Department: **UAMS Institutional Review Board**

Policy Number: **15.5**

Section: **Consent Process**

Effective Date: April 5, 2007 ; March 5, 2008

Revision Date:

Subject: The Informed Consent Process

Policy: In studies for which informed consent must be obtained, no investigator may involve a human being as a subject in research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. This SOP describes, in general terms, the requirements for the informed consent process and the IRBs duty to monitor this process in certain situations. Additional requirements may also apply in certain instances, such as the inclusion of vulnerable populations, and are described in UAMS IRB SOP Nos. 17.1 through 17.13.

Procedure:

1. In the initial IRB submission, the PI will explain in detail the consent process, both initial and ongoing. Investigator should identify at a minimum:
    - Who will conduct the consent interview;
    - The timing of obtaining informed consent;
    - The waiting period between providing information about the research and obtaining consent;
    - Whether the medical or research record will be noted; and
    - How the Investigator will assure that there will be ongoing communication between the research team and participant regarding issues related to ongoing informed consent to participate.

    The IRB may request further clarification of or amendments to the informed consent process as part of its study review.
2. The PI or study staff is also required to document the informed consent process in either the subject's research record or medical record.
    A note separate from the consent form itself that includes, at a minimum, the following items is appropriate documentation of the informed consent process:

- The date the subject was entered into the study
- The title of the study

- The name of the Principal Investigator
- The name of the person obtaining the informed consent

● A statement that the subject had an opportunity to ask questions about the research and have those questions answered and that they were given a copy of the signed form. The person who obtained consent should sign and date this note.

At the time of the informed consent process, each subject must be given a copy of the signed and dated informed consent document. For those subjects that have a medical record, a copy of the subject's informed consent should be placed in the medical record. The original should be retained by the PI.

Monitoring the Consent Process

The IRBs can have a third party observe the informed consent process in research projects as necessary. (AAHRPP Element II.7.G.) An IRB may require that a staff member or an outside third party observe the consent process as it takes place with the human subject accounting for the following:

- Is or was consent appropriately completed and documented?
- Did the participant have sufficient time to consider study participation and did the subject appear to be coerced by those consenting?
- Was the process understandable, both the form and the information presented on the day of consent?

The IRB can order monitoring of consent based on the following criteria:

- Risk greater than minimal
- Complicated procedures, interventions or research designs.
- Any vulnerable population.
- Staff with minimal experience.
- In any situation where the IRB sees the need for extra protections