WESLEYAN UNIVERSITY

ESCRO Application Form

Office Use Only
Project #_____
Approval Date_____

Application Date: ☐ New ☐ Amendment ☐ Renewal

A. Identifying Information			
Principal Investigator(s):			
Name(s):			
Department:	**Email:**	**Phone:**	
Study Title:			
Project Start Date:	**Duration:**		
***Contact Person (Name):**			
(Email):	**(Phone):**	**(Fax):**	
**Contact person is required if different than PI. List all study personnel as well, one line per person.*			
***Mailing Address:**			
**This is the address where you would like signed materials delivered.*			
Co-Investigator(s) at Wesleyan University:			
Name:	**Email:**	**Phone:**	**Fax:**
Name:	**Email:**	**Phone:**	**Fax:**
Non-Wesleyan Investigators:			
Name:	**Email:**	**Institutional Affiliation:**	
Name:	**Email:**	**Institutional Affiliation:**	

B. Identify hES Cell Line
Identify hES cell line:

Provenance of hES cell lines (attached documentation, if not NIH approved lines, otherwise indicate NIH code):

C. Source of Funding (Check all that apply)

☐Federal ☐State of Connecticut ☐Commercial ☐Foundation ☐Internal
☐**Other (please specify):**

Name of Sponsor(s):

Grant or Contract Title:

Grant or Contract #:

Principal Investigator of Grant or Contract:

D. ESCRO Approvals

- Attach documentation where IRB approval was obtained
- External ESCRO approval (attach documentation)
- Identify any internal ESCRO approvals by number

E. Facilities (Please check all that apply)

☐**On Campus List Building(s) and Room Number(s):**

☐**Off Campus List Addresses:**

F. Categories of Research That Best Describe This Project (Check all that apply)

Identify category of research being proposed:

☐ Category I ☐ Category IIa ☐ Category IIb ☐Category IIc

Category I. Research that is **permissible after notification** to the ESCRO Committee and completion of the reviews mandated by current requirements:

Purely *in vitro* work with pre-existing coded or anonymous hES cell lines.

- Documentation of the provenance of the cell lines, and evidence of compliance with mandated reviews must be provided to the ESCRO Committee.

Category IIa. Research that is **permissible only after additional review and approval** by the ESCRO Committee:

Work involving the derivation of new hES cell lines.

- The scientific rationale for the need to generate new hESC lines must be presented to the ESCRO Committee.
- The basis for the number of blastocysts or oocytes needed must be justified.
- Requests must be accompanied by evidence of Institutional Review Board (IRB) approval of the procurement process.

Category IIb. Work that introduces hES cells into nonhuman animals:

- Describe the non-human animal used and the state of development (embryonic, fetal, or postnatal) when hES cells will be introduced.
- Describe the probable pattern and effects of differentiation, integration, and/or migration of the human cells with the non-human animal tissue.
- Identify and address ethically sensitive issues raised (attach WACC approval documentation).

Category IIc. hES cell work in which personally identifiable information about the embryo, oocyte or somatic cell donor is readily ascertainable by the investigator.

- If private personally identifiable information about the donor is readily ascertainable by the investigator, IRB approval for the use of material from identifiable donors must specifically address the process by which informed consent was obtained and confidentiality waived (attach complete IRB documentation.

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 formation of the primitive streak begins, which ever occurs first;
- Research involving the introduction of embryonic stem cells obtained from any species (including humans) into human embryos;
- Breeding of animals in which human embryonic stem cells have been introduced at any stage of development.

G. Justification

Justify the use of hES cell lines as opposed to alternate sources of stem-cells in relation to the goals of this project:

H. Intellectual Property

☐ Yes ☐ No

I. Conflict of Interest

Does the principal investigator, any co-investigator, or research coordinator involved with this study have a financial relationship with the source of funding.

☐ Yes ☐ No

If Yes, explain.

J. State Verification Form (attach pdf)

K. Principal Investigator's Certification

As the Principal Investigator of this research project, I certify the following:

- The information provided in this application is complete an accurate.
- All research will be performed according to ethical principles and in compliance with all federal, state and local laws, as well as institutional regulations and policies regarding human embryonic stem cell research.
- All individuals associated with this project have the appropriate credentials to conduct the portion of the study in which they are involved.
- 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.
- Prompt and accurate response will be provided for all requests for information or materials solicited by the ESCRO.
- Complete, current and accurate records of data, outcomes and adverse events will be maintained at all times.
- Approval for this study and any revisions will be obtained prior to initiation.

By signing in this box, I certify that I have read and will comply with responsibilities outlined in H of this document.
Signature of PI:
Date:

Submit Reset