

NIH StrokeNet Network Standard Operating Procedure

SOP Number: ADM 24

SOP Name: Central Electronic Informed Consent Process

Effective Date: 29-May-2020 (rev 13-Feb-2023)

1. Policy

The purpose of this Standard Operating Procedure (SOP) is to describe the central process for utilizing an electronic platform for obtaining informed consent. The ready availability of electronic media and smartphones provides opportunities for documentation of informed consent processes using electronic informed consent (eIC). eIC does not change the essential informed consent process for StrokeNet Trials. HIPAA authorizations may also be obtained electronically per this SOP.

The informed consent process is still expected to be a compassionate and respectful direct conversation between study personnel and potential participants or their representatives. This verbal discussion involves concisely and efficiently describing the research, reviewing the content of the informed consent document, including the HIPAA authorization, and answering questions about participation in the study. Substituting the paper informed consent document with eIC only changes how the informed consent document is presented to the participants or their legally authorized representative (LAR) and how consent to participate is recorded and shared. The intent of using an eIC is to improve the experience of the person providing consent, make consent information available to them electronically, allowing consent to be obtained remotely if needed, and to document consent more easily. eIC is also intended to make retention and monitoring of consent processes easier, secure, and more accessible to better ensure compliance. This standard operating procedure (SOP) is intended to provide a standardized process for trial-specific implementation of eIC for all Clinical Performance Sites (CPS) participating in StrokeNet. StrokeNet expects all participating CPS will eventually use this central eIC process unless special consideration and approval is given for a local process by the Central Institutional Review Board (CIRB). Should a CPS participating in an exception from informed consent (EFIC) trial determine a participant or LAR is able to give consent, this SOP can be implemented for eIC. This SOP is informed by, and consistent with, the FDA and OHRP harmonized final guidance titled “Use of Electronic Informed Consent in Clinical Investigations” that provides recommendations on procedures that may be followed when using an eIC.

Platform (REDCap)

StrokeNet will be using the University of Cincinnati and Cincinnati Children’s Hospital Medical Center’s REDCap platform for eIC. REDCap is a mature, secure web application for building and managing online surveys and databases. The StrokeNet centrally managed eConsent process meets the requirements of 21 CFR Part 11 by combining the technical features of REDCap with StrokeNet policies, procedures, training, validation, and documentation. A REDCap database will be created for each clinical performance site (CPS) participating in each trial. Each trial’s REDCap database will contain an entry for each participant enrolled using eIC. The primary instrument collected for each participant will be the electronic consent document (eICD). Secondary instruments could include a standalone HIPAA Authorization (if not embedded in the eICD) and an electronic informed consent process attestation.

Electronic Informed Consent Document (eICD)

The database and instruments will be constructed, tested, and approved in the REDCap test environment. The database will be moved to the production environment when approved by the CIRB. The eICD is

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located on a static URL that can be accessed from any web browser. An example of the eICD can be found here: [link](#)

Electronic Informed Consent (eIC) Process Attestation Form

A secondary instrument, the Electronic Informed Consent Process Attestation is a required form when the consent process is completed remotely. An example of the form can be found here: [link](#)

2. Definitions and Abbreviations

CFR - Code of Federal Regulations
CIRB - Central Institutional Review Board
CPS - Clinical Performance Site
EFIC – Exception from Informed Consent
eIC – Electronic Informed Consent
eICD – Electronic Informed Consent Document
ICD - Informed Consent Document
LAR - Legally Authorized Representative
NCC – National Coordinating Center
NDMC - National Data Management Center
NIH - National Institute of Health
PI - Principal Investigator
SOP - Standard Operating Procedure
* - except when obtaining informed consent for an EFIC trial

3. Scope

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

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

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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 or electronic 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 participant or LAR's questions and concerns.

5. Procedures

The informed consent process is described previously and will be performed consistent with the study protocol and the approved CIRB application. Informed consent via eIC will be obtained for each research participant/LAR prior to any study procedure(s) or altering a participant's care for the purpose of research*. This includes screening laboratories, vital signs, questionnaires, or interventions associated with the study. The eICD must be presented to the participant and/or LAR during the consent process. Transmission of the eICD must use the online survey (via REDCap). To access and complete an online survey, the participant and/or LAR must have a smartphone, tablet or computer with Wi-Fi or cellular internet connectivity. The steps below are to be followed when documenting consent using the eICD:

1. If applicable, the consenting study staff member will identify who is legally authorized to give consent following the applicable law according to 45 CFR 46.102.
2. Using the REDCap platform, the delegated study personnel obtaining consent will share the eICD via emailing or texting the URL link to the participant or LAR. If obtaining eIC remotely, the delegated study personnel will also have a copy of the current eICD in his/her possession to reference and contact the participant/LAR over the phone to confirm that they are able to open and view the eICD before proceeding with the informed consent discussion.
3. The date and version number of the eICD should be confirmed between the consenting study team member and the participant/LAR prior to beginning the consent process.
4. The consenting study team member will fully inform the participant/LAR of all pertinent aspects of the study and the HIPAA authorization. The process will include all the written information as currently approved by the CIRB, per the informed consent SOP, NIH StrokeNet SOP Number: GCP 03, ensuring that the possibility of coercing or unduly influencing an individual to participate is minimized.
5. Following the informed consent discussion, if the participant/LAR elects to participate in the clinical study, they will use the eConsent platform (REDCap) to complete the eICD. Essential eICD

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elements include documenting the participant and LAR identity, confirming that all clinical and study-related and HIPAA authorization questions have been answered, and entering their signature using a mouse or touch screen. After entering all required information, the eConsent platforms asks the participant or LAR to confirm the information entered is accurate.

6. If the respondent expresses a sustained interest in study participation, the study team member obtaining consent will give instructions about completing the information fields on the eICD, where to sign and date and how to transmit the entire signed and dated form back to the study team using the REDCap platform.
7. When eIC is used in-person, the completed eICD is signed and dated by the participant or LAR and by the delegated study team member at the time of consent by entering their signature using a mouse or touch screen. If eIC is used for remote consent, the participant or LAR signs the eICD by entering their signature using a mouse or touch screen and the delegated research team member will subsequently complete a remote attestation form. A copy of the signed eICD may also be provided to the pharmacy (if needed) or scanned into the participant's medical record as required.
8. 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 must 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 the StrokeNet eConsent process will not be used. REDCap is programmed to hide witness signature fields if remote consent is selected in the eICD.
9. A copy of the signed eICD will be automatically saved in the REDCap database and should be immediately accessible to the research team for review. A printed copy of the eICD should be provided to the participant/LAR if the participant/LAR does not request an electronic copy be emailed to the address provided during the online survey. CPS should print a copy of the completed eICD and save it with the participant's research file.
10. In the case of technical difficulties with the eIC platform, informed consent must proceed using a paper ICD, or other approved method.
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 signed eICD in its entirety, signed HIPAA and remote consent attestation form, when applicable, will be uploaded to WebDCU™ for remote monitoring by the NDMC per standard procedure. In the case that the eIC platform fails and consent is obtained using a paper ICD, a scanned copy of the signed ICD will be uploaded to WebDCU™

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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 eICD. 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. Participants may also be re-consented using eIC if they regain capacity after surrogate consent, if required by a local IRB or the protocol. Re-consenting may be completed by any trained investigator or coordinator listed on the study who is delegated the informed consent responsibility

Vulnerable Participants:

13. Guidelines for enrolling vulnerable participants will follow the informed consent SOP, NIH StrokeNet SOP Number: GCP 03, and good clinical practice. If a participant has an impairment that would make informed consent inappropriate, and they do not have a LAR available, this participant would not be enrolled in the study.
14. When the study team member obtaining consent and the participant or LAR are not physically in the same location, obtaining consent form a vulnerable or impaired individual which requires a confirmed impartial witness, is not possible.

6. NCC Responsibilities, Site Responsibilities & Process

1. The NCC will create a REDCap database for each CPS participating in each trial.
2. The NCC will ensure and verify that the most recent site specific CIRB-approved version of the ICD and HIPAA is available in REDCap for eICD use.
3. The NCC will provide the site with their CIRB approval to use the central eIC process and access to their study-specific and site-specific link and/or QR code in REDCap.
4. The site will designate a primary and back-up user to access to their site-specific eICD link or QR code in REDCap. These users will be responsible for distributing the link/QR code to the wider study team.
5. The completed eICD will be provided as a PDF document in the site-specific REDCap database under the File Repository - PDF Survey Archive tab.
6. When an eICD Remote Consent Attestation is required the site's designated individuals who have access to REDCap will be responsible for ensuring the attestation is completed by the person who obtained consent within 5 days of eICD completion. This form and the signed eICD will be maintained for each participant in REDCap.
7. The PDF versions of both documents, as applicable, are combined and uploaded to WebDCU™ within 5 days of signature.

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After the primary instruments are submitted, the REDCap database will record any edits made to the documents. This should always be strictly avoided; however, REDCap will capture date/time and username who altered any data.

7. Applicable Regulations and Guidelines

FDA and OHRP harmonized final guidance titled “Use of Electronic Informed Consent in Clinical Investigations”

21 CFR Part 11

45 CFR 46.102

8. References to Other Applicable SOPs

NIH StrokeNet SOP Number: GCP 03 and GCP 13

9. Document History

Version	Description of Modification	Completion Date	Issue Date	Effective Date
1.0	Final	29-May-20	29-May-20	Upon date of last signature
2.0	General edits, addition of EFIC, and confirmation of 21CFR Part 11 compliance	13-Feb-23	14-Feb-23	14-Feb-23



The NIH StrokeNet Network

Standard Operating Procedure (SOP)

Central Electronic Informed Consent Process

Version 1

ADM 24

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