



<b>Standard Operating Procedure Title</b>	Submission of Annual Reports and Study Closures for IACUC Approved Studies		
<b>Date Last Revised</b>	02/22/2017	<b>Revision #</b>	
<b>SOP Number</b>	4	<b>Required by:</b>	<input type="checkbox"/> OHRP <input type="checkbox"/> Funding Agency <input type="checkbox"/> OLAW
<b>Applicability</b>	<input type="checkbox"/> RGC Internal	<input checked="" type="checkbox"/> Researcher	<input type="checkbox"/> Institutional
<b>Subgroup</b>	<input type="checkbox"/> NKU Compliance	<input type="checkbox"/> IRB	<input checked="" type="checkbox"/> IACUC <input type="checkbox"/> IBC

### 1.0 PURPOSE

The purpose of this SOP is to describe the process for:

- Researchers submitting annual reports for IACUC approved studies
- Researchers notifying the IACUC of study closures

### 2.0 SCOPE

This SOP applies to all IACUC approved studies. Annual reports are due for the first two years for all IACUC studies on the annual anniversary of the study. After which, the researcher may:

- Submit a continuation application
- Close the study. The researcher must notify the IACUC when the study closes using the Annual Report and Study Closure Form.

### 3.0 PROCEDURE – SUBMITTING ANNUAL REPORTS AND STUDY CLOSURES

#### 1) Complete the Annual Report and Study Closure Form

Step 1. Download the Annual Report and Study Closure Form from the NKU IACUC website

Step 2. Complete Section 1.

- The signature must be an actual signature, not a typed signature
- Based on the selection made in the Annual Report/Closure row:
  - Complete the relevant sections
  - Attach the relevant forms (if required)
  - Attach the revised application (if required)

#### 2) Submission of documents

Step 3: The Annual Report and Study Closure Form with required documents should be submitted electronically, via email to [IACUC@nku.edu](mailto:IACUC@nku.edu). Paper copies will not be accepted.

### 3.1 PROCEDURES – DELINQUENT ANNUAL REPORTS TO THE IACUC

Researchers must submit annual reports the first 2 years of the study. If the researcher fails to submit the annual report:

- 1) The IACUC 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 IACUC Administrator, the IACUC Administrator will contact the researcher and copy the Chair of the IACUC and the Chair 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 IACUC Administrator, the IACUC Administrator will contact the researcher and copy the Chair of the IACUC, 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 IACUC Administrator, the IACUC Administrator will contact the researcher and copy the Chair of the IACUC, 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 IACUC Administrator, the research study will be placed on an administrative hold until the report has been submitted.

#### 4.0 REFERENCES

[Guide for the Care and Use of Laboratory Animals Eighth Edition](#)

#### 5.0 FORMS OR ATTACHMENTS

[IACUC Minor Revision Form](#)

[IACUC Major Revision Form](#)

#### 6.0 DEFINITIONS

IACUC – Institutional Care and Use Committee

Researcher or PI – Principal Investigator

Annual Report – report due annually, on the project’s approval anniversary to the IACUC

Study Closure – when a study is no longer collecting data

##### Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	<input checked="" type="checkbox"/>	11/01/2017	<input type="checkbox"/>
IACUC Chair	<input checked="" type="checkbox"/>	11/01/2017	<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"/>	