Office of Human Research Ethics Training Tips

Waiver of Consent: Alternation or Documentation OHRE SOP 28.3, 4, 7

Basic Common Rule Requirements:

- Request for Waiver or Alteration of Consent: Study is minimal risk, includes identifiers & non-health related information (no PHI). Examples are telephone screening, questionnaires, focus groups, use of the short form.

- Request for Waiver of Documentation of Informed Consent: Study where documentation is a risk for the subject; study involves minimal risk and written consent is not required outside the research setting; & non-health related information—no PHI. This is not an option for FDA-regulated research.

28.3 Exceptions to informed consent requirements:

An IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

28.3.1: The research or demonstration project is to be conducted by or subject to the approval of State or local government officials and is designed to study, evaluate, or otherwise examine:

(1) public benefit of service programs; (45 CFR 46.116(c)(1)(i))

(2) procedures for obtaining benefits or services under those programs; (45 CFR 46.116(c)(1)(ii))

(3) possible changes in or alternatives to those programs or procedures; or (45 CFR 46.116(c)(1)(iii))

(4) possible changes in methods or levels of payment for benefits or services under those programs; and (45 CFR 46.116(c)(1)(iv))

(5) The research could not practicably be carried out without the waiver or alteration. (45 CFR 46.116(c)(2))

28.4 Other exceptions to informed consent requirements 45 CFR 46.116(d)

An IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of inform consent set forth above, or waive the requirement to obtain informed consent, provided the IRB finds and docume that:

28.4.1 The research involves no more than minimal risk to the subjects;

28.4.2 The waiver or alternation will not adversely affect the rights & welfare of the subjects;

28.4.3 The research could not practicably be carried out without the waiver or alternation;

28.4.4 Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

These exception do not apply to FDA-regulated research.

28.5 Other information concerning informed consent

28.5.1 The informed consent requirements in this policy are not intended to preempt any applicable federal, State, or local laws that require additional information be disclosed in order for informed consent to be legally effective.

28.5.2 Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, State or local law.

28.7 Waiver of written consent

The IRB may waive the requirement for the investigator to obtain a signed consent form in cases where circumstances warrant such a waiver. Such a waiver is allowable if:
• The consent document is the only link between the subject and the research and the principal risk of harm would come 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; or [45 CFR 46.117 (d)(1)]

• The research presents no more than a minimal risk of harm to the subjects and involves no procedures for which written consent is normally required outside of the research context. [45 CFR 46.117 (d)(2)]. In lieu of a signed consent form the IRB may require the investigator to provide subjects with a written statement regarding the research in the form of an information or fact sheet. This information will be reviewed by the IRB. The written statement should contain, at a minimum:

• A statement that the project involves research;

• A description of the level of involvement and amount of time expected from subjects;

• A description of the study

• A description of the risks and benefits to subjects;

• A statement describing the subject's rights;

• A description of the compensation to be provided to subjects;

• Contact information for both the investigator and the IRB.

Examples of circumstances in which a waiver of written consent may be considered include situations where the researcher plans to use an abbreviated consent process, as in recruiting passersby for a brief, minimal risk survey. Similarly, a waiver may be granted to allow researchers to obtain oral consent for a telephone survey. Finally, a waiver may also be granted if researchers want subjects to imply their consent by returning a survey via the mail or the internet. This last approach is especially useful in preserving the anonymity of the subjects surveyed. For research using PHI, see SOP 29.3 on the additional criteria for waiver or modification of the HIPAA requirement for written authorization.

28.7.1 Waiver of written consent does not apply to FDA-regulated studies.