

Office of Research, Grants and Contracts Standard Operating Procedures (SOP)

SOP Title	(IACUC) PI – Submitting a Protocol Amendment (Pre 07-01-2019)				
Date Last Revised	07/03/2024	Date Created	05/21/2019	Revision #	1.3
SOP Number	2	Required by:	□OHRP □Funding Agency □OLAW		٩W
Applicability	□ RGC Internal	⊠Resea	rcher 🛛 🗆 Ir	stitutional	
Subgroup	🗆 NKU Compliar	nce 🗆 IRB		BC	

# 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 <u>here</u> 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. If prompted, 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 dropdown...

### 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 of the screen, there are three tabs, "Annual Reports", "Amendments", and "Protocol Deviations/Adverse Events". Select "Amendments".

- 5. Click "New Amendment +".
- 6. Select the amendment type. Do not select an IACUC Protocol options if these appears.
- 7. Click "Create Amendment".
- 8. Click "Answer".
- 9. Answer the questions that appear.
- 10. Click "Save Answers".
- 11. Click "Return to Protocol Page"
- 12. Click "Upload".
  - 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".
- 13. 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	$\boxtimes$	06/18/2019		
IACUC Chair			$\boxtimes$	
Institutional Official			$\boxtimes$	

#### Revisions

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	$\boxtimes$	08/03/2020		Formatting approved by A. Southwick
IACUC Chair			$\boxtimes$	
Institutional Official			$\boxtimes$	

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	$\boxtimes$	11/04/2022		Updated Mentor wording
				and website links
IACUC Chair			$\boxtimes$	
Institutional Official			$\boxtimes$	
Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance		07/03/2024		Mentor interface changes
IACUC Chair			$\boxtimes$	
Institutional Official			$\boxtimes$	