

Department: UAMS Institutional Review Board
Policy Number: 15.3
Section: Consent
Effective Date: July 31, 2002
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SUBJECT: Waivers of Signed Informed Consent Documents and Waivers of Informed Consent Elements

I. Policy

Upon determining that the regulatory criteria have been met, the IRB or Experienced IRB Reviewer may waive or alter:

- *The consent process
- *Parental permission
- *Written documentation of the consent process

The IRB or Experienced IRB Reviewer must document its findings justifying the waiver or alteration.

II. Waivers

A. WAIVER or ALTERATION of CONSENT PROCESS – Does not apply to research regulated by the FDA, except as outlined in IRB Policy 18.3. For research not subject to FDA regulations, the IRB may approve a waiver of some or all of the consent elements provided that the research fits into one of two scenarios:

1. Some or all elements of consent may be waived if all of the following apply:

- a. The research involves no more than minimal risk to subjects;
- b. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- c. The research could not practicably be carried out without the waiver or alteration; and
- d. Whenever appropriate, the subjects will be provided with additional pertinent information after they have participated in the study.

2. Some or all elements of consent may be waived if the project meets all of the following criteria:

- a. It is conducted by or subject to the approval of state or local government officials;
- b. It could not practicably be carried out without the waiver or alteration;
- c. It is designed to study, evaluate or examine one of the following four categories:
 - i. Public benefit of service programs;
 - ii. Procedures for obtaining benefits or services under those programs;
 - iii. Possible changes in or alternatives to those programs or procedures;or
- iv. Possible changes in methods or levels of payment for benefits or services under those programs.

B. WAIVER of DOCUMENTATION of CONSENT. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if the research fits into one of two scenarios. In each case, the IRB will review a written description of the information that will be provided to the subjects.

- 1. Applies to both FDA and non-FDA research.
 - a. Research involves no more than minimal risk of harm to subjects; and
 - b. Involves no procedures for which written consent is normally required

outside the research context.

2. Applies only to non-FDA Research.

- a. The only record linking the subject and the research would be the consent document;
and
- b. The principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

C. Procedure – Applicable to all expedited and full review studies.

1. Investigators requesting a waiver or alteration under this policy must provide written rationale in the IRB e-system that shows how the study meets each element of the requirements for either a waiver of written consent or a waiver/alteration of consent.

The requirement for justification applies even in cases where the Investigator needs to use deception due to the possibility that subjects would behave differently if they knew they were being observed.

2. The IRB will:

- a. Review the submission to see if it is subject to FDA regulations in order to determine regulatory options.
- b. Review the waiver request, taking into account the importance of the research, the extent to which privacy will be invaded, the sensitivity of the information to which the investigators will have access, plans for further contact of the subjects, and the feasibility of obtaining consent from all subjects.
- c. For studies requesting to use deception, first decide whether the information to be withheld would influence the decision of prospective subjects about participating in the research. Research should not be permitted at all if the subjects are not being informed of things they would consider material to a decision to participate. Also decide if subjects should be debriefed either after participating in research unwittingly or after knowingly participating in research that involved some form of deception. Then in order to grant the waiver, document the following three things:
 - i. the study presents no more than minimal risk;
 - ii. the waiver would not adversely affect the rights and welfare of subjects; and
 - iii. the waiver is essential to the ability to carry out the research.
- d. Decisions on informed consent, waivers of informed consent, documentation of informed consent, or requirements for debriefing will be described in the letter to the Investigator and reflected in the IRB minutes.