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

SOP Title	(IACUC) PI- Submitting a Protocol Amendment (Post 07-01-2019)				
Date Last Revised	07/03/2024	Date Created	04/16/2019	Revision #	1.3
SOP Number	20	Required by:	☐OHRP ☐Funding Agency ☐OLAW		
Applicability	☐ RGC Internal	☒Researcher	☐Institutional		
Subgroup	☐ NKU Compliance	☐IRB	☒IACUC	☐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. If prompted, 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 dropdown.
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 "New Amendment +".
6. Select the amendment type.

7. If you are editing a protocol section, choose the appropriate section/s under "Add Sections". You will have the capability to add additional sections later in this procedure.
8. Click "Create Amendment".
9. Click "Answer".
10. Answer the questions that appear.
11. Click "Save".
12. Click "Return to Protocol Page".
13. If you chose to edit protocol sections:
    a. Click "Edit IACUC Protocol".
    b. If you aren't sure which section will be revised or if the amendment alters multiple sections, select "Add Sections" and select all sections in click "Save".
    c. To change the information, click "Edit Section Data" for each section's dropdown.
    d. Edit information under dropdowns as needed, changes will be tracked via track changes.
    e. To add additional sections for editing, click "add sections" on the protocol sections page which shows all protocol sections.
    f. After editing relevant protocol sections, select "View Protocol Page".

14. If you need to upload a document, click the three dots next to the amendment and click "Upload docs".
15. Click "Choose File".
16. Click "Save".
17. Click "Submit". The protocol will then be submitted to the IACUC.

Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	☒	06/18/2019	☐
IACUC Chair	☐		☒
Institutional Official	☐		☒

Revisions

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	☒	08/12/2020	☐	Formatting approved by A. Southwick
IACUC Chair	☐		☒	
Institutional Official	☐		☒	

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	☒	11/04/2022	☐	Updated Mentor wording and website links
IACUC Chair	☐		☒	
Institutional Official	☐		☒	

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	☒	07/03/2024	☐	Mentor interface update
IACUC Chair	☐		☒	
Institutional Official	☐		☒	