CASE WESTERN RESERVE UNIVERSITY

CWRU HRPP Guidance for Electronic Informed Consent (eIC)

December 2024

This document serves as a reference point for Investigators and Study Teams who will be utilizing electronic informed consent (eIC, e-consent) as an element of CWRU IRB-approved protocols.

Per the Case Western Reserve University Investigator Manual, Electronic Informed Consent is a valid and acceptable substitute for paper-based informed consent provided that (a) the electronic informed consent process, including the e-Consent form, meets all regulatory criteria for informed consent outlined by HHS and FDA in 45 CFR 46.116 and 21 CFR 50.25 and (b) is approved by the CWRU IRB. **See the Investigator Manual, Chapter 10 – General Requirements for Informed Consent here:** CWRU Institutional Review Board | Office of Research and Technology Management | Case Western Reserve University
Also see HHS guidance here: Use of Electronic Informed Consent: Questions and Answers | HHS.gov

Electronic Informed Consent (eIC, e-consent) is a valuable alternative to paper-based forms, providing freedom and flexibility in terms of space, time, and storage and participant/study team convenience. However, eIC must still adhere to the basic elements of informed consent, such as providing accurate and comprehensive information to potential participants, acting as the source of documentation of consent (i.e., signatures and dates), and ensuring participant understanding. This guide provides institutional eIC recommendations and policies to ensure that the use of eIC at CWRU aligns with both federal regulations and general best practices.

COMMON QUESTIONS

What information does my Electronic Informed Consent (eIC) Form need to contain?

The eIC is simply a different *medium* than a paper Informed Consent Form (ICF) and, therefore, it is essential that it retains all elements of informed consent. Your study's eIC must exactly mirror the text and format of the current CWRU IRB-approved Informed Consent Form and/or Assent Form. All sections must be present and all formatting, such as bullet points, checkboxes, and signature and date fields, must be maintained to the extent possible within the electronic framework. Additionally, **the eIC should include the IRB Approval Stamp that includes the IRB Study Number, Approval Date, Effective Date, and Expiration Date.**

I plan to use *only* eIC to obtain consent. How should my protocol reflect this?

If you intend to consent participants using exclusively eIC, particularly remotely, your protocol should (a) state that you will exclude participants who are unable to utilize this technology or (b) include detailed procedures for alternative methods to consent individuals who are unable to utilize eIC. Some potential study participants may lack an internet connection, have diminished eyesight or mobility issues that prevent scrolling and applying an electronic signature, or experience other difficulties navigating or using electronic systems. While there are circumstances in which it may be in the study's best interest to exclude these individuals, alternative consent procedures ensure that otherwise eligible participants are able to participate.

I have a waiver of consent or a waiver of written documentation (signatures). Do I still need to use the eIC framework?

Generally, studies with consent or documentation waivers still require the use of information sheets or verbal scripts. In these scenarios, the IRB-approved Study Information Sheet or Script should replace the eIC in your electronic application with options for documenting that the participant has read or been read the information. This can be done in multiple ways depending on study procedures. For example, if the study employs online surveys, the information sheet or script should be presented as the first survey and include text indicating that selecting the "Next" or forward button signifies that the participant understands the nature of the study and wishes to proceed.

Can my Electronic Consent Forms and data collection forms be employed in the same REDCap or Qualtrics project page?

If you do *not* have a waiver of consent, collecting no identifiable data, then eICs with identifiable names/signatures and data collection forms with unique Participant ID numbers should have separate project pages. Because the regulations require that identifiable information be stored separately from de-identified data, it is a best practice to separate that information at the start of study recruitment and data collection. This will save time and effort and mitigate potential loss of data when the study is closed and/or when study team members lose access to REDCap or Qualtrics.

Do I have to update my eICs every time a new version of the consent form is approved by CWRU IRB?

Yes, with each new IRB-approved version of the consent form, assent form, information sheet, or information script the electronic documents must be updated to exactly mirror the text, format, and stamp of the current CWRU IRB-approved forms. **Do not overwrite your outdated consent** (see REDCap instructions below).

What platforms can I use for administering electronic consent?

Currently, CWRU IRB only permits eIC utilizing REDCap or Qualtrics. If you want to use a different platform, please contact the CWRU IRB administrators at cwru-irb@case.edu. REDCap is administered separately by institution (CWRU, UH, MetroHealth, Cleveland Clinic). Be certain that your IRB-approved protocol specifies CWRU REDCap before creating your project page. Qualtrics is administered by CWRU UTech, and an account can be activated here: Account activation | Qualtrics (case.edu) Again, be certain that your IRB-approved protocol specifies CWRU Qualtrics before creating your project page.

Should I use REDCap or Qualtrics?

Generally, CWRU recommends that REDCap be used for eICs with no waiver or alteration to the consent process. However, which platform you choose to use may depend on your consent process, study timeline, analysis plan, and personal preference. For instance, if you have a waiver of consent documentation, you may prefer Qualtrics. If your study has informed consent or assent forms with checkbox selections (for audio recording, for example), you may prefer REDCap. Additionally, your study or department statisticians or data managers may be helpful in making the platform decision, or you can request support here: Research Data | Case Western Reserve University

How do I set up my electronic consent forms?
See the instructions below for REDCap. For Qualtrics, see Building a Consent Form

USING REDCAP for ELECTRONIC INFORMED CONSENT

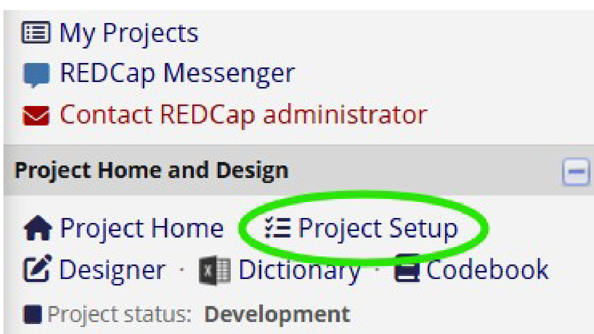
The following instructions are specific to consent processes that require consent documentation (no waivers or alterations) and can be used in either remote or in-person settings.

REDCap (Research Electronic Data Capture) is a secure, web-based, HIPAA-compliant data collection platform that can be used to deliver information to and collect information from research teams and participants in real time. For more information about REDCap, see REDCap | Clinical and Translational Science Collaborative (CTSC) | Case Western Reserve University

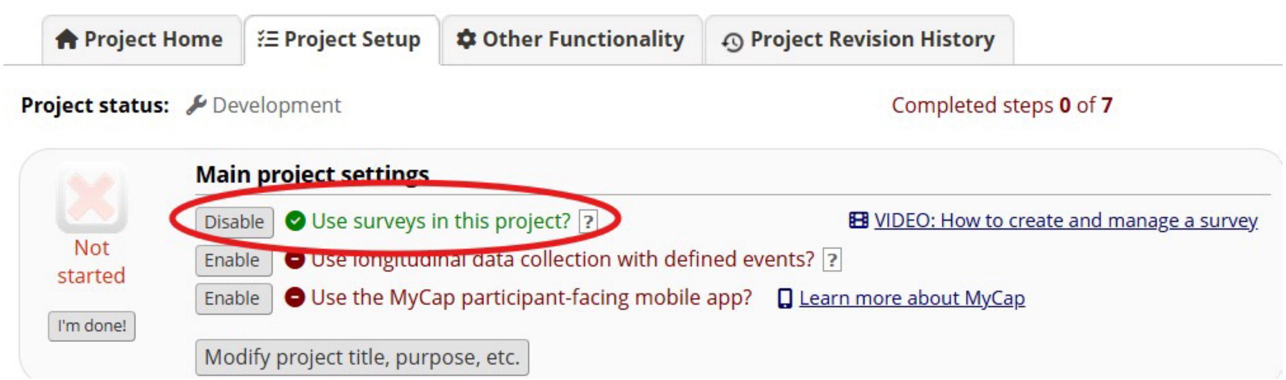
To create a CWRU REDCap Project, navigate to https://redcap.case.edu/ and on the Home page select the *NEW PROJECT Request Form* link. If you do not yet have CWRU REDCap access, you will receive an account as ~~part of your request. Before creating your eIC form, it~~ will be helpful to view the E-consent Framework video: e-Consent Framework and PDF Snapshots (vumc.org)

The following instructions can also be found in the REDCap Help & FAQ page, Project Setup/Design tab, and are the preferred method for creating e-Consent forms. ***NOTE:* This method requires uploading a copy of your informed consent form in PDF form.** Make sure you have downloaded and saved the **IRB-stamped PDF** from your SpartaIRB study page.

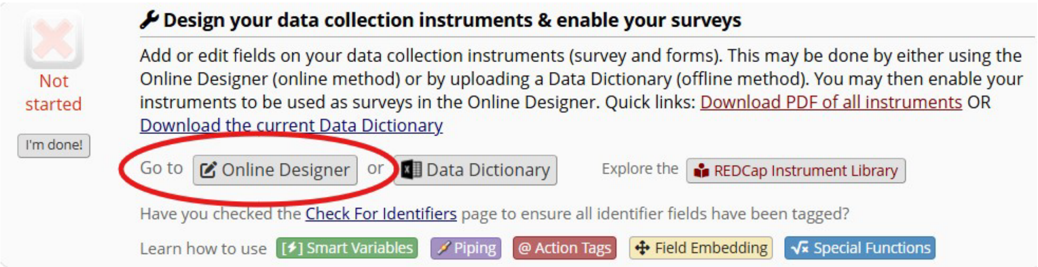
1. Once you have created your REDCap Project, on the upper left of the project's home page, select the **Project Setup** link under **Project Home and Design**.



2. In the Project Setup Tab, under **Main project settings**, select **Enable** next to "Use surveys in this project?"

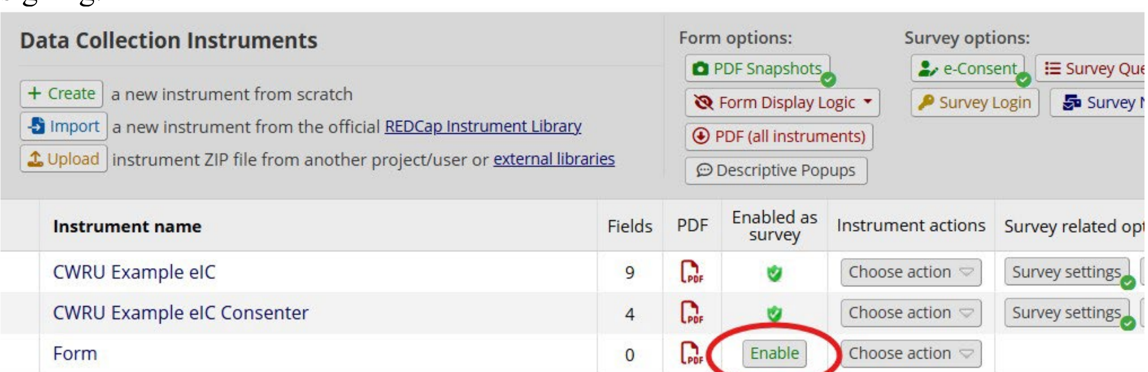


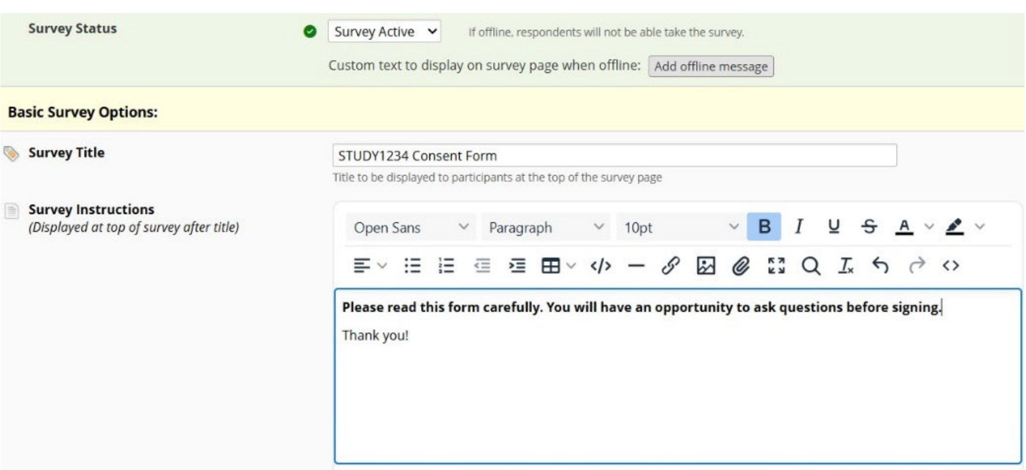
3. Still in the Project Setup tab, scroll down to **Design your data collection instruments & enable your surveys**. Select **Online Designer**.



4. A **Data Collection Instruments** box will automatically open with a pre-populated, blank "Form 1" Instrument. Under **Instrument actions** select **Choose action** and select **Rename**. Change the name of the form to your preferred consent title, e.g., STUDY12345678 ICF. Select **Save**. **NOTE: The e-Consent Framework manages versioning so DO NOT add a version number in the Form Name. This instrument will be used for all of your consent versions.**

5. Under the "Enabled as survey" column, select **Enable**. The **Set Up My Survey** tab will automatically open. In the **Basic Survey Options** box edit the Survey Instructions with language that reflects the nature of the consent survey, e.g., "Please read this form carefully. You will have an opportunity to ask questions before signing."





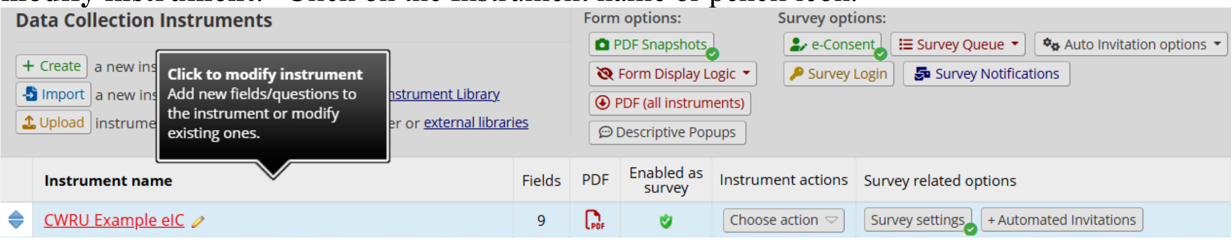
Review all the pre-populated Survey Design Options fields and edit where necessary. It is recommended that they stay as are <u>with these exceptions</u>:

- Selecting "Yes" for **Allow participants to download a PDF of their responses at end of survey?**

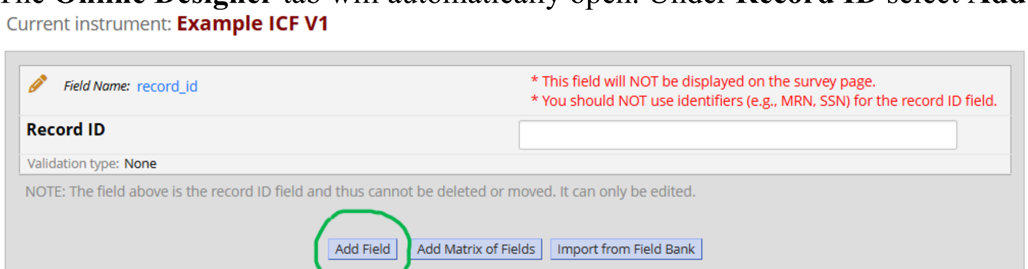
- Selecting "Enabled – initially Off but can be turned On" for **Text-To-Speech functionality**.
- Changing the Survey Completion Text to "Thank you for completing the consent form."

When complete, select **Save Changes**.

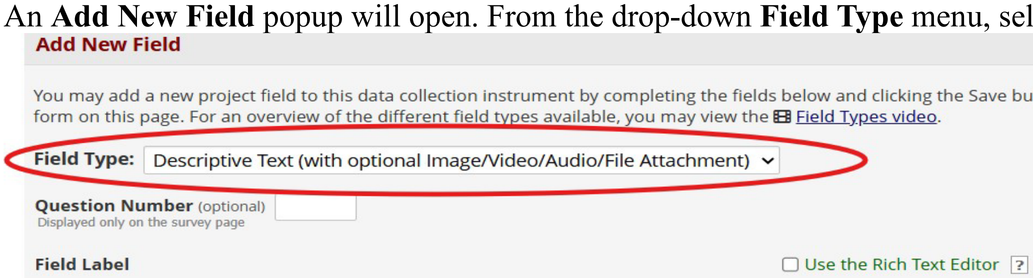
6. After selecting Save Changes, the Data Collection Instruments box will automatically open. Hover your cursor over the **Instrument name** field until a pencil icon appears. A comment bubble will appear: "**Click to modify instrument**." Click on the Instrument name or pencil icon.



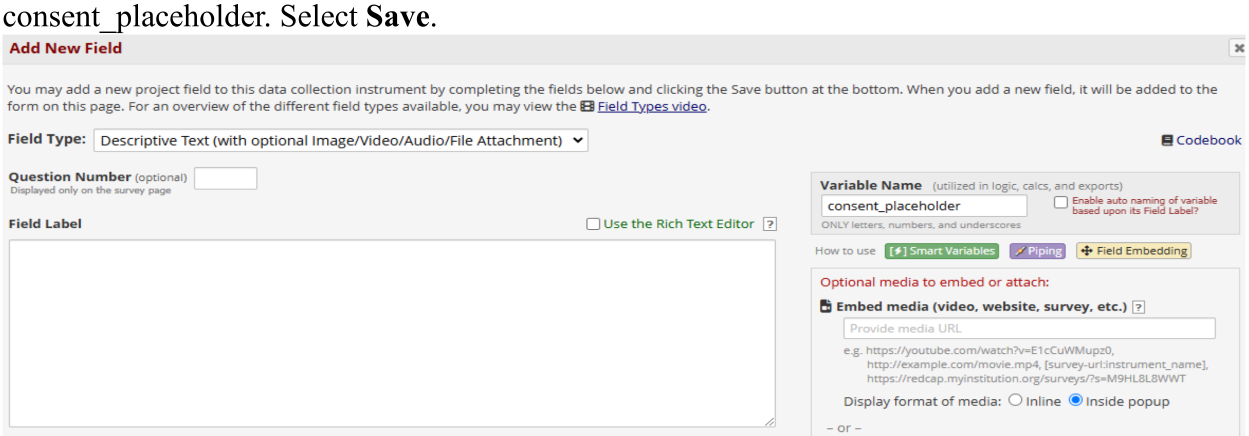
The **Online Designer** tab will automatically open. Under **Record ID** select **Add field**.



An **Add New Field** popup will open. From the drop-down **Field Type** menu, select **Descriptive Text**.

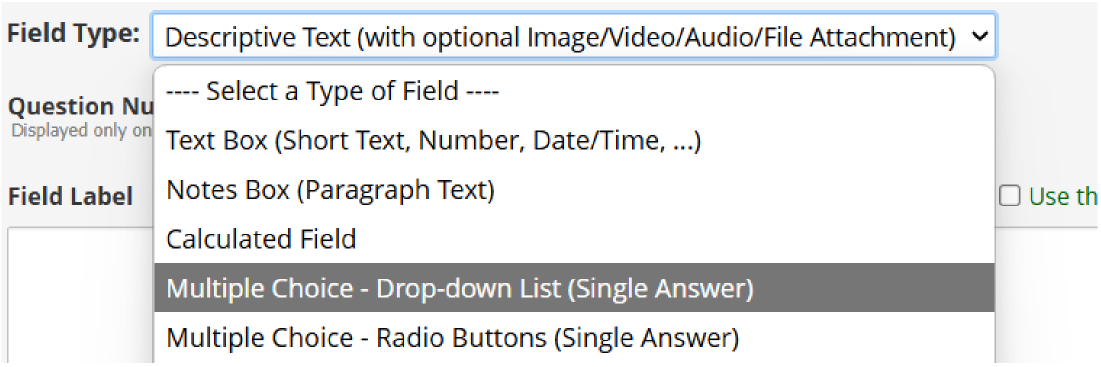


Leave Question Number and Field Label blank and enter a placeholder in **Variable Name** such as consent_placeholder. Select **Save**.

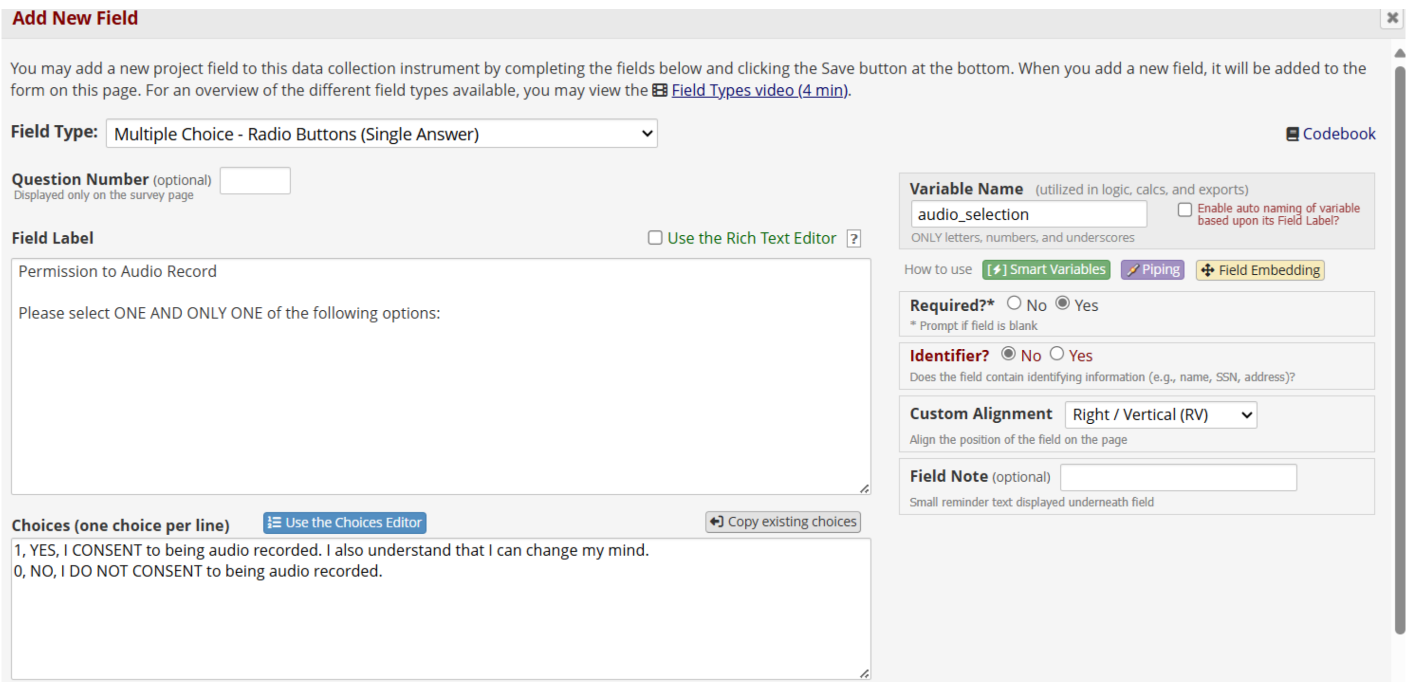


7. When **Save** is selected, you will be automatically returned to the Online Designer tab. You can now proceed with adding fields for checkboxes**, such as for audio recording, future samples, and any Q&A questions for validating participant understanding.**

To set up <u>checkboxes for optional study procedures</u> such as audio recording and future contact, scroll down to the last page and select **Add Field**. In the popup, from the drop-down **Field Type** menu, select either of the single answer options: Multiple Choice – Drop-down List or Multiple Choice – Radio Buttons.

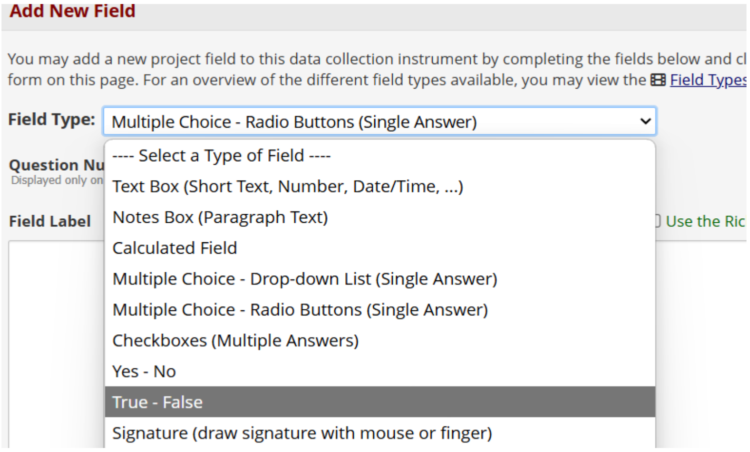


In **Field Label**, enter the text of the section as it appears in the consent form (see screenshot below). In **Choices**, enter the value and name of the selection (again, see screenshot below). Enter a unique **Variable Name** and in **Required** select **Yes**. Select **Save**.

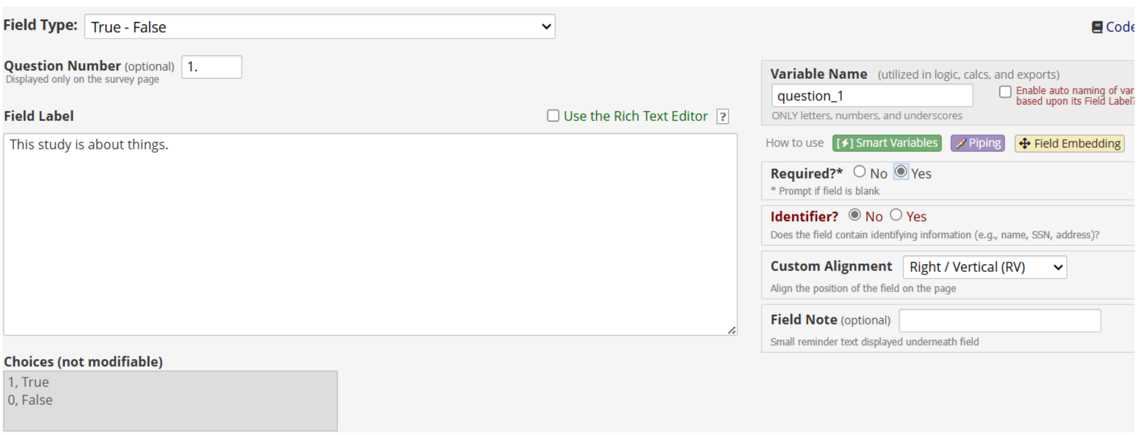


Repeat for all checkbox selection questions as they appear in the IRB-approved consent form.

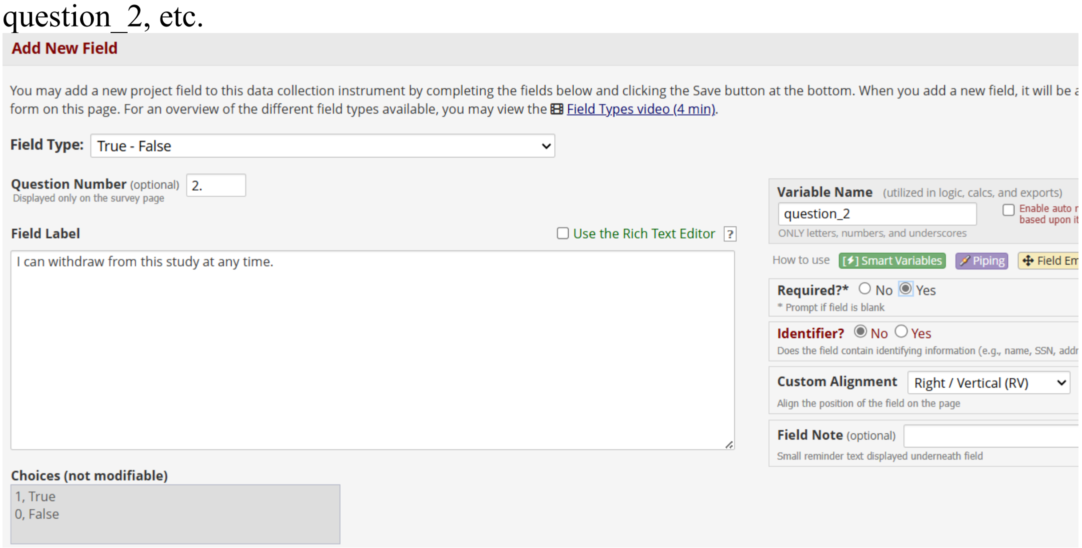
8. To set up <u>questions for validating participant understanding</u>, scroll down to the last page and select **Add Field**. In the popup, from the drop-down **Field Type** menu, select True – False.



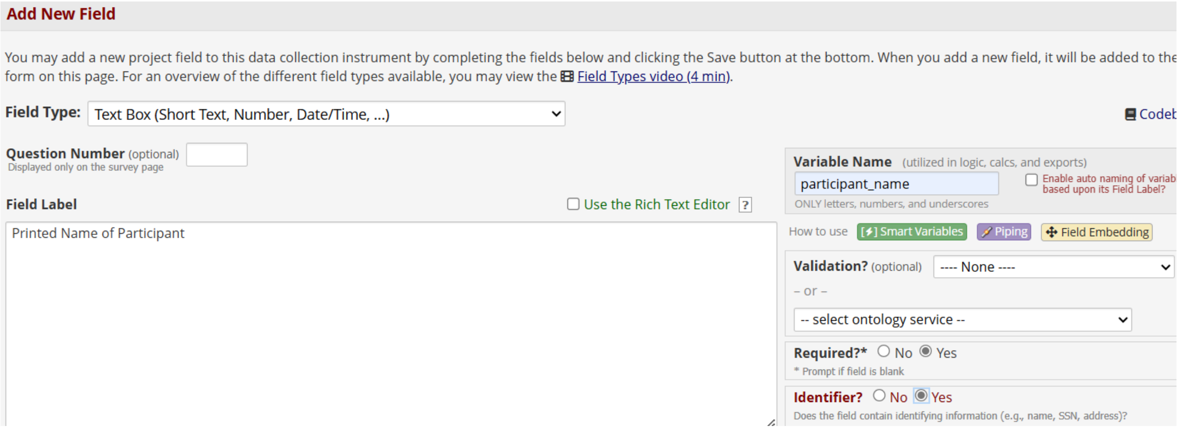
The **Choices** field is pre-populated with the values, but you will need to add the Question Number, Field Label, Variable Name, and Required selections. In **Question Number**, enter 1. In **Field Label**, enter the question text. In **Variable Name**, enter a unique variable name, and in **Required** select **Yes**. Select **Save**.



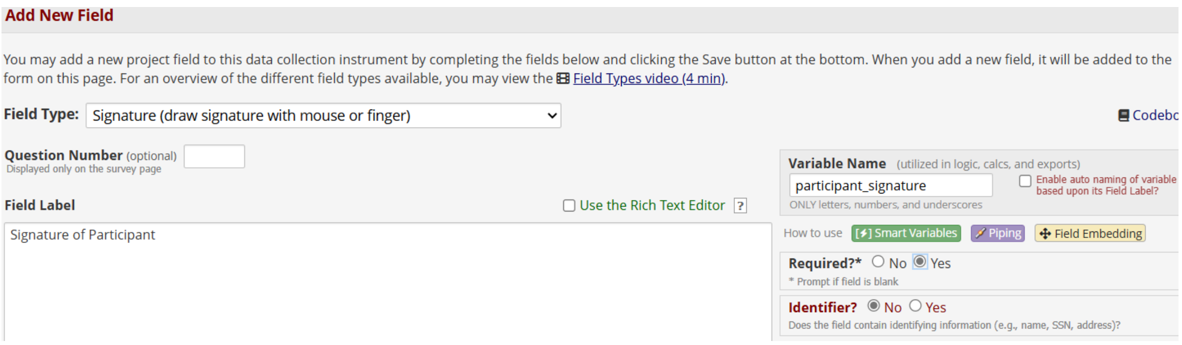
Repeat for all validation questions, changing the Question Number to 2, 3, etc. and the Variable Name to question_2, etc.



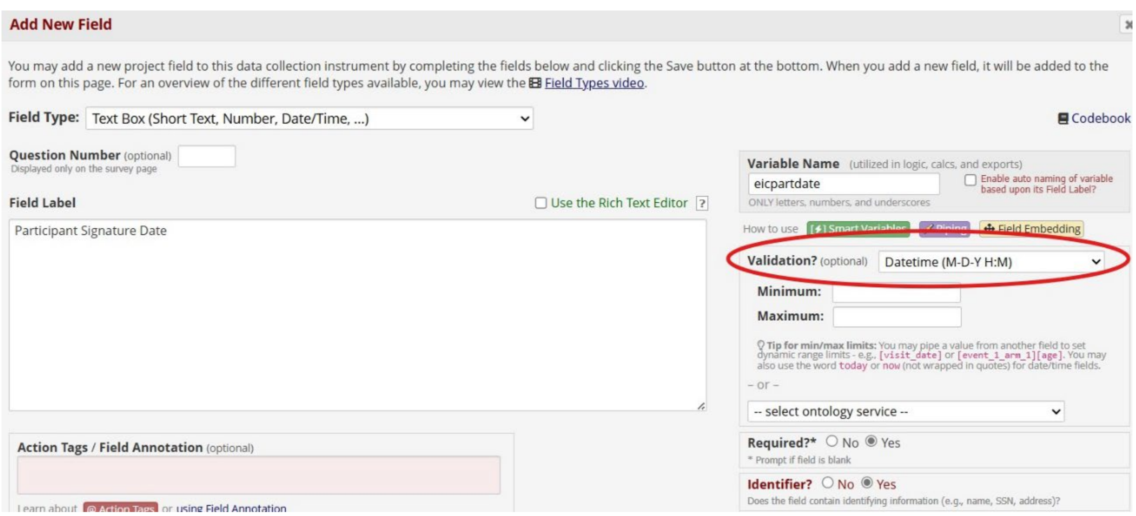
9. Once all the validating questions are created, you will need to set up the Participant Name, Date, and Signature fields. Select **Add Field**. In the popup, from the drop-down **Field Type** menu, select **Text Box**. In **Field Label** enter Printed Name of Participant, participant_name (or another unique name) in **Variable Name**, and select Yes for **Required** and **Identifier**. Select **Save**.



Select Add Field. In the popup, from the drop-down **Field Type** menu, select Signature. In **Field Label** enter Signature of Participant, participant_signature (or another unique name) in **Variable Name**, and select Yes for **Required** and Yes for **Identifier**. Select **Save**.



Select Add Field. In the popup, from the drop-down **Field Type** menu, select Text Box. In **Field Label** enter Participant Signature Date, a unique name in **Variable Name**, and select Yes for **Required** and Yes for **Identifier**. In **Validation**, select Datetime (M-D-Y H:M). Leave Minimum and Maximum blank. Select **Save**.



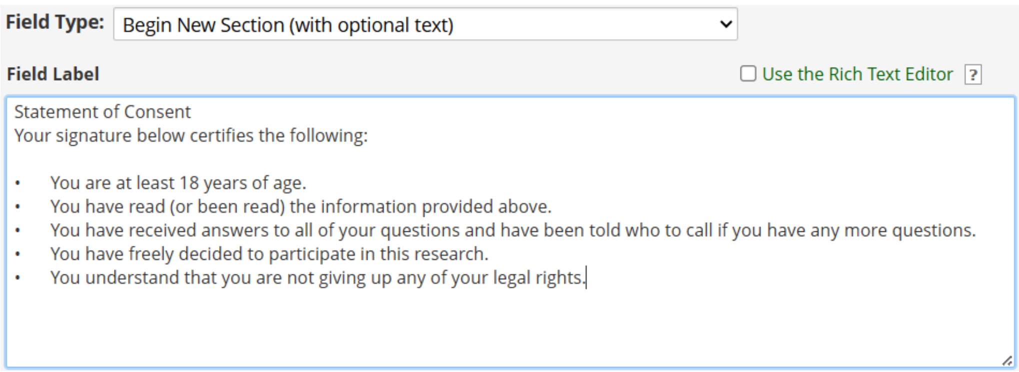
10. **Once all fields have been created, set up the name, date, and signature fields as a separate section and, if you have used participant understanding validation questions, set up branching logic.** Branching logic is crucial to ensure that the consent form is signed only when a correct True/False answer is entered.

Above the Printed Name of Participant field, select **Add Field**. In the popup, select **Begin New Section**. In the **Field Label**, enter the pre-signature language as it exists in your IRB-approved consent, for example:

Statement of Consent

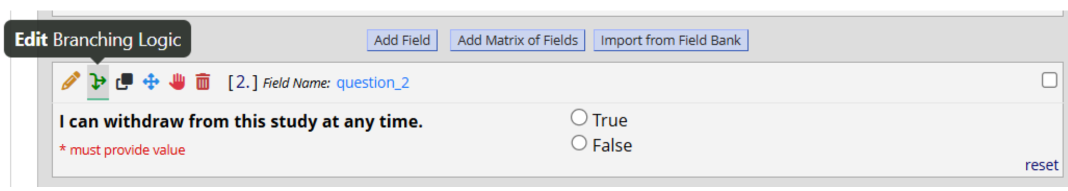
Your signature below certifies the following:

- You are at least 18 years of age.
- You have read (or been read) the information provided above.
- You have received answers to all of your questions and have been told who to call if you have any more questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.

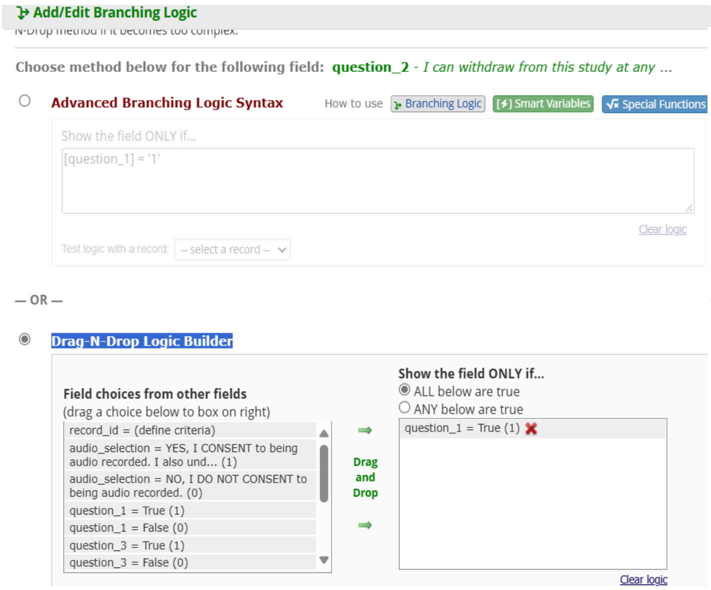


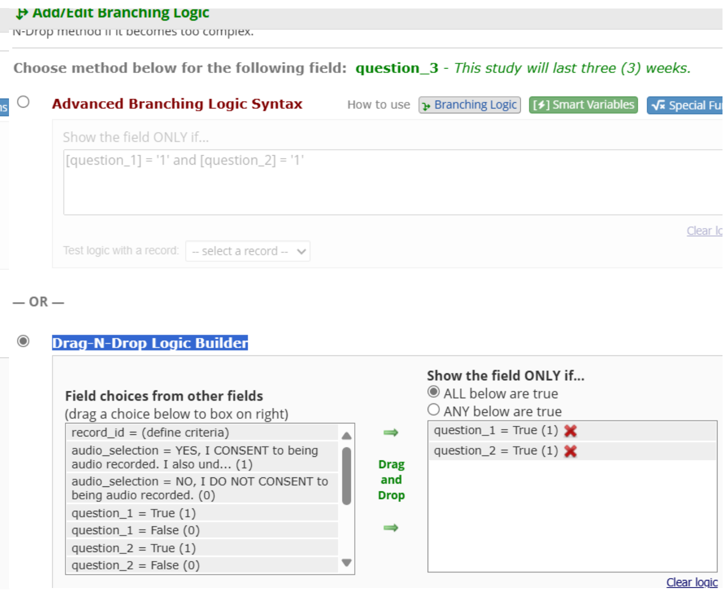
Select **Save**

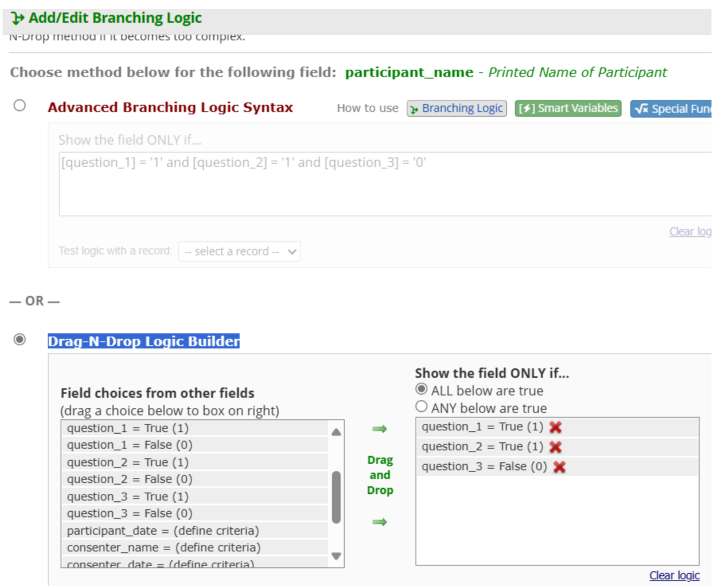
11. To set up your branching logic, start with your validation Question #2. In **Online Designer** scroll down to the 2nd question and select the green arrows above the field.

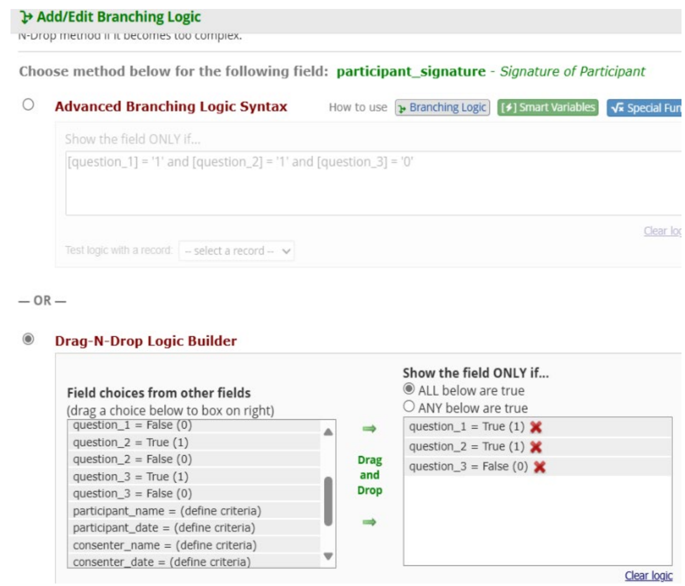


An **Add/Edit Branching Logic** pop-up will open. Scroll down and select the button next to **Drag-N-Drop Logic Builder**. A list of field choices will open. Select the item that needs to be True or False in order to advance to the next field (see screenshots below). Continue for Question #3, Printed Name of Participant, Signature of Participant, and Participant Signature Date, each time selecting ALL the items that must be correct or completed to continue advancing. Keep the "Show the field Only if..," selection as "ALL below are true."

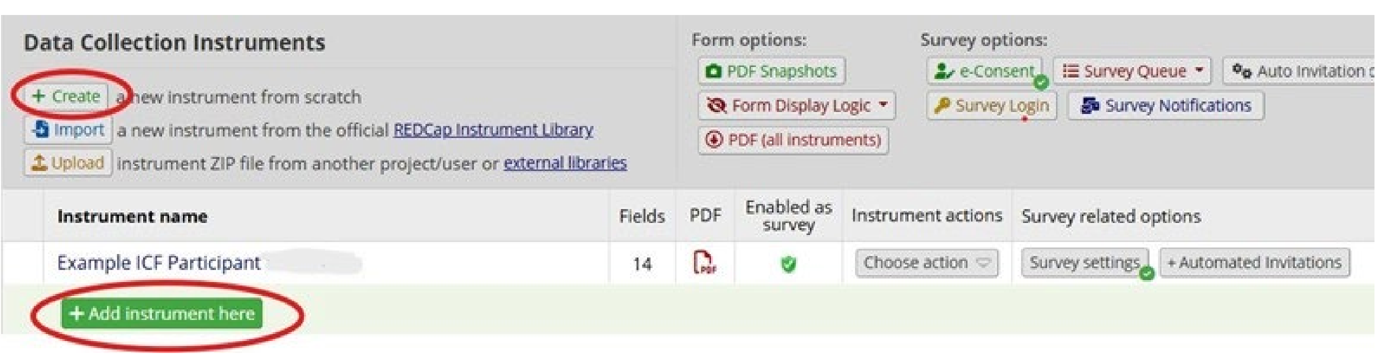


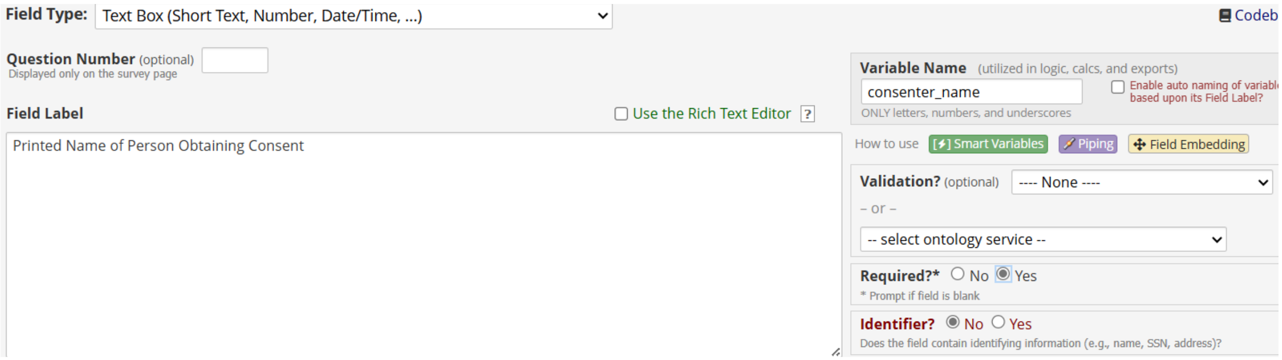


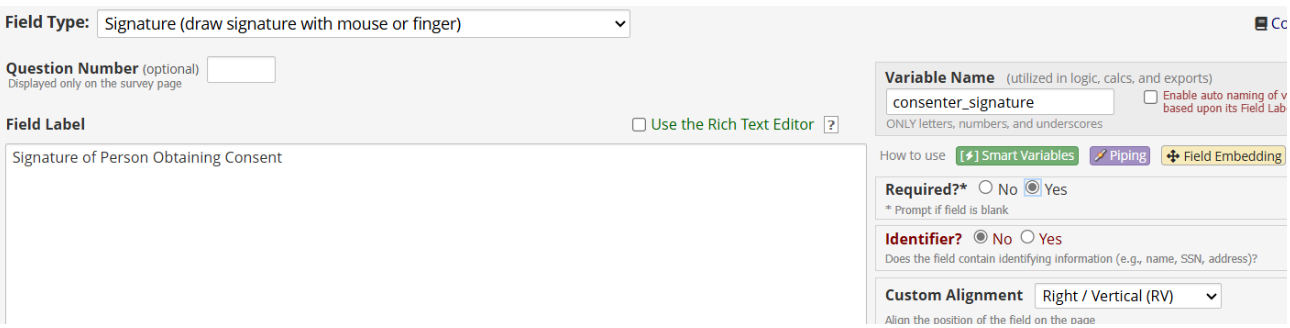


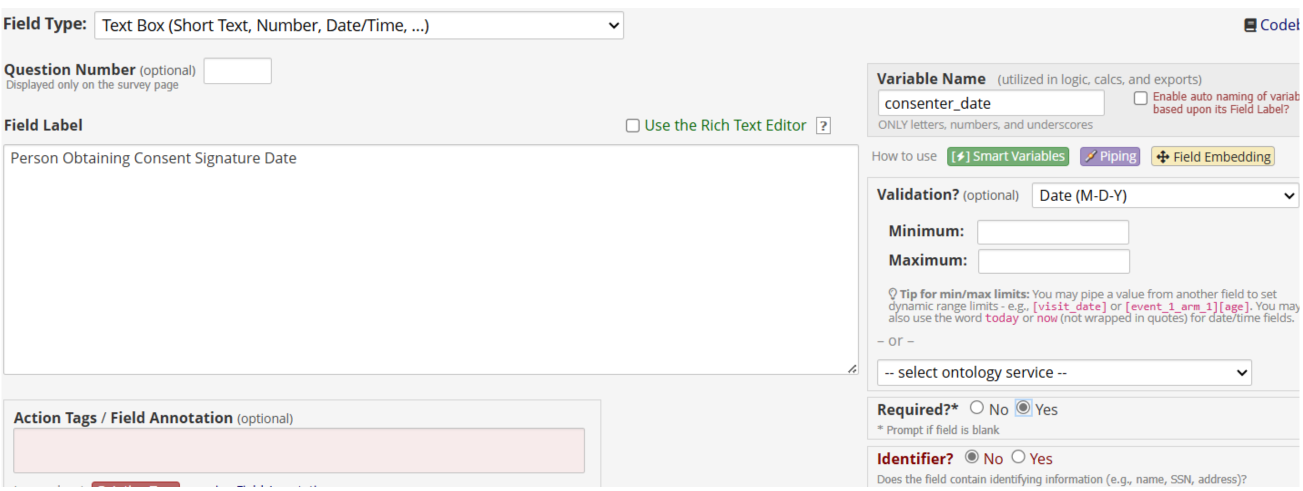


12. Return to Online Designer. Select **Create a new instrument from scratch**, select **Add instrument here** under the participant form, select Enabled as survey, and rename (e.g., STUDY12345678 ICF Consenter). Repeat the instructions in item 9 for Person Obtaining Consent/Consenter (see screenshots below) leaving all Identifier options as “No.” Select **Save**.

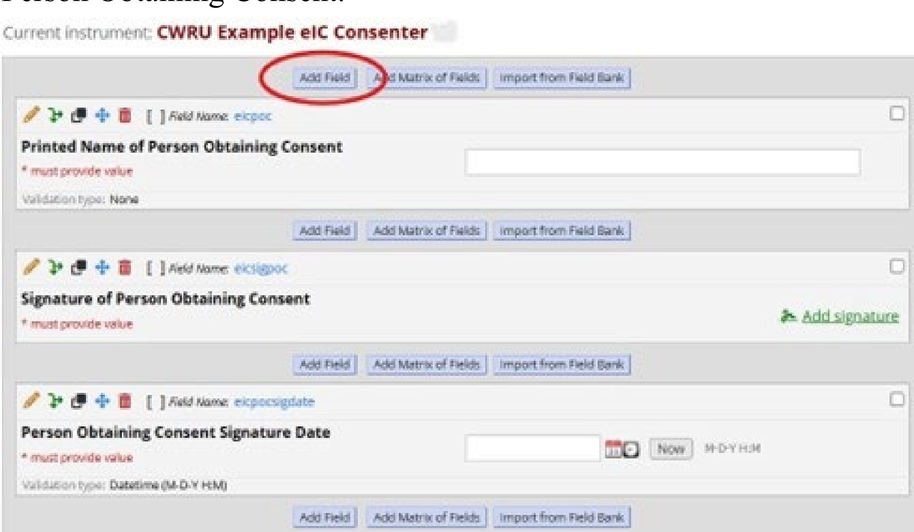




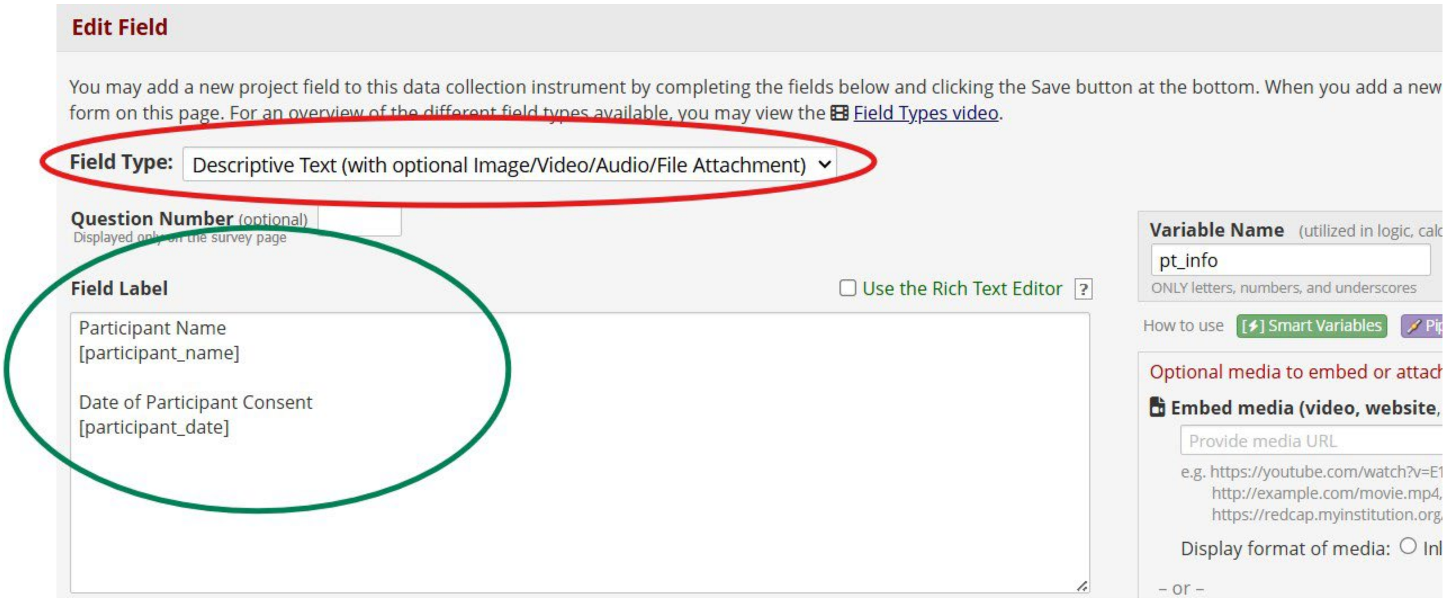




13. To ensure that the consenter's form is linked to the correct participant, add a field above Printed Name of Person Obtaining Consent.



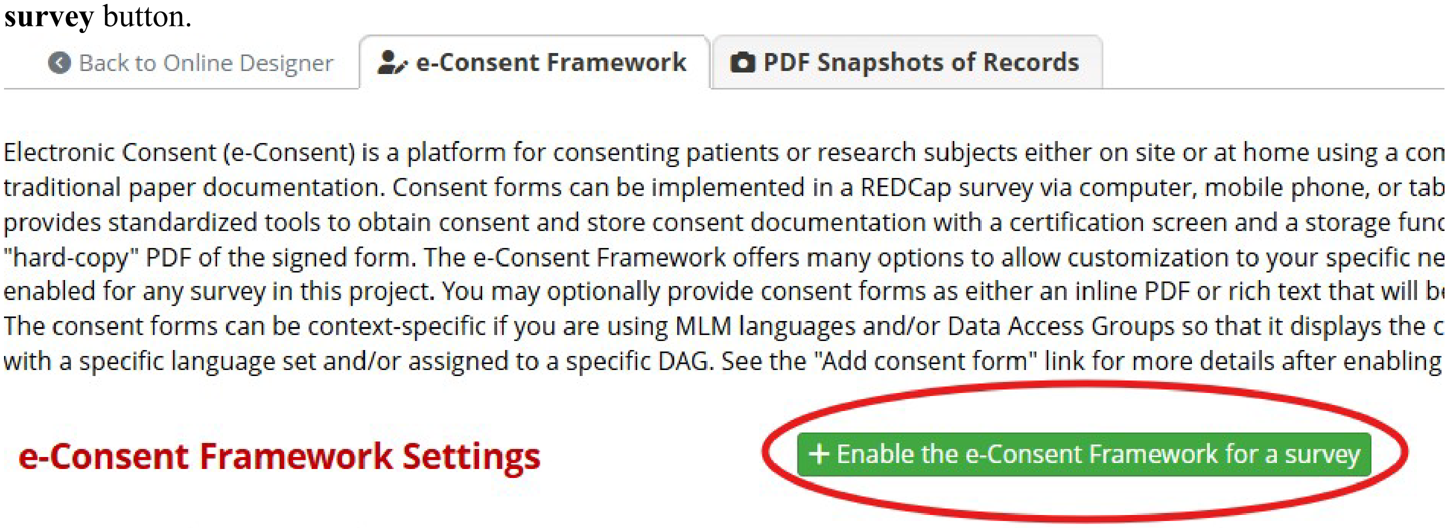
From the dropdown list select **Descriptive Text**. In Field Label enter Participant Name and Date of Participant Consent, separated by a blank line space. Under Participant Name, enclosed in brackets, enter the variable name you assigned to Printed Name of Participant (see screenshot below). Repeat for Date of Participant Consent (see screenshot below).



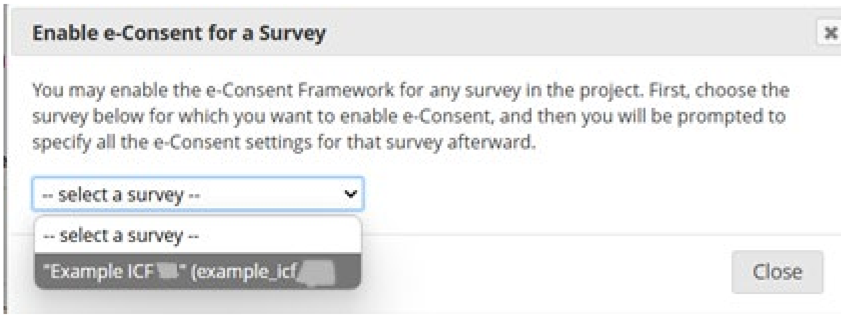
Select **Save**. Select **Return to List of Instruments**.

14. Set up your surveys as e-Consents. Under **Survey options** select **e-Consent**.

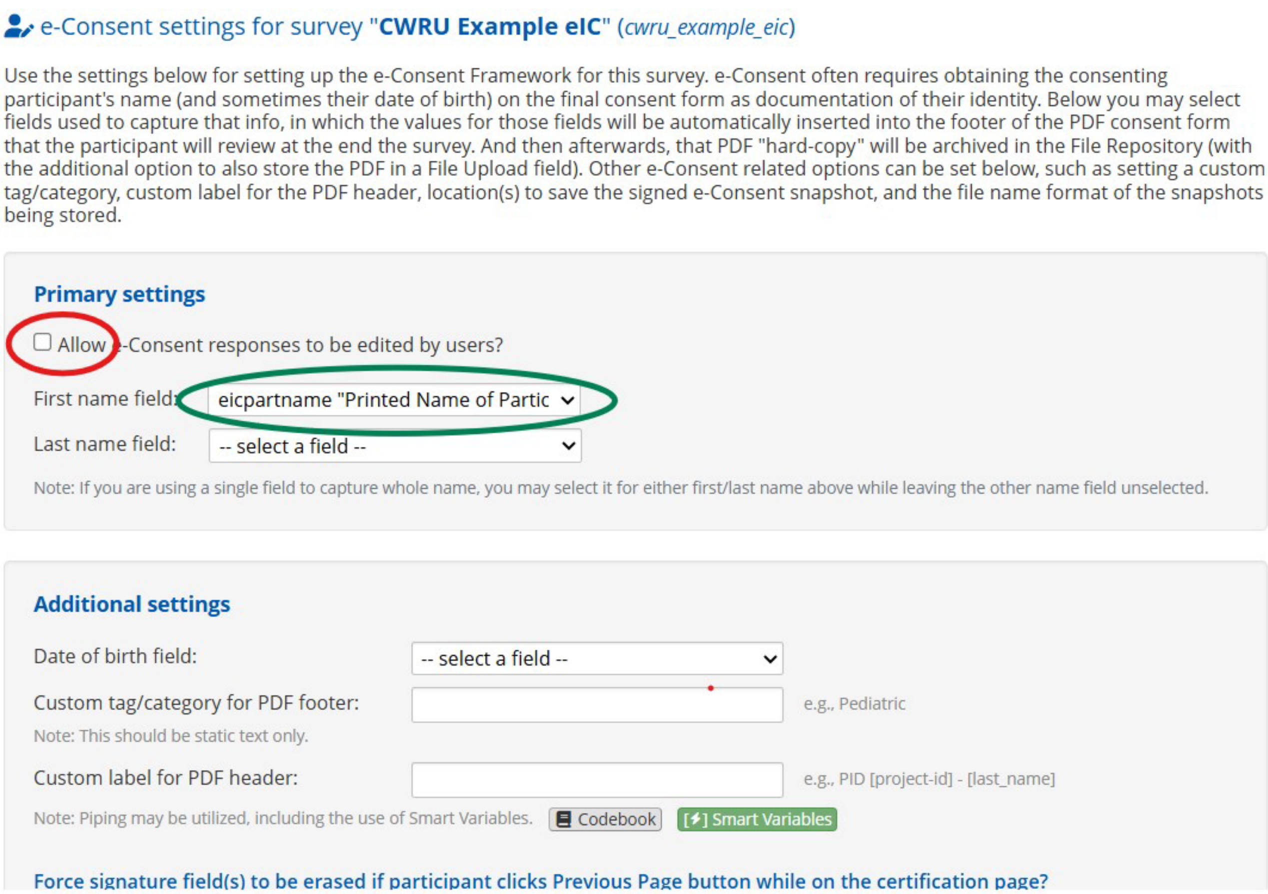
The **e-Consent Framework** tab will automatically open. Select **Enable the e-Consent Framework for a survey** button.



A pop-up window will open asking for a survey selection for the e-Consent. Using the drop-down menu, select your participant ICF survey.

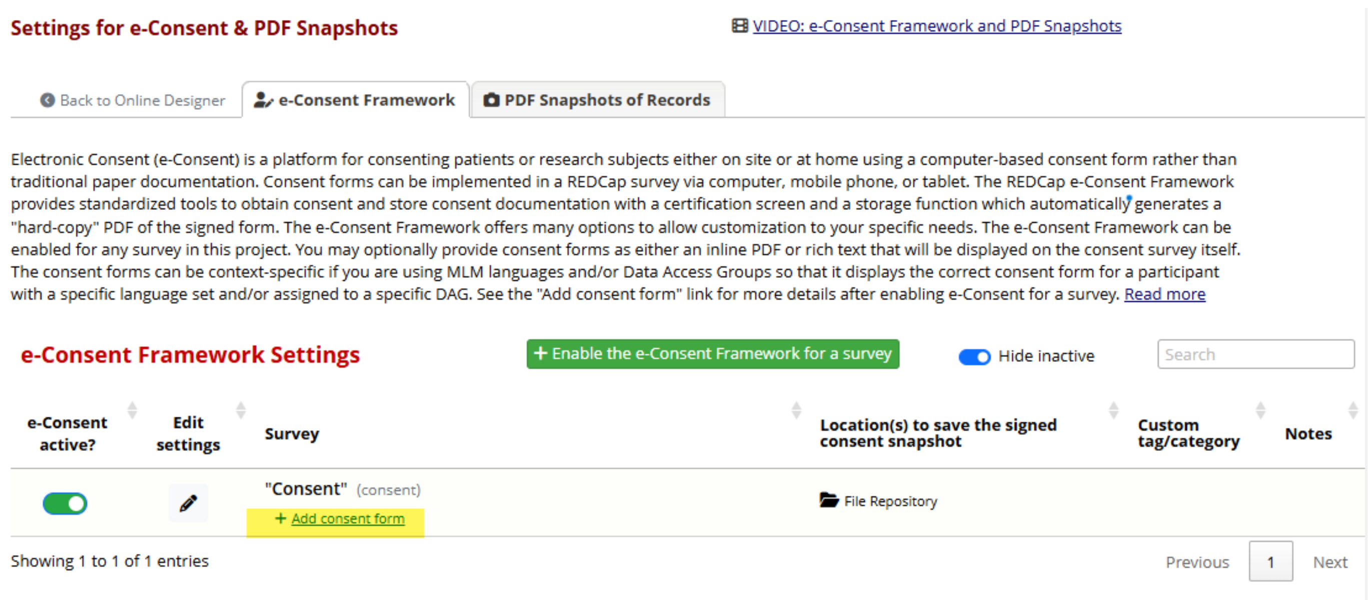


An e-Consent settings for survey "[Your Survey Name]" pop-up window will open. Under **Primary settings** leave “Allow e-Consent responses to be edited by users” unselected. In First name field select the Printed Name of Participant from the dropdown menu and leave Last name field unselected. Leave all other setting as they are. Scroll down and select **Save settings**.



15. Repeat steps above in item 14 for the consenter form.

16. Once the e-Consent Framework has been completed, you will need to upload an inline PDF of the <u>**IRB approved and stamped consent form**</u> to the Participant-specific survey. To do so, select the green + Add consent form link (see highlighted area in screenshot below).



An **Add consent form** dialogue box will open. Complete as follows and see screenshot below for reference:

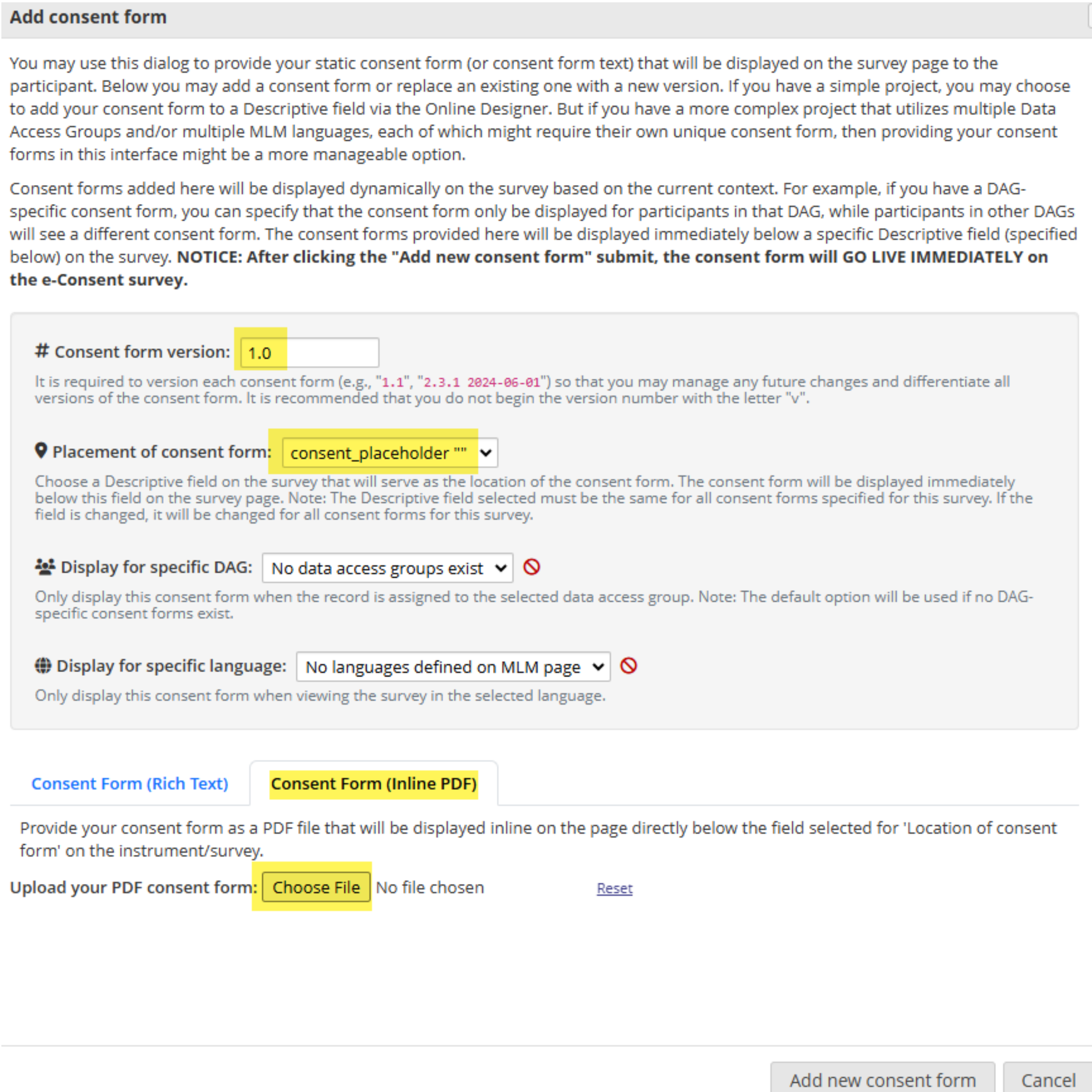
a) **# Consent version**: enter the version number. If this is the first version, enter as 1.0 or, if updating the consent form, enter as 2.0, 3.0, etc.

b) **Placement of consent form**: from the dropdown list select or enter your placeholder variable from item # above, i.e., consent_placeholder “”

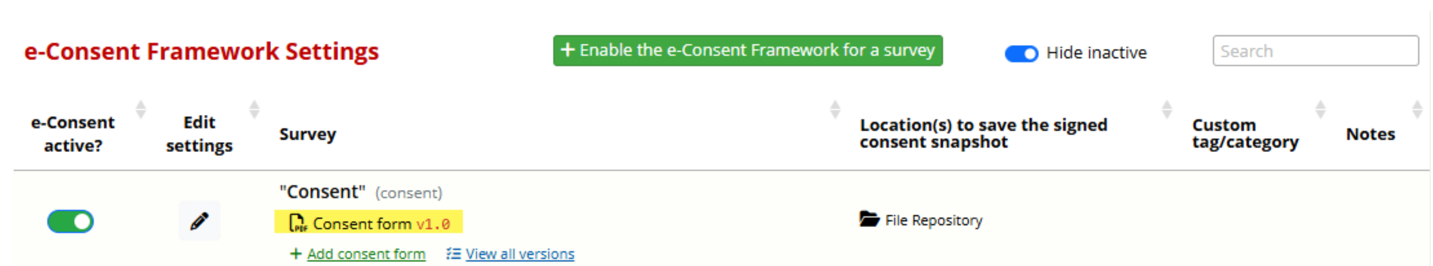
c) **Display for specific DAG**: can stay as is.

d) **Display for specific language**: can stay as is.

Below the grey dialogue box are two selections: Consent Form (Rich Text) and Consent Form (Inline PDF). Select **Consent Form (Inline PDF)**. Use the **Upload the PDF consent form: Choose File** link to select your current, IRB-approved and stamped form from whichever file/folder it is saved in on your computer. Select Open. The PDF will automatically upload. Once uploaded select the grey Add new consent form button at the bottom right of the box (next to the Cancel button). The PDF addition happens automatically, and you should get a popup stating “Success!”

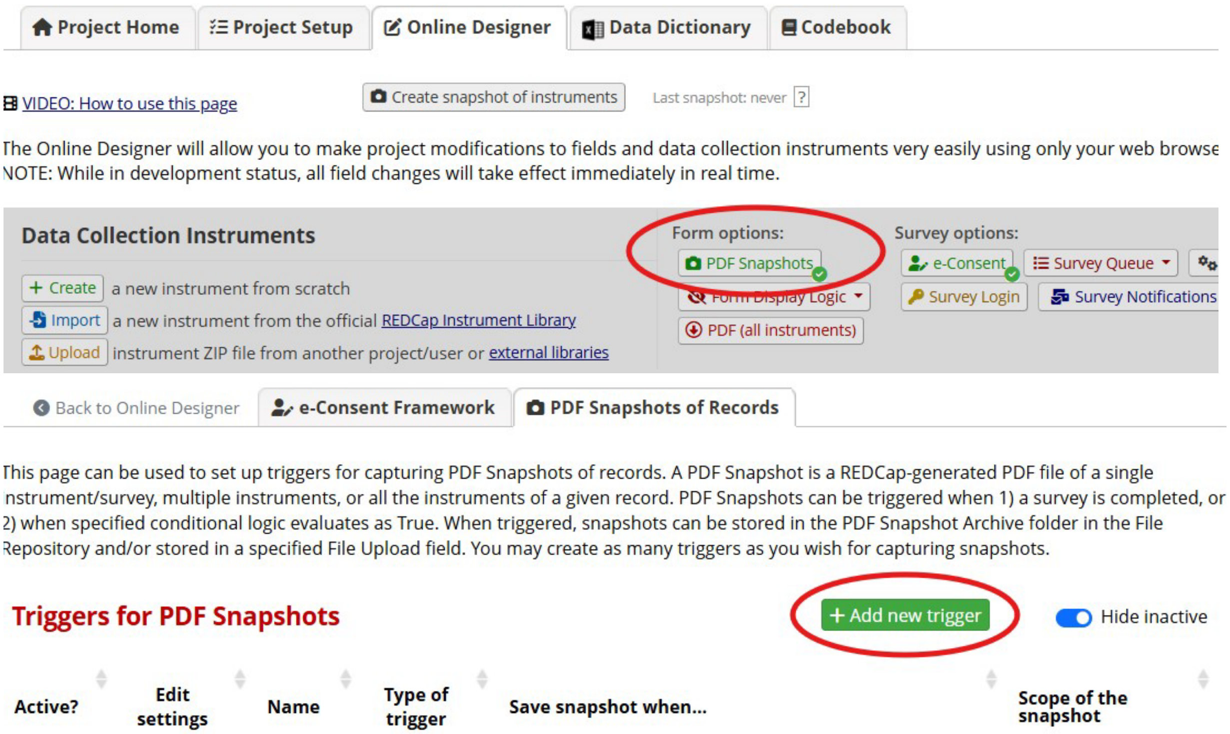


Once the consent form PDF has been successfully added, the e-Consent Framework tab will open. The display should resemble the screenshot below, with a PDF icon and the version number in red text.

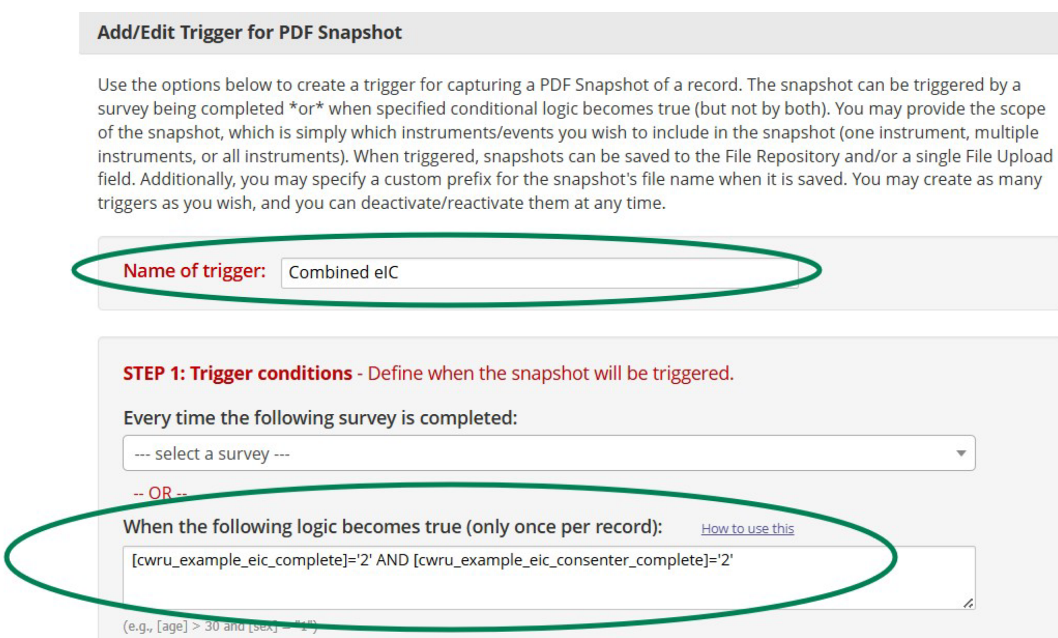


You will not need to upload a PDF for the Consenter survey.

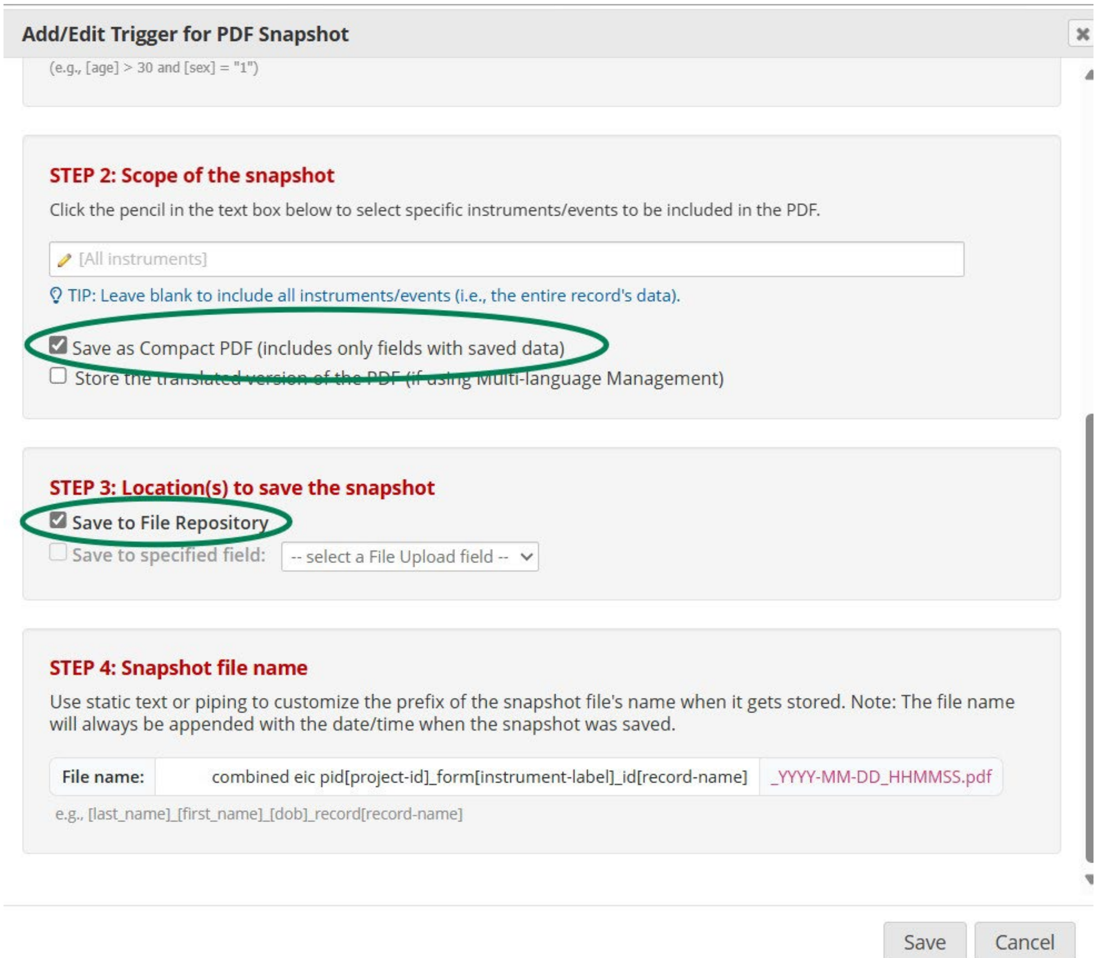
17. REDCap automatically creates PDF Snapshots for each enabled e-consent, which results in separate PDFs for the completed Participant and Consenter surveys being saved to the File Repository. Therefore, it is recommended that you **create an additional trigger to combine the two surveys into one PDF**. To do so, go back to **Online Designer** and, under Form options, select **PDF Snapshots** and Select **Add new trigger**.



Name your trigger (e.g., Combined Consent). In **Trigger conditions**, enter the logic as seen in the screenshot below, with the completion variable names in brackets. ***Note that you will need to use your exact variable names.** (The screenshot below is an example; do not copy the bracketed language word for word.) The logic of ='2' indicates that the survey is complete, i.e., the Form Status has been recorded as "Complete." See [REDCap](#) Help & FAQ for more information on functions for logic.



Scroll down and make sure **Save as Compact PDF** and **Save to File Repository** are selected. You can leave Snapshot File Name as is. Select **Save**.



18. Once all the above steps are completed, **you will need to thoroughly test your project**. **DO NOT SKIP THE TESTING PHASE!** Ensure that all branching logic works, required fields can't be skipped, and PDF snapshots are saved appropriately.

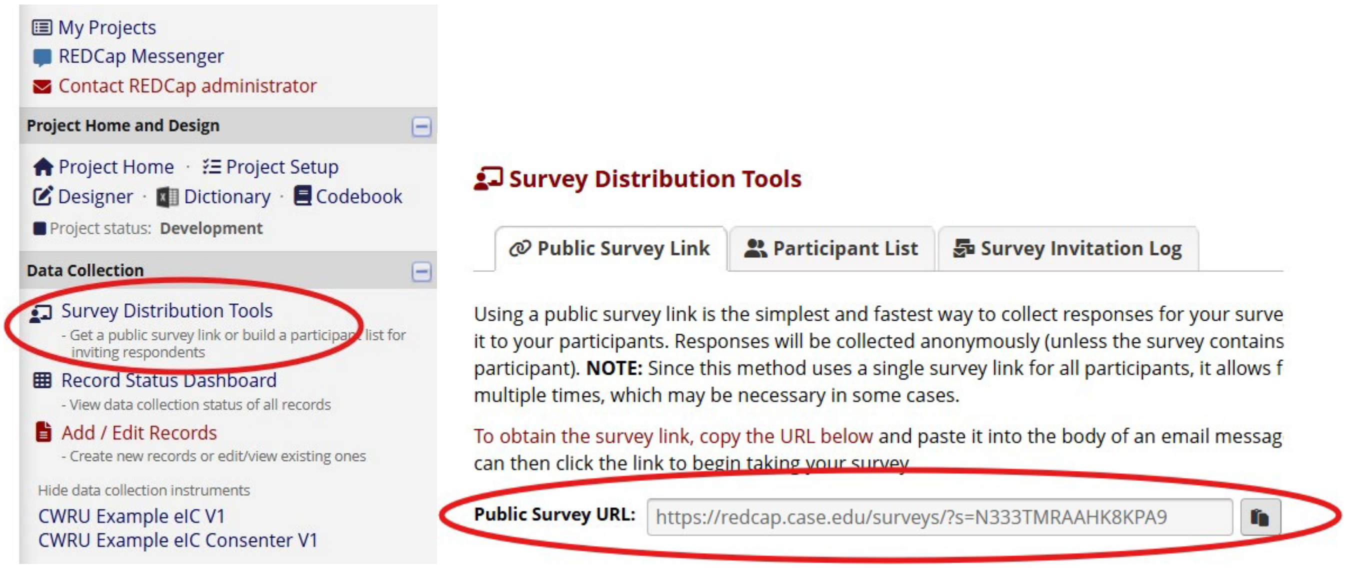
19. When you are certain that the REDCap project is ready, move your project to production by going to Project Setup and selecting "Move project to production." All test records will be deleted once this is completed. **DO NOT COLLECT ACTUAL PARTICIPANT DATA WHILE THE PROJECT IS IN DEVELOPMENT STATUS.**

<u>COMPLETING INFORMED CONSENT in REDCap</u>

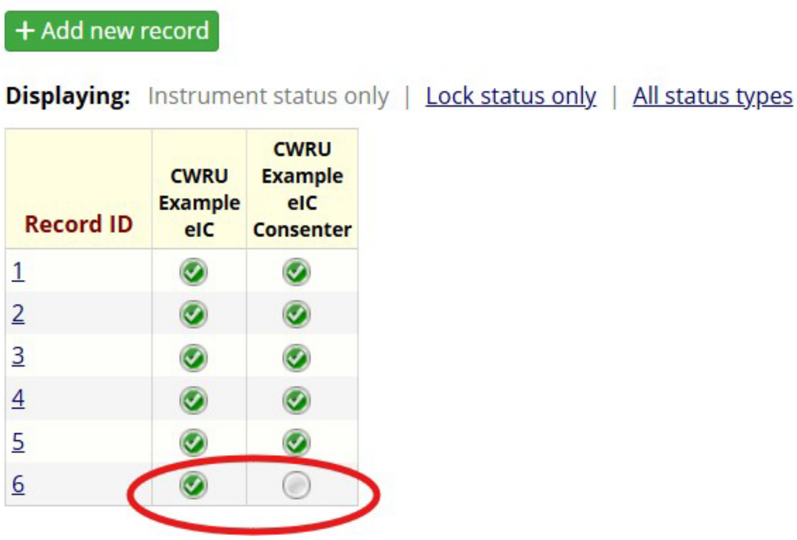
IMPORTANT NOTE: To ensure that the signed consent forms save to the File Repository, the forms must be opened and completed as a survey and NOT completed directly from the Record Status Dashboard.

<u>Remote Procedure:</u>

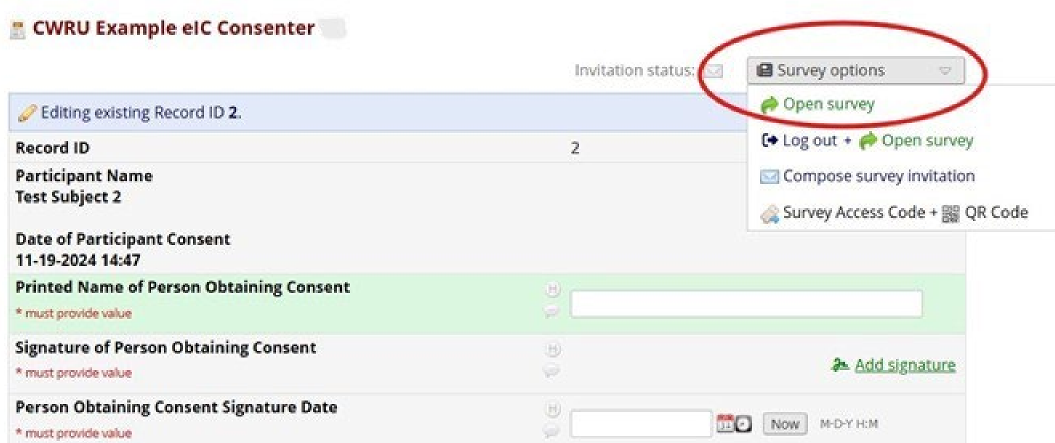
1. If you are performing the consent process remotely, such as by Zoom or another videoconferencing platform, you may send the participant a web link generated from Survey Distribution Tools via the Public Survey URL or generating an invitation using the Participant List. See the screenshots below.



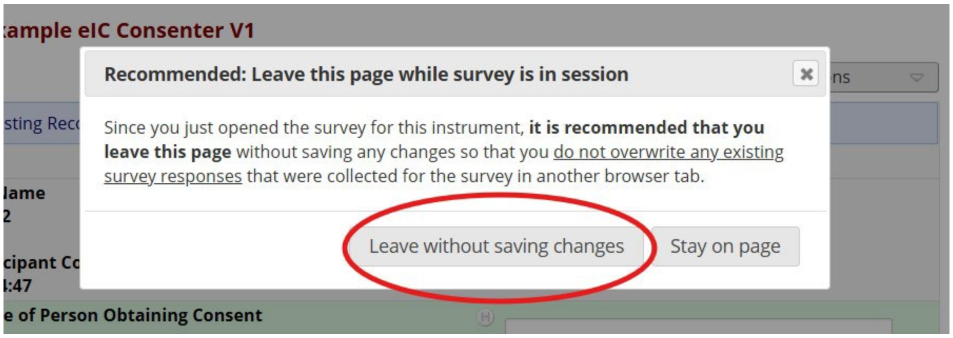
2. Once the participant completes the form remotely using the URL, it will save in the Record Status Dashboard. Open the **Record Status Dashboard** and select the grey status icon under the Consenter survey, next to the completed participant form.



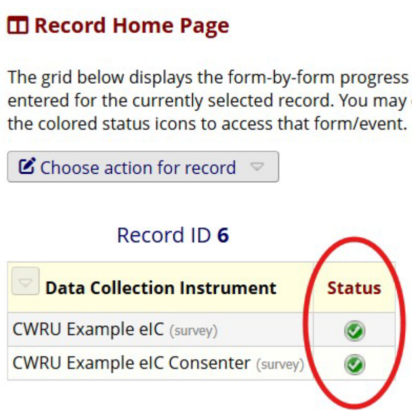
3. In Survey options select **Open survey**. A new window will open with the survey.



4. Fill in your printed name, signature, date, and then certify and submit. The new window will close. Select “Leave without saving changes” in the popup on the original page.

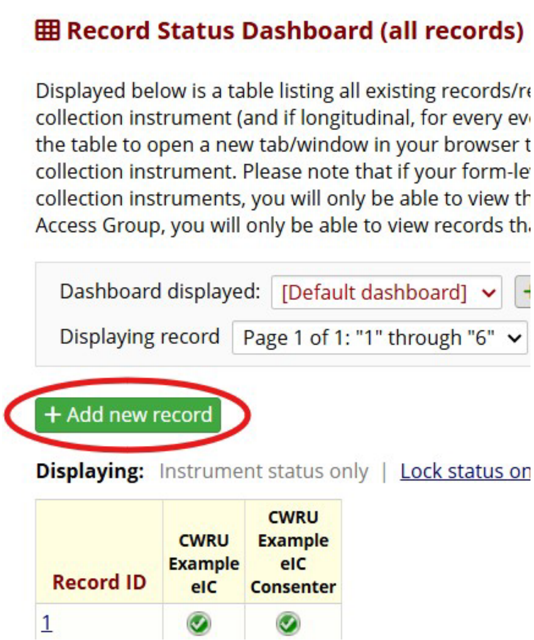


5. Selecting “Leave without saving changes” will take you back to the Record ID. The status of both forms will now be marked as complete.

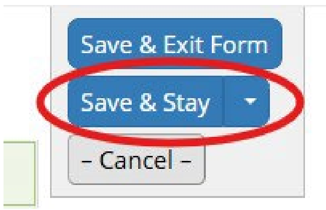


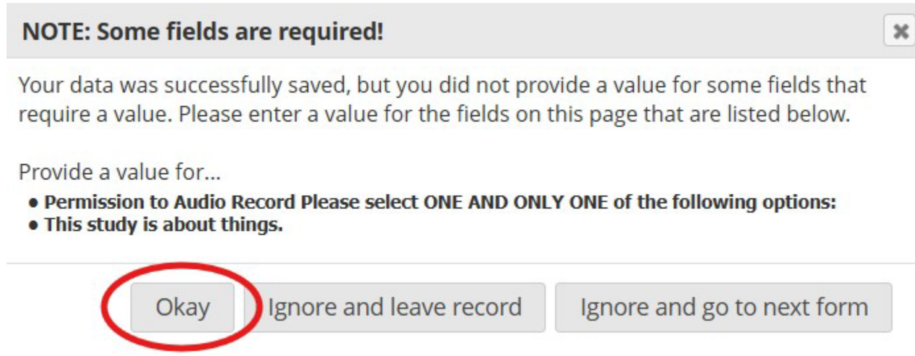
In Person Procedure

1. If you are performing the consent in person, open **Record Status Dashboard** and select **Add new record**. Select the grey status icon next to the consent form.

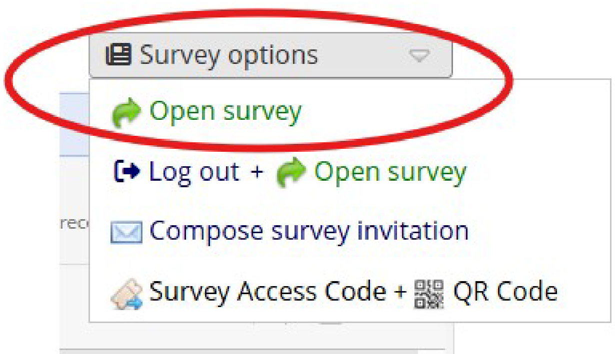


2. When the form opens, at the top right of the page, select **Save & Stay**. Select **Okay**.

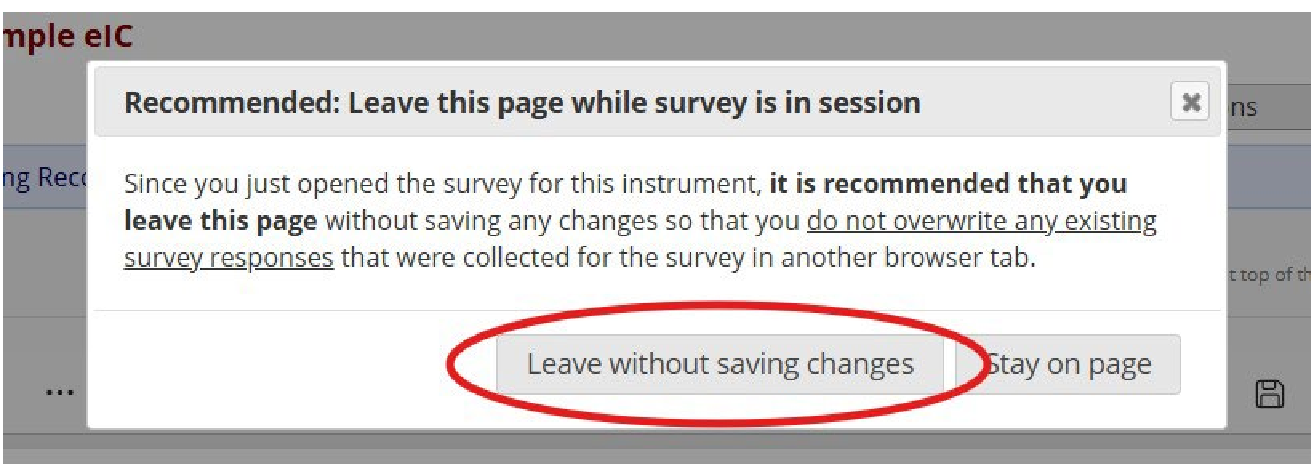




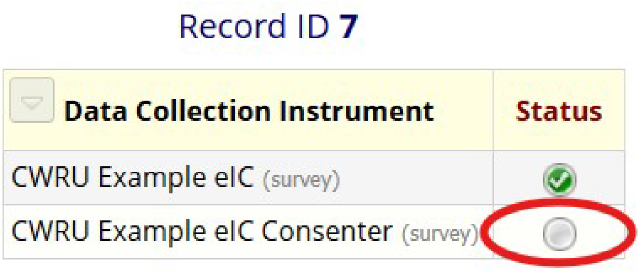
3. Select **Survey options** and select **Open survey**.

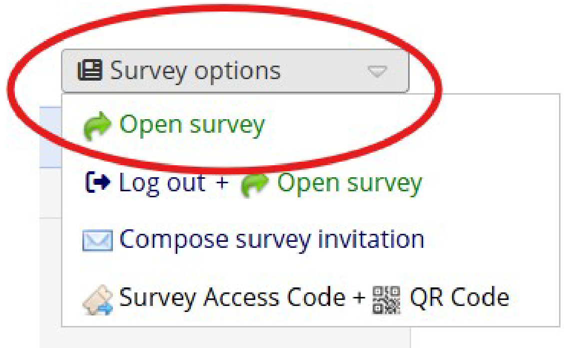


4. From the popup select “Leave without saving changes.”

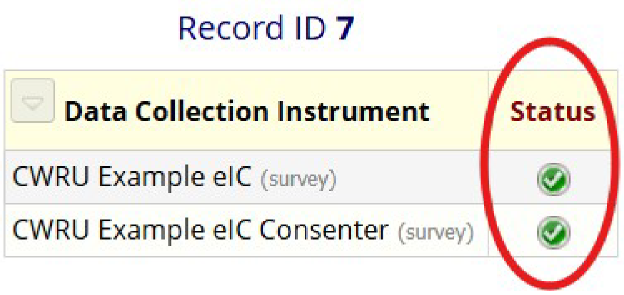


5. When the participant has submitted the completed survey, return to Record Status Dashboard. Select the grey status icon next to the consenter’s form. Select **Survey options** and select **Open survey**. Sign, certify and submit.





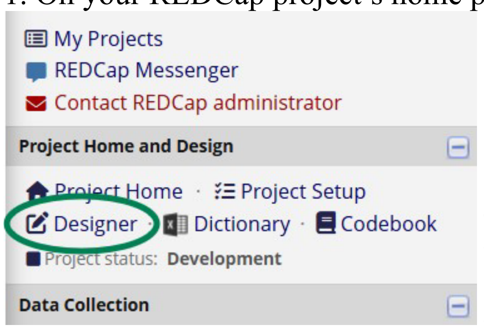
6. Again, from the popup select "Leave without saving changes." This will take you back to the Record ID. The status of both forms will now be marked as complete.

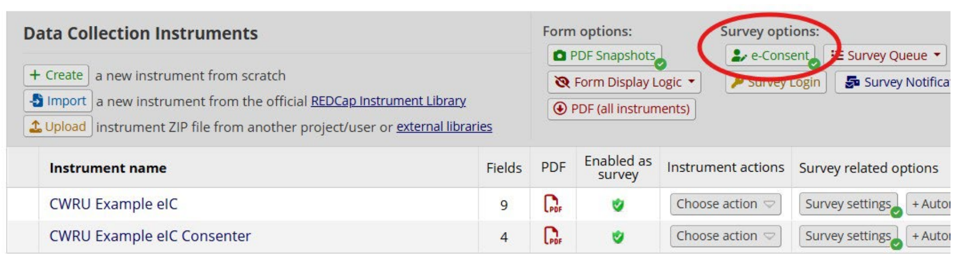


Adding An Updated Consent Version

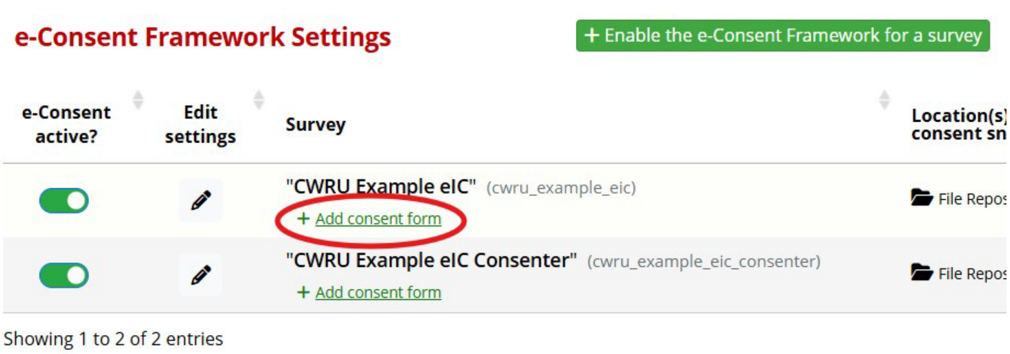
When a new consent form is approved by the CWRU IRB, it must immediately replace the previous version in REDCap. To do so, take the steps outlined below.

1. On your REDCap project's home page, select **Designer**. From the Online Designer tab, select **e-Consent**.

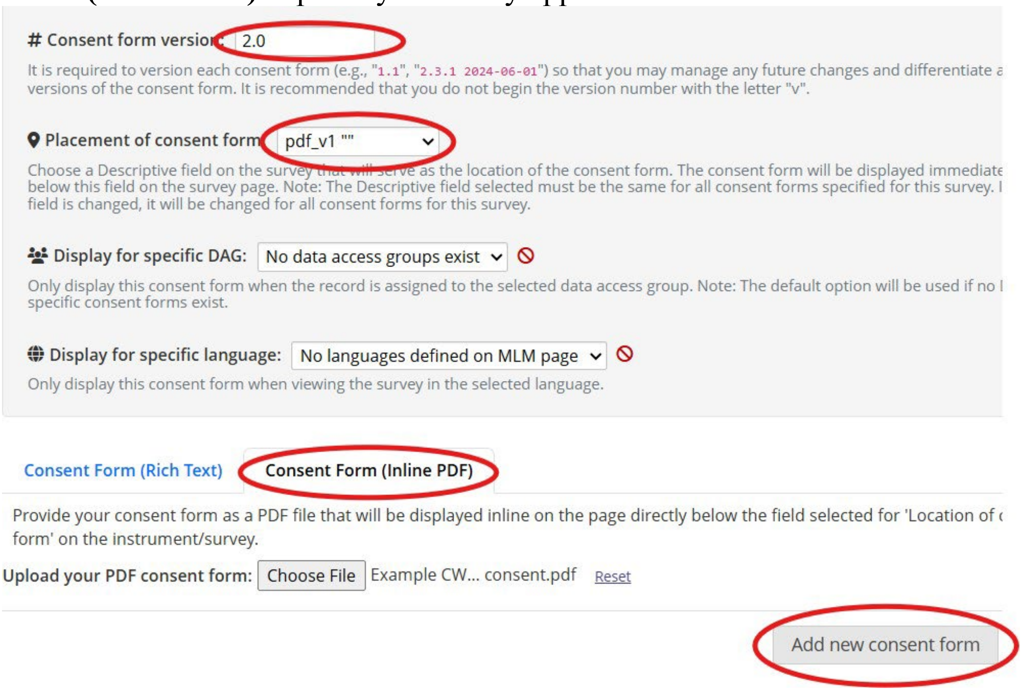




2. Under your original or most recent consent version, select **Add consent form**.



3. In **# Consent form version** enter the version number, e.g., 2.0, 3.0, or use the IRB approval date, e.g., 1-25-2025. In **Placement of consent form** select from the dropdown list. At the bottom of the tab select **Consent Form (Inline PDF)**. Upload your newly approved Consent Form PDF. Select **Add new consent form**.



4. After selecting **Add new consent form**, the old version is immediately made inactive, and the new version is activated. All web links will now route to the new version. Your e-Consent Framework settings should resemble the screenshot below.

5. Repeat this process every time a new consent version is approved by the CWRU IRB or when a Continuing Review results in a new Stamp Expiration Date.