VERIFY REDCap E-Consent Guide

Version 1.0

5/18/2022

NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY

Contents

A. Overview of NCC-Managed Electronic Informed Consent....3

B. When to Use eIC....3

1. In-person Consent....3

2. Remote Consent....4

C. How to Set Up REDCap eIC....4

1. StrokeNet NCC....4

2. CCHMC REDCap Access....4

3. Clinical Performing Site (CPS)....4

D. How to Use eIC....4

1. Accessing the Link....4

2. Completing the eICD....5

2.1 General....5

2.2 Response Fields in eICD....5

3. Completing the Stand-Alone HIPAA Authorization (if applicable)....10

4. Automated Emails....10

4.1 Participant....10

5. Post-Consent Procedures....11

5.1 Subject ID....11

5.2 Remote Consent Attestation....11

5.3 PDFs for WebDCU Upload....12

5.4 Incomplete Records....13

E. Contacts....13

1. Reference Documents....13

2. NCC Project Manager....13

3. REDCap Helpdesk....13

F. Document History....14

A. Overview of NCC-Managed Electronic Informed Consent

The StrokeNet Standard Operating Procedure (SOP) ADM 24 Central Electronic Informed Consent Process describes electronic informed consent (eIC) in detail. If you are using the StrokeNet National Coordinating Center (NCC) managed eConsent through University of Cincinnati REDCap, you have agreed to follow these procedures.

The following is a summary of the NCC responsibilities, site responsibilities and the general eIC process:

1. The StrokeNet (NCC) will create a REDCap database for each trial and a unique form by site for every version of an informed consent form.
2. The NCC will ensure and verify that the most recent site specific CIRB-approved version of the informed consent 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 in REDCap.
4. The site will designate a primary and back-up user to have access to their site-specific eICD link in REDCap. These users will be responsible for distributing the link to the wider study team.
5. 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 24 hours of participant signature. This form and the signed eICD will be maintained for each participant in REDCap.
6. The PDF versions of both documents, as applicable, are combined and uploaded to WebDCU within 5 days of signature.
7. A hard copy of the completed eICD and Remote Consent Attestation Form (if applicable) will be kept at the site with the subject's research record.
8. If applicable, the site standalone HIPAA Authorization will also be obtained electronically through the REDCap platform and is signed in the same manner as the electronic informed consent document (eICD).

B. When to Use eIC

The eIC process may be implemented when obtaining consent in-person or remotely. In both cases, the eICD takes the place of a paper ICD. Access to a smartphone, tablet or computer with Wi-Fi or cellular internet connectivity is required.

1. In-person Consent

It is preferred that the eICD is utilized during an in-person consent conversation over a paper ICD. During a traditional in-person consent conversation, the eICD is shared with the participant. All pertinent aspects of the study and HIPAA Authorization are reviewed by the study team member during the face-to-face conversation. If the participant elects to participate, they complete and sign the eICD using a mouse or touch screen. The person obtaining consent and the witness, when required, also completes and signs the eICD in real time.

2. Remote Consent

Remote consent describes the process of obtaining and documenting informed consent when the participant and the person obtaining consent are not physically in the same location.
For remote eIC, the study team shares their REDCap link with the participant via text or email. The study team contacts the participant to ensure they are able to open and view the eICD, and then proceeds with the informed consent discussion. If the participant elects to participate, they complete and sign the eICD using a mouse or touch screen. The person obtaining consent subsequently completes a remote consent attestation form (Section D.5.3) within 5 days of the participant signing the eICD. Using an impartial witness will not be feasible during the remote consent process.

C. How to Set Up REDCap eIC

1. StrokeNet NCC

The StrokeNet NCC is responsible for creating a REDCap project for each site and ensuring the most recent cIRB-approved version of the ICD is available for eIC use. After a site sends the NCC their completed VERIFY Remote and Electronic Informed Consent Implementation Form indicating their request to use the central eIC process, the NCC provides each site access to their study-specific project and site- specific REDCap link. Sites do not need to wait for their cIRB acknowledgement of the Implementation Form to use the central eIC process.

The NCC provides the DOA-assigned primary study coordinator (PSC) and designated back-up with login credentials for the University of Cincinnati REDCap system so they have access to their site-specific eIC project.

2. CCHMC REDCap Access

For individuals who do not have access to CCHMC REDCap, a self-request survey can be filled out here: https://redcap.research.cchmc.org/surveys/?s=RE8EHCK9YH When asked, 'Would you like to inform another person of your REDCap Account Creating and REDCap Username', please respond 'Yes' and enter verifystudy@ucmail.uc.edu– this will allow us to add you as a user to your VERIFY eConsent project.

For individuals who have access the CCHMC REDCap, you can login at the following link: https://redcap.research.cchmc.org. Ensure Cincinnati Children's Hospital Medical Center is selected under the Select your identity provider section, then click Go to Login page button. REDCap will redirect you to the CCHMC federated login page. Enter your CCHMC credentials (individual's email address) and click Login. As of January 2022, CCHMC REDCap will use Multi Factor Authentication (MFA) and users will be prompted to use Duo for authentication. Sites will need to set up Duo MFA Registration to get their account ready: https://mfa.research.cchmc.org (please refer to step by step instructions here: https://confluence.research.cchmc.org/display/RESITHUB/Duo+MFA+Registration). Once authenticated with CCHMC, users will be redirected back to REDCap.

3. Clinical Performing Site (CPS)

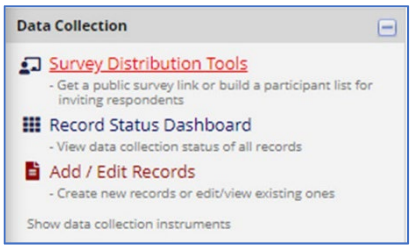
It is the responsibility of the study team to assign a second team member access to the site-specific REDCap eIC project as a back-up for the PSC. The study team should communicate with the NCC Project Manager to request login credentials for the back-up and should notify the NCC Project Manager if there are changes to the personnel with REDCap access.

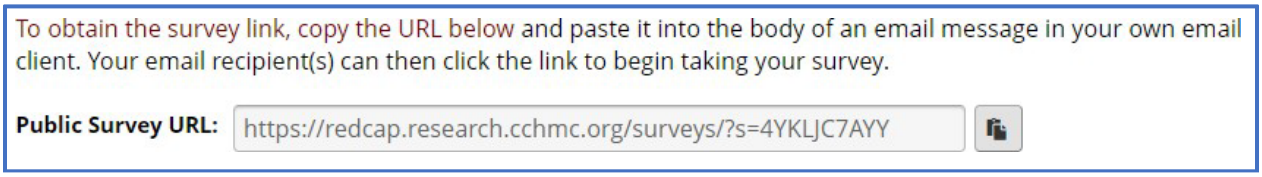
D. How to Use eIC

The StrokeNet NCC provides each Clinical Performing Site (CPS) with a unique URL that links directly to the site-specific REDCap eICD. Each eICD will be an exact copy of the cIRB-approved ICD for that CPS.

1. Accessing your REDCap eIC Project

The StrokeNet NCC provides each CPS with a unique URL. Individuals who have access to REDCap may also obtain their URL at any time by clicking 'Survey Distribution Tools' in their site-specific eIC project.





2. Completing the eICD

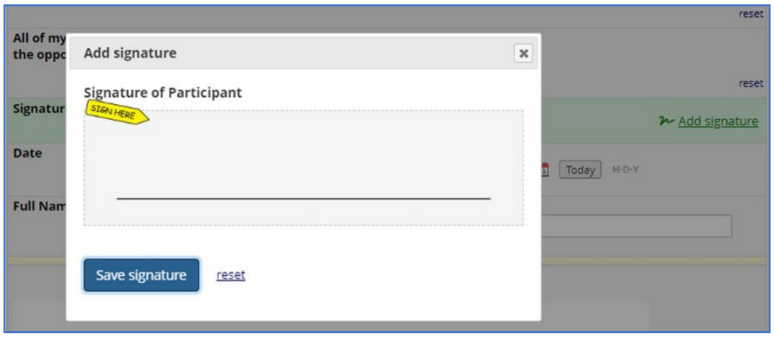
2.1 General

Prepopulating the eICD survey with participant information prior to sending to the participant is prohibited.

After reviewing the informed consent language in its entirety with the person obtaining consent, the participant will enter information into the ICD if they choose to participate in the study. The study team member obtaining consent should guide the participant through the form to ensure all fields are completed correctly.

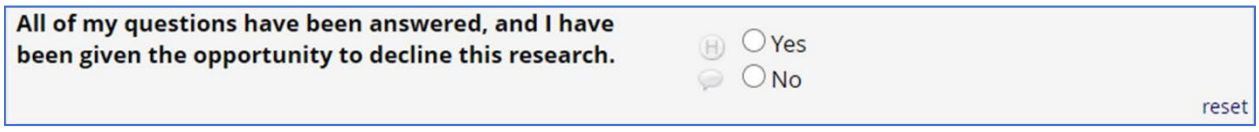
If the participant mistakenly exits the eICD by closing the web browser, they must use the link to re-enter the eICD and start the form over again.

In order to complete the signature field, select 'Add signature' and a pop-up window allows a free-hand signature using a finger, stylus or mouse. The date of signature may be entered by clicking the 'Today' icon that will auto-populate the current date according to the device on which the eICD is completed.

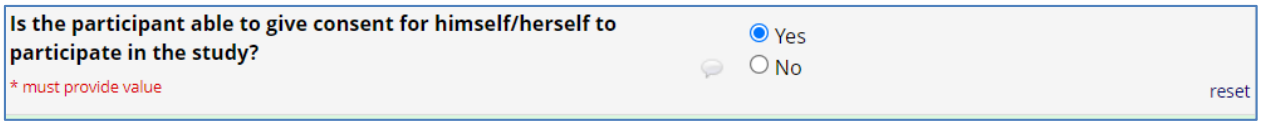


2.2 Response Fields in eICD

The following response fields appear at the end of the main consent for trial participation:



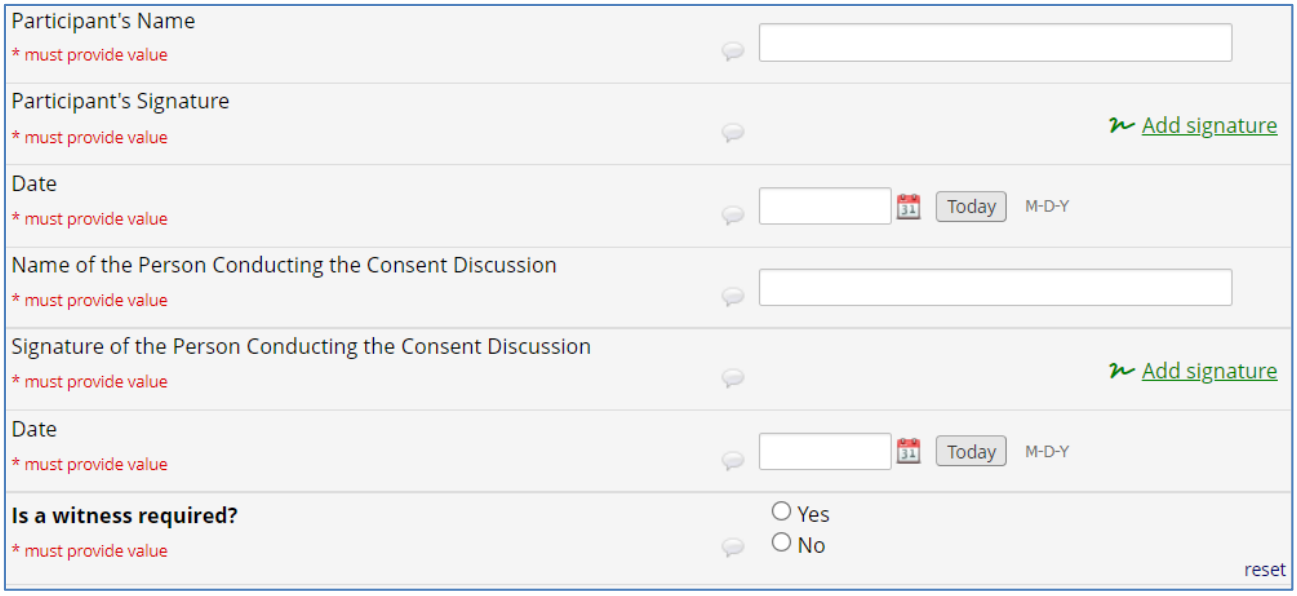
- The participant must confirm that all of their questions have been answered for the signature fields to appear on the form.



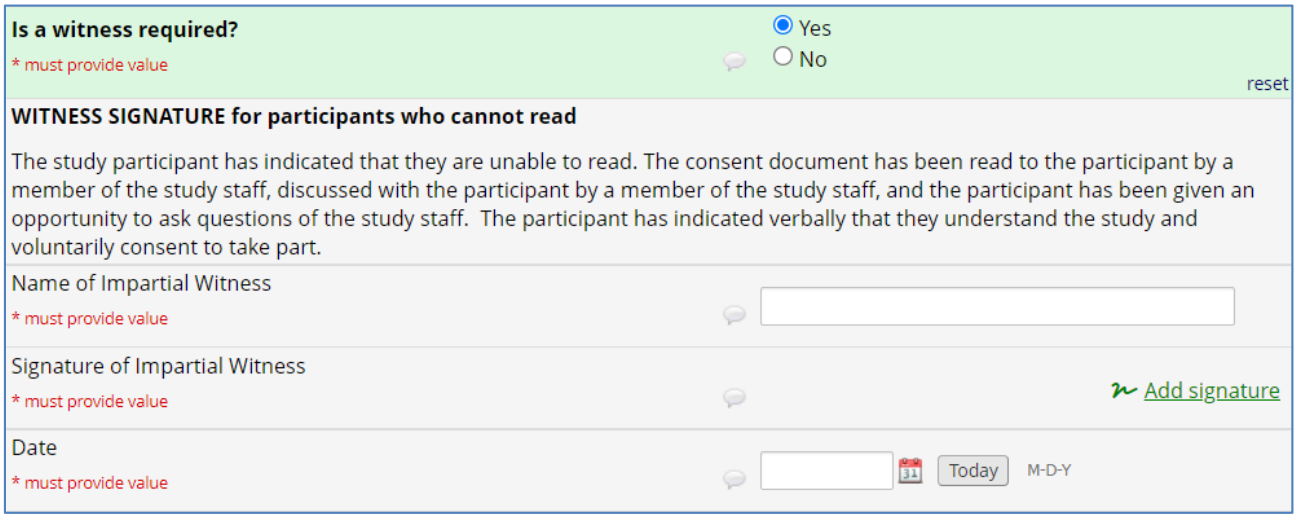
- If the participant gives consent for himself/herself, the response to the question should be marked 'Yes'. If 'No' is selected, then the survey will end the subject will not be consented.

- The participant indicates whether they are completing the eICD in-person with the study team, or remotely. Remote consent indicates that the participant and the study staff are not physically in the same location.

  If the participant is remote to study staff, signature lines will not populate for the study team member to sign the eICD. In this scenario, a remote consent attestation will be completed retrospectively (Section D.5.3).



- If the participant completes the eICD in-person with study staff, the appropriate signatures lines will populate for the person obtaining consent to sign in real time. A question regarding need for witness will also appear and, if a witness is required, the appropriate signature lines will appear. Using an impartial witness will not be feasible during a remote consent process.



- The Witness should enter their full name and relationship to the participant. If the selects 'Other', they should enter their relationship in the free text field that populates.

- After submitting the form, the participant is prompted whether they would like to receive a PDF copy of the eICD.
  - If 'Yes' is selected, a field requesting the email address to use appears. The PDF eICD will be sent to the email address provided.
  - If 'No' is selected, it is the study team's responsibility to ensure the participant receives a paper copy of the ICD.

3. Completing the Stand-Alone HIPAA Authorization (if applicable)

The StrokeNet NCC will be responsible for integrating each CPS-specific HIPAA Authorization Form into the REDCap eIC project. Similar to the eICD, HIPAA will be an exact copy of the CIRB-approved paper HIPAA Authorization. Upon completion of the eICD, the project will automatically navigate the participant to the HIPAA Authorization form.

After reviewing the HIPAA Authorization language in its entirety with the person obtaining consent, the participant completes the signature and date fields. All other information fields automatically copy over from the responses on the eICD.

Similar to the eICD, the participant is asked to certify and submit their responses, and they are prompted whether they would like to receive a PDF copy of the HIPAA Authorization form.

4. Automated Emails

Participant

If the participant elects to receive a PDF of the signed eICD and HIPAA Authorization form, automated emails are sent to the email address entered on the eICD with those documents as attachments. The email is sent securely through the Cincinnati Children's Hospital network.

Please note, if the participant indicates "No" to the question regarding receipt of a PDF copy, the eICD and HIPAA are not be sent to them automatically. In this case, it is the responsibility of the study team to ensure the participant receives a paper copy of the ICD and HIPAA.

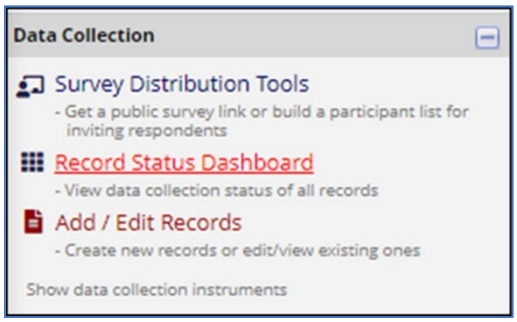
5. Post-Consent Procedures

5.1 Subject ID

Once a participant completes the eIC, REDCap creates a new record with an automated numbering system (beginning with 1 and incrementing by 1 for sequential records).

After consent if obtained, it is the responsibility of the CPS study team to obtain a WebDCU generated Subject ID for the participant. This subject ID should be entered into the form 'WebDCU Subject ID' in REDCap for the subject. This subject ID will be appended to the REDCap ID automatically to link the numbers (e.g., 1 (1054)).

Log into REDCap account and access the Record Status Dashboard and click on the 'WebDCU Subject ID' form for the subject. Enter the Subject ID and change form status to 'complete'.



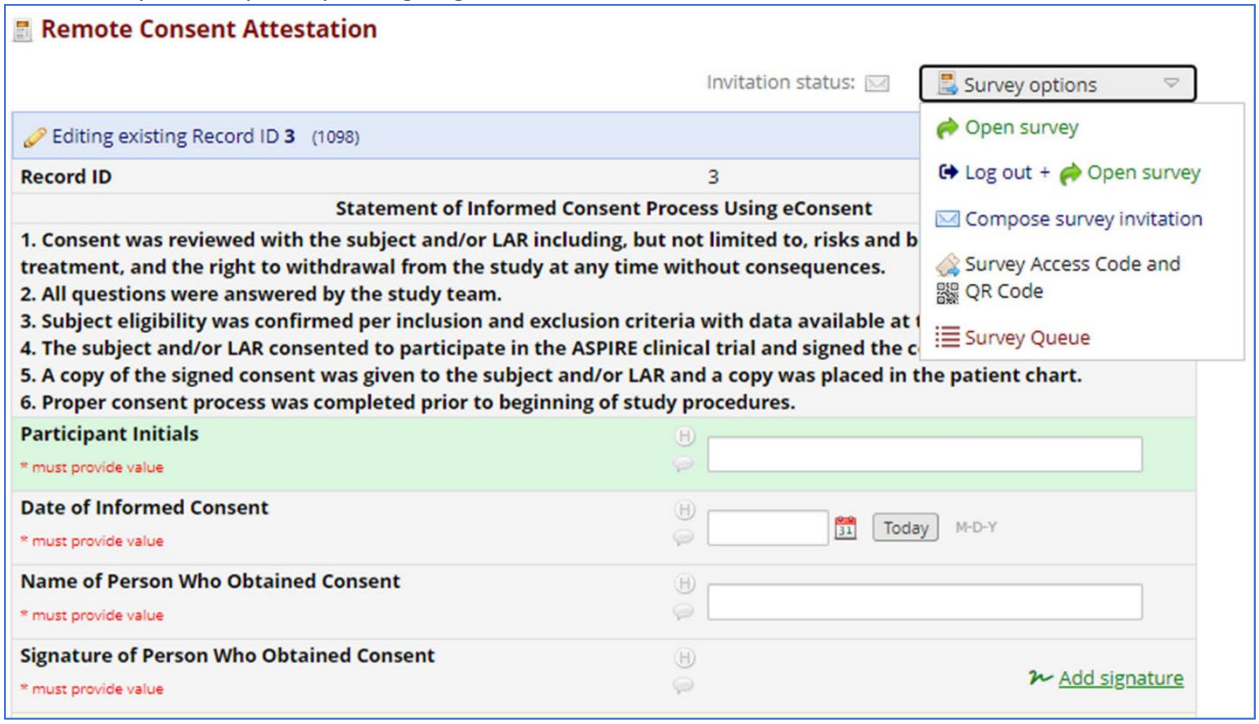
Record ID	VERIFY eCONSENT	VERIFY HIPAA Authorization	eConsent and HIPAA Form PDF	Remote Consent Attestation	WebDCU Subject ID
1					
2					
3					

5.2 Remote Consent Attestation

If the person obtaining consent and the participant are not in the same physical location, it is not possible for both parties to sign the eICD in real time. Therefore, the person obtaining consent must subsequently attest that all elements of the informed consent process were completed by signing a remote consent attestation form.

It is the responsibility of the PSC or back-up to manage completion of a remote consent attestation

form for any participant enrolled using remote eIC. All fields on this form are required to be completed within 5 days of the participant signing the eICD.



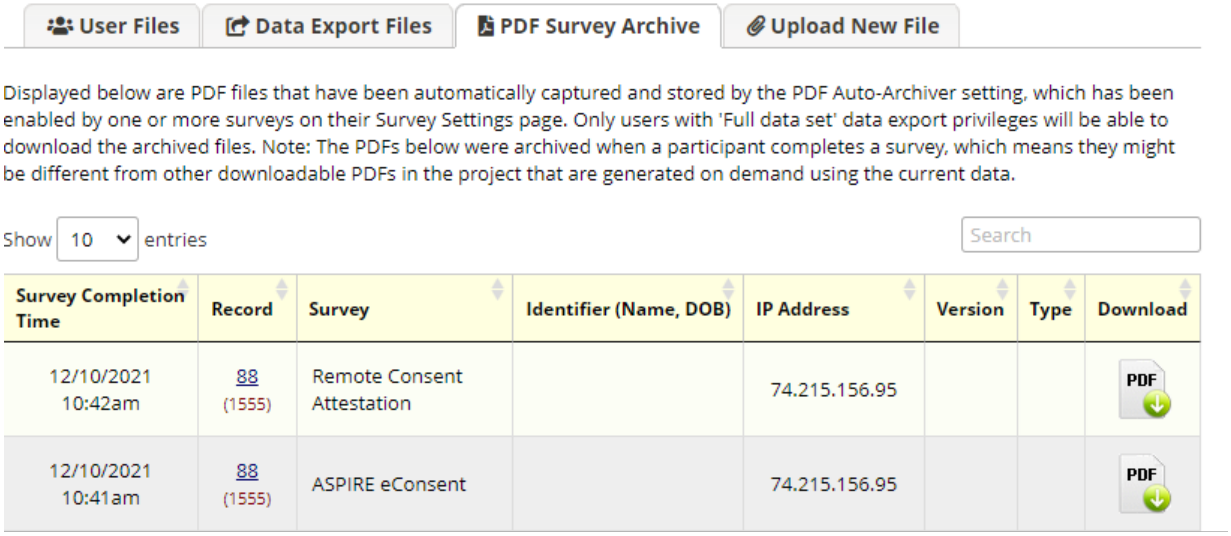
- The individual with REDCap user permissions can either open the form for the person who obtained consent to complete in-person, or they can send that person a link to complete the attestation form online. To do this, click on the 'Remote Consent Attestation' circle for the appropriate subject record in the Record Status Dashboard.
  1. Click on 'Survey options', then select 'Open survey' from the drop-down list.
  2. This opens the subject-specific remote consent attestation form in a new window. The web address in the new window can be shared with the person who obtained remote consent.
  3. The option to 'Compose survey invitation' may also be used. The user will be prompted to enter the email address of the person who should receive the invitation to complete the form. An automated email with the web link is sent through the REDCap system.

5.3 PDFs for WebDCU Upload

A PDF file of the completed eICD is uploaded to WebDCU for remote monitoring according to standard data management procedures. The eICD is considered complete once the signature of both the participant and the person obtaining consent are captured. When eIC occurs remotely, the eICD is complete once the remote consent attestation form is completed.

To download and print a PDF of a completed eICD in REDCap:

1. From the 'File Repository' > click on the 'PDF Survey Archive' > download the VERIFY eConsent PDF for the appropriate participant.
2. If consent was obtained remotely or other stand-alone documents exist for the site, follow the same steps for the 'Remote Consent Attestation' form or any stand-alone documents. Combine eICD and all other forms if applicable into one PDF document for upload to WebDCU.
3. These PDFs should also be printed and kept with the subject's research record.



5.4 Incomplete Records

A participant generates a new eIC record in REDCap when any data is entered into the form. If the participant mistakenly exits the eICD by closing the web browser, they must use the link to re-enter the eICD and start the form over again. In this case, two REDCap records are generated for the same participant. It is the site's responsibility to ensure the appropriately completed eICD is uploaded to WebDCU for remote monitoring.

E. Contacts

1. Reference Documents

Please reference the following documents that support a comprehensive overview of the centrally managed eIC process.

- StrokeNet SOP ADM 24 Central Electronic Informed Consent Process (https://www.nihstrokenet.org/sop_gcp)
- CIRB eConsent Webinar FAQs 2020-06-02

2. NCC Project Manager

The NCC Project Manager for each trial will be the main contact for questions regarding eIC using REDCap. NCC PM responsibilities include:

- Creating accounts and updating permissions for primary and secondary users at each site.
- Ensuring the most recent version of the informed consent is used for the eIC
- Answering questions about navigating REDCap and managing eIC records.

3. REDCap Helpdesk

For username and/or password issues, contact the REDCap helpdesk, help-redcap@bmi.cchmc.org. The helpdesk should ONLY be contacted if you are having trouble logging in. If you do not remember your password, use the 'Forgot Password' self-service.