Department: **UAMS Institutional Review Board**
Policy Number: **12.2**
Section: **Quality Assurances**
Effective Date: **July 31, 2002**
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SUBJECT: IRB Monitoring or Audits

The Institutional Review Board is charged with the task of ensuring the protection of human research participants and compliance with federal regulations and local IRB policies. The IRB has the authority to observe or appoint a designee to observe the informed consent process and conduct of the IRB approved research process.

The UAMS Office of Research Compliance (ORC) serves as the independent auditing body for the UAMS IRB. (See IRB Policy 2.3).

The Director of the IRB Office the Chairperson(s) of the IRB and/or the IRB committee may request the ORC to initiate,,as necessary, one of the following types of reviews:.

1. **Periodic Review** - a systematic examination of an IRB approved research protocol on a regular basis due to safety concerns or prior compliance issues.
2. **Directed Review -** conducted in response to identified concerns that require an IRB determination of protocol compliance.

In addition to reviews, the IRB may undertake or request ORC assistance with the following activities:

1. Request progress reports from investigators
2. Examine research records
3. Contact research subjects
4. Assign observers to the sites where research involving human subjects and/or the informed consent process is being conducted
5. Examine advertisements and other recruiting materials as deemed appropriate by the IRB
6. Review projects to verify from sources other than the investigator(s) that no unapproved changes have occurred since previous IRB review; and/or
7. Observing research procedures
8. Review manuscripts resulting from protocols
9. Other monitoring or auditing activities deemed appropriate by the IRB

IRB May Suspend or Terminate Research. If the information gained during the monitoring or reviewing process indicates that human subjects of a research project were exposed to unexpected serious risk or harm, or that the policies of the IRB were not met, the IRB may suspend or terminate the research (45 CFR46.113; 21 CFR56.113; 38 CFR16.123).

Safety Monitoring. The IRB may request documentation from additional safety monitoring or the creation of an independent data safety monitor.

Additional Requirements for Activities Involving Vulnerable Populations. For activities involving vulnerable populations such as fetuses, pregnant women, human *in vitro* fertilization, prisoners, children, or the cognitively impaired, the IRB will require assurance that the investigator has made adequate provisions for monitoring the actual informed consent process.. The IRB may oversee the actual informed consent process, not limited to the following activities:

1. Verifying that subject selection is appropriate and observing the actual informed consent process by which individual consents are obtained, or

2. Monitoring the progress of the activity and intervening as necessary through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen.

Reporting of Monitoring and/or Review Results to IRB Committee. The results of any monitoring or reviewing activity by the IRB will be reported in writing to the Chairperson of an IRB Committee and other person(s) who authorized the review. The IRB Chairperson will determine the need for full IRB Committee review. The findings will be discussed as an agenda item of an IRB meeting. A summary of the review will be maintained in the IRB File of that protocol and provided to the primary reviewers at the time of the next continuing review.

Complete reports of review activity will be considered legally privileged documents. A copy will be given to the principal investigator and a copy will be maintained in the ORC files which are open for inspection by IRB committee members upon request.

If the monitoring or auditing activity finds that a human subject participating in a research project has been exposed to unexpected serious harm, the ORC will promptly report such findings to the IRB Director, the Chairperson of the IRB Committee and the Administration's Chief Research Officer.. In addition, the study will be placed on the agenda of the next meeting for discussion. A decision may be made to suspend or terminate the research prior to that IRB meeting by the IRB chair or the Chief Research Officer.

Verification of Information. The IRB with the assistance of the ORC must determine which projects require verification from other sources other than the investigator to ensure that no unapproved changes have occurred since the previous IRB review. The IRB may do this by:

1. Conducting audits or inquiries to collect information, and/or
2. Having the IRB or its designee observe the informed consent process and conduct of the research, and/or
3. Examining contents of manuscripts or reports resulting from protocol activities.

Determining the need for such additional supervision or participation by the IRB is made by the IRB on a case-by-case basis during the initial and continuing review, or as new information is presented. Factors to be considered by the IRB in determining whether to undertake such additional supervision or participation may include, but are not limited to:

a. Involvement of vulnerable populations

b. Research conducted internationally

c. The involvement of recombinant DNA or other types of gene transfer protocols

d. The use of waiver of informed consent procedures, *e.g.* surrogate consent

e. Classified research

f. Breach for which subjects would be exposed to additional risks, *e.g.* breach of confidentiality, Phase 1 studies, disproportionate number or severity of SAEs

g. Previous suspension of the research due to compliance, record-keeping or other concerns

h. Recommendations from other institutional committees.