Department: **UAMS Institutional Review Board**
Policy Number: **12.2**
Section: **Quality Assurances**
Effective Date: **July 31, 2002**
Revision Date: **June 1, 2005; June 10, 2004**

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** - 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.
3. **Consent Process Observation-** the IRB may require the ORC to conduct this review in special situations as described below under the heading "conditions under which the IRB might monitor the consent process":

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.

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 in accordance with IRB Policy 2.6. 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.

Conditions under which the IRB might monitor the consent process

1) Participants have limited decision making capacity.
2) Vulnerable population participating in a greater than minimal risk study
3) Multiple consent forms are used.
4) Consent forms are long and complicated and might require extra explanation.
5) Studies deemed greater than minimal risk and the only benefit to doing the study would be advancement of knowledge.
6) When healthy populations are used in risky and early phase drug clinical trials.
7) Short form consent is used for non-English speaking participants.
8) If the consent is verbal.
9) Behavioral study that utilizes deception
10) Gene Therapy trials
11) Studies with reported non-compliance

Criteria for Monitoring the Consent Process

The following criteria will be used to monitor the consent process:

1) Does the investigator or designee explain the risk, benefits, and alternatives of the study and allow the subject some time to ask questions?
2) Does the investigator or designee give the subject enough information (verbally or written) about the study that may help the subject understand whether to participate?
3) Does the subject deliberate enough to make an informed decision? A quick answer to participate is probably not adequate (see number 5).
4) Is the investigator or designee able to answer questions posed by the subject?
5) Does the investigator or designee ask enough questions to determine if the subject has indeed understood the procedures, i.e., does the investigator or designee ask the subject to explain the procedures back to him/her? Does the investigator or designee discuss ask if the subject understands risks and benefits or alternatives to the procedure or procedures under question? If at all the possible, questions should not be close ended because there is no clear measure of comprehension.
6) Is verbal consent clear? (if the consent is verbal and see 5 above)
7) Have all the IRB required signatures been applied?
8) Were subject advocates present (if required by the IRB)?
9) Were witnesses present and signed the consent (if required by the IRB)?

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.

The IRB will obtain verification from sources other than the investigator that no material changes have occurred since previous IRB review when:

1. The IRB doubts the veracity of the information provided by the investigator.
2. The information provided by the investigator is internally inconsistent and the inconsistency cannot be resolved through discussion with the investigator.
3. The information provided by the investigator is inconsistent with other information known to the IRB and the inconsistency cannot be resolved through discussion with the investigator.
4. The investigator has been found to be in serious or continuing non-compliance in the previous year.
5. Any other situation where the IRB requests verification from sources other than the investigator that no material changes have occurred since previous IRB review.