

**SEATTLE CHILDREN'S RESEARCH INSTITUTE
OPERATING POLICIES / PROCEDURES**

DEPARTMENT: Institutional Biosafety Committee (IBC)
POLICY NUMBER: IBC-004
REPLACES: IBC-04 (6/7/06)
EFFECTIVE DATE: 10/15/08
REVISION DATE: 10/15/08
POSTED FROM: Exempt per RIA-01-14.2.3

TITLE: Protocol Review and Approval Process

SUMMARY:

The purpose of this policy is to describe the process used by the IBC to review bio-safety protocols to ensure that the criteria established by the *NIH Guidelines*, are implemented. The primary goal is to facilitate compliance with applicable laws, regulations, and policies consistent with the performance of appropriate and productive scientific endeavors.

POLICY/PROCEDURE:

004-1 Content

004-1.1 Investigators must submit a complete "Biosafety Memorandum of Understanding" (BMUA) application to the IBC Chair. The application must include all requested information, including but not limited to:

- 003-1.1.1 Identification of the bio-hazardous agents to be used;
- 003-1.1.2 Location where bio-hazardous agents will be used,
- 003-1.1.3 A complete description of the proposed use of the bio-hazardous agents, and;
- 003-1.1.4 Names and qualifications (training) of all personnel who will be working with the bio-hazardous agents.

004-2 Protocol Review

004-2.1 Procedures for protocol review are initiated through the IBC Chair. IBC members are provided with submitted documents, via e-mail, to provide all committee members with the opportunity to call for full review. If full review is requested by any committee member, a quorum of not less than half the committee plus one member will convene to review the protocol. Approval is granted only after all concerns are satisfied. A letter of approval, signed by the IBC Chair, is then provided to the principal investigator.

- 004-2.2 If Full Review is requested by any committee member, a quorum of not less than half the committee plus one member will convene to review the protocol. Following discussion, the committee will vote on the protocol. A written minority report will be requested by the Chair of all dissenting voters.
- 004-2.3 If the IBC feels that it does not have the scientific or technical expertise to evaluate all aspects of a proposal it may elect to use outside expert consultants (non-voting) to provide information. It may also request that the investigator attend the meeting to justify and explain the proposed experiments.
- 004-2.4 The IBC shall review any grant application associated with a funded bio-hazardous research protocol. The committee designee shall compare the funded application with any approved or pending IBC protocol to ensure uniformity in design and conduct.
- 004-3 Designated Review
- 004-3.1 If full review is not requested by any committee member, a Designated Reviewer (may not disapprove a protocol) will be appointed by the IBC Chair. Direct dialog between the reviewer and the principal investigator results in direct responses to any concerns raised.
- 004-4 Expedited Review
- 004-4.1 The IBC may use the expedited review procedure for:
- 003-4.1.1 Review of protocol amendments in accordance with IBC-03.3, and;
- 003-4.1.2 Annual review of approved protocols.
- 004-4.2 Under expedited review, the IBC Chair, or a designated member of the IBC, reviews the protocol. In reviewing the protocol, the designated reviewer may exercise all of the authorities of the IBC except disapproval. A protocol may be disapproved only after review in accordance with Full Review procedures (4.2b).
- 004-4.3 Any protocol approved by expedited review shall be reported at the next convened IBC meeting.
- 004-4.4 Any IBC member may request that an activity which has been approved under the expedited (not Designated Review) procedure be reviewed by the full committee. A vote of the members shall be taken concerning the request which may be: (1) for more information, (2) requiring modification, or (3) disapproving the project.
- 004-5 Committee Actions
- 004-5.1 **Approval.** All review criteria have been adequately addressed by the investigator. Approved bio-hazardous materials may be purchased and used in the approved protocol only. Approval is given for five years, with a requirement for review when modified (e.g. – personnel, location, agent, or procedure).

- 004-5.2 **Modifications required to secure approval.** In some cases, the protocol may be approved pending specific modifications to the application (approval with changes). At the conclusion of the committee meeting, the IBC Chair will prepare a letter outlining the specific concerns presented by the committee. These concerns must be addressed to the satisfaction of the IBC Chair (or designated reviewer) within 30 days of receipt. No animals may be ordered until the final approval is received by the investigator.
- 004-5.3 **Deferred.** Deferred protocols are neither approved nor disapproved. Clarification and/or revisions/additions are needed to properly assess the proposed research. The investigator may be asked to submit significant additional information or a new protocol. No bio-hazardous agents may be ordered until the final approval is received by the investigator.
- 004-5.4 **Disapproved.** The Committee did not approve the protocol. A new revised protocol must be submitted for review based on the observations/recommendations/criticisms of the IBC.
- 004-6 Approval Period
- 004-6.1 Protocols are approved for five years, after which the protocol must be rewritten and resubmitted as a new protocol. The re-submission must include an updated review of the available literature and a synopsis of the status of the study.
- 004-6.2 The IBC Chair will initiate a full review of the re-submitted application in accordance with 4.2a.
- 004-7 Review and Renewal
- 004-7.1 All approved protocols must be reviewed when modified.
- 003-7.1.1 The IBC Chair will advise the investigator of renewal one month before the expiration date (five years from initial approval);
- 003-7.1.2 The investigator shall submit a “Modification/Renewal Bio-safety Memorandum of Understanding and Agreement” to the IBC Chair, for each ongoing study, no later than two weeks before the expiration date and prior to any modifications.
- 004-7.2 Modifications review will employ the Expedited Review Process.

Submitting Office: Institutional Biosafety Committee

Approved by:

\\s\ David Moore 10/15/2008
IBC Chair | Director, Research Technical Operations

\\s\ James B. Hendricks, PhD 10/15/2008
President, Seattle Children's Research Institute