

REDCap User Guide - eConsent Build Instructions & Requirements

Special IRB Note:

- If you have an existing IRB approved consent form, an IRB review is NOT needed if you already have REDCap in your Data Security Plan. Otherwise, please revise your Data Security Plan and submit that for IRB review.
- **During the COVID Pandemic** the IRB is not requiring revision to the Data Security Plan to utilize REDCap for eConsent until further notice.
- If you plan to make changes to the content of your existing Consent, you must submit that for IRB review.

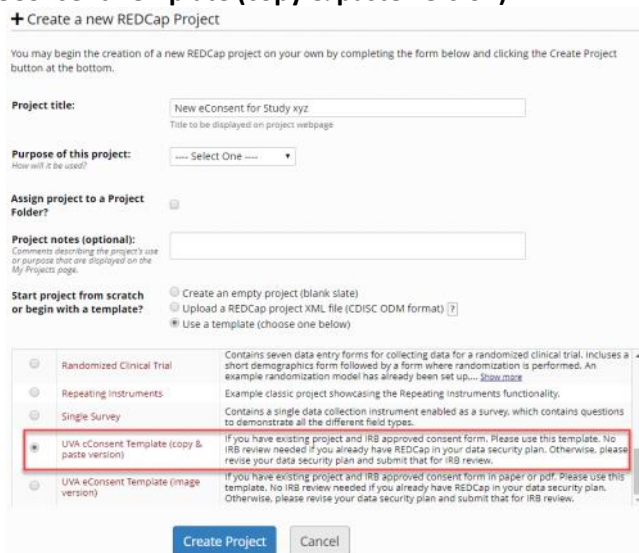
Recommended:

- Please watch REDCap training videos before attempting REDCap build for the first time:
<https://s3.amazonaws.com/ithriv-media/prod/ithriv/resource/attachment/325.pdf>

How to create an eConsent Project in REDCap

Create a new REDCap project by using one of the 2 provided templates

1. Create a New eConsent by **Copying & Pasting** the text of your current consent
 - a. What you will need:
 - i. Current Consent - A PDF or Microsoft Office Word document of your current consent
 - Exclude the name, signature, and date fields
 - ii. REDCap Create new project Template:
 UVA eConsent Template (copy & paste version)



- iii. Copy and paste the consent content into the first Descriptive Field type in instrument

+ Create a new REDCap Project

You may begin the creation of a new REDCap project on your own by completing the form below and clicking the Create Project button at the bottom.

Project title:
Title to be displayed on project webpage.

Purpose of this project:

Assign project to a Project Folder? ☐

Project notes (optional):
Comments describing the project's use or purpose that are displayed on the My Projects page.

Start project from scratch or begin with a template?

- ☐ Create an empty project (blank slate)
- ☐ Upload a REDCap project XML file (CDISC ODM format) [?](#)
- ☒ Use a template (choose one below)

☐ Randomized Clinical Trial	Contains seven data entry forms for collecting data for a randomized clinical trial. Includes a short demographics form followed by a form where randomization is performed. An example randomization model has already been set up... View more
☐ Repeating Instruments	Example classic project showcasing the Repeating Instruments functionality.
☐ Single Survey	Contains a single data collection instrument enabled as a survey, which contains questions to demonstrate all the different field types.
☐ UVA eConsent Template (copy & paste version)	If you have existing project and IRB approved consent form. Please use this template. No IRB review needed if you already have REDCap in your data security plan. Otherwise, please revise your data security plan and submit that for IRB review.
☒ UVA eConsent Template (image version)	If you have existing project and IRB approved consent form in paper or pdf. Please use this template. No IRB review needed if you already have REDCap in your data security plan. Otherwise, please revise your data security plan and submit that for IRB review.

v. Modify the existing fields as necessary:

- ◆ Edit the existing fields (first 3 in red text), add more Descriptive Text field as needed.
- ◆ Delete the text
- ◆ Import the PNGs
- ◆ Select to display as inline image
- ◆ Select Save when done

Edit Field

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button at the bottom. When you add a new field, it will be added to the form on this page. For an overview of the different field types available, you may view the [IRB Field Types video \(4 min\)](#).

Field Type: Descriptive Text (with optional image/video)

Question Number (optional):

Field Label:
[Use the Rich Text Editor](#) [?](#)

Action Tags: ☒ Choose File ☐ No file chosen (Max file size: 1024MB)

Attach an image, file, or embedded audio

Select a file then click the 'Upload Document' button.

Variable Name:
ONLY letters, numbers, and underscores. Enable auto naming of variable based upon its Field Label?

Optional file attachment, image, audio, or video:

☒ Embed an external video (provide video URL) [?](#)

[https://vimeo.com/62730281](#)
[http://example.com/movie.mp4](#)

Display format of video: ☒ Inline ☐ Inside popup

Attach an image, file, or embedded audio

vi. See next section for IRB requirements

Recommendation: if you have a multipage consent with over 5 pages, we recommend you use option for copy and paste because a large number of images can cause slow loading of content.

For each eConsent created please ensure you comply with the following IRB requirements:

1. Include full Study Title *in the body of the consent*
 2. Include IRB-HSR number or UVA Study Tracking Number *in the body of the consent*
 3. Include PI Name *in the body of the consent*
 4. Update in the Survey Setting, anywhere you see the word "Survey" replace with "Consent" - *already updated in the templates under the Survey Settings section.*
 5. Turn on eConsent framework - *already turned on in the templates under the Survey Settings section.*
- Note: the Survey feature must first be enabled - already enabled in the templates.*

6. Must use version field in eConsent Framework - enter version date approved by IRB

a. Standard naming: Date_Vx.x = 10/04/2019_v1.0

- 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](#)

☒ Allow e-Consent responses to be edited by users?

e-Consent version: e.g., 4

First name field: "PARTICIPA" in

Last name field: "PARTICIPA" in

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.

Additional REDCap setting

User Rights for your project/study team

- You must add users to your REDCap project that will be using the system to process and manage the eConsents. These include CRCs, Project Coordinators/Managers, etc...
- If your users have UVA Health System network accounts, then provide those individuals with these instructions: <https://s3.amazonaws.com/ithriv-media/prod/ithriv/resource/attachment/103.pdf>
- If your users have only UVA Academic accounts, follow these instructions for sponsorship: <https://s3.amazonaws.com/ithriv-media/prod/ithriv/resource/attachment/108.pdf>.
- For questions or assistance email a request to the REDCap team: redcap@hscmail.mcc.virginia.edu

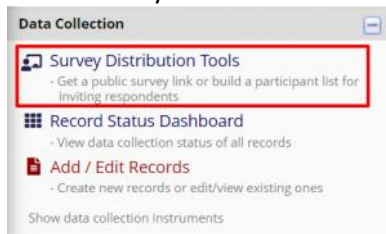
Note: Do not add participants to the REDCap project, they will be receiving email invites to fill out the eConsent.

Complex Workflows and/or project needs

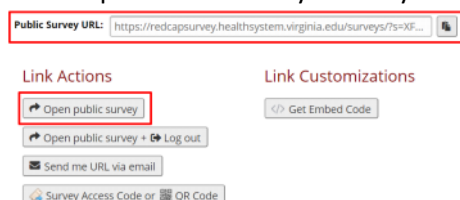
For more complex eConsent needs please contact the REDCap team via email for guidance. This could include multiple consents such as Spanish consents or other short forms, multiple signature needs, questions or build guidance on additional fields contained within the consent, or workflow guidance: redcap@hscmail.mcc.virginia.edu.

How to Test and deliver your eConsent form

1. Select Survey Distribution Tools under Data Collection panel on the left side:



2. Select Open Public Survey to test your consent form or copy the Public Survey URL to email participant.



3. Depending on your workflow and the number of signers needed, you may need to send the survey invite to each participant individually. Under Survey Distribution Tools, send the invite to a participant; refer back to the training

materials for more guidance. For more complex signature needs contact the REDCap team to define the appropriate workflow: redcap@hscmail.mcc.virginia.edu.

Before placing your project in Production & How to request for Production

1. Follow the outlined requirement in the [REDCap User Guide - Production Status Requirements](#)