

Institutional Biological Safety Committee (IBC) Procedures

Last Revised: Dec 2022

- I. Protocol Registration
- II. Protocol Pre-Review
- III. Protocol Review
- IV. Protocol Update
- V. Approval Notifications
- VI. Post-Approval Monitoring

I. Protocol Registration

1. To register with the IBC, the Principal Investigator (PI) must submit an electronic protocol for full IBC review and approval.
 - A. If the Biosafety Office (BSOf) becomes aware of a research project requiring IBC registration, the responsible PI will be contacted and information about the requirements and procedures for protocol submission will be provided.
 - B. For new PIs, the BSOf will schedule a virtual meeting to provide detailed information on the IBC review process and electronic application.

II. Protocol Pre-Review

1. The IBC Chair and the BSOf will pre-review all protocol submissions.
2. Pre-review findings will be entered into the protocol's Review Form (REDCap) and will also be included in the meeting's agenda.
3. Protocols submitted less than two weeks in advance of a meeting may be held for review at the subsequent regularly scheduled meeting.

III. Protocol Review

1. Primary Reviewer – IBC presenter
 - A. The following protocols will be assigned to a Primary Reviewer who will present them during the meeting:
 - i. Recombinant or synthetic nucleic acid experiments which are subject to the NIH Guidelines, including clinical protocols.
 - ii. Experiments involving BSL2 research other than human derived materials, and
 - iii. Experiments involving BSL3 research.
 - B. A Primary Reviewer must be a voting member of the IBC.
 - i. For clinical protocols, the Primary Reviewer may be an *ad hoc* consultant with expertise relevant to the protocol's items.

- ii. The IBC Chair is the secondary reviewer on all BSL2 protocols. The IBC Chair will present protocols for a reviewer who is absent.
 - iii. The reviewers may contact the PI directly or through the BSO of for additional information prior to the IBC meeting. If contacting the PI directly, all correspondence with the PI must be forwarded to the BSO of.
- C. The BSO of will send the protocol's link to the Primary Reviewers before the meeting packet is released to the rest of the Committee.
- D. Assigned Primary Reviewers are expected to provide their review comments in REDCap prior or during the meeting.

2. Full Committee Review

- A. Members of the IBC will receive the meeting packet with the links for the protocols one week before the meeting.
- B. Issues identified during the pre-review will be included in the meeting agenda and will be included in the Review form for consideration.
- C. IBC voting members are encouraged to review all protocols and enter their comments in the Review form in REDCap.

3. Meetings

- A. The IBC meets on the first Thursday of every month, 12 months per year.
- i. Exceptions to the schedule (e.g. meeting cancellation) will be determined by the IBC Chair and BSO of.
 - ii. A quorum is required to conduct routine committee business. In order to establish a quorum:
 - a. The IBC Chair or Vice-Chair must be present,
 - b. The number of attendances must correspond to half of the number of voting members plus one.
- B. The PI may attend the IBC meeting or be available by phone to address any Committee's concerns directly. However, the PI should not be present for Committee's discussion or voting on his/her protocol.
- C. In cases where IBC members have a conflict of interest with a protocol to be discussed, they must excuse themselves during voting.
- D. The BSO of will be responsible for providing administrative support to the Committee, including the development of the meeting agenda as well as meeting minutes for review and approval at the subsequent meeting.

IV. Protocol Updates

1. Protocol amendments which only involve an update in personnel and/or location will be reviewed by the BSO of.
2. Upon verification that no other changes that may change the initial risk assessment have been presented and all training requirements are completed, the BSO of will release a notification to the PI.
 - A. This is effectively an administrative approval indicating that the change has been accepted and no other action is required by the PI.
 - B. Copies of these protocols will not be provided to the IBC for review, however, they will be listed in the meeting agenda.
 - C. The IBC Chair and/or BSO of may elect to forward any of these protocols to the Committee for review.

V. Approval Notification

1. The PI will be notified of the decision on the protocol within 5 business days.
 - A. Final approval will be granted by the IBC if there are no outstanding issues.
 - B. If the protocol is not approved, the review will continue with the assigned reviewer, if applicable, and the BSO of will send a summary of the Committee questions and concerns to the PI. A denied protocol will be reviewed again once a revised protocol is submitted.
 - C. Conditional Approval:
 - i. Research activities involving BSL2 research, recombinant or synthetic nucleic acid molecules and human derived materials must not be initiated before full IBC approval.
 - ii. The PI will be notified in writing about the issues that need to be addressed before the protocol can be approved.
 - iii. In case of amendments, research items that have been previously approved by the IBC may continue per the PI's initial approval.
 - iv. The PI must submit the revised protocol form(s) for final approval.
2. Once approved, protocols will be valid for a period of 3 years from the initial date of approval.
 - A. An approved protocol can be amended to include agents as well as any additional procedures. This will not alter the 3-year expiration date.
 - B. In an emergency (e.g. to keep or transfer funding, to obtain and/or keep animals), the IBC Chair and BSO of may provide an extended approval until a protocol is renewed by the IBC.

VI. Post-Approval Monitoring

The BSO of is responsible for the post-approval compliance monitoring.

1. New approved BSL2 locations will be inspected within two months of the protocol approval followed by annual inspections.
2. BSL2 and BSL3 protocol locations will be inspected at least annually.