



SOP Title	(IRB) PI- Submitting Continuing Review				
Date Last Revised	08/01/2024	Date Created	06/07/2017	Revision #	1.2
SOP Number	14	Required by:	<input checked="" 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 Principal Investigators (PI) submitting continuing review of active IRB research project approved as Full Board/Convened Board.

## 2.0 GENERAL INFORMATION AND SCOPE

As required by federal guidelines, the Northern Kentucky University (NKU) Institutional Review Board (IRB) has written these procedures to guide Principal Investigators (PI) through the process of requesting a yearly continuation of an ongoing and previously approved protocol.

The approval to conduct your study lasts for up to one year. A continuing review must be submitted within 30 days of your study expiration date. You will receive a reminder 30 days before the continuing review due date and reminders weekly after that. All study-related activities must stop if the continuing review is not completed by the expiration date.

All studies approved as full board and select studies approved as expedited must undergo continuing review.

## 3.0 PROCEDURES

### 3.1 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.

### 3.2 HOW TO SUBMIT A CONTINUING REVIEW

1. After logging into Mentor IRB, click "IRB" in the dropdown.
2. Click "My "Protocols" (all of your protocols will be listed here).
3. Select the protocol you would like to renew.
4. At the bottom, there are three tabs, "Continuing Reviews", "Amendments", and "Adverse Events"; select "Continuing Reviews".
5. Click "Complete and Submit".
6. Answer all questions on the "Continuing Review" page.
7. If the study is not being terminated, upload copies of unstamped versions of any informed consent, assent and parental permission forms. These will be restamped upon reapproval.
8. Add additional comments if needed.

9. Click "Submit Report".

### 3.3 CONTINUING REVIEW NOT SUBMITTED PRIOR TO EXPIRATION DATE

If a PI wants to continue a research study but has failed to submit a continuing review prior to the expiration date and it is within 30 days of the study expiration, the PI must submit an adverse event by following the NKU IRB SOP #1 Reporting Unanticipated Problems or Adverse Events.

If a PI wants to continue a research study but has failed to submit a continuing review before the expiration date and it is more than 30 days past the study expiration, the PI must terminate the current study (See NKU IRB SOP #15 Terminating a Protocol) and submit a new study (See NKU IRB SOP #12 Submitting a New Protocol).

#### Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	<input checked="" type="checkbox"/>	06/15/2017	<input type="checkbox"/>
IRB Chair	<input type="checkbox"/>		<input checked="" type="checkbox"/>
Institutional Official	<input type="checkbox"/>		<input checked="" type="checkbox"/>

#### Revisions

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	<input checked="" type="checkbox"/>	06/22/2020	<input type="checkbox"/>	Formatting approved by A. Southwick
IRB Chair	<input type="checkbox"/>		<input checked="" type="checkbox"/>	
Institutional Official	<input type="checkbox"/>		<input checked="" type="checkbox"/>	

Summary of Revision	Revised	Date Revised
Removal of expedited CR	<input checked="" type="checkbox"/>	01/04/2018

#### Revisions

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	<input checked="" type="checkbox"/>	08/01/2024	<input type="checkbox"/>	Updates for new Mentor UI approved by A. Southwick
IRB Chair	<input type="checkbox"/>		<input checked="" type="checkbox"/>	
Institutional Official	<input type="checkbox"/>		<input checked="" type="checkbox"/>	