Consent Process and Challenges When Enrolling Non-English-Speaking Subjects

February 15, 2023

Objectives as related to the consent process when potential subjects are non-English speaking

Attendees submitted questions and comments in advance of today's session, and this presentation will attempt to respond to the submissions.

Today's objectives as they relate to your submitted comments/questions:

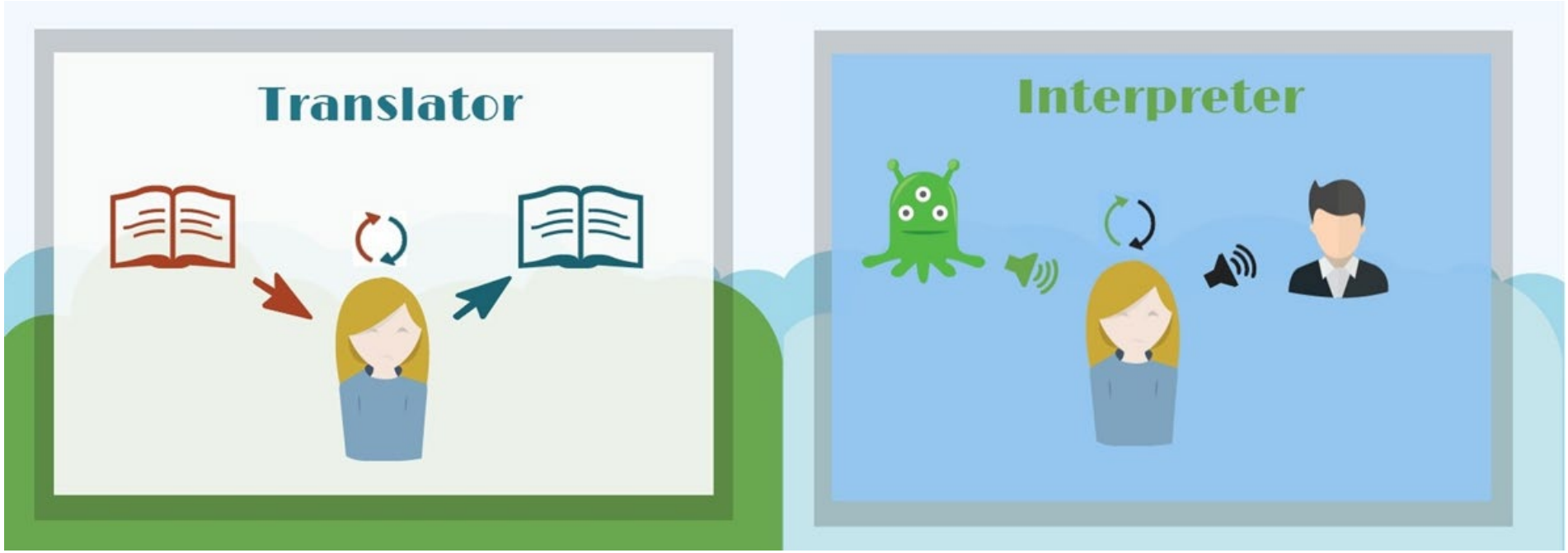
Attendees will

- Better understand the role and need for interpreters and witnesses during the consent process
- Appreciate the differences in use of a translated long form consent vs. the short form consent process
- Become familiar with the how assent is obtained when a short form process is used
- Be better able to determine if errors or omissions related to signatures on consents constitute reportable noncompliance
- Understand the process for obtaining remote consent

Interpreters vs. Translators

Q. What is the difference between a translator and an interpreter?

A. Translators translate the written words while interpreters translate spoken language orally.



Use of Professional Interpreters

Q. What is meant by the term "professional interpreter" in NIH policy 301? Can an NIH employee serve as interpreter?

A. This means an individual who is a trained and functions as a professional interpreter. This individual may be an NIH staff member or contractor (if at the CC, with the Social Work Department), or another individual with a telephone interpreter service. Individuals who are not professional interpreters should generally not be providing interpreter services.*

Q. Is it required to document in CRIS that the interpreter is professional?

A. That would be a best practice. However, any use of a non-professional interpreter should be documented. Explain why a professional interpreter was not used (e.g., none available), and describe who interpreted instead.*

*Use of an adult family member for interpretation is not permitted unless a professional medical interpreter cannot be located. The research record must document the reasons for using a family member and the attempts made to locate a professional interpretor.

Comments Submitted

"This does not involve consent but has to do with imaging. We need to be aware that an in-person interpreter is needed when a subject will be getting contrast for imaging and interpreters are only available from 8am-5pm. I had to find a provider who speaks the subject's language to be available and be able to go to the imaging department in person for a 6 PM MRI in order for the subject to get the scan he needed."

"Our team had a subject that came to clinic without an interpreter order, it took a long time before an interpreter can be contacted. It's best to order interpreting services for non-English speaking subjects (even when they have family that speaks the language, especially when consenting is involved)."

Response

- Obtain consent in advance of the visit.
- If scheduled after 5 PM, have subject come before 5 PM when interpreter is available.
- Order interpreter services ahead of time.
- Use of a non-professional interpreter must be documented. Explain why a professional interpreter was not used (e.g., none available).

Use of Translated Long Form Consent vs. Short Form Consent Process

When obtaining the consent of non-English speaking subjects, consent must be obtained using an IRB-approved translated long form consent or, if enrollment of a non-English speaking subject is not anticipated, an IRB-approved short form consent in the language of the subject.

Translated Long Consent Form Consent Process- NIH Policy 301

- When non-English speaking subjects are **anticipated** to enroll in the research:
  - The PI must submit a certified translated long form consent document in the language of the anticipated subjects to the IRB for approval.
  - IRB approval of the certified translation must be obtained before the translated long form consent document is used.

Signatures when using a translated long form consent document in the language of the subject

Required signatures when the English long form consent has been fully translated into the subject's language approved by the IRB:

- 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).
- A witness is not required on the long form consent.
- 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.

Long Form Consent Document in the Language of the Subject

***SECCIÓN ADMINISTRATIVA DE LOS NIH QUE DEBERÁ DILIGENCIARSE RESPECTO AL USO DE UN INTÉRPRETE:**

_____ Un intérprete, u otra persona que habla inglés y el idioma de preferencia del participante facilitó la administración del consentimiento informado y actuó como testigo. El investigador que obtiene el consentimiento no puede actuar al mismo tiempo como testigo.

_____ Un intérprete, u otra persona que habla inglés y el idioma de preferencia del participante facilitó la administración del consentimiento informado, pero no actuó como testigo. El nombre o el código de identificación de la persona que prestó los servicios de apoyo de interpretación es _____.

Long Form in the Language of the Subject Form

No witness signature needed

Signature of Witness	Print Name of Witness	Date

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

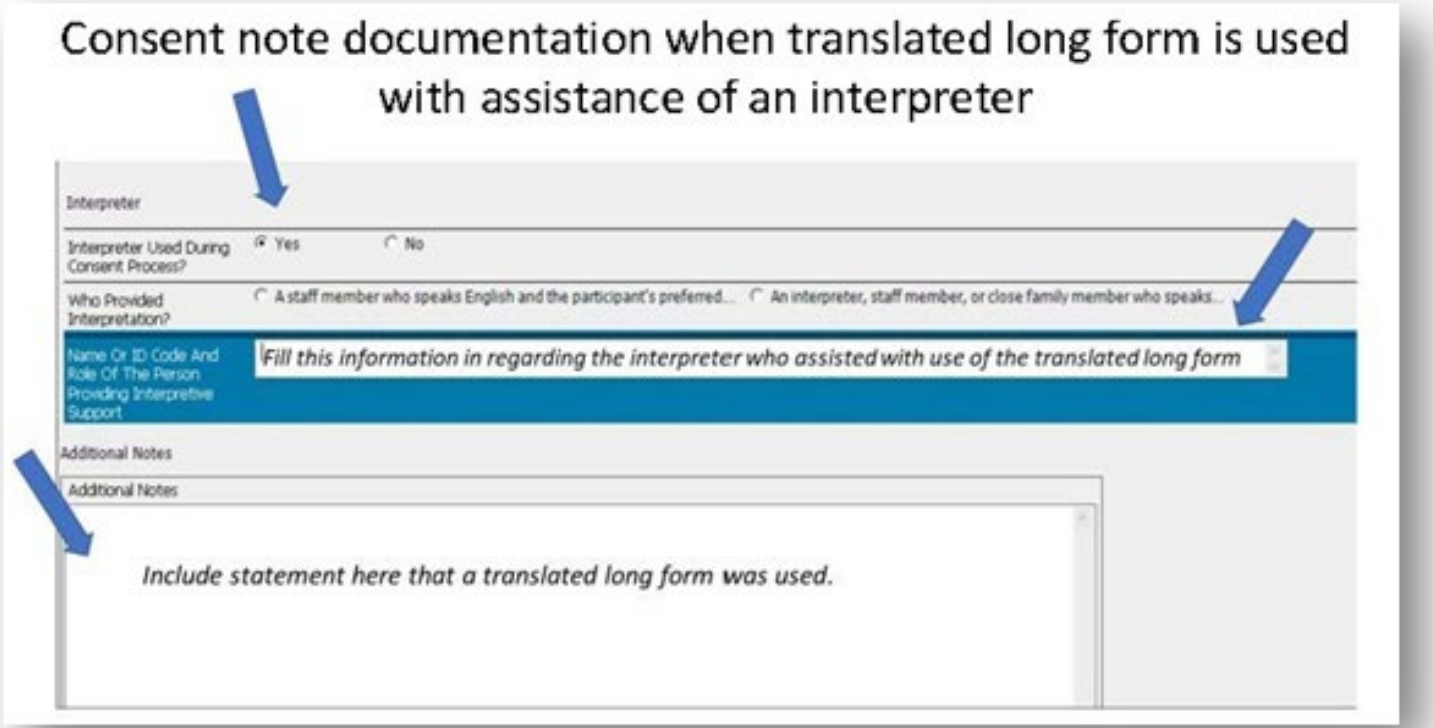
____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

✓ 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:

Interpreter information goes here

CRIS documentation when a translated long form consent document in the language of the subject is used

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.



Short Form Consent Process- NIH Policy 301

When a non-English speaking subject seeks to enroll unexpectedly and there is no IRB-approved long form consent document in the language of the subject:

- The investigator must use an IRB-approved short form consent document in the language of the subject, if one is available, or
- If there is no IRB-approved short form consent document in the language of the subject, the NIH PI must submit to the IRB (before use), a certified translation of the short form consent in the language of the subject that meets the requirements of 45 CFR 46.116 and 46.117(b)(2), for approval by the IRB.
- At the discretion of the IRB, the PI may be directed to translate the English informed consent document into a foreign language (most commonly when frequent use of a short form is noted at the time of CR.)

Comment submitted

- “The team was going to enroll a Portuguese lady from Brazil.
- There are 2 Portuguese language types available- Brazil and Portugal- but when they looked at the IRBO website for the short form consents, only “Portuguese-European” was available.
- The patient and family were speaking Brazilian.
- The team had to submit a Single Patient deviation in iRIS for the patient and request that a verbal consent process be used since there is no short form available in the patient’s language.”

Response

Good news!

Portuguese Brazilian Revised Common Rule Short Form (

Portuguese European Revised Common Rule Short Form

What happens when there is no short form in the language of the proposed subject? (Consent FAQ # 21)

- If the long form has not been translated into the language of the proposed subject, the subject should not be enrolled until a short form in their language is available.
- If you need a short form that is in a language which is not available on the IRB website, then you must obtain a translation of the appropriate English short form version. A resource for obtaining a translation is the NIH Library.
- Once you receive the translation, submit the translated short form and the certificate of accuracy to the IRB via PROTECT using modification form.
- (Contact the IRB if further discussion is needed.)

Signatures Required for the Short Form Consent Process

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

A. An interpreter and witness are needed.

- The interpreter may also act as the witness (but is not required to do so).
- The witness must be fluent in the language of the subject and in English*
- For the English long form consent: the investigator obtaining consent and the witness sign the English long form consent document.
- For the short form in the language of the subject, the subject and the witness sign. The interpreter may serve as the witness if they are willing to do so.

* Later slide will discuss what should be a very rare exception to this requirement and process required in such cases

Signatures Required for the Short Form Consent Process-the English Long Form

English long form consent

Investigator:

Investigator obtaining consent

Signature of Investigator | Print Name of Investigator | Date

Witness should sign below if either:

1. **A short form consent process has been used to enroll a non-English speaking subject or**
2. **An oral presentation of the full consent has been used to enroll a blind or illiterate subject**

Interpreter or separate witness to the entire consent process

Signature of Witness | Print Name of Witness | Date

Signatures Required for the Short Form Consent Process

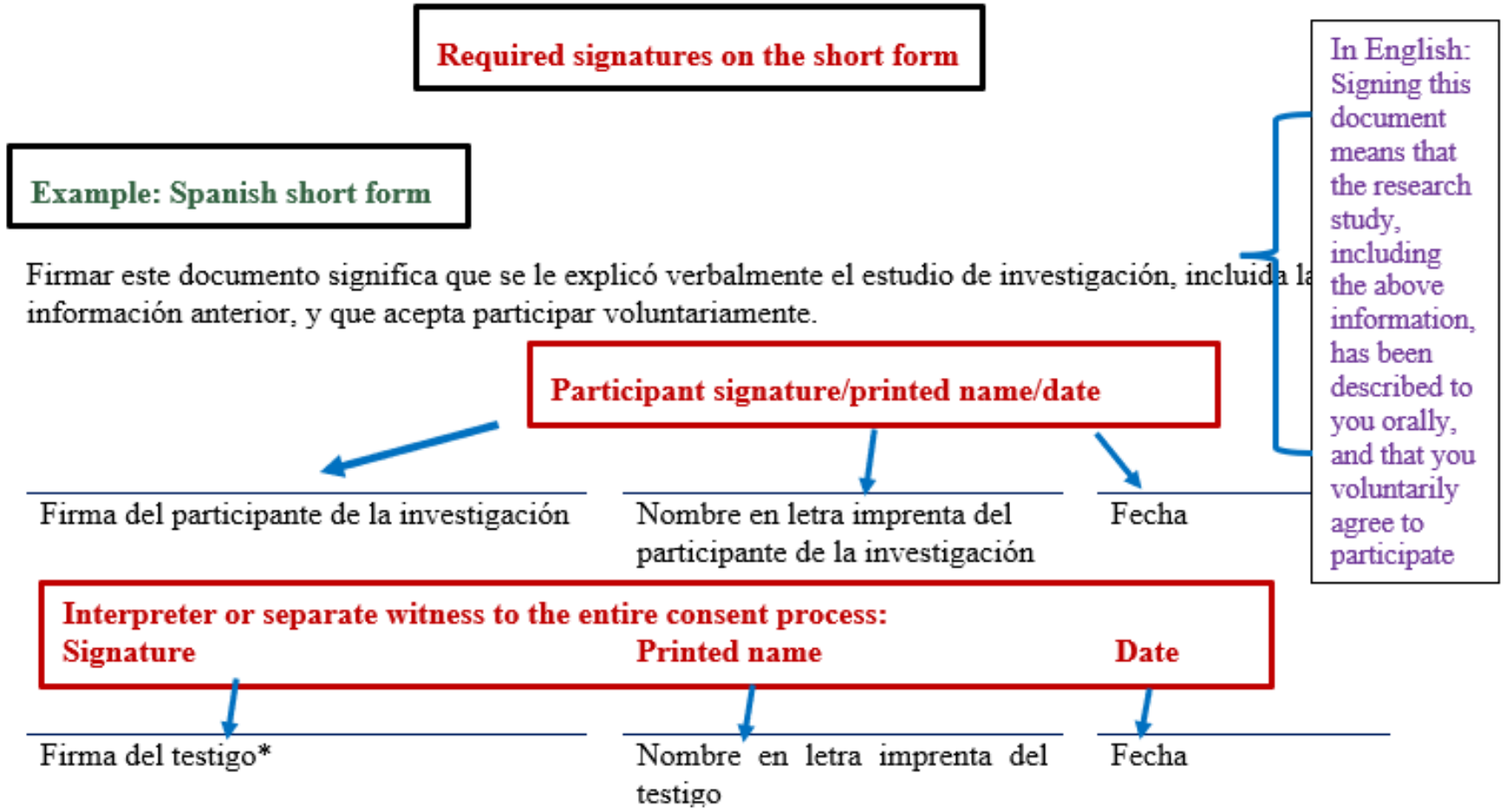
For the short form consent that is in the language that can be read by the participant: The participant and the witness sign the short form consent document.

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 Research Participant	Print Name of Research Participant	Date
Signature of Witness*	Print Name of Witness	Date

Signatures Required for the Short Form Consent Process

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



NIH Administrative Section Options

Signature of Witness	Print Name of Witness	Date

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: _____.

Inability to locate a witness who is not bilingual-comment submitted

"Especially for more uncommon languages, there are often times when an in-person interpreter is not available. When doing consent with a phone interpreter, we have had to use a witness who does not speak both languages."

Witness who is not bilingual-response per NIH Policy 301.2 (h)(VII)

i. When the short form consent procedure is used to consent subjects, there must be a witness who is present for the entire oral consent presentation.

ii. Either the interpreter or a second individual (fluent in both languages) can serve as the witness.

iii. The witness must be fluent in the language of the subject and in English.

- In the vary rare instance that the interpreter is unable to act as the witness, and if the witness is not fluent in both the language of the subject and English, then the witness should verify with the interpreter that
  - The subject understands the information presented
  - All questions have been satisfactorily addressed **and**
  - The subject agrees to participate

The witness, or investigator obtaining informed consent, should document this as a note in the record documenting the short form consent procedure.

Bilingual Investigators

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

Bilingual Investigators

A. If the investigator is truly fluent in English and the language of the participant, consent may be obtained using the IRB approved translated long form if it exists, and no witness or interpreter is needed.

   For the short form process (when there is no long form in the participant's language):

   - The bilingual investigator conducts the consent process in the language of the participant and explains all applicable elements of consent using the English long form as the summary of what is said to the participant.
   - The investigator obtaining consent cannot act as the witness, so the second option in the administrative block 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.

Bilingual Investigator-Short Form

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: Name of bilingual investigator obtaining consent _____.

How is the consent process conducted for non-English speaking subjects who are unable to read the short form in their own language because they are illiterate?

- If the subject is non-English speaking and illiterate in their own language, the same process for illiterate English speakers would be utilized. (The short form cannot be used since the illiterate subject is not able to read the short form in their own language.)
- In such cases, there should be an oral presentation of the English long-form consent by the investigator, using an interpreter.
- There must be a witness at the location of the investigator who is present during the entire oral presentation.
- The witness can be the interpreter if they are willing to act as the witness.

(continued)

How is the consent process conducted for non-English speaking subjects who are unable to read the short form in their own language because they are illiterate?

- The witness then signs the witness line on the English long form consent.
- 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.) If the subject is unable to indicate the date, the investigator may add this next to the subject’s mark.
- The administrative block for interpreters must be completed.
- The consent note in Clinical Records Information System (CRIS) or the research record should document the process and include a statement that there was a witness to the entire consent process and any special circumstances regarding documentation of consent.

Comment submitted and response

"Arabic speaking participant initialed the embedded questions in the English long form."

However, the participant cannot read the questions, so they should not be indicating their response on the form.

Correct process when the participant is non-English speaking and the IRB approved long form consent document (i.e., English version) has embedded questions (Consent FAQ #22)

- The interpreter should ask the subject the embedded question and convey their response to the investigator obtaining consent.
- The investigator indicates the subject's response on the long form ICF. (The investigator enters their own initials.)
- Neither the interpreter nor the subject should record the response.
- This process should also be described in the consent note in CRIS or the research record.

Comments submitted

"CRIS note indicates written assent was obtained; however, English written assent was used for Spanish speaking minor participant."

"Written assent is not possible for older pediatric patients when the assent form is not written in their language."

Response

Consent FAQ #23: 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?

- NIH does not have translated short form assent documents.
- Verbal assent should be obtained from the minor.
- The process should be documented in the consent note.
- When obtaining assent from 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 may read and indicate their assent on the translated long form. (Otherwise, verbal assent should be obtained and documented as above.)

Comment submitted

“The participant's primary language is indicated as Amharic in CRIS records. Participant signed English informed consent and there is no documentation he is fluent in English. If CRIS indicated non-English-speaking language and patient requested consent in English, the CRIS note must include this information.”

Response

- The investigator obtaining consent should note the situation in the medical/research record consent note.
- The investigator should respect the subject's request and should document their understanding of the subject's ability to read and understand English based on the consent conversation.

Comment submitted and response

"Investigator obtaining consent didn't sign English long form."

Response: If this is a case of the subject who reads and understands English, and the short form process is not being used:

- Policy 301 does not require signature on the ICF by the investigator
- The guidance document that accompanies policy 801, on the OHSRP website describes examples of minor vs. major deviations.* A missing investigator signature on a consent form is a minor deviation.
- The Prior MAS policy related to consent (M77-2) **was superseded by Policy 301.**

(continued)

*Policy 801, *Reporting Research Events,* and the associated guidance can be found on the OHSRP HRPP Policy and Guidelines webpage.

Response (Continued)

§ 46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form.

§ 50.27 Documentation of informed consent.

(a) Except as provided in § 56.109(c), informed consent shall be 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. A copy shall be given to the person signing the form.

Comment and Response

"The French speaking patient signed English long form." Noncompliance?

It depends:

- If the participant only signed the English long form and not the short form, this is noncompliance that should be submitted as it potentially affects the subject's rights and should be reported as noncompliance.
- If the they also signed the French short form, this is not noncompliance since the subject provided consent on the short form that they were able to read.

Comment

“The Amharic (both versions) short forms do not have an area for parents/guardians or LARs to sign on behalf of a minor patient.”

Response

Spanish short form signature lines

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

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

English short form signature lines

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 Research Participant	Print Name of Research Participant	Date
Signature of Witness*	Print Name of Witness	Date

Response

- Short forms do not have a line for parents/guardians or LARs to sign on behalf of a minor patient.
- Enter the name of the person signing rather than the printed name of the research participant (e.g., LAR or parent).
- The process (who provided consent/parental permission for the participant) should be clearly documented in the medical/research record.
- Per OHSRP, changing all the short form consents would be too difficult a task given how many languages/versions exist.

Comment and Response

“The person served as a witness signed both witness and LAR sections on English long ICD.” Noncompliance?

- Assuming this refers to the short form consent process, the English long form ICD would not require the signature of LAR who does not speak English.
- The long form requires the signature of the witness and the investigator.
- If the witness signed both the English long form and the short form in the witness section, the extra signature on the long form that normally would be blank would not be a major deviation as it does not potentially affect the subject’s rights.

Questions related to procedure consents used with non-English Speaking subjects

"For CC procedure forms, there is no alternative for non-English speakers; they need to sign on the English form. We have been using the interpreter as the witness in these instances."

Response: OHSRP cannot speak to clinical procedure forms as it's not in our purview. HIMD would be the entity to address this.

Question that was submitted

"Another instance where one parent was at the CC and the other was in quarantine with a young pediatric patient. Is it permitted to do consent with the parent present and get assent from the pediatric patient over the phone? This would be to eliminate extra delays in undertaking assessments once the patient is off isolation."

- There are some unknown details that would be important to understand to fully respond.

Assumptions and Response

- The way this is written, it sounds like the IRB approved this under 45.404 or 45.405 and that the IRB is permitting signature by one parent (unless they have joint custody) and that you will obtain parental permission from the parent who is present with you.
- It also is not clear what process for assent was approved by the IRB (written vs. verbal).
- It sounds as if consent/assent by phone has not already been approved by the IRB (?)
- If written assent is required and this is a case of quarantine for COVID-19, see the OHSRP Guidance on Guidance on Conducting Informed Consent during the COVID-19 Outbreak and the FDA Conduct of Clinical Trials of Medical Products During COVID-19 PHE for options for obtaining consent in such situations.
- Submit a modification to allow for remote assent and describe the process you are proposing.

Questions About Remote Consent

Remote Consent

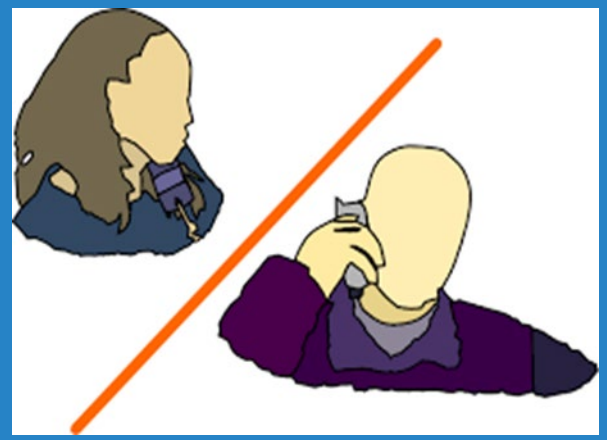
Q. **What does remote consent mean? Is it the same as telehealth consent? What are the options for remote consent?**

A. Remote consent processes include:

- telephone consent
- consent using NIH-approved audio-or-video conferencing platforms, e.g., MS Teams (“virtual” or “telehealth”)
- “online” consent form

- The planned method for obtaining consent must be described in the protocol.
- The consent process should be documented in the medical or research record.

Remote Consent-by Telephone*



For consent processes conducted by telephone, the description of the consent process in the protocol should describe:

- Whether the ICF will be provided to the participant in advance of the consent discussion
- If the ICF will be provided electronically or in hard copy
- Where the participant will be located during the consent process
- How the privacy of the participant will be ensured during the consent process
- How much time the potential participant will have to consider their participation
- If the potential participant will have the opportunity to consult with others (family, friends, private physician) prior to consent

(continued)

* See OHSRP *Guidance For Protocol Language Regarding The Consent Process And Remote Consent* AND FAQs *Everything you need to know about consent*.

Remote Consent-by Telephone- (continued)

After the consent process has been conducted and the participant's questions have been answered:

- The participant signs the consent using current date.
- The investigator documents the process in CRIS/medical record (or the research record if there is no medical record) in real time on the day of the consent conversation.
- When the signed/dated consent form is returned to the investigator who conducted the consent discussion, the investigator signs and dates the consent form with the date they received the signed the consent from the participant.

(continued)

Remote Consent-by Telephone-continued

- The investigator should then record another note in CRIS/research record indicating the updated status and send a copy to medical records (or research record if there is no medical record) and provide a copy of the completed consent form to the participant.
- If, after the participant has signed the consent form, specimens and/or data are collected locally for research purposes, no analyses of these specimens and/or data may occur until the investigator has verified that the participant has returned a signed and dated informed consent document, unless the IRB has granted a waiver of documentation of consent.

Remote Consent-by Telephone: Permission from the Parent and Assent from the Minor

Q. What is the process for obtaining informed consent on the phone with a minor and parent of the minor?

A. The processes for obtaining parental permission from the parent on the IRB approved ICF and obtaining assent from the child are the same as the process for an adult providing consent.

- If written assent is required by the IRB, if the child agrees to participate, they sign the IRB approved assent document.
- For older minors, if the IRB has approved use of the long form, assent may be documented on the long form along with the parent(s) signature.
- If verbal assent is approved by the IRB, this is documented in the consent note in the medical/research record.

Telephone Consent When Written Consent is Being Obtained and the Short Form Process is Used

Q. What is the process for obtaining informed consent on the phone with an interpreter and a non-English speaking participant who are not on site using a short form process?

A. The participant 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.

(continued)

Telephone Consent-Short Form Consent Process (continued)

After completion of the consent process, the following should be completed in real time:

- The participant 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 participant's medical chart or research record (in real time after the consent discussion).

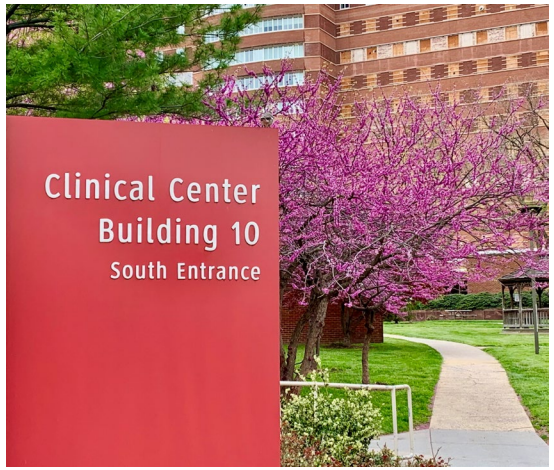
(continued)

Telephone Consent-Short Form Consent Process (continued)

Upon receipt of the signed and dated short form consent from the participant:

- 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 participant 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 participant.

Thank You!



QUESTIONS ?