1.0 Reason for Policy

This policy explains the composition and maintenance of the roster of the Institutional Biosafety Committee (IBC).

2.0 Scope of Policy

This policy applies to IBC committee members.

3.0 Policy Statement

The HRPP office maintains IBC member rosters that meet the regulatory requirements IV-B-2-a-(1), IV-B-2-a-(2), and IV-B-2-a-(3) of the NIH Guidelines for Research involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines).
Procedure:

- **Nominations:**
  - University Institutional Official for Research appoints members to the IBC, after a review performed by the IBC chair and HRPP staff.
  - Fairview's Director for Research Administration will recommend and approve prospective members or ad hoc consultant appointed on behalf of Fairview Health Systems.
  - Prospective members may be nominated by those identified above, or they may nominate themselves.

- **Members:**
  - The *NIH Guidelines* outline the following minimum requirements for the University of Minnesota IBC:
    - A minimum of five members who collectively have expertise in rDNA technology sufficient to assess the safety of the research and identify the potential risk to public health and protection of the environment.
    - At least two community members not affiliated with the University that represents the surrounding community with respect to health and the environment.
    - A plant containment expert is required because the University reviews research utilizing Appendix P (*NIH Guidelines*).
    - An animal containment expert is required because the University reviews research utilizing Appendix Q (*NIH Guidelines*).
    - A Biological Safety Officer is required because the University is involved in rDNA research involving BL3, BL4, or Large Scale (greater than 10L).
  - The University of Minnesota IBC may maintain representation in the following areas:
    - A member or ad hoc consultant with expertise in human gene therapy
    - A member of the laboratory technical staff.
    - At least one member with expertise in the use of biological toxins.
    - At least one member with expertise in infectious agents.
    - At least one member with expertise in animal infectious disease.
    - At least one member or ad hoc consultant from each partner institution.
    - Other members as determined by the Institutional Official

- **New Members:**
  - The candidate shall provide documentation of the expertise s/he brings to the process by providing HRPP staff a current copy of their resume or curriculum vitae. Appointed HRPP staff will, in consultation with IBC leadership, review the candidate's qualifications.
  - HRPP staff may ask the nominating party to supply more information, including a letter of endorsement. HRPP staff may check the credentials with the needs of the panel in mind and question the candidate on any conflicts of interest. HRPP staff may contact the prospective member and may arrange for a meeting or email in which the HRPP staff explains the requirements for membership.
  - Threshold membership requirements include:
    - The candidate or the IBC can decide that IBC membership is not an appropriate endeavor;
The candidate must be able to attend meetings on a regular basis;
The candidate must be in good standing with his or her affiliation, i.e. no research privileges in suspension;
The candidate must not be excluded from participating in federal or state reimbursement programs, debarred from contracting with the federal or any state government, nor have been sanctioned by any federal agency regarding the conduct of research, and such other threshold criteria as determined by the IBC, with the approval of the University's Institutional Official for Research.
The candidate will be responsible for attending new member training, continuing education and required/recommended activities
  o The Institutional Official letter of appointment is prepared by HRPP staff.

Community Members:
The IBC must have at least two community members. Community members or their immediate family cannot have any financial ties to the University, including former University employees who may be unaffiliated for a minimum of three years before appointment. Community members with some related expertise are preferred. Former University students may be considered on a case-by-case basis.

Alternates:
In acknowledgement of the substantial time commitment involved in membership, the IBC permits the use of alternate membership. Members may alternate their attendance at IBC meetings provided they are of similar enough background so as to maintain the diversity of the panel. This arrangement both accommodates the service of members who are not available for full-time service and allows the IBC a broader range of experience and expertise.

Ex-Officio Members:
Ex-officio members are appointed for reasons of authority, expertise, or resource management. Ex-officio members may be knowledgeable in University policies, applicable laws, standards of professional conduct, etc. Ex-officio members are non-voting members of the IBC and are not counted for quorum.

Ad-Hoc Consultants for Human Gene Transfer Review:
If a human gene transfer expert is not available for review of a human gene transfer project, an ad hoc consultant will be sought in accordance with the NIH Guidelines.

Rosters:
HRPP maintains the IBC membership roster under the direction of the appropriate Assistant Director, which is available for inspection at anytime, and includes:
  - Names of IBC members
  - Earned degrees of IBC members
  - Alternate status
  - The representative capacity of IBC members (i.e. Animal Containment Expert, Plant Containment Expert, Biosafety Officer, etc.)
  - Sex (male/female)
An additional database is maintained by HRPP staff to include all membership attributes to fill criteria, including:

- Place of employment
- Membership start date
- Licensures/Certificates
- Area of expertise and background
- Current Curriculum Vitae/Resume

**Exclusions from Membership:**
Persons who make or oversee financial decisions for the institution or its partners are excluded from serving in a voting capacity on the IBC.

**NIH-OBA Annual Report:**
In accordance with *Section IV-B-2-a-(3)*, the institution shall file an annual report with NIH-OBA which includes:

- A roster of all IBC members clearly indicating:
  - Chair
  - Contact person
  - Biological Safety Officer (if applicable)
  - Plant expert (if applicable)
  - Animal expert (if applicable)
  - Human gene therapy expertise or *ad hoc* consultant (if applicable)

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### 4.0 Required approvals for this document

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<thead>
<tr>
<th>Title</th>
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<tbody>
<tr>
<td>Executive Director</td>
<td>Debra Dykhuis</td>
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### 5.0 Revision History

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