

Michigan State University Human Research Protection Program	
<i>Subject:</i> Informed Consent	
<i>Sub-Topic:</i> Documentation of Informed Consent	
<i>Section:</i> 6-4-A	<i>This policy and procedure supersedes those previously drafted.</i>
<i>Reviewed by: IRB, URC, UGC, MSU Legal Counsel; Revision reviewed by HRP/IRB Administrative Committee</i>	<i>Approved by: Vice President of Research and Graduate Studies, 4-21-05; Revision approved by the Vice President of Research and Graduate Studies on 11-2-2005</i>
<i>Related Sections: 5-5, 8-2, 8-3</i>	

Policy

Documentation of informed consent is required unless the Institutional Review Board (IRB) approves a waiver of documentation.

Documentation of informed consent usually involves the use of a written consent form that subjects sign and date. A copy of the consent form must be given to the subject as a reference and a reminder of information reviewed. The IRB requires full board review medical protocols to include proof of subject receipt. The consent form, however, does not by itself constitute informed consent. The consent form should be used as a tool by which the investigator explains and discusses the research procedures with the subject, allowing the subject ample opportunity to ask questions.

The consent form must contain all the elements of consent required by 45 CFR 46.116 or 21 CFR 50.25 for approval, unless a short form has been approved and is used (see below for details of the use of a short form).

If the investigator will not be obtaining the signature of the subject or the subject's legally authorized representative, a waiver of documentation should be requested.

Regulatory Requirements for Documentation of Informed Consent

DHHS: "Except as provided in paragraph (c) of this section, 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" 45 CFR 46.117(a)

FDA: "Except as provided in § 56.109(c), 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" 21 CFR 50.27(a)

DHHS (45 CFR 46.117(b)) & FDA (45 CFR 50.27(b)), "Except as provided in [45 CFR 46.117(c) or §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 [§46.116 or §50.25]. 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.”
- “(2) A *short form* written consent document stating that the elements of informed consent required by [§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.”

Documentation

The consent form must be signed and dated by the subject or the subject's legally authorized representative, unless a waiver of documentation is granted.

Short Form Requirements

1. A witness is required when this method is used.
2. A summary (oral script) with all the elements of informed consent required by *45 CFR 46.116 or 21 CFR 50.25* is presented orally to the subject or the subject's legally authorized representative.
3. This summary (oral script) must be submitted to and approved by the IRB.
4. The short form should include a statement that the elements of informed consent required by *45 CFR 46.116 or 21 CFR 50.25* have been presented orally to the subject or the subject's legally authorized representative.
5. Signature and Date:
 - a. Subject or legally authorized representative: short form
 - b. Witness: short form and summary (oral script)
 - c. Person obtaining consent: summary (oral script)
6. A copy of the short form and summary (oral script) should be given to the subject or legally authorized representative.

Waiver of Documentation

In some instances, particularly with regard to special populations and international studies, the IRB should consider whether documented informed consent is appropriate. It is up to the responsible investigator to inform and educate the IRB about special cultural situations. The IRB's responsibility is to consider the information and make decisions appropriately.

Oral Consent

To approve oral consent, the IRB must find the criteria for a waiver of documentation are met. While the informed consent document is usually written, occasionally informed consent may be obtained orally in situations in which written consent is deemed culturally disrespectful or inappropriate. In all cases, the IRB must review in advance

the language that will be used in obtaining oral informed consent. Researchers proposing to obtain informed consent orally must include a script of the oral consent language and content with their IRB application. Oral informed consent should include all the elements of informed consent and contact information, and should be given to subjects in writing. Investigators should keep a log documenting the oral consent process throughout the duration of the study.

Criteria for Waiver of Documentation

DHHS - 45 CFR 46.117:

“(c) 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 - 21 CFR 56.109:

“(c) An IRB shall require documentation of informed consent in accordance with §50.27 of this chapter, except as follows:”

“(1) The IRB may, for some or all subjects, waive the requirement that the subject, or the subject’s legally authorized representative, sign a written consent form if it finds 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 the research context; or”

“(2) The IRB may, for some or all subjects, find that the requirements in § 50.24 of this chapter for an exception from informed consent for emergency research are met.”

“(d) In cases where the documentation requirement is waived under paragraph (c) (1) of this section, the IRB may require the investigator to provide subjects with a written statement regarding the research.”

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.

To request a waiver of documentation, the investigator must provide documentation that the criteria for (1) or (2) is met.

Review and approval of Waiver of Documentation follows the procedures as required by the category of review. See Section 8-2, "Expedited Review Procedure", and/or Section 8-3, "Full Board Review Procedure", of the HRP Manual for policies and procedures.

The IRB or an IRB member shall review the investigator's documentation and determine if the waiver criteria have been satisfied.

If the waiver criteria have been satisfied, an IRB member shall document that the conditions for a waiver have been met and how. A standard form shall be used for documentation.

For full board review protocols, the waiver of documentation information shall be recorded in the minutes of the IRB meetings. See Section 5-5, "Meetings", of the HRP Manual.