



SOP Title	(IACUC) PI – Submitting a Protocol Amendment (Pre 07-01-2019)				
Date Last Revised	11/04/2022	Date Created	05/21/2019	Revision #	1.2
SOP Number	2	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 type="checkbox"/> Institutional	
Subgroup	<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 IACUC protocols initially approved before July 1, 2019.

2.0 GENERAL INFORMATION AND SCOPE

The Northern Kentucky University (NKU) Institutional Animal Care and Use Committee (IACUC) has established this written procedure to guide Principal Investigators (PI) through the process of requesting 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 for 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.

Submitting an amendment to a protocol approved prior to July 1, 2019, will be similar to the previous procedures of submitting amendments. The PI is required to edit the most current paper version protocol and highlight any requested amendments.

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.
5. Click “IACUC” in the black banner.

3.2 HOW TO SUBMIT AN AMENDMENT

1. Click “IACUC” on the tab.
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. Do not select an "IACUC Protocol" if this option appears.
7. Click "Create Amendment".
8. This will take you back to the three tabs on the protocol submission page.
9. Under the "Amendment" tab, click "Questionnaire":
 - Click "Answer".
 - Answer the questions that appear.
 - Click "Save Answer".
 - Click "Return to Protocol Page".
10. Upload a revised copy of the most current IACUC protocol with the requested amendments highlighted by clicking the paper icon next to the bold "Revised IACUC Protocol (projects approved before 07/01/2019) then click "Upload".
11. Click "Submit". A pop-up will appear asking for confirmation to submit. Click "OK". 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"/>	08/03/2020	<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"/>	