Department: **UAMS Institutional Review Board**
Policy Number: **7.14**
Section: **Procedures for Study Review**
Effective Date: **September 8, 2021**
Revision Date:

SUBJECT: Equivalent Protections Using Flexible IRB Review Procedures

POLICY

The UAMS Institutional Review Board shall promote the protection of human research subjects' rights, safety, and welfare with institutional policies and applicable guidances, regulations, and laws. The UAMS Human Research Protection Program (HRPP) has indicated, via its Federalwide Assurance with the Office for Human Research Protections, that it will not extend the Common Rule to studies not otherwise subject to the Common Rule. This policy describes the procedures to review and approve certain studies under flexible review procedures intended to provide equivalent protections for human subjects while streamlining IRB review procedures.

PROCEDURE

A. Applicability
   1. This policy applies only to the IRB review and approval process, and not to any ancillary reviews or reviews by other HRPP components.
   2. Studies involving prisoners or fetuses are specifically excluded from this policy.
   3. This policy applies only to certain studies that, after review by an expedited reviewer, are found to meet the following criteria:
      a. Are not, at the time of initial submission, conducted, supported, or otherwise subject to regulation by any federal agency that has adopted the Common Rule, and the IRB reviewer confirms there are no plans to seek funding or support from an agency that has adopted the Common Rule.
      b. Are not under the jurisdiction of the Food and Drug Administration.
      c. Are not required to follow federal regulations by contract or other legal obligation.
      d. Do not hold a Certificate of Confidentiality.
   4. In addition to the criteria in A.3 above, studies subject to this policy are those that would qualify for exempt or expedited status review except for a minor discrepancy between the study procedures and the allowable exempt or expedited categories described in IRB Policies 7.3 (exempt) and 7.5 (Expedited). Examples of such research include, but may not be limited to:
      a. Survey or interview research involving minors
      b. Secondary research of identifiable private information or biospecimens that does not meet the exempt category 4 criteria
      c. Studies involving blood draws that do not meet the expedited category 4 criteria solely because blood is drawn more frequently than 2 times per week.
      d. Studies involving only adult subjects that include up to two standard DEXA scans.

B. Review process
   1. All submissions will undergo the usual prereview process in the IRB office.
   2. An expedited reviewer will make and document the rationale for a determination that the study qualifies for review under this flexible review policy in the IRB e-system.
   3. If a study otherwise meets the criteria for exempt status review, with the exception of a minor discrepancy that would require it to be reviewed using expedited procedures, the study may be reviewed using exempt procedures as described in IRB Policy 7.3, assuming it meets the requirements of this policy.
   4. If a study otherwise meets the criteria for expedited status review, with the exception of a minor discrepancy that would require it to be reviewed using full board procedures, the study may be reviewed using expedited procedures as described in IRB Policy 7.5, assuming it meets the requirements of this policy.
   5. The reviewer will ensure all appropriate human subject protection requirements are met, and that the study meets any applicable criteria for approval.

C. Documentation
   1. The IRB reviewer will be responsible for assuring the applicability of this policy for each study considered.
   2. The IRB reviewer shall document this process in the IRB e-system.
   3. The IRB approval letter shall indicate the study was approved using flexible review procedures, and shall remind the study team to notify the IRB of any changes that would require rereview with standard procedures.
   4. The IRB reviewer has the authority to determine that a study that otherwise qualifies for review using flexible procedures should be reviewed using standard review procedures described in IRB policies. This determination shall also be documented in the IRB e-system.

REFERENCES

AAHRPP Elements I.1.A, I.1.D, II.2.A, II.2.F
AAHRPP Standard II.4
AAHRP Tip Sheet 27, *Developing and Applying Equivalent Protections*
UAMS IRB Policies 7.3 and 7.5