Review of Amendments

Table of Contents: Review of Amendments

Policy Statement

Federal regulations require that amendments to approved protocols are not initiated without prior IRB review and approval except when necessary to eliminate immediate hazards to subjects (in which case the investigator must promptly report the modification to the IRB).

Description and Procedures

A. Amendment Submission

Changes to an approved study must be submitted online by the principal investigator using the IRB Amendment Request Form. Such changes include but are not limited to: the addition or elimination of an investigator, changes in consent form, supportive materials, flyers, questionnaires, surveys, script for person-to person or telephone interviews, etc. After approval, the principal investigator will receive an amendment approval letter listing the approved changes. The changes cannot be implemented until the approval letter is received.

B. Amendment Review

In general, modifications or addenda that do not result in increased risks to human subjects may be considered minor and be eligible for administrative review. However, the IRB Chair may determine that the proposed change is more than minor and requires full Board review. Each request will be judged on a case-by-case basis by the IRB chair who may decide that more than minor changes were made and additional review is required.

Effective Date

August 24, 2020

Revision History