Determination of Post-Approval Review Interval

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

A. Standard continuing review time interval for progress reports
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 45CFR46.109(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. Progress report content may be tailored to studies.

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

- An investigator’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 or previous studies
- The research project involves novel interventions
- Investigators’ limited experience could affect risk

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.

C. Circumstances that may permit less frequent progress reports

Background and rationale for an extended continuing review time interval. As allowed by federal policy, UM limits the contractual applicability of its Federalwide Assurance (FWA) to federally funded human subjects research. Although the IRB has always applied all federal regulations to all human subjects research regardless of funding, this allows the IRB to adjust application of the regulations for those human subjects studies that are not funded by federal agencies and departments.

The maximum post-approval time interval for IRB continuing review allowed by the federal regulations is one year. In order to focus human subject protection resources on studies that pose risks for human subjects, the IRB extends continuing review up to 3 years for expedited review (i.e., certain “minimal risk”) studies that are not funded by a federal agency or department. This
also serves to reduce administrative burden for investigators, which will foster investigator compliance with federal regulations and will promote human subject research at UM.

- When any question of applicability arises, studies will be reviewed on a case by case basis. Inclusion/exclusion of any expedited study will be at the discretion of the IRB Executive Committee.
- At the 3-year review date (or earlier), these studies will be reviewed using a process identical to that used for federally funded research in accordance with 45CFR46.109(e) and OHRP’s “Guidance on IRB Continuing Review of Research.”
- Investigators are responsible for reporting changes in funding or sponsor status that involves federal agencies to the IRB.

1. Exclusions

- Research reviewed by convened meeting of the IRB
- Research funded by a federal agency or federal department
- No cost extensions for research funded by a federal agency or federal department
- Student projects with faculty sponsor-received federal funding
- Federal sponsorship, including federal training grants
- Studies conducted in a laboratory entirely federally funded and/or part of a federally funded program project grant
- Studies with FDA regulated components
- Studies with contractual obligations or restrictions precluding this amendment
- Studies using prisoners as subjects
- Studies seeking or obtaining Certificates of Confidentiality

2. Monitoring

Investigators will be queried annually on:

a. Any changes in funding
b. Whether the study is completed (if so, investigators will submit a progress report for review, and the file will be closed)