

# Review Application- Emory Human Embryonic Stem Cell Research Oversight Committee (ESCROC)

## Instructions for Investigators:

Studies involving Human Embryonic Stem Cells (hESCs) or Induced Pluripotential Stem Cells (iHPSCs) will need approval by one of the following bodies:

- **IRB Office:** Any proposed Research that involves hESCs, germ cells, stem cell-derived test articles, and Human Fetal Tissue shall be reviewed by the Emory IRB to determine the applicability of (a) HHS Regulations; (b) FDA Regulations; and (c) other states, federal or local regulatory requirements, depending on the type and location of Research, and the funding source for the Research.
- **hESCROC:** For studies conducted at Emory, by Emory personnel, and involving Human Embryonic Stem Cells (hESCs) or Induced Pluripotential Stem Cells (iHPSCs) not conducted in human subjects or animals.

## Research that is not permitted at this time:

- Research involving in vitro culture of any intact human embryo, regardless of derivation method, for longer than 14 days or until the formation of the primitive streak begins, whichever occurs first.
- Research in which hESCs are introduced into non-human primate blastocysts or any embryonic stem cells is presented into human blastocysts.
- Research in which any products involve human totipotent or pluripotent cells that are implanted into a human or non-human primate uterus
- No animal into which hESCs have been introduced at any stage of development is permitted to breed.

**hESCROC Review-** To apply for hESCROC review, fill out this form, sign, scan, and e-mail to the Office of Research Integrity and Compliance (ORIC) at [oric@emory.edu](mailto:oric@emory.edu) along with the required attachments. Attachments must include:

- This form plus a scientific description of the study design and research procedures. Include the hypothesis to be tested and a general description of the methodology to be used.
- Please also include a scientific rationale for why hESCs are needed to answer the scientific questions.
- If the research plan includes creating new lines, specific permission from the Executive Associate Dean for Research must be included.

Office of Research Integrity and Compliance

<b>A. Identifying Information</b>			
Title of Research Project:			
Principal Investigator:			
First Name:	Last Name:	Degree(s):	Title:
Campus Phone:	Fax:	Pager:	E-mail:
Campus Address:			
Conflict of Interest? <sup>1</sup> Yes      No			
Protocol Correspondent:			
First Name:		Last Name:	
Campus Phone:	Fax:	E-mail:	
Campus Address:			
Conflict of Interest?      Yes      No			
Co-Investigators: (i.e. one who has <i>authority</i> over the conduct of the Research in the PI's absence)			
Name:	Conflict of Interest? <input type="checkbox"/> Yes <input type="checkbox"/> No		
Name:	Conflict of Interest? <input type="checkbox"/> Yes <input type="checkbox"/> No		
Laboratory Personnel (i.e. anyone involved in the conduct of the Research)			
Name:	Conflict of Interest? <input type="checkbox"/> Yes <input type="checkbox"/> No		
Name:	Conflict of Interest? <input type="checkbox"/> Yes <input type="checkbox"/> No		
Name:	Conflict of Interest? <input type="checkbox"/> Yes <input type="checkbox"/> No		
Name:	Conflict of Interest? <input type="checkbox"/> Yes <input type="checkbox"/> No		
Name:	Conflict of Interest? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<b>B. Source of Funding (Check all that apply; use a separate application for Federally-funded projects)</b>			
<input type="checkbox"/> Federal <input type="checkbox"/> State of Georgia <input type="checkbox"/> Commercial <input type="checkbox"/> Foundation <input type="checkbox"/> Internal <input type="checkbox"/> Other (please specify):			
Name of Sponsor(s):			
Grant or Contract Title:			
Grant of Contract #:			
Cell Line Name/Number:			
Principal Investigator of Grant or Contract:			
<b>C. Facilities (Please check all that apply)</b>			
On-Campus	List Building(s) and Room Number(s):		
Off-Campus	List Addresses:		

**D. Categories of Research That Best Describe This Project (If more than one category applies, describe what the project involves in each category, specifying line to be used and facilities to be used for each category)**

**Attach a scientific description of the study design and research procedures. The description should include the hypothesis to be tested and a general description of the methodology used. Please also have a scientific rationale for why hESCs are needed to answer the scientific question. Note: The creation of new lines requires specific permission. Check here if this is the case, and someone will contact you.**

Research that is **not permitted** at this time:

- Research involving in vitro culture of any intact human embryo, regardless of derivation method, for longer than 14 days or until the formation of the primitive streak begins, whichever occurs first.
- Research in which hESCs are introduced into non-human primate blastocysts or any embryonic stem cells is presented into human blastocysts.
- Research in which any products of Research involving human totipotent or pluripotent cells are implanted into a human or non-human primate uterus
- No animal into which hESCs have been introduced at any stage of development is permitted to breed.

**E. Material Transfer Agreements**

Emory University researchers must ensure that a Material Transfer Agreement has been executed before obtaining any human stem cell lines from an external entity.

**Material Transfer Agreement should be negotiated with Grants and Contracts Administration.**

**By signing in this box, I certify that I will use the cells as described in this document and follow the Human Embryonic Stem Cell policy requirements.**

Signature of PI:

Date: