



## **Guideline for Using REDCap for Electronic Informed Consent (eConsent)**

### **Background**

The research community is showing increasing interest in using electronic media to supplement or replace paper-based informed consent processes. Electronic informed consent (eConsent) is media that can be used to provide information contained in a consent document to a potential subject or legally authorized representative and can be used to obtain documentation of consent. It can also be used as a method to evaluate comprehension of the study, with questions built into the eConsent. It is important to note that the consent process does not change regardless of the media used to obtain consent (refer to [OHSP Policy 701 Informed Consent](#) and the [Guideline for Informed Consent](#) for further information).

Electronic processes to obtain informed consent may use an interactive interface, which may facilitate the subject/subject's legally authorized representative ability to retain and comprehend the information. Furthermore, these electronic processes may allow for rapid notification to the subjects of any modifications pertaining to the informed consent that may affect their willingness to continue to participate. Electronic processes may also promote timely entry of any eConsent data into a study database and allow for timely collection of the subject's informed consent data from remote locations.

### **1. Using REDCap to Consent Research Subjects**

Obtaining written consent is a critical step in the clinical research process, but managing paper forms can be problematic. REDCap offers a digital method to acquire and store subject consent forms through an e-Consent Framework and PDF Auto-Archiver. This functionality provides the ability to consent subjects remotely or consent subjects in clinic via computer, mobile phone, or tablet. Subjects will have the capability to sign electronically with a stylus, mouse, or finger. Once the consent form is signed and submitted, subjects will be able to receive a print out of the paper copy, download a pdf, and/or receive an email with a PDF attachment of the signed consent form.

### **2. What is eConsent?**

Electronic Informed Consent (eConsent) is a platform for consenting research subjects using a computer-based consent form rather than traditional paper documentation.

Subjects can 'sign' their consent electronically by typing their name or by utilizing REDCap's 'Signature' field type on the survey, which uses a stylus, mouse, or finger

to “write” their signature on the form. Please note that the signature process will be approved by the Institutional Review Board as part of the approval of the consent process and will be determined by the type of study conducted. It is **NOT** implemented by REDCap automatically; but each eConsent must be constructed using one or both methods in order to capture a signature.

### **3. Can eConsent be used on all projects?**

No. The IRB must ensure that the consent process is appropriate for the risk level of the proposed research. In some cases, the IRB may decide that informed consent must be obtained face-to-face, which may preclude the use of an eConsent.

In addition, the IRB must approve the use of eConsent for the study, before it will be implemented in REDCap. The research protocol must outline the consent process, and how eConsent will be used to obtain consent for the study. Once the consent form is signed and submitted, subjects will be able to receive a print out of the paper copy, download a PDF, and/or receive an email with a PDF attachment of the signed consent form. If a signed copy of the consent will be emailed to the subject using REDCap, the subjects must provide their e-mail address on the completion page, the following statement will be included in the field where the email address will be provided:

**Enter your email to receive confirmation message?**

A confirmation email is supposed to be sent to all respondents that have completed the survey, but because your email address is not on file, the confirmation email cannot be sent automatically. If you wish to receive it, enter your email address below.

Additionally, eConsent process requires that [Research and Academic IT](#) assist in setting up the consent form in REDCap, and while UR templates are used to create the eConsent, each needs to be set up on a per project basis.

### **4. What eConsent materials should the investigator submit to the IRB?**

The IRB will require a WORD document of each consent document to be uploaded into the study application, just like with any other submission. In addition, the investigator must submit to the IRB all informational materials, including any videos (a link would be acceptable because video files are not an accepted format in Click IRB) and web-based presentations, which the subject will receive and view during the eConsent process. The research protocol will need to explain the consent process, which includes how eConsent will be used (e.g. computers, electronic tablets, smart phones) and the mechanism for authentication, if required. The IRB will approve the use of the eConsent and the process before [Research and Academic IT](#) will build the eConsent in REDCap. This will ensure the consent process with eConsent is approvable for the applicable research. If the consent process will use

questions or methods to gauge subject comprehension of key study elements, this must also be submitted to the IRB.

If there is a modification to the consent, this must be reviewed and approved by the IRB, before [Research and Academic IT](#) will implement a change to the eConsent. The investigator must obtain IRB approval for any subsequent modifications to the study-related information, whether electronic or in hard copy.

While WORD documents will be watermarked and finalized in the IRB system, eConsents will not have that same IRB watermark. The approved, watermarked consent documents will be used by [Research and Academic IT](#) to create the eConsents in REDCap to ensure the final eConsent document in REDCap is consistent with the language the IRB has approved

**5. Should a signature section for the person obtaining consent be included on the eConsent form?**

Yes. Consistent with consent obtained on paper, the person obtaining consent will be required to document that he/she obtained consent from the subject/subject's legally authorized representative. The person obtaining consent will be required to initiate the eConsent process from within REDCap for their name and a timestamp to appear on the study subjects signed consent form. If you feel it is not practical to include that signature, please provide your justification to the IRB as part of your submission.

**6. How should information in the eConsent be presented to the subject?**

Any eConsent 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. The eConsent should be broken into pages that the subject must click through to promote understanding and easier reading of the information. Hyperlinks may be provided where helpful. The eConsent may also incorporate electronic strategies to encourage subjects to access all of the consent material before documenting their consent.

eConsents 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. Other subjects may have difficulty navigating or using electronic systems because of, for example, a lack of familiarity with electronic systems, poor eyesight, or impaired motor skills. It is important to consider the population under study, and whether eConsent is a good option for the study population. In such cases, the eConsent process may not be appropriate for these subjects. In addition, if there are technical difficulties with the platform or internet connection, paper-based consent processes may be needed as a back-up. Therefore, subjects must have the option to use paper-based or electronic informed consent methods completely or

partially throughout the informed consent process. It is important to document how consent was obtained in the subject files to ensure an accurate representation of the consent process used to obtain consent with each subject.

**7. How and where may the eConsent process be conducted?**

The consent process may take place at the study site when both the investigator and subject/subject's legally authorized representative are at the same location, or it may take place remotely (e.g., at the subject's/subject's legally authorized representative home or another convenient venue). The eConsent materials may be used for both on-site and remote access. In some cases, the link to the eConsent can be emailed or texted to the potential subject/subject's legally authorized representative to allow review in advance of the consent process. The study team must obtain verbal permission to send the eConsent via email or text. Verbal permission should state: "Because URMC can't control the security of email or text messages once we send them, we need your permission to text or email you. Do you want to receive the link to the eConsent via text or email?" The permission should be documented. The email/text should not include PHI. Regardless of where the eConsent process is conducted, the process must still be approved by the IRB and include adequate time to review the consent materials, the opportunity for the subject/subject's legally authorized representative to have the research explained, and for questions to be asked and answered.

**8. How do you authenticate that the individuals signing (subject/subject's legally authorized representative) is that person?**

If any or all of the consent process takes place remotely and is not personally witnessed by study personnel, the process must include a method for identity verification to ensure that the person electronically signing the informed consent is the subject who will be participating in the research study or is the subject's legally authorized representative.

When consent is obtained remotely the web-form sent to the subject/subject's legally authorized representative is not entirely secure in the sense that anyone who has access to the particular unique link for that individual can enter data and submit signatures without verifying their identity. There are a few options for ensuring additional real-time identity verification prior to eConsent. Each revolves around requesting the subject/subject's legally authorized representative enter a passcode, which is established with the study staff outside of electronic communication. This can occur during an in-person meeting, but typically will occur through a telephone or Zoom call, or through information already known by both parties.

Through the use of the "Survey Login" feature, an individual will be prompted to reply with the appropriate answer to one or more pre-designed questions or passcode, which have saved expected answers. Matching responses to questions or

the passcode will grant entry and non-matching responses will block the individual based on specified settings.

**Verification with an Established Passcode:** In this approach, an agreed passcode is communicated between the subject/subject's legally authorized representative and the study team. This passcode is saved as part of the subject's record for verification use later. The subject/subject's legally authorized representative at the time of accessing the survey/eConsent must then enter the passcode which is compared with the stored version entered by the study staff.

**Verification with Known Information:** In this approach, the study team choose to simply add questions to answer at the time of accessing the survey/eConsent. These questions should be pre-established security questions such as "What is your favorite color?" or "What is the name of the street you grew up on?" that are included on the signature page of the eConsent. The responses should be agreed upon by both the study team and the subject/subject's legally authorized representative during an in person or during a remote (video or telephone) conversation. The answers will be saved as part of the subject's research record for verification use later.

**Verification with a Passcode Based on Known Information:** In this approach, a study team who has collected sufficient demographic data can verify authentication without agreeing to a prior known passcode by simply informing the subject/subject's legally authorized representative that a combination of their demographic data will be used as their passcode. This is a more robust form of authentication in the sense that no transmission of information between the subject and study team is required, because the information should already be known by both. For example, when obtaining eConsent a study coordinator who has collected or has access to the subject's date of birth, middle name, and street name may choose a combination of these variables to represent the passcode, which the subject/subject's legally authorized representative would then be prompted to answer when accessing the eConsent.

**Verification with Identity Document Upload:** In this approach, a government-specific identity verification would be required. The study team could verify identity using a government issued ID during the Zoom conference by taking an image or screenshot during the conversation, or implement a post-process verification method, which requires the subject/subject's legally authorized representative to upload a picture or scanned version of a specific identity document such as a passport or state issued ID card to accompany the e-Consent submission. This method would require manual document review by the study staff to ensure the information matches what is expected.

**9. How and when should questions from subjects be answered?**

The Investigator should follow the IRB-approved consent process, and as such have methods in place to ensure that the eConsent process allows subjects the opportunity to consider whether or not to participate and to ask questions. This may be accomplished by in-person discussions with study personnel or through a combination of telephone calls or video conferencing with a remotely located investigator or study personnel.

**10. How can electronic signatures be used to document eConsent?**

The procedure for eConsent may include an electronic method to capture the signature of the subject/subject's legally authorized representative. The University of Rochester Office for Human Subject Protection (OHSP) and FDA regulations permit the use of electronic signatures when written informed consent is required, if such signatures are legally valid within the jurisdiction where the research is to be conducted. For example, they are acceptable in the United States, but may not be acceptable internationally.

**11. What special considerations should be given to the use of eConsent for pediatric studies?**

When approving an assent process, an IRB considers whether the study population has the ability to provide assent, this is not different whether assent is obtained by paper or electronically. The method used to obtain assent (paper or eConsent) should not impede the child's capability to provide assent.

**12. Should subjects receive a copy of their eConsent and have easy access to the materials and information presented to them in their eConsent?**

Yes. HHS and FDA regulations require that the subject/subject's legally authorized representative be provided a copy of the consent form. The HIPAA regulations require that the subject/subject's legally authorized representative receive a signed copy of the consent form with authorization.

When the study team will not physically interact with the subject/subject's legally authorized representative, REDCap should be set up to display a button for the subject/subject's legally authorized representative to download the signed consent form. If this is not possible, other methods need to be used to provide the subject/subject's legally authorized representative a signed copy (e.g. paper copy through the mail, emailed PDF).

When the study team will physically interact with the subject/subject's legally authorized representative, REDCap can be set up to send the subject/subject's legally authorized representative an email with a PDF attachment of the signed

consent form, if an email address is provided, or a signed paper copy can be provided to the subject/subject's legally authorized representative.

### **13. What materials or documents will FDA require during an inspection?**

During inspections of clinical investigation sites, FDA regulations require that FDA be granted access to records and reports made by the investigator, including site-specific versions of the eConsents, the materials submitted to IRBs for review and approval, all amendments to the site-specific eConsents, and all subject-specific signed eConsents. These should be available at the site either in electronic or paper form. FDA reserves the right to review the content of the eConsent program or informed consent document and the corresponding informed consent of the subject/subject's authorized representative and the signature of a witness, where applicable, along with the date that the eConsent was signed. Any updates to the documentation should also be available for review.

### **14. What do I need to do if I want to use REDCap to provide an eConsent alternative?**

The University of Rochester IRB (RSRB) has approved the REDCap template of the eConsent process, and confirmed that it meets all local and federal consenting requirements. If you wish to use REDCap as your eConsent option, please comply with the following steps:

- Please read this guideline to ensure you are familiar with the requirements on eConsents
- The research protocol will need to explain the consent process, which includes how eConsent will be used (e.g. computers, electronic tablets, smart phones) and the mechanism for authentication, if required. Refer to [OHSP Policy 701 Informed Consent](#) and the [Guideline for Informed Consent](#) for further information about writing a consent process and what should be described.
- Create WORD versions of all consent documents and submit your study application to the IRB as usual.
- Keep in mind that the questions can be built into the bottom of each page or into the signature page of the eConsent. Therefore, they should be included in the location requested in the WORD document(s) submitted to the IRB.
  - Checkboxes for optional participation (e.g. future contact, storage of samples).
  - Questions used to gauge subject comprehension of key study elements
  - Authentication questions should be built into the end of the consent
- Once your protocol and consent documents are approved, the watermarked version of your consent form will be available in Click IRB under your newly approved study.

- After IRB approval, to get the eConsent creation process started, the PI/Study Contact will need to submit the [REDCap eConsent Request Survey](#)
- The REDCAP Administrator will:
  - Review the submitted [REDCap eConsent Request Survey](#) and contact the Study Contact/PI with any questions
  - Obtain IRB-approved consent documents from the Click IRB System
  - Save each page of the approved consent form as .JPEG or .PNG
  - Build 2 REDCap instruments
    1. Consent Security Verification
      - Set up survey login passcode(s)
    2. eConsent Form
      - Load each page of the consent form (individually)
      - Create any additional consent fields based on the IRB-approved consent form
      - Set up survey settings
  - Schedule meeting with Study Contact/PI to do the following:
    1. Review e-Consent procedure
    2. Finalize custom survey login and survey settings
  - Release eConsent form for use by the study team

**15. What if I need to revise my consent form, and I'm using the REDCap eConsent system?**

You should first submit your modification to change the WORD consent document in Click IRB. Submit a revised WORD consent form, refer to the [Click IRB Study Staff Manual](#) for information about submitting a modification (page 22) and how to update study documents (page 39). Once your modification is approved, you will need to work with [Research and Academic IT](#) to update your eConsent(s) in REDCap. REDCap has versioning control built into the technology to allow for versioning control.



## eConsent Research Protocol Template Language

**Please find below template text that can be used in a research protocol to describe the specific steps for obtaining eConsent. This language should be modified to describe the eConsent process:**

The consent document will be created using a REDCap-based electronic consent form. The IRB-approved consent form will be developed in REDCap, a secure, web-based, HIPAA-compliant, data collection platform with a user management system allowing project owners to grant and control varying levels of access to data collection instruments and data (e.g. read only, de-identified-only data views) for other users. Potential subjects will participate in the consent process by (**select method**):

- 1.) **eConsent Obtained in Person** – Subject/Subject’s legally authorized representative is approached in-person at (INSERT) and accesses the REDCap eConsent via University-owned iPad or other portable electronic device. During the in-person consent process...(Describe the consent process and how the signed consent will be provided to the subject/subject’s legally authorized representative)

and/or

- 2.) **eConsent Obtained Remotely with Required Remote Consent Process (e.g. video/telephone)** – eConsents accessed on personal electronic devices (e.g., computers, portable tablets, smart telephones). During the remote consent process ... (Describe the consent process that occurs remotely between the subject/subject’s legally authorized representative and the study team member, the authentication method, and how the signed consent will be provided to the subject/subject’s legally authorized representative). The study team will request verbal permission to send the eConsent via email or text. The request will state: “Because URMIC can’t control the security of email or text messages once we send them, we need your permission to text or email you. Do you want to receive the link to the eConsent via text or email?” The permission will be documented. The email/text will not include PHI.

and/or

- 3.) **eConsent Obtained Remotely (e.g., link provided using posted QR codes, web-links on study posters, brochures, or websites; email link)** – eConsents accessed on personal electronic devices (e.g., computers, portable tablets, smart telephones). The study team provides contact information (email and phone) for prospective subject to contact a study team member with questions, if any. (Describe the process in detail and any authentication method, if required).

Most studies in this category would be determined to be exempt research by the IRB.

Subject signatures will be obtained using a (**select method: typed signature, PIN number, written signature - via stylus/cursor, etc.**). Once the consent form is signed and submitted, subjects will be able to receive a print out of the paper copy, download a pdf, and/or receive an email with a PDF attachment of the signed consent form.