



<b>Standard Operating Procedure Title</b>	Submitting Protocol Revisions for IACUC Approved Studies		
<b>Date Last Revised</b>	01/05/2017	<b>Revision #</b>	
<b>SOP Number</b>	2	<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 process for:

- Researchers submitting revisions for IACUC approved studies
- IACUC review of revisions

### 2.0 SCOPE

This SOP applies researchers revising IACUC approved studies.

### 3.0 PROCEDURES - GENERAL

There are three types of revisions:

- 1) Minor Revisions – Administrative Review – Determined by using the Minor Revision List
- 2) Minor Revisions – Expedited Review – Determined by using the Minor Revision List
- 3) Major Revisions – all revision not listed on the Minor Revision List

To determine which category the revision falls into, the PI should refer to the IACUC Minor Revision Form. If the revision, is not listed in the minor revision table, the revision is considered a major revision.

### 3.1 PROCEDURES – SUBMITTING MINOR REVISIONS

After determining that the revision is a minor revision, the PI should:

- 1) Complete the IACUC Minor Revision Form
  - Step 1. Download the IACUC Minor Revision Form from the NKU IACUC website
  - Step 2. Fill in Section 1
    - o The signature must be an actual signature, not a typed signature
  - Step 3. Make the appropriate selection in Section 2
    - o A PI may select items in both columns, however, if a selection is made in column 2 (expedited review), the revision will automatically go through the expedited review process
- 2) Submission of the form
  - Step 4. The form should be submitted electronically, via email to [IACUC@nku.edu](mailto:IACUC@nku.edu). Paper copies will not be accepted.

### 3.2 PROCEDURES – SUBMITTING A MAJOR OR COMBINATION MAJOR/MINOR REVISIONS

After determining that the revision is a major revision or a combined minor/major revision, the PI should submit:

- 1) Complete the IACUC Major Revision Form

Step 1. Download the IACUC Major Revision Form from the NKU IACUC website

Step 2. Fill in Section 1

- o The signature must be an actual signature, not a typed signature

Step 3. Complete relevant sections for the Major Revision Type in Section 1

2) Revise the IACUC application

Step 4. Any revision listed on the Major Revision Form should be highlighted in the application

3) Submission of the Major Revision Form and revised application:

Step 5. The Major Revision Form and the revised application should be submitted electronically, via email to [IACUC@nku.edu](mailto:IACUC@nku.edu). Paper copies will not be accepted.

## 5.0 FORMS OR ATTACHMENTS

[IACUC Minor Revision Form](#)

[IACUC Major Revision Form](#)

## 6.0 DEFINITIONS

IACUC – Institutional Care and Use Committee

PI – Principal Investigator

Revision – any change to a currently approved IACUC study

### 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"/>	