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Subject: Post-IRB Approval Reviews
Division: IRB
Date: March 1, 2012

IRB Policy 111.3: SIGNIFICANT NEW FINDINGS

Policy

During the course of a study, the IRB may review reports generated from a Data and Safety Monitoring Board (DSMB), adverse event reports, current literature, and other sources to ascertain the status of the study and assess whether or not the risk/benefit balance is still acceptable. The IRB will review the information to determine whether or not new information needs to be conveyed to subjects, or if a segment of the population may be bearing an undue burden of research risk or being denied access to promising therapy.

Consent Form

When appropriate, the consent form must include a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject. If significant new findings develop which require a revision to the consent form an amendment request should be submitted to the IRB for review and participants may need to be re-consented.

Responsibility

IRB Administrators and Chairperson (or designee) are responsible for preliminary assessments of significant new findings. IRB Members are responsible for reviewing these reports, and determining their affect on human subjects and whether study or consent procedures should be revised accordingly.

Applicable Regulations and Guidelines

45 CFR 46.116(b)(5)