Policy Statement

This policy describes the policy and procedures for Institutional Review Board (IRB) review of research involving the required documentation of informed consent and waivers of required documentation of informed consent.

Initial Screening

Upon acceptance of a complete package, the Research Integrity office staff makes a preliminary determination as to whether this policy applies to the study. If the process for documenting written informed consent or the request for a waiver of documentation of informed consent does not meet the criteria for review per this policy, the Research Integrity office staff returns the application to the researcher for further clarification.

Documentation of Informed Consent (45 CFR §46.117b)

Informed consent must be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form. The informed consent form may be either of the following:

1. A written informed consent form that meets the requirements of §46.116. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative.
2. A short form written informed consent form 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, and that the key information required by §46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. When the use of the short form consent process is approved:
    a. The IRB must approve a written summary of what is to be said to the subject or to the person authorized to consent for the subject.
    b. There shall be a witness to the oral presentation and the witness shall sign both the short-form and a copy of the written summary.
    c. The person obtaining consent shall sign a copy of the summary.
    d. A copy of the written summary shall be given to the subject or the person authorized to consent for the subject, in addition to a copy of the short-form consent language.

Waiver of Documentation of Informed Consent (45 CFR §46.117c)

The IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

1. The only record linking the subject and the research would be the informed consent form, the research is not FDA-regulated, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
2. 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; or
3. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

Review

All required elements related to documentation of informed consent are included in the informed consent templates provided by the IRB. The templates should be modified as appropriate for the study. The informed consent form submitted with the study package should be the final version of the form.

The assigned reviewers are expected to evaluate the procedure for documenting informed consent from the perspective of addressing the requirements described within 45 CFR 46.117, 21 CFR 50 (if applicable), and any other relevant ethical or compliance considerations.

The IRB reviewers make the final determination as to whether the procedures for documenting informed consent meet the criteria for review and approval under this policy.

Additional Information

For additional information on the informed consent process, see the informed consent guidance offered by the Office of Human Research Protections (OHRP).

For information on requirements for informed consent and waivers of informed consent, refer to the policy: Informed Consent / Waiver of Informed Consent

Policy Updates

Date	Update
21-Jan-2019	Updated to reflect the implementation of the Revised Common Rule regulations