Department: **UAMS Human Research Advisory Committee**
Policy Number: **10.2**
Section: **Principal Investigator Responsibilities**
Effective Date: **July 31, 2002**
Revision Date: **October 10, 2002**

SUBJECT: Principal Investigator Reporting Requirements

Human Subject Protections. The individual investigator is the ultimate protector of the subject's rights and safety. Each investigator is obligated to be personally certain that each subject is adequately informed and freely consents to participate in the investigator's research. The investigator must personally assure that every reasonable precaution is taken to minimize any risk to the subject. The investigator also assumes responsibility for compliance with all federal, state and institutional rules and regulations related to research involving human subjects and human subject-derived information and materials. All investigators sign a statement of assurance with the HRAC and may not initiate any research involving human subjects without HRAC review and approval (see HRAC policy 16).

The table below describes what investigators must report, and the time frame allowed for reporting:

Investigator Must Report:	Time Frame for Reporting:
· Serious and unanticipated adverse events	Within 7 days of the event
· Deaths	Within 3 days; if subject currently is in the protocol. Otherwise, within 60 days of investigator's notification of death.
· Protocol deviations	Immediately if it represents a significant alteration in the approved protocol and / or if it affects the safety or welfare of the subject. Otherwise, report during continuing review.
· Protocol violations	Immediately, if it represents a significant alteration in the approved protocol and / or if it affects the safety or welfare of the subject. Otherwise report during continuing review.

· Changes in approved research procedures or protocols (amendments)	Prompt notification within 30 days
· Noncompliance with conducting of research protocols	Immediately upon discovery of noncompliance
· Restrictions, suspension or termination of study by the sponsor or principle investigator	Within 3 days
· Any activity which involves a potential or actual unanticipated risk to subjects or others	Within 7 days

The Use of Investigational Devices and/or Investigational Drugs. Prior to the initiation of any research involving an investigational device or drug, it is the responsibility of the individual investigator to obtain the IND or IDE from the FDA in accordance with federal regulations. The HRAC requires information such as the IND number or date of issuance of an IND or IDE for HRAC review, but the HRAC will remind the individual investigator of this requirement in its final approval letter (see HRAC policy 18.2).

Additional Committee Approvals. Prior to the initiation of any research that requires additional review and approval from other University committee(s) and/or institution(s), it is the responsibility of the individual investigator to obtain the necessary approval from that committee and/or institution.

The HRAC requires written approval from the following committees and/or institutions at the time of submission of the HRAC application:

1. Arkansas Cancer Research Center (ACRC) Protocol Review and Monitoring Committee (PRMC)
2. General Clinical Research Center (GCRC)
3. Office of Research and Sponsored Programs (ORSP)
4. CAVHS R & D Committee (for studies done at CAVHS)
5. Pharmacy of the institution where research is conducted (UAMS, ACH, or CAVHS)

Investigator/Sponsor Additional Reporting Requirements: Investigators who initiate their own research may also act as the sponsor of the research. These investigators often hold the IND for a drug or IDE for a device. These investigators must also satisfy the reporting requirements of a sponsor to the appropriate regulatory agency. Reporting to the HRAC does not substitute for the investigator / sponsor responsibility of reporting to these bodies.

The HRAC application will include the documentation of required external committee approvals. The HRAC will document in the Final Approval Letter that HRAC approval has been granted but it is the investigator's responsibility to obtain approval from any other required committees before initiating the research. The HRAC does not require a copy of written approval from the following committees:

1. Institutional Biosafety Committee

2. Radiation Safety Committee

3. Arkansas Children's Hospital Research Institute

Supervision and Monitoring of Research Process. It is the responsibility of each investigator to assure that all procedures in a study are performed, with the appropriate level of supervision, only by individuals who are licensed or otherwise qualified to perform them under the laws of Arkansas and the policies of the University of Arkansas for Medical Sciences. Persons involved in the research should be trained to the protocol by the principle investigator or his/her designee (21 CFR812). Further, it is the responsibility of the investigator to regularly review their research process and address any deficiencies identified (see HRAC policy 12.2).

Congruence with Funding Proposals. It is the responsibility of the investigator to ensure that the HRAC protocol is consistent with the proposal for funding for extramural or intramural support. Further, the investigator should act as a liaison between the HRAC and the sponsor.

Amendments/Requests for Change in HRAC Application. It is the responsibility of the investigator to not deviate in any way from the HRAC-approved protocol until the investigator has received written approval from the HRAC (see HRAC policy 8.3).

Investigator's Records. At a minimum, investigators must maintain research records for at least three (3) years from the date of completion of the research. All records must be accessible for inspection and copying by authorized representatives of the HRAC and the department or agency supporting the research. Beyond three (3) years, requirements for record retention vary with the type of research conducted and provisions of the investigator's funding source. It is the investigator's responsibility to clearly understand the retention requirements of the sponsor [21 CFR56.115(b); 45 CFR]. Drug studies require that the principle investigator retain research records for a minimum of 2 years after the marketing application is approved or denied by the FDA (21 CFR).

Notifying HRAC of pending audits or inquiries. Investigators conducting research involving human subjects are required to report any communication from a federal or state department or agency or sponsor that questions the conduct of research or suggests an impending inquiry audit or investigation. The investigator should inform the HRAC chair or Administrator by phone immediately upon notification of inquiry. A formal written notice to the HRAC committee that includes a detailed description of the proposed inquiry is required within 3 days from the notification of the investigator.

Confidentiality. The conditions for maintaining confidentiality of the subjects and the research records are required for the life of the data. These rules apply equally to any and all research conducted or assisted by students, staff, and faculty. Protocols conducted with FDA regulated articles must be kept in accordance with current FDA regulations (see HRAC policy 13.2).

Adverse Events. The investigator must promptly report to the HRAC any adverse experiences or unanticipated problems involving risks to human subjects or others that occur in the course of the research (21CFR56.108b1; 45 CFR). Reporting to the HRAC does not substitute for the investigator's responsibility of reporting to a sponsor. Serious and anticipated adverse events must be reported within 7 days of the event. Deaths must be reported within 3 days if the subject is currently in the protocol, otherwise within 60 days of the investigator's notification of death.

Additional Requirements for Activities Involving Fetuses, Pregnant Women, or Human in Vitro Fertilization. For activities involving fetuses, pregnant women, or human in vitro fertilization, the investigator must ensure that adequate provision has been made for monitoring the actual informed consent process. For example, the investigator may, when appropriate, require participation of subject advocates in (a) overseeing the actual process by which individual consents are secured, or (b) monitoring the progress of the activity and intervening as necessary. (See HRAC policy 17.8).

Prisoner Research. If a subject becomes a prisoner after enrollment in research, the investigator is responsible for reporting in writing this situation to the HRAC immediately. (See HRAC policy 17.9).

Continuing Review. All approved research proposals, with the exception of those which qualify for exemption in accordance with 46 CFR 46.101(b), must receive continuing review at intervals appropriate to the degree of risk as determined by the HRAC. Continuing review must be conducted not less than once per year. It is the responsibility of the investigator to provide the HRAC with all of the information requested on the Continuing Review Application. (See HRAC policy 7.6).

Final Report. At the conclusion of any study, the PI must furnish a final report to the HRAC, including applicable data analysis and long-term follow-up, so that the study can be closed. The final report of study results should be received by the HRAC no later than 6 months after the completion of the study. When a protocol is complete except for data analysis or long-term follow-up, the PI should indicate the status of the protocol on the CRR so that approval can be expedited. Studies are not to be closed until the investigator has determined that the study is ready to be closed. (See HRAC policy 7.7).