Department: **UAMS Human Research Advisory Committee**
Policy Number: **12.2**
Section: **Quality Assurances**
Effective Date: **July 31, 2002**
Revision Date:

SUBJECT: HRAC Monitoring or Audits

The Institutional Review Board is charged with the task of overseeing all internal and external monitoring and/or auditing efforts in order to ensure the protection of human research participants and compliance with federal regulations and local HRAC policies. The HRAC has the authority to observe or appoint a designee to observe the informed consent process and HRAC approved research.

The Director of the HRAC Office, the Compliance Office, and/or the Chairpersons of the HRAC Committees may direct the HRAC Compliance Officer or designee to initiate periodic and/or directed audits when deemed necessary.

1. **Periodic Audit.** A periodic audit is a systematic method to audit HRAC approved research on a regular basis.

2. **Directed Audit.** A directed audit is an audit conducted in response to identified concerns that require an HRAC determination.

Monitoring and/or auditing activities may include, but are not limited to the following:

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. Audit advertisements and other recruiting materials as deemed appropriate by the HRAC

6. Review projects to verify from sources other than the investigator(s) that no unapproved changes have occurred since previous HRAC review; and/or

7. Screening enrollment logs

8. Other monitoring or auditing activities deemed appropriate by the HRAC

HRAC May Suspend or Terminate Research. If the information gained during the monitoring or auditing process indicates that human subjects of a research project were exposed to unexpected serious risk or harm, or that the policies of the HRAC were not met, the HRAC may suspend or terminate the

research (45CFR46.113; 38 CFR16.123).

Safety Monitoring. The HRAC may request 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 HRAC should determine that the investigator for monitoring the actual informed consent process has made adequate provisions. The HRAC 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 Auditing Results to Full Committee. The results of any monitoring or auditing activity by the HRAC will be reported in writing to the Chairperson of the HRAC Committee responsible for the review of the study. The HRAC Chairperson will determine the need for full HRAC Committee review. The results will be placed on the agenda of the next regularly scheduled meeting for notification or discussion, as appropriate. All monitoring and/or auditing information will be maintained in the HRAC File and provided to the primary reviewers at the time of the next continuing review.

If the monitoring or auditing activity finds that a human subject participating in a research project has been exposed to unexpected serious harm, the HRAC Compliance Officer will promptly report such findings to the Director of the HRAC Office, the HRAC Medical Director, and the Chairperson of the HRAC Committee responsible for the review of the study. In addition, the study will be placed on the agenda of the next regularly scheduled meeting for discussion. Note: A decision may be made to suspend or terminate the research prior to next regularly scheduled HRAC meeting.

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

1. Conducting audits or inquiries to collect information, and/or

2. Having the HRAC or its designee observe the informed consent process and conduct of the research

Determining the need for such additional supervision or participation by the HRAC is made by the HRAC on a case-by-case basis during the initial and continuing review, or as new information is presented. Factors to be considered by the HRAC 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 (e.g., HSRC, RDRC, IBC, HGTAG, CPRMC, etc.)