



Electronic Consent (e-consent) Guidance



THE UNIVERSITY OF
CHICAGO MEDICINE &
BIOLOGICAL SCIENCES



CENTER FOR
RESEARCH
INFORMATICS

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Help Resources

For all technical questions, design guidance, or all other questions related to REDCap e-consent, contact the CRI REDCAP Administrator, Julissa Acevedo at redcap@rt.cri.uchicago.edu.

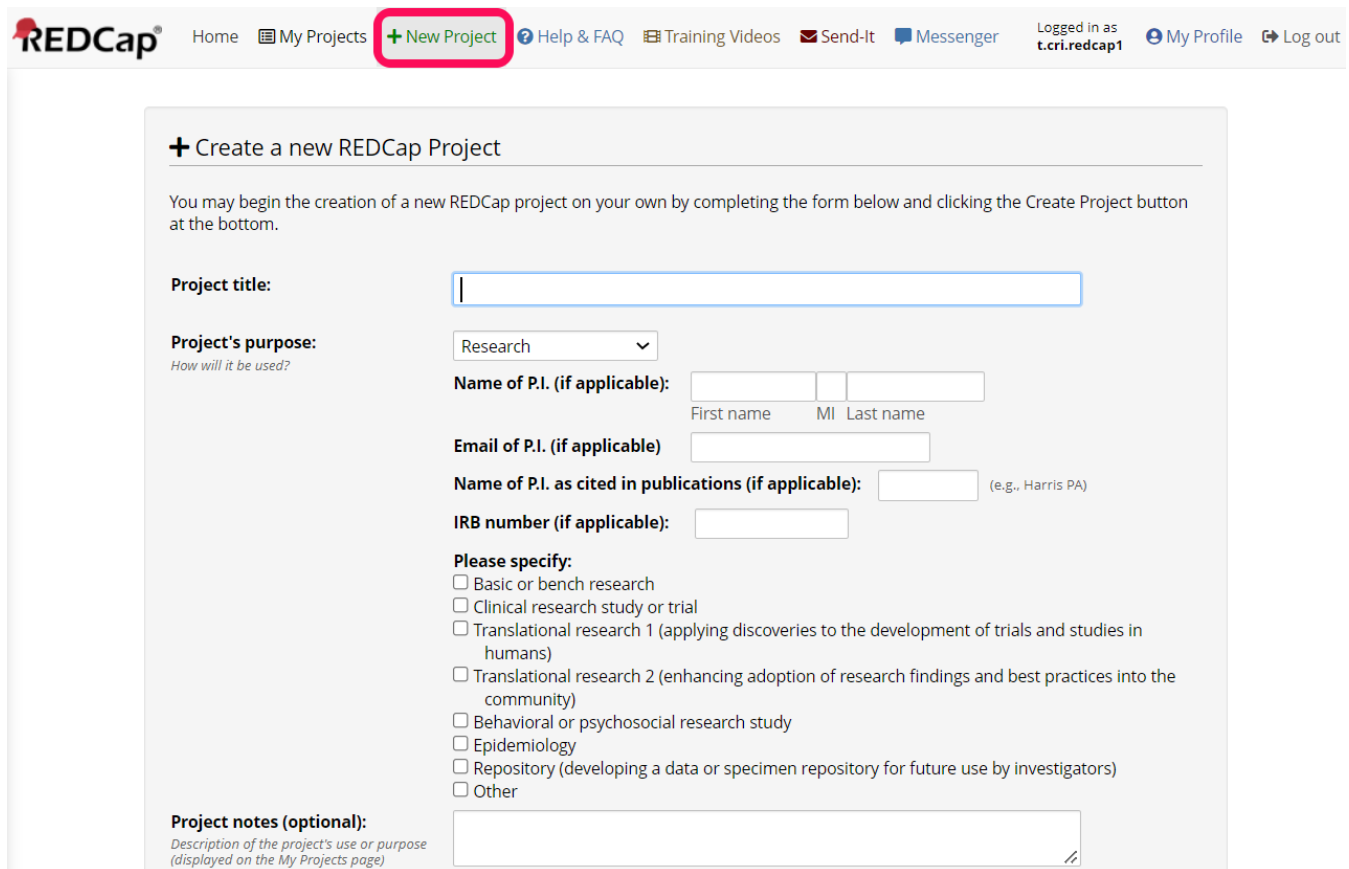
REDCap E-Consent Template for Existing Studies

If a REDCap project has already been created for the study, contact the CRI REDCAP Administrator, Julissa Acevedo at redcap@rt.cri.uchicago.edu so that the e-consent instruments can be added to your project.

REDCap E-Consent Template for New Studies

If a REDCap project has not yet been created for the study, use these steps to start your project using the UChicago e-consent template.

1. Navigate to REDCap at <https://redcap.uchicago.edu/>. Log in with either your **BSDAD** or **UCHAD** account.
2. Click on **+New Project**. Fill in the fields on the page with your study details.



REDCap Home My Projects **+New Project** Help & FAQ Training Videos Send-It Messenger Logged in as t.cri.redcap1 My Profile Log out

+ Create a new REDCap Project

You may begin the creation of a new REDCap project on your own by completing the form below and clicking the Create Project button at the bottom.

Project title:

Project's purpose: How will it be used?

Name of P.I. (if applicable):
First name MI Last name

Email of P.I. (if applicable):

Name of P.I. as cited in publications (if applicable): (e.g., Harris PA)

IRB number (if applicable):

Please specify:

- Basic or bench research
- Clinical research study or trial
- Translational research 1 (applying discoveries to the development of trials and studies in humans)
- Translational research 2 (enhancing adoption of research findings and best practices into the community)
- Behavioral or psychosocial research study
- Epidemiology
- Repository (developing a data or specimen repository for future use by investigators)
- Other

Project notes (optional):
Description of the project's use or purpose (displayed on the My Projects page)

3. For **Project creation option**, select **Use a template**, scroll to the bottom of the template list, and click **UChicago eConsent**. Then click **Create Project**.

Project creation option:

- Empty project (blank slate)
- Upload a REDCap project XML file (CDISC ODM format) [?](#)
- Use a template (choose one below)

<input type="radio"/>	Piping Example Project	Example classic project showcasing the variable Piping feature.
<input type="radio"/>	Project Dashboards, Smart Functions, Smart Tables, & Smart Charts	Example of Project Dashboards, Smart Functions, Smart Tables, & Smart Charts with fifty records included.
<input type="radio"/>	Project Tracking Database	Contains fifteen data entry forms dedicated to recording the attributes of and tracking and progress of projects/studies.
<input type="radio"/>	Randomized Clinical Trial	Contains seven data entry forms for collecting data for a randomized clinical trial. Includes a short demographics form followed by a form where randomization is performed. An example randomization model has already been set up.... Show more
<input type="radio"/>	Repeating Instruments	Example classic project showcasing the Repeating Instruments functionality.
<input type="radio"/>	Single Survey	Contains a single data collection instrument enabled as a survey, which contains questions to demonstrate all the different field types.
<input checked="" type="radio"/>	UChicago eConsent	University of Chicago approved Electronic Informed Consent (eIC) project with Subject Identification form instrument and eConsent survey instrument

Create Project

4. Under the **Project Setup** tab, click on the **Online Designer**.

REDCap
Logged in as t.cri.redcap1 | Log out
My Projects
REDCap Messenger

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

- Project Dashboards
- Alerts & Notifications
- Calendar
- Data Exports, Reports, and Stats

University of Chicago Electronic Informed Consent (eIC) Template PID 6425

[Project Home](#) [Project Setup](#) [Other Functionality](#) [Project Revision History](#)

Project status: [Development](#) Completed steps 4 of 7

Main project settings

- Use surveys in this project? [?](#) [VIDEO: How to create and manage a survey](#)
- Use longitudinal data collection with defined events? [?](#)

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 [Online Designer](#) or [Data Dictionary](#) Explore the [REDCap Instrument Library](#)

Have you checked the [Check For Identifiers](#) page to ensure all identifier fields have been tagged?

Learn how to use [Smart Variables](#) [Piping](#) [Action Tags](#) [Field Embedding](#) [Special Functions](#)

5. Click on *****READ INSTRUCTIONS HERE FIRST*****

The screenshot shows the REDCap Online Designer interface for the University of Chicago Electronic Informed Consent (eIC) Template. The interface includes a sidebar with navigation options such as 'Project Home', 'Project Setup', 'Designer', 'Dictionary', and 'Codebook'. The main content area displays 'Data Collection Instruments' with a table listing three instruments: 'Documentation of Consent', 'Subject eConsent Form', and 'Subject Assent Form'. The 'Subject Assent Form' row is highlighted with a red box containing the text '***READ INSTRUCTIONS HERE FIRST***'.

Instrument name	Fields	View PDF	Enabled as survey	Instrument actions	Survey-related options
Documentation of Consent	22		Enable	Choose action	
Subject eConsent Form	40			Choose action	Survey settings + Automated Invitations
Subject Assent Form	14			Choose action	Survey settings + Automated Invitations
READ INSTRUCTIONS HERE FIRST	1		Enable	Choose action	

6. Follow the guidance and instructions in the instrument:

Instructions for using this project template:

This project is a template. It serves as a starting point. There are three instruments in this project:

- 1. Documentation of Consent**
 - This is a data entry form instrument for the study team.
 - This form serves to document the consent method, and the verification of identity for the subject or representatives.
 - This form is to be completed by the study team prior to consenting.
- 2. Subject eConsent Form**
 - This is a survey instrument for subjects or their representatives.
 - This survey instrument serves as the e-consent form for the subject or representatives.
 - This survey instrument should be updated to match your IRB approved consent form.
 - This survey instrument has sections for the consent form text and the varied signatures sections which should be modified to match your approved consent form.
 - The survey instrument uses the Auto-Archiver+e-Consent Framework in order to provide the subject copy and to store a copy in the project.
- 3. Sample Assent Form**
 - This is a survey instrument for minors.
 - This survey instrument serves as an assent form for the subject or representatives.
 - This survey instrument should be updated to match your IRB approved consent form.
 - This survey instrument has sections for the consent form text and the varied signatures sections which should be modified to match your approved consent form.
 - The survey instrument uses the Auto-Archiver+e-Consent Framework in order to provide the subject copy and to store a copy in the project.

TESTING: The best way to see how these e-consent instruments work is to test them.

1. Add a test record and enter test data in the Documentation of Consent form.
2. For the test record, open the Subject eConsent Form, and from the dropdown at the top right of the form, email the survey to your email address or to a colleague's email address.
3. Click the survey link in the email message and fill out the consent form survey as a subject would.
4. Return to the project to view the completed form and to complete the consentor/PI signatures.

ADDING MORE INSTRUMENTS: This template can be used as the basis for your study's project.

- You can add the rest of your forms and surveys to this project (*Online Designer > Add new instrument Actions > Create a new instrument from scratch*).
- Be sure to delete this instructional instrument before requesting your project be moved to Production Mode (*Online Designer > Instrument Actions > Choose action > Delete*).
- All other REDCap functionality is available in this template as well, such as longitudinal data collection, repeating forms, randomization, etc.

NEED HELP? Click the blue button 'Contact REDCap Administrator' or email redcap@rt.cri.uchicago.edu.