

I. Introduction

The University of Illinois at Chicago (UIC) Embryonic Stem Cell Research Oversight (ESCRO) committee shall apply standard practices to the review of research activities submitted for approval. This policy sets forth the initial, continuing review and amendment process to be performed by ESCRO.

II. Levels of review and approval

The Chair or the Chair's designee shall screen submitted protocol applications to determine the level of review.

- A. Registration and administrative review: When the research activities involve only the in vitro use of human embryonic stem (hES) cells listed on the NIH Registry for approved hES cell lines, the protocol application is eligible for administrative review and approval by the chair or the chair's designee.
 1. Research activities receiving administrative review may be approved by the reviewer, but may not be denied approval by the reviewer. Rather, studies not receiving approval must be referred for convened committee review.
 2. Continuing review of a study initially approved under this procedure may be conducted in the same manner, unless there have been changes since the initial (or last) review that would require designated or convened review.

- B. Designated review: When the research activities involve the in vivo use of hES cells listed on the NIH Registry in animals and the hES cells are not anticipated to make a significant contribution to the behavior or phenotype of the chimeric animal, the protocol application is eligible for designated review. The ESCRO office will provide a written summary of the protocols eligible for designated review to the Committee. The ESCRO members will have 3 working days in which to determine if review at a convened meeting is required. Any ESCRO member may request that the review be transferred to a convened meeting. When it has been documented that a quorum have received the report, and that no objection has been raised within the prescribed time frame, a designated reviewer will be assigned by the chair or the chair's designee to review the protocol application.
 1. Activities receiving designated review may be approved by the reviewer, but may not be denied approval by the reviewer. Rather, studies not receiving approval must be referred for convened committee review.
 2. Continuing review of a study initially approved under this procedure may be conducted in the same manner or if it is determined by the chair that no changes have been made since the initial (or last) review that have not been approved, continuing review may be done administratively.

- C. Convened committee review: Submissions that require convened committee review are those which involve any of the following:

1. Any activity eligible for designated review that a member of ESCRO indicates should be reviewed at a convened committee meeting.
2. Any activity that involves the use of an approved hES cell line in vivo in humans.
3. Any activity that involves any use of an established non-federally approved hES cell line.
4. Any activity that involves the development of new hES cell lines, regardless of the method of development.

Submissions meeting any of the criteria above will be assigned a primary and a secondary reviewer by the Chair or the Chair's Designee. However, all ESCRO members will receive copies of the submission for review and consideration in sufficient time prior to the meeting.

Continuing review of a study initially approved under this procedure must be conducted in the same manner if it falls under category C2 through C4 above. Continuing review of studies approved under C1 may, at the discretion of the committee, receive continuing administrative or designated review.

- D. At any point in the process, if questions arise, the ESCRO office will contact the investigator before the next stage in the review.
- E. At any point in the review or oversight process, ESCRO members may call for a convened committee review of any activity in its entirety.

III. Review process

- A. Activities subject to review by the convened committee shall be submitted to the ESCRO office by the submission deadline in order to be eligible for review at the next scheduled convened meeting. The ESCRO Chair or chair's designee shall assign a primary and secondary reviewer.

The ESCRO office shall distribute meeting agendas (identifying assigned reviewers) and submissions to the committee members no later than prior to the convened meeting date to allow for review and comment.

1. Reviewers shall provide review summaries and concerns to the ESCRO office prior to the convened meeting date for distribution to the other members.
2. Convened committee review refers to a convened meeting at which a quorum of the full membership of ESCRO is present. A quorum is defined as a simple majority (one-half plus 1) of the membership of the ESCRO. For approval, all protocols require a majority vote of the quorum present.
3. When conducting business in the absence of the chair or when the chair has a conflict of interest on an activity under review, another experienced member of the committee will serve as the chair.
4. Investigators may be invited to appear before the ESCRO to present their protocols or respond to questions.
5. The following decisions can be made during the process of convened review:
 - a. Approval.

- b. Modifications required. Approved pending minor clarifications/modifications eligible for administrative review and approval.
- c. Deferred for further review at a convened meeting. (Substantive issues must be addressed and reviewed by the convened ESCRO committee.)
- d. Denial.

Clarifications/modifications include additions, deletions or corrections that may be required at any step in the review process. They may be resubmitted by submission of the appropriate pages of the application/protocol on which changes were made if revisions result in an exact page-for-page exchange. If an exact page-for-page exchange is not possible, then all pages affected must be resubmitted. To assist the committee in their review, clarifications/modifications should be highlighted in a manner that separates them from the original submission (e.g., bolded, underlined, highlighted, etc.).

6. Meeting minutes will be maintained that document attendance and summarize the controverted issues, their resolution and the vote (for, against, abstained).
 7. The determinations of the committee will be conveyed to the investigator in writing in a timely manner by the ESCRO office. Reasons for denial will likewise be documented and conveyed to the investigator in writing.
- B. Activities eligible for designated review shall be submitted to the ESCRO office by the submission deadline. Following submission, a written summary report will be sent to all members of the ESCRO. The Committee members will have three working days to determine if a protocol should be reviewed at a convened meeting. Any member may request that a review be done at a convened meeting. Following determination that a quorum of the committee have received the report, and that no member has requested review at a convened meeting, the chair or the chair's designee will assign a reviewer.
1. Reviewers shall provide review summaries and concerns to the ESCRO office within 7 working days of being assigned as a reviewer and receiving protocol.
 2. Determinations of the reviewer will be conveyed to the investigator in writing in a timely manner by the ESCRO office
 3. Revised protocol applications shall be submitted to the ESCRO office and the office will forward the revisions to the reviewer for review.
 4. Reviewers shall provide further concerns to the ESCRO office or approval within 7 working days of receipt of the revisions.
 5. Approval of the protocol will be conveyed to the investigator in writing in a timely manner by the ESCRO office.
 6. The ESCRO office shall regularly prepare a report of all protocols reviewed and approved by designated review and present the report to the committee for acknowledgement at the next convened meeting.
- C. Activities eligible for administrative review will not be subject to the above submission deadline. The Chair or the Chair's designee will assign a reviewer promptly after submission.
1. Reviewers shall provide review summaries and concerns to the ESCRO office within 7 working days of being assigned as a reviewer and receiving protocol.

2. Determinations of the reviewer will be conveyed to the investigator in writing in a timely manner by the ESCRO office
 3. Revised protocol applications shall be submitted to the ESCRO office and the office will forward the revisions to the reviewer for review.
 4. Reviewers shall provide further concerns to the ESCRO office or approval within 7 working days of receipt of the revisions.
 5. Approval of the protocol will be conveyed to the investigator in writing in a timely manner by the ESCRO office.
 6. The ESCRO office shall regularly prepare a report of all protocols reviewed and approved by administrative review and present the report to the committee for acknowledgement at the next convened meeting.
- D. Timeliness: In order to avoid unnecessary delays in the initiation of research activities, the review process should be accomplished within 30 days of the timely receipt of a properly completed protocol application. At any stage of the review process, if an investigator does not submit requested clarifications/modifications within 60 days of notification, the submission review may be terminated and the file closed. If clarifications/modifications cannot be submitted within 60-days of notification, the investigator should contact the ESCRO office to request an extension of response time.

IV. Appeals

- A. Appeals of ESCRO decisions should be directed to the chair. While an approval by ESCRO may be subject to additional institutional review and may be subsequently denied, a denial by ESCRO may not be overturned by another institutional body or official.

V. Approval, re-approval, and amendments

- A. Initial approval will be for a maximum of one-year from the date of review by the convened committee, or the designated or administrative review, but may be granted for less than one year at the discretion of the committee.
- B. Approval may be continued upon re-approval of the activity by ESCRO after receipt and review of an activity update report (continuing review form).
- C. To support the continuation of approval process, the ESCRO office will send each investigator a notice of expiration and a request for updates, including an inquiry as to whether any unapproved changes have been made or any additional risks identified. The ESCRO chair or designee shall review requests for re-approval to determine if the request should receive administrative, designated, or convened committee review.
- D. Substantive changes in the research activity will require prospective review and approval by ESCRO before they are implemented. The investigator will submit a request for amendment that outlines the proposed changes and a revised application (with changes identified), which will be subjected to the required review process (see section II above). *Note: The expiration date will not be altered by a subsequently approved amendment.*