

Guidelines for Creating a Consent Form Process and Documentation

What is a Consent Process?

(1) Process of shared decision making by the physician and patient; (2) Active communicative process; (3) Educational activity for physician and patient; and (4) a process of building trust and mutual respect.

The purpose of the consent process has two functions: (1) Inform participants about research and (2) to allow participants to ask questions and engage in a dialogue with experience research personnel regarding the research and if the risks are acceptable for them.

The process of providing information and obtaining informed consent from prospective research participants is a crucial factor in determining the ethical acceptability of a research proposal. IRB must be satisfied that the researcher has provided the participant with information that a reasonable person would wish to know and comprehend before making a voluntary decision to participate.

The key components of the consent process are: Information; comprehension; voluntary participation of the subject and signature indicating consent. How should the three components be utilized?

1. **Information:** Use "The reasonable person" standard i.e. provide enough information to enable the person to decide whether or not to participate in the research.

The subject needs to be provided with sufficient information on the following in order to make an informed decision about participating:

- Purpose of the Study
 - Procedures (Investigative and Standard of Care; the difference of each)
 - Possible risks
 - Anticipated benefits
 - Alternative procedures
 - Opportunity to ask questions and to withdraw if desired
2. **Comprehension:** The manner and context in which the information is conveyed is as important as the information itself.
 - Subjects must be able to understand information that is presented to them. The familiarity of the patient with medical terms, diagnoses, stress level of the patient, emotional status and other factors which may hinder the process.
 - Reading and understanding level.
 3. **Voluntary:** Subjects must be told that they have the right to decline participation and to withdraw from the study at any time after it has begun.
 - Must be no coercion or undue influence.
 - Ethical remuneration.

4. **Signatures:** Subjects sign and date; confirms permission to participate in the research.
- Subjects should be given a copy of the consent form.
 - The signed and dated form must be kept with investigator's records.

What Goals should the Principal Investigator and Research Staff strive for during the consent process?

- (1) Give the subject enough **information** about the research.
- (2) Make sure the subject has **time** to consider all options.
- (3) Answer all of the subject's **questions** before the decision is made
- (4) Make sure that all information is **understood** by the subject
- (5) Obtain the subject's voluntary informed **consent** to participate
- (6) **Continue to inform** the subject throughout the research study-this is especially important with studies with long-term follow-up procedures or multiple steps in the procedures.

Continue to re-affirm subject consent to participate throughout the research study. This is extremely important to ensure subjects still want to stay involved with the research study in long-term follow-up or data collection.

The IRB will consider where the consent process will take place and the individuals who will be obtaining consent (e.g. the investigator, collaborator, or qualified designee) in its determination regarding the appropriateness of the consent process. When the potential participant's understanding of the research may be impaired due to the timing, location, or individuals participating in the proposed consent process, the IRB will require an alternative process. If someone other than the investigator conducts the interview and obtains consent, the investigator needs to formally delegate this responsibility and the person so delegated must have received appropriate training to perform this activity.

What is the Consent Form?

The consent form is a written summary of the communication taking place between the investigator and the study participant and serves as documentation that consent was requested. It does not take the place of personal interaction between the participant and the researcher, but it may serve as a catalyst for discussion about the research and participating in it. It is used as written presentation of information. It provides a base for the consent process. Allows the subjects a reference point to go back to when questions arise regarding procedures, follow-up appointments to be scheduled or if a subject experiences a side effect. The document must be signed by subject or subject's LAR and a Copy **MUST** be given to subject. The elements required in the informed consent document are listed in 45 CFR 46.116 and 21 CFR 50.25.

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.

For information regarding when a written consent is not required, waiver of informed consent, and waiver of documentation of informed consent please review the guidelines provided in the NYU SoM IRBs policies and procedures.

The language and syntax of the consent form should be directed to the reader at the sixth to eighth grade reading level. Font size should be easy to read such as 11 or 12. Scientific or medical terminology should be defined within the document itself, and avoided when possible. It is important to remember that people who use medical terms in conversation may not really understand their meaning. Write the form as if you are speaking directly to the subject about the project. The IRB prefers that consent forms adhere to a standard format, as shown in the sample consent form. The sample consent form contains all the required elements of consent. This format uses national guidelines that were developed to assist researchers and IRBs create consent forms for lay persons.

Children's Research Consent Forms

See the Guidance Document on Children in research for specific information what should included in the consent form.