

How do I build an eConsent?

[Copy & Paste or Type Content]

There are two ways to build an electronic consent document (eConsent) using REDCap. These instructions explain how to copy and paste (or type) content into REDCap. To build an eConsent by scanning an image of the consent form, please refer to [FAQ: Build an eConsent \[Scanned Image\]](#).

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

- STEP 1. Create a new project
- STEP 2. Build your eConsent document
- STEP 3. 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.

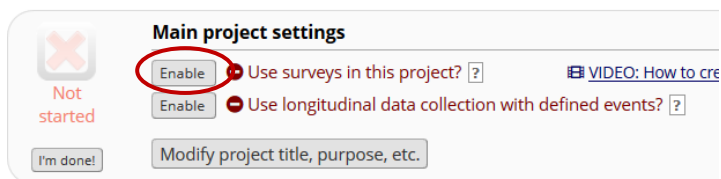
STEP 1: Create a new project

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 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 *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.

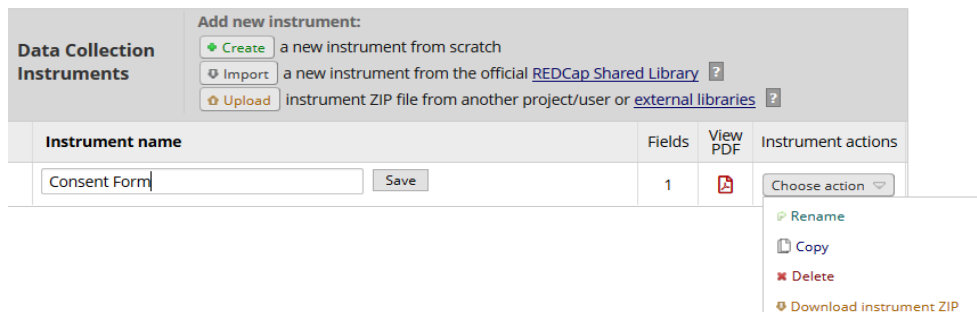
- a. Under **'Main Project Settings'** select the **'Enable'** button for the question **'Use surveys in this project?'**



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

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- 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'.

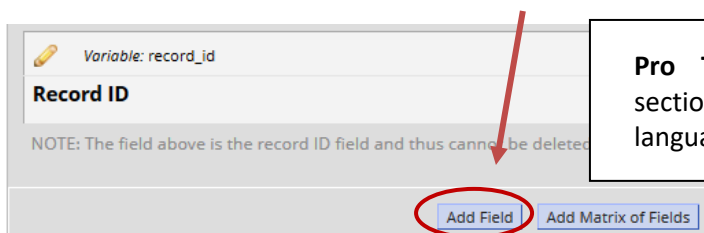


STEP 2: Build your eConsent document

- Select your newly named instrument to build your consent form.
- To insert the language from the consent document into the eConsent form, you will create a descriptive field that corresponds with each section of your consent document:

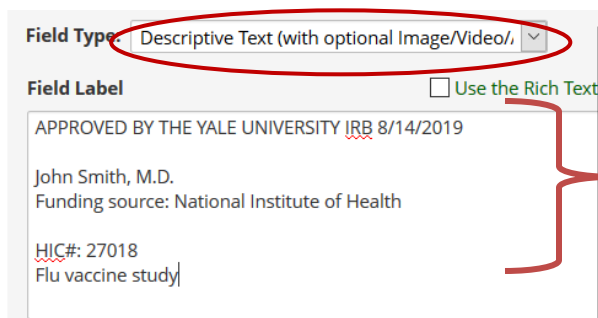
Pro Tip: To adjust the appearance of the eConsent, use the **rich text editor**. When you copy and paste the text from a Word document to REDCap, uncheck the rich text editor before pasting your text. After pasting the text, check the rich text editor to format your text.

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



Pro Tip: For lengthy consent document sections, divide up the section and copy the language into more than one descriptive field.

- Under the **Field Type** drop down menu, choose 'Descriptive Text'.



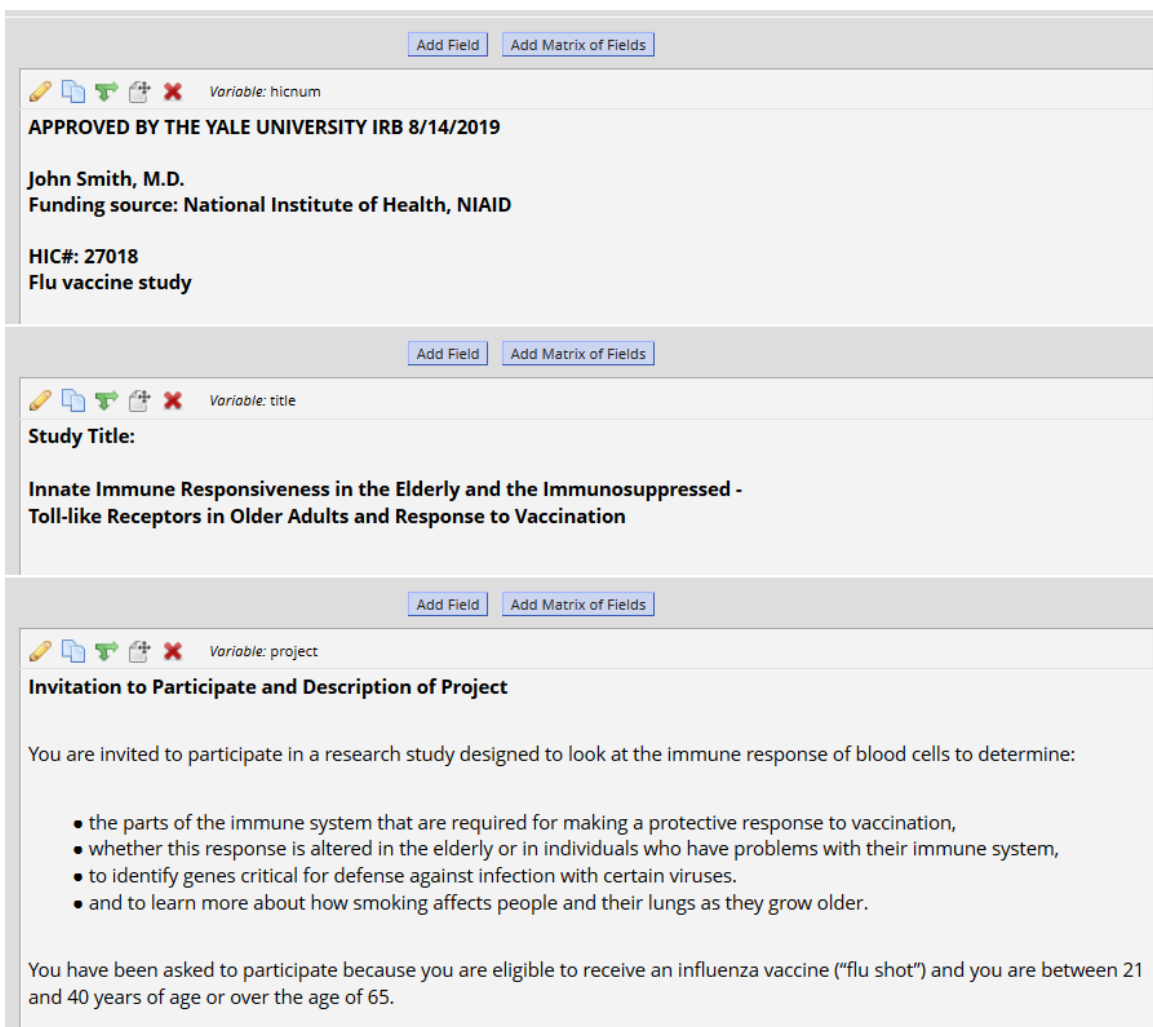
Pro Tip: The first field in your project should contain study information: *Study Title, Principal Investigator, Funding Source, IRB #, and IRB Approval Date.*

You may need to create placeholders (i.e. headers with no content) for *to-be-determined* fields such as IRB approval date. Remember to revisit your eConsent and update this information when you receive IRB approval.

Frequently Asked Question (FAQ) Library

- c. Insert the text from each section of your consent document into a **Field Label** and create a variable name. Repeat the process for the remaining sections of the consent form.
- d. In addition to formatting, there are other ways to customize your consent form including:
- i. **Inserting pictures and videos.**
 1. To insert pictures or videos, use the “Descriptive Text” field with the “Optional file attachment” features. See [FAQ: Insert Image, Insert Video](#)
 - ii. **Adding study-specific consent questions.**
 1. This may include questions about participation in optional study procedures (e.g. photographs, sharing data in a repository, future contact).

Your eConsent fields should look like this:



The image shows three examples of REDCap eConsent fields, each with a variable name and a descriptive text area.

Field 1: Variable: hicnum. Text: APPROVED BY THE YALE UNIVERSITY IRB 8/14/2019, John Smith, M.D., Funding source: National Institute of Health, NIAID, HIC#: 27018, Flu vaccine study.

Field 2: Variable: title. Text: Study Title: Innate Immune Responsiveness in the Elderly and the Immunosuppressed - Toll-like Receptors in Older Adults and Response to Vaccination.

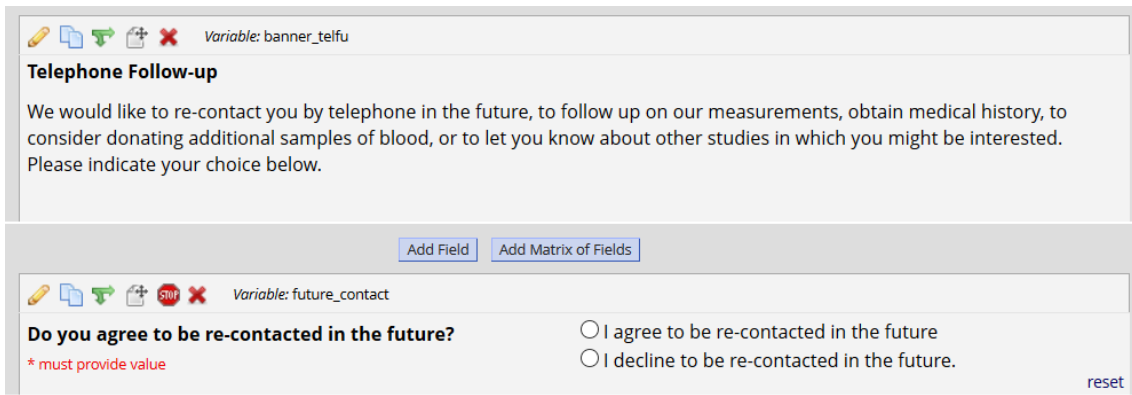
Field 3: Variable: project. Text: Invitation to Participate and Description of Project. You are invited to participate in a research study designed to look at the immune response of blood cells to determine:

- the parts of the immune system that are required for making a protective response to vaccination,
- whether this response is altered in the elderly or in individuals who have problems with their immune system,
- to identify genes critical for defense against infection with certain viruses.
- and to learn more about how smoking affects people and their lungs as they grow older.

You have been asked to participate because you are eligible to receive an influenza vaccine (“flu shot”) and you are between 21 and 40 years of age or over the age of 65.

Frequently Asked Question (FAQ) Library

(cont'd)



The screenshot shows the REDCap form editor interface. The top field is titled 'Telephone Follow-up' with variable name 'banner_telfu'. The text reads: '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 indicate your choice below.' Below this field are 'Add Field' and 'Add Matrix of Fields' buttons. The bottom field is titled 'Do you agree to be re-contacted in the future?' with variable name 'future_contact'. It contains two radio button options: 'I agree to be re-contacted in the future' and 'I decline to be re-contacted in the future.' A red asterisk indicates a required field. A 'reset' button is visible in the bottom right corner of the field editor.

3. Once the consent form language is complete, 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 entered the consent language, 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. Create 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](#).

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Your signature fields should look like this:

Authorization and Permission

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

By signing this form, I give permission to the researchers to use and give out information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to be in this research.

[Add Field](#) [Add Matrix of Fields](#)

Variable: date

Date Consent Form Signed Today M-D-Y
* must provide value

[Add Field](#) [Add Matrix of Fields](#)

Variable: fname

Participant First Name
* must provide value

[Add Field](#) [Add Matrix of Fields](#)

Variable: lname

Participant Last Name
* must provide value

[Add Field](#) [Add Matrix of Fields](#)

Variable: sign

Signature [Add signature](#)
* must provide value

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

4. 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 a survey.

Data Collection Instruments

Survey options: [Survey Queue](#) [Survey Login](#) [Survey Notifications](#) [Upload or download Auto Invitations](#)

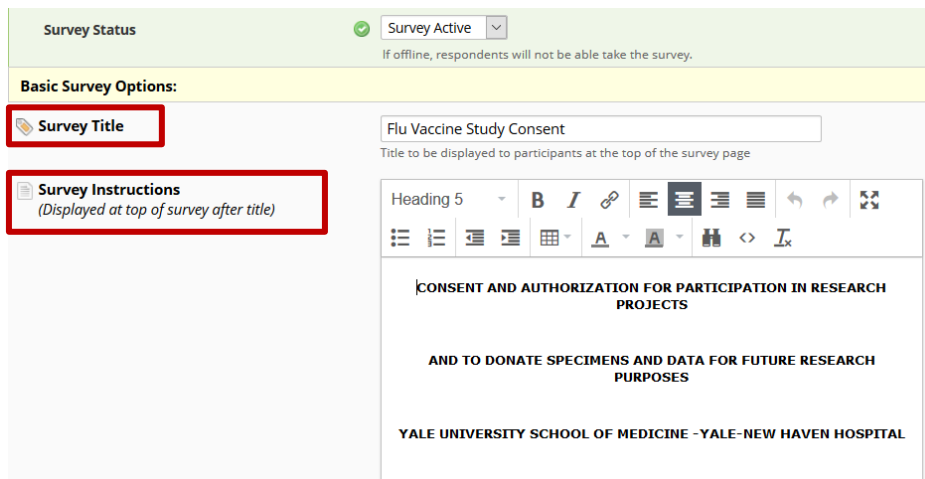
Add new instrument: [Create](#) a new instrument from scratch | [Import](#) a new instrument from the official REDCap Shared Library | [Upload](#) instrument ZIP file from another project/user or external libraries

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
Consent Form	2		Enable	Choose action	

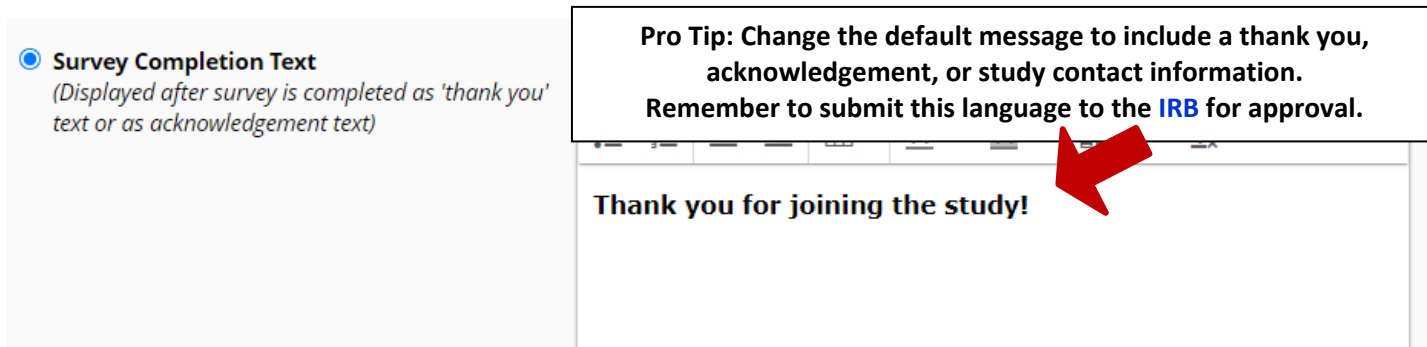
Frequently Asked Question (FAQ) Library

STEP 3: Enable Settings with eConsent Framework and Auto Archiver

- 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.

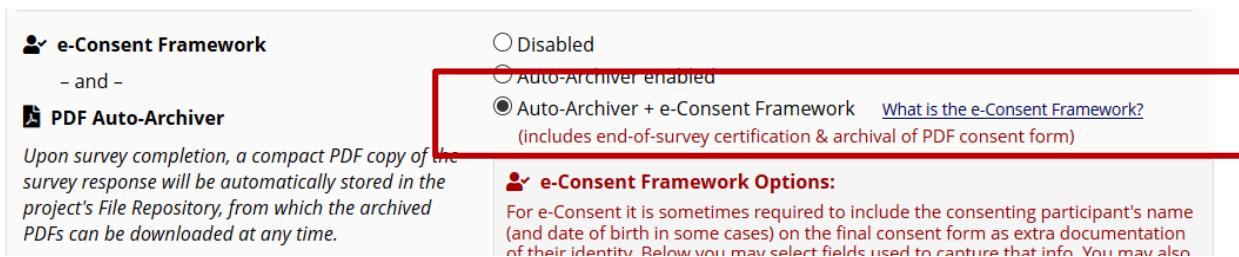


- Once you have entered your title and header, scroll down to '**Survey Termination Options**' and edit the text in the **Survey Completion Text Box** which is set to default to "Thank you for taking the survey. Have a nice day!".



Pro Tip: Change the default message to include a thank you, acknowledgement, or study contact information. Remember to submit this language to the IRB for approval.

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



Frequently Asked Question (FAQ) Library

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.

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 of 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:

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.

Because the IRB approval date is included in the Descriptive Field 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 2 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**

- 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 1.
- ii. **Date of Birth field:** Do not include.

Optional fields (these are not always necessary for e-Consent):

e-Consent type: e.g., Pediatric

Date of birth field:

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:

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- i. Identify the field in STEP 2 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](#)