



<b>IRB Standard Operating Procedures</b>		
<b>SOP#: 001</b> <b>Revision#: 2</b> Revised Common Rule provisions added on February 12, 2019	<b>Title: Continuing Review</b>	<b>Effective Date:</b> <b>January 13, 2017</b>
<b>Approved By:</b>	<b>Institutional Review Board</b>	<b>Approval Date:</b> <b>January 13, 2017</b>

## **PURPOSE**

This document describes the policies and procedures for continuing review of on-going research.

## **DEFINITIONS**

**Common Rule** - also known as the Federal Policy for the Protection of Human Subjects - subpart A of the HHS Code of Federal Regulations [CFR] 45 Part 46. The Common Rule was updated on January 18, 2017 and went into effect on January 21, 2019.

**Continuing Review** - annual review of a study for renewal of IRB approval.

**Continuing Review Application** - the form that investigators complete and submit to the IRB to initiate the continuing review process.

**Expiration Date** - the last day of the IRB approval period.

**IRB** - an institutional review board established in accord with and for the purposes expressed in the federal regulations for the protection of human research subjects.

**Lapsed Approval** - the status of a study for which the IRB approval has expired.

## **POLICY**

The IRB shall conduct continuing review of research at intervals appropriate to the degree of risk, not less than once per year.

Continuing review must occur within one year of the last approval date, unless the IRB determines that review should occur more frequently. There is no regulatory basis for a “grace period” extending research activities beyond the expiration of IRB approval. The IRB emails two courtesy reminders to investigators about providing materials for continuing review. However, it is ultimately the investigator’s responsibility to track the approval periods and

ensure that IRB approval does not lapse. Failure to receive or notice IRB reminders does not absolve investigators of this responsibility, nor does it change the consequences of a lapsed approval.

If the approval has lapsed before continuing review approval has been issued by the IRB, all research must stop. No human subject activity may take place on or after the research expiration date unless the IRB finds it is in the best interest of individual subjects to continue participation in research interventions or interactions.

Continuing review must occur at a convened meeting of the full IRB.

IRB review of a proposed modification is not considered to be continuing review.

Continuing review must be substantive and meaningful, and focusing on the following:

- Whether the risk/benefit ratio for the study had changed
- Whether there are unanticipated findings involving risks to participants and/or others
- Whether any new information regarding risks and benefits should be provided to participants.

Per the revised [Common Rule](#), unless the IRB determines otherwise, continuing review of research is not required in the following circumstances:

- Research eligible for expedited review in accordance with §46.110;
- Research reviewed by the IRB in accordance with the limited IRB review described in §46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8);
- Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
  - a) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
  - b) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

The IRB has the authority to decide which expedited studies will require continuing review. Expedited studies not subject to continuing review will receive an annual survey reminder of researcher responsibilities and study termination. Failure to respond to the survey will result in a hold on the PI's future submissions to the IRB.

## **RESPONSIBILITIES**

The IRB conducts the continuing review, as described below. The IRB staff sends continuing review reminders to investigators, follows standard procedures for pre-review and all staff-performed procedures that support the review process. Investigators track the expiration date and provide materials for IRB review with sufficient time so that IRB approval does not lapse.

## **PROCEDURES**

### **Courtesy Reminders**

The IRB sends two reminders to investigators about providing the materials for continuing review. The reminders are generally sent 60 and 30 days before study expiration. They are sent via email to the NEIU email account of the investigator.

## Pre-review Procedures

- The principal investigator (PI) will complete the most current application and forms available on the IRB website and submit a complete packet, including all supporting documentation electronically.
- The investigators are required to submit the following documents:
  - Continuing Review application
  - A copy of the current approved stamped recruitment and consent documents
  - A copy of the clean recruitment and consent documents, if enrollment is on-going
  - A copy of IRB approvals from partner sites, e.g., Chicago Public Schools
  - Any new amendments
  - Any adverse event reports
  - Any reports to the sponsors
- Incomplete applications will not be reviewed. Missing items will be identified and requested during the administrative pre-review. If the items are not submitted within 1 week following the IRB request, the entire application packet will be sent back to the PI without review.
- Once completed application materials have been submitted, IRB staff will conduct an "Administrative Pre-review" and make note of possible issues on a pre-review document.
- All application material and pre-review notes from the administrative pre-reviewer will be shared with the IRB chair.
- The IRB chair will review the submitted material. The IRB chair will either conduct the review, or in consultation with IRB staff, assign an IRB member for formal review of the submission.

## Review Process

The IRB conducts the continuing review in the same way as the initial review and using the same criteria for approval and with the same possible actions. In case any conditions need to be met before the study can be re-approved for continuation, the IRB may issue a request for modification.

The IRB re-approves the study without any conditions or changes if the reviewer finds that:

- No issues of concern have arisen since the prior IRB review
- No changes are being proposed by the investigator
- Adverse events have been of the type and frequency expected
- The research appears to still satisfy all criteria required for IRB approval.

## Approval Expiration Date

There are logistical advantages to keeping the approval expiration date constant from year to year. Federal guidance states that the IRB may retain the anniversary of the expiration date of the initial IRB approval as the expiration date of each subsequent one-year approval period if the IRB re-approves the research within 30 days before the IRB approval period expires. Whenever possible, the IRB maintains a fixed anniversary date for the expiration of IRB approvals of a study.

## Documentation of Approval

The IRB approval memo documents that all of the applicable criteria for IRB approval continue to be met and the study may continue. The memo also documents:

- Approval Period
- Performance Site(s)
- Subject Enrollment

- Funding
- Risk Level
- Vulnerable Population(s)
- Consent/Waiver(s) if applicable

### **Submission Timeline**

The continuing review materials should be provided far enough in advance to allow for IRB review so that there will be no lapse in the study approval. The IRB must receive the materials at least 30 days prior to the expiration date in order to ensure timely review. The date by which the materials must be submitted is noted on the approval memo for the most recent review (i.e. initial review, last continuing review).

### **Review of Early Submissions**

If the materials are submitted and reviewed before the 30-day period preceding the study expiration date, they will be held by the IRB staff and reviewed within the 30-day period preceding the study expiration date to maintain the date for the expiration of IRB approval constant.

### **Review of Late Submissions**

If an application for continuing review is not submitted by the expiration date, the IRB will issue a suspension notice to the investigator. The investigator must suspend all research activities including, but not limited to subject contact, data collection, and data analysis until IRB approval is granted again for the study. The responsible IRB staff will follow up with the investigator to ensure that the application for continuing review is submitted as quickly as possible. Along with the materials required for continuing review, the investigator must also submit a memo documenting the reason for the lapse and identify steps that will be taken to prevent future lapses.

The IRB will complete the review of a late continuing review submission as soon as possible and the investigator may resume the suspended activities once approval of the research has been issued. The date that final approval extended by the IRB Chair or his/her designee will become the new "Date of IRB Approval." The date of expiration is calculated 365 days from the date of approval minus one day for a 12 month review interval.

The lapse in approval will be documented via a textbox on the approval memo. Research will be administratively closed 60 days after the expiration of IRB approval, if the materials for continuing review have not been submitted to the IRB.

### **Regulations**

[45 CFR 46.108](#)

[45 CFR 46.109\(e\)](#)

[45 CFR 46.110](#)

[21 CFR 56.109\(f\);](#)

[21 CFR 56.108\(a\)](#)

OHRP, "[Guidance on IRB Continuing Review of Research.](#)" November 10, 2010

### **Author Reference**

NEIU IRB

[University of Louisville IRB SOP "Continuation Review and Lapse in Approval"](#)

## Contact Information

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