

**Department:** UAMS Institutional Review Board  
**Number:** 7.12  
**Section:** Procedures for Study Review  
**Effective Date:** July 30, 2019  
**Revision Date:** October 15, 2024

**SUBJECT: Limited IRB Review**

**POLICY:**

The UAMS Institutional Review Board will conduct a limited IRB review (LIRB) as described in the Revised Common Rule implemented January 21, 2019. The review will be carried out in the IRB office by the expedited review mechanism, i.e. either the IRB chair or an experienced IRB member/expedited reviewer. The project will be routed through the exempt review queue.

**DEFINITIONS:**

Limited IRB Review (LIRB) – A type of IRB review to be used with studies qualifying for certain types of exempt status review to confirm there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.

**PROCEDURE**

- A. Research falling into one of the following exempt status review categories must undergo limited IRB review.
  - 1. Exemption 2c: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) and the information is recorded by the investigator in such a manner that the identify of the human subjects can be readily ascertained.
  - 2. Exemption 3c: Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection, and the information is recorded by the investigator in such a manner that the identity of the human subjects can be readily ascertained.
  - 3. Exemptions 7 and 8: When investigators plan to store, maintain, or use identifiable private information or identifiable specimens and the information/specimens are obtained with a broad consent process. (Note: Research involving broad consent is not to be undertaken at UAMS unless and until compliance with technical and regulatory requirements can be confirmed.
- B. The LIRB will be conducted via the expedited review mechanism, i.e. by the chair or by an experienced IRB member/expedited reviewer. It will be routed through the exempt status queue in the IRB's e-system.
- C. The reviewer will have access to the full protocol, new submission form, consent and recruitment materials, and any related documents for the review.
- D. The LIRB will be conducted to ensure that there are adequate provisions to protect the privacy of subjects and the confidentiality of data, as per 45 CFR 46.111(a)(7). The LIRB requirements related to exemptions 7 and 8 will be considered if and when the UAMS IRB oversees those types of research.

- E. The LIRB review will be documented in the electronic submission system along with the study's exempt status approval.
- F. The LIRB reviewer may not disapprove research.
- G. No continuing review is required for studies qualifying for a limited review. A brief annual update must be submitted through the IRB e-system to keep the study open.
- H. The organization retains the authority to suspend or terminate IRB approval of research approved with a limited review.

#### References

45 CFR 46.104, Exempt Research

45 CFR 46.111, Criteria for Approval of Research

OHRP Revised Common Rule Q and A, IRB review section (Accessed July 18, 2019)