

Department: UAMS Institutional Review Board
Policy Number: 15.5
Section: Consent
Effective Date: April 5, 2007
Revision Date: March 5, 2008; January 24, 2011; February 15, 2016; August 24, 2020

SUBJECT: 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 (LAR). 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 policy describes, in general terms, the requirements for the informed consent process, documentation thereof, and the IRB's authority to monitor this process in certain situations.

Details of the informed consent process are addressed in UAMS IRB Policy 15.1. Additional requirements applicable in certain instances, such as the inclusion of children or the use of LARs, and are described in IRB Policies 17.1 through 17.13.

PROCEDURE

- A. The initial IRB submission shall include a description of the consent process, both at the time of a potential subject's initial enrollment and, if appropriate, throughout study participation.
- B. The description of the process shall include, at a minimum:
 1. The person who will conduct the consent interview;
 2. The person who will provide consent or permission;
 3. The language used by those obtaining consent and by the prospective subject or LAR;
 4. The language understood by the prospective subject or LAR;
 5. The timing of obtaining informed consent;
 6. The waiting period between providing information about the research and obtaining consent;
 7. Steps taken to minimize the possibility of coercion or undue influence;
 8. The information to be communicated to the prospective subject or LAR.
- C. Unless the IRB specifically waives this requirement, the person obtaining consent is also required to document the informed consent process in either the subject's research record or medical record.
- D. A note in addition to the consent form itself that includes, at a minimum, the following items is required to document the informed consent process:
 1. The date the subject was entered into the study
 2. The title of the study
 3. The name of the Principal Investigator
 4. The name of the person or people obtaining the informed consent
 5. Statement that the subject or LAR was given a copy of the signed form.
- E. While not required, the following additional elements are strongly encouraged to fully document the process:
 1. A description of anyone else present during the process (e.g. subject's spouse or other family; study coordinator; Principal Investigator).
 2. The types of questions the subject had during the process or that the subject had no questions.
 3. Any other details specific to that particular consent process, such as the reason for any date discrepancies on consent form signatures, that help complete the description of the process.
- F. If a written consent form is used, the person signing that form as the person obtaining consent shall sign the consent process note. If no written form is used, or if the written form used does not include a person obtaining consent signature line, at least one of the people who obtained consent shall sign and date the consent process note.
- G. A separate informed consent process note is required for each subject enrolled. However, the IRB may, at its discretion, approve different types of consent process notes for special consenting situations, such as group processes.

- H. 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 study team.
- I. The IRB has the authority to observe, or have a third party observe, the informed consent process in research projects as necessary.
 - 1. Monitoring the consent process may be warranted in studies that involve vulnerable populations, complicated procedures or processes, studies utilizing deception or in any situation where the IRB believes the consent process should be monitored to provide further protections.
 - 2. Observations may be done by an IRB Reviewer, research compliance personnel, or a neutral third party. The consent process observation should take into account such things as time allowed for questions, how the study team assessed understanding, how the research was presented and whether results were promised.

REFERENCES

45 CFR 46.109(g) and 117
21 CFR 50.27(a) and 56.109(f)
IRB Policies 15.1 and those in section 17
AAHRPP elements II.3.F and III.1.F