E-Consenting Research Participants Through REDCap: A Quick guide

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IWK Health

nova scotia health authority
Research Ethics Board

RMU Research Methods Unit
RMU

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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 theirs 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.

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Does Reading Before Bed Increase Sleep Quality? An Observational Study

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 Obesrvational 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 <u>unless the need is clearly defined by policy or logic</u> 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 ROMEO 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

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

Delete section (only if section is optional)

Edit:
Used to edit your form

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

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

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

Survey Settings: General

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

Survey Settings: the e-consent framework

Survey Settings: the e-consent framework

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

Distributing the e-consent to participants

📧 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: https://research-study.nshealth.ca/surveys/?s=YPMAWXTJAD 📋

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

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: [Default dashboard] ▼

Displaying record [Page 1 of 1: "1" through "14" ▼] of **14** records

ALL (14) ▼ records per page

✏️ Create custom dashboard

➕ 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.

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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.

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 <u>will not</u> affect branching.

- Changing the "variable name" or deleting the question <u>will</u> affect the branching.

Branching logic

Variable name

With branching logic

Additional Resources

- REDCap e-consent: https://www.youtube.com/watch?v=8xMcfgqUsOg

- General REDCap: https://projectredcap.org/resources/videos/

For additional queries:

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