

# eConsenting Using REDCap – Instructions

## Introduction

This guide describes how you can use REDCap to administer electronic Informed Consents. Each consent is implemented in REDCap using the survey functionality. The survey functionality presents the pages of the traditional paper consent, including the IRB stamp, to a potential research subject, then uses REDCap to present the questions and signature fields that appear on the paper consent. Once an individual agrees to participate, electronically signs the informed consent, then hits submit, a PDF of the completed consent *can* be automatically generated and saved in REDCap to preserve the exact consent text along with the research subject's responses (you must configure this in the survey settings).

If you do not want to build the eConsent form from scratch you can use the eConsent project template when creating a new REDCap project, that you would then modify for your project needs, such as uploading your project-specific Informed Consent and adding additional data fields to collect the subject's responses that are relevant to your study's ICF.

Home My Projects **+ New Project** Help & FAQ Training Videos Send-It Control Center

**+ Create a new REDCap Project**

**Project creation option:**

Upload a REDCap project XML file (CDISC ODM format) ?

Use a template (choose one below)

<input type="radio"/>	Piping Example Project	Contains a single data collection instrument enabled as a survey, which contains questions to demonstrate the Piping feature.
<input type="radio"/>	Project Dashboards, Smart Functions, Smart Tables, & Smart Charts	Example of Project Dashboards, Smart Functions, Smart Tables, & Smart Charts with fifty records included.
<input type="radio"/>	Randomized Clinical Trial	Contains seven data entry forms for collecting data for a randomized clinical trial. Includes a short demographics form followed by a form where randomization is performed. An example randomization model has already been set up,... <a href="#">Show more</a>
<input type="radio"/>	Repeating Instruments	Example classic project showcasing the Repeating Instruments functionality.
<input type="radio"/>	Single Survey	Contains a single data collection instrument enabled as a survey, which contains questions to demonstrate all the different field types.
<input checked="" type="radio"/>	<b>UCH eConsent Template</b>	Use the following template to start your eConsent project. The eConsent will need to be customized depending on the type of study you are conducting. All ICFs must be approved by the IRB in Word document version/format, using the... <a href="#">Show more</a>

You can use the process described on the following pages to make a stand alone consent or make the consent the first step in a larger project that includes data collection forms and other surveys.

## Requirements

You will need an electronic PDF of the IRB-approved and stamped informed consent form, which can be obtained in *myIRB* under *Stamped Documents*.

## Instructions for Creating the eConsent form:

- 1) Obtain an electronic PDF version of the stamped, IRB-approved Informed Consent, which can be found in *myIRB* under *Stamped Documents*, and save it to your computer.
- 2) Open the PDF file of the Informed Consent on your computer and save it as a JPEG or PNG file (this will make each page of the Informed Consent its own separate image). Save these JPEG or PNG files to your computer with the current date in the title of the file.
- 3) In your REDCap survey form, using the “Descriptive Text (with optional Image/Video/Audio/File attachment)” fields type, upload each *individual* page of the Informed Consent with the display type as an ‘Inline image.’
- 4) Add a ‘Descriptive Text’ field type between each page of the ICF that lets the users know to click on ‘Next Page’ in the survey to view the full ICF documents.
- 5) Add a ‘Begin New Section’ field type between each page of the ICF and the instructional ‘Descriptive Text’ fields so that *each page of the ICF is it’s own page in the survey*.

Note: If the Informed Consent is 20 pages long, you’ll need to create 20 Descriptive Text fields since each Descriptive Text field can only accommodate one JPEG or PNG upload.

The screenshot shows the 'Edit Field' dialog box in REDCap. The 'Field Type' is set to 'Descriptive Text (with optional Image/Video/Audio/File attachment)'. The 'Variable Name' is 'icf\_page1'. The 'Field Label' is empty. The 'Action Tags / Field Annotation' is empty. The 'Optional file attachment, image, audio, or video' section is active, showing 'Embed an external video' and 'Attach an image, file, or embedded audio'. The 'Attach an image, file, or embedded audio' option is selected, and the file name '2017-09-21 at 2.18.56 PM.png' is entered. The 'Display format of attachment on page' is set to 'Inline image'. The 'Save' and 'Cancel' buttons are at the bottom.

**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 \(4 min\)](#).

**Field Type:** Descriptive Text (with optional Image/Video/Audio/File attachment)

**Question Number (optional)**

Displayed only on the survey page

**Field Label** [How to use Piping](#)

**Action Tags / Field Annotation (optional)**

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

**Variable Name (utilized during data export)**

icf\_page1  Enable auto naming of variable based upon its Field Label?

ONLY letters, numbers, and underscores

**Optional file attachment, image, audio, or video:**

**Embed an external video** (provide video URL)

e.g. <https://youtube.com/watch?v=E1cCuWMupz0>,  
<https://vimeo.com/62730281>,  
<http://example.com/movie.mp4>

Display format of video:  Inline  Inside popup

- or -

**Attach an image, file, or embedded audio**

[2017-09-21 at 2.18.56 PM.png](#) [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**

Each page of the Informed Consent, when uploaded to the 'Descriptive Text' fields, will look something like this:

Variable: icf\_page1

Study ID: [REDACTED] Date Approved: 10/26/2018 Expiration Date: 7/26/2019

 Institutional Review Board  
UNIVERSITY of FLORIDA



**INFORMED CONSENT FORM**  
*to Participate in Research, and*  
**AUTHORIZATION**  
*to Collect, Use, and Disclose Protected Health Information (PHI)*

We ([REDACTED], on behalf of the University of Florida Institute of Aging) are asking permission from you,

\_\_\_\_\_

*Printed name of study participant ("study subject")*

to store some of your personal and contact information in a registry of volunteers who have expressed an interest in taking part in future research; we will build and maintain this registry in order for investigators to be able to contact you with information about future research.

The Principal Investigator (the person in charge of this research) or a representative of the Principal Investigator will describe this contact information registry bank to you and answer all of your questions. Your participation is entirely voluntary. Before you decide whether or not to take part, please read the information below and ask questions about anything you do not understand. If you choose not to participate in this study you will not be penalized or lose any benefits that you would otherwise be entitled to.

**1. What are we asking to store?**

If you agree, the following contact and personal information will be collected and stored in our participant registry:

- name,
- address,
- home phone number,

- 6) Add instructions to click on Next Page using a “Descriptive Text” field type. Do this for every page of the ICF. This is so the potential subjects know to go to the next page in the survey.

**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 \(4 min\)](#).

**Field Type:** Descriptive Text (with optional Image/Video/AI)

**Question Number** (optional)   
Displayed only on the survey page

**Field Label**  
<center>Click on Next Page to go to Page 2</center>

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

**Variable Name** (utilized in logic, calcs, and exports)  
page1  Enable auto naming of variable based upon its Field Label?  
ONLY letters, numbers, and underscores

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

Optional file attachment, image, audio, or video:  
 **Embed an external video** (provide video URL) [?](#)  
  
e.g. <https://youtube.com/watch?v=E1cCuWMupz0>,  
<https://vimeo.com/62730281>,  
<http://example.com/movie.mp4>  
Display format of video:  Inline  Inside popup  
- or -

Once added, these “Descriptive Text” fields should look similar to this on the survey:

Click on Next Page to go to Page 3

<< Previous Page

Next Page >>

Save & Return Later

- 7) Once all pages have been uploaded, create a blank “Begin New Section (with optional text)” field **between each page** of the Informed Consent so that *each page* of the Informed Consent will be on a *separate page* of the survey.

**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 \(4 min\)](#).

Field Type:

Field Label

- 8) After uploading the pages of the ICF, add another “Descriptive Text” field right after the images and upload the PDF copy of the Informed Consent that you got from myIRB for the potential participant to download *before agreeing* to consent, with the display type being ‘Link.’

**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 \(4 min\)](#).

Field Type:

Question Number (optional)

Displayed only on the survey page

Field Label

Copy of Informed Consent for download.

Please click on the PDF document below to download and save to your computer.

Action Tags / Field Annotation (optional)

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

Variable Name (utilized in logic, calcs, and exports)

Enable auto naming of variable based upon its Field Label?

ONLY letters, numbers, and underscores

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

Optional file attachment, image, audio, or video:

Embed an external video (provide video URL) [?](#)

e.g. <https://youtube.com/watch?v=E1cCuWMupz0>,  
<https://vimeo.com/62730281>,  
<http://example.com/movie.mp4>

Display format of video:  Inline  Inside popup

- or -

Attach an image, file, or embedded audio

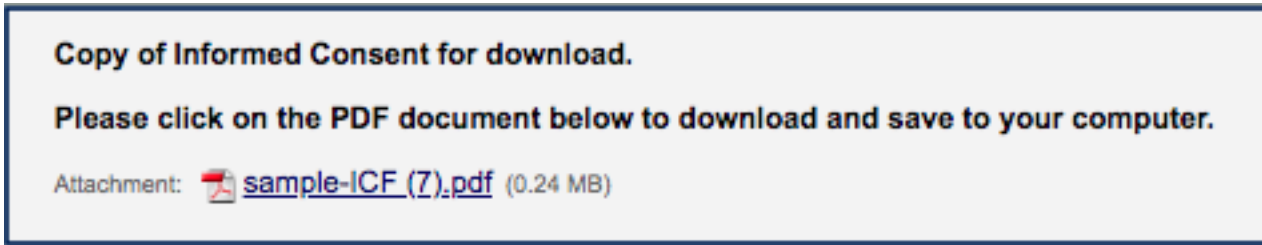
[sample-ICF \(7\).pdf](#)

Display format of attachment on page:

Link   
 Inline image  
 Audio file (play in embedded player on page)

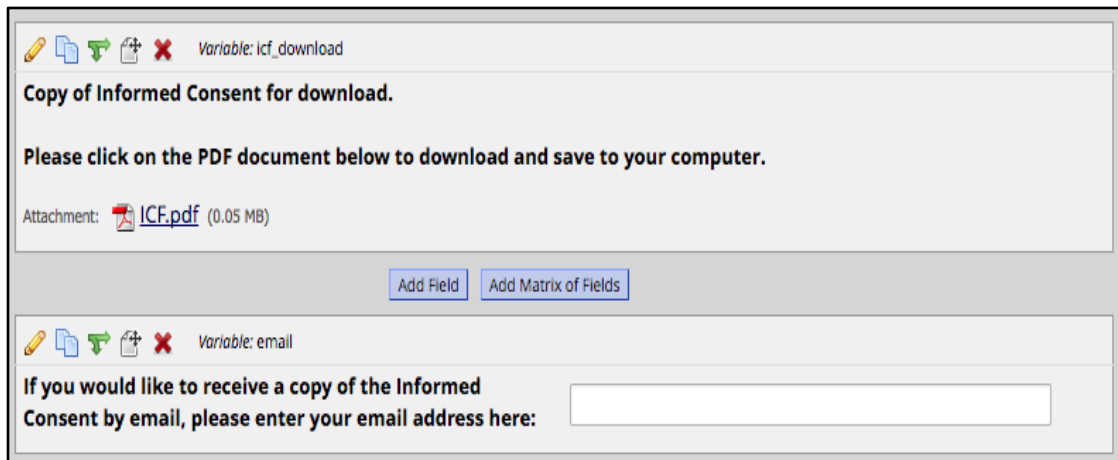
This will allow the subjects to download the ICF for themselves so they can review prior to consenting.

This is how the field looks on a survey:



9) *Optional:* To allow the participant to email a copy of the Informed Consent to themselves (instead of downloading it to their computer/device as shown above), add a “Text Box” field type (validated as an ‘Email’) to capture the subject’s email address.

**Note:** If you collect the participant’s email address as part of the eConsent process, the participant’s email address **will be stored in the system permanently** unless you go in and manually delete it from the eConsent form. They will also be able to download a copy of the signed consent form once they submit the eConsent **without** having to store their email address in the system.



If emailing them a copy of the ICF, make sure you specify that in the ‘Field Note’ that “*Your email address will not be used for any other purpose.*”







10) Create a “Signature” field type to capture the participant’s signature.

The screenshot shows the 'Edit Field' configuration interface in REDCap. At the top, it says 'Edit Field' with a close button. Below is an introductory paragraph: '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 [IBI Field Types video \(4 min\)](#).' The 'Field Type' is set to 'Signature (draw signature with mouse or finger)'. The 'Question Number' is optional and empty. The 'Field Label' contains the text 'Please click on the link to the right to add your signature.' The 'Variable Name' is 'signature', with a checkbox for 'Enable auto naming of variable based upon its Field Label?' which is unchecked. Below this are links for 'Smart Variables' and 'Piping'. The 'Required?' section has 'Yes' selected. The 'Identifier?' section has 'Yes' selected. The 'Custom Alignment' is set to 'Right / Vertical (RV)'. The 'Field Note' is optional and empty.

11) Add any additional data fields to the consent form in REDCap that you want to capture from the participant, such as their agreement to be in the study, their first and last name, the consent date and time, their email address (for emailing a copy of the consent form), etc. **Make sure you mark each field as ‘Required’ so they cannot submit the eConsent form without filling in all required data fields.**

Note: You can add branching logic to the additional data fields so that they do not appear if the subject does not agree to be in the study.

Note: If your study is deemed more than ‘low-risk’ by the IRB, you will need to add fields to collect the consenters’ name and signature. See next 2 pages for examples.







 Variable: agree\_yn







**Do you agree to participate in the study?**

\* must provide value

Yes  
 No

reset







---







 Variable: icf\_first\_name    *Branching logic: [agree\_yn] = '1'*

**Your First Name:**

\* must provide value







---







 Variable: icf\_last\_name    *Branching logic: [agree\_yn] = '1'*

**Your Last Name:**

\* must provide value







---







 Variable: signature    *Branching logic: [agree\_yn] = '1'*

**Please click on the link to the right to add your signature.**

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

---








 Variable: icf\_date    *Branching logic: [agree\_yn] = '1'*




**Today's date:**

\* must provide value

M-D-Y  
 MM-DD-YYYY













 Variable: email

**If you would like to receive a copy of your signed Informed Consent by email, please enter your email address here:**






Note: Your email address will not be used for any other purpose.

---







 Variable: office\_use\_header *Branching logic: [agree\_yn] = '1'*

**-----Office use only -----**



---








 Variable: consenter\_name *Branching logic: [agree\_yn] = '1'*

**Signature of person obtaining consent and authorization**

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


---








 Variable: consenter\_date *Branching logic: [agree\_yn] = '1'*

**Today's date**

\* must provide value


 M-D-Y

---






 Variable: not\_agree *Branching logic: [agree\_yn] = '0'*

**Thank you for your interest. If you agree to participate in the future, please let us know. You can close this window or click on Submit below.**

This is the end of the instructions for building the eConsent. The next page starts the instructions for completing the survey settings of the eConsent.

## Survey Settings for the eConsent Form:

Once the eConsent form is built, enable it as a survey on the 'Online Designer' page and then configure your survey settings by clicking on 'Survey Settings' on the 'Online Designer' page:

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
eConsent Form	21			Choose action ▾	Survey settings  + Automated Invitations
Saved Consents	3		Enable	Choose action ▾	

- 1) Under *Survey Customizations*, select the following:
  - a. Question Display Format – 'One section per page (multiple pages).'
  - b. Allow participants to download a PDF copy of their responses at the end of the survey – 'Yes.'

**Survey Customizations:**

**Question Numbering** Custom numbered ▾  
Question numbers will not display correctly if using auto numbering if some questions have branching logic employed. Question auto numbering has been automatically disabled because some of your survey questions use branching logic.

**Question Display Format**  
*(One page or multiple pages?)*  
**One section per page (multiple pages) ▾**  
 Display page numbers at top of survey page  
 Hide the 'Previous Page' button (i.e., Back button) on the survey page  
(prevents respondents from going back to previous pages)

**Allow participants to download a PDF of their responses at end of survey?**  
**Yes ▾**  
This option will not be available if the Survey Auto-continue or Survey Queue auto-start option is enabled. Also, if a field utilizes the @HIDDEN action tag, it will not be displayed in the PDF.

For Question Display Format, select **One section per page (multiple pages)**.

- This will make each page of the ICF its own page in the survey.

**Allow participants to download a PDF of their responses at the end of the survey? – Yes.**

- This will allow the subject to download their signed ICF once they submit the eConsent.

- 2) Under *Survey Access*, select:
  - a. 'Yes' for 'Allow "Save & Return Later" option for respondents?'
  - b. Check "Allow respondents to return without needing a return code'.
  - c. **DO NOT SELECT** 'Allow respondents to return and modify completed responses'.

**Allow 'Save & Return Later' option for respondents?**  
*(Allow respondents to leave the survey and return later.)* ?

**Yes ▾**

Allow respondents to return without needing a return code ?

Allow respondents to return and modify completed responses ?

3) Under *Survey Termination Options*, select either Auto-Archiver or Auto Archiver + eConsent Framework:

- a. Auto-Archiver: This option saves a PDF copy of the eConsent in the project’s File Repository (not in the individuals record). If needed, the archived PDFs can be downloaded at any time and manually saved to the individuals record in a *File Upload* field.

To enable: Go to *Survey Settings* for the *eConsent Form* instrument, towards the bottom, under *Survey Termination Options*, click on *Auto-archiver enabled*, then click *Save Changes*.

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
eConsent Form	21			Choose action ▾	<input checked="" type="radio"/> Survey settings <input type="radio"/> +Automated Invitations
Saved Consents	3		Enable	Choose action ▾	

**PDF Auto-Archiver**  
 Upon survey completion, a compact PDF copy of the survey response will be automatically stored in the project's File Repository, from which the archived PDFs can be downloaded at any time.

Disabled  
 Auto-Archiver enabled  
 Auto-Archiver + e-Consent Framework [What is the e-Consent Framework?](#)  
 (includes end-of-survey certification & archival of PDF consent form)

- b. Auto-Archiver + eConsent Framework: This option has two components. 1) It automatically saves a PDF copy of the eConsent in the project’s File Repository, which can be downloaded later. 2) It also includes an extra certification page at the end of the survey that displays an in-line PDF copy of the survey responses in which the respondent will be asked to confirm that all of the information in the document is correct. Once the respondent confirms the information is correct, the survey will be marked as complete. This option also allows you to have versioning of a form.

To enable: Go to *Survey Settings* for the *eConsent Form* instrument, towards the bottom, under *Survey Termination Options*, click on *Auto-Archiver + e-Consent Framework*, enter the e-Consent version and the First and Last name fields then click *Save Changes*.

**PDF Auto-Archiver**  
 Upon survey completion, a compact PDF copy of the survey response will be automatically stored in the project's File Repository, from which the archived PDFs can be downloaded at any time.

Disabled  
 Auto-Archiver enabled  
 Auto-Archiver + e-Consent Framework [What is the e-Consent Framework?](#)  
 (includes end-of-survey certification & archival of PDF consent form)

**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 the survey, after which that PDF 'hard-copy' will be archived in the File Repository. [Read more](#)

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.

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

e-Consent type:  e.g., Pediatric

Date of birth field:

**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 the survey, after which that PDF 'hard-copy' will be archived in the File Repository. [Read more](#)

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.

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

e-Consent type:  e.g., Pediatric

Date of birth field:

**Note:** the *Auto-Archive* feature only works if the eConsent is distributed as a **survey**. For non-survey responses, a manual download of the ICF PDF and subsequent PDF upload into the record or File Repository must be done to comply with IRB rules on versioning.

- 4) Optional: Under *Survey Termination Options*, select:
  - a. “Yes” for “Send confirmation email (optional)?”
  - b. Fill out the ‘From’ (your email address), ‘Subject line,’ and any text you want include in the email.
  - c. Attach the stamped PDF copy of the ICF where it says ‘Attachment.’
    - i. This will send the subject a copy of ICF via email if they provided an email address on the consent form. **This is a copy of the unsigned consent, not a copy of the completed, signed consent.**
    - ii. **If you want to send the subject a PDF copy of the completed, signed consent click on ‘Include PDF of completed survey as attachment’.**
  - d. Click on ‘Save Changes’ when finished.
  - e. If you decide to use the Send Confirmation email option, please see the next section called “Instructions for Setting Up the Confirmation Email with the PDF of the ICF” to complete the setup.

**Send confirmation email (optional)?**  
(Email the respondent when they complete the survey)

**Yes** ▾

Provide email subject, email message, and (optionally) an attachment to be sent to respondent when they complete the survey. [How to use Piping here](#)

From:

Subject:

Compose Preview Send test email

Here is a copy of the consent form

Attachment:  Consent.pdf unsigned consent

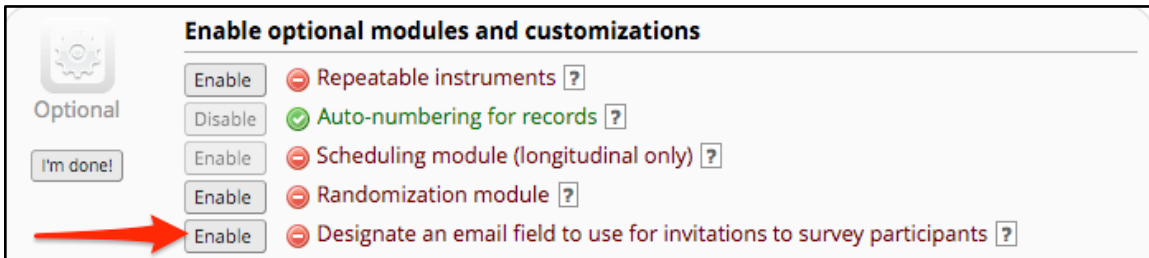
**Include PDF of completed survey as attachment**

**WARNING:** Since email is not considered a secure form of communication, the PDF attachment option is NOT recommended if the survey contains questions asking for identifying information (e.g., PHI).

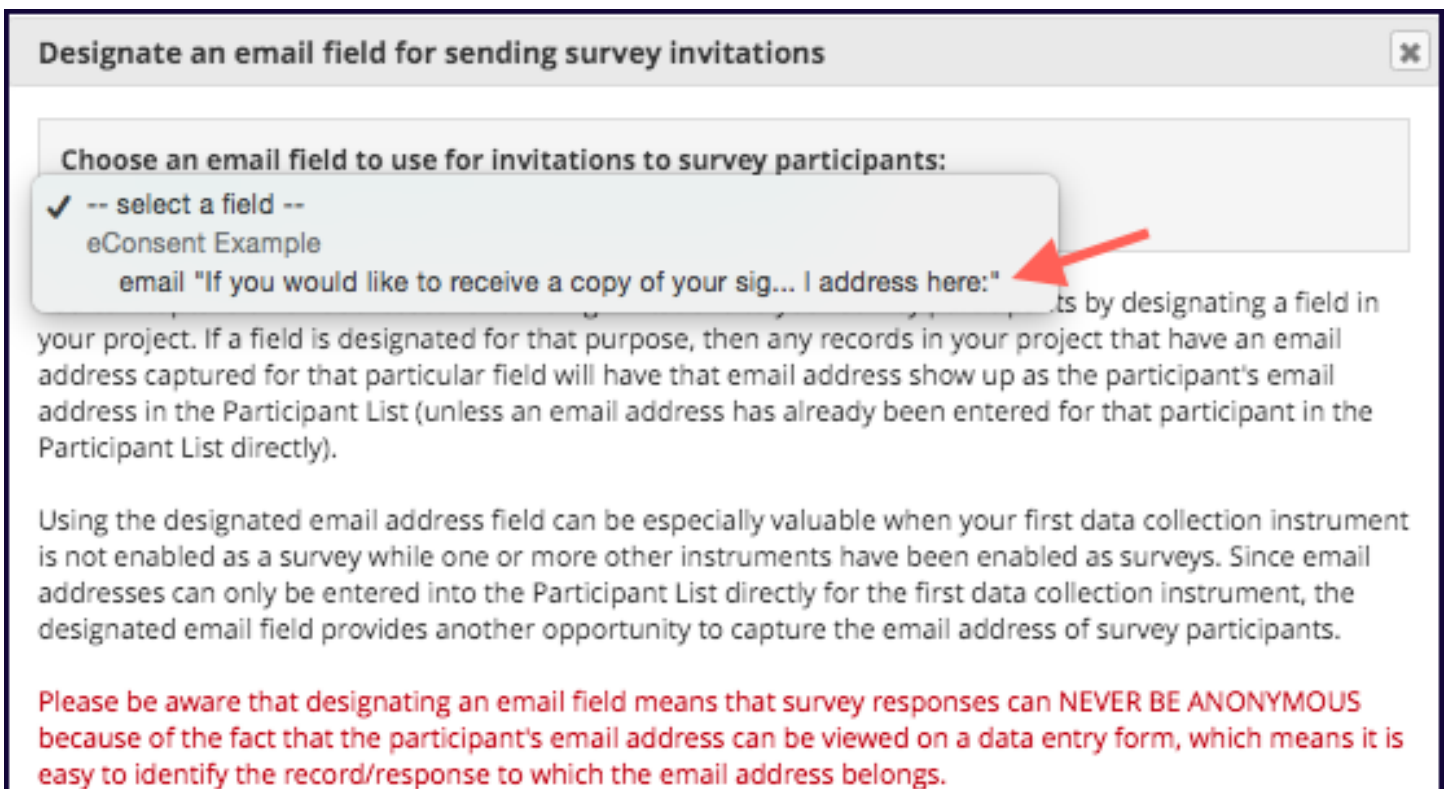
Please see the next page with the section called “Instructions for Setting Up the Confirmation Email with the PDF of the ICF” to complete the setup.

## Instructions for Setting Up the Confirmation Email with the PDF of the ICF:

- 1) Go to the *Project Setup* page.
- 2) Under 'Enable optional modules and customizations,' click on 'Enable' next to "Designate an email field to use for invitations to survey participants."



- 3) Select the field that you created to collect the subject's email and click on 'Save.'



- 4) This will email the subject a PDF copy of the **unsigned Informed Consent** to the email address they provided on the eConsent form.  
Note: this will save a copy of the subject's email addresses in the database. This is PHI.
- 5) **To email the subject a PDF of the completed, signed consent to the email address they provided, click on 'Include PDF of completed survey as attachment'.**

**Send confirmation email (optional)?**  
 (Email the respondent when they complete the survey)

Yes ▾

Provide email subject, email message, and (optionally) an attachment to be sent to respondent when they complete the survey. [How to use Piping here](#)

From: j.johnston@ufl.edu ▾

Subject:

Compose Preview Send test email

Here is a copy of the consent form

Attachment: Choose File Consent.pdf ← **unsigned consent**

Include PDF of completed survey as attachment

⚠ WARNING: Since email is not considered a secure form of communication, the PDF attachment option is NOT recommended if the survey contains questions asking for identifying information (e.g., PHI).

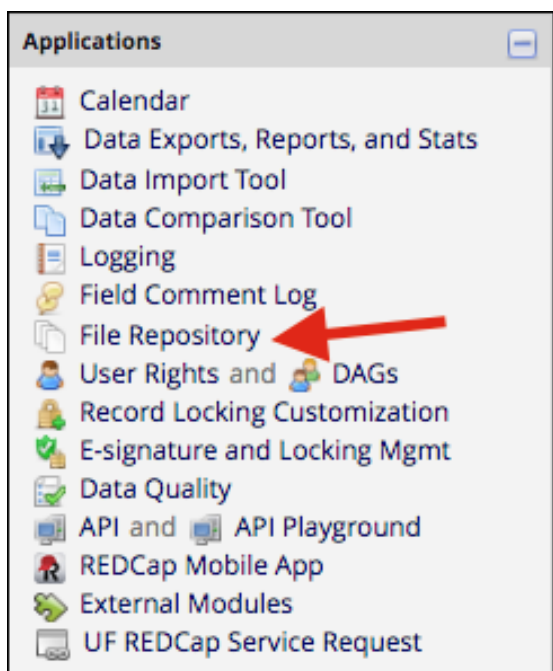
Must select this if you want to send a PDF copy of the completed, signed consent to the subject.

## File Repository:

- 1) **File Repository:** this page may be used for storing and retrieving files and documents used for this project. You may upload files here to save for retrieval later, or you may download previously uploaded files in the file list below. Whenever a data export is performed, the resulting data and syntax files are stored here also.

This is where the consents will be archived by the Auto-archiver or the Auto-archiver and eConsent Framework..

The project's file repository is located on the left side *Applications Menu*.



**File Repository**

This page may be used for storing and retrieving files and documents used for this project. You may upload files here to save for retrieval later, or you may download previously uploaded files in the file list below. Whenever a data export is performed, the resulting data and syntax files are stored here also.

[User Files](#)
[Data Export Files](#)
[PDF Survey Archive](#) (highlighted with a red arrow)
 [Upload New File](#)

Displayed below are PDF files that have been automatically captured and stored by the PDF Auto-Archiver setting, which has been enabled by one or more surveys on their Survey Settings page. Only users with 'Full data set' data export privileges will be able to download the archived files. Note: The PDFs below are archived when a participant completes a survey, which means they might be different from other downloadable PDFs in the project that are generated on demand using the current data.

Show  entries Search

Survey Completion Time	Record	Survey	Repeat Instance	Download
11/19/2018 10:35am	<u>2</u>	Informed Consent Form	1	
11/19/2018 10:34am	<u>1</u>	Informed Consent Form	1	

Previous  Next

If needed you can download a PDF copy of the consent and save it to the participant’s record. You can also download the PDF copy of the consent for the IRB.

In the *File Repository*, click on the *PDF* icon in the *Download* column.





**File Repository**

This page may be used for storing and retrieving files and documents used for this project. You may upload files here to save for retrieval later, or you may download previously uploaded files in the file list below. Whenever a data export is performed, the resulting data and syntax files are stored here also.

[User Files](#)
[Data Export Files](#)
[PDF Survey Archive](#)
[Upload New File](#)

Displayed below are PDF files that have been automatically captured and stored by the PDF Auto-Archiver setting, which has been enabled by one or more surveys on their Survey Settings page. Only users with 'Full data set' data export privileges will be able to download the archived files. Note: The PDFs below are archived when a participant completes a survey, which means they might be different from other downloadable PDFs in the project that are generated on demand using the current data.

Show  entries

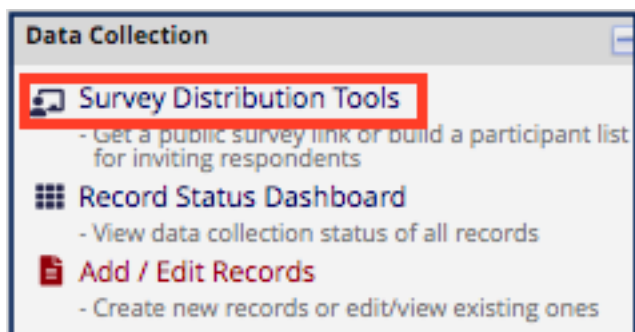
Survey Completion Time	Record	Survey	Repeat Instance	Download
11/19/2018 10:35am	<a href="#">2</a>	Informed Consent Form	1	
11/19/2018 10:34am	<a href="#">1</a>	Informed Consent Form	1	

**Optional:** There is an external module named ‘Save Survey PDF to a Field’ that will automatically save a PDF copy of the completed, signed consent directly to the subject’s record in a ‘File Upload’ field on a form, besides saving a copy in the File Repository.

## Test Your Project Thoroughly

Once you’re finished building the consent, have configured the survey settings, enabled the *Save Survey PDF to Field* Module, and have enabled survey notifications, test out the eConsent form and make sure you receive the Survey Confirmation email and the automatic uploading of the signed ICF into File Repository in the project.

The quickest way to do this is to go ‘Survey Distribution Tools’ (under *Data Collection*) and then click on ‘Open Public Survey.’



**Data Collection**

- Survey Distribution Tools**  
- Get a public survey link or build a participant list for inviting respondents
- Record Status Dashboard**  
- View data collection status of all records
- Add / Edit Records**  
- Create new records or edit/view existing ones

Public Survey URL:

### Link Actions

- [↪ Open public survey](#)
- [↪ Open public survey + ↪ Log out](#)
- [✉ Send me URL via email](#)
- [📄 Survey Access Code or QR Code](#)

### Link Customizations

- [🔗 Get Short Survey Link](#)
- [🌿 Create Custom Survey Link](#)
- [</> Get Embed Code](#)

Fill out the eConsent as you would if you were a subject and submit it.


## Re-Consenting Subjects Using a Revised Consent Form and/or Updating the Consent Form

If a subject needs to sign a **revised** consent form or the consent form needs to be replaced with a newer version, you'll need to replace the ICF in the existing project or create a new project that contains the revised/updated consent form.

If you create a new project, just follow the same steps outlined above.

To replace the existing ICF in your current project, follow the steps below.

- 1) **Make sure all records have a saved copy of the PDF of the signed eConsent. Once you change the ICF in the project, all existing records will have this new ICF showing up on the eConsent page. This is why the automated saving of the signed ICFs is crucial.**
- 2) Obtain an electronic PDF version of the new/revised stamped, IRB-approved Informed Consent, which can be found in *myIRB* under *Stamped Documents*, and save it to your computer.
- 3) Open the PDF file of the Informed Consent on your computer and save it as a JPEG or PNG file (this will make each page of the Informed Consent its own separate image). Save these JPEG or PNG files to your computer with the current date in the title of the file.
- 4) Click on *Online Designer* on the Project Setup page.
- 5) Click on *Enter Draft Mode*.



**Design your data collection instruments & enable your surveys**

Add or edit fields on your data collection instruments (survey and forms). This may be done by either using the Online Designer (online method) or by uploading a Data Dictionary (offline method). You may then enable your instruments to be used as surveys in the Online Designer.

Quick links: [Download PDF of all instruments](#) OR [Download the current Data Dictionary](#)

Go to  or

Learn how to use

**NOTE:** The project is currently in PRODUCTION status, and thus changes cannot be made in real time to the project as when in Development status. However, changes to the project may be drafted in DRAFT MODE, after which such changes will be reviewed and approved by a REDCap administrator. Once those changes are approved, you will then receive an email confirmation informing you that those changes have taken effect on your production project.

**Would you like to enter DRAFT MODE to begin drafting changes to the project?**

6) Click on the form that contains the Informed Consent:

**Data Collection Instruments**




Survey options:

Add new instrument:

a new instrument from scratch

a new instrument from the official [REDCap Shared Library](#)

instrument ZIP file from another project/user or [external libraries](#)

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
eConsent Form 	21		<input checked="" type="checkbox"/>	Choose action <input type="button" value="v"/>	<input checked="" type="button" value="Survey settings"/> <input type="button" value="+ Automated Invitations"/>
Saved Consents	1		<input type="button" value="Enable"/>	Choose action <input type="button" value="v"/>	

7) Go to the field that contains the first page of the ICF and click on Edit (pencil icon in top left corner).



- 8) Click on *Remove* next to the file upload name and then replace it with the new first page of the ICF.
- 9) Do this for EVERY field that contains the images of the ICF. Each 'page' of the eCosent will need to be replaced.

### 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 \(4 min\)](#).

**Field Type:** Descriptive Text (with optional Image/Video/Ai)

**Question Number** (optional)   
Displayed only on the survey page

**Field Label**

**Action Tags / Field Annotation** (optional)

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

**Variable Name** (utilized in logic, calcs, and exports)

Enable auto naming of variable based upon its Field Label?

ONLY letters, numbers, and underscores

How to use (+) Smart Variables ✂ Piping

Optional file attachment, image, audio, or video:

**Embed an external video** (provide video URL) ?

e.g. <https://youtube.com/watch?v=E1cCuWMupz0>,  
<https://vimeo.com/62730281>,  
<http://example.com/movie.mp4>

Display format of video:  Inline  Inside popup

- or -

**Attach an image, file, or embedded audio**

[Screen Shot 2017-09-21 at 2.18.56 PM.png](#)

✕ Remove

Display format of attachment on page:

Link

Inline image

Audio file (play in embedded player on page)

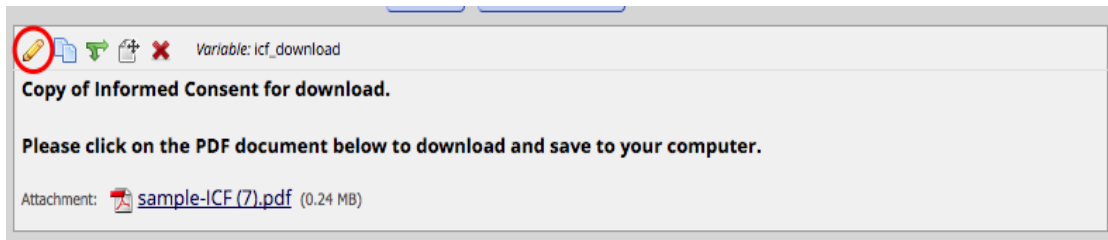
[Compatibility notice for embedded audio](#)

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

➔ Save Cancel

Once you click on Remove upload the first page of the new IFC and click on Save.

10) You will also need to replace the copy of the ICF for the subject's to download with the new/revised ICF.



### 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 \(4 min\)](#).

**Field Type:** Descriptive Text (with optional Image/Video/AI)

**Question Number** (optional)   
Displayed only on the survey page

**Field Label**

Copy of Informed Consent for download.

Please click on the PDF document below to download and save to your computer.

**Action Tags / Field Annotation** (optional)

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

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

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

Optional file attachment, image, audio, or video:

**Embed an external video** (provide video URL)   
e.g. <https://youtube.com/watch?v=E1cCuWMupz0>,  
<https://vimeo.com/62730281>,  
<http://example.com/movie.mp4>  
Display format of video:  Inline  Inside popup

- or -

**Attach an image, file, or embedded audio**  
[sample-ICF \(7\).pdf](#) **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**

After you click on Remove, upload the PDF copy of the ICF and click Save.

Once all the changes have been made, go back to the Online Designer page and click on *Submit Changes for Review*. Since these changes will not affect existing data, the changes should take affect immediately.

Project Home Project Setup Online Designer Data Dictionary

Since this project is currently in **PRODUCTION**, changes will not be made in real time. [Tell me more](#)

Submit Changes for Review

Fields to be added: 0 / Total resulting field count: 19  
Fields to be deleted: 0 / Existing field count: 19

[Remove all drafted changes](#) [View detailed summary of all drafted changes](#)