Translation: The written process of converting the meaning of a text from a source language into an equivalent text of another target language(s). This involves accurately

Protocol Deviation for Use of the ShortForm

Before utilizing the ShortForm to enroll a non-English speaking subject, Investigators and project teams must submit a protocol deviation as a Reportable Event (RE). Research teams must submit a RE each time they use a ShortForm to enroll a non-English speaking subject.

1. The IRB Committee and/or designated reviewer will review and evaluate the RE to confirm the following elements are met:
    a. The RE must explain the context of the consenting and enrollment taking place, the process that will be followed to consent and enroll the subject, and

a. In addition, the AME must also include one of the following:
    i. A plan for providing a copy of the approved English Consent Form translated into the spoken language of the subject. The translation of the consent form must follow the translation policies for subject-facing documents in IRB SOP: Recruitment and Enrollment of Non-English Speaking Subjects.

    OR

    ii. A detailed rationale explaining why it is not appropriate to provide the subject a copy of the consent form in their spoken language.
3. If additional enrollment of non-English speaking subjects in a specific language population is expected, the project should be amended following the process outlined under *IRB SOP: Recruitment and Enrollment of Non-English Speaking Subjects* section *Planning For Inclusion of Non-English Speakers.*
4. The AME must be approved before additional non-English speaking subjects in the specific language population are enrolled.

Reviewing CPRs After Use of the ShortForm

1. Investigators must report the protocol deviation for use of the ShortForm in their next Continuing Progress Report (CPR).
    a. IRB Committee should confirm the CPR in section 14 includes the following:
        i. Call out the use of the ShortForm in that reporting period.
        ii. Reference the previous submitted RE (protocol deviation)
        iii. Reference the submitted AME describing the plan for continued consent and communication with non-English speaking subject(s)

Planning for Recruitment and Enrollment of Non-English Speakers:

When a project will recruit, consent and enroll non-English speaking subjects, Investigators must plan and prepare accordingly and describe how they will carry out these activities in the eBridge SmartForm.

The IRB Committee or designated reviewer should review the protocol and eBridge SmartForm to identify who the target populations are, the respective language(s) that research will be conducted in, and who will provide ongoing translation and/or interpretation for the duration of the project, along with their qualifications.

The Protocol (if applicable) eBridge SmartForm must include the following:

1. A description of the subject population, the procedures for eliciting informed consent, the process for conducting project activities, and the process of administering project documents.
2. The plan for ensuring continued consent and communication with the subjects for the entirety of the project.
3. Uploaded translations of ALL subject-facing documents in the subjects' spoken/preferred language.

The qualifications of Translators and Interpreters will also be assessed by the IRB Committee and/or designated reviewer.

Translation of Subject-Facing Documents

When reviewing a submission that involves non-English speakers, the IRB Committee or designated reviewer ensure the Investigator and project team has completed the following steps and requirements:

1. The English and translated versions of all subject-facing documents must be uploaded to Section 52.