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

SOP Title	(IRB) Reviewer – Amendment Review				
Date Last Revised	06/07/2017	**Date Created**	06/06/2017	**Revision #**	
SOP Number	9	**Required by:**	☐OHRP ☐Funding Agency ☐OLAW		
Applicability	☒ RGC Internal	☐Researcher	☐Institutional		
Subgroup	☐ NKU Compliance	☒IRB	☐IACUC ☐IBC		

1.0 Purpose

The purpose of this SOP is to describe the process for IRB reviewers to review an IRB protocol amendment in the Mentor IRB system.

2.0 Procedures

2.1 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

2.2 Finding Protocols Assigned to You
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.
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.

2.3 Review Strategies
- Click on email link
- At the bottom of the page, select you will see three tabs, select "Amendments"
- Review attached documents, amendment questionnaire, and edited application sections
- Click review

There are two options
1. Revisions required
2. Complete the review (no revisions required)

Revision Required:

- Click "Edit Review"
- Type comments

- Click "Save"
- If the PI must make revisions, select Pending – Revisions Required

A memo to the PI should appear. Edit if needed and click "Send"
You may also upload study related documents in track changes version by clicking "Upload Revisions"

Completing the Review (No revision required):

- Change "Review Status" to "Completed"
- Click "OK"

2.4 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	☒	06/15/2017	☐
Institutional Official	☐		☒