Electronic Informed Consent

Purpose

The recent ready availability of electronic media and smartphones provides new opportunities for documentation of informed consent processes using electronic informed consent (eIC) to replace paper informed consent documents. eIC does not change the essential informed consent process in SIREN. In SIREN trials 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 in the emergency setting involves concisely and efficiently describing the research, reviewing the content of the informed consent document, and answering questions about participation in the study. Replacing 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 written information available to them in more ways, allow them to retain and share written information more easily, and to document their 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 guideline for trial-specific implementation of eIC in the SIREN network. 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)

Although other platforms may be considered in the future, SIREN currently uses only the University of Michigan REDCap implementation for eIC. A REDCap database will be created for each trial and a unique form (REDCap survey) by site within the database will be utilized for every version of an informed consent form (ICF).

REDCap is a mature, secure web application for building and managing online surveys and databases. The REDCap platform can support processes that are 21 CFR part 11 compliant. Each trial REDCap database will contain an entry for each enrolled participant. The primary instrument collected for each participant will be the electronic consent form (eICF). Secondary instruments will include an electronic informed consent process attestation, and a backup contingency for device failure permitting upload of a scanned paper version of the ICF. Other secondary instruments may include collection of process metadata if consented to, and if requested and approved by the IRB.

Creating Electronic Informed Consent Form

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 IRB of record.

The eICF is located on a static URL that can be accessed from any web browser. An example of the HOBIT eICF can be found here: link.

Electronic Informed Consent Form – Structure (HOBIT)

The primary instrument is the eICF. Link
The structure and sections of the primary instrument as created for HOBIT are outlined below. Note that in HOBIT eligible patients are comatose and will never be able to consent for themselves. The required fields described here reflect that consent will always be sought from an LAR.:

Element/Section	**Description**	**Notes**
Form version and IRB Approval Date	Dates posted on top of first page, text box	Manually entered by the Clinical Coordinating Center (CCC)
Key Information	Key information from the ICF, text box	Consistent with the requirements of the July 2018 new common rule. Addresses each of the eight required elements.
Detailed Information	Standard consent form including HIPAA authorization, scrolling text box	This is the detailed information that expands upon and reinforces the required elements and additional informed consent elements
Confirmation the eICF has been read and how the study information was presented (in person or by telephone)	Radio button	Required data entry field
Confirmation that all LAR questions have been answered and their decision to participate (Y/N)	Radio button	Required data entry field

Participant's Name	Regulatory requirement; free text entry	Required data entry field
LAR Name	Regulatory requirement; free text entry	Required data entry field
LAR relationship to patient	Regulatory requirement; Radio buttons and open text field	Required data entry field
LAR Signature	Electronic handwritten signature box; using finger or mouse	Required data entry field
LAR E-mail	Free text entry, which allows automated emailing of a PDF of the signed completed eIC to LAR	Optional data entry field. Provision of this information by the LAR indicates consent to obtain a signed copy of the eIC by email, and is required if the LAR wants a copy sent by email.
Investigator/Delegate Name	Good clinical practice; free text entry	Required field when the form is completed in person
Investigator/Delegate Title	Good clinical practice; free text entry	Required field when the form is completed in person
Investigator/Delegate Signature	Electronic handwritten signature box; using finger or mouse	Required field when the form is completed in person

Electronic Informed Consent (eIC) Process Attestation Form (HOBIT)

A secondary instrument, the Electronic Informed Consent Process Attestation is a required form when the consent process is completed remotely. An example of the HOBIT eIC Process Attestation Form can be found here: link

The structure and sections of the eIC Process Attestation is outlined below:

Element/Section	**Description**	**Notes**
Participant/Subject Name	Regulatory requirement; free text entry;	Required field
Study Subject Number	To facilitate matching to consent form entry	May be entered subsequent to completing and submitting the form.
Study Team Member Name	Regulatory requirement; free text entry	Required field
Study Team Member Title	Regulatory requirement; free text entry	Required field
GCP IC process statements	Checkbox -- All that apply to be selected	Required field
Comments	Free text	
Signature of the study team member obtaining consent	Electronic handwritten signature box; using finger or mouse	Required field when the form is completed in person

Documentation of Informed Consent Process using eIC (HOBIT)

The informed consent process is described elsewhere and will be performed consistent with the study protocol and the approved IRB application. HOBIT eligible patients are comatose and will never be able to consent for themselves. The steps below will be followed when documenting consent from a legally authorized representative (LAR) using the eICF:

1. The study team will locate an LAR and ask to discuss the study with them.

2. If an LAR is onsite, the study team will link to the eICF on a study team tablet device, hand it to the LAR, and allow the LAR to review the consent form on the tablet during and after the verbal informed consent process. The LAR and other family members may also be given the link allowing them to follow along on their own devices as well if desired.
3. If an LAR is offsite, the study team will determine if they have access to a touch-screen device, typically an internet enabled smartphone or tablet device, allowing for documentation of the informed consent process by eIC. If not, informed consent will not be pursued remotely. If a device is available, the LAR will be sent the static link to the eICF via email or text messaging. This will allow the LAR to review the consent form on their own device during and after the verbal informed consent process conducted by telephone.
4. A study team member will perform the standard verbal informed consent process. Whether conducted in person or on the phone, the verbal standard informed consent processes includes but is not limited to:
    A. Describing the purpose of the study, and the procedures, potential risks and potential benefits of participation in the study.
    B. Describing study activities, the duration of participation, and expectations for follow up visits to assess outcome.
    C. Ensuring the LAR understands that participation is voluntary. Ensuring the LAR understands alternatives to participation, and that neither participation or declining to participate will affect access to standard medical care.
    D. Informing the LAR about protections and risks related to confidentiality, and ensuring HIPAA authorization.
    E. Reviewing the eICF with the LAR, answering all questions, and providing adequate time to consider the decision whether to consent to participation
5. If the LAR consents to the subject's participation, they will be instructed how to complete the data entry boxes on the eICF on whichever device they are using, including provision of a handwritten signature collected on the device's touch-screen.
    A. The date and time of the electronic handwritten signature are automatically recorded, indicating when informed consent was obtained.
    B. The eICF cannot be submitted or advanced to the next page unless all required items are completed. Missing items will be flagged if an attempt is made to submit an incomplete form.
    C. The LAR will be asked to provide an e-mail address on the eICF if they wish to be e-mailed a completed PDF copy of the signed eICF.
6. If the LAR is onsite, the device with the eICF signed by the LAR will be returned to the study team member obtaining consent, who will advance the form to the next page, counter sign, and submit the eICF.
7. If the LAR is offsite, the LAR will then submit the eICF. The counter signature by the study team member obtaining consent is not required on the eICF. In this case, the study team member obtaining consent will subsequently complete the separate informed consent process attestation instrument.

8. When the eICF is submitted, a PDF of the signed document is automatically sent by email to the LAR if an email address was provided, and to the site Principal Investigator or study team delegate. If the LAR is onsite, the PDF sent to the study team can be printed and provided to the LAR on paper as well.
9. The informed consent process **AND** the LAR signature will be used to confirm LAR consent to enroll the patient into the study. When the LAR is remote, the study team's receipt of the signed eICF by email will be used to confirm the LAR signature.
10. The study team member obtaining consent will review the eICF prior to enrollment. If the eICF is completed incorrectly, the LAR will be asked to complete a new eICF.

CCC Responsibilities & Process

1. The CCC will create a REDCap database for each trial and a unique form by site for every version of an informed consent form (ICF).
2. The CCC will ensure and verify that the most recent site specific IRB-approved version of the ICF is available in REDCap for eICF use.
3. The completed eICF and eIC Process Attestation (when applicable) will be maintained along with the audit trail in REDCap.
4. When an eIC Process Attestation is required the CCC will send the Principal Investigator/delegate a link to the form. The forms data will be maintained with the signed eICF for that participant in REDCap.
5. The CCC will receive an email notification from REDCap once a completed eIC Process Attestation has been submitted.
6. The CCC will verify the eIC Process Attestation was completed accurately and will change its status in REDCap to "Complete".

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