

Department: UAMS Institutional Review Board
Policy Number: 9.2
Section: IRB Decisions
Effective Date: July 31, 2002
Revision Dates: August 26, 2004; February 8, 2005; August 17, 2015; February 15, 2016;
August 25, 2020

SUBJECT: IRB Notification of Decisions

POLICY

IRB decisions for any type of submission (new submission, modification, continuing review, etc.) shall be reported to the study team in writing through the IRB e-system. Decisions shall be reported for full board, expedited, exempt status, or any other type of review.

Any exceptions to this policy (e.g. using email to report results of an expedited status-type review of a request to use a short form consent process) are addressed in other IRB policies.

PROCEDURE

- A. Upon completion of the review of any submission (new, modified, continuing review, etc.), regardless of exempt, expedited or full classification, a letter noting the outcome of the review will be prepared through the IRB e-system.
- B. This letter shall include:
 1. Outcome of the review by the Chair or IRB and if study is declined, suspended or terminated, the reason for the decision;
 2. Any contingencies that must be addressed before the IRB can approve the submission;
 3. Any notes provided for informational purposes only (i.e. no response is required before approval)
 4. Date the decision was reached; and
 5. Date of next scheduled continuing review, as appropriate.
- C. The letter will be electronically signed by either the chair of the convened committee that made the decision or by the office staffer or expedited reviewer handling the submission.
- D. The Principal Investigator and any other study staff listed as receiving notifications in the IRB e-system will receive a notification that the letter is finalized.

REFERENCES

45 CFR 46.108(a)(3)(i)
21 CFR 56.108(a)(1)
AAHRPP Element II.5.B