

Continuing Review (HRPP 2.7)

Description:

This policy describes UNMC's requirements for continuing review of approval research.

Definitions:

Continuing Review of Research: the process by which the IRB re-evaluates whether a protocol continues to satisfy the regulatory and ethical criteria for approval.

Continuing Review **REQUIRED for:**

- Research which was reviewed by the convened IRB (has "FB" suffix for the IRB number).
- Research that is regulated by the FDA.
- Research that underwent expedited review (has "EP" suffix for the IRB number) that was approved prior to January 20, 2019.

Continuing Review **NOT REQUIRED for:**

- Research that underwent expedited review on or after January 20, 2019 that is not subject to FDA regulations, unless the IRB determines otherwise.
- Exempt research (has "EX" suffix for the IRB number) unless the ORA determines otherwise.

There are exceptions to our policy. You will be notified by the IRB/ORA prior to the deadline for continuing review if your research needs it.

Frequency:

Non-exempt research subject to the Common Rule or FDA Regulations:

- Once a year (unless the IRB determines it's needed more often).

Non-exempt research NOT subject to the Common Rule or FDA Regulations:

- Intervals are selected based on the degree of risk, but typically once a year.

Review Criteria:

- All criteria for IRB approval (HRPP Policy 2.5).
- In addition, the IRB (full IRB or expedited reviewer) must also determine:
 - Whether continuing review should occur more often than annually.
 - Whether the research needs verification from sources other than the PI that no material changes occurred.
 - Whether the current consent form is still accurate and complete.
 - Whether the research requires an audit of the research records.
 - Whether any new findings arise that might relate to a subject's willingness to continue participating.
 - Whether subject accrual is adequate to achieve the scientific goals.
- During continued review by an expedited reviewer, if the reviewer believes any of the above situations apply, the protocol will be referred to the full IRB.

Investigator Responsibilities:

- Submit a continuing review form in RSS prior to the expiration date of the approved protocol.
 - For most full board (FB) studies, HUD studies, or SROC studies, you must submit enough in advance that the continuing review can be reviewed at a convened IRB meeting before the expiration date (see <https://www.unmc.edu/irb/procedures/deadlines.htm> for deadlines).
- If the research is completed, complete the closure of on-going research process prior to the approval expiration date. (HRPP Policy 2.9).

General Considerations:

- The ORA sends emails to the PI and lead coordinator and/or regulatory contact approximately 60 days and 45 days prior to expiration.
- If continuing review is not approved by the expiration date, the study will be expire and all research activities, including data analysis, must cease.
- Studies that continue in “approval expired” status for 30 days may be administratively closed by the IRB/ORAs.
- The expiration date for the next continuing review is based on the date that the IRB reviewed the continuing review and either approved or conditionally approved the continuing review.