

**STEM CELL RESEARCH OVERSIGHT
APPLICATION TO CONDUCT HUMAN STEM CELL RESEARCH**



PPM 220-02 governs the conduct of human stem cell research at the University of California, Davis. Please read this policy prior to completing this application ([PPM 220-02 Stem Cell Research](#)).

Principal Investigator:	
Phone #:	Email:
Department:	
Contact Person (Name, Phone #, Email):	
Title of the Research:	
Funding Source (including Grant # if applicable):	
Location of the Study:	

HUMAN STEM CELL LINES

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RESEARCH PERSONNEL

Name	Employee ID #	Title	Department

ADDITIONAL REQUIREMENTS

Depending on the scope of the research, you may need to obtain additional approvals from the Biological Safety Administrative Advisory Committee (BSAAC), the Institutional Animal Care and Use Committee (IACUC), and/or the Institutional Review Board (IRB). Additionally, you must obtain a Material Transfer Agreement (MTA) from the entity providing the stem cells. You must obtain these approvals/agreements **prior** to SCRO Committee review of your application. Attach copies of approvals/agreements to this application.

JUSTIFICATION AND PROJECT DESCRIPTION

Although some of the information requested below may be redundant with the information provided in your IRB and/or IACUC protocol, the SCRO Committee asks that you provide this information in order to facilitate its review.

1. Provide a description of the project.

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2. Provide assurance that all covered stem cell lines have been acceptably derived. (See the [CIRM Regulations](#) Chapter 2 for further guidance).

3. State the scientific rationale for the project.

4. Describe the procedures to be used.

5. Do any of the investigators or key personnel working on this project (or their spouses, domestic partners or dependent children) have any financial interests related to the research sponsor, other entities associated with the project, or the work to be performed under the proposed project? If yes, please obtain approval from the Conflict of Interest Committee. For further guidance, please go to [Office of Research Financial Conflict of Interest](#).

Please check any of the following that apply to your research and answer the applicable questions.

- Research involving human embryonic stem cells (including somatic cell nuclear transfer (SCNT)).**

Are the embryonic stem cell lines used, derived or collected in this research on the existing NIH Human Embryonic Stem Cell Registry?

- Yes. NIH Code:

No. Complete and submit Appendix A with this application. NOTE: You may not use federal funds to support this research.

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

- Evaluate the probable pattern and effects of differentiation and integration of the human cells into the non-human animal tissues.
- Will human pluripotent cells be placed in non-human primate blastocysts?
- If any human pluripotent cells are introduced into a non-human animal at the blastocyst stage, how are you guaranteeing that the animals will not breed?

Research involving the derivation or creation of new embryonic or other human pluripotent stem cell lines (through somatic cell nuclear transfer (SCNT) or work on donated blastocysts or created embryos).

- How long will blastocysts be kept developing in culture?
- If the research involves SCNT, provide a justification.
- Is there any payment or reimbursement to any donors of gametes, blastocysts, or somatic cells?
- Document how stem cell lines will be characterized, validated, stored, and distributed to ensure that the privacy of the donor is protected, and confidentiality of identifiable information is maintained.
- Describe the Principal Investigator's experience, expertise or training in derivation or culture of human or nonhuman stem cell lines.
- Provide a copy of the IRB approved informed consent documents that were used to obtain any gametes, blastocysts, or somatic cells.

Research involving human oocytes in stem cell research or somatic cell nuclear transfer. (SCNT)

- State the number of oocytes needed and provide a justification for using this quantity.
- If the research involves SCNT, provide a justification.
- Describe the Principal Investigator's experience, expertise or training in derivation or culture of human or nonhuman stem cell lines.
- Provide a copy of the IRB approved informed consent document.

Research involving human embryos in stem cell research.

- State the number of embryos needed and provide a justification for using this quantity.
- Describe the Principal Investigator's experience, expertise or training in derivation or culture of human or nonhuman stem cell lines.
- Provide a copy of the IRB approved informed consent document.

Research involving introduction of stem cell lines into humans.

- Evaluate the probable pattern and effects of differentiation and integration of the human cells into human tissues.
- Provide a copy of the IRB approved informed consent document.

CERTIFICATION: I certify that I have reviewed PPM 220-02, the UC Davis policy on Stem Cell Research and that the information provided on this form is true and correct to the best of my knowledge.

Principal Investigator: _____ Date: _____

Submit this completed application via email to: RECO@ucdavis.edu

FOR COMMITTEE USE ONLY

SCRO Chair / Designee: _____ Approval Date: _____

Extramural Accounting Review Required. Sent to Extramural Accounting on _____.

STEM CELL RESEARCH OVERSIGHT

APPENDIX A: SUPPLEMENT FOR RESEARCH INVOLVING HUMAN EMBRYONIC STEM CELLS NOT LISTED ON THE NIH REGISTRY

Submit this supplement to the SCRO Committee with the Application to Conduct Human Stem Cell Research.

Principal Investigator:	
Phone #:	Email:
Department:	
Contact Person (Name, Phone #, Email):	
Title of the Research:	

1. List the location of non-federally funded facilities used for this research and the DaFIS account and fund number(s) supporting this research.

Building	Room	DaFIS Acc't #	Fund #

2. Is there any other research activity in any of the rooms listed in # 1?

- No
 Yes - If yes, please provide the following information about the other research activities:

Activity	Building	Room	DaFIS Acc't #	Fund #

3. **Equipment Identification:** (List all equipment planned for use in the stem cell research. Attach additional pages if necessary.)

Property Number	Description	Serial ID	Building