nova scotia health
research + innovation

+ *NS Health*

Research, Innovation & Discovery

Using the eConsent: REDCap User Guide

Research Methods Unit
Research Ethics Board
December, 2020

Table of Contents

1. Introduction 3
   1.1. User Guide 3
2. Requesting a REDCap project for eConsent 4
3. Setting up your project for eConsent 5
4. Modifying the eConsent Form Template 6
   4.1. Editing functions in REDCap 7
   4.2. Branching logic in REDCap 9
5. Survey settings for the eConsent form 12
   5.1. Optional: automatic email of eConsent form 15
   5.2. Designating the Email field 16
6. Adding eConsent to an existing REDCap project 17
7. Test Your Project Thoroughly 18
   7.1. Move project to production 19
8. Distributing eConsent to participants 20
9. Monitoring responses and adding signatures to submitted eConsent forms 21
   9.1. The use of E-signatures in REDCap for Health Canada-regulated trials 22
10. File Repository 23
11. Modifying eConsent 25
   11.1. Updating the Consent Form 25
12. ReConsenting and Updating Consent 28

1. Introduction

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

The use of eConsent must follow the REDCap Terms of Services found on the NSH REDCap website: https://www.cdha.nshealth.ca/REDCap.

Note: the NSH REB will recommend the required fields needed for your eConsent. The NSH REDCap Administrator does not have the ability or authority to approve individual eConsent designs and procedures.

You can view an example of such an eConsent here: Mock EConsent

1.1. User Guide

This guide showcases a number of recommended features that you can implement in your eConsent design. No one design will exactly fit all studies and situations. Map out your workflow and use the correct features accordingly. The necessary items to include in your REDCap eConsent are:

- eConsent framework
- Use of Production mode for real data
- Study participants should not be able to modify a completed consent form. If changes or updates are needed a new form should be initiated.
- Staff and study team must login to REDCap to sign the documents.

eConsent at NSH is an ongoing and evolving activity so please send any feedback to the REB office at ResearchEthics@nshealth.ca.

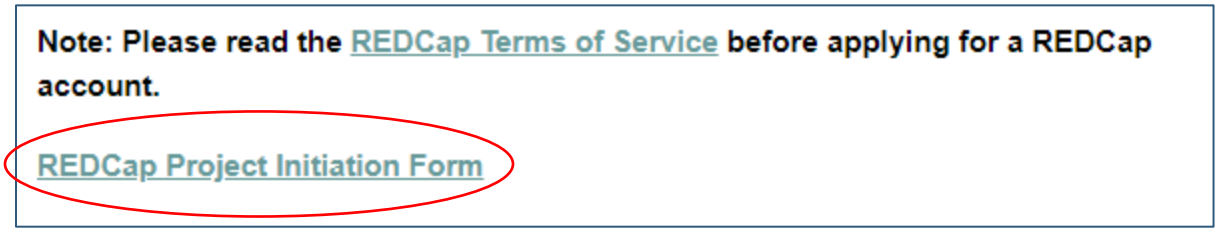
Best of luck with your research!

2. Requesting a REDCap project for eConsent

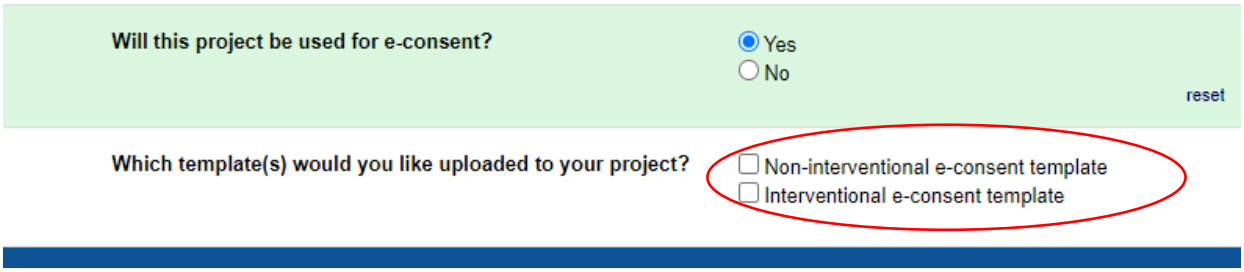
Please submit an NSH REDCap Project Initiation Form, which you can access here:

https://www.cdha.nshealth.ca/REDCap

Click on the link shown below to access the form:



eConsent templates have been developed that can be included in your project at the time of setup. Please indicate on the project initiation form, which consent template you need.

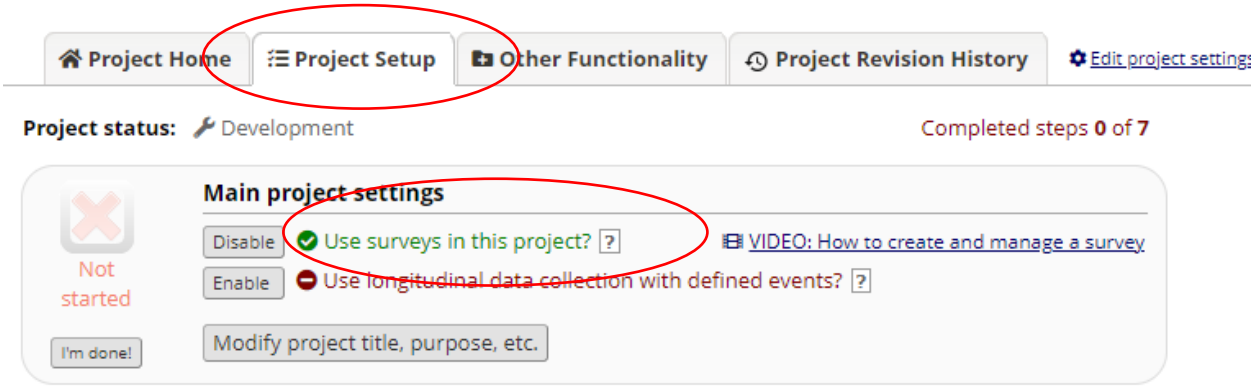


The REDCap administrator will include the template for you when the project is initiated. **Please allow up to 10 business days for your REDCap project request to be processed.** If you do not receive a response after 10 business days please email: REDCap.Administrator@nshealth.ca to inquire.

Note: This is just a **general** template for eConsenting. You will need to modify it to fit your project's needs, such as modifying or adding data fields that your particular consent requires and configuring the eConsent survey settings. **This template alone does not guarantee REB compliance for eConsent. Your team must test the eConsent to ensure it meets your study's needs and functions the way you want it to. You must also send a copy of your built eConsent to the REB for approval before you can use it.**

3. Setting up your project for eConsent

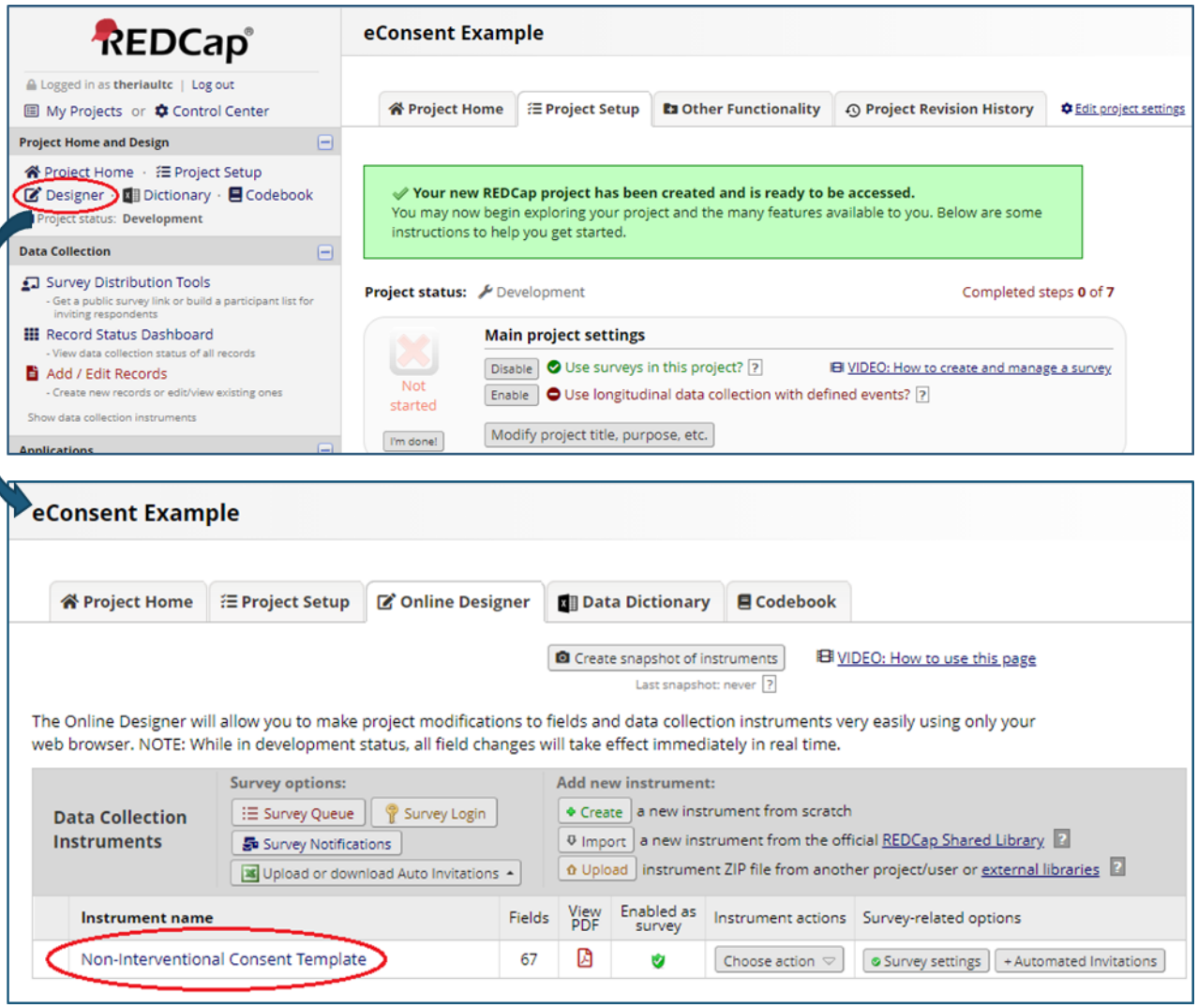
Before you can begin editing your consent, you need to enable surveys on the Project Setup page:



4. Modifying the eConsent Form Template

To start editing your consent form, navigate to **My Projects** and select your project. Click on **Designer** to start editing fields.

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

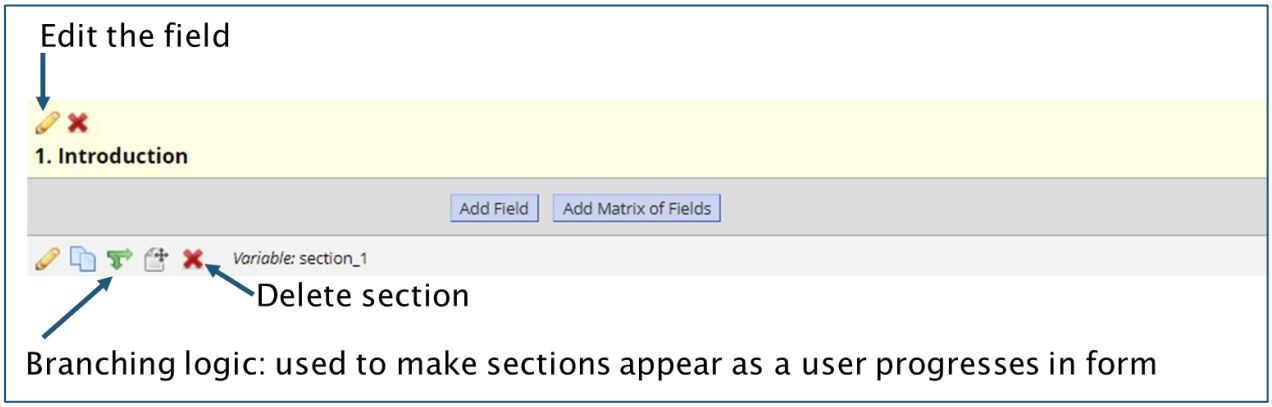


The wording from the current paper templates was transcribed into the eConsent templates. Each section from the Word document was turned into a descriptive field. Embedded questions are editable and optional. They were added for the purpose of reinforcing the informed portion of the consent.

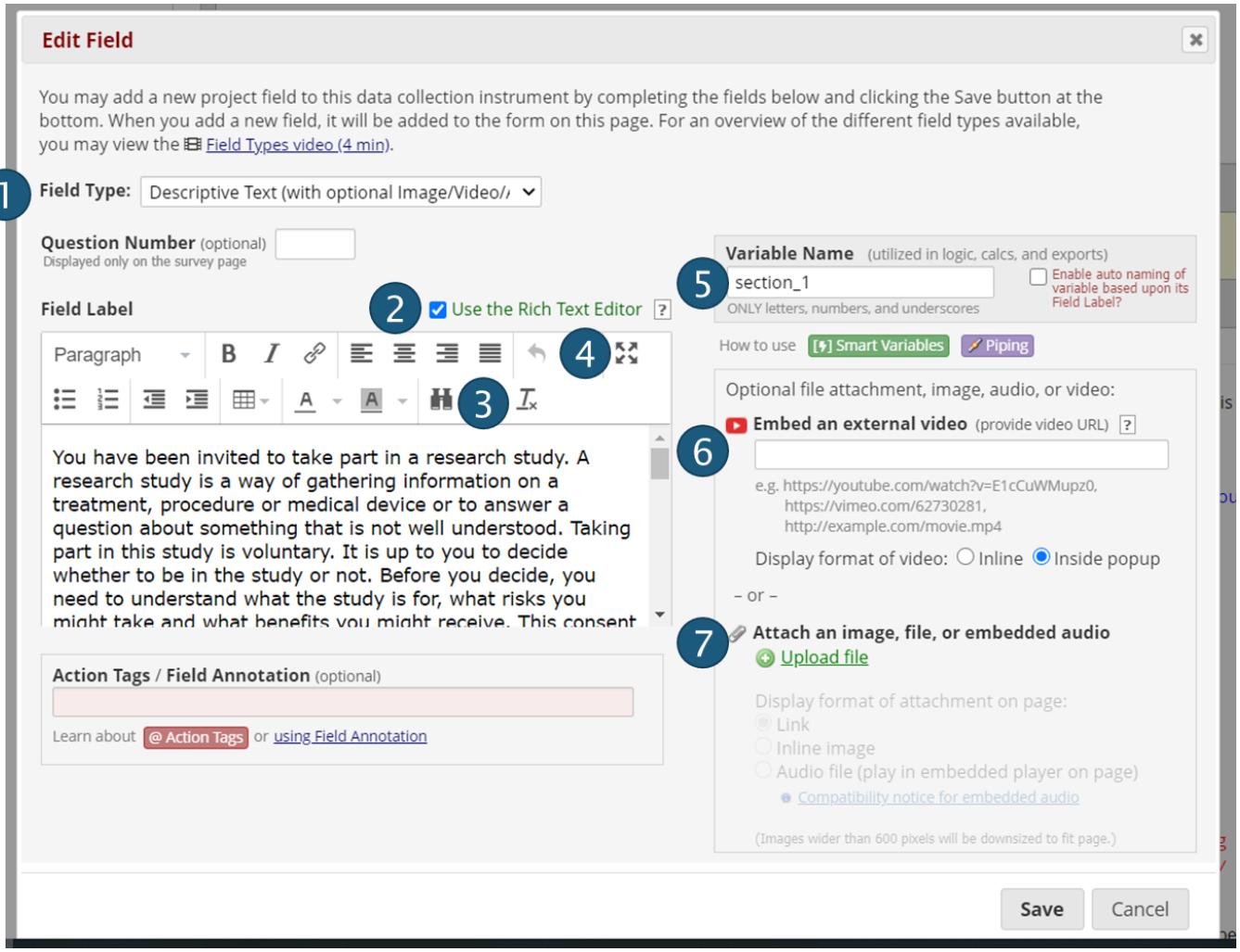
Removing embedded questions will require the branching logic and question numbering to be updated.

4.1. Editing functions in REDCap

If you want to make changes to the content of the eConsent, click on the "pencil" icon to open the field.



Once you open the field, you will see a window like the one below.



The numbers above represent:

1. Field Type: Descriptive text is what you will use to insert text into your eConsent. If you wish to insert a question, select another field from the drop down menu.

2. **To copy-paste from a Word document, de-select "Rich Text Editor" before pasting**, then re-select the "Rich Text Editor" to format the text. Otherwise, REDCap keeps the Word formatting, which you can't easily change.

3. The "T_x" is used to remove some (not all!) of the formatting from your copy/pasted text. The underline option is not available as a formatting button but can be done by flanking the underline section with <u> to start underlining and <u/> to stop the underline. (e.g., <u>Insert underline section here</u>).

4. These arrows will expand the editing section to fit your screen. Recommended to use for any type of editing.

5. The variable name is what you will use for branching logic. It is recommended to use a straightforward naming strategy to help format/de-bug the branching logic at a later time.

6. Insert any link here for a video to play.

7. Upload an image using this link. Note the option of "inline" image which embeds the image into the form.

4.2. Branching logic in REDCap

Branching Logic may be employed when fields/questions need to be hidden under certain conditions. If branching logic is defined, the field will only be visible if the conditions provided are true (i.e. show the field only if...). Branching logic is used in the eConsent to make sections appear as questions are answered. Changing the wording (Field Label) of the question will not affect branching. However, changing the Variable Name or deleting the question will affect the branching.

Branching logic is pre-loaded into the NSH eConsent templates as the embedded questions are pre-set to be answered before continuing to the next section. If you remove embedded questions from the eConsent template, you will need to ensure that the branching logic is fixed by recognizing which subsequent sections were linked to the deleted question. You will need to update the branching logic on the subsequent questions to reflect the new continuation logic.

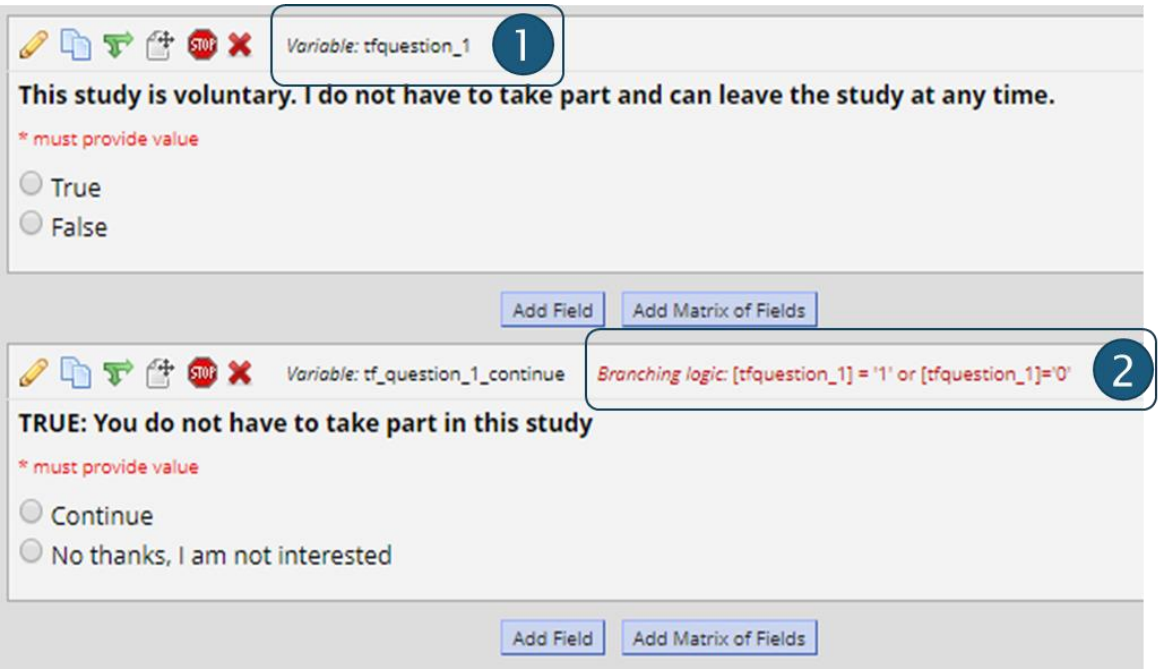
You can update your branching logic either via "Advanced branching logic", which requires that you add/edit the logic statement. Alternatively, you can use the drag and drop logic builder to develop/update your branching logic statements. If you have identified multiple statements, please ensure that you selected whether "all" or "any" of the statements must apply.

This is a common source of error when building the eConsent form, but it becomes a simple and effective tool once users figure it out. Take your time and trace the steps.

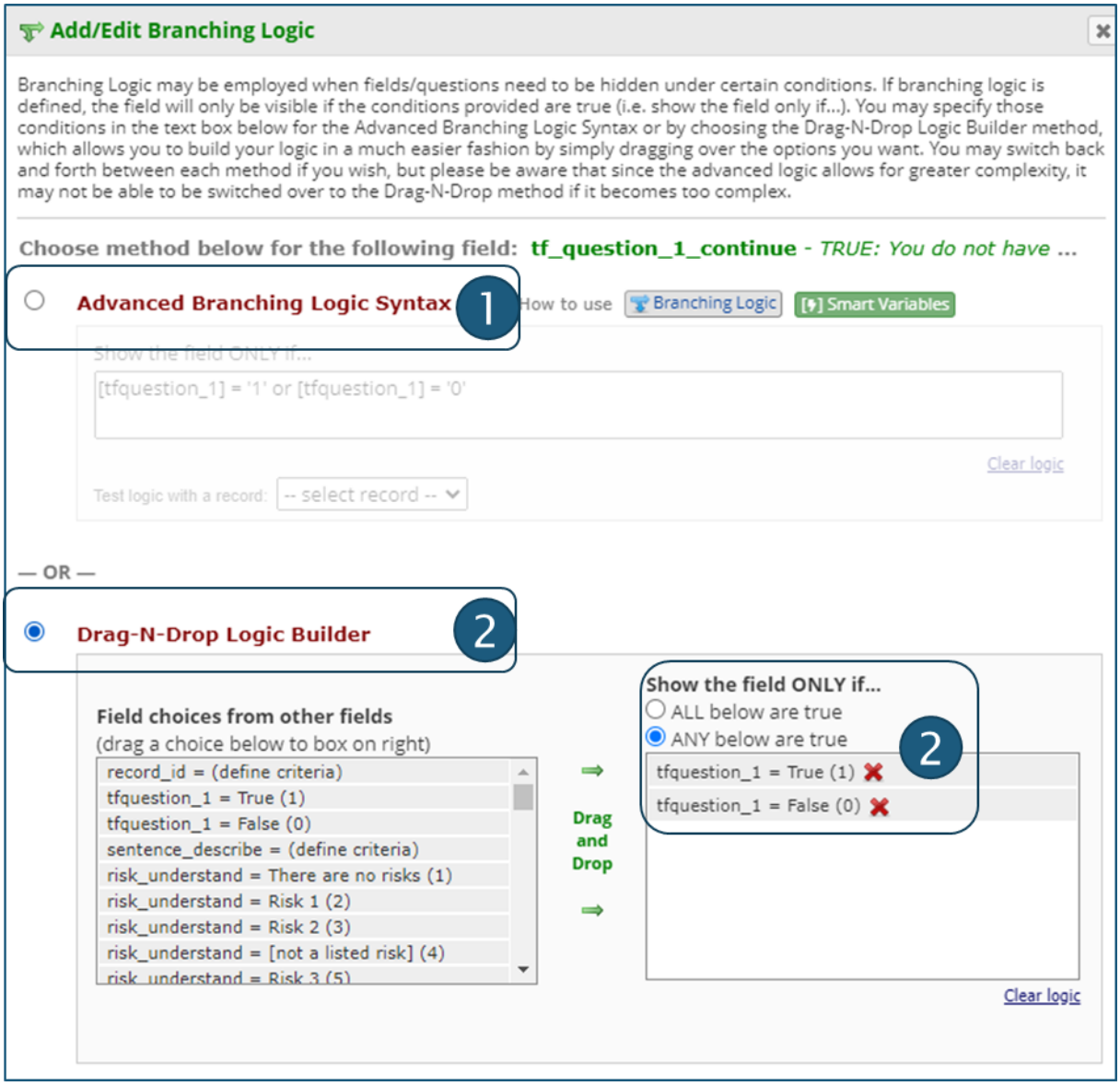
Please ensure thorough testing of your branching logic before moving your project into production mode.

Take a look at the example below for branching logic:

➔ To avoid any errors, before removing any fields please ensure that your all your variable names (i.e. tfquestion_1) are deleted in the branching logic (2) before removing the field.



To edit the branching logic, click on the branching logic icon in the editing functions (green arrows). You will be brought to the screen below:



The above example allows the user to proceed to the next section if either True OR False is indicated. If you want the participant to only proceed if they answer “True” then you would remove tfquestion_1=’0’ from the branching logic.

5. Survey settings for the eConsent form

If you are receiving the eConsent template from the REDCap Administrator, then many of the survey settings will be pre-set. However, it is important to understand the survey settings and the options available to you. Below is an outline of some of the survey options that should be used in your eConsent design.

Ensure that you enable survey

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

1) Under *Survey Customizations*, select the following:

   a. Question Display Format – 'One section per page (multiple pages).'

   b. Allow participants to download a PDF copy of their responses at the end of the survey – 'Yes.'

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

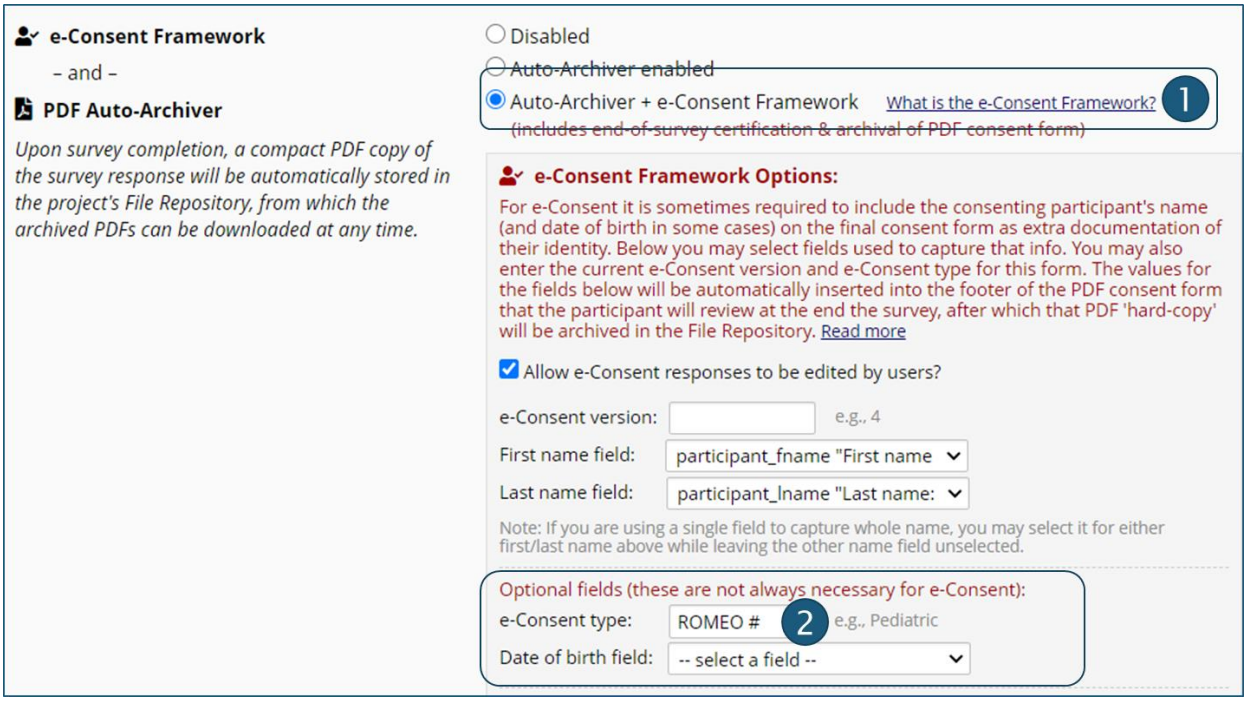
3) Under *Survey Termination Options*, **Auto Archiver+ eConsent Framework has been pre-selected for the template. Please <u>do not</u> change this setting (#1 figure below).**

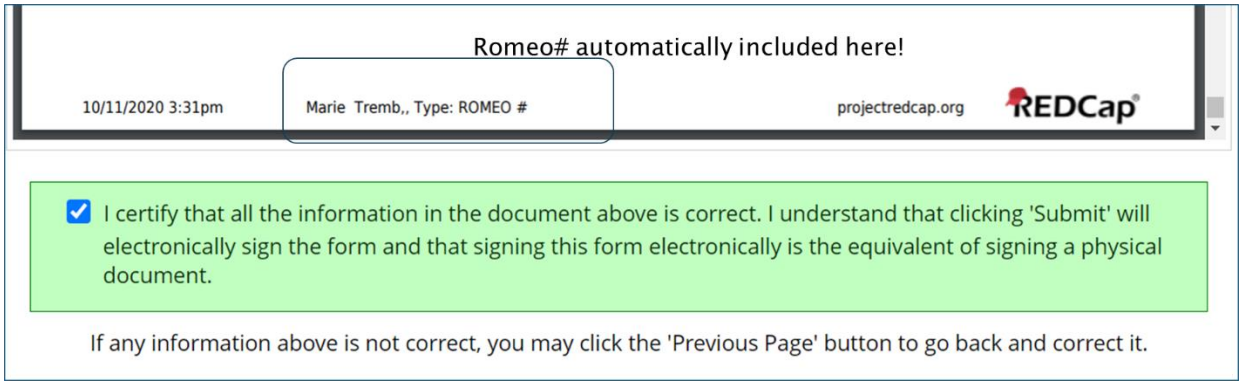
Auto-Archiver + eConsent Framework: This option has two components

a. It automatically saves a PDF copy of the eConsent in the project's File Repository, which can be downloaded later.

b. It also includes an extra certification page at the end of the survey that displays an in-line PDF copy of the survey responses in which the respondent will be asked to confirm that all of the information in the document is correct. Once the respondent confirms the information is correct, the survey will be marked as complete. This option also allows you to have versioning of a form.

c. You must add your ROMEO# to the eConsent PDF version (#2 figure above; figure below)! This can be added by accessing the optional fields of the eConsent framework as outlined below.


e-Consent Framework
– and –
PDF Auto-Archiver
Upon survey completion, a compact PDF copy of the survey response will be automatically stored in the project's File Repository, from which the archived PDFs can be downloaded at any time.
Disabled
Auto-Archiver enabled
Auto-Archiver + e-Consent Framework
What is the e-Consent Framework?
1
(includes end-of-survey certification & archival of PDF consent form)
e-Consent Framework Options:
For e-Consent it is sometimes required to include the consenting participant's name (and date of birth in some cases) on the final consent form as extra documentation of their identity. Below you may select fields used to capture that info. You may also enter the current e-Consent version and e-Consent type for this form. The values for the fields below will be automatically inserted into the footer of the PDF consent form that the participant will review at the end the survey, after which that PDF 'hard-copy' will be archived in the File Repository. Read more
Allow e-Consent responses to be edited by users?
e-Consent version:
e.g., 4
First name field:
participant_fname "First name
Last name field:
participant_lname "Last name:
Note: If you are using a single field to capture whole name, you may select it for either first/last name above while leaving the other name field unselected.
Optional fields (these are not always necessary for e-Consent):
e-Consent type:
ROMEO #
2
e.g., Pediatric
Date of birth field:
-- select a field --


Romeo# automatically included here!
10/11/2020 3:31pm
Marie Tremb,, Type: ROMEO #
projectredcap.org
REDCap
I certify that all the information in the document above is correct. I understand that clicking 'Submit' will electronically sign the form and that signing this form electronically is the equivalent of signing a physical document.
If any information above is not correct, you may click the 'Previous Page' button to go back and correct it.

5.1. Optional: automatic email of eConsent form

REDCap has the ability to automatically send the participant a copy of their signed consent form. This is set up through the "Survey Termination Options" at the bottom of the "Survey settings".

Follow these steps to set up the auto-email:

a. "Yes" for "Send confirmation email (optional)?"

b. Fill out the 'From' (your email address), 'Subject line,' and any text you want include in the email.

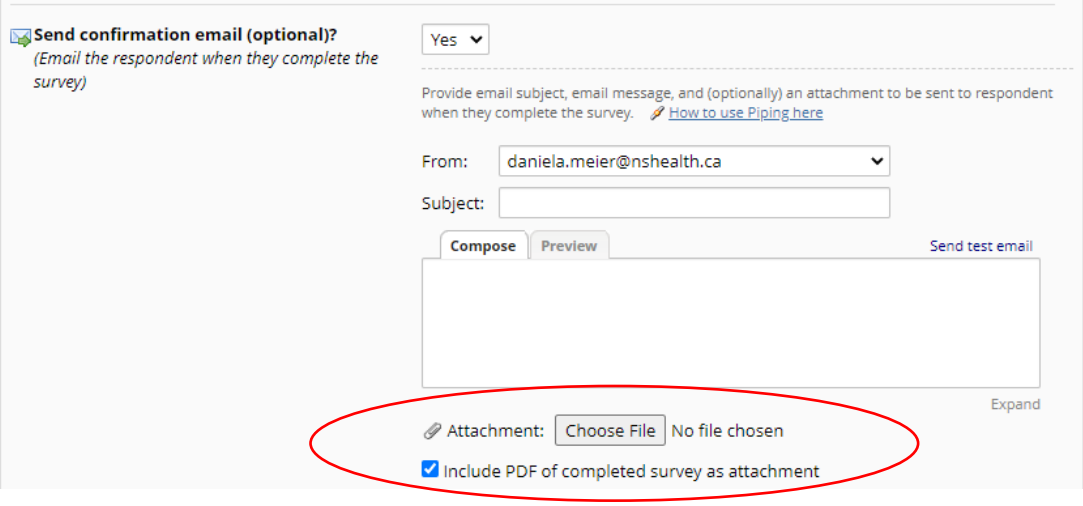
c. You can attach the stamped PDF copy of the consent form where it says 'Attachment.'

   i. This will send the subject a copy of consent form via email if they provided an email address on the consent form. This is a copy of the unsigned consent, not a copy of the completed, signed consent.

   ii. If you want to send the subject a **PDF copy of the completed, signed consent** click on 'Include PDF of completed survey as attachment'**.**

d. Click on 'Save Changes' when finished.

e. If you decide to use the **Send Confirmation Email** option, please see the next section called "Instructions for Setting Up the confirmation Email with the PDF of the consent form" to complete the setup.

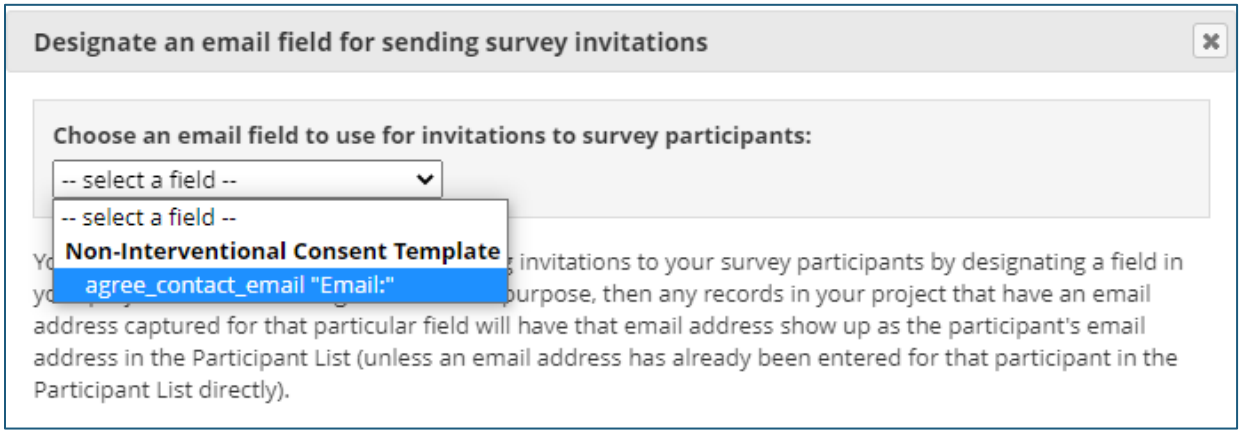


5.2. Designating the Email field

Now we need to designate the field that contains the participants email address:

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

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



The participant will now receive a copy of the consent form with their signature. The PI and study staff have not signed the consent form at this point so their signatures are not included in the automatic email. From a regulatory perspective, there is no requirement for a participant to receive a full executed copy of the consent with all of the signatures.

6. Adding eConsent to an existing REDCap project

The REDCap Administrator will add the NSH eConsent template to an existing REDCap project on request. You must still have the REB approval to perform eConsent using an existing REDCap project. You will need to understand and apply the steps to enable this template as an eConsent form (see above section on survey settings).

Study staff will still need to test the eConsent form within an existing project so label any test records as such.

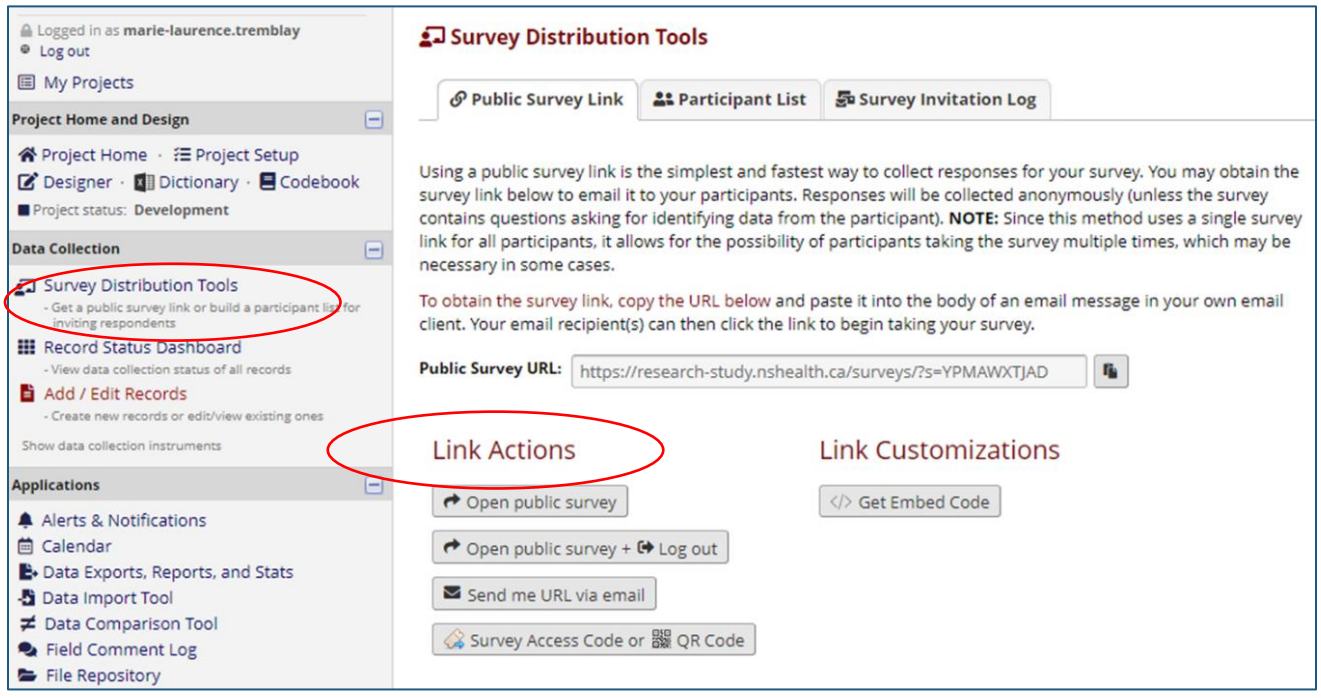
Hint: if you would like to use the eConsent form as a public survey you will need to move the eConsent form to the top of your form list within the Designer. More on survey distribution in the next section.

7. Test Your Project Thoroughly

It is the PI/study team's responsibility to enter test records to ensure the eConsent fits your workflow. The REDCap administrator will <u>not</u> review or test the build/construction of your eConsent (i.e., auto-archiver enabled, eConsent is a survey, test record PDF consent is in File Repository, etc.)

It is the PI and the study staff's responsibility to ensure that the person electronically signing the informed consent is the subject who will be participating in the research study.

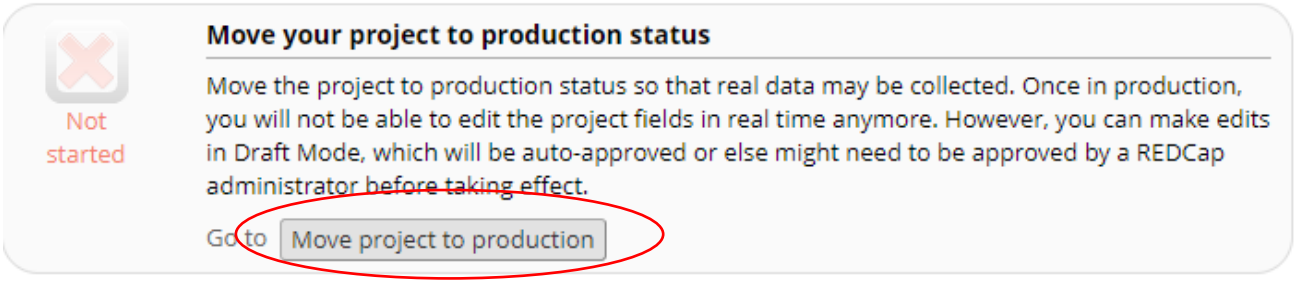
The quickest way to test your eConsent is to go 'Survey Distribution Tools' (under *Data Collection*) and then click on 'Open Public Survey.'



Fill out the eConsent as you would if you were a participant and submit it. If and when you find errors you will return to the Designer for edits before re-testing.

7.1. Move project to production

Once you are done testing your eConsent and you have REB approval to use it, then submit the 'Move to Production' request, which you can find in the "Project Setup" tab.

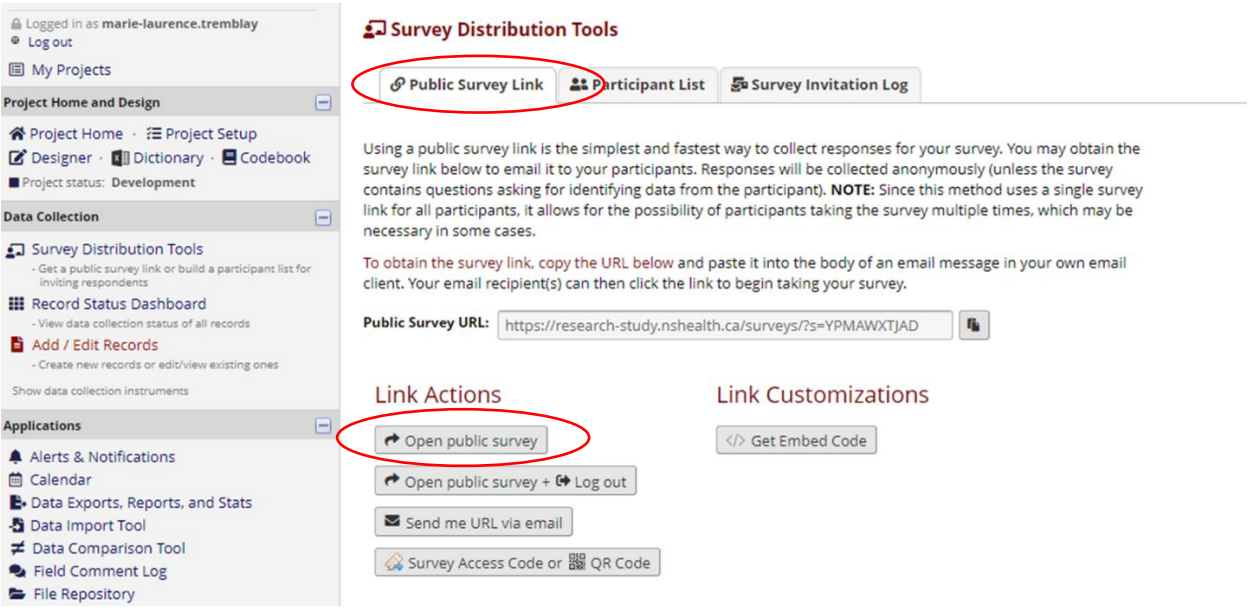


The REDCap administrator will then move your project to production mode.

8. Distributing eConsent to participants

REDCap surveys (and thus eConsent forms) can be distributed as either a "public" or "targeted" survey.

A **public survey link** is a single URL that can be used many times. Upon submission of an eConsent form using of the public survey link, a record in the database will be created. That record will be assigned an auto-generated, sequential "Record ID" (1,2,3,4, etc.). Other study forms can then be completed and linked to the Record ID generated from the completed eConsent form. There can only be one public survey link per REDCap project. This tends to be the most used method of eConsent distribution.



A **targeted survey link** is an email invitation that contains a unique URL for a single individual to complete. Targeted surveys can be distributed in bulk through the "Participant List" tool or can be sent individually using a custom invitation within a multi-form project. Targeted surveys start to get into some of the more powerful features of REDCap. Please see below section on "re-consenting or updating eConsent" to see how a custom survey invitation can be sent.

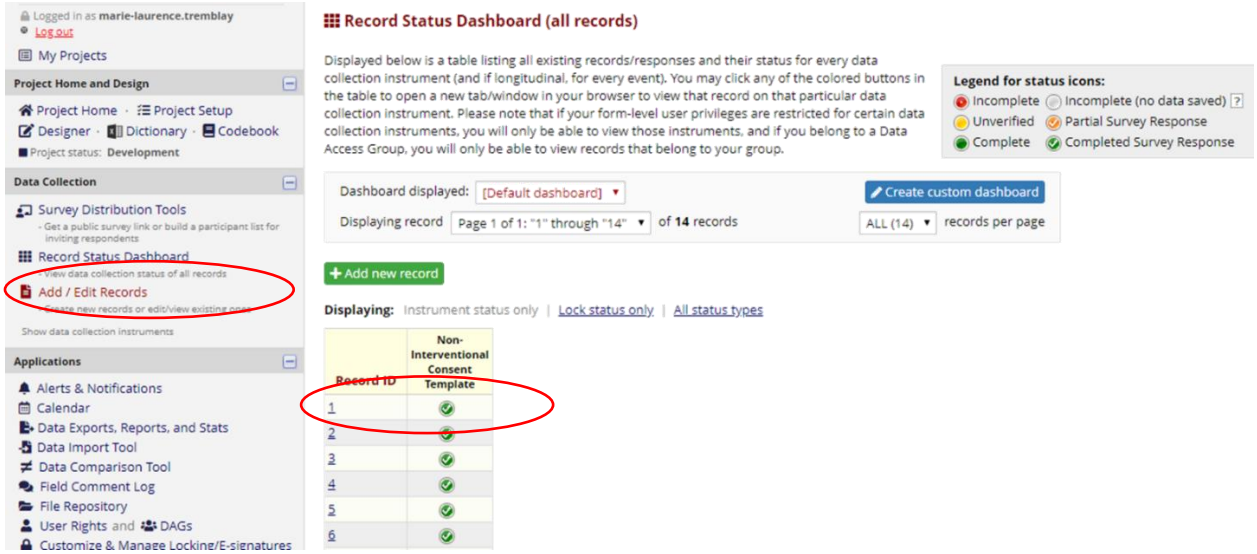
Remember to test and re-test your project, especially when using these types of features.

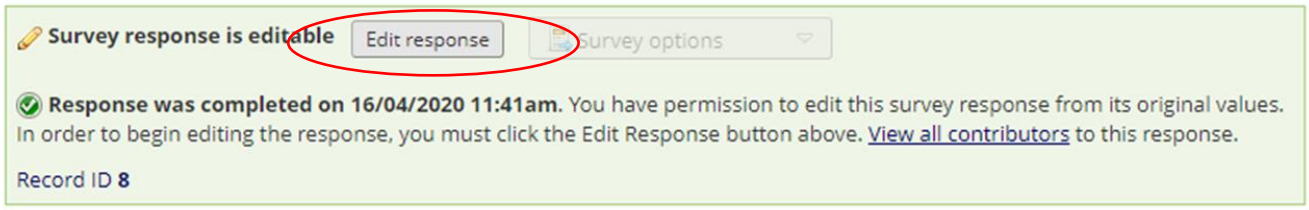
9. Monitoring responses and adding signatures to submitted eConsent forms

The first step for the PI and study staff to sign the eConsent documents is to **sign into REDCap**. You will have received a username from the REDCap Administrator when your REDCap project was created. When you first log into REDCap you will set your password or you can reset your password here using your username. When you are logged into REDCap, any data edits are logged in the audit trail and thus there is documentation of who signed and when.

Do not send the public survey link to the PI or study staff members to sign the form. This may seem like an efficient method but the activity is not documented within REDCap.

Once logged in, the PI and other research staff can sign the eConsent form by going to "Add/Edit records". Click on the ID and click on "edit response". Sign and type your name at the bottom of the form and click on "save and exit form".





If on your initial REDCap Project Initiation Form you did not request REDCap accounts for individuals who need to sign eConsent documents, please submit the request to add new users (see 3rd option on the initiation form).

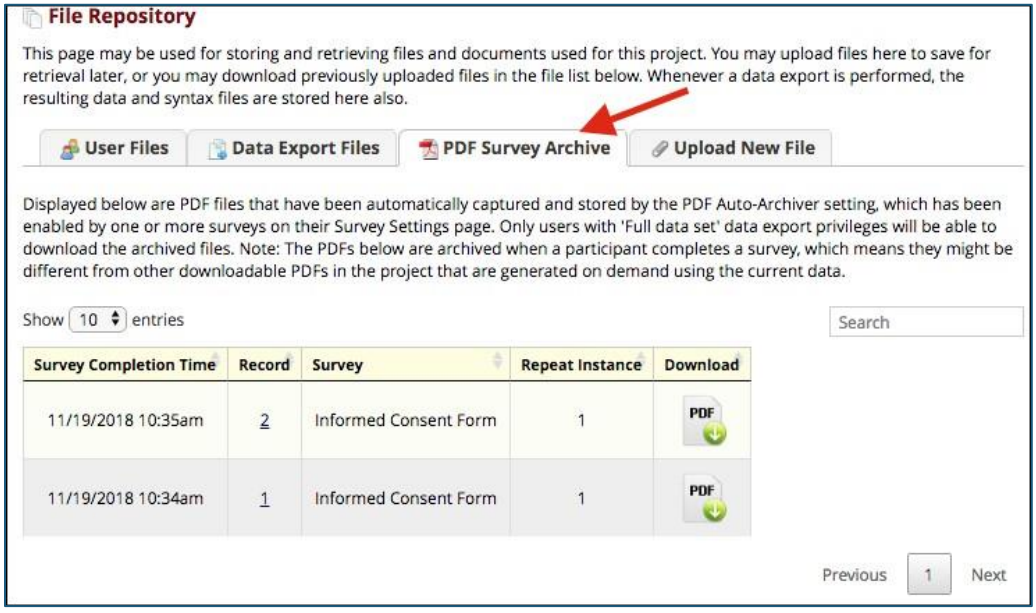
9.1. The use of E-signatures in REDCap for Health Canada-regulated trials

All signatures for EConsent in REDCap are obtained via the REDCap signature field using a stylus, pen, or finger to provide the written signature. As per NSH Privacy Office this constitutes a valid signature. The REDCap signature field works on all devices.

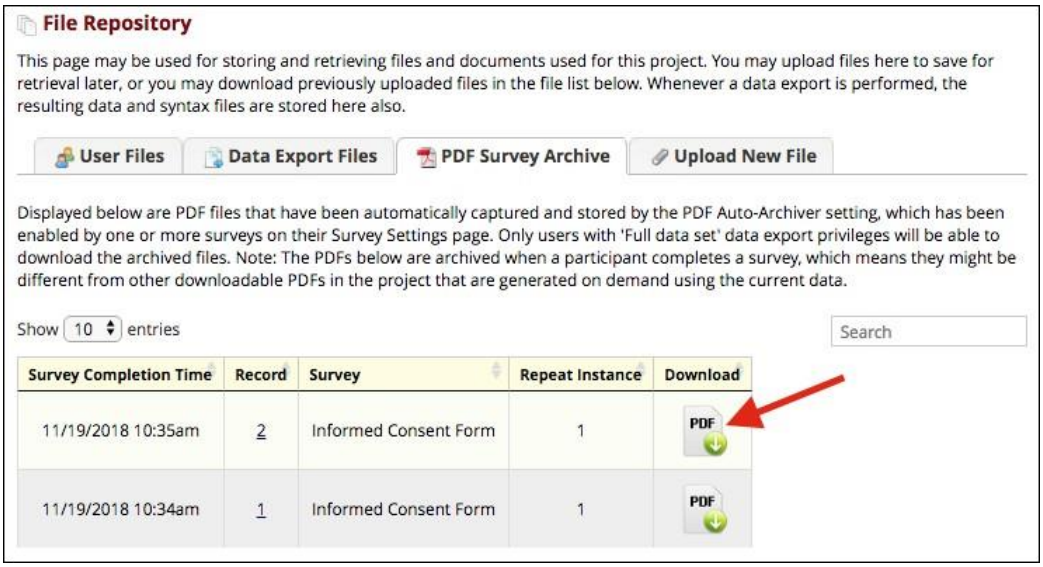
ICH-GCP states the study participant or the substitute decision maker should receive a copy of the signed consent prior to participation in the study. REDCap has the ability to provide the study participant immediate access to their signed consent. As explained in section 5.1., NSHREB requires the PI to sign the consent form within two weeks of the study participant's signature. However, there is no regulatory requirement for a study participant to receive a fully executed copy of the consent.

10. File Repository

PDF copies of the participant consent forms are saved in the File Repository. This is a feature of the eConsent Framework. Note the PDF only contains the participant's consent and does not include PI and staff signatures. The project's file repository is located on the left side *Applications Menu*.



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



If you do not see the "File Repository" option, please contact REDCap.Administrator@nshealth.ca to request access to it.

11. Modifying eConsent

Informed consent of research participants should be an ongoing process. For eConsent using REDCap, it is important that research participants CANNOT make changes to their original consent form. REDCap does not automatically save previous "snapshots" of individual consent form states, and any changes made to an existing consent form overwrites previous content. Therefore, it is important to limit who has access to the consent form and can make changes to it.

Please note: If you are using both eConsent and paper consent for your study, you must make the same changes in both documents and update each version accordingly.

The following settings should be implemented in "Survey Settings" when setting up your eConsent in REDCap. Under "allow 'save and return later option for respondents, do not click 'allow respondents to return and modify completed responses.'

If participants want to make changes to their original consent, have them fill out a new consent form instead of overwriting the previous one. This is the only way to properly document the consenting process and to preserve the original content of the consent. For more information, please see section on re-consenting.

11.1. Updating the Consent Form

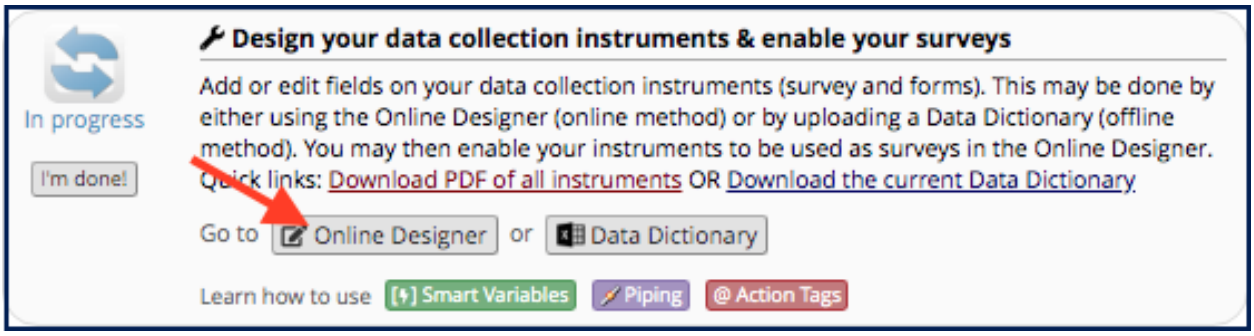
If the consent form needs to be replaced with a newer version, you'll need to update the eConsent form in the existing project with the revised/updated content. Note the URL of the new eConsent form will not change if updates are made. Each REDCap project enables a single public survey link so if a separate public survey link is required then another REDCap project must be created.

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

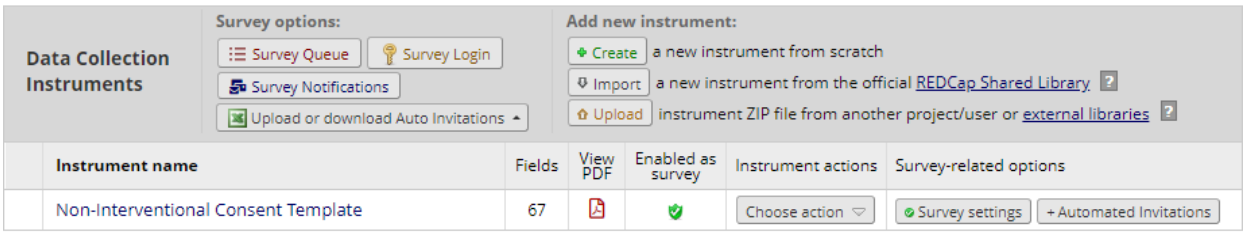
a) Make sure all records have a saved copy of the PDF of the signed eConsent in the File Repository, PDF Survey Archive. **Once you change the form in the project, all existing records will be in the new format. This is why the automated saving (auto-archiver enabled) of the signed eConsents is crucial.**

b) Click on *Online Designer* on the Project Setup page.

c) Click on *Enter Draft Mode.*

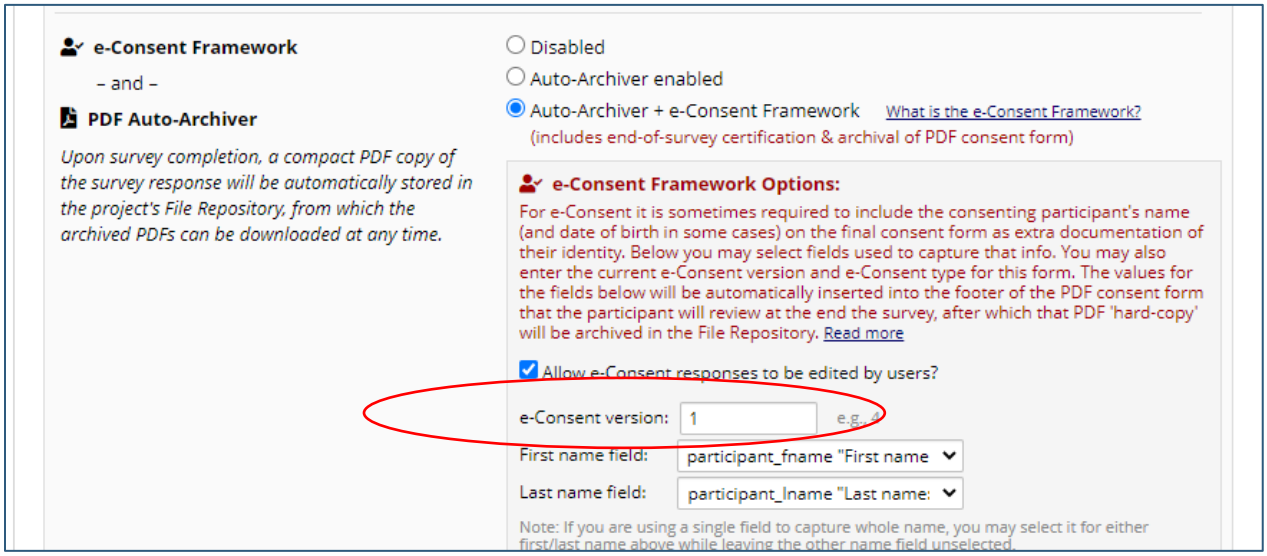


d) Click on the form that contains the Informed Consent:

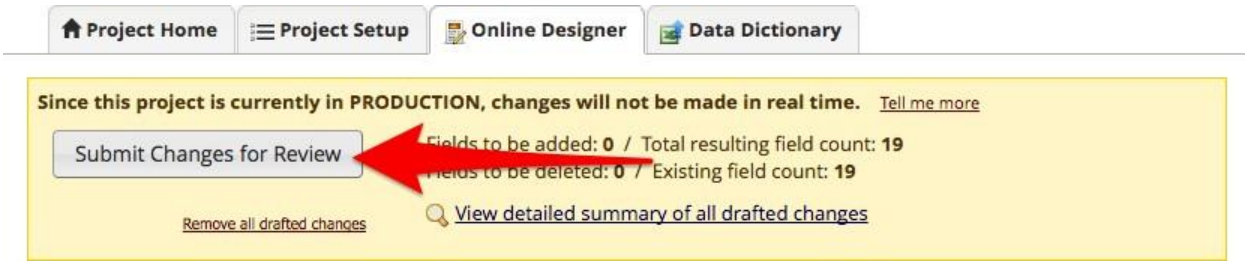


e) Make the required changes to the eConsent form.

f) Update your version in the “Survey settings - eConsent Framework”



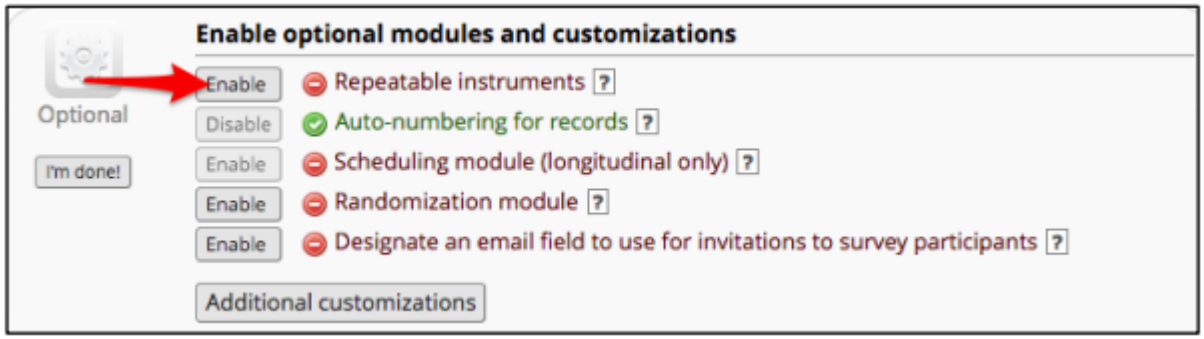
g) Once all the changes have been made, go back to the Online Designer page and click on *Submit Changes for Review*. Since these changes will not affect existing data, the changes should take effect immediately. Make sure you have all of the required fields built before submitting changes.



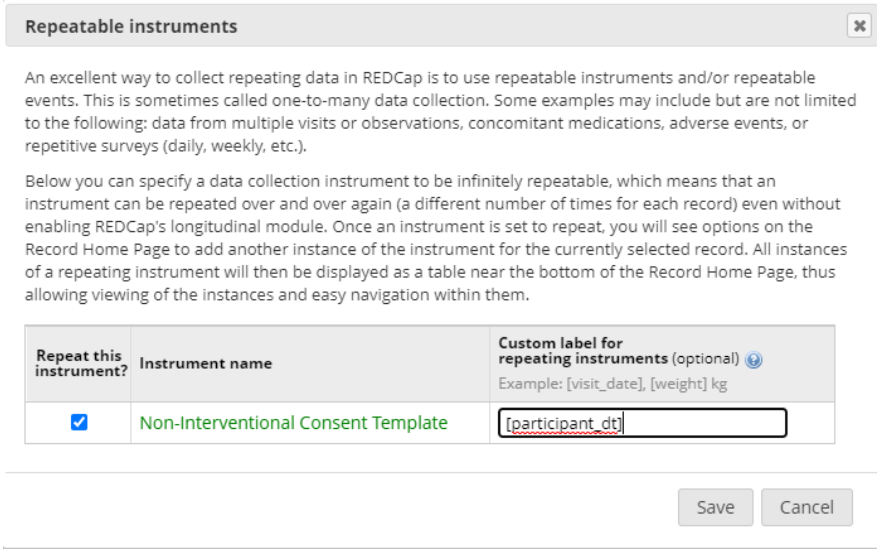
12. ReConsenting and Updating Consent

If a participant needs to sign a revised consent form or make changes to their consent you have the option to create a new, linked consent form. Instead of sending the participant the original URL, you can take advantage of a feature in REDCap called “Repeating Events”. This module allows you to create multiple, linked event forms per participant.

a) Enable the Repeating Events Module in the Project Setup

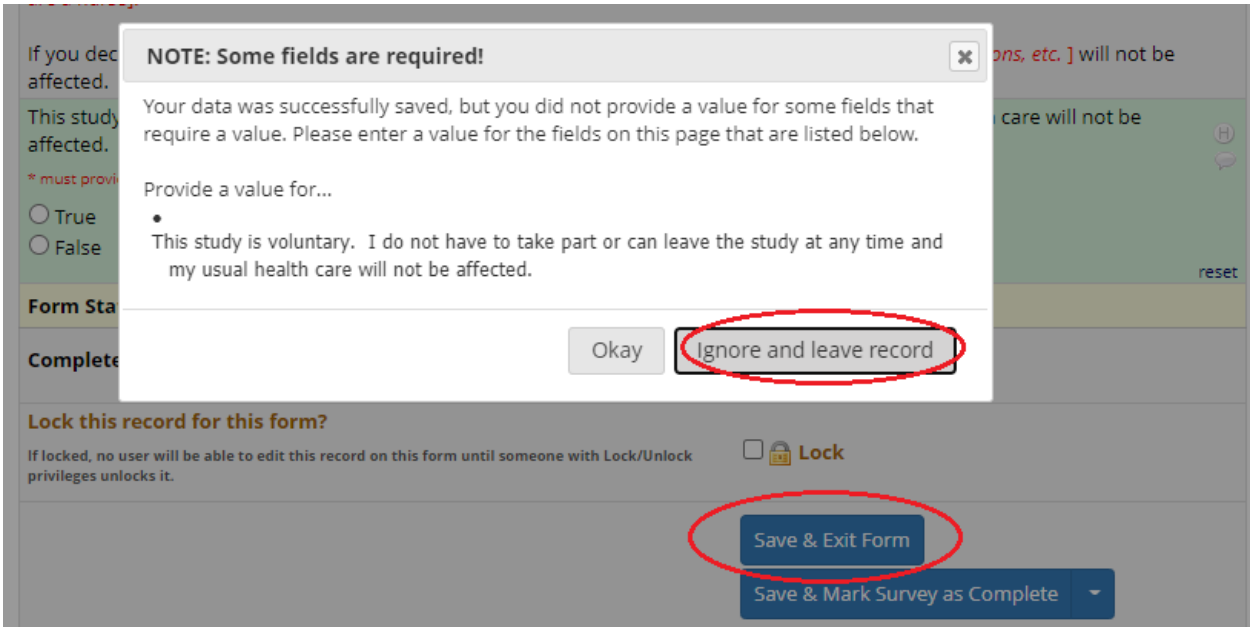


b) Enable the consent form as a repeating event. Optional: if you want the date the participant indicated as the date signed to appear in the record name you can add the custom label.

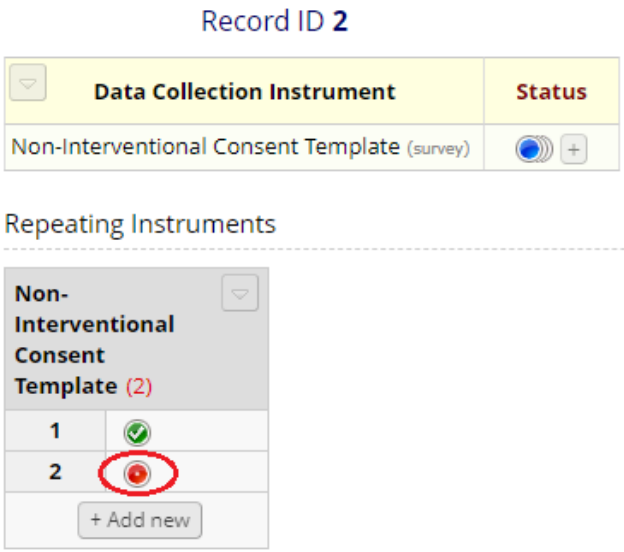


c) Find the subject's record in REDCap who needs to be re-consented via Add / Edit Records or the Record Status Dashboard. Click on the plus sign next to the eConsent Form to add another instance of the consent form.

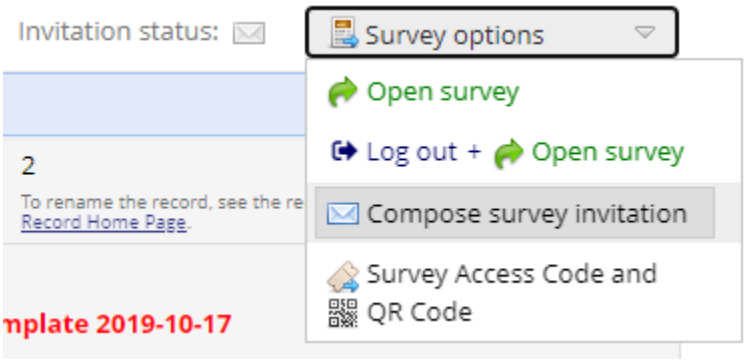
d) This will bring you to the data entry screen for a fresh eConsent form. Now you want to initiate the record by using the Save and Exit Form Button. Ignore the required fields for now. This step creates a linked database record for this participant.


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...
This study is voluntary. I do not have to take part or can leave the study at any time and my usual health care will not be affected.
Okay
Ignore and leave record
Lock this record for this form?
If locked, no user will be able to edit this record on this form until someone with Lock/Unlock privileges unlocks it.
Lock
Save & Exit Form
Save & Mark Survey as Complete

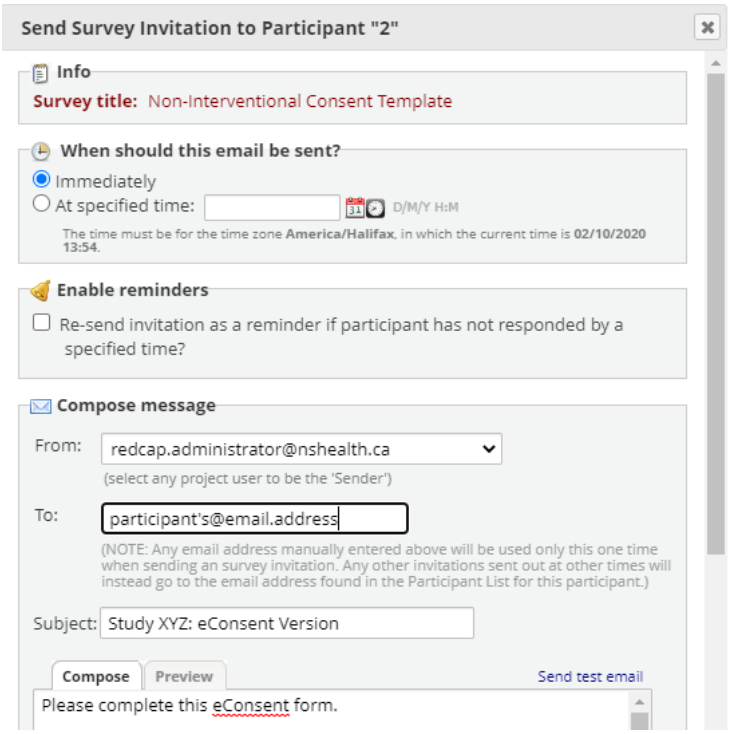
Result:


Record ID 2
Data Collection Instrument
Status
Non-Interventional Consent Template (survey)
Repeating Instruments
Non-Interventional Consent Template (2)
1
2
+ Add new

e) You can now share the unique URL with the participant. Go back into the newly initiated eConsent form and locate the survey options.



These options can open or send an invitation to this unique eConsent record. Test the Compose Survey Invitation as this is a nice feature if it works for your study.



It is recognized that this may take some practice and effort to implement. However, after the initial learning commitment, many users find these features helpful and efficient.

nova scotia
health