



SOP Title	(IACUC) PI – Submitting a New IACUC Protocol				
Date Last Revised	06/06/2024	Date Created	06/17/2020	Revision #	1.3
SOP Number	1	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 a new IACUC protocol to the NKU IACUC through the Mentor IACUC system.

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). The IACUC protocol review process is managed through the Mentor IACUC system.

Investigators must complete the required [CITI training](#) and [Animal Contact Assessment](#) form prior to approval.

The IACUC protocol is now completely electronic in the Mentor IACUC System. The system will walk you through relevant sections using advanced logic models. This will reduce the requirement of answering questions that are not relevant to your specific study.

Documents such as wildlife permits can be uploaded into the system.

3.0 PROCEDURES

3.1 ACCESSING MENTOR IACUC

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

3.2 NAVIGATING MENTOR IACUC

Upon login, click “IACUC” in the dropdown on the left-hand side. You will then be directed to the IACUC Info/Welcome page, which includes general guidelines and information for submitting studies through Mentor IACUC. The links along the left direct you to the following sections:

- **Resources:** Various links to external sites for regulatory reference.
- **My Protocols:** The page where you will create and manage your protocols.
- **CITI Training:** A record of the CITI training courses you have completed.

NOTE: CITI course certificates should automatically load into Mentor system from the CITI training site if you registered for CITI with your NKU email. You are responsible for keeping your

certifications up to date. The IACUC is required to verify the training certification status of all researchers as part of the review process.

3.3 SUBMITTING A PROTOCOL FOR IACUC REVIEW

SUBMITTING A NEW NKU IACUC PROTOCOL

1. Log into [Mentor IACUC](#).
2. Click "IACUC" in the dropdown on the left hand side.
3. Click "My Protocols".
4. Click "Create a New Protocol".

PROTOCOL PAGE

5. 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.
- **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".
- **Application Type** – select the appropriate application type.
- **Link to IBC Protocol** – if this project is linked to an IBC protocol please add the IBC # if known. If not know, state not known at this time.
- **Message to IACUC**– optional.

6. Click "Save".

ADDING RESEARCH PERSONNEL

If you need to add additional research personnel:

7. Click "Personnel" on the protocol page.
8. Type the researcher's last name in the appropriate section (Co-PI's or Research Staff).
9. Select their name.
10. Click "Add +".
11. Click "Save".
 - a. Note, you will provide additional information (i.e. positions and responsibilities) within the IACUC Protocol.

PROTOCOL SECTIONS

12. Click "IACUC Protocol – Click Here".
13. Each section will contain questions relevant to your project. Complete all sections by answering all of the questions within them. 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.
 - **Personnel Qualifications:** Click on "Edit Section Data" in the right corner and answer questions under Responsibilities; Click "Add/Edit Answers" under "Questions" and answer all; click "Save".
 - **Animal Information:** Click on Add Species and answer the questions; click save – this takes you back to an "Edit Animal Information" page. Click on add/edit questions and answer these questions; click "Save Answers".
 - **Scientific Justification:** Click on "Edit Section Data" and then Click on Add/Edit Answers; enter answers and click "Save Answers".
 - **Procedures – Non-wildlife or wildlife (non-invasive/non-surgical):** Click on "Start answering questions" for both sections.
 - **Invasive or Surgical Procedures:** Click on "Start answering questions" for both sections.
 - **Housing and Husbandry:** Click on "Start answering questions" for both sections.
 - **Pain/Distress and Treatment of Pain/Distress:** Click "Edit Section Data" then click "Start Answering".
 - **Experimental and/or Hazardous Agents or Chemical Use:** Click "Edit Section Data" then click "Start Answering".
 - **Euthanasia:** Click "Edit Section Data" then click "Add/Edit Answers"; click "Save Answers".
14. Click "View Protocol Page" from the IACUC Protocol window.

ELECTRONIC SIGNATURE

1. Click "Personnel" on the protocol page.
2. Click "Sign Electronically" next to your name.

UPLOADING RELEVANT DOCUMENTS

1. From the protocol page, click the "Files" dropdown.
2. Click "Upload".
3. Select the relevant file type.
4. Click "Choose File" and locate 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.

5. Click "Save".

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

Note: Remember to upload all relevant documents (wildlife permits, etc.) before submitting.

SUBMITTING

3. Click the “Submit for Protocol Review” button.

3.4 MONITORING REVIEW OF RESEARCH PROTOCOLS

After submission, you can track where the protocol is in the process by opening the protocol in Mentor IACUC and looking in the top right-hand corner.

1. 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.
2. 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 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"/>	02/19/2020	<input type="checkbox"/>	Updated web links
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"/>	07/31/2020	<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"/>	

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	<input checked="" type="checkbox"/>	09/18/2024	<input type="checkbox"/>	Mentor users interface update
IACUC Chair	<input type="checkbox"/>		<input checked="" type="checkbox"/>	
Institutional Official	<input type="checkbox"/>		<input checked="" type="checkbox"/>	