University of Colorado Boulder

Institutional Review Board
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Guidance Document:

Waiver of Written Documentation of Consent for Non-Exempt Research

Background

Informed consent is one of the fundamental principles of ethical conduct in the use of human subjects. In most cases, informed consent for non-exempt research must be documented by the use of a written consent form or short form, approved by the IRB and *signed by the subject* or the subject's legally authorized representative. It is the signature by the research subject or the subject's legally authorized representative that is referred to as "written documentation of informed consent" at 45CFR46.117.

However OHRP regulations provide for exceptions to the requirement to obtain a signed Consent Form. Three sets of conditions may now be used to justify not obtaining a signed consent form:

> 1) 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;
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> 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
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> OR
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> 3) 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.

The third criteria is new in the 2018 regulations.

If your research fits one of these exceptions, the IRB may approve a waiver of documentation of informed consent. A waiver of documentation of informed consent must be approved by the IRB in order to obtain verbal or other non-signed consent from potential subjects, including some forms of electronic or online consent documentation.

When is a waiver of documentation of consent used?

Obtaining verbal or non-signed consent in place of written consent may be the only feasible way to obtain consent from subjects:

- For example, this could be true when working with non-literate populations.
- Obtaining consent in many online interactions may require a waiver of documentation of consent. This would include both the use of a checkbox or radio button item to indicate consent for a survey, as well as any non-verifiable form of signature such as a simple typed name and

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date. The use of secure, verifiable online-signature services, such as DocuSign (used by CU Boulder) meets the requirement for signed, documented consent and does not require this waiver.

- Waiver of written documentation of consent may also be appropriate when doing research about dangerous, illegal, or stigmatizing activities, but only where no other identifying information is collected.
- The regulatory criteria for waiver of written documentation of consent now includes issues of tradition, stigma, taboo, etc. that may be encountered in some cultures or settings.

When is a waiver of documentation of consent not appropriate?

- A waiver of written documentation of informed consent refers *only* to the requirement to obtain a signature on a consent form provided to the participant. This does not absolve the investigator from conducting the rest of the Consent Process, to include providing the potential participant all of the regulatorily-required consent information, in a manner that is readily understandable to that participant, and ensuring that the participant is provided adequate time to consider their participation and make a free and voluntary choice to participate or not in the research. If any of this information is not provided, or the consent process will not be accomplished, a "waiver of consent" would likely be required instead. For more information please see the IRB's guidance document, here: Waiver of Informed Consent.
- If your research is **Exempt**, a formal waiver of written documentation of consent is **not** required in order to use an alternative means of documenting consent as described in this document. The requirement to obtain a signature to document consent stems from the federal human subjects regulations. If a study is Exempt, the regulatory requirements, including this one, do not apply. In an Exempt study, simply describe in the Protocol the process by which you will be obtaining and documenting consent, to the extent appropriate for your research. If you are unsure whether your study will be Exempt when developing the Protocol, the IRB suggests including the waiver information anyway to save time on possible revisions later.

Other reasons for using verbal consent that would not be approved by the IRB include:

- I don’t have enough money in my research grant to print consent forms
- I don’t have a staff member who can handle all the paperwork involved in written consent.
- I already have access to the patient records.
- If I try to consent people, they will not want to participate in the study.
- The consent form template is too long and people won’t want to participate.

What should I do if I want to waive written documentation of consent in my research?

1. Your Protocol Document must describe your consent process:
   - Describe how the consent information will be provided to the study participants. You or an IRB-approved co-investigator may explain the study to the potential subject verbally, or the information may be included as a mandatory pre-requisite to starting the research if online. For

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verbal consent, a script must be submitted to the IRB for review. A verbal consent script should include the same elements of consent as would be in a consent form, but in a more conversational style. An online consent form should follow the general IRB-provided Consent Form Template.

- If appropriate, you should give subjects a written statement about the research. This statement should also include the basic elements of informed consent. You could use an IRB-approved consent form, a study information sheet, or other written materials. These written materials must also be provided for IRB review.
- In some cases, it is not appropriate to give out written material - for example, if the written record could be damaging to the subject. If you will not provide subjects with a written statement about the research, you should provide a justification in your protocol. You should consider if any written information could be given to subjects that could be helpful, e.g., a card with your contact information. Again, any written information must be submitted for IRB review.
- As with all consent procedures, subjects must be given sufficient time to consider whether or not to participate in the research. After allowing the potential subject sufficient time, you should answer any additional questions they may have. Then you may obtain verbal consent to participate in the research.
- For online consent, you should describe in the protocol a method to allow research participants to contact you with any questions they may have before deciding to participate in the research.
- We also suggest that investigators include a mechanism for tracking those who were approached about the study and have provided verbal consent. For example, a chart or log could be used to indicate the subjects in a non-identifiable manner (e.g., S001, S002, S003) and the date verbal consent was given.
- When it is important to have some record of the informed consent but when written or signed consent would place the subject at risk or be difficult for the subject to read, it can be useful to have a colleague witness the verbal consent.

2. Your Protocol Document must include justification for the waiver of documentation of informed consent. The justification must be directly on-point to one of the exceptions described in the Background section of this Guidance Document.
3. The Consent Form or Script must be consistent with the described consent documentation process. If a checkbox mechanism will be used, provide the text and example checkbox in place of the signature block. If no documentation will be obtained in conjunction with the Consent Form itself, remove the signature block entirely from the submitted document.

Additional Reading:

Regulatory Requirements for Documentation of Informed Consent per 45CFR46.117

The Office of Human Research Protections provides an Informed Consent Checklist, here: http://www.hhs.gov/ohrp/policy/consentckls.html. This includes the required Elements of Consent, and a brief discussion of Waivers.