FLORIDA STATE UNIVERSITY

Human Embryonic Stem Cell Research Oversight (HESRAC) Program
Application for Derivation and/or Use of hESCs

Principal Investigator (PI) Information

PI Name:		Job Title:	
Phone:		Email:	
Dept. Name:	Supervisor Name (if PI is not Faculty):		
Admin. Contact Name:		Phone:	Email:

In accordance with FSU's Policy for the Use of Human Embryonic Stem Cells (Policy 7A-30) the derivation of and/or research with a human embryonic stem cell line requires review and approval by FSU's Human Embryonic Stem Cell Research Advisory Committee (HESRAC) **before** the research can begin. HESRAC provides local oversight of the complex ethical issues related to human embryonic stem cell research, including but not limited to subject consent, derivation method, and use in animals.

This application pertains to the derivation of and/or research with **human embryonic stem (hES)** cell lines. This form does not fulfill related IRB project review requirements (if relevant). IRB submissions must be made separately, but compliance reviews for these submissions may be conducted in parallel with the HESRAC Committee review.

Form Instructions: **Sections A and B are required**. **Sections C may be required** if you will be obtaining unregistered hESC lines or deriving new hESC lines. Complete this form in Microsoft Word, print it to sign, then scan to save the form with the signature as a PDF.

Submission Instructions: Click the SUBMIT button after all signatures have been obtained. The form will be emailed automatically to the HESRAC chair at gilbert@bio.fsu.edu. If ink signatures are obtained, send a scan to the HESRAC chair.

Review Process: Prior to committee review, the HESRAC chair may request clarification of information provided on the application form. If approved, the Principal Investigator will receive an approved copy of the application form from the HESRAC Committee.

Questions: Email the HESRAC chair at gilbert@bio.fsu.edu for assistance. Please see https://www.research.fsu.edu/research-compliance/stem-cell-research/ for additional information on the use of human embryonic stem cells at FSU.

SECTION A: CELL LINE INFORMATION

A.1. RESEARCH TYPE (check all that apply)

Note: Related application sections or questions are listed in parenthesis.

Check	Human Embryonic Stem Cells (hESC)
☐	In vitro research with pre-existing NIH-registered hES cell lines
☐	In vitro research with pre-existing hES cell lines that are **NOT** NIH-registered
☐	Human research with hESC
☐	Personally identifiable information from donors linked to hESC
☐	Derivation of new hESC lines

Other Research: (indicate hESC and briefly describe):

A.2. CELL LINE OR SOURCE MATERIAL (list all that apply)

Instructions: Complete the table for each line or material source.

- Indicate the number of lines and whether you are obtaining the line (O) or deriving the line (D) from source material. Spell out the names of providers, commercial vendors, and PIs.
- If the cell line was derived at FSU or the source material for derivation comes from FSU, list the FSU IRB number.
- If the cell line was derived at another institution or the source material for derivation comes from outside FSU, list the vendor or institution's name and the applicable external IRB NUMBER.
- **Attach a copy of the Material Transfer Agreement (MTA) approved by the Office of the Vice President for Research.**
- **Be prepared to provide informed consent and/or transfer agreement documentation upon HESRAC request.**

# of lines	Action: Obtain (O) Derive (D)	Provider / vendor / repository (e.g., patient sample, WiCell, etc.)	Line/source material: • NIH Registry # or Name (e.g., H9) • Vendor # • Cell source: embryo or tissue	FSU IRB # or External IRB name/#

SECTION B: RESEARCH INFORMATION

B.1. OBJECTIVES OF THE RESEARCH (briefly describe; be clear and concise)

B.2. SCIENTIFIC RATIONALE (briefly explain why the proposed experiments require the use of hES cells rather than alternative methodologies)

B.3. PROPOSED EXPERIMENTS (briefly describe; especially work that involves human subjects, non-NIH Registry hES cell lines, or the progeny of hESC in animals)

B.4. LOCATION OF WORK (list the building and room number)

B.5. STORAGE OF LINES WHEN NOT ACTIVELY USED (list the method and location)

B.6. SHARING OF CELLS OR DERIVATIVES

☐ Yes ☐ No

If you check **Yes**, briefly describe your plan for sharing below.

B.7. OTHER RELEVANT INFORMATION (e.g., potential ethical concerns, applicable training for derivation, research collaborators, etc.)

SECTION C: hES CELL LINE RESEARCH

Instructions: **Complete this section only if you will be obtaining unregistered hESC lines or deriving new hESC lines**.

C.1. FUNDING

Instructions: Research with unregistered cell lines is not eligible for NIH funding. List the funding source(s) for personnel, supplies, equipment, and animal care associated with your work with the unregistered cell lines.

Source of support	Title of funded project	Cell line(s) used in project

C.2. FACILITIES AND EQUIPMENT

Does the location(s) identified in **B.4** contain NIH-funded equipment or supplies?

☐ Yes ☐ No

If you check **yes**, list the location (building and room number) and describe the plan for ensuring that federally funded items are not used for work with unregistered cell lines.

C.3. EFFORT

Instructions: List all research personnel involved in this project and their total percentage of NIH-funded effort beginning with the Principal Investigator.

Last Name, First Name, Degree, Title	% Effort (NIH-supported)
(PI):	

Principal Investigator Certification:

I certify that the information provided in this application is complete and correct.

I understand that as Principal Investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, and strict adherence to any stipulations imposed by the HESRAC Committee.

I agree to comply with all Florida State University policies and procedures, as well as with all applicable Federal, State, and local laws regarding human embryonic stem cell research, including, but not limited to, the following:

- Performing the project by qualified personnel according to the approved protocol,
- Seeking advance approval by the HESRAC Committee for any anticipated change in the research represented in this application,
- Compliance with the requirements of relevant Material Transfer Agreements.

I agree not to distribute human pluripotent stem cells or their living derivatives without prospective review and approval by the HESRAC Committee.

Principal Investigator Date

ADDITIONAL APPROVALS

Supervisor if PI is not Faculty Date

Department Chair Date

Dean Date

HESRAC APPROVAL

HESRAC Chair Date

CLEAR FORM SUBMIT FORM