This stem cell research protocol, signed by the Principal investigator (PI), must be submitted for all human embryonic and induced pluripotent stem cell research. Submit the form to scro\_office@berkeley.edu. For more information, see <https://rac.berkeley.edu/scro.html>.

Tip: When completing tables below, highlight the cell before entering text. Use the tab key and shift+tab keys to navigate within the fields.

**Part I: PROJECT INFORMATION**

**Protocol Title:**

**Principal Investigator:**

**Phone:** (   )       **Email:**

**Department/College:**

**Administrative Contact/Lab Manager:**

**Phone:** (   )       **Email:**

**Application Type:** New  Renewal  Amendment  **SCRO # (Office Use):**

**Part II: RESEARCH OVERVIEW AND APPROVALS**

Check either “Yes” or “No” and provide information where requested.

1(a). Do you intend to use human embryonic stem cells (hESCs) in your research?

Yes  / No  If yes, BUA #:       Pending:

If yes, answer 1(b) and 1(c):

1(b). Do you intend to use hESCs that ARE listed on the NIH Registry?

Yes  / No

1(c). Do you intend to use hESCs that ARE NOT listed on the NIH Registry?

Yes  / No

2. Do you intend to use human induced pluripotent stem (iPS) cells in your research?

Yes  / No  If yes, BUA #:       Pending:

3. Do you intend to use radiological agents, materials or radiation producing devices in your research? See [EH&S Radiation Safety](https://ehs.berkeley.edu/radiation-safety) for more information.

Yes  / No  If yes, RUA #:       Pending:

4. Do you intend to use lasers of any sort in your research? See [EH&S Laser Safety](https://ehs.berkeley.edu/laser-safety) for more information.

Yes  / No  If yes, LUA #:       Pending:

5. Do you intend to involve vertebrate animals in your research?

Yes  / No  If yes, AUP #:

6. Will this research involve introduction of human pluripotent stem cell lines into non-human animals?

Yes  / No  If yes, provide additional information in Section 3(a).

7. Will this research involve introduction of human neural progenitor cells into the brain of non-human animals?

Yes  / No  If yes, provide additional information in Section 3(b).

8. Do you intend to involve human subjects in your research?

Yes  / No  If yes, CPHS #:

9. Will this research involve the procurement of human oocytes?

Yes  / No

10. Will this research involve the use of fertilized human oocytes, blastocysts or embryos?

Yes  / No

11. Will this research involve introduction of human pluripotent stem cell lines into a live-born human?

Yes  / No

12(a). Will this research involve the derivation of a human pluripotent stem cell line(s)?

Yes  / No

If yes:

12(b). From what cell(s) will the pluripotent cell line(s) be derived?

**Part III: FUNDING (including gifts)**

List all current sources of support for this project.

|  |  |  |  |
| --- | --- | --- | --- |
| Funding Agency / Source | Fund Type (grant/gift/other) | Title of Grant or Project | SPO Proposal / Award # |
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**Part IV: COLLABORATING INSTITUTIONS**

Are there collaborators involved in your stem cell research? Yes  / No  If yes:

UC Berkeley Affiliated Collaborators

|  |  |  |
| --- | --- | --- |
| Principal Investigator | UCB SCRO Approval Date | UCB IRB/IACUC Approval Date |
|  |  |  |
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Non-UC Berkeley Affiliated Collaborators

|  |  |  |  |
| --- | --- | --- | --- |
| Principal Investigator | Institution | Local SCRO Approval and Expiration Date | Local IRB/IACUC Approval and Expiration Date |
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**Human Stem Cell Research Description**

**SECTION 1: PURPOSE AND BACKGROUND OF STUDY**

1(a). Purpose – General: Provide a brief, generalized summary written in lay language. What is your research about and how are stem cells to be involved?

1(b). Using keywords, identify the related disease area(s), if applicable (i.e., who might ultimately benefit from this research).

1(c). Purpose – Specific: Provide an explanation of the proposed research, including specific study hypothesis, objectives, and rationale.

1(d). Background: Summarize relevant background information, including previous or current related studies to place your research in context.

**SECTION 2: RESEARCH DESIGN**

2. Outline the experimental design and methods to be used in the proposed research.

**SECTION 3: INTRODUCTION OF STEM CELLS INTO NON-HUMAN ANIMALS *(if applicable)***

3(a). If you indicated that the proposed research will involve introduction of human embryonic/pluripotent stem cells into non-human animals, then provide the scientific rationale for introduction of human pluripotent stem cells into non-human animals, and evaluate the probable pattern and effects of differentiation and integration of the human cells into the nonhuman animal tissues.

3(b). If you indicated that the proposed research will involve introduction of human neural progenitor cells into the brain of non-human animals, then provide the scientific rationale for introduction of human neural progenitor cells into the brain of non-human animals, and evaluate the probable pattern and effects of differentiation and integration of the human cells into the nonhuman animal tissues.

**SECTION 4: USE OF INDUCED PLURIPOTENT STEM CELLS**

4(a). Will the proposed research involve the use of previously derived human induced pluripotent stem cells?

Yes  / No  If yes, list the provider(s) and cell(s) of origin, and if published, the reference describing the derivation of the iPS cells.

4(b). Will the proposed research involve the derivation of induced pluripotent stem cells from previously existing human cell lines or from human tissues for which the identity of the donor cannot be ascertained?

Yes  / No  If yes, list the cell line(s) or tissues and provider(s).

4(c). Will the proposed research involve the derivation of induced pluripotent stem cells from tissues obtained from identifiable human donors?

Yes  / No  If yes, complete **SECTION 8** of this application.

**SECTION 5: USE OF PREVIOUSLY DERIVED HUMAN EMBRYONIC STEM CELL LINES**

List the name and source of all previously derived human embryonic stem cell lines to be used in the proposed experiments. List only lines currently available in your laboratory, or that you are likely to obtain in the upcoming year. Additional lines in categories 5(a) and 5(b) can be added at any time by contacting the SCRO Office.

5(a). hESC lines **listed** on the **NIH Human Embryonic Stem Cell Registry**, to be used in the proposed experiments.

|  |  |  |
| --- | --- | --- |
| Cell Line | NIH Registration Number | Provider/Submitting Organization |
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5(b). hESC lines **not** listed on the NIH Human Embryonic Stem Cell Registry, but **considered without further documentation** to be **acceptably derived**, to be used in the proposed experiments. hESC lines in this category must be deposited in the United Kingdom Stem Cell Bank, **or** derived or approved for use by a licensee of the United Kingdom Human Fertilization and Embryology Authority, **or** derived under approval of the Canadian National Stem Cell Oversight Committee **or** derived in accordance with the Japanese Guidelines for Derivation and Utilization of Human Embryonic Stem Cells, **or** be derived in accordance with California Code of Regulations, title 17, section 100090. List all cell lines, where they were derived, and the agency that assured that the cell line was acceptably derived.

|  |  |  |
| --- | --- | --- |
| Cell Line Provider’s Code | Provider (Institution) | Agency Approving Derivation |
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5(c). hESC lines **not** registered or approved by any of the agencies listed in 5(a) or 5(b). List the name of each cell line, the principal investigator responsible for derivation of the cell line, and the principal investigator’s institution. **Attach copies of the provider institution’s IRB (or equivalent) and SCRO (if applicable) approvals for material procurement and hESC derivation** to this application.

|  |  |  |
| --- | --- | --- |
| Cell Line Provider’s Code | Principal Investigator | Provider (Institution) |
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**SECTION 6: USE OF NON-NIH REGISTRY hESC LINES**

6(a). Describe your plan to ensure that federal funds are not used to support research using hESC lines not listed on the NIH Stem Cell Registry.

6(b). Personnel: Provide the following information for all personnel working with non-registry hESCs.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name | Position | Source(s) of salary support (fund #, % time) | % time  working on non-registry hESCs | % time  working on NIH  hESCs | % time working on other projects |
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6(c). Facility: Will non-NIH registry hESC work be performed in a separate room(s), designated for this purpose?

Yes  / No  If yes, which rooms?

If no, where will non-registry hESC research be performed, and how will this research be physically isolated from any federally funded research?

6(d). Equipment (property with a useful life of more than one year and an acquisition cost of $5,000 or more):

List the name and inventory number of all equipment to be used with non-registry hESCs, and the name of the administrator who has verified that the equipment can be used for this purpose.

6(e). Expendable materials, supplies, travel and purchased services:

List the fund numbers of all sources of support for these items to be used with non-registry hESCs. Describe how materials and supplies will be segregated from those purchased with federal funds.

**SECTION 7: RESEARCH INVOLVING THE PROCUREMENT OF HUMAN OOCYTES**

If human oocytes will be procured in the course of the proposed studies,address the following questions in the space below, or check “Not Applicable.”

(1) Provide an acceptable scientific rationale for the need to use oocytes, including a justification for the number needed.

(2) If somatic cell nuclear transfer is proposed, provide a justification for the use of this procedure.

(3) Discuss the experience, expertise or training of research personnel in derivation or culture of human or nonhuman stem cell lines.

(4) Describe the plan for maintenance of written records of all oocyte donations, to include demographics of subjects, provenance and disposition of donated oocytes, and adverse health outcomes resulting from oocyte retrieval, and the plan for assuring that donor confidentiality is maintained, as required by CA state law.

(5) Attach all CPHS protocol forms to this application.

Not Applicable **or**

Answers to questions (1), (2), (3), (4), and (5):

**SECTION 8: RESEARCH INVOLVING THE USE OF FERTILIZED HUMAN OOCYTES, HUMAN BLASTOMERES, HUMAN BLASTOCYSTS OR HUMAN EMBRYOS**

If fertilized human oocytes, human blastomeres, human blastocysts or human embryos will be used in the course of the proposed studies, address the following questions in the space below, or check “Not Applicable.”

(1) Provide an acceptable scientific rationale for the need to use fertilized human oocytes, human blastomeres, human blastocysts, or human embryos, including a justification for the number needed.

(2) Discuss the experience, expertise or training of research personnel in derivation or culture of human or nonhuman stem cell lines.

(3) Attach all CPHS protocol forms to this application.

Not Applicable **or**

Answers to questions (1), (2), and (3):

**SECTION 9: RESEARCH INVOLVING THE DERIVATION OF HUMAN PLURIPOTENT STEM CELL LINE(S) FROM GAMETES OR EMBRYOS; OR FROM SOMATIC CELLS OR TISSUES OF IDENTIFIABLE HUMAN DONORS**

If human pluripotent stem cell line(s) will be derived or created from human gametes or embryos, or from somatic cells or tissue of identifiable human donors in the course of the proposed studies, address the following questions in the space below, or check “Not Applicable.”

(1) Provide an acceptable scientific rationale for the need to derive human pluripotent cell line(s), including a justification for the number needed.

(2) If somatic cell nuclear transfer is proposed, provide a justification for the use of this procedure.

(3) Demonstrate the experience, expertise or training of research personnel in derivation or culture of human or nonhuman stem cell lines.

(4) Document how stem cell lines will be characterized, validated, stored, and distributed, and the method of ensuring that the confidentiality of the donor(s) is protected.

(5) Attach all CPHS protocol forms to this application.

Not Applicable **or**

Answers to questions (1), (2), (3), (4), and (5):

**SECTION 10: RESEARCH INVOLVING INTRODUCTION OF HUMAN PLURIPOTENT STEM CELLS INTO A LIVE-BORN HUMAN**

If human pluripotent stem cell line(s) will be introduced into a live-born human in the course of the proposed studies, address the following questions in the space below, or check “Not Applicable.”

(1) Provide an acceptable scientific rationale for introducing human pluripotent cells into humans.

(2) Demonstrate that all human pluripotent stem cell lines to be used were acceptably derived.

(3) Evaluate the probable pattern and effects of differentiation and integration of the human cells into the recipient human tissues.

(4) Attach all CPHS protocol forms to this application.

Not Applicable **or**

Answers to questions (1), (2), (3), and (4):

**INVESTIGATOR ASSURANCE**

I certify that the information provided in this application is complete and correct to the best of my knowledge.

I acknowledge my responsibility to conduct this study according to the requirements of the UC Berkeley Human Stem Cell Research Policy, California State and U.S. Federal laws, and the regulations of the agencies funding this work.

If any changes to this study are needed (e.g., a change in the answer to any questions in Parts II or III from “No” to “Yes”), I will contact the SCRO Office and await approval before implementation.

|  |  |  |  |
| --- | --- | --- | --- |
| Principal Investigator Signature: |  | Date: |  |

Please sign the form and submit this protocol to the SCRO Office. You may choose to convert this to a PDF to add your electronic signature.