



SOP Title	Submitting Three Year Protocol Renewals				
Date Last Revised	09/28/2017	Date Created	06/2010	Revision #	
SOP Number	5	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 type="checkbox"/> IRB	<input type="checkbox"/> IACUC	<input checked="" type="checkbox"/> IBC	

1.0 PURPOSE

The purpose of this SOP is to describe the process for submitting three year annual renewals for IBC protocols.

2.0 GENERAL INFORMATION AND SCOPE

This SOP applies to all IBC approved protocols for which the PI wishes to extend the protocol for another three years past the expiration date.

Approved BAR applications are valid for no more than three years. After three years, a new BAR form is required if the researcher wishes to continue the study. Upon re-approval, a new IBC number will be generated and full IBC review completed. Studies cannot be continued without an approved renewal application.

To avoid expiration, the protocol renewals should be submitted thirty (30) days prior to expiration.

3.0 PROCEDURES

A. THREE YEAR PROTOCOL RENEWAL SUBMISSION

- The protocol should be submitted electronically to the IBC Administrator (biosafety@nku.edu).
- Actual signatures are needed but can be scanned.
- If no revisions are being made, the researcher may use the original or most current BAR application and check “Three Year Renewals with No Revisions” on the application.
- If revisions are being made, the researcher should check “Three Year Renewal with Revisions” on the application and ensure:
 - All changes are highlighted
 - A memo is attached to assist reviewers in determining the revisions to be reviewed
 - Training is current for the PI and all personnel listed on the protocol

B. THREE YEAR PROTOCOL RENEWAL REVIEW

- The IBC Administrator will facilitate the communication between the PI and the IBC.
- If there are comments or revisions required, the IBC Administrator will submit those to the PI.
- PI revision, based on reviewer comments, if any, should be sent to the IBC Administrator and dispersed for further IBC review.

- The IBC Administrator will notify the PI via email of an approval and send a formal approval notice.

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"/>	06/12/2018	<input type="checkbox"/>
IBC Chair	<input checked="" type="checkbox"/>	06/12/2018	<input type="checkbox"/>
Institutional Official	<input type="checkbox"/>		<input checked="" type="checkbox"/>

Revisions

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	<input type="checkbox"/>		<input type="checkbox"/>	
IACUC Chair	<input type="checkbox"/>		<input type="checkbox"/>	
Institutional Official	<input type="checkbox"/>		<input type="checkbox"/>	