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).

Note: The IRB will dictate the required fields needed for your eConsent, i.e., whether the person obtaining consent's name/signature/date is required to be in the eConsent. The REDCap Support Staff does not and cannot determine what the IRB requires for your eConsent or how you plan to identify and consent the participant (face to face, over Zoom, via a phone call, link to eConsent sent via email, etc.).
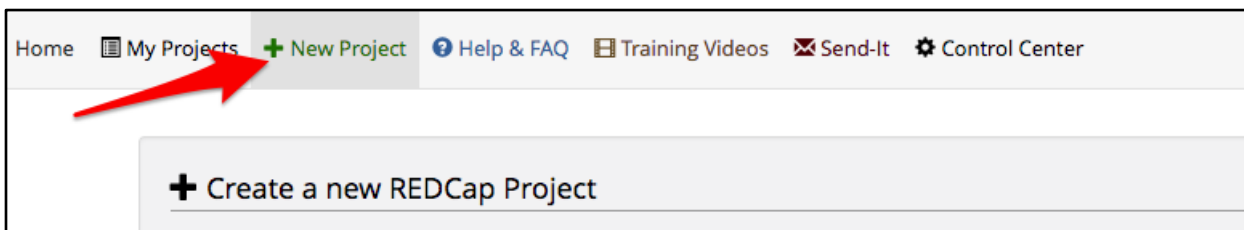
You can view an example of an approved eConsent for a low-risk study here:
https://redcap.ctsi.ufl.edu/redcap/surveys/?s=F8YYC9AC7D

Please read the UF IRB's eConsent Guidance document to ensure you are following UF's specific guidelines for obtaining eConsent: https://irb.ufl.edu/wp-content/uploads/Electronic-Informed-Consent.pdf.

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.

Note: This is just a general template for eConsenting. You will need to modify it to fit your project's needs, such as uploading your version of the consent, adding additional data fields that your particular consent requires and configuring the eConsent survey settings. This template alone does not guarantee IRB compliance for eConsenting. Also, your team **must test** the eConsent to ensure it meets your study's needs and functions the way you want it to.

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). A free resource to convert the PDF to images is https://pdf2png.com/.
    a. Do not take screenshots of the pages of the ICF to create the image files. You must use a PDF converter, such as Adobe Acrobat Pro or https://pdf2png.com/
3) Save these JPEG or PNG files to your computer.
4) 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 images with the display type as an 'Inline image.'
5) 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.
6) 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.

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

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

Once added, these "Descriptive Text" fields should like similar to this on the survey:

8) 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: [Begin New Section (with optional text) ⬍]

Field Label

[   ]

9) 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: [Descriptive Text (with optional Image/Video/A ⬍]

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.   ]

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

[icf_download   ]   ☐ Enable auto naming of
                                  variable based upon
ONLY letters, numbers, and   its Field Label?
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 –

Action Tags / Field Annotation (optional)

[   ]

Learn about [@ Action Tags] or using Field Annotation

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

📎 **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)
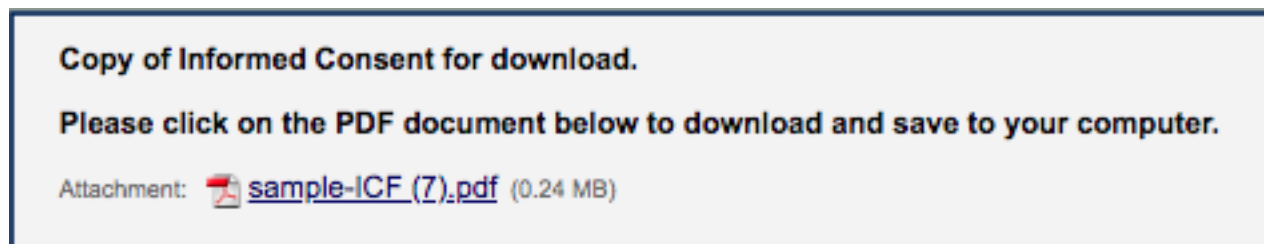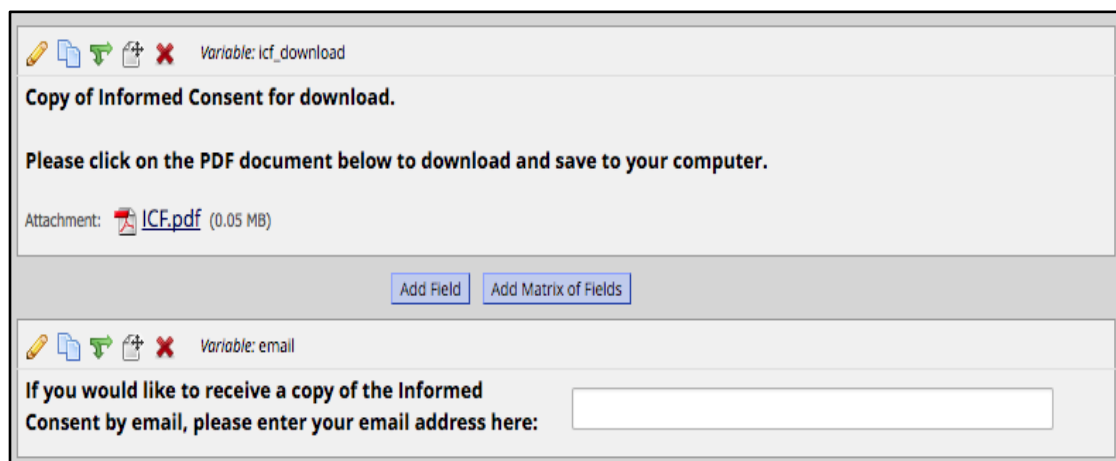
This is how the field looks on a survey:

Copy of Informed Consent for download.

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

Attachment: sample-ICF (7).pdf (0.24 MB)

10) *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 manully delete it from the eCosent 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.*"

11) Create a "Signature" field type to capture the participant's signature.

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: [Signature (draw signature with mouse or finge ⬍]

Question Number (optional) [   ]
Displayed only on the survey page

Field Label
Please click on the link to the right to add your signature.

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

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

How to use [⚡ Smart Variables] [✎ Piping]

Required?* ○ No ⦿ Yes
* Prompt if field is blank

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

Custom Alignment [Right / Vertical (RV) ⬍]
Align the position of the field on the page

Field Note (optional) [   ]
Small reminder text displayed underneath field

12) 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. See example below.

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

Required 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:

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.'

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: 'Yes' for 'Allow Save & Return Later option for respondents?'
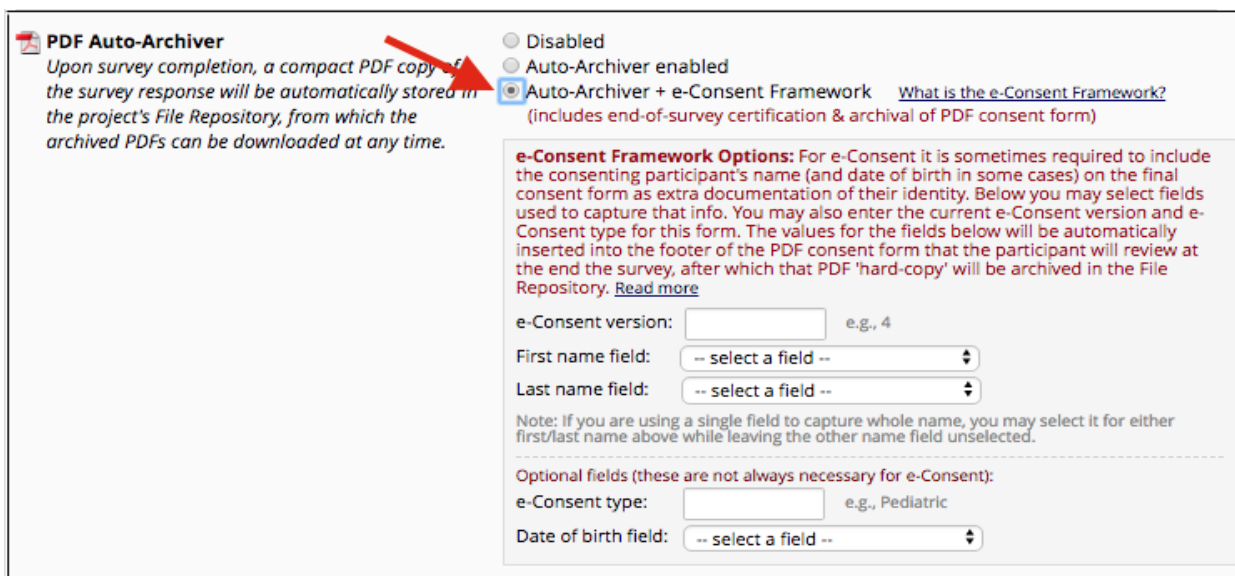
3) Under *Survey Termination Options*, you **MUST** select either **Auto-Archiver** or **Auto Archiver + eConsent Framework**:
   a. <u>Auto-Archiver</u>: This option saves a PDF copy of the eConsent in the project's File Repository (not in the individuals record). If needed, the archived PDFs can be downloaded at any time and manually saved to the individuals record in a *File Upload* field.

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 Repositiory, 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.

Note: the PDF *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.

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

Instructions for Setting Up the Confirmation Email with the PDF of the signed 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.'

Designate an email field for sending survey invitations

Choose an email field to use for invitations to survey participants:

✓ -- select a field --
  eConsent Example
  email "If you would like to receive a copy of your sig... l address here:" ...ts by designating a field in

your project. If a field is designated for that purpose, then any records in your project that have an email address captured for that particular field will have that email address show up as the participant's email address in the Participant List (unless an email address has already been entered for that participant in the Participant List directly).

Using the designated email address field can be especially valuable when your first data collection instrument is not enabled as a survey while one or more other instruments have been enabled as surveys. Since email addresses can only be entered into the Participant List directly for the first data collection instrument, the designated email field provides another opportunity to capture the email address of survey participants.

Please be aware that designating an email field means that survey responses can NEVER BE ANONYMOUS because of the fact that the participant's email address can be viewed on a data entry form, which means it is easy to identify the record/response to which the email address belongs.

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 addresss 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'.**

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*.

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.

Test Your Project Thoroughly

Once you're finished building the consent, have configured the survey settings, and have enabled survey notifications (if applicable), 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' (if the eConsent is the first form in the project).
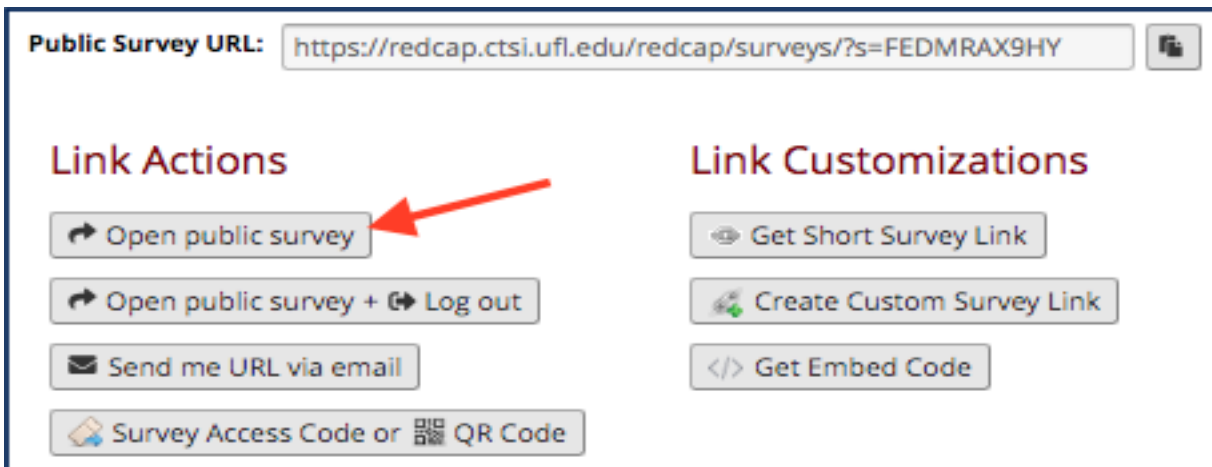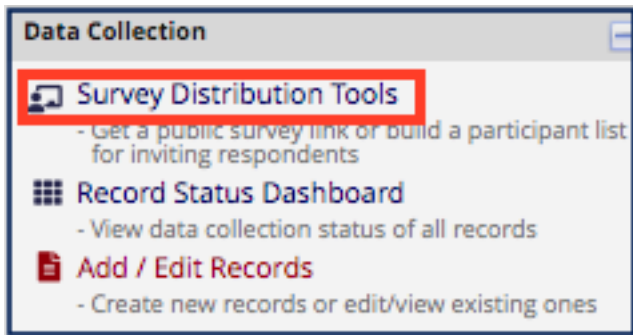
Fill out the eConsent as you would if you were a subject and submit it.

Updating the Consent Form

If 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 existitng 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 IFC showing up on the eConsent page in their record. This is why the automated saving of the signed ICFs is required.
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.*

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

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.

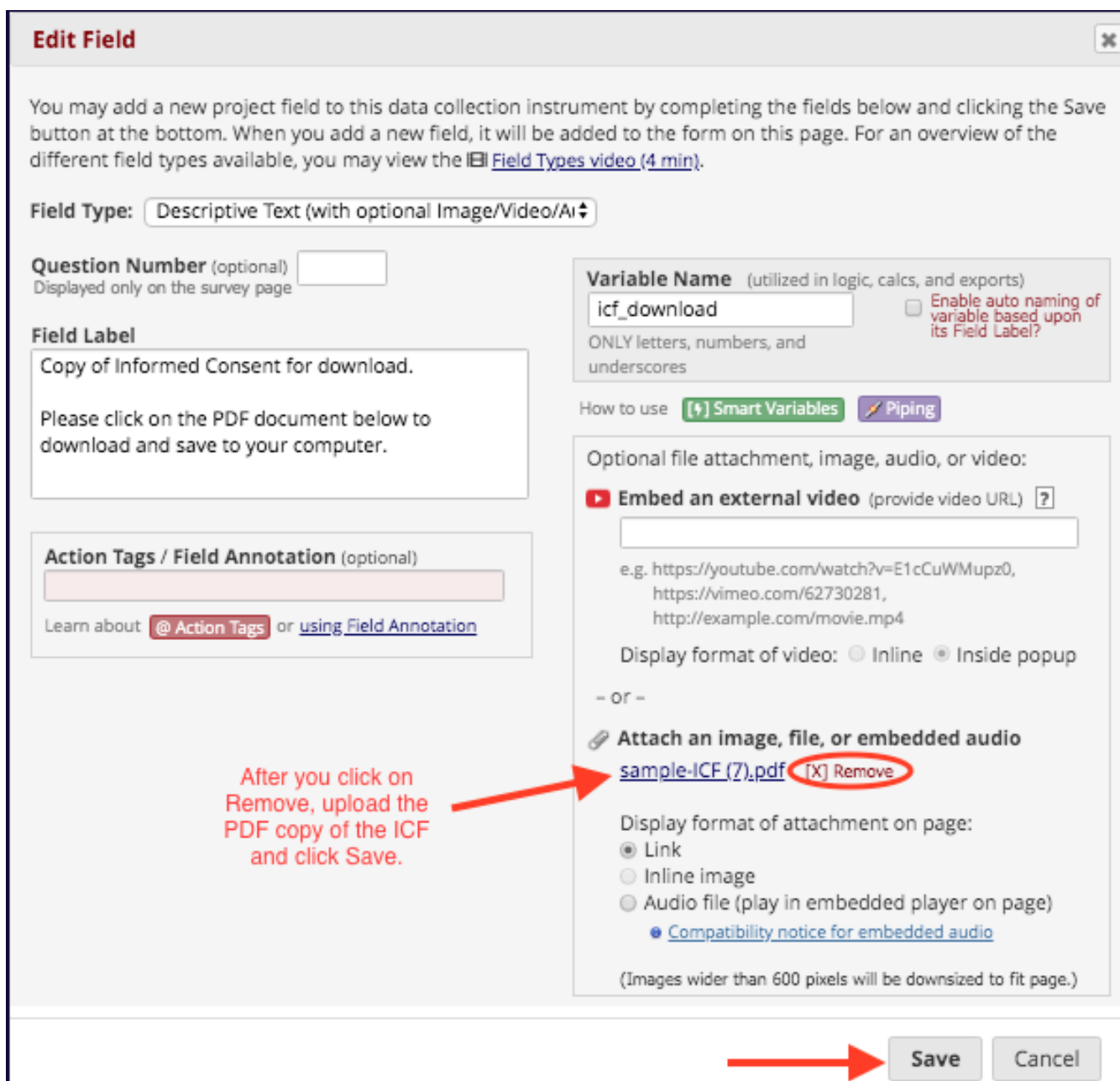10) You will also need to replace the copy of the ICF for the subject's to download with the new/revised ICF.

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.
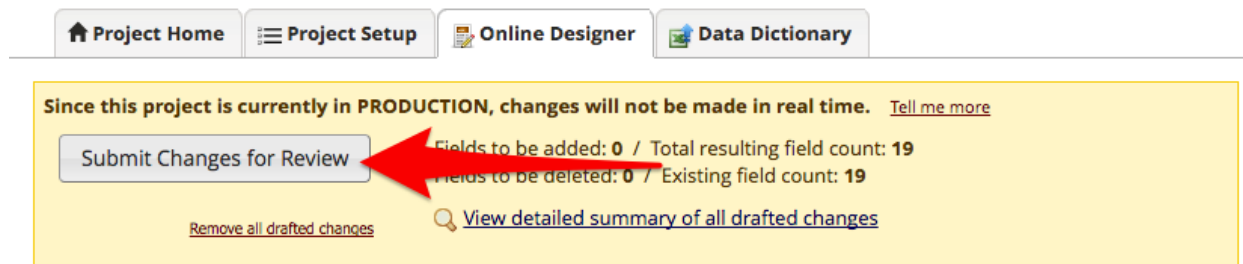
Questions? Email the REDCap Support Team at: https://redcap.ctsi.ufl.edu/redcap/surveys/?s=DUPrXGmx3L