



Unlocking the Power of eConsent in REDCap

Friday, June 2nd, 2023

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Learning Objectives:

- 1) Identify the what, why, where, and how of eConsent in REDCap (Research Electronic Data Management)
- 2) Explain REDCap Access and New Project Request
- 3) Provide an overview of the eConsent tools in REDCap and how they work to provide research respondents a valid eConsent experience.

Target Audience:

Clinical Research Professionals (CRPs) at UC/H and Cincinnati Children's Hospital Medical Center (CCHMC): including Principal Investigators (PIs), Research Nurses (RNs), Critical Care Unit Nurses (RNs), Pharmacy Technicians and Regulatory Specialists.

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Disclaimer Statement

The opinions expressed during the live activity are those of the faculty and do not necessarily represent the views of the University of Cincinnati. The information is presented for the purpose of advancing the attendees' professional development.

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All relevant relationships have been mitigated. The following disclosures were made:

Planning Committee Members:

- Maria Stivers, MS; Course Director – *No Relevant Relationships*
- Nathaniel L. Harris, BS, Course Coordinator – *No Relevant Relationships*
- Heather Muskopf, CME Program Manager – *No Relevant Relationships*

Speakers:

Maxx M Somers, MA

Information Services For Research (IS4R)

Manager, IS

REDCap Program Manager

No Relevant Relationships

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June 2023 Study of the month:

Binge Eating Disorder Study

Are you struggling with overeating?

What

A twelve week study assessing an investigational medication for binge eating disorder.

Who

Adults aged 18-65 years of age with binge eating disorder.

Pay

All study visits, tests, procedures, and medication will be provided at no cost to participants. Eligible participants will be compensated \$50 per visit for their time and travel.

Details

For more information, contact us at 513-536-0710 or visit www.LCOH.info to complete a pre-screen questionnaire.

Located at the Lindner Center of HOPE, Mason, Ohio.

 LCOH Health.

12-20 IRB # PENDING

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UC / UC Health Clinical Research Orientation and Training (CRO&T)

Thursday, June 8th, 2023

9:00 am - 3:00 pm

Virtual presentation

The last day of registration
TODAY!!!

Friday, June 2nd, 2023

Register [Here](#)

Please reach out to Nate Harris,
nate.harris@uchealth.com for any questions

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SOCRA CRP CERTIFICATION EXAMINATION

Hosted by CCHMC

Tuesday, October 10th, 2023

Please visit the [SOCRA website](#) for more details.

The Registration Deadline is Monday, August 28th, 2023

[Register Here](#)

CCHMC CRP will be hosting open review sessions prior to the exam date for anyone interested on in August (Dates and times TBD) hosted on Microsoft Teams (link to be provided).

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For any questions or further information, please contact the CCHMC CRP Group at CRP@cchmc.org or Nate Harris at harrisnl@ucmail.uc.edu

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**Office of Clinical Research
Lunch & Learn**

**Thursday, June 15th, 2023, 12:00noon - 1:00pm
Virtual Presentation**

**From Blood and Guts To Bits and Bytes:
Clinical Research Informatics Using TriNetX**

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Jason Keller, MS
Associate Director, Data Services
UC Center for Health Informatics
Department of Biomedical Informatics



Today's Presentation: Unlocking the Power of eConsent in REDCap

An informative session where you will gain a deep understanding of eConsent in REDCap, covering its fundamental aspects. Discover the seamless integration of eConsent tools in REDCap and learn how they enable researchers to deliver a robust and valid electronic Consent experience to research participants, while also exploring an introduction to REDCap access and new project request processes.

Maxx M Somers, MA

Manager, IS

REDCap Program Manager

Information Services For Research (IS4R) Cincinnati Children's Hospital
Medical Center

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Research Electronic Data Collection – REDCap and eConsent

Maxx Somers, MA

Information Services for Research (IS4R)

Cincinnati Children's Hospital Medical Center

What is REDCap (Research Electronic Data Capture)

- REDCap is a mature, secure web application for building and managing online surveys and databases. While REDCap can be used to collect virtually any type of data, it is specifically geared to support data capture for research studies.

It is not a TRUE relational database application, such as Microsoft Access or MS SQL Server, which allow users to create tables with complex relationships between them. Nevertheless, using newer REDCap features like "Repeating Instruments and Events" can add some "one to many" functionality to a project.

REDCap's survey functionality has become increasingly sophisticated over the years. Although it is easy to create a basic public survey, there are many add-on options that make surveys in REDCap a flexible and powerful tool. Possibilities include using multiple surveys in any project, survey automation, notifications, and many others.

REDCap is engineered by an active team of programmers at Vanderbilt University. Updates and bug fixes are released regularly. It is currently in production use or development build-status at nearly three thousand institutions worldwide.



UC and CCHMC REDCap – Some Useful Links

- How to get the ability to log into REDCap: <https://redcap.link/CCTST>
- How to request a new project: <https://confluence.research.cchmc.org/display/CCTSTRED/Requesting+a+REDCap+Project>
- How to request Twilio (SMS Messaging Capability) for your existing REDCap Project: <https://redcap.link/CCTSTtwilio>
- REDCap Help: help-redcap@bmi.cchmc.org

REDCap – Intro Training

- REDCap Intro Training: 1 hour on the basics of REDCap
 - Surveys
 - Longitudinal Design
 - Events
 - Online Designer
 - Form Building
 - Branching logic
 - Automated Invitations
 - Exports and Reports

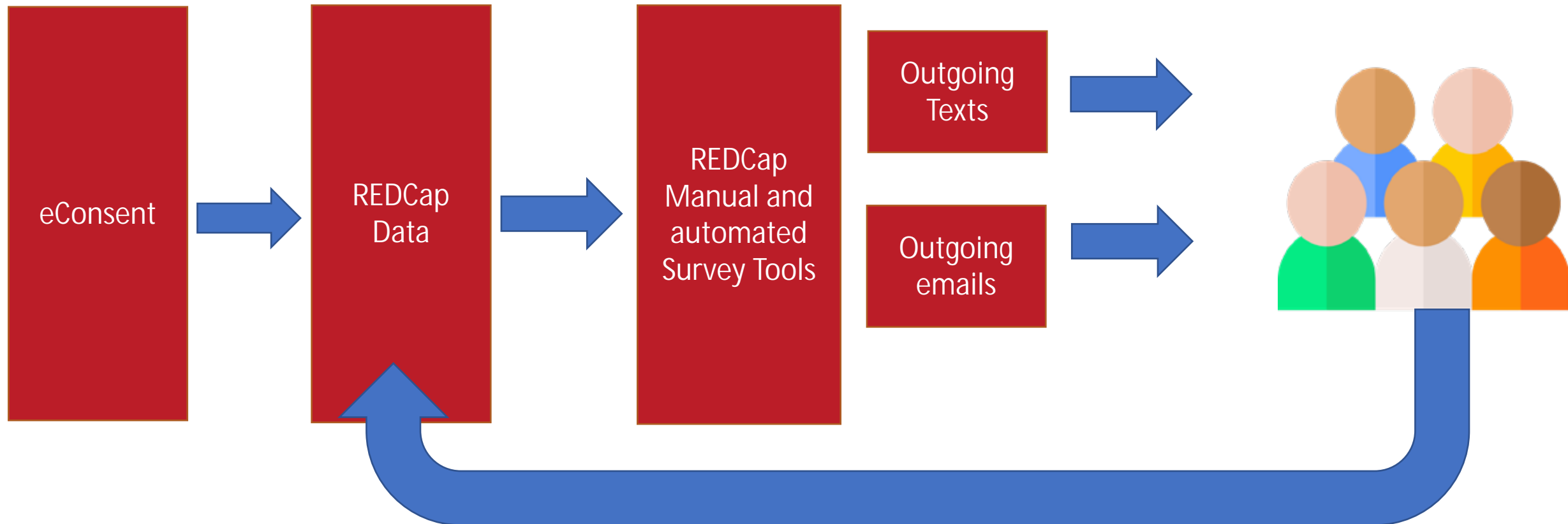
<https://www.cctst.org/events>

REDCap – eConsent Trainings

- REDCap eConsent Training: 1 hour on the basics of eConsent
 - Building eConsent Form
 - Signature attestation
 - eConsent Framework and Auto-Archiving
 - Sending a copy of the PDF to participants

<https://www.cctst.org/events>

REDCap Data Flow



eConsent Overview



Using
REDCap
for eConsent

REDCap is a web-based platform that allows for the digital capture and storage of participant consent, whether participants are consented in clinic or remotely. Being able to manage consents virtually enables flexibility and a critical step to expedite the clinical research process.

HOW PARTICIPANTS USE e-CONSENT

- The participant will open the survey and read through the consent form. When they get to the bottom, they will have the opportunity to fill in their information and sign their name if they agree to participate.
- They will select “Next Page” and a read only copy of the consent will be generated that they can review, download, and/or print. At the bottom of the page they will need to select “I certify that all the information in the document above is correct, and I understand that signing this form electronically is the equivalent of signing a physical document.” Once this is selected they will be able to submit the survey.

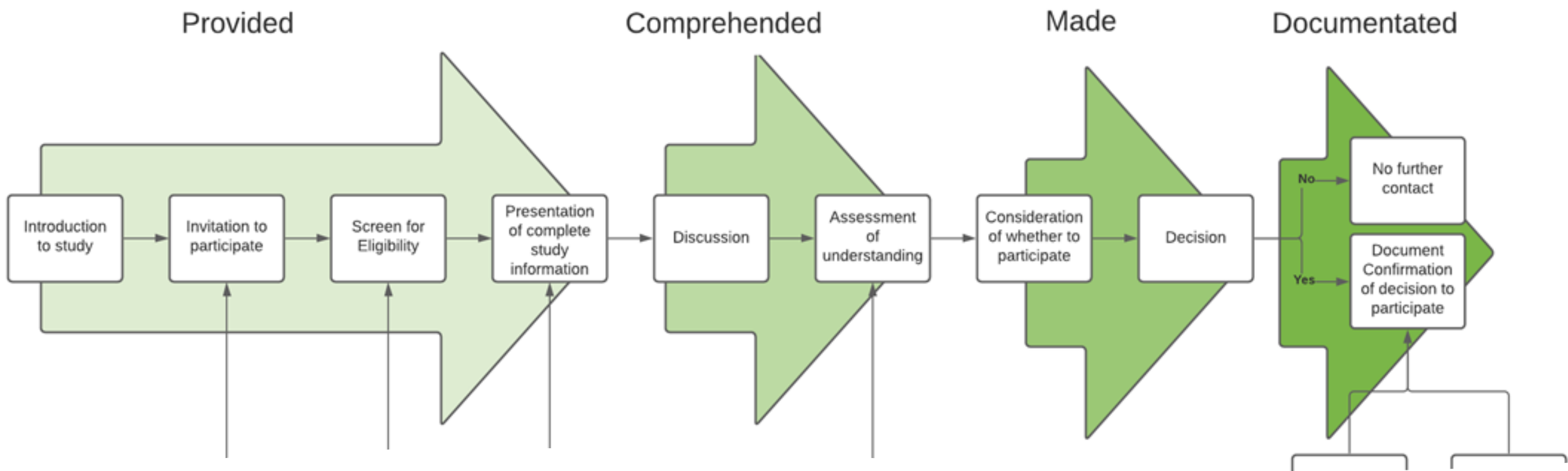


The screenshot displays a digital consent form interface. At the top, there is a header bar with a close button (X). Below the header, the form contains text explaining the study and the requirement for a signature. A large, dashed rectangular box is provided for the participant's signature, which contains a handwritten signature that reads "Maxx". Below the signature box, there are two buttons: a blue "Save signature" button and a "reset" button. At the bottom right of the form, a date stamp indicates "02-06-2023".

eConsent Current State

Widely adopted

- e-Consent Framework	
- Projects with surveys utilizing e-Consent Framework	1,869
- PDF consent files stored via e-Consent Framework	78,277



eConsent Process

- <https://confluence.research.cchmc.org/display/CCTSTRED/eConsent+Process+Guide>



Quick eConsent Settings Summary

- **SETTING UP e-CONSENT FRAMEWORK**

- **Enable surveys** on the “Project Setup” page.
- **Set up a survey instrument** with the consent language as well as first, last, signature, and a date validated field. Optional fields may be included, such as ‘date of birth’.
- **Enable the consent instrument as a survey.**
- If it is already enabled **go into survey settings and turn on “auto-archiver + e-Consent Framework”**.
 - A pop up will appear requesting first and last name variables as well as version number. ** Versioning of a form is a concept whereby you may give it a number or alpha-numeric designation to represent the current version.*
 - If the form is modified **AFTER** data collection begins, then it is recommended that a new version be applied. For example, the first version might simply be ‘1’, and after collecting the consent of a few participants, a question is modified or added, which represents a new version of the form, so you might increment the version to ‘2’ (and so forth).
- You can **select the optional fields** like date of birth or the e-consent type.
*The e-Consent ‘type’ is another free-form text field that can be used to signify the type of e-Consent that this survey represents (e.g., pediatric). ‘Type’ is often used to distinguish between multiple e-Consent forms within a project.
- **Finish up** by clicking the “Save Changes” button.

How the eConsent Framework Works

SIGNATURES

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you/your child should participate in this research, you will document your permission by signature below.

You will receive a copy of the signed consent form.

Do you consent to the study?
* must provide value

Do you assent to the study?
* must provide value

Participant's Signature


By signing this consent form, I, Maxx Somers, certify that I agree to participate in this study.* must provide value

Participant Consent Date
* must provide value

02-06-2023 Now D-M-Y H:M

Add signature [X]

Participant's Signature By signing this consent form I, Maxx Somers, certify that I agree to participate in this study.* must provide value



Save signature [reset](#)

- Once an individual agrees to participate, electronically signs the informed consent, then hits submit, a PDF of the completed consent can be automatically generated and saved to a REDCap form to preserve the exact consent text along with the research participant's responses. Signed Consent can be e-mailed directly to the participant or downloaded and printed.

How the eConsent Framework Works

- The 'Auto-Archiver + e-Consent Framework' survey option adds two things to the typical survey-taking process.
- Before a participant completes the survey, an extra certification page is added to the end of the survey that displays an in-line PDF copy of the document in which they will be asked to confirm that all information in the document is correct.
 - The survey will not be considered complete until they fulfill the certification step.

Informed Consent Form



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

7 / 7 | 58% | [Icons]

06/02/2023 7:58am Maxx Somers, Version: 4, Type: online projectredcap.org REDCap®

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SIGNATURES

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you/your child should participate in this research, you will document your permission by signature below.

You will receive a copy of this signed document for your records.

Do you consent to the study? Yes, I consent to participate in the study.

Do you assent to the study? Yes, I assent to participate in the study.

Participant's Signature

By signing this consent form I, Maxx Somers, certify that I agree to participate in this study.

Participant Consent Date 02-06-2023 07:58

I certify that all of my 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

How the eConsent Framework Works

- Upon completion of the survey, a static copy of their responses in the form of a consent-specific PDF will be stored in the project's File Repository.
 - The consent-specific PDF will have the values of the e-Consent Framework Options inserted at the bottom of each page in the PDF.
 - These values (i.e., name, date of birth, etc.) are added to the PDF as extra documentation of the identity of the person who is consenting.

File Repository

The File Repository allows users to store, organize, and share files used for this project. Folders and sub-folders can be created, and there is no limit to number of folders that can be created or the number of files that can be stored within them. If you are using Data Access Groups or user roles in the project, you may limit access to a new folder so that it is DAG-restricted and/or role-restricted. All deleted files will go to the Recycle Bin where they can be restored/undeleted for up to 30 days, after which they will be permanently deleted.

Show entries

0 MB used

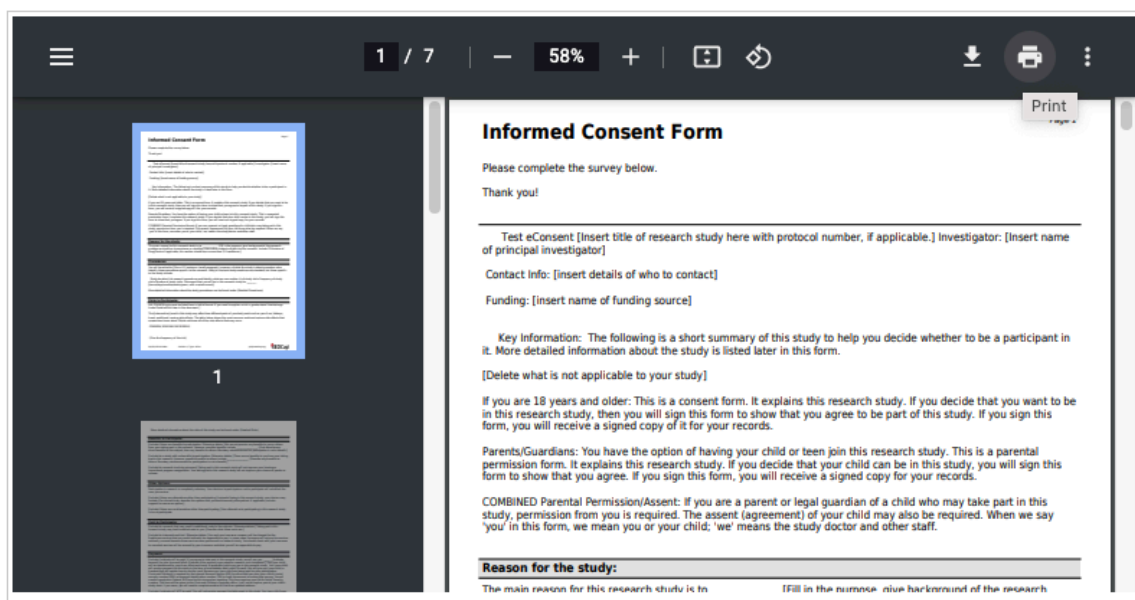
All Files / PDF Survey Archive

[Download all \(zip\)](#)

Name	Record	Survey	Survey Completion Time	Identifier (Name, DOB)
 Maxx_Somers_pid8199_formInformed_Consent_Form_id2_2023-06-02_075922.pdf	2	Informed Consent Form (Event 1 (Arm 1: Arm 1))	06/02/2023 7:59am	Maxx Somers
 Maxx_Somers_pid8199_formIndividual_Obtaining_Consent_Child_version_2_id24_2023-05-16_142210.pdf	24	Individual Obtaining Consent Child version 1 (Event 1 (Arm 1: Arm 1))	05/16/2023 2:22pm	Maxx Somers

How the eConsent Framework Works

- Once an individual agrees to participate, electronically signs the informed consent, then hits submit, a PDF of the completed consent can be automatically generated and saved to a REDCap form to preserve the exact consent text along with the research participant's responses. Signed Consent can be e-mailed directly to the participant or downloaded and printed.



The screenshot displays a digital form titled "Informed Consent Form" within a web browser interface. The browser's address bar shows "1 / 7" and "58%". A "Print" button is visible in the top right corner of the form area. The form content includes:

- A header section with the text: "Please complete the survey below. Thank you!"
- A section for "Test eConsent" with a placeholder: "[Insert title of research study here with protocol number, if applicable.] Investigator: [Insert name of principal investigator]"
- Fields for "Contact info: [insert details of who to contact]" and "Funding: [insert name of funding source]"
- A "Key Information" section: "The following is a short summary of this study to help you decide whether to be a participant in it. More detailed information about the study is listed later in this form. [Delete what is not applicable to your study]"
- A section for participants 18 and older: "This is a consent form. It explains this research study. If you decide that you want to be in this research study, then you will sign this form to show that you agree to be part of this study. If you sign this form, you will receive a signed copy of it for your records."
- A section for Parents/Guardians: "You have the option of having your child or teen join this research study. This is a parental permission form. It explains this research study. If you decide that your child can be in this study, you will sign this form to show that you agree. If you sign this form, you will receive a signed copy for your records."
- A section for COMBINED Parental Permission/Assent: "If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say 'you' in this form, we mean you or your child; 'we' means the study doctor and other staff."
- A section titled "Reason for the study:" with a placeholder: "The main reason for this research study is to [Fill in the purpose, give background of the research]"

Enter your email to receive confirmation message?

A confirmation email is supposed to be sent to all respondents that have completed the survey, but because your email address is not on file, the confirmation email cannot be sent automatically. If you wish to receive it, enter your email address below.

* Your email address will not be associated with or stored with your survey responses.

4 Key Points of eConsent

1: Add a clear Attestation of Consent Question:

On Paper Consent we often consider the signature an attestation of consent. In electronic processes we ask you to add a question that clearly notes a yes or no to Consent

SIGNATURES

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you/your child should participate in this research, you will document your permission by signature below.

You will receive a copy of this signed document for your records.

Do you consent to the study?

* must provide value

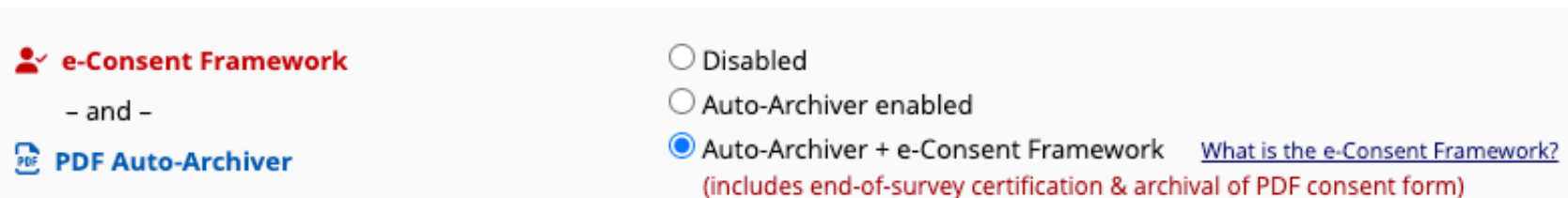
Yes, I consent to participate in the study.
No, I DO NOT consent to participate in the study.

4 Key Points of eConsent


2 & 3: Turn on the Auto Archiver + eConsent Framework

The Auto Archiver will save an uneditable copy of the Consent form in your File Repository


The eConsent Framework displays a PDF copy of the Consent to the participant and asks them to confirm the signature



The screenshot shows a settings interface with two main sections. The first section, 'e-Consent Framework', is indicated by a red person icon and text. Below it, a separator '- and -' is shown. The second section, 'PDF Auto-Archiver', is indicated by a blue PDF icon and text. To the right of these sections are three radio button options: 'Disabled', 'Auto-Archiver enabled', and 'Auto-Archiver + e-Consent Framework'. The third option is selected with a blue dot. A blue link 'What is the e-Consent Framework?' is positioned to the right of the selected option. Below the selected option, a red note states '(includes end-of-survey certification & archival of PDF consent form)'.

 **e-Consent Framework**

- and -

 **PDF Auto-Archiver**

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)

4 Key Points of eConsent

4: Send Confirmation email with Consent Copy to the participant

In paper consent processes we would copy a signed version of the consent. In eConsent we ask you to send a copy of the signed consent via email .

The screenshot shows a web interface for configuring a confirmation email. On the left, a blue header reads "Send confirmation email?" with a sub-note "(Email the respondent when they complete the survey)". To the right, a "Yes" dropdown menu is selected. Below this, a text box prompts the user to "Provide email subject, email message, and (optionally) an attachment to be sent to respondent when they complete the survey." with a link to "How to use Pipeline here". The "From:" field is set to "maxx.somers@cchmc.org" and the "Subject:" field contains "Consent #secure". A rich text editor follows, with a toolbar showing options like Paragraph, Bold, Italic, Underline, Link, and Unlink. The message body contains the text: "Hi, Thanks for consenting to the X project. Please find a copy of your consent attached." Below the editor, an "Attachment:" section has a "Choose File" button and "No file chosen" text. At the bottom, a checkbox labeled "Include PDF of completed survey as attachment" is checked.

Requesting an eConsent Template

<https://chi.uc.edu/cctst/research/request>

4. Request Services

REDCap

A software toolset and workflow data capture methodology designed for small to medium clinical research studies.

Please give us some information to help us get started with your request.

Does your project need a template applied? Please select below from the following options if applicable:

- eConsent Template
- eScreener Template
- Remote eConsent Template
- No Template Needed

Types of Electronic Signature (Scribble)

- <https://confluence.research.cchmc.org/display/CCTSTRED/e-Signature>
- **Scribble Signature:** Mobile Forms are increasingly being used on touch devices, and one common requirement is to support signatures. Scribing is becoming an accepted way of signing documents on mobile devices. The user can scribble a signature in the draw area designated by a dotted rectangle.

Types of Electronic Signature (Scribble)

- Actual image of the signature is captured
 - Has useful feature such as IP Address or Geographic location detection, date and time
 - Allows users to apply their pen signature on an electronic form on Mobile devices
 - Becoming an accepted way of signing forms on mobile devices
 - *REDCap signature field is a scribble signature*

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=11.3>

Protocol Language for Electronic Informed Consent Procedure

When writing electronic informed consent into a protocol, it is most important to:

- describe each step of the informed consent process,
- why the step is being performed,
- how each step will be performed,
- when will each step be performed,
- and where each step will be performed.

Example eConsent language for IRB protocols

Please find below template text that can be used in the IRB application to describe the specific steps for obtaining consent electronically. This language may be used as is or modified when initially completing or amending IRB applications for use of e-Consent:

The patient consent process will be conducted using a REDCap-based electronic consent form. The consent form has been developed in REDCap, a secure, web-based, HIPAA-compliant, data collection platform with a user management system allowing project owners to grant and control varying levels of access to data collection instruments and data (e.g. read only, de-identified-only data views) for other users. Potential participants will participate in the consent process by (**select method**):

- Being approached in-person at a CCHMC Clinic and accessing the REDCap survey via iPad or other portable electronic device and/or
- Self-initiated access of consent forms on personal portable electronic devices using posted QR codes or web-links on study posters, brochures, or websites. Self-initiated accessing of consent forms may occur in clinic or at home.

During the in-person consent process, patients will be consented by a member of the key study personnel.

For self-initiated consent, contact information will be provided (email and phone) for prospective patients to contact a member of the key study personnel with questions, prior to consent.

Patient signatures will be obtained using a (**select method: typed signature, PIN number, written signature – via stylus/cursor, etc.**). Upon completion of the consent, patients will be provided with a copy of their version of the consent document by (**select method: printing a pdf copy of the consent form in clinic, emailing copy of the consent form, providing participants with a business card/brochure with the web link to the appropriate version of the consent, provide home address for mailing of a hard copy of the consent**).

Signed consent documents will be housed electronically in REDCap's File Repository.

In Summary

- eConsent in REDCap is commonly used
- Training and help are available, start with help-REDCap@cchmc.org
- eConsent and other REDCap documentation is available in our REDCap Resource Center at:
<https://confluence.research.cchmc.org/display/CCTSTRED/Introduction+to+REDCap>
- eConsent Trainings Posted at: <https://www.cctst.org/events>