# StrokeNet CIRB eConsent Webinar FAQs

**Are slides and video recording of the webinar available?**

http://nihstrokenet.org/education/nih-strokenet-webinars-and-meetings

**Is there a difference between remote consent and eConsent?**

*Remote consent describes the process of obtaining and documenting informed consent when the patient or LAR and the person obtaining consent are not physically in the same location. Examples of remote consent include faxing, emailing or mailing the signed document. eConsent is another method of remote consent that can be utilized by StrokeNet sites through approval by the cIRB. However, eConsent is also a process that can be used when the patient or LAR are reviewing it in person.*

**Is RedCap Part 11 compliant?**

*REDCap supports part 11 compliant processes. In other words, REDCap has the technical features necessary to serve as the database component of a 21 CFR Part 11 compliant study. However, a project in REDCap must have policies, procedures, training, validation and documentation meeting the requirements of Part 11 and the predicate rules for the underlying legislation. This will be ensured centrally by StrokeNet NCC with documentation for eConsent projects that align with guidance for Part 11.*

**How do you confirm the identity of the person signing the eICD?**

*eConsent does not change the process by which consent is obtained; it only changes the method that documentation is captured. As such, sites should continue to communicate with the LAR or subject using in-person, telephone or video communication. Existing measures completed during routine clinical care and in-person consent procedures should be used to verify with whom the study team member is speaking, according to local and institutional regulations. In addition, the consent process should be revisited during any follow-up visits. It is important to remember that informed consent is an ongoing process and not a single event built around signing the ICF*

**Patient/LAR email is a required field. How do you handle the eConsent if they do not have email?**

*Email will not be a required field but will be suggested if the patient/LAR wishes to receive an electronic copy of the signed ICD. In the case that an email address is not provided, the study team will be responsible for delivering a paper copy of the completed ICD, HIPAA Authorization and other applicable forms (Ex: MOST Participant Information Sheet) to the patient/LAR either in-person or through the postal mail.*

**Is eConsent an all or nothing option?**

*If a site elects to use the central eConsent platform for a given trial, this does not eliminate the possibility of using other methods of obtaining consent (ex, paper, or fax if IRB-approved process). For example, if technical difficulties occur such that the use of eConsent is not*

*feasible, then paper ICDs may still be utilized. Furthermore, other options for remote consent, such as fax, will remain available for use upon approval by the CIRB.*

**Our institutional policy requires a witness line for remote consent. Is this feasible with the central eConsent platform?**

*Impartial witness signatures are only required by federal regulations in very limited circumstances; however, witnesses may be required by some institutions as part of their local policy. IRBs may also require witnesses to assure an adequate informed consent process for some research studies. The cIRB will not require witnesses for StrokeNet studies approved to use the central eConsent platform.*

*Federal regulations require witness signatures if a person is unable to read the consent form or if a "short form" consent process is used. Using an impartial witness in these situations will often not be feasible during the remote consent process.*

*In other situations, a witness does not need to be impartial. For example, some institutions require two study team members to witness the consent conversation if consent is obtained remotely. In this situation, witness documentation should be maintained at the site level according to local policies. Since witnesses will not be required by the cIRB for studies approved for eConsent, any local requirements for witnesses will not be managed centrally.*

**Can the central eConsent platform accommodate site-specific ICD/HIPAA language?**

*Yes. Each site has a unique project in REDCap that will contain the precise language of the CIRB approved ICD, HIPAA Authorization and supporting documents.*

**Can a person sign on a device that is not their own? For example, the link is sent to a friend's phone, and the LAR signs it?**

*The patient/LAR must have access to an internet or WiFi capable device in order to access the eICD and provide their handwritten signature. The device does not need to belong to them.*

**Will the eIC be available in other languages?**

*For this first iteration of the eConsent platform, only English versions of the eConsents are being provided. As the process is refined, translated eICDs will be made available. Please continue to use the paper short form translations, or fully translated consent (if available to your site) for consenting non-English speaking subjects.*

**Can HIPAA Authorization be signed electronically?**

*HIPAA Authorization will be signed in the same manner that the eICD is signed. It will appear through the REDCap platform upon signing the eICD. It is important to remember that the signature used in the eConsent platform is considered a "handwritten signature" and not an "electronic signature."*

**If the eICD is delivered to the patient/LAR giving them time for consideration, how do we ensure they do not sign prematurely, or sign more than once?**

*In non-emergent trials, the eICD may be provided to the patient/LAR for their consideration before consent is actually obtained. If the patient/LAR accidentally completes the eICD before the consent conversation has occurred, or completes the eICD incorrectly, the study team should direct the patient/LAR to access the link again to complete the form. Only the correct eICD will be considered. This is similar to the process for ensuring a paper ICD is completed correctly.*

**What kind of electronic signatures are acceptable in RedCap on eConsents?**

*REDCap will only allow a handwritten signature. Individuals will provide their signature using a computer mouse, a stylus or their finger. Electronic signatures, such as DocuSign or Adobe Signature, are not compatible with the REDCap eConsent platform.*

*Per 21CFR Part 11, a handwritten signature means the scripted name or legal mark of an individual handwritten by that individual and executed or adopted with the present intention to authenticate a writing in a permanent form. The act of signing with a writing or marking instrument such as a pen or stylus is preserved. The scripted name or legal mark, while conventionally applied to paper, may also be applied to other devices that capture the name or mark. An electronic signature means a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.*

**Is DocuSign an alternate approach for remote consent in StrokeNet trials?**

*Although REDCap is the centrally approved, centrally-managed and typically most time-efficient method of obtaining remote consent, sites may choose to set up an alternate local process to obtain remote consent, such as with DocuSign, upon approval by the CIRB.*

**What are the next steps to activate eConsent?**

1. Sites will receive the eConsent central SOP and trial-specific Remote Consent Implementation form from the NCC as each study is approved by the cIRB for eConsent use.
2. Each site will review the eConsent central SOP and complete the implementation form to indicate whether they will use the central process. The site will send this implementation form back to the NCC, who will submit it on behalf ofthe site for cIRB approval.
3. Sites will receive documentation of cIRB approval to use the central eIC process and access to their study and site-specific link in REDCap from the NCC.
    a. The NCC will ensure and verify that the most recent site specific CIRB-approved version of the ICF is available in REDCap for eICD use.
    *b.* The eICD can be downloaded as a PDF from REDCap for submission to local IRBs if needed.

# Additional Information on 21 CFR Part 11 Compliance of REDCap

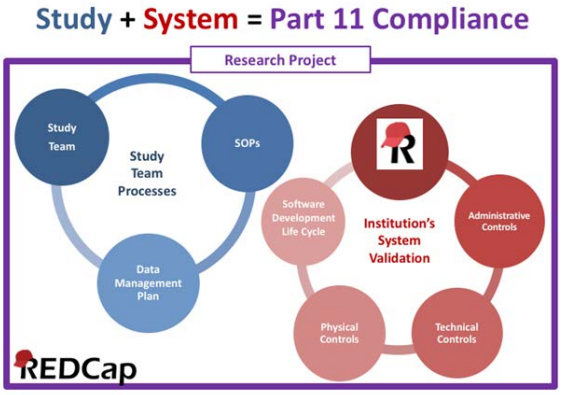
## 1. What is 21 CFR Part 11?

Title 21 Code of Federal Regulations governs Food and Drugs. Part 11 consists of the Food and Drug Administration (FDA) guidelines that set forth the criteria under which the Agency considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper. This regulation, which applies to all FDA program areas, was intended to permit the widest possible use of electronic technology, compatible with FDA's responsibility to protect public health. Please see the link for the Code of Federal Regulations Title 21:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=11%20%20

## 2. Is REDCap 21 considered to be CFR Part 11 compliant?

REDCap has the technical features necessary to serve as the database component of a 21 CFR Part 11 compliant study. However, a project in REDCap must have policies, procedures, training, validation and documentation meeting the requirements of Part 11 and the predicate rules for the underlying legislation. An FDA auditor will review all project documentation to determine **AT THE PROJECT LEVEL** if a given study is compliant.

*Cincinnati Children Hospital Medical Center (CCHMC) REDCap Support will supplement some validation documentation. The majority of the documentation, training, policies, and project validations are the responsibility of the research investigator.*

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## 3. What documentation is available to demonstrate that policy and process align with 21CFR part 11 guidance?

The StrokeNet National Coordinating Center (NCC) has a Central IRB (cIRB) approved StrokeNet Central eConsent SOP that outlines process and policy that aligns with 21CFR part 11 guidance. This includes the descriptions of acceptable handwritten signatures captured on the eConsent templates in REDCap. Training attestations and security validation documentation are also collected and maintained.

## 4. What types of electronic signature are acceptable in RedCap on eConsents?

REDCap will only allow a handwritten signature. Individuals will provide their signature using a computer mouse, a stylus, or their finger. Electronic signatures, such as DocuSign or Adobe Signature, are not compatible with the REDCap eConsent platform.

Per 21CFR Part 11, a handwritten signature means the scripted name or legal mark of an individual handwritten by that individual and executed or adopted with the present intention to authenticate a writing in a permanent form. The act of signing with a writing or marking instrument such as a pen or stylus is preserved. The scripted name or legal mark, while conventionally applied to paper, may also be applied to other devices that capture the name or mark. An electronic signature means a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

## 5. Is DocuSign an alternate approach for remote consent in StrokeNet trials?

Although REDCap is the centrally approved, centrally-managed and typically the most time-efficient method of obtaining remote consent, sites may choose to implement an alternate local process to obtain remote consent, such as with DocuSign, upon approval of that local process by the CIRB.

## 6. How do you confirm the identity of the person signing the eICD?

eConsent does not change the process by which consent is obtained; it only changes the method that documentation is captured. As such, sites should continue to communicate with the LAR or subject using in-person, telephone, or video communication. Existing measures

completed during routine clinical care and in-person consent procedures should be used to verify with whom the study team member is speaking, according to local and institutional regulations. In addition, the consent process should be revisited during any follow-up visits. It is important to remember that informed consent is an ongoing process and not a single event built around signing the ICF.

## 7. Is REDCap HIPAA-compliant? Can it store personal health information (PHI) and Confidential Information?

Yes, REDCap is validated by CCHMC REDCap Support team to ensure it meets HIPAA Compliance.

## 8. Will the HIPAA Authorization form be signed electronically?

The HIPAA Authorization will be signed in the same manner that the eICD is signed. It will appear through the REDCap platform upon signing the eICD. It is important to remember that the signature used in the eConsent platform is considered a “handwritten signature” and not an “electronic signature.”

***The CCHMC approach to validating REDCap***
*CCHMC utilizes a two-step, OQ (Operational Qualification)/PQ (Production Qualification) approach to the validation. The OQ covers general system functionality as well as any functionality specific to the CCHMC implementation (such as Shibboleth LDAP connector). The PQ verifies that study parameters for a specific database work as expected (such as calculated fields). An audit of the system would consist of reviewing the OQ documentation plus the PQ for the study being audited. The combination of documentation demonstrates comprehensive control of the system. Additional validation documentation can be made available upon request*

## 9. When will REDCap be "certified" as 21 CFR Part 11 compliant?

The FDA does not provide an overarching determination of compliance. Even after a successful FDA audit of a study using REDCap, this assessment of compliance will only imply that REDCap was *used in compliance* with 21 CFR Part 11 in that specific study.