1.0 Reason for Policy

This policy describes the purpose of the University of Minnesota Institutional Biosafety Committee (IBC); both the institutional role and authority under which the IBC operates and the organizational structure and regulatory charge for review of research according to NIH Guidelines.

2.0 Scope of Policy

This policy applies to the University of Minnesota research community.

3.0 Policy Statement

The University of Minnesota (UMN) Human Research Protection Program (HRPP) and the IBC are under the authority of the Institutional Official (IO) /Vice President of Research (OVPR). UMN faculty, staff and students must comply with federal and state regulations and UMN policies and procedures when conducting research and teaching activities with, or storage of, potentially hazardous biological agents.
The IBC is a committee established by the president or delegate in accordance with the federal regulations to review UMN research activities involving recombinant and synthetic nucleic acids or other potentially hazardous biological agents. The IBC reviews applications for research to ensure regulatory guidance is upheld.

**Regulatory Charge**

- *NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules*
- Biosafety in Microbiological and Biomedical Laboratories (BMBL)
- UMN Board of Regents Policy, Activities Involving Recombinant DNA or other potentially hazardous biological agents
- UMN Policy 2.1.13 Using Potentially Hazardous Biological Agents for Research or Teaching and associated procedures

**Authority of the IBC**

To carry out its charge as required under *NIH Guidelines* and Regents Policy, the IBC has the following responsibilities and authorities:

- The IBC reviews and has authority to approve, require modifications of, or disapprove all research involving the use of recombinant and synthetic nucleic acid molecules, infectious agents (including non-virulent and vaccine strains), and/or biologically derived toxins (including mutated, truncated, or inactivated toxins)
- Review, approve, modify, disapprove initial, ongoing, or continuing proposals to ensure that activities conform to the *NIH Guidelines*
  - Set containment level for agents, animals and plants
  - Assess and inspect facilities, procedures, training and expertise of personnel
  - Ensure coordination of Recombinant DNA Advisory Committee (RAC) review and Institutional Review Board (IRB) review for activities involving human gene transfer
- The IBC maintains the authority to disapprove studies or requested changes/additions if the appropriate safety standards for are not met
- Continuing Review: All on-going research must be reviewed by IBC Senior Staff or IBC member in conjunction with additional information and updates provided by the investigator, at least once per year
- Adopt emergency plans covering accidental spills and personnel contamination
- Report significant problems with, and violations of, the guidelines or activities-related accidents or illnesses to Institutional Official (IO) for subsequent reporting as required by guidelines

### 4.0 Required approvals for this document

<table>
<thead>
<tr>
<th>Title</th>
<th>Name</th>
</tr>
</thead>
</table>

Page 2 of 3
Executive Director HRPP | Debra Dykhuis

<table>
<thead>
<tr>
<th>Revision</th>
<th>Reason for change</th>
<th>Date of release</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/08/12</td>
<td>Update staff and minor text</td>
<td>01/08/13</td>
</tr>
<tr>
<td>12/06/11</td>
<td>Update policy</td>
<td>12/06/11</td>
</tr>
<tr>
<td>09/27/11</td>
<td>Update policy</td>
<td>09/27/11</td>
</tr>
<tr>
<td>01/22/10</td>
<td>Revision</td>
<td>02/26/10</td>
</tr>
<tr>
<td>12/17/09</td>
<td>Revision</td>
<td></td>
</tr>
<tr>
<td>11/13/09</td>
<td>New Format</td>
<td></td>
</tr>
<tr>
<td>07/11/06</td>
<td>Policy Development</td>
<td></td>
</tr>
</tbody>
</table>

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