1.0 Reason for Policy

This policy explains what is delivered to Institutional Biosafety Committee (IBC) members before the convened meeting.

2.0 Scope of Policy

This policy applies to HRPP internal.

3.0 Policy Statement

Application materials meeting the requirement for full committee review will be distributed electronically to all the IBC members, generally at least seven days prior to the meeting, unless deemed urgent by HRPP staff or IBC Committee Chair. Each member (voting and non-voting) of the IBC, and any alternate members attending the meeting in place of a regular member will have access to the meeting materials. Consultants will only receive materials pertinent to their requested review.

Agenda/Transmittal to Members

Prior to a scheduled meeting, the agenda is prepared by IBC staff. All submissions to be reviewed are listed by category of review (Minutes of Previous Meeting, Human Proposals, Response to Committee...
Requests/Deferral, New Proposals and Three-year Renewals, Changes in Protocol, Informational Items and Actions by Biosafety Officer) with explanatory text included as needed.

If a member is new to the review process, he or she begins acting as primary reviewer (after an observation period) with an experienced member acting until such time as the new member has logged sufficient reviewing experience. Committee members will not be assigned as primary reviewer of proposals on which they may have a potential conflict of interest. Furthermore, the member with the potential conflict must recuse him/herself from the deliberation, discussion, and vote on that study. Unless the conflicted member’s presence is requested to provide additional information, the member must leave the room until after the vote is taken.

**Selection of Primary Reviewer(s)**

Primary reviewer(s) are assigned based on a perceived lack of conflict of interest and expertise in the subject matter. If a member is assigned to review a project on which they have a conflict of interest, they are directed to call the IBC office, at which time a new primary reviewer is assigned.

**Planning for Quorum**

When the number of those planning to attend falls below quorum, alternate members are contacted until the number of members with confirmed attendance meets or exceeds quorum. IBC staff will make every effort to ensure the presence of at least one member over the required quorum at each convened meeting.

The IBC staff member prepares the agenda materials to be distributed to members. The agenda indicates:

- Date
- Time
- Location
- List of IBC members in attendance (voting and ex-officio non-voting)
- Guests (if any)
- Consultants (if any)
- Items for review
  - Minutes of Previous Meeting
  - Human Proposals
  - Responses to Committee Requests/ Deferral
  - New Proposals and Three-Year Renewals
  - Changes in Protocol
  - Discussion Items (if any)
  - Informational Items (if any)
  - A List of Administrative Actions taken on Behalf of the IBC

**Procedure:**

- **All IBC Members receive:**
  - Full application, including protocol summary and other relevant information and attached documents to determine if the proposed research fulfills the criteria for approval.
• The Primary Reviewer(s) may receive: (in addition to above, if it is applicable and received):
  o Relevant grant applications
  o Investigator Brochures (if applicable)
  o Cover letter, if meaningful during the IBC meeting (or any other time a reviewer would like to see them)
  o An appropriate IBC review guide to complete during their review

Changes in Protocol

• All members for changes in protocol receive:
  o Copy of the cover letter requesting modifications
  o Detailed explanation of the modifications with justification for request for change and an indication of any potential implications the changes may have on health and safety
  o Copy of the initial application

• The primary reviewers receives (in addition to the items listed above):
  o An appropriate IBC review guide to complete during their review

Administrative Actions on Behalf of IBC
All IBC members will receive a brief description on the agenda of the actions taken by the IBC senior staff, IBC chair or other IBC member. If an IBC member would like to review application materials for a project or amendment approved by this process, they may contact IBC staff to receive copies of the materials.

Confidentiality
All materials received by the IBC are considered confidential. Excess hard-copy materials produced for IBC members to review are collected at the conclusion of meetings and destroyed. Confidential materials are posted on the internet in a location that can only be accessed by persons who are given password protected access. All confidential materials will be removed from the internet within two weeks of the date on which the meeting occurred.

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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5.0 Revision History

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