Translation Requirements for Research

5/31/2024

Purpose:

All research participants, regardless of language, have the right to understand the study and make informed decisions about participation. When prospective subjects who do not understand English are to be enrolled in a clinical study, IRBs and investigators must ensure that the information given to such prospective subjects or their legally authorized representatives (LARs) is in language understandable to the subjects or their LARs (45 CFR Part 46.116 and 21 CFR 50.20). This requirement includes the consent document, the ongoing consent process, and communications during all phases of study participation.

Definitions:

Back-translation: Involves taking the translated version ("forward" translation) of a document or file and then having a separate independent translator (who has no knowledge of or contact with the original text) translate it back into the original language. This allows for translation comparison with the original text for quality and accuracy.

Oral Summary: A written summary of the verbal information that would be presented to a participant, including all required elements of consent. In most cases, this is the IRB-approved English Long Form Consent.

Short Form Consent: Summarizes key elements of informed consent and refers participants to an oral explanation in a language understandable to them.

Certified translator: A certified translator is someone who has been recognized by a government agency or other organization as having the skills and qualifications needed to translate written documents from one language into another.

Interpreter: A qualified interpreter, preferably someone trained in healthcare interpreting and research ethics. The interpreter should not be a family member as they may not have adequate medical knowledge and may not be impartial. The interpreter can be in-person

or remote (i.e., Duke Interpreter Services in-person, phone or video-based services).

Witness: An adult who is fluent in both English and the language understandable to the participant or, at a minimum, has sufficient proficiency in the language of the oral presentation to be able to attest to the information that is presented orally to the prospective participant (21 CFR 50.27(b)(2). Study team members or direct reports of study team members cannot serve as the witness. The interpreter may also serve as the witness if they agree and no other option is available. The witness must be present physically or by some other means (e.g., by phone or video conference) during the oral presentation, not just the signing of the consent form (21 CFR 50.27(b)(2)).

Requirements:

- The IRB must review and approve consent documents (long form or short form with written summary) that are to be used by investigators to document the informed consent of subjects (21 CFR 50.27(a), 45 CFR Part 46.111 and 21 CFR 56.111). This includes review of the translation process of those documents (by either certified translation OR forward and back translation by two different people).
- Other materials that require IRB submission and review of the translation process are those that impact participant safety or data integrity. Please refer to the list of examples of these documents at the end of this policy.
- Study documents that do not impact participant safety and/or data integrity may be translated (and must be submitted to IRB) but do not require translation certification or forward/back translations. Examples of these documents are found at the end of this policy. Note that documents in this category could vary study by study and may be at the discretion of the IRB.

<u>Short Form Consent:</u> Should be used sparingly. At renewal, the IRB will review the continued use of the short form and may require that the long form be translated (considerations include enrollment status, complexity, population, industry-funded, etc.)

1. May be used in one of the situations below:
    a. The study provides potential direct benefit to a participant that is not available outside of the research, or
    b. The study is minimal risk where the oral explanation can adequately address potential concerns, or

c. The study will enroll small numbers of participants (not more than 1-2 people) who do not speak English.

2. Process:
    a. Obtain IRB approval of short form consent and consenting process.
    b. Obtain IRB approval of oral summary (if not using the approved long form English consent).
    c. The investigator (or their designee) obtains informed consent, with the assistance of an interpreter (if the investigator is not bilingual) and in the presence of a bilingual witness. The process is an oral presentation to the potential participant and witness, including the elements of informed consent and any additional pertinent information included in the IRB-approved summary.
    d. The person obtaining consent should assess the potential participant's comprehension of the consent document, and the interpreter should continue to translate the consent discussion for the two parties.
    e. The potential participant should have time to ask questions, and the person obtaining consent should answer the questions. The interpreter should translate this conversation for both the potential participant and the person obtaining consent.
    f. Provide a copy of the translated Short Form to the potential participant. If the potential participant is unable to read, the translator should read the Short Form to the participant.
    g. Obtain signatures:
        i. Short form: Signed by Participant/Parent/LAR and Witness
        ii. Summary/Long form consent: Signed by Person obtaining consent and Witness
    h. Provide the participant with signed copies of the Short form (in their language) and Summary/Long form consent (in English).
    i. Document the consent process including who served as the witness, who did the interpretation, including name of bilingual interpreter and qualifications, and ID number (if using Duke Interpreter Services).

Long Form Consent:

1. Used when:
    a. Investigator expects enrollment of a particular population (more than 1-2 participants) who do not speak English, or
    b. The study is greater than minimal risk and does not meet any of the criteria above for use of the short form.

2. Process:
    a. Obtain IRB approval of translated long form consent and consenting process.
    b. The investigator (or their designee) obtains informed consent, with the assistance of an interpreter (if the investigator, or their designee, is not bilingual).
    c. The person obtaining consent should assess the participant's comprehension of the consent document, and the interpreter should continue to translate the consent discussion for the two parties.
    d. The potential participant should have time to review the consent document, ask questions, and the person obtaining consent should answer the questions. The interpreter should translate this conversation for both the participant and the person obtaining consent.
    e. Obtain signatures:
        i. Participant/Parent/LAR signs: consent form
        ii. Investigator (or designee): consent form
    f. Provide the participant with signed copies of the long form consent (in their language).
    g. Document the consent process including who did the interpretation, including name of bilingual interpreter, qualifications, and ID number (if using Duke Interpreter Services).

The following must be provided:

- If using a certified translation service, the translated form(s) and the certificate of translation are required.
- If using non-certified translators (i.e., bilingual staff), forward and back-translations, as well as attestation by the PI of the persons' bilingual abilities are required.
- If using sponsors' translated documents (e.g., NIH, private industry), copies of the documents must be uploaded into iRIS; no further translation documentation is required.
- If using validated and translated surveys/questionnaires, these must be uploaded into iRIS; no further translation documentation is required.

Examples of documents potentially impacting safety and/or data integrity, that must be submitted along with the translation process:

- Consent forms
- Participant instructions (e.g., drug or device handling)
- Survey/Interview questions

Examples of documents that should be submitted to IRB but may not require review of the translation process include:

- Study advertisements
- Phone scripts
- Pregnant partner form
- Simple diaries
- Validated surveys or questionnaires that are publicly available
- Sponsor-provided translated documents
- Study communication (e.g., newsletters, birthday cards, contact information cards)

Resources:
DUHS IRB Consent form templates:
https://irb.duhs.duke.edu/forms/consent-form-templates
DOCR Service Center (translation and interpreter services):
https://medschool.duke.edu/research/research-support/research-support-offices/duke-office-clinical-research-docr/get-docr-19
Interpreter Services at Duke Health: https://www.dukehealth.org/diversity-equity-and-inclusion/interpreter-services
International Patient Services: https://www.dukehealth.org/hospitals/duke-university-hospital/international-patient-services
Commercial Translation Services: https://irb.duhs.duke.edu/standard-language/translation-services
HHS: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/obtaining-and-documenting-infomed-consent-non-english-speakers/index.html
FDA: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/informed-consent