



SOP Title	(IACUC) PI – Submitting Three Year Renewals				
Date Last Revised	11/04/2022	Date Created	05/14/2019	Revision #	1.2
SOP Number	3	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 of submitting three-year renewals for approved IACUC protocols.

2.0 GENERAL INFORMATION AND SCOPE

All research, wildlife or classroom projects involving vertebrate animals are required to be reviewed by the Northern Kentucky University (NKU) Institutional Animal Care and Use Committee (IACUC) every three years. The IACUC protocol review process is managed through the Mentor IACUC system.

Investigators must complete the required CITI training courses and complete the Animal Contact Assessment form prior to submit a protocol through Mentor IACUC.

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.

There are two ways to submit a three-year renewal available to the PI:

1. Create a new protocol from scratch. See Section 3.2 for instructions.
2. Copy the current approved protocol. This will copy the protocol question sections and protocol page information. Please note, if amendments have been submitted that revised the protocol question sections, this will not be reflected in the copy. See Section 3.3 for instructions.

3.2 SUBMITTING A THREE-YEAR RENEWAL

SUBMITTING A THREE-YEAR RENEWAL USING A NEW NKU IACUC PROTOCOL

1. Click “IACUC” in the black banner.
2. Click “My Protocols”.
3. Click “Create a New Protocol”.

PROTOCOL PAGE

4. Enter required and relevant information:

Anything with a red asterisk (*) in Mentor IACUC is required

- **PI** – you will be able to edit this if you have been identified as a research coordinator for a PI.
- **Co-PI's** - Anyone with a leading role on the project with you. Type the last name first.
- **External PIs** – Researchers involved in the project outside of NKU.
- **Research Staff** - Any researchers involved in your project who will have access to identifiable data. They will have the ability to access and edit the project in Mentor.
- **Protocol Title** – The title of the IACUC project. If you are using a short title for your consent form or recruitment purposes, please include that as well.
- **Projected Start Date** – The project's ideal start date. Please note, per federal regulations, the project cannot start without IACUC approval.
- **Project Type** – Select the appropriate study type.
- **Funding Source** – if the project is funded, list the funders (i.e. NIH, NSF, etc.). If funding is still undermined, state "funding in progress".
- **Grant Number** – include if known.
- **Application Type** – Select "Three Year Renewal".
- **Link to IBC Protocol** – if this project is linked to an IBC protocol please add the IBC # if known. If not known, state not known at this time.
- **Message to IACUC Chair** – optional.

5. Click "Save".

6. Click the grey "Sign Electronically" button next to the PI.

PROTOCOL SECTIONS

7. Scroll to the bottom of the page and select "IACUC Protocol – Click Here" by the green arrow.

8. Each section will contain questions relevant to your project. Answer all of the questions. You may need to click "Edit Section Data" to answer the questions in certain sections. Please note, additional sections may be added after answering certain questions within previous sections.

9. After answering each individual section, click "Back to All Sections".

SUBMITTING

10. When ready to submit to the IACUC for review, click "View Protocol Page" from the IACUC Protocol window.

11. Click "Submit Project for Review".

UPLOADING RELEVANT DOCUMENTS

1. From the protocol page, click “Upload Docs” in the top banner.
2. Select the relevant file type.
3. Click “Choose File” and find the file on your computer for upload.

Note: It is recommended that you rename the document to something that will help you remember which document has been uploaded. Include a version number or date. If you do not rename the document, the document will appear as saved on your computer.

4. Click “Save”.

Your document will now appear at the bottom of the screen.

3.3 SUBMITTING A THREE YEAR REVEWAL (COPY PREVIOUS PROTOCOL)

1. Log into [Mentor IACUC](#).
2. Click “IACUC” in the black banner.
3. Click “My Protocols”.
4. Open the original approved protocol you wish to “copy”.
5. Click the grey “Copy” button in the top banner.
6. Remove the words “copy of” in the title and change title if desired.
7. Edit start date.
8. Click “Yes”. This will take you to the copy of the protocol (the three-year renewal protocol). This will copy the protocol questions and protocol page information. **Please note, if amendments have been submitted that revise the protocol question sections, this will not be reflected in the copy.**
9. To see previous revisions, open the original protocol, scroll to the bottom and click the “Amendments” tab. Here you can see all amendments that have been submitted.
10. Click “Edit” to change any information (i.e. adding researchers, updated funding information, etc.) on the protocol page.
11. Review the copied IACUC Protocol and edit any information that has changed or should change.
12. After reviewing and editing, click “Save”.
13. Electronically sign the protocol. The red “Signature Missing” will go away at this time.
14. Click the “Submit Protocol for Review” button then click the blue “OK” button.

3.4 MONITORING REVIEW OF RESEARCH PROTOCOLS

1. After submission, you will receive additional email notifications as your protocol moves through the IACUC review process. Quite often, a protocol requires revisions prior to final review. You may log into Mentor IACUC at any point to view the status of your protocol.
2. For questions specific to your Protocol, please use the “Messages” link while viewing your protocol in Mentor (upper right side of page). All messages become part of the Protocol record, which is useful for both the IACUC and Investigator.
3. For questions about Mentor IACUC, CITI training, or the NKU Research Compliance program, please contact Anita Southwick: iacuc@nku.edu.

3.5 DOWNLOADING THE APPROVED PROTOCOL

At any time, a PI can download the approved protocol for project approved after 07/01/2019 by:

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

Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	<input checked="" type="checkbox"/>	06/17/2019	<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"/>	