



<b>SOP Title</b>	(IACUC) PI- Submitting a Protocol Amendment (Post 07-01-2019)				
<b>Date Last Revised</b>	11/04/2022	<b>Date Created</b>	04/16/2019	<b>Revision #</b>	1.2
<b>SOP Number</b>	20	<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 submitting amendments for an Institutional Animal Care and Use Committee (IACUC) protocol that was initially approved on or after July 1, 2019.

## 2.0 GENERAL INFORMATION AND SCOPE

The NKU IACUC has established this written procedure to guide Principal Investigators (PI) through the process of requesting changes or amendments to an ongoing and previously approved IACUC protocol. Federal regulations require that any changes to existing protocols must first be reviewed and approved by the IACUC as they may impact the animal care and use of this protocol.

There are three types of amendments that can be submitted to the IACUC: minor amendments, major amendments and combined minor and major amendments. Click [here](#) for more information about the difference between minor and major amendments.

It is helpful for PIs to download and view a copy of their approved protocol to understand where in the protocol changes should be made. PIs can do this by:

- Opening the protocol.
- In “Approved IACUC Protocols” select the link to “ApprovedIACUCProtocols.pdf”.

## 3.0 PROCEDURES

### 3.1 ACCESSING MENTOR IACUC

1. Go to the [Mentor website](#).
2. The Institution ID = NKU.
3. Click “Log in”.
4. Use your NKU ID (NKU email username) and NKU password to log in.

### 3.2 HOW TO SUBMIT AN AMENDMENT

1. After logging into Mentor, click “IACUC” in the black banner.
2. Click “My “Protocols”. All of your protocols will be listed here.
3. Select the protocol you would like to amend.
4. At the bottom, there are three tabs, “Annual Reports”, “Amendments” and “Protocol Deviations/Adverse Events”. Select “Amendments”.
5. Click “Create New Amendment”.
6. Select the amendment type.

7. If you are editing a protocol question section, choose the appropriate section/s under “Add Sections”. If you aren’t sure which section will be revised or if the amendment alters multiple sections, select all protocol sections.
8. Click “Create Amendment”. This will take you back to the three tabs on the protocol submission page.
9. If you chose to edit protocol sections:
  - Click “Edit IACUC Protocol”.
  - To change the information, click “Edit Section Data” for each section’s dropdown.
  - Edit information under dropdowns as needed, changes will be tracked via track changes.
  - To add additional sections for editing, click “add sections” on the protocol sections page which shows all protocol sections.
  - After editing relevant protocol sections, select “View Protocol Page”.
10. Select “Questionnaire”.
  - Click “Answer”.
  - Answer the questions that appear.
  - Click “Save Answer”.
  - Click “Return to Protocol Page”.
11. Click “Submit”. The protocol will then be submitted to the IACUC.

Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	<input checked="" type="checkbox"/>	06/18/2019	<input type="checkbox"/>
IACUC Chair	<input type="checkbox"/>		<input checked="" type="checkbox"/>
Institutional Official	<input type="checkbox"/>		<input checked="" type="checkbox"/>

Revisions

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	<input checked="" type="checkbox"/>	08/12/2020	<input type="checkbox"/>	Formatting approved by A. Southwick
IACUC Chair	<input type="checkbox"/>		<input checked="" type="checkbox"/>	
Institutional Official	<input type="checkbox"/>		<input checked="" type="checkbox"/>	

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	<input checked="" type="checkbox"/>	11/04/2022	<input type="checkbox"/>	Updated Mentor wording and website links
IACUC Chair	<input type="checkbox"/>		<input checked="" type="checkbox"/>	
Institutional Official	<input type="checkbox"/>		<input checked="" type="checkbox"/>	