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

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 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.