Guidance on Waiver or Alteration of Informed Consent

Federal regulations require that informed consent be obtained from research participants for all non-exempt research unless a waiver or alteration is approved by the IRB. Further, the federal regulations specify that informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

The consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed;

or

(2) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

As mentioned above, unless a waiver or alteration is approved by the IRB, written consent must be obtained from research participants. Researchers must indicate that a waiver or alteration is being requested and provide a justification of how the applicable federal regulations are met in their applications. There are three ways the informed consent process can be changed so as long as the research meets the applicable regulations.

**Waiver of Informed Consent** – Informed Consent will not be obtained from subjects to participate in research.

**Alteration of Informed Consent** investigators can leave out or alter elements of informed consent.

**Waiver of documentation of Informed consent** signing of the consent form has been waived by the IRB
**Waiver of Informed Consent**

When a complete waiver of consent is granted, the Principal Investigator does not prepare a Consent Form or Information sheet and the participant is not told that his/her information is being used in a research study. The PI must explain why the research could not practically be carried out without the waiver.

Examples when a Waiver of Informed Consent may be requested:

- A study involving a retrospective chart review study extracting minimal risk data, where it is impracticable to contact all participants for consent.
- A study involving minors in a school setting and parental permission will not be obtained either by verbal or written confirmation. (Please see below section under special considerations)

What are the regulations:

An IRB may waive the requirement to obtain informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration;
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

**Alteration of Informed Consent**

In certain circumstances, the IRB may grant a partial waiver or alteration of certain required elements of the informed consent process. When a Principal Investigator requests an alteration to the consent form, a protocol-specific justification must be provided. IRB can approve the elimination or alteration of one or more of the 8 required elements of consent as per federal regulations which are listed below:

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.

Example of When an Alteration of Consent may be requested:

- A study involving the use of deception or non-full disclosure of the purpose of the study when the study design requires that subjects be left unaware of a particular purpose of the research because the subject’s response might be biased if they know in advance what the investigators are seeking.

What are the regulations?:

Please note the same regulations apply to both waiver of informed consent and alteration of informed consent.

An IRB may waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration;

and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
Waiver of documentation of consent

If a Principal Investigator is proposing to obtain informed consent for the research activity without obtaining the subject’s signature on a consent form, this is considered requesting a waiver of documentation of consent. If research participants will be given all the relevant consent information and have been asked for consent verbally, but a written consent document is not used, this is considered a waiver of documentation of consent. Waiving the requirement for a written form does not eliminate the requirement for informed consent. Subjects must be informed of the nature of the research, and their consent (or the consent of their legal representatives) must be obtained whenever appropriate. This type of waiver is useful for some telephone or internet surveys, questionnaires, or when signing the consent document could have a negative consequence for the subject.

The IRB will require the use of an Information Sheet to be given to the potential subject or an oral script to be read to the potential subject. Investigators will use the information sheet or script to guide them through the informed consent discussion/process. The Principal Investigator will not need to obtain the subject’s signature on a consent form. The script or information statement must be provided to the IRB at the time of original protocol submission for review and approval. The PI and/or research staff will document the participant's consent, as well as date, and the name of the person conducting consent in the study files.

Examples of when a Waiver of Documentation of consent for study may be requested:

- A study involving an online or phone survey.
- A study involving a procedure that does not normally require consent.
- A study where having the signatures/names on record could put the participant at risk of harm.
- A study involving minors will use “passive consent” where parents/guardians will be given all of the consent information but not asked for their signature on the form. (Please note, the parents/guardians must still agree to have their child participate.)

What are the regulations:

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects it if finds either:

(1) That 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. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That 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.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.
Special Considerations:

When Consent can be waived for Public Benefit or Service Programs

The federal regulations state consent can be waived when:

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

2. The research could not practicably be carried out without the waiver or alteration.

Research Involving Minors: Waiver or alteration of parental/guardian permission

The IRB may waive parental or guardian permission if:

a. regular conditions for waiver of consent are met (see 45 CFR 46.116(c) or 46.116(d));

   1. The research involves no more than minimal risk to the subjects;
   2. The waiver or alteration will not adversely affect the rights or welfare of the subjects;
   3. The research could not be practicably carried out without the waiver; and
   4. Whenever appropriate, the subjects (and parents) will be provided with additional pertinent information after participation.

OR

b. parental or guardian permission is not a reasonable requirement to protect the children and an appropriate mechanism is substituted; for example, if the study: focuses on a condition or is a study of such a private and sensitive nature that it is not reasonable to require permission, (for example, adolescents in studies concerning treatment of sexually transmitted disease); or involves a subject population such as abused or neglected children. [45CFR46.408(c)]