



Avenues of Consent

Options available under 45
CFR 46.116(d) & 46.117

Overview

- **One of the challenges of human research is effectively implementing the method of informed consent that is both compliant with regulation and best suited to the research situation at hand.**

Overview

- **Choosing the method of consent serves two potentially conflicting aims:**
 - **1. Obtaining the most effective informed consent from a participant**
 - **2. Conducting the consent process in the most efficient way possible**
 - **What is most efficient may not be best for the participant**

Regulations

- **Regarding consent, the federal regulations provide for two categories of research:**
 - **Research where consent is required**
 - **Research where consent may be waived**

...and two broad categories of consent:

- **Written consent**
- **“Verbal” consent (i.e., waiver of written consent)**

Regulations

- **The consent regulations work from the basic assumptions that consent will be:**
 - 1. **sought from research subjects, and**
 - 2. **documented (i.e., “written”)**

This is why the specific regulatory language deals with “waivers,” that is, waivers of one or both of these basic assumptions (i.e., situations where consent will not be sought, or will be sought but not documented.)

Regulations

- **Research for which the consent process as a whole can be waived must meet the following criteria [46.116(d)]:**
 - **research involves no more than minimal risk**
 - **the waiver of consent will not adversely affect the rights and welfare of the subjects**

Regulations

- the research could not practicably be carried out without the waiver
- When appropriate, the subjects will be provided with additional information participation

By far, the most challenging criterion to apply is the one pertaining to practicability of conducting research without the waiver. We gather this information via question #5 in the OHR-3.

Regulations

- **If the informed consent process cannot be waived per 46.116(d), then informed consent must be obtained from each participant prior to their enrollment in the research.**

Regulations

- **There are 3 regulatory options for consent:**
 - **Written consent form - embodies elements of informed consent as required by FDA & HHS regulations. (OHR-8)**
 - **Short form written consent – Sometimes erroneously referred to as “verbal” consent. (OHR-8S)**

Regulations

- **Waiver of written consent, if (choose 1):**
 - **The only record linking the subject and the research would be the consent document and the principal risk would be harm resulting from a breach of confidentiality.**
 - **The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.**

Short form consent

- **States that the elements of informed consent required by FDA & HHS regulations have been presented orally to the subject/ representative. A witness must be present. There must be a written summary of what is said to the subject. The subject/ representative signs and dates the short form consent statement (OHR-8S). The witness signs and dates both the short form and the summary. The person obtaining consent signs and dates the summary. Copies of the signed and dated short form and summary are given to the subject/ representative.**

Short form consent

- **This is an overly complicated process that is rarely used.**

Waiver of written consent

- **Used for:**
 - **Telephone surveys**
 - **Email surveys (e.g., Survey Monkey)**
 - **Interviews**
 - **Focus groups**

Waiver of written consent

- **OHR-8E is a verbal script template**
- **Used in tandem with OHR-8H (HIPAA verbal consent) where PHI is collected**

Regulatory Determinations

- **These regulatory determinations are made on a checklist for every study submitted to the IRB.**
- **Generally, they are made in the pre-review process.**
- **Checklist is filed in study folder, and consent determinations are documented in minutes of each meeting.**



THANKS