

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

| SOP Title         | IBC Protocol Revisions |                       |                             |                |  |  |
|-------------------|------------------------|-----------------------|-----------------------------|----------------|--|--|
| Date Last Revised | 06/23/2018             | Date Created          | 06/2010                     | Revision #     |  |  |
| SOP Number        | 6                      | Required by:          | □OHRP □Funding Agency □OLAW |                |  |  |
| Applicability     | ☐ RGC Internal         | ☐ RGC Internal ☐ Rese |                             | □Institutional |  |  |
| Subgroup          | ☐ NKU Complia          | nce □IRB              | □IACUC                      | ⊠IBC           |  |  |

## 1.0 PURPOSE

The purpose of this SOP is to describe the process for submitting protocol revisions for approved IBC protocols.

## 2.0 GENERAL INFORMATION AND SCOPE

A revision is any planned change to an IBC approved protocol. All revisions must be submitted to and approved by the IBC prior to initiation.

## 3.0 PROCEDURES

#### A. REQUIRED DOCUMENTS:

The PI should:

- Complete the IBC Revision Form
- Edit the BAR application:
  - o Select "Revision" at the top of the BAR application.
  - o If necessary, revise the BAR form to include the relevant edits. All revisions should be highlighted in some way.
- If applicable, complete the "Addition of Personnel" form or "Addition of Students Teaching Protocols" form

Please note, a new BAR may be requested if there are substantial revisions.

#### B. SUBMITTAL AND REVIEW PROCESS

The Principal Investigator must submit the aforementioned documents to the IBC Administrator (biosafety@nku.edu) by the annual report due date.

Revisions submitted will be reviewed by the IBC and comments, if any, will be returned to the IBC Administrator for compilation and dissemination to the PI. The PI will then make the required revision and resubmit to the IBC Administrator who will then redistribute the revisions to the IBC. The PI will be notified of approval by the IBC Administrator.

## 4.0 REFERENCES

# **5.0 FORMS OR ATTACHMENTS**

NKU IBC Revision Form

# 6.0 DEFINITIONS

# Approvals

| Title                          | Approved    | Date Approved | Not Applicable |
|--------------------------------|-------------|---------------|----------------|
| Manager of Research Compliance | $\boxtimes$ | 06/12/2018    |                |
| IBC Chair                      | $\boxtimes$ | 06/12/2018    |                |
| Institutional Official         |             |               |                |

# Revisions

| Title                          | Approved | Date Approved | N/A | Summary |
|--------------------------------|----------|---------------|-----|---------|
| Manager of Research Compliance |          |               |     |         |
| IACUC Chair                    |          |               |     |         |
| Institutional Official         |          |               |     |         |