators and administrators in response to federal and state legislation regarding human adult and embryonic stem cell research. Because of prohibitions on the use of federal funds to support some stem cell research, investigators and administrators are advised to take extra care in managing space, equipment use and direct expenditures related to this research. As the campus gains experience with stem cell research, this guidance will be revised as necessary.

### **II. Definitions**

**Derivatives** - Derivatives are DNA, RNA, proteins, and any other products secreted by or extracted from human embryonic stem cells. They do not include data obtained from stem cell research, which are treated separately in the protocols. The federal funding prohibition applies both to the cell lines themselves and to their derivatives.

**Equipment** – Tangible personal property with an expected useful life of more than one year and an acquisition cost of \$5,000 or more.

**Exempt Equipment** – Items specifically identified in a federal award as UCD property without further obligations to the government. This occurs infrequently.

**Fair Market Value** – The depreciated value of an equipment item at a specific date and time as determined by UCD Materiel Management. Fair market value will change over time and should be reassessed at least annually.

**Human Adult Stem Cells** – stem cells found in different tissues of developed adults that can give rise to specialized cell types of the tissue from which they originated.

**Human Embryonic Stem Cells (hESCs)** – Pluripotent cells that are self-replicating derived from human embryos and are capable of developing into cells and tissues of three primary germ layers. Although hESCs may be derived from embryos such stem cells are not themselves embryos. There are two classes of hESCs: (a) **Registered hESCs**, and (b) **Non-Registered hESCs**

**Non-Registered hESCs** – Those **hESCs** that are not included in the Human Embryonic Stem Cell Registry maintained by the National Institutes of Health, <http://stemcells.nih.gov/research/registry>.

**OMB Circular A-21** – Entitled “Principles for Determining Costs Applicable to Grants, Contracts and Other Agreements with Educational Institutions,” this is a guidance document from the Office of Management and Budget (OMB) to federal agencies, which they then apply to award recipients. This Circular describes the process for determining what costs may be charged to federal awards and the method of calculating a Facilities and Administrative (or indirect cost) rate. See the full text at [http://www.whitehouse.gov/omb/circulars/a021/a21\\_2004.html](http://www.whitehouse.gov/omb/circulars/a021/a21_2004.html).

**OMB Circular A-110** – Entitled “Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations,” this document establishes award recipient standards for pre-award activities; post-award activities including management of fiscal, property, procurement, reporting and record retention systems, and termination; and after-the-award activities including close out responsibilities. See the full text at <http://www.whitehouse.gov/omb/circulars/a110/a110.html>.

**Registered hESCs** – Those hESCs that are included in the Human Embryonic Stem Cell Registry maintained by the National Institutes of Health and available at the following website: <http://stemcells.nih.gov/research/registry>.

**Stem Cells** - Cells with the ability to divide for indefinite periods in culture and to give rise to specialized cells. All stem cells—regardless of their source—have three general properties: they are capable of dividing and renewing themselves for long periods; they are unspecialized; and they can give rise to specialized cell types, e.g., muscle, neuron, bone, or skin.

### **III. Financial Management for Research Using Registered hESC and Human Adult Stem Cells**

Research with Registered hESCs as well as Human Adult Stem Cells is unrestricted, meaning that there are no conditions imposed on the use of federal funds to support research activities with these lines.

### **IV. Financial Management for Non-Registered hESC Research**

The NIH and the Division of Cost Allocation of the U.S. Department of Health and Human Services confirm that institutions can comply with the federal stem cell funding policy by strictly adhering to the cost accounting principles from the OMB Circulars. This is consistent with the procedures currently used by the University to account for charges on individual federal grants and contracts. That is, charges to federal funds must be allowable, reasonable, allocable (directly attributable to the project in proportion to the benefit received), and the methodology for determining costs consistently applied. The NIH Stem Cell Frequently Asked Questions website (<http://stemcells.nih.gov/info/faqs.asp>) provides general and specific information regarding charges for registered and non-registered cell line research.

Principal Investigators have primary responsibility for programmatic and fiscal management of their research projects. As such, they are responsible for reviewing and adhering to these Guidelines and must ensure that all members of the research teams utilizing non-registered hESC lines are informed of these Guidelines and the restrictions on the use of federal funds for non-registered hESC research.

**A. Allowable** - Federal policy is clear with respect to human embryonic stem cell research:

Federal funding (NIH, National Science Foundation, Department of Defense or any other federal agency) may not be used directly or indirectly for research on non-registered hESC lines.

Federal policy does not prohibit research with non-registered hESC lines, but the above limitation requires investigators to secure non-federal sources to support the activities. Non-federal sources include awards (grants, contracts or gifts) from private sponsors and state agencies including the California Institute for Regenerative Medicine (CIRM).

Because of the federal restriction, stem cell investigators and administrators should closely monitor research activities in order to prevent the shift of non-registered stem cell research costs to federal awards.

**B. Allocation of Costs** –Investigators and department administrators should continue to follow the cost principles described in OMB Circular A-21 and the Cost Accounting Standards. In addition, investigators and department administrators should develop an allocation methodology for expenses that are split between or among projects. Cost allocation can be based on actual usage, a percentage determined by the quantity of activities performed or the number of staff working on each project, or another reasonable method. In any case, the methodology must be documented in writing for audit purposes by the department and consistently applied to costs during the life of the project unless justified by documented changes.

1. Personnel Costs (Salaries and Fringe Benefits) – All personnel compensated for performing research on non-registered hESC lines must be paid from non-federal funds.

Confirmation of cost allocation is provided by the Principal Investigator or another person identified by the Principal Investigator who has first hand knowledge of the person's total institutional activities the direct supervisor of the individual

regularly reviewing time sheets or expenditure ledgers and, for federally-supported projects, certifying annual effort reports (Personnel Activity Report) for personnel. This is especially important for personnel splitting time between research supported by federal awards and research involving non-registered hESCs.

Due to the nature of federal awards that support a major portion of salary and benefits, e.g., Mentored Scientist and Career Scientist, it may be difficult to document an allocation methodology separating federal training/research activities from non-registered research activities. To discuss the acceptability of an investigator's plan to separate costs, please contact your Dean's Office or their designee.

2. Students (undergraduates, graduates, postdoctoral) – All employed students performing research on non-registered hESC lines must be paid from non-federal funds. Students who are supported by federal training grants or fellowships are not eligible to participate in projects involving non-registered hESC lines due to the impracticality of separating training and research activities.
3. Expendable Supplies – Excess supplies purchased, but unused, on federally funded projects may not be used for non-registered hESC research. New supplies purchased for the performance of research on non-registered hESC lines must be charged to non-federal funds.

It is recommended that a separate supply inventory be established for projects utilizing non-registered hESC lines. In situations where federally-supported hESC research and non-registered hESC research are conducted in close proximity, inventory purchased with federal funds should be clearly identified as unavailable for use in other projects. This may, but need not, include maintaining locked supply cabinets, usage logs, or color tags indicating availability or unavailability for non-registered hESC lines.

4. Equipment –Federal regulations in OMB Circular A-110 (Section C.34) and 45 CFR §74.33 and §74.34 apply additional restrictions on the use of equipment. Note the equipment definition in Section II.

In some cases, use and disposition of equipment depends upon the Fair Market Value of the item. Determinations must be obtained in writing from the UCD Equipment Manager, 530-757-8836. In the following section, the term “owned by” means “title held by.”

Equipment purchased solely for use in research on non-registered hESC lines must be charged to non-federal funds.

Equipment owned by UC may be used for **non-registered hESC line research** if the equipment was purchased solely with non-federal funds or if the title to the equipment belongs to UC. (Note: If previously funded by the federal government, the government must relinquish/transfer title to UC before use on non-registered lines.)

Equipment purchased with federal funds may be used for **non-registered hESC research** only in the following circumstances:

- The federal funds supporting the equipment purchase has been completed (including all competitive segments); UCD has submitted the equipment inventory report required by the award and at least 120 have elapsed from the date the report was submitted; the federal government has not invoked its right to transfer the equipment within the 120 day period; UCD retains title to the equipment without restriction (exempt property); and pursuant to approval of the appropriate federal agency; or
- UC purchases the equipment from the federal government and has documentation of such transaction, including title transfer.

Otherwise, in order to ensure that federally-funded equipment is **not used** for non-registered hESC research in co-located space (see also Section V. Facilities Management), Equipment Management will review the equipment identification information provided on the Human Stem Cell Research Supplement form completed by the Principal Investigator and will issue red labels, indicating that the equipment is federally-funded and cannot be used for non-registered hESC research, to the responsible asset representative to be affixed to the federally-funded equipment.

Equipment purchased as a shared resource and funded by federal and non-federal sources may be used for **non-registered hESC lines research**, only if the use is thoroughly documented and does not exceed the non-federally-funded proportion of usage based upon the purchase share. The Principal Investigator or the supervisor of the research equipment is responsible for maintaining a log of equipment utilization. This log should identify any use on projects involving non-registered cell lines and provide periodic cost analysis to ensure appropriate use. Refer to UCD policy 350-80.III.A.2, Disposition of Excess and Surplus Property, for disposition requirements.

5. Recharge Activities – Recharge activities are approved through UCD Policy and Procedures Section 340-25 to provide services to other campus units at rates calculated to recover the costs associated with that service. To comply with federal policy it is necessary to consider the source of funds used to establish the recharge activity apart from the funding that is purchasing the service. Additionally, the Recharge Center must determine if other restrictions arise due to location of the recharge activity in space constructed or improved with federal funds. See also Section V. Facilities Management.

**For recharge activities established in whole or in part with federal funds,** the proportionate use for non-registered stem cell research should not exceed the percentage of non-federal support for the operating costs of the recharge activity. On at least an annual basis, the recharge center must determine the amount, if any, of federal funding supporting the direct operation of the recharge center, e.g. support grant, core facility. If federal funding exists, the recharge center should also determine: a) title status of any equipment being used by the recharge center; b) the identity of all users and whether the use involved non-registered hESC; and c) data to allow for periodic cost analyses to ensure appropriate use within the limits. See also B.4.Equipment.

6. Subawards, Consultants, Travel and Other Expenses – Expenditures in these categories related to research on non-registered hESC lines must be charged to non-federal funds. Cost allocation should follow the above concepts and documentation methodologies.

## V. Facilities Management

1. Shared Space - The National Institutes of Health acknowledge that research on registered hESC lines and non-registered hESC lines may occur in the same laboratory space or room provided that an effort is made to separate and identify costs with the appropriate funding source. However, in order to ensure adequate management systems exist based upon these Guidelines, UCD has determined that non-registered hESC research should be conducted in space that is separate from federally-funded projects. See also Section B.4.Equipment in co-located space.
2. Federally-Supported Facilities – UCD investigators performing research involving non-registered hESCs may not use facilities constructed or supported directly by the federal government. This

restricts the conduct of non-registered hESC research in California National Primate Research Center space as well.

The University has taken additional steps to oversee activities conducted in UCD buildings that were constructed in part with federal funds. The locations identified in the attached report **(pending)** have been constructed with federal funding and, thus, have restrictions requiring active departmental management.