INDIVIDUAL INFORMED CONSENT
AND
CONSENT WAIVERS

DHHS and FDA GENERAL REQUIREMENTS FOR INFORMED CONSENT (45 CFR 46.116, 21 CFR 50.20)

Information given to a subject or a subject's legally authorized representative shall be in language understandable to the subject or the representative.

No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

BASIC ELEMENTS OF WRITTEN INFORMED CONSENT (45 CFR 46.116(a) and 21 CFR 50.25)

Except as provided in 45 CFR 46.116(c) or 45 CFR 46.116(d) below, in seeking informed consent the following information shall be provided to each subject:

- 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;
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others which may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- 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;
- 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
- 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 OF WRITTEN INFORMED CONSENT (45 CFR 46.116(b))

When appropriate, 1 or more of the following elements of information shall also be provided to each subject:

- 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;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- 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; and
- The approximate number of subjects involved in the study.

21 CFR 50.25 and 45 CFR 46.116(a) elements of informed consent are virtually identical except:

- 50.25(a)(5) requires the confidentiality statement to note "the possibility that the FDA may inspect the records."
- 46.116(c) and (d) state the conditions under which the IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent (the conditions *could not apply in FDA regulated research*).

WAIVER UNDER SPECIFIC LIMITED CONDITIONS (45 CFR 46.116(c))

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

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:
    a. Public benefit or service programs;
    b. Procedures for obtaining benefits or services under those programs;
    c. Possible changes in or alternatives to those programs or procedures; **OR**
    d. 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.

COMPLETE WAIVER OF ALL INFORMED CONSENT (45 CFR 46.116(d))

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements 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 (no signed consent, information sheet provided) (45 CFR 46.117(c))

NOTE: THIS TYPE OF WAIVER IS NOT ALLOWED UNDER FDA REGULATIONS.

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

FDA DOCUMENTATION OF INFORMED CONSENT (21 CFR 50.27)

(a) Informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent. A copy shall be given to the person signing the form.

(b) Except as provided in 56.109(c), the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by 50.25. This form may be read to a subject or a 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.

21 CFR 50.27 and 45 CFR 46.117 Documentation of informed consent are virtually identical except:

- 46.117(c)(1) is not included in FDA's comparative section contained in 56.109(c). 46.117(c)(1) allows the IRB to waive the requirement for the investigator to obtain a signed consent form if it finds 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.

SHORT FORM (45 CFR 46.117(b)(2) and 21 CFR 50.27(b)(2))

A short form written consent document stating that the elements of informed consent required by 45 CFR 46.116 or 50.25 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.

References:

- DHHS Human Subject Regulations Decision Charts
- DHHS regulations: 45 CFR 46
- DHHS Informed Consent Checklist - Basic and Additional Elements
- DHHS Tips on Informed Consent
- DHHS Guidance documents on informed consent
- DHHS Exculpatory language in Informed Consent
- DHHS Informed Consent FAQs
- FDA A Guide to Informed Consent
- FDA 21 CFR 50, consent regulations
- Comparison of FDA and HHS Human Subject Protection Regulations
- DHHS Short form use guidance
- FDA Short form use guidance