OFFICE OF REGULATORY COMPLIANCE INSTITUTIONAL BIOSAFETY COMMITTEE STANDARD OPERATING PROCEDURE		
SOP Title: IBC Application Submission, Review and Approval		
SOP Number: IBC-PP-012	Revision Number: 3	Section: Biosafety
Author: Patricia Cox		Effective Date: 9/2/09

1. Purpose

   1.1. This procedure refers to IBC applications: registration documents including the full IBC application and the recombinant/synthetic nucleic acid registration form.

   1.2. The purpose of this procedure is to describe the process for application submission, review, and approval of IBC applications.

2. Key Word Definitions

   2.1. BSO: Biological Safety Officer

   2.2. IBC: Institutional Biosafety Committee

   2.3. PI: Principal Investigator

   2.4. NIH OBA: National Institutes of Health Office of Biotechnology Activities

   2.5. *NIH Guidelines*: *NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules*

3. Responsibilities and Authorities

   3.1. Biological Safety Officer

      3.1.1. Processes new applications;

      3.1.2. Forwards applications to the IBC Chair;

      3.1.3. Writes letters related to application and sends to PI;

      3.1.4. Monitors fulfillment of conditions;

      3.1.5. With IBC Chair, gives final approval when all conditions are met;

      3.1.6. Maintains applications and any associated paperwork including hard and electronic copies of the meeting minutes;

      3.1.7. Fills out Risk Assessment Checklist during the IBC review process. This checklist covers the risk assessment requirements of the *NIH Guidelines*.

3.2. IBC Chair

3.2.1. Creates meeting packet which includes agenda, previous meeting minutes, new IBC applications , other relevant information;

3.2.2. Sends meeting packet to IBC Administrator for upload to IBC website;

3.2.3.Records minutes during meeting;

3.2.4.Manages and directs the meeting;

3.2.5.With BSO, gives approval when conditions are met.

3.3. IBC Member

3.3.1.Reviews IBC packet in a timely manner and is ready to discuss.

4. Items Needed

4.1. IBC application packet

5. Procedure

5.1. Submission

5.1.1.The BSO checks the application for completeness including;

5.1.1.1. Signatures of PI and Department Head (if required);

5.1.1.2. All sections are completed;

5.1.1.3. The most current version of the application form is used.

5.1.2. If the application is incomplete, the BSO will contact the PI and return for revision.

5.1.3.When a complete application is received, the BSO will assign the next consecutive number and enter the data into a spreadsheet;

5.1.3.1. IBC applications are numbered in the order they are received and by the two digit year (e.g. 001-15).

5.1.3.2. The BSO routes the electronic version to the Chair.

5.1.3.3. If the proposed research involves the use of recombinant or synthetic nucleic acid molecules only, the BSO and Chair will determine if the research is exempt (Section III-F) from the *NIH Guidelines* (with guidance from NIH OBA if necessary)

5.1.3.3.1. If the research is determined to be exempt, it will be indicated on the original application, and the BSO will draft a letter to that effect and send to the PI.

5.1.3.3.2. If the research is determined not to be exempt, the Chair will process the application as described in Section 5.2.

5.2. Review

5.2.1. The IBC has the authority to approve, require modification, or disapprove all research activities that fall within its jurisdiction.

5.2.2. The Chair will choose a minimum of two members as primary reviewers.

5.2.3. Each reviewer will receive the application, Application Reviewer's Form and the Risk Assessment Checklist.

5.2.4. Each primary reviewer may submit his/her analysis to the Chair either prior to the meeting or at the meeting before discussion begins.

5.2.4.1. The Application Reviewer's Forms are kept by the Chair as signed hard copies and (when applicable) signed electronic copies.

5.2.5. If the IBC does not have the appropriate expertise to evaluate a particular application, the use of subject matter experts may be used as outlined in IBC-PP-006.

5.2.6. The application will be placed on the agenda for the next meeting for full committee review in accordance with submission deadlines.

5.2.6.1. The application deadline is 10 business days before the next scheduled meeting.

5.2.7. The application packet will be posted approximately one week before the meeting to the IBC website.

5.2.7.1. Any member without internet access may have the packet mailed to a previously identified address.

5.2.8. All decisions of the IBC will be communicated in writing to the PI by the BSO.

5.3. Approval

5.3.1. A quorum (more than half of the voting members) must be present to vote on an application.

5.3.2. Application Decisions

5.3.2.1. **APPROVAL**: The PI will be notified in writing that the application has been approved and registered.

5.3.2.2. **NOT APPROVED**: The PI will be notified in writing as to the reasons for rejection of the application. The PI will be given the opportunity to respond either in person or in writing as per IBC-PP-015.

5.3.2.3. **PENDING APPROVAL UNTIL CONDITIONS ARE MET (APPROVAL PENDING CONDITIONS)**: The PI will be notified in writing as to the conditions for approval. The PI is responsible for documentation that conditions have been met. The PI will be given the opportunity to respond either in person or in writing as per IBC-PP-015. If the conditions for approval are not met within 6 months of the initial IBC review date, submission of a new application will be required.

5.3.2.4. **DEFERRED**: The PI will be notified in writing as to the reasons for deferral of the application. The PI is responsible for correcting deficiencies and resubmitting a revised application.

5.3.2.5. **REGISTERED**: The PI will be notified in writing that the research has been approved and registered with the IBC and requires no further action on the part of the PI.

5.3.2.6. **EXEMPTED**: The PI will be notified in writing that the research does not require IBC oversight.

5.3.3. The BSO and Chair sign the approved application.

6. Associated SOPs

6.1. IBC-PP-006 Use of Consultants in IBC Application Review

6.2. IBC-PP-009 IBC Application Annual Update-Modification-Termination

6.3. IBC-PP-015 Appeals SOP

7. Associated Forms

7.1. IBC application

7.2. Application Review Form

7.3. Risk Assessment Checklist

8. References

8.1. *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* Section IV-B-2.

8.2. Biosafety in Microbiological and Biomedical Laboratories

8.3. Mississippi State Department of Health "Adopted Standards for Regulation of Medical Waste"

8.4. Department of Transportation 49 CFR 171-175

9. Revision History

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

9.2. Revised on 8/23/2013 and approved 9/18/2013

9.3. Revised 8/20/2015 and approved 9/16/2015

10. Approvals

Reviewed by: _____ Date Reviewed: _____
Biological Safety Officer

Approved by: _____ Date Approved: _____
IBC Chair