Institutional Biological Safety Committee (IBC) Procedures

Last Revised: April 2013

I. Protocol Registration

1. To create a protocol and initiate the IBC review process, the Principal Investigator (PI) must contact the Biosafety Office (BSOf) to enable access to the electronic IBC forms.
    A. If the protocol involves BSL3 experiments, access to the electronic BSL3 applications, by permission of the BSL3 Facility Director (FD), must also be granted.
    B. If the BSOf becomes aware of a research project requiring IBC registration, responsible PI will be contacted and information about the requirements and procedures for protocol submission will be provided.

2. For all new PIs, the BSOf will schedule a visit in order to provide detailed information on the IBC review process and electronic application. At this moment, assigned locations will also be visited to verify adequacy.

3. The PI must complete the electronic web-based application for the IBC protocol.
    A. BSL3 protocols must be accompanied by a protocol specific Standard Operating Procedure (SOP) to be attached to the IBC protocol in the database.
        i. The Biosafety Officer (BSO) and/or BSL3 FD will assist the PI with the development of the SOP.
4. The completed registrations are subsequently submitted via the BSOf to the IBC for review.

II. Protocol Pre-Review

1. The IBC Chairman and the BSOf will meet, on a weekly basis, to pre-review all protocol submissions.

2. Issues identified during the pre-review will be forwarded to the primary reviewer for consideration. For those protocols not assigned to an IBC presenter, pre-review issues will be forwarded to the full committee during the protocols' packet release.
3. Protocols received 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. Protocols will be assigned to a primary reviewer during the pre-review weekly meetings.
    B. The following protocols will be assigned to a primary reviewer who will present them during the meeting:
        i. Recombinant DNA experiments which are subject to the NIH Guidelines, including HGT protocols;
        ii. Experiments involving BSL2 research other than human source materials, and
        iii. Experiments involving BSL3 research.
    C. A primary reviewer must be a voting member of the IBC.
        i. For a Human Gene Transfer (HGT) protocol, the primary reviewer may be an ad hoc consultant with expertise relevant to the protocol's items.
        ii. The IBC Chairman is the secondary reviewer on all BSL2 protocols. The IBC Chairman will present protocols for a reviewer who is absent.
        iii. The reviewers may contact the PI directly or through the BSOf for additional information prior to the IBC meeting. If contacting the PI directly, all correspondence with the PI must be forwarded to the BSOf.
    D. The BSOf will send electronic copies of all protocol review materials and supporting documentation to the primary reviewers.
    E. Assigned primary reviewers are encouraged to provide their review comments in writing prior or immediately after the meeting to the BSOf.

2. Full Committee Members
    A. Members of the IBC will be provided with the copy of protocols one week before the meeting
    B. Issues identified during the pre-review will accompany their corresponding protocols for consideration.

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 Chairman and BSO.

ii. A quorum is required in order to conduct routine committee business. In order to establish a quorum:

a. The Committee Chairperson or Vice-Chairperson must be present,

b. The number of attendance must correspond to the 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 concerns directly. However, the PI should not be present for committee discussion or voting on his or her protocol.

C. In case IBC members have any conflict of interest with a protocol to be discussed, they must excuse themselves during discussion and voting of the protocol.

D. The BSOf will be responsible for providing administrative support to the committee, including the development of 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 BSOf.
2. Upon verification that no other changes have been presented and all requirements of the initial IBC approval are being met, the BSOf will release 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. These protocols will not be provided to the IBC for review, however, they will be listed in the agenda.

C. The IBC Chairman and/or BSO may elect to forward any of these protocols to 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 and the BSOf will send a summary of committee questions and concerns to the PI. The denied protocol will be reviewed again once revised protocol is submitted.

C. Conditional Approval:

i. In an emergency (*e.g.* to keep or transfer funding, to obtain and/or keep animals), the IBC Chairman and BSO may provide a conditional approval to a PI in advance of the full committee review.

ii. Research activities involving BSL2 agents, recombinant DNA and human source materials must not be initiated before full IBC approval.

iii. The PI must be notified in writing and the conditions must be specified

iv. Research that has been previously approved by the IBC may continue per the PIs initial approval.

v. The PI must submit the final protocol for full committee review and approval for the next scheduled IBC meeting.

vi. The primary reviewer will be advised of the action upon assignment.

2. A final approval will be valid for a period of 3 years from the initial approval without requiring renewal;

A. An approved protocol must be amended to include agents as well as additional procedures.This will not alter the 3 year expiration date.

VI. Post - approval Monitoring

The BSOf is responsible for post-approval compliance monitoring.

1. New approved BSL2 locations will be inspected within two months of the protocol approval followed by annual inspections.
2. BSL3 protocol locations will be inspected biannually in accordance to the BSL3 Facility SOP.
3. For HGT protocols, inspections will be provided prior to clinical trial initiation. Annual inspections will be performed.