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

SOP Title	(IRB) PI – Submitting Continuing Review				
Date Last Revised	12/06/2018	Date Created	06/07/2017	Revision #	2.0
SOP Number	14	Required by:	☒OHRP ☐Funding Agency ☐OLAW		
Applicability	☐ RGC Internal	☒Researcher	☐Institutional		
Subgroup	☐ NKU Compliance	☒IRB	☐IACUC	☐IBC	

1.0 PURPOSE

The purpose of this SOP is to describe the process for PI's submitting continuing review of active IRB research project approved as Full Board/Convened Board and projects approved as expedited for which the IRB has required a continuing review.

2.0 GENERAL INFORMATION AND SCOPE

1. As required by federal guidelines, the NKU IRB has written these procedures to guide Principal Investigators through the process of requesting a yearly continuation for a full board protocol and for expedited projects for which the IRB has required continuing review of ongoing and previously approved protocols.

2. Research approved under an expedited category after January 20, 2019 does not require continuing review unless the IRB deems necessary (45 CFR 46.109(f)(1)). If the IRB requires continuing review of an expedited project the rational for doing so must be documented. Reasons for requests of continuing review include but are not limited to the following:

- Subparts/vulnerable populations;
- Criminal behavior;
- Substance use/mental health data;
- External sites;
- Complex research procedures;
- Use of devices;
- Serious or continuing noncompliance by the PI in the past two years
- Projects involving Native Americans
- or other issues, which must be detailed in the justification by the reviewer/IRB Chair.

3. Research approved under an expedited category before January 21, 2019 will require annual continuing review.

3. All projects reviewed and approved by a convened IRB require continuing review.

4. If a study is reviewed by a full/convened board or approved as expedited but requires continuing review, the approval to conduct the 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 approximately 30 days before the continuing review due date and reminders weekly thereafter. If the continuing review is not completed by the study expiration date, all study-related activities must stop.

3.0 PROCEDURES

3.1 ACCESSING MENTOR IRB

1. Go to the Mentor website
2. 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"
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 on the little red page icon (i.e. context menu) next to the latest year and select "Complete and Submit"
6. Answer all questions on the "Continuing Review" page
7. Add additional comments if needed
8. Upload a new copy of the informed consent document.
9. Click "Submit Report"

3.3 CONTINUING REVIEW NOT SUBMITTED PRIOR TO EXPIRATION DATE

1. 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.
The adverse event must be submitted in Mentor IRB using the NKU IRB "Note to File – Unanticipated Problem or Adverse Event Memo.

2. 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 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	☒	11/15/2018	☐
IRB Chair	☒	11/15/2018	☐
Institutional Official	☒	11/15/2018	☐

Revisions

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	☒	12/06/2018	☐	Revision to remove CR for expedited studies per the revised common rule
IRB Chair	☒	12/06/2018	☐	
Institutional Official	☐		☐	