

**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

**SUBJECT: IRB Independence from Undue Influence**

**I. Policy**

Individual IRB Reviewers, whether employed by the institution or affiliate or community reviewers, have both the obligation and right to report any undue pressure upon them to make decisions at the convened IRB meetings that would favor an individual investigator or the institution over the welfare and safety of the research subject. The IRB is supported by other individuals (i.e. IRB Director and staff, compliance personnel, research administrators) who also have an obligation to report under this policy. These individuals may be pressured to provide guidance, take certain actions or to ignore certain events that would favor an investigator or the institution over the welfare and safety of the research subject.

**II. Procedure for Reporting of Undue Influence**

Concerns may be reported, in person or in writing, to the IRB Chair, IRB Director, Vice Chancellor for Research, Legal Counsel, Deans, or Department Chairs. Individuals may also report concerns anonymously basis by calling the Compliance Hotline at (888) 511-3969.

**III. Response to Reports of Undue Influence**

Regardless of the reporting option chosen, the Vice Chancellor for Research at UAMS will be informed and will be responsible for the official investigation of the reported undue pressure. In a timely manner, the Vice Chancellor for Research at UAMS will inform the person making the report (if the reporter did not wish to remain anonymous) of the investigation findings and actions taken.

**IV. Examples of Undue Influence that Must be Reported**

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 that has received 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.

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 makes decisions and how the process could be made more favorable to the department's applications. Specific protocols are not discussed but the Chairman clearly 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 Director for more information about IRB operations.

The Office of Research Compliance identifies a study for routine audit. The study involves a product developed by a start-up company in which the Institution has an interest. The compliance office contacts the study team to schedule the audit. The next day, the Research Compliance Officer is contacted by an individual in upper administration involved in the budget process. The administrator mentions that he's just been notified the study is up for an audit and how the timing is unfortunate since great strides are being made with the product. The compliance officer explains that this is just a routine audit and that if everything is in order there should be no impact on the study. The administrator ends the conversation by reminding the compliance officer that the budget for the research compliance office is up for review soon and it would be a shame if the recent budget cuts had to be applied to the compliance office. The audit should continue as planned and the Research Compliance Officer should notify the Vice Chancellor for Research.