

+

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:

Note: Please read the [REDCap Terms of Service](#) before applying for a REDCap account.

[REDCap Project Initiation 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.

Will this project be used for e-consent? Yes No reset

Which template(s) would you like uploaded to your project?

Non-interventional e-consent template

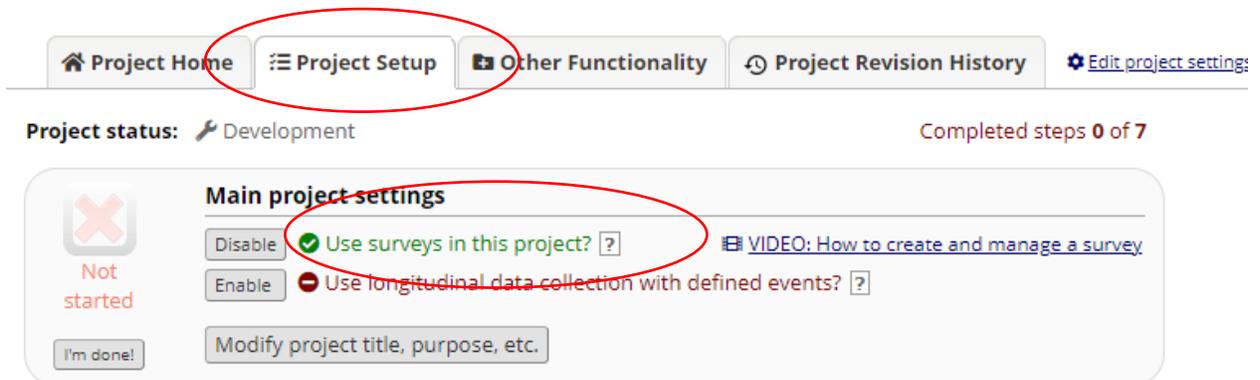
Interventional e-consent template

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 image shows two screenshots of the REDCap interface. The top screenshot shows the 'eConsent Example' project page. The left sidebar menu has 'Designer' circled in red, with a blue arrow pointing to the bottom screenshot. The main content area shows a green notification box: 'Your new REDCap project has been created and is ready to be accessed. You may now begin exploring your project and the many features available to you. Below are some instructions to help you get started.' Below this, the 'Main project settings' section is visible, with 'Use surveys in this project?' set to 'Enable' and 'Use longitudinal data collection with defined events?' set to 'Disable'. The bottom screenshot shows the 'Online Designer' tool. The 'Data Collection Instruments' table is visible, with the 'Non-Interventional Consent Template' instrument circled in red.

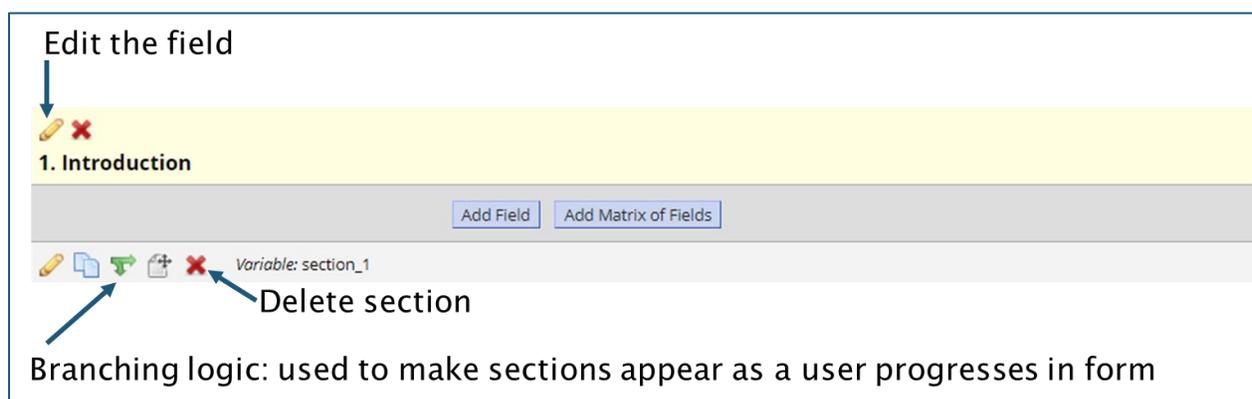
Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
Non-Interventional Consent Template	67			Choose action	Survey settings + Automated Invitations

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.



Edit the field

1. Introduction

Add Field Add Matrix of Fields

Variable: section_1

Delete section

Branching logic: used to make sections appear as a user progresses in form

Once you open the field, you will see a window like the one 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 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 \(4 min\)](#).

1 Field Type: Descriptive Text (with optional Image/Video/...

Question Number (optional)
Displayed only on the survey page

Field Label **2** Use the Rich Text Editor **3**

Paragraph **4** **B** **I**

You have been invited to take part in a research study. A research study is a way of gathering information on a treatment, procedure or medical device or to answer a question about something that is not well understood. Taking part in this study is voluntary. It is up to you to decide whether to be in the study or not. Before you decide, you need to understand what the study is for, what risks you might take and what benefits you might receive. This consent

Action Tags / Field Annotation (optional)

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

5 Variable Name (utilized in logic, calcs, and exports)
section_1 Enable auto naming of variable based upon its Field Label?
ONLY letters, numbers, and underscores

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

Optional file attachment, image, audio, or video:

6 Embed an external video (provide video URL)
e.g. <https://youtube.com/watch?v=E1cCuWMupz0>,
<https://vimeo.com/62730281>,
<http://example.com/movie.mp4>
Display format of video: Inline Inside popup
- or -

7 Attach an image, file, or embedded audio
[Upload file](#)
Display format of attachment on page:
 Link
 Inline image
 Audio file (play in embedded player on page)
[Compatibility notice for embedded audio](#)
(Images wider than 600 pixels will be downsized to fit page.)

Save **Cancel**

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.

The screenshot displays the REDCap branching logic configuration interface. It shows two questions in a list:

- Question 1:** Variable: tfquestion_1. Text: "This study is voluntary. I do not have to take part and can leave the study at any time." Options: True, False. A blue circle with the number "1" highlights the variable name.
- Question 2:** Variable: tf_question_1_continue. Text: "TRUE: You do not have to take part in this study". Options: Continue, No thanks, I am not interested. A blue circle with the number "2" highlights the branching logic: "[tfquestion_1] = '1' or [tfquestion_1]=0".

Each question has "Add Field" and "Add Matrix of Fields" buttons below it. The interface also includes editing icons (pencil, copy, paste, add, stop, delete) at the top of each question's configuration area.

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:

Add/Edit Branching Logic

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...). You may specify those conditions in the text box below for the Advanced Branching Logic Syntax or by choosing the Drag-N-Drop Logic Builder method, which allows you to build your logic in a much easier fashion by simply dragging over the options you want. You may switch back and forth between each method if you wish, but please be aware that since the advanced logic allows for greater complexity, it may not be able to be switched over to the Drag-N-Drop method if it becomes too complex.

Choose method below for the following field: **tf_question_1_continue - TRUE: You do not have ...**

Advanced Branching Logic Syntax 1 [How to use](#) [Branching Logic](#) [Smart Variables](#)

Show the field ONLY if...

`[tfquestion_1] = '1' or [tfquestion_1] = '0'`

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

— OR —

Drag-N-Drop Logic Builder 2

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

- record_id = (define criteria)
- tfquestion_1 = True (1)
- tfquestion_1 = False (0)
- sentence_describe = (define criteria)
- risk_understand = There are no risks (1)
- risk_understand = Risk 1 (2)
- risk_understand = Risk 2 (3)
- risk_understand = [not a listed risk] (4)
- risk_understand = Risk 3 (5)

Drag and Drop

Show the field ONLY if...

ALL below are true

ANY below are true 2

- tfquestion_1 = True (1) ❌
- tfquestion_1 = False (0) ❌

[Clear logic](#)

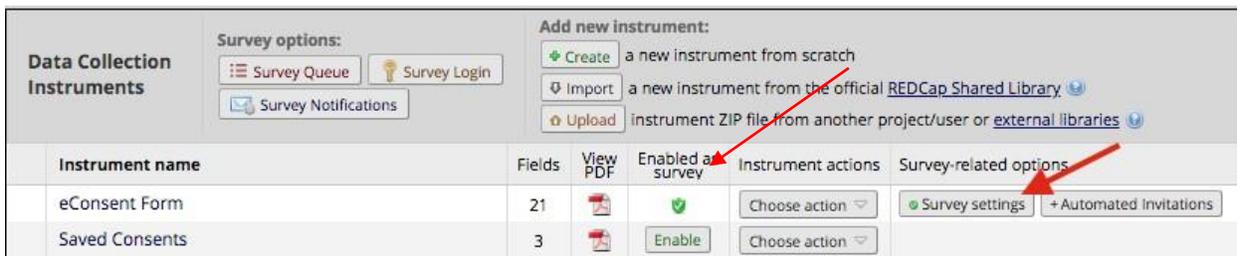
The above example allows the user to proceed to the next section if either True OR False is indicated. If you want the participant to only proceed if they answer “True” then you would remove `tfquestion_1='0'` from the branching logic.

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.

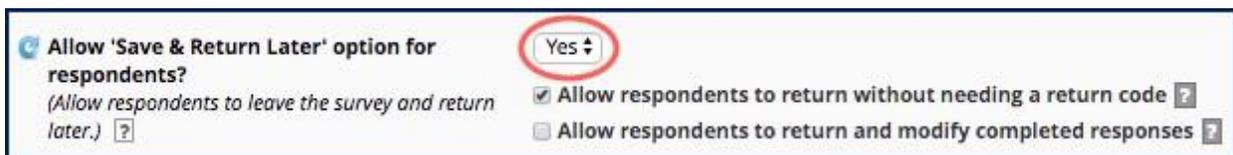
Ensure that you enable survey

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:



Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
eConsent Form	21		<input checked="" type="checkbox"/>	Choose action	Survey settings + Automated Invitations
Saved Consents	3		Enable	Choose action	

- 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'.



Allow 'Save & Return Later' option for respondents?
(Allow respondents to leave the survey and return later.) ?

Allow respondents to return without needing a return code ?

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 do not 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 ROME0# 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: "First name" ▾

Last name field: "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: **2** e.g., Pediatric

Date of birth field: ▾

Romeo# automatically included here!

10/11/2020 3:31pm

Marie Tremb., Type: ROME0 #

projectredcap.org



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.

Send confirmation email (optional)?
(Email the respondent when they complete the survey)

Yes ▾

Provide email subject, email message, and (optionally) an attachment to be sent to respondent when they complete the survey. [How to use Piping here](#)

From:

Subject:

Compose Preview Send test email

Attachment: No file chosen

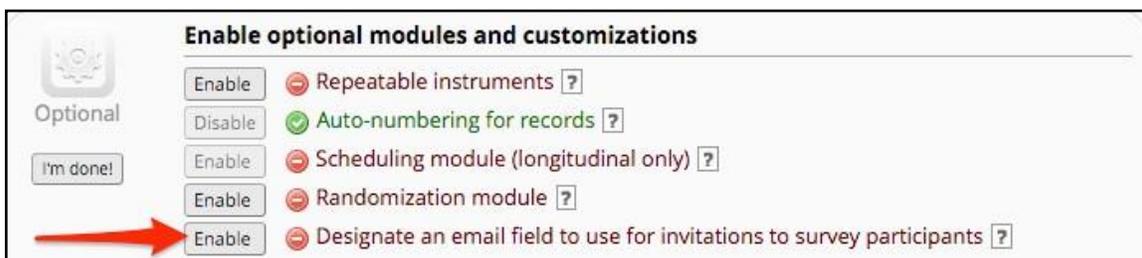
Include PDF of completed survey as attachment

Expand

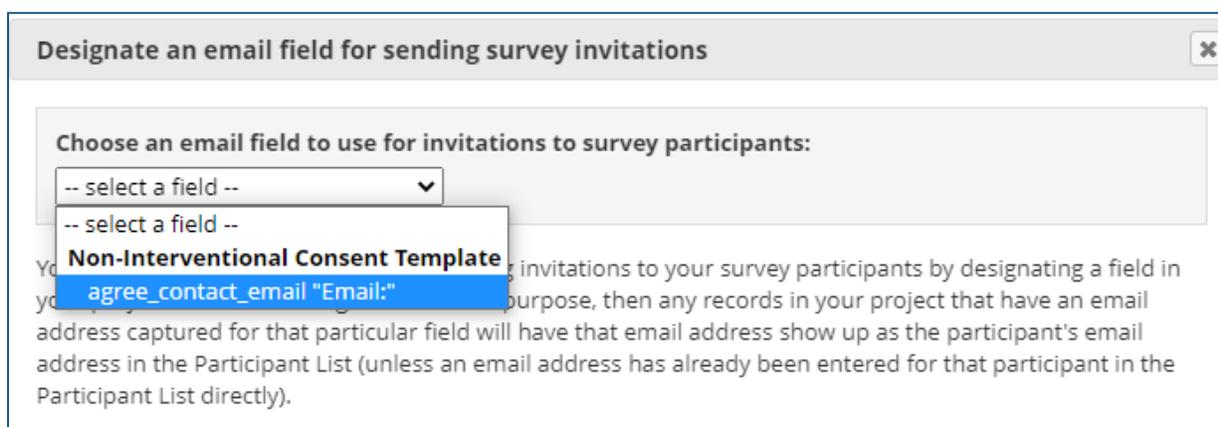
5.2. Designating the Email field

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 not 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.'

The screenshot displays the REDCap interface for 'Survey Distribution Tools'. The left sidebar shows the user is logged in as 'marie-laurence.tremblay' and is in the 'Data Collection' section, where 'Survey Distribution Tools' is highlighted. The main content area shows the 'Survey Distribution Tools' page with three tabs: 'Public Survey Link', 'Participant List', and 'Survey Invitation Log'. The 'Public Survey Link' tab is active, showing instructions on how to use a public survey link and a 'Public Survey URL' field containing 'https://research-study.nshealth.ca/surveys/?s=YPMAXTJAD'. Below the URL are sections for 'Link Actions' and 'Link Customizations', each with several buttons for survey distribution options.

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.



Not started

Move your project to production status

Move the project to production status so that real data may be collected. Once in production, you will not be able to edit the project fields in real time anymore. However, you can make edits in Draft Mode, which will be auto-approved or else might need to be approved by a REDCap administrator before taking effect.

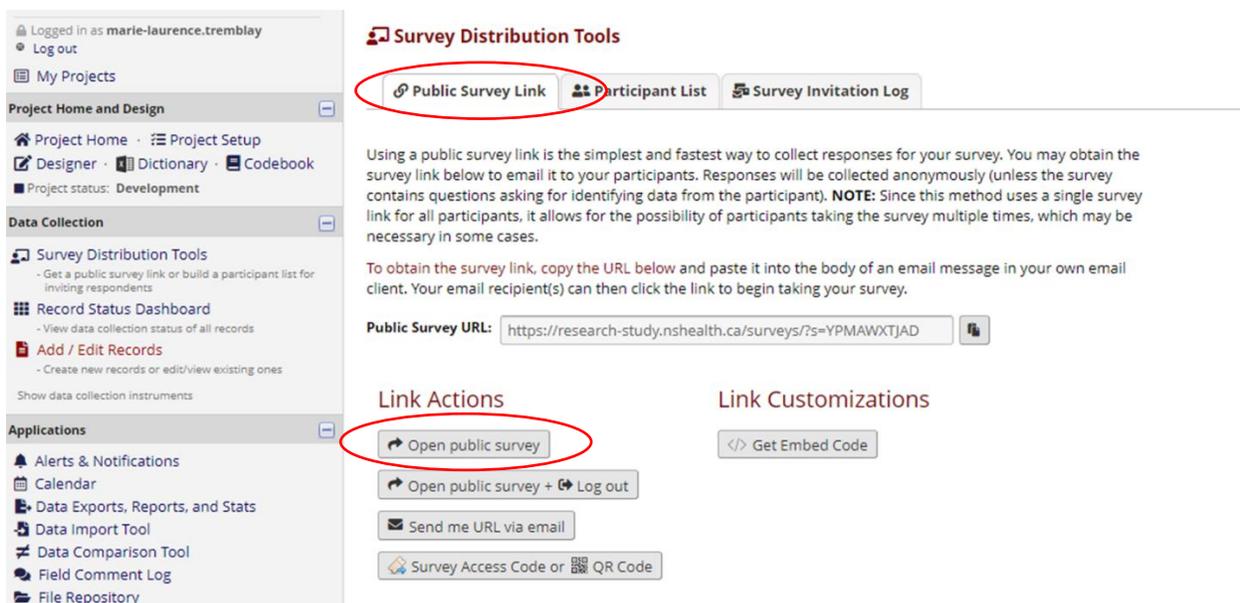
Go to [Move project to production](#)

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.



The screenshot shows the REDCap interface for a user named marie-laurence.tremblay. The main content area is titled "Survey Distribution Tools" and has three tabs: "Public Survey Link", "Participant List", and "Survey Invitation Log". The "Public Survey Link" tab is selected and circled in red. Below the tabs, there is a text box for the "Public Survey URL" containing the link "https://research-study.nshealth.ca/surveys/?s=YPMAXWTJAD". Underneath, there are two sections: "Link Actions" and "Link Customizations". The "Open public survey" button in the Link Actions section is also circled in red.

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”.

The screenshot shows the REDCap Record Status Dashboard. The sidebar on the left has a menu with 'Add / Edit Records' circled in red. The main content area shows a table of records with columns for Record ID and Non-Interventional Consent Template. The first row of the table is circled in red. A legend for status icons is visible on the right.

Record Status Dashboard (all records)

Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

Dashboard displayed: [Default dashboard] [Create custom dashboard](#)

Displaying record Page 1 of 1: "1" through "14" of 14 records ALL (14) records per page

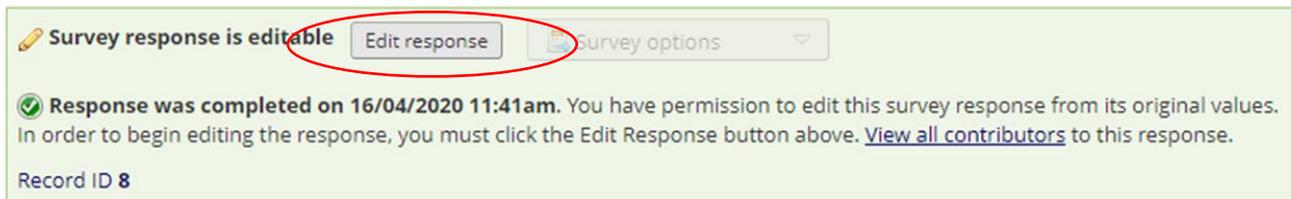
[+ Add new record](#)

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

Record ID	Non-Interventional Consent Template
1	Complete
2	Complete
3	Complete
4	Complete
5	Complete
6	Complete

Legend for status icons:

- Incomplete
- Incomplete (no data saved)
- Unverified
- Partial Survey Response
- Complete
- Completed Survey Response



Survey response is editable Edit response Survey options

Response was completed on 16/04/2020 11:41am. You have permission to edit this survey response from its original values. In order to begin editing the response, you must click the Edit Response button above. [View all contributors](#) to this response.

Record ID 8

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*.

File Repository

This page may be used for storing and retrieving files and documents used for this project. You may upload files here to save for retrieval later, or you may download previously uploaded files in the file list below. Whenever a data export is performed, the resulting data and syntax files are stored here also.

[User Files](#) [Data Export Files](#) [PDF Survey Archive](#) [Upload New File](#)

Displayed below are PDF files that have been automatically captured and stored by the PDF Auto-Archiver setting, which has been enabled by one or more surveys on their Survey Settings page. Only users with 'Full data set' data export privileges will be able to download the archived files. Note: The PDFs below are archived when a participant completes a survey, which means they might be different from other downloadable PDFs in the project that are generated on demand using the current data.

Show entries

Survey Completion Time	Record	Survey	Repeat Instance	Download
11/19/2018 10:35am	2	Informed Consent Form	1	
11/19/2018 10:34am	1	Informed Consent Form	1	

Previous Next

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

File Repository

This page may be used for storing and retrieving files and documents used for this project. You may upload files here to save for retrieval later, or you may download previously uploaded files in the file list below. Whenever a data export is performed, the resulting data and syntax files are stored here also.

User Files Data Export Files PDF Survey Archive Upload New File

Displayed below are PDF files that have been automatically captured and stored by the PDF Auto-Archiver setting, which has been enabled by one or more surveys on their Survey Settings page. Only users with 'Full data set' data export privileges will be able to download the archived files. Note: The PDFs below are archived when a participant completes a survey, which means they might be different from other downloadable PDFs in the project that are generated on demand using the current data.

Show 10 entries

Survey Completion Time	Record	Survey	Repeat Instance	Download
11/19/2018 10:35am	2	Informed Consent Form	1	
11/19/2018 10:34am	1	Informed Consent Form	1	

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.’

 Allow 'Save & Return Later' option for respondents? <i>(Allow respondents to leave the survey and return later.)</i> 	Yes 
	<input checked="" type="checkbox"/> Allow respondents to return without needing a return code 
	<input type="checkbox"/> 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*.

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](#).

Go to or

Learn how to use

Project Home | Project Setup | Online Designer | Data Dictionary | Codebook

NOTE: The project is currently in PRODUCTION status, and thus changes cannot be made in real time to the project as when in Development status. However, changes to the project may be drafted in DRAFT MODE, after which such changes will be reviewed and approved by a REDCap administrator. Once those changes are approved, you will then receive an email confirmation informing you that those changes have taken effect on your production project.

Would you like to enter DRAFT MODE to begin drafting changes to the project?

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

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
Non-Interventional Consent Template	67			<input type="button" value="Choose action"/>	<input type="button" value="Survey settings"/> <input type="button" value="+ Automated Invitations"/>

- e) Make the required changes to the eConsent form.
- f) Update your version in the “Survey settings - eConsent Framework”

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?](#)
 (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. v1

First name field:

Last name field:

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.

- 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.

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

Since this project is currently in **PRODUCTION**, changes will not be made in real time. [Tell me more](#)

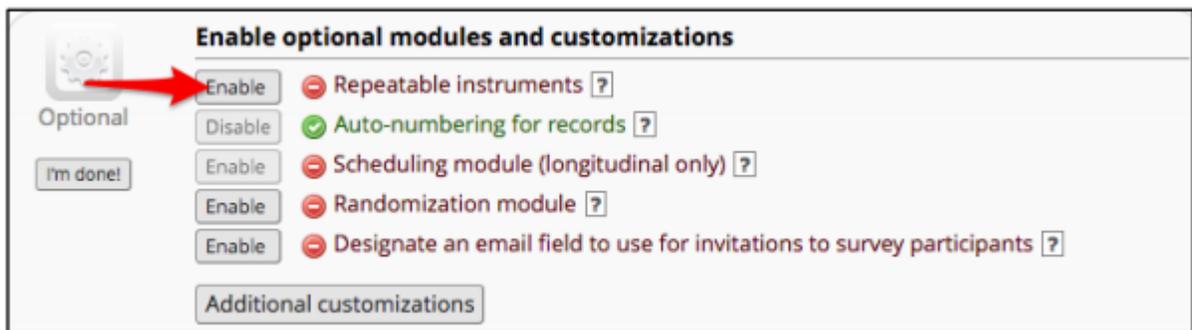
Fields to be added: 0 / Total resulting field count: 19
Fields to be deleted: 0 / Existing field count: 19

[Remove all drafted changes](#) | [View detailed summary of all drafted 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.

Repeatable instruments ✕

An excellent way to collect repeating data in REDCap is to use repeatable instruments and/or repeatable events. This is sometimes called one-to-many data collection. Some examples may include but are not limited to the following: data from multiple visits or observations, concomitant medications, adverse events, or repetitive surveys (daily, weekly, etc.).

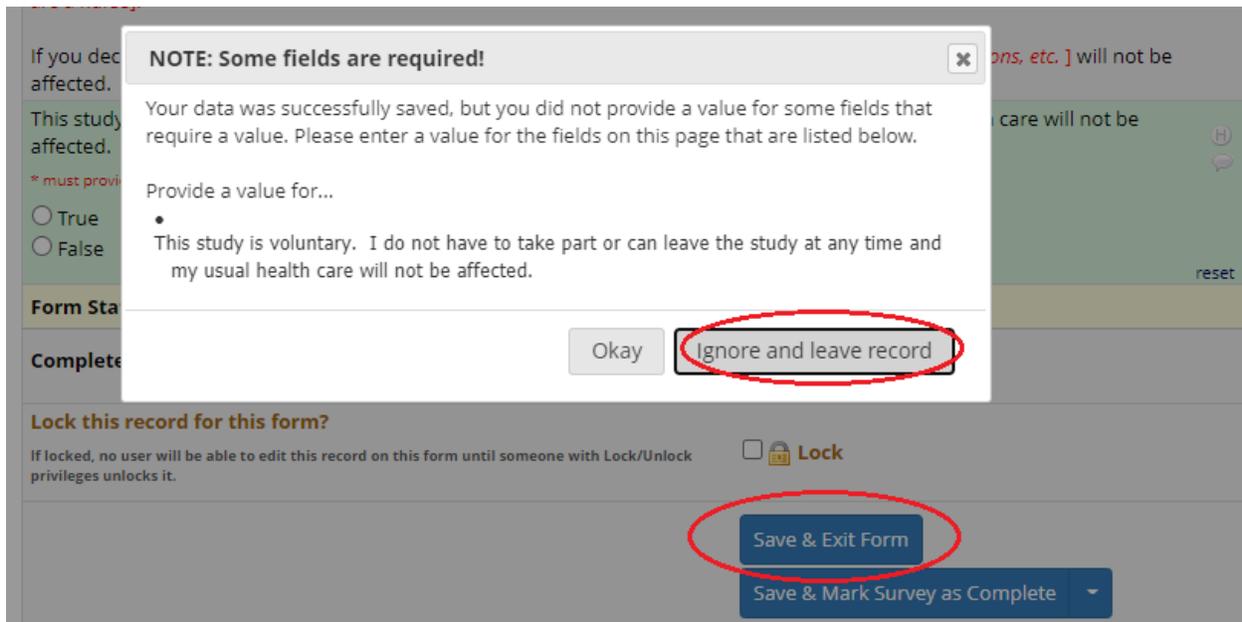
Below you can specify a data collection instrument to be infinitely repeatable, which means that an instrument can be repeated over and over again (a different number of times for each record) even without enabling REDCap's longitudinal module. Once an instrument is set to repeat, you will see options on the Record Home Page to add another instance of the instrument for the currently selected record. All instances of a repeating instrument will then be displayed as a table near the bottom of the Record Home Page, thus allowing viewing of the instances and easy navigation within them.

Repeat this instrument?	Instrument name	Custom label for repeating instruments (optional) ⬇ Example: [visit_date], [weight] kg
<input checked="" type="checkbox"/>	Non-Interventional Consent Template	<input type="text" value="[participant_dt]"/>

- 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.

Record ID	Non-Interventional Consent Template
<u>1</u>	<input checked="" type="checkbox"/> <input type="button" value="+"/>
<u>2</u>	<input checked="" type="checkbox"/> <input checked="" type="button" value="+"/>

- 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.



Result:

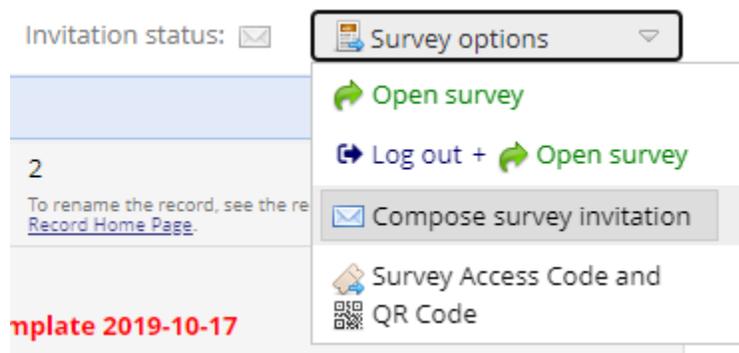
Record ID 2

Data Collection Instrument	Status
Non-Interventional Consent Template (survey)	

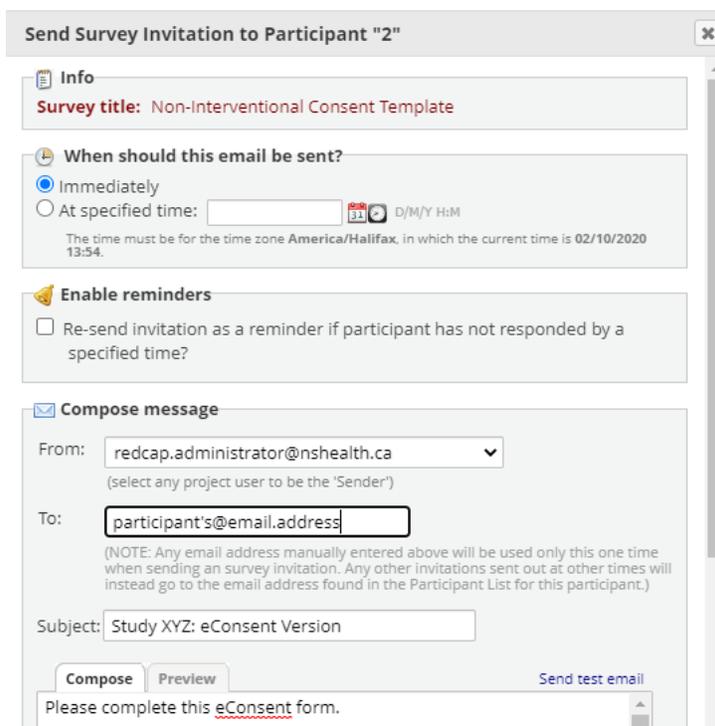
Repeating Instruments

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.

