IRB Guidance on REDCap Consenting

This guidance outlines ways to navigate consenting research subjects using REDCap to obtain all necessary signatures and document the process accordingly.

Remote consenting can occur via REDCap at MCW, but it's important to know that this platform does not allow for two individuals to sign a consent form at the same time. This is important for research projects that require multiple signatures (e.g., individual obtaining consent, PI, etc.) to sign the consent form.

There are three options which the IRB has identified for obtaining signatures via REDCap:

1. The consenter may e-sign the consent form BEFORE the subject does.
    a. The consenter contacts the subject.
    b. Once they are sure the subject can discuss the consent form, the study team member can add their name to the form and then email the link to the subject. The consent form will be fully reviewed with the entire consent process taking place over the phone/an acceptable remote platform with the subject, and then the subject will e-sign the form using REDCap. The IRB PRO SmartForm submission in eBridge should also include language describing the process for consenting via REDCap and obtaining both signatures.
2. The study team can create two consent forms in REDCap under each subject's record; one for the participant to sign and one for the consenter to sign. Both would be enabled as surveys, and both would utilize the REDCap E-Consent Framework.

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options	
Participant Consent	26	📄	✅	Choose action ▽	✅ Survey settings	+ Automated I
Consenter Consent	0	📄	✅	Choose action ▽	✅ Survey settings	+ Automated I

    a. The study team member contacts the subject and sends the Participant Consent survey link to the subject.
    b. The consent conversation takes place and the subject e-signs the consent survey.
    c. Once the participant signs their consent survey file, the consenter can open the Consenter Consent survey to sign.
    d. This Consenter Consent should include language documenting the consenting process and the creation of two signature pages and the reasoning.
        i. An example of this is: "The individual signing this form consented subject <<<subject ID>>> over the phone on <<<insert date>>> due to <<<insert reason>>>"
        ii. The submission IRB PRO SmartForm in eBridge should also include language describing the process for obtaining both signatures using two consent forms.
    e. By utilizing this option, both files will generate a pdf of the signed consent forms, both will be placed in the File Repository within the project, and both will be tied to the same record in REDCap.
3. The consenter signature box may be removed completely if it is not required.
    a. This would require an amendment submission if the currently approved consent forms have a signature box.
    b. The consenter's signature may be optional depending on the type of activities being performed as not all research activities require this option.

      c.   It is possible for Sponsors, funders, and departments to require the consenter's signature on signed research consent forms.

Please note that consenting via REDCap is not an option for FDA regulated studies because MCW REDCap is not Part 11 compliant.

Department of Health and Human Services human subject research (HSR) regulations do NOT require subjects to be given a copy of the consent form with a wet signature. This is a commonly misunderstood component of the regulations. This is a requirement of the Health Insurance Portability and Accountability Act (HIPAA).

- For projects that use a HIPAA authorization embedded within the consent form, the subject should be provided with a copy of the consent form that they sign and date.
- This copy should also be signed and dated by the consenter if the signature box is present.

This article outlines ways to navigate consenting subjects via REDCap to obtain all necessary signatures and document the process accordingly. There are additional processes that can be followed to remotely consent subjects. These include mailing or emailing using encrypted methods. The complete guidance for remote consenting can be found [here](#).

To find the most recent MCW approved ICF templates please [click here](#). Additionally, if you have further questions about the consenting process for your research project, please reach out to your assigned IRB Coordinator II or email IRBOffice@mcw.edu.

If you require assistance or have any questions about REDCap, please contact [CTSI REDCap Support](#).