

**Department:** UAMS Institutional Review Board  
**Policy Number:** 7.6  
**Section:** Procedures for Study Review  
**Effective Date:** July 31, 2002  
**Revision Date:** February 5, 2005; June 1, 2005; March 8, 2008; July 28, 2008; January 24, 2011; March 11, 2011

**SUBJECT: Continuing Review**

**I. Background**

Periodic review of all human research activities is necessary to determine (1) whether the risk/benefit ratio has changed, (2) whether there are unanticipated problems involving risks to subjects, and (3) whether any new information regarding the risks and benefits should be provided to subjects.

**II. Policy**

The IRB must conduct substantive and meaningful continuing review of research at intervals appropriate to the degree of risk. The IRB must decide the frequency of continuing review for each study protocol necessary to ensure the continued protection of the rights and welfare of research subjects. The IRB must review each study at least once per year and can require more frequent reviews. All non-exempt research protocols must be periodically reviewed, not less than one time per year, in accordance with this policy.

Studies deemed as Exempt must complete an Annual Update form. See Policy 7.3.

**III. Information for Investigators and Continuing Review Submission Process**

**A. Reminders:** As a service, ARIA automatically emails the Principal Investigator and Primary Contact listed in ARIA continuing review expiration notices at approximately 8 and 12 weeks prior to the project's continuing review expiration date with a suggested return deadline. However, Investigators should not rely solely on the ARIA emails. Investigators retain responsibility for submitting and receiving continuing review approval on time. Sufficient time should be allowed for processing the report and IRB approval prior to the project's expiration.

**B. Expiration Date and Calculation.** The expiration date is the last date on which study activities may occur. The expiration date may change from year to year. Each time the convened IRB conducts continuing review, the study calendar is reset to the date of that meeting.

Several scenarios for determining the date of continuing review apply for protocols reviewed by the convened IRB. To determine the date by which continuing review must occur, focus on the date of the convened meeting at which IRB approval occurs. (These examples presume the IRB has determined that it will conduct continuing review no sooner than within 1 year).

Scenario 1: The IRB reviews and approves a protocol without any conditions at a convened meeting on October 1, 2010. Continuing review must occur within 1 year of the date of the meeting, so the expiration date is September 30, 2011.

Scenario 2: The IRB reviews a protocol at a convened meeting on October 1, 2010, and approves the protocol contingent on specific minor conditions the IRB chair or his/her designee can verify. On October 31, 2010, the IRB chair or designee confirms that the required minor changes were made. Continuing review must occur within 1 year of the date of the convened IRB meeting at which the IRB reviewed and approved the protocol. Since changes did not require review by the convened IRB, the expiration date is September 30, 2011.

Scenario 3: The IRB reviews a study at a convened meeting on October 1, 2010, which requires major revisions or is tabled. The study is reviewed at subsequent convened meetings on October 15 and October 29, 2010. At the October 29, 2010 meeting, the IRB completes its review and approves the study. Continuing review must occur within 1 year of the date of the last convened meeting at which the IRB reviewed and approved the protocol, so the expiration date is October 28, 2011.

**C. Consequences of Study Expirations:** Failure to submit a timely continuing review will result in expiration of the protocol. If the IRB has not reviewed and approved a research study by the continuing review expiration date, all research activities must stop. No new subjects may be recruited or enrolled.

Interventions and interactions with current subjects must stop. If the Investigator believes there are current subjects whose safety might be at risk by stopping all procedures, the Investigator must contact the IRB immediately upon expiration notice. Interventions and interactions with current subjects may only then occur if the IRB finds an over-riding safety concern or ethical issue involved that makes it in the best interests of individual subjects to continue participating in the research interventions or interactions. Only an IRB Chair may authorize this continued interaction. Investigators may not make this decision. No other research activities may be authorized by the IRB Chair.

If continuing review expires on a drug/device study, the involved Pharmacy contact will be notified.

Generally, study expirations do not need to be reported to regulatory agencies. However, a pattern of study expirations may indicate non-compliance and will be reviewed and classified as per IRB Policies 12.5 and 12.6.

**D. Submission Requirements for Continuing Review Form:** For all studies undergoing review by the convened IRB or expedited review process, the Investigator must provide the following:

1. A completed Continuing Review Form in ARIA. This form requires the number of subjects accrued, withdrawn and reasons for withdrawal. See IRB Policy 14.5 for accrual and enrollment definitions. The form also requires a summary of activity since the last IRB review. Activities to be summarized include:
  - a. Adverse events and adverse outcomes experienced by subjects;
  - b. Unanticipated problems involving risks to participants/others;
  - c. Complaints about the research and resolution thereof
  - d. Relevant recent literature
  - e. Interim findings
  - f. Relevant multi-center trial reports
  - g. Current risk-benefit assessment based on study results to date
2. Informed Consent Document Verification – ARIA automatically loads the currently approved consent document, if applicable, into the CR form. The Investigator **MUST** verify that the document listed as the current approved form is correct.

#### **IV. IRB Review Process**

**A. Convened IRB.** For all studies requiring review by the convened IRB, the processes outlined in IRB Policy 7.4 will be followed.

**B. Expedited Review.** Studies which qualify for expedited continuing review will be handled according to IRB Policy 7.5.