



SOP Title	IBC Annual Reports Procedure				
Date Last Revised	09/27/2017	Date Created	06/2011	Revision #	
SOP Number	3	Required by:	<input type="checkbox"/> OHRP	<input type="checkbox"/> Funding Agency	<input type="checkbox"/> OLAW
Applicability	<input type="checkbox"/> RGC Internal	<input checked="" type="checkbox"/> Researcher	<input checked="" type="checkbox"/> Institutional		
Subgroup	<input type="checkbox"/> NKU Compliance	<input type="checkbox"/> IRB	<input type="checkbox"/> IACUC	<input checked="" type="checkbox"/> IBC	

1.0 PURPOSE

The purpose of this SOP is to describe the process of submitting required annual reports to the IBC.

2.0 GENERAL INFORMATION AND SCOPE

Though each IBC BAR application is approved for three years, the NKU IBC requires an annual report to be completed per project. Based on the approval date of the BAR, a report will be due by the annual anniversary of approval.

3.0 PROCEDURES

A. REQUIRED DOCUMENTS:

Documents (electronic or paper) that must be submitted with the annual report depend on type of annual report. See below.

Type of Annual Report	Required Documents	Optional Forms
Annual Report No Revisions	-Annual Report and Study Closure Form	N/A
Annual Report Revisions	-Annual Report and Study Closure Form -BAR application with changes highlighted OR -A new BAR application might be requested	-Addition of Personnel form -Addition of Students – Teaching Protocols form

B. SUBMITTAL AND REVIEW PROCESS

The Principal Investigator must submit the aforementioned documents to the IBC Administrator (biosafety@nku.edu) by the annual report due date.

Annual reports with no changes will be administratively approved by the IBC Administrator.

Annual reports with revisions will be reviewed by the IBC and comments, if any, will be returned to the IBC Administrator for compilation and dissemination to the PI. The PI will then make the required revision and resubmit to the IBC Administrator who will then redistribute the revisions to the IBC. The PI will be notified of approval by the IBC Administrator.

C. FAILURE TO SUBMIT ANNUAL REPORTS

The following steps will be taken if the PI does not submit the annual report:

1. The IBC Administrator will contact the researcher to notify the researcher that the annual report is late (30 days after due date)
2. After another 30 days, if the annual report has not been submitted to the IBC Administrator, the IBC Administrator will contact the researcher and copy the Chair of the IBC and the IBC of the department, or immediate supervisor, on the email (60 days after due date)
3. After another 30 days, if the annual report has not be submitted to the IBC Administrator, the IBC Administrator will contact the researcher and copy the Chair of the IBC, the Chair of the department, or immediate supervisor, and the Dean of the college on the email (90 days after due date)
4. After another 30 days, if the annual report has not be submitted to the IBC Administrator, the IBC Administrator will contact the researcher and copy the Chair of the IBC, the Chair of the department, or immediate supervisor, the Dean of the college, and the Vice Provost for Graduate Education, Research, and Outreach on the email (120 days after due date)
5. After another 30 days, if the annual report has not been submitted to the IBC Administrator, the research study will be placed on an administrative hold until the report has been submitted.

4.0 REFERENCES

5.0 FORMS OR ATTACHMENTS

6.0 DEFINITIONS

Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	<input checked="" type="checkbox"/>	06/12/2018	<input type="checkbox"/>
IBC Chair	<input checked="" type="checkbox"/>	06/12/2018	<input type="checkbox"/>
Institutional Official	<input type="checkbox"/>		<input checked="" type="checkbox"/>

Revisions

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	<input type="checkbox"/>		<input type="checkbox"/>	
IACUC Chair	<input type="checkbox"/>		<input type="checkbox"/>	
Institutional Official	<input type="checkbox"/>		<input type="checkbox"/>	