

Guidance Document: Verbal Consent in Non-Exempt Research

Background

Verbal consent means that subjects do not provide written consent to participate in research. Sometimes it is called oral consent.

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 document or short form approved by the IRB and signed by the subject or the subject's legally authorized representative. OHRP regulations provide for exceptions to this rule under two conditions:

1. 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. This is not applicable for FDA-regulated research;

- Or -

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.

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 consent from potential subjects.

When is verbal consent used?

Obtaining verbal consent in place of written consent may be the only feasible way to obtain consent from subjects. For example, this could be true when recruiting subjects and completing screening surveys over the phone or working with non-literate populations. It may also be appropriate when doing research about dangerous, illegal, or stigmatizing activities where no other identifying information is collected.

When is verbal consent not appropriate?

Here are some reasons for using verbal consent that would not be approved by the IRB:

- 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 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 use verbal consent in my research?

1. Your IRB application (Initial Application - eForm and protocol) must describe your consent process:
 - You or an IRB-approved designee should explain the study to the potential subject verbally. A **script for verbal consent** 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. (Please see <http://www.hhs.gov/ohrp/policy/consentckls.html> for the elements of consent.)

- 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. The 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.
 - 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. It is important that you do not enroll more subjects than were approved by the IRB.
 - 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 IRB application must include justification for the waiver of documentation of informed consent. The justification must be directly on-point to one of the two exceptions described in the [Background](#) section of this Guidance Document.