# Consent Process and Documentation

Federal regulations governing human subjects research require informed consent to be obtained from all subjects, unless a waiver of informed consent is granted by the IRB. This guidance document provides information on how to plan, develop, and execute the consent process; including obtaining written informed consent, obtaining verbal consent, and requesting a waiver of informed consent from the IRB.

## What is a Consent Process?

The consent process is the active and ongoing information exchange between a researcher and a potential research participant. It begins at the time of initial introduction of the study and subject recruitment, and serves to provide a potential subject or subject’s Legally-Authorized Representative (LAR) with sufficient information so they can make an informed decision about participation in the research. 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 experienced 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. IRBs 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 as follows:

1. Information: Researchers should use "the reasonable person" standard i.e. provide enough information to enable the person to make an informed decision of whether or not to participate in the research:

* Purpose of the Study
* Procedures (including distinctions between procedures that are Investigational and those that are Standard of Care)
* Possible risks
* Anticipated benefits
* Alternative procedures
* Contact information, in order 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 study team must consider the familiarity of the subject with medical terms, diagnoses, stress level of the subject, emotional status, and other factors which may hinder the process.
* Ensure that subjects have sufficient time to review the document, ask questions, and consider all other possible options before agreeing to participate.
* 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.

3. Voluntary Participation: 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. Ongoing Process: Researchers should 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, in order 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 individual’s current mental or psychological state, 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 a Key Information Sheet?

Federal Regulations require that informed consent begins with a concise and focused presentation of key information that will most likely assist a potential subject or subject’s LAR in making an informed decision on whether or not to participate in the research. The key information sheet precedes the consent form, and is a focused presentation of the key elements of consent; such as the purpose, a statement that the study involves research, the risks and benefits, and alternatives.

## 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. The consent form provides subjects with a reference point to go back to when questions arise regarding procedures, follow-up appointments to be scheduled, or potential side effects.

Federal regulations require a number of elements to be included within the informed consent document. These elements are listed in 45 CFR 46.116 and 21 CFR 50.25 (for FDA-regulated research).

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

***NOTE****: The NYU Consent Form Templates and Standard Language Templates available on the IRB Website are designed for researchers to use and include all required elements of consent.*

## What is Broad Consent?

Under Federal Regulations, a broad consent may be used for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens. Specific criteria and elements for broad consent can be found in 45 CFR 46.116 (d).

***NOTE:*** *At this time, NYU Langone Health will not be implementing the use of broad consent.*

## Documenting the Informed Consent Process

The document must be signed by subject or subject’s LAR and a signed copy MUST be given to subject.

For clinical research, it considered a best practice to document in the subject file that the informed consent process has occurred. An example of a subject file note documenting this is noted below:

“I met with the participant or participant’s LAR to obtain informed consent for enrollment into the study. The informed consent was discussed in its entirety, the participant or participant’s LAR was given the opportunity to ask questions, and all questions were answered. The participant or participant’s LAR signed and dated the study informed consent form.”

***NOTE****: For FDA-regulated clinical trials, it is considered a required process to document in the subject file that the informed consent process has occurred, and lack of such documentation will result in a non-compliance finding by the FDA auditor inspecting the study.*

## Posting of Consent Forms for Clinical Trials Only

In accordance with the Federal Regulations as outlined in 45 CFR 46.116 (h), a copy of the IRB-approved informed consent form(s) used to enroll subjects for clinical trials must be posted on a publicly available Federal website that will be established as a repository for such informed consent forms. Only one copy for a multi-site study is required, and the posting can be done by either the prime awardee of a federal grant, lead Principal Investigator or site, Sponsor, or other organization/agency leading the study. The consent form must be posted no later than 60 days after the last study visit by any subject as per the study protocol. .

***NOTE****: If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal website (e.g. confidential commercial information), redactions to the information posted may be permitted or required.*

Please contact Research Regulatory Services at david.wallach@nyumc.org for guidance related to posting a clinical trial consent form on a Federal website (in accordance with 45 CFR 46.116(h)

# Obtaining and Documenting Informed Consent of Non-English Speaking Subjects

Informed consent information must be presented in language understandable to the subject, and in most situations, informed consent must be documented in writing. Investigators should carefully consider the ethical/legal ramifications of enrolling a subject when there is a language barrier. If subjects do not clearly understand the consent document or freely ask and receive answers to their questions, then their consent will not be truly informed and may not be legally effective.

Thus, the consent process for subjects who do not speak English must include:

1. A written, IRB-approved, consent document in a language understandable to them,
2. A translator fluent in both English and the subject's spoken language
3. A witness to the consent process

Depending upon the research, the written consent document can be either: (I.) a translation of the entire English version of the NYU SoM IRB approved consent document; or (II.) a translation of a "short form."

## Using a Written Translation of the Entire English Version of the IRB-Approved Consent Document

Use of a written translation of the entire IRB-approved English version is always preferred. If researchers can reasonably expect that more than an incidental number of subjects speaking the same non-English language will be enrolled (for example, if the investigator is targeting a non-English speaking group), translation of the entire English version is required. The IRB must approve all translated versions of the consent form and recommends that the translation be done by a certified translator from Interpreter Services. However, the IRB will consider, on a case-by-case basis, allowing other translators to perform this function with verification that the translation is an accurate and acceptable presentation of the entire English version. All translated documents must be accompanying by a statement of certificate of accuracy, signed by the individual who translated the document.

## Using a Written Translation of the “Short Form” Consent Document

Investigators cannot always anticipate the interest of a particular non-English speaking individual and provide him/her with a translation of the entire IRB-approved English version of the informed consent document in a timely manner. Under these circumstances, a translation of the "short form" (which attests that the elements of consent have been presented orally) can be used to document informed consent in writing. When a "short form" is used to document informed consent, the consent process must include oral presentation of the entire English version of the consent form in language understandable to the potential subject. The informed consent process for enrolling subjects using the "short form" consent document is outlined below. ALL of the following requirements (1, 2, 3 and 4) must be completed:

1. A translator must orally present the entire IRB-approved English version of the consent form to the subject in a language understandable to him/her, a researcher must be present to conduct the informed consent process and answer questions, and the subject must be given a written translation of the "short form" consent document to read;
2. The entire consent process must be witnessed by an individual who is fluent in both English and the language understandable to the subject. The translator may serve as the witness;
3. The IRB-approved English version of the consent form must be signed by the investigator authorized by the IRB to obtain consent and the witness to the consent process, and the translated "short form" must be signed by the subject and the witness to the consent process (see 2 above); AND
4. The subject must be given copies of both the IRB-approved English version of the consent form and the translated version of the "short form" consent document. The original signed English version with the original signed "short form" attached should be placed in the subject's research record and a copy of both placed in his/her medical record, if appropriate.

IRB approved "short form" consent documents are available on the IRB web page. All other translations of the "short form" must be submitted to the IRB for approval. The consent documents are available as "PDF" files and can be printed with Adobe Acrobat.