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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).

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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

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
3. Any additional costs to the subject that may result from participation in the research.
4. (The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
6. The approximate number of subjects involved in the study.

For Clinical Trials

- If study involves research on standard of care (SOC) procedures, the SOC risks should be outlined and provided;
- HIPAA authorization language should be part of the consent document and process;
- If study meets criteria for clinicaltrials.gov registration, include language stating such.

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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 assent;
  - *Therefore, once a minor reaches age of majority, they must consent using the approved IRB document for direct subject consent.*

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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.

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Writing a Consent

Tips

- Keep it simple
- Have a friend, colleague, sibling review the consent for readability and comprehensiveness
- 6th to 8th grade reading level. Use the Flesch-Kincaid tool in MS Word to check for language level and reading difficulty.
- Examples:

  12th grade level: *If any significant new information about the study drug becomes available during your participation in the study, and that information might affect your willingness to continue in the study, the doctor in charge of the study will tell you about it.*

  5th grade level: *If we find out anything new about the study drug while you are in the study, we will let you know. This will help you to decide if you would like to continue.*

Top Consent Writing Errors

1. Rtyposd “Typos”.
2. Not outlining the risks- every study has a risk. State them and how they affect the subjects.
3. Using “I” language such as “I understand this study…”
4. Not ensuring your protocol matches your consent.
5. Overstating benefits and understating risks.
6. Not including interviews may be recorded via audio/visual .
7. Not telling subjects refusal to participate will not affect their employment status, academic standing, etc.
8. Not explaining what your survey/ interview/ study is about and how long it will take.
9. Not including your IRB number on the document.
10. Not detailing different populations in consent title. For example, include if consent is for 1) teachers, 2) students, or 3) parents.
11. Not including correct contact information for PI and IRB.

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