



<b>SOP Title</b>	(IRB) Enhanced Continuing Review				
<b>Date Last Revised</b>	06/07/2017	<b>Date Created</b>	04/26/17	<b>Revision #</b>	1.0
<b>SOP Number</b>	2	<b>Required by:</b>	<input checked="" type="checkbox"/> OHRP	<input type="checkbox"/> Funding Agency	<input type="checkbox"/> OLAW
<b>Applicability</b>	<input type="checkbox"/> RGC Internal	<input type="checkbox"/> Researcher	<input checked="" type="checkbox"/> Institutional		
<b>Subgroup</b>	<input checked="" 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 enhanced continuing review for IRB protocols.

### 2.0 General Information and Scope

As required by Federal Guidelines, the Institutional Review Board (IRB) has established this written policy to educate Principal Investigators of the requirements for a continuing review of an approved IRB more than once a year.

### 3.0 Procedures

Federal guidelines mandate that IRB protocols cannot be approved for more than one year. The IRB may require a protocol to be reviewed more than once a year due to the following criteria:

1. A history of non-compliance by the Principal Investigator (PI) or other researchers associated with the study.
2. If the IRB deems the risk/benefit ratio to be questionable.
3. A potential conflict of interest.
4. Other issues as decided by the IRB.

If an IRB receives approval with the requirement of enhanced continuing review, the PI will be notified via Mentor IRB in the approval notice. The PI will receive an email reminder approximately 60 days in advance of the review due date.

It is the PI's responsibility to submit a continuing review according to the IRB procedures described in SOP #14 (IRB) PI – Submitting Continuing Review found on the NKU IRB website.

### 4.0 References

45 CFR 46.103(5), 45 CFR 46.103

#### Approvals

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