

Department: UAMS Institutional Review Board
Policy Number: 9.1
Section: IRB Decisions
Effective Date: July 31, 2002
Revision Date: August 26, 2004; June 1, 2005; April 5, 2007; March 5, 2008;
July 28, 2008; January 24, 2011; August 17, 2015; February 15, 2016;
July 3, 2020; June 24, 2025; September 17, 2026

SUBJECT: Range of IRB Decisions

POLICY

In its research reviews, the IRB may make one of the below decisions, after assessing whether the appropriate regulatory, policy, and ethical requirements are met. These decisions may be made by the convened board or by the expedited reviewer, with the exception that the expedited reviewer may not decline research.

PROCEDURE

When the IRB reviews research, it will consider the material submitted and the applicable regulatory, policy, and ethical requirements, and make one of the following decisions:

1. **Acknowledged:** When approval is not required, submitted documents may be acknowledged.
2. **Approved:** The submission, including associated documents, is approved. The approval letter will list all documents approved with the submission. Studies may not begin until an initial approval letter is received. Modifications may not be implemented until the corresponding approval letter is received.
3. **Not Yet Approved, Major Contingencies:** The submission approval is deferred pending resolution of major revisions (contingencies). A Major Contingency is a substantive clarification or modification that is directly relevant to one or more regulatory criteria for approval under 45 CFR 46.111 and/or 21 CFR 56.111, or other determinations that must be made by the convened IRB. The Investigator's response to these major revisions must be reviewed by the convened IRB before approval can be granted. The IRB Letter to the Investigator will list the required revisions that must be addressed.

Major Contingencies are generally broad or not sufficiently specific for verification by a single reviewer, such as: "The IRB needs more information about why Arm 2 of the study is needed"; "The IRB is concerned that the PI has not done enough to reduce risks to human subjects. Please revise or explain"; "The consent form was written in a very scientific manner. Please revise so that it is understandable"; or "The IRB is concerned that there are not enough resources to complete this project. Please explain." Responses to major contingencies must be returned to the convened IRB for review and determination.

Studies may not begin until an initial approval letter is received. Modifications may not be implemented until the corresponding approval letter is received. Continuing Review contingencies must be resolved prior to the study's expiration date. All major contingencies issued by the convened IRB must be documented in the IRB record and designated as Major. The designation must be reflected in IRB correspondence to the investigator and documented in the electronic IRB system.

4. **Not Yet Approved, Minor Contingencies:** The submission approval is deferred pending resolution of the minor revisions (contingencies). A Minor Contingency is a specific and limited clarification or modification for which the convened IRB or Expedited Reviewer has already

made the required regulatory determinations, and the response can be verified by an IRB Chair or Experienced IRB Reviewer. The Investigator's response to these minor revisions may be reviewed by an IRB Chair or Experienced IRB Reviewer designated by the IRB. The IRB Letter to the Investigator will list the required revisions that must be addressed.

Minor revisions are limited, specific, and non-substantive changes for which the convened IRB has already made the required regulatory determinations. They are sufficiently specific and direct to allow an IRB Chair or Experienced IRB Reviewer to readily verify that the requested revisions have been completed. Verification that the requested revisions have been completed may be performed by an IRB Chair or Experienced IRB Reviewer designated by the IRB. Examples include: "Please revise consent form page 4 to add the study procedures described in your protocol on page 2"; "Please add the PI's name to the consent form on page one in accordance with UAMS IRB policy"; or "Please remove the second sentence from your recruitment advertisement as it may unduly influence a decision regarding participation."

Studies may not begin until an initial approval letter is received. Modifications may not be implemented until the corresponding approval letter is received. Continuing Review contingencies must be resolved prior to the study's expiration date. All minor contingencies issued by the convened IRB must be documented in the IRB record and designated as Minor. The designation must be reflected in IRB correspondence to the investigator and documented in the electronic IRB system.

5. **Prereview Contingencies:** A prereview contingency is a required clarification, modification, or response that must be addressed before IRB approval can be granted. While in the prereview process, contingencies are not designated as Major or Minor.
6. **Tabled:** The submission lacks information necessary for the IRB to determine that the regulatory approval criteria are met. The IRB Letter to the Investigator will list the information needed and any required revisions. The Investigator's response must be reviewed by the convened IRB and may receive additional contingencies
7. **Declined:** The research or modification as presented has serious deficiencies affecting the safety and welfare of the projected subject population. These deficiencies cannot be addressed as written. The IRB letter will provide the rationale for the decision. For new studies that are declined, the Investigator may choose to address the deficiencies. For modifications that are declined, the Investigator may not implement any of the proposed changes.
8. **Suspended for Cause:** An action taken by the IRB to temporarily stop some or all research procedures until the outlined requirements are met. The IRB can, at its discretion, take a range of actions regarding the conduct of a given protocol in order to better secure the protection of participants. This action is a suspension of IRB approval and must be reported in accordance with IRB Policy 2.6.
9. **Terminated for Cause:** An action taken by the IRB to permanently stop some or all research procedures. The IRB can, at its discretion, take a range of actions regarding the conduct of a given protocol in order to better secure the protection of participants. This action is a termination of IRB approval and must be reported in accordance with IRB Policy 2.6.

REFERENCES

45 CFR 46.108(a)(3)(i)

21 CFR 56.108(a)(1)

AAHRPP Elements II.2.E, II.2.F, II.2.H