SOP Number: ADM 26
SOP NAME: Consenting Non-English Speaking or Literacy-Challenged Participants
Effective Date: 17-Nov-2022 (revised 07-Aug-2023)

1. Policy

A full translation of the informed consent document (ICD) into Spanish 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 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. A certification of translation must be provided for all site-specific translations as well as translations provided by the NCC.

2. Definitions and Abbreviations

CIRB	Central Institutional Review Board
CIRBI	Electronic protocol administration system for the Advarra IRB
ICD	Informed Consent Document
LAR	Legally Authorized Representative
NCC	National Coordinating Center
RAP	Electronic protocol administration system for StrokeNet CIRB

Impartial Witness - A person who is independent of the trial, cannot be unduly influenced by the people involved with the trial, who is present during the entire informed consent process and who attests to the adequacy of the consent process and to the participant's voluntary consent. A non-research staff member or the participant's adult relative if there is no reasonable concern that the proposed witness is not acting in the best interest of the individual.

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 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 and a fully translated Informed Consent Document (ICD) is used.
    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. The full version of the ICDs translated into Spanish will be made available to all sites, upon request, in each trial.
    4. The StrokeNet National Coordinating Center (NCC) and the Advarra IRB will provide translations of Short Form ICDs for use by request. There is a "bank" of Short Form ICDs in approximately 40 languages available, other languages may be added on case-by-case basis.
    5. The NCC will provide fully translated ICDs in languages other than Spanish once the short form consent process is used for consenting in that specific language.
    6. Site investigators must 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 follow-up for the study. Sites should also describe if interpreters are utilized in person or remotely during the informed consent process. This information should be documented on the StrokeNet CIRB Local Context Form or on the Advarra IRB CIRBI application.
    7. A witness is needed during the informed consent process when the participant or LAR is **unable to read or sign** the consent form for the following reasons:
        i. The participant or LAR is non-English speaking.
        ii. The participant or LAR is illiterate.
        iii. The participant or LAR is visually impaired.
        iv. The participant or LAR is physically unable to sign the consent form.
        v. Another reason with an explanation.

C. Informed Consent Procedures when Enrollment of Participants who do not Understand English is Unexpected and a fully Translated ICD is not available.
   1. A short form ICD 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. 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. The StrokeNet NCC and the Advarra IRB will provide translations of Short Form ICDs for use by request.
   4. There is a "bank" of Short Form ICDs in approximately 40 languages available and other languages may be added on a case-by-case basis.
   5. Informed Consent Process for participants 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 a 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, as defined above. 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 CIRB-approved English version of the ICD and gives a copy 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 CIRB-approved ICD must be translated into the participant's native language (coordinated by the NCC) and receive CIRB approval for use. The translated ICD must be provided to the participant within 30 days from initial consent with the short form process and the date of provision should be documented.

ix. Site investigators must provide the CIRB with a description of how interpreters for oral communication will be made available to participants during the consent process and while participating in follow-up for the study. Sites should also describe if interpreters are utilized in person or remotely during the informed consent process. Interpreters can be used as witnesses to the informed consent process; therefore, the site should describe their process for capturing the interpreter/witness signature if they are located remotely. This information should be documented on the StrokeNet CIRB Local Context Form or on the Advarra IRB CIRBI application.

D. Informed Consent Procedures for Participants 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. For participants with apparent low literacy, oral presentation of the information contained in the ICD is especially important.
2. Informed Consent Process for 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 (defined above) 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 ICD, when consistent with applicable state law. In the situation where a mark is used, a progress note in the participant's case history and research record should indicate the reason for the lack of a signature.
    v. The witness signs the CIRB-approved English version of the ICD.
    vi. The investigator obtaining consent signs the CIRB-approved English version of the ICD.

5. Applicable Regulations and Guidelines

21 CFR 50.23 – Exceptions from General Requirements
45 CFR 46.116-117 – Documentation of Informed Consent
Advarra IRB Handbook for Investigators, Institutions, Sponsors, and Sponsors' Representatives

6. References to Other Applicable SOPs

7. Attachments and References

8. Document History

Version	Description of Modification	Completion Date	Issue Date	Effective Date
1.0	Final	17-Nov-2022	17-Nov-2022	17-Nov-2022
2.0	Definition and use of an impartial witness and interpreter during informed consent	15-May-2023	**07-Aug-2023**	**07-Aug-2023**

NIH StrokeNet Network

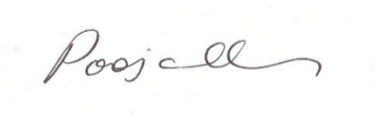
Standard Operating Procedure (SOP)

Consenting Non-English Speaking or Literacy-Challenged Participants

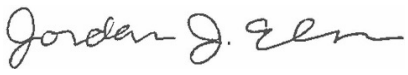
Version 2.0

ADM #26

Reviewed and Approved by:



Pooja Khatri, MD, (StrokeNet NCC Principal Investigator)



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