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Informed Consent: Understanding the Process and Documentation Requirements

Informed Consent

Informed consent must meet the regulatory requirements of the US Department of Health and Human Services (DHHS) ([45 CFR 46.116](#)) and the US Food and Drug Administration (FDA) ([21 CFR 50.20](#)). Investigators may involve human participants in research only with the consent of the participant or his/her legally authorized representative, unless the IRB waives the requirement for informed consent. Consent designees who obtain informed consent must have human subjects research training and be knowledgeable about the study procedures. Children who may participate in research must be asked for their assent, unless the IRB waives that requirement. Consent and assent must be documented, and must have these elements:

Voluntary Participation: The potential study participant must be given enough time to consider whether or not to participate in the research, without coercion or undue influence. The circumstances surrounding the consent discussion must be such that the privacy of the potential participant is protected. It must be clear that the participant may say “no”.

Understandable Language: Consent forms or oral consent explanations must be in language understandable to the potential study participant or the individual’s legally authorized representative.

Comprehension: The investigator must be sure that the potential study participant understands what’s being asked of him/her. When appropriate, the application should address how the investigator will assess comprehension.

Waiver of Rights Prohibited: The consent (whether written or oral) may not include language through which the participant or LAR is made to waive the participant's legal rights or release the investigator, the sponsor, the institution or its agents from liability for negligence.

Waiver of Documentation

Under certain circumstances, the IRB may waive the documentation requirement and permit the investigator to obtain informed consent through a discussion with the potential participant that does not result in a signed consent document. This “**oral consent**” process involves the use of an IRB approved “oral script” which the investigator will use to guide the informed consent discussion. The waiver of documentation is limited to a waiver of the signature requirement; the discussion must still include all the required elements of informed consent, unless one or more of those elements is waived by the IRB. The investigator must also keep



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appropriate records of the discussion as part of the investigator's responsibility to keep study records under 45 CFR 115(b). The circumstances under which the DHHS regulations permit the IRB to waive consent documentation under 45 CFR 46.117(c) are:

- a. The only record connecting the participant to the research is the consent document, and that link poses a potential risk of harm to the participant if there is a breach of confidentiality; or
- b. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is generally required outside of the research context. In such cases, the IRB has the option of requiring that the investigator give the subjects a written statement about the research.

The FDA regulations also permit waiver of documentation under item (b) above (21 CFR 56.109(c)(1)).

There is no requirement that the consent designee or a witness sign the oral consent script itself as evidence that the consent discussion took place. However, the PI must keep a record that consent was obtained, when it was obtained, where, and by whom. This record may or may not include the identification of the study subject, depending upon IRB requirements.

Waiver or Alteration of the Elements of Informed Consent

The IRB may waive some or all of the basic and/or additional elements of informed consent that are listed in 45 CFR 46.116(a and b). This is a DHHS provision only – the FDA does not have a counterpart to this provision. A complete waiver of the consent elements means that the investigator does not have to ask the potential participant for agreement to be part of a study. The IRB may approve such a waiver if the following conditions are present and are documented by the IRB:

- a. The research involves minimum risk to subjects;
- b. The waiver or alteration will not adversely affect the rights and welfare of the participants;
- c. The research could not practicably be carried out without the alteration or waiver; and
- d. Whenever appropriate, the subject will be given additional information about the research after it is completed.

The IRB is most likely to approve a waiver of informed consent for research that involves use of existing, identifiable data or specimens; in such cases, it is often "impracticable" to obtain consent from the people linked to those specimens or data. Research which involves internet survey mechanisms, like surveymonkey,



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involves “implied consent” because the respondent has the choice of completing the survey or not completing the survey. Completion implies agreement, just as non-completion implies a negative decision. The IRB will require these types of research interactions to have some consent language on the first page of the survey.