

Department: UAMS Institutional Review Board
Policy Number: 1.5
Section: Principles and Authority
Effective Date: August 12, 2004
Revision Dates: February 8, 2005

SUBJECT: IRB Independence from Undue Influence

Policy: Individual IRB members, whether employed by the institution or an affiliate or lay members, 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.

Procedure: **Reporting of Undue Influence**

The manner in which the IRB member chooses to report such undue pressure can take various pathways, depending upon the member's perceived need for anonymity. Reports can be made orally or written (with or without identity). Options of reporting are as follows:

- IRB Chair
- IRB Administrator/Associate Director, Office of Research and Sponsored Programs
- Director of Office of Research and Sponsored Programs
- Director of Office of Research Compliance
- Vice Chancellor for Academic Affairs and Sponsored Research at UAMS

Response to Reports of Undue Influence

Regardless of the pathway chosen by the IRB member, the Vice Chancellor for Academic Affairs and Sponsored Research at UAMS will be informed by the other individuals and will be responsible for the official investigation of the reported undue pressure. In a timely manner, the Vice Chancellor for Academic Affairs and Sponsored Research at UAMS will inform the IRB member of the investigation findings and actions taken to alleviate the undue pressure.

EXAMPLES:

The IRB member is an Assistant Professor in an academic department and is due for consideration of promotion and tenure. A full Professor in the department who is on the Promotion and Tenure Committee has a grant that has received a favorable score for funding but the IRB has found problems with the protocol and consent as written that has resulted in what the full Professor considers needless delays. The full Professor goes to the IRB member and seeks to have him disclose proceedings of the convened IRB at which his protocol was discussed and voted on. Particularly, the full Professor desires to obtain names of IRB Committee members who reviewed and/or spoke up against his protocol or voted in an unfavorable manner so he can contact them to express his displeasure and perhaps even to make waves with the Dean. Because the

IRB member knows that all proceedings of the convened meetings are confidential, he must refuse the full Professor's request and report the incident.

A Departmental Chairman requests that an IRB member, who is a senior faculty member in their department come by for a visit. The Chairman expresses concern that the IRB committee has been making too many unfavorable decisions regarding protocols submitted by persons in the department. The IRB member is requested to divulge information concerning how the convened IRB Committee makes decisions and how the process could be made more favorable to applications from the department. Specific protocols are not discussed but it is obvious that the Chairman is seeking to "take names and kick butt" to influence decisions made by the IRB. The IRB member knowing of the confidential nature of all IRB proceedings, respectfully suggests that the Chairman should schedule a meeting with the IRB Chairman and the Vice Chancellor for Academic Affairs and Sponsored Research at UAMS to discuss how the IRB could better educate researchers in Federal regulations and the need for more guidance in preparing protocol submissions for IRB consideration.

A lay member of the IRB, who is not affiliated with the institution, is contacted by a reporter for the local newspaper. There has been an unexpected death in a research study and the reporter is investigating the death following prompting by the family of the deceased. The reporter has found the name of the lay member from the IRB web site and believes that since she is not affiliated with the institution information might be available that would not be forthcoming from other IRB members. Particularly, the reporter is interested in information concerning how the IRB approved the study and information concerning how the death was reported to the Committee. The lay member is courteous to the reporter but lets him know that all proceedings of the IRB Committee are confidential and that any release of information will have to come from the Vice Chancellor for Academic Affairs and Sponsored Research at UAMS. The lay member then reports the incident.