Guidance for the Use of Electronic Informed Consent
Electronic informed consent refers to 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.

This document provides information on the use of processes/systems that might use electronic media to obtain informed consent. It does not provide consent language or requirements, but considerations to keep in mind while determining the feasibility of using Electronic Informed Consent (eIC).

The goal of Informed consent process is to provide study participants with information that is needed to make an informed decision to participate in research, the informed consent form (ICF) paper or electronic is a tool to aid this process. eIC should follow the same regulatory guidelines and provide the same information as paper ICF. It is not meant to replace the informed consent process between research participant and study staff. Office of Human Research Protections (OHRP) and the Food and Drug Administration (FDA) support the use of eIC.

General Requirements for Electronic Informed Consent process over the course of the study:

1. **Pre-Implementation**:
   - Must include all elements of informed consent similar to the paper ICF, in a language understandable to the potential subject or subject’s Legally Authorized Representative (LAR).
   - All versions of eIC must be reviewed and approved by IRB of record prior to use. Submit all forms and materials that subject will receive during eIC process for approval. Include description of the econsent process and mechanism for ensuring validity of subject/LAR authenticity when obtaining remote consent in AURA IRB submission.
   - eIC for Federally regulated trials must be 21 CFR 11 compliant, requiring system validation, audit trail and secure record retention practices. UChicago REDCap has been 21 CFR Validated as compliant for use of eConsents.
   - HIPAA authorization may be combined with eIC when both are presented in electronic format
   - Design eIC form in a way that is easy to navigate in order to allow the user to proceed forward or backward within the system, and to stop and continue the process later.

2. **Implementation**:
   - The investigator or his/her qualified delegate is responsible for obtaining legally effective informed consent, an electronic system cannot be a delegate. The informed consent process must be identical regardless of the mode (electronic or paper).
   - If the eIC process is conducted 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 - not personally witnessed by the study personnel, the electronic system must include a method to ensure that the person electronically signing the informed consent is the subject who will be participating in the research study or 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.
   
   In addition, use of security questions to confirm an individual’s identity can also be considered.
• 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.
• 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 re-consent process via eIC must provide sufficient opportunity to the subject to consider continuing participation.
• Subject/LAR who signed the eIC must receive a copy that includes the date eIC was signed. Paper or electronic copies are acceptable, information provided via hyperlinks, websites etc. should be included in print. Hyperlinks to information on the Internet included in consent forms should be maintained and remain accessible through study completion.

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 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/Auditing - Requires that the executed eIC be reviewed in addition to the authenticity verification if obtained remotely and evidence of study team member who obtained consent, date and time consent was executed and review of the documentation process in the EMR.

References:
• ²Part 11, Electronic Records; Electronic Signatures – Scope and Application

Resources:
• For REDCAP electronic informed consent development at UChicago, please contact the Center for Research Informatics’ REDCAP Administrator, Julissa Acevedo (redcap@rt.cri.uchicago.edu).
Center for Research Informatics - Information on Use of Electronic Informed Consent

The purpose of this document is:
• To explain the current options UChicago 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 UChicago 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).
• 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.

UChicago has approved several options for eIC for your studies. 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 before proceeding.**

**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 UChicago IRB, including document approval and version date, and should be the final version the participants will see.

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.

**Studies not collecting PHI or sensitive information**

**Sending/receiving a signed consent (wet signature)**
If after reviewing our guidance you realize you do not need Office of Clinical Research (OCR) 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, and because you are not using, collecting or disclosing PHI or sensitive information, OCR will not need to conduct a security review. The IRB still needs to approve the use of any software for eIC. We recommend discussing with the Center for Research Informatics (CRI) the option of using REDCap.
**Studies using, disclosing or collecting PHI 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 UChicago. 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.

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 only approved software/apps to obtain e-signature for eIC at UChicago is Redcap.

**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.
- FDA regulations do not specify a specific method for verifying the identity of an 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.

**Informed Consent Discussion**
You can have the informed consent discussion with subject via phone or using Zoom. Make sure you are using your UChicago licensed Zoom account as this has been vetted and approved for this use.

**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.

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:

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**TO BE FILLED OUT BY STUDY TEAM ONLY**

<table>
<thead>
<tr>
<th>Name of Person Conducting Informed Consent Discussion</th>
<th>Date/Time when IC discussion took place</th>
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i FDA information Sheet: Informed Consent
ii FDA Q&A: Use of Electronic Informed Consent
REDCap Setup for use of Electronic Informed Consent

After securing the use of electronic consent for your study from the University’s IRB office, use the following steps to setup the necessary e-consent fields and features. This is the basic setup. For additional requirements (such as sklfds), please contact the CRI REDCap Administrator, Julissa Acevedo at redcap@rt.cri.uchicago.edu.

1. Navigate to REDCap at https://redcap.uchicago.edu/. Log in with either BSDAD or UCHAD.

2. After logging into REDCap, create a new project. Enter a project title, select Research as the purpose, fill in the rest of the fields, select Create an empty project, and click Create Project.

3. On the Project Setup tab, click ‘Enable’ next to Use surveys in this project?

4. Contact Julissa Acevedo (redcap@rt.cri.uchicago.edu) to schedule a Zoom demonstration of eConsent, and obtain a zip file of the UChicago approved eConsent form template. Please provide a copy of your IRB protocol document with approved use of eConsent.

5. When you receive the zip file, go to your project’s Online Designer page, and upload the zip with this option:

6. Enable the eConsent instrument as a survey by clicking Enable in the Enabled as Survey column. Set the survey settings on the next page, and save the survey.