

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

DEPARTMENT:	<u>Institutional Biosafety Committee (IBC)</u>
POLICY NUMBER:	<u>IBC-003</u>
REPLACES:	<u>IBC-03 (6/7/06)</u>
EFFECTIVE DATE:	<u>10/15/08</u>
REVISION DATE:	<u>10/15/08</u>
POSTED FROM:	<u>Exempt per RIA-01-14.2.3</u>

TITLE: Protocol Amendments

SUMMARY:

The purpose of this policy is to describe administrative procedures for review of amendments to approved biosafety protocols.

POLICY/PROCEDURE:

- 003-1 Modifications to approved protocols may occur during the course of experimentation and must be submitted for IBC review and approval prior to any protocol change. Modifications may include change in personnel, protocol, or location. These should be addressed by submitting a "Modification/Renewal Bio-safety Memorandum of Understanding and Agreement" form to the IBC Chair.
- 003-2 All protocol modifications are submitted to 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 membership plus one member will convene to review the modification. If full review is not requested by any committee member, a designated reviewer will be appointed by the IBC Chair.
- 003-3 Expedited review of protocol amendments, conducted by the IBC Chair, may be used whenever proposed changes will have little or no effect on biosafety. Expedited review may be used for the following:
- 002-3.1 Addition of new biosafety procedures that have been approved in advance by the IBC, and;
 - 002-3.2 Addition of new personnel involved in biosafety procedures.

003-4 Any proposed change that, in the judgment of the IBC Chair, is too extensive to be addressed by amendment shall be returned to the investigator for submission as a new protocol. The occasion may arise where multiple amendments have been submitted to an existing protocol during the course of the approval period. If, in the judgment of the IBC Chair, additional changes requested to an existing protocol make monitoring and review of the existing protocol too complex, the investigator may be requested to submit a new protocol.

003-5 Copies of all approved amendments will be maintained by the IBC Chair to assure proper tracking of biosafety numbers and procedures for the IBC.

Submitting Office: Replace this text with your Department or Office Name

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