



SOP Title	(IRB) PI – Submitting a New Protocol				
Date Last Revised	09/08/2017	Date Created	06/07/2017	Revision #	3.0
SOP Number	12	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 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 PIs to submit an IRB application through 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 NAVIGATING MENTOR IRB

Upon login, you will be directed to the IRB Info/Welcome page, which includes general guidelines and information for submitting studies through Mentor IRB. 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. If your certificates do not appear on the CITI Course Completion page, you may upload them manually using the Upload button next to the relevant course title. You are responsible for keeping your certifications up to date. The Mentor system does not allow new Protocol activity unless your certifications are current. IRB reviewers are required to verify the certification status of all Investigators as part of the review process.

There are two overall parts to the NKU Mentor System:

THE NKU IRB APPLICATION

The IRB application is now completely electronic in the Mentor IRB 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.

DELEGATION OF IRB STUDY CREATION AND SUBMISSION

As the lead researcher (Principal Investigator), you have the ability to delegate the creation and submission of the research project in Mentor IRB to a “research coordinator”. To do so, see [SOP #18 \(IRB\) PI - Assigning a Research Coordinator for Study Creation and Submission](#).

RELEVANT DOCUMENTS

Documents such as the informed consent, recruitment materials, and data collection forms will be uploaded into the system.

3.3 SUBMITTING A RESEARCH PROTOCOL FOR IRB REVIEW

SUBMITTING A NEW NKU IRB APPLICATION

1. Log into Mentor IRB

This will open under a “Home” tab or an “IRB” tab. If it opens under the “Home” tab, click on “IRB”

2. Click “My Protocols”
3. Click “Create a New Protocol”

“Select a New Protocol Method” will pop up.

Use Human Subjects Determination Diagnostic Survey - allows you to complete a diagnostic survey if you are unsure if your project meets the federal definition of research and aides you in determining if the project requires IRB review and approval.

Go Directly to New Protocol Page - allows you to start the process of creating a new study.

4. Select “Go Directly to New Protocol Page”

PROTOCOL PAGE

5. Enter required and relevant information:

Anything with a red asterisk (*) in Mentor IRB 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 IRB 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 IRB approval
 - Projected End Date – The project’s projected end date
 - Is this study funded by NIH AND is it a clinical trial? Select the appropriate answer
 - Participant Age Group – The age group of participants, if applicable. If this is a retrospective review of data, make that selection. Application sections will be automatically loaded based on your answer to this question.
 - What types of data are you collecting? – Select the type/s of data you are collecting. Application sections will be automatically loaded based on your answer to this question.
 - Is another institution requesting that NKU acts as the IRB of record? Select yes if this project is taking place at multiple institutions that have IRBs and they would like NKU to provide oversight of the project. Please contact the IRB with questions at irb@nku.edu.
 - Review Type – Select the appropriate review type.
 - Select “NKU IRB Review Request” if you are requesting IRB review at NKU.
 - If you select “IRB Review not Required” or “Quality Improvement Requested”, additional questions will appear at the bottom of the screen to provide the IRB with additional information to make a formal determination stating that IRB review is not required.
 - Select “Delegate to External IRB” if another IRB will be the IRB of record. Additional questions and requirements will appear at the bottom of the screen.
 - Waiver of Informed Consent – This option is ONLY valid for studies involving adults. Waivers of informed consent can only be requested for specific reasons per federal regulations. Application sections will be automatically loaded based on your answer to this question.
 - Waiver of Documentation of Informed Consent – Select this if you are requesting to not collect a signature on the informed consent document. This may be necessary if you are using an electronic consent/data collection strategy such as Survey Monkey or Qualtrics. Application sections will be automatically loaded based on your answer to this question.
 - Participants – Select the participant type that you will be recruiting. Application sections will be automatically loaded based on your answer to this question. If “Other” is selected, please explain in the “Other Participant Type” text field.
 - Message to IRB Chair - optional
6. Click “Save”
 7. Click the grey “Sign Electronically” button next to the PI

APPLICATION SECTIONS

8. Scroll to the bottom of the page and select “Application Sections”

9. Each application section will contain questions relevant to your project. Answer all of the questions.
10. Click “Submit Survey” after surveys are complete.
 - Changes can be made to the application prior to submitting.

SUBMITTING

11. Click “View Protocol Page”
12. When ready to submit to the IRB for review, click “View Protocol Page”
13. Click “Submit protocol for Review”. If there is a faculty advisor or other signatures required, click “Request Signatures”. Please note, if no other signatures are required, this will appear until the PI clicks “Sign Electronically”.

Note: Remember to upload all relevant documents (informed consent, data collection forms, recruitment materials) prior to submitting.

UPLOADING RELEVANT DOCUMENTS

1. Log into Mentor IRB
2. Click “My Protocols”
3. Select the appropriate study title
4. Click “Upload Docs” in the top banner
5. Select the relevant file type (i.e. Consent form, recruitment materials, etc.)
6. Click “Choose File” and find the file on your computer for upload

Notes:

- Only select document types that say “revised” if you are revising based on reviewer comments or revising documents for an amendment.
- 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.

7. Click “Save”

Your document will now appear at the bottom of the screen

SPECIAL INFORMATION ABOUT DOCUMENTS

- Anything a potential participant may see or hear related to a research study must be reviewed by the IRB.
- The NKU Informed Consent/Assent/Parental Permission templates must be used.

3.4 MONITORING REVIEW OF RESEARCH PROTOCOLS

1. After submission, you will receive additional email notifications as your protocol moves through the IRB Review process. Quite often, a protocol requires revisions prior to final review. You may log into Mentor IRB 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 IRB and Investigator.
3. For questions about Mentor IRB, CITI training, or the NKU Research Compliance program, please contact Anita Southwick: irb@nku.edu

3.5 DOWNLOADING THE APPROVED PROTOCOL

At any time a PI can download the approved application by:

1. Opening the protocol
2. In “Approved Application Sections” select the link to “ApprovedApplicationSections.pdf

Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	<input checked="" type="checkbox"/>	06/17/2017	<input 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"/>	12/11/2018	<input type="checkbox"/>	Minor revisions to reflect changes in Mentor
IRB Chair	<input type="checkbox"/>		<input checked="" type="checkbox"/>	
Institutional Official	<input type="checkbox"/>		<input checked="" type="checkbox"/>	