

Conducting the consent process when a subject is unable to read the English long form version of the IRB-approved consent

Question 1: When is the “short form consent” process used?

Answer: The short form consent process is used when the subject is **unable to read** the long form version of the consent due to a language barrier or illiteracy. An interpreter is utilized for subjects who are unable to understand the language in which the long form consent is written.

Question 2: Who can be an interpreter for the short-form consent process?

Whenever possible, a professional interpreter, who is in-person, should be used or, alternatively, professional translation can be via a phone translation service. Use of a family member for interpretation is not permitted unless a professional medical translator cannot be located. The reasons for using a family member and the attempts made to locate a professional translator must be documented in the research record. Family members may not have adequate medical knowledge and are not trained as professional medical interpreters. Additionally, family members may not be impartial or may try to speak for the subject which can limit the subject’s decision-making process.

Question 3: How is the consent process conducted when the subject speaks and understands English but is unable to read or write in English?

Answer: When the subject speaks and understands English but is illiterate, there should be a witness to the entire consent process. Although use of the short form (in English) is not ideal since the subject cannot read the short form, it does provide the opportunity to document that there was a witness to the consent process. Even though an interpreter is not needed in this case, the signature section of the short form indicates the presence of the witness. Subjects who are unable to sign their name can make their mark on the signature line. (e.g. They may make an “X,” or provide a fingerprint.) The consent note should document the process and include a statement that there was a witness to the entire consent process.

Question 4: How is the consent process conducted for non-English speaking subjects for whom no written language exists?

Answer: An interpreter is required, and the short form process is used. This includes obtaining consent using the English short form with the interpreter using the English long form as the basis of translation. A witness must be present for the entire oral presentation and must sign both the short form and the long form used as the basis of translation. (See question 5 below for more information about signatures.) The interpreter is often also the witness, but if the interpreter cannot sign as the witness, another witness who will sign must be present. See additional information in question 2 about who may serve as an interpreter. See question 3 about alternatives to a written signature for the subject.

Question 5: When a short form consent document in the language that can be read by the subject is used, and the written IRB-approved summary of what is to be said to the subject is the English long consent form, who signs the English long form and who signs the short form?

Answer: For the **English long form consent**: the investigator obtaining consent and the witness sign the English long form consent document. The interpreter may also act as the witness.

Required signatures when using the short form process

English Long Form

Investigator: Investigator obtaining consent

Signature of Investigator Print Name of Investigator Date

Witness to the oral short-form consent process only: This section is only required if you are doing the oral short-consent process with a non-English speaking subject and this English consent form has been approved by the IRB for use as the basis of translation.

Witness: Interpreter or separate witness to the entire consent process

Signature of Witness* Print Name of Witness Date

For the **short form consent that is in the language that can be read by the subject**: The subject and the witness sign the short form consent document.

Confirm that the witness has signed **both** the short form in the language of the subject and the English long form used as the summary of what is to be said to the subject.

Required signatures when using the short form process

Short form consent

Example: Spanish Short Form

Firmar este documento significa que se le explicó verbalmente el estudio de investigación, incluida la información anterior, y que acepta participar voluntariamente.

Participant

Firma del participante de la investigación Nombre en letra imprenta del participante de la investigación Fecha

Firma del testigo* Nombre en letra imprenta del testigo Fecha

(In English, this says, *Signing this document means that the research study, including the above information, has been described to you orally, and that you voluntarily agree to participate.*)

(Signature of participant/printed name/date)

(Signature of witness/printed name/date)

Interpreter or separate witness to the entire consent process

Question 6: When a Clinical Center (CC) interpreter facilitates the informed consent process, is the interpreter **required** to also serve as the witness?

Answer: NIH staff members who are federal employees and whose job description involves interpretation services should sign the short and long form consent as the witness when facilitating the short form consent process. Contract staff or volunteers providing interpreter services may sign as witnesses but cannot legally be required to do so. If the interpreter declines to act as the witness, a separate individual must witness the entire short form consent process and sign as the witness. In all cases, the identity of the interpreter will be noted as indicated in Question 8 below.

Before starting the consent process, confirm with the interpreter if they are willing to witness the consent. If the interpreter will not serve as the witness, a separate adult witness must be identified, and NIH strongly encourages that the witness be fluent in both English and the language of the subject. The witness must be present for the entire oral presentation.

Question 7: What should you do if the short form consent process is conducted in person, but the interpreter is on the phone?

Answer: A phone service interpreter **cannot** act as a witness since they are not physically present to observe the consent process. Another individual must observe the entire consent process at the site of the investigator and sign as the witness. Information regarding the interpreter should be included in the administrative section of the long form consent document as described below.

Question 8: How do you document the use of an interpreter on the long and short form consents?

Answer: Both the English long form and the translated short form includes a section titled **NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER** which must to be completed when the short form consent process is used. (Note: On the translated short form, this section will be in the subjects preferred language.) This section allows NIH staff to attest that an individual speaking both English and the subject's preferred language facilitated the consent process and also indicates whether the individual acting as the interpreter also served as the witness to the short form consent process.

If the individual providing interpretation services did not serve as a witness, the interpreter's name (for on-site interpreters), or ID number (for telephone-based interpreters), should be entered in the designated 2nd field below.

English long form administrative block

***NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:**

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is:_____.

Examples of scenarios

- *An NIH staff member who is a federal employee and whose job description involves interpretation services acted as interpreter and signed as witness:* The first option is checked and the interpreter signs as the witness.
- *An NIH contract interpreter is used but states they cannot sign as witness:* The second option is checked, and the interpreter's name or ID code is entered on the provided line. In such cases there must be a separate individual present to observe the entire consent process and who signs as the witness.
- *A telephone translation service (trans-telephonic interpreter service, e.g. "blue phone" service) is used and the consent is obtained in person (person obtaining consent and the subject are co-located):* Since the interpreter is not physically present and cannot serve as witness, the second option is selected, and the name or ID of the interpreter is entered. In such cases there must be a separate individual present with the investigator to observe the entire consent process and who signs as the witness.

Question 9: What is required when you are using the short form consent process to obtain consent by phone from a subject who is not in the same location as the investigator? This includes consent processes using an interpreter who is either on the phone (remote from the investigator) or who is present with the investigator.

Answer: The difference from the earlier examples relates to the location of the individual who will serve as the witness and timing of the investigator and witness signatures.

- The subject should be provided with both the short form consent and the long-form English consent prior to the phone discussion.
- The investigator who is obtaining consent is in the same place as the witness (this may/may not be the interpreter).
- The investigator, interpreter, and witness (if the interpreter will not/cannot serve as the witness) must all be involved for the duration of the consent process conducted via phone.
- After completion of the consent process, the following should be completed in real time:

- The subject signs and dates the short form consent and returns it to the investigator.
- At the time of the consent process, the investigator and the witness sign and date the long form English consent that was used as the basis of translation.
- The administrative section on the last page of the long form English consent is completed.
- The investigator documents the process in a consent note in the subject's medical chart or research record (in real time after the consent discussion).
- Upon receipt of the signed and dated short form consent from the subject, the investigator completes the administrative section of the short form, and the same witness signs and dates the short form consent using the current date. (It is not backdated to the date that the consent process was conducted by phone.)
- The subject is provided with copies of the signed short and long form consent documents.
- The investigator adds a note to the medical/research record regarding the date the signed short form was received and signed by the witness and indicates when the copies were returned to the subject.

Question 10: What documentation should be entered in the Clinical Records Information System (CRIS) when an interpreter is used for the **short form** consent process?

Answer: The CRIS documentation of the Informed Consent Progress Note has been updated to include the required fields related to use of interpreters and witnessing the consent process. Whenever an interpreter facilitates the informed consent process, the PI or investigator who is obtaining consent should complete the check box fields in the progress note and include the name or ID number of the interpreter in the designated field.

Documentation of the interpreter in CRIS when the short form consent process is used

Interpreter	
Interpreter Used During Consent Process?	<input checked="" type="radio"/> Yes <input type="radio"/> No
Who Provided Interpretation?	<input type="radio"/> A staff member who speaks English and the participant's preferred... <input checked="" type="radio"/> An interpreter, staff member, or close family member
Name Or ID Code And Role Of The Person Providing Interpretive Support	Interpreter ID#12345

Question 11: Who signs the IRB-approved fully translated (non-English) **long form consent** document?

Answer: If investigators anticipate enrolling subjects who speak a specific language other than English, the English long form consent should be fully translated into that language and submitted to the IRB for approval. In this case, an interpreter is also used to facilitate the discussion and answer the subject's

questions, and the investigator obtaining consent and the subject both sign the fully translated long form consent (as they would if the long form was in English).

In this case, since an interpreter is used but a witness is not required on the long form consent, the second box in the administrative section should be checked to indicate that the interpreter facilitated the consent process but did not serve as the witness.

Question 12: When an interpreter is used during the consent process using a **translated long form**, how is this documented in the consent note in CRIS?

Answer: Check “yes” to the question, “*Interpreter used during the consent process?*” Fill in the name or ID code of the person providing interpretive support. Under additional notes, include a statement that a translated consent long form was used. See below.

Consent note documentation when translated long form is used with assistance of an interpreter

Interpreter

Interpreter Used During Consent Process? Yes No

Who Provided Interpretation? A staff member who speaks English and the participant's preferred... An interpreter, staff member, or close family member who speaks...

Name Or ID Code And Role Of The Person Providing Interpretive Support: *Fill this information in regarding the interpreter who assisted with use of the translated long form*

Additional Notes

Additional Notes: *Include statement here that a translated long form was used.*

Question 13: Can a bilingual investigator approved by the IRB to obtain consent do so using the translated long consent form or the short form process?

Answer: If the investigator is truly fluent in English and the language of the subject, consent may be obtained using the IRB approved translated long form if it exists, and no witness is needed. When the short form process is used because the long form has not been translated into the subject’s language, the bilingual investigator conducts the consent process in the language of the subject and explains all applicable elements of consent using the English long form as the summary of what is said to the subject. The investigator obtaining consent cannot act as the witness, so the second option in the administrative block noted in question 8 above is checked, and the investigator’s name is noted on the provided line. In such cases, there must be a separate individual present to observe the entire consent process who signs as the witness.

Question 14: How should assent of a potential minor subject who does not read/speak English be conducted when the IRB has only approved use of an English assent form for minor subjects of a specific age?

Answer: Verbal assent should be obtained from the minor, and the process should be documented in the consent note. NIH does not have translated short form assent documents.

When assenting a non-English speaking older minor, if there is a translated long form and the IRB has approved a process that allows older minors to provide their assent on the long form, then the older minor can read and indicate their assent on the translated long form. Otherwise, verbal assent will be obtained and documented as above.

Question 15: What if the consent form for my protocol has not been updated to the current consent template?

Answer: All the above guidance still applies. Consent forms are being updated to the new template when IC specific IRBs are incorporated into the NIH Intramural IRB. If there is not a place on your current consent to document any of the above information, that information should be included in the CRIS documentation of consent progress note.