| OFFICE OF REGULATORY COMPLIANCE INSTITUTIONAL BIOSAFETY COMMITTEE STANDARD OPERATING PROCEDURE | | |
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| SOP Title: IBC Application Annual Update, Modification and/or Termination | | |
| SOP Number: IBC-PP-009 | Revision Number: 3 | Section: Biosafety |
| Author: Patricia Cox | | Effective Date: 8/18/10 |

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 requirements for annual review, modification and/or termination of approved IBC applications.

1.3. Annual review and application modification demonstrate post-approval compliance as required by the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*.

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*

2.6. Modification: Can be an annual update, a modification or a termination

3. Responsibilities and Authorities

3.1. Biological Safety Officer

3.1.1. Reviews the modification form for completeness and will return to PI for revision if necessary;

3.1.2. Writes letters related to the modification and sends to PI;

3.1.3.Notifies other review committees in the event of termination of a project;

3.1.4. Maintains IBC Reminder database.

3.2. IBC Chair

3.2.1. Sends modification out for review per section 5.

3.3. IBC Member

3.3.1.Reviews/approves modification as needed.

4. Items Needed

4.1. IBC Reminder database

4.2. IBC application packet

4.3. IBC modification submitted by PI

5. Procedure

5.1. All approved current full IBC applications must undergo administrative review on an annual basis. PIs are required to submit a modification form to initiate this process.

5.2. All approved current registered (III-E) recombinant/synthetic nucleic acid research does not require review on an annual basis but does require the submission of a modification for changes in recombinant material as per section 5.3.

5.3. PIs must also submit the modification form any time there is a change in personnel, location, lab procedures, animal procedures, biohazardous material, recombinant material and/or biosafety level.

5.4. PIs must submit the modification form at the completion of a project so that the file may be closed and archived.

5.4.1.As per IBC-PP-032, all IBC applications have a 5 year expiration date from date of final approval.

5.5. The Chair and BSO (and or assigned IBC subcommittee if required) will conduct an administrative review on all approved non-recombinant applications to identify any significant modifications to personnel, location, lab procedures, animal procedures, biohazardous material, and/or biosafety level that increases risk. The review of these changes may result in request for full IBC review or submission of a new application.

5.6. For modifications in research involving recombinant/synthetic nucleic molecules that fall under Section III-E of the *NIH Guidelines*, the modification will be placed on the agenda for the next scheduled IBC meeting for full IBC review and approval.

5.7. An annual update reminder email will be sent to the PI at least 10 days prior to the anniversary approval date. Reminder e-mails will be sent out on a regular basis until the modification has been received and approved. In the case of termination of the project, the reminder for that particular IBC application will be removed from the system, and the file marked as complete.

5.7.1. The BSO will contact the PI by phone and/or email if the anniversary date has passed to remind the PI to submit the form.

5.7.2. If the IBC modification form is not received within 30 days after the anniversary date, a letter of non-compliance will be sent to the PI and department head by the IBC Chair.

5.7.2.1. This letter will serve as the first written warning and informs the PI of the potential consequences of non-compliance.

5.7.3. If the PI does not respond within 15 days of the first letter, the Intent to Terminate Project letter will be sent to the PI and department head by the IBC Chair.

5.7.3.1. This letter states that the application will be reviewed for termination at the next IBC meeting.

5.7.4. To prevent termination of the project, the PI will have until the day prior to the next IBC meeting to submit the IBC modification form.

5.8. The official Termination of Project letter will be sent to the PI following application review and termination by a quorum of the IBC by the BSO.

5.8.1. The PI will be instructed to discontinue work on the project immediately.

5.8.2. A copy of the Termination of Project letter will be sent to the appropriate Dean or Department Head and other University officials as appropriate by the BSO.

5.8.2.1. If the project involves human or animal subjects or radioactive materials, the appropriate institutional review committee will be notified by the BSO.

5.8.2.2. The Office of Sponsored Projects will be notified if the project is externally funded.

6. Associated SOPs

6.1. IBC-PP-012 IBC Application Submission, Review and Approval

6.2. IBC-PP-032 Policy on IBC Expiration Dates

7. Associated Forms

7.1. IBC application Update/Amendment/Termination form

7.2. Template of "Non-compliance letter" letter

7.3. Template of "Intent to Terminate Project" letter

7.4. Template of" Termination of Project" letter

8. References


*8.1. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* Section IV-B-2-b-(5)


9. Revision History

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

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

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

10. Approvals

Reviewed by: _____ Date Reviewed: _____
Biological Safety Officer

Approved by: _____ Date Approved: _____
IBC Chair