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| **or-logo-stacked** | **Human Stem Cell Research Oversight (hSCRO)**  **Protocol Narrative**  *Version March 2019* | |
| Submit this completed narrative and any supplemental documentation to the hSCRO Administrator ([OR-hSCRO@exchange.uci.edu](mailto:OR-hSCRO@exchange.uci.edu)) | | **hSCRO USE ONLY –**  **hSCRO#:** |
| **Lead Researcher Name:** <Type here> | | |
| **Study Title:** <Type here> | | |

***IMPORTANT NOTE****: For sections such as the background information, aims, outcome variables, methods and procedures, the investigators are encouraged to provide information listed in grant applications to ensure that the Committee has sufficient and complete information for review.*

**NON-TECHNICAL SUMMARY**

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| Provide a brief non-technical summary or synopsis of the study that can be understood by hSCRO members with varied research backgrounds, including non-scientists and non-affiliated members. |
| <Type here>*This summary should not exceed ½ of a page.* |

**SECTION 1: PURPOSE AND BACKGROUND OF THE RESEARCH**

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| 1. Provide the scientific or scholarly rationale for the research. Describe the relevant background information and the specific gaps in current knowledge that this study intends to address. |
| <Type here> |
| 1. Describe the purpose, specific aims or objectives. Specify the hypotheses or research questions to be studied. |
| <Type here> |
| 1. Describe the primary outcome variable(s), secondary outcome variables, and predictors and/or comparison groups as appropriate for the stated study objectives/specific aims. |
| <Type here> |
| 1. List up to ten relevant references/articles to support the rationale for the research. Do not append an extensive NIH-grant-style bibliography. |
| <Type here> *The list of references/citations should not exceed one page in length.* |

**SECTION 2: ROLES AND EXPERTISE OF THE STUDY TEAM**

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| 1. List all research team members who will perform research procedures that includes the use of cells listed on the protocol, interact or intervene with human subjects or will have access to identifiable private information about human subjects. *Include additional rows for Co-researchers and Research Personnel, as needed.* 2. If applicable, list the Faculty Sponsor as a Co-Researcher who will have research oversight responsibilities. |
| **Lead Researcher:**  Name and Degree: <Type here>  UCI net ID/email: <Type here>  Position/Title and Department: <Type here>  Describe expertise/ training:  Role in the study: |
| **Co-Researcher:**  Name and Degree: <Type here>  UCI net ID/email: <Type here>  Position/Title and Department: <Type here>  Team Member will: **[ ]** serve as Faculty Sponsor with research oversight responsibilities  Describe expertise/ training:  Role in the study: |
| **Research Personnel:**  Name and Degree: <Type here>  UCI net ID/email: <Type here>  Position/Title and Department: <Type here>  Describe expertise/ training:  Role in the study: |
| **Research Personnel:**  Name and Degree: <Type here>  UCI net ID/email: <Type here>  Position/Title and Department: <Type here>  Describe expertise/ training:  Role in the study: |

**SECTION 3: CELL LINE USE AND TRACKING**

1. **Storage and Processing of Stem Cells**

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| 1. Describe the process for characterizing the cells. 2. Describe the process for expanding, maintaining, and storing the cells. 3. Outline the system for quality assurance and control of the cells. 4. If the cells will be banked or distributed to other investigators provide detailed information for the existing bank or receiving investigator. 5. **Complete the CELL TRACKING APPENDIX** |
| <Type here> |

**SECTION 4: RESEARCH METHODOLOGY AND STUDY PROCEDURES**

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| 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 and include tables and charts where needed or applicable. |
| <Type here> |

**SECTION 5: CONFIDENTIALITY OF RESEARCH DATA**

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| Indicate **how data and specimens are obtained, stored, and secured**. |
| **Specimens / hardcopy data (check all that apply):**  **[ ] Anonymous or de-identified only** i.e., no access to subject identifiable information via a code key or key destroyed (in this case, re-tracing of donors is not possible):  Lines: all / or specify:  **[ ] Coded specimens or data** – code key kept in separate location or kept by the source of specimens (this allows for re-tracing of donors with the help of the source holding the key)  Lines: all / or specify:  **[ ] Locked** lab/refrigerator/freezer/room at UCI/UCIMC with **restricted access**  Lines: all / or specify:  **[ ] Provide a brief description of how the confidentiality of data/specimens is assured**: <Type here>  Lines: all / or specify:  **Electronic Data (check all that apply):**  **[ ] Encryption or password protection** software will be used  **[ ] Secure network** server will store data  **[ ] Stand alone desktop** computer will house data (not connected to server/internet)  **[ ] Other** (specify here): <Type here> |