

Informed Consent

Human study participants are required to give their informed consent prior to undergoing any research activities. This requirement for informed consent is spelled out in the Belmont Report, 45 CFR 46 (also known as The Common Rule), and UAMS IRB policies 15.1-15.5.

During the informed consent process, study staff and potential subjects discuss the research study. This discussion's aim is to let potential subjects know about the study and what it involves, and to allow people considering joining the study to ask questions and have those questions answered.

Most consent processes also involve the use of a written informed consent form, which can serve as a guideline for the informed consent discussion. Federal regulations require that subjects sign this form; the UAMS IRB currently requires that the person obtaining consent, a witness to the subject's signature, and the principal investigator sign the consent form as well. The UAMS IRB also currently requires that all signatures be dated and timed.

In addition to the signed informed consent document, the IRB also requires separate documentation related to the informed consent process. Per UAMS IRB policy 15.5, study staffers are required to write a separate note to file for each subject describing the informed consent process that occurred with that participant. This note is invaluable in documenting that a thorough informed consent process took place. In addition to including the required elements spelled out in IRB Policy 15.5, this note can describe any circumstances specific to a particular consent process. For example, if a prospective subject had a lot of questions about one study aspect, you could note that in the informed consent process note. This note is also an excellent place to document such items as why a legally authorized representative signed a particular consent form instead of the subject.

The UAMS IRB considers the entire informed consent process as it reviews new studies. New submission materials should include a complete description of the entire informed consent process, such as where the discussion will take place; whether it will occur in person, by phone, or some other means; and how much time potential subjects will have to consider participation before having to make a decision.

Please note that you are required to abide by the informed consent process that is approved by the IRB, and you can't change it without getting IRB approval first. For example, if you are approved to obtain consent in person, telephone consenting is not allowed without prior IRB approval. Also, don't make any marks, marginal notes, edits, or line-throughs on an approved consent form version. Any extraneous marks change the approved version to an unapproved consent form version. Deviations from the approved consent process have to be reported to the IRB.

UAMS IRB Policies 15.1 through 15.5 describe informed consent requirements. Note that special subject populations, such as cognitively impaired persons or children, may have additional requirements for study participation, including for the informed consent process. These requirements are described in UAMS IRB Policies 17.1 through 17.13. Periodic review of relevant IRB policies can be helpful in assuring that your studies meet the IRB's requirements.

Questions? Call Edith Paal at the UAMS Research Compliance office at 526-6270