University of Wisconsin-Madison Policy for Initial Review, Continuing Review and Changes of Protocol Application

Adopted By: Stem Cell Research Oversight Committee
Adoption Date: October 27, 2010

POLICY

I. Initial Review

A. Per UW-Madison’s Policy for Human Pluripotent Stem Cell Research, all research on campus involving campus faculty or staff that involves the following must be submitted to the SCRO Committee for review and approval:

1. The use of hESCs or their derivatives; or

2. The introduction of hPSCs, or their derivatives, obtained from a non-embryonic source, into non-human animals at any embryonic, fetal, or postnatal stage, if an expected effect is that human cells will be integrated into the central nervous system, testes, or ovaries of the animal.

B. All new protocols that are not determined to be eligible for expedited review are reviewed by the full SCRO. See Full and Expedited Review Policy.

C. To apply for review of a new protocol, the investigator must submit an Application for Initial Review of Research Projects Involving Human Pluripotent Stem Cells.

D. The SCRO staff conducts a preliminary review of each protocol to determine whether the materials provided by the investigator are complete and contacts the investigator to obtain missing documents. Incomplete submissions may be returned to the investigator.

E. Once all requested information is received, the SCRO staff determines whether the protocol will be reviewed by the full SCRO or is eligible for expedited review. If the protocol is eligible for expedited review, the SCRO staff will follow UW-Madison’s expedited review procedures. See Full and Expedited Review Policy.

F. On initial review of a protocol, the SCRO Committee or expedited reviewer may:

1. Approve the protocol;

2. Approve the protocol pending resolution of required modifications,
3. Defer the protocol until additional information is obtained; or

4. Disapprove the protocol. Note however that only the SCRO Committee may disapprove an initial review application.

In each case, the SCRO staff notifies the investigator in writing of the action taken and, except in the case of an approval, the reasons for that action.

G. To approve a protocol pending resolution of requested modifications:

1. If a protocol is approved pending resolution of requested modifications, the SCRO staff will notify the investigator of those modifications and instruct the investigator that he or she must respond to these requests as directed.

2. Upon receipt of the investigator’s response to requested modifications, SCRO staff will forward the response to the SCRO Chair (if the full SCRO Committee approved the protocol pending requested modifications) or the expedited reviewer. When appropriate, the investigator’s response may also be forwarded to the full SCRO Committee. Upon review, the Chair, expedited reviewer, or SCRO Committee shall determine that:

   a. The protocol may be approved; or

   b. The investigator’s response is not consistent with the requested modifications. In this case, the investigator may be asked for further modifications.

3. At intervals of 60 and 120 days from the date the modification request was first sent to the investigator, the electronic protocol management system automatically sends a reminder to the investigator of the need to respond to modification requests and obtain SCRO approval of the research before research can begin. If a response is not received from the investigator within 180 days of the first request for modifications, the electronic protocol management system automatically sends a notice to the investigator that the protocol has been closed and will need to be re-submitted for reconsideration before the research may proceed.

H. To defer a protocol until additional information is obtained:

1. The SCRO Committee or expedited reviewer must defer approval of a protocol if, to approve the protocol, the SCRO Committee or expedited reviewer requires substantive clarifications or modifications.

2. The SCRO staff will notify the investigator of the substantive clarifications or modifications needed to allow approval of the research.
3. The investigator may supply the substantive clarifications or modifications or provide a rationale for not doing so. The protocol will then be re-reviewed by the full SCRO Committee or expedited reviewer.

4. At intervals of 60 and 120 days from the date of the notice requesting additional information was first sent to the investigator, the electronic protocol management system automatically sends a reminder to the investigator of the need to respond to information requests and obtain SCRO approval of the research before research can begin. If a response is not received from the investigator within 180 days of the first request for additional information, the electronic protocol management system automatically sends a notice to the investigator that the protocol has been closed and that a new application will need to be submitted and approved before the research may proceed.

I. If the SCRO Committee decides to disapprove a protocol, the Committee gives the investigator an opportunity to respond in person or in writing.

J. SCRO Records on Initial Review

1. The full SCRO Committee’ discussion, action and vote on each Application for Initial Review are documented in the minutes for each meeting.

2. Votes for and against approval of each Application for Initial Review and the name of any SCRO Committee member abstaining from the vote on each protocol or leaving the room before the vote due to a conflict of interest are recorded in the meeting minutes.

3. Expedited review is documented by using the SCRO Expedited Review Form. This form is filled out by the staff reviewer and forwarded to the expedited reviewer to complete. The completed form is maintained in the paper file.

II. Continuing Review

A. UW-Madison’s SCRO Committee conducts continuing review of human pluripotent stem cell research protocols once every year. Depending upon the nature of the proposed research, the SCRO Committee may determine that the protocol requires more frequent continuing review.

B. Continuing review of human pluripotent stem cell research is conducted by the full SCRO Committee, except that those protocols that qualify for expedited initial review may undergo expedited continuing review. Additionally, protocols which initially qualified for full SCRO Committee review may qualify for expedited continuing review when there have been no changes and no problems reported. See Full and Expedited Review Policy.
C. At 90 days, 60 days, and 30 days before the expiration date of a protocol approval period, the electronic protocol management system automatically sends an email to the principal investigator, co-investigator(s) and point of contact noting that, if the research is continuing, an application for continuing review of research must be submitted and approved by the SCRO Committee before the existing approval period expires.

1. “Expiration date” refers to the last date that the protocol is approved and the last date on which research can be conducted.

2. The “expiration date” is calculated in the following manner:

   a. For protocols reviewed by the full SCRO Committee, the expiration date one year minus one day from the SCRO Committee meeting date at which the protocol was approved or approved pending modifications unless the SCRO Committee has required a shorter approval period.

   b. For protocols reviewed under the expedited procedure, the expiration date is one year minus one day from the date the approval was granted by the expedited reviewer.

D. To apply for continuing review of a protocol, the investigator must submit an online Application for Continuing Review form. If the investigator is also making changes to the protocol at the time of the continuing review, the investigator must indicate on the continuing review form that a change is being proposed.

E. On application for continuing review, the SCRO Committee or expedited reviewer may:

   1. Approve the application;

   2. Require modifications in the application for continuing review,

   3. Defer the application until additional information is obtained; or

   4. Disapprove the application. Note however that only the SCRO Committee may disapprove a continuing review application.

   In each case, the SCRO Office notifies the investigator of the action taken and, except in the case of an approval, the reasons for that action.

F. If an application for continuing review is not reapproved by the expiration date, the protocol will be closed and no further research activities may be conducted.

III. Changes of Protocol
A. Most changes in an approved human pluripotent stem cell research protocol may be submitted at the time of continuing review. However, a change of protocol application must be submitted before a change is made for the following actions:
   1. Addition of a new cell line not listed on the National Institutes of Health Human Embryonic Stem Cell Registry or on the UW-Madison Human Embryonic Stem Cell Registry;
   2. A change in the PI;
   3. A change in funding source;
   4. A significant change in research type, study design or research question.

B. Applications for change of protocol are reviewed by the full SCRO Committee, except for those changes that qualify for expedited review. See *Full and Expedited Review Policy*.

C. To apply for review of a change in a protocol, the investigator must submit an online Application for Change of Protocol. Once submitted, the SCRO Committee staff will determine whether the application will be reviewed by the full SCRO Committee, or whether it is eligible for expedited review.

D. On application for change of protocol, the SCRO Committee or expedited reviewer may:
   1. Approve the application;
   2. Require modifications in the application,
   3. Defer the application until additional information is obtained; or
   4. Disapprove the application. Note however that only the SCRO Committee may disapprove an application for change of protocol.

In each case, SCRO Committee staff shall notify the investigator of the action taken and, except in the case of an approval, the reasons for that action.