

Guidance Document on Creating a Verbal Consent and Template

If you are obtaining a verbal informed consent, you must submit script containing all of the elements of informed consent that will be presented verbally to the patient: 1) research/purpose/procedures, 2) risks, 3) benefits 4) alternatives, 5) confidentiality, 6) compensation for injury, 7) whom (and how) to contact, and 8) the voluntary nature of human research and the ability to withdraw. Additionally, in some studies 9) risk to fetus, 10) investigator termination of subject participation, 11) additional costs, 12) consequences of withdrawal, 13) reporting of significant new findings and 14) the approximate number of subjects to be enrolled may be required to be disclosed as part of consent.

If you are using a verbal consent, you must apply for a *waiver of informed consent* and a *waiver of signed informed consent*.

Waiver of Informed Consent

Even though the researcher is getting a verbal consent, the regulations state: The IRB may approve a consent **procedure** which does not include, or which **alters**, some or all of the elements of the informed consent set forth in 45 CFR 46.116. The IRB must find and document the following evidence to approve the waiver:

1. the research involves no more than minimal risk to the subjects;
2. the waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. the research could not practicably be carried out without the waiver or alteration;

and

4. whenever appropriate, the subjects must be provided with additional pertinent information after participation;

OR

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.

Note: Informed Consent cannot be waived under these criteria for FDA-regulated research. Note that some research involving FDA-regulated products is not FDA-regulated and that some research that does not involve FDA-related products is FDA-regulated. Exceptions from the FDA requirements for informed consent may be waived for emergency situations (21 CFR 50.23) or for emergency research (21 CFR 50.24).

Waiver of Authorization

The IRB may approve a authorization **procedure** which does not include, or which **alters**, some or all of the elements of the authorization informed consent set forth in 45 CFR 164.512(2)(ii). The IRB must find and document the following evidence to approve the waiver:

1. The risks to privacy involved in this study and explain why the study involves no more than minimal risk to privacy
2. Investigator's plan to protect identifiers from improper use or disclosure and to destroy them at the earliest time
3. It is not possible to seek subjects' authorization for use or disclosure of the PHI

4. It is not possible to conduct this research without use or disclosure of the PHI

Documentation of Informed Consent (Signed Consent)

Informed consent must be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117 or 21 CFR 50.27.

1. Informed consent is documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent.
2. A copy of the signed and dated consent form must be given to the person signing the form.
3. The consent form may be either of the following:
 - a) a written consent document that embodies the elements of informed consent may be read to the subject or the subject's legally authorized representative, but the subject or representative must be given adequate opportunity to read it before it is signed; or
 - b) a short form written consent document stating that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. When this method is used:
 - there must be a witness to the oral presentation; and
 - the IRB must approve a written summary of what is to be signed by the subject or representative; and
 - the witness must sign both the short form and a copy of the summary; and
 - the person actually obtaining consent must sign a copy of the summary; and
 - a copy of the summary must be given to the subject or representative, in addition to a copy of the short form.

Note: Waiver of documentation of consent does not release the researchers from obtaining fully informed consent.

Protocol Information

The protocol must describe formally how, when and where the verbal consent process will be completed. Who will be completing the process and how documentation and information about the study will be given.

Below is a template should be used if you are seeking a verbal consent. This template is also available on the IRB Web site under the Consent Tab.

Verbal Consent Template

Here is some sample text to get you started:

Hello, my name is _____. I am a (*student/faculty member/staff member*) from the New York University School of Medicine conducting a survey (research) about _____ (*what and why studying it*). Your participation is completely voluntary. This means that you do not have to participate in this survey unless you want to. Would you be willing to answer some questions about _____? The research survey will take (*approximate time*) (*If yes, continue. If no, thank them for their time and end the call.*)

Thank you for agreeing to participate. I hope that you will do your best to answer all the questions, as it is helpful to have the most complete survey possible. (*If applicable*) However, if you find some of the questions difficult or sensitive in nature and do not wish to answer a question, just tell me and we will skip it, and go on to the next one. I appreciate your time.

The purpose of this research study survey is to look at the relationship between _____.

We estimate that approximately (number of subjects) will enroll in this study

As part of our formal study, we will be asking people to complete a series of questionnaires and interviews about their (mood state, their levels of self esteem, the kinds of problems they experienced growing up, and the like.) There is a possibility that some of these questions may make you uncomfortable or

distressed; if so, please let me know. You don't have to answer those questions if you don't want to. You also need to understand that all information that I receive from you by phone, including your name and any other identifying information {if applicable}, will be strictly confidential and will be kept under lock and key.

I will not identify you or use any information that would make it possible for anyone to identify you in any presentation or written reports about this study. If it is okay with you, I might want to use direct quotes from you, but these would only be cited as from a person (or if person has a specific label or title, it might be used). There is no expected risk to you for helping me with this study. There are no expected alternatives or benefits to you either. When I get back all the surveys of everyone who has agreed to participate, I will group all the answers together in any type of report or presentation. There will be no way to identify individual participants.

Do you still want to talk with me? Remember, your participation is voluntary; you do not have to complete these questions.

(If applicable) You will be told of any significant new findings developed that may influence your willingness to continue to participate in the research.

(If applicable) study-related costs associated with your being in this study will be paid by the sponsor, [Sponsor Name]. You or your insurance company will [will not] be charged or held responsible for the costs of your routine care (the care you would have received if you were not in this study)."

(If applicable) If you do not agree to verbally consent to participating in this study, you will continue to receive care, but not as a part of this study.

- The sponsor of this study, [Sponsor Name], is paying New York University to perform this research."
- This study is being sponsored by a grant from the National Institutes of Health. Portions of Dr. [PI name]'s and [his/her] research team's salaries are being paid by this grant."

HIPAA Authorization Section, applicable if collecting identifiable information. You must qualify for a waiver of authorization to exclude this section:

To do this research, we need to collect health information that identifies you. We may collect the results of tests, questionnaires and interviews. We may also collect information from your medical record. We will only collect information that is needed for the research. For you to be in this research, we will need your permission to collect and share this information.

We will share your health information with people at the hospital who help with the research. We may share your information with other researchers outside of the hospital if they are also participating in the study. We may also share your information with people outside of the hospital who are in charge of the research, pay for or work with us on the research. Some of these people may share your health information with someone else. If they do, the same laws that the hospital must obey may not protect your health information.

If you agree to let us use and disclose your protected health information, we will collect your health information until the end of the research. We may collect some information from your medical records even after your direct participation in the research project ends. We will keep all the information forever, in case we need to look at it again. We will protect the information and keep it confidential.

Your information may also be useful for other studies. We can only use your information again if a special committee in the hospital gives us permission. This committee may ask us to talk to you again before doing the research. But the committee may also let us do the research without talking to you again if we keep your health information private.

NYU SoM Guidance Document and Telephone Consent Template

If you agree to participate in this study, you are giving us permission to collect, use and share your health information. If you decide not to verbally agree to allow for us to use and disclose your protected health information, you cannot be in the research study. We cannot do the research if we cannot collect use and share your health information.

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to the researcher. The letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

Do you have any questions? You can also call (Principal Investigator) at (telephone) with questions about the research use of your health information or the research study.

Do I have your permission to begin asking you questions?