

**Department:** UAMS Institutional Review Board  
**Policy Number:** 1.5  
**Section:** Principles and Authority  
**Effective Date:** August 12, 2004  
**Revision Date:** February 8, 2005; January 24, 2011; April 6, 2015; February 15, 2016; June 10, 2020

**SUBJECT: IRB Independence from Undue Influence**

## **POLICY**

Individual IRB Reviewers, whether employed by the institution or affiliate or community reviewers, have both the obligation and right to report any undue influence to make particular review decisions or take other actions that would favor an individual investigator or the institution over the rights, safety and welfare of research subjects and/or the ethical conduct of research. The IRB is supported by other individuals and offices (i.e. IRB Director and staff, compliance personnel, research administration) who also have an obligation to report under this policy.

## **DEFINITION**

**Undue influence:** The act of influencing parties to make decisions or take actions that go against the interest the parties are supposed to protect and/or maintain.

## **PROCEDURE**

### **A. Reporting**

1. Concerns about possible undue influence may be reported, in person or in writing, to the IRB Chair, IRB Director, Vice Chancellor for Research and Innovation, Legal Counsel, Deans, or Department Chairs. Individuals may also report concerns anonymously by calling the Compliance Hotline at (888) 511-3969.
2. The IRB office and Chair should be notified of any reports of undue influence received by anyone outside the IRB office.

### **B. Response to Reports of Undue Influence**

1. Any report of undue influence on an IRB reviewer shall be forwarded to the Institutional Official, the IRB Chair, and the IRB Director.
2. These three parties shall work cooperatively to investigate and remediate reports of undue influence.
3. In a timely manner, the Institutional Official, IRB Chair, and/or the IRB Director will inform the reporter, if the reporter's identity is known, of the investigation findings and actions taken.

## **EXAMPLES OF REPORTABLE UNDUE INFLUENCE**

- A. The IRB member is an Assistant Professor in an academic department and is due for consideration of promotion and tenure. A full Professor on the same department's Promotion and Tenure Committee has a grant with a favorable score for funding. The IRB has found problems with the proposed protocol and consent resulting in what the full Professor considers needless delays. The full Professor asks the IRB member to disclose proceedings of the convened IRB meeting at which his protocol was discussed and voted on. In particular, the full Professor asks for names of IRB Committee members who reviewed and/or spoke up against his protocol or voted unfavorably so he can contact them to express his displeasure and perhaps to bring his concerns with them to the Dean. Because the IRB member knows that all convened meeting proceedings are confidential, he must refuse the full Professor's request and report the incident.

- B. A Departmental Chairman requests a visit with an IRB member who is a senior faculty member in their department. The Chairman expresses concern that the IRB committee has been making too many unfavorable decisions regarding protocols from that department. The IRB member is asked to divulge information concerning how the convened IRB Committee made certain decisions and whether the IRB's review processes could be made more favorable for the department's submissions. While the Departmental Chairman is not asking for reconsiderations of specific protocols, the IRB member feels the Chairman is seeking to influence decisions made by the IRB. The IRB member, knowing that all IRB proceedings are confidential, should refer the Chairman to the IRB Chair or Director for more information about IRB operation and report the undue influence.

#### **REFERENCES**

AAHRPP Element I.1.C

AAHRPP Tip Sheet 12, IRB or EC Authority and Independence