1.0 Reason for Policy

This policy describes the actions the Institutional Biosafety Committee (IBC) may take resulting from its review of research.

2.0 Scope of Policy

This policy applies to the University of Minnesota IBC and its Committee Members.

3.0 Policy Statement

The IBC has the authority to decide to approve, withhold approval (pending clarification), disapprove the proposed research activity, or specify modifications required to secure IBC approval of the proposed activity. These actions will be taken by a vote of a majority of the members present. When a proposal is reviewed by the IBC chair or other IBC member, they can make any of the following actions, except to table or disapprove a study.

Process:

The IBC may make one of the following determinations as a result of its review of research submitted for initial review or for continuing review:

Policy Owner: Executive Director, HRPP

Definitions:
None
• **Approval:** The protocol and accompanying documents are approved as submitted. Final approval will commence on the day the study is approved by an action of the convened IBC and expire within (1) year of the approval date.

• **Approval with Stipulations:** The IBC will stipulate specific revisions that require simple agreement by the investigator. Approvals are conditional to the Investigator. The conditions for approval and the time frame (if any) within which they must be met will be clearly stated in the approval letter. If the conditions of the approval are not met, approval may be withdrawn.

• **Deferred:** Significant questions are raised by the proposal requiring its reconsideration after additional information is received from the Investigator. Investigators are given 90 days in which to respond to the deferral notice. Response from the researcher must be returned to the full committee for review and consideration.

• **Not Approved:** The proposal fails to meet one or more criteria used by the IBC for approval of research. Disapproval may only be given by majority vote at a convened meeting of the IBC.

• **Verification from other sources:** The IBC may determine that it needs additional information or verification from other sources when:
  - reviewing new proposals,
  - conducting continuing review,
  - reviewing unanticipated problems or incident reports,
  - there is a complaint or an allegation of non-compliance, or a history of such,
  - there is a perceived conflict of interest or a proposed management plan,
  - reviewing a monitoring or regulatory affairs review, or
  - in the opinion of members, chair, or staff, it is determined that another perspective or expert point of view would be helpful.

Investigators may not begin working with recombinant DNA, Infectious Agents or Biological Toxins until final approval has been granted.

**Procedure:**

• Approval Date: is issued as of the date that the requested information or materials are approved.

• Expiration Date: is calculated from the date of the convened meeting at which the IBC approved the protocol or approved the research with modification. Approval is usually one year, but may be given for a lesser period of time (less than one year) based on the relative perceived level of risk, previously reported issues with the biological agent, previous issues with the PI, or the nature and location of the study.

• The IBC may decide at the time of review that, due to concerns regarding the nature of the technology involved, the study in question should be reviewed on a more frequent basis than annually. This condition may be imposed at any time during the life of the study while under IBC review. If concerns are eventually found to be unwarranted, the IBC may opt to return the study to an annual review schedule.
• The IBC may at any time during the initial or continuing review of a project, seek verification of study components or study conduct from additional sources. Such sources may include, but are not limited to: bioethics consultation, regulatory affairs consultation, compliance committees, Investigational Pharmacy, institutional officials. Circumstances which might prompt such verification may include, but are not limited to: novel technologies, use of exceptionally hazardous biological materials, proposals from novice researchers or researchers whose work had undergone inquiry or investigation. Such verification will be documented in IBC study files.

• Upon review of a protocol, the IBC may find that it lacks the specific expertise necessary to adequately review the research. IBC members may nominate known individuals for consultation.

• In fair service to the investigator, the IBC is willing to reconsider new applications or requests for changes that have been denied. In such cases, the investigator should make a written appeal to the IBC, addressing the panel’s concerns regarding the research. If the IBC finds that the written appeal does not satisfy its concerns, the investigator may be asked to attend an IBC meeting to discuss the concerns and answer specific member questions. Written documentation of such meetings will be recorded in the minutes.

### 4.0 Required approvals for this document

<table>
<thead>
<tr>
<th>Title</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Executive Director, HRPP</td>
<td>Moira A. Keane</td>
</tr>
</tbody>
</table>

### 5.0 Revision History

<table>
<thead>
<tr>
<th>Revision</th>
<th>Reason for change</th>
<th>Date of release</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/08/11</td>
<td>Policy revisions</td>
<td>12/08/11</td>
</tr>
<tr>
<td>06/21/10</td>
<td>Policy approved at IBC meeting</td>
<td></td>
</tr>
<tr>
<td>03/02/10</td>
<td>Revision</td>
<td>03/02/10</td>
</tr>
<tr>
<td>12/10/09</td>
<td>New format</td>
<td></td>
</tr>
<tr>
<td>05/02/07</td>
<td>New policy</td>
<td></td>
</tr>
</tbody>
</table>

To obtain a copy of a historical policy, e-mail at ibc@umn.edu or call 612-626-5654