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Stem Cell Research Regulatory Q&A and Resources

Regulatory Q&A

Resources

Regulatory Q&A

What are the procedures for conducting human stem cell research at UCSF?

1. UCSF activities involving any human stem cell research shall be in accordance with the applicable federal, state and funding agency regulations governing such research, including any restrictions on the use of federal funds for such research as issued under the NIH Stem Cell Guidelines ^[1].
2. All individuals conducting human stem cell research must submit a GESCR application for review and approval prior to initiation of the study. Application procedures are located under GESCR Submission and Review Process ^[2] page.
3. Additional approvals must be obtained from the Institutional Biosafety Committee (IBC) ^[3] or Institutional Animal Care and Use Committees (IACUC) ^[4] as appropriate.
- 4.

Investigators who are conducting research deriving or using human embryonic stem cells that are not on the NIH Human Embryonic Stem Cell Registry [5] must adhere to all terms of the NIH Stem Cell Guidelines [1], and should charge the costs of the research to appropriate non-Federal funding sources.

5. When managing federal funds for projects using human embryonic stem cell lines that are on the NIH Human Embryonic Stem Cell Registry, investigators must adhere to all federal cost principles as clarified under the UCSF Cost Accounting Standards (CAS) Guidelines (Charging Practices for Sponsored Projects). [6]

Does UCSF have a specific review and approval process for non-NIH Registry hESC Lines?

The GESCR Committee requires that all state and/or federal requirements are met before a human stem cell line can be approved by the Committee. The pre-approval considerations may include, but are not limited to, consent from the gamete and/or embryo donors and payment reimbursement of donors. There may be conflicts between state and federal guidelines/regulations. The GESCR Committee reviews the history of all stem cell lines and weighs this information with the state and federal guidelines/regulations to determine if a specific stem cell line can be approved for use at UCSF.

What about California law?

Per California law, GESCR approval is required for any research involving human stem cells, with special provisions for the use of human embryos and oocytes to create stem cell lines. Depending on the source of funding, other laws and regulations may require GESCR review protocols using human embryos and oocytes, and the derivation and use of human embryonic stem cells (hESC), human embryonic germ cells, induced pluripotent stem cells (iPS) and human adult stem cells from any source, including somatic cell nuclear transplantation (SCNT).

How does a PI appropriately dispose of research materials?

As long as the materials and results cannot be traced to an individual donor, they can be handled in the same manner as other research materials and data. Contact the Environmental Health and Safety Office [7] for assistance with material disposal.

What other reviews are required at UCSF?

In addition to GESCR, the IRB will review research involving human subjects. Protocols that require both GESCR and IRB review are submitted in iRIS with a single protocol application.

The Institutional Animal Care and Use Committee (IACUC) must review and approve all

research using vertebrate animals. This review is not done through iRIS and must be coordinated through the IACUC office [4].

Is financial conflict of interest (COI) review required when submitting a GESCR Application?

You will be asked if there is a conflict of interest when completing your submission. If yes, a separate document must be completed and submitted with your application.

Does hESC research require additional or different occupational health and safety review, guidelines or programmatic oversight as compared to other human materials work?

The requirement to obtain biosafety office approval is dependent upon the type of hESC work being performed. To determine if your hESC work requires biosafety committee approval you should contact the Environmental Health and Safety Office [7].

Can researchers share materials derived from the NIH Registry Materials within UCSF? What about outside UCSF?

Transferring materials, whether within or outside an institution, is best accomplished with a Material Transfer Agreement [8] (MTA) that respects the developer's property rights, as applicable, in the materials and stipulates the terms and conditions under which the recipient may use the materials. You will need to process the MTA in different ways depending on whether the Registry-derived materials are being transferred into, within or from UCSF.

The Office of Innovation, Technology & Alliances (ITA) [9] is responsible for outgoing transfers of all UCSF proprietary materials other than human clinical specimens. Stem cells and their derivatives are not considered by UCSF to be human specimens (e.g. tissue, urine, blood, etc.) because they are the result of inventive laboratory activities. Investigators who want to send Registry-derived materials from UCSF to another UC Campus, university, government lab, or research institute should contact the ITA which will negotiate and sign the MTA. The ITA will also review requests for transfers by UCSF investigators of their Registry-derived materials to companies because different terms and conditions may apply.

Researchers who want to receive Registry-derived materials from outside of UCSF also should contact the ITA [10].

How does a PI commercialize materials and research results derived from pluripotent cells, such as hESC and iPS Cells?

As long as the materials and results cannot be traced to an individual donor, they can be commercialized in the same manner as other materials and data that comprise licensable subject matter. Contact the Office of Innovation, Technology & Alliances (ITA) [9] early in the process. Do not make any public disclosures or transfer any materials outside of UC without first contacting the ITA, and do not wait until you start writing a manuscript or start planning a

public presentation before engaging the ITA. Inventions can be disclosed to the ITA on forms available from the ITA webpage ^[11] or by first contacting the ITA staff for a preliminary discussion.

How are inventions and patents managed at UCSF?

As a condition for employment, and subject to state and federal laws, all UC investigators sign an agreement that allows UC to own inventions and other patentable subject matter UC employees create. Furthermore, that same agreement obligates investigators to promptly disclose their inventions to the responsible technology transfer office, which at UCSF is the Office of Innovation, Technology & Alliances (ITA) ^[9].

The ITA also can advise you on:

- Data needed to support your patent application
- What proof of concept data will be important for engaging industry partners
- Market opportunity for your idea
- Resources to help you advance your program

What are WiCell's hESC patent rights?

WiCell holds broad patent rights in the U.S. covering human embryonic stem cells and thus most if not all R&D in this area, academic or commercial, whether with Registry or non-Registry stem cells will most likely be subject to those patent rights. Although WiCell previously required universities to obtain a research license from WiCell so their investigators could conduct human embryonic stem cell research, WiCell ceased asserting its patent rights against not-for-profit research organizations and has stopped requiring universities to take licenses. Several citizens? groups have contested the validity of the WiCell?s patent rights, but no final decision has yet been announced.

How should the origins and derivation of new materials be documented to ensure their future value to researchers and commercial entities?

Complete and accurate records should always be kept for research and patent purposes. While keeping detailed information about donors, including their identities, may increase the value of new materials, ethical considerations and individual donors? preferences may limit the information that can be kept or disseminated.

Sponsors such as the CIRM and NIH may have other, specific requirements for reporting derivation and certification of human embryonic stem cell lines and iPS cell lines.

The GESCR Committee will ask each PI to state the number and ID of each cell line derived during the prior approval period. This information should be provided on the Status Report form submitted with the renewal application.

What are the different roles and responsibilities for stem cell research at UCSF?

Executive Vice Chancellor (EVC)

The EVC appoints members of GESCR and also may invoke special procedures to resolve disagreements regarding stem cell matters.

Associate Vice Chancellor, Research

The EVC has delegated the operational oversight of these guidelines to the Associate Vice Chancellor of Research.

Principal Investigator

In conducting hESC research the PI must conduct their research in compliance with applicable federal and state regulations, restrictions on use of federal funds, and any conditions of approval issued by GESCR, IRB, IBC or IACUC. Enforcement and sanctions shall be in accordance with the Faculty Code of Conduct (APM-015). [12]

HRPP

The HRPP [13] is responsible for providing administrative assistance to the UCSF Human Gamete, Embryo and Stem Cell Committee (GESCR), for collecting and reviewing proper completion of all GESCR application forms, and coordinating the review of all applications with the GESCR Committee as needed. Additionally they are responsible for establishing and maintaining a registry of UCSF hESC investigators, the types of research being carried out, and the hESC lines in use and serving as the office of record for all GESCR application and approval records.

GESCR

GESCR functions as the Stem Cell Research Oversight (SCRO) Committee for the UCSF campus. It is responsible for:

- Developing procedural guidelines for human stem cell research on campus that are in accordance with appropriate government regulations.
- Establishing categories of research that require different levels of review by GESCR.
- Reviewing, requiring modification, or disapproving human stem cell research protocols.
- Reviewing and making recommendations on ethical issues regarding human stem cell research when requested by the EVC Research, Campus oversight and advisory committees, or individual researchers.
- Overseeing requirements for training in human stem cell ethics as required under guidelines from the National Academies of Science [14], and the California Institute for Regenerative Medicine [15].

Resources

Outside Links

- American Society for Cell Biology [16]

- California Institute for Regenerative Medicine (CIRM) [15]
- National Academies' Guidelines for Human Embryonic Stem Cell Research [17] (Free PDF copy)
- National Academies Human Embryonic Stem Cell Research Advisory Committee [14]
- NIH FAQs [18]

UCSF Links

- UCSF Eli and Edyth Broad Center of Regeneration Medicine and Stem Cell Research [19]
- Environmental Health and Safety [7]
- Institutional Animal Care and Use Committee (IACUC) [20]
- Office of Sponsored Research (proposals and awards) [21]

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Links

[1] <http://stemcells.nih.gov/>

[2] <http://irb.ucsf.edu/review-process-gescr>

[3] <http://www.ehs.ucsf.edu/biological-safety-program-0>

[4] <http://iacuc.ucsf.edu/>

[5] http://grants.nih.gov/stem_cells/registry/current.htm

[6] http://controller.ucsf.edu/pam/cas_guidelines.asp

[7] <http://www.ehs.ucsf.edu/>

[8] <https://ita.ucsf.edu/researchers/mta>

[9] <https://ita.ucsf.edu/>

[10] <http://industry.ucsf.edu/icd/home.html>

[11] <https://ita.ucsf.edu/researchers/commercialize-invention/disclose>

[12] http://www.ucop.edu/academic-personnel-programs/_files/apm/apm-015.pdf

[13] <http://www.research.ucsf.edu/chr/index.asp>

[14] <http://nas-sites.org/stemcells/>

[15] <http://www.cirm.ca.gov/>

[16] <http://www.ascb.org/>

[17] http://www.nap.edu/catalog.php?record_id=11278

[18] <https://stemcells.nih.gov/info/faqs.htm>

[19] <http://stemcell.ucsf.edu/>

[20] <http://www.iacuc.ucsf.edu/>

[21] <http://osr.ucsf.edu/>