



SOP Title	(IRB) Submitting a Protocol Amendment (Studies Approved Before 07/01/2017)				
Date Last Revised		Date Created	07/20/2017	Revision #	
SOP Number	17	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 submitting a project amendment for all IRB studies approved before July 1, 2017.

2.0 General Information and Scope

The NKU 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. 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 10 business days.

3.3 Amending the Protocol

Amendments for studies approved before 07/01/2017 will be documented the same way as previously documented. The PI should:

1. Make the revisions in the most recent version of the NKU IRB application (the paper IRB application used until 07/01/2017)
2. Revisions must be highlighted.
3. Any documents (informed consents, recruitment materials, etc.) that are revised must be done so in track changes. A track changes and clean version must be uploaded (see Sections 3.4 for more instructions)

3.4 How to Submit the Amendment

1. After logging into Mentor IRB, click “IRB”
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 “Create New Amendment”
6. Select the amendment type. Minor revisions would be small changes like study staff, small increase in study numbers, etc.
7. Click “Create Amendment”
8. Click “Amendment Questionnaire”
 - a. Answer the amendment questionnaire question, save answer, submit survey
9. Click “Back”
10. Upload the revised application using the “Other” upload
11. Upload any additional revised documents
12. Click “Sign Electronically”
13. Click “Submit”

4.0 References

5.0 Forms or Attachments

6.0 Definitions

Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	<input checked="" type="checkbox"/>	06/20/2017	<input type="checkbox"/>
Institutional Official	<input type="checkbox"/>		<input checked="" type="checkbox"/>