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 (CR) 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 (CR) 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 must also determine:
    - Whether research requires more frequent review than annually
    - Whether independent verification (not just from the PI) is needed to confirm no material changes have occurred
    - Whether the current consent form is still accurate and complete
    - Whether a third party should observe the consent process
    - Whether the study requires an audit of research records
    - Whether any significant new findings have emerged that may affect subjects' willingness to continue
    - Whether enrollment is sufficient to meet the scientific aims of the study
    - If PI is leading a multi-site trial, whether information management processes are adequate
- **NOTE**: if an expedited review identifies issues listed above, the protocol must be referred to the full IRB

Investigator Responsibilities:

- **Timely Submission:**
    - If CR is required, the PI must:
        - Submit a continuing review application via RSS before the protocol's expiration
        - **NOTE**: 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).

- **ClinicalTrials.gov Updates**
    - The PI must update ClinicalTrials.gov records, when applicable, following HRPP Policy 1.29
- **Study Closure (*When Research is Completed*)**
    - The PI must follow procedures in HRPP Policy 2.9 for properly closing out completed research
- **Study Closure (*Due to Non-Submission*)**
    - If the study is closed due to failure to submit a continuing review or a demographics reporting form, then the PI must still complete study closure per HRPP Policy 2.9

General Considerations:

- The ORA sends emails to the PI and lead coordinator/point of contact 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 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/ORA
- 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