

How to Use the E-Consent Framework

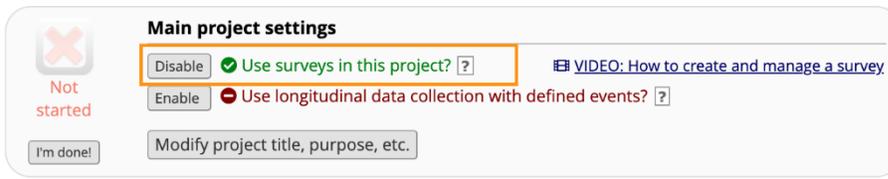
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Create an electronic consent (e-Consent) form

Step 1. Enable surveys

Navigate to 'Project Setup' and turn on surveys for your e-Consent project.



Main project settings

Not started

Disable Use surveys in this project? [?](#) [VIDEO: How to create and manage a survey](#)

Enable Use longitudinal data collection with defined events? [?](#)

Step 2: Create your e-Consent form

Fields in your e-Consent form instrument should include the following:

- Descriptive field with the consent language
- "I consent" yes/no or text box signature field
- Identifier fields (name, date of birth, personal health number)

Current instrument: **Electronic Consent (e-Consent) Demo**

Preview instrument

Add Field Add Matrix of Fields

Variable: consent_language

You are being asked to take part in a research study. Before you decide to participate in this study, it is important that you understand why the research is being done and what it will involve. Please read the following information carefully. Please ask the researcher if there is anything that is not clear or if you need more information.

The purpose of this study is to... demonstrate a demo of the new electronic consent framework.

Add Field Add Matrix of Fields

Variable: fname

First Name

Add Field Add Matrix of Fields

Variable: lname

Last Name

Add Field Add Matrix of Fields

Variable: dob

Date of Birth Today D-M-Y

Add Field Add Matrix of Fields

Variable: consent

I consent to participate in this study. Yes No

* must provide value reset

Add Field Add Matrix of Fields

Step 3. Enable e-Consent form as survey

Enable consent instrument as survey by selecting the 'Enable' button. Then navigate to the survey settings.

Project Home
Project Setup
Online Designer
Data Dictionary
Codebook

Create snapshot of instruments VIDEO: How to use this page
Last snapshot: never

The Online Designer will allow you to make project modifications to fields and data collection instruments very easily using only your web browser. NOTE: While in development status, all field changes will take effect immediately in real time.

Data Collection Instruments

Survey options:

- Survey Queue
- Survey Login
- Survey Notifications
- Upload or download Auto Invitations

Add new instrument:

- Create a new instrument from scratch
- Import a new instrument from the official REDCap Shared Library
- Upload instrument ZIP file from another project/user or external libraries

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
Electronic Consent (e-Consent) Demo	6		Enable	Choose action	

Project Home | Project Setup | **Online Designer** | Data Dictionary | Codebook

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Electronic Consent (e-Consent) Demo	6			Choose action	Survey settings +Automated Invitations

Step 4. Disable "Allow respondents to return and modify completed responses" under Survey Access

Survey Access:

Response Limit (optional)
(Maximum number of responses to collect. Prevents respondents from starting the survey after a set number of responses have been collected.)

(e.g., 150) If left blank, the response limit will not be enforced.
Will include:

Custom text to display to respondent on survey when limit is reached:

Time Limit for Survey Completion (optional)
(The amount of time that each respondent has to complete the survey based on when they were initially sent the survey invitation. Note: This feature excludes public survey links.)

days hours minutes
If the respondent loads the survey after this time has passed, it will not allow them to begin or continue the survey. (If all are left blank, the time limit will not be enforced.)

Survey Expiration (optional)
(Time after which the survey will become inactive.)

M/D/Y H:M
The time must be for the time zone **America/Los_Angeles**, in which the current time is 04/09/2021 13:01.

Allow 'Save & Return Later' option for respondents?

Allow respondents to return without needing a return code
NOTE: If you are collecting identifying information (e.g., PII, PHI), for privacy reasons it is HIGHLY recommended that you leave the option unchecked so as to enforce a return code.

Allow respondents to return and modify completed responses

Participants should not modify their already-completed consent forms. If participants would like to update their consent they should communicate directly with the study team to determine how to proceed.

Step 5. Request access the Auto-Archiver + e-Consent Framework

Contact DM team (redcap@healthresearchbc.ca) to enable the "Auto-Archiver + e-Consent Framework" function.

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 of the survey, after which that PDF 'hard-copy' will be archived in the File Repository. [Read more](#)

Allow e-Consent responses to be edited by users?

e-Consent version: e.g., 4
First name field:
Last name field:

Note: If you are using a single field to capture whole name, you may select it for either first/last name above while leaving the other name field unselected.

Optional fields (these are not always necessary for e-Consent):
e-Consent type: e.g., Pediatric
Date of birth field:

Force signature field(s) to be erased if participant clicks Previous Page button while on the certification page?
Select a field below that serves as a signature field in this survey. It could be a [free-form text field](#), a [signature field](#), or a [number field](#) (e.g., to collect a PIN), and it must be a [Required field](#). If any fields are selected below, then if the participant gets to the last page of the survey where it asks them to certify their responses, if they then choose to click the Previous Page button, it will erase the value of these signature fields, thus forcing them to 'sign' the field(s) again before completing the survey. If you do not want this behavior, do not select any fields below. You may use up to five signature fields.

Signature field #1:

[+ Select another signature field](#)

In the second section outlined in the above screenshot requirements for the signature field are listed. The "free-form text field" criteria allows fields without validation to qualify as a signature field.

Step 6. Fill out the e-Consent Framework Options

Once enabled, specify your e-Consent details under survey settings.

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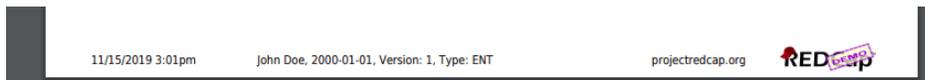
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[+ Select another signature field](#)

Consent-specific PDF Footer

Upon participants completion of an e-Consent survey, a PDF with a consent-specific footer will be generated. It will have values of the e-Consent Framework Options inserted at the bottom of each page in the PDF as extra documentation (i.e. participant consent information).

Example



The footer has mandatory, recommended, and optional fields.

Mandatory field

- e-Consent version (*a version number or alpha-numeric designation to represent the current version for e-Consent form*)

Recommended fields

- First name
- Last name

If the consent form is modified AFTER data collection begins, then it is recommended that a new e-Consent version number be applied (e.g. 2, 3, 4, etc.).

Optional Fields

- e-Consent type (*to distinguish between multiple e-Consent forms within a project (e.g. paediatrics)*)
- Date of Birth (*DOB*)

Signature Field: to indicate which field is the signature so that if the participant had to change something in the form and click previous page, the signature field values get erased and it forces participant to 'sign' (fill in) the field again before submitting the form.

If any of the descriptive fields containing the consent text span across more than one page in the PDF, the footer will not display properly or it will not display at all. Break the consent text into multiple descriptive fields to resolve this.

Certification page

Before a participant completes the survey, an extra certification page is added to the end of the survey that displays a PDF copy of the document in which they will be asked to confirm that all information in the document is correct. The survey will not be complete until they certify and “submit” in the certification.

e-Consent Framework Resize font: 

Displayed below is a read-only copy of your survey responses. Please review it and the options at the bottom.

e-Consent Framework Page 1 of 1

Please complete the survey below.

Thank you!

You are being asked to take part in a research study. Before you decide to participate in this study, it is important that you understand why the research is being done and what it will involve. Please read the following information carefully. Please ask the researcher if there is anything that is not clear or if you need more information.

The purpose of this study is to... make an example of an e-consenting survey

1) First Name John

2) Last Name Doe

I certify that all the information in the document above is correct. I understand that clicking 'Submit' will electronically sign the form and that signing this form electronically is the equivalent of signing a physical document.

If any information above is not correct, you may click the 'Previous Page' button to go back and correct it.

<< Previous PageSubmit

Static copy of survey responses are stored in the **File Repository**.

File Repository

This page may be used for storing and retrieving files and documents used for this project. You may upload files here to save for retrieval later, or you may download previously uploaded files in the file list below. Whenever a data export is performed, the resulting data and syntax files are stored here also.

[User Files](#)
[Data Export Files](#)
[PDF Survey Archive](#)
[Upload New File](#)

Displayed below are PDF files that have been automatically captured and stored by the PDF Auto-Archiver setting, which has been enabled by one or more surveys on their Survey Settings page. Only users with 'Full data set' data export privileges will be able to download the archived files. Note: The PDFs below were archived when a participant completes a survey, which means they might be different from other downloadable PDFs in the project that are generated on demand using the current data.

Displaying

[Download all \(zip\)](#)

Show entries

Survey Completion Time	Record	Survey	Identifier (Name, DOB)	Version	Type	Download
03/07/2022 9:33am	1	E-Consent	1 dsad	2		

Special Characters

Not all special characters (such as symbols, some accent marks, and international language characters) render properly in the PDF files generated by REDCap. If your e-Consent form contains special characters or has been translated to a language that uses international language characters, you can attach a blank PDF copy of the e-Consent form (created outside of REDCap) to a descriptive text field within the e-Consent for participants to download. Unfortunately, participants will not be able to download a legible PDF file of their completed responses but they will be able to download a blank copy of the e-Consent form for their records.