INSTITUTIONAL BIOSAFETY COMMITTEE STANDARD OPERATING PROCEDURE		
SOP Title: Post Approval Monitoring		
SOP Number: IBC-PP-030	Revision Number: 3	Section: Biosafety
Author: Patricia Cox		Effective Date: 12/15/10

1. Purpose

   1.1. This procedure refers to projects requiring IBC oversight.

   1.2. The purpose of this procedure is to describe the process for conducting post approval monitoring of current IBC applications. Monitoring of approved applications occurs through a variety of methods (laboratory/facility inspections, IBC application modifications and annual updates, etc.) The procedure described herein represents another mechanism for supervision.

2. Key Word Definitions

   2.1. BSO: Biological Safety Officer

   2.2. IBC: Institutional Biosafety Committee

   2.3. PI: Principal Investigator

   2.4. PAM: Post-Approval Monitoring

3. Responsibilities and Authorities

   3.1. Biological Safety Officer

      3.1.1. Participates *ex officio* on every PAM subcommittee;

      3.1.2.Provides a list of all current IBC applications to PAM Chair and a link to a random number generator;

      3.1.3. Is responsible for follow-up on the PAM subcommittee recommendations.

      3.1.4. Will maintain copies of all reports.

   3.2. IBC Chair

      3.2.1. Will initiate the review by calling for a committee to be created and asking for a PAM Chair;

      3.2.2. Will send the final report to the BSO for follow-up and archiving[CP1].

   3.3. PAM Chair

3.3.1. Is responsible for contacting the PI, scheduling the interviews, and submitting the final report to the IBC Chair;

3.3.2. Select the IBC applications to be reviewed.

3.3.3. Sends final report to PI.

3.4. PAM Member

3.4.1. Is responsible for actively participating in each review and assisting in the compilation of the final report.

4. Items Needed

4.1. IBC application packet(s) including lab inspection results and any other documents related to the project.

5. Procedure

5.1. One to two times a year, a PAM subcommittee will be organized. This committee will consist of at least two voting IBC members, but no IBC member will be excluded from participation. The BSO will sit on the committee *ex officio*.

5.2. The PAM subcommittee will:

5.2.1. Randomly select or target up to 3 active IBC applications for review. An application for review may also be requested by the Vice President for Research and Economic Development. Reasons for targeting an application may include but are not limited to:

5.2.1.1. The use of highly pathogenic organisms or highly toxic materials;

5.2.1.2. The use of biohazardous material in animals;

5.2.1.3. Studies or groups with previous compliance issues.

5.2.2. Thoroughly review the selected application(s).

5.2.3. Conduct an interview with the PI(s) of each application selected. This interview can be done via phone conversation, email or personal visit. The interview will consist primarily of:

5.2.3.1. Questions covering procedures stated in application;

5.2.3.2. Questions on any changes in personnel, material, location, animal use, or recombinant DNA;

5.2.3.3. Questions on safety practices in use.

5.2.4. Visit specific laboratories and animal facilities if needed.

5.2.5. Write a report for each application stating:

5.2.5.1. The overall impression of the PAM subcommittee based upon the interview and/or inspection;

5.2.5.2. Any deviations from the stated procedures;

5.2.5.3. Any recommendations made by the subcommittee to the PI(s) during the interview and/or inspection;

5.2.5.4. Any actions the subcommittee requests from the IBC.

5.2.6. The PAM subcommittee will decide the timeline for the PI response.

5.2.6.1. If the PI does not respond by the date set by the PAM subcommittee, the procedure to terminate will follow IBC-PP-028.

6. Associated SOPs

6.1. IBC-PP-028 Suspension and Termination of Previously Approved Research

7. Associated Forms

7.1. IBC application file

7.2. PAM Review Form

8. References

8.1. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

9. Revision History

   9.1. Revised on 4/1/2013 and approved on 5/15/2013

   9.2. Revised 7/29/15 and approved 9/16/2015

   9.3. Revised 11/18/16 and approved 12/14/16

10. Approvals

Reviewed by: _____ Date Reviewed: _____
Biological Safety Officer

Approved by: _____ Date Approved: _____
IBC Chair