SOP Number: ADM 26
SOP NAME: Consenting Non-English Speaking or Literacy-Challenged Participants
Effective Date: 17-Nov-2022

1. Policy

Full version translation of the Spanish informed consent document (ICD) will be made available to all sites (upon request) in the StrokeNet trials. A short form ICD bank is available for all trials. Once a short form is utilized and the StrokeNet National Coordinating Center (NCC) Project Manager is notified, a fully translated ICD in that language will be requested for the purpose of re-consenting the participant/LAR in their own language. The trial will cover the cost of translations approved by trial-specific project managers. HIPAA language embedded into the protocol ICD will be translated as part of the ICD. If a site requires a site-specific stand-alone HIPAA document, the site will be responsible for the expense of translation. If the site chooses to use the StrokeNet stand-alone HIPAA document, there is no translation cost. All translations provided for review are required to provide certification of the translation.

2. Definitions and Abbreviations

cIRB	Central Institutional Review Board
CIRBI	Electronic protocol administration system for the Advarra IRB
ICD	Informed Consent Document
NCC	National Coordinating Center
RAP	Electronic protocol administration system for StrokeNet cIRB

3. Scope

The NIH StrokeNet investigators are strongly encouraged to use the following procedures for conducting the informed consent process with individuals that do not understand English or have low literacy skills. If these procedures are not used, investigators must provide a copy of their local approved procedures for enrolling these populations to the cIRB. If no local approved procedures are available, the StrokeNet procedures must be used.

4. Procedures

A. Informed Consent Procedures for Participants who do not understand English

1. Individuals who do not understand English may ask or be asked to participate in a clinical trial at locations where English is the predominant language. Consistent with the requirement that selection of participants be equitable, individuals should not routinely be excluded from participating in StrokeNet research simply because they do not understand English.

2. When individuals 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 participants, or their legally authorized representatives is in language understandable

to the participants or their representatives. Understandable means the information presented to potential participants is in a language and at a reading level they can comprehend, including an explanation of scientific and medical terms.

B. Informed Consent Procedures when Enrollment of Participants who do not understand English is Expected using a fully translated Informed Consent Document (ICD)

1. StrokeNet investigators are required to provide a fully translated ICD in a language understandable to the participants.
2. When investigators reasonably expect that the participant population for a proposed study will include individuals who do not understand English and can anticipate the specific language(s) that they will understand, appropriately translated ICD(s) are required.
3. The StrokeNet National Coordinating Center (NCC) has determined that Spanish will be considered standard by the NCC. The full version translation of the informed consent document(s) (ICD) will be made available to all sites (upon request) in the particular trial.
4. The StrokeNet National Coordinating Center (NCC) and the Advarra IRB will provide translations of Short Form ICDs for use by request.
5. There is a "bank" of Short Form ICDs in approximately 40 languages available, other languages may be added on case by case basis.
6. The NCC will provide the full translated ICDs that include site-specific language for use at sites as needed.
7. The investigators must also provide the cIRB with a description of how interpreters for oral communication will be made available to participants that do not understand English during the consent process and while participating in the study (on the StrokeNet cIRB Local Context Form or on the Advarra IRB CIRBI application).

C. Informed Consent Procedures when Enrollment of Participants who do not Understand English is Unexpected and fully Translated ICD is not available

1. A short form consent in a language the potential participant understands must be used to obtain informed consent. In addition, the investigator must determine that there is sufficient justification (e.g., due to a limited therapeutic window) for obtaining the participant's consent without waiting for a fully translated ICD to be reviewed and approved by the IRB prior to enrollment of the participant. In making a decision to allow enrollment of a participant who does not understand English into a research protocol without using a fully translated ICD, the investigator should consider whether the consent process, under this circumstance, would provide the participant with sufficient opportunity to understand the information being presented. If consent is sought and the investigator believes that the prospective participant has not understood the information presented, then the individual should not be enrolled in the research.

2. The "short form" method for obtaining informed consent should only be used for the occasional and unexpected enrollment of a potential participant that does not understand English in a study for which no fully translated ICD is available in a language the individual understands.
3. Informed Consent Process for Individuals that do not understand English using a Short Form
    i. The investigator performing the informed consent process, with the assistance of an interpreter if needed, provides an oral translation of the cIRB-approved English ICD. The oral presentation must be in language understandable to the participant.
    ii. The investigator, with the assistance of an interpreter if needed, answers any questions from the prospective participant.
    iii. There must be an impartial witness to the oral presentation. The witness must not be the person obtaining informed consent and must be fluent in the language of the oral presentation.
    iv. During the informed consent process, the participant is given the cIRB-approved translated short form and a copy of the cIRB-approved English version of ICD, which serves as the written summary.
    v. The short form is signed and dated by the participant.
    vi. The witness signs both the short form and the copy of the cIRB-approved English version of the long form. (Note that when an interpreter assists the person obtaining consent, the interpreter may serve as the witness, but is not required to do so.)
    vii. The investigator obtaining consent signs the copy of the cIRB-approved English version of the ICD and gives a copy of the summary to the participant, in addition to a copy of the short form.
    viii. Once the participant has consented and eligibility is confirmed, the English version of the IRB-approved ICD translated into the participant's language must be provided to the participant within 30 days from the participant's initial consent. The date of provision of this ICD to the participant should be documented.
    ix. The investigators must also provide the cIRB with a description of how interpreters for oral communication will be made available to participants while participating in the study (on the Local Context Form or Advarra IRB CIRBI application).

D. Informed Consent Procedures for Individuals with Apparent Low Literacy or who are Illiterate

1. Individuals with apparent low literacy may not be excluded from participating in a study without justification. If greater than 10% of your patient population has low

literacy, a witness signature block will be added to the ICD. For participants with apparent low literacy, oral presentation of the information contained in the ICD is especially important.

2. Informed Consent Process for potential participants that have low literacy skills
    i. The investigator performing the informed consent process provides an oral presentation of the entire cIRB-approved English ICD.
    ii. The investigator answers any questions from the prospective participant.
    iii. There must be an impartial witness to the oral presentation. The witness must not be the person obtaining informed consent.
    iv. Participants who cannot write, can indicate their consent by "making their mark" on the consent form, when consistent with applicable state law. In the situation where a mark is used, a progress note in the participant's case history should indicate the reason for the lack of a signature.
    v. The witness signs the copy of the cIRB-approved English version of the ICD.
    vi. The investigator obtaining consent signs the copy of the cIRB-approved English version of the ICD.

5. Applicable Regulations and Guidelines

Advarra IRB Handbook for Investigators, Institutions, Sponsors, and Sponsors' Representatives

6. References to Other Applicable SOPs

7. Attachments and References

8. Document History

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1.0	Final	17-Nov-2022	17-Nov-2022	17-Nov-2022