

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

SOP Title	(IACUC) – Reviewer- IACUC Member Protocol Voting, Review and Approval							
Date Last Revised	07/03/2024	Date Created		06/11/2019		Revision #		1.3
SOP Number	17	Required by:		OHRP	□OHRP □Funding Agency □			DLAW
Applicability	🛛 RGC Intern	CInternal 🛛 🗆 Researche		r 🛛 Institutional				
Subgroup	□ NKU Compliance		□IRB	⊠IACUC	Ľ	JIBC		

1.0 PURPOSE

The purpose of this SOP is to describe the process for IACUC board members (aka "Reviewers") to:

- Vote for designated member review (DMR) or full convened review (FCR) for new protocols and amendments (Section 3.2);
- Review new IACUC protocols in the Mentor system when assigned as DMR (Section 3.4);
- Review amendments in the Mentor system when assigned as DMR (Section 3.4).

2.0 GENERAL INFORMATION AND SCOPE

All research and classroom involving vertebrate animals are reviewed by the Northern Kentucky University (NKU) Institutional Care and Use Committee (IACUC).

The IACUC Administrator will conduct an IACUC pre-review which includes verifying the completion of the required training and the completion of the Animal Contact Assessment prior to IACUC voting, DMR and FCR.

3.0 PROCEDURES

3.1 ACCESSING MENTOR IACUC

- 1. Go to the Mentor website.
- 2. Institution ID = NKU.
- 3. Click "Log in".
- 4. Use your NKU ID (NKU email username) and NKU password to log in.

3.2 VOTING DESIGNATED MEMBER REVIEW VERSUS FULL CONVENED BOARD REVIEW

A. VOTING FOR REVIEW TYPE OF NEW PROTOCOLS

Per the Office of Laboratory Animal Welfare (OLAW) requirements, all new protocols must be voted on by all IACUC members to determine if the protocol will be reviewed by a designated reviewer (DMR) or by a full convened board (FCR). Instructions for voting are explained below:

- 1. Each reviewer will receive an email after the IACUC pre-review is completed announcing the vote for DMR or FCR.
- 2. The email will contain a link to vote with the due date for voting. All members must have the opportunity to vote before a final decision can be issued.
- 3. After clicking the link in the email, the protocol will open.

- 4. Conduct a review to determine the review type by clicking and reviewing "IACUC Protocol" and reviewing any documents uploaded.
- 5. After conducting the review, select either "Designed Member Review" or "Full Convened Review" from the Review Level vote dropdown.
- 6. The vote automatically saves. Mentor can be closed after voting.
- 7. Vote must be submitted within 7 days of receipt.

B. VOTING FOR REVIEW TYPE OF AMENDMENTS

Amendments that do not qualify for administrative or expedited review must also undergo the same voting procedures.

- 1. Each reviewer will receive an email after the IACUC pre-review is completed to vote for DMR or FCR.
- 2. The email will contain a link to vote with the due date for voting. All members must vote before a final decision can be issued.
- 3. After clicking the link in the email, the protocol will open.
- 4. Select the "Amendments" tab.
- 5. Conduct a review to determine the review type by clicking and reviewing "Questionnaire" and "IACUC Protocol" and reviewing any documents uploaded.
- 6. After conducting the review, select either "Designed Member Review" or "Full Convened Review" from the drop-down under the "Amendments" tab at the bottom of the page.
- 7. The vote automatically saves. Mentor can be closed after voting.
- 8. Vote must be submitted within 7 days of receipt.

3.3 FINDING PROTOCOLS ASSIGNED TO YOU

A. OPENING THE PROTOCOL THROUGH EMAIL NOTIFICATION

When assigned a protocol to review, you should receive an email with the subject "Reviewer Assigned Notification".

If you are unable to complete the review (i.e. conflict of interest, busy schedule, etc.) use the "Decline" at the top of the Mentor page for the appropriate protocol.

A. OPENING THE PROTOCOL IN THE MENTOR SYSTEM (NOT THROUGH THE EMAIL NOTIFICATION) EMAIL NOTIFICATION

- 1. Open Mentor IACUC.
- 2. Select "IACUC" from the dropdown on the left.
- 3. Click "Reviewer" in the left-hand column. All protocols assigned to you for review will list.

If you are unable to complete the review (i.e. conflict of interest, busy schedule, etc.) use the "Decline" at the top of the Mentor page for the appropriate protocol.

3.4 REVIEW STRATEGY

A. REVIEWING A NEW PROTOCOL

After clicking on the protocol title or opening the review email notification, you will see the protocol page. This contains everything you will need to complete the review. There are three parts to conducting

the review.

The reviewer should read through:

- 1. Protocol Page The basic study information (title, Principal Investigator (PI), start date, review type, etc.).
- 2. IACUC Protocol On the protocol page, you will see "IACUC Protocol Click Here". This contains the actual study protocol. Questions are grouped into sections for ease of use for the PI and to allow a more thorough review.
- 3. Uploaded Documents Under the "Files" dropdown you will see any documents that were uploaded by the PI. All documents that are uploaded will be here. Some protocols will not have any uploaded documents.

Please note, the reviewer does not need to verify training or the completion of the Animal Contact Assessment form.

Finalizing the review:

- 1. After reviewing the IACUC protocol and files, click "Review".
- 2. Answer the question "As written, this protocol is ready for approval".
 - If the protocol is not ready for approval, explain the required revisions after selecting "No. Please explain the required revisions.
- 3. Select either "Pending Required Revisions" or "Completed" in the "Review Status".
 - o If revisions are not required, change the review status to "Completed".
 - o If revisions are required, change the status to "Pending Revisions Required".
- 4. If you selected "Pending -Required Revision" you will now see a memo that will be sent directly to the PI. The reviewer's name is not listed on the memo.

B. REVIEWING AN AMENDMENT

- 1. You can either access the assigned amendment by clicking the link directly from the email notification or in the "Reviewer" section in Mentor.
- 2. After clicking on the protocol title, you will see the protocol page.
- 3. Select the "Amendment" tab at the bottom of the page.
- 4. Conduct a review by clicking and reviewing "Questionnaire" and "IACUC Protocol, and reviewing any documents uploaded.
- 5. Click the "Review" button at the bottom of the page.
- 6. Answer the question "As written, this protocol is ready for approval".
 - If the protocol is not ready for approval, explain the required revisions after selecting "No. Please explain the required revisions".
- 7. Select either "Pending Required Revisions" or "Completed" in the "Review Status".
 - o If revisions are not required, change the review status to "Completed".
 - If revisions are required, change the status to "Pending Revisions Required".
- 8. If you selected "Pending -Required Revision," you will now see a memo that will be sent directly to the PI. The reviewer's name is not listed on the memo. Click "Save"
- 9. <u>Click "Send"</u>

Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	\boxtimes	06/17/2019	
IACUC Chair			\boxtimes
Institutional Official			\boxtimes

Revisions

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	\boxtimes	08/12/2020		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	\boxtimes	04/30/2025		Mentor UI update
IACUC Chair			\boxtimes	
Institutional Official			\boxtimes	