Department: **UAMS Institutional Review Board**
Policy Number: **15.3**
Section: **Consent**
Effective Date: **July 31, 2002**
Revision Date: **February 8, 2005; June 1, 2005; March 13, 2008; January 24, 2011; September 1, 2015; February 15, 2016; January 21, 2019; June 30, 2020; September 15, 2023**

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

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 their findings justifying the waiver or alteration.

PROCEDURE
A. **WAIVER or ALTERATION of CONSENT PROCESS –** In addition to the scenarios described in IRB Policy 17.14, *Planned Emergency Research at UAMS,* and Policy 18.3, *Emergency Use of a Test Article*, the IRB may waive the requirement to obtain informed consent or approve a consent procedure that omits some, or alters some or all, of the required elements of informed consent subject to the conditions below:
   1. All of the following apply (see exception at d):
      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;
      d. (applicable only to non-FDA-regulated research; this criterion does not need to be met for FDA-regulated research) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; and
      e. Whenever appropriate, the subjects or LAR will be provided with additional pertinent information after they have participated in the study.

      Note: The IRB may not waive consent for the storage, maintenance, or secondary research use of identifiable private information or identifiable biospecimens if an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private specimens and refused to consent.

OR

   2. 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.

3. For the conditions described in sections A1 and A2, the IRB may grant a **waiver of the entire consent process** when the listed conditions are met. The IRB may also approve **a consent process that omits some, or alters some or all**, of the required elements except those listed in UAMS IRB Policy 15.1, paragraphs A 1 through 7.

4. **For non-FDA-regulated studies only**, the IRB may approve a research study that involves obtaining information or biospecimens for the purpose of screening, recruiting, or determining eligibility of prospective subjects without the informed consent of the prospective subject or LAR if either of the following conditions is met:
    a. The investigator obtains information through oral or written communication with the prospective subject or LAR, or
    b. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

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. For both FDA- and non-FDA-regulated 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. For non-FDA-regulated research
        a. The only record linking the subject and the research would be the consent document; AND the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or LAR) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; OR
        b. If the subject or LAR are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.
    3. When the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

C. **Investigator Procedure**
    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.
    2. The protocol shall also include language describing the waiver/alteration request and its rationale.
    3. The requirement for justification of the request also applies when the investigator must use deception due to the possibility of subjects' behavior changing if they knew they were being observed.

D. **IRB Procedure**
    1. The IRB will:
        a. Determine the appropriate criteria to use in evaluating the waiver request.
        b. Review the waiver request against the relevant criteria, taking into account the nature 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 subject contact, and the ability to practicably carry out the research with or without the requested waiver.

c. For studies requesting to use deception, first decide whether the information to be withheld would influence prospective subjects' decision about research participation. Research should not be permitted if the subjects are not being given information material to their participation. 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.
d. To grant the waiver, the IRB shall confirm the appropriate criteria are met.

2. 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 or e-system.

REFERENCES

45 CFR 46.116(e) and (f)
21 CFR 56.109(c) and (d)
FDA Guidance titled *IRB Waiver or Alteration of Informed Consent*
AAHRPP Elements II.3 G and III.1.F