1.0 Reason for Policy

This policy describes how the IBC conducts review of modifications to previously approved research.

2.0 Scope of Policy

The scope of this policy is the University research community and its partners.

3.0 Policy Statement

Changes in protocol in approved research for which approval has been given may not be initiated without prior IBC review (full committee review or review by IBC member, as appropriate) and approval, except where necessary to eliminate apparent immediate hazards. In such cases, the investigator must promptly inform the IBC of the implemented change.

Procedures:
Investigators must submit requests for changes to the IBC (with the IBC Change in Protocol Form) electronically from the e-mail account assigned to the Principal Investigator.
The form includes:
- Description of the changes
- Reason for the change
- Whether or not changes impact safety procedures and/or laboratory standard operating procedures
- The impact the change will have on the study and/or safety considerations
- All appropriate documents as required by the IBC

Upon receipt of the Change in Protocol form, IBC senior staff or IBC member will determine the appropriate level of review.

**Full Committee Review**

If the change in protocol requires full committee review, the IBC must review and approve the proposed change at a convened meeting before the change can be implemented. When feasible, the reviewers of the initial IBC submission will be assigned as the reviewers of the change in protocol. All other members will receive a copy of the change in protocol request.

**Notification of Investigator**

All approvals or requested revisions will be reported to the investigator in the usual manner.

### 4.0 Required approvals for this document

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

### 5.0 Revision History

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<tr>
<th>Revision</th>
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<tbody>
<tr>
<td>12/08/11</td>
<td>Policy update</td>
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<tr>
<td>03/02/10</td>
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<td>03/02/10</td>
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<tr>
<td>12/10/09</td>
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<tr>
<td>04/24/07</td>
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To obtain a copy of a historical policy, e-mail ibc@umn.edu or call 612-626-5654.