

Department: UAMS Institutional Review Board

Policy Number: 15.3

Section: Consent

Effective Date: July 31, 2002

Revision Date: June 1, 2005; February 06, 2005; March 13, 2008

Subject: Waivers of Signed Informed Consent Documents and Waivers of Informed Consent Elements

Definitions:

FDA Regulated Research (Also called a “Clinical Investigation” in FDA terms):

Any experiment that involves a test article and one or more human subjects. This includes ALL research using a test article in a human subject, even if test article is approved for usage, as well as experiments that support applications for research or marketing permits for products.

Test Article: Any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product or any other article subject to FDA regulations.

Policy:

A. WAIVER of SOME or ALL ELEMENTS of CONSENT

1. Non-FDA Regulated Research: 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.

1.1 Some or all elements of consent may be waived if:

1.1.1 The research involves no more than minimal risk to subjects;

1.1.2 The waiver or alteration will not adversely affect the rights and welfare of the subjects;

1.1.3 The research could not practicably be carried out without the waiver or alteration; and

1.1.4 Whenever appropriate, the subjects will be provided with additional pertinent information after they have participated in the study.

1.2 Some or all elements of consent may be waived if the project is:

1.2.1 Conducted by or subject to the approval of state or local government officials;

1.2.2 Could not practicably be carried out without the waiver or alteration;

1.2.3 Designed to study, evaluate or examine one of the following four categories:

a) Public benefit of service programs;

b) Procedures for obtaining benefits or services under those programs;

c) Possible changes in or alternatives to those programs or procedures; or

d) Possible changes in methods or levels of payment for benefits or services under those programs.

2. FDA Regulated Research: For research subject to FDA regulations, consent may only be waived in certain life threatening situations. See Policies 15.2; 18.3 or 18.4 for more information.

B. WAIVER of DOCUMENTATION of CONSENT

1. Refer to the SAM Consent Checklist for waiver of documentation procedure.

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

1. Investigators must:

1.1 Submit a consent form or request and justify in the ARIA application why the study meets 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

2.1 Review the submission to see if it is subject to FDA regulations in order to determine regulatory options.

2.2 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.

2.2.1 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: a) the study presents no more than minimal risk; b) the waiver would not adversely affect the rights and welfare of subjects; and c) the waiver is essential to the ability to carry out the research.

2.3 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.