

	VERBAL INFORMED CONSENT AND VERBAL HIPAA AUTHORIZATION			
	P & P	VERSION DATE	REPLACES P & P	PREVIOUS VERSION DATE
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VERBAL INFORMED CONSENT

In cases where a waiver of documentation of informed consent is requested, verbal informed consent may be allowed.

Verbal informed consent occurs when a member of the research team and a potential subject verbally interact, and the subject gives their consent to participate verbally. The member of the research team and the subject can be in the same location or can be communicating over the phone or through some other electronic means (i.e. Zoom).

Requirements for Granting Waiver of Documentation of Informed Consent

For research regulated by the 2018 Common Rule [45 CFR 67.117(c)], the IRB may waive the requirement for documentation of informed consent and allow for verbal informed consent if either of the following apply:

- (i) The only record linking the subject and the research would be the signed informed consent form, and the principal risk would be potential harm resulting from a breach in confidentiality, and each subject or LAR will be asked whether the subject wants documentation linking them with the research; or,
- (ii) 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.

For research involving distinct cultural groups that is regulated by the 2018 Common Rule [45 CFR 67.117(c)(iii)], the IRB may waive the requirement for documentation of informed consent and allow for verbal informed consent if all of the following apply:

- The research presents no more than minimal risk of harm to subjects;
- The subject or LAR is a member of a distinct cultural group or community in which signing forms is not the norm; and,
- There is an appropriate, alternative mechanism for documenting that informed consent was obtained.

For research regulated by the FDA [21 CFR 56.109(c)(1)], the IRB may waive the requirement for documentation of informed consent and allow for verbal informed consent if:

- 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 where the documentation requirement is waived and verbal informed consent is allowed, the IRB requires the investigator to provide the subject, either printed or electronically, with an information sheet. When verbal consent will be obtained over the phone or via other electronic means, the IRB also requires that the study team have a script to be used by the person obtaining consent.

**A waiver of documentation of informed consent does not release the research team from obtaining a fully informed consent*

Basic Elements of Verbal Informed Consent

In seeking verbal informed consent, the following information shall be provided via script, information sheet, or both to each subject:

- A brief description of the purpose of the study, and the procedures to be followed;
- A statement clarifying participation is voluntary;
- A brief description of any reasonably-foreseeable risks to the subject;
- A brief description of any benefits to the subject or others which may reasonably be expected;
- A disclosure of appropriate alternatives to participation;
- A brief description of how confidentiality of records will be maintained;
- A brief description about compensation and costs to the subject;
- Contact name and information for a subject's questions, suggestions, or concerns;
- A brief description of circumstances when a subject's participation might be terminated;
- A brief description of the consequences of a subject's decision to withdraw; and,
- A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

Addressing Verbal Informed Consent in the Protocol

The study protocol must describe the following information about verbal informed consent:

- The research team members who are responsible for obtaining verbal informed consent;
- How the information will be presented to the subject;
- When the verbal informed consent will take place;
- Where the verbal informed consent will take place; and,
- How verbal informed consent will be documented.

VERBAL HIPAA AUTHORIZATION

Requirements for Granting Alteration of HIPAA Authorization

Under the Privacy Rule, the IRB may grant an alteration of HIPAA authorization and allow for verbal HIPAA authorization if some or all of the following apply:

- The use or disclosure of protected health information involves no more than minimal risk to the privacy of the subjects based on, at least, one of the following:
 - An adequate plan to protect the identifiers from improper use or disclosure; and/or,
 - An adequate plan to destroy the identifiers at the earliest opportunity, unless there is a health, legal, or research justification for retaining the identifiers; and/or,
 - Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information; and/or
- The research could not practicably be conducted without the waiver or alteration; and/or,
- The research could not practicably be conducted without access to and use of the protected health information.

In cases where the HIPAA authorization requirement is altered and verbal HIPAA authorization is allowed, the IRB may require the investigator to provide the subject, either printed or electronically, with a HIPAA Authorization document without subject information lines and signature lines. When verbal authorization will be obtained over the phone or via other electronic means, the IRB also requires that the study team have a script to be used by the person obtaining authorization.

DOCUMENTING VERBAL INFORMED CONSENT AND HIPAA AUTHORIZATION

When a waiver of documentation of informed consent is granted under 45 CFR 67.117(c)(i) (*the only record linking the subject and the research would be the signed informed consent form, and the principal risk would be potential harm resulting from a breach in confidentiality, and each subject or LAR will be asked whether the subject wants documentation linking them to the research*), the IRB requires that the person consenting provide the option for the subject or LAR to sign the verbal informed consent document (*e.g.*, script and/or information sheet). Whether or not the subject or their LAR decides to sign, the person consenting should also sign the verbal informed consent form and document how verbal consent was obtained.

When the waiver of documentation of informed consent is granted under any other category, the IRB requires the person consenting to sign either the verbal informed consent form (information sheet) if consenting in person or the verbal informed consent script if consenting over the phone or via other electronic means. The person consenting should also document how verbal consent was obtained.

The same requirements apply for documenting verbal HIPAA authorization when the IRB has granted an alteration of HIPAA authorization.