CMU CENTRAL MICHIGAN UNIVERSITY | Office of Research Compliance

Institutional Biosafety Committee
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Title: IBC Review Standard Operating Procedures
Effective Date: October 1, 2018
Authorized by: IBC, Vice President for Research
History: 08/2018, 09-October-2018 JC

I. Background

The NIH Guidelines and Central Michigan University Biosafety Program Policy assign the following responsibilities with regard to submission, review and oversight of potentially biohazardous projects including those specifically addressed in the NIH Guidelines.

The NIH Guidelines require that **"**The institution, that is ultimately responsible for the effectiveness of the Institutional Biosafety Committee, may establish procedures that the Institutional Biosafety Committee shall follow in its initial and continuing review and approval of applications, proposals, and activities" (Section IV-B-2-a-(5)) and that This review shall include: (i) independent assessment of the containment levels required by the *NIH Guidelines* for the proposed research; (ii) assessment of the facilities, procedures, practices, and training and expertise of personnel involved in recombinant or synthetic nucleic acid molecule research;" (Section IV-B-2-b-(1)). Further, the IBC is responsible for "Notifying the Principal Investigator of the results of the Institutional Biosafety Committee's review and approval" (Section IV-B-2-b-(2)).

Also in compliance with the NIH Guidelines (Section IV-B-7-c), the Principle Investigator (PI) must do the following:

- Make an initial determination of the required levels of physical and biological containment in accordance with the *NIH Guidelines*;
- Select appropriate microbiological practices and laboratory techniques to be used for the research;
- Submit the initial research protocol and any subsequent changes (e.g., changes in the source of DNA or host-vector system), if covered under Sections III-A, III-B, III-C, III-D, or III-E (*Experiments Covered by the NIH Guidelines*), to the Institutional Biosafety Committee for review and approval or disapproval;
  And
- Remain in communication with the Institutional Biosafety Committee throughout the conduct of the project.

II. Purpose

This SOP defines the process for IBC Review of new registrations, continuing review forms and amendment requests and will ensure that protocol reviews are conducted effectively and according to the timeline outlined below. This SOP does not apply to minor amendments reviewed by qualified/designated administrative staff.

III. Overview/Typical timeline

The timeline for a typical IBC review, after the Principle Investigator (PI) has signed and submitted their protocol, is as follows:

A. **Administrative Review** (AR) by IBC Coordinator/Staff: **3-6 business days** plus time with PI
   1. Protocol returned to PI for clarifications: undefined
   2. Subsequent preliminary review phases: up to 3 business days per round, however;
   3. The vast majority of preliminary reviews are completed in 1-2 rounds.
   4. Minor amendments (e.g. personnel additions or changes in non-key personnel) or registering of projects conducted at BSL1 or in ordinary clinical settings may be acknowledged or approved by AR.

5. If there is any uncertainty regarding NIH category, risk group, or containment level, the administrative reviewer will forward the project to the Chair and Biosafety Officer (BSO) for confirmation.

B. **Initial Committee Review by the Chair and BSO**: **8-15 business days**
   1. Project review and initial risk group/containment designation: 3-5 business days
   2. Laboratory/containment assessment by BSO (**concurrent with Designated Member Review (DMR) or Full Committee Review (FCR)**): 5-10 business days

C. **Designated Member Review** (DMR). If specific expertise is required for effective review, or the Chair wishes to assign members to review protocols due to high volume of submissions, a member or members will be selected by the Chair.
   1. Initial review: **up to 5 business days**
   2. Subsequent rounds of questions/clarifications, if required: **Up to 5 business days per round** plus time with Investigator for responses.
   3. Chair may intervene and call for Full Committee Review (FCR) and/or invite the PI to attend meeting after one or more rounds of questions if it is clear multiple rounds of questions may not resolve issues.

D. **Full Committee Review**: FCR may be requested by the BSO, Chair or designated reviewer and may be required if the risk group or containment level is 3 or uncertain.
   1. Reviewer questions and PI responses must be received at least 3 business days prior to convened meeting to be considered, late questions or responses may delay IBC action.
   2. If an IBC meeting is not scheduled to be held **within 15 business days** of a completed submission, a special convened meeting will be scheduled to consider the protocol.

By following this process, the vast majority of protocols would be in the hands of the IBC approximately 11-21 business days (3-4 weeks), with prompt PI responses, most protocols reviews will be completed in under one month.

IV. Procedures:

A. Administrative Review

1. In order to initiate review, the PI must submit their protocol, continuing review or amendment form using the most recent version of the application available. Older versions of the application may not include all required questions and may be rejected by the IBC.
   a. Investigators submitting protocols directly to the IBC must utilize the IBC registration form.
   b. Investigators submitting protocols first to the IRB will only need to complete the IBC registration if directed to do so in response to the Biosafety questions on the IRB application.
      i. Protocols involving RG1 organisms or bio-specimens only, that are conducted at BSL1 or in routine clinical settings, will not typically require a full IBC registration.
      ii. RG1/BSL1 IRB protocols not requiring a registration will be added to the IBC database using the IRB approval number and location and Blood Borne Pathogen (including needle safety)/Lab Safety training will be verified with OLFS.
      iii. For protocols where the IRB has indicated that training is relevant to risks to subjects, the IRB will be informed when training is verified.
      iv. If an IRB protocol is considered RG2/BSL2 or higher, or utilizes synthetic or recombinant nucleic acids covered by the NIH Guidelines, a full IBC registration will be required.
   c. The approach described above for the IRB will be similar to the approach for protocols first submitted to the IACUC; however, IACUC protocols are more likely to involve biohazardous organisms or use of recombinant technology requiring a full IBC registration.
   d. An administrative review is conducted by the IBC Coordinator, IBC Chair or other appropriately trained administrative staff or committee member to ensure completeness of the submission.
   e. Administrative reviews will typically be completed within three business days.
2. At the conclusion of administrative review, the IBC Coordinator will send a list of questions,

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clarifications and missing information to the PI. The administrative reviewer may also provide suggestions to expedite the review process once the application is sent to reviewers.

3. Once the PI has made corrections, they will resubmit a corrected protocol. If submitted on a paper form, the original registration may be used utilizing “track changes” or highlighting.
    a. The process may be repeated until all issues have been addressed.
    b. The administrative reviewer may invite the PI for an in person meeting to clarify any issues that prove difficult to resolve by electronic communication.
4. If the administrative reviewer has no questions or comments, the submission is advanced to the Chair and BSO.
5. The Chair will either:
    a. Assign themselves as the reviewer of the protocol or;
    b. assign another committee member or members with appropriate expertise to review the protocol or;
    c. assign the protocol to full committee review with designated member(s) serving as the lead reviewer(s)

B. BSO Review, Risk Assessments and Laboratory inspections

1. Project review and initial risk group/containment designation will be evaluated by the BSO concurrent with DMR or FCR.
2. The extent of laboratory assessment by the BSO for RG1/BSL1 will be at the discretion of the BSO:
    a. For existing laboratory spaces where other IBC projects have already been approved the BSO will, at a minimum, affirm that the available equipment and containment procedures are appropriate.
    b. For new laboratory spaces, the BSO will conduct and document a laboratory assessment.
3. For RG2/BSL2 or higher, the BSO will conduct and document a full independent laboratory assessment (e.g. containment practices, safety equipment and laboratory training) as required by the NIH Guidelines.

C. Chair or Designated Member Review

1. If specific expertise is required for effective review, or the Chair wishes to assign members to review protocols due to high volume of submissions, a member or members will be selected by the Chair.
2. When assigned, if a member is unable to conduct their review within five business days, they must notify the IBC Administrator so that another reviewer can be assigned.
3. If the designated member does not submit their review at the end of 5 business days and has not made contact with the IBC Administrator, it will be assumed that the review has not been completed and the review will be re-assigned to another reviewer.
4. Upon completion of their review, the designated member(s) may:
    a. Approve the protocol as submitted
    b. Approve the protocol with minor modifications (e.g. modifications that do not impact risk assessment, safety practices or containment level)
    c. Request modifications to secure approval
    d. Request FCR
5. To facilitate tracking of application status, any stipulations/modifications required by the DM should generally be transmitted to the PI via a stipulation letter sent by the IBC Coordinator.
6. If DMR stipulated changes are addressed directly with the PI via e-mail, the Coordinator must be copied or the e-mails must be forwarded to the IBC Coordinator at the conclusion of the process for documentation of review.
7. A summary of any in-person conversations between designated reviewers or the BSO and the PI should be provided in writing to the IBC Coordinator to be maintained as documentation of the review.
8. The Chair may intervene and call for Full Committee Review (FCR) and/or invite the PI to attend meeting after 1 or more rounds of questions if it is clear multiple rounds of questions may not

resolve issues.

D. Full Committee Review: FCR may be requested by the BSO, Chair or designated reviewer and may be required if the risk group or containment level is 3 or uncertain.

1. Reviewer questions and PI responses must be received at least three business days prior to convened meeting to be considered; late questions or responses may delay IBC action.
2. The Chair or Designated Member will present a summary of the protocol.
3. The BSO will address any concerns regarding risk group determination and containment level or procedures.
4. The committee will vote to either:
    a. Approve the protocol as submitted
    b. Approve the protocol with minor modifications
    c. Request modifications to secure approval
    d. Withhold approval of the protocol
5. A successful vote requires a majority of the quorum. Quorum is more than one-half of the voting members of the committee and should include at least one non-affiliated member.

E. BSL3 Sub-committee/Institutional Review Entity (IRE):

1. Protocols involving ~~and~~ organisms in RG3 or to be performed at BSL3 and Standard Operating Procedures impacting operations within a BSL3 facility must be reviewed and approved by the BSL3 sub-committee prior to being considered by the full committee.
2. The BSL3 sub-committee will also act as the IRE for any projects potentially involving Select Agents or Dual Use Research of Concern (DURC).
3. Reviews will be conducted similar to the DMR process with the BSL3 sub-committee taking the place of the designated member. A BSO will always be part of this review.
4. Upon completion of the review, the sub-committee will present the protocol or SOP at a convened meeting along with their recommendation.
5. The remainder of the procedure will be as described in section D steps 3-5.

F. Notification of the Outcome of IBC review:

1. **Assignment of protocol numbers** will be based on the location where the work is to take place and will consist of:
    a. A two or three letter building designator (e.g. BR for Brooks Hall)
    b. A number based on the number of IBC projects approved in that building (e.g. 23 for the 23rd protocol approved in Brooks Hall would be BR-0023)
    c. A two-digit number based on the iteration of the protocol (e.g. a protocol that has been renewed 5 times would be -05, so BR-0023-05)
    d. A lower case letter indicating any amendments that have occurred during the current approval period (e.g the second amendment would be “b”, so BR-0023-05b)
    e. Protocol number designations may change upon implementation of an electronic protocol management system; however, these legacy designations will likely be retained due to their usefulness in determining the location and period of the approved work.
2. **Approval Periods** may be designated by the reviewer or full committee based on the following criteria:
    a. PI request for a specific approval period for a project.
    b. Protocols associated with external funding may receive an approval period that runs concurrently with the grant or contract.
    c. The default approval period will be 3 years with the following exceptions:
        i. For PIs or protocols where there have been past concerns regarding non-compliance:
        ii. For projects conducted at BSL2 or involving RG2 organisms where the committee has specific concerns (e.g. regarding personnel safety, containment)
        iii. All projects conducted at BSL3 or involving RG3 organisms.
        iv. If any of the exceptions above apply the following approval and continuing review considerations may be imposed:
            a. A shorter approval period may be granted or;

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   b. Continuing review may be required in order to maintain approval.
   c. Failure to comply with continuing review requirements as specified in the approval letter or within 30 days of the anniversary of approval will be considered as a lapse in approval.
3. **Approval letters** will be stamped and/or protected from editing and will be delivered electronically to the PI, the IBC Chair, the BSO and the Office of Research Compliance (on behalf of the IO) and will include the following information:
   a. The name and department/college of the PI
   b. An IBC protocol/approval number
   c. The risk group(s), containment level(s) and NIH category determinations of the IBC
   d. The agents/vectors approved may be listed if RG and containment levels vary
   e. Approval date and periods
   f. Approved location(s)
   g. Any continuing review requirements imposed by the committee
   h. Any lab safety/BSO mandated requirements that must be met including lab inspections, training materials and records, SOPs, equipment certifications

G. IBC Record Retention:

1. All records documenting IBC protocol review and approval will be maintained electronically whenever possible and will be stored according to PI name and/or the location of the project.
2. All records associated with risk assessments, laboratory inspections, verification of training or certification of equipment or facilities will be stored electronically whenever possible. Records will be maintained based on protocol, PI or location/building as appropriate (e.g., autoclave certifications for CMEDs RLB will be stored in the OLFS database under that building, rather than each approved protocol in RLB).
3. When use of electronic records is not practical (e.g. legacy paper lab inspection/risk assessment forms), paper records will be stored securely in the IBC Office.
4. All official IBC records will be accessible to any IBC member upon request.
5. Records will be maintained in accordance with CMU Policy and record retention schedules and in compliance with the requirements of all applicable regulations and funding agencies.
   a. At a minimum, all records described above will be maintained for at least 3 years after the completion of the project unless required otherwise.
   b. Records may be maintained beyond 3 years if they are deemed relevant to currently approved projects or to maintaining institutional memory unless destruction is specifically required.
   c. In all other cases, records will be permanently deleted/destroyed after 3 years or the relevant minimum period based on regulatory or funding agency requirements.
   d. Destruction of electronic records will be confirmed by the ORC and/or OIT.

For questions or clarifications, please contact the IBC Office IBC@cmich.edu or Office of Research Compliance RESCOMPLIANCE@cmich.edu.