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Electronic Consent (e-consent) Guidance

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Contents

What is Electronic Consent or "e-Consent"?

Defined by the FDA, e-consent (eIC) is "the use of electronic systems and processes that may employ multiple electronic media, including text, graphics, audio, video, podcasts, passive and interactive Web sites, biological recognition devices, and card readers, to convey information related to the study and to obtain and document informed consent."

Much like traditional Informed Consent is a document *and* a process, eIC can refer to the modality of the consent document *or* the process.

For example:

Signing the consent via an iPad with the subject sitting directly across from you. Or, discussing the trial with a subject via Zoom while physically separated.

The goal of implementing eIC is to better aid the study team in delivering all information in a way that ensures comprehension and voluntary participation.

How should e-Consent be presented to a potential Subject?

The information must be in language understandable to the potential subject or the subject's LAR and conveyed in a manner that minimizes the possibility of coercion or undue influence regarding the subject's decision to participate in a study (45 CFR 46.116 and 21 CFR 50.20).[1] This is no different than the paper informed consent process.

Electronic informed consent may be used to either supplement or replace paper-based informed consent processes in order to best address the subject's needs throughout the course of the study. For example, some subjects may prefer one method over another.[1]

Provide sufficient opportunity for the subject to consider participation, include methods like electronic messaging, telephone calls, video conferencing etc. to aid discussion. Use interactive electronic technology to assist the subject in understanding the material.

Any eIC should be easy to navigate, allowing the user to proceed forward or backward within the system and to stop and continue at a later time. Hyperlinks may be provided where helpful. The eIC may also incorporate electronic strategies to encourage subjects to access all of the consent material before documenting their consent.[1]

Subject's should have access to all consent related materials, including hyperlinks or other external documents.

In an event of an amendment or significant new findings developed during the lifecycle of the research, the re-consent process via eIC must provide sufficient opportunity to the subject to consider continuing participation.

HIPAA authorization may be combined with eIC documentation when both are presented in electronic format.

Remote Consent

Remote consent: the process of obtaining informed consent while the research subject and study personal are *physically separated*.

- You may not be able to sign the same hardy copy consent form.
- You may be unable to utilize the same device for e-consent.

Remote consent does *not* explicitly mention use of technology although technology is undeniably part of most remote consenting.

What are the Advantages of using eIC?

- It can facilitate subject comprehension.
- It can be tailored to needs of a specific study population.
- It can be easily accessed and shared with family and a subject's medical care team.
- It can be accessed remotely.
- It promotes "rapid" information sharing & improves efficiency.
- It can engage "hard-to-reach" populations.
- There can be a greater opportunity to ask questions and consider participation.
- Potential for enhanced privacy.
- Enables inclusion of a subject's family/caregivers.

Why use e-Consent or Remote e-Consenting?

To understand whether or not you should implement e-consent or remote e-consent, determine if your protocol or potential subject is well suited or better suited using the technology.

Things to consider for e-consent (eIC):

- Does your protocol focus on a contagious disease?
- What are your subjects' locations or travel situations?
- Who is the study population?

It is important to note that eIC is not for every protocol and study population. There is a need:

- To have technology
- To understand how to utilize/be familiar with certain types of technology
- To account for physical considerations e.g. impaired eyesight or impaired motor skills

What laws and regulations govern e-Consent?

The eIC must contain all elements of informed consent required by HHS and/or FDA regulations (45 CFR 46.116 and 21 CFR 50.25). eIC is simply another modality for executing the exact same process. It is subject to the same fundamentals for obtaining informed consent:

- Information
- Comprehension
- Voluntariness

All FDA, HHS, and HIPAA guidelines and regulations still apply. You must still:

- Utilize "lay language"
- Not use "exculpatory language"
- Get review and approval by the IRB on the document and the process
- Get the document signed and dated by the subject (or LAR) and the PI (or individual obtaining consent)
- Give a copy to the participant
- Document the consent process

Additionally, eIC documentation for Federally regulated trials must be 21 CFR 11 compliant, requiring system validation, audit trail, and secure record retention practices.

What are Electronic Signatures?

The procedure for eIC may include an electronic method to capture the signature of the subject or the subject's LAR commonly referred to as electronic signatures or e-signatures.

Defined by the FDA, electronic signatures are considered ”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.”

FDA and OHRP allow for electronic capture of the subject’s signature as long as it complies with all applicable requirements under 21 CFR part 11:

- Must include the printed name of the signer
- Identity of the signer must be verified
- Subject must understand the e-signature is intended to be the legally binding equivalent of a handwritten signature
- The meaning of the signature is detailed i.e., consent to participate in research
- Capture date and time the signature was obtained
- Must be linked to the respective electronic record to ensure that it cannot be tampered with i.e., audit trail

What laws and regulations govern the use of e-Signatures for eIC?

Federal Law (ESIGN Act and & UETA), FDA (21 CFR 11), and Illinois Law (ECSA) all govern the use of electronic signatures for eIC.

Summary of Requirements necessary for e-Signatures under Federal Law

Legally Compliant

- Demonstrate intent of signer i.e., to participate in research
- Signer must have option to receive printed or emailed copy of the signed document

Authentic

- Validate the identity of all signers

Secure

- Ensure the inability to be digitally tampered with or altered post-signature
- Provide time-stamp of signatures
- Provide an audit trail that includes dates, times, and locations of signatures

What laws and regulations govern communication systems utilized during eIC?

HIPAA Privacy Act and HIPAA Security Act govern communication systems including telephone, email, live chat, telehealth visits, video conferencing systems.

What makes communication systems HIPAA compliant for use during eIC?

Ensure you are using a "non-public facing" communication platform i.e., Zoom. As a rule, allow only the intended parties to participate in the communication. Ensure there is video privacy and security. For example, end to end encryption and routing that is peer-to-peer or via a secure server. Use methods for authenticating users and employees with access to encryption keys. Make sure there are individual user accounts, logins, and passcodes. Finally, the communication system should provide additional privacy safeguards and settings for users. For example, ability to mute, record, and turn camera on/off.

What platforms and communication systems does the University of Chicago support for eIC?

Electronic Consent and e-Signature Platform – REDCap

UChicago REDCap has been 21 CFR Validated as compliant for use of eIC.[3]

For guidance on how to get started with REDCap e-consent, please visit the guidance page.

Please contact the Center for Research Informatics REDCap Administrator Julissa Acevedo at redcap@rt.cri.uchicago.edu for further guidance and assistance.

Communication System – Zoom

Please note: These systems must be linked to your CNET/UCHAD account and can be accessed using those credentials.

What if the Sponsor or study team wants to use a Different e-Consent platform or communication system for eIC?

1. Reach out to BSDIS/UCMIT.
2. Obtain documents from sponsor that aid in the data security review:
    a. Vendor contracts
    b. System/Platform overview
    c. Implementation plan
3. If approved, submit necessary documents with the IRB application. Give the IRB a clear picture of the platform.
4. Include the platform in the IRB application's description of the informed consent process.
5. In some cases, there may need to be legal involvement to establish a business agreement.

IRB Application: Details to include regarding eIC and PHI for use of eIC

There are details that must be included in your application to the IRB when eIC is used for your protocol. Make sure that you include details and explain:

- How will the study team first approach potential participants about the study?
- What systems will be used if you are consenting subjects remotely?
- What platform will you use to obtain signature if electronic?
- How will you ensure participants have access to technology and are familiar enough to use the technology?
- What technology be required for participation? What, if any, alternatives will be available?
- How will the subject receive a copy of the signed consent?

PHI Specific Details:

- Make sure to include identifiers you plan to use for verifying participants' identities, an email for participant if obtaining e-signature, the plan to email a copy of signed consent, utilization of communication systems where invitation will be sent to email, and a telephone number if remotely consenting via phone.
- State the patient identified needed to verify subject's identity and email/telephone number needed to communicate remote in justification
- It may also be a good idea to include information that systems are 21 CFR 11 and HIPAA compliant, a business agreement is in place, and any additional study safeguards (University of Chicago equipment only or UChicago email addresses).

Verification of Subjects' Identities:

Study Site

If identity is verified at Study site, the study personnel can personally verify subject/LAR identification and go over the consent process similar to paper consent process.

Remote eIC

If the signature is not personally witnessed by the study personnel, the electronic platform must include a method to ensure that the person electronically signed the informed consent is the subject who will be participating in the study or the subject's LAR. FDA regulations do not specify any particular method for verifying the identity of an individual and accepts many different methods.

For example, verifying someone's identity can be done by using information from some form of official identification, such as a birth certificate, government-issued passport, or a driver's license. ***OR***, if you have met someone before/they are a patient at UCM and you cannot see them: 1) Look in Epic, 2) Ask subject to state their name, 3) Ask for two personal identifiers (i.e., date of birth, last 4 of SSN)

Appropriate Methods to give the Subject Copy of Signed eIC

Per the FDA, the copy provided to the participant can be paper or electronic. Hyperlinks to information on the Internet included in consent forms should be maintained and remain accessible through study completion.

If the consent that is emailed to a subject is:

- a signed version
- a consent with sensitive information
- a consent with a diagnosis

Then it **must** be sent encrypted.

Giving subjects a signed copy is best practice and expected. However, guidance recommends a "risk-based" approach. For example, if sending a signed copy poses higher risk to subject's PHI, it may be best to give a copy that is not signed. [1]

It is important to note that subjects may decline a copy. If that occurs, document accordingly.

The Process of eIC Documentation:

Electronic informed consent is subject to the same requirements as traditional, paper informed consent (45 CFR 46). In *addition* to those requirements, informed consent process documentation for eIC should contain these elements:

- When/Where the consent process began
- How did you verify the subject's identify? And what identifiers were used?
- How/Where did the consent process take place?
- How was the subject's signature obtained (i.e. REDCap e-signature)?
- Did the subject receive a copy of the consent document? How did they receive it?

Requirements Post Implementation

FDA regulations do not specify a preferred method for archiving documents; however, the eIC process should incorporate procedures to ensure that electronic documents can be archived appropriately and that all versions of the IRB-approved eIC document can be retrieved easily.

During FDA inspections access should be granted to all versions of eIC and all its materials to FDA for review.

Monitoring and auditing requires that the executed eIC be reviewed in addition to authenticity verification, if obtained remotely, and evidence of the study team member who obtained consent, date, and time the consent was executed. The documentation process in the EMR will also be reviewed.

References

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