Consent / E-Consent

OCTRI worked closely with the OHSU's IRB to develop a REDCap-based electronic consent toolkit and methodology for research teams to use in research studies that are not FDA regulated (21 CFR Part 11).

If you need an electronic consent for an FDA regulated study, contact OCTRI Research Navigator at octri@ohsu.edu and request a consultation.

💡**Tip:** An Information Sheet is a type of consent form and this e-consent guidance applies to distributing an Information Sheet electronically in REDCap.

Toolkit Sections:

The toolkit includes:

- Guidance and instruction
- Training video
- e-consent templates

This toolkit covers:

- Information Sheet (*in English & requirement for participant signature waived*)
- Information Sheet and Authorization (*in English & requires participant's signature*)
- Consent and Authorization (*in English & requires participant and study staff signatures*)

This toolkit does not cover:

- Re-consent
- Consent or assent for persons under 18
- Consent that accommodates an LAR or a translator/interpreter
- Consent in a language other than English

For these types of consents, contact the REDCap Team and see the section below in the yellow call out box, *When Charges Apply*.

Disclaimer: *In our guidance and instruction, we will refer to REDCap features and functionality that are common to all survey projects and are covered in detail in our Basics and Survey trainings. Functionality and features not specific to consenting will not be described in detail.*

***For general information about electronic consent at OHSU**, please refer to IRB's Use of Electronic Consent - Quick Guide, which provides definitions and requirements for implementation of systems that support electronic consent.*

⚠️ Considerations & Limitations

Start with a Template

Effective May 1st, 2021, project builders are required to use an OCTRI REDCap e-consent template. There are fees for any help, including drop-in help, for consent forms built from scratch. Using templates is covered in: 3 - Building: Decision Points & Instructions . . .

💡**Tip:** Select the e-consent template that corresponds to the paper document submitted to IRB approval.

Multi-Site Studies

We can support an OHSU e-consent that is approved by an external IRB if the external site approves how OHSU implements e-consent. Please contact the REDCap Team for more information.

We are not able to support e-consents for other institutions in OHSU's REDCap. This is because other institutions' legal and IRB teams would need to approve the methods used at OHSU for obtaining e-consent and agree to the level of oversight provided by the REDCap Team. Also, an assessment by our legal team would be required for studies that are more than minimal risk.

When E-Consent is NOT Supported

IND, IDE and FDA
REDCap and the instructions in the wiki should not be used for studies conducted under an IND (21 CFR part 312) or an IDE (21 CFR part 812) or where data is intended to be submitted to FDA in support of a 510K submission.

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1 - Getting Started: Understanding the Process & Setting Expectations

It is essential to understand, at a high level, the activities and efforts involved, as well as the requirements for using REDCap for consenting, not just for the personnel building and managing the project, but also for the PI, the CO-PI and the regulatory personnel on the study team.

Who should review this material:

- PI
- Co-PI
- Personnel building project
- Personnel managing the project
- Regulatory personnel on the study team

Review *Getting Started* documentation

Getting Started: Key Points

REDCap e-consent is for studies *that are NOT FDA regulated (21 CFR Part 11)*.

REDCap e-consent *requires using survey functionality.*

Basics and Survey training is required for REDCap personnel building a project that will be used for e-consent.

Plan for extended development and testing time , and possibly additional support costs.

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2 - Planning: Regulatory Considerations & Preparing to Use REDCap

To determine the scope of work for setting up a REDCap project for consenting your participants, it's critical to understand: 1) the related regulatory issues that will need to be addressed by the study team, and 2) OCTRI's model of support for consent implementations, including requirements for the personnel building the project and when additional help from the REDCap Team will be needed.

Who should review this material:

- PI
- Co-PI
- Personnel building project
- Personnel managing the project
- Regulatory personnel on the study team

Review *Planning* Documentation

Planning: When Charges Apply

Additional help, for which there are charges, applies to implementing e-consents that involve:

- Re-consenting
- Consenting persons under 18
- Accommodating an LAR or a translator /interpreter
- Distributing consent in language other than English
- Adding consent to a project in production

Charges depend on the consent requirements and the personnel's REDCap experience. For more information contact the RED Cap Team.

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3 - Building: Decision Points & Instructions for Setting Up Consent in a Project

It's essential that the personnel building and managing the project understand both how to set up their REDCap project for consenting, and for using the project, real-time, for consenting their research participants. They will need to consider the workflow that pertains to their study's consent process as they plan for 1) testing the project, 2) training the study team on using the project for consenting, and 3) documenting consent operations.

Project Building: Training

Watch Training video (*from 08/2020 training*)

Download Training Slide Deck

💡**Tip:** Building an e-consent form in REDCap involves transforming the paper document for electronic distribution. Select the e-consent template that corresponds to the paper document submitted to IRB approval.

Who should review this material:

- Personnel building project
- Personnel managing the project

⭐ **Review *Building* Documentation**

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4 - **Project Management:** Documentation, User Permissions & Making Revisions

To be effective at managing a project used for consenting research participants, it's important for the personnel who build and manage the project to understand: 1) what to address in documentation, 2) how to account for users permissions related to the consent survey, and 3) how to make revisions to the consent form.

Who should review this material:

- Personnel building project
- Personnel managing the project

⭐ **Review *Project Management* Documentation**