Determination of Post-Approval Review Interval

Summary/Purpose: This policy specifies conditions and procedures for determining post-approval review intervals.

Most UM human subjects studies pose minimal risks to subjects. Therefore, the post-approval time interval for IRB progress reports is commonly one year, the maximum interval allowed by the regulations at 45 CFR 46.109(e), and a standard reporting form is used. However, additional reporting may be necessary:

1. The IRB requires more frequent progress reports, including observations by the IRB or a third party of the consent process and the research, when deemed necessary to monitor or further assess risk following protocol approval.
2. The IRB may require more frequent reports either at regular intervals or after small subsets of subjects are exposed to study procedures.
3. Reporting requirements may be altered during the course of a study based on new information.
4. Reports will be tailored to studies.

Circumstances that may require more frequent progress reports include, but are not limited to, the following:

- a researcher’s history of noncompliance with federal regulations or IRB requests
- research procedures with high or unknown risks, particularly with vulnerable subjects
- complaints from subjects or others
- unexpected adverse events occurring during the course of the study

Investigators will be informed of reporting requirements in the approval letter.

Adjustments to initial reporting requirements will be determined by the IRB Executive Committee (IRB Chair, IRB Research Compliance Specialist, and Director of Research Integrity and Compliance) in consultation with the full IRB if deemed advisable.

Approved by IRB December 6, 2006