

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

SUBJECT: Modifications to previously approved research

I. POLICY

The UAMS IRB must review and approve all proposed modifications to approved research prior to implementation. The term “approved research” encompasses all study documents, processes and procedures.

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

II. PROCESS

A. Investigator Process:

1. Modifications must be submitted through the ARIA Modification Form. Each modification 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.

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.

Investigator may submit a PI letter to the IRB to supplement the brief overview requested at the beginning of the Modification Form.

b. Revisions to the appropriate sections of the submission form.

c. All modified documents, including but not limited to consent forms, protocols, recruitment materials, and Form 1572s. If a sponsor or a granting agency has requested the modification, a copy of the communication from the sponsor should be submitted.

NOTE: All documents to be modified must be submitted with the proposed modifications tracked. The IRB reserves the right to defer review if the changes are not highlighted or tracked on the document to be revised. If a document is received from a sponsor where tracking changes is not possible, then an outline of the protocol changes may be substituted.

If the change affects the consent form, both a tracked version and a clean version must be submitted.

d. If the modification is to change study personnel, information must be provided to show who specifically is being added to the study and their role and qualifications. In order to add an individual as study personnel, that person must have an ARIA account and current CITI training. If the personnel change or addition impacts the information in the consent form, tracked and clean versions of the consent form should also be submitted.

2. 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 Process:

1. Major Modifications – Will be reviewed by the convened IRB in accordance with IRB Policy 7.4.

2. Minor Modifications – Will be reviewed by an Experienced Reviewer in accordance with IRB Policy 7.5.