

University of California, San Francisco

Procedures for Review of Human Stem Cell (HSC) Research Proposals

Introduction

University of California San Francisco (UCSF) [policy](#) is to ensure that all research involving the use of human stem cells is in compliance with all adopted State and Federal regulations and compliance standards developed by campus committees.

Of particular interest is any research that uses embryonic human stem cells (hESC) which are in two broad categories referred to as those listed on NIH Human [Embryonic Stem Cell Registry](#) and those that are not.

While research on both categories of hESC may be conducted, the use of Federal funds* for such research is *restricted to only* those lines for NIH Registry.

**Note: the term federal funds is used to broadly describe utilization of direct funds, staff salaries, supplies and other expendables, equipment purchased and owned by the Federal Government.*

To ensure compliance with the criteria for separation of funding, UCSF has established a process to review all proposed uses of facilities and equipment to ensure that their use in research involving non-Registry hESC lines does not violate the restriction for use of Federal funds.

Review Process

All applicants who propose to use any stem cells in their research are required to complete a copy of the [Human Stem Cell Research Supplement](#) (HSCRS). If the applicant intends to work with Non-Registry hESC Lines:

- Applicants submit a copy of the completed HSCRS to the Office of Associate Vice Chancellor, Research
- Applicants must complete a copy of the "[Request for hESC Equipment Approval](#)" form and submit to the Office of Associate Vice Chancellor, Research
- The Compliance Coordinator will review the forms for completeness and create a folder for each Principal Investigator (PI). The applicant will be contacted for missing information.
- If the funding application requires the submittal of a Letter of Intent (LOI) prior to the full application, the PI is required to submit a copy of the LOI to the Office of Associate Vice Chancellor, Research along with the completed forms. The Compliance Coordinator will contact the applicant and request copies of any missing forms.
- Copies of the relevant completed forms will be forwarded to Budget and Resource Management, and Capital Asset Management (CAM), for review.
- A copy of the HSCRC will be forwarded to the committee on Human Research Office who will process it in accordance with their existing processes for human stem cell approval.
- Once completed, Budget and Resource Management, and CAM, will send their findings (i.e. approval, disapproval or conditional approvals) to the Compliance Coordinator who will

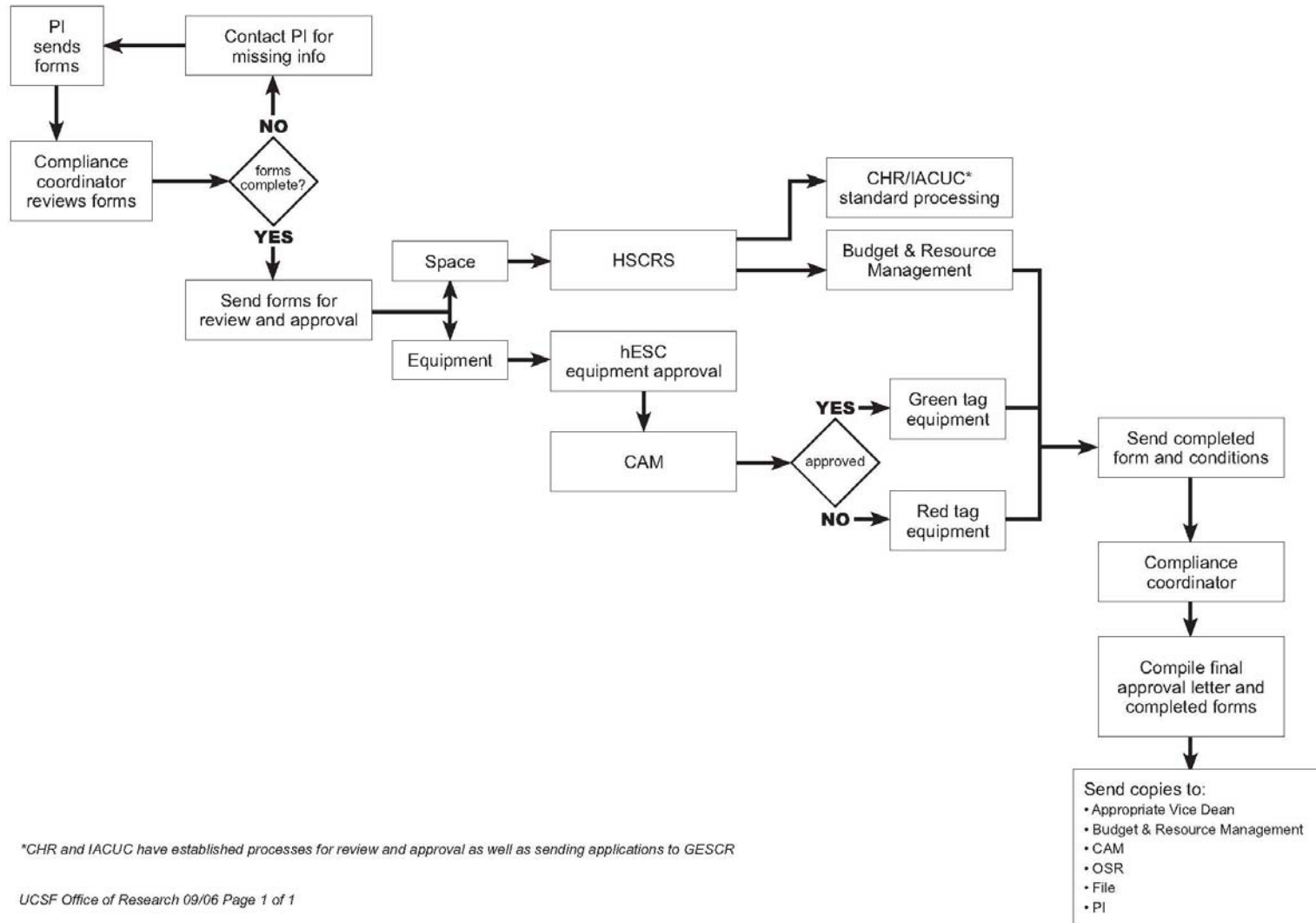
consolidate the documents and prepare a final letter to the applicant with the results of the review. This letter will have copies of the completed forms attachments.

- A copy of the final letter and attachments will be sent to the applicant, Budget and Resource Management, CAM, Office of Sponsored Research (OSR), appropriate Dean's Office and the applicant's file.

Grant Application Process:

All grant applications must go through OSR. OSR will ensure that the applicant has received approval for the use of the proposed space and equipment by comparing the information on the application form to information on the approval letter.

University of California, San Francisco
 Flow Chart: Procedure for Review of hESC Forms



*CHR and IACUC have established processes for review and approval as well as sending applications to GESCR

UCSF Office of Research 09/06 Page 1 of 1

Human Stem Cell Research Supplement

If your application involves the collection, derivation, or use of human stem cells, please complete the relevant section(s) of this form and include with your application to the Committee on Human Research (CHR).

Principal Investigator: _____ Date: _____
 Application type: New _____ Renewal: CHR # _____

1. **Are the stem cell lines used, derived or collected:** *(please check all that apply)*
- a. Adult *(if only adult cells, stop here. Submit application to CHR)*
 - b. Embryonic *(includes somatic cell nuclear transfer) (Continue with question 2)*
 - c. Other –
 Explain:
 (Consult with CHR office regarding possible additional requirements)

2. **Are the embryonic stem cell lines on the existing NIH Human Embryonic [Stem Cell Registry](#)?**
- a. If Yes - NIH Code:
 - You may use Federal funds for this research. *(Submit application to CHR)*
 - b. If No - You may *not* use Federal funds for this research. *(Complete questions 3 & 4 below)*

3. **If the answer to question 2 is No, list the location of non-federally funded facilities used for this research and the DPA(s) and fund(s) supporting this research, if available.**

Campus	Building	Room	DPA	Fund

4. **Is there any other research activity in any of the rooms listed in 3?**
- a. Yes
 - b. No

If yes, please provide the following information about the rooms and other research activities:

Campus	Building	Room	DPA	Fund

Send a copy of this form and the Request for the hESC Equipment Approval to The Associate Vice Chancellor, Research, Box 0407, and submit application to CHR.

Office of Research Use

CHR Approval #: _____ Date: _____
 Budget and Resource Management Review Required? Yes No *(if Yes date sent: _____)*
 Research start date: _____
 Conditions: _____

Copy to Vice Dean Research, School of Medicine
 HSCRSupp Form Rev 09/20/06



University of California
San Francisco
Controller's Office

REQUEST FOR hESC EQUIPMENT APPROVAL

Instructions to the Department: Submit this form to obtain approval for use of equipment in hESC activities.

Note: Use of federal funds for human embryonic stem cell (hESC) activity is currently restricted to those listed on 'NIH Stem Cell Registry.' All other activity involving human embryonic stem cell lines not on the approved list must be conducted in a manner that does not utilize federal funds. To request use of equipment in hESC activities, please enter all the information available. Capital Asset Management will provide confirmation of equipment approved for Non-registry hESC use and will provide special property tags to be affixed to the equipment for quick identification. If you have any questions or comments, please contact Capital Asset Management at (415) 502-3042.

1. EQUIPMENT IDENTIFICATION: (List all equipment planned for use. If using an attachment, please indicate here.)

Property Number:	Description:	Serial ID:	Building:	Room:	Approval Stat: (For CAM use only)

2. PI INFORMATION:

Principal Investigator: _____
 Department Name: _____
 Phone Number: _____
 Email: _____
 Additional Contact: _____
 Accounting Units: DPA: _____ Dept Code: _____

3. ADDITIONAL INFORMATION:

Remarks: _____

4. PI SIGNATURE:

PI Signature:
 Date:

Controller's Office Use Only:

5. APPROVAL SIGNATURE:

EMF: CAM:
 Date: Date:

All equipment approved for hESC research must be properly tagged and labeled.
 Forward completed form to Office of Research, Box 0407, Bldg: Mission Bay Genentech Hall Room S-272, Fax 476-2721.

Revision Date: 9/1/2006