

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

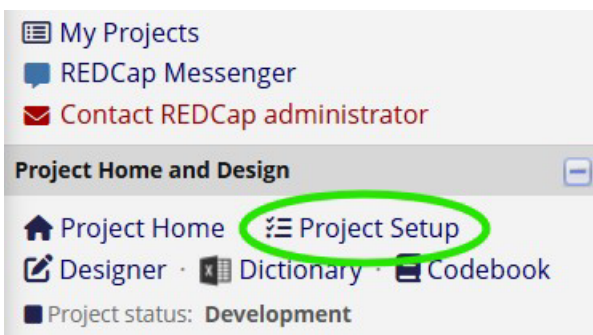
The following instructions are specific to consent processes that require consent documentation (no waivers or alterations) and can be used in either remote or in-person settings.

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](#)

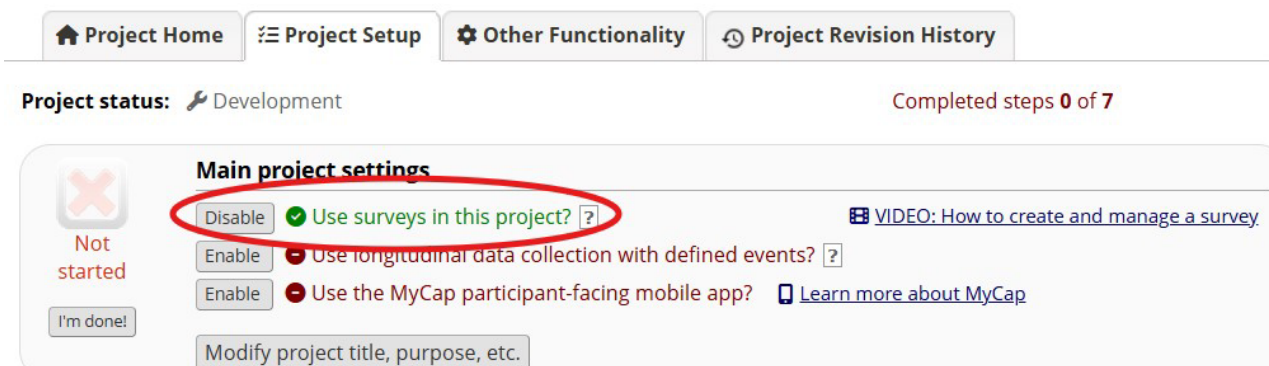
To create a CWRU REDCap Project, navigate to <https://redcap.case.edu/> and on the Home page select the *NEW PROJECT Request Form* link. If you do not yet have CWRU REDCap access, you will receive an account as part of your request. ~~Before creating your eIC form, it will be helpful to view the E-consent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

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](#)

I'm done!

Go to [Online Designer](#) or [Data Dictionary](#) Explore the [REDCap Instrument Library](#)

Have you checked the [Check For Identifiers](#) page to ensure all identifier fields have been tagged?

Learn how to use [Smart Variables](#) [Piping](#) [Action Tags](#) [Field Embedding](#) [Special Functions](#)

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.**

Instrument name	Fields	PDF	Enabled as survey	Instrument actions	Survey related options
STUDY1234 Consent Form	1	PDF	✓	Choose action Rename Copy Delete Download instrument ZIP	Survey settings

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.”

Data Collection Instruments

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

Form options:
[PDF Snapshots](#)
[Form Display Logic](#)
[PDF \(all instruments\)](#)
[Descriptive Popups](#)

Survey options:
[e-Consent](#)
[Survey Login](#)
[Survey Questions](#)

Instrument name	Fields	PDF	Enabled as survey	Instrument actions	Survey related options
CWRU Example eIC	9	PDF	✓	Choose action	Survey settings
CWRU Example eIC Consenter	4	PDF	✓	Choose action	Survey settings
Form	0	PDF	Enable	Choose action	

Survey Status
 Survey Active If offline, respondents will not be able take the survey.
 Custom text to display on survey page when offline: [Add offline message](#)

Basic Survey Options:

Survey Title
 STUDY1234 Consent Form
 Title to be displayed to participants at the top of the survey page

Survey Instructions
 (Displayed at top of survey after title)

Open Sans Paragraph 10pt **B** *I* U ~~S~~ ~~A~~ ~~U~~

Please read this form carefully. You will have an opportunity to ask questions before signing!
 Thank you!

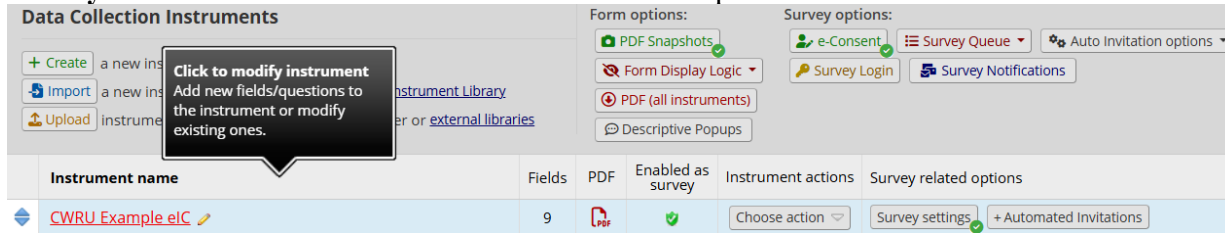
Review all the pre-populated Survey Design Options fields and edit where necessary. It is recommended that they stay as are with these exceptions:

- 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.”

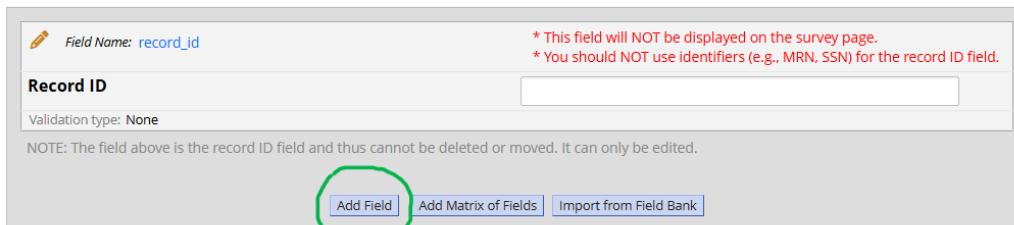
When complete, select **Save Changes**.

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.

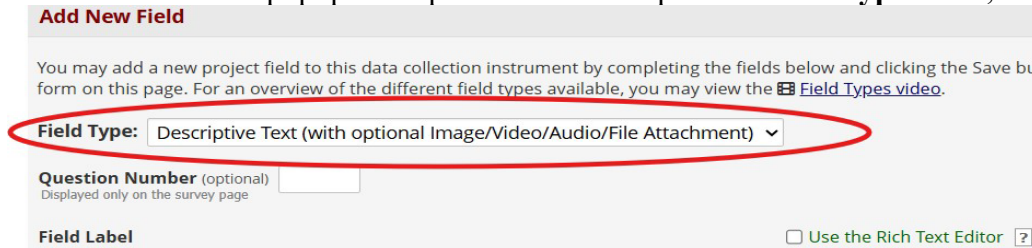


The **Online Designer** tab will automatically open. Under **Record ID** select **Add field**.

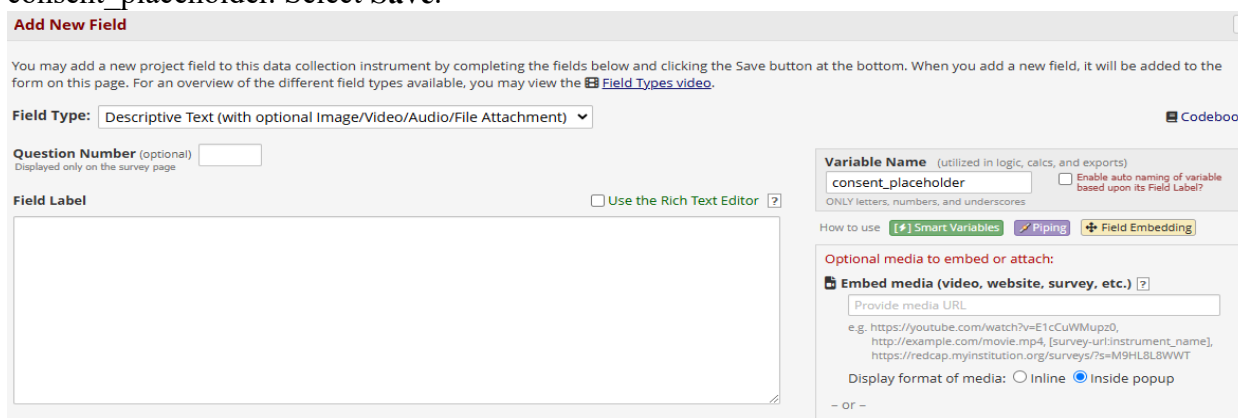
Current instrument: **Example ICF V1**



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

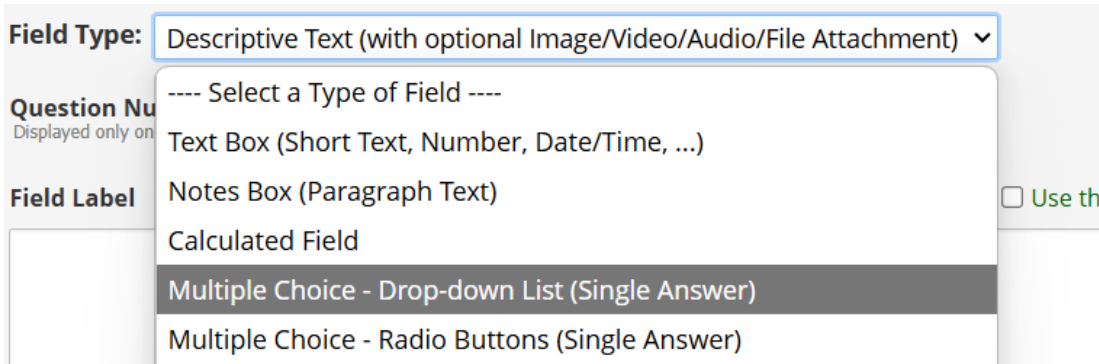


Leave Question Number and Field Label blank and enter a placeholder in **Variable Name** such as **consent_placeholder**. Select **Save**.

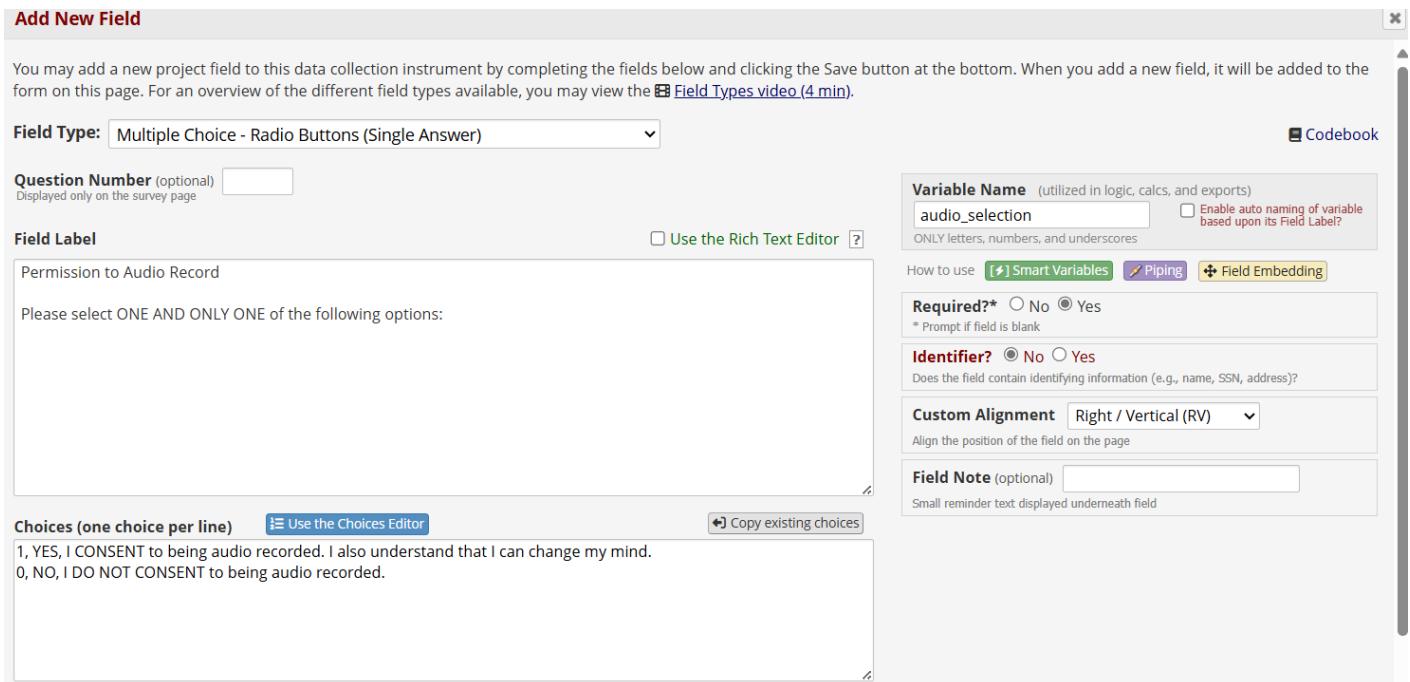


7. When **Save** is selected, you will be automatically returned to the Online Designer tab. You can now proceed with adding fields for checkboxes, such as for audio recording, future samples, and any Q&A questions for validating participant understanding.

To set up checkboxes for optional study procedures 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 questions for validating participant understanding, scroll down to the last page and select **Add Field**. In the popup, from the drop-down **Field Type** menu, select True – False.

Add New 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. For an overview of the different field types available, you may view the [Field Types](#) form on this page.

Field Type: Multiple Choice - Radio Buttons (Single Answer)

Question Number (optional)
Displayed only on the survey page: ---- Select a Type of Field ----

Field Label: Notes Box (Paragraph Text) Use the Rich Text Editor

Calculated Field

Multiple Choice - Drop-down List (Single Answer)

Multiple Choice - Radio Buttons (Single Answer)

Checkboxes (Multiple Answers)

Yes - No

True - False

Signature (draw signature with mouse or finger)

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**.

Field Type: True - False

Question Number (optional)
Displayed only on the survey page: 1.

Field Label: This study is about things. Use the Rich Text Editor

Variable Name (utilized in logic, calcs, and exports)
question_1 Enable auto naming of variable based upon its Field Label

ONLY letters, numbers, and underscores

How to use: [Smart Variables](#) [Piping](#) [Field Embedding](#)

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

Choices (not modifiable)
1, True
0, False

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

Add New 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: True - False

Question Number (optional)
Displayed only on the survey page: 2.

Field Label: I can withdraw from this study at any time. Use the Rich Text Editor

Variable Name (utilized in logic, calcs, and exports)
question_2 Enable auto naming of variable based upon its Field Label

ONLY letters, numbers, and underscores

How to use: [Smart Variables](#) [Piping](#) [Field Embedding](#)

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

Choices (not modifiable)
1, True
0, False

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**.

Add New 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: Text Box (Short Text, Number, Date/Time, ...)

Question Number (optional)

Field Label Use the Rich Text Editor ?

Printed Name of Participant

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](#) [Field Embedding](#)

Validation? (optional) --- None ---

- OR -

-- select ontology service --

Required?* No Yes
* Prompt if field is blank

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

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**.

Add New 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 finger)

Question Number (optional)

Field Label Use the Rich Text Editor ?

Signature of Participant

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](#) [Field Embedding](#)

Required?* No Yes
* Prompt if field is blank

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

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**.

Add New 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](#).

Field Type: Text Box (Short Text, Number, Date/Time, ...)

Question Number (optional)

Field Label Use the Rich Text Editor ?

Participant Signature Date

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](#) [Field Embedding](#)

Validation? (optional) Datetime (M-D-Y H:M)

Minimum:

Maximum:

Tip for min/max limits: You may pipe a value from another field to set dynamic range limits - e.g., [visit_date] or [event_1_arm_1][age]. You may also use the word today or now (not wrapped in quotes) for date/time fields.

- OR -

-- select ontology service --

Required?* No Yes
* Prompt if field is blank

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

Action Tags / Field Annotation (optional)

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

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.

Field Type:

Field Label Use the Rich Text Editor [?](#)

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.

Edit Branching Logic

[2.] Field Name: question_2

I can withdraw from this study at any time. True False

* must provide value

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.”

Add/Edit Branching Logic
N-Drop method if it becomes too complex.

Choose method below for the following field: **question_2 - I can withdraw from this study at any ...**

Advanced Branching Logic Syntax How to use [Branching Logic](#) [Smart Variables](#) [Special Functions](#)

Show the field ONLY if...

[question_1] = '1'

Test logic with a record: -- select a record -- [Clear logic](#)

— OR —

Drag-N-Drop Logic Builder

Field choices from other fields
(drag a choice below to box on right)

- record_id = (define criteria)
- audio_selection = YES, I CONSENT to being audio recorded. I also und... (1)
- audio_selection = NO, I DO NOT CONSENT to being audio recorded. (0)
- question_1 = True (1)
- question_1 = False (0)
- question_3 = True (1)
- question_3 = False (0)

Show the field ONLY if...

ALL below are true
 ANY below are true

question_1 = True (1) ❌

[Clear logic](#)

Add/Edit Branching Logic
N-Drop method if it becomes too complex.

Choose method below for the following field: **question_3 - This study will last three (3) weeks.**

Advanced Branching Logic Syntax How to use [Branching Logic](#) [Smart Variables](#) [Special Fu](#)

Show the field ONLY if...

[question_1] = '1' and [question_2] = '1'

Test logic with a record: -- select a record -- [Clear lo](#)

— OR —

Drag-N-Drop Logic Builder

Field choices from other fields
(drag a choice below to box on right)

- record_id = (define criteria)
- audio_selection = YES, I CONSENT to being audio recorded. I also und... (1)
- audio_selection = NO, I DO NOT CONSENT to being audio recorded. (0)
- question_1 = True (1)
- question_1 = False (0)
- question_2 = True (1)
- question_2 = False (0)

Show the field ONLY if...

ALL below are true
 ANY below are true

question_1 = True (1) ❌
question_2 = True (1) ❌

[Clear logic](#)

Add/Edit Branching Logic
N-Drop method if it becomes too complex.

Choose method below for the following field: **participant_name - Printed Name of Participant**

Advanced Branching Logic Syntax How to use [Branching Logic](#) [Smart Variables](#) [Special Fun](#)

Show the field ONLY if...

[question_1] = '1' and [question_2] = '1' and [question_3] = '0'

Test logic with a record: -- select a record -- [Clear log](#)

— OR —

Drag-N-Drop Logic Builder

Field choices from other fields
(drag a choice below to box on right)

- question_1 = True (1)
- question_1 = False (0)
- question_2 = True (1)
- question_2 = False (0)
- question_3 = True (1)
- question_3 = False (0)
- participant_date = (define criteria)
- consenter_name = (define criteria)
- consenter_date = (define criteria)

Show the field ONLY if...

ALL below are true
 ANY below are true

question_1 = True (1) ❌
question_2 = True (1) ❌
question_3 = False (0) ❌

[Clear logic](#)

Add/Edit Branching Logic
N-Drop method if it becomes too complex.

Choose method below for the following field: **participant_signature - Signature of Participant**

Advanced Branching Logic Syntax How to use [Branching Logic](#) [Smart Variables](#) [Special Fur](#)

Show the field ONLY if...

[question_1] = '1' and [question_2] = '1' and [question_3] = '0'

Test logic with a record: -- select a record -- [Clear log](#)

— OR —

Drag-N-Drop Logic Builder

Field choices from other fields
(drag a choice below to box on right)

- question_1 = False (0)
- question_2 = True (1)
- question_2 = False (0)
- question_3 = True (1)
- question_3 = False (0)
- participant_name = (define criteria)
- participant_date = (define criteria)
- consenter_name = (define criteria)
- consenter_date = (define criteria)

Show the field ONLY if...

ALL below are true
 ANY below are true

question_1 = True (1) ❌
question_2 = True (1) ❌
question_3 = False (0) ❌

[Clear logic](#)

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**.

Data Collection Instruments

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

Form options: PDF Snapshots, Form Display Logic, PDF (all instruments)

Survey options: e-Consent, Survey Queue, Auto Invitation, Survey Login, Survey Notifications

Instrument name	Fields	PDF	Enabled as survey	Instrument actions	Survey related options
Example ICF Participant	14			Choose action	Survey settings + Automated Invitations

[+ Add instrument here](#)

Field Type: Text Box (Short Text, Number, Date/Time, ...)

Question Number (optional)
Displayed only on the survey page

Field Label Use the Rich Text Editor ?
Printed Name of Person Obtaining Consent

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

How to use Smart Variables Piping Field Embedding

Validation? (optional) ---- None ----
- OR -
-- select ontology service --

Required?* No Yes
* Prompt if field is blank

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

Field Type: Signature (draw signature with mouse or finger)

Question Number (optional)
Displayed only on the survey page

Field Label Use the Rich Text Editor ?
Signature of Person Obtaining Consent

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

How to use Smart Variables Piping Field Embedding

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 Type: Text Box (Short Text, Number, Date/Time, ...)

Question Number (optional)
Displayed only on the survey page

Field Label Use the Rich Text Editor ?
Person Obtaining Consent Signature Date

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

How to use Smart Variables Piping Field Embedding

Validation? (optional) Date (M-D-Y)
- OR -
-- select ontology service --

Minimum:
Maximum:

Tip for min/max limits: You may pipe a value from another field to set dynamic range limits - e.g., [visit_date] or [event_1_arm_1][age]. You may also use the word today or now (not wrapped in quotes) for date/time fields.

Required?* No Yes
* Prompt if field is blank

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

Action Tags / Field Annotation (optional)

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

Current instrument: **CWRU Example eIC Consenter**

Add Field Add Matrix of Fields Import from Field Bank

Field Name: eicpoc

Printed Name of Person Obtaining Consent
* must provide value
Validation type: None

Add Field Add Matrix of Fields Import from Field Bank

Field Name: eicsigdoc

Signature of Person Obtaining Consent
* must provide value Add signature

Add Field Add Matrix of Fields Import from Field Bank

Field Name: eicpocsigdate

Person Obtaining Consent Signature Date
* must provide value Now M-D-Y H:M
Validation type: Datetime (M-D-Y H:M)

Add Field Add Matrix of Fields Import from Field Bank

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).

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 form on this page. For an overview of the different field types available, you may view the [Field Types video](#).

Field Type: Descriptive Text (with optional Image/Video/Audio/File Attachment) ▼

Question Number (optional)
Displayed only on the survey page

Field Label Use the Rich Text Editor ?

Participant Name
[participant_name]

Date of Participant Consent
[participant_date]

Variable Name (utilized in logic, calc)
pt_info
ONLY letters, numbers, and underscores

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

Optional media to embed or attach

Embed media (video, website,

Provide media URL

e.g. <https://youtube.com/watch?v=E1>
<http://example.com/movie.mp4>
<https://redcap.myinstitution.org>

Display format of media: Inl

- or -

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

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

Data Collection Instruments

[+ Create](#) a new instrument from scratch

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

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

Form options:

- PDF Snapshots
- Form Display Logic
- PDF (all instruments)

Survey options:

- e-Consent
- Survey Queue
- Survey Login
- Survey Notifications

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

[Back to Online Designer](#) **e-Consent Framework** [PDF Snapshots of Records](#)

Electronic Consent (e-Consent) is a platform for consenting patients or research subjects either on site or at home using a con traditional paper documentation. Consent forms can be implemented in a REDCap survey via computer, mobile phone, or tab provides standardized tools to obtain consent and store consent documentation with a certification screen and a storage func "hard-copy" PDF of the signed form. The e-Consent Framework offers many options to allow customization to your specific ne enabled for any survey in this project. You may optionally provide consent forms as either an inline PDF or rich text that will be The consent forms can be context-specific if you are using MLM languages and/or Data Access Groups so that it displays the c with a specific language set and/or assigned to a specific DAG. See the "Add consent form" link for more details after enabling

e-Consent Framework Settings

[+ Enable the e-Consent Framework for a survey](#)

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.

The screenshot shows a window titled "Enable e-Consent for a Survey" with a close button in the top right. The text inside reads: "You may enable the e-Consent Framework for any survey in the project. First, choose the survey below for which you want to enable e-Consent, and then you will be prompted to specify all the e-Consent settings for that survey afterward." Below the text is a dropdown menu with "-- select a survey --" and a list of survey options, including "Example ICF" (example_icf). A "Close" button is located at the bottom right of the window.

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**.

e-Consent settings for survey "CWRU Example eIC" (cwr_u_example_eic)

Use the settings below for setting up the e-Consent Framework for this survey. e-Consent often requires obtaining the consenting participant's name (and sometimes their date of birth) on the final consent form as documentation of their identity. Below you may select fields used to capture that info, in which the values for those fields will be automatically inserted into the footer of the PDF consent form that the participant will review at the end the survey. And then afterwards, that PDF "hard-copy" will be archived in the File Repository (with the additional option to also store the PDF in a File Upload field). Other e-Consent related options can be set below, such as setting a custom tag/category, custom label for the PDF header, location(s) to save the signed e-Consent snapshot, and the file name format of the snapshots being stored.

The "Primary settings" section includes a checkbox labeled "Allow e-Consent responses to be edited by users?" which is unselected and circled in red. Below it are two dropdown menus: "First name field:" with "eicpartname 'Printed Name of Partic'" selected and circled in green, and "Last name field:" with "-- select a field --" selected. A note at the bottom states: "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."

The "Additional settings" section includes a "Date of birth field:" dropdown menu with "-- select a field --" selected. Below it is a text input field for "Custom tag/category for PDF footer:" with "e.g., Pediatric" as an example. A note says: "Note: This should be static text only." Below that is another text input field for "Custom label for PDF header:" with "e.g., PID [project-id] - [[last_name]]" as an example. At the bottom, there is a note: "Note: Piping may be utilized, including the use of Smart Variables." with buttons for "Codebook" and "Smart Variables". A link at the bottom reads: "Force signature field(s) to be erased if participant clicks Previous Page button while on the certification page?"

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

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

Electronic Consent (e-Consent) is a platform for consenting patients or research subjects either on site or at home using a computer-based consent form rather than traditional paper documentation. Consent forms can be implemented in a REDCap survey via computer, mobile phone, or tablet. The REDCap e-Consent Framework provides standardized tools to obtain consent and store consent documentation with a certification screen and a storage function which automatically generates a "hard-copy" PDF of the signed form. The e-Consent Framework offers many options to allow customization to your specific needs. The e-Consent Framework can be enabled for any survey in this project. You may optionally provide consent forms as either an inline PDF or rich text that will be displayed on the consent survey itself. The consent forms can be context-specific if you are using MLM languages and/or Data Access Groups so that it displays the correct consent form for a participant with a specific language set and/or assigned to a specific DAG. See the "Add consent form" link for more details after enabling e-Consent for a survey. [Read more](#)

e-Consent Framework Settings + Enable the e-Consent Framework for a survey Hide inactive

e-Consent active?	Edit settings	Survey	Location(s) to save the signed consent snapshot	Custom tag/category	Notes
<input checked="" type="checkbox"/>		"Consent" (consent) + Add consent form	File Repository		

Showing 1 to 1 of 1 entries Previous 1 Next

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

- # 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.
- Placement of consent form:** from the dropdown list select or enter your placeholder variable from item # above, i.e., consent_placeholder ""
- Display for specific DAG:** can stay as is.
- 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!"

Add consent form

You may use this dialog to provide your static consent form (or consent form text) that will be displayed on the survey page to the participant. Below you may add a consent form or replace an existing one with a new version. If you have a simple project, you may choose to add your consent form to a Descriptive field via the Online Designer. But if you have a more complex project that utilizes multiple Data Access Groups and/or multiple MLM languages, each of which might require their own unique consent form, then providing your consent forms in this interface might be a more manageable option.

Consent forms added here will be displayed dynamically on the survey based on the current context. For example, if you have a DAG-specific consent form, you can specify that the consent form only be displayed for participants in that DAG, while participants in other DAGs will see a different consent form. The consent forms provided here will be displayed immediately below a specific Descriptive field (specified below) on the survey. **NOTICE: After clicking the "Add new consent form" submit, the consent form will GO LIVE IMMEDIATELY on the e-Consent survey.**

Consent form version:

It is required to version each consent form (e.g., "1.1", "2.3.1 2024-06-01") so that you may manage any future changes and differentiate all versions of the consent form. It is recommended that you do not begin the version number with the letter "v".

📍 Placement of consent form:

Choose a Descriptive field on the survey that will serve as the location of the consent form. The consent form will be displayed immediately below this field on the survey page. Note: The Descriptive field selected must be the same for all consent forms specified for this survey. If the field is changed, it will be changed for all consent forms for this survey.

👤 Display for specific DAG:

Only display this consent form when the record is assigned to the selected data access group. Note: The default option will be used if no DAG-specific consent forms exist.

🌐 Display for specific language:

Only display this consent form when viewing the survey in the selected language.

[Consent Form \(Rich Text\)](#)

Consent Form (Inline PDF)

Provide your consent form as a PDF file that will be displayed inline on the page directly below the field selected for 'Location of consent form' on the instrument/survey.

Upload your PDF consent form: No file chosen [Reset](#)

Add new consent form

Cancel

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.

e-Consent Framework Settings

[+ Enable the e-Consent Framework for a survey](#)

Hide inactive

e-Consent active?	Edit settings	Survey	Location(s) to save the signed consent snapshot	Custom tag/category	Notes
<input checked="" type="checkbox"/>		"Consent" (consent) 📄 Consent form v1.0 + Add consent form 🔗 View all versions	File Repository		

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**.

[Project Home](#)
[Project Setup](#)
[Online Designer](#)
[Data Dictionary](#)
[Codebook](#)

[VIDEO: How to use this page](#)
[Create snapshot of instruments](#)
 Last snapshot: never [?](#)

The Online Designer will allow you to make project modifications to fields and data collection instruments very easily using only your web browser.
 NOTE: While in development status, all field changes will take effect immediately in real time.

Data Collection Instruments

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

Form options: PDF Snapshots
 Form Display Logic
 PDF (all instruments)

Survey options: e-Consent, Survey Queue, Survey Login, Survey Notifications

[Back to Online Designer](#)
[e-Consent Framework](#)
[PDF Snapshots of Records](#)

This page can be used to set up triggers for capturing PDF Snapshots of records. A PDF Snapshot is a REDCap-generated PDF file of a single instrument/survey, multiple instruments, or all the instruments of a given record. PDF Snapshots can be triggered when 1) a survey is completed, or 2) when specified conditional logic evaluates as True. When triggered, snapshots can be stored in the PDF Snapshot Archive folder in the File Repository and/or stored in a specified File Upload field. You may create as many triggers as you wish for capturing snapshots.

Triggers for PDF Snapshots

+ Add new trigger
 Hide inactive

Active?	Edit settings	Name	Type of trigger	Save snapshot when...	Scope of the snapshot
---------	---------------	------	-----------------	-----------------------	-----------------------

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.

Add/Edit Trigger for PDF Snapshot

Use the options below to create a trigger for capturing a PDF Snapshot of a record. The snapshot can be triggered by a survey being completed *or* when specified conditional logic becomes true (but not by both). You may provide the scope of the snapshot, which is simply which instruments/events you wish to include in the snapshot (one instrument, multiple instruments, or all instruments). When triggered, snapshots can be saved to the File Repository and/or a single File Upload field. Additionally, you may specify a custom prefix for the snapshot's file name when it is saved. You may create as many triggers as you wish, and you can deactivate/reactivate them at any time.

Name of trigger: Combined eIC

STEP 1: Trigger conditions - Define when the snapshot will be triggered.

Every time the following survey is completed:

--- select a survey ---

-- OR --

When the following logic becomes true (only once per record): [How to use this](#)

[cwru_example_eic_complete]=2' AND [cwru_example_eic_consenter_complete]=2'

(e.g., [age] > 30 and [sex] = 'M')

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**.

Add/Edit Trigger for PDF Snapshot ✕

(e.g., [age] > 30 and [sex] = "1")

STEP 2: Scope of the snapshot

Click the pencil in the text box below to select specific instruments/events to be included in the PDF.

✎ [All instruments]

🔗 TIP: Leave blank to include all instruments/events (i.e., the entire record's data).

Save as Compact PDF (includes only fields with saved data)

Store the translated version of the PDF (if using Multi-language Management)

STEP 3: Location(s) to save the snapshot

Save to File Repository

Save to specified field: -- select a File Upload field --

STEP 4: Snapshot file name

Use static text or piping to customize the prefix of the snapshot file's name when it gets stored. Note: The file name will always be appended with the date/time when the snapshot was saved.

File name: combined eic pid[project-id]_form[instrument-label]_id[record-name] _YYYY-MM-DD_HHMMSS.pdf

e.g., [last_name]_[first_name]_[dob]_record[record-name]

Save
Cancel

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.**

COMPLETING INFORMED CONSENT in REDCap

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.

Remote Procedure:

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.

My Projects

- REDCap Messenger
- Contact REDCap administrator

Project Home and Design

- Project Home · Project Setup
- Designer · Dictionary · Codebook
- Project status: Development

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

Hide data collection instruments

- CWRU Example eIC V1
- CWRU Example eIC Consenter V1

Survey Distribution Tools

Public Survey Link Participant List Survey Invitation Log

Using a public survey link is the simplest and fastest way to collect responses for your survey to your participants. Responses will be collected anonymously (unless the survey contains participant). **NOTE:** Since this method uses a single survey link for all participants, it allows for multiple times, which may be necessary in some cases.

To obtain the survey link, copy the URL below and paste it into the body of an email message. You can then click the link to begin taking your survey.

Public Survey URL:

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.

+ Add new record

Displaying: Instrument status only | Lock status only | All status types

Record ID	CWRU Example eIC	CWRU Example eIC Consenter
1	✓	✓
2	✓	✓
3	✓	✓
4	✓	✓
5	✓	✓
6	✓	⊖

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

CWRU Example eIC Consenter

Invitation status:

Editing existing Record ID 2.

Record ID: 2

Participant Name: Test Subject 2

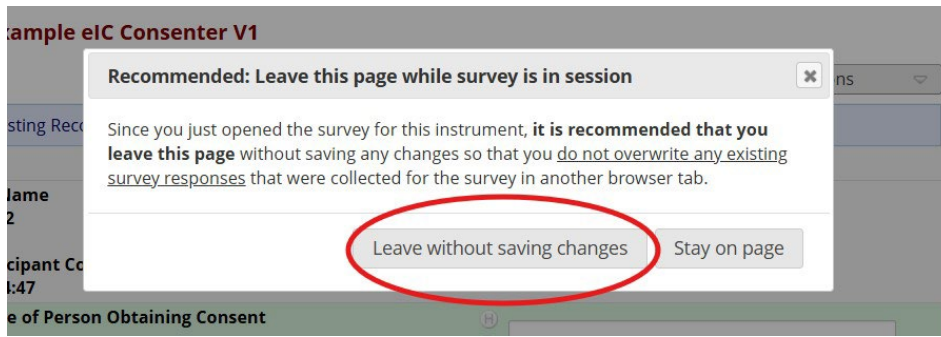
Date of Participant Consent: 11-19-2024 14:47

Printed Name of Person Obtaining Consent:

Signature of Person Obtaining Consent: Add signature

Person Obtaining Consent Signature Date: Now M-D-Y H:M

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.

Record Home Page

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event.

Choose action for record

Record ID 6

Data Collection Instrument	Status
CWRU Example eIC (survey)	✓
CWRU Example eIC Consenter (survey)	✓

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.

Record Status Dashboard (all records)

Displayed below is a table listing all existing records/record collection instrument (and if longitudinal, for every event in the table to open a new tab/window in your browser to view that collection instrument. Please note that if your form-level collection instruments, you will only be able to view records that you have access to. If you are in a restricted Access Group, you will only be able to view records that you have access to.

Dashboard displayed: [Default dashboard] | Page 1 of 1: "1" through "6"

+ Add new record

Displaying: Instrument status only | [Lock status on](#)

Record ID	CWRU Example eIC	CWRU Example eIC Consenter
1	✓	✓

Record Home Page

Record "7" is a new Record ID. To create the record, click the + icon.

The grid below displays the form-by-form progress entered for the currently selected record. You may click on the colored status icons to access that form/event.

NEW Record ID 7

Data Collection Instrument	Status
CWRU Example eIC (survey)	○
CWRU Example eIC Consenter (survey)	○

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



NOTE: Some fields are required!

Your data was successfully saved, but you did not provide a value for some fields that require a value. Please enter a value for the fields on this page that are listed below.

Provide a value for...

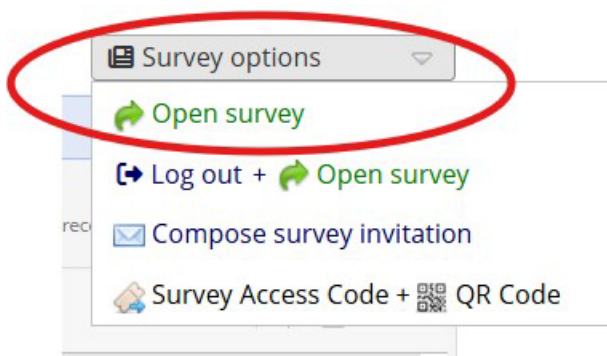
- **Permission to Audio Record** Please select **ONE AND ONLY ONE** of the following options:
- **This study is about things.**

Okay

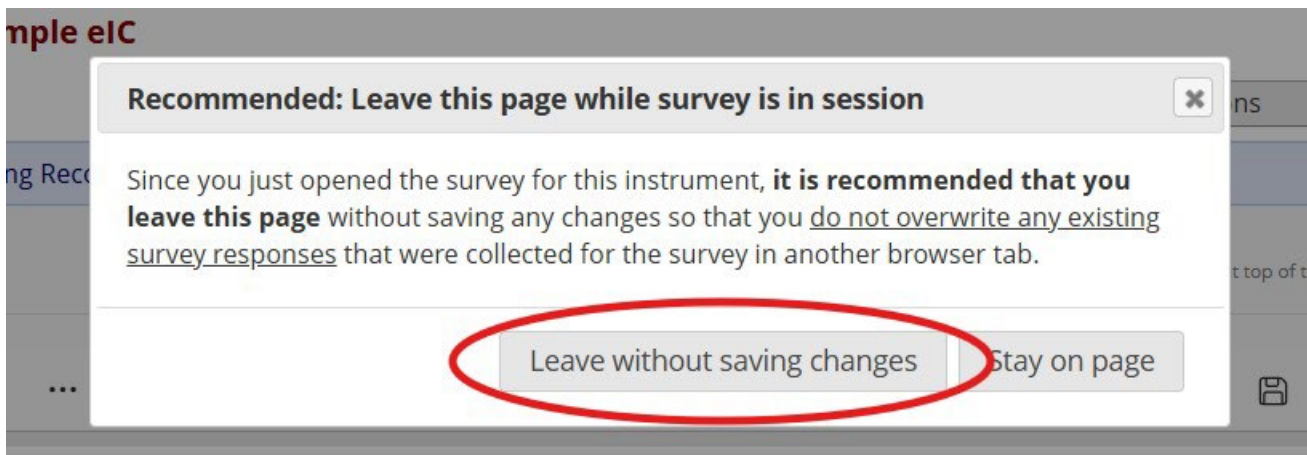
Ignore and leave record

Ignore and go to next form

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



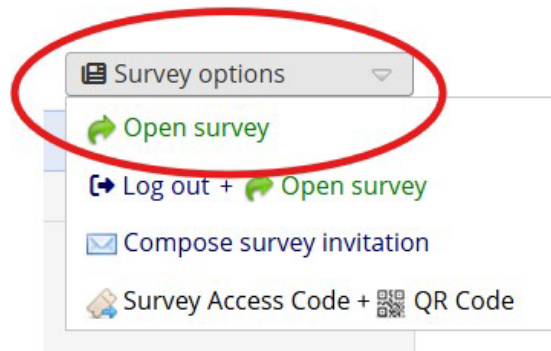
4. From the popup select “Leave without saving changes.”



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

Record ID 7

Data Collection Instrument	Status
CWRU Example eIC (survey)	
CWRU Example eIC Consenter (survey)	



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.

Record ID 7

Data Collection Instrument	Status
CWRU Example eIC (survey)	
CWRU Example eIC Consenter (survey)	

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**.

My Projects

- REDCap Messenger
- Contact REDCap administrator

Project Home and Design

- Project Home
- Project Setup
- Designer**
- Dictionary
- Codebook
- Project status: Development

Data Collection

Data Collection Instruments

- Create: a new instrument from scratch
- Import: a new instrument from the official REDCap Instrument Library
- Upload: instrument ZIP file from another project/user or external libraries

Form options:

- PDF Snapshots
- Form Display Logic
- PDF (all instruments)

Survey options:

- e-Consent**
- Survey Queue
- Survey Login
- Survey Notifica

Instrument name	Fields	PDF	Enabled as survey	Instrument actions	Survey related options
CWRU Example eIC	9			Choose action	Survey settings + Auto
CWRU Example eIC Consenter	4			Choose action	Survey settings + Auto

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

e-Consent Framework Settings

[+ Enable the e-Consent Framework for a survey](#)

e-Consent active?	Edit settings	Survey	Location(s) consent sn
		"CWRU Example eIC" (cwr_u_example_eic) + Add consent form	File Repos
		"CWRU Example eIC Consenter" (cwr_u_example_eic_consenter) + Add consent form	File Repos

Showing 1 to 2 of 2 entries

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**.

Consent form version:

It is required to version each consent form (e.g., "1.1", "2.3.1 2024-06-01") so that you may manage any future changes and differentiate versions of the consent form. It is recommended that you do not begin the version number with the letter "v".

Placement of consent form:

Choose a Descriptive field on the survey that will serve as the location of the consent form. The consent form will be displayed immediately below this field on the survey page. Note: The Descriptive field selected must be the same for all consent forms specified for this survey. If the field is changed, it will be changed for all consent forms for this survey.

Display for specific DAG:

Only display this consent form when the record is assigned to the selected data access group. Note: The default option will be used if no specific consent forms exist.

Display for specific language:

Only display this consent form when viewing the survey in the selected language.

Consent Form (Rich Text) **Consent Form (Inline PDF)**

Provide your consent form as a PDF file that will be displayed inline on the page directly below the field selected for 'Location of consent form' on the instrument/survey.

Upload your PDF consent form: Example CW... consent.pdf

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.

e-Consent Framework Settings

e-Consent active?	Edit settings	Survey	Location(s) to save consent snapshot
<input checked="" type="checkbox"/>		"CWRU Example eIC" (cwr_u_example_eic) Consent form v2.0 + Add consent form View all versions	File Repository
<input checked="" type="checkbox"/>		"CWRU Example eIC Consenter" (cwr_u_example_eic_consenter) + Add consent form	File Repository

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.