CMU CENTRAL MICHIGAN UNIVERSITY | Office of Research Compliance

Institutional Biosafety Committee
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Title: Review and Approval of Laboratory Standard Operating Procedures
Effective Date: 31-January, 2019
Authorized by: IBC and Office of Research Compliance: 9-January, 2019
Draft History: 5-August, 2019, 20-December, 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)).

II. Purpose

This policy describes the expectations of the Vice President for Research (VPR) and the Institutional Biosafety Committee (IBC) regarding the procedures required for acceptable evaluation and implementation of Standard Operating Procedures (SOPs) or any other reference documents that affect the Institutional Biosafety Program at Central Michigan University. The intent of this policy is to ensure that SOPs are used in a manner that is consistent with the NIH requirements and CDC Guidance. The purpose of an SOP is to describe the specific operational details often lacking in a protocol form. As an extension of the IBC protocol that describes "activities, procedures, practices", IBC review and oversight responsibilities that apply to IBC protocols also extend to laboratory SOPs and practices.

The procedures described below are designed to:

- Allow researchers to maintain control of their SOPs to enable the greatest degree of flexibility for implementation of required changes.
- Ensures access of SOPs to researchers to minimize the chance of protocol drift (non-compliance).
- Ensure access to the IBC to meet their obligations for review and oversight as described above.
- Ensure that SOPs and other reference documents are reviewed and updated at appropriate intervals.

I. Procedures

A. Drafting Standard Operating Procedures:

1. Anyone may draft an SOP, the individual drafting the SOP or the faculty member whose laboratory they work in will be considered the "owner" of the SOP.
2. When drafting an SOP, researchers are encouraged to obtain a blank template from the Office of Research Compliance. This will allow for uniformity of SOPs across the program.

B. Access to and Evaluation of Standard Operating Procedures:

1. SOPs developed for limited use (single laboratory/single location)
    - An SOP developed for single laboratory use should be made accessible to all members of the research team in the laboratory where the procedure is carried out. This can be accomplished by:
        i. Maintaining a binder of SOPs within the laboratory or;
        ii. By maintaining electronic copies of the SOPs on a shared drive or computer accessible to all members of the research team.
    - SOPs should be reviewed, at a minimum, once every three years
    - If SOPs are to be referenced in an IBC protocol, additional procedures will apply, see section C below.

2. SOPs developed for multiple users (multi laboratory, department or facility use).
    - Multi user SOPS must be made available to all researchers who will employ the procedures.
    - The mechanisms employed to provide access can be the same as described above or can be accomplished by following the additional procedures outlined in section C below.
    - SOPs should be reviewed, at a minimum, once every three years
3. SOPs developed for use by the entire Institutional Biosafety Program (e.g. all animal work conducted at ABSL2) or for an entire facility/unit (e.g. Biosafety Level 3 Containment Facility)
    - Due to their wide use, these SOPs must be made available to the entire research community. For the BSL3 facility this may be accomplished by maintaining a binder near the facility and accessible to all users or via a Sharepoint folder accessible to all BSL3 facility users. For all SOPs related to work conducted at BSL2 or BSL1, SOPs will be posted to the IBC web page.
    - Program wide SOPs must follow the additional review and access procedures outlined in section C below.
    - These SOPs **must** be reviewed every three years at a minimum.

C. Additional procedures for SOPs or other documents that will be referenced in an IBC protocol or used by multiple users in different physical locations.

1. To facilitate meeting their review responsibility, any SOP or other document referenced in and IBC protocol must be accessible to the IBC for review.

2. Additionally, the IBC must be able to confirm that the SOP or document has been reviewed and updated as needed and is in in compliance with NIH Regulations and CDC Guidelines.

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3. To facilitate access and confirmation of review, any document or SOP referenced in an IBC protocol or employed in multiple physical locations must follow additional steps related to evaluation and access.
    - The owner of an SOP must submit the document to the Office of Research Compliance or IBC Office to initiate review.
    - The SOP will be reviewed by the ORC and IBC Office staff to ensure that it is in compliance with NIH Guidelines and CMU Policies and will consult with the Biosafety Officer to ensure compliance with CDC Guidelines and best practices.
    - If changes are needed, the ORC and IBC Office will work with the owner to arrive at a final draft.
        i. The IBC Office and ORC will provide the owner with specific regulatory references any time a change is requested.
        ii. If the regulatory reference is a requirement (a “must”) the owner will be required to edit in a specific manner to meet that requirement
        iii. If the regulatory requirement provides non-specific direction (a “should”) the owner should decide the best approach to meet the requirement in consultation with the BSO, IBC Chair or ORC as appropriate.
    - The final draft will be maintained on the IBC web page under “Policies, Guidelines and SOPs”. BSL3 SOPs will not be posted to the web page but will be made available to all BSL3 users by other means.
    - A database will be maintained by the ORC to ensure that SOP owners are notified when the document is due for review or update.
    - Disputes regarding the acceptability of an SOP that cannot be resolved between the ORC/IBC Office and the SOP owner will be referred to the IBC.

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