

UC Davis Policy and Procedure Manual

Chapter 220, Research--General

Section 02, Human Stem Cell Research

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Responsible Department: Office of Research

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I. Purpose

This policy describes the requirements, roles, and responsibilities for the review and approval of human stem cell research to ensure that the derivation, procurement, and use of human stem cells and the conduct of the research is performed in a scientifically responsible and ethical manner, and complies with all federal, state, and University regulations. This policy applies to all human stem cell research conducted at UC Davis regardless of funding source.

II. Policy

- A. UCD activities involving human stem cell research, regardless of the type of stem cells or whether the stem cells are adult or embryonic, shall be conducted in compliance with the applicable University, state, and federal regulations governing such research, including any restrictions on the use of federal funds for such research.
- B. All research involving human stem cells must be reviewed by the Stem Cell Research Oversight Committee (SCRO) at least once each year.
- C. Additional approvals must be obtained from the Biological Safety Administrative Advisory Committee (BSAAC) or other committees such as the Institutional Animal Care and Use Committee (IACUC) or Institutional Review Board (IRB) as appropriate.
- D. Investigators conducting research deriving new human embryonic stem cell lines or using human embryonic stem cells that are not on the NIH Human Embryonic Stem Cell Registry must financially separate the direct and indirect costs of the research and charge the costs to a non-federal funding source as described in the Guidance Related to Fiscal Management of Stem Cell Research at UC Davis.
- E. Clinical personnel who have a conscientious objection shall not be required to provide information to donors or secure donor consent for the use of gametes or embryos in research.
 1. Personnel must notify their manager of the objection.
 2. Managers shall consult Employee and Labor Relations for advice consistent with applicable personnel policies and labor agreements when considering objection notices.
 3. The privilege for conscientious objection shall not extend to the care of a donor or recipient.

III. Roles and Responsibilities

- A. Vice Chancellor--Research
 1. Is responsible for the UC Davis human stem cell research oversight program.
 2. Selects and appoints members of the SCRO.
 3. Recommends, subject to review of the SCRO, remedial action in the event of a violation of applicable University, state, or federal regulations.
 4. Provides staff support to the SCRO.
- B. Institutional Review Board (IRB) -- Reviews and approves, requires modification, or disapproves human stem cell research studies involving human subjects.

C. SCRO Committee

1. Performs scientific and ethical review of all human stem cell research.
2. Approves, requires modification, or disapproves human stem cell research studies.
3. Oversees and monitors issues related to acquiring and using human stem cell lines for research.
4. Develops educational programs for investigators conducting human stem cell research.
5. Reviews instances of noncompliance with University, state, and federal policies regarding human stem cell research.
6. Provides information regarding human stem cell research to government agencies as required by law.
7. Transmits copies of Human Stem Cell Research Applications to Accounting and Financial Services when necessary.

D. Principal Investigators (PI)

1. Understand and comply with applicable University, state, and federal regulations.
2. Ensure that all personnel engaged in the research project comply with applicable University, state, and federal regulations.
3. Submit a completed Human Stem Cell Research Application to the SCRO Committee for approval prior to starting research.
4. Obtain applicable approvals required by the SCRO Committee, IRB, BSAAC, or IACUC.
5. Obtain approval from the SCRO Committee for proposed changes to a protocol prior to initiating the change.
6. Obtain continuing SCRO Committee approval prior to the expiration date of the current protocol.
7. Provide the SCRO Committee with any information or documents requested.
8. Complete training as required by the SCRO Committee.
9. Conduct research in accordance with financial management guidelines provided by Accounting and Financial Services.
10. Obtain any necessary Material Transfer Agreements (MTA) prior to starting research, complying with all provisions of the MTA or any other agreement associated with the acquisition.
11. Distribute human embryonic stem cells or their derivatives only with specific written approval to do so from the entity providing the stem cells.
12. Record all information and maintain documents as required by applicable University, state, and federal regulations.

E. Accounting & Financial Services

1. Reviews Human Stem Cell Research Applications forwarded by the SCRO and advises the PI regarding specific restrictions or information requirements related to financial management and costing policy.
2. Provides all PIs and financial administrators with guidelines outlining processes required for maintaining clearly delineated and separate financial records and identifying other

physical resources as appropriate.

IV. Violations

- A. Violations of this policy or federal or state laws or regulations regarding human stem cell research shall be reported to the SCRO committee.
- B. The SCRO committee may be required to report noncompliance to the relevant government agency.
- C. Noncompliance may be grounds for discipline under the applicable University policy.

V. Further Information

For further information, contact Research Compliance, (530) 747-3943.

VI. References and Related Policies

- A. UCD Policy and Procedure Manual:
 - 1. Section 290-30, Use and Care of Animals in Teaching and Research.
 - 2. Section 290-55, Biological Safety.
- B. Federal laws and regulations
 - 1. OMB Circular A-21: Cost Principles for Educational Institutions (<http://www.whitehouse.gov/omb/circulars/a021/a021.html>).
 - 2. National Institutes of Health, Stem Cell Information (<http://stemcells.nih.gov/index.asp>).
- C. California laws and regulations
 - 1. Health and Safety Code
 - a. Sections 125118-125119.5, California Embryonic Stem Cell Guidelines (CA Codes (hsc:125050-125119.5)).
 - b. Sections 125300-125320, Embryo Registry (<http://www.leginfo.ca.gov/cgi-bin/displaycode?section=hsc&group=125001-126000&file=125300-125320>).
 - c. Section 125330-125355, Procuring of Oocytes for Research.
 - 2. California Code of Regulations, Title 17, Sections 100010-100110.