
What is eConsent?

eConsent refers to including electronic formats into the informed consent process and/or documentation.

eConsent can be incorporated into the overall consent process in a few different ways. Some examples include:

- Projects in which social distancing must be maintained, or where in-person consent discussions are not feasible. eConsent can be used to obtain signed consent in conjunction with remote consent discussions (such as telephone, Skype, or online conference), with the consent document presented in an electronic format.
- Projects that use online surveys can incorporate eConsent into the beginning of the survey process.
- Projects that have an in-person consent discussion where technology such as tablets are used to present the consent text or supplement the consent discussion.
- eConsent can also be used to obtain an electronic signature in both in-person and remote consent processes.
- Note that there are specific requirements when utilizing eConsent for FDA regulated research, which are outlined in this guidance document.

IRB submission guidance

Researchers who want to utilize eConsent will need to prospectively report this to the UIC Office for the Protection of Research Subjects (OPRS) during the review process, whether the project requires Institutional Review Board (IRB) approval (expedited review, convened review) or acknowledgment of a claim of exemption.

When submitting to the IRB a new protocol or Modification (amendment) to a currently approved protocol that proposes to use eConsent, you must describe the eConsent process in detail.

Include the following information as part of your submission to OPRS:

1. A full description of the consent process. You should include the details of this plan in the informed consent section of the protocol document.
2. Relevant information for eConsent may include:
 - a. Whether the consent discussion will be face-to-face and/or remote;
 - b. Who will conduct this discussion;
 - c. If this discussion will be conducted remotely
 - i. how participants are identified
 - ii. how participants have been approached for consent
 - iii. who is introducing consent
 - iv. when they will be asked to provide consent in relation to the start of the research intervention
 - v. The means used to conduct a remote consent discussion (for example, phone, skype, virtual conference)
 - d. Description of how the study will be explained to participants, how their understanding will be assessed, and how questions will be answered.
 - e. Description of the plan to provide participants with a copy of their signed consent document. For example, REDCap allows for participants to download a pdf of the signed consent, have a pdf copy sent to them, or for the research staff to download & send (paper copy or email) the signed pdf of the consent.
 - i. If a pdf of the signed consent will be emailed to participants, remember to include collection of email addresses as part of the data security plan in the application form, and inform participants in the privacy/confidentiality section of the consent form.
 - f. Plans in place to account for special circumstances, as applicable. For example:

- i. Obtaining assent and parental permissions for minors
 - ii. Obtaining two parent signatures when required for the enrollment of a minor
 - iii. Use of translators for non-English speaking participants
 - iv. Use of witnesses when required for the consent process
 - v. Participants that lack the technology needed to conduct remote consent discussions or provide electronic signatures
3. Consent document:
- a. The consent document to be used in the eConsent process and/or uploaded to an electronic format should be submitted to the OPRS / IRB.
 - i. If both standard paper consent and eConsent will be used, and the same document will be used for both processes, this should be noted in the submission.
 - ii. In some cases, the language in the eConsent might need to be different than the language in the paper consent, for example, because eConsent allows for the collection of email addresses, or where social distancing requires some changes to study procedures. If this is the case, the eConsent should be provided to the OPRS / IRB as a separate document, and identified as the eConsent in the footer.
 - iii. It is recommended that the eConsent submitted to the OPRS / IRB be in Word document.

Modifications (formerly known as Amendments): If the research is already approved and will be modified to incorporate eConsent processes, then a Modification should be submitted to OPRS / IRB. The revised protocol and consent documents should be uploaded into UIC Research with the Modification submission, and this submission should include in the summary of changes a rationale for making these changes. Furthermore, if applicable, include a statement whether the eConsent is a permanent addition to the study or a temporary means to obtain consent while social distancing requirements are in place, or if it is replacing or supplementing the current consent process.

eConsent in FDA regulated research

Researchers that want to utilize eConsent to obtain a signature documenting consent in FDA regulated research must use a method that is compliant with the Federal regulations under 45 CFR Part 11. As of October 11, 2023, UIC OPRS announced that Adobe Sign is a compliant eConsent option for FDA regulated research. There are specific instructions on how to utilize Adobe Sign in the consent process, and information about the process can be found here: [eSignature - web.uillinois.edu](https://web.uillinois.edu)

FDA regulated research refers to research that is testing the safety or efficacy of an FDA regulated product. It also refers to the treatment use of investigational FDA regulated products where IRB review is required. Common types of FDA regulated research are drug and medical device clinical trials.

eConsent in REDCap

REDCap (Research Electronic Data Capture) is a secure, web-based application for building and managing online surveys and databases. REDCap's easy design environment allows researchers to quickly create web-based databases and data capture forms with special features like ad-hoc reporting and scheduling, as well as eConsent capabilities. UIC's Center for Clinical and Translational Science (CCTS) administers the UIC-specific installation of REDCap and provides training and consultation services for UIC health researchers. More information on CCTS REDCap can be found at: <https://ccts.uic.edu/tools/redcap/>.

The eConsent function within REDCap involves accessing the consent document as well as recording informed consent using an electronic device such as a computer, tablet or other touchscreen device. Participants can sign using a stylus, finger, mouse or other method to obtain a signature, and this can be done either in-person or remotely.

Some important things to note:

- **UIC's REDCap eConsent signature process cannot be used when conducting FDA-regulated research, such as testing a drug, blood product, or medical device.** The FDA has specific requirements for electronic signatures, and UIC CCTS REDCap account currently does not meet these requirements.
- **IRB approval / acknowledgement must be obtained before setting up eConsent in REDCap**
- **UIC CCTS staff can help navigate both the regulatory aspects of using eConsent in research and technical support for setting up eConsent in REDCap.**

REDCap allows for electronic signatures from parents, legal guardians, witnesses, and the person obtaining consent. It can be configured to include optional components to research, such as additional tests or procedures that have opt-outs. The e-signature/auto archive function in REDCap automatically store the date and time that signatures are obtained allowing this information to be accessed at any time (e.g., during an audit). Through Redcap, you can also generate pdf copies of the signed consent document to give to participants.

To use eConsent in REDCap, you can **either**:

- upload a pdf of the IRB approved consent document; **OR**
- use the survey function in REDCap to upload the text from the IRB approved consent