WAIVERS OR ALTERATIONS OF CONSENT AND HIPAA AUTHORIZATION

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I. OVERVIEW

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, HIPAA authorization information (referred to hereafter as the consent form). 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 their legally authorized representative. The consent form template is available on the DUHS IRB web site: https://irb.duhs.duke.edu/forms.

When 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.

II. SCREENING, RECRUITMENT, OR DETERMINING ELIGIBILITY

Under the revised Common Rule, an IRB may approve a proposal for the investigator to obtain information or biospecimens to screen, recruit, or determine eligibility of prospective subjects for a research study without informed consent. Essentially, the revised Common Rule removes the pre-2018 Common Rule requirement for an IRB to approve a waiver of informed consent for these types of activities. This is applicable if:

- The information is obtained through oral or written communication with the subject or the subject's legally authorized representative, OR
- Identifiable private information or identifiable biospecimens are obtained by accessing records or stored identifiable biospecimens.

This change harmonizes with FDA.

III. WAIVERS AND ALTERATIONS OF CONSENT

A. Research Not Subject to FDA Oversight

Under certain circumstances the Common Rule allows the IRB to modify the standard consent procedure (45 CFR 46.116(e) - (f)).

For research involving public benefit and service programs conducted by or subject to the approval of state or local officials, 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 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:
   - Public benefit or service programs
   - Procedures for obtaining benefits or services under those programs
   - Possible changes in or alternatives to those programs or procedures, OR
   - 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.

For other research, 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 provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects
2. The research could not practicably be carried out without the requested waiver or alteration
3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects
5. Whenever appropriate, the subjects will be provided with additional pertinent information after participation

B. Research Subject to FDA Oversight

In accordance with FDA Guidance (https://www.fda.gov/media/106587/download), a waiver of informed consent for certain FDA-regulated minimal risk clinical investigations may facilitate investigators' ability to conduct studies that may contribute substantially to the development of products to diagnose or treat diseases or conditions, or address unmet medical needs. Under that guidance, the FDA indicated an intention to revise its informed consent regulations to add this waiver or alteration. Until the regulations are updated, however, the FDA has indicated that it will not "object to an IRB approving a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth in 21 CFR 50.25, or waiving the requirements to obtain informed consent when the IRB finds and documents that:

1. The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects
3. The clinical investigation 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.

IV. WAIVER OF DOCUMENTATION OF CONSENT

A. Research Not Subject to FDA Regulation

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 any of the following:

1. That the only record linking the subject and the research would be the informed consent form 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. 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
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 with a written statement regarding the research.

B. Research Subject to FDA Regulation

When the research involves an FDA-regulated product, 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 (21 CFR 56.109(c)(1)).

C. IRB Considerations

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 their legally authorized representative?

- If the written description or script is to be signed and dated by the subject or their 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?

V. SHORT FORM CONSENTS

The HHS and FDA consent documentation requirements permit the use of a "short form" written consent document that states that the elements of consent have been presented orally to the subject. (45 CFR 46.117(b)(2) and 21 CFR 50.27(2)) The DUHS IRB generally 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 *"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".

VI. IRB DOCUMENTATION

The IRB will document any such waivers or alterations of consent/authorization (and its documentation) in the IRB application, and in the meeting minutes of a convened board meeting or by the authorized IRB reviewer if through the expedited review procedure.

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