

REDCap e-Consent Tool

CCCR: HOW TO Series

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Agenda

1. **What** is the CRU's REDCap e-Consent tool?
2. **Why** use the CRU's REDCap e-Consent tool?
3. How does this e-Consent tool meet **regulatory requirements**?
4. How does the e-Consent module **work**?
5. How do researchers **access** the CRU's e-Consent tool?



What is the CRU's REDCap e-Consent tool?

The CRU recently launched validated REDCap version 10.0.32!

- Fully validated platform can now host regulatory trials, like multi-centre phase 3 clinical trials
- Introduction of multiple new valuable features, including the e-Consent Framework

The screenshot shows the 'e-Consent Framework' settings in REDCap. It includes a description of the PDF Auto-Archiver feature and a section for 'e-Consent Framework Options' with radio button selections.

e-Consent Framework
- and -

PDF Auto-Archiver
Upon survey completion, a compact PDF copy of the survey response will be automatically stored in the project's File Repository, from which the archived PDFs can be downloaded at any time.

Disabled
 Auto-Archiver enabled
 Auto-Archiver + e-Consent Framework [What is the e-Consent Framework?](#)
(includes end-of-survey certification & archival of PDF consent form)

e-Consent Framework Options:
For e-Consent it is sometimes required to include the consenting participant's name (and date of birth in some cases) on the final consent form as extra documentation of their identity. Below you may select fields used to capture that info. You may also enter the current e-Consent version and e-Consent type for this form. The values for the fields below will be automatically inserted into the footer of the PDF consent form that the participant will review at the end the survey, after which that PDF 'hard-copy' will be archived in the File Repository. [Read more](#)

- The e-Consent Framework is a built-in REDCap 10.0.32 feature that can be accessed from within the 'Survey Settings' of any REDCap survey → limited in scope
- The CRU's REDCap e-Consent tool provides a UofC specific e-Consent Framework template and workflow, and explicit instructions of how to use the REDCap e-Consent Framework to ensure all regulatory requirements are met.

Why use the CRU's REDCap e-Consent tool?



- **e-Consent** provides researchers with a **robust and templated approach** to collecting consent in REDCap.
- The **CRU** provides researchers with instructions about how to set-up and use the REDCap e-Consent Framework based on UofC regulatory requirements and guidelines:
 - How to send the consent form
 - Consent form structure and content requirements
 - Templated form to collect data about the consent process
 - How to send and track participant withdrawal

How does this e-Consent tool meet regulatory requirements?

- Can be used when obtaining consent in multiple settings:
 - Electronically – minimal risk (e.g. questionnaires, surveys)
 - Ability to create ‘I Agree’ field to allow participants to provide consent
 - In Person – higher risk (e.g. clinical intervention)
 - Provides template for documenting consent given in person
- Ensuring identity of individual providing consent:
 - Ability to designate identifier fields entered in consent form. These fields are automatically added as footers on the completed form.
- Electronic Signature - need to be able to confirm that the signature is legitimate
 - REDCap signature field – signed with a stylus
- Ability to provide the participant with a copy of the consent form – both blank and signed/complete

NOTE – the CRUs e-Consent tool needs to be verified and approved by the REB before it can be used.

Demo: How does the e-Consent module work?

1. Preparation & Customization of e-Consent tool
2. Workflow

How do researchers access the CRU's e-Consent tool?

How to request - REDCap 10.0.32 [Intake Survey](#)

- As a part of a new project
- To add to an existing project
- As a stand-alone project dedicated to collecting consent

The intake survey can also be accessed from the [REDCap 10 landing page](#), or from the [CRU website](#).

How to implement

- **Self-service:** Researchers can use this template to independently implement this tool in their projects
- **CRU support:** Researchers can request support from the CRU to implement (included in Advanced Support from annual platform maintenance fees or at an additional fee to be estimated on a project-by-project basis)

Cost - [New CRU Pricing Structure](#)

- No additional fee for the use of the e-Consent tool itself – part of the annual platform maintenance fee for each project
- Each REDCap project is subject to an annual maintenance fee
 - Tiers of support – each tier includes set hours of advanced support, which can be used to implement e-Consent at no additional cost to the researcher.

Links to Resources

- [CRU's REDCap Resource Centre](#)
- [CRU Website](#)
- [REDCap 10.0.32 landing page](#)

- [CHREB Guidance on Electronic Consent](#)