

3.1 Assessing the Need for Increased Monitoring, Interim Continuing Review, and Verification from Sources Other than the PI

1.0 Purpose

The purpose of this policy and procedure is to describe the Organization'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.

2.0 Policy

It is the policy of the Organization that that all non-exempt research will be assessed at both initial and continuing review in accordance with the requirements set forth by HHS regulations at 45 CFR 46.103(b)(4), FDA regulations at 21 CFR 56.108(a)(2), and all applicable state and local laws.

3.0 Increased Monitoring and/or Interim Continuing Review

- **3.1.** At the time of initial review, continuing review, or any other event, the IRB may decide that a research protocol requires increased monitoring and/or interim continuing review. Types of research which might require such actions include, but are not limited to:
 - **3.1.1.** Studies that utilize drugs or treatments associated with a higher than typical risk of toxicity.
 - **3.1.2.** Studies where there is an expectation of high morbidity and mortality due to the underlying medical condition of the subjects.
 - **3.1.3.** Studies whose design includes one or more group of subjects who will receive less than standard care (for example, use of placebo where there is an active alternative treatment, or withholding standard treatments during some point in the study), or where there is a significant risk intervention that is performed solely for research purposes.
 - **3.1.4.** Studies where the FPBCC Scientific Review Committee (SRC), or other equivalent scientific review body, has indicated the need for interim review or

additional monitoring.

- **3.1.5.** Any other situation where the IRB believes that increased monitoring or interim continuing review will meaningfully protect the rights and welfare of human subjects of the research.
 - **3.2.** 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 an IRB member(s). The PI will be notified of these requirements in writing.
 - **3.3.** If the IRB determines the need for more frequent continuing review the PI will be notified in writing and the IRB approval period will be set accordingly.
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4.0 Verification from Sources Other than the Investigator

- **4.1.** At the time of initial review, continuing review, or any other event, the IRB may decide that a research protocol requires verification from sources other than the PI that no material changes have occurred since the previous IRB review. Research that falls in any of the following categories may warrant consideration of verification from sources other than the PI:
 - **4.1.1.** Research performed by investigators with a history of significant noncompliance, recurrent delays in submitting amendments, high number of IRB approval expirations, or failure to respond to IRB review letters or other correspondence in a timely manner.
 - **4.1.2.** Research conducted at external sites where the UNMC IRB is the IRB of record.
 - **4.2.** When the IRB determines that verification from sources other than the PI is necessary the designated IRB Administrator and/or IRB member(s) will perform the necessary verification by conducting an audit.
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