# **Brown University ESCRO Committee Project Review Form**

Project Title: Click or tap here to enter text.

Project Type:

New Project/First Review

Periodic Update

(Note: projects must be re-reviewed at least every 3 years)

Last Reviewed: Click or tap here to enter text.

Addition/Modification to Previously Reviewed Project

Last Reviewed: Click or tap here to enter text.

Submission Date: Click or tap here to enter text.

Requested Project Approval Period (max 3 years): Click or tap here to enter text.

Principal Investigator: Click or tap here to enter text.

1. **Project Data** (This section is to be completed by the Principal Investigator)
   1. **Project Objectives and Activities:** Please indicate a brief (<1 page) description of the project, including the following information: (i) goals of the project, (ii) importance of the project for human health, (iii) reasons for use of hESCs, and (iv) major anticipated experimental directions during the project review period.

Click or tap here to enter text.

* 1. **hESC lines to be used in the research (check all that apply):**

H1  H7  H9  H13  H14

ES117  ES135  Other: Click or tap here to enter text.

* 1. **PLEASE NOTE THAT THE FOLLOWING ACTIVITIES ARE FORBIDDEN AT THIS TIME:**
     + **Transplantation of hESCs into human or non-human primate blastocysts.**
     + ***In vitro* culture of an intact human embryo for longer than 14 days or until formation of the primitive streak, whichever occurs first.**
     + **Breeding of animals that have had hESCs introduced into the germ line.**

By Checking this box, I certify that the proposed project does not include any of the above listed activities.

* 1. **Will efforts under this project, during this project review period, include transplantation of hESCs or hESC-derived cells to nonhuman animals?**

Yes

No

If no, proceed directly to section e.

If yes, complete the following:

Study Design 1:

1. Species of animal to be used:

Click or tap here to enter text.

1. Stage of development at which cells will be introduced:

Click or tap here to enter text.

1. Describe stage of differentiation of transplanted cells:

Click or tap here to enter text.

1. Describe route of cellular administration:

Click or tap here to enter text.

1. Comment on likelihood of transplanted cell contribution to brain or cognitive function:

Click or tap here to enter text.

1. Describe steps that will be taken to ensure that transplanted animals do not breed:

Click or tap here to enter text.

*(the above sections should be duplicated as necessary to describe each significantly different animal experimental design)*

* 1. **Will efforts under this project, during this project review period, include transplantation of hESC or hESC-derived cells to humans?**

Yes

No

If no proceed directly to section f.

If yes, please attach the planned clinical protocol and complete the following:

1. Please list the regulatory (FDA, EMEA, etc.) approvals that have been or will be obtained prior to initiation of any human implantation:

Click or tap here to enter text.

1. Please describe rationale for key aspects of the clinical protocol (cell dose, patient inclusion/exclusion criteria, delivery method):

Click or tap here to enter text.

1. Please describe any factors contributing to potential risk of infectious disease (ex. culture in presence of animal-derived materials) and efforts taken to minimize this risk (ex. testing procedures).

Click or tap here to enter text.

1. Please describe efforts taken to identify, quantify and minimize risk of tumor formation.

Click or tap here to enter text.

1. Please describe efforts taken to identify, quantify and minimize risk of immune rejection.

Click or tap here to enter text.

1. Please describe completed and/or planned IRB review process.

Click or tap here to enter text.

* 1. **Will efforts under this project involve the derivation of new hESC lines or destruction of human embryos?**

Yes

No

If no, please proceed directly to section g.

If yes, please attach proposed informed consent documents for donation of materials and complete the following:

1. Intended methods of hESC derivation:

From excess IVF embryos

From embryos created by IVF for the purpose of making hESC lines

From embryos created using SCNT

Other (ex. from embryos created via parthenogenesis or androgenesis; from single blastomeres; from non-viable embryos; from genetically altered embryos; etc.)

Describe: Click or tap here to enter text.

1. Please provide an estimate and justification of numbers of donated embryos, oocytes, or other human materials to be used in derivation efforts:

Click or tap here to enter text.

1. Please provide reasons for need for derivation of new lines.

Click or tap here to enter text.

1. Please describe intended uses of new line, and plans for distribution to the scientific community:

Click or tap here to enter text.

1. Please describe methods that will be used to characterize and bank new lines:

Click or tap here to enter text.

* 1. **Project Personnel:** Please list key project personnel and qualifications below.

|  |  |  |
| --- | --- | --- |
| **Name** | **Role on Project** | **Brief Description of Relevant Training** |
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**Signature of Principal Investigator:**

I certify that to the best of my knowledge, the above information is complete and correct; that the research proposed herein is not unnecessarily duplicative of previous work; that all personnel have received reasonable and appropriate training for the performance of their responsibilities in this research; and that any work involving the destruction of embryos or use of human gametes has been thoughtfully designed and will be executed in such a way as to limit the number of embryos or gametes required.

I further certify that I have obtained or will obtain approval of all other relevant committees (IRBs, IACUCs, Biosafety, etc.) before initiating the project, and that I will obtain approval of the ESCRO Committee before initiating any significant changes or additions to the work described above.



Name: Click or tap here to enter text.

Date: Click or tap here to enter text.

1. **Project Review:** This section is to be completed by the ESCRO Committee chair or primary reviewer and approved according to ESCRO Committee procedures.
   1. **Project Category:**

Permissible after notification of ESCRO Committee

Requires minimal review and approval

Requires full review and approval

Not permissible

* 1. **Date(s) of ESCRO Committee review:**

Click or tap here to enter text.

* 1. **Committee members in attendance:**

Click or tap here to enter text.

* 1. **Key issues for consideration and committee conclusions:**

Provenance of lines:

Click or tap here to enter text.

Informed Consent:

Click or tap here to enter text.

Protection of donor anonymity:

Click or tap here to enter text.

Chimeric animal experiments (potential for contribution to brain & reproductive function):

Click or tap here to enter text.

Appropriate use of donor oocytes & embryos:

Click or tap here to enter text.

Scientific merit of project:

Click or tap here to enter text.

Appropriate oversight by other agencies/committees (IACUCs, IRBS, IBCs, etc.):

Click or tap here to enter text.

* 1. **Approval Status:**

Approved as submitted

Approved with modifications (list below)

Click or tap here to enter text.

Further information needed (list below)

Click or tap here to enter text.

Rejected

* 1. **Action items for Principal Investigator (ex. required protocol modifications or additional information):**

Click or tap here to enter text.

* 1. **Suggest date of next review:**

Click or tap here to enter text.

**Signatures:**

**I certify that this project has met the criteria for ESCRO Committee approval, as documented in the Policies and Procedures of Brown University’s ESCRO Committee.**

**ESCRO Committee Chair**

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signatures of approving ESCRO Committee members:**

**My signature is provided as evidence of my vote to approve this project.**

1. Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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