TTUHSC Embryonic Stem Cell Research Oversight (ESCRO) Application

This application should be submitted for research involving the use of human embryonic stem cells, *in vivo* use of human induced pluripotent stem cells in animals, or research that involves risks (i.e. destruction) of human embryos.

Completed forms can be emailed to research@ttuhsc.edu or can be hand-delivered/campus-mailed to the TTUHSC Research Integrity Office (HSC Lubbock Suite 1C165), MAIL STOP 8146.

PART 1—For NEW and Renewal Applications:

☐ **New application**

☐ **Renewal/Update (Provide assigned ESCRO #)**: Click here to enter text.

Principal Investigator (first name, last name, credentials): Click here to enter text.

TTUHSC Campus/Department: Click here to enter text.

Email address: Click here to enter text. **Phone**: Click here to enter text.

Protocol Title: Click here to enter text.

Stem Cell Source if applicable (Please include NIH Code if the source is registered:

Click here to enter text.

Source(s) of Funding (Check and provide details for all that apply):

☐ ☐ Industry sponsor: Click here to enter text.

☐ ☐ Federal Agency (Grant #): Click here to enter text. *OR* Date of expected submission to NIH Click here to enter text.

☐ ☐ Other external funding: Click here to enter text.

☐ ☐ Department or other internal funding Click here to enter text.

☐ ☐ Other: Click here to enter text.

PART 2—For NEW applications only:

2.1 Choose the category or categories that best describe your research (please note that, even in cases where ESCRO review is not required, we need this document to be completed):

☐ ☐ Use of non-Human stem cells (ESCRO review not required)

☐ ☐ Use of human cord blood (ESCRO review not required)

☐ ☐ Transplantation of stem cells as part of a recognized and accepted medical treatment for a disease or condition (ESCRO review not required)

☐ ☐ Creation and *ex vivo* passage of human pluripotent stem cells (hPSC) (ESCRO review not required)

☐ ☐ NIH-Registered Cell Lines (May receive designated/expedited review)

☐ ☐ De-identified cell lines—In vitro research using human stem cells that have been obtained using an IRB-approved process and the cell lines have been de-identified such that the identity will never

be released to the Investigator (Note that you must provide documentation to include provenance of all hES cell lines, evidence of IRB approval of the procurement process. May received designated/expedited review)

☐ New hESC cell line or a new hPSC cell line by any means (Full ESCRO review required)

☐ Animal transplant: Research involving human stem cells being transplanted into animals, except transplantation into animal embryo or animal's germ line or brain (Full ESCRO review required)

☐ Identifiable donors: Research in which personally identifiable information about the donor of the blastocysts, gametes, or somatic cells from which the hESCs or hPSCs were derived is known or could become known by the investigator (IRB approval is required prior to ESCRO review. Provide documentation of IRB approval. Full ESCRO review required)

☐ Ineligible hESC lines: Research using NIH Ineligible hESC lines.

☐ Neural or gametic cell lines: hPSC research which includes experiments designed or expected to yield neural or gametic cells and tissues (Full ESCRO review required)

☐ Mixing cells and embryos (in no case will such experiments be allowed to progress for more than 14 days of development in vitro, or past the point of primitive streak formation, whichever is first. Full ESCRO review required)

☐ Culturing human embryos (Full ESCRO review required)

☐ Chimeric human cells including, but not limited to introducing new hESC's or hPSCs into non-human animals at any state of embryonic, fetal, or postnatal development (Full ESCRO review required)

☐ Other (Describe in detail in Question 2.2)

2.2 **Please describe in lay language the research aims. Include the specific use and the rationale for the use of hESC lines, human iPSC lines or the destruction of human embryos:** Click here to enter text.

2.3 **If you are not planning to use an NIH-registered cell line, please provide a rationale for not using one of the available lines:** Click here to enter text.

2.4 **If you are planning to generate new hESC lines, please a) Explain the scientific rationale for generating new hESC lines and b) Explain the basis for the number of blastocysts or oocytes.**
Click here to enter text.

2.5 **Describe how you plan to acquire the biospecimens (explain the procurement process).**
Click here to enter text.

2.6 **Where will the research take place? (Include ancillary support rooms such as freezer storage areas. Indicate campus, building, and room number):** Click here to enter text.

2.7 **Will equipment or supplies that were purchased with federal funds be used in this study? If yes, provide details.** (Federal regulations prohibit the use of federally funded equipment, supplies and personnel to support research using non-Registry stem cell lines. It is the responsibility of the principal investigator and all research personnel involved in hESC research to understand and adhere to these Federal restrictions). Click here to enter text.

2.7.a **Will any personnel working on this study be supported in whole or in part by federal funds?** If the project uses non-Registry stem cell lines, provide your plan for ensuring that no federal funds will be used to support the personnel. Click here to enter text.

NOTE: For all studies except those using NIH-registered cell lines: In order to comply with federal regulations, the ESCRO must verify that research using non-NIH registered cell lines or involving the destruction of human embryos does not interfere with TTUHSC's commitment to federally sponsored projects in regard to facilities, equipment, and personnel. The Research Compliance Officer may contact you to provide further instructions and to ensure ongoing auditing of the effort and expenditures related to this project.

2.8 **For studies involving hESC lines obtained from another institution, please provide the following information:**

☐ Cell line provenance

☐ Evidence of donor informed consent/ other institution's IRB approval

☐ A copy of the Material Transfer Agreement (MTA)

Click here to enter text.

PART 3—For New and Renewal Applications:

3.1 **Please provide a list of all individuals who will be involved in the design, conduct or reporting of this research:**

Name	**Department/Title/Role in Research**	**For renewals, is this individual new since the last submission?**

PART 4—For renewal applications only:

4.1 **Please provide a summary of the study progress since initial approval (if no progress has been made please indicate so here):** Click here to enter text.

4.2 **Please provide a summary of any changes to the protocol (review your original responses to Part 2 questions) since the last approval:** Click here to enter text.

PART 5—Certification:

By signing below, I certify that:

- I have reviewed this protocol submission in its entirely 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 regulations and TTUHSC policies 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 and will comply with the current regulations and TTUHSC policies regarding this research.
- I will ensure that all co-investigators and others assisting in the conduct of the project have been provided a copy of the entire current version of the protocol and are fully informed of the current study procedures, any potential risks and methods to minimize those risks, and the data and record-keeping requirements for the study.
- I will respond promptly to all requests for information or materials solicited by the TTUHSC ESCRO Committee, the Research Compliance Officer, Research Integrity Officer, or other representatives to the TTUHSC or TTU System administration.
- I will maintain adequate, current, and accurate records of research data and outcomes or adverse events to permit an ongoing assessment of this project.
- **I have read and understood all of the questions in this application. All of the foregoing information and statements submitted in this application and its attachments and supporting documents are true and correct to the best of my knowledge. All responses to the questions are full and complete, omitting no material information.**

_____ _____

Signature of Principal Investigator Date signed

FOR ESCRO USE ONLY

ASSIGNED PROTOCOL #: _____

DESIGNATED or FULL COMMITTEE REVIEW DATE:_____

APPROVAL DATE:_____

RENEWAL DATE:_____

ESCRO CHAIRPERSON SIGNATURE: _____