1.0 Reason for Policy

This policy describes how the Institutional Biosafety Committee (IBC) will interact with the Institutional Review Board (IRB) in the review of research that includes human research participants; including, but not limited to, Recombinant DNA/Human Gene Transfer (HGT) and research with biologically derived toxins or infectious agents. In general, the IBC advises the IRB on risk assessment and biosafety issues according to the NIH Guidelines. It is essential that good communication exist between the IBC and the IRB.

2.0 Scope of Policy

This policy applies to the University of Minnesota research community.
3.0 Policy Statement

Recombinant DNA

For experiments involving the deliberate transfer of recombinant DNA (rDNA), or DNA or RNA derived from rDNA, into human research participants (human gene transfer (HGT)), no research participant shall be enrolled until the:

- Recombinant DNA Advisory Committee (RAC) review process has been completed
- Institutional Biosafety Committee (IBC) approval (from the clinical trial site) has been obtained
- Institutional Review Board (IRB) approval has been obtained
- All applicable regulatory authorization(s) have been obtained (1-A-1-a)

The IBC is responsible for ensuring that final IBC approval is granted only after the RAC review process has been completed. The IBC will not review an HGT application until RAC review is completed. In addition to NIH Guidelines and review, HGT clinical trials are subject to FDA regulations as biological products.

The IBC review process for HGT research may proceed as follows:

- The researcher submits protocol to the RAC, including Appendix M and additional NIH required documents
- RAC review is completed
- The researcher develops and submits an IBC HGT application that includes the RAC review comments and Appendix M
- The IBC full committee reviews the HGT application. When all stipulations have been addressed by the researcher, the IBC forwards its comments about biosafety and consent form recommendations to the IRB
- The researcher submits an IRB application for the human subject portion of the HGT research. The IRB full committee reviews the application. The IBC and IRB collaborate on safety and the informed consent process
- Researchers may submit IBC and IRB applications simultaneously. However, the application must first be reviewed by the IBC to assure that biosafety comments are available to the IRB for discussion and review
- Both the IBC and IRB will review unanticipated problems, serious adverse events, changes in protocol, informational items or updates submitted during the course of the research.
Biologically Derived Toxins or Infectious Agents

According to University Board of Regents policy, experiments that use human research participants and include biologically derived toxins or infectious agents must be reviewed by the IBC:

- The researcher may submit both IBC and IRB applications. IBC and IRB applications may be submitted simultaneously, but IBC review may occur prior to IRB review.
- The IBC advises the IRB on risk assessment and biosafety issues.
- The IBC and IRB will collaborate on the informed consent process to assure risk and benefit is described appropriately.
- Both the IBC and IRB will review unanticipated problems, serious adverse events, changes in protocol, informational items or updates submitted during the course of the research.
- IBC must approve the project before the IRB grants approval.

Informed Consent Process

The IBC and IRB will collaborate to review and revise the consent form(s) in order to ensure that risks and benefits are clearly described to human subjects.

Continuing Review Process

Both the IBC and IRB will review unanticipated problems, serious adverse events, changes in protocol, informational items or updates submitted during the course of the research.

Reporting Requirements

The IBC and IRB will report serious adverse events to the full committee, IO, or funder as required by FDA and OHRP regulations and NIH Guidelines.

4.0 Required approvals for this document

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<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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