

Frequently Asked Question (FAQ) Library

How do I build an eConsent?

[pdf upload]

There are several ways to build an electronic consent document (eConsent) using the REDCap eConsent framework. These instructions explain how to upload a portable document file (pdf) of the consent form and enable the eConsent framework to capture the written elements of informed consent. At Yale, this method can be used for research, including FDA-regulated studies subject to 21 CFR Part 11 requirements. For more information, refer to [Yale's Human Research Protection Program \(HRPP\) eConsent Guidance](#).

To build an eConsent you will follow the steps outlined below:

- STEP 1. Create a new project.
- STEP 2. Build your eConsent instrument(s).
- STEP 3. Set up your Signature(s).
- STEP 4. Enable the eConsent Framework.
- STEP 5. Upload your PDF Consent Form.
- STEP 6. Test eConsent.

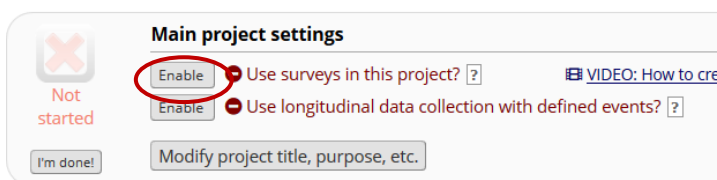
In this tutorial, you will build an eConsent in a new, stand-alone project that is distinct from your REDCap project with data collection forms. This ensures that the personal identifiers collected on the consent forms are securely maintained and separated from the participant study ID and research data.

STEP 1: Create a New Project

1. Your eConsent should be set up as a new project, not an instrument within the main research project. To create a new project, follow the instructions found under [FAQ: Create a New Project](#). Your REDCap project can contain more than one consent form for the same study.

Pro Tip: Use a project title that includes or “*Study Name/ID/Acronym*” + *eConsent*

2. After your project is created, open it, and go to the ‘**Project Setup**’ tab to enable the survey design.
 - a. Under ‘**Main Project Settings**’ select the ‘**Enable**’ button for the option ‘*Use surveys in this project?*’

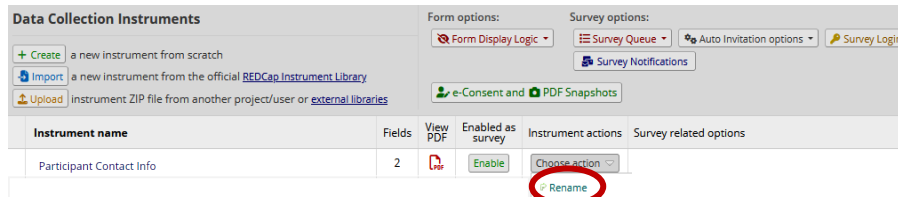


3. Next, click ‘**Online Designer**’ under ‘**Design your data collection instruments & enable your surveys.**’

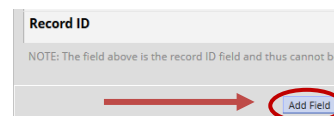
Frequently Asked Question (FAQ) Library

- Change the default 'My First Instrument' name by selecting the 'Rename' option found under the 'Choose action' drop down menu. Your first instrument will contain the participant's contact information. Rename this instrument. Then click 'Save'.

In the example below, the first instrument is renamed 'Participant Contact Info'.



- Open the first instrument, click the 'Add Field' button.
- Add field(s) to the Participant Contact Information form.

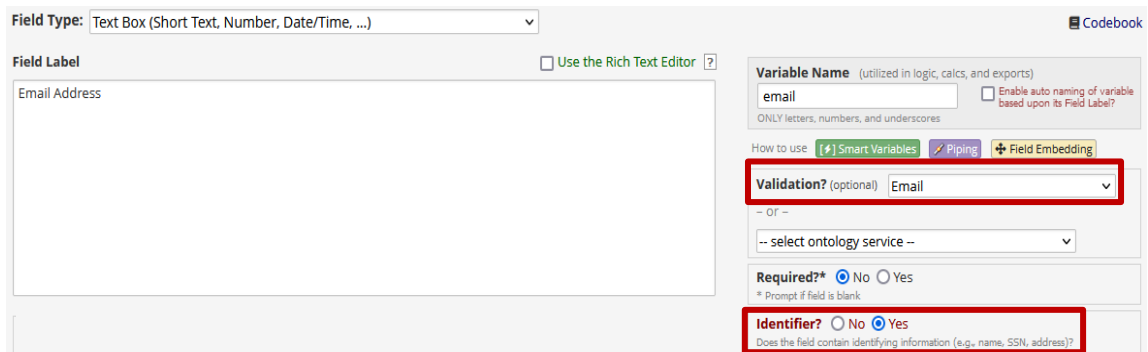


IMPORTANT: You must obtain Institutional Review Board (IRB) approval through a consent/HIPAA waiver to collect and use identifiers prior to informed consent.

Pro Tip: Duplicate information can create data discrepancies.

Participant name will be captured on the eConsent survey with their signature. To avoid discrepancies, you may wish to limit this form to other identifiers, such as email.

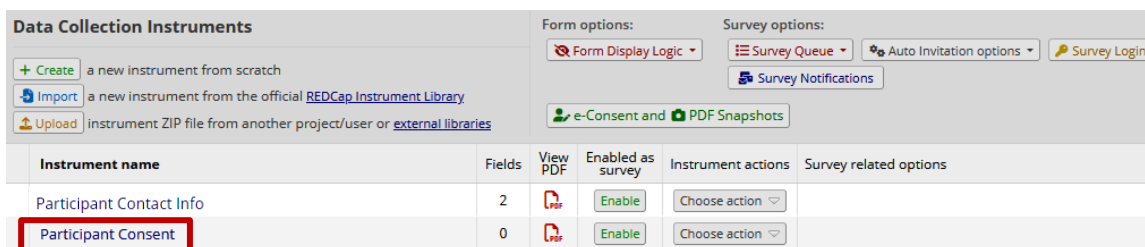
- If you are consenting remotely or plan to share the signed eConsent electronically, create a field to capture the participant email.
 - Under the 'Validation', select the **Email** option.
 - Under 'Identifier?', select **Yes** to tag the field as an identifier.



- Return to the Online Designer by clicking on [Return to list of instruments](#)

Frequently Asked Question (FAQ) Library

8. Create another instrument by clicking “+ **Create button**”. This form will be your consent instrument.



The screenshot shows the 'Data Collection Instruments' section of the REDCap interface. It includes options to 'Create', 'Import', or 'Upload' instruments. Below these options is a table listing existing instruments. The 'Participant Consent' instrument is highlighted with a red box.

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey related options
Participant Contact Info	2		Enable	Choose action	
Participant Consent	0		Enable	Choose action	

Pro Tip: If you are using more than one eConsent on the same study, create multiple forms within you project for each participant population. To do so, repeat Step 4, but be sure to use a nomenclature that allows you to distinguish your eConsents (e.g. *Adult, Child*).

STEP 2: Build your eConsent instrument.

1. Select the newly created **Consent Form** instrument.

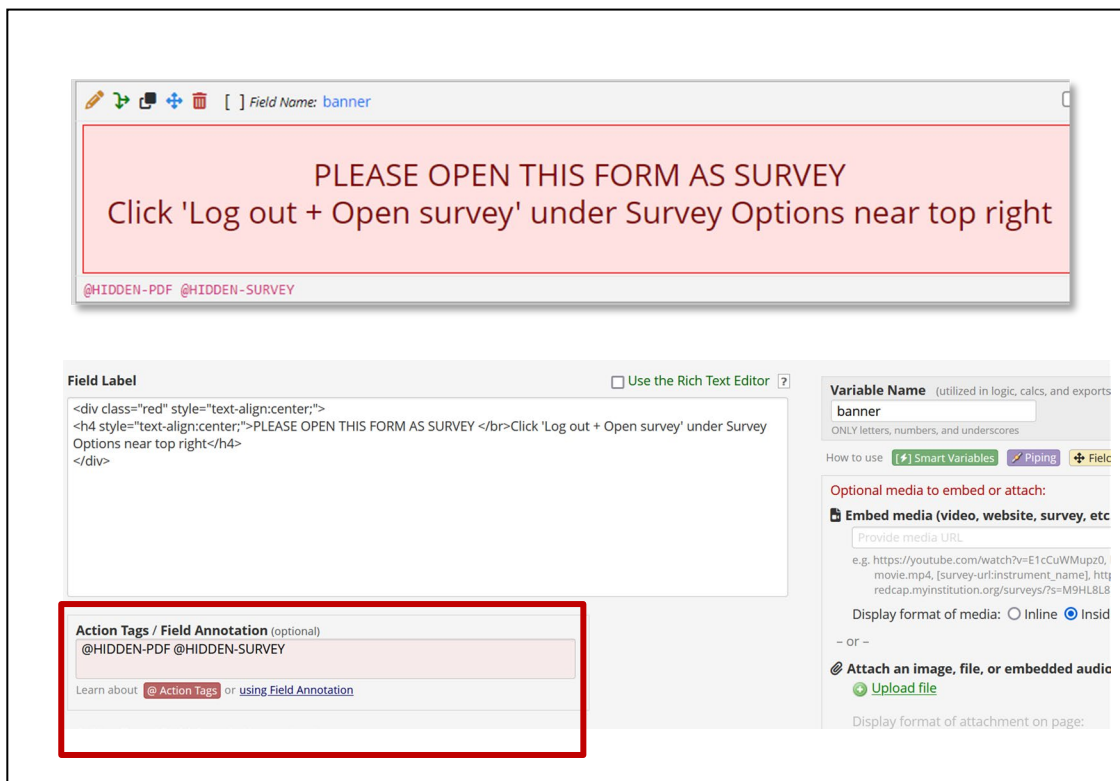
Pro Tip: Do NOT use embedded fields or the rich text editor in your eConsent Form. These features do not work well with the PDF snapshot in the eConsent Framework.

2. **If you will be consenting in-person/onsite**, add an instruction banner at the top of the instrument to remind staff to open the instrument as a survey.
 - a. Insert a descriptive field.
 - b. Copy the code below to the 'Field Label' box:

```
<div class="red" style="text-align:center;">
<h4 style="text-align:center;">PLEASE OPEN THIS FORM AS SURVEY </br>Click 'Log out +
Open survey' under Survey Options near top right</h4>
</div>
```
 - c. Add the following '**Action Tags**' to the **Action tags/Field Annotation box**:
 - i. @HIDDEN-SURVEY – this action tag will ensure the warning message appears on the instrument but not on the survey.
 - ii. @HIDDEN-PDF – this action tag will ensure the warning message will not be included on the PDF copy of the consent form.

Frequently Asked Question (FAQ) Library

Instruction banner for in-person consenting:



Field Name: banner

PLEASE OPEN THIS FORM AS SURVEY
Click 'Log out + Open survey' under Survey Options near top right

@HIDDEN-PDF @HIDDEN-SURVEY

Field Label Use the Rich Text Editor ?

```
<div class="red" style="text-align:center;">
<h4 style="text-align:center;">PLEASE OPEN THIS FORM AS SURVEY </br>Click 'Log out + Open survey' under Survey Options near top right</h4>
</div>
```

Variable Name (utilized in logic, calcs, and exports)
ONLY letters, numbers, and underscores
banner

How to use Smart Variables Piping Field Embedding

Optional media to embed or attach:
Embed media (video, website, survey, etc)
Provide media URL
e.g. https://youtube.com/watch?v=E1cCuWmUpz0...
movie.mp4, [survey-url[instrument_name]].htm
redcap.myinstitution.org/surveys/?s=M9HL8LB

Display format of media: Inline Insid

- or -

Attach an image, file, or embedded audio
 Upload file

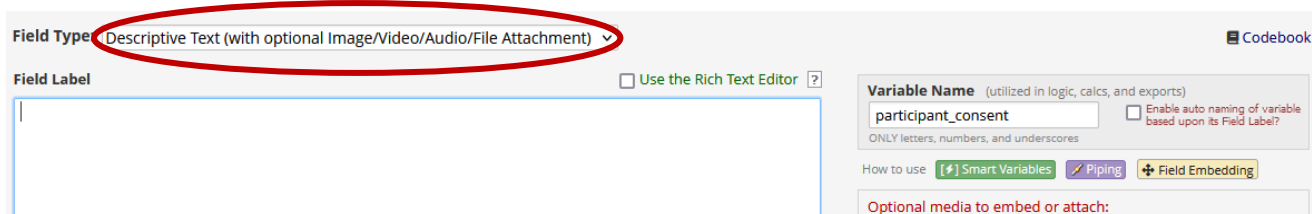
Display format of attachment on page:

Action Tags / Field Annotation (optional)
@HIDDEN-PDF @HIDDEN-SURVEY

Learn about [@ Action Tags](#) or [using Field Annotation](#)

3. Create ONE descriptive field as a placeholder for your eConsent pdf document.

- To add a descriptive field, click the 'Add Field' button.
- Under the **Field Type** menu, choose 'Descriptive Text' and create variable name.



Field Type: Descriptive Text (with optional Image/Video/Audio/File Attachment) ▾

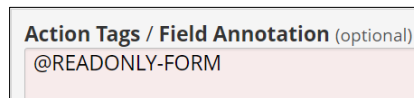
Field Label Use the Rich Text Editor ?

Variable Name (utilized in logic, calcs, and exports)
ONLY letters, numbers, and underscores
participant_consent Enable auto naming of variable based upon its Field Label?

How to use Smart Variables Piping Field Embedding

Optional media to embed or attach:

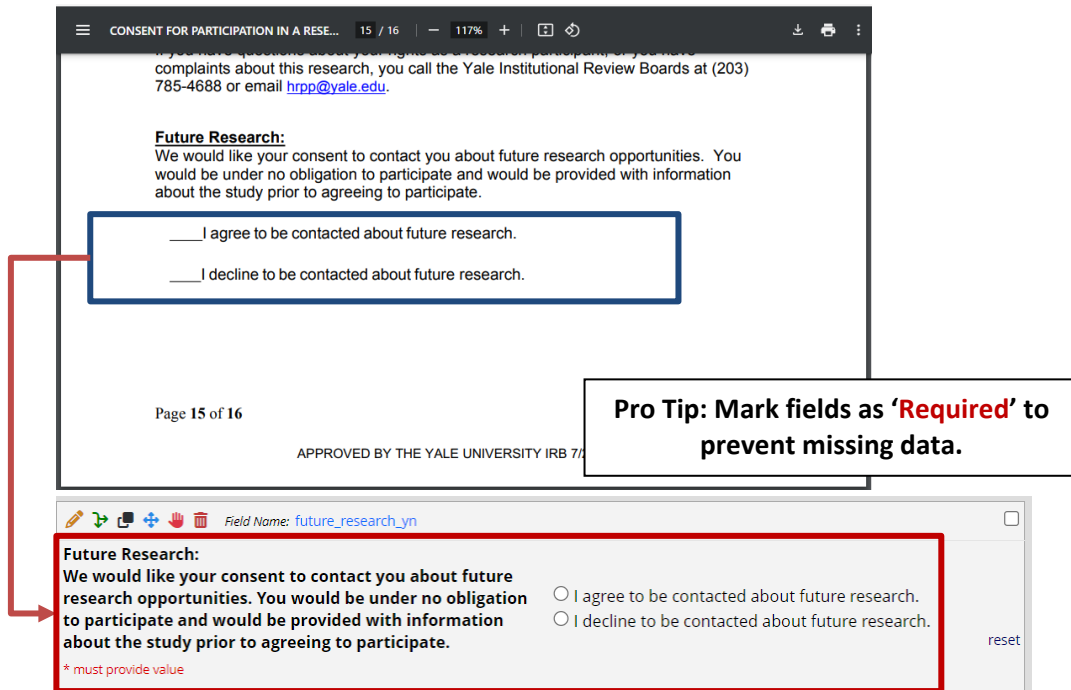
- You will use this field to upload your eConsent in **STEP 4- eConsent Framework**. The Field Label and other field settings can remain blank.
4. If your research consent contains study-specific permissions, add fields to capture response items, as shown in example.
- To prevent study staff completing this instrument in form mode, add @READONLY-FORM action tag to these fields.



Action Tags / Field Annotation (optional)
@READONLY-FORM

Frequently Asked Question (FAQ) Library

To contact participants for future research, your eConsent fields would look like this:



complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

Future Research:
We would like your consent to contact you about future research opportunities. You would be under no obligation to participate and would be provided with information about the study prior to agreeing to participate.

I agree to be contacted about future research.

I decline to be contacted about future research.

Page 15 of 16

APPROVED BY THE YALE UNIVERSITY IRB 7/18/25

Pro Tip: Mark fields as 'Required' to prevent missing data.

Field Name: future_research_yn

Future Research:
We would like your consent to contact you about future research opportunities. You would be under no obligation to participate and would be provided with information about the study prior to agreeing to participate.

I agree to be contacted about future research.

I decline to be contacted about future research.

* must provide value

reset

Step 3: Setup Signature

Electronic signature procedures and verification procedures will vary based upon the regulatory requirements for your research. Refer to [Yale HRPP eConsent Guidance](#) for more information. If your consent requires a signature (i.e. you do not have a waiver) you will collect the *name, signature, and date of consent from the participant and person obtaining consent* to comply with 45 CFR 46 regulations. To limit the collection of personal information, do not include date of birth as a validation field.



Data Collection Instruments

+ Create a new instrument from scratch

Import a new instrument from the official REDCap Instrument Library

Upload instrument ZIP file from another project/user or external libraries

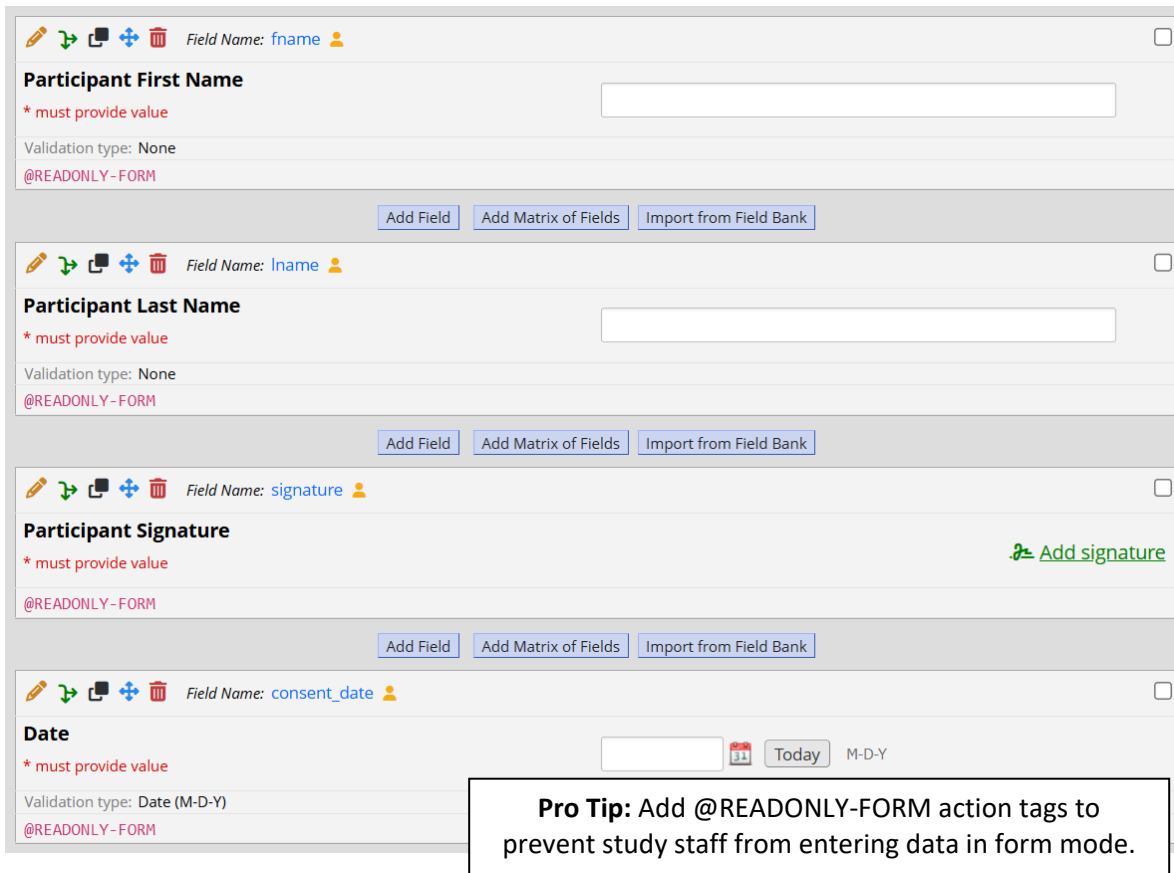
Instrument name	Fields
Participant Contact Info	2
Participant Consent	5
Person Obtaining Consent	9

Signatures of participant and person obtaining consent are captured as **two separate forms** under one Study eConsent Framework as shown.

Frequently Asked Question (FAQ) Library

Participant

1. Click **Add Field** to the consent instrument.



The screenshot shows the REDCap field configuration interface with four fields:

- Participant First Name**: Field Name: fname, Validation type: None, @READONLY-FORM.
- Participant Last Name**: Field Name: lname, Validation type: None, @READONLY-FORM.
- Participant Signature**: Field Name: signature, Validation type: None, @READONLY-FORM, with an "Add signature" link.
- Date**: Field Name: consent_date, Validation type: Date (M-D-Y), @READONLY-FORM, with a calendar icon and a "Today" button.

Pro Tip: Add @READONLY-FORM action tags to prevent study staff from entering data in form mode.

2. Add fields for identification and signature.

- a. **Name (First, Last)**

- i. Create two separate fields for (1.) first name and (2.) last name.
- ii. Tag as identifiers and mark as required.
- iii. Add @READONLY-FORM action tag.
- iv. The eConsent framework will insert the first and last name on each page of the snapshot PDF consent for audit purposes.

- b. **Signature**

- i. Create field for signature. The signature field allows participants to electronically sign via stylus, mouse or finger.
- ii. Tag as an identifier and mark as required.
- iii. Add @READONLY-FORM action tag.

Frequently Asked Question (FAQ) Library

c. Date

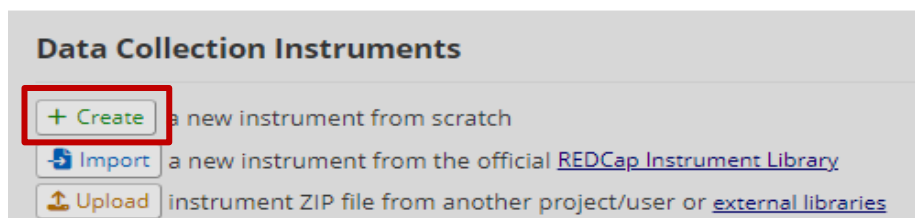
- i. Create field for date.
- ii. To ensure data quality and prevent errors, use validation and minimum/maximum range.
- iii. Tag date as an identifier and mark as required.
- iv. Add @READONLY-FORM action tag.

Pro Tip: Mark each field as **'Required'** to prevent missing data and non-compliance with regulatory requirements

Person Obtaining Consent

To ensure best practices and prevent errors, the participant and the person obtaining consent will sign the eConsent in separate REDCap forms.

1. Return to the online designer and create a new instrument *'Person Obtaining Consent.'*



2. This form must be completed in survey mode to use the eConsent framework feature in REDCap. Add descriptive fields to support administration.

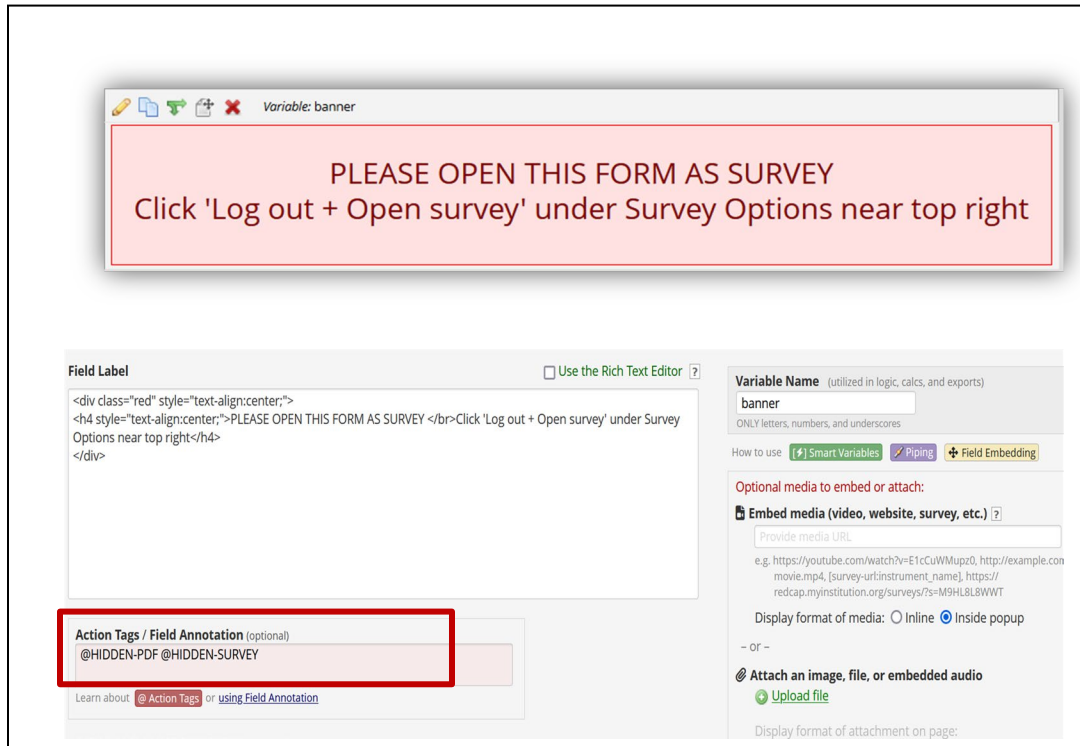
a. Instruction Banner

- i. Add a descriptive field to display instructions.
 1. Copy the code below to the 'Field Label' box:

```
<div class="red" style="text-align:center;">
<h4 style="text-align:center;">PLEASE OPEN THIS FORM AS A SURVEY </br>Click
'Log out + Open survey' under Survey Options near top right</h4>
</div>
```
 2. Add these two **'Action Tags'** to the Action tags/Field Annotation box:
 - a. @HIDDEN-SURVEY - the warning message will appear on the instrument and not the survey.
 - b. @HIDDEN-PDF - the warning message will not print on the PDF copy of the consent form.

Frequently Asked Question (FAQ) Library

Instruction banner:



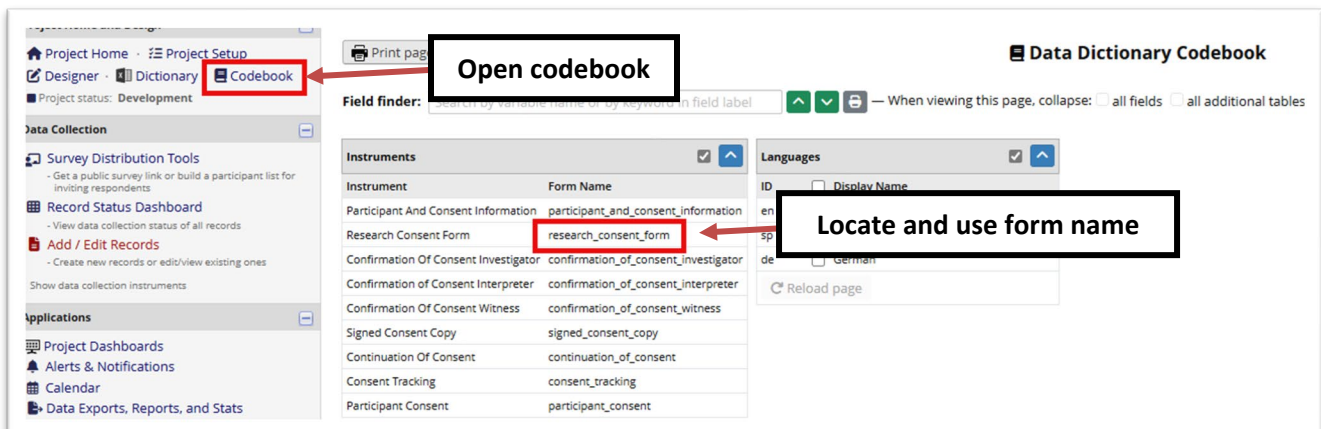
The screenshot shows the REDCap form editor interface. At the top, a pink banner contains the text: "PLEASE OPEN THIS FORM AS SURVEY" and "Click 'Log out + Open survey' under Survey Options near top right". Below the banner, the "Field Label" section shows HTML code for the banner. The "Action Tags / Field Annotation" section is highlighted with a red box, showing "@HIDDEN-PDF @HIDDEN-SURVEY". The "Variable Name" section shows "banner" and "Optional media to embed or attach" options.

3. Consent Summary

a. Add a descriptive field to pipe information from participant consent form. To learn more about piping, see [FAQ: Piping](#).

i. Pipe the following fields:

1. **Participant first and last name.**
2. **Participant consent completion time** - use smart variable [survey-time-completed:instrument]. Replace 'instrument' with the form name of your participant consent form as shown below.

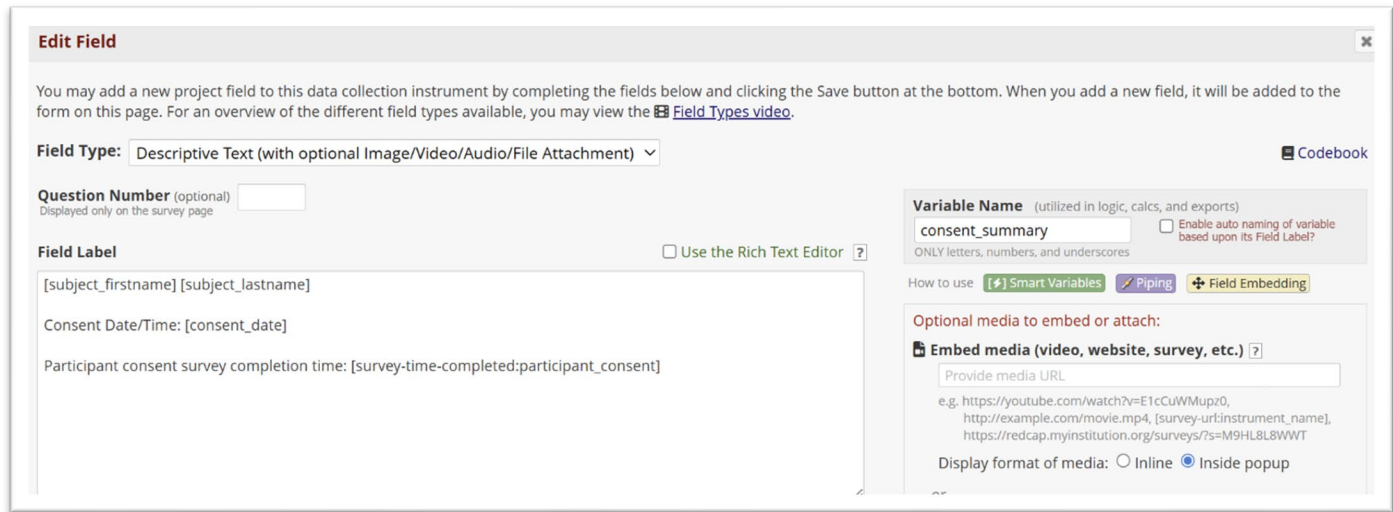


The screenshot shows the REDCap Instruments list. A red box highlights the "Codebook" link in the top navigation bar, with an arrow pointing to it and the text "Open codebook". Another red box highlights the "research_consent_form" entry in the Instruments list, with an arrow pointing to it and the text "Locate and use form name".

Instrument	Form Name
Participant And Consent Information	participant_and_consent_information
Research Consent Form	research_consent_form
Confirmation Of Consent Investigator	confirmation_of_consent_investigator
Confirmation of Consent Interpreter	confirmation_of_consent_interpreter
Confirmation Of Consent Witness	confirmation_of_consent_witness
Signed Consent Copy	signed_consent_copy
Continuation Of Consent	continuation_of_consent
Consent Tracking	consent_tracking
Participant Consent	participant_consent

Frequently Asked Question (FAQ) Library

Example of piping:



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 [Field Types video](#).

Field Type: Descriptive Text (with optional Image/Video/Audio/File Attachment) Codebook

Question Number (optional)
Displayed only on the survey page

Field Label Use the Rich Text Editor ?

[subject_firstname] [subject_lastname]

Consent Date/Time: [consent_date]

Participant consent survey completion time: [survey-time-completed;participant_consent]

Variable Name (utilized in logic, calcs, and exports)
consent_summary Enable auto naming of variable based upon its Field Label?
ONLY letters, numbers, and underscores

How to use [Smart Variables](#) [Piping](#) [Field Embedding](#)

Optional media to embed or attach:

Embed media (video, website, survey, etc.) ?

Provide media URL
e.g. <https://youtube.com/watch?v=E1cCuWMupz0>,
<http://example.com/movie.mp4>, [survey-url;instrument_name],
<https://redcap.myinstitution.org/surveys/?s=M9HL8LBWWT>

Display format of media: Inline Inside popup

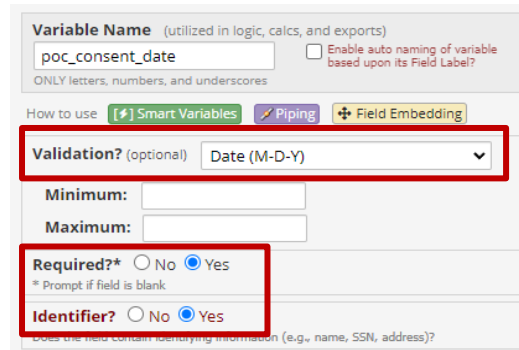
Add fields for identification and signature:

- a. **Name (First, Last) of Person Obtaining Consent**
 - i. Create two separate fields for (1.) first name and (2.) last name.
 - ii. Tag as an identifier and mark as required.
 - iii. Add @READONLY-FORM action tag.
- b. **Optional: Method of Consent**
 - i. If the consent administration process varies, capture the method (e.g. phone, in-person).
 - ii. If including, add @READONLY-FORM action tag.
- c. **Optional: Documentation of Consent process**
 - i. You may wish to include an acknowledgement that documents the consent process.
 - ii. If including, add @READONLY-FORM action tag.
- d. **Signature of Person Obtaining Consent**
 - i. REDCap options include electronically signing via stylus, mouse or finger.
 - ii. Tag as an identifier and mark as required.
 - iii. Add @READONLY-FORM action tag.

Frequently Asked Question (FAQ) Library

e. **Date**

- i. Create field for date.
- ii. To prevent errors, use validation and minimum/maximum range.
- iii. Tag as an identifier and mark as required.
- iv. Add @READONLY-FORM action tag.



Variable Name (utilized in logic, calcs, and exports)
poc_consent_date Enable auto naming of variable based upon its Field Label?
ONLY letters, numbers, and underscores

How to use Smart Variables Piping Field Embedding

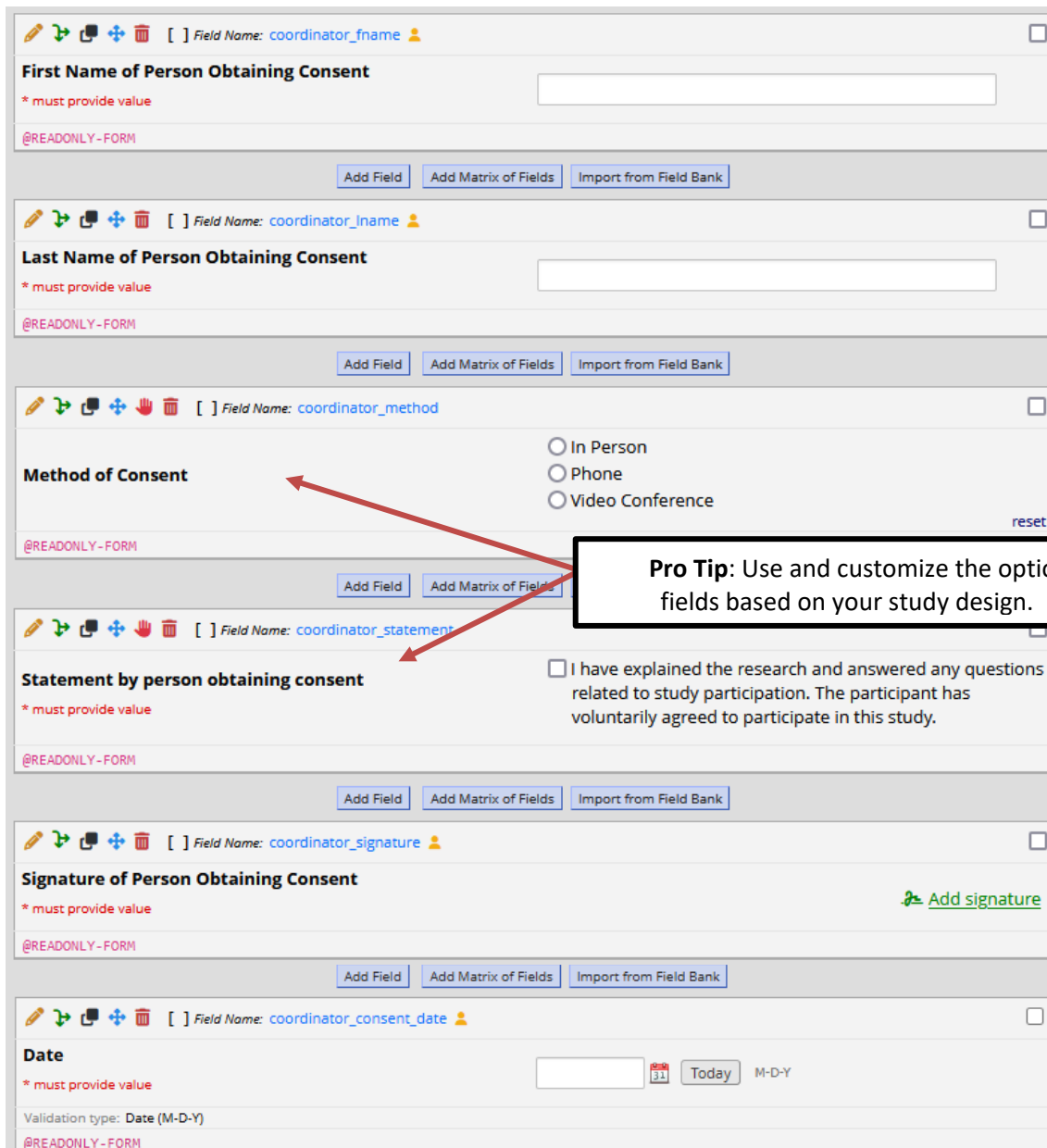
Validation? (optional) Date (M-D-Y)

Minimum:
Maximum:

Required?* No Yes
* Prompt if field is blank

Identifier? No Yes
Does this field contain identifying information (e.g., name, SSN, address)?

Example of person obtaining consent signature fields:



Field Name: coordinator_fname

First Name of Person Obtaining Consent
* must provide value
@READONLY-FORM

Field Name: coordinator_lname

Last Name of Person Obtaining Consent
* must provide value
@READONLY-FORM

Field Name: coordinator_method

Method of Consent
 In Person
 Phone
 Video Conference
reset

Field Name: coordinator_statement

Statement by person obtaining consent
* must provide value
@READONLY-FORM

Field Name: coordinator_signature

Signature of Person Obtaining Consent
* must provide value
@READONLY-FORM
[Add signature](#)

Field Name: coordinator_consent_date

Date
* must provide value
Validation type: Date (M-D-Y)
@READONLY-FORM

Pro Tip: Use and customize the optional fields based on your study design.

Frequently Asked Question (FAQ) Library

Enable Survey

- When you have finished building your Participant and Person Obtaining Consent Forms, click the **'Enable'** button to enable the instruments as surveys.

Data Collection Instruments		Form options:		Survey options:	
+ Create	a new instrument from scratch	Form Display Logic	Survey Queue	Auto Invitation options	Survey Login
Import	a new instrument from the official REDCap Instrument Library	Survey Notifications			
Upload	instrument ZIP file from another project/user or external libraries	e-Consent and PDF Snapshots			
Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey related options
Participant Contact Info	2		Enable	Choose action	
Participant Consent Form	5		Enable	Choose action	
Person Obtaining consent	9		Enable	Choose action	

- For each survey instrument, go to Survey Settings to configure your survey. Enter the eConsent name in the **'Survey Title'** as well as any study-specific instructions and survey customizations.
 - Do *not* include version number in **'Survey Title'**. The survey will be used for multiple versions.

Survey Status ✔ [Survey Active](#) If offline, respondents will not be able take the survey.
 Custom text to display on survey page when offline: [Add offline message](#)

Basic Survey Options:

[Survey Title](#)
Title to be displayed to participants at the top of the survey page

[Survey Instructions](#)
(Displayed at top of survey after title)

Open Sans Paragraph 10pt **B** *I* U ~~S~~ **A**

- Scroll down to **'Survey Termination Options'** and edit the text in the **Survey Completion Text Box** which is set to default to *"Thank you for taking the survey. Have a nice day!"*.

Survey Completion Text
(Displayed after survey is completed as 'thank you' text or as acknowledgement text)

Pro Tip: Change the default message to include a thank you, acknowledgement, or study contact information. This language must be submitted to the IRB for approval.

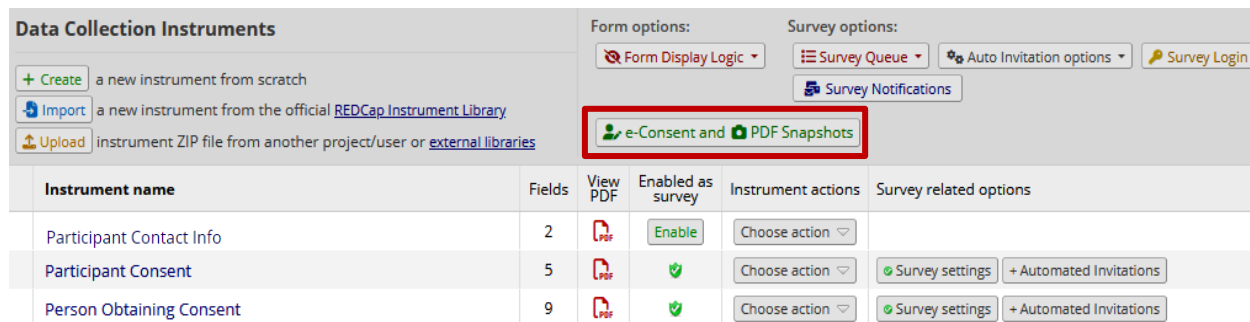
Thank you for joining the study!



Frequently Asked Question (FAQ) Library

STEP 4: Enable the eConsent Framework

- Once your surveys are enabled, return to the Online Designer and select the **'eConsent and PDF Snapshots'** option.



Data Collection Instruments

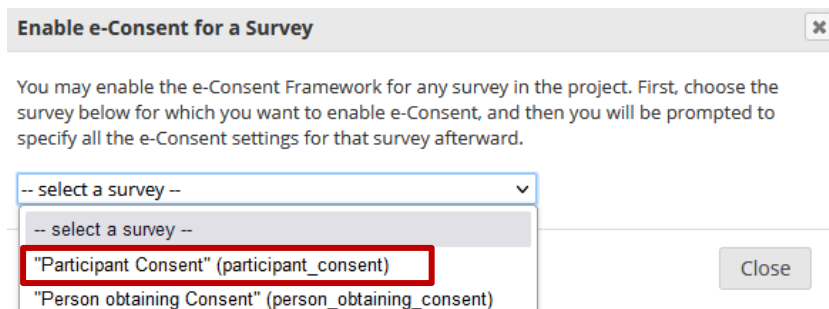
Form options: Form Display Logic, Survey Queue, Auto Invitation options, Survey Login

Survey options: Survey Notifications

e-Consent and PDF Snapshots

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey related options
Participant Contact Info	2	PDF	Enable	Choose action	
Participant Consent	5	PDF	✓	Choose action	Survey settings + Automated Invitations
Person Obtaining Consent	9	PDF	✓	Choose action	Survey settings + Automated Invitations

- Click on **'Enable the eConsent Framework'** for a survey. You will enable and configure the eConsent Framework for each eConsent survey individually.
 - In this tutorial, you will enable the eConsent framework for the (1.) Participant Consent form and (2.) Person Obtaining Consent form.
- Select your eConsent forms:



Enable e-Consent for a Survey

You may enable the e-Consent Framework for any survey in the project. First, choose the survey below for which you want to enable e-Consent, and then you will be prompted to specify all the e-Consent settings for that survey afterward.

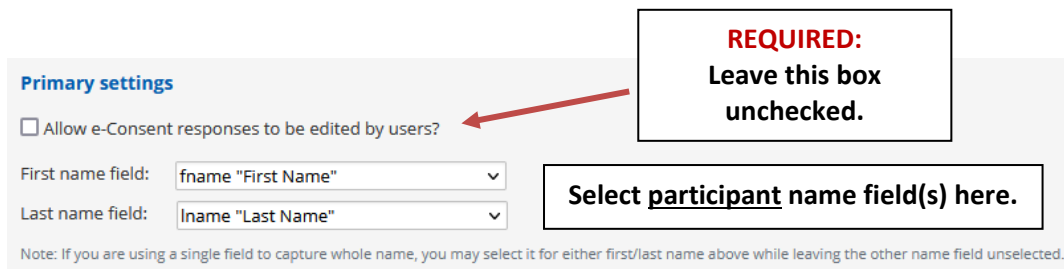
-- select a survey --

"Participant Consent" (participant_consent)

"Person obtaining Consent" (person_obtaining_consent)

Close

- Configure the eConsent Framework settings.



Primary settings

Allow e-Consent responses to be edited by users?

First name field: fname "First Name"

Last name field: lname "Last Name"

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.

REQUIRED: Leave this box unchecked.

Select participant name field(s) here.

- Primary settings:**
 - Allow eConsent to be edited by users:** Yale HRPP requires to leave this box unchecked to ensure the validity of the consent process. Checking this option allows you to edit a signed consent form.

Frequently Asked Question (FAQ) Library

- ii. **First and last name fields:** Select the fields where the participant's name was entered by the participant. The eConsent framework will insert the *first and last name* in the footer and the filename of the PDF snapshot for auditing and archiving.

b. **Additional settings:**

Additional settings

Date of birth field:

Custom tag/category for PDF footer: e.g., Pediatric
Note: This should be static text only.

Custom label for PDF header: e.g., PID [project-id] - [last_name]
Note: Piping may be utilized, including the use of Smart Variables. [Codebook](#) [Smart Variables](#)

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](#)

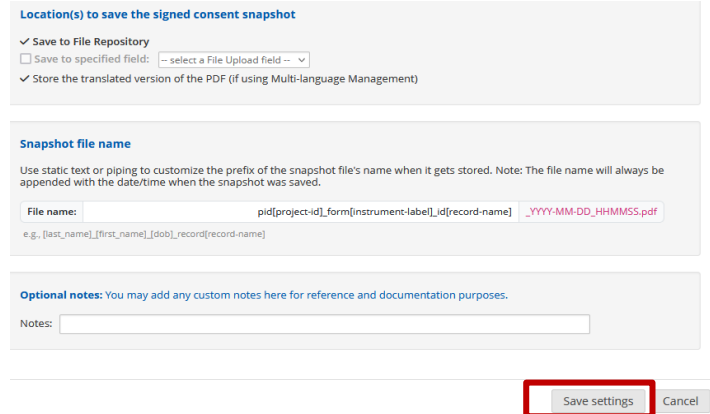
- i. **Date of birth fields:** Yale HRPP discourages the collection of date of birth for eConsent.
- ii. **PDF footer and header:** All eConsent PDFs will contain version, first name, and last name in the footer (if identified in the eConsent settings) and the date/time the PDF is generated.
 1. You may add additional fields or text to the footer or header by defining '**Custom tag/category for PDF footer**' and '**Custom label for PDF header**' and these will be automatically captured in the eConsent PDF snapshot.
- iii. **Signature field #1:** Associate your signature field here. If multiple signatures are required on a single eConsent instrument, you may add additional signature fields (e.g. Participant, Legally Authorized Representative).

c. **Snapshot settings:**

When the eConsent is activated on a survey, a 'trigger' for an automated snapshot is automatically created for the survey in the '**PDF Snapshots of Records**' tab. When the eConsent survey is completed, each instrument with the eConsent framework enabled will generate a PDF snapshot that is automatically saved to the File Repository. See [FAQ: eConsent Administration](#) for more information.

Frequently Asked Question (FAQ) Library

- i. In the eConsent 'Edit Settings', you may customize the PDF Snapshot's file name or keep the default settings.
- ii. Review and save the settings.



Location(s) to save the signed consent snapshot

Save to File Repository
 Save to specified field: -- select a File Upload field --
 Store the translated version of the PDF (if using Multi-language Management)

Snapshot file name

Use static text or piping to customize the prefix of the snapshot file's name when it gets stored. Note: The file name will always be appended with the date/time when the snapshot was saved.

File name:
e.g., [last_name]_[first_name]_[dob]_record[record-name]

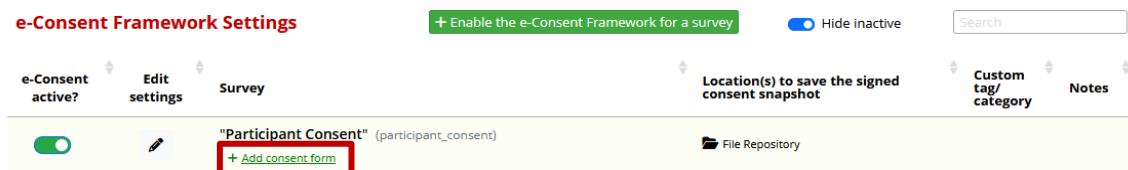
Optional notes: You may add any custom notes here for reference and documentation purposes.

Notes:

Save settings Cancel

STEP 5: Upload your PDF Consent Form

1. To utilize eConsent 2.0 versioning, you must upload your PDF consent form in the eConsent Framework Settings.

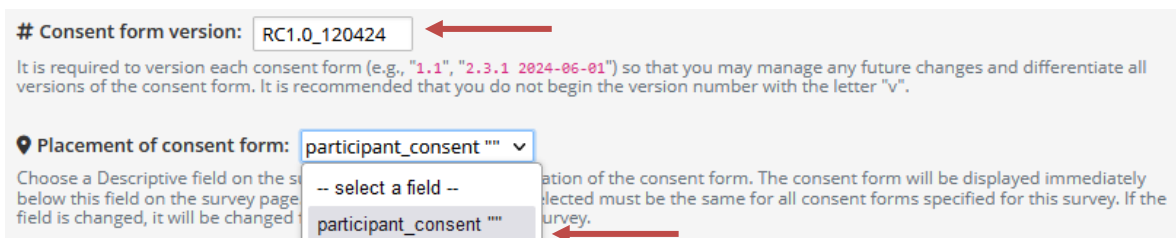


e-Consent Framework Settings

Enable the e-Consent Framework for a survey Hide inactive

e-Consent active?	Edit settings	Survey	Location(s) to save the signed consent snapshot	Custom tag/category	Notes
<input checked="" type="checkbox"/>		"Participant Consent" (participant_consent) + Add consent form	File Repository		

- a. Click the "Add consent form".
2. Identify and upload the consent form.



Consent form version: ←

It is required to version each consent form (e.g., "1.1", "2.3.1 2024-06-01") so that you may manage any future changes and differentiate all versions of the consent form. It is recommended that you do not begin the version number with the letter "v".

Placement of consent form: ←

Choose a Descriptive field on the survey page below this field on the survey page. If the field is changed, it will be changed.

-- select a field --
 ←

- a. Define the REDCap consent version in the '# Consent form version' field.
 - i. The '# Consent form version' tracks the unique version of the consent form to be displayed.
 - ii. We recommend using a version system that begins with "RC" (REDCap), a sequential number, and the IRB consent approval date.
 1. Once a value is used for a survey, *it cannot be reused even in Development mode*. Duplicate or incorrect uploads cannot be deleted and may result in misalignment with your IRB-approved consent document versioning.

Frequently Asked Question (FAQ) Library

- b. In the “Placement of consent form”, select the field that will display the IRB-approved consent PDF. This is the descriptive field you created in STEP 2 for this consent form.
- c. Click the **Consent Form (Inline PDF)** tab.
- d. Click **Choose File** to upload the PDF of your consent form.
- e. Once the upload is complete, click **Add new consent form**.

[Consent Form \(Rich Text\)](#) **Consent Form (Inline PDF)**

Provide your consent form as a PDF file that will be displayed inline on the page directly below the field selected for 'Location of consent form' on the instrument/survey.

Upload your PDF consent form: No file chosen [Reset](#)

WARNING: If you upload an incorrect consent form, you cannot delete the PDF.

You can deactivate the upload by clicking the '**View all versions**' link and selecting '**Set as inactive.**' You can then repeat the steps above to re-upload the correct PDF. However, you will not be able to reuse the version number.

Frequently Asked Question (FAQ) Library

Person Obtaining Consent

1. Repeat STEP 4 for the Person Obtaining Consent instrument with the considerations below. Do **NOT** re-upload the consent form (skip STEP 5).

e-Consent settings for survey "Person"

Use the settings below for setting up the e-Consent name (and sometimes their date of birth) on the final capture that info, in which the values for those fields will review at the end of the survey. And then afterwards to also store the PDF in a File Upload field). Other e-label for the PDF header, location(s) to save the signature.

Primary Settings: Select the Participant Name here, NOT the name of the person obtaining consent. The eConsent framework will insert the first and last name on each page of the PDF snapshot. Participant name should be used for audit purposes.

Additional Settings: Select the Person Obtaining Consent signature field here.

The forced signature field will erase the signature if the Previous Page button is clicked and will require that the person obtaining consent re-enter a signature to complete the eConsent. **Enable this option.**

Primary settings

Allow e-Consent responses to be edited by users?

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.

Additional settings

Date of birth field:

Custom tag/category for PDF footer:

Note: This should be static text only.

Custom label for PDF header:

Note: Piping may be utilized, including the use of Smart Variables.

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 checkbox (e.g., to collect a PIN), and it must be a Required field. If any fields are selected below, then if the participant chooses to certify their responses, if they then choose to click the Previous Page button, the signature fields, thus forcing them to 'sign' the field(s) again before completing the survey. If you do not select any fields below, you may use up to five signature fields.

Signature field #1:

STEP 6: Test eConsent

Once your consent form is built, it is important that you test the project to verify that the form functions as expected, the consent process described in your protocol can be implemented, and the resulting PDF is correct and readable.

Pro Tip: Test thoroughly and carefully before moving your project to production.

Ask a variety of people with different roles on your project to enter test data in your eConsent, to check the functionality and to confirm the legibility of the eConsent found in your file repository.

We have provided a self-evaluation checklist to support testing in STEP 6. You can customize this checklist by adding study-specific quality controls checks to ensure your requirements are being met.

See: [eConsent New Build: Self Evaluation Checklist](#)

Frequently Asked Question (FAQ) Library

Revision History

Version	Effective Date	Section	Page	Description/Rational
2.0	03/24/25	<i>STEP 2: Build your eConsent instrument</i>	4	Added instructions to use 'read-only' action tag to study-specific permission fields to prevent data being entered in form mode.
2.0	03/24/25	<i>Step 3: Setup Signature</i>	5-6	Removed (non-substantive) language.
2.0	03/24/25	<i>Step 3: Setup Signature</i>	6	Removed time field from participant consent form.
2.0	03/24/25	<i>Step 3: Setup Signature</i>	6-10	Included instructions and pro-tip to use 'read-only' action tag fields to prevent data being entered in form mode.
2.0	03/24/25	<i>Step 3: Setup Signature</i>	8	Added a descriptive field 'Consent Summary' to serve as a cross-reference between participant and person obtaining consent forms.
2.0	03/24/25	<i>Step 3: Setup Signature</i>	9	Removed time field from person obtaining consent form.
2.0	03/24/25	<i>Step 3: Setup Signature</i>	9-10	Updated screenshots.
2.0	03/24/25	<i>STEP 5: Upload your PDF Consent Form</i>	14	Updated screenshot.
2.0	03/24/25	<i>STEP 5: Upload your PDF Consent Form</i>	14	Added recommendation to include a <u>sequential number and the IRB consent approval date</u> to the RC version information.
2.0	03/24/25	<i>STEP 5: Upload your PDF Consent Form</i>	15	Included instructions not to re-upload consent form to person obtaining consent form (skip STEP 5).
3.0	07/18/25	<i>STEP 1: Create a New Project</i>	9	Updated screenshot of piping.