

NIH StrokeNet Network Standard Operating Procedure

SOP Number: GCP 13

SOP NAME: Remote Informed Consent Process - Local Management

Effective Date: 29-May-2020

1. Policy

The purpose of this Standard Operating Procedure (SOP) is to describe the requirements for obtaining informed consent. This procedure establishes the informed consent process in situations where it is not possible for the subject or legally authorized representative (LAR) and the person obtaining informed consent to physically be in the same location for an in-person informed consent discussion. For example, the subject/LAR lives outside of Clinical Performing Site (CPS) area, inclement weather, schedule constraint, hospital visitor restrictions, etc. The process begins when the Principal Investigator (PI), or designee, determines or identifies a situation where it is not possible for an in-person informed consent discussion. The process ends when the subject is no longer a research subject or potential research subject.

When there is a situation, where it is not possible for an in-person informed consent discussion, the informed consent process may be performed remotely as described below. Note that federal regulatory agencies do not regard verbal telephone consent as constituting the documentation of signed informed consent that is required by federal regulations. The process described below should not be confused with the IRB finding that a protocol meets the criteria for a waiver or alteration of the consent document /process.

2. Definitions and Abbreviations

CFR - Code of Federal Regulations
CIRB - Central Institutional Review Board
CPS - Clinical Performing Site
eIC - Electronic Informed Consent
ICD - Informed Consent Document
LAR - Legally Authorized Representative
NDMC - National Data Management Center
NIH - National Institute of Health
PI - Principal Investigator
SOP - Standard Operating Procedure

3. Scope

Applies to all personnel involved in the implementation and coordination of obtaining informed consent for clinical trial participation.

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Personnel responsible: Investigator/Co-investigator(s) and, when delegated by the investigator, sub-investigator(s), clinical research coordinators, or other research team members and hospital personnel caring for the patient.

4. Persons Responsible

The Principal Investigator (PI) is responsible and accountable for gaining participants' informed consent to participate in the study in accordance with federal and local law, rules, regulations and StrokeNet policy. The PI may delegate the informed consent process to another **qualified individual** involved in the study but may not delegate accountability.

When the discussion or consent process takes place by a means other than face-to-face communication, but still requires written documentation of consent, follow the procedures below to ensure adequate documentation of prospective informed consent for research. The person conducting the informed consent process must carefully review each section of the informed consent document (ICD) and address the subject or LAR's questions and concerns.

5. Procedures

1. Informed consent will be obtained for each research subject prior to any study procedure(s) or altering a subject's care for the purpose of research. This includes screening laboratories, vital signs, questionnaires, or interventions associated with the study.
2. The current Central Institutional Review Board (CIRB) approved version of the Informed Consent Document (ICD) will be maintained at each CPS and will be easily accessible to the medical staff or on-site coordinator.
3. The consenting study staff member will identify who is legally authorized to give consent following the applicable law according to 45 CFR 46.102.
4. The ICD (and any stand-alone HIPAA or stand-alone Bill of Rights if applicable) must be presented to the subject and/or LAR during the consent process. Transmission of these documents must use one of the following 21 CFR part 11 compliant methods:
 - online survey (via REDCap or other secure software),
 - E-consent module in EMR,

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- fax,
- postal mail, or
- Email.

The method of transmission used will depend on the options approved at the local site and the subject's circumstances. To access and complete an online survey, the subject and/or LAR must have a smartphone, tablet or computer with Wi-Fi or cellular internet connectivity. Fax transmission will require access to a fax machine.

5. The remote consent (and/or applicable stand-alone HIPAA or Bill of Rights documents) must be documented by an acceptable signature.
 - The subject or LAR must document consent with a handwritten signature. The scripted name or legal mark, while conventionally applied to paper, may also be applied to other devices that capture the name or mark (e.g., signature capture using touchscreen or a mouse).
 - The participant or LAR may print the form, sign the paper copy, and then email a scan or picture of the completed form, or mail the completed form back to the study team. Email may only be used if the subject/LAR agrees after being informed that there is a small risk of emails being intercepted in route.
 - The participant or LAR may also document consent by signing using a signature pad or touchscreen on a tablet or cell phone with a stylus, mouse, or their finger. The electronic document may then be transmitted back to the site using a secure database transmission (e.g., REDCap).
 - While OHRP and FDA regulations permit the use of electronic signatures, the NIH StrokeNet NCC determined that only the handwritten signatures will be accepted on eICD's signed remotely for StrokeNet studies. This requirement is necessary for administrative purposes.
 - The identity of the subject who will be electronically signing an eIC must be verified per local and institutional regulations. FDA guidance does not specify any particular method for verifying the identity of an individual and accepts many different methods.
6. The date and version number of the ICD should be confirmed between the consenting clinician and the subject and/or LAR prior to beginning the consent process.
7. The consenting study staff member will fully inform the consenting party of all pertinent aspects of the study including the written information as approved by the CIRB per the informed

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consent SOP, NIH StrokeNet SOP Number: GCP 03, ensuring that the possibility of coercing or unduly influencing an individual to participate is minimized.

8. If the respondent expresses a sustained interest in study participation, give instructions about where they need to sign and date the ICD and how to transmit the entire signed and dated form back using one of the 21 CFR part 11 -compliant methods listed above.
 9. If a participant is unable to read a witness will be present during an in person eIC with the study staff member conducting the consent process. The witness will be able to hear both sides of the conversation per the informed consent SOP, NIH StrokeNet SOP Number: GCP 03. If remote consent requires a witness then remote consent will not be used.
 10. After receipt of the signed and dated ICD, the person obtaining consent should sign and date the form with the current date (the date they received the ICD). A transmitted copy of the fully signed consent form should be sent back to the patient/LAR for his/her records using a 21 CFR part 11 -compliant method for transmission. The ICD is not valid and study enrollment cannot proceed unless all pages are received, and the form is appropriately filled out/signed/dated by the patient/LAR.
 11. Documentation of the informed consent process will follow CPS institutional policy per SOP, NIH StrokeNet SOP Number: GCP 03. A pdf file of the ICD in its entirety will be uploaded to WebDCU™ for remote monitoring by the National Data Management Center (NDMC) per standard procedure.
 12. If, during the course of a research study, the informed consent changes in such a way that the CIRB requires re-consent of a participant, participants will be re-consented using the updated ICD. This re-consent process may occur in person or through the remote consent process steps listed above. The participant may be re-consented at the next patient contact unless otherwise stated by the CIRB or study sponsor. Re-consenting may be completed by any trained investigator or coordinator who is delegated the responsibility on the delegation of authority log.
- Vulnerable Subjects:
13. Guidelines for enrolling vulnerable subjects will follow the informed consent SOP, NIH StrokeNet SOP Number: GCP 03, and good clinical practice. If a subject has an impairment that would make informed consent inappropriate, and they do not have a LAR available, this subject would not be enrolled in the study.

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6. Applicable Regulations and Guidelines

- Title 21 CFR 50.20 - General Requirements for Informed Consent
- Title 45 CFR 46 – Protection of Human Subjects
- 21 CFR part 11. For additional information, see the guidance for industry Part 11, Electronic Records; Electronic Signatures – Scope and Application, available at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm>.
- UC Human Research Protection Policy Number: HPR-090 Informed Consent Process for Research
- NIH StrokeNet Network Standard Operating Procedures
- Use of Electronic Informed Consent: Questions and Answers Guidance for Institutional Review Boards, Investigators, and Sponsors
<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/use-electronic-informed-consent-questions-and-answers/index.html#toc1>

7. References to Other Applicable SOPs

- NIH StrokeNet SOP Number: GCP 03

8. Attachments and References

9. Document History

Version	Description of Modification	Completion Date	Issue Date	Effective Date
1.0	Final	29-May-2020	29-May-2020	29-May-2020
2.0	Update e-signature requirements	09-Sept-2020	09-Sept-2020	09-Sept-2020