Department: UAMS Human Research Advisory Committee
Policy Number: 7.7
Section: Procedures for Study Review
Effective Date: July 31, 2002
Revision Date:

SUBJECT: Progress and Final Reports

Progress Reports: Continuing review requires HRAC review of a written progress report from the principle investigator. Generally the Continuing Review Report Form (CRRF) may be used. For a significant risk device, the principle investigator must also submit the progress report to FDA. The principle investigator must notify FDA and all reviewing HRAC's of any request that an investigator return, repair, or dispose of any unit of an investigational device. The notice must be made within 30 working days after the request is made and must state why the request was made.

If the HRAC has not reviewed and approved a research study by the study's current expiration date, i.e., HRAC approval has expired, the principal investigator will be notified in writing that approval of the study has expired and research activities must stop. No new subjects may be enrolled in the study (see HRAC policy 7.6).

The HRAC will mail out the CRRF approximately eight weeks prior to expiration of the continuing review approval period. The CRRF submitted by the investigator to the HRAC office MUST be generated by the HRAC office. Investigators who do not receive a CRRF from the HRAC office within six weeks prior to expiration of continuing review approval should contact the HRAC office to obtain the form.

Final Report: A final "progress report" is required by the HRAC within 6 months after completion or termination. If a significant risk device was used in the study, the principle investigator must also submit a final report to FDA and all reviewing HRACs and participating investigators within 6 months after the completion or termination of the investigation.