

 <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, November, 2023</p>
<p>Title: Protocol Review Procedures</p>	<p>Page 1 of 6</p>

Guiding Principle

The IBC shall review and approve, require modifications in , or withhold approval of activities related to biohazard use on campus. This Guiding Principle pertains to all protocols, proposed significant changes, annual updates, and re- reviews of approved protocols related to biohazards.

There are two methods of protocol review: Full Committee Review (FCR) and Designated Member Review (DMR). Any IBC member, at any time, for any reason can request FCR of any protocol.

Protocols will be posted for review via the DMR process unless the following are proposed which require full committee review:

- Research is NON-EXEMPT under the NIH guidelines
- Research involves potential BSL-3 infectious agents, such as prions

Protocol Review

All personnel proposing to use any of the following in their research must submit a completed IBC protocol in the [Novelution](#) system for review. Submissions are reviewed as described previously.

- Recombinant and Synthetic Nucleic Acids;
- Infectious agents;
- Human blood, bodily fluids, tissues and cell culture

Change in Protocol Requests

An amendment can be submitted to an approved Novelution protocol (or paper form for legacy protocols). If the change is significant, it may require a new protocol submission or be called to FCR. Changes listed below can be reviewed and approved by DMR.

- Title Change
- Facility Change
- Risk Group Change
- Methods and Procedures

The changes below will be reviewed and approved administratively without consultations or notifications.

- Personnel changes
- Correction of typographical errors
- Correction of grammar
- Contact information updates

The approval of significant changes are communicated to the committee at the IBC meetings.

Annual Update/Review Requirement

The IBC will conduct annual update reviews of all IBC protocols.

Annual updates are reviewed administratively by the IBC administrator, and the IBC Chair if needed. Current training for all listed personnel is required for approval.

Submission of a required annual review will be done within Novolution on the anniversary of the approval date. When a legacy protocol requires an annual update, the protocol will be moved into the Novolution system via a new protocol submission by the PI.

Review Procedures:

1.0 Designated Member Review (DMR)

1.1 Each eligible protocol is distributed to the entire IBC with specific instructions regarding the designated member review process and a deadline to call for FCR which is five business days. Affirmation from all IBC members is not required.

1.2 Under extenuating circumstances, the deadline can be reduced by the IBC Chair/designee to a minimum of one day with affirmation required from all members regarding their decision whether or not to call for FCR.

1.3 Designate Member Review Assignment

1.3.1 Two members of the IBC are assigned by the chair or designee.

- 1.4 Any member of the IBC can make the decision to send the protocol for FCR at any time during the set deadline period. If no member of the IBC refers the protocol to full committee review at a convened meeting, at the end of the set deadline period the assigned IBC DRs have the authority to approve, require modifications in (to secure approval) or request full committee review.
- 1.5 The DR decisions must be unanimous for approval; if not, the protocol will be set for revisions or referred for FCR. The DRs do not have the power to withhold approval.
- 1.6 The IBC minutes contain notification of all actions approved by DMR.

3.0 Administrative Review

- 3.1 The Request for Change form will be reviewed by IBC Office personnel.
- 3.2 IBC Office personnel will make a determination or refer the change request to DMR or FCR.

4.0 Full Committee Review (FCR)

- 4.1 Full committee review of protocols requires a convened meeting of a quorum of the IBC members. For a protocol to be approved, it must receive the approval of the majority of those members present at the convened meeting.
- 4.2 A quorum consists of at least 50% of the total voting members of the committee and a vote of approval requires at least a simple majority. The Chair or designee must be present. Protocols scheduled for full IBC review are distributed to all members of the IBC at least one week prior to the meeting. The IBC meets once per month with additional meetings to address extenuating circumstances convened when necessary.
- 4.3 The IBC chair, or his/her designee, assigns at least two members to serve as technical reviewers. The technical reviewers present their findings to other member of the committee at a properly convened IBC meeting for discussion.
- 4.4 When it is determined that consultants or experts will be required to advise the IBC in its review of a protocol, the protocol shall also be distributed to the consultants or experts prior to the meeting, and if necessary, the consultant or expert may be invited to the Full Committee Meeting. Consultants may not approve or withhold approval of any activity or vote with the IBC.
- 4.5 No member may participate in the IBC review or approval of a protocol in which the member has a conflicting interest (e.g. is personally

involved in the project) except to provide information requested by the IBC; nor may a member who has a conflicting interest contribute to the constitution of a quorum. At the beginning of each meeting the Chair of the IBC reminds investigators to declare any conflicting interest not previously disclosed.

5.0 IBC Actions Following Full Committee Review

- 5.1 Following review of the protocol, a motion is made and vote taken to either: 1) approve, 2) require modification to secure approval, or 3) withhold approval.
- 5.2 If the motion is to require modifications (to secure approval), the motion must include how those modifications will be reviewed: 1) Designated Member Reviewers assigned or 2) FCR. When the motion is to review the modifications by DMR, the vote must be unanimous. Reviewers are then assigned by the IBC Chair. All members of the IBC will be provided with an electronic copy of the revised protocol and may request FCR of the revised protocol at that time. Providing no one requests FCR, the assigned designated reviewers are authorized to approve or require further modification to secure approval and their decision must be unanimous.
- 5.3 All protocols approved by the IBC will be approved for a five (5) year period. Submission of a required annual review will be done within Novelution on the anniversary of the approval date (or paper form for legacy protocols) to remain in good standing. At the end of that period, if the project will continue, a new IBC application protocol must be submitted in Novelution. There will be no extensions of protocols.

6.0 Notification Following Review

- 6.1 The IBC Office will notify investigators in writing of its decision to approve or withhold approval of those activities related to biohazards, or of modifications required to secure IBC approval as set forth in the PHS Policy.
- 6.2 The IBC procedures to notify investigators and the Institution of its decisions regarding the protocol review are as follows:
 - 6.2.1 The IBC shall notify the investigator in writing of the IBC's decision to approve the protocol, require modification in (to secure approval), or withhold approval (disapproval). Notification will come through the Novelution system to the PI. In order to secure approval, the investigator must revise the IBC application and/or respond to other conditions set by the IBC and re-submit in Novelution. All comments and communication will take place within the system.

- 6.2.2 Investigators have 60 days after the request is received to address the required modifications. After 60 days, the protocol or change request will be withdrawn from the review process.
 - 6.2.3 Protocols or change requests that have been withdrawn from the review process will need to be resubmitted and the review timeline will start over. All submission deadlines on the IBC website will apply.
 - 6.2.4 The IBC Chair and/or designee shall provide the investigator with reasons, in writing, for the IBC's decision to withhold approval of a protocol and shall provide an opportunity for the investigator to respond and appeal.
 - 6.2.5 All appeals are required to be in writing and must be submitted within two weeks.
 - 6.2.5.1 The investigator may appeal a determination of the IBC only if new information becomes available, or evidence is provided that the IBC has failed to follow their own procedures, or incorrectly applied federal regulations, state law, or NDSU policy for the protection of research participants. A written appeal, citing specific federal regulations, NDSU policy or procedures, may be made to the IBC office or the IO within 10 business days after receipt of communication from the IBC. Upon receipt of the appeal, the IBC administrator will notify the IBC and the IO. The IBC Chair or Chair's designee makes an initial assessment, and forwards the appeal to the IBC for consideration at the next convened meeting. The board's determination is considered final, and communicated in writing to the investigator and other entities as applicable.
 - 6.2.6 In addition to the written appeal, investigators are provided an opportunity to appear, in person, before a full convened quorum of the IBC.
 - 6.2.7 Applications and proposals that have been approved by the IBC may be subject to further review by officials of the institution who can overturn an IBC approval. However, those officials may not approve a study which has been previously denied by the IBC.
- 6.3A copy of IBC meeting minutes, which record all decisions regarding protocol review and activities, is available to the Institutional Official.