



SOP Title	(IRB) Reviewer – Reviewer Comments and Process				
Date Last Revised	07/12/2017	Date Created	06/07/2017	Revision #	
SOP Number	10	Required by:	<input type="checkbox"/> OHRP	<input type="checkbox"/> Funding Agency	<input type="checkbox"/> OLAW
Applicability	<input checked="" type="checkbox"/> RGC Internal	<input type="checkbox"/> Researcher	<input type="checkbox"/> Institutional		
Subgroup	<input type="checkbox"/> NKU Compliance	<input checked="" type="checkbox"/> IRB	<input type="checkbox"/> IACUC	<input type="checkbox"/> IBC	

1.0 Purpose

The purpose of this SOP is to describe the process for IRB board members (aka “Reviewers”) to review IRB protocols in the Mentor IRB system.

2.0 General Information and Scope

All research involving human subjects is reviewed by the Northern Kentucky University (NKU) Institutional Review Board (IRB). The IRB protects the rights and welfare of human subjects and assures compliance with all federal, state and institutional policies. The IRB protocol review process is managed through the Mentor IRB system.

Investigators must complete the required CITI training courses to submit a protocol through Mentor IRB.

3.0 Procedures

3.1 Accessing Mentor IRB

1. Go to the [Mentor website](#)
2. Institution ID = NKU
3. Use your NKU ID (NKU email username) and NKU password to log in.

3.2 Finding Protocols Assigned to You

Email Notification

When assigned a protocol to review, you should receive an email with the subject “Reviewer Assigned Notification”. Click on the link within the email.

Finding Protocols in the Mentor System

Step 1: Upon login, you will be directed to the IRB Info/Welcome page, find and click “Reviewer” in the left hand column. All protocols assigned to you for review will list.

Step 2: Select the protocol you would like to review.

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.

3.3 Reviewing the Protocol

After completing 3.2 (above), you will see the protocol submission page. This contains everything you will need to complete the review.

Protocol Submission Page – the basic study information (title, PI, start date, review type, etc.)

Application Sections – If you scroll down, you will see a red “Application Sections”. This contains the actual study protocol. Questions are grouped into application sections for ease of use for the PI and to allow a more thorough review.

Uploaded Documents – under the red “Application Section” you will see any documents that were uploaded by the PI. All documents that are uploaded will be here.

3.4 Review Strategies

System Edits - Edit Review and Reviewer Worksheet

To review the protocol and simultaneously take notes in the system, while in the protocol submission page, right click on “Application Sections”, select “Open Link in a New Tab”.

Return to the tab with the protocol submission page open, and follow these instructions:

- Click “Review”
- Upon clicking “Review” you will be taken to the protocol review worksheet. Click “Add/Edit Answers”. This will take you through a Reviewer Worksheet that covers areas for review.
- Answer questions
- The second to last question is a text box to summarize reviewer comments (Summary Comments)

The last question asks if you recommend this proposal for approval. Your options are:

1. Yes
2. No. Revisions are required before approval can be recommended. After revisions are completed, revisions will be resubmitted to the reviewer

The next box will ask if you want to complete the review.

- a. Select “Pending – Revisions Required” for options 2
- b. Select “Completed” for option 1 above or after revisions are satisfactory for option 2.

Click “Update”

You will now see a memo that will be sent directly to the PI. The reviewer name is not listed on the memo.

Study Related Documents Edits

You have two options for providing feedback for study related documents (i.e. consents, recruitment materials, etc.)

Option 1 – You may edit study related documents in track changes and upload them to the review

After you complete the revisions in Review Type 1, before changing the review status, select “Upload Revisions” and attach the track changes version of the study related documents.

Option 2 – You can summarize required edits in the reviewer worksheet

Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	<input checked="" type="checkbox"/>	06/15/2017	<input type="checkbox"/>
Institutional Official	<input type="checkbox"/>		<input checked="" type="checkbox"/>