UC Berkeley Human Stem Cell Research Policy
June 23, 2022

1. Purpose

This policy is intended to ensure that all research involving the derivation or use of human stem cells at UC Berkeley is conducted with the highest ethical and scientific research standards, and in compliance with all applicable federal and state regulations, including the California Institute for Regenerative Medicine (CIRM) and California Department of Public Health (CA DPH) regulations, UC policies, and the requirements of extramural research sponsors.

2. Authority

These policies are issued by the Vice Chancellor for Research under the authority delegated by the Chancellor of the University of California, Berkeley. The Vice Chancellor for Research (VCR) is the UCB official authorized to approve stem cell research projects on campus. The VCR may delegate this authority to another campus official.

3. Definitions

human pluripotent stem cell line: A culture-derived, human stem cell population that is capable of: 1) sustained propagation in culture; 2) self-renewing to produce daughter cells with equivalent developmental potential, and 3) differentiation into mesoderm, ectoderm and endoderm. This definition includes both embryonic and non-embryonic human stem cell lines regardless of the tissue of origin.

human adult stem cell line: A culture-derived stem cell population established from a differentiated human tissue, including umbilical cord or placenta, capable of: 1) sustained propagation in culture; 2) self-renewing to produce daughter cells with equivalent developmental potential; and 3) differentiation into one or more adult cell types.

"human stem cell": For the purposes of this policy, "human stem cell" refers to both human pluripotent and human adult stem cell lines.

somatic cell nuclear transfer (SCNT): The transfer of a somatic cell nucleus into an oocyte.

Stem Cell Research Oversight (SCRO) Committee: A campus committee appointed by the Vice Chancellor for Research and charged with review and approval of human stem cell research performed at UC Berkeley.

4. Policy

4.1 Research using human stem cells may be conducted at UC Berkeley, subject to the terms, conditions, and requirements of this Policy, and in conformance with all applicable federal and state regulations, as well as those of the University of California, and extra-mural research sponsors.

4.2 The following types of research on or with human stem cells are prohibited at UC Berkeley:

A. Human reproductive cloning as defined in California Health and Safety Code

Section125292.10. subdivision (k).

B. Reproductive uses of SCNT as are prohibited by article XXXV section 3 of the California Constitution.

C. In vitro culture of any product of sperm/egg fertilization, SCNT, parthenogenesis or androgenesis, beyond the appearance of the primitive streak or after 12 days, whichever is earlier. The 12-day prohibition does not count any time during which the embryo and/or cells have been stored frozen.

D. The introduction of human pluripotent stem cells into non-human primate embryos.

E. The introduction of any pluripotent stem cells, whether human or nonhuman, into human embryos.

F. Breeding any animal into which human pluripotent stem cells have been introduced.

G. The transfer of a genetically modified human embryo to a uterus.

4.3. Prior to commencing research using human stem cells or deriving human stem cell lines, UC Berkeley investigators must have their research protocol approved by the campus Stem Cell Research Oversight (SCRO) Committee.

A. SCRO Committee approval will remain in effect for a maximum of one year.

B. SCRO Committee review does not preclude the necessity of review by other research oversight committees as applicable, such as the Committee for the Protection of Human Subjects (CPHS), the Animal Care and Use Committee (ACUC), the Committee on Laboratory and Environmental Biosafety (CLEB), and the Conflict of Interest Committee (COI). Such reviews may take place simultaneously with review by the SCRO committee.

C. Annual protocol renewal reviews will confirm compliance with all applicable rules and regulations. The SCRO committee may establish guidelines and procedures for expedited review of renewals so that review by the entire SCRO committee is not required.

5. SCRO Committee Membership

5.1 The Chair and members of the SCRO Committee are appointed by, and report to, the Vice Chancellor for Research.

5.2 The SCRO Committee will comprise up to 20 members, of which *five* will constitute a quorum with the proviso that the five include one member of the public, one patient advocate, one member with expertise in human stem cell (HSC) research, and one member with expertise in ethical aspects of HSC research.

5.3 The SCRO Committee shall be composed of persons with expertise including, but not

limited to, stem cell research, developmental biology, molecular biology, assisted reproduction, and ethical issues in stem cell research.

5.4 The SCRO Committee shall include at least one non-scientist member of the public who is not employed by, appointed to, or remunerated by UC Berkeley in any capacity other than as a member of research ethics review committees, and is not in the immediate family of a person employed by UC Berkeley. Additionally, the SCRO Committee shall include at least one patient advocate who meets the same affiliation requirements.

5.5 No SCRO Committee member shall have a financial conflict of interest in the research under review.

5.6 No member may participate in the SCRO initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the SCRO.

5.7 SCRO Committee members who are involved in a research project that is being considered by the Committee must recuse themselves from the review and approval of that research project.

5.8 A SCRO Committee member may be reimbursed for reasonable out-of-pocket expenses, not including lost wages, for attending the meeting.

5.9 The usual term of service for committee members is three years; annual appointment for the chair.

6. SCRO Committee Meetings

6.1 The SCRO Committee Administrator will maintain minutes of the meetings and relevant correspondence with investigators, including approvals and disapprovals. The minutes shall be in sufficient detail to show:

A. Attendance at the meetings

B. Actions taken by the SCRO

C. The vote on these actions including the number of members voting for, against, and abstaining

D. The basis for requiring changes in or disapproving research; and

E. A written summary of the discussion of controverted issues and their resolution

6.2 The SCRO Committee Administrator will maintain copies of:

A. Reviewed SCRO protocol applications for new and continuing projects;

B. Reports of adverse events

C. Correspondence with investigators

D. A list of SCRO members

7. SCRO Committee Functions

7.1 The SCRO Committee shall report annually to the California State Department of Health Services on the number of human pluripotent stem cell research projects that the SCRO Committee has reviewed, and the status and disposition of each of those projects, including information on oocyte retrieval collected.

7.2 The SCRO Committee shall also report to the California State Department of Health Services regarding unanticipated problems, unforeseen issues, or serious investigator noncompliance with the requirements or determinations of the SCRO committee.

7.3 The designated SCRO Committee shall provide scientific and ethical review and approval of UC Berkeley research on human stem cell lines as described in section 9 of this policy. The SCRO Committee shall ensure that human stem cell research protocols conform to the research and ethics guidelines and regulations of the organization(s) funding the research.

7.4 In instances of multi-institutional collaboration, the Vice Chancellor for Research may enter into Memoranda of Understanding, permitting the UC Berkeley SCRO Committee to accept the review and approval of the SCRO Committee at another research institution. Likewise, such collaborations and Memoranda of Understanding can allow for the review and approval by the UC Berkeley SCRO Committee of research conducted at another research institution.

7.5 The SCRO Committee shall facilitate the education of investigators and other stem cell researchers with requirements of this policy, as well as the ethical issues surrounding stem cell research.

7.6 The SCRO Committee is responsible for maintaining records pertaining to all human stem cell research conducted at UC Berkeley. Such records must include, but may not necessarily be limited to:

A. A registry of all human stem cell research conducted at UC Berkeley

B. A registry of human pluripotent stem cell lines derived or imported by UC Berkeley investigators

C. A record of every gamete donation, somatic cell donation, embryo donation, or product of SCNT that has been donated, created, or used. This record should be sufficient to determine the provenance and disposition of such materials. However, the SCRO record of these materials will not include uncoded information that would allow donors to be identified.

8. SCRO Committee Review & Notification

8.1 UC Berkeley stem cell research may not commence without SCRO Committee approval in writing. In all cases, the investigator must provide to the SCRO Committee documentation of compliance with any required review of the proposed research by the CPHS, the ACUC, COI, CLEB, or other mandated review. In cases where SCRO Committee review and approval is required, the committee shall notify investigators in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure SCRO Committee approval of the research activity. If the SCRO Committee decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

8.2 SCRO Review Appeals Process

If a researcher disagrees with the decision of the SCRO Committee, s/he can request an opportunity to present her/his case before the entire membership of the SCRO. Appeals must be in writing and submitted directly to the SCRO Administrator prior to an investigator's personal presentation to the SCRO. Appeal decisions will be made by a "super majority" consisting of two thirds of the entire membership. Members unable to attend such an appeal review in person, must participate via video or other appropriate synchronous real-time electronic communication

8.3 Levels of Review:

A. Full Committee Review:

i. Review conducted by at least a quorum of the SCRO Committee. Full Committee Review may be held by tele/video conference or other appropriate synchronous real-time electronic communication.

ii. Full Committee Review is required for new protocols that involve human stem cell research:

a. Involving procurement of human oocytes

b. Involving use of fertilized human oocytes or blastocysts

c. With the aim to derive or create a human pluripotent stem cell line

d. Introducing human pluripotent stem cell lines into non-human animals or introducing human neural progenitor cells into the brain of non-human animals at any state of embryonic, fetal, or postnatal development

e. Introducing human pluripotent stem cell lines into a live born human

B. Expedited Review: Expedited review means the chair and other qualified member with expertise in the relevant science on the committee has the authority to review and approve a protocol or request modifications in order to approve a protocol without

convening a quorum of the committee. If the new protocol does not require full Committee review based on the definition above, it may be reviewed at the expedited level. A protocol under expedited review may be referred to the SCRO for a full committee review at the discretion of the designated reviewer or any Committee member.

C. Administrative Review:
    i. Review performed by SCRO Committee Administrator with approval by the SCRO chair, including applicable annual review, iPSC notifications, and non-substantive amendments to personnel and/or funding source.

    ii. UC Berkeley research that is purely in vitro utilizing previously derived human pluripotent stem cell lines may not commence without written notification to and approval by the SCRO Office, via administrative review with concordance by the committee chair. The notification shall:

        a. Provide assurance that all pluripotent stem cell lines have been ethically derived.

        b. Provide documentation of approval by ACUC, COI, CLEB, or other mandated review.

8.4 Annual Review: Annual reviews that include amendments are subject to the same review category determinations as an initial or amendment review. Annual review applications with amendments as described under 8.3A ii. a- e must go FCR. Annual review applications with in vitro procedural changes involving hESC will undergo Expedited review. All other non-substantive changes may undergo Administrative review, with the Chair's approval.

9. **Acceptable Practices for the Procurement and/or Derivation of Research Materials**
All human pluripotent stem cell lines that will be used in UC Berkeley research must be acceptably derived. To be acceptably derived, the pluripotent stem cell line must have either:

A. Been listed on the National Institutes of Health Human Embryonic Stem Cell Registry, or

B. Been deposited in the United Kingdom Stem Cell Bank, or

C. Been derived by, or approved for use by, a licensee of the United Kingdom Human Fertilisation and Embryology Authority, or

D. Been derived in accordance with the Canadian Institutes of Health Research Guidelines for Human Stem Cell Research under an application approved by the National Stem Cell Oversight Committee, or

E. Been derived under the following conditions:
    i. Donors of gametes, embryos, somatic cells or human tissue gave voluntary and

informed consent.

ii. Donors of gametes, embryos, somatic cells or human tissue did not receive valuable consideration. This provision does not prohibit reimbursement for permissible expenses as determined by an Institutional Review Board (IRB).

iii. A person may not knowingly, for valuable consideration, purchase or sell gametes, embryos, somatic cells, or human tissue for research purposes. This provision does not prohibit reimbursement for permissible expenditures as determined by an IRB or SCRO Committee. “Permissible expenditures” means necessary and reasonable costs directly incurred as a result of persons, not including human subjects or donors, providing gametes, embryos, somatic cells, or human tissue for research purposes. Permissible expenditures may include but are not limited to costs associated with processing, quality control, storage, or transportation of materials.

iv. Donation of gametes, embryos, somatic cells or human tissue was overseen by an IRB (or, in the case of foreign sources, an IRB-equivalent).

v. Individuals who consented to donate stored gametes, embryos, somatic cells or human tissue were not reimbursed for the cost of storage prior to the decision to donate.