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|  | **Human Stem Cell Research Oversight (hSCRO)**  **New Application for hSCRO Review**  *Version Sept 2020* | |
| Submit this application and any supplemental documentation to the hSCRO Administrator ([OR-hSCRO@exchange.uci.edu](mailto:OR-hSCRO@exchange.uci.edu)) | | **hSCRO USE ONLY –**  **hSCRO#:** |

Activities that Require UCI hSCRO Review

1. Generation of new lines of human pluripotent stem cells from whatever source and by whatever means.
2. Use of human gametes, human embryos, human adult pluripotent, human fetal tissue, human fetal stem cells, or, human embryonic stem cells.
3. Transplantation of neural stem cells into humans.
4. Activities involving the introduction of human adult pluripotent, human fetal tissue, human fetal stem cells, human embryonic stem cells, or their neural derivatives into nonhuman animals at any stage of embryonic, fetal, or postnatal development; provided that investigators evaluate the probable pattern and effects of differentiation and integration of the human cells into the nonhuman animal tissues.
5. Activities in which the identity of the donors of blastocysts, gametes, or somatic cells from which human stem cells were derived is readily ascertainable or might become known to the investigator.

For more information, check the link <https://www.research.uci.edu/compliance/hscro/activities-that-require-hscro-review.html>.

Activities that are reviewed and approved by UCI hSCRO may require additional review by UCI IRB, IACUC, IBC and/or COI committees. The review of other regulatory committees will be [concurrent](https://www.research.uci.edu/compliance/human-research-protections/docs/chart-ancillary-committee-review-needed.pdf) with the hSCRO review.

**All new research protocol submissions must be reviewed by the hSCRO Full Committee.**

**SECTION 1: INVESTIGATOR AND STUDY INFORMATION**

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| Provide the below information for the Principal Investigator and study information. |
| PRINCIPAL INVESTIGATOR: <Type here>  DEPARTMENT OR RESEARCH UNIT: <Type here>  PRINCIPAL INVESTIGATOR EMAIL: <Type here>  STUDY TITLE: <Type here> |
| **Administrative contact(s)**  **Note:** the individuals listed below will be copied on all future correspondence related to this hSCRO study:  Name: <Type here>  Position/Title and Department: <Type here>  Email: <Type here> |

**SECTION 3: STUDY FUNDING**

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| Indicate how the study costs will be supported. |
| Grant/Sub-award (provide details below)  Contract/Subcontract (provide details below)  Department or campus funds (includes department support, unrestricted funds, start-up funds, etc.)  Non-cash support from manufacturer/sponsor (e.g., free drug, device, research materials)  List all extramural proposals or awards that will support this study:  Agency/Sponsor: <Type here>  Title of Proposal/Award: <Type here>  Award #: <Type here>  PI of Award: <Type here> |

**SECTION 4: OTHER UCI COMMITTEE REVIEWS**

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| Indicate all applicable committee reviews that are required for this research. If a protocol has already been approved specify the protocol number. ***The review by the Committees indicated below may be concurrent with the hSCRO review; however, their approval must precede the hSCRO approval.*** |
| Indicate the status of the **Institutional Biosafety Committee (IBC) review.**  *Note: all research involving the use of human stem cells must be reviewed and approved by the IBC before beginning research procedures.*  *For UCSB: This approval may also be called Biological Use Authorization.*  IBC protocol/or BUA number: \_\_\_\_\_\_\_\_\_\_\_\_ Approved on: \_\_\_\_\_\_\_\_\_\_\_\_ Expires on: \_\_\_\_\_\_\_\_\_\_\_\_  or  submission to IBC is pending  **Other committee reviews:**  Institutional Review Board (IRB)  Institutional Animal Care and Use Committee (IACUC)  Conflict of Interest Oversight Committee (COIOC) |

**SECTION 5: LOCATION AND STORAGE OF CELLS**

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| Complete the below table describing the location or research procedures and storage of the cell line materials used in this study. Add rows if necessary.  If you wish to maintain the cells after the completion of the research, please explain how and where the cells will be maintained. |
| **Location of research and storage: (Building and Room):**  *Example: Building Name - Room XXXX (research – cell culture); Building Name - Room XXXX (storage); Building Name - Room XXXX (research – animal surgery)* |

**SECTION 6: DEPARTMENTAL OR ORGANIZED RESEARCH UNIT (ORU) APPROVAL**

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| The Department Chair’s signature is required if the study will be performed under the auspices of a Department (includes campus centers and school-based research units). If the Department Chair is a member of the research team on this application (including Faculty Sponsor), approval must be obtained from the next highest level of administrative authority (i.e., School Dean, Executive Vice Chancellor).  The Organized Research Unit (ORU) Director’s signature is required if the study will be performed under the auspices of an ORU. If the ORU Director is a member of the research team on this application (including Faculty Sponsor), approval must be obtained from the Vice Chancellor for Research. |
| Department or ORU Assurance Statement:  By signing below, I hereby confirm that I have read the Application for hSCRO Review and hSCRO Protocol Narrative or IRB Protocol Narrative and I certify that:   1. The research is appropriate in design (i.e., the research uses procedures consistent with sound research design, the study design can be reasonably expected to answer the proposed question, and the importance of the knowledge expected to result from the research is known). 2. The Lead Research (and Faculty Sponsor) is competent to perform (or supervise) the study. 3. All study team members have disclosed to the COIOC any personal financial interests in the research. 4. There are adequate resources and funds available to support performance of this research, including costs associated with subject injury if applicable.   \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Typed Name of Signature of Date signed  UCI Department Chair/ORU Director UCI Department Chair/ORU Director |

**SECTION 8: LEAD RESEARCHER CERTIFICATION STATEMENT**

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| **I certify that the following Lead Researcher/Principal Investigators’ responsibilities are met** as follows:  1. Provide accurate **information on applications and forms** submitted for each project.  2. Ensure that all named **individuals on each study have read and understand the procedures outlined in the protocol** and their role on the study.  3. Ensure that all named **individuals on the project have been made aware** of institutional Human Stem Cell Research Oversight Committee (hSCRO) **policies, as well as applicable state and federal regulations** related to stem cell research are available on the [Human Research Protections Program (HRP) website](https://www.research.uci.edu/compliance/hscro/index.html).  4. Certify that e**xperiments and procedures involving stem cell research are performed under lead researcher’s supervision** or **that of another qualified professional** listed on this protocol.  5. Once this research study has received hSCRO approval, any subsequent **changes to the research plan, research team or research materials** (such as source material or cell lines) **will be submitted** for review and approval by hSCRO. *Exception: updates can be made at the time of continuing review when generation of new cell lines is ongoing from previously verified material if collected under an active UCI IRB-approved protocol.*  6. **Report any unanticipated problems** including protocol violations per UCI hSCRO policy.  7. Promptly **provide the hSCRO with any information requested relative to the project**.  8. **Obtain continuing review prior to study expiration** (I understand if I fail to apply for continuing review, approval for the study will automatically expire, and all stem cell research activities must cease until hSCRO approval is obtained).  9. **Promptly and completely comply with the hSCRO decision** when the hSCRO approval for some or all research activities is suspended or terminated.  10. **Submit to an audit review of stem cell research records**. The Compliance & Privacy Office at UCI Health performs ongoing routine reviews of open biomedical research protocols, in an effort to ensure in part that human subject research activities are conducted in accordance with regulations, laws and institutional policies regarding the protection of human subjects.  11. Submit a **final Closing notification (by email)** with UCI hSCRO at the conclusion of this project. |
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