

***Human Stem Cell Research Oversight (hSCRO) Application***

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| **A. Demographic Information**  |
| **Date of Submission:** **hSCRO Number:**   |
| **Reason for Submission:** |
| [ ]  New Project | [ ]  Response to Comments | [ ]  Reconsideration  | [ ]  Disapproval resubmission  |
| [ ]  Modification  | [ ]  Renewal | [ ]  Renewal with Modifications  | [ ]  Response to Audit  |
| **Project Title:** |
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| **Principal Investigator** |  |
| First Name  | Last Name | Degree(s) | Faculty Position |
| **School** | **Department** | **Division** | **Specialty** |
|  |  |  |  |
| **Phone** | **E-mail** |
|  |  |
| **Alternative Contact with Knowledge of this Protocol**  |
| First Name  | Last Name |
| **Alternate Contact’s Phone** | **E-mail** |
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| **Co-investigators:**  |
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| **Source of Support (Please check all that apply)** |
| [ ]  Federal[ ]  State [ ]  Commercial[ ]  Foundation[ ]  Internal[ ]  Other: Please Specify:  | Name of Funder | Grant # | Title |
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| **B. Research Facilities**  |
| [ ]  University of Pittsburgh/UPMC Facility  Building(s) & Room Number(s): [ ][ ]  Non University/UPMC Facility  Address: [ ][ ]  hESC Research - If using embryonic stem cells (hESCs), identify the storage and use location(s):  Address: [ ] |
| **C. Qualifications of PI -** Please describe the qualifications of the principal investigator to conduct the proposed research. A bio-sketch should also be included . |

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| **NOTE: Investigators submitting their first hSCRO application are required to complete the Human Stem Cell Research Module:** <http://www.citi.pitt.edu/citi/>  |

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| **D. Categories of Research (Choose ALL that apply)** |
| **Categories 2 – 4 and 7a qualify for Administrative review by the hSCRO Chair (Registration)****The hSCRO approval is in addition to all other required University oversight approvals. Investigators may initiate all the required approval processes (hSCRO, IACUC, IBC, IRB) *in parallel*, following the submission guidelines of each oversight office.**  |
| **2** [ ]  Clinical trial (human subjects) where the administration of stem cells is considered to be experimental  |
| **3** [ ]  Research involving human embryonic stem cells **(hESCs)** on the NIH Registry **NOTE: Research on non-NIH Registry hES cells is NOT permitted using University of Pittsburgh facilities. Investigators must check “Other” and contact the hSCRO Office prior to beginning any research on non-NIH Registry hES cell lines at the University of Pittsburgh.**  |
| **4** [ ]  Transplantation of **ANY** human **stem** cells and/or **cells originating from human iPS cells or ES cells** into **animals EXCEPT** transplantation into an animal embryo, blastocyst, germline, or central nervous system (exception is captured in Category 6)  |
| **7a** [ ]  Other; meeting Administrative review (please describe): **[**  **]****NOTE: Research on non-NIH Registry hES cells is NOT permitted using University of Pittsburgh facilities. Investigators must check “Other” and contact the hSCRO Office prior to beginning any research on non-NIH Registry hES cell lines at the University of Pittsburgh.**  |
| **Categories 1, 5, 6 and 7b require review and approval by the full hSCRO Committee****The hSCRO approval is *in addition to* all other required University oversight approvals. Investigators may initiate all the required approval processes (hSCRO, IACUC, IBC, IRB) *in parallel*, following the submission guidelines of each oversight office.** **Categories 1, 5, 6 and 7b research requires hSCRO Committee approval before final IACUC approval will be granted.**  |
| **1** [ ]  In vitro research involving any type of **human pluripotent stem (hPs) cell** where the experiment is designed or expected to yield **gametes (oocytes or sperm)** |
| **5** [ ]  Transplantation of human stem cells **derived from** adult or fetal gonadal or central nervous system tissue into animals |
| **6** [ ]  Transplantation of **ANY** human **stem** cells and/or **cells originating from human iPS cells or ES cells** into an **animal embryo, blastocyst, germline, or central nervous system**  |
| **7b** [ ]  Other (please describe): **[**  **]****NOTE: Research on non-NIH Registry hES cells is NOT permitted using University of Pittsburgh facilities. Investigators must check “Other” and contact the hSCRO Office prior to beginning any research on non-NIH Registry hES cell lines at the University of Pittsburgh.**  |

| **E. Specific Aim (s) and Experimental Design**  |
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Please address each text field and provide a project description. **The description should provide enough detail to facilitate the hSCRO review of the research. Additional information for animal research is required in the next section.**

Type of stem cell(s): [ ] Source(s) of stem cell/Provider**: [**   **]**

If the project involves **hESCs,** list cell lines being utilized: **[**   **]**

**Specific Aims & Experimental Design:**

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| **F. Animal Research** |
| [ ]  NA - **Go to Section G** |

**Animal Research**: NOTE: the hSCRO application should be congruent with the supporting IACUC protocol(s).

**The following detail is required – Address each bullet point below:**

* **What is the stage of differentiation when cells are transferred?**
* **Indicate the assays used to confirm the stage (e.g. undifferentiated – teratomas formation)**
* **Animal model(s) used:**
* **Indicate the developmental stage of the animal when cells transferred (e.g. fetal, neonatal, adult):**
* **Site(s) AND Route(s) of transplantation:**
* **Describe the methods to assess cell survival and host tissue integration:**

* **Cell migration is theoretically possible. Address the likelihood of cell migration to other sites, how you will assess for migration, and the effects expected of that migration should it occur:**
* **For research involving the transplantation of human stem cells into the central nervous system or germline – address the potential for animals to develop human-like traits. Include the reporting plan should this occur.**
* **Endpoint when the chimeras will be sacrificed:**
* **Per University hSCRO policy, no animal into which any human stem cells have been introduced is allowed to breed. Describe the animal management plan to prevent breeding.**

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| **G. Approvals from other oversight committees *within* the University of Pittsburgh** |
| **Indicate the applicable related approvals from other committees within the University and include the related protocol number. If approval is pending, please note.** [ ]  Institutional Review Board Protocol Number: [ ] [ ]  Institutional Biosafety Committee (IBC) Protocol Number(s): [ ][ ]  Institutional Animal Care and Use Committee (IACUC) Protocol Number(s): [ ] |
| **H. Approvals from IRB committees *outside* the University of Pittsburgh** |
| For clinical trials processed through the UPMC OSPARS Office, please indicate in the space below, the IRB approvals obtained from IRB committees outside the University. **\*\*Please *do not* include the sponsor clinical protocol with the hSCRO application!** [ ] |
| **I. Agreement to Obtain Research Materials** |

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| **J. Agreement for Material**[ ]  Internal Source - Materials are from University of Pittsburgh/UPMC:  Indicate the ***internal*** source(s): [ ][ ]  External Source - Prior to receiving/sending research materials from/to an ***external*** source an appropriate University endorsed agreement/contract must be in place.  External sources may include other universities, the government (e.g. NIH), and the for-profit sector. **Please indicate the agreement in place for the transfer of material**[ ]  MTA (**To initiate the MTA process visit:** [**http://www.research.pitt.edu/ccc-material-transfer-agreements**](http://www.research.pitt.edu/ccc-material-transfer-agreements)**.)** [ ]  MTA Process Initiated [ ]  MTA Process Completed  [ ]  Purchase Order [ ]  Other: Please identify  **[ ]**  |

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| **INVESTIGAGTOR CERTIFICATION** |

* I have reviewed this protocol submission in its entirety and I am fully cognizant of and in agreement with, all submitted statements.
* I have adequate resources and facilities to carry out the proposed research.
* I will comply with the current state and federal regulations and University of Pittsburgh hSCRO policy requirements governing this research.
* I will ensure that all individuals associated with this project have the appropriate credentials to conduct the portion of the study in which they are involved.
* I will ensure that all co-investigators, and other personnel assisting in the conduct of this research study have been provided a copy of the entire current version of the research protocol and are fully informed of the current  (a) study procedures (including procedure modifications); (b) potential risks associated with the conduct of this study and the steps to be taken to prevent or minimize these potential risks; (c) data and record-keeping requirements; and (d) the current approval status of the research study.
* I will respond promptly to all requests for information or materials solicited by the hSCRO Office.
* I will maintain adequate, current, and accurate records of research data, outcomes, and adverse events (if applicable) to permit an ongoing assessment of this research project.

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| **Signature of Investigator:** |  **Date:** |
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**Please submit the electronic hSCRO Application Form and any other related supporting documents to** **hSCRO@pitt.edu**

**If the application is not sent from the Investigator’s e-mail address, a faxed copy of the signature page is required. Investigator must sign and date the Investigator’s Certification page and that one page is to be faxed to the office at 412-383-1769 or alternatively scan and send to** hscro@pitt.edu