The UCI Human Research Protections (HRP) Program strives to ensure that people with disabilities have access to all services and content. If you experience any accessibility-related issues with this form or any aspect of the application process, email OR-Web-Support@uci.edu for assistance.

INSTRUCTIONS

This information is necessary for the hSCRO to determine that the study complies with the [California Department of Public Health regulations](https://www.cdph.ca.gov/Programs/CFH/DMCAH/HSCR/CDPH%20Document%20Library/HSCR-StemCellResearchGuidelines.pdf) and the [California Institute for Regenerative Medicine regulations](https://www.cirm.ca.gov/our-funding/cirm-stem-cell-grant-regulations) (as applicable). Additionally, the information collected assists the hSCRO in following [UCI hSCRO Policies and Procedures](https://research.uci.edu/wp-content/uploads/2021/03/hscro-policy-and-sops.pdf).

Answer all questions succinctly using non-technical language as much as possible.

* If a question is a numbered list, respond with a corresponding numbered list.
* If a question is not applicable to the research, state “N/A”.
* If a question is not answered, the hSCRO does not know if the question was overlooked. This will result in unnecessary “back and forth” for clarification.

Attach this protocol to the “Basic Study Information” section of the ZOT hSCRO application. Other supplemental documentation (i.e. consent forms, material transfer agreements) can be attached in “Supporting Documents”.

1. **STUDY OVERVIEW**

**Short Title:** Specify the short study title.

|  |
| --- |
|  Click or tap here to enter text. |

1. **STUDY DESIGN**

**Describe the purpose, specific aims, or objectives of the study, and specify the hypothesis or research questions to be studied:**

|  |
| --- |
|  Click or tap here to enter text. |

**Provide the scientific or scholarly rationale for the research, and describe the relevant background information and the specific gaps in current knowledge that this study intends to address:**

|  |
| --- |
| Click or tap here to enter text. |

**Describe the primary outcome variables, secondary outcome variables, and predictors and/or comparison groups as appropriate for the stated study objectives and specific aims:**

|  |
| --- |
| Click or tap here to enter text. |

**List up to ten relevant references/articles to support the rationale for the research:**

|  |
| --- |
| Click or tap here to enter text. |

1. **CELL LINES / TISSUES / MATERIALS PROVENANCE**

**Complete the below table for each cell line / tissue / materials to be used for this research protocol. Add multiple rows by clicking the [+] icon, if necessary.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Material** | **Cell Line Name / Tissue ID #** | **Supplier** | **Provenance / Source Information** | **If registered embryonic cell line, provide the Registry # or hyperlink:** | **Is the cell line / specimen anonymous or de-identified?** |
| Choose an item. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | Choose an item. |

1. **LOCATION AND STORAGE OF CELLS**

**Complete the table below by indicating the location of research procedures and storage of the cell lines / tissues / materials used in the study. Add multiple rows by clicking the [+] icon, if necessary.**

|  |  |  |
| --- | --- | --- |
| **Building Name / Room Number** | **Research Procedures or Storage (check all that apply)** | **If Research Procedures, which type? (e.g., cell culture, animal surgery, etc.):** |
| Click or tap here to enter text. | [ ]  Research Procedures[ ]  Storage | Click or tap here to enter text. |

1. **GENERATION, USE, AND SHARING OF STEM CELLS / TISSUES / MATERIALS**

**Describe the process for the generalization, differentiation, and characterization of any cells that will be used on this protocol:**

|  |
| --- |
| Click or tap here to enter text. |

**Describe the process for expanding, maintaining, and storing the cells:**

|  |
| --- |
| Click or tap here to enter text. |

**Outline the system for quality assurance and control of the cells:**

|  |
| --- |
| Click or tap here to enter text. |

**If the cells will be banked or distributed to other investigators, provide detailed information for the existing bank or receiving investigator(s):**

|  |
| --- |
| Click or tap here to enter text. |

**Indicate how the biospecimens (cells, tissues, etc.) will be maintained should the responsible investigator leave UCI (or UCSB):**

[ ] Responsibility for biospecimens will be transferred to another investigator via Amendment transaction

[ ] Biospecimens will have been depleted or will be destroyed

[ ] Other, *describe/explain*

|  |
| --- |
| Click or tap here to enter text. |

**If you wish to maintain the cells after the completion of the research, please explain how and where the cells will be maintained:**

|  |
| --- |
| Click or tap here to enter text. |

1. **RESEARCH METHODOLOGY**

**Provide a concise description of the study design to include all experiments to be performed. Briefly describe the rationale behind the experiment or the hypothesis being tested (i.e., the reason for performing the procedure). Provide precise definitions of the measures and outcome variables:**

|  |
| --- |
| Click or tap here to enter text. |

1. **CONFIDENTIALITY OF RESEARCH DATA**

**Indicate how the stem cells / tissues / biospecimens are obtained, stored, and secured (check all that apply):**

[ ]  Coded biospecimens or data cell lines

[ ]  Locked lab / refrigerator / freezer / room at UCI / UCI Health with restricted access

[ ]  Locked lab / refrigerator / freezer / room at UCSB with restricted access

[ ]  Other, *describe/explain*

|  |
| --- |
| Click or tap here to enter text. |

**Indicate how stem cell / tissue / biospecimen data from procedures and experiments will be stored and secured (check all that apply):**

[ ]  Encryption or password protection software will be used

[ ]  Secure network server will store data

[ ]  Standalone desktop computer will house data (i.e., computer is not connected to server/internet)

[ ]  Other, *describe/explain*

|  |
| --- |
| Click or tap here to enter text. |