

IRB Rules and Procedures

MEETINGS SCHEDULE AND DEFINITION OF QUORUM

Meetings Schedule

The IRB shall hold meetings as necessary for the timely and effective review of proposed research projects. The IRB chairperson shall schedule and preside over the meetings. *For the 2005-2006 Academic Year, the IRB convenes meetings of the full membership on the first Monday of each month.*

Quorum

Meetings shall only proceed when a quorum exists. A quorum exists when a majority of the IRB members are present and those present include at least one member whose primary concerns are in a non-scientific area.

CORRESPONDENCE WITH THE IRB

Manner

Correspondence to and from the IRB shall be done electronically via email. All Requests for Review and Approval shall be submitted to the IRB chairperson electronically as an email attachment.

Timing of Submissions

All requests for IRB review and approval shall be done in advance of the start of the proposed research project. When funding is sought from sponsors to support the proposed research, the Chairperson of the IRB shall be notified of any applicable grant proposal deadline at the time the IRB Request for Review and Approval form is submitted.

Timing of Responses

Investigators shall receive prompt notification of IRB decisions. The Chairperson shall notify the investigator who submitted the IRB Request for Review and Approval form of the decision of the IRB conferring approval, exemption or disapproval of the proposed research project within 1 working day of the IRB decision irrespective of the source of the decision (ie. full IRB review, expedited review, or exemption). In the case of disapproval, the notification will include specific citation of the reason(s) for the disapproval.

IRB REVIEW

Initial Review

All proposed research projects submitted for review shall be directed to the IRB Chairperson who shall conduct an initial review to determine whether the research is eligible for expedited review or exemption.

Expedited Reviews

In cases where the IRB Chairperson determines that a proposed research project is eligible for expedited review, he/she shall either conduct the review him/herself or shall designate another IRB member to conduct the review and report back to the Chairperson with a recommendation for action. IRB meetings are not necessary for the approval of proposed research projects that

have been subjected to expedited reviews or for determining that research projects are exempt from IRB review.

Conferring Exemption

The chairperson of the IRB alone shall deem a proposed research project exempt from further review. The conferral of an exemption does not require the convention of the IRB.

Full IRB Review

Proposed research that is deemed ineligible for either expedited review or exemption shall be reviewed by the full IRB at a scheduled meeting.

Member Voting

In the final consideration of each proposed research project submitted for the review of the entire IRB, IRB members shall each cast one vote to either approve or disapprove. The votes shall be counted and the majority shall prevail. Any IRB member with a conflict of interest in considering a proposed research project must recuse himself/herself from its review and consideration and may not vote on its approval. Should such recusals result in less than a simple majority of the IRB members remaining to review the proposed research (i.e. less than a quorum), the IRB shall take no further action until such time as a simple majority can be re-established.

IRB DECISIONS

Conferring Approval

Proposed research projects shall be deemed approved by the IRB when:

- a) in the case of expedited reviews, the designated IRB member conducting the review and the chairperson both confer approval, or
- b) in the case of all other reviews, a simple majority of the IRB members present at the meeting vote to confer approval.

Conferring Disapproval

IRB meetings are required for the disapproval of proposed research projects even if such proposals were initially subjected to expedited review. Such disapprovals shall be the result of the vote of a simple majority. In the communication of the disapproval to the investigator, the IRB shall state the reasons the proposed research project was disapproved.

Reapplication to the IRB

Investigators proposing research projects that have been disapproved by the IRB after review may resubmit a Request for Review and Approval at any time after necessary changes have been made to the project design.

RECORD OF IRB WORK

Record of IRB Proceedings

The minutes of IRB meetings shall be taken and shared with all IRB members within a reasonable period following each meeting. Actions of the IRB that take place outside of regular meetings (conferring approvals through expedited reviews and exemptions) shall be shared with all IRB members within a reasonable period following each such action. Files documenting the composition and work of the IRB shall be kept in the Office of the Provost.

Instructions/Procedures for Submitting Research Proposals to the IRB

BSC has a responsibility to protect the welfare of human subjects in research conducted at or sponsored in some part by the college. To that end, and in compliance with federal rules, the college has established an Institutional Review Board, or IRB, charged with reviewing all proposed research that would involve the use of human subjects.

If you are proposing a research project involving human subjects, before you begin, you must submit a ***Request for IRB Review and Approval*** via email to the Chairperson of the IRB, Dr. Robert Slagter, rslagter@bsc.edu. The request serves to provide the IRB with the information about your project that it needs to make a determination.