

UAMS

UNIVERSITY OF ARKANSAS
FOR MEDICAL SCIENCES

Executive Memorandum

DATE: 8/13/2004

REVISION:

SECTION: ACADEMIC AFFAIRS RESEARCH
AREA: ADMINISTRATION
SUBJECT: Authority of the Institutional Review Board (IRB)

Policy

The IRB has the authority to review all research conducted by UAMS faculty, staff and students to ensure that human subjects involved in research activities are given the broadest protections provided by the canons of ethical research, applicable federal, state, and local laws and regulations, institutional guidelines, and common practice guidelines as set forth by the International Committee on Harmonisation.

The IRB will function as an independent and autonomous deliberative body within the University, free of undue influence on its judgments regarding the appropriateness of research and protections afforded human participants. Organizationally, the IRB will operate under the auspices of a Human Research Subjects Protection Program that provides for management by the campus' senior science officer, the Vice Chancellor for Academic Affairs/Research Administration (the VCAA), who in turn reports directly to the campus' chief executive, the Chancellor.

The IRB has the right to constitute itself with regard to structure, governance, and operating principles (within its management framework), that it determines most effective in pursuing its mission to protect human research subjects under its purview, whether at UAMS or other organizations for whom the UAMS IRB conducts research review.

Specific authority is given to the Institutional Review Board (IRB) to:

1. Approve, disapprove, or require modifications of research activities
2. Require progress reports and safety information from the investigators and oversee the conduct of the studies
3. Suspend or terminate approval of an ongoing study.
4. Suspend or terminate an investigator's privileges to conduct research.
5. Reopen terminated/closed protocols and reinstate investigator's privileges.
6. Function as the Institution's privacy board for research.

In its review of human subject research, the IRS has jurisdiction over all aspects of the research including, but not limited to:

1. Methods of identifying potential subjects
2. Methods proposed for contacting potential subjects
3. Materials to recruit subjects and proposed compensation
4. Pilot studies
5. Proposals to use or provide stored blood, tissues, or confidential data
6. Surveys and questionnaires
7. The informed consent process and forms
8. The protocol and summary of the research
9. Evaluation of risks and benefits to subjects
10. Unanticipated problems involving risk to subjects
11. Proposed changes to the research
12. Continuing reviews
13. Use of investigational drugs and devices in emergencies
14. Humanitarian use of drugs and devices
15. Eligibility for exemption or expedited review

In order to approve research, the IRS shall determine that a minimum of all of the following requirements are satisfied

1. Risks to subjects are minimized
2. Risks to subjects are reasonable in relation to anticipated benefits,
3. Selection of subjects is equitable.
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
5. Informed consent will be appropriately documented ..
6. The research plan makes adequate provision for monitoring the data collected, when necessary.
7. Provisions to protect the privacy of subjects and to maintain the confidentiality of patient data are adequate, when necessary.

Undue Influence

Individual IRS 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 IRS meetings that would favor an individual investigator or the institution over the welfare and safety of the research subject. The manner in which the IRS 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:

IRS Chairman
IRS Administrator
Director of Research Administration

Director of Office of Research Compliance
Vice Chancellor for Academic Affairs and Sponsored Research at UAMS

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.

I. Dodd Wilson, M.D.
Chancellor

Date