

How do I build an eConsent?

[Scanned Image of Consent Form]

There are two ways to build an electronic consent document (eConsent) using REDCap. These instructions explain how to scan an image of the consent form into REDCap. To build an eConsent by copying and pasting (or typing) content into REDCap, please refer to [FAQ: Build eConsent \[Copy & Paste or Type Content\]](#).

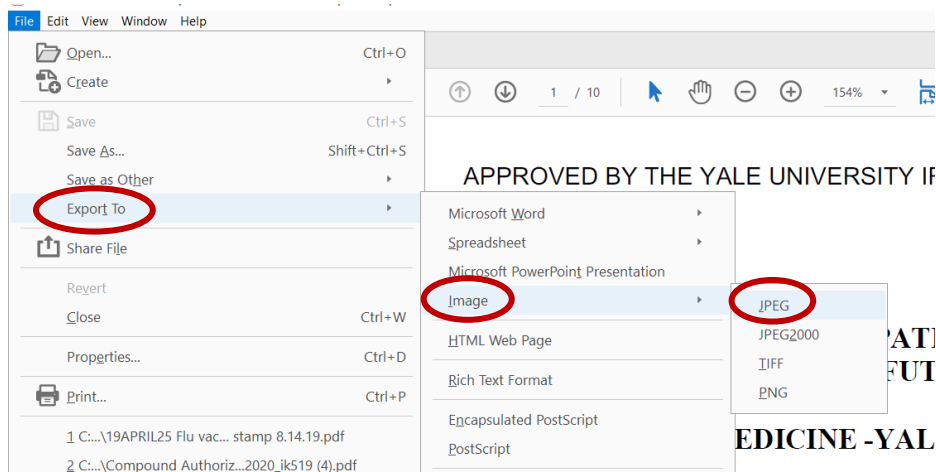
To build an eConsent you will follow the steps outlined below:

- STEP 1. Create image files of the consent form
- STEP 2. Create a new project
- STEP 3. Build your eConsent document
- STEP 4. Enable settings with the eConsent framework and auto-archiver

In this tutorial, you will build your eConsent in a new, stand-alone project that is distinct and separate from your study project with data collection forms. This ensures that the personal identifiers collected on consent forms (e.g. name, date) and archived within eConsent documents are securely maintained and separated from the participant study ID and data.

STEP 1: Create image files of the consent form

1. Open the *IRB-approved* consent form in Adobe Acrobat. If you use an unapproved consent for this step, you will need to re-upload the stamped version and any changes requested during the IRB prior to study implementation.
2. Choose **File -> Export To -> Image -> JPEG**. Adobe will export each page of the consent form to an individual image file. For example, a 10-page consent form would result in 10 image files.



Frequently Asked Question (FAQ) Library

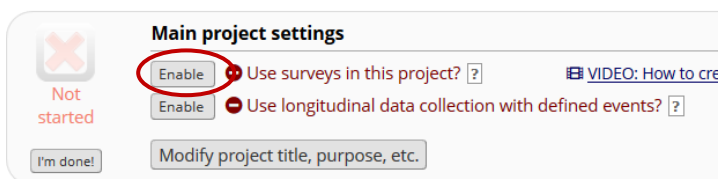
STEP 2: Create a new project

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

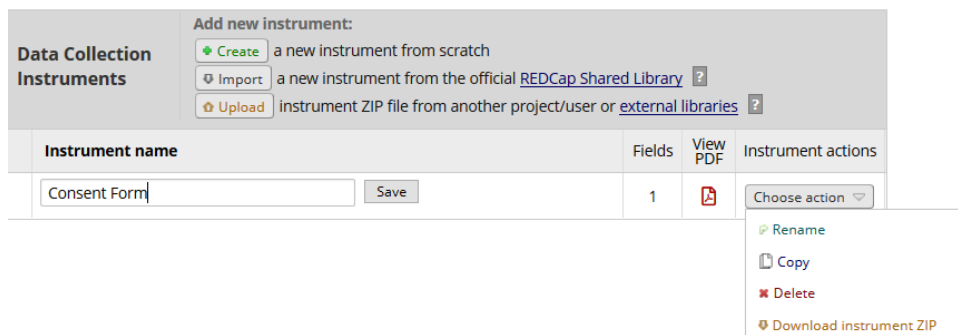
Pro Tip: Use a project title that includes *eConsent + Study Name/Acronym*. If you are using more than one eConsent on the same study, you can create multiple forms, but be sure to use names that differentiate each consent (e.g. *Adult, Children, Students*).

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 question **'Use surveys in this project?'**



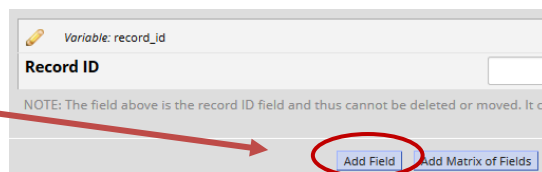
3. Next, click **'Online Designer'** under **'Design your data collection instruments & enable your surveys.'**
4. Change the default **'My First Instrument'** name by selecting the **'Rename'** option found under the **'Choose action'** drop down menu. Label your eConsent instrument (see Pro Tip) and then click **'Save'**.



STEP 3: Build your eConsent document

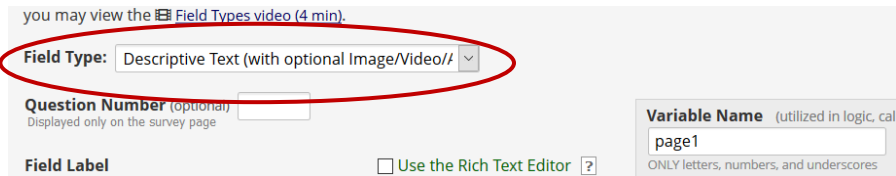
1. Select your newly named instrument to build your consent form.
2. To upload the image files of the consent document into the eConsent form, you will create one descriptive field per image file:

- a. To add descriptive fields, click the **'Add Field'** button.



Frequently Asked Question (FAQ) Library

- b. Under the **Field Type** menu, choose '**Descriptive Text**' and create a variable name.



you may view the [Field Types video \(4 min\)](#).

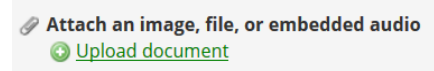
Field Type: Descriptive Text (with optional Image/Video//

Question Number (optional)
Displayed only on the survey page

Variable Name (utilized in logic, cal)
page1
ONLY letters, numbers, and underscores

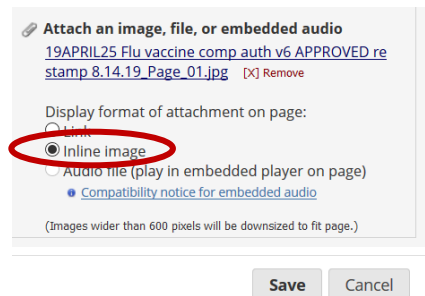
Field Label Use the Rich Text Editor ?

- c. Under **Attach an image, file, or embedded audio**, upload the image starting with the first page of the consent form.



Attach an image, file, or embedded audio
[Upload document](#)

- d. Select '**Inline Image**' for display format and click save.



Attach an image, file, or embedded audio
[19APRIL25 Flu vaccine comp auth v6 APPROVED re stamp 8.14.19_Page_01.jpg](#) [X] Remove

Display format of attachment on page:

Link

Inline image

Audio file (play in embedded player on page)
[Compatibility notice for embedded audio](#)

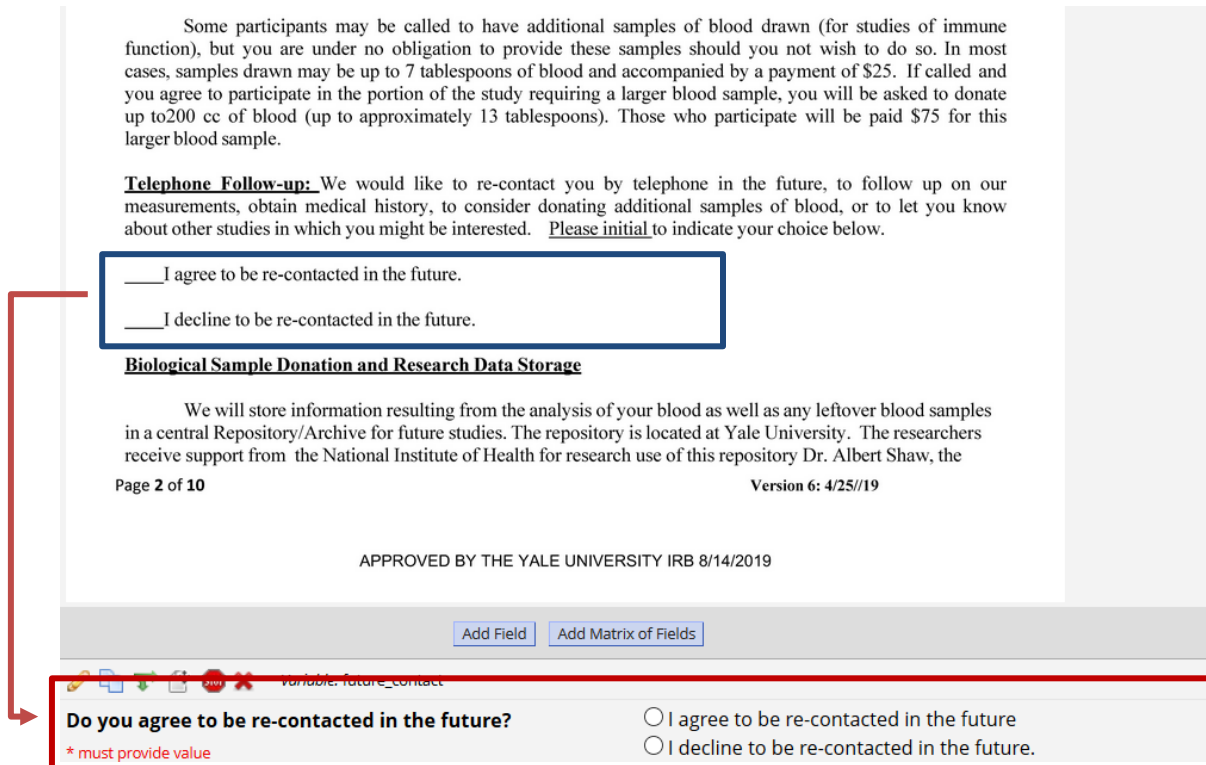
(Images wider than 600 pixels will be downsized to fit page.)

Save Cancel

- e. Repeat the process for remaining pages of the consent form.

3. For optional study procedures, you can add questions after the descriptive field that contains the consent page (i.e. image file) where the procedure is described.

Your eConsent should look like this:



Some participants may be called to have additional samples of blood drawn (for studies of immune function), but you are under no obligation to provide these samples should you not wish to do so. In most cases, samples drawn may be up to 7 tablespoons of blood and accompanied by a payment of \$25. If called and you agree to participate in the portion of the study requiring a larger blood sample, you will be asked to donate up to 200 cc of blood (up to approximately 13 tablespoons). Those who participate will be paid \$75 for this larger blood sample.

Telephone Follow-up: We would like to re-contact you by telephone in the future, to follow up on our measurements, obtain medical history, to consider donating additional samples of blood, or to let you know about other studies in which you might be interested. Please initial to indicate your choice below.

I agree to be re-contacted in the future.
 I decline to be re-contacted in the future.

Biological Sample Donation and Research Data Storage

We will store information resulting from the analysis of your blood as well as any leftover blood samples in a central Repository/Archive for future studies. The repository is located at Yale University. The researchers receive support from the National Institute of Health for research use of this repository Dr. Albert Shaw, the

Page 2 of 10 Version 6: 4/25/19

APPROVED BY THE YALE UNIVERSITY IRB 8/14/2019

Add Field Add Matrix of Fields

variable: future_contact

Do you agree to be re-contacted in the future? I agree to be re-contacted in the future
 I decline to be re-contacted in the future.
* must provide value

Frequently Asked Question (FAQ) Library

4. Add participant validation and signature fields.

Electronic signature and verification procedures will vary based upon IRB requirements for the project. If your consent requires a signature (i.e. you do not have a waiver) you will collect the participant name, signature, and date of consent. This information is needed for regulatory compliance. To limit the personal information that is collected, do not include date of birth as a validation field.

a. After you have uploaded the consent form pages (i.e. image files), add the appropriate fields:

i. **Date Consent Form Signed**

1. Dates are needed for audit purposes. To ensure data quality and prevent errors, use rules and date validation.

ii. **Participant First and Last Name**

1. Set up first and last name in two separate fields. The name fields are needed for identification. The eConsent framework will insert the *first and last name* on each page of the archived PDF consent for audit purposes.

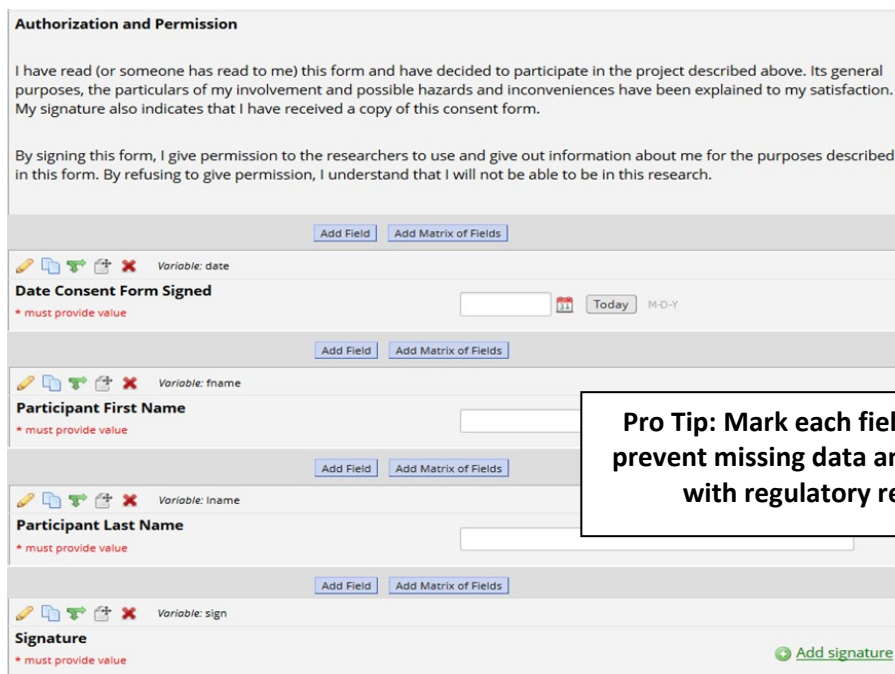
iii. **Participant Signature**

1. REDCap options include electronically signing via stylus, mouse or finger, free text, or entering a number (i.e. PIN).

iv. **Person Obtaining Consent**

1. If you are consenting in-person, add the name and signature fields for person obtaining signature to this eConsent form (two signatures on the same form).
2. If you are consenting remotely (from a different location) or using a hybrid method, you should set up a separate form for this signature. Refer to the [FAQ: Administer eConsent](#).

Your signature fields should look like this:

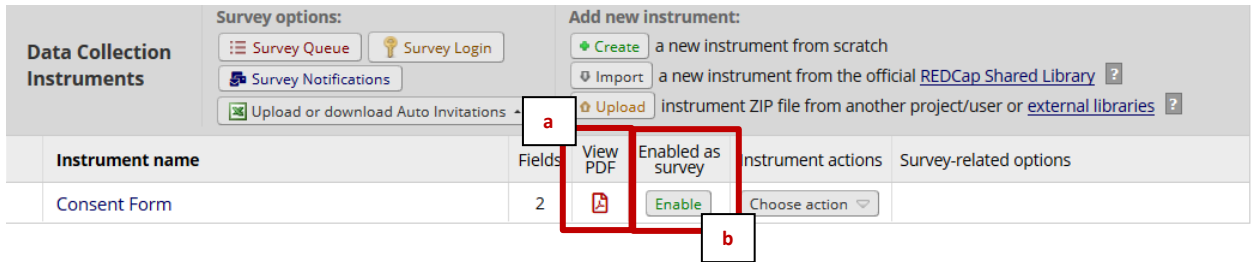


The screenshot shows a REDCap form builder interface for an "Authorization and Permission" form. It includes a consent text block and four required fields: "Date Consent Form Signed" (with a date picker), "Participant First Name", "Participant Last Name", and "Signature" (with a signature tool icon). Each field has a red asterisk and the text "* must provide value".

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

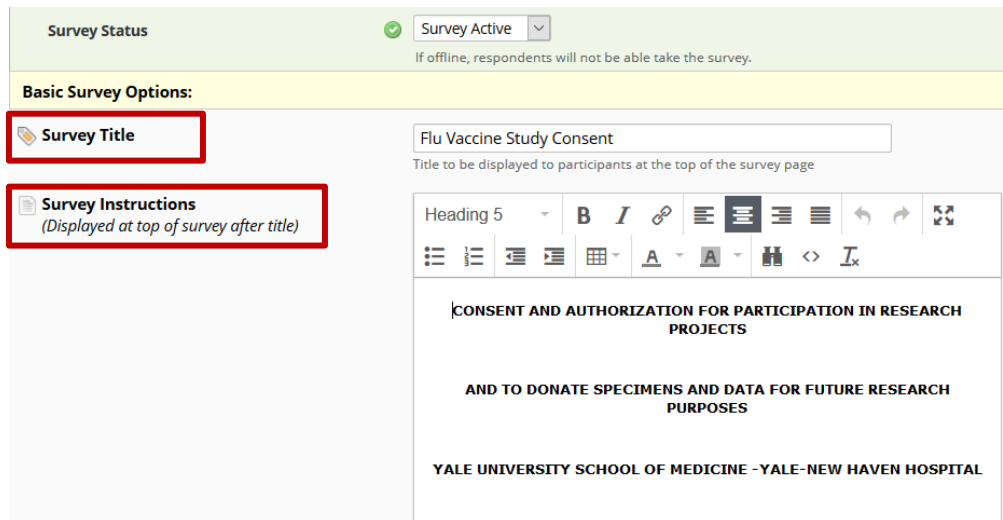
Frequently Asked Question (FAQ) Library

5. When you have finished building your eConsent form, click '**view PDF**' in the Online Designer to open the form in PDF.
 - a. Review the eConsent form for content, accuracy, and formatting.
 - b. Once your review is complete, click the '**Enable**' button to enable the form as survey.

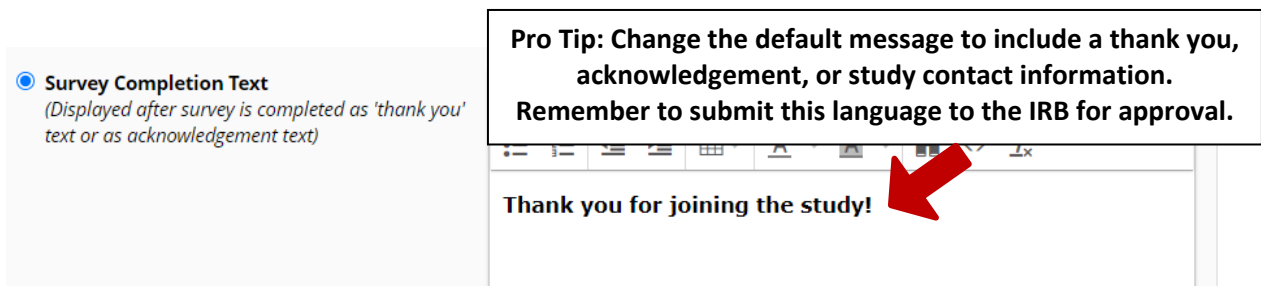


STEP 3: Enable Settings with eConsent Framework and Auto Archiver

1. Once the form is enabled as a survey, the survey setting page will open. Enter the title and header of your consent form in the **Survey Title** and **Survey Instructions** box.

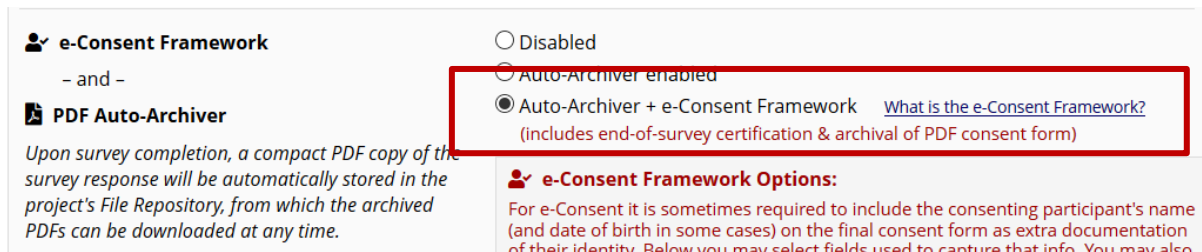


2. Once you have entered your title and header, scroll down to '**Survey Termination Options**' and edit the text in the **Survey Completion Text Box** which is set to default to "Thank you for taking the survey. Have a nice day!".



Frequently Asked Question (FAQ) Library

3. Next in the survey settings, under eConsent Framework, select “**Auto-Archiver + eConsent Framework**”.

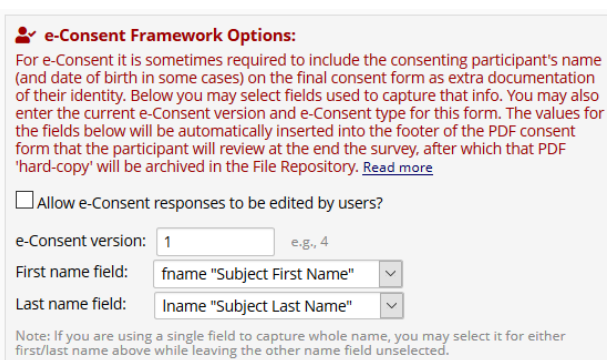


The screenshot shows the 'e-Consent Framework' settings. The 'Auto-Archiver + e-Consent Framework' option is selected and highlighted with a red box. Below it, the 'e-Consent Framework Options' section is visible, with a note about including participant names and birth dates.

4. Enable your eConsent Framework options which include:

a. **Documentation Options**

- i. **Allow eConsent to be edited by users:** It is important to leave this box unchecked to ensure the validity of the consent process. Checking this option allows you to edit a signed consent form.
- ii. **eConsent version:** This is an open text space allowing you to track the version of the consent form signed by the participant. This field is used to support auditing.

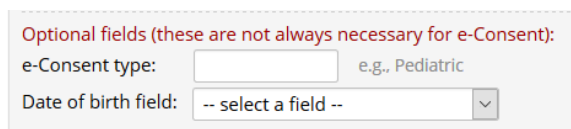


The screenshot shows the 'e-Consent Framework Options' section. It includes a checkbox for 'Allow e-Consent responses to be edited by users?' (unchecked), an 'e-Consent version' text field (value: 1), and dropdown menus for 'First name field' and 'Last name field' (both set to 'Subject First Name' and 'Subject Last Name' respectively). A note at the bottom explains that if a single field is used for the whole name, the other field should be left unselected.

Because the IRB approval stamp is included on the scanned image in STEP 1, it is not necessary to include the IRB approval date in the framework. Include the Version Number and Version Date (if applicable). To make version changes, refer to [FAQ: Changes to eConsent Form](#).

- iii. **First and Last name fields:** Identify the fields in STEP 3 where the participant’s name was captured. The eConsent framework will insert the *first and last name* on each page of the archived PDF consent for audit purposes.

b. **Optional Fields**



The screenshot shows the 'Optional fields' section. It includes an 'e-Consent type' text field (value: Pediatric) and a 'Date of birth field' dropdown menu (value: -- select a field --).

- i. **eConsent type:** This is an open text space allowing you to categorize the consent form for unique groups. The eConsent framework will insert the **eConsent type** within each page of the archived PDF consent for audit purposes whereas the **instrument name** is displayed within the data dictionary. For consistency, you may want to use the same eConsent (instrument) name used in STEP 2.
- ii. **Date of Birth field:** Do not include.

Frequently Asked Question (FAQ) Library

c. **Forced signature [fields to be erased if participant clicks previous page button]**

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:

- i. Identify the field in STEP 3 where the signature was captured. The forced signature field will erase the signature if the Previous Page button is clicked and will require that participants re-enter a signature to complete the eConsent. You **should** enable this option for eConsent.

5. Your eConsent is now created. Move your project to production status.

6. To manage and use your eConsent, please review [FAQ: Administer eConsent](#)