UNMC College of Nursing REDCap eConsent Training Manual

Sponsored by the Center for **C**hronic **I**llness **S**elf-**M**anagement and **P**revention (CRISP)

Created by: Gisele Tlusty, PhD, RN

(Updated 7/2024)

Table of Contents

Creating a REDCap Project

1. Go to https://unmcredcap.unmc.edu and login in with your UNMC credentials.
2. Click on + New Project button on the top bar menu.
3. Fill in the **Project Title**, select the **Purpose** of the project and choose **"empty project (blank slate)"** for the **Project creation option**.
4. Click "Create Project."
5. Complete the UNMC REDCap Disclaimer questions and fill in secondary owner and department admin name and email (Enter the PI if you are a research assistant, Advisor if you are a student).
6. Click "Submit".

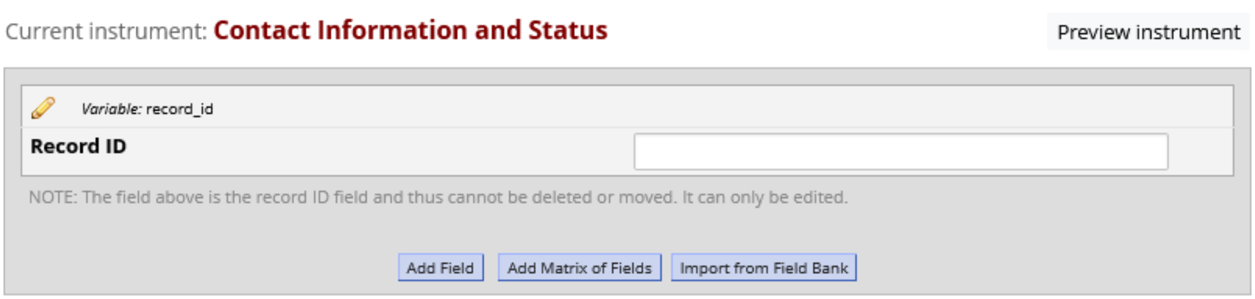
Contact Information and Status Form

Create this form to collect participants' contact information and **enable** the electronic consent feature. Automatic triggers for longitudinal surveys can also be added here.

1. From Project Home and Design on the left side menu, click on the **Designer** button.

2. Click the + Create button in the gray **Data Collection Instruments** box in the center.
3. Click on the + Add instrument here button.
4. Type instrument name (Example: Contact Information and Status) then click **create**. REDCap will refresh the page and there will be a link to the new instrument.
5. Next, click on the **Contact Information and Status** form

6. Click **Add Field**

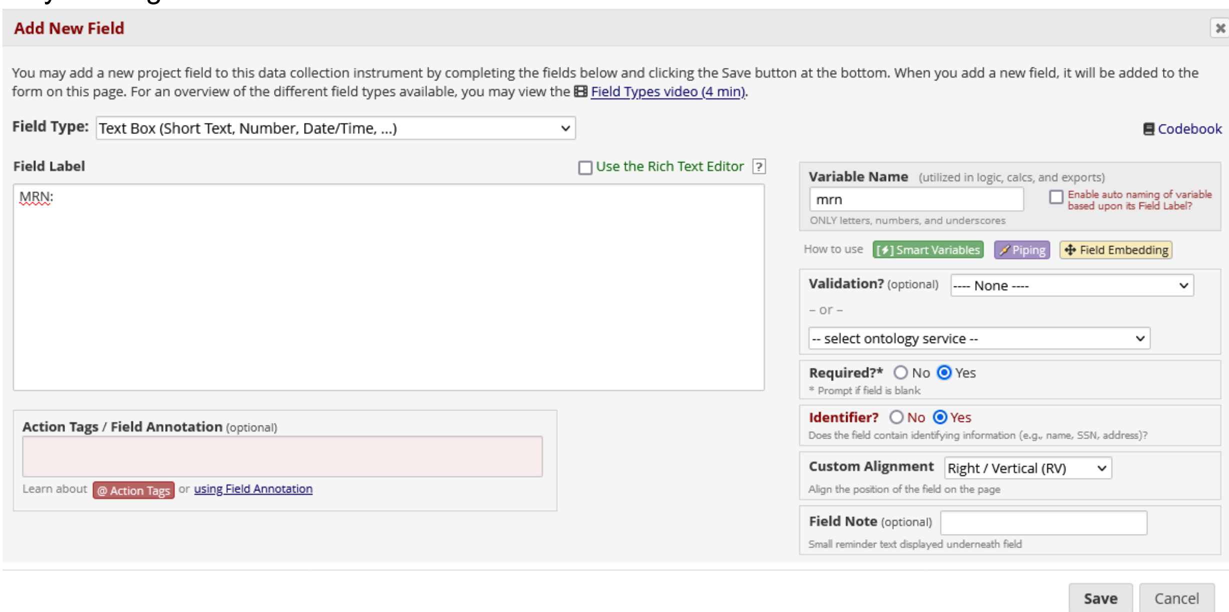


**Note: REDCap will automatically create a "Record ID" field as the first field of your first instrument/form.

7. You can add variables of your choice for the **Contact Information and Status** Form. Here are the steps to add "MRN".
   a. For **Field Types**: Choose "Text Box (Short Text, Number, Date/Time …)"
   b. In the **Field Label**: Type "MRN"
   c. In the **Variable Name**: Type: mrn

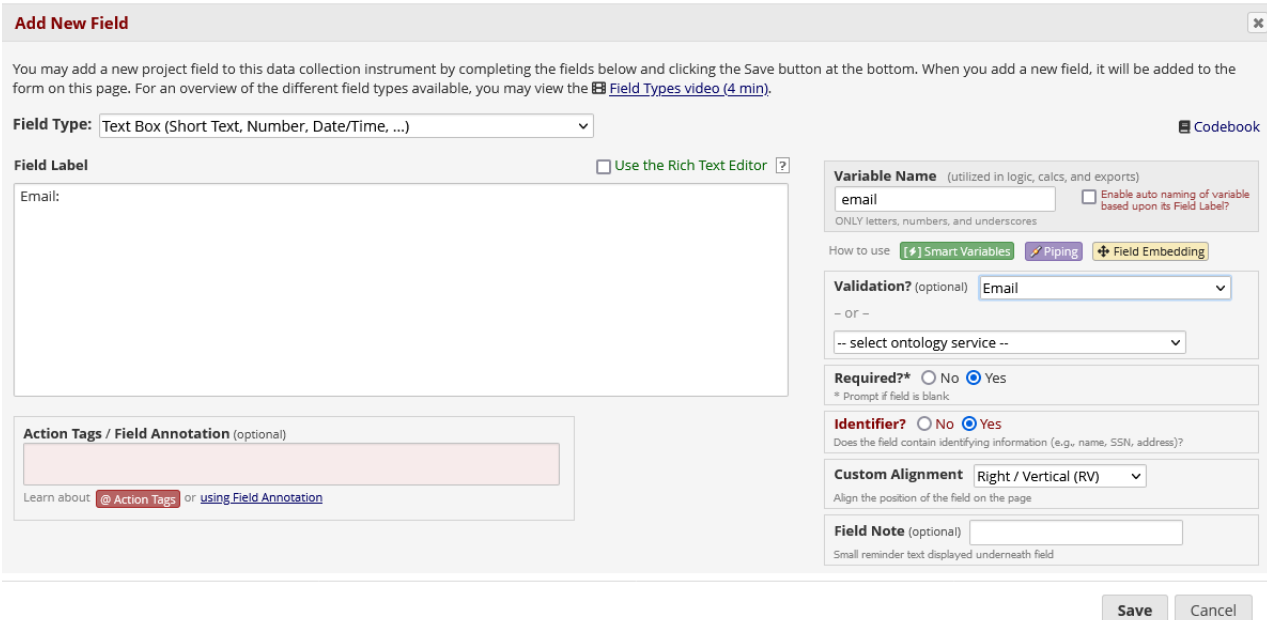
d. Check “Yes” for **Required**
e. Check “Yes” for **Identifier**
f. Click “Save”

Note: Retyping the name into the **Variable Name box will enable the label to be transferred to SPSS when you download data. You can check the “Enable auto naming of variable based upon its field label?” box to the right of the **Variable Name** box to assist with this if desired but it may be long.

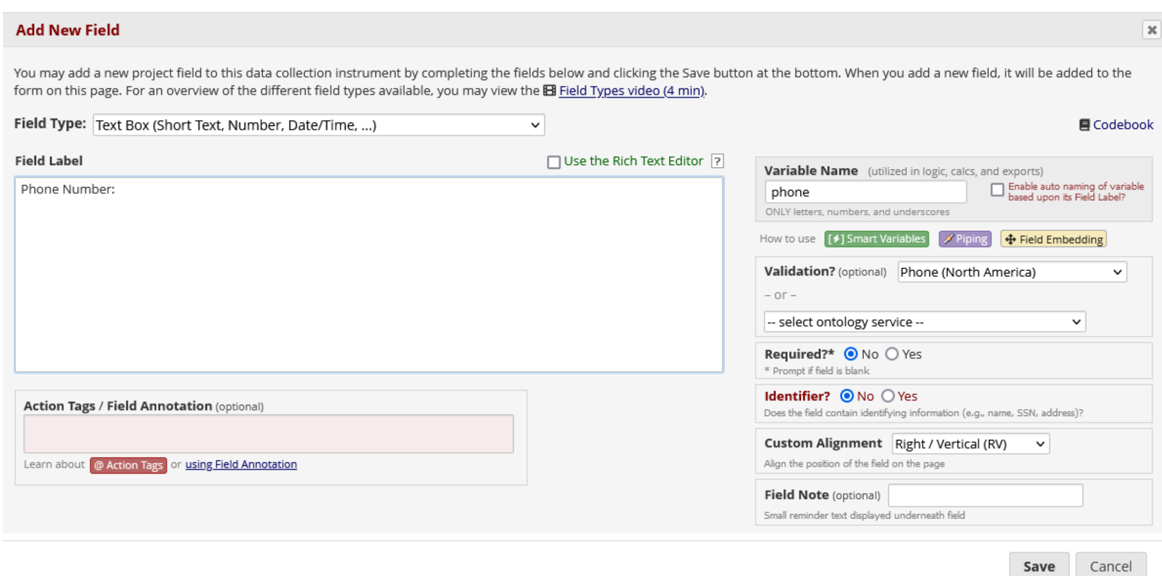


8. Repeat step 7 to add **Contact Information** as a header:
    a. Click **Add Field** above
    b. For **Field Type**: Choose “Begin New Section (with optional text)”
    c. In the **Field Label**: Type “Contact Information”
    d. Click “Save”
    e. This will create a section header before the variables you are wanting to collect. You can rename “contact information” to what is applicable for the project.
9. Repeat step 7 to add additional variables desired. It is important to add “first name” and “last name” fields if using REDCap’s eConsent option. (For example: **Field Label** “First Name:” and **Variable Name** “first_name”).
10. To add an **email** field (will need an email to be able to send invitations to complete surveys):
    a. Click **Add Field** below “mrn” field. You can customize where your “email” field will be by selecting the **Add Field** below the variable you want the **email** field to follow.
    b. For **Field Type**: Choose “Text Box (Short Text, Number, Date/Time, …)”
    c. In the **Variable Name**: Type “email”
    d. In the **Field Label**: Type “Email:”
    e. For **Validation**: Choose “Email”
    f. Check “Yes” for **Required**
    g. Check “Yes” for **Identifier**

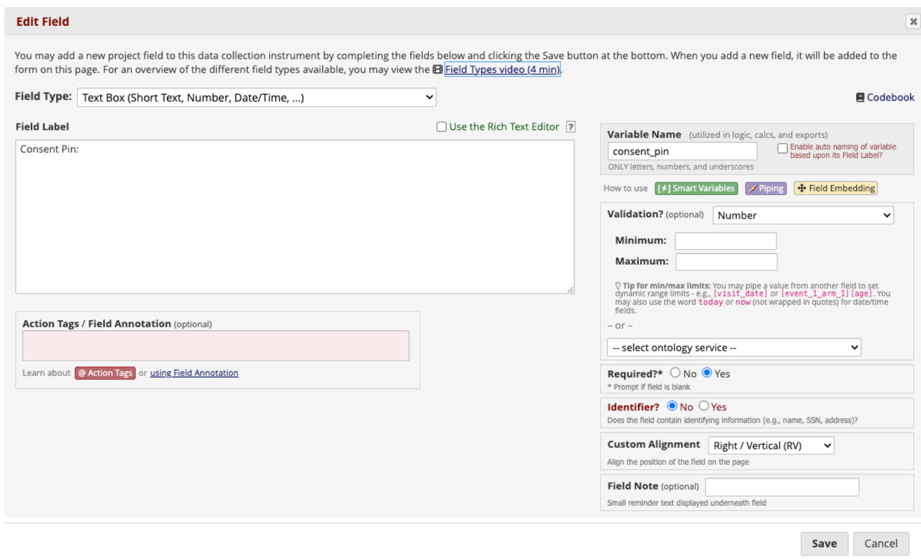
h. Click “Save”.



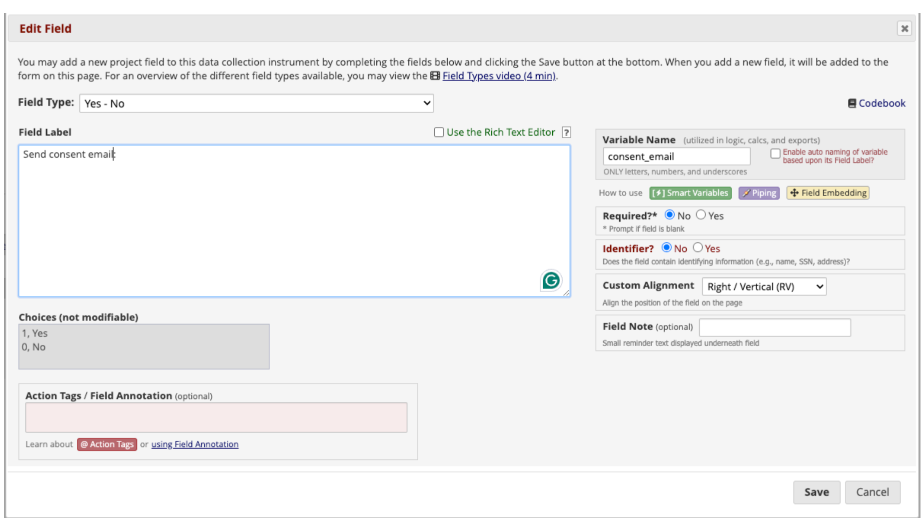
11. To add a phone number field (Optional)
    a. Click **Add Field** below “email” field
    b. For **Field Type**: Choose “Text Box (Short Text, Number, Date/Time, …)”
    c. For **Field Label**: Type “Phone Number:”
    d. In the **Variable Name**: Type “phone”
    e. For **Validation**: Choose “Phone (North America)”
    f. Check “Yes” for **Required**
    g. Check “Yes” for **Identifier**
    h. Click “Save”.



12. To add a **Consent Pin/Survey Login**: (This is *optional* but **required** if setting up electronic consent via REDCap.)
    a. Click **Add Field** below phone number field
    b. For **Field Type**: Choose “Text Box (Short Text, Number, Date/Time, ...)”
    c. In the **Variable Name**: Type “consent_pin”
    d. In the **Field Label**: Type “Consent Pin”
    e. For **Validation**: Choose “Number”
    f. Check “Yes” for **Required**
    g. Check “No” for **Identifier**
    h. Click “Save”

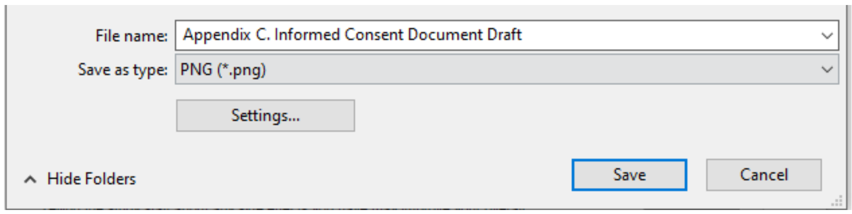


13. To add a **consent email trigger**: (Required if completing Step 11)
    a. Click **Add Field** below “Consent Pin” field
    b. For **Field Type**: Choose “Yes - No”
    c. In **Variable Name**: Type “consent_email”
    d. In **Field Label**: Type “Send consent email:”
    e. Click “Save”.

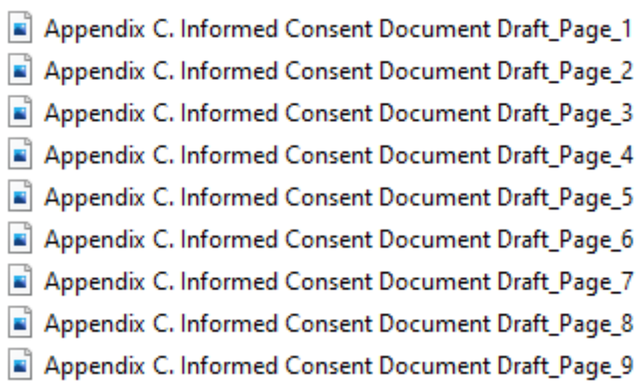


Setting Up Electronic Consent

1. If the approved **consent** document is a Word document, open the file and save it as a PDF. Conversion is needed before adding the consent in Step 9 below.
    a. To convert to a JPEG or a PNG, after saving it as a PDF, click "File" and "Save As" and then "Save as JPEG". Depending on operating system used, one may have to "Export" the PDF and save as a "JPEG" or a PNG. Name the file name accordingly (Appendix C. Informed Consent Document Draft is an example).



    b. It will save each page of the consent form as an individual image. Example:



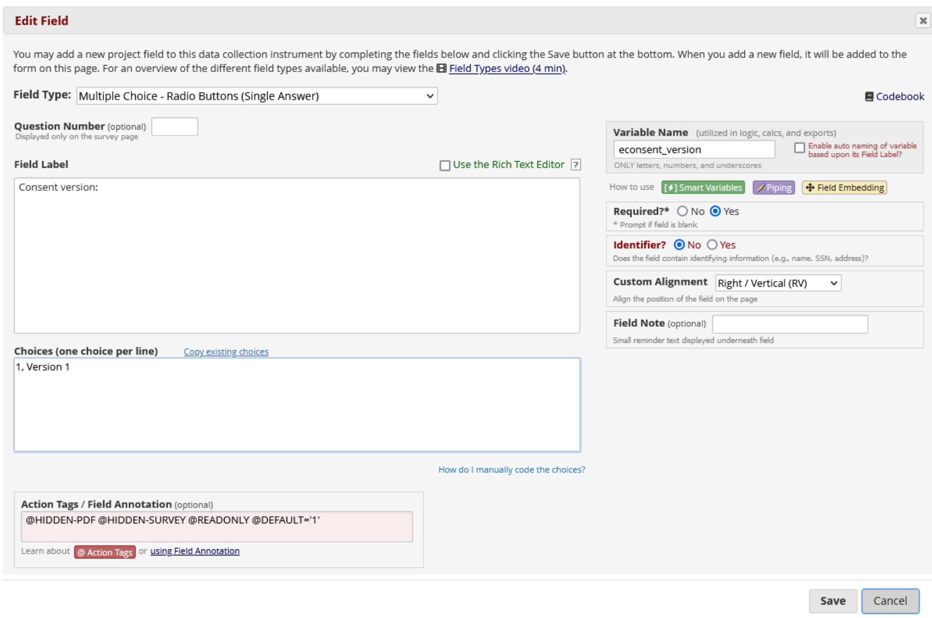
** **Important Note:** A **Contact Information and Status** instrument **must** exist in your project and include fields for the participant's email address and eConsent pin/password to setup electronic consent.

2. From Project Home and Design on the left side menu, click on **Designer** button.
3. Click the + Create button in the gray **Data Collection Instruments** box.
4. Click on the + Add instrument here button beneath the **Contact Information and Status** instrument name.
5. Type the desired instrument name (Example: Consent Form) then click **create**. REDCap will refresh the page and there will be a link to the new instrument.
6. Click on the **Consent Form** instrument, then **Add Field**.

**Note: The next step allows for automatic documentation of what version of the consent was used and makes it so that this field is hidden in the consenting process.

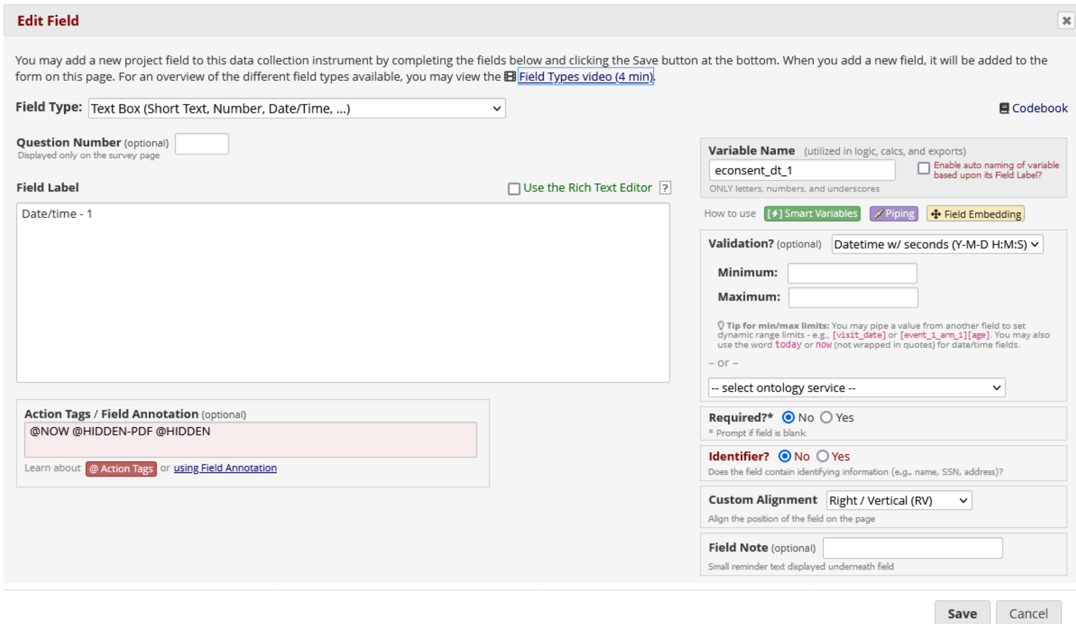
7. In **Field Type**, choose “Multiple Choice – Radio Buttons (Single Answer).
    a. For **Field Label**: Type in “Consent version:”
    b. For **Variable Name**: Type in “econsent_version”
    c. For **Choices:** Type in “1, Version 1”.
    d. Check “Yes” for **Required**
    e. For **Action Tags**: Type in “@HIDDEN-PDF @HIDDEN-SURVEY @READONLY @DEFAULT=’1’ ” and click **Update & Close Editor**.
    f. Click “Save”.

   **Note – if the consent is modified during the study, you will need to add more rows for the different versions of the consent.

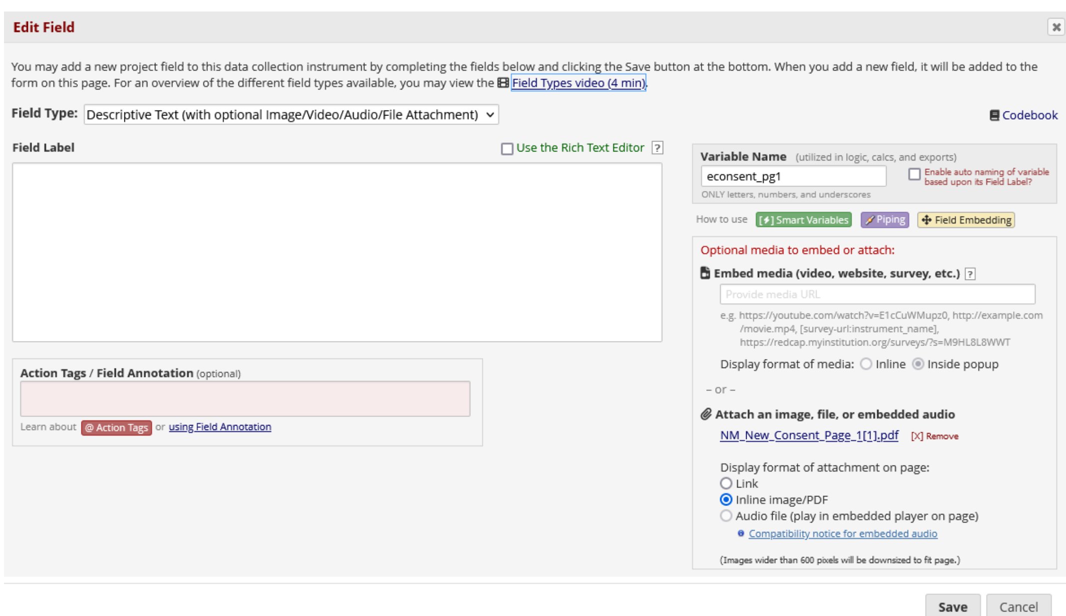


8. To document date and time of consent, click **Add Field** to add a second field below the **Consent Version** field.
    a. In **Field Type**: Choose “Text Box (Short Text, Number, Date/Time,…)”
    b. For the **Variable Name**: Type in “econsent_dt_1”
    c. For the **Field Label**: Type in “Date/time 1”
    d. For **Validation**: Choose “Datetime w/ seconds (M-D-Y H:M:S)” or choose your preference for format.
    e. In the **Action Tags**: Type “@NOW @HIDDEN-PDF @HIDDEN” and click **Update & Close Editor**.
    f. Click “Save”.

   **Note: These actions will automatically fill in the date and time on the PDF print-out of the consent but will hide it from the survey view.



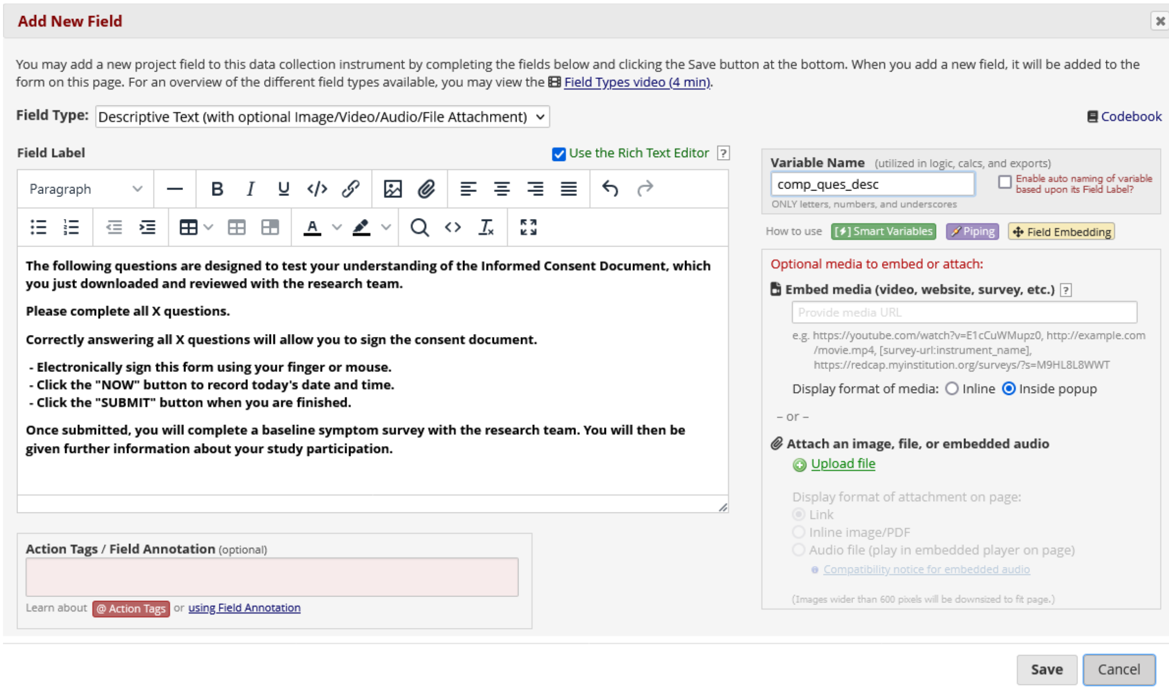
9. Now to upload the consent. Click **Add Field** below the **Date/time** field to add the first page of the consent.
   a. For the **Field Type**: Choose "Descriptive Text (with optional Image/Video/Audio/File Attachment)"
   b. In the **Variable Name**: Type "econsent_pg1"
   c. For the **Attach an image, file, or embedded audio** (under Variable Name on the right side): Click + Upload file and select the .png or .jpeg file of the first page of the consent.
   d. For the **Display format of attachment on page**: Choose "Inline image/PDF."
   e. Click "Save".



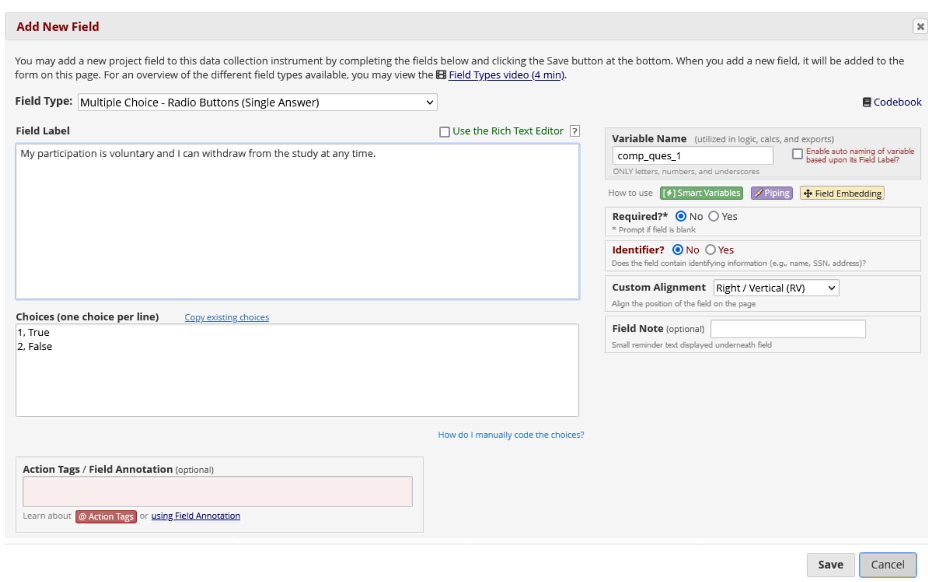
10. Click **Add Field** *above* the first consent page.
    a. For the **Field Type**: Choose “Begin New Section (with optional text)” to create a section header.
    b. Click “Save”.
11. **Repeat** step 9 until all pages of the consent form have been added.
12. OPTIONAL – If you want to add comprehension questions regarding the consent, follow Steps 12-16 below.
    a. Click **Add Field** below last page of consent.
    b. For the **Field Type**: Choose “Descriptive Text (with optional Image/Video/Audio/File Attachment)”
    c. In the **Variable Name**: Type “comp_ques_desc”
    d. In the **Field Label**: Type in the language below. Replace # with number of comprehension questions.

> “The following questions are designed to test your understanding of the Informed Consent Document, which you just downloaded and reviewed with the research team.
> (Continued below)
>
> Please complete all # questions.
>
> Correctly answering all # questions will allow you to sign the consent document.
>
> - Electronically sign this form using your finger or mouse.
> - Click the "NOW" button to record today's date and time.
> - Click the "SUBMIT" button when you are finished.
>
> Once submitted, you will [enter the next step as applicable to your study here].”

    e. Check the box next to Use the Rich Text Editor. (You may have to remove extra parentheses if you copy and paste text.)
    f. Click “Save”.



13. Click **Add Field** *above* the comp_ques_desc field.
    c. For the **Field Type**: Choose “Begin New Section (with optional text)”
    d. Click “Save”.
14. OPTIONAL – Adding consent comprehension questions.
    a. Click **Add Field** below “comp_ques_desc” field.
    b. For the **Field Type**: Choose “Multiple Choice – Radio Buttons (Single Answer)”
    c. In the **Variable Name**: Type “comp_ques_1”
    d. In the **Field Label**: Type in the first consent comprehension question (See example below).
    e. For **Required**: Mark “Yes”

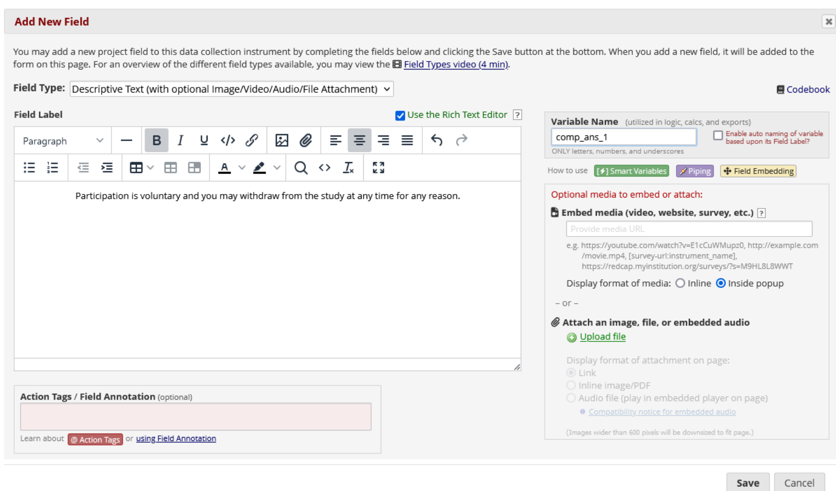


f. In **Choices** (enter in separate lines):
   1, True
   2, False
g. Click “Save”.

15. OPTIONAL - Add branching logic for correct answers for consent comprehension questions.
    a. Click **Add Field** below “comp_ques_1”.
    b. For the **Field Type**: Choose “Descriptive Text (with optional Image/Video/Audio/File Attachment)”
    c. In the **Field Label**: Check the Use the Rich Text Editor box and enter the correct answer for your consent comprehension question.

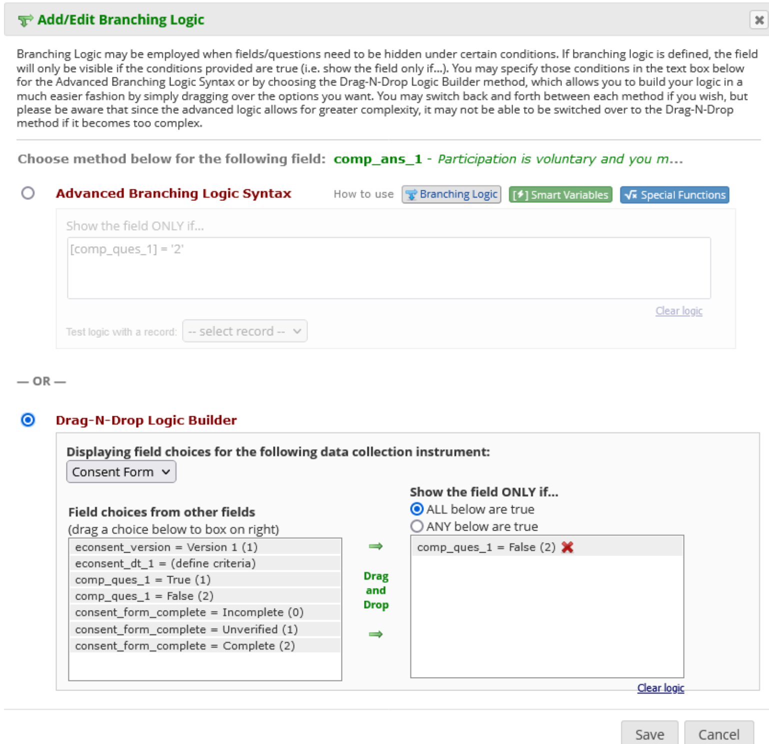
       Example: “Participation is voluntary, and you may withdraw from the study at any time for any reason.”

    d. Click on the **align center** button to center the response. **Uncheck** the Bold font function.
    e. In the **Variable Name**: Type “comp_ans_1”.
    f. Click “Save”.

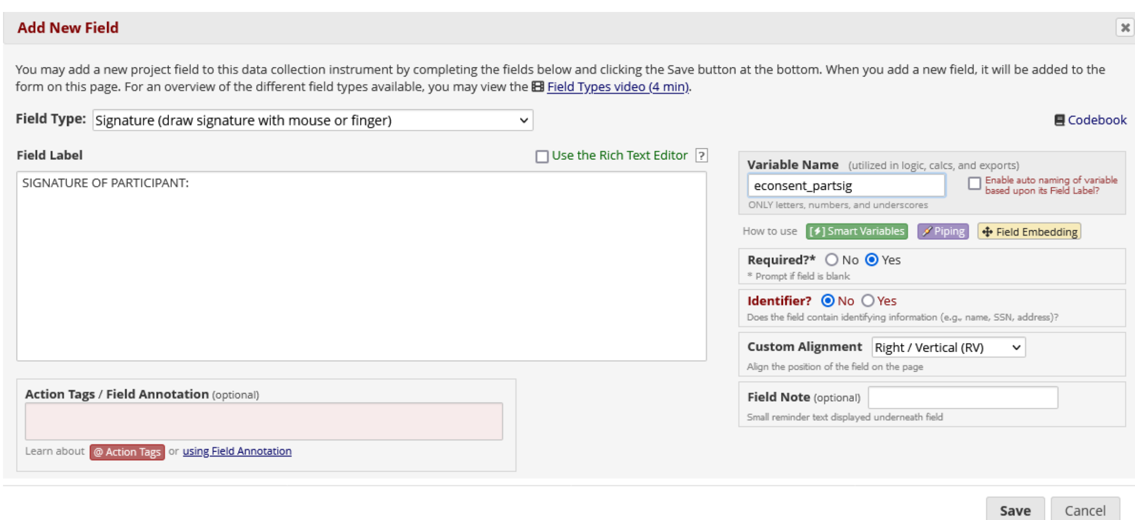


    g. Click on the  button in the “comp_ans_1 field”.
    h. Click the circle next to **Drag-N-Drop Logic Builder**.
    i. Drag the incorrect answer from the box on the left to the box on the right.
    j. Click “Save”.

**Note: This message will only display if the participant selects the incorrect answer for the consent comprehension question.

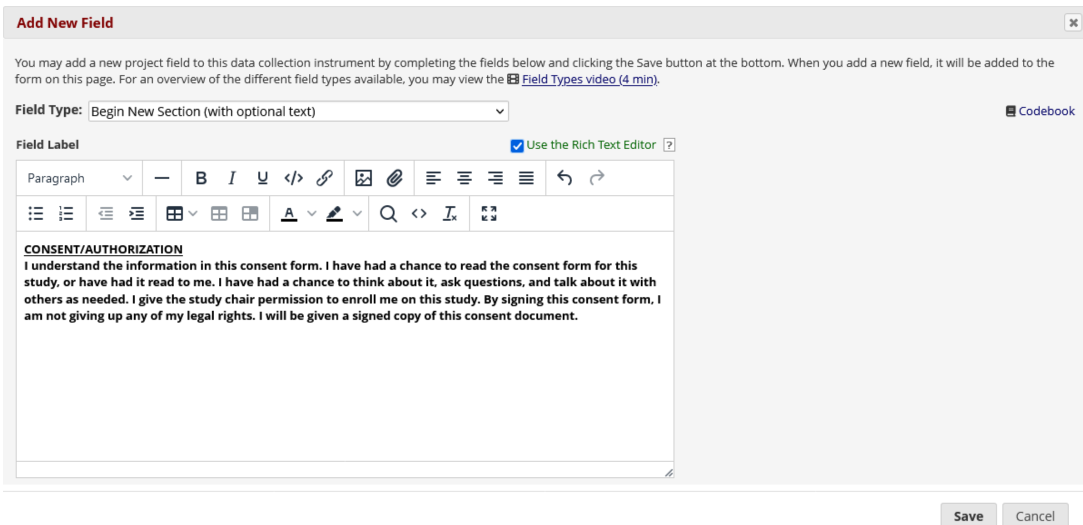


16. Repeat steps **14** and **15** for each consent comprehension question.
17. For the **Signature of Participant**:
    a. Click **Add Field** below the last consent comprehension question.
    b. For the **Field Type**: Choose "Signature (draw signature with mouse or finger)".

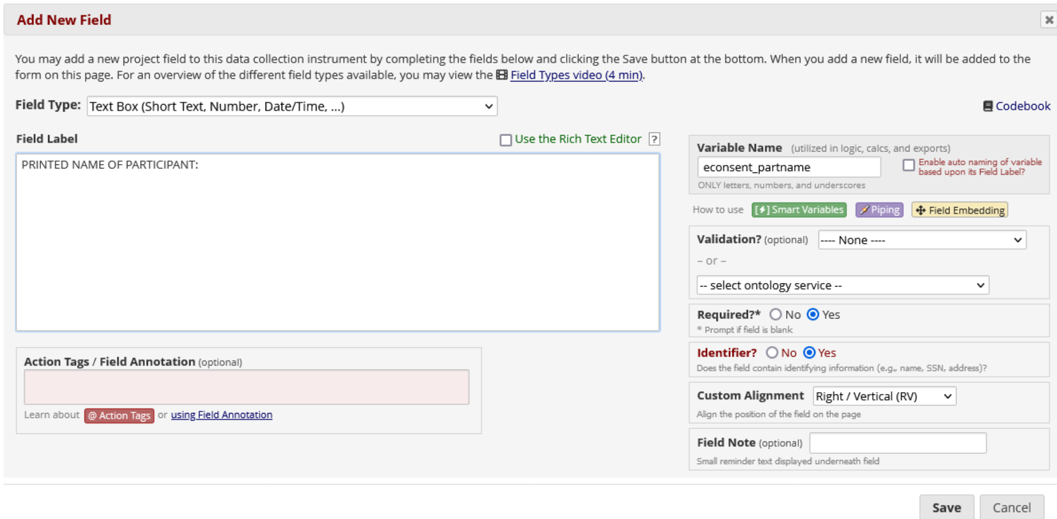


    c. In the **Variable Name**: Type "econsent_partsig".
    d. In the **Field Label**: Type "SIGNATURE OF PARTICIPANT:"
    e. Mark "Yes" for **Required**
    f. Click "Save".

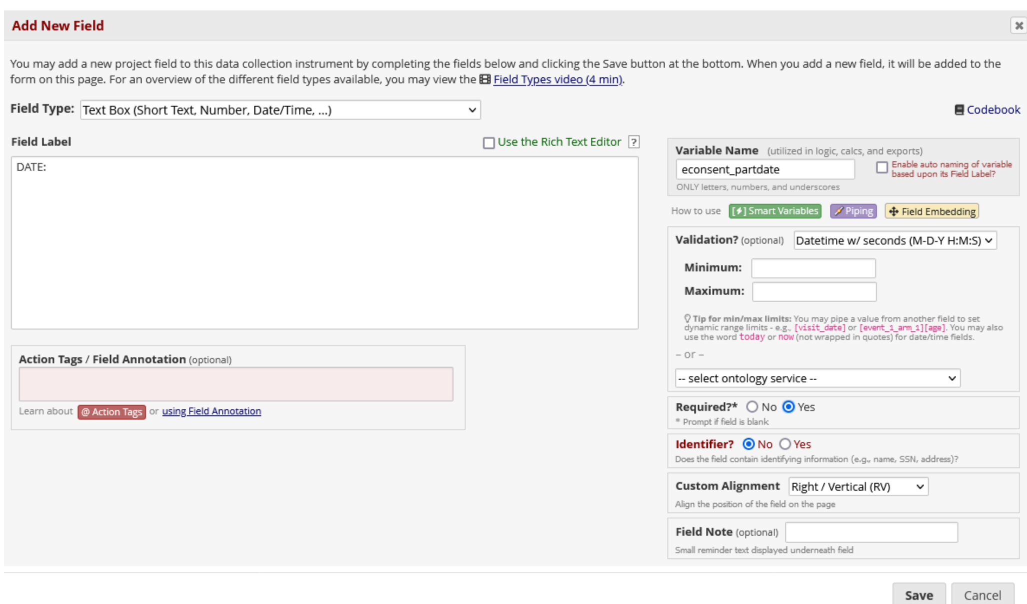
18. To add **Consent Authorization Language**:
    a. Click **Add Field** above the "econsent_partsig" field.
    b. For the **Field Type**: Choose "Begin New Section (with optional text)".
    c. Check the Use the Rich Text Editor box to the right of **Field Label**.
    d. In the **Field Label**: Enter the desired consent authorization language.
    Example:
    CONSENT/AUTHORIZATION
    I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.
    e. Click "Save".



19. To add a **Participant Printed Name**:
    a. Click **Add Field** below "econsent_partsig" field.
    b. For the **Field Type**: Choose "Text Box (Short Text, Number, Date/Time,…)"
    c. In the **Variable Name**: Type "econsent_partname".
    d. In the **Field Label**: Type "PRINTED NAME OF PARTICIPANT:"
    e. Mark "Yes" for **Required**
    f. Mark "Yes" for **Indentifier**
    g. Click "Save".



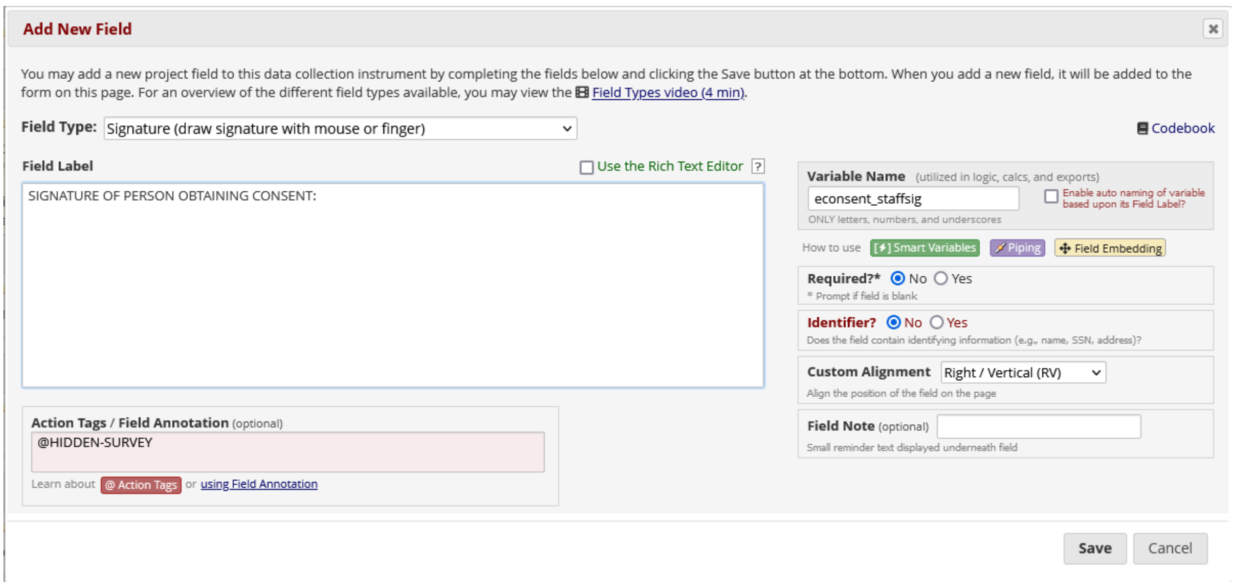
20. To add a **Date/Time signed** field.
    a. Click **Add Field** below “econsent_partname” field.
    b. For the **Field Type**: Choose “Text Box (Short Text, Number, Date/Time,…)”
    c. In the **Variable Name**: Type “econsent_partdate”
    d. In the **Field Label**: Type “DATE:”
    e. For **Validation**: Choose “Datetime w/ seconds (M-D-Y H:M:S)” or choose your preference for format.
    f. Mark “Yes” for **Required**.
    g. Click “Save”.



21. OPTIONAL – Only if using comprehension questions (This will make the signature, printed name of the participant and date **only** appear if all the comprehensive questions are correct):
    a. Click on the  button in the “econsent_partsig” field.
    b. Click the circle in the Drag-N-Drop Logic Builder.
    c. Click the circle to select “ALL below are true” under **Show the field ONLY if…**

d. Drag correct answers for each comprehension question you created to the box on the right.
e. **Repeat** these steps for the following fields: “econsent_partname” and “econsent_partdate”

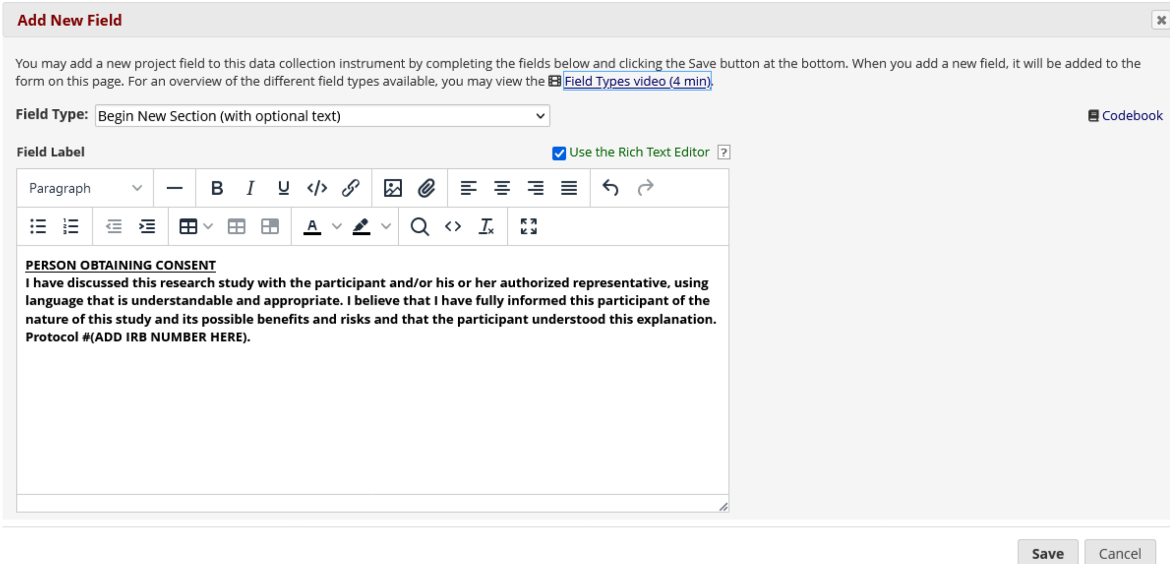
22. To add a section for the **Person Obtaining Consent**:
    a. Click **Add Field** below “econsent_partdate” field.
    b. For the **Field Type**: Choose “Signature (draw signature with mouse or finger)”.
    c. In the **Variable Name**: Type “econsent_staffsig”
    d. In the **Field Label**: Type “SIGNATURE OF PERSON OBTAINING CONSENT:”
    e. In the **Action Tags**: Type “@HIDDEN-SURVEY" and click **Update & Close Editor**.
    f. Click “Save”



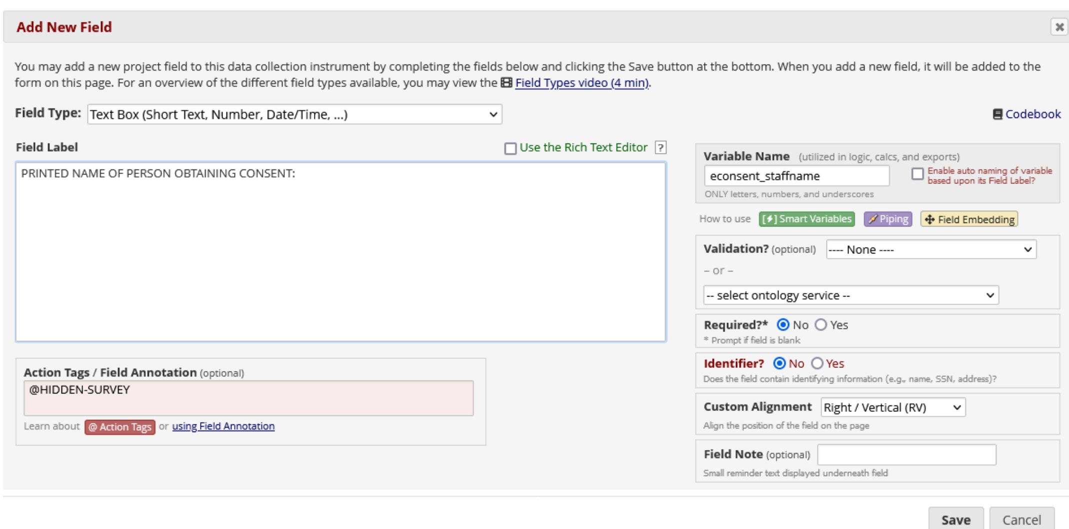
23. To add **Language for Person Obtaining Consent**:
    a. Click **Add Field** above “econsent_staffsig” field.
    b. For the **Field Type**: Choose “Begin New Section (with optional text)”.
    c. Check the Use the Rich Text Editor box.
    d. Add desired language in the **Field Label** box.

    Example:
    <u>PERSON OBTAINING CONSENT</u>
    I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks, and that the participant understood this explanation. Protocol # (ADD IRB NUMBER HERE).

e. Click “Save”

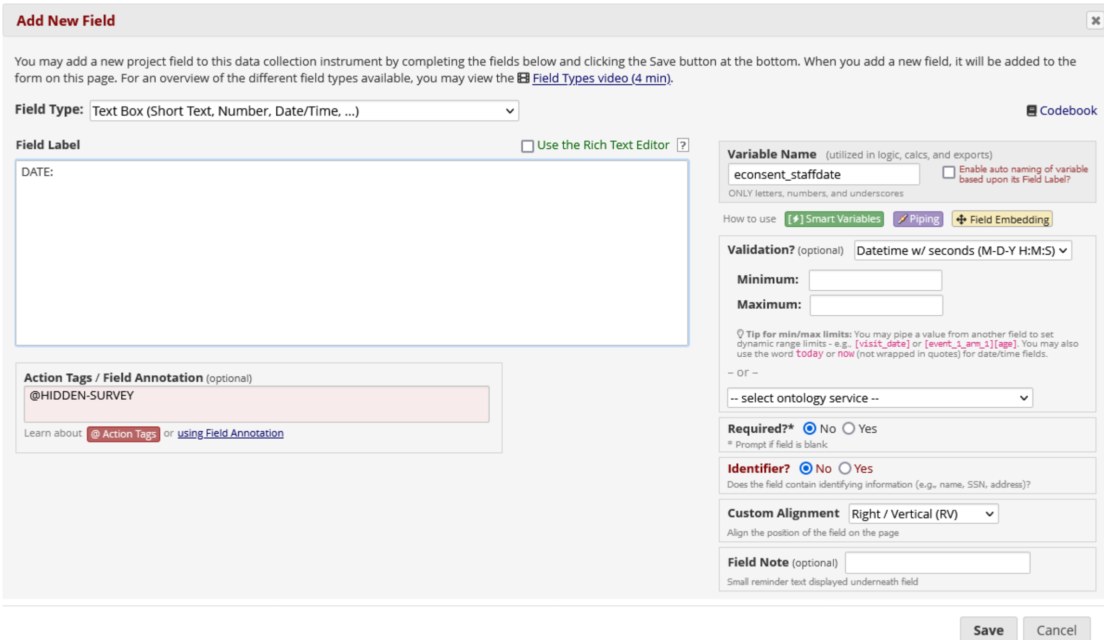


24. To add a **Printed Name of Person Obtaining Consent**:
   a. Click **Add Field** below “econsent_staffsig” field.
   b. For the **Field Type**: Choose “Text Box (Short Text, Number, Date/Time,…)”
   c. In the **Variable Name**: Type “econsent_staffname”
   d. In the **Field Label**: Type “PRINTED NAME OF PERSON OBTAINING CONSENT:”
   e. In the **Action Tags**: Type “@HIDDEN-SURVEY" and click on **Update & Close Editor**.
   f. Click “Save”.



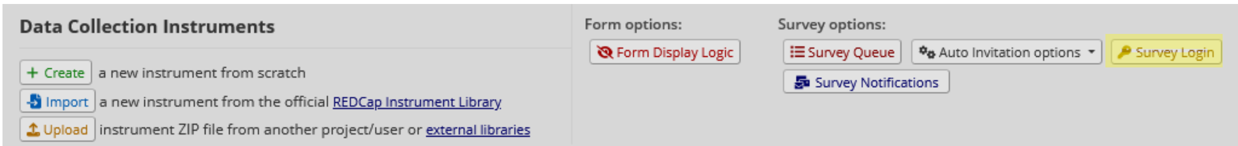
25. To add a **Date/Time Signed** field for the witness:
   a. Click **Add Field** Below “econsent_staffname” field
   b. For the **Field Type**: Choose “Text Box (Short Text, Number, Date/Time, …)”
   c. In the **Variable Name**: Type “econsent_staffdate”
   d. In the **Field Label**: Type “DATE:”

e. For **Validation**: Choose "Datetime w/ seconds (M-D-Y H:M:S)"
f. In the **Action Tags**: Type "@HIDDEN-SURVEY" and click **Update & Close Editor**.
g. Click "Save"

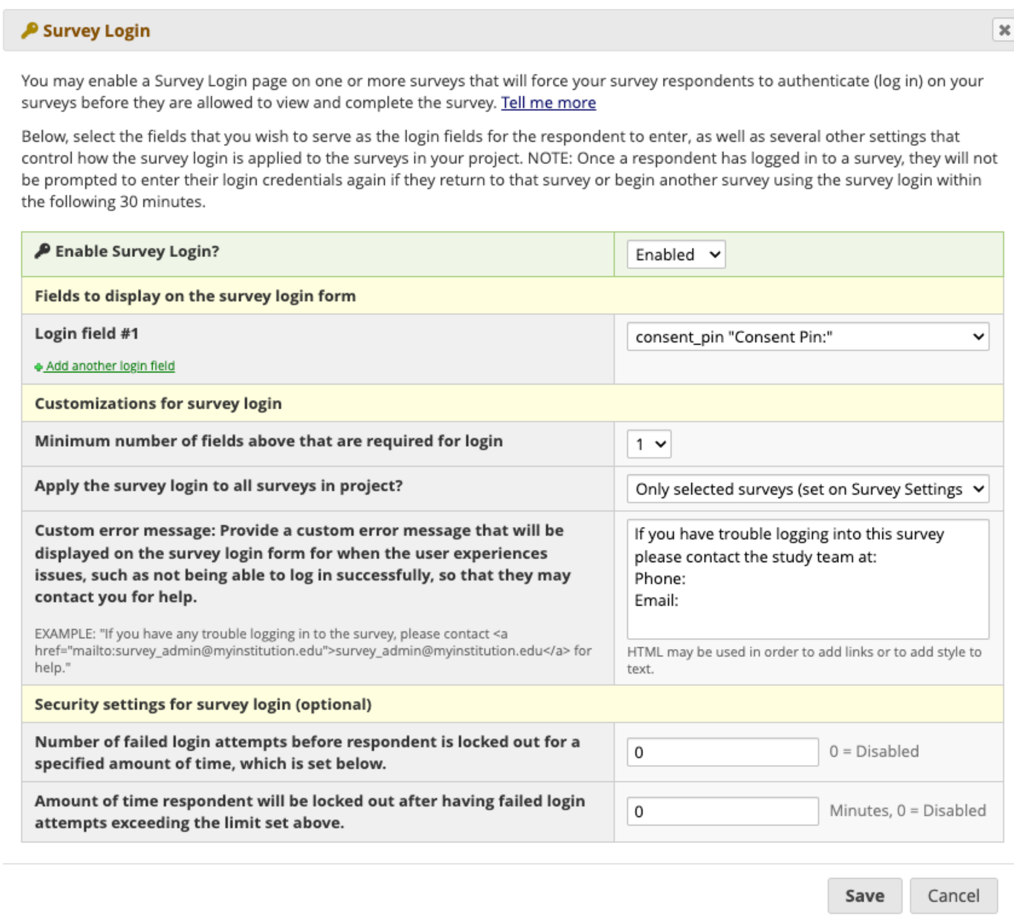


EConsent Survey Login

1. EConsent Survey Login requires participants to authenticate (log in) to your surveys before being allowed to view and complete the surveys. To set this up, click on the **Designer** button in the **Project Home and Design** section on the left side menu.
2. Click "Survey Login" at the right of the Designer page under "Survey options"

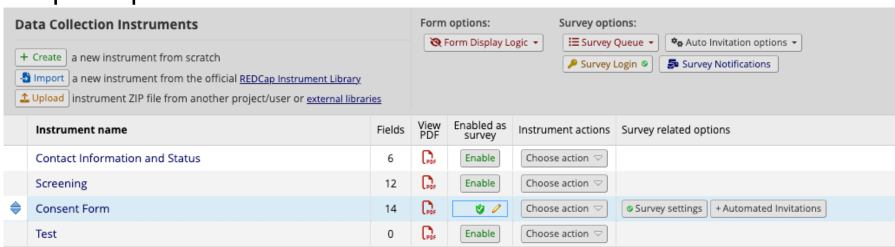


3. For **Enable survey login?**: Choose "Enabled"
4. For **Login field #1**: Choose "consent_pin: 'Consent Pin' "
5. For **Apply the survey login to all surveys in project?**: Choose "only to selected surveys"
6. You can customize how many failed login attempts before locking a participant out if desired.
7. Type a custom error message: (See example below)
8. Click "Save"



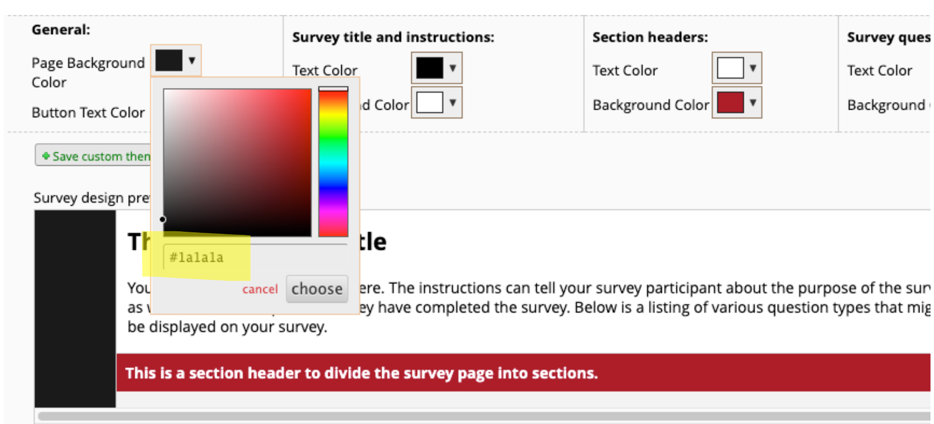
EConsent Survey Settings

1. From the **Project Home and Design** on the left side of the screen, click on the "Designer" and then click "enable" to enable the eConsent (or title of your consent) as a survey. Now you can edit the appearance of the survey and how it will be displayed to the participant.

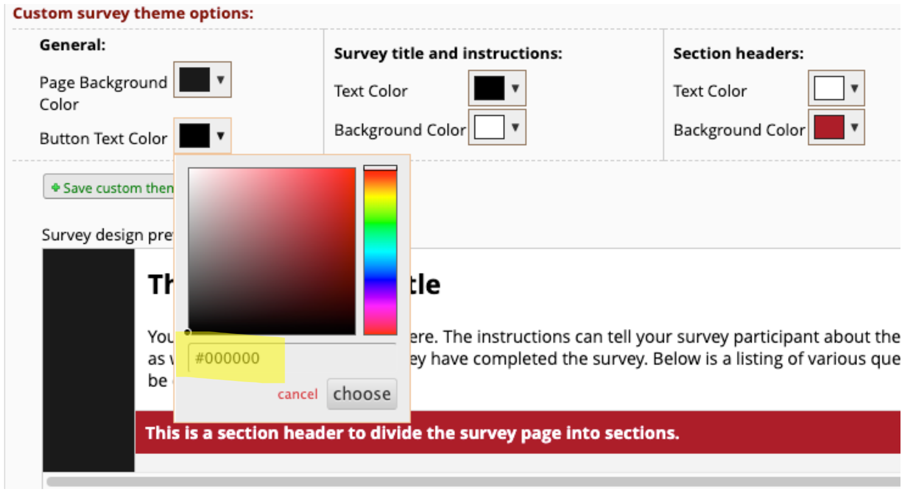


2. Clear survey title and survey instruction under **Basic Survey Options.**
3. In **Survey Design Options**, update survey design options per your institutions branding guidelines (i.e. logo, theme/colors)
   a. **Logo** (save the image below [final file needs to saved as a JPEG or PNG to be uploaded] or you can request a logo at https://brandwise.unmc.edu/unmc/logo/) and upload it to REDCap for the **Logo** option

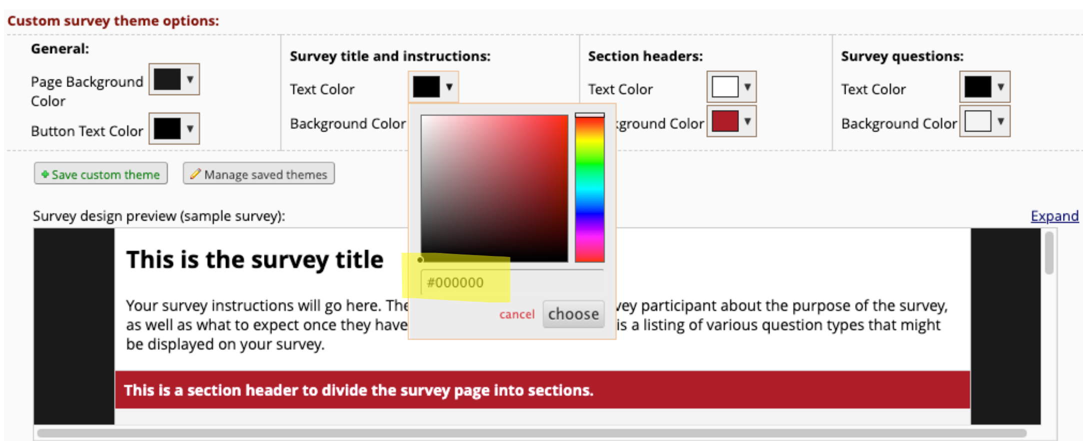
   b. Leave the default settings for **radio buttons** = "standard radio buttons and checkboxes", **size of survey text** = "large" and **font of survey** text = "open sans".
   c. For **survey theme**: To make a customized UNMC theme, you will need to click on "Customize". To choose colors according to UNMC branding, see the following screenshots for each custom color code.
      i. In the **General** section on the left-hand side, for **Page Background**: Click on the down arrow next to the color, and default setting should state **#lalala.** If not, change it to **#lalala.**



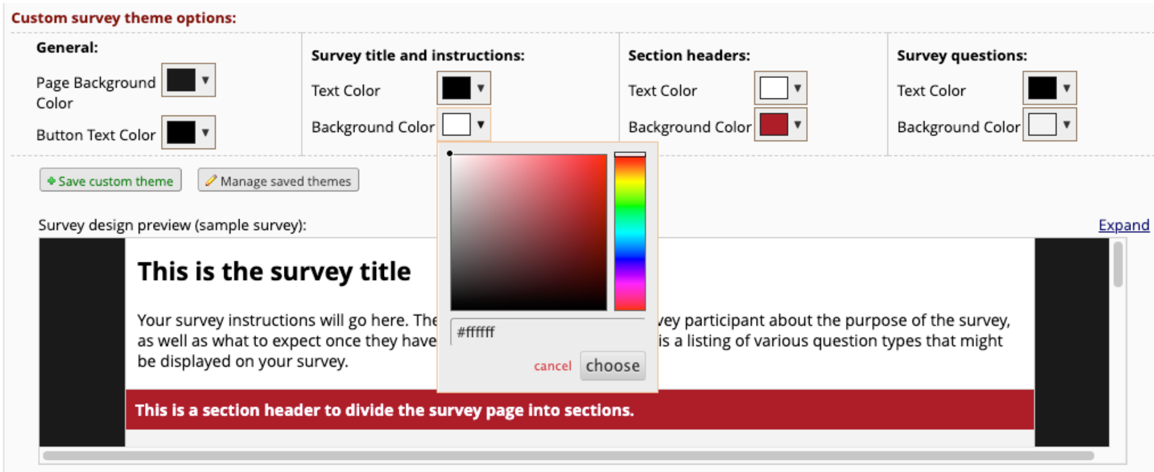
ii. For **Button Text Color**: Keep it at **#000000** or change it to **#000000** if it is not.



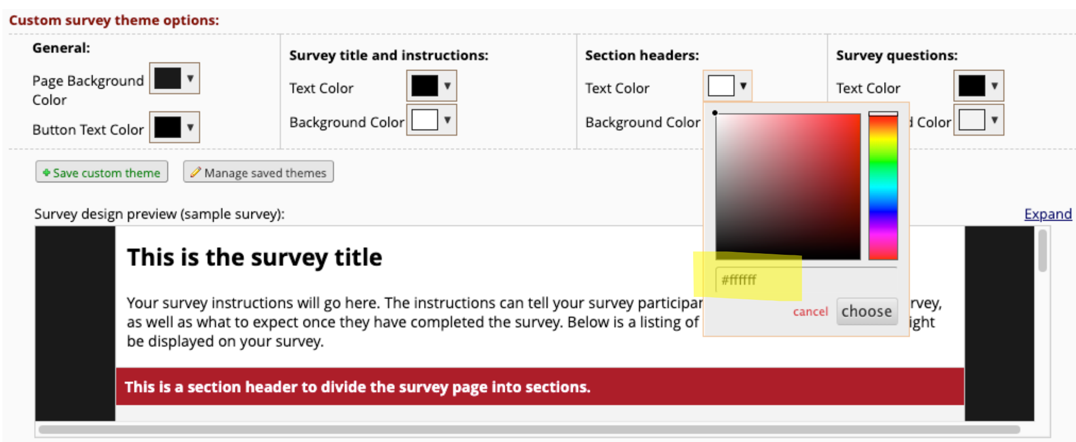
iii. For **Text Color** under **Survey title and instructions**: Keep it at **#000000.**



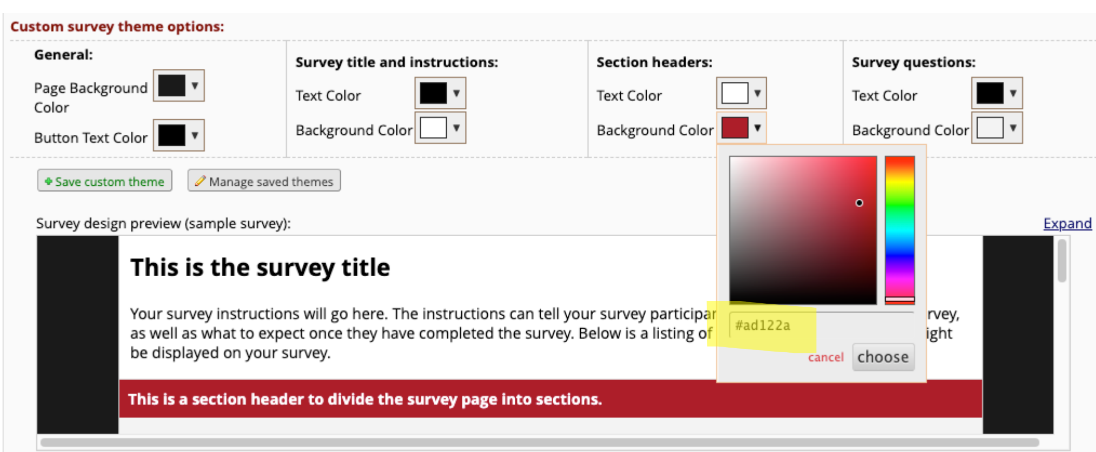
iv. For **Background Color** under **Survey title and instructions**: Keep it at **#ffffff.**



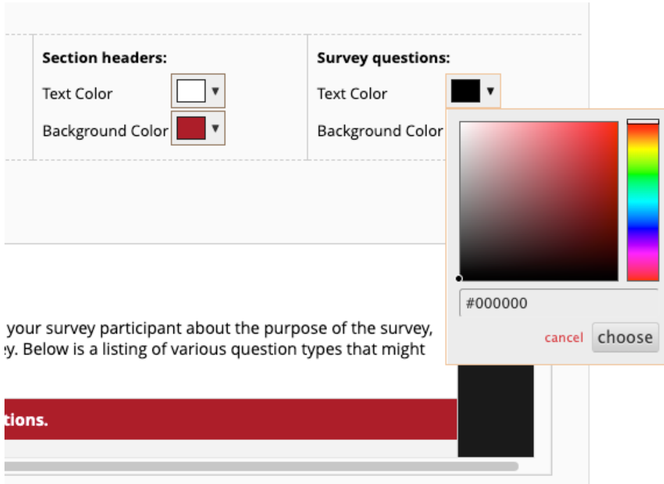
v. For **Text Color** under **Section headers**: Change it to white. Type **#ffffff** (there are six of them to type).



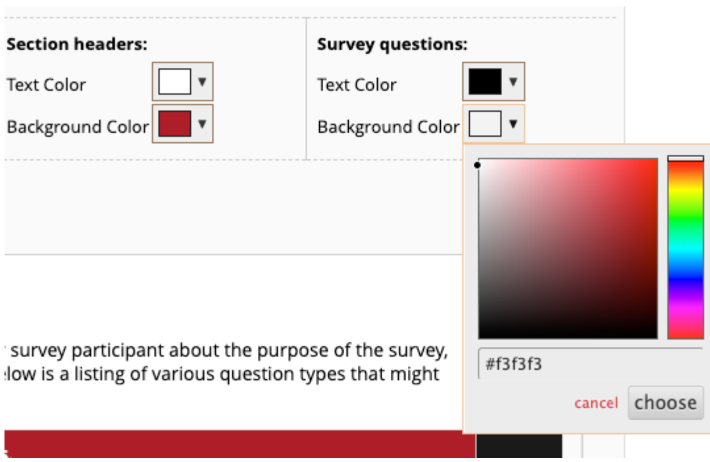
vi. For **Background Color** under **Section headers**: Change it to UNMC red. Type **#ad122a**.



vii. For **Text Color** under **Survey questions**: Keep it at **#000000**.



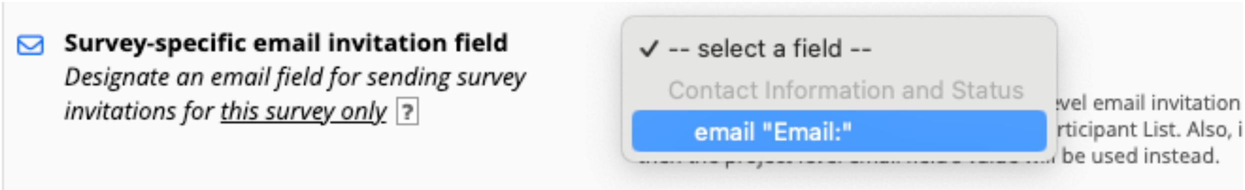
viii. For **Background** under **Survey questions**: Keep it at **#f3f3f3**.



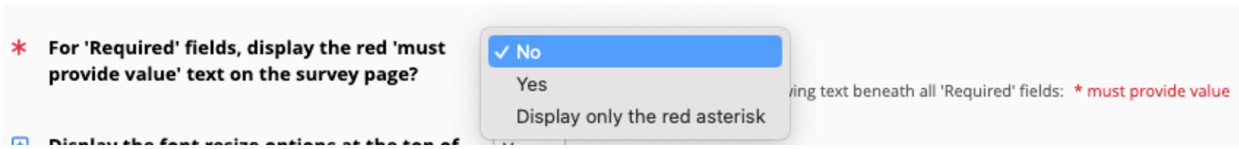
d. After entering colors and logo, be sure to save this theme (click on the Save custom theme below the **General** section on the left-hand side and name the theme as desired).
e. **Note:** You will apply this custom theme to all surveys once you have created all instruments for your project and for future projects.

4. Now in **Survey Customizations**: Update question numbering to "Custom numbered."
5. For **Pagination**, choose "Single page."
6. For **Allow participants to download a PDF of their responses at end of survey?**, choose default setting "no." If fields have the action tag **@HIDDEN**, that field/s will not be displayed in the PDF.

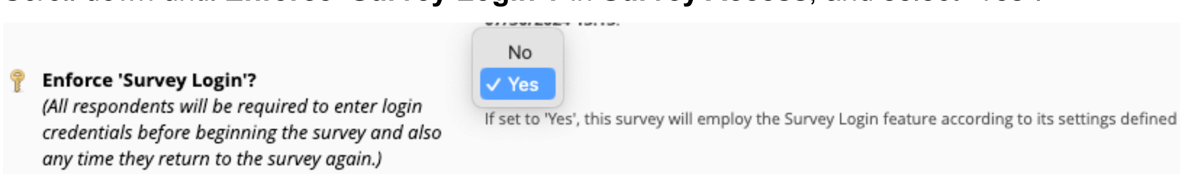
7. For **survey-specific email invitation field**, choose ‘email “email”.’



8. **For ‘Required’ fields, display the red ‘must provide value’ text on the survey page?**, choose “no”.



9. Keep the default setting as “disabled” for **allowing survey respondents to view aggregate survey results after completing the survey?** and **text to speech functionality**.
10. Scroll down until **Enforce ‘Survey Login’?** in **Survey Access**, and select “Yes”.



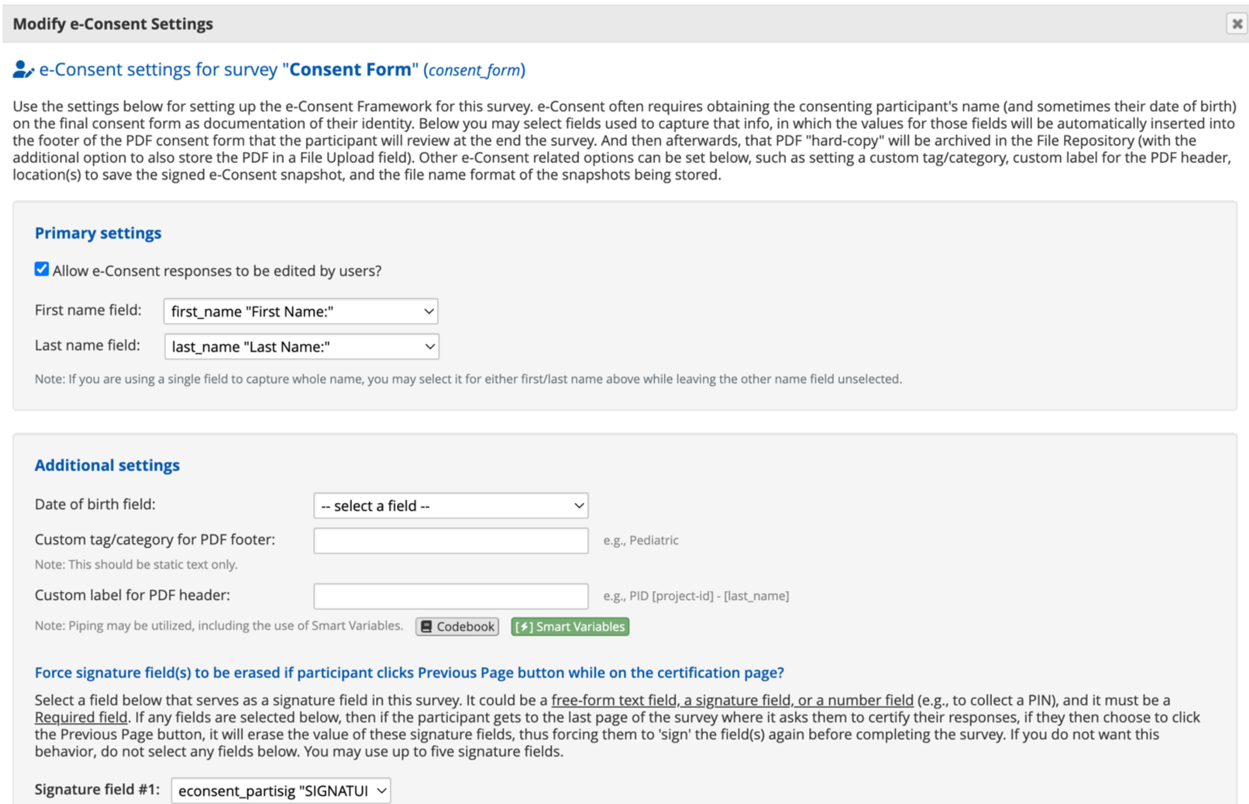
11. For the rest of **Survey Access**: Limiters are not necessary (response limit, time limit, survey expiration, etc). Do not enable **Save & Return Later** option as the **Survey Login** will override this setting.
12. For **Survey Termination Options**, enable “auto-continue to continue to next survey?” if desired (baseline surveys).
13. For **Survey Completion Text,** you can delete this default text if desired.
14. Please do customize options accordingly.
15. Click “Save Changes”

To enable and modify **Auto-Archiver + eConsent Framework** (to store signed consent files in the REDCap “File Repository” for the project and allow for witnesses to sign consent after the participant signs):

1. Click on the **Designer** button in the **Project Home and Design** section on the left-side menu.
2. Under form options on the right-hand side, click on e-Consent and PDF Snapshots. There are 2 tabs on the top “e-Consent Framework and PDF Snapshots of Records”.
3. Click on “e-Consent Framework” and then click on “+Enable the e-Consent Framework for a survey”. (The consent form needs to be ‘enabled’ before this step. If it has not, click on “Back to Online Designer**”** and click enable next to the consent form that will be used. It will have a ‘check mark on a green shield’ icon if it is already enabled.)
4. Under **Primary settings**, check the box next to “Allow eConsent responses to be edited by users?”
    a. Select “first_name “First Name:” for the **First name field** and “last_name “Last Name:” for the **Last name field**.

b. Under “**Force signature fields to be erased….**”, select ‘econsent_partsig “SIGNATURE OF PARTICIPANT:” ’ If the participant happens to go back and change a previous answer, this option will have the participant resign the consent form.

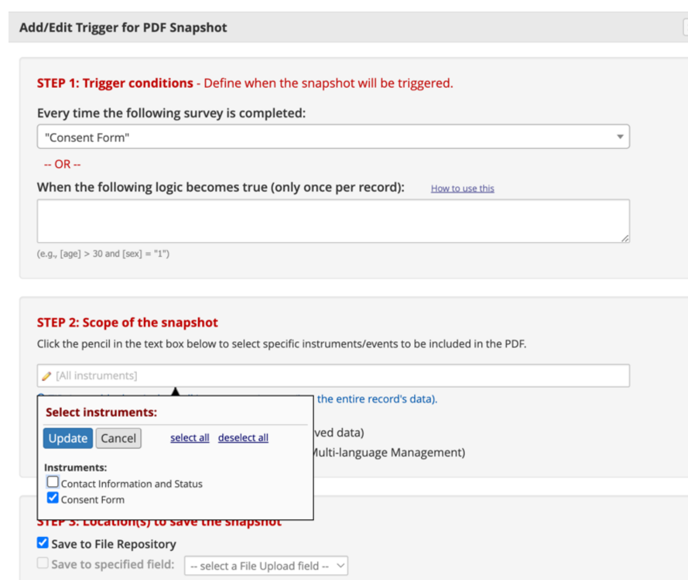
5. Click on “Save settings”.



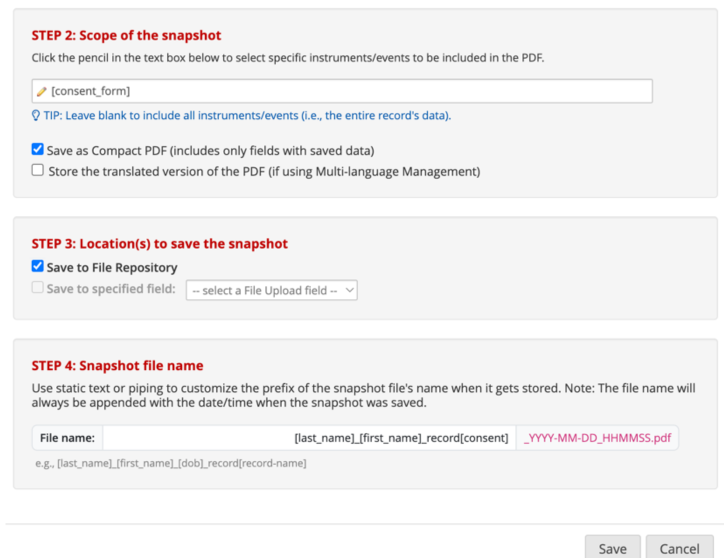
6. Next click on the tab “PDF Snapshots of Records.” This will add a trigger for REDCap to capture a PDF of a record of your choice (need for to activie this function to store a copy of the consent).

7. For **Step 1: Trigger conditions**, choose “Consent Form” under **Every time the following survey is completed**.

8. For **Step 2: Scope of the snapshot**, click on the yellow pencil icon and select only “Consent Form”. Click “Update”

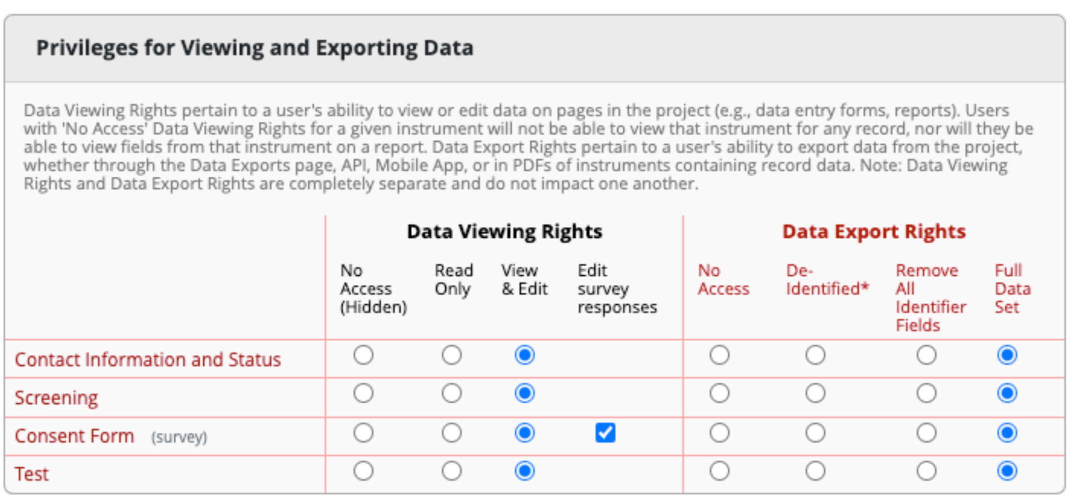


9. For **Step 3: Location(s) to save the snapshot**: Keep the checkmark next to “Save to File Repository”.
10. For **Step 4: Snapshot file name**, you can setup the file name to match the participant’s name so downloaded consent files are easier to locate for a participant. Type in **[last_name]_[first_name]_record[consent]** if this step is applicable.
11. Click “Save”.



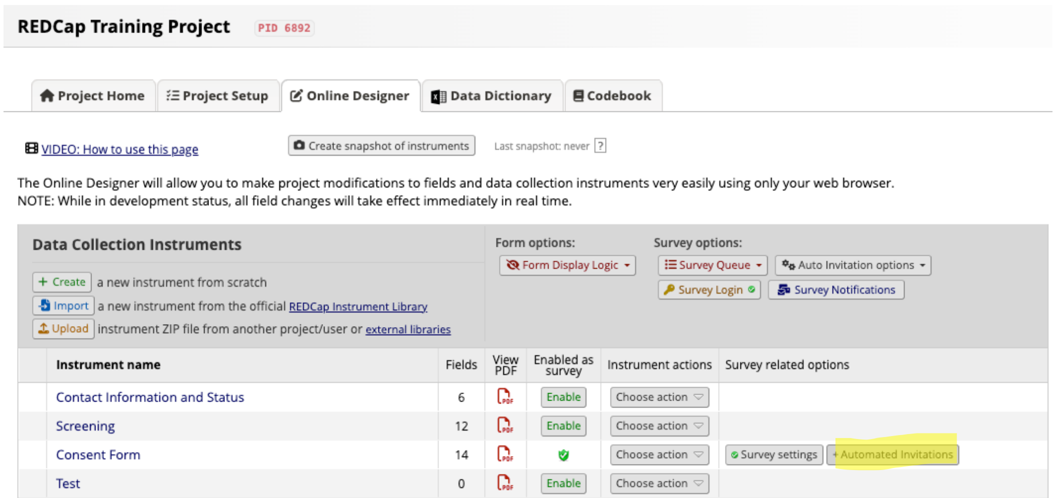
Other survey settings

1. Allow eConsent to be edited by users so research staff can return and sign after participant completes eConsent.
    a. On the **Applications** section on the left-hand side, Click on **User Rights**
    b. Click on the staff member’s UserName that needs to be edited and then click on “Edit user privileges”. This is also where you can **remove the user** if applicable.
    c. Check the checkbox under “Edit Survey Responses” in line with the “Consent Form”
    d. There are Basic Privileges to the left-hand side that can be modified as well for the username selected.
    e. Click “Save Changes”.

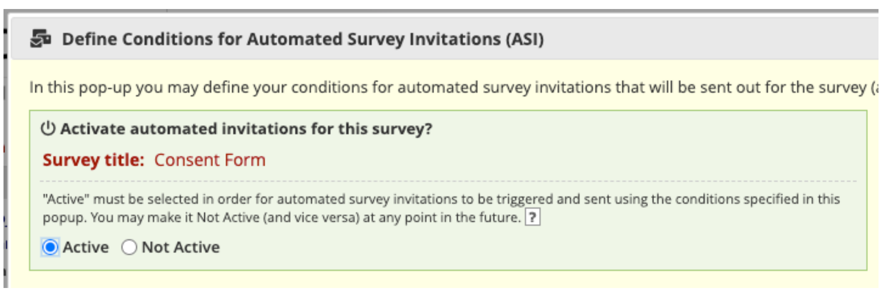


Setting Up Automated Survey Invitation for eConsent

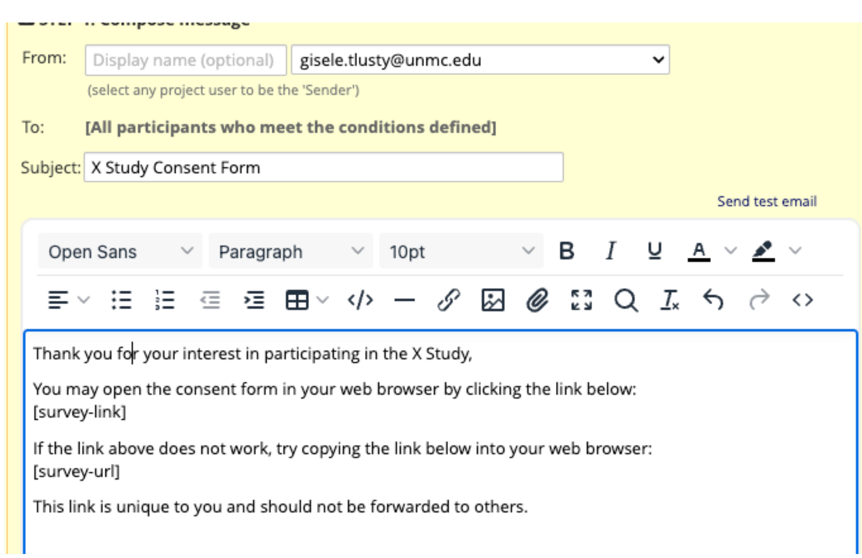
1. In **Designer** (left-hand side), click on “Automated Survey Invitations” button for the survey needed to be automated (helpful if wanting to send out repeated measures).



2. Be sure the default “Active” is selected.

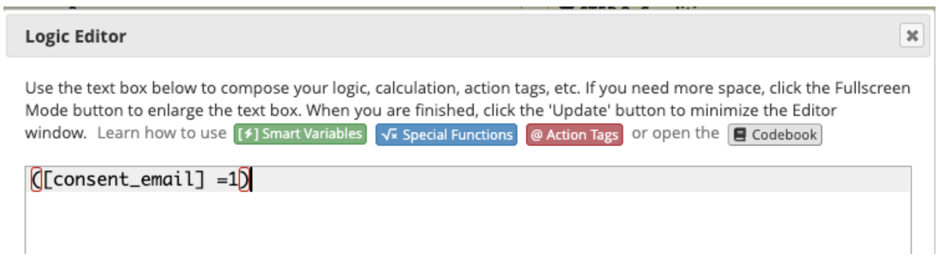


3. Complete **Step 1**:
   a. Enter the PI’s email in the “From” field
   b. Change subject to include the name of your study “X (enter name) Study Consent Form”
   c. Optional - Modify survey invitation text (See example below)

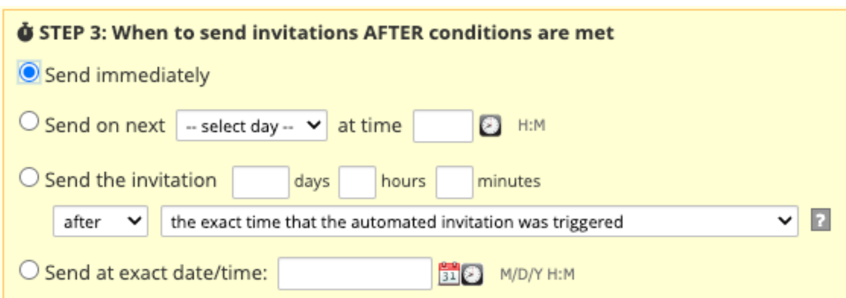


4. Complete **Step 2**:
    a. Check box for “When following logic becomes true

    b. Enter the following logic: ([consent_email] = 1)



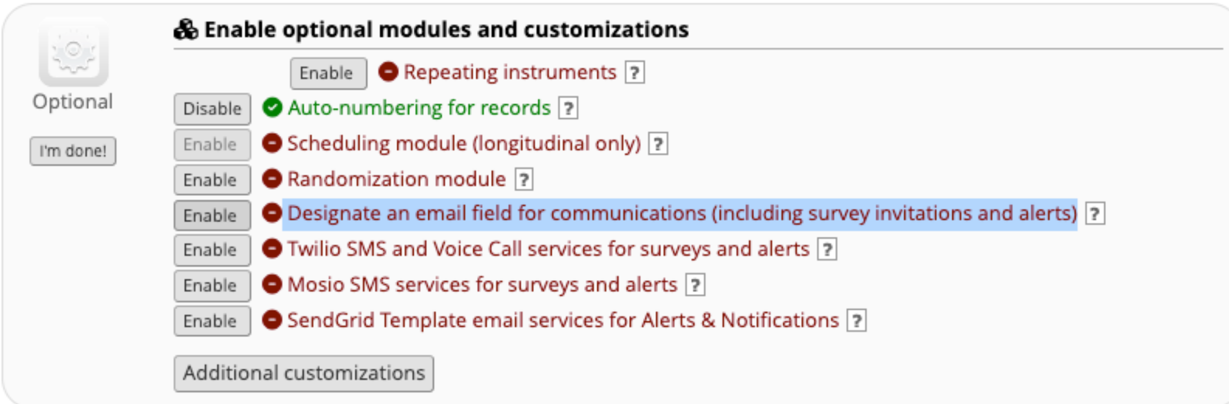
5. Complete **Step 3**:
    a. Select “Send immediately”



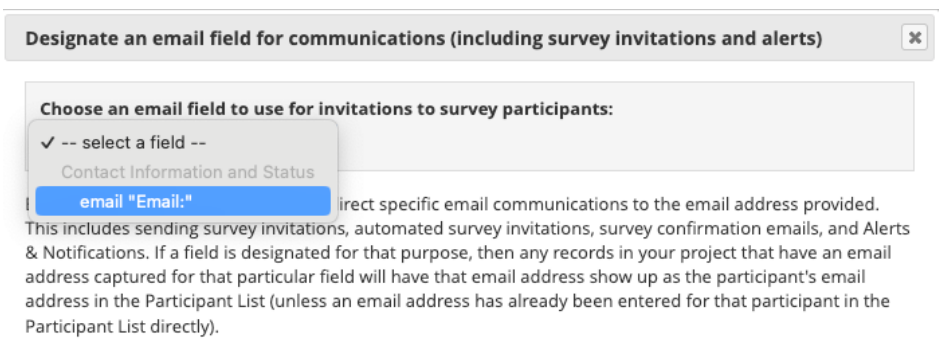
6. Click “Update & close editor or Save”

Enabling Email Communication for Surveys

1. Click on “Project Setup” either on the tab on the top or on the left-hand side near the top.
2. Under the third group **Enable optional modules and customizations**: click “Enable” for “Designate an email field for communications (including survey invitations and alerts)”



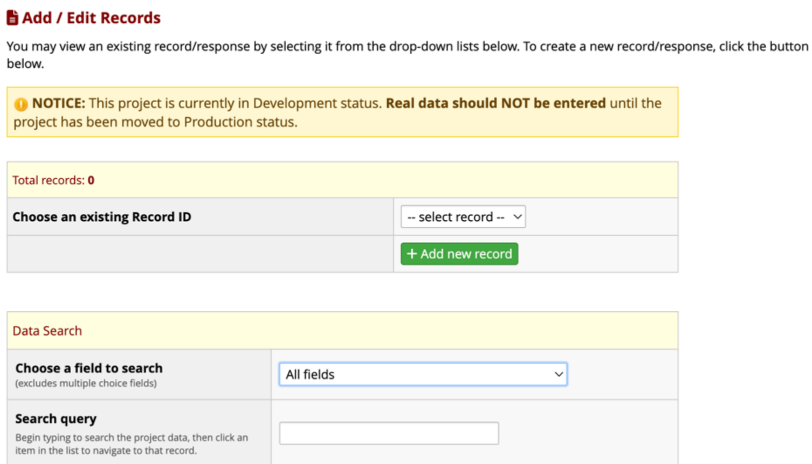
3. Choose “email” for the designated field
4. Click “Save”



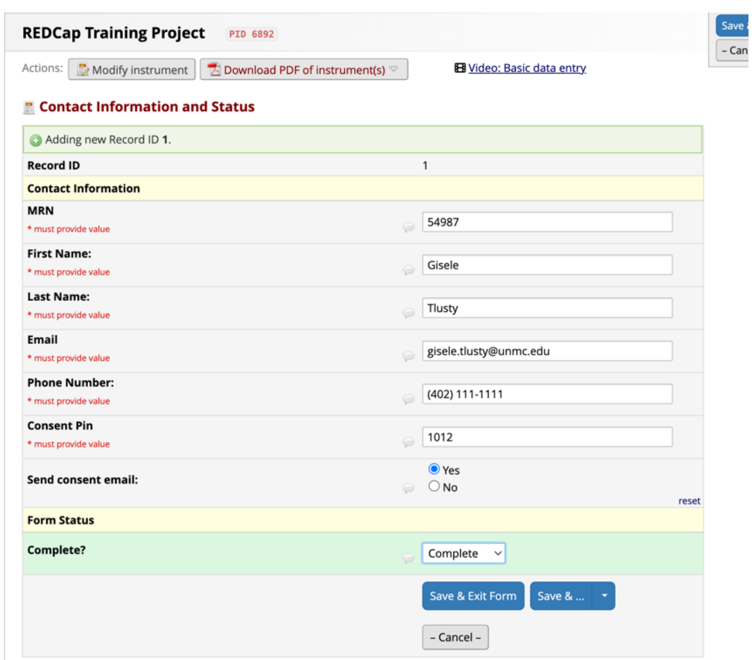
Testing your project

Be sure to **fully test your project** prior to sending it to production by creating sample participants and testing the consent functionality. Sending the consent to yourself is a great way to test your project.

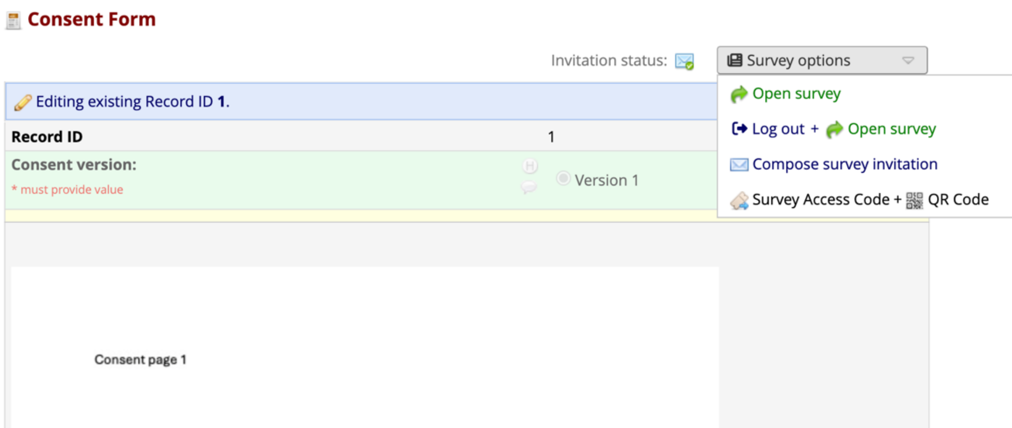
1. Click on Add / Edit Records. Click on + Add new record.



2. The next screen will display the **Data Collection Instruments** that are available for participants to complete. Click on the **grey round circle** next to “Contact Information and Status”. (If it is green, it is already done). Enter in random information for the fields except for the “Consent Pin” (will need to reenter the same pin to test the consent) and “Email” fields (need an accessible **email** test the consent). Choose “Complete” and click on “Save & Exit Form”



3. Now click on the grey circle next to “Consent Form”. On the top right of the consent, there is an **Invitation status** option. Click on “Survey options”. Then “Compose survey invitation”.

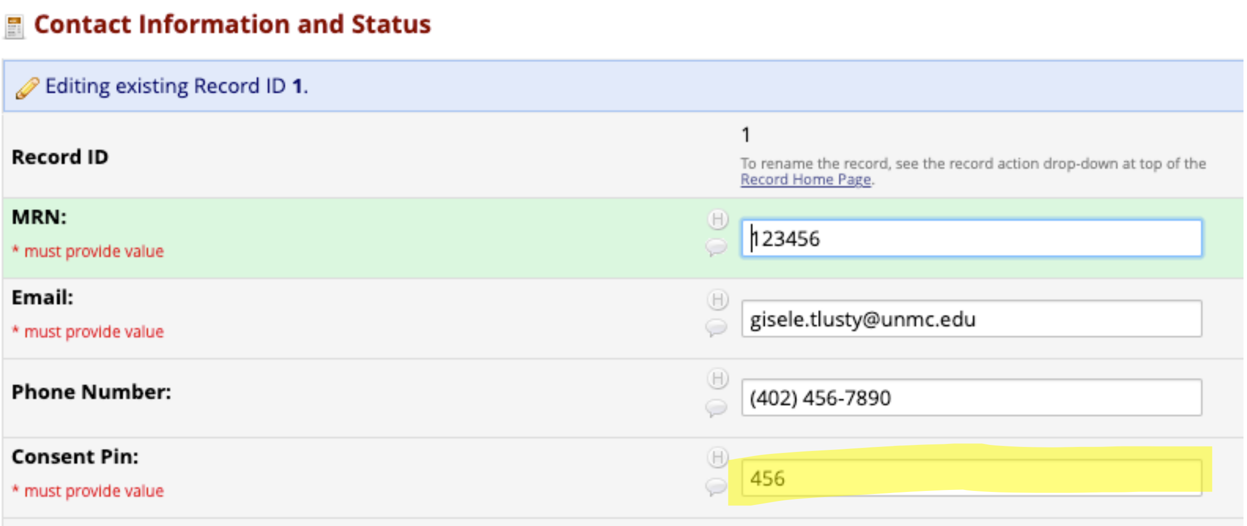


4. Keep the default “Immediately” selected for **When should this email be sent?**
5. Select the **emails** applicable for the “To” and “From” fields. Select the **correct email for the “To” field to be able to test out the consent form**.
6. Add a Subject title.
7. Click “Send Invitation”
8. Click “Leave page”
9. In one’s email account, click on the Consent Form link in the email sent.
10. Enter the “Consent Pin” (the example uses ‘1012’). Complete the survey. Go back and modify any spelling errors and applicable changes if necessary, before moving the project to “Production” status.

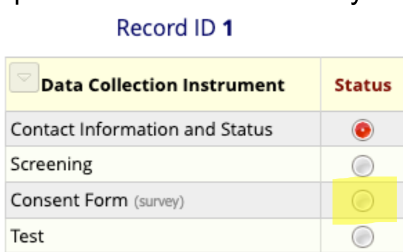
Completing the eConsent form with the Participant

In-Person Consenting

1. Open the “Contact Information and Status” form.
    a. Ask the participant for the PIN or Password that they would like to use to access the eConsent form. The PIN/Password field is not validated so the participant can use as many or as few digits, letters, or characters as they would like. The PIN/Password should be memorable for the participant to remember but should not contain any identifiable information (birthday, etc.).

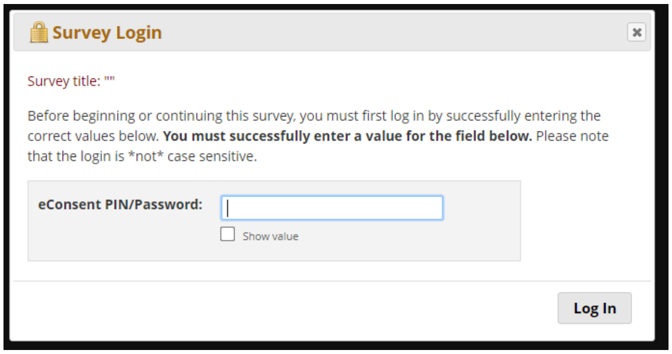


    b. Enter “no” in “Send consent email” field.
    c. Leave the form status as “Incomplete” and then click “Save and Exit Form.”
2. Open the “Consent Form” by clicking on the grey circle.



3. Click “Survey options” at the top of the eConsent from and then “Open survey” and give the iPad/laptop to participant.

4. REDCap will prompt the participant for the PIN/Password that they just set up.



Survey Login

Survey title: ""

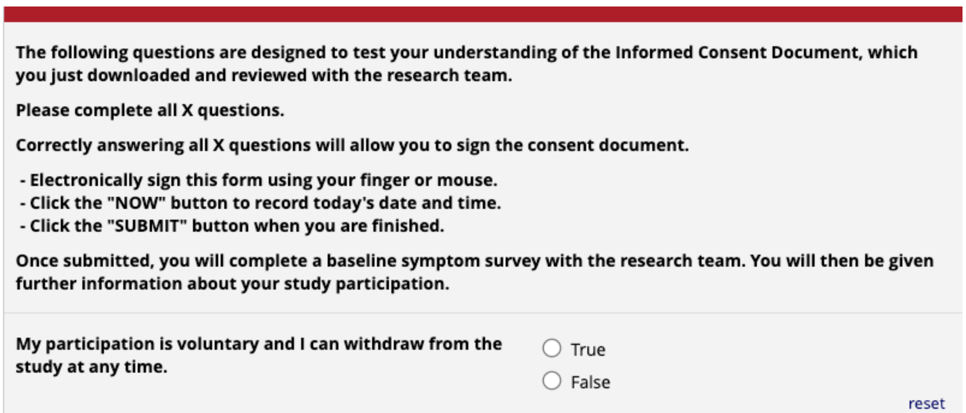
Before beginning or continuing this survey, you must first log in by successfully entering the correct values below. **You must successfully enter a value for the field below.** Please note that the login is *not* case sensitive.

eConsent PIN/Password:

Show value

Log In

5. Review contents of the consent form with participant.
6. Have participant complete the comprehension questions.
   a. Signature fields will not open unless all the comprehension questions are answered correctly. Popups have been added if a participant answers a question incorrectly.



The following questions are designed to test your understanding of the Informed Consent Document, which you just downloaded and reviewed with the research team.

Please complete all X questions.

Correctly answering all X questions will allow you to sign the consent document.

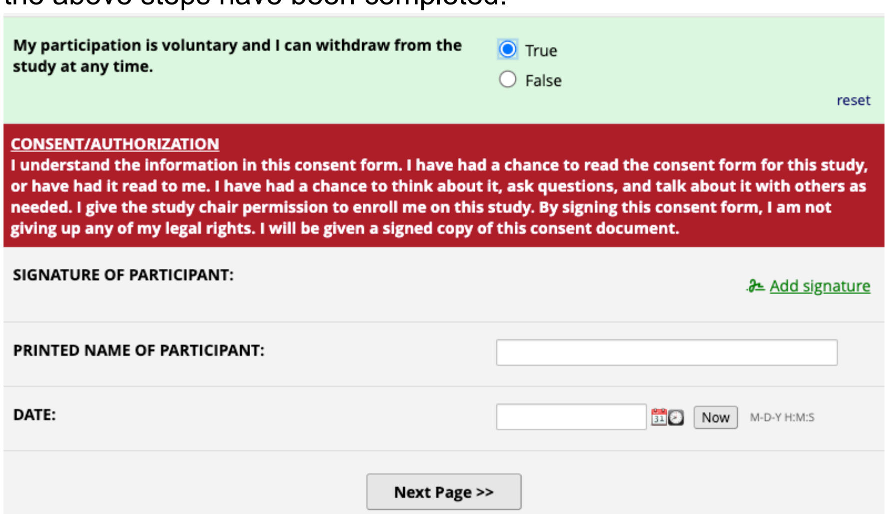
- Electronically sign this form using your finger or mouse.
- Click the "NOW" button to record today's date and time.
- Click the "SUBMIT" button when you are finished.

Once submitted, you will complete a baseline symptom survey with the research team. You will then be given further information about your study participation.

My participation is voluntary and I can withdraw from the study at any time. True / False

reset

7. Have participant enter their name, signature, and today's date at the bottom of the eConsent form.
   a. If the participant requests additional time to review the consent, that is okay if all the above steps have been completed.



My participation is voluntary and I can withdraw from the study at any time. True / False

reset

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

SIGNATURE OF PARTICIPANT: Add signature

PRINTED NAME OF PARTICIPANT:

DATE: Now M-D-Y H:M:S

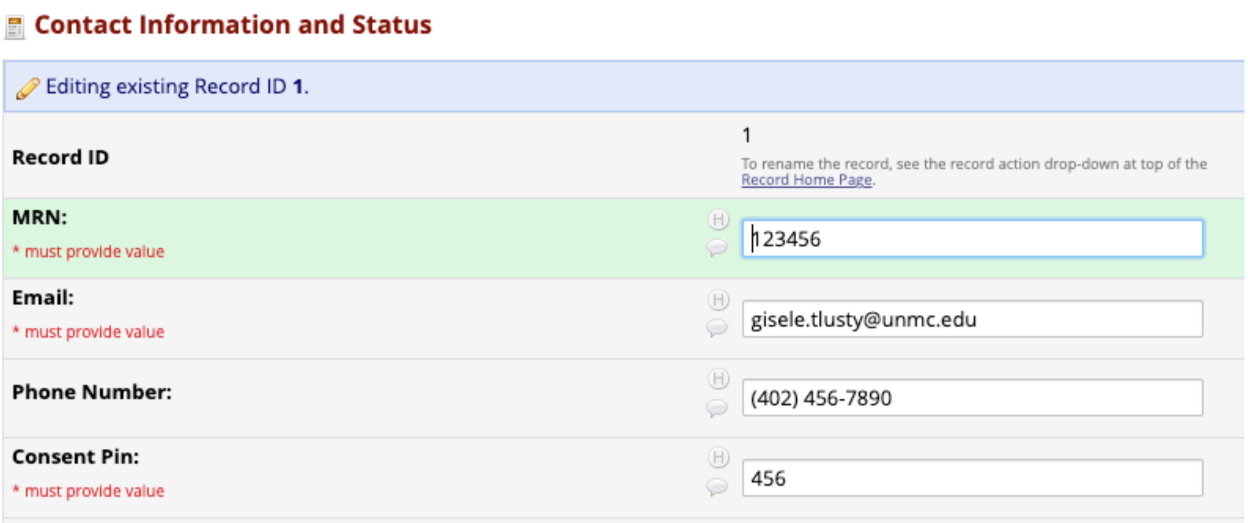
Next Page >>

8. Inform the participant that once they sign and date, the survey will auto-continue into the remaining baseline surveys (if this step was completed above).

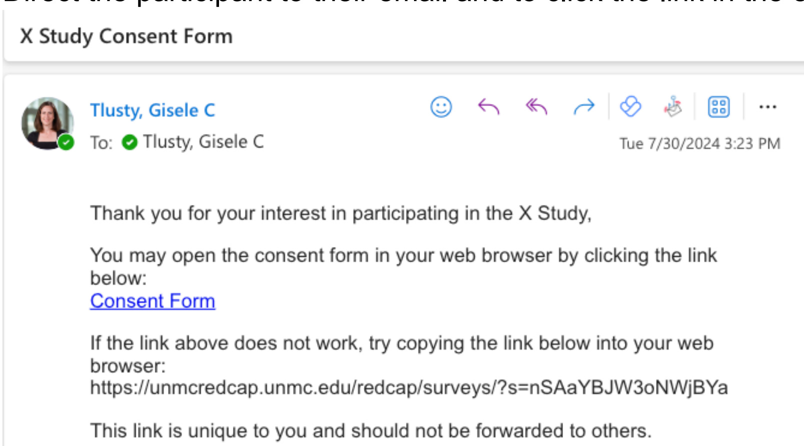
****Continue to "Adding Staff Signature and Downloading PDF of Consent" below*

Over the Phone Consenting

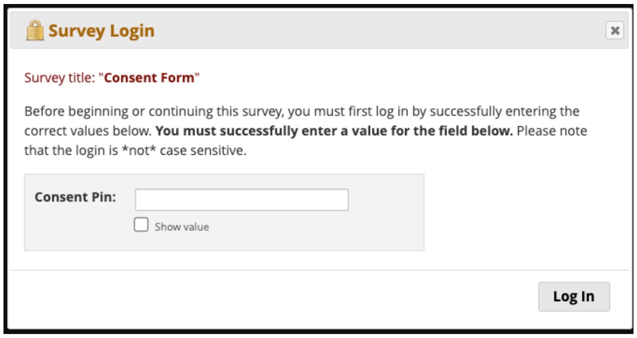
1. Open "Contact Information and Status" form.
    a. Ask the participant for the PIN or Password that they would like to use to access the eConsent form. The PIN/Password field is not validated so the participant can use as many or as few digits, letters, or characters as they would like. The PIN/Password should be memorable for the participant to remember but should not contain any identifiable information (birthday, etc.).



    b. Enter "yes" in the "Send consent email" field.
    c. Leave the form status as "Incomplete" and then click "Save & Exit Form."
        i. Once the Contact Information and Status Form is saved, an email containing a link to the eConsent form will be **<u>immediately</u>** sent to the participant's email.
2. Direct the participant to their email and to click the link in the email they just received.



3. REDCap will prompt the participant for their PIN/Password that they just set up.



Survey Login

Survey title: "**Consent Form**"

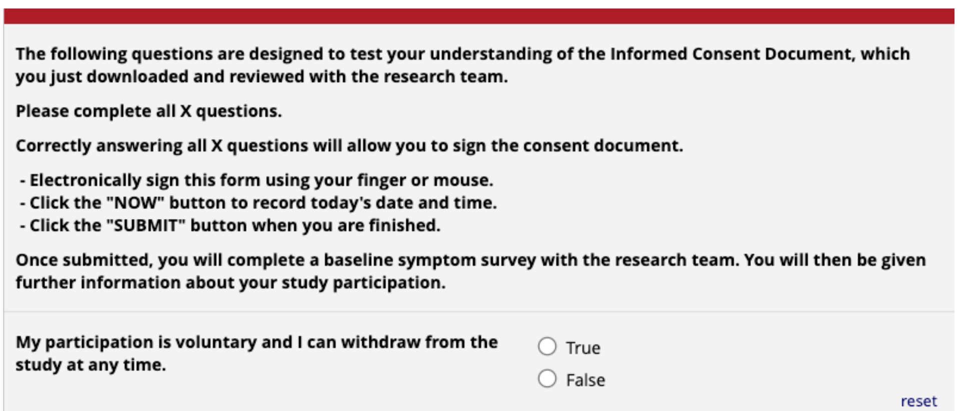
Before beginning or continuing this survey, you must first log in by successfully entering the correct values below. **You must successfully enter a value for the field below.** Please note that the login is *not* case sensitive.

Consent Pin:

Show value

Log In

4. Review contents of the consent form with participant.
5. Have participant complete the comprehension questions.
    a. Signature fields will not open unless all the comprehension questions are answered correctly. Popups have been added if a participant answers a question incorrectly.



The following questions are designed to test your understanding of the Informed Consent Document, which you just downloaded and reviewed with the research team.

Please complete all X questions.

Correctly answering all X questions will allow you to sign the consent document.

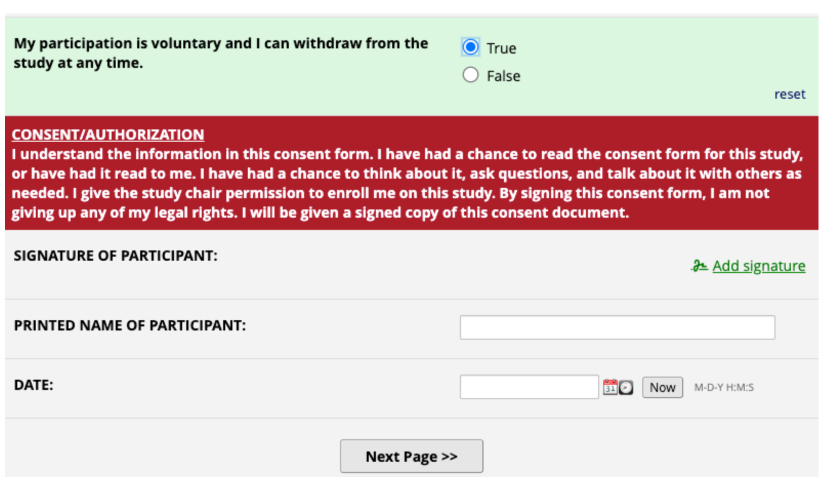
- Electronically sign this form using your finger or mouse.
- Click the "NOW" button to record today's date and time.
- Click the "SUBMIT" button when you are finished.

Once submitted, you will complete a baseline symptom survey with the research team. You will then be given further information about your study participation.

My participation is voluntary and I can withdraw from the study at any time. True / False

reset

6. Have participant enter their name, signature, and today's date at the bottom of the eConsent form.
    a. If the participant requests additional time to review the consent, that is okay if all the above steps have been completed.
7. Inform the participant that once they sign and date, the survey will auto-continue into the remaining baseline surveys (if this step was completed above).



My participation is voluntary and I can withdraw from the study at any time. True / False

reset

CONSENT/AUTHORIZATION
I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

SIGNATURE OF PARTICIPANT: Add signature

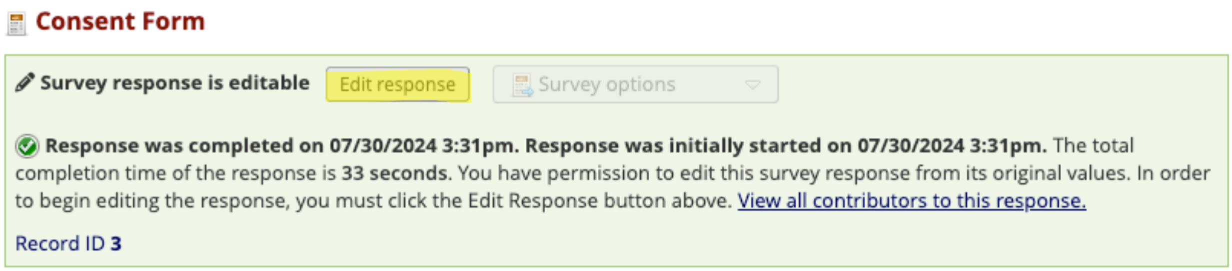
PRINTED NAME OF PARTICIPANT:

DATE: Now M-D-Y H:M:S

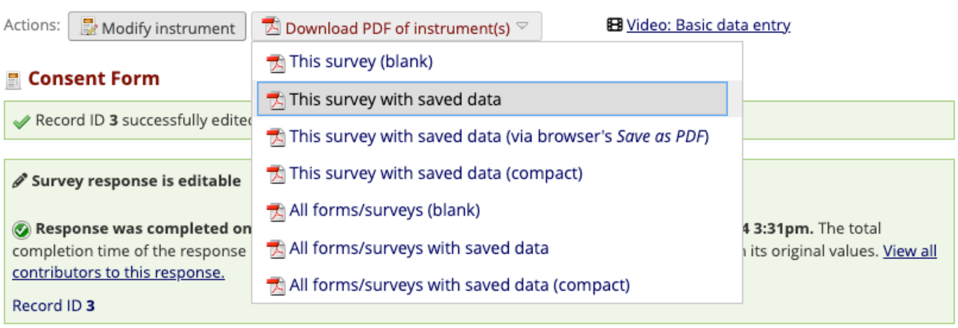
Next Page >>

Adding Staff Signature and Downloading PDF of Consent

1. Return to eConsent form after participant has completed it and add staff name and signature.
    a. At the top of the "Consent Form," click on "Edit Response."



    b. Scroll down to the "Person Obtaining Consent" section and add staff name, signature, and date/time.
        i. Leave form status as "Complete" and then click "Save & Stay"
2. To download completed eConsent form, scroll back to the top of the "Consent Form."
    a. Click "Download PDF of Instrument(s)" and the "This survey with saved data."



    b. A PDF will download. Save the PDF per protocol procedures.