

Department: UAMS Institutional Review Board
Policy Number: 3.9
Section: Committee Membership
Effective Date: July 31, 2002
Revision Date: November 18, 2002; March 12, 200; February 8, 2005;
January 24, 2011; August 6, 2015; February 15, 2016; May 27, 2020

SUBJECT: Consultants

POLICY:

The IRB may invite individuals who have specific scientific, scholarly, or cultural expertise to serve as consultants to assist the IRB in its reviews when necessary to ensure individuals with appropriate expertise participate in reviews. Consultants may be, but are not required to be, from within UAMS. Consultants' identities will be kept confidential to the extent feasible and as allowed by federal regulations.

DEFINITION:

Conflict of interest: A financial or non-financial interest in either the research itself or the research sponsor. See IRB Policy 3.3, IRB Reviewer and Consultant Conflict of Interest, for definitions of financial and non-financial interests. The term "conflict of interest" may be used interchangeably with "competing interest."

PROCEDURE:

- A. An IRB office staffer, expedited reviewer, or convened board reviewer assigned to a submission may recommend the need to use a consultant.
 1. Requests for a consultant shall be routed to the IRB Chair or IRB Director for assistance in identifying and contacting a consultant.
 2. The IRB Chair or Director will confirm the consultant:
 - a. Understands the confidential nature of IRB review processes and study materials
 - b. Has no conflict of interest related to the study under review, in accordance with IRB Policy 3.3, Conflict of Interest.
 3. The reviewer, chair, or director will document in the IRB e-system that a consultant was used, the consultant's qualifications, and a summary of the consultant's review.
- B. The IRB chair, in reviewing the meeting agenda, may determine an item requires a consultant. If so, the chair may use the procedure described in Section A above to use a consultant.
- C. Consultants shall:
 1. Have access to documents submitted to the IRB relevant to the specific review. These documents shall be provided via email or similar methods.
 2. Not be given direct access to the IRB e-system solely for the purpose of the review.
 3. Confirm they have no competing interest in the project under review and that they understand the confidentiality of the IRB review process and materials.
 4. Provide comments to the person requesting the consultation, who is to summarize them in the IRB e-system.
 5. If requested, attend the IRB meeting to participate in deliberations and make recommendations on the item reviewed.
 6. Not be included in determining or establishing meeting quorum.
 7. Not vote.

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REFERENCES

AAHRPP Standard I-3
AAHRPP Elements II.1.D; II.1.E; II.2.D; II.2.F
AAHRPP Tip sheet 16, Convened IRB Review
UAMS IRB Policy 3.3, Conflict of Interest
45 CFR 46.107(e)
21 CFR 56.107(f)