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|  | **Submit Applications to:** **Office of Research Integrity and Ethics****Email:** **orie@wustl.edu****Campus Box 1054****Phone: 314-747-0767**  |

**EMBRYONIC STEM CELL RESEARCH OVERSIGHT COMMITTEE (ESCRO) Application**

This application should be submitted for (1) all research using materials derived from a human embryo, including human embryonic stem cell lines and hESC derivatives; (2) research *in vivo* using non-embryo derived hPSC including hiPSC or their derivativesor *in vitro* experiments designed or expected to yield gametes; or (3) research proposing to generate new hESC lines.

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|  | **New [ ]**  | **ESCRO #** | **IRB ID:**  |
| Principal Investigator | (Last) (First) (Credentials) |
| Department/Division |  |
| PI’s Title  |  |
| Faculty Sponsor/Mentor *(Required if PI is a postdoc)* | (Last) (First) (Credentials) |
| Title of Research Project |  |
|  |  |
| Stem Cell line(s) used in this research *(Include NIH Code if applicable)* |  |

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| Sources of Funding that support this research |  |
| [] Industry Sponsor [] Federal Agency (Grant #\_\_\_\_\_\_\_\_\_\_\_\_ **or** Date of expected submission to NIH \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)[] Non-Federal Agency [] Dept [] None |

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| Signature of Principal Investigator Date*I am responsible for the overall conduct of this research and will comply with all applicable federal, state, and local laws and WU policies and procedures. (If a postdoc: I will meet with my mentor regularly and keep him/her apprised of the status of the research.)* |  | Signature of Department Chair Date*My signature affirms that a scientific review of this research has been* *conducted, that the researcher has adequate resources and budget to conduct the research, and represents my approval of the research.* |
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| Signature of Faculty Sponsor/Mentor Date*My signature affirms that I have expertise in the proposed research. I will directly supervise the postdoc and convey the knowledge/ technical skills necessary to perform the procedures described in this proposal.* |  | Chair’s Printed Name |
|  |  |   |
| **FOR ORIE/ESCRO USE ONLY** |
| **ESCRO Scientific Review/****Provisional Approval:** | **HRPO/IRB Approval:** |
| **ESCRO Committee Review/****Final Approval:** | **ESCRO Expiration:** |
| **Signature of ESCRO Chair:** |  |
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**New Application**

1. **Please answer the following questions** (cells will expand as needed)

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| 1. **Please describe in lay language the research aims. Include the specific use and the rationale for the use of hESC lines, human iPSC, or the destruction of human embryos.**
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| 1. Explain why the selected stem cell line(s) will be used (i.e. why was that line selected instead of other available lines?)
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| **Note: For research using hESC lines not on the NIH Registry or the destruction of human embryos:** **I**n order to comply with federal regulations, ESCRO must verify that research using non-NIH registered cell lines or involving the destruction of human embryos does not interfere with the University’s commitment to federally sponsored projects in regard to facilities, equipment, and personnel. You may be contacted with further instructions. |
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| 1. Do you plan to generate new hESC lines?
 | **[ ] No [ ] Yes** |
| If yes, please answer the following questions: |  |
| * Explain the scientific rationale for generating new hESC lines.
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| * Explain the basis for the number of blastocysts or oocytes.
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| 1. **Describe how you plan to acquire the bio-specimens (hESC, iPSC, human embryos)**

For example: from an external stem cell bank (e.g., WiCell); internally from the WU GEiC or a WU investigator; an investigator outside of WU; from patient donors. |  |
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| 1. **Describe the consenting process (**If applicable) **SKIP – If you are using hESC line(s) on the NIH Registry**
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| 1. **Where will the research take place?** Identify all space where the research will be performed. This includes ancillary support rooms such as tissue culture rooms and freezer storage areas (Indicate building, floor, and room number).
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| 1. **Will equipment or supplies that were purchased with federal funds be used in this research?**
 | **[ ] No [ ] Yes** (If yes, please provide details) |
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| 1. **Will personnel be working on this research whose salary is partially or entirely federally funded?**
 | **[ ] No [ ] Yes** (If yes, please provide details) |
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| 1. **If proposing to use hESCs not on the NIH Registry provide: documentation regarding derivation process of donated gametes or blastocysts; IRB approval including informed consent, cell line provenance, and MTAs**
 | **[ ] N/A (**Research does not involve hESCs not on NIH Registry) |

**II. Attachments (for new applications)**

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| **Research Plan/Research Proposal *(required)**** For department-funded research see [ESCRO Research Plan Template](https://research.wustl.edu/ComplianceAreas/StemCells/Documents/Research%20Plan%20Template%205-16-16.docx).
* For sponsored research, attach awarded grant application(s) that supports this research.
 | **[ ] Attached** |
|  |  |
| **Budget for this research *(required)**** For department-funded research see [ESCRO Sample Budget Template.](https://research.wustl.edu/ComplianceAreas/StemCells/Documents/Sample%20ESCRO%20Budget%205-16-16.docx)
* For sponsored research, attach budget(s) submitted with grant application(s).
 | **[ ] Attached** |
|  |  |
| **IBC approval letter *(required) IBC review may occur concurrent with ESCRO review**** IBC approval is required before ESCRO final approval will be made
 | **[ ] Attached** **[ ] Not attached. IBC review is in process.** |
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| **Animal Studies protocol *(if applicable)***Required if transplanting hESC, products derived from a human embryo, hPSC (including hiPSC) or their derivatives into animals at any stage of development or maturity | **[ ] Attached [ ] N/A** |

**III. List all individuals involved in the design, conduct, or reporting of this research** (table will expand)

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| **Name** | **Title** | **Department/Division** |
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**IV. Other Required Reviews/Approvals**

[ ] IRB review/approval

***WU requires ESCRO and IRB approval for all research using human embryonic stem cells***

* Research using only hESC lines on the NIH Registry and only *in vitro* experiments or *in vivo* in animals
	+ Submit ESCRO application.
	+ Upon receipt of “provisional” ESCRO approval letter, contact Mitchell Saulisbury-Robertson, HRPO Manager, to request *non-human research* review.
	+ ESCRO will provide specific instructions with the provisional approval letter.
* Research using hESC line(s) not on the NIH Registry and/or including interaction/intervention with human subjects
	+ Complete application via [*myIRB*](https://myirb.wusm.wustl.edu/) prior to, or the same time as, the ESCRO application is submitted. The myIRB application will be downloaded and included with your ESCRO application. ESCRO review will not be scheduled until a myIRB application is received.

[ ] Material Transfer Agreement

***An MTA or appropriate approval/authorization from the provider of the biospecimen(s) is required after ESCRO approval is obtained. Contact the*** [***Office of Technology Management***](https://otm.wustl.edu/for-inventors/material-transfer/) ***for guidance on how to begin the process.***

**Stem cells may not be obtained, until after the appropriate agreements are in place.**