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.

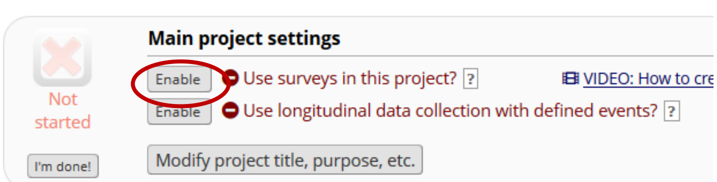
In this tutorial, you will build an eConsent in a new, stand-alone project that is distinct from your REDCap project with data collection forms. This ensures that the personal identifiers collected on the consent forms (e.g. name, date) and archived within eConsent documents are securely maintained and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

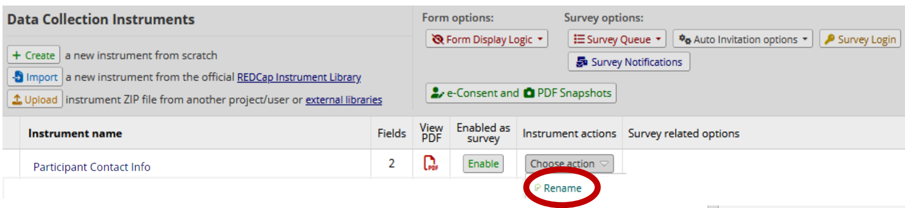
2. After your project is created, open it, and go to the '**Project Setup**' tab to enable the survey design.
   a. Under '**Main Project Settings**' select the '**Enable**' button for the option '***Use surveys in this project?***'



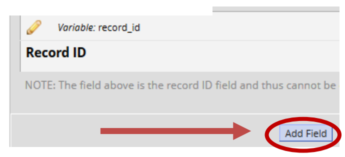
3. Next, click '**Online Designer**' under '**Design your data collection instruments & enable your surveys**.'

4. 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**'.

   <u>In the example below, the first instrument is renamed '*Participant Contact Info*'</u>.



5. Open the first instrument, click the '**Add Field**' button.



6. 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.

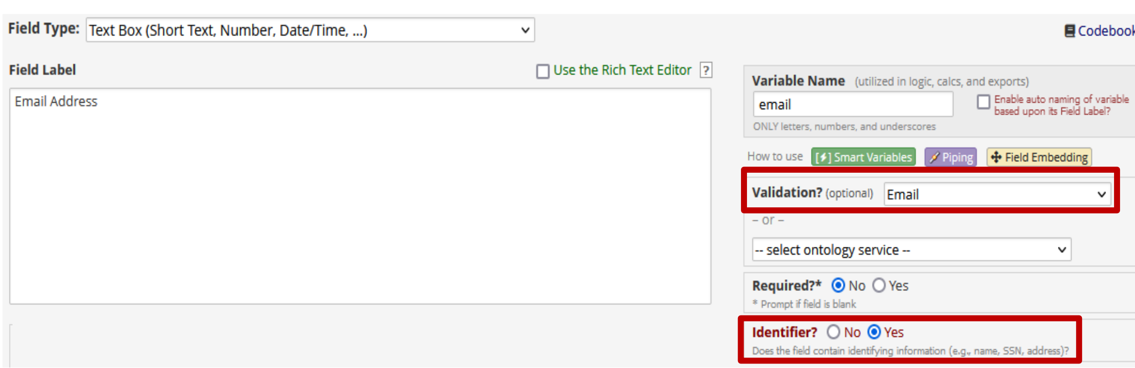
Pro Tip: Duplicate information can create data discrepancies.

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.

   a. If you are consenting remotely or plan to share the signed eConsent electronically, create a field to capture the participant email.

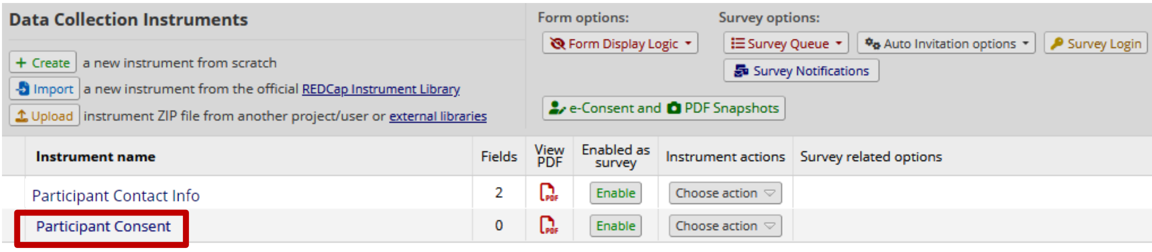
      i. Under the '**Validation**', select the **Email** option.

      ii. Under '**Identifier?**', select **Yes** to tag the field as an identifier.



7. Return to the Online Designer by clicking on **Return to list of instruments**

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



> **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:

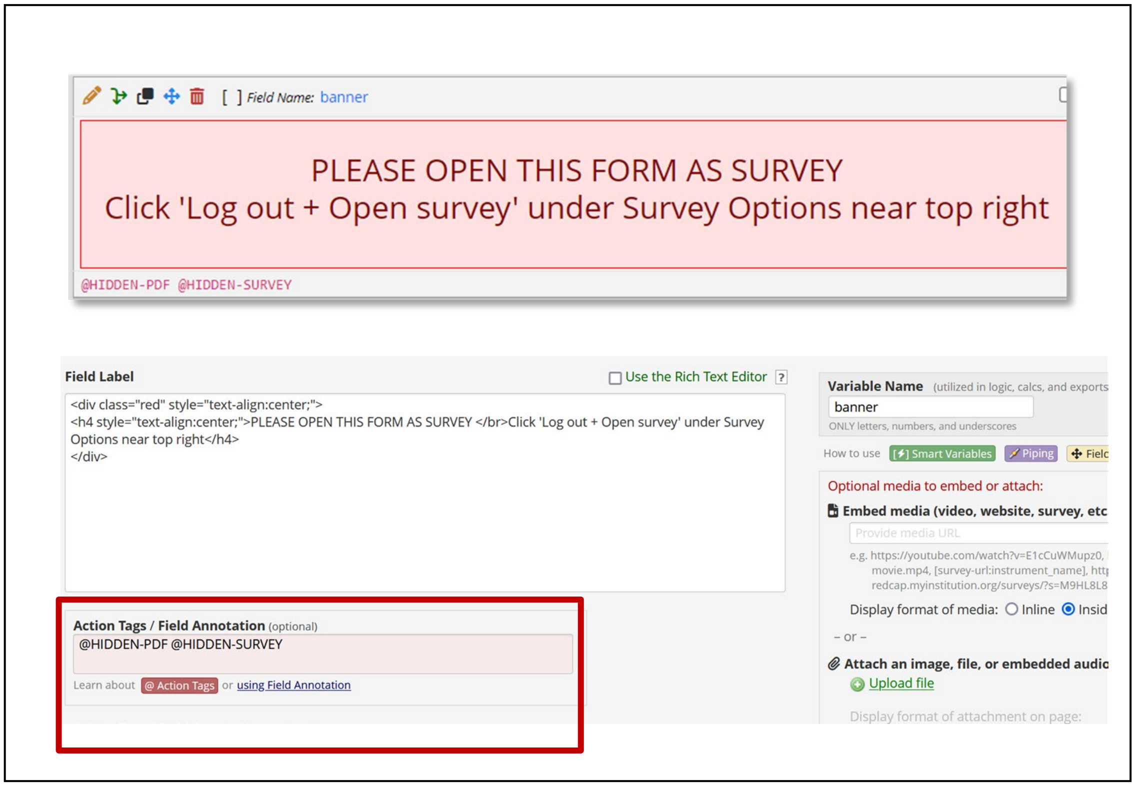
```
<div class="red" style="text-align:center;">
<h4 style="text-align:center;">PLEASE OPEN THIS FORM AS SURVEY </br>Click 'Log out + Open survey' under Survey Options near top right</h4>
</div>
```

   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.

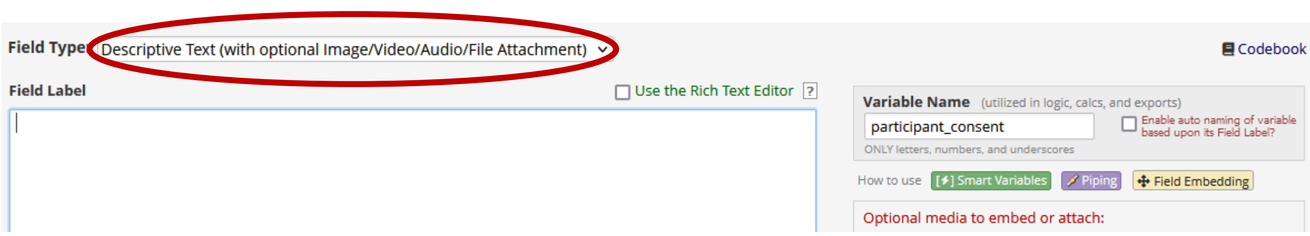
Instruction banner:



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

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

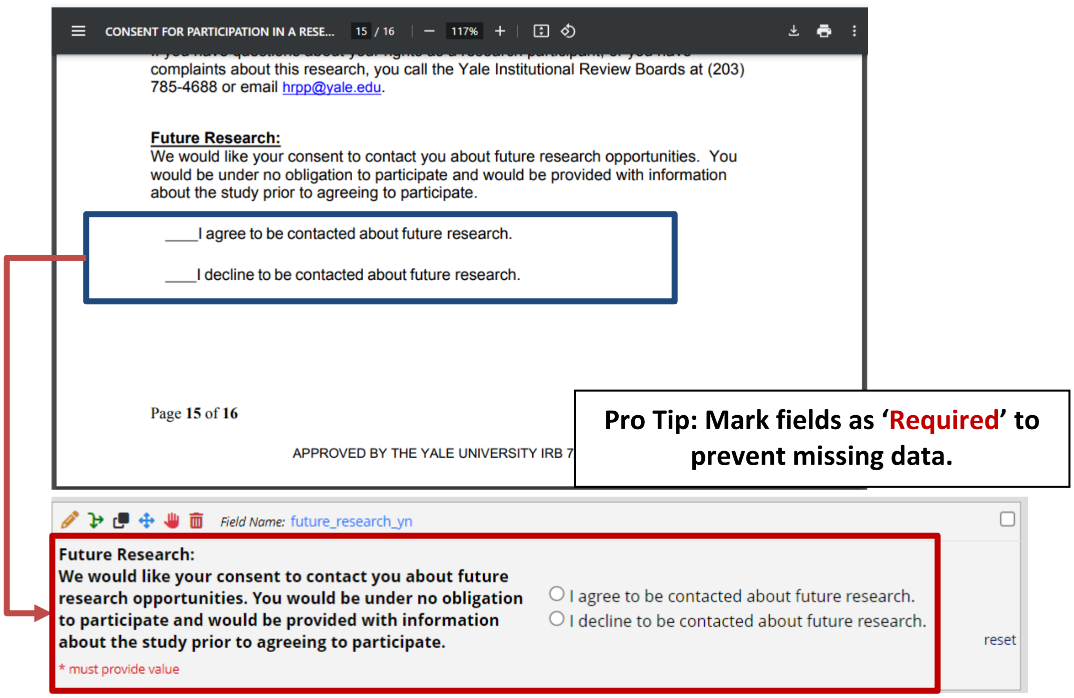
   b. Under the **Field Type** menu, choose '**Descriptive Text**' and create variable name.



   c. You will use this field to upload your eConsent **in STEP 4- eConsent Framework**. The Field Label and other field settings can remain blank.

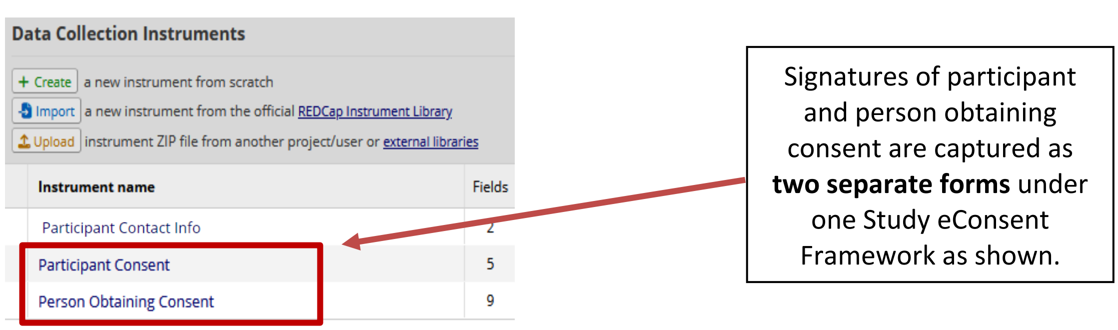
4. If your research consent contains study-specific permissions, you can add fields to capture response items, as shown below.

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



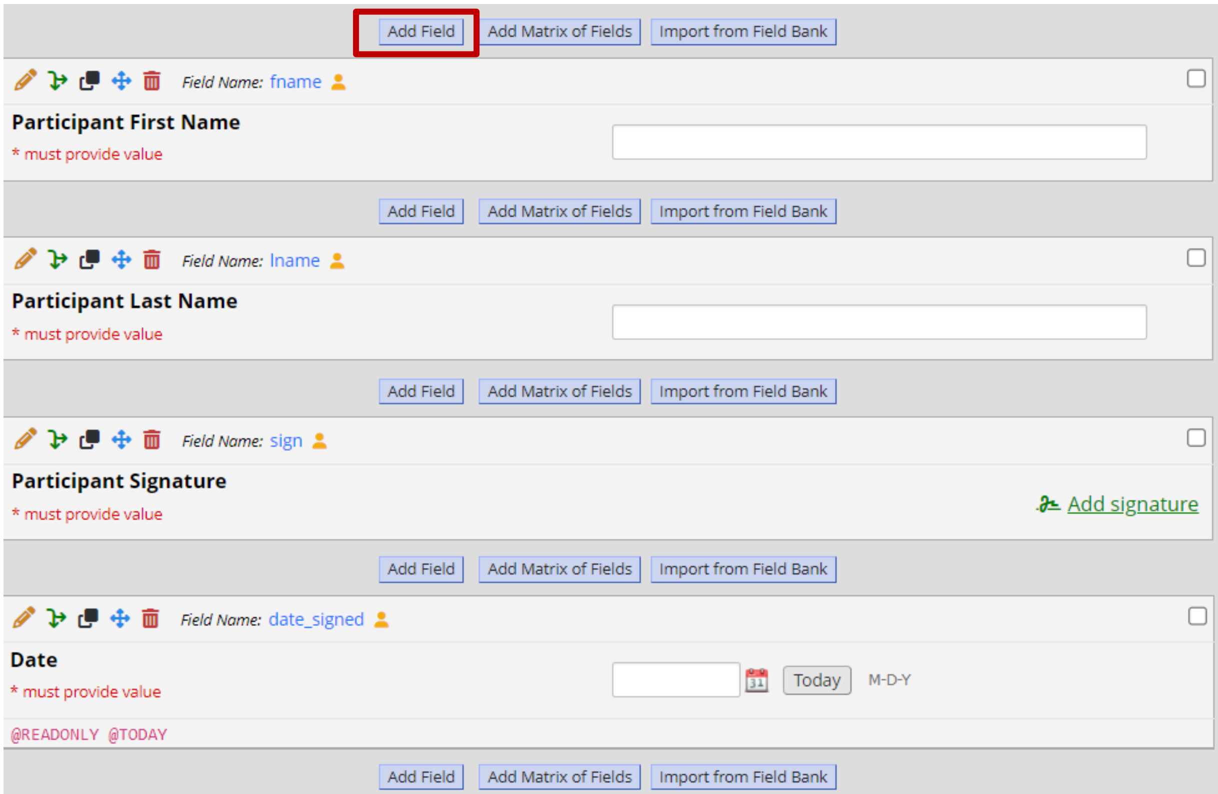
Step 3: Setup Signature

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. If your research is subject to 21 CFR Part 11 requirements (i.e. IND/IDE studies, FDA-regulated studies), you will also collect *time of consent*. To limit the collection of personal information, do not include date of birthdate as a validation field.



Participant

1. Click **Add Field** to the Consent instrument. The signature & date should be the last entries on the form.



2. Add fields for signature and verification:

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

      i. Create two separate fields for (1.) first name and (2.) last name.

      ii. Tag these fields as identifiers and mark as required.

      iii. The eConsent framework will insert the first and last name on each page of the snapshot PDF consent for audit purposes.

   b. **Signature**

      i. The signature field allows participants to electronically sign via stylus, mouse or finger. FDA-regulated research subject to 21 CFR Part 11 requirements must use the REDCap 'signature' field.

      ii. Tag this field as an identifier and mark as required.

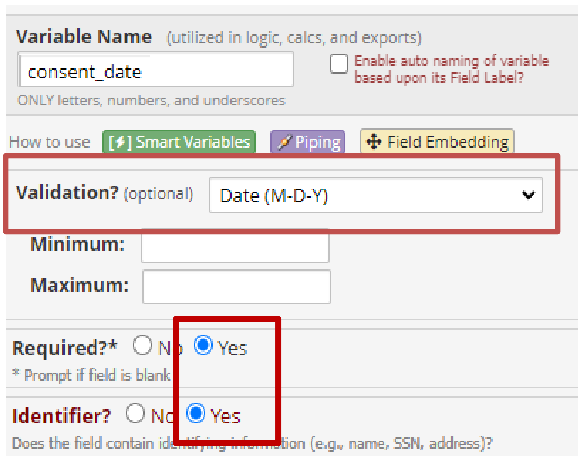
> **Pro Tip:** Mark each field as '**Required**' to prevent missing data and non-compliance with regulatory requirements.

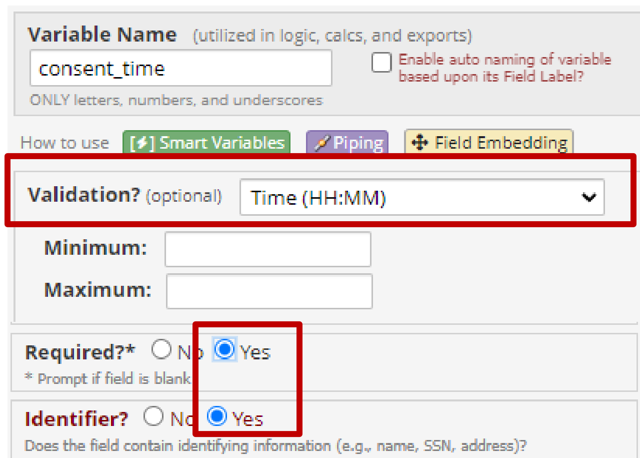
c. **Date & Time**

i. Create fields for (1.) date and (2.) time.

ii. To ensure data quality and prevent errors, use validation and minimum/maximum range.

iii. Tag date field as an identifier and mark both fields as required.

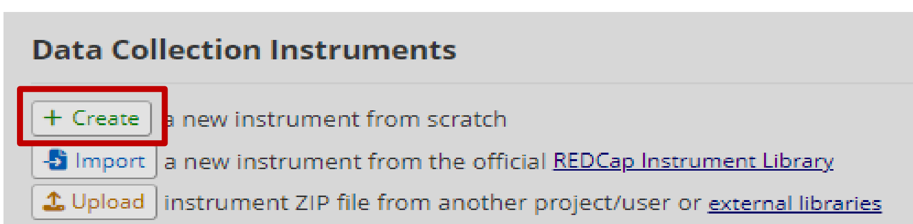




Person Obtaining Consent

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 an instruction banner at the top of the instrument by inserting a descriptive field as shown in the example below.

   a. Copy the code below to the 'Field Label' box:

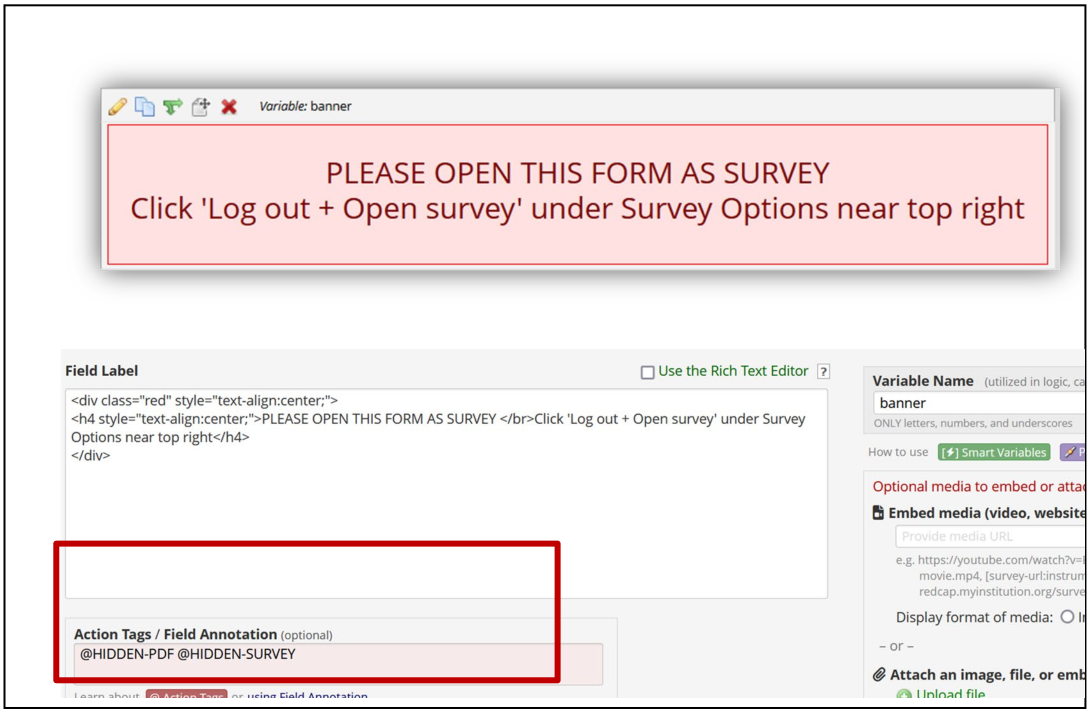
      <div class="red" style="text-align:center;">
      <h4 style="text-align:center;">PLEASE OPEN THIS FORM AS SURVEY </br>Click 'Log out + Open survey' under Survey Options near top right</h4>
      </div>

b. Add these two '**Action Tags**' to the Action tags/Field Annotation box:

   i. @HIDDEN-SURVEY - the warning message will appear on the instrument and not the survey.

   ii. @HIDDEN-PDF - the warning message will not print on the PDF copy of the consent form.

Instruction banner:



3. Add fields for signature and verification:

   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.

   b. **Optional: Method of Consent**

      i. If the consent administration process varies, capture the method (e.g. phone, video conference, in-person).

   c. **Optional: Documentation of Consent process**

      i. You may wish to include an acknowledgement that documents the consent process as shown in the example below.

d. **Signature of Person Obtaining Consent**

   i. REDCap options include electronically signing via stylus, mouse or finger, free text, or entering a number (i.e. PIN). Describe the signature method in your protocol- some methods may require a waiver of consent documentation.

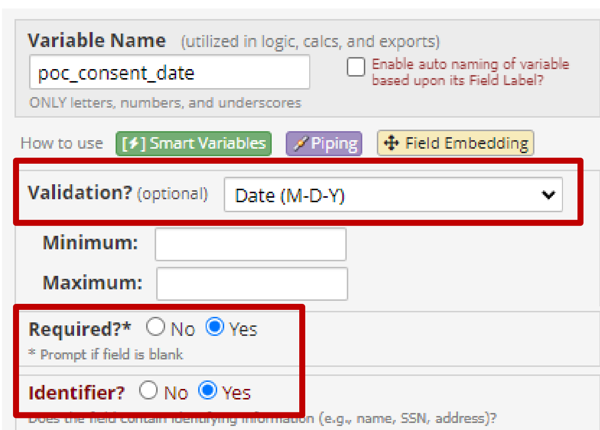
   ii. Tag this field as an identifier and mark as required.

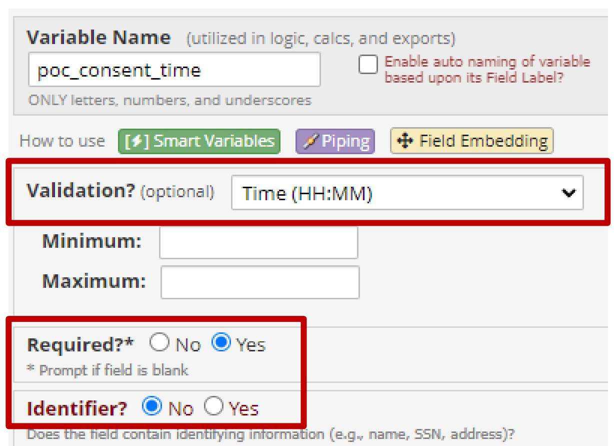
e. **Date & Time**

   i. Create fields for (1.) date and (2.) time.

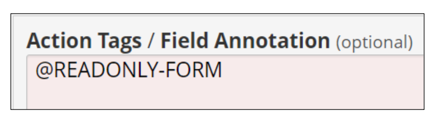
   ii. To ensure data quality and prevent errors, use validation and minimum/maximum range.

   iii. Tag date field as an identifier and mark both fields as required.

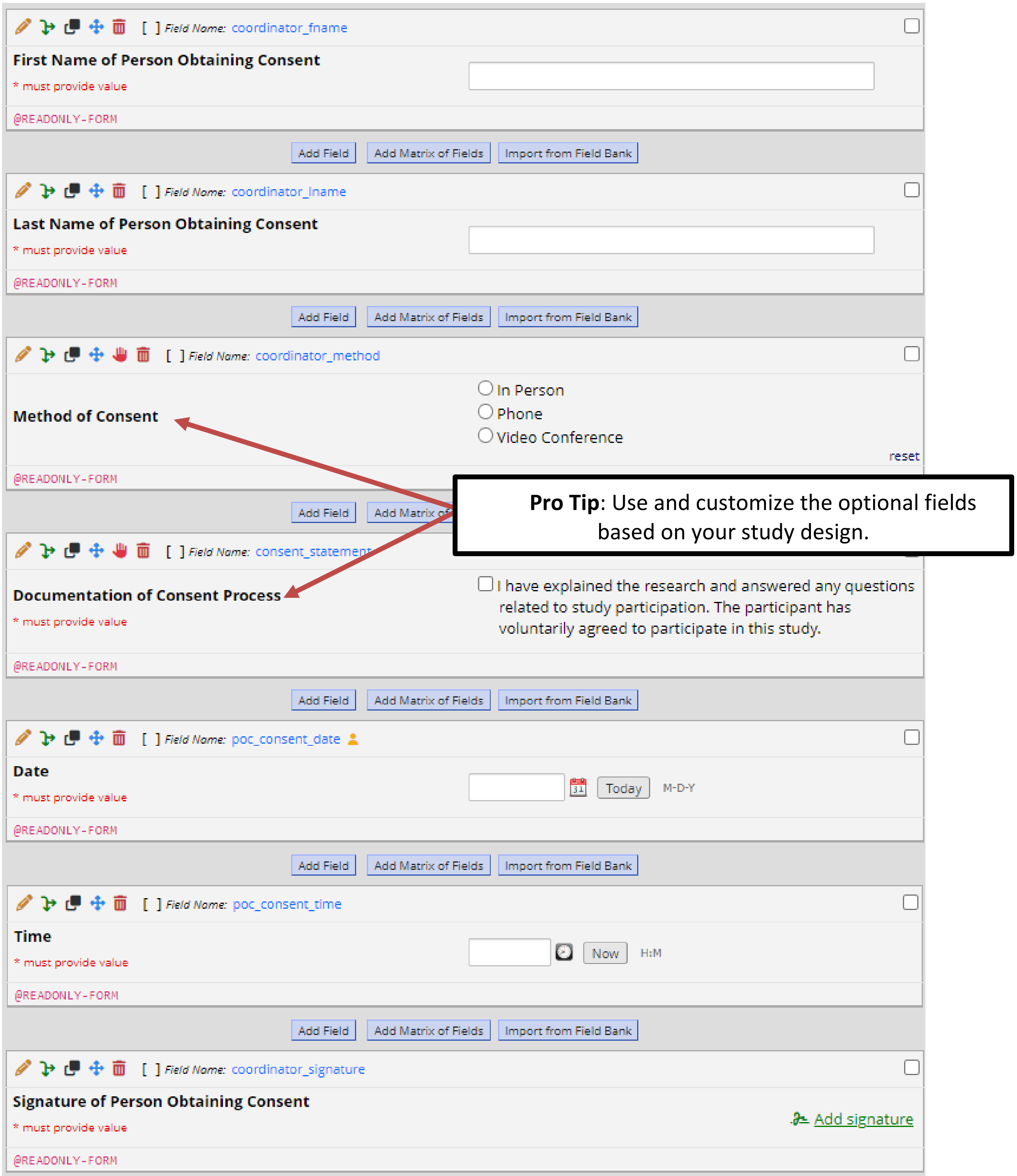




4. To prevent study staff completing this instrument in form mode, which is not valid for eConsent Framework, add **@READONLY-FORM** action tag to all fields.

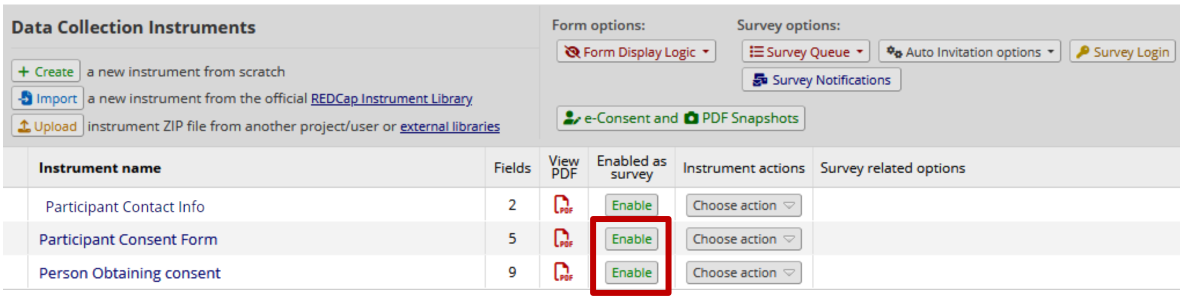


Examples of person obtaining consent signature fields:



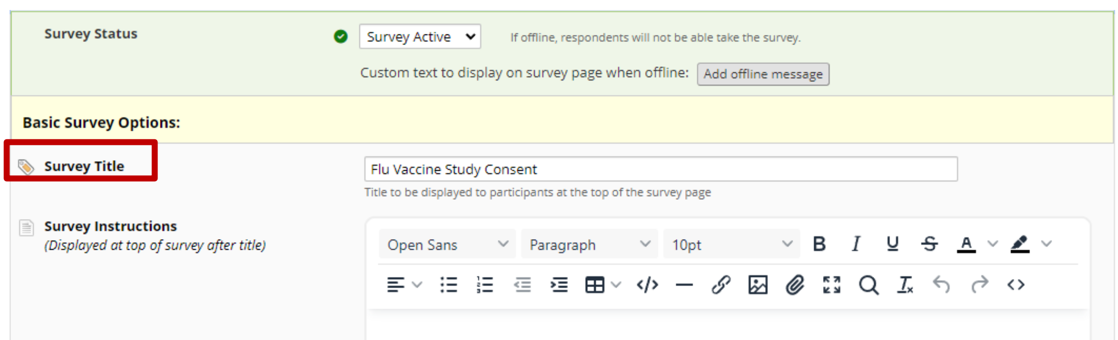
Enable Survey

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



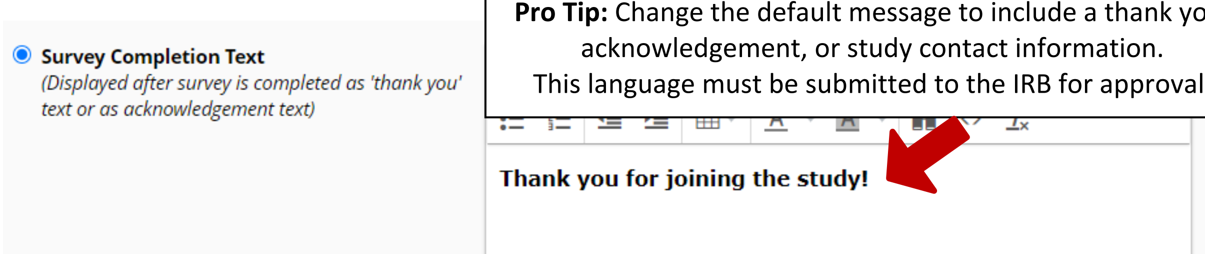
2. For each survey instrument, go to Survey Settings to configure your survey. Enter the eConsent name in the '**Survey Title'** as well as any study-specific instructions and survey customizations.

   a. Do *not* include version number in '**Survey Title'**. The survey will be used for multiple versions.



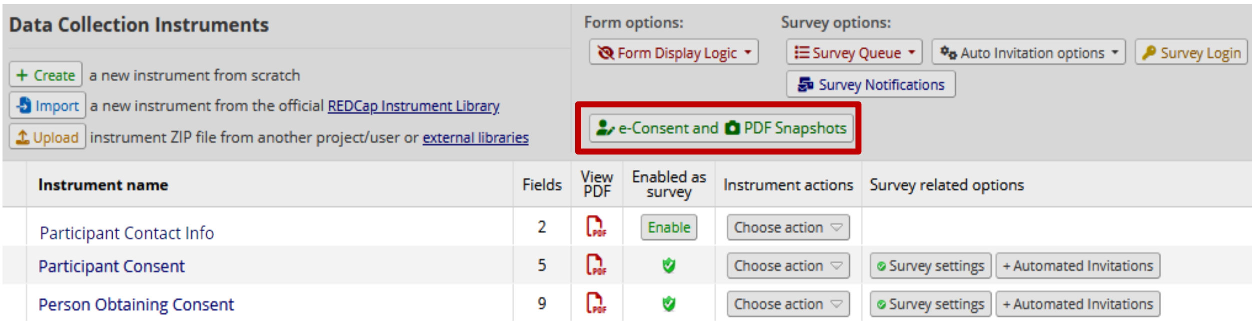
3. Scroll down to '**Survey Termination Options'** and edit the text in the **Survey Completion Text Box** which is set to default to "*Thank you for taking the survey. Have a nice day!*".

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.

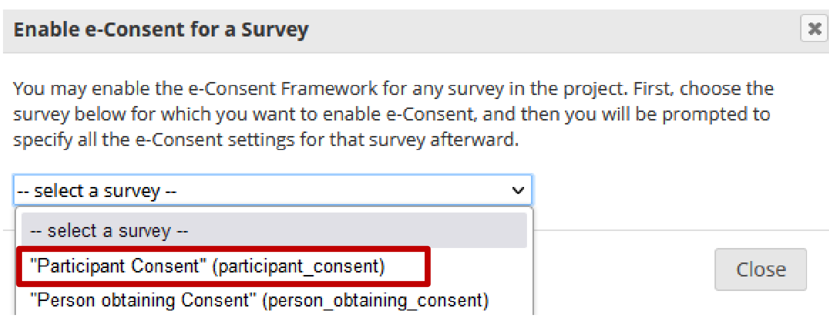


STEP 4: Enable the eConsent Framework

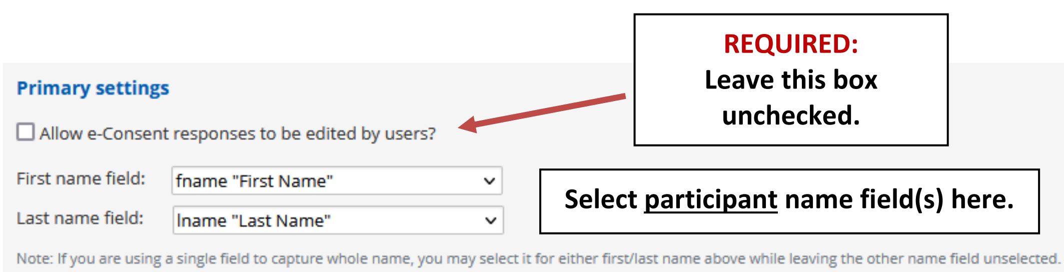
1. Once your surveys are enabled, return to the Online Designer and select the '**eConsent and PDF Snapshots**' option.



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



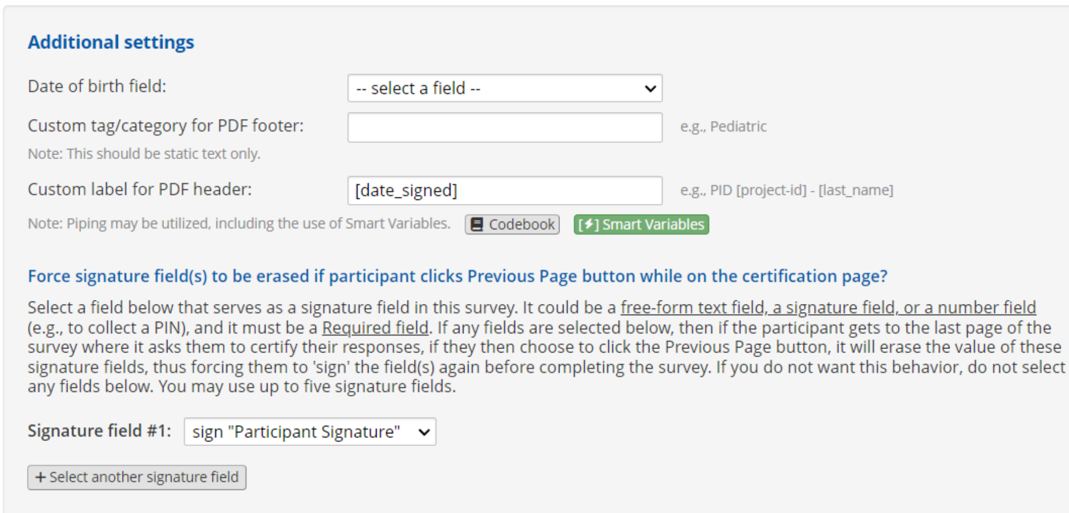
4. Configure the eConsent Framework settings.



   a. **Primary settings:**
      i. **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.

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**:



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.

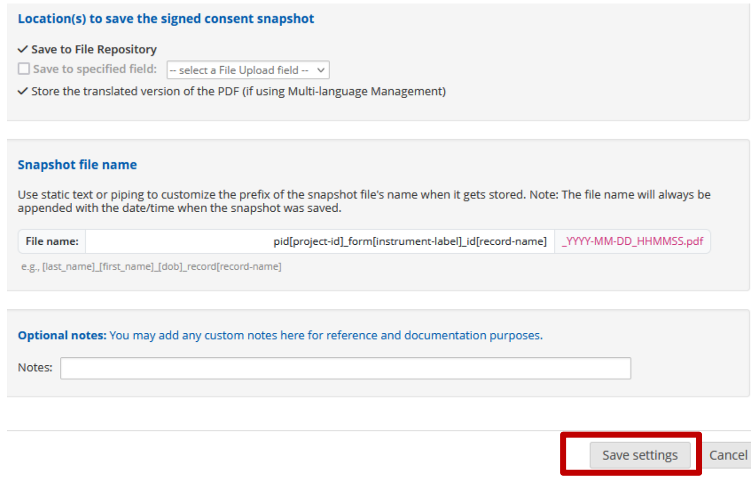
iii. **Signature field #1:** Associate your signature field here. If multiple signatures are required on a single eConsent instrument, you may add additional signature fields (e.g. Participant, Legally Authorized Representative).

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.

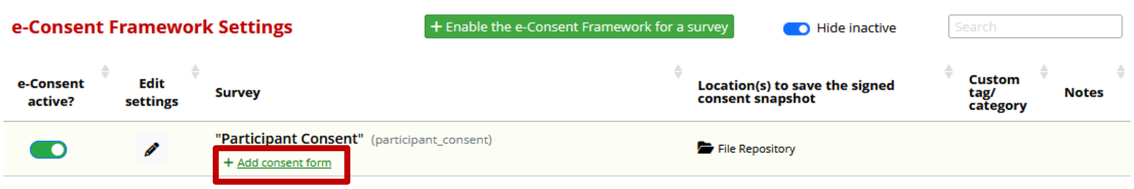
i. In the eConsent 'Edit Settings', you may customize the PDF Snapshot's file name or keep the default settings.

ii. Review and save the settings.



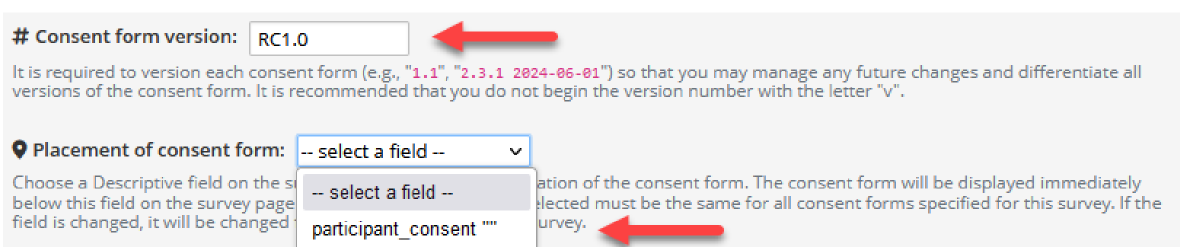
STEP 5: Upload your PDF Consent Form

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



   a. Click the "**Add consent form**".

2. Identify and upload the consent form.



   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 numbering system that beings with **"RC"** (REDCap).

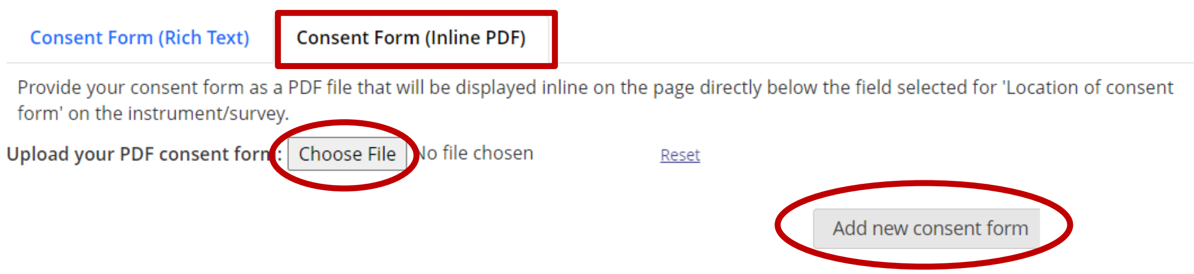
         1. Once a value is used for a survey, *it cannot be reused even in Development mode*. Duplicate or incorrect uploads cannot be deleted and may result in misalignment with your IRB-approved consent document versioning.

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**.

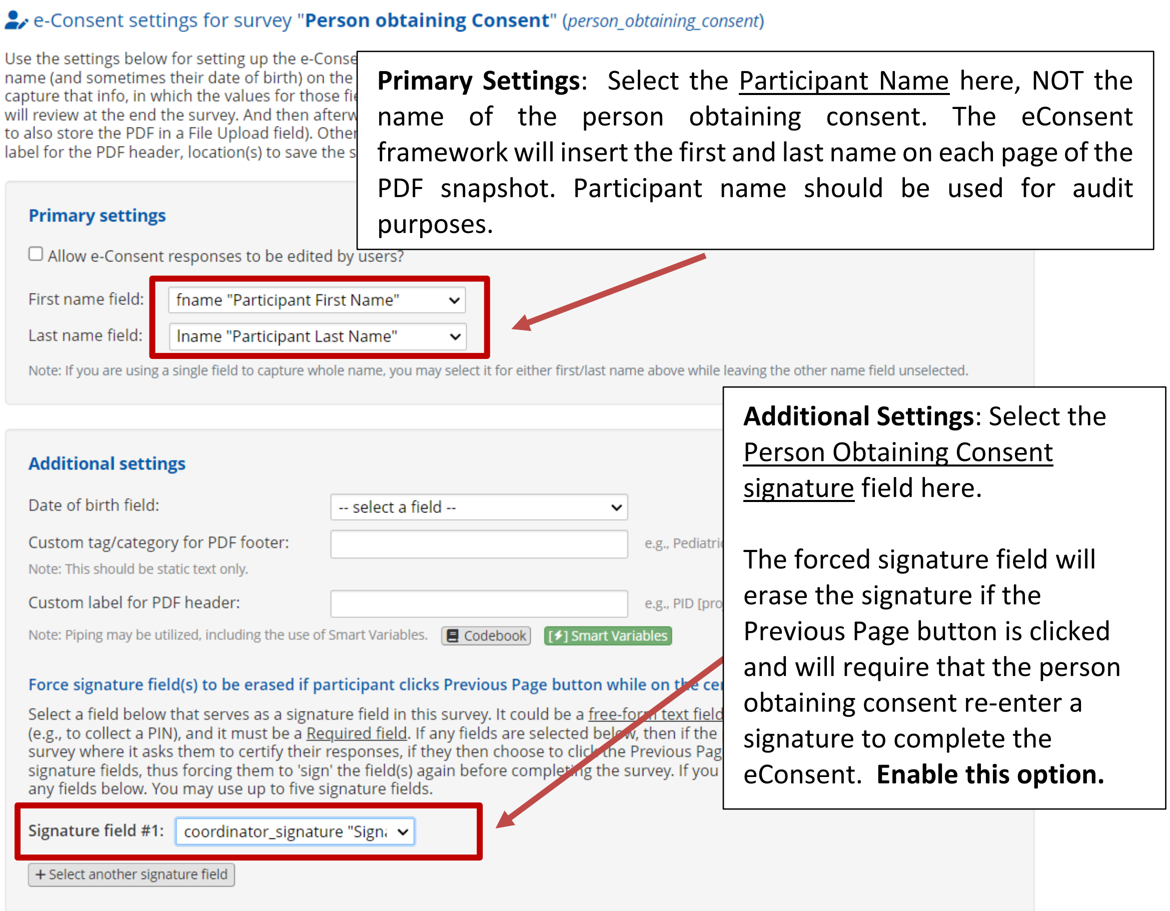


WARNING: If you upload an incorrect consent form, you cannot delete the PDF.

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.

Person Obtaining Consent

1. Repeat STEP 4 for the Person Obtaining Consent instrument with the following considerations.



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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***