

	Human Embryonic Stem Cell and Human Fetal Tissue Research Policies and Procedures	Policy # 1.0 Title: Charge to the Scientific Research Oversight Committee (SROC) Date: January 1, 2016 Version: 1.0 Page 1 of 2
Research Compliance Services		

A. Charge

The University of Nebraska-Lincoln’s Scientific Research Oversight Committee (SROC) is responsible for the oversight of research involving human embryonic stem cells (hESCs) and human fetal tissue (hFT).

1. The SROC will meet once a month unless there is no business to review.
2. The SROC will conduct a review of 1) initial proposals to use hESCs and hFT, 2) amendments to approved protocols and 3) continuing review (CR) no less often than annually as determined by the committee and/or the UNL IRB.
3. The SROC will ensure the research and the use of hESC and/or hFT are scientifically justified.
4. The SROC will ensure the research uses only NIH approved hESC lines in compliance with the University of Nebraska and Board of Regents policy and any applicable state laws.
5. The SROC will approve, require modifications (to secure approval), or disapprove all protocol review items listed under #2.
6. The SROC will inform a) the UNL IRB and, if applicable, b) the UNL IACUC and c) UNL IBC of initial protocols, amendments and continuing reviews which have received approval. The UNL IRB, in accordance with University of Nebraska policy must review and also approve any protocols that the SROC Committee has approved. If the protocol involves animals, and/or biohazardous agents, the UNL IACUC and/or UNL IBC must also approve the protocol.
7. If the SROC disapproves a protocol or amendment the PI has the right to appeal to the committee, who is authorized to make the final decision.
8. The SROC will inform the UNL Chancellor of all initial protocols, amendments and continuing reviews that have been approved or disapproved.

B. SROC

1. The committee will be appointed by the Institutional Official (IO) for variable renewable terms of 1-3 years.
2. The committee will consist of a chair, vice-chair and no less than 7 additional members for a total of 9.
3. The committee must have scientists who have appropriate expertise and at least 2 non-affiliated members, one of which must be a non-scientist.
4. The committee will operate according to Robert’s Rules.
5. The chair will not vote unless it is to break a tie.

6. Any members of the committee who are also members of the IRB must abstain from voting at the IRB meeting when hESC and hFT protocols are brought before the IRB.

C. Review Procedures

1. The SROC will review initial research proposals and conduct CR at a Full Committee Review (FCR) meeting when a quorum of the committee is present including at least one non-affiliated member (NAM). Real time electronic communication is permitted.
2. The SROC Administrator will conduct a pre-review of the funding source before the protocol is reviewed by the FC.
3. The UNL IRB will not review any hESC or hFT research until the SROC has approved the protocol.
4. The UNL IRB must be given a) the hESC or hFT research application, and b) all pertinent SROC correspondence.
5. The SROC will review amendments that require a change in cell lines/hFT, procedures, and/or study objectives by FCR. Amendments must also be reviewed and approved by the UNL IRB. Other minor amendments, such as change in personnel, will be reviewed by expedited review, which only requires approval by the chair/designee.
6. The SROC will conduct Continuing Review (CR) at a FCR meeting. The UNL IRB will not review continuation of any hESC or fetal tissue research until the SROC has re-approved the protocol.

D. Record

- a. The SROC administrator will maintain minutes of all FCR meetings, which include time, date, members present, members recused and actions of the committee.
- b. The SROC Chair and the administrator will develop SROC review letters to PIs requiring modifications and/or clarifications.