University of Minnesota: Clinical and Translational Science Institute

e-Consent Guide

Process effective date: May 13, 2026

V1.1 Last Updated: September 18, 2026

This resource provides comprehensive instructions for using University of Minnesota (UMN) REDCap e-Consent in compliance with regulatory requirements. In addition to technical guidance for those building, managing, or using e-Consent projects, it outlines the foundational principles of electronic consent, including current federal guidelines.

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Introduction

Background: Informed Consent

According to the Belmont Report, “Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.” Informed consent in human research refers to the process in which potential study volunteers are provided sufficient information about the research study to allow them to make an informed decision as to

whether or not they wish to voluntarily participate in the study. Part of that process involves confirming that the potential participant comprehends the study details, and by inviting and responding to all questions that they may have. The informed consent process continues throughout each human research study because additional information must be provided to participants as the study progresses or changes.

Typically, the informed consent process has involved the development of a paper-based informed consent form that each study participant (or their legally authorized representative (LAR)) signs as documentation of their understanding and consent. Electronic media can now be used to supplement or replace that paper-based system.



For more on the informed consent process:

- HRP202: Implementing a Patient-Centered Informed Consent Process
- CTSI Informed Consent in Human Research Workshop
- CTSI Research Toolkit: Get Informed Consent

What is e-Consent, and when should it be used?

Electronic informed consent (e-Consent or eIC) can be used to provide the same information that is usually contained in the hard copy or paper-based informed consent document, to help with the process of confirming a participant's comprehension of the study details, and to document the consent of the participant or their LAR. In addition, the electronic process can provide for rapid communication with current study participants about changes and updates that may affect their decision to continue participating in an ongoing study.

e-Consent can supplement or replace the paper-based informed consent process in a research study; however, it may not be appropriate for all potential participants. While many participants may appreciate the flexibility of using an electronic process on-site, some participants may have difficulty navigating or using electronic systems because of, for example, a lack of familiarity with the systems, poor eyesight, or impaired motor skills. Additionally, some participants may not have private or secure access to an electronic device. Therefore, participants should be provided the opportunity to select their preferred consent option.

It's important to remember that electronic consent and remote consent are different things. For example, electronic consent can be obtained in person, such as on an iPad in a clinic exam room. Remote consent can also be obtained on paper, such as mailing a consent form and a self-addressed, stamped envelope (SASE) to a participant and having a consent conversation over the phone. Commonly, electronic consent and remote consent are combined, so that a link to the

consent form is sent to a participant and the form is signed electronically after a phone conversation with study staff.

How does the e-Consent process work, in general?

The e-Consent process is the responsibility of the Principal Investigator (PI) and of appropriately delegated study personnel. The PI must provide a detailed e-Consent plan within the protocol as well as a Microsoft Word-based consent form that is first submitted for IRB review. If a detailed e-Consent plan is not included in an external protocol, then it must be added to a local protocol addendum.

Examples of what to include in the plan:

- ☐ If there is a need to assess capacity to consent remotely, describe how this will be done.
- ☐ Describe who is maintaining/updating the e-Consent when there are modifications.
- ☐ Confirm that the UMN-provided, Part 11 compliant, e-Consent solution will be used.
- ☐ How will the e-Consent be accessed? What alternate consent method will be used if an electronic device is unavailable?
- ☐ Process for consent - same level of detail as standard consent plan.

Following IRB approval of the protocol and consent form, the PI and study staff develop the actual e-Consent form on an electronic platform (such as REDCap) that meets the necessary federal, regional, and local compliance requirements. The PI and study staff also develop videos and web-based supplemental information that participants will receive and view during the e-Consent process. These electronic materials must all be submitted (use screenshots) to and approved by the IRB prior to implementation.

e-Consent can take place at the study site with both the PI/delegated study personnel and participant present; or remotely, when the participant is at home or another convenient and private location. When done remotely, the participant discusses the e-Consent document with a person authorized to obtain study consent; this discussion often occurs via phone or video conference.

If the entire e-Consent process occurs at the study site, study personnel must:

- Verify the potential participant's identification using at least two distinct identification components
- Allow sufficient time for the participant to review and consider the consent materials
- Review the informed consent content with the participant
- Answer the participant's questions
- Witness the participant (or LAR) signature of the e-Consent
- Return a PDF of the signed Informed Consent and HIPAA forms to the participant.

When some or all of the e-Consent process occurs remotely in the absence of actual study personnel, the electronic system or process must:

- Allow sufficient time for the participant to review and consider the consent materials

- Provide a method for the participant to ask questions and be responded to (for example, by live chat, video-conferencing, messaging, or phone contact with study personnel)*
- Include a method to gauge the participant's comprehension of study details
- Include two distinct identification components to verify that the participant signing the e-Consent is the individual who will be participating in the research study (or their LAR)
- Return an electronic copy of the signed Informed Consent and HIPAA forms to the participant.

*Note that, in some cases, the IRB may require the use of a video platform to aid the study team in evaluating the participant's understanding.

What are the federal guidelines for e-Consent?

FDA regulations, 21 CFR Part 11, provide the criteria under which the FDA accepts electronic records, electronic signatures, and handwritten signatures executed to electronic records as being equivalent to paper records and handwritten signatures written on paper. Part 11 defines all requirements for electronic signatures to be considered equivalent to handwritten signatures, and stipulates that the electronic system must also capture and record the date that the participant (or their LAR) provides consent.

Remember that a process can be validated as 21 CFR Part 11 compliant, even if the overall system being used is not validated. The use of REDCap e-Consent templates and following this guide will ensure your e-Consent process is Part 11 compliant. **REDCap itself is not Part 11 compliant, and cannot be used for electronic signatures outside of the templated consent process.**

For more details about e-Consent federal guidelines, review the requirements of 21 CFR Part 11.

What are the University of Minnesota IRB Requirements for e-Consent?

The UMN Human Research Protection Program (HRPP) has stipulated that research studies integrating e-Consent must use the REDCap web-based, data collection system that has been validated as compliant with FDA 21 CFR Part 11. The process of developing e-Consent forms on the REDCap platform ensures the security and validity of electronically-signed consent forms. REDCap e-Consent is available for studies that require FDA compliance and those that do not; all studies using e-Consent must follow the process described in this document.

Each unique form approved by the IRB requires an identical eConsent form built in REDCap. If the IRB approves a combined consent and HIPAA form, it may be built as a single form in REDCap. If the project requires both parental consent and the assent of a minor, these forms must be built as separate, unique REDCap forms. Parental consent and assent forms should not be combined into one REDCap form. Even if the same study team member is responsible for both the consent and assent process, both forms must include the "Consented By" signature to avoid confusion and to mirror the process the IRB approved.

Note: If you are attempting to conduct e-Consent remotely and may have potential participants with diminished or limited capacity, the IRB may require a video connection during the consent conversation.

All UMN research studies planning to use e-Consent must obtain approval of an e-Consent plan and e-Consent document and supporting consent materials from the IRB. Criteria for IRB approval for Electronic Consent can be found on page 8 of Worksheet HRP-314, Criteria for Approval.

What is REDCap?

REDCap is a secure web platform for building and managing online databases and surveys. REDCap's streamlined process for rapidly creating and designing projects offers a vast array of tools that can be tailored to virtually any data collection strategy.

REDCap provides automated export procedures for seamless data downloads to Excel and common statistical packages (SPSS, SAS, Stata, R), as well as a built-in project calendar, a scheduling module, ad hoc reporting tools, and advanced features, such as branching logic, file uploading, and calculated fields.

REDCap uses a secure MySQL database located on a University server that is backed up daily, updated regularly, and is supported by the Clinical and Translational Science Institute.

REDCap contains an e-Consent module that has been validated for the FDA's Title 21 CFR Part 11 compliance.

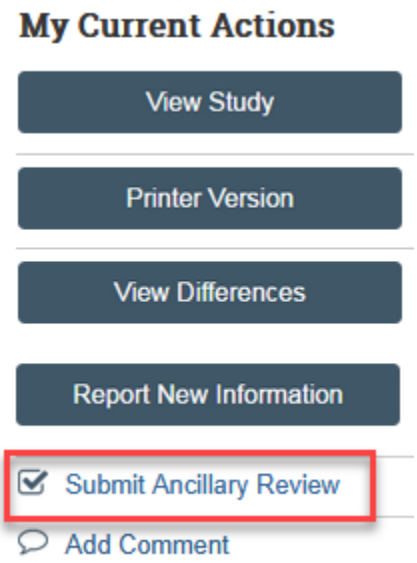
Before you Begin . . .

Before creating an e-Consent project in REDCap:

- If not previously completed, you must take the REDCap New User Training to create any REDCap projects.
- You must first have submitted your consent plan (in the protocol) and consent form (as a Microsoft Word document) to the IRB, using the appropriate IRB template for your project.
- You must complete the e-Consent Training course in Canvas. This will be verified by the REDCap Administration team as part of the move to production request.

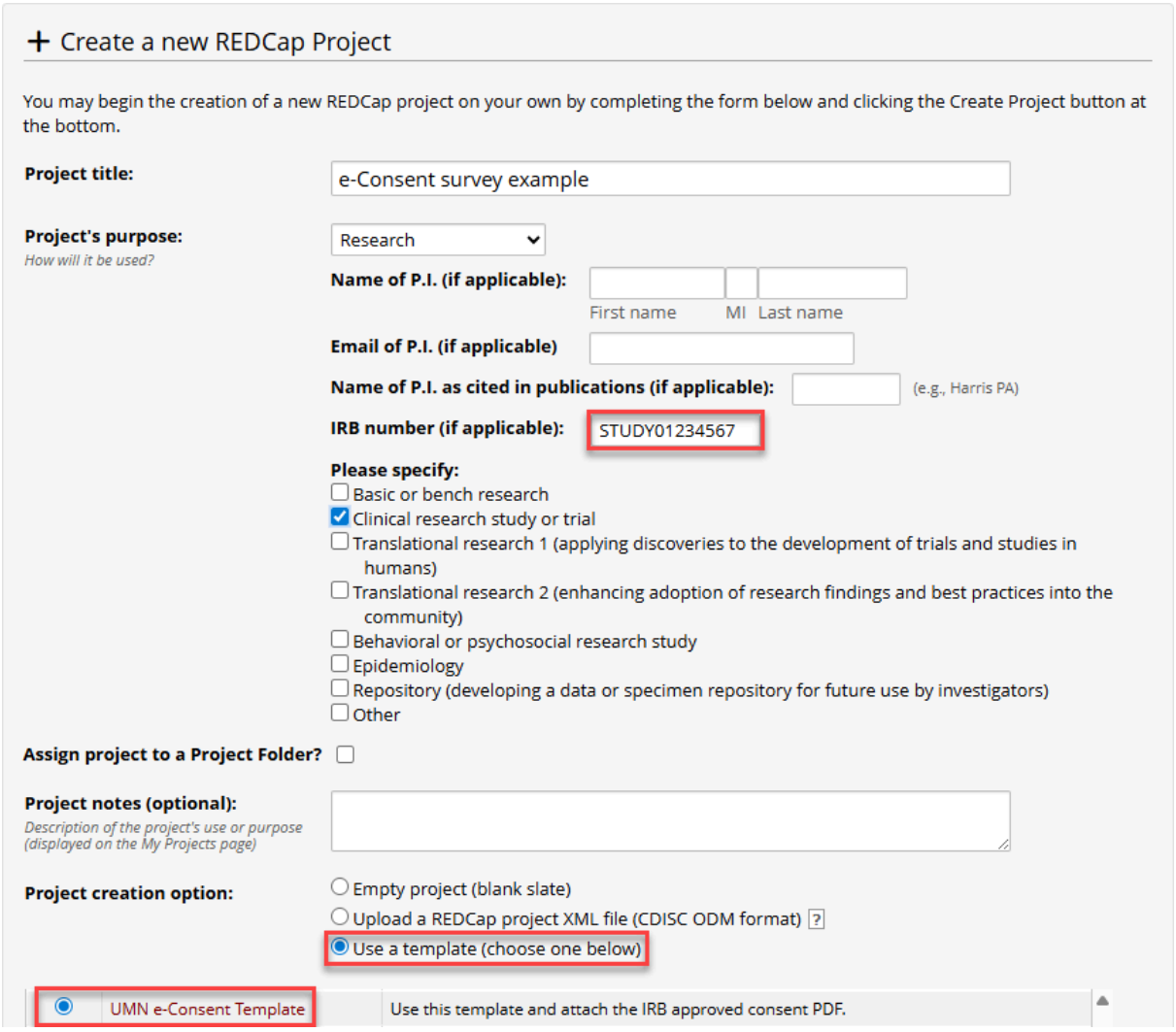
After you have received IRB approval of the consent form and you have completed the training referenced above, you are ready to log in to REDCap and develop your e-Consent project.

REDCap staff require ETHOS study access:
Typically the IRB Analyst will assign the REDCap e-Consent Ancillary Review in ETHOS. If not completed by the IRB Analyst, the Study Team may also assign this ancillary review. This is required for the REDCap Team to complete their review and move the study to Production.


My Current Actions
View Study
Printer Version
View Differences
Report New Information
Submit Ancillary Review
Add Comment

Develop Your REDCap e-Consent Survey

Set Up Your New Project



Select **+New Project** to begin developing your new e-Consent project.

- Complete all pertinent fields with your project information.
- Be certain to include the local IRB Number, or your research study e-Consent project will not be moved into production in REDCap.
- Select “Use a template” to begin your project with a template. This will ensure that your project will be FDA Part 11 compliant.
  Select **UMN e-Consent Template**.
- Click Create Project.

Project Setup Tab

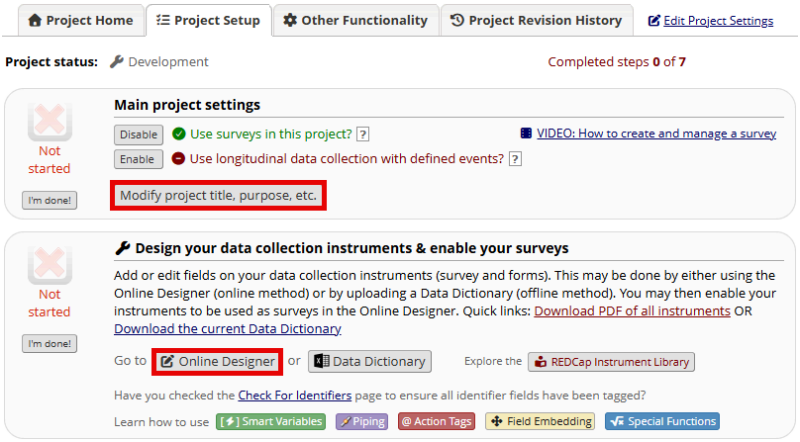
You are now in the Project Setup tab. Your new REDCap project has been created, and you can select the features you want to use and include. As you work through creating your e-Consent project:

- Note that the enabled options are typically printed in **green**
- Click on this symbol ⍰ when you wish to learn more about various options. In addition, you will find multiple opportunities to click **Read more, Tell me more**, or watch videos to learn additional details

Under **Main project settings**, note that **Use surveys in this project?** is checked, because you want to use a survey for your e-Consent form.

Note: If you wish to make any changes or edits to your project description, click the grey button: Modify project title, purpose, etc.

Under **Design your data collection instruments & enable your surveys**, select **Online Designer**. This will allow you to add or edit fields on your e-Consent form.



Online Designer Tab

Use the Online Designer to easily modify your project fields and collection instruments. As you customize your survey, all changes you make to the fields take effect immediately in real time.

Familiarize yourself with this tab. This is the central location from which you'll customize the:

- Participant Information Form
- e-Consent survey
- Consented By survey
- Optional 2nd Parent e-Consent 2 survey.

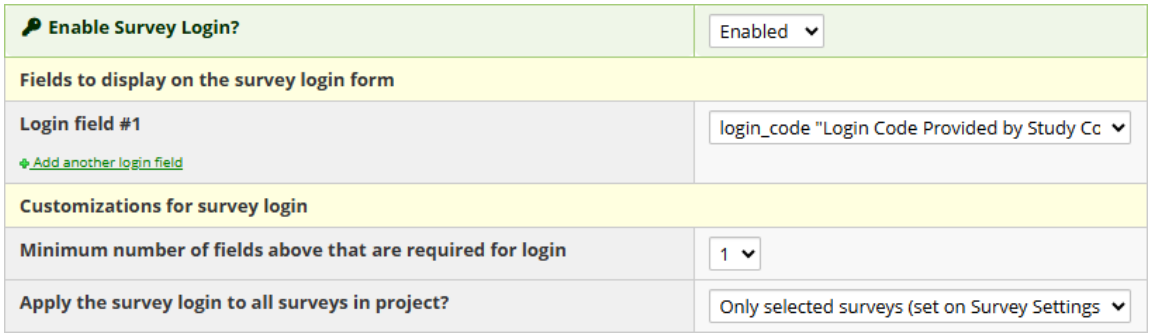
Before you click these instruments and develop each REDCap survey, first follow the instructions below for selecting settings to help ensure a successful and FDA Part 11 compliant e-Consent process. After you have selected these settings, you can return to the Online Designer tab and customize each of the instruments that are needed for your study.

Select Settings for Your e-Consent Survey

Survey Login Screen

First, select **Survey Login**. This will take you to a pop-up screen. Here, you'll confirm the type of authentication your survey respondents will be required to respond to before they can view and complete the e-Consent survey. Prior to a respondent logging in to complete the survey, the information they will enter into the login code field should already have been entered and saved to their record in the Participant Information Form.
In this screen, select the fields that you'll use for login fields as well as other authentication settings.

1. Confirm that **Enable Survey Login?** is set to: **Enabled**
2. Confirm that **Login field #1** is set to: **login_code** "Login code for e-Consent."
3. Confirm that the response to **Apply the survey login to all surveys in project?** is set to: **Only selected surveys** (set on Survey Settings page).
4. Other setting changes on this screen for survey login are rare. Reach out to redcap@umn.edu with questions. Save the changes, if any were made, otherwise click Cancel to close this tab, returning to the **Online Designer tab**.



e-Consent Survey Settings Screen

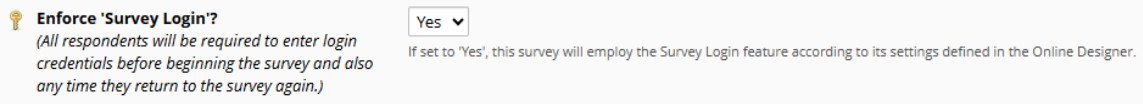
Back in the **Online Designer** tab, in the **e-Consent row**, select **Survey settings**. This page allows you to design how the basic information in your survey will be presented, including the logo you use, your user instructions, the type of numbering for survey questions, display formats, field formats, and accessibility options.
In addition, you can activate a 'text-to-speech' function that allows the written information to be digitally read to users.
Scan the page to note the sections of the **Survey settings** screen:

- Basic Survey Options
- Survey Design Options
- Survey Customizations
- Survey Access
- Survey Termination Options

Let's begin, though, by ensuring you set some critical settings for e-Consent.

Survey Access Section

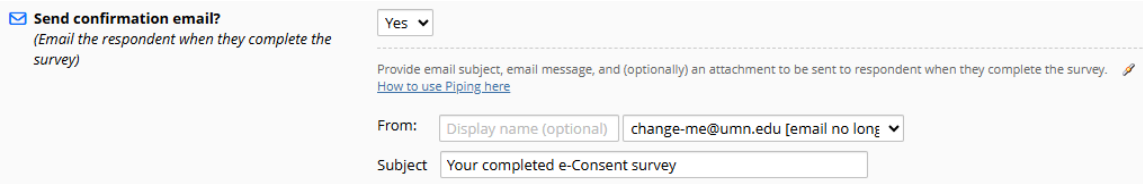
The **Enforce 'Survey Login'?** option requires all participants to enter login credentials before beginning the survey and each time they return to the survey. As you design your **e-Consent survey** and the **Optional 2nd Parent e-Consent 2 survey**, be certain that you have selected **Yes** in response to this prompt.



Survey Termination Options Section

At the very bottom of the **Survey settings** page is called **Send confirmation email ?(optional)**. Here, you can plan the email that respondents will receive after they complete your survey. In this section,

- Confirm that **Yes** is entered in the first box. This will allow you to draft the actual email that will be sent to your participants.
- In the **From** field, change the sender of the survey confirmation email to a **study or department email**. Do not use the email of an individual in the project. To select the study or department email, someone with access to the e-Consent project must have set up this email address as their secondary or tertiary email address in their REDCap profile.
    - **Do not leave** the email address set as change-me@umn.edu.



Tips

To add a secondary or tertiary email address, click on **Profile** in the upper right navigation bar of the REDCap home page. Towards the bottom of the page under **Additional Options**, click **Add email**, enter the study or department email address, and Save. This will send an email to the study or department email with a link to validate that you have access to that email address. A study or department email address can be created by visiting: https://my-account.umn.edu/create-dept-acct

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- In the **text box** for your automated confirmation email,
    - Refer to the consent form with a study-specific title because participants may be signing multiple consents and need to be able to differentiate them.

    - Include a phrase such as “Do not reply to this email” or “For the protection of your health information privacy, please don’t reply directly to this email.” You may want to add a name and phone number for potential participants to call with questions. **Don’t** include an email address, so that you can avoid the use of unencrypted email for communicating about the study.
- At the very bottom of the screen, be certain that the **Include PDF of completed survey as attachment** option is checked, and then click **Save Changes**, returning you to the **Online Designer** tab.

Repeat this process for selecting settings for each consent related survey you are using for your study.

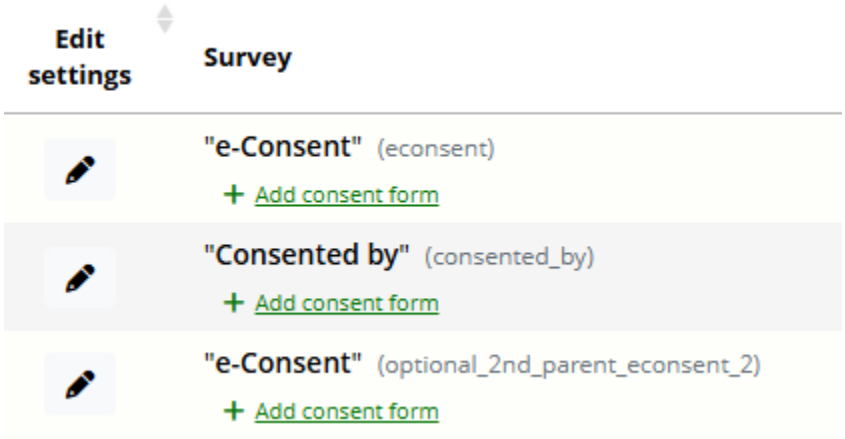
e-Consent Framework Settings

On the **Online Designer** tab, select the **e-Consent** button. If you are using the template, the e-Consent Framework is already enabled and active for the instruments titled, "e-Consent", "Consented By" and "2nd Parent e-Consent."

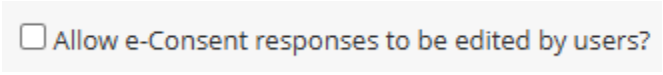
Before completing the information on the page titled **e-Consent Framework Settings**, read through the Q&A below to ensure you understand the decisions you will make in this important section.

- What is this e-Consent Framework?
  This is the mechanism which allows you to provide e-Consent to study participants, and is merely one mechanism within the e-Consent process. As a survey administrator, you still must create your e-Consent survey and all of its questions, including name and date of birth, and you must determine how you wish to capture participants' signatures. This framework allows you to both customize your survey to your study and to use a set of standardized tools (certification screen + automatic consent form storage as a PDF).
- What happens when a study participant completes the REDCap e-Consent survey?
  Before a participant completes the survey, REDCap adds an extra certification page to the end of the survey. This displays as a PDF copy of their survey responses, for which they'll be asked to confirm that all information is correct. The participant must complete this certification so that the survey can then be marked as 'complete'.
- What are the **PDF Snapshots**?
  When a survey is complete, a PDF copy of the participant's responses is automatically stored in the project's File Repository (within the REDCap system). This consent specific PDF contains the values of the e-Consent Framework options that were inserted automatically at the bottom of each page of the PDF, including name, date of birth, etc. These values are added to the PDF as extra documentation of the consenting person's identity.

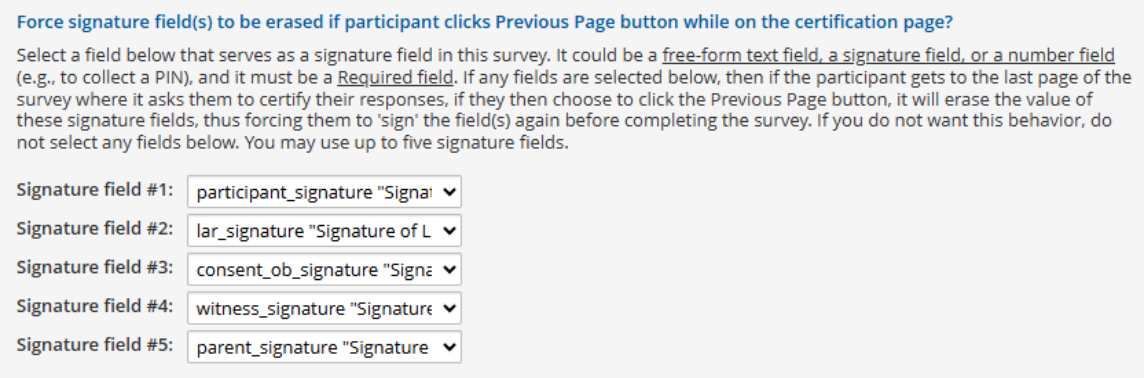
Now, complete the information in the **e-Consent Framework Settings**. To do this, click on Edit settings for each instrument individually.



- Confirm that **Allow e-Consent responses to be edited by users?** remains unchecked.

- Confirm that **first_name** and **last_name** are selected in their respective fields.
- **Force signature field(s) to be erased if the participant clicks the Previous Page button while on the certification page?** This option, which is required for the FDA-compliant e-Consent process, allows you to require a participant to re-sign the e-Consent survey if they have gotten to the final page of the survey where they certify their responses and, at that point, click the **Previous Page** button. If you select this option, the initial signature(s) will be erased, and the signature(s) must be re-entered.
    - **You need to** force signatures to be erased, select one or more of the signature fields that will need to be re-entered should the participant use the **Previous Page** button. Select as Signature field #1: **participant_signature**; as Signature field #2: **lar-signature**; Signature field #3: **consent_ob_signature**; Signature#4: **witness_signature**; and Signature #5: **parent_signature**. Be certain that the fields selected match the signature fields in your IRB-approved form.
    - Note: When you select settings for your Consented By and Optional 2nd Parent e-Consent 2 surveys, you will select different fields.
        - For the **Consented By** survey, select: **consent_ob_signature_2**.
        - For the **Optional 2nd Parent e-Consent 2** survey, select: **parent_signature_v2**.

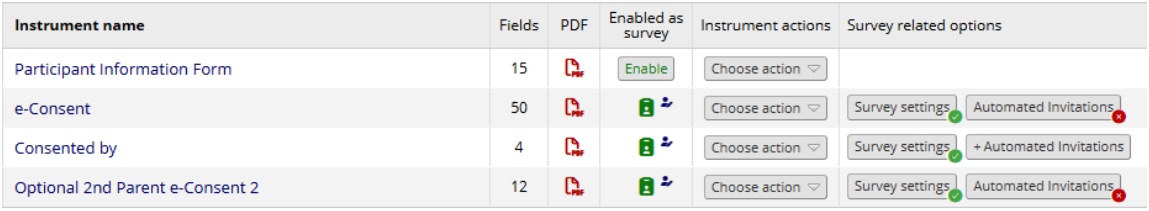


Make sure to click **Save settings** when done. Repeat this process for the remaining Surveys added to the e-Consent Framework.

Note: The e-Consent Framework settings are also applicable to the HIPAA Authorization form, Unsecured Email Authorization form and the Unsecured SMS Authorization form. If you are using any of these you must enable them in the e-Consent Framework and follow the settings listed above.

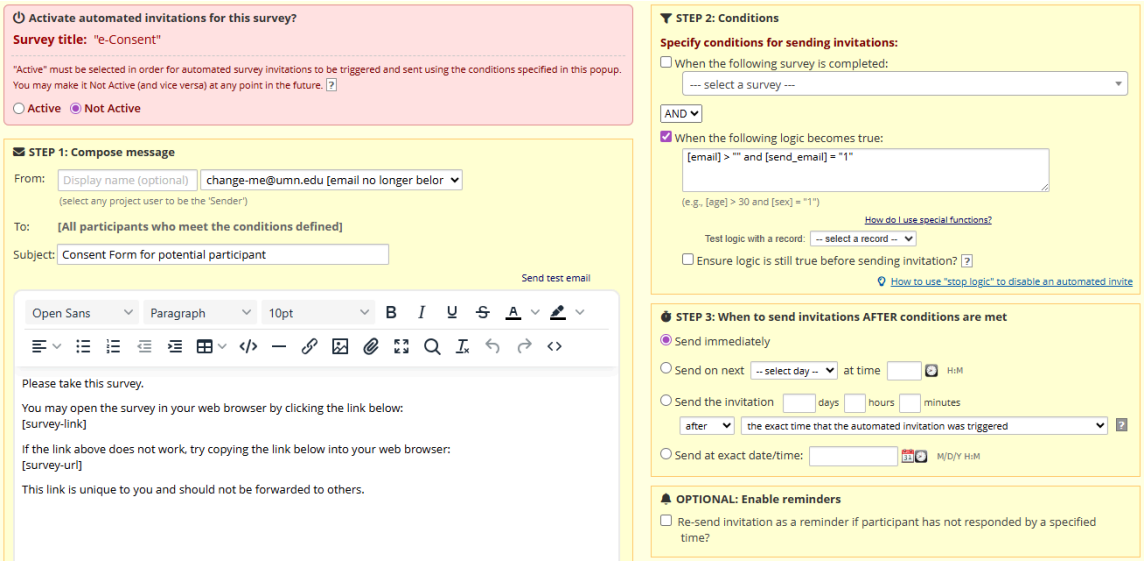
Automated Invitations Screen

From the **Online Designer** tab, click **Automated invitations** in the **e-Consent** row. Here, you can **define conditions for sending automated survey invitations**. Using this function allows you to define specific conditions which, when met, will trigger the automatic sending or scheduling of invitations to participants to open and complete your e-Consent survey(s).



Before completing this screen, consider:

- What are the conditions that you wish to trigger an invitation to potential participants to complete your survey, for example, when the participant has completed another survey, or when data values of a specific record fulfill a requirement, etc.?
- At what point do you want the invitation to be sent once the conditions are fulfilled, for example, immediately or after a fixed amount of time?
- Activate automated invitation settings so REDCap can monitor your preset conditions and automatically send or schedule invitations.



1. Under **Activate automated invitations for this survey?**, set the automated invitations to **Active**.
2. Under **Step 1: Compose message**, in the **From**: field, change the email address to a study or department email. Complete the Subject and email body fields.
3. Under **Steps 2** and **3**, enter the conditions that will trigger the automated invitation as well as the time frame in which the invitation will be sent.
4. Click **Save** to save the changes and return to the **Online Designer** tab.
5. Repeat this process for selecting automated invitation settings for each consent survey you are using for your study. (Note that Automated Invitations are not usually used for the Consented By survey.)
    a. You must have a Consented By survey for each consent form, and an Assented By survey for each assent form, even if consent/assent were done at the same time and by the same person.

Create and Customize Your e-Consent Surveys

From the **Online Designer tab**, you can now customize each of the e-Consent forms that you'll use for your study from the list:

- Participant Information Form
- e-Consent
- Consented By
- Assented By
- Optional 2nd Parent e-Consent 2

Click on the name of the form to customize it to your study-specific consent document that was approved by the IRB. This includes the additional questions that require the participant to initial or sign. The Participant Information Form includes REDCap's branching logic so that the fields will match each individual consent for your specific study (for example, adult participant, LAR,

interpreter, etc.). Be certain that the signature fields in your REDCap e-Consent surveys match the ones in the approved forms.

There are two types of signature fields: Classic or Enhanced. The Classic signature field requires the participants to draw their signature using a finger or pointing device. The Enhanced signature field allows the user to choose between Typing or Draw (aka Classic style) their signature.

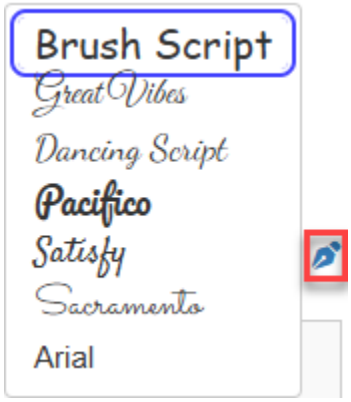
Classic Signature Example



New Enhanced Signature example



Clicking on the pen icon in red below will allow the participant to pick from a variety of fonts.





- Selecting Dancing Script resulted in a different font style.

Customizing Your Participant Information Form

When customizing your Participant Information Form, be certain to:

- Change the consent version field to contain the latest IRB effective date. There is no centralized standard for a version number; however, if you have a departmental or area version number, you may optionally add it prior to the effective date. Add @DEFAULT="#" in the lower left Action Tag/Field Annotation section to add this information as a default value. By doing so, staff won't need to enter the version number for each record.
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Attaching Your Consent Form

For each consent form, including Assent forms, follow the following steps:

On the **Online Designer** tab, select the **e-Consent** button. On the e-Consent row, click on **+Add consent form** to attach the consent form. On the Assent row, click on **+Add consent form** to attach the assent form.

- In the **Consent form version:** enter the latest approved consent version for your study. We recommend including the local IRB effective date.
- In the **Placement of consent form:** select **consent_pdf** ""
- Click on the **Consent Form (Inline PDF)** tab and click Choose File to select the latest approved consent PDF for attaching to the **consent_pdf** field.
- Click on the **Add new consent form** button to save and add the new form.

Repeat this process for the remaining Surveys added to the e-Consent Framework, including but not limited to: Assent, Assented By, HIPAA Authorization, Text Authorization, or Unsecured Email Authorization.

More information about these forms:

- Email and Text Correspondence with Research Participants
- HIPCO Forms

Quick Tips for Creating REDCap Surveys

You can build and customize your data collection instruments one field at a time to replicate the documents you have developed and had approved by the IRB. As you work in the REDCap Online Designer to create your forms, you may add new fields or edit those that are included in the REDCap template.

- Add a new field by clicking the Add Field buttons.
- Edit an existing field by clicking the edit icon.
- Delete a field by clicking on the delete icon.
- Reorder field by simply dragging and dropping the field to a different position within the form.

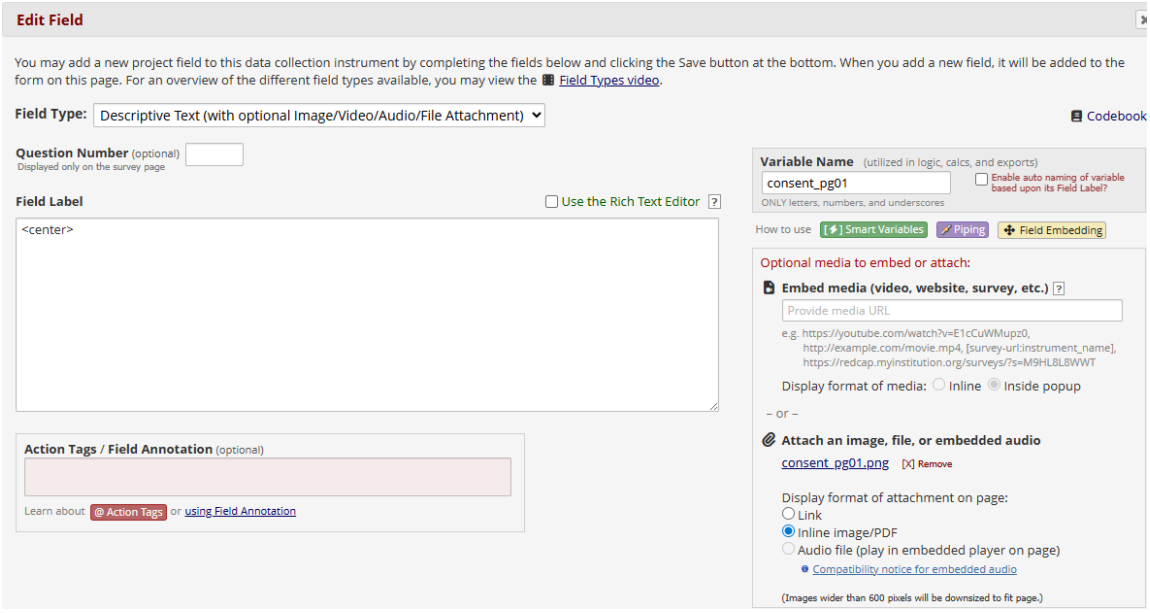
While developing your form in the Online Designer, all changes you make to fields will take effect as soon as you click on the Save button in the Edit Field window.

A very important note before you begin creating your surveys. . .
Because you are developing your surveys in an HTML system, most formatting of your e-Consent documents will not be included in the PDF snapshots, including:

- Bolding
- Changes of text color
- Formatted tables
- Bulleted lists

To incorporate those features, you'll need to:

1. Take a screenshot of the desired feature in your e-Consent document
2. Save it as an image file
3. Use a descriptive text field to display the screenshot image as an **Inline image**.



Accessibility

The REDCap Digital Accessibility Guidance document is available to help you ensure your surveys meet digital accessibility compliance requirements.

Test and Submit Your e-Consent Survey

Congratulations! At this point, you should have created your e-Consent forms, which means you are almost through the e-Consent survey development process. A couple important steps remain:

- Viewing and testing your PDF e-Consent forms.
- Requesting e-Consent project move to production after IRB approval to use REDCap for e-Consent.
- Verifying that you have assigned the REDCap ancillary review within ETHOS.

Review and test your e-Consent forms.

1. In the Online Designer tab, view your PDF documents to review that the formatting and content is actually as you wish.
2. With other members of the study staff, work through your e-Consent process to ensure each document is working properly.
    a. Create a record and ask the study team to pretend to be participants in order to test each survey.
    b. You may want to jump ahead in this guidebook and read through the section “Remote Consent Study Participants”.

3. Use the Online Designer to make any necessary edits to your project.

After your project has been moved to production, any changes to your consent form will require a modification in ETHOS and receive approval for the changes. First, make the updates in tracked changes to the Word version of your consent form and get IRB approval. After approval, you will need to upload the new version of your consent form to match the newly approved Word version. Be sure to update the IRB approval date to match the latest consent effective date. The e-Consent version field is optional because there is no universal versioning standard; feel free to enter a version number that aligns with any departmental or area standards, if desired. These dates are both found in the "Participant Information Form" of the REDCap project. It is the investigator's responsibility to ensure that the e-Consent form is the latest approved consent form in ETHOS.

If you are submitting to an external IRB, you must obtain approval from the IRB to use e-Consent and follow any requirements imposed by them. If the reviewing IRB has questions about compliance or if you need help getting IRB reviewers access to your REDCap forms, you can reach out to the REDCap Administration Team to help resolve questions. Their email address is redcap@umn.edu.

Request to move your e-Consent project to production

After the IRB has reviewed and approved your consent form and you have added the REDCap ancillary review in ETHOS, you may submit your project to be moved to production in REDCap. Please also note that you are required to have completed the e-Consent training in Canvas. Once the move to production has been approved, you will be notified via email. Now you may proceed to consent participants.

Please allow two business days for your project to be reviewed by the REDCap Administration Team. Be sure to budget additional time in the event that changes are needed upon review of the e-Consent setup. The REDCap Administration Team will review e-Consent project using the following checklist:

- ☐ Provided IRB # matches ETHOS
- ☐ Verified IRB Approved specifically for using REDCap eConsent
- ☐ Verified consent version number matches latest ETHOS consent, when any version number is listed in ETHOS
- ☐ Project Setting:
    - ☐ Do not move a project to production if the project purpose is for fun/practice.
    - ☐ Make sure that the "PI" fields are filled out
    - ☐ Make sure that the "IRB number" field is filled out
- ☐ Logging:
    - ☐ If they have continued making changes to the project since they submitted the request to move the project to production then check with them to make sure that they are really ready to move the project to production.

- [ ] If they requested to delete all data and they have been entering data since they submitted the request to move the project to production then check with them to make sure that they are really ready to move the project to production and they really want all of the data to be deleted. You can then close the browser tab and come back after they have responded to your email. (If you notice that the data that they entered said that it was for test then you don't need to check with them.)

- [ ] Survey Login:
    - [ ] Survey Login is enabled, and
    - [ ] Uses the login_code field and
    - [ ] should be applied to "Only selected surveys (set on Survey Settings page)".
- [ ] e-Consent survey settings:
    - [ ] "Enforce 'Survey Login'? option in survey settings set to Yes.
    - [ ] The survey confirmation email should NOT use change-me@umn.edu as the "From" email address.
    - [ ] Ensure that the "Include PDF of completed survey as attachment" is checked.
- [ ] e-Consent Framework Settings for each survey:
    - [ ] Check to make sure that "Allow e-Consent response to be edited by users?" is unchecked.
    - [ ] Verify the version includes the IRB effective date.
    - [ ] Check to make sure that there is a signature field selected under "Force signature field(s) to be erased if participant clicks Previous Page button while on the certification page"
- [ ] Consented By (and Assented By, if applicable) survey settings:
    - [ ] Check to make sure that "Allow e-Consent response to be edited by users?" is unchecked.
    - [ ] Check to make sure that there is a signature field selected under "Force signature field(s) to be erased if participant clicks Previous Page button while on the certification page"
    - [ ] The survey confirmation email should NOT use change-me@umn.edu as the "From" email address.
    - [ ] Ensure that the "Include PDF of completed survey as attachment" is checked.
- [ ] ASI:
    - [ ] Should NOT use change-me@umn.edu as the "From" email address.

Consent Study Participants

The instructions in this section will walk you through the process of implementing e-Consent remotely with study participants using the REDCap surveys. **These instructions assume that it is the adult participant completing the e-Consent and not an LAR or parent or witness**.

You should confirm with the participant that they:

1. Have a device that is capable of handling REDCap e-Consent, such as a smartphone, tablet or computer, in a location where they feel comfortable discussing the details of their possible participation in the study.

Complete the Participant Information Form

You will typically complete this step before you actually are communicating with and consenting the participant.

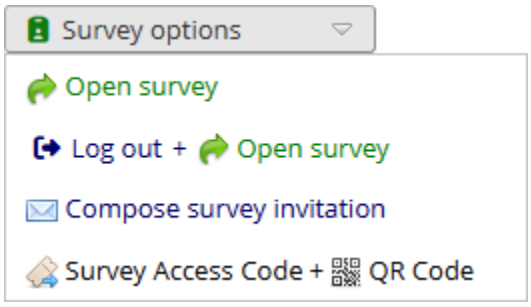
1. In the **Data Collection section** of the left navigation bar on your project home screen, click **Add/Edit Records**.
2. On the **Add/Edit Records** screen, click the green button **+Add new record**.
3. You'll arrive at the **Record Home Page**. This screen displays the form-by-form progress of data entered for the current record. You may click on the colored status icons to access that form. Click on the icon for the Participant Information Form.
4. Complete the **Participant Information Form**.
    a. Confirm or select the **Consent version**.
    b. Confirm or fill in the **IRB Number**, if applicable.
    c. Confirm or fill in the **IRB Approval date**, if applicable.
    d. Enter the **First Name** and **Last Name** of the participant.
    e. Enter the **Email address** to which the e-Consent survey should be sent.
    f. Select: **The Adult Participant**.
    g. Select: **In Person** for when the participant is physically present to give consent, **Remotely** when consenting the participant from a separate location.
    h. If consenting the participant from a separate location, the system will ask: **Do you want to send the participant the consent form?** Select: **Yes.**
    i. Enter a code into the **Login code** box. Your study team can create your own coding system, but must ensure that each participant is given a unique login code.
    j. In the yellow and green **Form Status, Complete?** field, set the box to **Complete**.
    k. Click **SAVE & Exit Form**.

Consent the Participant

Two options based on whether the participant is consenting remotely or in person:

- Remote consent: Now that you've completed the participant's information form and asked the system to email the participant a survey link if done remotely, they will receive the emailed invitation , including instructions and a link to open the e-Consent survey.

- In Person consent: You will have to open their e-Consent survey manually. To do this, open the e-Consent instrument for the record and click on survey options within the survey.



With either option, the participant must enter the login code you have entered into the Login code field in order to open their survey. The code must be unique within the e-Consent project for each participant. **This is the second part of the authentication process that is required for 21 CFR Part 11 compliance of the REDCap e-Consent.**

Important Note:
Never have a participant's consent instrument open on your computer or tablet while the participant is completing the survey. This can lead to you accidentally over-writing their responses with the blank fields that are shown on your screen.

Using your original e-Consent form (on your computer or tablet, or a printed copy), confirm that the participant is ready to complete the e-Consent survey.

1. Walk the participant through the e-Consent document, ensuring that they fill out all of the fields, that they understand what they need to understand about the study, and answer all of their questions.
2. (Optional) If assessing the participant's capacity to consent, also have that form in front of you.
3. If they consent, have them sign their name, enter their name, and click **Now** for the **Date** field.
4. After they have completed the e-Consent, refresh the **Record Home Page** for their record. You should now see a green circle with a checkmark in it for their e-Consent survey.
5. If consenting the participant remotely, you must now click the button next to **Consented By**.
    - In the **Consented By** survey, select **Open Survey** from the Survey options drop down list at the top. Fill out this form while it is open as a survey to successfully complete the e-Consent process. Doing so will automatically:
        i. Save the PDF to the PDF Snapshot Archive
        ii. Send an email with a copy of the **Consented By** document with your signature to the participant.
        iii. When you return to the **Consented By** instrument after closing the survey page, please select to **Leave without saving changes**.

- **Note:** Each consent signed requires an associated **Consented By** survey completion. For example, if there is an assent and consent form signed, there should be one **Consented By** form and one **Assented By** form completed as well.

For additional questions about e-Consent in REDCap or REDCap questions in general, contact redcap@umn.edu.

For regulatory questions, contact: umncrsc@umn.edu.