CORNELL UNIVERSITY
EMBRYONIC STEM CELL RESEARCH OVERSIGHT COMMITTEE

Instructions for Investigators:

- All research involving human embryonic stem cells (hESCs) must be reviewed and approved by the ESCRO Committee.
- It is essential that Federal funds and general Cornell facilities ONLY be used for work involving NIH-registered lines. ALL OTHER WORK WITH ALL OTHER LINES MUST BE DONE IN A SITE CERTIFIED BY THE UNIVERSITY.
- Separate and specialized financial tracking is required for work with non-NIH-registered lines. THEREFORE, A SEPARATE ESCRO APPLICATION SHOULD BE SUBMITTED THAT ADEQUATELY DESCRIBES ANY PROPOSED WORK WITH NON-NIH-REGISTERED LINES.
- Cornell University must certify that the proposal in compliant with all State and Federal guidelines for the use of hESCs in research. Therefore, the researcher must submit adequate documentation to the ESCRO Committee, including:
  - **A)** An ESCRO application, with an orderly scientific description of the study design and research procedures.
    1. This should include the hypothesis to be tested as well as a general description of the methodology to be used.
    2. Include a scientific rationale for why hESCs are needed to answer the scientific question.
    3. If the research plan includes the creation of new lines, describe the methods by which these lines will be created.
  - **B)** The exact hESC line to be used must be specified. If the cell line is not commercially available or a NIH registered hESC line then evidence of IRB approval of the derivation of the line and a copy of the approved template consent form used for the donation are required (The actual consent form signed by donors should not be submitted). ESCRO will review the documents to determine if they adequately provide evidence of compliance with the New York Statute regarding the protection of human participants and the Federal Common Rule.
  - **C)** The ESCRO Committee must deem that the proposal meets scientific and ethical requirements. Thus, the description of the project must address scientific rationale, justification for any new derivations or destruction of embryos, justification for the use of hESCs. If a new cell line is being developed please provide evidence that no compensation was made to donors, and that informed consent meets the standards established by New York State and the Federal Common Rule 45 CFR Part 46 Subpart A.
- Complete applications can be submitted to cu_ibc@cornell.edu . IBC staff also provide administrative support for the Cornell ESCRO committee but please note that the IBC and ESCRO are separate committees and approval from both are required before you can begin work. If your work also involves IRB and/or IACUC review and approval, those approvals must be issued before you can begin work. IBC/IRB/IACUC approval will be held until the ESCRO approval has been issued.

Cornell University ESCRO Application Form

Version 6-22-2023

Research Information:

Title of Project:

Contact Information:
Principal Investigator:
Name:
Department:
Phone:
E-mail:
Campus Address:

Protocol Correspondent: (one who has *authority* over the conduct of the research in the PI's absence)
Name:
Department:
Phone
E-mail:
Campus Address:

Source of Funding:
Check all that apply (Please note a separate application must be used for Federally funded work)

☐ Federal ☐ State of New York ☐ Commercial ☐ Foundation
☐ Internal ☐ Other (please specify):

Name of Sponsor 1:
OSP#:
Grant or contract#
Principal Investigator of award:

Name of Sponsor 2:
OSP#:
Grant or contract#
Principal Investigator of award:

Name of Sponsor 3:
OSP#:
Grant or contract#
Principal Investigator of award:

Project Description: Provide a description of the research being proposed. This should include the hypothesis to be tested as well as a general description of the methodology to be used. Include a scientific rationale for why hESCs are needed to answer the scientific question and provide a justification for why alternatives (iPSCs, human cell lines, or other methods) cannot be used to answer the question.

Select the categories below that your research project with hESCs are covered by. Select all that apply.

Category 1: Research that is permissible after notification and approval by the Chair of the ESCRO committee and completion of reviews mandated by current requirements (IACUC, IBC, IRB, etc.).

☐ Purely *in vitro* hESC research with pre-existing coded or anonymous hESC lines.

Please provide additional information about the cell lines in the Cell line registry section below.

Category 2: Research that is permissible only after review and approval by the ESCRO committee.

☐ 2.1 Attempted derivation of new hESC lines from donated blastocysts, or from in vitro fertilized oocytes, or by nuclear transfer, or from other Embryo-like entities.

Provide a scientific justification for why new hESC lines must be used for this research. Additionally provide an estimate of the number of blastocytes or oocytes needed to complete this work.

I will provide the ESCRO with the IRB consent form template (Not the Signed Version) and confirmation that IRB approval has been given for this work. ☐ Yes ☐ No

☐ 2.2 Introduction of hESCs into humans

Provide a scientific justification for why the introduction of hESCs into humans must occur to fulfill the scientific objective.

I will provide the ESCRO with the IRB consent form template (Not the Signed Version) and confirmation that IRB approval has been given for this work. ☐ Yes ☐ No

☐ 2.3 Introduction of hESCs into non-human animals at any stage of embryonic, fetal, or postnatal development.

Provide a scientific justification for why the introduction of hESCs into animals must occur to fulfill the scientific objective.

Category 3: RESEARCH THAT IS NOT PERMITTED. Must certify that your research does not involve any of the below:

- 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 occur first.
- Research in which hESCs are introduced into nonhuman primate blastocysts or in which any embryonic stem cells 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-hum primate uterus.
- No animal into which hESCs have been introduced at any stage of development are permitted to breed.

☐ My research does not include any of the above activities:

Additional Approvals required for this research proposal:

Approvals from Cornell University committees. hESC work must be described in these applications. Please begin the amendment process if you have not already started.

Institutional Review Board (IRB)

IRB protocol#: Current approval status: NHPR

IRB protocol#: Current approval status: Not submitted

Institutional Animal Care and Use Committee (IACUC)

IACUC Protocol#: Current approval status: Not submitted

IACUC protocol#: Current approval status: Not submitted

Institutional Biosafety Committee (IBC)

IBC MUA#: Current approval status: Not submitted

Laboratory personnel who will be handling hESC:

Primary Contact: (will be cc'd on correspondence concerning this application
Name: NetID: Email:

Laboratory Personnel working with hESCs:

1. Name: NetID:
2. Name: NetID:
3. Name: NetID:
4. Name: NetID:
5. Name: NetID:
6. Name: NetID:
7. Name: NetID:
8. Name: NetID:
9. Name: NetID:
10. Name: NetID:

Facilities where research will be conducted:
On Campus:

Building: Room Numbers:

Building: Room Numbers:

Building: Room Numbers:

Building: Room Numbers:

Building: Room Numbers:

Off Campus:
Please provide the address and explanation for why this work is occurring off campus.

Stem Cell Registry Status:

NIH hESC registered cell lines:

Below enter the following information about each of the NIH hESC registered cell lines you will be using in your research.

1. Name of cell line
2. Cell line restrictions
3. Link to commercial vendor's cell line catalogue

Cell lines that are not registered with the NIH:

Below enter the following information about each of your non-registered cell lines you will be using in your research.

1. Name of the cell line
2. Source of the cell line
3. Include with your registration a copy of the IRB and ESCRO approval letters for the generation of the cell line.

Verification of confidentiality of donor:

Please answer the following questions:

1. Are the hESC being used in this research linked to any information whereby it would be possible for your research team to identify the donors of the original blastocytes?
   ☐ Yes ☐ No
   If "Yes" explain:

2. Are the hESCs being used in this research linked to any information whereby it would be possible for the source institution to identify the donors of the original blastocytes
   ☐ Yes ☐ No
   If "Yes" explain:

Assurance Statements:

Material Transfer Agreements
I will work with the Cornell Office of Sponsored Programs to execute a Material Transfer Agreement (MTA) during the acquisition of all hESCs described in this application.
☐ Yes ☐ No

Conflict of Interest
I and everyone else listed on this application, have completed Conflict of Interest disclosures and certifythat I have no COIs associated with the materials or the work being performed regarding this project.
☐ Yes ☐ No

Training
I will ensure that all individuals working with these cell lines will be trained in the appropriate use of these cell lines including ensuring that my research staff understand what research activities are restricted with regards to the cell lines.
☐ Yes ☐ No

My research staff and I understand that we should not share hESCs with other researchers at this institution without verifying that the other research group has the appropriate ESCRO approvals.
☐ Yes ☐ No

Principal Investigator's Certification:

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

- The information provided in this application is complete and accurate.
- All research will be performed 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. This provision will be kept current for relevant personnel.
- Prompt and accurate response will be provided for all requests for information or materials solicited by the ESCRO.
- Complete, current and accurate records of research data, outcomes and adverse events will be maintained at all times.
- Approval for this study and any revisions will be obtained prior to their initiation.

By signing below, I certify that I have read and will comply with the responsibilities outlined above.

Signature of PI: Date: