



WAIVER OF DOCUMENTATION OF CONSENT/AUTHORIZATION

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A potential research subject's agreement to participate in a research study is usually documented by the subject indicating his/her approval to participate by signing and dating the consent form which includes, where appropriate, the HIPAA authorization information (referred to hereafter as the consent form). However, for certain types of research, the DUHS IRB may approve a waiver of documentation of consent (45 CFR 46.117(c) and 21 CFR 56.109(c)(1)) and HIPAA authorization (45 CFR 164.512(i)(2)). In this case, evidence of the subject's research participation would be evidence that the research subject had been willing to participate. These forms are available on the DUHS IRB website.

Whenever the DUHS IRB approves a consent process involving waiver of documentation of consent/authorization, the IRB ordinarily would need to approve a written description of the study that also contains all of the elements of consent/authorization. This written description may be in the form of a script for verbal use, such as during a telephone conversation. However, the IRB may approve an alteration of consent/authorization if some elements are omitted. The IRB must always approve a waiver of documentation of consent and, where appropriate, an alteration of authorization if the investigator will not obtain a consent form signed and dated by the research participant.

Under certain circumstances the Common Rule allows the IRB to waive written consent (documentation of consent) (45 CFR 46.117(c)):

An IRB may waive the requirement for the investigator to obtain a signed and dated 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 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.

When the research involves an FDA-regulated product, the IRB may waive written consent only for research that meets item (2) above (21 CFR 56.109(c)(1) and 45 CFR 46.117(c)(2)).

The DUHS IRB considers the following points when assessing whether to approve waiver of documentation of consent:

- Does the written description or script for presentation to the potential subject include the required elements of consent, and additional elements, if applicable?
- Does the written description or script for presentation to the potential subject include the required elements of authorization?
- Does the written description or script include the requirement for the signature of the subject or his/her legally authorized representative?
- If the written description or script is to be signed and dated by the subject or his/her legally authorized representative, and the consent process occurs by telephone, does the written description or script include the requirement for signature by a witness to confirm the identity of the subject?
- Does the research involve no more than minimal risk, and would written consent be required for the study procedures if they were not part of a research study?

In most cases a written consent form must be used to document consent/authorization of the subject or the subject's legally authorized representative. The consent form must include the elements of consent required by 45 CFR 46.116 and 21 CFR 50.25, and must be signed and dated by the subject or his/her legally authorized representative. However, unless required by the research protocol and the nature of the research, the research subject is not required (21 CFR 312.62(b)) to indicate the time of signing the consent form. The consent form template is available on the DUHS IRB web site: <http://irb.mc.duke.edu/>.

The DHHS and FDA consent documentation requirements [45 CFR 46.117(2) and 21 CFR 50.27(2)] permit the use of a "short form" written consent document that states that the elements of consent have been presented orally to the subject. The DUHS IRB permits use of the "short form" written consent document when the investigator unexpectedly encounters a non-English speaking subject and a written translation of the entire IRB-approved consent form cannot be provided in a language understandable to the subject in a timely manner. In such cases, the investigator must follow the "DUHS IRB Policy on Research Involving Non-English Speaking Subjects" found at the IRB web site.

The use of a "short form" also requires an alteration of HIPAA authorization unless all elements of a valid authorization are included in the "short form".

Examples of situations where the IRB may waive or alter the requirement for documentation of consent/authorization include studies limited to focus groups, or mail or telephone surveys or interviews. When the IRB waives or alters the requirement for written documentation of consent/authorization, the findings will be documented by the IRB Writer in the Minutes or in supporting documents submitted by the PI, or if through the expedited review procedure, in the review form completed by the authorized IRB reviewer or in supporting documents submitted by the PI.