

Department: UAMS Institutional Review Board
Policy Number: 8.1
Section: Change in Protocol
Effective Date: July 31, 2002
Revision Date: February 1, 2005; June 1, 2005; March 5, 2008; January 24, 2011;
August 17, 2015; February 15, 2016; May 14, 2020

SUBJECT: Modifications to previously approved Research

I. POLICY

The UAMS IRB shall review and approve all proposed modifications to approved research prior to implementation, unless a modification must be implemented immediately to eliminate an apparent immediate hazard to subjects. The term “approved research” encompasses all approved study documents, processes and procedures.

All modifications will be reviewed to determine the research satisfies all of the regulatory approval criteria outlined in IRB Policy 7.1. Modifications affecting one or more of the approval criteria, also called Major Modifications, must be reviewed by the convened IRB. Minor Modifications may be reviewed by the expedited review process.

II. PROCEDURE

A. Investigator Procedure:

1. All modifications must be submitted through the IRB e-system.
2. The IRB must be notified within 30 days of a change in the Principal Investigator (PI). When changing principal investigators, the study team shall submit the following:
 - a. Modification form revised throughout as necessary; revised protocol, consent forms, HIPAA authorizations and/or advertisements, and any other relevant material as applicable, through the IRB e-system. The new PI’s profile in the IRB e-system must contain his/her CV.
 - b. The new PI will sign off on the modification.
 - c. If the modification also changes other study personnel, information must be provided to show who specifically is being added to the study and their role and qualifications. If the personnel change or addition impacts the information in any other documents, those documents should also be submitted with tracked and clean copies.
3. All modifications will include:
 - a. A summary describing the changes; the reason for the change; Investigator’s opinion as to impact of change on study and on subjects; and whether changes are needed to the consent form.
 - b. If the modification constitutes a change that might affect a subject's willingness to continue in the study, the Investigator must submit a plan for informing all currently enrolled subjects. The plan should address timing (e.g. immediately, next visit) and method (e.g. mailed notification, re-consent) and should be tailored to the nature of the research and the new information.
 - c. Investigator may submit a PI letter to the IRB to supplement the brief overview requested at the beginning of the Modification Form.
 - d. Revisions to the appropriate sections of the submission form.
 - e. All modified documents, including but not limited to consent forms, protocols, recruitment materials. If a sponsor or a granting agency has requested the modification, a copy of the communication from the sponsor should be submitted.
 - f. All revised documents must be submitted with the proposed modifications tracked. Either separate clean and tracked-changes copies can be submitted, or, if a feature such as Word’s track-changes is used, a single copy from which the IRB can see both the clean and tracked copies will meet this requirement. The IRB may defer review if no highlighted or tracked-changes documents are submitted. If a document is received from a sponsor where tracking changes is not possible, a revision summary may be substituted.
 - g. Revised documents must be stacked correctly in the IRB e-system. The IRB may return the submission with a request for correcting the document uploading before review.

4. No changes may be implemented until IRB, and as applicable Sponsor, approval is received. The only exception is a change necessary to eliminate apparent immediate hazards to the research participants. In such cases, the Investigator will promptly inform the IRB, and as applicable the Sponsor, of the implemented change.

B. IRB Procedure:

1. Experienced IRB Office staff will determine whether the proposed change is a major or minor modification.
2. Major modifications will be reviewed by the convened IRB in accordance with IRB Policy 7.4.
3. Minor modifications will be reviewed using an expedited procedure in accordance with IRB Policy 7.5.

III. REFERENCES

45 CFR 46.108(a)(3)(iii)

21 CFR 56.108(a)(4)

AAHRPP Elements II.2.E.3; II.2.F.3; III.2.C

AAHRPP Tip Sheets 16 and 17