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; August 15, 2022; September 15, 2023; October 15, 2024

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. Investigators shall ensure modification submissions address the following points:
   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. Investigators should use the responses to the "Please describe the requested change" and "Notes for the IRB reviewer(s)" queries to fully describe the change and related elements.
   d. The appropriate sections of the rest of the form are revised as indicated by the change.
   e. All modified documents, including but not limited to consent forms, protocols, recruitment materials are included. 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. 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.
5. Document versions superseded prior to IRB submission and without implementation will generally not be reviewed by the IRB. In such cases, only the most current document version will be reviewed. Document versions superseded without implementation may be acknowledged by the IRB but not reviewed. The Investigator must ensure the modification fully explains any omitted versions or inclusion of superseded versions within the modification and must clearly indicate within the modification whether IRB acknowledgement of superseded versions is requested. The modification form's "Note to IRB Reviewers" section must list the items that are to be acknowledged such that the IRB review can copy and paste this list into the approval letter. All documents should be stacked as usual into a single stack, with the most recent version needing approval on top.
6. Modifications changing study staff that do not change the PI shall be submitted on a separate "staff-only modification" form unless the staff change also affects previous approved study documents. The IRB no longer reviews staff only modification forms. However, study staff listings in the IRB e-system must remain current.
   a. No revised documents shall be submitted with a staff-only modification form.
   b. If the staff change affects study documents, the revised documents must be submitted on a regular modification form. The staffing change can also be made on this same modification form, if the study team prefers.

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