

E-Consenting Research Participants Through REDCap: A Quick guide

September 2020



Table of Contents

What is e-consent?	3
REB submission requirements	7
Editing the template	8
Distributing e-consent to participants	18
Monitoring responses and signatures	19
Branching logic	21
Additional Resources	23

What is e-Consent?

- Electronic consent (e-consent) is a method of obtaining consent from patients or research participants through an electronic form as opposed to paper. The NSHA REDCap platform provides the ability to complete the e-consent process through a web-enabled form.
- E-Consent forms are implemented as REDCap surveys that can be viewed on any computer, smartphone, or tablet in a web browser.
- **Process:** Research participants will read through the consent form and at the end, sign their name to the best of their ability, type their name, and insert the date. Then, they will be brought to an extra certification page that displays the PDF version of their responses, in which they will be asked to confirm that all information in the document is correct. This is analogous to “I agree to the terms and conditions” on software packages. *See next slide.*

What is e-Consent?

Displayed below is a read-only copy of your survey responses. Please review it and the options at the bottom.

Does Reading Before Bed Increase Sleep Quality? An Observational Study Page 1 of 6

Please read this consent form carefully and make sure that a researcher on the team reviews this form with you before signing

PDF can be downloaded by participant

STUDY TITLE: Does Reading Before Bed Increase Sleep Quality? An Observational Study

PRINCIPAL INVESTIGATOR: Dr. Marie-Laurence Tremblay, Center for Clinical Research, room 121, 5790 University Ave, B3H 1V7

STUDY SPONSOR: Indigo Bookstore

FUNDER: Sleep Inc.

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.

<< Previous Page

Submit

Save & Return Later

The purposes of e-consent:

- To reduce the use of paper while ensuring safe storage of documents
- Informed consent of research participants with contagious diseases (i.e. COVID-19) and/or respecting social distancing protocols
- Informed consent of research participants unable/have difficulties travelling to the research center for in-person meeting

NSHA legal and privacy implications

- The use of e-consent must follow the **REDCap Terms of Service**.
- To use e-consent with IWK REB approval, the e-consent must be administered on IWK servers.
- The signed e-consent PDFs must be stored on REDCap and not downloaded on a desktop unless the need is clearly defined by policy or logic to the REB. Storage of signed e-consent must be kept at a minimum for security and privacy of information.
 - IWK servers hosting our REDCap platform are regularly backed up, minimizing the loss of data over time.

NSHA legal and privacy implications

If you use e-consent in your research, please use the acknowledgement statement below and reference the REDCap software.

Acknowledgement statement:

- Study data were collected and managed using REDCap electronic data capture tools hosted at IWK Health. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing:
 1. An intuitive interface for validated data entry;
 2. Audit trails for tracking data manipulation and export procedures;
 3. Automated export procedures for seamless data downloads to common statistical packages; and
 4. Procedures for importing data from external sources.

Citation example:

- Paul A. Harris, Robert Taylor, Robert Thielke, Jonathon Payne, Nathaniel Gonzalez, Jose G. Conde, Research electronic data capture (REDCap) - A metadata-driven methodology and workflow process for providing translational research informatics support, J Biomed Inform. 2009 Apr;42(2):377-81.

REB requirements at submission

Fill in your sections as usual in ROME0 with the addition of:

- In your EAF, please describe your consent process in section 6.12.
 - Keep in mind that embedded questions do not replace the informed conversation between participant and research staff, as required by TCPS2, chapter 3.
- Attach a copy of your PDF e-consent (what the participant will download to their device/computer).
- Insert the link to the web version in section 6.7 of the EAF.
- Edit your departmental or research group informed consent SOPs to reflect e-consenting procedures.
- For further information on consenting research participants, please consult the REB SOP 701 General Requirements of Informed Consent found on the [IWK Research website](#)

Getting started

- Browser compatibility:    
- To consent patients with the REDCap e-Consent, you need
 1. An internet connection
 2. An internet browser
- The browser is usable on a desktop computer, smartphone (android or Apple), or on a tablet.

Getting started



- Fill out the IWK REDCap project initiation form, which can be found on the IWK web page (<https://iwkhealth.ca/research/support-researchers/redcap>).
- Once your project request has been initiated, connect with Dr. Jill Hatchette to request either a **Non-Interventional** or **Interventional** e-consent template..

Getting started

The screenshot shows the REDCap Online Designer interface. The browser address bar indicates the URL: `research-survey.nshealth.ca/redcap_v7.4.18/Design/online_designer.php?pid=76`. The page title is "Test-Project-Jill Hatchette". The interface includes a navigation menu on the left with sections for "Data Collection", "Applications", and "Help & Information". The main content area has tabs for "Project Home", "Project Setup", "Online Designer", and "Data Dictionary". Below the tabs, there are buttons for "Create snapshot of instruments" and "VIDEO: How to use this page". A text block explains that the Online Designer allows for project modifications to fields and data collection instruments. Below this, there are "Survey options" (Survey Queue, Survey Login, Survey Notifications) and "Add new instrument" options (Create, Import, Upload). A table lists the instruments:

Instrument name	Fields	View PDF	Enabled a survey	Instrument actions	Survey-related options
Noninterventional Consent Template F0c9ee	67			Choose action	Survey settings + Automated Invitations

To upload the e-consent template, navigate to **My Projects** and select **Online Designer**. Under **Add a New Instrument**, select **Upload**. Upload the entire zip file. Instrument will appear under **Instrument Name**. Select the instrument to open and edit.

How is the e-consent currently set-up?



- The wording from the current paper templates were transcribed into the e-consent.
- Each section from the Word document was turned into a 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 to be updated.

Editing in REDCap

Branching logic: Use to make sections appear in this template

Edit:
Used to edit
your form

1. Introduction

Delete section (only if section is optional)

Variable: section_1

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 form explains the study.

If time permits you may take as much time as you wish to decide whether or not to participate. Feel free to discuss it with your friends and family, family doctor, or health care provider.

If time is limited The research team will tell you if there are any study timelines for making your decision.

Please ask the research team or the principal investigator to clarify anything you do not understand or would like to know more about. Make sure all your questions are answered to your satisfaction before deciding whether to participate in this research study.

The researchers will:

- Discuss the study with you;
- Answer your questions;
- Be available during the study to deal with problems and answer questions.

Include a statement indicating why a particular person was flagged as a possible candidate for inclusion in the trial. You are being asked to consider participating in this study because [you have [condition X / are about to undergo procedure Y OR are a healthy individual / are a nurse].

Copying from a Word document: tips & tricks

If you copy-paste from a Word document, **de-select** “Rich Text Editor”* before pasting, then **reselect** the “Rich Text Editor” to format the text. Otherwise, REDCap keeps the Word formatting, which you can’t change easily

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 \(4 min\)](#).

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

Question Number (optional)
Displayed only on the survey page

Field Label

Use the Rich Text Editor ?

Paragraph

B *I*

A

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)

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:

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 -

Attach an image, file, or embedded audio
 Upload file

Save Cancel

Name of field. Used for branching logic.

Expand section to full screen

The underline option 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. Ex: `<u>Insert underline section here</u>`

*Currently Rich Text Editor is not available in the IWK version of REDCap.

Survey Settings: General

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

Create snapshot of instruments | VIDEO: How to use this page
Last snapshot: never ?

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

Data Collection Instruments
Survey options: Survey Queue | Survey Login | Survey Notifications | Upload or download Auto Invitations
Add new instrument: Create | Import | Upload

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
Non-Interventional Consent Template	66			Choose action ▾	Survey settings + Automated Invitations

This is to edit the survey title, intro/outro messages, etc.

Survey Settings: General

Modify survey settings for data collection instrument "Non-Interventional Consent Template" Save Changes Cancel

Survey Status ✓ Survey Active ▼
If offline, respondents will not be able take the survey.

Basic Survey Options:

Survey Title Non-Interventional Consent Template
Title to be displayed to participants at the top of the survey page

Survey Instructions
(Displayed at top of survey after title)

Paragraph B I 🔗 ☰ ☰ ☰ ☰ ↶ ↷ 🔄

☰ ☰ ☰ ☰ ☰ A A 🏠 <> I_x

Please read this consent form carefully before signing

Thank you!

[How to use Piping here](#)

Survey Design Options:

These sections of the survey settings can be modified or omitted.

Survey Settings: the e-consent 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., 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: e.g., Pediatric

Date of birth field: ▼

Force signature field(s) to be erased if participant clicks Previous Page button while on the certification page?
Select a field below that serves as a signature field in this survey. It could be a free-form text field, a signature field, or a number field (e.g., to collect a PIN), and it must be a Required field. If any fields are selected below, then if the participant gets to the last page of the survey where it asks them to certify their responses, if they then choose to click the Previous Page button, it will erase the value of these signature fields, thus forcing them to 'sign' the field(s) again before completing the survey. If you do not want this behavior, do not select any fields below. You may use up to five signature fields.

Signature field #1: ▼

Survey Settings: the e-consent framework

- You must add your ROME0# to the e-consent!
- This can be added by accessing the optional fields of the e-consent framework as outlined below.

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: e.g., Pediatric

Date of birth field: ▾

Displayed below is a read-only copy of your survey responses. Please review it and the options at the bottom.

30/04/2020 10:37am Version: April 30, 2020 Type: ROME0 #: 123 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.

Distributing the e-consent to participants

Logged in as marie-laurence.tremblay
Log out

My Projects

Project Home and Design

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

Data Collection

- Survey Distribution Tools**
- Get a public survey link or build a participant list for inviting respondents
- Record Status Dashboard
 - View data collection status of all records
- Add / Edit Records
 - Create new records or edit/view existing ones
- Show data collection instruments

Applications

- Alerts & Notifications
- Calendar
- Data Exports, Reports, and Stats
- Data Import Tool
- Data Comparison Tool
- Field Comment Log
- File Repository

Survey Distribution Tools

Add participants for survey distribution via participant email list

Public Survey Link Participant List Survey Invitation Log

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

To obtain the survey link, copy the URL below and paste it into the body of an email message in your own email client. Your email recipient(s) can then click the link to begin taking your survey.

Public Survey URL:

Link Actions

Open public survey

Open public survey + Log out

Send me URL via email

Survey Access Code or QR Code

Link Customizations

Get Embed Code

Or distribute e-consent to participants directly using a single URL that can be used multiple times.

Monitoring responses

Logged in as marie-laurence.tremblay
[Log out](#)

My Projects

Project Home and Design

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

Data Collection

- Survey Distribution Tools
- Get a public survey link or build a participant list for inviting respondents
- Record Status Dashboard**
- View data collection status of all records
- Add / Edit Records
- Create new records or edit/view existing ones
- Show data collection instruments

Applications

- Alerts & Notifications
- Calendar
- Data Exports, Reports, and Stats
- Data Import Tool
- Data Comparison Tool
- Field Comment Log
- File Repository
- User Rights and DAGs
- Customize & Manage Locking/E-signatures

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.

Legend for status icons:

- Incomplete
- Incomplete (no data saved) [?](#)
- Unverified
- Partial Survey Response
- Complete
- Completed Survey Response

Dashboard displayed: [Create custom dashboard](#)

Displaying record of 14 records records per page

[+ Add new record](#)


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


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

Completed e-consents. Click on number to **view/sign** the PDF.

Signing the e-Consent: researcher

- Go to Add/Edit Record
- Select the file you wish to sign and click on “Edit Response”
- Sign and type your name at the bottom of the form, then save the file.

 **Survey response is editable**

 **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**

Branching logic



- Branching logic is used in the e-consent to make sections appear as questions are answered.
- The sections will appear regardless of the answer chosen by the participant.
- Changing the wording of the question will not affect branching.
- Changing the “variable name” or deleting the question will affect the branching.

Branching logic

Variable: tfquestion_1

This study is voluntary. I do not have to take part and can leave the study at any time.

* must provide value

True

False

Add Field Add Matrix of Fields

Variable: tf_question_1_continue Branching logic: [tfquestion_1] = '1' or [tfquestion_1]='0'

TRUE: You do not have to take part in this study

* must provide value

Continue

No thanks, I am not interested

Add Field Add Matrix of Fields

Variable name

With branching logic

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 \(4 min\)](#).

Field Type: True - False

Question Number (optional)

Field Label Use the Rich Text Editor

This study is voluntary. I do not have to take part and can leave the study at any time.

Choices (not modifiable)

1, True

0, False

Variable Name (utilized in logic, exports, and exports)

tfquestion_1

ONLY letters, numbers, and underscores

Enable auto naming of variable based upon its Field Label?

Required?* No Yes

* Prompt if field is blank

Identifier? No Yes

Does the field contain identifying information (e.g., name, SSN, address)?

Custom Alignment Left / Vertical (LV)

Align the position of the field on the page

Field Note (optional)

Small reminder text displayed underneath field

Save Cancel

Additional Resources

- REDCap e-consent: <https://www.youtube.com/watch?v=8xMcfgqUsOg>
- General REDCap: <https://projectredcap.org/resources/videos/>

For additional queries:

jill.hatchette@iwk.nshealth.ca