REDCap
Research Electronic Data Capture

Electronic Consent (e-consent) Guidance

THE UNIVERSITY OF CHICAGO MEDICINE & BIOLOGICAL SCIENCES

CENTER FOR RESEARCH INFORMATICS

Version Date: 7/31/24

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@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@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.

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**.

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

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

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 store a copy in the project.
- The survey instrument settings has an option for subjects to download a consent form copy. Additionally, there is an optional survey setting for emailing a copy as well.

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 store a copy in the project.
- The survey instrument settings has an option for subjects to download a consent form copy. Additionally, there is an optional survey setting for emailing a copy as well.

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@uchicago.edu.