



IBC Title:	Annual Report review		
SOP #108	IBC	IBC Approval Date:	03/08/2021

1 SCOPE

This SOP applies to IBC applications, comprised of a PI's registration documents including the full application and the biohazard use protocol (BUP) registration form.

2 PURPOSE

2.1 The purpose of this SOP is to describe the requirements for annual review of approved IBC applications as required by the NIH *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*.

2.2

This process ends when the IBC reviews the annual report and has approved, denied or terminated the application.

3 RESPONSIBILITIES

3.1 The university's Research Compliance Coordinator (RCC):

3.1.1 will review the annual report submitted by the PI for completeness, return an incomplete form to the PI, and inform the PI of any information needed to complete the form

3.1.2 sends reminders to PIs of any upcoming reviews of their applications; and

3.1.3 notifies the IBC in the event of a termination of a project.

3.2 The IBC reviews, approves, or denies the annual report, as applicable.

3.3 The IBC Chair:

3.3.1 Conducts the preliminary review and makes a recommendation to RCC to distribute the annual review to IBC members for review.

3.3.2 Sends a letter to the PI following the IBC's review to inform the PI of the IBC's decision.

4 PROCEDURE

4.1 An annual update reminder email will be sent to the PI at least 10 days prior to the anniversary of each application's approval date that the application needs to be reviewed. Reminder e-mails will be sent out on a regular basis until the Annual Report has been received and approved. If a project is terminated for any reason, reminders will not be sent and the file will be marked as complete.

4.2 The RCC will contact the PI by email if the anniversary date of the application's approval has passed to remind the PI to submit the form.

4.3 If the Annual Review form is not received within 30 days after the anniversary date, a letter of non-compliance will be sent to the PI and the PI's department head by the IBC Chair, which will serve as the first written warning and inform the PI of the potential consequences of non-

compliance.

- 4.4 If the PI does not respond within 15 days of the letter referred to in Section 4.3, an Intent to Terminate Project letter will be sent to the PI and the PI's department head by the IBC Chair, informing the PI that the application will be reviewed for termination at the next IBC meeting.
- 4.5 To prevent termination of the project, the PI will have until the day prior to the next IBC meeting to submit the IBC Annual Report.
- 4.6 If the Annual Report is not submitted, an official Termination of Project letter will be sent to the PI by the RCC following the review and vote to terminate by a quorum of the IBC, which will instruct the PI to discontinue work on the project immediately.
- 4.7 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 RCC.
- 4.8 If the project involves human or animal subjects or radioactive materials, the appropriate institutional review committee will be notified by the RCC of the Termination of Project letter.
- 4.9 Once terminated, the PI must submit a new application before restarting any work in the lab, except for those activities necessary to safely store or destroy laboratory specimens.

5 REFERENCED MATERIALS

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

6 VERSION HISTORY:

6.1 Version 1.0. – Approved 03/08/2021