1.0 Reason for Policy

This policy outlines the requirements for all University of Minnesota Principal Investigators (PI) or researchers.

2.0 Scope of Policy

This policy applies to the University of Minnesota research community.

3.0 Policy Statement

Principal Investigators (PIs) or researchers must comply with the University of Minnesota- Code of Conduct. PIs are required to ensure that they and their research staff follow the approved IBC application and comply with all applicable NIH Guidelines and UMN Board of Regents Policy.
Tasks relating to the conduct of the research project may be delegated to individuals listed on the project, such as co-investigators or research staff, but the ultimate responsibility for ensuring the integrity of the research rests with the PI. The responsibilities include but are not limited to the following:

- The PI is responsible for obtaining initial IBC review/approval and continuing review for the course of the research project
- The PI is required to obtain appropriate education and to conduct research that meets all NIH Guidelines and UMN requirements
- The PI is required to ensure that members of the research team receive all required and ongoing training or education
- The PI is responsible to report incidents to the IBC and/or DEHS according to NIH Guidelines
- The PI is responsible for submitting a revised application for the 3 year renewal process
- The PI is required to ensure that accurate and current copies of the following are in the researcher study file records: application, amendments, standard operating procedures, changes in protocol, inspection results, consent documents, and IBC communication documents, for example
- When a research project changes from one PI to another, such as a result of resignation or retirement, the change in PI responsibility must be approved by the IBC
- The PI may bring forward to the Institutional Official, the director of HRPP, or the IBC Committee, any concerns or suggestions regarding the HRPP or IBC program, including but not limited to the review process of the committee.

**IBC Research that includes Human Subjects:**

- PIs whose research includes human subjects, such as Human Gene Transfer (HGT) or infectious agents/toxins, are responsible for ensuring that informed consent is obtained from each subject or the subject's legally authorized representative, unless the requirement has been waived by the IBC and IRB
- PIs are required to report all serious adverse events, in HGT or other research which may involve risk to the human subjects or others, to the IBC and IRB for consideration and action
- PIs must request approval for all amendments to or modifications of the research proposal, including the HGT consent form, to the IBC and IRB prior to initiating the changes
4.0 Required approvals for this document

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<thead>
<tr>
<th>Title</th>
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<tr>
<td>Executive Director, HRPP</td>
<td>Moira Keane</td>
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5.0 Revision History

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<tr>
<th>Revision</th>
<th>Reason for change</th>
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<td>10/18/10</td>
<td>Policy approved at IBC meeting</td>
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<tr>
<td>03/05/10</td>
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<tr>
<td>12/11/09</td>
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