How to Enable e-Consent in REDCap (v15.3.2)

Step 1: Set Up the e-Consent Form

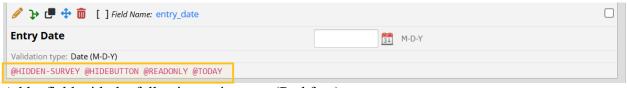
1. Go to the Online Designer. (Survey must be enabled in project setup first.)



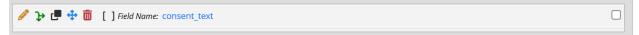
2. Choose or create the instrument that will serve as the consent form. (Suggestions below)



The following fields should be added to the Consent instrument.



Add a field with the following action tags (Red font)



Add a descriptive field titled consent text (This will serve as a placeholder for the Inline PDF consent form)







(Optional) You can add a couple of fields (Descriptive Text) to inform your participants about the study, and in case you have an image or logo.

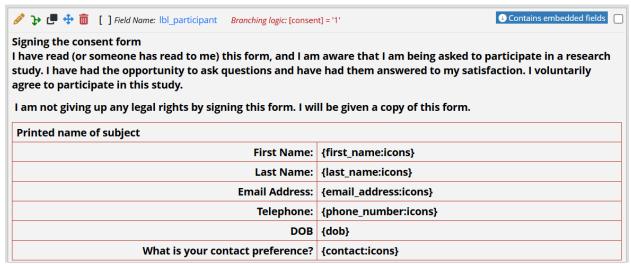


Add a Text Box field and apply the action tag @CONSENT-VERSION. This tag automatically captures the version of the consent form being used in the current e-Consent context, based on the specific record, event, survey, Data Access Group (DAG), or MLM language.

⚠ Note: The @CONSENT-VERSION tag will only populate the field if it is initially blank and only when the instrument is being completed as a survey (not during data entry via the project dashboard or record status dashboard).







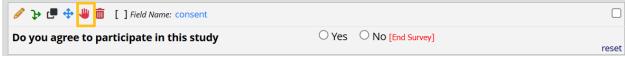
We recommend embedding your fields directly within the consent instrument for a cleaner, more streamlined appearance. However, please note that **signature fields cannot be embedded**. They must remain as separate fields on the form of functioning properly.



Lastly, apply branching logic to display the signature field only if the participant chooses to consent. Following the signature field, include a final field to automatically capture the signature date and time using the action tags: @HIDDEN, @NOW-SERVER, and @READONLY.

Mote: Do not embed the signature field, as embedded signature fields will not appear on the PDF snapshot of the consent form.

3. Add a Hard Stop on Consent and Eligibility (We suggest including this)



If you have a question about the consent instrument, if they would like to participate, you can add a hard stop. Click the red hand.





Set up Stop Actions for this Survey Question

1

Stop Actions (for survey questions only):

The survey participant will be prompted to end the survey when ANY choices checked below are selected for this question on the survey. Stop Actions will not be enabled on the form when viewing in REDCap as an authenticated user, but only become enabled when a participant views this data collection instrument as a survey.

Please note that there are other Stop Action settings on the Survey Settings page for a given instrument, such as the ability to set custom text when a survey ends via Stop Action.



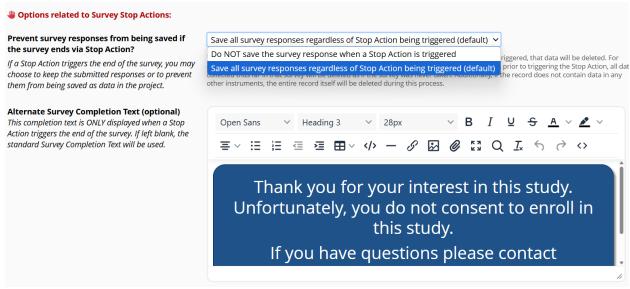
Select the response that should end the survey and click save. Repeat the same process for your eligibility questions, which is generally a separate instrument.



(Optional) If you use a hard stop for your informed consent, we suggest setting up the hard stop survey completion text. Click on "Survey Settings" to adjust the Completion text.



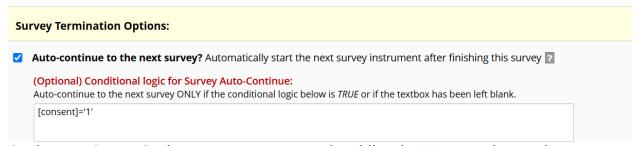




In this section, you have two options:

- 1. Choose whether to **save the record** if a participant selects *No* (i.e., chooses not to consent).
- 2. Optionally, display **alternative text** to inform the participants that they have opted out of the study.

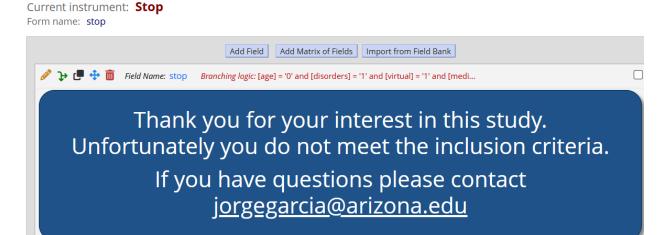
You can also use a **stop action trigger** to prevent further survey progression if the participant does not consent.



On the same Survey Settings page, we recommend enabling the "Auto-continue to the next survey?" option and applying branching logic to ensure that only participants who consent to enroll in your study (e.g., 1 = Yes in this example) are directed to the next survey. Without this logic, participants who do not consent may still proceed to the next survey.







Add an instrument for your eligibility responses that would exclude a participant from joining your study. You will use branching logic to trigger this alert.

4. eConsent Settings: Go to Online Designer, click "e-Consent" (you'll see a green button)







5. Configure the e-Consent settings:

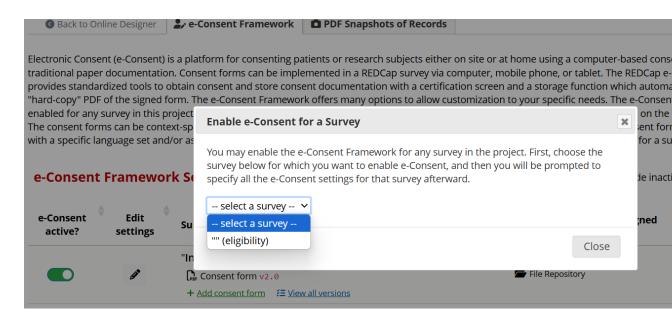


ectronic Consent (e-Consent) is a platform for consenting patients or research subjects either on site or at home using a considerable distribution. Consent forms can be implemented in a REDCap survey via computer, mobile phone, or take ovides standardized tools to obtain consent and store consent documentation with a certification screen and a storage fundard-copy. PDF of the signed form. The e-Consent Framework offers many options to allow customization to your specific negabled for any survey in this project. You may optionally provide consent forms as either an inline PDF or rich text that will be econsent forms can be context-specific if you are using MLM languages and/or Data Access Groups so that it displays the optional provide consent form.

2-Consent Framework Settings

+ Enable the e-Consent Framework for a survey

Check "Enable the e-Consent Framework for a survey".



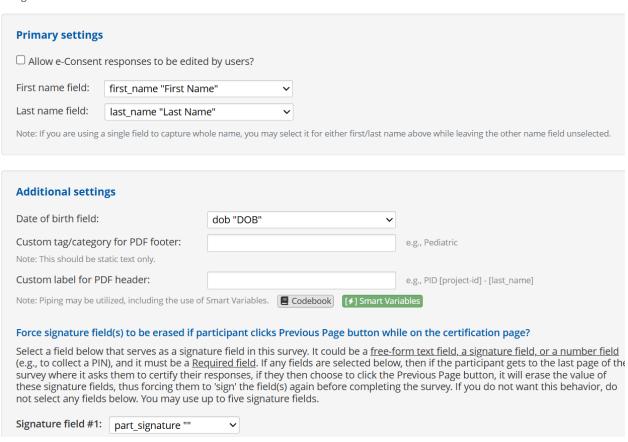
Select the survey you want to enable the e-consent for. (This will be the instrument that has the consent version and information in step 2)



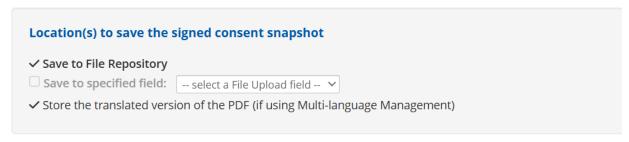


Modify e-Consent Settings

additional option to also store the PDF in a File Upload field). Other e-Consent related options can be set below, such as setting a custom tag/category, custom label for the PDF header, location(s) to save the signed e-Consent snapshot, and the file name format of the snapsh being stored.



Select the fields that include the participant's first and last name. Optionally, you may also include fields such as date of birth (DOB), a custom tag, and a custom label. If you select the Signature Field #1 option, be aware that any signature entered will be cleared if the participant clicks the *Previous Page* button while on the certification page.



Select save to file repository (recommended) and the default setting. Click save at the bottom of the page.



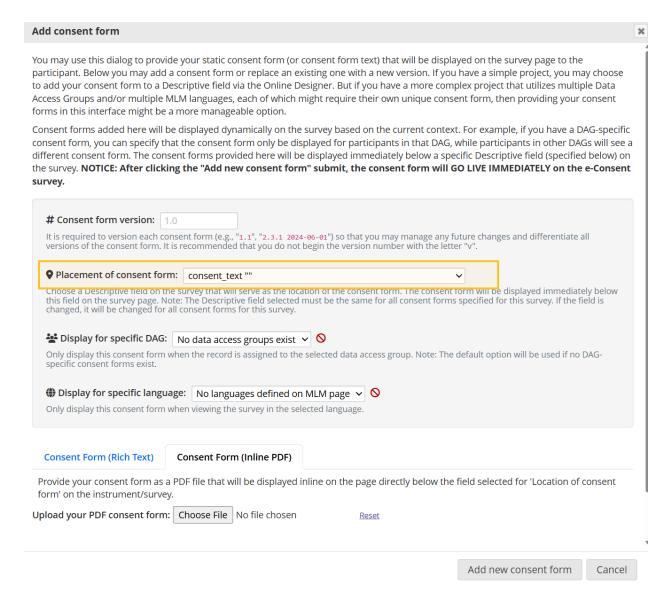




Return to the e-consent framework and click Add consent form.







Fill out the required information. Please note that the Consent Version refers to the version used in REDCap, not the IRB-approved version.

Next, choose where you would like the PDF consent form to appear (Part 1, Step 2). If your project uses Data Access Groups (DAGs) or Multi-Language Management (MLM), be sure to select the appropriate DAG group and language for this consent form.

You have two options when uploading a consent form: Rich Text or Inline PDF. After uploading your file, click "Add New Consent Form" to complete the process.

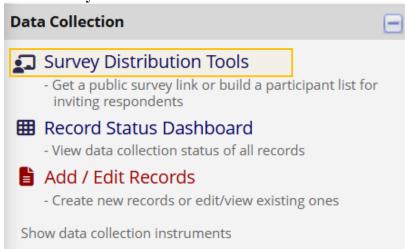
According to guidance from the UA IRB, the recommended format is the Inline PDF option.





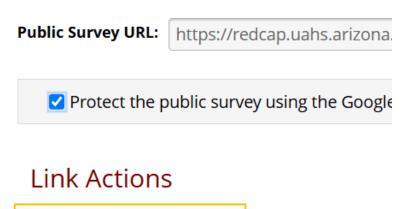
Step 3: Testing the e-Consent Process

1. Go to Survey Distribution Tools



2. Click Open Public Survey

can then click the link to begin taking your survey



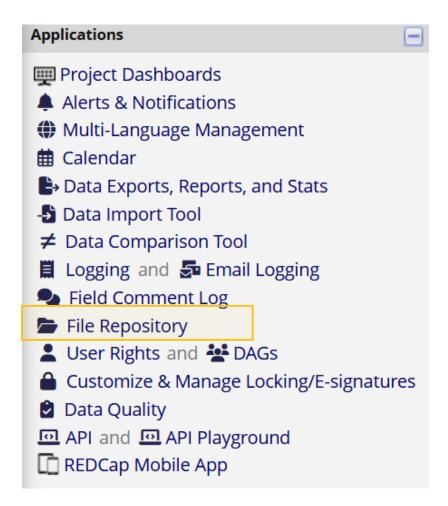
3. Fill it out like a participant would.

Open public survey

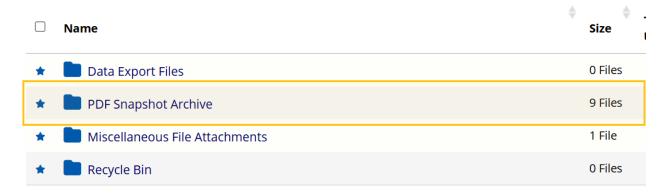
4. Sign it and submit.







All Files





5. Make sure the PDF Snapshot archive is created and show e-consent under the type.



Done!

Now your e-Consent is live and working. You can monitor signed consents, download PDFs, and include them in audit trails.



