

**Department:** UAMS Institutional Review Board Policy  
**Number:** 8.4  
**Section:** Change in Protocol  
**Effective Date:** February 8, 2005  
**Revision Dates:** August 17, 2015; February 15, 2016; August 15, 2022; June 24, 2025

**SUBJECT:** Study Closure

## **POLICY**

Once all study activities are complete and there is no longer a need to access identifiable participant information, Investigators should close the study out with the IRB within 30 days of decision to close study. Investigators may request closure of a study by submitting a study closure form through the IRB e-system.

## **PROCEDURE**

### **I. Investigator Procedure**

- A. The investigator shall assess whether the study is closing for a reason normally reported on a Reportable New Information form. These reasons can include, but are not limited to, restriction, suspension, or termination by the study sponsor; premature completion of the study; or a loss of study funding or other support. The study team shall submit a Reportable New Information form to the IRB for review before submitting a closure form in these instances.
- B. Once the study team determines a closure form is appropriate, the study team shall complete and submit a study closure form in the IRB e-system, ensuring the form is complete and correct.

### **II. IRB Office Procedure**

- A. The study closure will be assigned to an experienced IRB office staffer.
- B. The IRB office staff will review the form to ensure it is complete and that study closure is appropriate.
- C. This review may entail comparing the closure form information with previously reported study information and/or sending back contingencies as necessary.
- D. Once any outstanding issues are handled, the IRB office staff will send a study closure letter via the IRB e-system.

## **REFERENCES**

UAMS IRB Policy 10.2, *Information that must be reported to the Institutional Review Board and Institutional Review Board Actions*