

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

| SOP Title | (IRB) Responding to Reviewer Revisions Required | | | | | | | |
|-------------------|---|----------------------------|------|------------|----------------------|------------|--|-----|
| Date Last Revised | 05/01/2025 | Date Created | | 09/08/2017 | | Revision # | | 1.1 |
| SOP Number | 19 | Required by: | | OHRP | OHRP Funding Agency | | | LAW |
| Applicability | RGC Interna |] RGC Internal ⊠Researcher | | - 🛛 🗆 🗆 🗆 | | | | |
| Subgroup | □ NKU Compliance | | ⊠IRB | | C | JIBC | | |

1.0 PURPOSE

The purpose of this SOP is to describe the process for responding to revisions that are required in the Mentor IRB system. Revisions may be required by the Institutional Review Board (IRB) Administrator or an IRB Reviewer for new study submission, amendments, continuing reviews, etc.

2.0 GENERAL INFORMATION AND SCOPE

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.

3.0 PROCEDURES

You will receive an email either notifying you of approval or notifying you that revisions are required.

- 1. Click on the link in the email.
- 2. Open IRB from the dropdown on the left side of the screen.
- 3. Select "My Protocols"
- 4. Select the appropriate protocol.
- 5. This will open your protocol. Please be aware that there may be attached documents with track changes comments.
 - a. To see the required revisions click "Reviewer (type of review) Review Notes" or "Pending Revisions Required".

You will now see the reviewer checklist and comments.

- 6. After reviewing the required revisions, click "Cancel".
- 7. Make the required revisions and upload edited documents (if applicable).
- 8. Documents must be uploaded in track changes AND with track changes accepted.
- 9. Click "Submit Revisions for Review", which should be located at the top of the page and highlighted in yellow.
- 10. Click "OK".

Approvals

| Title | Approved | Date Approved | Not Applicable | |
|--------------------------------|-------------|---------------|----------------|--|
| Manager of Research Compliance | \boxtimes | 09/08/2017 | | |
| IRB Chair | | | \boxtimes | |
| Institutional Official | | | \boxtimes | |

Revisions

| Title | Approved | Date Approved | N/A | Summary |
|--------------------------------|-------------|---------------|-------------|--|
| Manager of Research Compliance | \boxtimes | 07/07/2020 | | Formatting approved by A. Southwick |
| IRB Chair | | | \boxtimes | |
| Institutional Official | | | \boxtimes | |

| Title | Approved | Date Approved | N/A | Summary |
|--------------------------------|-------------|---------------|-------------|------------------|
| Manager of Research Compliance | \boxtimes | 05/01/2025 | | Mentor UI update |
| IRB Chair | | | \boxtimes | |
| Institutional Official | | | \boxtimes | |