



Tips for Consenting

FAU HRPP



Overview

- Elements of consent
- Consent waivers
- Writing a Consent
- Art of Consenting



Informed Consent: General Requirements

(45CFR46.116)

- An investigator may not involve a subject in research without obtaining legally effective informed consent from the subject or the subject's legally authorized representative.
- An investigator shall seek consent only under circumstances that provide the subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.
- No use of exculpatory language that appears to waive the subject or representative's legal right or appear to release the investigator or sponsor from liability for negligence.
- Use of language that is understandable to subject or subject's legal representative (ie: Spanish speaking only must be consented with a Spanish language consent and must be presented in layman's terms).

Informed Consent: Basic Elements

(45CFR46.116 & 21CFR50.25(a))

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 - (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
 - (ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.



Informed Consent: Additional Elements

(45CFR46.116 (b) & 21CFR50.25(b))

As applicable



Consent Process and Documentation



Types of Consent

- Direct subject consent
 - For study populations over the age of majority
- Parental Permissions
 - When enrolling minors
- Legally Authorized Representative
 - For study populations with impaired decision-making capacity
- Assent
 - Minors
 - Persons with impaired decision-making capacity



Parental Consent vs. Parental Permission

Consent

- Should be used when the parent is a research subject
- Use standard direct subject consent
- If parent is also providing permission AND participating, use “you/your child” wording in document
- Include line for child’s name in signature section.

Permission

- Should be used when parent is ONLY providing permission
- Document should mirror all elements of consent, but use phrase “your child”
- Include line for child’s name in signature section.

Assent

- Used for subjects who have not reached age of majority;
- Written assent templates are available for ages 7-12 and 13-17;
- Children under age 7 generally may provide only verbal assent with parental permission and/or consent;
- When a child who was enrolled in research with parental or guardian permission reaches the legal age of consent to the procedures involved in ongoing research, the subject's participation in the research is no longer meets regulations regarding parental or guardian permission and subject

Obtaining Informed Consent

Time to read the consent

Ask questions and receive explanations

TAPC

Prior to study related procedures

Copy of document is provided to participant



Waiver of Documentation (WOD)

(45 CFR 46.117.c(2))

- An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all of the subjects if it finds any of the following:
 - 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.
 - The research presents no more than minimal risk of harm to the subjects and involves no procedures for which written consent is normally required outside the research context.
 - If the subjects or legally authorized representatives 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.

Examples of WOD

- Association with the study via a signature (or possession of consent form) poses risk- there is still an informed consent conversation, with a script.
- An expedited review study involves a phone survey. Subjects give oral consent over the phone but are not available to sign a form. Telephone call may be followed with mailing of information.
- An expedited review internet survey that retains the identity of the respondent provides all required elements of informed consent, however documentation is waived.

Waiver of Consent (WOC)

(45CFR46.116(e))

- An IRB may approved the waiver of consent or altering of the elements of consent provided the IRB finds and documents that:
 1. The research involves no more than minimal risk
 2. The waiver or alteration will not adversely affect the rights and welfare of the subjects
 3. The research could not practically carried out without the waiver or alteration; and
 4. whenever appropriate the subjects will be provided with additional pertinent information after participation.

Examples of WOC

- Non-sensitive data will be obtained from 5,000 medical records. Data will be coded but a key is necessary to verify accuracy of extracted data (retrospective).
- At-risk teens enroll in research but a WOC for parents is granted for protection of study population; IE: abusive situations.



Writing a Consent



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