

Requirements for Obtaining Approval to Conduct Research or Research Training Involving Human Embryonic Stem Cells (hESC) at UCSD

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A. Overview

Investigators planning to conduct research or teaching involving human embryonic stem cells (hESC) must submit applications and obtain approval from the ESCRO, IRB, and Biosafety Committees. Additional approvals may be required if the project includes animal subjects (IACUC). A Material Transfer Agreement (MTA) or research agreement (including investigator-initiated clinical trials) (OCGA), Industry-initiated Clinical Trial Agreement (CTA) or agreement for services involving hESC lines (CTAS), or Purchase Order (Purchasing) may be required for incoming hESC lines from a non-UCSD source. Further, an MTA may also be required for outgoing transfers of UCSD-developed hESC lines (TechTIPS) and transfers of hESC derivatives between UCSD investigators (TechTIPS). There is no fixed sequence, in which approvals must be requested, or required agreements have been finalized, but the proposed research or teaching may not begin until such approvals and agreements have been finalized in accordance with current practices.

Qualified UCSD Principal Investigators conducting research with hESC will require approvals as described below. Under UCSD policy, other individuals from UCSD or outside institutions working under the direct supervision of a qualified UCSD Principal Investigator must be identified as key personnel in the ESCRO, IRB, Biosafety and IACUC application(s).

B. Initial Review

All research or teaching use involving covered stem cell lines as defined in the UCSD Guidelines* must have current approvals and agreements as described below for the named investigator(s) to conduct the proposed project.

1. All projects:
 - a. ESCRO
 - b. IRB
 - c. Biosafety Committee (human cells; DNA, pathogens, radiation as needed)
 - d. IRC (Conflict of Interest Review)
2. Projects involving the use of animal subjects:
IACUC
3. Projects requiring transfer of cells to or from an outside institution, or between UCSD laboratories:
Material Transfer Agreement (MTA) (OCGA or TechTIPS) or purchase agreement (Purchasing)
4. Projects receiving external funds:
Contract/grant Review (OCGA or CTAS); Services Review (CTAS)
5. Projects using Department or Gift funds:
Principal Investigator's department business office/Chair

C. Continuing Review

Federal regulations mandate that IRB approvals last no longer than 365 days from the date of initial approval and continuing review approval, if applicable. This guidance extends that requirement to ESCRO approvals. When applying for continuing review, a separate application

must be submitted to each office listed in Part B, Section 1a and 1b. Continuing review forms include a facesheet and a narrative summary of progress. It is the Principal Investigator's (PI's) responsibility to submit applications for annual continuing review. Projects may receive up to three continuing approvals. After four years, the PI must submit a new application for review and approval.

D. Amendments

Investigators wishing to revise their approved research protocol are required to obtain approval. Requests for amendment to an approved protocol should be submitted to each of the three scientific/ethical review offices: ESCRO, IACUC, and IRB, as appropriate. Amendment approval requests consist of a cover letter describing the amendment, appropriate facesheets, and a revised research plan (for ESCRO and IRB only). Amendment materials must be submitted to respective offices electronically using on-line process. Approval of an amendment does not alter the 365-day IRB or ESCRO approval period.

For amendments where the existing MTA is sufficient to cover the expanded research, an amended or new MTA is not needed.

E. Checklist of Committee Approvals

The following checklist serves as a guide for the PI seeking approval for hESC research or teaching. Forms for obtaining all required approvals are available on the UCSD ESCRO web site. Verification of such approvals prior to the initiation of research or training shall be in accordance with existing campus practices. Use this checklist to ensure that all campus offices have reviewed and approved hESC research.

- ESCRO <http://research.ucsd.edu/ESCRO/index.html>
- IRB <http://irb.ucsd.edu>
- Biosafety <http://blink.ucsd.edu/Blink/External/Topics/Policy/0,1162,15498,00.html>
- Conflict of Interest (IRC)
http://ocga3.ucsd.edu/robo/projects/cgaweb/COI/COI_Overview.htm
- If using animal subjects, IACUC <http://animalhealth.ucsd.edu:9000/>
- If cells provided by non-UCSD source, MTA (OCGA) or Purchase Agreement (Purchasing) <http://ocga3.ucsd.edu>
- If UCSD-developed cells sent outside UCSD or transferred between UCSD investigators (TechTIPS) http://invent.ucsd.edu/index_flash.htm
- If research, training, services funded by non-UCSD source, OCGA or CTAS
- If research, training funded by department or gift funds, department business office/Chair

**Human Embryonic Stem Cells, defined for the purpose of this document as any: culture-derived, human pluripotent stem cell population that is capable of: 1) sustained propagation in culture; and (2) self-renewal to produce daughter cells with equivalent developmental potential. "Pluripotent" means capable of differentiation into mesoderm, ectoderm, and endoderm. This definition includes both embryonic and non-embryonic human stem cell lines regardless of the tissue of origin."