

Setting up eConsent With Auto-Archiving

It is highly recommended that you have a discussion with the Institutional Review Board (IRB) if you wish to do e-Consent in REDCap.

How the e-Consent Framework works

The 'Auto-Archiver + e-Consent Framework' survey option adds two things to the typical survey-taking process. 1) Before a participant completes the survey, an extra certification page is added to end of the survey that displays an in-line PDF copy of their survey responses in which they will be asked to confirm that all information in the document is correct. Once they confirm all is correct, the survey will then be marked as complete. The survey will not be considered complete until they fulfill the certification step. 2) Upon completion of the survey, a static copy of their responses in the form of a consent-specific PDF will be stored in the project's File Repository. The consent-specific PDF will have the values of the e-Consent Framework Options inserted at the bottom of each page in the PDF. These values (i.e., name, date of birth, etc.) are added to the PDF as extra documentation of the identity of the person who is consenting.

Why is this called a 'framework'?

The 'e-Consent Framework' is referred to as a 'framework' because enabling this option alone does not provide an e-Consent process but merely provides the general framework or mechanism to allow you to provide e-Consent to patients/subjects. As a survey administrator, you must still create your e-Consent survey and all the questions in it, including name, date of birth, and how you wish to capture the signature. This framework allows you to implement your e-Consent process by providing standardized tools (certification screen + automatic storage of consent form as a 'hard-copy' PDF) while still providing the ability to customize your survey how you wish.

How can the 'signature' process be handled for e-Consent?

Patients/subjects can 'sign' their consents by typing in their name or by utilizing REDCap's 'Signature' field type (i.e., 'wet signature') on the survey. One might also assign PIN numbers to prospective participants to aid in the signature process. Please note that the signature process will NOT be implemented by REDCap automatically, so it is your responsibility as a survey administrator to construct your survey using one of the methods above in order for the signature to get captured appropriately.


What is e-Consent version and type?


e-Consent version and type are both free-form text fields whose value will be inserted at the footer of each page in the PDF. Versioning of a form is a concept whereby you may give it a number or alpha-numeric designation to represent the current version or state of the form. So if the form is modified AFTER data collection begins, then it is recommended that a

new version be applied. For example, the first version might simply be '1', and after collecting the consent of a few participants, a question is modified or added, which represents a new version of the form, so you might increment the version to '2' (and so forth). The e-Consent 'type' is optional and is another free-form text field that is just a text label that you might want to display in the PDF footer to signify the type of e-Consent that this survey represents (e.g., pediatric). The type is often used to distinguish between multiple e-Consent forms within a project.

Once you have a REDCap project with Surveys enabled and your Consent form enabled as a survey, click the Online Designer Button, then Click the Survey Settings button.

Select Yes to allow participants to download a PDF version of their responses at the end of the survey.


 **Allow participants to download a PDF of their responses at end of survey?**
Display a button for the participant to download a PDF file of their responses for the survey they just completed.

Yes 

This option will not be available if the Survey Auto-continue or Survey Queue auto-start option is enabled. Also, if a field utilizes the @HIDDEN action tag, it will not be displayed in the PDF.

Note: Because the e-Consent Framework option is enabled on this page, the PDF included here will not be the full-length PDF but will be the 'compact' PDF, which omits unanswered questions and unselected choices.

Scroll down to PDF Archiver and fill this section out to meet the needs of your study.

 **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](#)

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:

Coordinators will now see the screen below when the consent is consented.

Participant Multi-Signature Consent Form

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

Participant Multi-Signature Consent Form

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Please note That this message is for the study team only and needs to be deleted before Moving to Production.

The EXACT language must be IRB approved prior to using the eConsent. This note is meant to provide instruction on how to develop this. Please highlight the underline then type the appropriate content for those blanks.

View the eConsent by going to the Manage Survey Participant and open the Public Survey Link. Then make the PDF from the on-screen version to be included in your electronic protocol. Note the Making the PDF from within REDCap is not the Version the IRB will approve.

Management of Consents

The management of your consent is very important.

Please consider the following:

1. Use eSignature on the EDC forms from a REDCap account
2. If you are uploading a new version, the best way to manage this is to add a new upload field with a new version of your approved consent. Then hide the previous version so that it does not get accidentally used.
3. Use record locking (review the online video)

☐ I confirm that all the information in the document above is correct, and I understand that signing this form electronically is the legal equivalent of a signed physical document.

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

<< Previous Page

Submit

The Participant must confirm that the information is correct and select the check box stating so.

☒ I confirm that all the information in the document above is correct, and I understand that signing this form electronically is the legal equivalent of a signed physical document.

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

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Submit

All consents are automatically archived in the File Repository found under the applications section of the REDCap Application.

• Create new records or edit/view existing ones

Show data collection instruments ▾

Applications

Calendar

Data Exports, Reports, and Stats

Data Import Tool

Data Comparison Tool

Logging

Field Comment Log

File Repository

User Rights and DAGs

Record Locking Customization

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Survey Wizard (**NEW**)

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Search

Survey Completion Time	Record	Survey	Identifier (Name, DOB)	IP Address	Version	Type	Download
05/09/2018 4:20pm	3	Participant Multi-Signature Consent Form	Teresa Bosler, 2000-05-09	129.112.115.42	1.0	Multiple Signatures	PDF
05/09/2018 3:57pm	2	Participant Multi-Signature Consent Form	Teresa2 Bosler, 2000-05-09	129.112.115.54	1.0	Multiple Signatures	PDF
05/09/2018 3:22pm	1	Participant Multi-Signature Consent Form	Teresa Bosler, 2018-05-09	129.112.115.41	1.0	Multiple Signatures	PDF

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