

 <p>Institutional Biosafety Committee Guiding Principles and Procedures</p>	<p>Effective: 2011</p> <p>Revised: June 13, 2014, October 2016, August 2021, October 2022, February 2023</p>
<p>Title: Committee Membership</p>	<p>Page 1 of 4</p>

Guiding Principle

To comply with federal regulation and guidelines, NDSU has created an IBC to oversee the University’s Biosafety program. The committee is comprised of members that fulfill the federal membership requirements. Members are appointed by the Institutional Official (IO).

1. Requirements and Composition

- 1.1.** As mandated by the NIH Guidelines, the IBC must be comprised of no fewer than five (5) members so selected that they collectively have experience and expertise in recombinant or synthetic nucleic acids technology and the capability to assess the safety of recombinant or synthetic nucleic acids research and to identify any potential risk to public health or the environment.
- At least two (2) members of the IBC are not affiliated with NDSU (apart from their membership on the IBC) and who represent the interest of the surrounding community with respect to health and protection of the environment.
 - At least one (1) member has expertise in plant, plant pathogen, or pest containment principles.
- 1.2.** When the institution participates in or sponsors recombinant or synthetic nucleic acids research involving human research participants, the institution must ensure the IBC has adequate expertise and training (using ad hoc consultants as deemed necessary).

According to the NIH Guidelines, in order to ensure the competence necessary to review and approve recombinant or synthetic nucleic acid activities it is recommended the IBC:

- Include persons with expertise in recombinant or synthetic nucleic acids technology, biological safety, and physical containment
- Include or have available as consultants; persons knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes and the environment
- Include at least one member representing the laboratory technical staff.
- May include at least one graduate student

2. Selection of Members

- 2.1. Affiliated members-may be considered non-scientists or scientists and are selected based on the need for relevant composition and/or expertise on the committee. The IBC Administrator or Chair will contact an Administrator (e.g. Chair, Dean, VP) within the desired unit and request a recommendation to fulfill the appropriate membership composition or expertise. Recommendations will be brought to the IO.
- 2.2. Non-affiliated members-may be considered non-scientists or scientists and are selected based on the need for relevant composition and/or expertise on the board. IBC members can recommend individuals to fulfill the non-affiliated member position. Recommendations will be brought to the IO.
- 2.3. Student members-The IBC Administrator requests recommendations from NDSU researchers to fulfill the student member position. The recommendations are reviewed by the IBC. The IBC forwards their recommendations on to the IO.

3. Appointment of Members

- 3.1. Members are appointed to the IBC by the IO for an initial period of up to 3 years, and may serve additional terms. To maintain an adequate level of experience the membership terms will be staggered.
- 3.2. Student members are appointed by the IO for a period of up to one year, and may serve additional terms.

4. Selection and Appointment of Officers

- 4.1. IBC Chair- The chair of the IBC is selected and appointed by the IO, based on experience and expertise from among the current membership. The chair is appointed for a period of one year and may be reappointed.
- 4.2. IBC Vice-Chair- The vice-chair is selected and appointed by the IO, based on experience and expertise from among the current membership. The vice-chair is appointed for a period of one year and may be reappointed.

5. Board Vacancies-the following process is employed for vacancies of affiliated and non-affiliated members. When a vacancy occurs prior to expiration of a term, the newly appointed member completes the remainder of the term.

- 5.1. Affiliated/Alternate Affiliated Members-Upon expiration of an affiliated members' term the IBC Office will ask for nominations to fill the appropriate composition or expertise on the committee. Re-nomination is subject to approval and appointment by the IO. Affiliated members have the option of not serving a full-term and resigning from the board. Such vacancies will be filled according to the procedures outlined in Section 3 above.
 - 5.1.1. If a member is unable or unwilling to fulfill expected duties and responsibilities on the committee or found to be in violation of IBC policies and procedures, they

may be asked to resign, or may be removed from the committee by the IO, in consultation with the IBC Chair, and IBC Administrator. A recommendation for removal may also originate from the affiliated member's Dean to the IO providing written justification for why the member is unable to fulfill expected duties and responsibilities on the committee.

5.2. Non-Affiliated/Alternate Non-Affiliated Members- Upon expiration of a non-affiliated member's term, the member may be reappointed to an additional term, subject to the need for appropriate composition and expertise, and approval by the IO. Non-affiliated members always have the option of not serving their full term and resigning from the committee. Such vacancies will be filled according to the procedures outlined in Section 3 above.

5.2.1. If a member is unable or unwilling to fulfill expected duties and responsibilities on the committee or found to be in violation of IBC policies and procedures they may be asked to resign or be removed from the committee by the IO, in consultation with the IBC Chair, and IBC Administrator.

5.3. Student Members- Upon expiration of a student member's 1-year term, they may be reappointed to a maximum of three years. Students have the option of not serving their full term and resigning from the committee. Such vacancies will be filled according to the procedures outlined in Section 3 above. If the vacancy occurs mid-term, a new student appointment may be delayed until the next academic year.

5.4. IBC Chair/Vice-Chair- Should the Chair/Vice-Chair be unable or unwilling to fulfill expected duties and responsibilities as Chair of the committee, they may be asked to resign or be removed by the IO. If removed as Chair, that member may retain their membership on the committee, unless otherwise removed.

6. Member Responsibilities- The charge of the IBC is to establish and maintain proper measures to ensure the appropriate use of biological materials in research, research training, teaching and biological testing activities conducted at NDSU or by NDSU faculty staff or students.

6.1. Regular Members-in carrying out responsibilities, IBC members are expected to:

- Maintain a working knowledge of issues pertaining to the IBC by completing training on the CITI website www.citiprogram.org "Training for IBC members"
- When required, perform timely reviews of protocols
- Assess risk and associated level of containment, facilities, and work practices
- Disclose any conflict of interest with respect to review of research protocols
- Attend meetings or notify IBC administrator of known absences
- Actively participate in meeting discussion and deliberation

6.3. IBC Chair-in carrying out responsibilities, the IBC Chair is expected to: Provide leadership to the IBC to help ensure safety in using biohazardous material are used on the NDSU campus;

- Maintain a good working knowledge of relevant federal regulations, state laws, and NDSU policies related to biosafety and recombinant DNA;
- Complete initial and continuing education requirements for IBC members;
- Conduct convened meetings in a professional manner, or arrange for the Vice-Chair to fulfill the role of Chair;
- Lead efforts to resolve controversial issues relating to the review or conduct of biohazard use;
- Perform timely review of protocols;
- Disclose any conflict of interest and request that IBC members with conflicts do not participate in the review and voting of relevant protocols;
- Regularly consult with the IO and IBC Staff on procedures and issues related to the biosafety program;
- Actively participate with IBC Office staff in initial assessment of complaints, unanticipated events and issues of noncompliance.

7. Use of Consultants

7.1. The IBC may invite individuals with expertise in special areas to assist in the review of issues beyond or in addition to the available expertise of the committee. These individuals serve as consultants on an as-needed basis, providing either written or verbal information to the committee. The individuals are not considered members and do not have voting privileges.