

Approved by IRB Executive Committee: March 11, 2009
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AAHRPP Element II.2.E.

POLICY

During the period for which approval has already been given, changes in approved research may not be initiated without prior IRB review (full or expedited review, as appropriate) and approval, except where necessary to eliminate apparent immediate hazards to human subjects.

Investigators must submit requests for proposed changes to the IRB using an amendment application in the ERICA system. Amendment applications should be submitted no later than 30 days upon receipt of changes from sponsors, collaborators, etc.

During amendment review, the IRB determines whether the research with the proposed changes continues to meet the regulatory criteria for approval and any other applicable requirements are met. Determinations are made using the board member checklist.

If an investigator makes changes that are necessary to eliminate apparent immediate hazards, a protocol deviation outlining the circumstances and any documents used must be submitted to the IRB (please see SOP 902: Protocol Deviations).