



SOP Title	IRB PI- Submitting a Protocol Amendment				
Date Last Revised	08/01/2024	Date Created	06/07/2017	Revision #	1.2
SOP Number	13	Required by:	<input checked="" 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 Principal Investigators (PI) to submit an amendment to an already approved protocol.

2.0 GENERAL INFORMATION AND SCOPE

The Northern Kentucky University (NKU) Institutional Review Board (IRB) has established this written procedure to guide Principal Investigators through the process of requesting changes or amendments to an ongoing and previously approved IRB protocol. Federal regulations require that any changes to existing protocols must first be reviewed and approved by the IRB as they may impact the risk/benefit ratio of the protocol.

3.0 PROCEDURES

3.1 ACCESSING MENTOR IRB

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

3.2 GENERAL INFORMATION

Minor Amendments – add or change of researchers, change in PI, change in number of participants, etc. This does not include a change in methodology.

Major Amendments – Include significant changes like addition or change of a survey, change in participant groups or locations, change in consent form, method, recruiting, data collection, etc.

The IRB will review the proposed changes with every attempt to respond within ten (10) business days. It is helpful for PIs to download and view a copy of their approved protocol to understand where in the application changes should be made. PIs can do this by:

1. Opening the protocol.
2. Under the “Files tab, in “Approved Application Sections” select the link to “ApprovedApplicationSections.pdf”.

3.3 HOW TO SUBMIT AN AMENDMENT

1. After logging into Mentor IRB, select “IRB” from the drop-down menu in top left-hand corner.

2. Click "My Protocols" (all of your protocols will be listed here).
3. Select the protocol you would like to amend.
4. At the bottom, there are three tabs, "Continuing Reviews", "Amendments" and "Adverse Events"; select "Amendments".
5. Click "New Amendment".
6. Select the amendment type- minor or major (minor revisions would be small changes like study staff, small increase in study numbers, etc.).
7. If you are editing an application section, choose the appropriate section/s under the "Select Application Sections You Wish to Revise".
8. Click "Create Amendment".
9. This will take you to the Amendment Summary Memo. Click the "Answer" button to answer the two questions listed.
10. Click "Return to Protocol Page".
11. This will take you back to the three tabs on the protocol submission page. If you chose to edit application sections, select "Edit Application Sections".
 - a. Edit relevant application sections.
 - b. After editing relevant application sections, select "View Protocol Page".
12. In the "Amendments" tab, upload relevant documents. Remember, if you are editing already approved documents (i.e. informed consent) track changes and a clean version must be uploaded.
13. Click "Submit".

Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	<input checked="" type="checkbox"/>	06/15/2017	<input type="checkbox"/>
IRB 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"/>	06/22/2020	<input type="checkbox"/>	Formatting approved by A. Southwick
IRB 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"/>	08/01/2024	<input type="checkbox"/>	Updates for Mentor UI switch approved by A. Southwick
IRB Chair	<input type="checkbox"/>		<input checked="" type="checkbox"/>	
Institutional Official	<input type="checkbox"/>		<input checked="" type="checkbox"/>	