



# EMBRYONIC STEM CELL RESEARCH OVERSIGHT APPLICATION TO CONDUCT HUMAN EMBRYONIC STEM CELL (hESC) RESEARCH

Updated 3/4/2021

<b>Principal Investigator:</b>	
<b>Phone #:</b>	<b>Email:</b>
<b>Department:</b>	
<b>Contact Person</b> (Name, Phone #, Email):	
<b>Title of the Project:</b>	
<b>Funding Source(s)</b> – include agency and grant # and Maestro # if applicable:	
<b>Location of the Study:</b>	

## ADDITIONAL REQUIREMENTS

As appropriate, the PI will obtain necessary approvals from the Institutional Biosafety Committee (IBC), the Institutional Animal Care and Use Committee (IACUC), and/or the Institutional Review Board (IRB). Additionally, a Material Transfer Agreement (MTA) from the entity providing the stem cells must be obtained. These approvals/agreements must be obtained prior to ESCRO committee review of this application. Attach copies of approvals and agreements to this application.

## JUSTIFICATION AND PROJECT DESCRIPTION

Although some of the information requested below may be redundant with the information provided in your IBC, IRB and/or IACUC protocol, the ESCRO Committee requests this information in order to facilitate review.

1. Provide a brief description of the project.

2. Briefly explain the rationale for the project and why hESCs are necessary to achieve project objectives.

3. Provide assurance that the cell lines have been acceptably derived, describe from whom/where the cell line(s) will be obtained, how they will be used, and how you will comply with any restrictions on use.

Please check any of the following that apply to your research and answer the applicable questions.

- Research involving hESC (including somatic cell nuclear transfer (SCNT)).**

Are the embryonic stem cell lines used, derived or collected in this research on the existing NIH hESC Cell Registry?

- Yes. Cell line description and [NIH code](#):
- No. Federal funds may not be used to support this research. Additional requirements may apply.

- Research activity that is solely *in vitro*, with pre-existing cell lines.
- Research introducing embryonic or other human pluripotent stem cell lines into non-human animals, or introducing neural-progenitor cells into the brain of non-human animals at any stage of embryonic, fetal, or postnatal development.
  - Describe the expected pattern and effects of differentiation and integration of the human cells into the non-human animal tissues.

- Will human pluripotent cells be placed in non-human primate blastocysts?  Yes  No
- If any human pluripotent cells are to be introduced into non-human animals at the blastocyst stage, how will you guarantee that none of the animals will breed?

- Research involving introduction of stem cell lines into humans.
  - Evaluate the probable pattern and effects of differentiation and integration of the human cells into human tissues.
  - Provide a copy of the IRB approved informed consent document.

## CERTIFICATION

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

1. The information provided in this application is complete and accurate.
2. All research will be performed in compliance with all federal, state and local laws, as well as institutional requirements
3. Prompt and accurate response will be provided for all requests for information or materials solicited by the ESCRO.
4. 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, whichever occurs first.
  - Research in which hESCs are introduced into nonhuman primate blastocysts or in which any hESCs are introduced 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 animals into which hESCs have been introduced at any stage of development are permitted to breed.
5. Approval for this project and any revisions will be obtained prior to their initiation.
6. I have read and will comply with the responsibilities outlined in the Texas A&M University Guidelines on Human Embryonic Stem Cell Research Oversight.

Principal Investigator: \_\_\_\_\_ Date: \_\_\_\_\_

### ESCRO Committee Use Only:

ESCRO Chair / Designee: \_\_\_\_\_ Approval Date: \_\_\_\_\_  
 Renewal Date: \_\_\_\_\_

SRS/TAMRA Review Required.  
 Sent to SRS and/or TAMRA on: \_\_\_\_\_

**Submit your complete document via:**  
**EMAIL** your document to: [roc@tamu.edu](mailto:roc@tamu.edu)

**DELIVER/MAIL** your document to: