Writing a Consent

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Overview

• After this workshop you should be able to:
  • Identify elements of consent
  • Understand consent waivers
  • Recognize when a consent form requires changes
  • Draft a consent form
Informed Consent- General Requirements 45 CFR 46.116

• Consenting subjects
  - 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.
Informed Consent – General Requirements (Cont’d)

- 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 Requirements

45 CFR 46.116 and 21 CFR 50.25 (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; and
- (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.
Additional Elements

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

• (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.
CONSENT PROCESS AND DOCUMENTATION
Informed Consent Documentation

- **TAPC**
- **Time** to read the consent
- **Ask** questions and receive explanations
- **Prior** to study related procedures
- **Copy** of the signed form is provided to the subject.
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 either:
  • 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.
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 Informed Consent (WOC)

• An IRB may approve the waiver of consent or altering of the elements of consent provided the IRB finds and documents that:
  • The research involves no more than minimal risk
  • The waiver or alteration will not adversely affect the rights and welfare of the subjects
  • The research could not practically be carried out without the waiver or alteration
  • And...whenever appropriate the subjects will be provided with additional pertinent information after participation.
Examples of WOC

- Deception about the purpose of the study is part of the research design (Milgram Study)
- 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).
- Non-sensitive survey of all middle school students in the county and parental permission is impracticable. WOC may be indicated even in opt-out is required by the school system.
The Good, Bad and Ugly- Writing the Consent Form

• Keep it simple
• Have a friend, colleague, sibling review the consent for readability and comprehensiveness
• 6th to 8th grade reading level
• 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 Ten Consent Writing Errors

• Rtyposd “Typos”.
• Not outlining the risks- every study has a risk.
• Using the information sheet verbatim even when it is not applicable to your study.
• Using “I” language such as “I understand this study…”
• Not ensuring your synopsis matches your consent.
• Not including interviews may be recorded via audio/visual.
• Not telling subjects refusal to participate will not affect their employment status, academic standing, ability to procure cupcakes...etc.
• Not explaining what your survey/ interview/ study is about.
• Not including your IRB number on the document (you get this during the pre-review and can include it in follow up communication).
• And…. USING ALL CAPS WHEN WRITING AND SUBMITTING YOUR CONSENT FORMS
Questions

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- Your study will focus on combating infectious diseases such as the flu virus and staph at a local gym. Your survey of clients includes asking questions about hand washing, wearing shower shoes and cleaning the gym equipment after use. You will be collecting names and email addresses to survey the clients after implementing your infection prevention program. The surveys are fairly short and consist of 20 questions.
- How would you draft a consent form for this population?