

Emory Guidance for the Use of Electronic Informed Consent

Background

The purpose of this document is:

- To explain the current options Emory researchers have for obtaining electronic informed consent (referred in this guidance as eIC), including those containing HIPAA authorization language. This may be necessary when consent is not obtained in person, or during in-person consent
- To describe best practice for remotely obtaining consent with traditional wet signature, e.g. via email or fax
- To describe IRB approval requirements for these consent methods, when Emory IRB is the reviewing IRB

NOTE: This guidance is not applicable for cases where the IRB can waive the written signature (aka “documentation”) of consent, aka “verbal consent” (e.g. online or phone survey studies).

- Children’s Healthcare of Atlanta and the Atlanta VA Healthcare System both have a separate review process of e-signature platforms.
- If a subject has limited English proficiency, the use of these methods would require a qualified interpreter and the use of a short form or a translated informed consent form previously approved by the IRB

If you are considering using software or an app not described below, and the consent document includes IIHI or sensitive information, you must submit a LITS security review request. [See this guide](#) for more information.

- In general, if your study involves a medical condition or the consent states that the participants may have X condition and that is why they are participating, you will need to use one of the methods described below.

Make sure that you have received IRB approval to use any of the following eIC methods (even if you do not need LITS security review) before proceeding.

Studies not collecting sensitive or IIHI or sensitive information

Sending/receiving a signed consent (wet signature)

If after reviewing [our guidance](#) you realize you do not need LITS review, you may email the consent form to a potential participant. After you have consented the participant over the phone the participant should email you a picture of the signature page.

- See the “Documentation of Consent” section at the end of this document for the required documentation of this process.

eIC

If you wish to use an eIC software platform, and because you are not using, collecting or disclosing IIHI or sensitive information, LITS will not need to conduct a security review. The IRB still needs to approve the use of any software for eIC. We recommend discussing your options with your department or IT

Emory IRB Guidance

group as you should use software from a reputable company to prevent data loss or any other unforeseeable issue.

Studies using, disclosing or collecting IHI or sensitive information

Encrypted Email for wet signatures

This is one of the easiest methods because it does not require the use of an additional eIC platform. Instead, you would use email to obtain a clear copy of the signature page of the current, IRB-approved version of your ICF.

[Review this information](#) about the use of encrypted email at Emory. You need to emphasize to the participants that they need to take a picture or scan the entirety of the signature page, signed by the participant after the consent process took place. When receiving the signed document, make sure you keep a copy of the whole consent for your records.ⁱ

When conducting the consent process via phone with an emailed copy of the consent please verify: that

- The form the subject received is the currently approved version
- That all the pages of the consent were received
- That the participant can read all the pages of the consent.

Electronic Signature for eIC

Using electronic signature (e-signature) software allows for better documentation of the process without the need to depend on the participant sending a good copy of the last page of the consent document. **The approved software/apps to obtain e- signature for eIC at Emory are REDCap and DocuSign. eSign Live** was supported but we do not recommend it for new studies. You will need to obtain a license to access REDCap or DocuSign.

Note: For FDA regulated studies, you need to use a platform that is also Part 11 compliant. REDCap is not Part 11 compliant. You may use DocuSign if using a part 11 compliant account.

Emailing eICF: As previously described, the study team should not send the consent form to subjects via email unless the email is encrypted. A link to an online consent form may be sent via email to the subject or LAR; this will not require encryption if the email itself does not refer to the potential participant's condition. Alternatively, for in-person consent, the eIC form (eICF) may be presented to the subject or LAR, via a touch-screen-enabled device.

Signature area format: The signature area could be the same as the normal ICF/HIPAA template or could be crafted to allow for the person obtaining consent to sign later if needed. See the "Documentation of eConsent" for more information.

Because the signature of the participants will be electronically captured, you should ensure that the method you use meets these requirements:

- eICF captures the signature of the subject in a way that it can be **electronically audited**. The protocol includes a plan for **verifying the identity** of the subjects that will be electronically signing the Informed Consent, for FDA-regulated investigations.ⁱⁱ
- FDA regulations do not specify a specific method for verifying the identity of an

Emory IRB Guidance

individual and accept 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. Also, the use of security questions to confirm an individual's identity can be considered.

- The protocol should include a plan **for providing copies of the consent to participants**. HHS and FDA regulations require that the person signing the informed consent be given a copy of the informed consent form (45 CFR 46.117(a) and 21 CFR 50.27(a)) unless the requirement for documentation of informed consent has been waived under 45 CFR 46.117(c) and 21 CFR 56.109(c)
 - Although FDA regulations do not require that the subject's copy include a signature, FDA recommends that a copy of the signed informed consent form that includes the date when the eICF was signed be provided to the subject.
 - The copy provided to the subject can be paper or electronic (i.e. be provided on an electronic storage device, **not** via email unless encrypted). If the copy provided includes one or more hyperlinks to information on the Internet, the hyperlinks should be maintained, and information should be accessible until study completion (if a paper version is provided, it should contain the necessary content from any hyperlinks)
- The investigator should submit to the IRB copies of all forms (electronic and paper forms) and informational materials, including any videos and Web-based presentations, which the subject will receive and view during the eIC process.

Using a non-previously approved eIC software platform

Before the platform can be used, the study team should submit a ticket requesting a data security review of the platform [using this link](#). The form has the information to provide under "more information". Depending on if all the information was provided and the potential back and forth with the software company, this process could take from a couple of weeks to two or three months.

IRB Review: the study team must receive the approval of the MS Word version of the informed consent language, before receiving approval of the final electronic version (eICF). The eICF should contain the same information as the ICF approved by the Emory IRB, including document approval and version date, and should be the final version the participants will see.

- If the platform does not capture the signature of the person obtaining informed consent, see under "Documentation of Consent" to ensure your document has additional signature lines.

You have two options for the approval of the eICF:

- You can submit the copy of the eICF with the submission, if ready, so the IRB can determine if the electronic copy is adequate for use.
- If the eICF is not ready, and after initial approval of the MS word copy of the ICF, the study team should submit a modification with the eICF.

The study team cannot enroll anyone with the electronic method until the eICF is reviewed and approved by the IRB.

Emory IRB Guidance

Informed Consent Discussion

You can have the informed consent discussion via phone or using Zoom. Make sure you are using your Emory licensed Zoom account as this has been vetted and approved for this use.

You could use Skype Business as well, but you need to ensure that we initiate the communication.

Documentation of Consent

The documentation part of any consent process is important as it is not only required by the IRB, OHRP, and FDA, but it is vital in keeping adequate records of your study.

First, if you are emailing a consent document, make sure you add additional lines to document that the consent process was done over the phone, for example. Of course, if you are using an eConsent method in person, additional lines would not be required if all signatures (participant and person obtaining consent) are captured as you would with an ICF. DocuSign allows for the use of the same IRB approved document, so you do not need to adjust the signature lines

Here is an example of how this will look like in your ICF in you are consenting over the phone and the subject is emailing back the last page of the signed consent, mailing a hard copy back, of the signature of the person obtaining consent cannot be documented real-time:

TO BE FILLED OUT BY STUDY TEAM ONLY

Name of Person Conducting Informed Consent Discussion

Date/Time when IC discussion took place

Signature of Person Conducting Informed Consent Discussion

Date/Time when IC was signed

ⁱ [FDA information Sheet: Informed Consent](#)

ⁱⁱ [FDA Q&A: Use of Electronic Informed Consent](#)