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 eIC1,2.

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:
• 2. Part 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).
**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 skilflis), 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.