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

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 Revisions Required:** The submission is not approved. There are Major Revisions required. The Investigator's response to those major revisions, also called contingencies, must be reviewed by the convened IRB. The IRB Letter to the Investigator will list the required revisions that must be addressed.

   Major revisions request substantive clarifications or modifications that are directly relevant to determinations that must be made by the convened IRB. They are broad and unspecific such as "The IRB needs more information about why ARM 2 of the study is needed" or "The IRB is concerned that the PI has not done enough to reduce risks to human subjects. Please revise or explain" or "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".

   Studies may not begin until an initial approval letter is received. Modifications may not be implemented until the corresponding approval letter is received.

4. **Not Yet Approved Minor Revisions Required:** The submission is not approved. There are Minor Revisions required. The Investigator's response to those minor revisions, also called contingencies, may be reviewed by an IRB Chair or Experienced IRB Reviewer. The IRB Letter to the Investigator will list the required revisions that must be addressed.

Minor revisions are very specific and direct which allows the IRB Chair or Experienced IRB Reviewer to readily verify the revisions have been met. Some examples are “Please revise consent form page 4 to add the study procedures described in your protocol on page 2” or “Please add the PIs name to the consent form 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.

5. **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

6. **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.

7. **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.

8. **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