

 BROWN	Embryonic Stem Cell Research Oversight (ESCRO) Committee Standard Operating Procedure	SOP 10.10.06
		Effective Date: April 7, 2017

1.0 Standard Operating Procedure (SOP) Purpose

The purpose of this SOP is to document the meeting procedures and project review procedures of the Brown University (“Brown” or “University”) Embryonic Stem Cell Research Oversight (ESCRO) Committee. The ESCRO Committee ensures that all human embryonic stem cell (hESC) research conducted at or funded by Brown is conducted in an ethical manner.

2.0 SOP

2.1 Meeting Procedures

2.1.1 Meeting Attendance

Members may attend ESCRO Committee meetings in person or via teleconference or videoconference. The chair or the chair’s designee shall make every effort to schedule meetings at times that are convenient for the largest number of ESCRO Committee members; however, meetings may be scheduled for any time at which a quorum can be obtained. Certain actions of the ESCRO Committee can be taken outside convened meetings, as described in this policy.

2.1.2 Voting

All matters shall be determined by majority vote of the committee, except as otherwise indicated in this SOP. Votes shall generally be taken by an informal oral poll at the conclusion of discussion. If any member of the ESCRO Committee so requests, any vote may be taken by secret ballot instead.

2.1.3 Quorum

To achieve quorum at meetings, at least half the number of roster members must be present. A vote shall pass with a majority vote of those present.

2.1.4 Meeting Minutes

The chair or the chair’s designee shall keep minutes for each ESCRO Committee meeting. A draft of the minutes shall be provided to all members in attendance at the meeting for review and comment within two weeks of each meeting. Following an opportunity for comment by other members, a copy of the minutes shall be circulated to all committee members in advance of the next ESCRO Committee meeting. At each ESCRO Committee meeting, a vote of committee members will be taken to approve the minutes of the previous meeting. A copy of all approved minutes shall be maintained in the ESCRO Committee files.

2.2 Project Review Procedures

2.2.1 Project Submission

All Brown University projects involving hESCs must be approved by the Brown University ESCRO Committee. Projects shall be submitted to the ESCRO chair by the Principal Investigator (PI) using [Brown University's ESCRO Committee Application](#). Projects may be approved for periods of up to three years as requested by the PI and at the discretion of the ESCRO Committee. It is the responsibility of all senior Brown University scientific staff to ensure that all activities relating the derivation or use of hESCs under their supervision have been approved by the Brown University ESCRO Committee prior to project initiation. Upon submission of the project, the ESCRO chair or another member designated by the chair ("primary reviewer") shall review the submission and categorize the project to one of the project review categories (see Section 2.2.2).

2.2.2 Project Review Categories

2.2.2.1 Category A: Projects requiring minimal ESCRO Committee review

This category shall be comprised of projects consisting entirely of *in vitro* research on (i) cell lines on the NIH registry, or (ii) cell lines that have been approved as "anonymous lines" by the Brown University ESCRO Committee (see Embryonic Stem Cell Research Oversight [ESCRO] Committee Policy Section 3.4).

2.2.2.2 Category B: Projects requiring additional ESCRO Committee review and approval

This category shall be comprised of projects involving any of the following: (i) the derivation of new hESC lines, (ii) the introduction of hESCs or their derivatives into humans or non-human animals, and/or (iii) the use of hESC lines classified by the ESCRO Committee as "non-anonymous lines" (see Embryonic Stem Cell Research Oversight [ESCRO] Committee Policy Section 3.4). "Derivatives" shall include any whole cell derived from hESCs, but not proteins, nucleic acids, or any other such products derived from such cells.

Category B1: Expedited Review

Projects involving the introduction of hESCs or their derivatives into post-pubertal non-human animals shall be eligible for expedited review if the proposed transplant experiments are deemed by the ESCRO chair or primary reviewer to have limited potential to contribute to brain or reproductive function. Projects involving the use of anonymous hESC lines may also qualify for expedited review.

Category B2: Standard Review

Projects involving the derivation of new hESC lines, the use of non-anonymous lines, or the introduction of hESCs or their derivatives to humans or pre-pubertal animals shall be subject to standard review and are not be eligible for expedited review. In addition, any project for which the chair believes broader ESCRO Committee consideration is in order may be categorized for standard review.

2.2.2.3 Category C: Projects not permitted by the ESCRO Committee

This category shall be comprised of projects that involve (i) the *in vitro* culture of an intact human embryo for more than 14 days or until the primitive streak begins, (ii) the introduction of hESCs into human or non-human primate blastocytes, or (iii) the breeding (or insufficient control to prevent breeding) of animals into which hESCs have been introduced.

2.2.3 Project Review Procedures

2.2.3.1 Category A Projects

For projects deemed by the ESCRO chair or primary reviewer to fall into Category A, the chair or primary reviewer shall sign the ESCRO Committee review form as certification of that determination. A copy of the completed project review form shall be provided to each member of the ESCRO Committee. ESCRO Committee members will have up to five business days to object to the categorization, after which time the project shall be deemed approved to proceed. If, within five business days of circulation, at least one committee member requests broader project review, the project shall be scheduled for [standard] review at a subsequent ESCRO Committee meeting.

2.2.3.2 Category B Projects

Category B1: Expedited Review

For projects deemed eligible for expedited review, the ESCRO chair or primary reviewer shall circulate the project submission form to ESCRO Committee members via electronic mail together with a statement indicating that the project has been deemed to require expedited review. If, within five business days of circulation, at least one committee member requests broader project review, the project shall be scheduled for standard review at a subsequent ESCRO Committee meeting. Otherwise, the project shall be deemed approved by the committee. Documentation of approval of expedited review projects shall require signature on the project review form by a majority of committee members.

Category B2: Standard Review

For Category B2 projects, the PI or the PI's designee shall present the project for review at an ESCRO Committee meeting. Approval of projects containing Category B2 activities shall require a vote for approval by a majority of present ESCRO Committee members. Approval shall be documented by the signatures of approving members on the project review form, as well as by the ESCRO chair as certification that the above procedure was followed.

2.2.3.3 Category C Projects

A project may be categorized as Category C by either the ESCRO chair upon initial review and categorization of the submitted project, or by the full committee by vote or a majority of members present at the project review meeting. In either case, the project shall not be eligible for ESCRO Committee approval. The Committee shall inform the PI of the reasons for the decision, and ask the PI to resubmit the project with modifications to remove or modify the objectionable

aspects of the proposal to ensure it meets Category A and/or Category B approval criteria.

2.2.4 Resubmissions

2.2.4.1 ESCRO Committee Requested Changes

Projects for which the ESCRO Committee has requested revisions must be resubmitted to the Committee upon completion of the requested changes in order to be considered further. Resubmitted projects deemed by the ESCRO chair or primary reviewer to have addressed the concerns of the committee shall be eligible for expedited review at the discretion of the chair/primary reviewer.

2.2.4.2 Project Modifications

If an approved project undergoes additions or changes from the ESCRO Committee approved project description that are substantial enough to require a substantive modification (*i.e.*, not administrative changes) to an approved Institutional Animal Care and Use Committee (IACUC) protocol or Institutional Review Board (IRB) protocol, it shall also be resubmitted to the ESCRO Committee with the modifications annotated. Such projects shall be eligible for expedited review at the discretion of the chair or the chair's designee.

If modifications are deemed by the chair or the chair's designee to alter the Category of review or otherwise significantly alter or expand the originally proposed project, the chair or the chair's designee may require the PI to submit a new ESCRO project application.

Minor project changes that, in the reasonable judgment of the PI, are unlikely to impact brain or reproductive function of transplanted animals (*e.g.*, minor changes to differentiation protocols) do not require ESCRO Committee notification.

2.2.4.3 Appeals

ESCRO Committee decisions may be appealed by the following procedure:

- 1) A written appeal shall be submitted to the ESCRO Committee at ESCRO@Brown.edu with a description of the appeal request and rationale for such request. A written appeal must be submitted within five business days of the ESCRO Committee's notification of a decision to the investigator.
- 2) The chair or the chair's designee will consider the appeal and accept or deny the appeal in writing, after consultation from internal scientific and/or regulatory experts at Brown or, if needed, consultation with scientific and/or regulatory experts external to Brown. This decision is considered final.

3.0 Definitions

For the purpose of this SOP, the terms below have the following definitions:

Human embryonic stem cell (hESC): cells that are derived from the inner cell mass of blastocyst stage human embryos, are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers

4.0 Responsibilities

All individuals to whom this SOP applies are responsible for becoming familiar with and following this SOP. University supervisors are responsible for promoting the understanding of this SOP and for taking appropriate steps to help ensure compliance with it.

5.0 Related Information

The following information compliments and supplements this document. The information is intended to help explain this SOP and is not an all-inclusive list of policies, procedures, laws and requirements.

5.1 Related University Policies:

- Embryonic Stem Cell Research Oversight (ESCRO) Committee Policy

5.2 Related SOPs: N/A

5.3 Related Forms:

- [Brown University's ESCRO Committee Application](#)

5.4 Frequently Asked Questions (FAQs): N/A

5.5 Other Related Information:

- [Brown ESCRO Website](#)
- [NIH Cell Line Registry](#)

6.0 SOP Owner and Contact(s)

6.1 SOP Owners: Vice President for Research

6.2 SOP Approved by: Vice President for Research

6.3 Subject Matter Contact: Office of Research Integrity

- Telephone: 401-863-3050
- Email: ESCRO@brown.edu

7.0 SOP History

7.1 SOP Effective Date: June 4, 2020

7.2 SOP Last Reviewed: June 4, 2020

7.3 SOP Update/Review Summary: N/A