

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

<b>DEPARTMENT:</b>	<u>Institutional Biosafety Committee (IBC)</u>
<b>POLICY NUMBER:</b>	<u>IBC – 001</u>
<b>REPLACES:</b>	<u>IBC – 01 (6/7/06)</u>
<b>EFFECTIVE DATE:</b>	<u>10/15/08</u>
<b>REVISION DATE:</b>	<u>10/15/08</u>
<b>POSTED FROM:</b>	<u>Exempt per RIA-01-14.2.3</u>

**TITLE:** Implementation of IBC Committee Action

**POLICY/PROCEDURE:**

IBC approval is granted if, after careful review, there are no controvertible issues relating to the protocol. Approval shall not be granted until all issues raised by the IBC have been satisfactorily addressed. The findings of the IBC shall be reported to the principal investigator and the institutional official.

001-1 If the study is approved, the IBC shall:

- 001-1.1 Provide the investigator a written letter, signed by the IBC Chair, of approval stating:
- 001-1.2 The term for which IBC approval was granted, which term shall not exceed twelve months;
- 001-1.3 The assigned IBC study number;
- 001-1.4 The protocol title, and;
- 001-1.5 Contact information for the IBC Chair.

001-2 If the study is approved, the IBC Chair shall:

- 001-2.1 Enter study information in the *Active Protocols Registry*.

001-3 If the study is disapproved, the IBC shall:

- 001-3.1 Provide the investigator a written letter, signed by the IBC Chair, of disapproval stating:
- 001-3.2 The reason(s) for disapproval;
- 001-3.3 The assigned IBC study number;
- 001-3.4 The protocol title;
- 001-3.5 The Appeals Process Policy (refer: IBC-16);
- 001-3.6 A reminder that no research involving recombinant DNA or bio-hazardous agents can take place without formal IBC approval, and;
- 001-3.7 Contact information for the IBC Chair.

001-4 If the study is deferred, the IBC shall:

- 001-4.1 Provide the investigator a written letter, signed by the IBC Chair, of deferment stating:
- 001-4.2 The specific revision(s), clarification(s), and/or modification(s) necessary for approval;
- 001-4.3 The deadline for receipt of materials, for further consideration, for substantive revision(s), clarification(s), and/or modification(s);
- 001-4.4 The assigned IBC study number;
- 001-4.5 The protocol title;
- 001-4.6 A reminder that no research involving recombinant DNA or bio-hazardous agents can take place without formal IBC approval, and;
- 001-4.7 Contact information for the IBC Chair.

001-5 Handle Investigator responses to disapproved or deferred studies as follows:

- 001-5.1 Full IBC (convened quorum) review;
- 001-5.2 The IBC will extend an invitation to the investigator to attend;
- 001-5.3 The IBC will vote only after the investigator has been excused;
- 001-5.4 The IBC will provide the investigator a written letter, signed by the IBC Chair, if approval is granted, and;
- 001-5.5 The IBC will provide the investigator a written letter, signed by the IBC Chair and the Institutional Official (IO), if approval is denied.

Submitting Office: Institutional Biosafety Committee

Approved by:

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

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