Increased Monitoring, Interim Continuing Review, and Verification from Sources Other than the PI (HRPP 3.1)

Description:

This policy describes UNMC's requirements for determining the need for: (1) IRB review more often than annually, (2) increased monitoring, and (3) verification from sources other than the PI that no material changes have occurred since previous IRB review.

General Considerations:

The IRB may decide a research protocol requires increased monitoring and/or interim continuing review at the time of initial review, continuing review, or any other event.

If the IRB determines the need for more frequent continuing review, the PI will be notified in writing.

When the IRB determines the need for increased monitoring, this may be accomplished by either:

1) Submission of interim reports by the PI, or
2) Auditing of PI records by the IRB administrator and/or IRB member(s)

Types of Research This Might Include:

- Studies that utilize drugs or treatments associated with higher than typical risk of toxicity.
- Studies where there is an expectation of high morbidity and mortality due to underlying medical conditions of subjects.
- Studies whose design includes 1 or more groups of subjects who will receive less than standard of care, or where there is a significant risk intervention that is performed solely for research purposes.
- Studies where the FPBCC Scientific Review Committee (SRC), or other equivalent scientific review body, indicates the need.
- Any other situation where the IRB believes it will meaningfully protect the rights and welfare of human subjects.

Verification From Sources Other Than the Investigator:

The IRB may decide at the time of initial review, continuing review, or any other event that a research protocol requires verification from other sources that no material changes have occurred since previous IRB review.

Instances may include:

- Research performed by investigators with a history of:
    - Significant noncompliance
    - Recurrent delays in submitting amendments
    - High number of IRB approval expirations
    - Failure to respond to IRB review letters or correspondence in a timely manner
- Research conducted at external sites where the UNMC IRB is the IRB of record.