Guideline for Using REDCap for Electronic Informed Consent (eConsent)

Key Information:
- *This guideline only addresses eConsent via REDCap.*
  - *The contents do not apply to other electronic platforms that may be utilized to facilitate the informed consent process.*
  - *REDCap is not compliant with 21 CFR 11, therefore cannot be used to obtain consent for studies subject to Food & Drug Administration (FDA) regulations.*
- *eConsent in this guideline refers to **written** documentation of consent through an electronic method*
  - *It does not apply to research approved with a waiver of documentation of consent (e.g., when an information sheet is provided electronically for participation in a survey study).*
- ***All eConsents are created by the [Office of Research IT](#).***
  - *The IRB must approve the use of eConsent for the study before it is created in REDCap by the Office of Research IT.*
  - *Refer to the [REDCap e-Consent Workflow](#) and [REDCap e-Consent Workflow Video](#)*
  - *The Office of Research IT will use the IRB-approved PDF version with watermark to create the eConsents in REDCap.*
- *The term subject in this guideline, refers to the subject and/or the subject's legally authorized representative (LAR).*
  - *The signature of a LAR can only be used to enroll a subject if your IRB-approved protocol permits this and your approved consent form includes a signature line for the legally authorized representative.*

eConsent & REDCap

Electronic Informed Consent (eConsent) is a platform for facilitating the informed consent process that uses a computer-based system to disclose the necessary elements of consent and document consent, rather than traditional paper consent forms. It can also be used as a method to evaluate comprehension of the study, with questions built into the eConsent process.

REDCap offers a digital method to obtain and store consent forms through an eConsent Framework and PDF Auto-Archiver. This functionality provides the ability to obtain consent from subjects remotely or in-person via an electronic device (i.e., computer, mobile phone, or tablet). Subjects 'sign' the consent electronically by typing their name or by utilizing REDCap's 'signature' field, which uses a stylus, mouse, or finger to 'write' their signature on the electronic form. Once the consent form is signed and submitted, subjects can receive a printout of the paper copy, download a pdf, and/or receive an email with a PDF attachment of the signed consent form.

Note: Utilizing eConsent to facilitate the consent process does not change the regulatory and/or institutional requirements related to obtaining informed consent (see to [Office for Human Subject Protection Policy 701 Informed Consent](#). **The manner in which consent will be obtained and**

documented (paper consent or eConsent) must be described in your protocol and approved by the Reviewing Institutional Review Board (IRB) _prior_ to implementation.

Can eConsent be used on all projects?

No. In accordance with the criteria for IRB approval defined by federal regulation ([Criteria for IRB Approval Quick Reference Guide](#)), the IRB must ensure the consent process is appropriate for the proposed research. In some cases, the IRB may decide that utilizing eConsent will hinder the ability of the study team to meet regulatory requirements and obtain a legally effective informed consent and therefore may not approve use of an eConsent process.

During the development process, it is important to consider the population under study, and whether eConsent is a good option for the study population. For example, some subjects may prefer one method over another. Other subjects may have difficulty navigating or using electronic systems, e.g., a lack of familiarity with electronic devices, poor eyesight, or impaired motor skills. 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, it may be necessary to have _both_ paper-based and eConsent methods described in the study protocol.

Additionally, while the method for documenting eConsent via REDCap involves the electronic capture of the subject's signature, REDCap is not compliant with [21 CFR 11](#) and therefore cannot be used to obtain consent for studies subject to Food & Drug Administration (FDA) regulations.

What needs to be included in the protocol?

The research protocol must explain the consent process, which may include both in-person and remote components. Regardless of where the process will take place, as with all research, the process must include:
- the disclosure of all necessary elements of consent;
- adequate time for the potential subject to review the consent materials and their consider participation; and
- the opportunity for the subject to have the research explained, and for questions to be asked and answered.

This may be accomplished by in-person discussions or through a combination of telephone calls and video conferencing with the person obtaining consent.

Specific to eConsent, the process of consent must further describe:
- If the consent will be sent to the potential subject for review in advance of the consent process (e.g., via email or text);
  - Verbal permission to send the eConsent by email or text is required.
    - Verbal permission should state: "Because URMC [UR] cannot control the security of email or text messages once we send them, we need your permission to text or email you. The email or text will not contain health information, but once the link is opened it may reveal health information. Do you want to receive the link to the eConsent via text or email?"
    - Verbal permission must be documented.
    - The email/text should not include health information.
    - If texting, the text must include an opt-out opportunity, which is a requirement of the Federal Trade Commission (FTC).
- How eConsent will be used (e.g., computers, electronic tablets, smart phones);

- How the link to the eConsent will be provided to potential subjects;
- The mechanism for identify verification; and
- How a copy of the signed eConsent will be provided to subjects.

Once the subject has provided consent, a signed copy of the consent form can be provided via printed copy, download, and/or via email with a PDF attachment. Because the subject can receive the signed consent by email, the protocol, consent form, and data security assessment form must include the collection of subject's email address. Subjects who indicate they wish to receive a copy of their signed consent form via email must provide their e-mail address within the REDCap eConsent.

As a reminder, federal regulations related to the protection of human subjects require that the subject be provided a copy of the consent form. HIPAA regulations further require that the subject receive a signed copy of the consent form when the consent form includes a HIPAA authorization.

What eConsent materials should the investigator submit to the IRB?

As with all submissions, the IRB requires a Microsoft Word version of each consent document and any other media (e.g., video scripts, web-based presentations) to supplement the consent process. If hyperlinks will be provided in the eConsent form, they must be included in the Word document(s) submitted to the IRB. Similarly, if questions will be used to gauge subject comprehension of key study elements and/or checkboxes for optional participation (e.g., future contact, sample storage), they must be included in the Word document(s) submitted to the IRB, in the location they should appear in the eConsent (e.g., on the specific page of the consent or on the signature page).

As a reminder, the IRB must approve the use of eConsent for the study, before the eConsent is created in REDCap by *Office of Research IT*. **All REDCap eConsents must be created by the Office of Research IT,** *REDCap e-Consent Workflow* describes the required process. As per the workflow, the IRB-approved PDF version with watermark will be used to create the eConsents in REDCap to ensure the final eConsent document in REDCap is consistent with the language the IRB has approved.

Should the eConsent include a signature section for the person obtaining consent?

Yes. Consistent with consent obtained on paper, the signature and date of the person obtaining consent is required to document that consent was obtained from the subject. The *REDCap e-Consent Workflow* describes the required process for obtaining signatures using REDCap eConsent.

How do you authenticate that the individual signing is that person?

When the eConsent process occurs remotely, the person obtaining consent may not personally witness the signature. This situation requires the consent process include a method to confirm the subject's identity, called identity verification. Identity verification ensures that the person signing eConsent is the subject who will participate in the research or is the subject's legally authorized representative. The method for identify verification should be included in the protocol (see below). Also, refer to the *REDCap e-Consent Workflow* for detailed methods for identify verification during eConsent.

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 can provide assent, which 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. As outlined above, it is important to consider the population under study and whether eConsent is a good option for the study population.

What do I need to do if I want to use REDCap to provide an eConsent alternative?

The IRB must approve the use of eConsent for the study, before the eConsent is created in REDCap by [Office of Research IT]. **All REDCap eConsents must be created by the Office of Research IT,** *[REDCap e-Consent Workflow]* describes the required process. As per the workflow, the IRB-approved PDF version with watermark will be used to create the eConsents in REDCap to ensure the final eConsent document in REDCap is consistent with the language the IRB has approved.

After IRB approval, the PI/Study Contact **must** submit the [REDCap eConsent Request]. The Office of Research IT will obtain approved consent forms from the Click IRB Review System. Please allow for a 2-week turnaround to process initial eConsent requests or modifications.

Refer to the [REDCap e-Consent Workflow] for detailed workflows.

What if I need to revise my consent form, and I am using the REDCap eConsent system?

Once the eConsent is created by the Office of Research IT and released to the study team to begin consenting subjects, all modifications to the consent must be reviewed and approved by the IRB, before the Office of Research IT will make the change to the eConsent.

Submit the modification to change the Word version of the consent document in Click IRB (refer to the [Click IRB Study Staff Guide] for information about submitting a modification). Once the modification is approved, the PI/Study Contact **must** submit a [REDCap eConsent Request]. The request will ask if the REDCap project exists already, answer YES, and add the REDCap Project Title. The Office of Research IT will obtain approved consent forms from Click IRB. Please allow for a 2-week turnaround to process eConsent modifications.

Please note that REDCap has versioning built into the technology. The Office of Research IT will update the version during creation of the modified eConsent. This will be visible in the PDF archive and in the document.

Refer to the [REDCap e-Consent Workflow] for detailed workflows and [REDCap e-Consent Workflow Video].

eConsent Research Protocol Template Language

Below is template language to be used in a research protocol to describe obtaining eConsent. This language should be modified as needed depending upon the population (e.g., if a legally authorized representative will be used) and the eConsent process. In addition, ensure that REDCap is marked as a technology used for data collection and as an identifier collected on the Data Security Assessment Form.

The consent document will be created using a REDCap-based electronic consent form, consistent with Office of Research IT REDCap e-Consent Workflow. Potential subjects will participate in the consent process by (**select method**):

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

and/or

2.) **eConsent Obtained Remotely with Required Remote Consent Process (e.g., video/telephone)** – eConsents will be 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 and the study team member).

    a. If the consent will be sent to the potential for review in advance of the consent process (e.g., via email or text);

        i. Verbal permission to send the eConsent by email or text is required.

        ii. Verbal permission should state: "Because URMC [UR] cannot control the security of email or text messages once we send them, we need your permission to text or email you. The email or text will not contain health information, but once the link is opened it may reveal health information. Do you want to receive the link to the eConsent via text or email?"

        iii. Verbal permission must be documented.

        iv. The email/text should not include health information.

        v. If texting, the text must include an opt-out opportunity, which is a requirement of the Federal Trade Commission (FTC).

    b. How eConsent will be used (e.g., computers, electronic tablets, smart phones);

    c. How the link to the eConsent will be provided to potential subjects;

    d. The mechanism for identify verification; and

    e. How a copy of the signed eConsent will be provided to subjects.

Identity Verification

When the subject opens the REDCap survey link, the subject will be required to verify their identity. Matching responses to questions or the passcode will grant entry and non-matching responses will

block the individual based on specified settings. Potential subjects will be required to verify their identity by (**select method**):

a) **Verification with an Established Passcode:** An agreed upon passcode is communicated between the subject and the study team. This passcode is saved as part of the subject's record for verification use later. The subject enters the passcode at the time of accessing the eConsent.

b) **Verification with Known Information:** The eConsent has specific questions to answer at the time of accessing the 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?" The responses are agreed upon by both the person obtaining consent and the subject during an in-person or remote conversation. The answers are saved as part of the subject's record for verification use later. The subject enters the answers at the time of accessing the eConsent.

c) **Verification with a Passcode Based on Known Information:** The eConsent has a subject-specific passcode based upon the subject's demographic data known by the person obtaining consent. This allows for identify verification without agreeing to a prior known passcode, but by informing the subject that a combination of their demographic data will be used as their passcode. This is a more robust form of identity verification because no transmission of information between the subject and person obtaining consent is required. 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 would then be prompted to answer when accessing the eConsent.

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 printout of the paper copy, download a pdf, and/or receive an email with a PDF attachment of the signed consent form.