C. Kenneth and Dianne Wright Center for Clinical and Translational Research

VCU REDCap eConsent Guide

REDCap®

This document provides a step-by-step guide on implementing the REDCap eConsent framework.

Please note that VCU IRB approval is required prior to developing and implementing the REDCap eConsent process.

It is intended that users of this guide have basic REDCap platform knowledge with experience designing and configuring REDCap projects.

HELP GETTING STARTED

To obtain technical assistance developing your REDCap eConsent project, please submit a *support request* and the Wright Center Informatics team will contact you.

SELF SERVICE RESOURCES

VCU HRPP Information

- OVPRI Blog
- VCU HRPP Policies & Guidance

REDCap Training

- Research Portal
- VCU REDCap YouTube Channel
- General FAQs

EMAIL REDCap SUPPORT

You may email redcap@vcu.edu for general REDCap questions.

INTRODUCTION

Obtaining informed consent electronically is an increasingly important capability for clinical research. The VCU IRB has released guidance (informed consent) that provides definitions and requirements for implementation of systems that support electronic consent (eConsent).

The Wright Center and the VCU Human Research Protections Program have worked collaboratively to develop REDCap-based eConsent templates and guidance to facilitate development of an eConsent process for either in-person or remote consent of research participants.

REDCap eConsent functionality ((IRB Guidance for Using REDCap Electronic Informed Consent) is intended for studies that **will require a signature** and are **not** FDA regulated (21 CFR Part 11). REDCap eConsent is **not** for use:

1. with studies conducted under an IND (21 CFR part 312) or an IDE (21 CFR part 812) or where data is intended to be submitted to FDA in support of a 510K submission. If eConsent is needed for an FDA regulated study the Part 11 DocuSign platform is available.

2. to obtain assent electronic signatures, although the REDCap eConsent may be used to facilitate the assent discussion with children or decisionally impaired adults.

For exempt studies not requiring a signature please refer to the IRB Guidance for Using REDCap Platform for EXEMPT Study Participant Information Sheet.

Using REDCap for eConsent development requires using REDCap survey functionality. Study team personnel build the eConsent using a REDCap eConsent template (strongly recommended) AFTER IRB approval of the consent form and use of REDCap eConsent functionality (IRB Guidance for Using REDCap Electronic Informed Consent).

The Wright Center's REDCap team does not prescribe the consent process. Study teams are responsible for obtaining IRB approval for the consent process and building a REDCap eConsent that is consistent with the IRB approval. The VCU IRB requires final approval of the REDCap eConsent product prior to use.

Depending upon the study requirements for consent, other more advanced features of REDCap may be required. eConsent support services are available through the Wright Center Informatics Request Form.

In order to ensure a successful eConsent implementation, study teams should plan for extended development and testing time, and possibly additional support. In addition to the technical complexities, the eConsent process may introduce some additional regulatory requirements that should be accounted for in planning.

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Disclaimer: *In this document, we will refer to REDCap features and functionality that are common to all survey projects and are covered in detail elsewhere. Functionality and features not specific to consenting will not be described in detail.*

1. VCU'S MODEL FOR eCONSENT SUPPORT

REDCap at VCU is largely a self-service platform. Personnel may review training materials, then build the eConsent project based upon a REDCap eConsent template (starting with a template is strongly recommended) and IRB approval. REDCap assistance via Wright Center Informatics is provided at no cost (8 hours provided gratis). There may be charges for efforts exceeding 8 hours. Self-help videos and FAQs are also available to help guide the REDCap build process.

In most cases, personnel who have basic REDCap survey development skills will be able to use this document to set-up their REDCap eConsent project.

Additional assistance may be needed:

1) for personnel who are new to REDCap and who have never built a survey project.
2) when the consent process is more involved and/or needs additional REDCap features (e.g. Inline popups, comprehension assessments).

2. REDCap eCONSENT FRAMEWORK OVERVIEW

Why is this called a framework?

The REDCap e-Consent Framework is referred to as a 'framework' because enabling this option alone does **not** provide an eConsent process but merely provides the general foundation or mechanism to allow you to provide eConsent to research participants. As the eConsent developer, you must still create the eConsent based upon the IRB approved consent. This framework and available templates allow you to implement your eConsent process by providing standardized tools (certification screen + automatic archival of consent forms as a PDF) while still providing the ability to customize the eConsent per IRB approval.

How does the framework function?

The 'Auto-Archiver + e-Consent Framework' survey (eConsent) option adds two things to the typical REDCap survey process.

1) Before a participant completes the eConsent process, a certification page is displayed which contains an in-line PDF copy of their eConsent responses. Once the participant certifies that all information in the eConsent is correct and the eConsent is submitted, the eConsent is then marked as complete. The eConsent is not considered complete until the participant fulfills the certification step and submits the eConsent.

2) Upon submission of the eConsent, a static copy of the signed eConsent PDF will be stored in the project's File Repository.

How does the signature process work?

With the provided REDCap eConsent templates (Section 6.1.d), participants will 'sign' their consents by entering in their first and last names and utilizing the REDCap 'Signature' field to provide their signature (e.g. stylus, finger, or mouse). However, if not using an eConsent template it is then the survey administrator's responsibility to ensure signature capture using the 'Signature' field feature.

What is eConsent version and type?

eConsent version and type are both free-form text fields whose value will be inserted at the footer of each page in the PDF.

1) Versioning of a consent form is a concept whereby you may give it a number or alpha-numeric designation to represent the current version or state of the form. So, 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).

2) Consent 'type' is optional and is another free-form text field that is just a text label that you might want to display in the PDF footer to signify the type of e-Consent that this survey represents (e.g. adult, pediatric). The type is often used to distinguish between multiple eConsent forms within a project.

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3. USING REDCap to FACILITATE PARTICIPANT eCONSENT

The REDCap templates provided are designed to have many of the components in place to help guide you through the development process. You will need to modify the REDCap template so it is congruent with the IRB approved form.

1. IRB Exempt Studies (no signature required) - please refer to the VCU IRB Guidance for Using REDCap Platform for Exempt Study Participant Sheet.

a. When creating a new REDCap project, a REDCap template is available to assist in the REDCap information sheet build-out.
b. REDCap template - layout for an exempt study information sheet
c. When creating a new project, select the 'Use a template' option. Then choose the Project Template titled **IRB Exempt Study – Participant Information Sheet**

2. Studies requiring a signature for in-person, remote or hybrid consenting. Please note that for remote consenting, the consent process includes a virtual consent session, via phone or video conferencing, for study staff to explain the study to the participant and answer their questions.

    a. VCU IRB guidance:
        i. Guidance for Using REDCap eConsent
        ii. Comparison of Different Methods of Obtaining Consent Signatures

    b. Creating the eConsent project using REDCap Templates: The templates incorporate a participant identity passcode verification process*

        i. **REDCap eConsent Template – Image Based**: A template which displays only inserted images of the IRB approved consent form.

        ii. **REDCap eConsent Template – Text Based**: A template from which the IRB approved consent is converted into individual fields incorporating any additional features (e.g. comprehension, video, definitions).

**** Identity Verification with an Established Passcode:*** *In this approach, an agreed upon passcode is communicated between the participant/participant's LAR and the study team. This passcode is saved as part of the participant's record for verification use at a later time. The participant/participant's LAR at the time of accessing the eConsent form must then enter the passcode which is compared with the stored version entered by the study staff.*

Disclaimer: *Consents and consenting processes that involve re-consenting, accommodating an LAR, and distributing the consent in multiple languages will require additional support.*

4. OVERVIEW OF eCONSENT WORKFLOWS

INFORMATION SHEET – EXEMPT STUDIES NO SIGNATURE REQUIRED	eCONSENT SIGNATURE REQUIRED
• Consent survey link distributed to potential participant • On their own, the participant completes and submits the consent survey • Once the eConsent survey is submitted, a participant can download a PDF copy of their completed eConsent survey	• eConsent link distributed to potential participant • During a consent session with the study staff, either held in-person or virtually, the participant completes the consent survey, verifies the information entered in the eConsent is correct, may download or print the signed eConsent document, and then submits the eConsent • The system automatically saves the PDF copy of the signed eConsent in the project's file repository • Study staff who obtained eConsent completes an eConsent attestation, verifies the accuracy of the information entered, provides their signature and then completes and submits the form • The principal investigator then completes their eConsent attestation and signature and then completes and submits the form • The system automatically saves a PDF of the completed eConsent including all signatures in project's file repository

5. FOUNDATIONAL ELEMENTS - REDCap eCONSENT PROJECTS

User Skills and Requirements

MINIMUM REQUIREMENTS

- Basics training
- Survey training
- Experience building a survey project

RECOMMENDED SKILLS

- Using the rich text editor to format a descriptive text field
- Using action tags
- Using piping
- Familiarity with smart variables
- Familiarity with File Repository
- Experience developing documentation for managing a REDCap project

REDCap Features and Functionality

REQUIRED

- Survey functionality
- Adding survey settings to an instrument
- Determining the survey distribution method
- Managing users' survey related permissions
- e-Consent framework*

DETERMINED BY PROJECT NEEDS

- Survey queue
- Automated Survey Invitations
- Alerts & Notifications

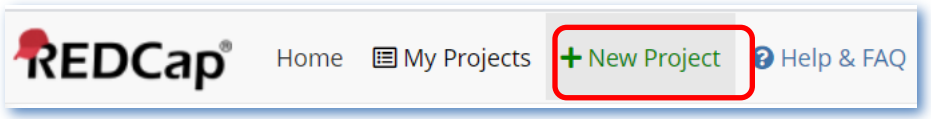
6. BUILDING THE REDCAP eCONSENT – Step-by-Step

The following are step-by-step instructions for implementing an eConsent for studies requiring a signature using the REDCap eConsent framework. Prior VCU IRB approval of the consent form and use of REDCap eConsent framework is required. These instructions assume basic knowledge and experience developing surveys within the VCU REDCap platform.

1. STEP 1: CREATING A NEW REDCap PROJECT

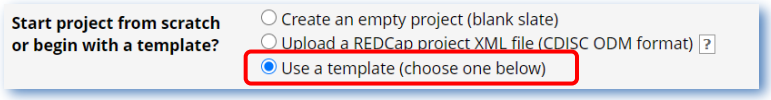
a. Log into REDCap using your VCU eID and PW (redcap.vcu.edu)
   i. If off-campus, a secure VPN connection must be established to access REDCap

b. From the Home page select **New Project** (only faculty and staff may create a new project)



c. Complete the **Create a new REDCap Project** form. Select **Research** as **Purpose of this Project** and provide all applicable information including **IRB** and **OCID numbers**.

d. Select **Use a Template** (strongly recommended)

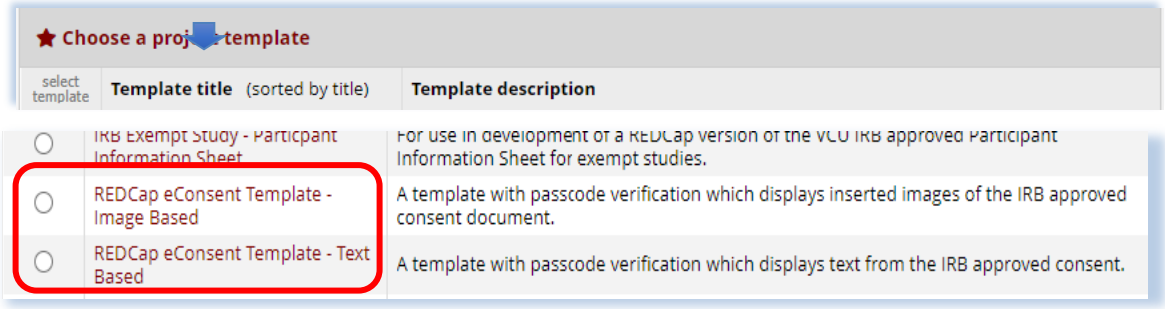


e. Select the appropriate template for your protocol (Information Sheet is for exempt studies only, eConsent templates for those studies requiring a signature with identity verification).
   i. REDCap eConsent Templates:
      a. Image Based:
         i. uses passcode identity verification of the research participant

ii. each page from the IRB approved consent is converted to an image and uploaded into the eConsent
iii. signature capture capabilities (participant, consenter, PI)

b. Text Based:

i. uses passcode identity verification of the research participant
ii. the IRB approved consent is used as the basis for creating the eConsent
iii. signature capture capabilities (participant, consenter, PI)

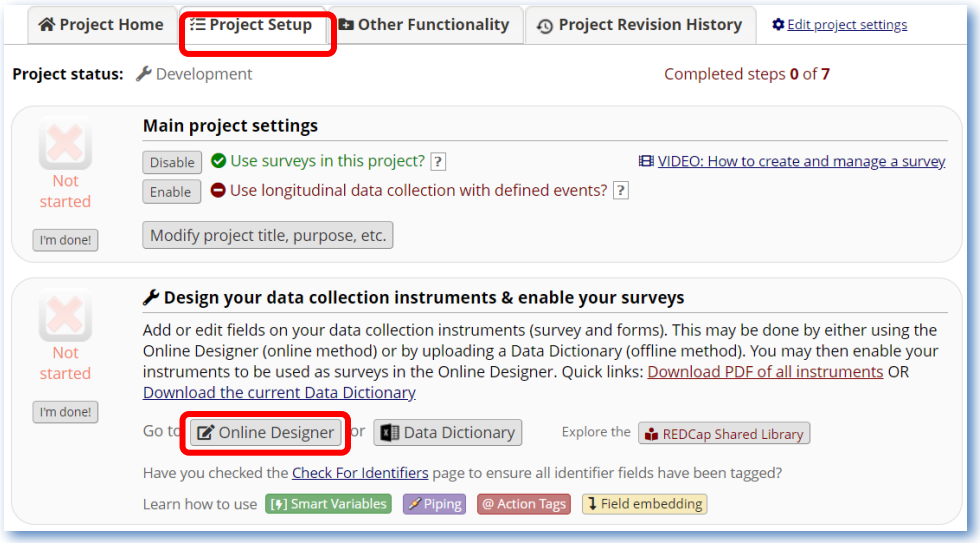


2. STEP 2: MODIFYING A REDCap eCONSENT TEMPLATE

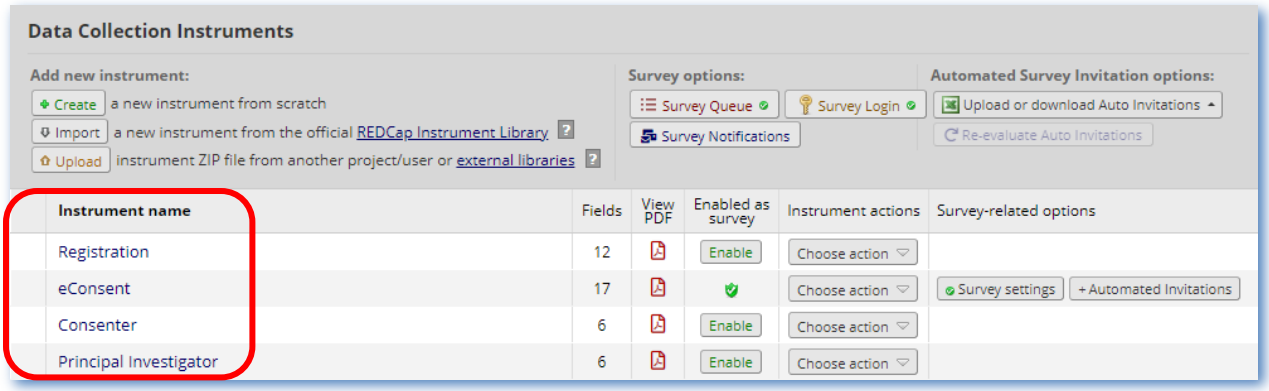
The REDCAP eConsent Templates (requiring a signature) are the foundation for developing the eConsent. **The template is modified to be congruent with the IRB approved consent form and associated processes.**

The following instructions are for <u>both</u> Image Based and Text Based Templates

a. In the **Project Setup** tab click on the Online Designer



b. Within the eConsent template there are four (4) separate "Data Collection Instruments": **Registration, eConsent, Consenter and Principal Investigator**. Details for each instrument are below.



i. **Registration Instrument:**
   a. used to register a potential research participant
   b. a unique passcode is entered for research participant identity verification (REDCap templates ensure unique passcodes for each participant)
   c. eConsent Version - *(note: see Step 4 - the default version must be congruent with the eConsent Survey Settings eConsent Version)*

d. indicate consent status (not initiated, in-person, remote, remove from eConsenting consideration)
    i. in-person consenting (note: see section 7.a and 7.b)
    ii. remote consenting: obtain permission to provide the eConsent link to the participant via email or text

ii. **eConsent Instrument:** research participant centric (*note: see Step 4 for eConsent instrument survey settings for enabling eConsent framework and participant confirmation email)*

a. research participant passcode identity verification
b. eConsent is provided to the research participant for their review and the consenting discussion
c. captures the research participant signature
d. an inline PDF of the eConsent document is reviewed by the research participant and may be downloaded or printed
e. research participant certification that eConsent information is accurate
f. research participant submits the eConsent (final step)
g. following submission of the eConsent, an alert and notification will be sent to the Consenter & Principal Investigator for their signatures (see alert & notification section- Step 4)

iii. Consenter Instrument:

a. Attestation – Allows the consenter to attest to accurately explaining the consent form and answering questions asked by the participant (checkbox).
b. Signature – provides accommodations for the consenter signature
c. Date – Automatically provides the date of attestation
d. Complete, Save and Exit – after providing their signature, the consenter will change form status to complete, then click on save & exit form

iv. **Principal Investigator (PI) Instrument:**

a. Attestation – Allows the PI to attest to obtaining consent as required and that the participant is enrolled (checkbox)
b. Signature– provides accommodations for the PI signature
c. Date – Automatically provides the date of attestation
d. Complete, Save and Exit – after providing their signature, the PI will change form status to complete, then click on save & exit form

3. STEP 3. SURVEY LOGIN

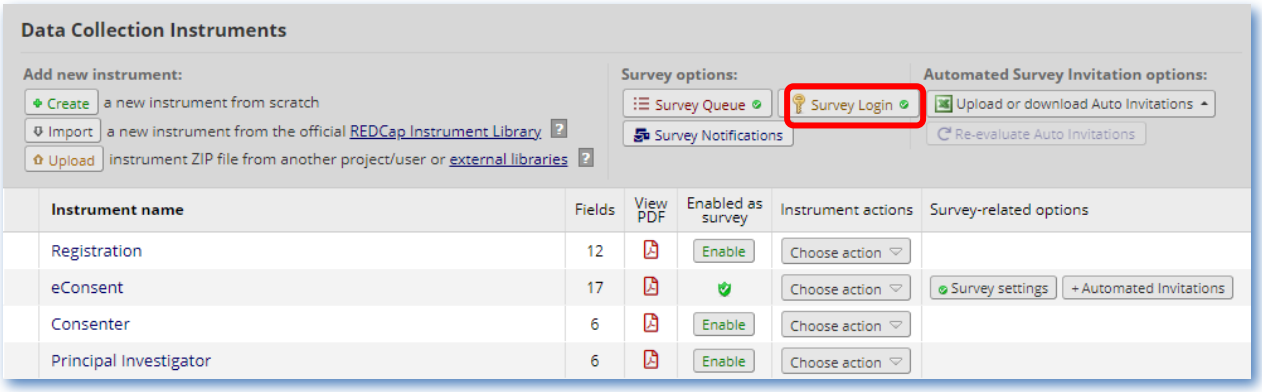
Within the REDCap Online Designer, the Survey Login is enabled to allow participants to verify their identity prior to viewing and completing the eConsent. *(note: this step may be modified when utilizing ONLY in person consent functionality for the entire study – see Section 7.b)*

a. A unique passcode for each potential study participant is predetermined and entered by the study team into the REDCap project database in the ***Passcode field***.

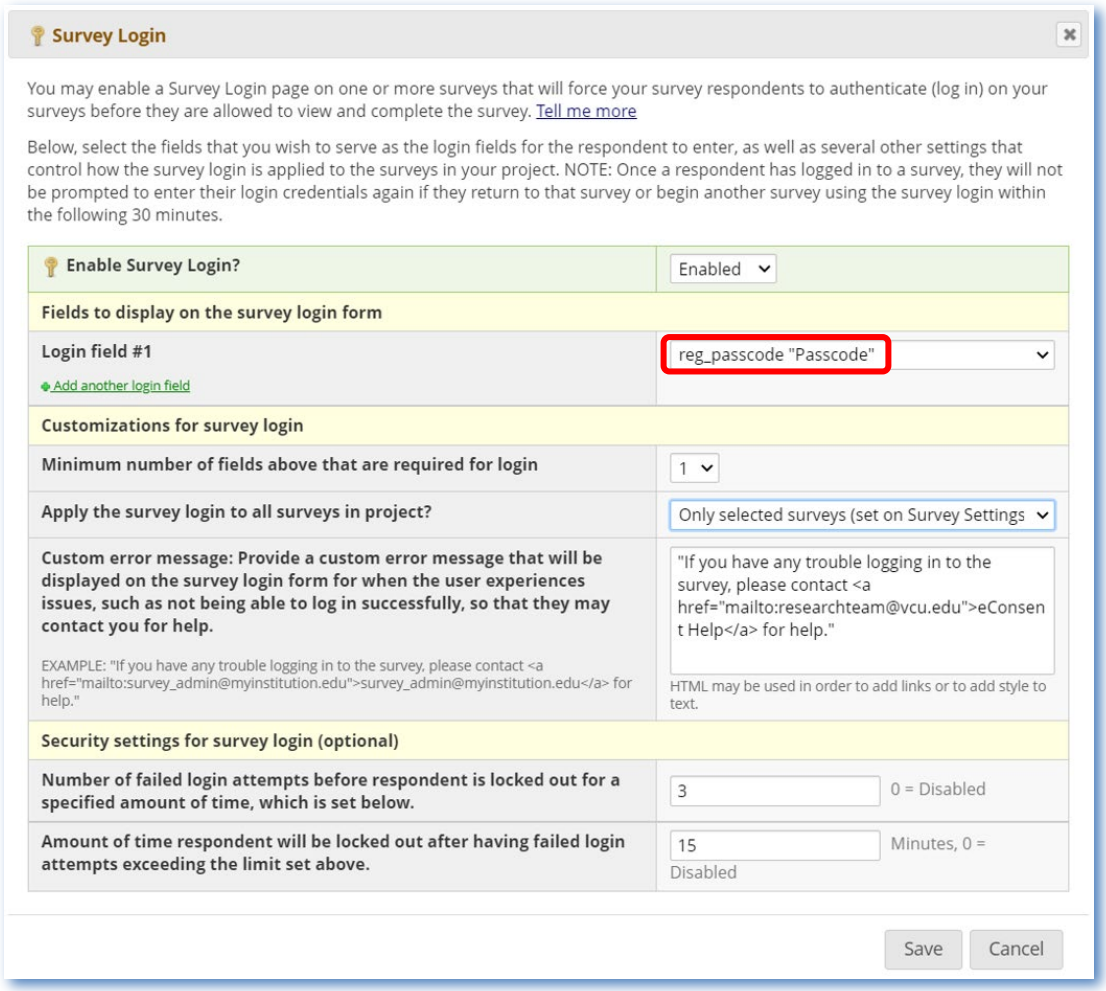
b. The passcode is then provided to the potential research participant (e.g. via email or text) allowing login, thus verifying the identity of the individual being consented.

c. Enabling the survey login feature:

i. Click on Survey Login

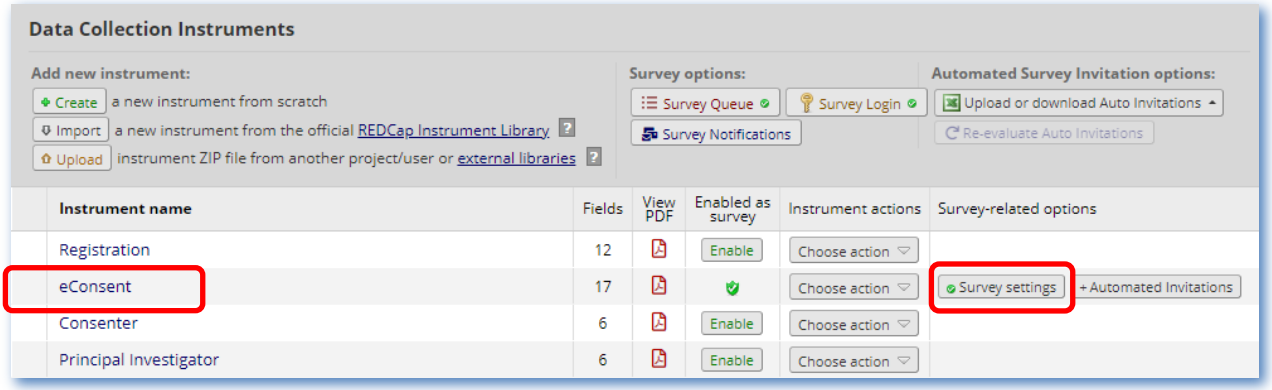


ii. Ensure the survey login features are as outlined below
iii. Security features may be adjusted although it is recommended to retain the templated security features



4. STEP 4. MODIFYING the REDCap *eCONSENT* instrument SURVEY SETTINGS

a. Click on the Survey Settings button associated with the eConsent instrument. The following items must be addressed within each template for the project.



b. Survey Access: enable the Enforce "Survey Login"?

c. Survey Completion Text: Displayed after the eConsent is completed, certified, and submitted by the participant as a thank you or acknowledgement. This field is modifiable although the template text is recommended.

d. Enabling the **REDCap e-Consent Framework -** scroll toward the bottom of the survey settings screen (see below).

i. You **must** select *Auto-Archiver + e-Consent Framework* to enable the REDCap e-Consent Framework.

ii. Do **not** select: *Allow e-Consent responses to be edited by users?*

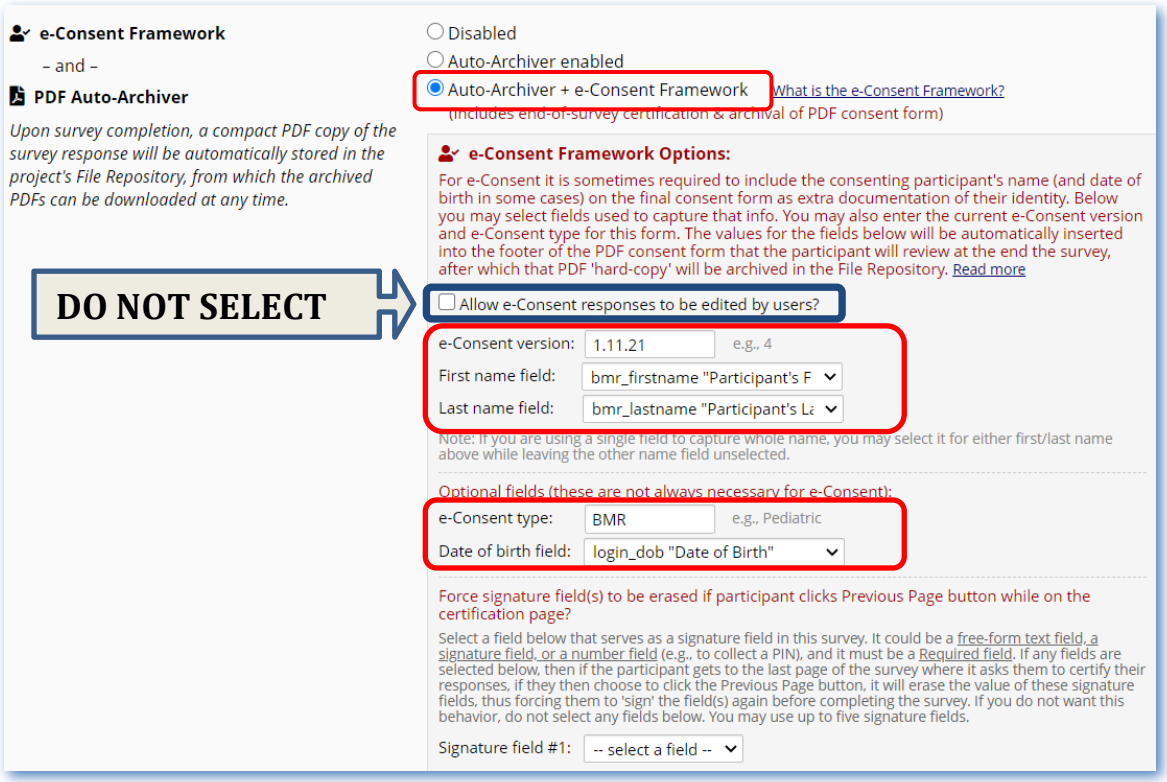
iii. Provide an *e-Consent version* identifier value (e.g. version date or v1.0) – ensure congruency with the Registration instrument consent version selection

iv. Provide the **field names** which correspond to the participants *FIRST and LAST NAMES*

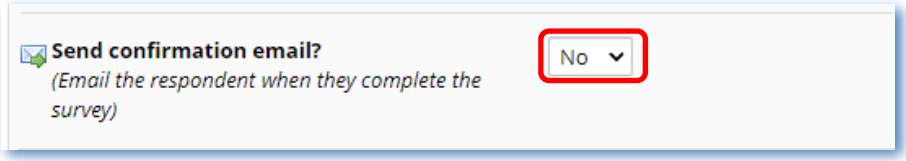
v. Optional fields

1) eConsent Type (e.g. adult, pediatric)

2) Date of Birth field



e. **"Send Confirmation email?"** setting is set to "no" (the participant will receive a confirmation email through the notification settings; see section 5.a.v)



5. STEP 5: CONFIGURING the REDCap ***ALERTS and NOTIFICATIONS***

The REDCap eConsent templates have several alerts and notifications built in for facilitation of the consenting process. The language and settings indicated within the VCU IRB REDCap eConsent Settings Worksheet are the VCU IRB preferred settings and text that will maximize privacy and confidentiality.

Note: the VCU IRB worksheet can be found under the VCU IRB accordion "Consent templates for specific types of studies" - REDCap eConsent settings worksheet; https://research.vcu.edu/forms/ > Consent templates for specific types of studies > REDCap eConsent settings worksheet)

a. There are five (5) eConsent notifications/alerts which have been configured within the template.
    i. **Participant eConsent Email**: used to provide (via email) the eConsent form link via to the prospective participant *(not triggered for in-person consenting).*
    ii. **Passcode Email:** used to provide (via email) the unique passcode to the participant *(not triggered for in-person consenting)*.
    iii. **Send Copy of eConsent PDF:** used only when the participant chooses to receive a PDF copy of their signed eConsent via email (selected within the eConsent).
    iv. **Consenter and PI Email Notifications** *(not addressed within the VCU IRB worksheet)*: this notification sends an email to the consenter and PI that an eConsent has been submitted by a research participant and is ready for the consenter and PI signatures.
    v. **Confirmation Email to Participant:** sent via email upon completion, certification, and submission of the eConsent providing research study team contact information.

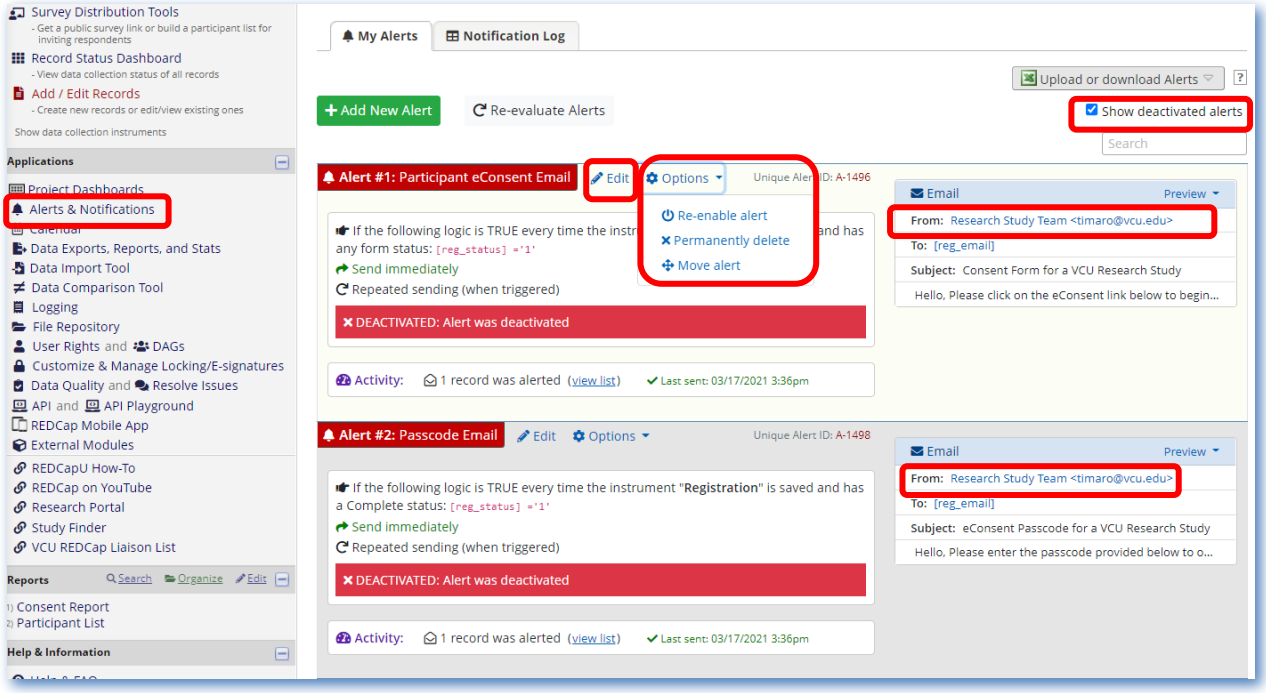
b. **Activation of Alerts & Notifications:** When utilizing the REDCap eConsent templates, alerts & notifications must be re-enabled (see images below).

    i. Select Alerts & Notifications under Applications in the left side panel,
    ii. Select "Show deactivated alerts" to show the preset alerts (upper right),
    iii. Select "options" and "re-enable alerts" to show preset alerts

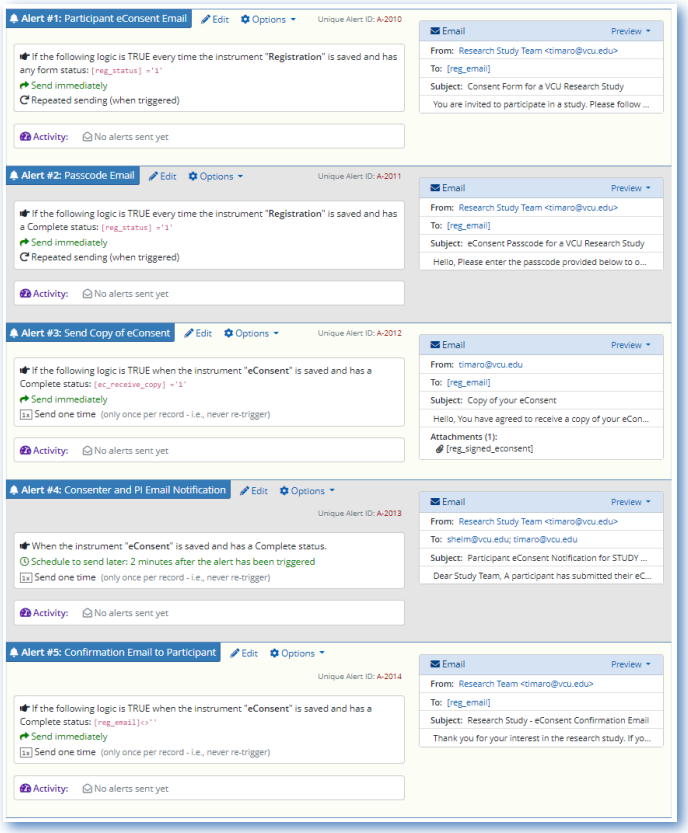
iv. **<u>Each alert must be re-enabled and edited appropriately</u>**

a. Modify the "Email From:" within each alert to the appropriate research team email address
b. Update the study contact information in the email message in the relevant alerts.
c. No study specific information should be incorporated in the subject line and body of the email per IRB guidance (template language is recommended).

*Note: Regarding in-person consenting, the Participant eConsent Email and Passcode Email alerts are **NOT** triggered when the in-person option is selected within the registration instrument.*



5 Alerts Now Activated and Ready to Configure



6. STEP 6: FINAL STEPS

a. Thoroughly test your eConsent process with your study staff to ensure it is functioning as intended.

a. Download a PDF of the REDCap eConsent form that you will add to your IRB submission in the RAMS-IRB amendment submission indicating that you have created an eConsent in REDCap that mirrors the IRB-approved consent form.

b. **After the eConsent framework is built in REDCap, submit an amendment in RAMS-IRB with the IRB required worksheet completed and the final eConsent materials as the participant will see them for IRB approval**:

   i. For the consent information and interactive elements, these may be submitted as an uploaded PDF, screenshots, a video walkthrough, or other type of documentation.

   ii. The IRB will not accept solely a weblink to the eConsent.

   iii. The IRB must maintain documentation of all consent versions that are approved, so the final eConsent materials need to be submitted as an upload.

iv. In addition, provide screenshots and/or other documentation for obtaining signatures.

c. After IRB approval, the REDCap eConsent may be implemented.

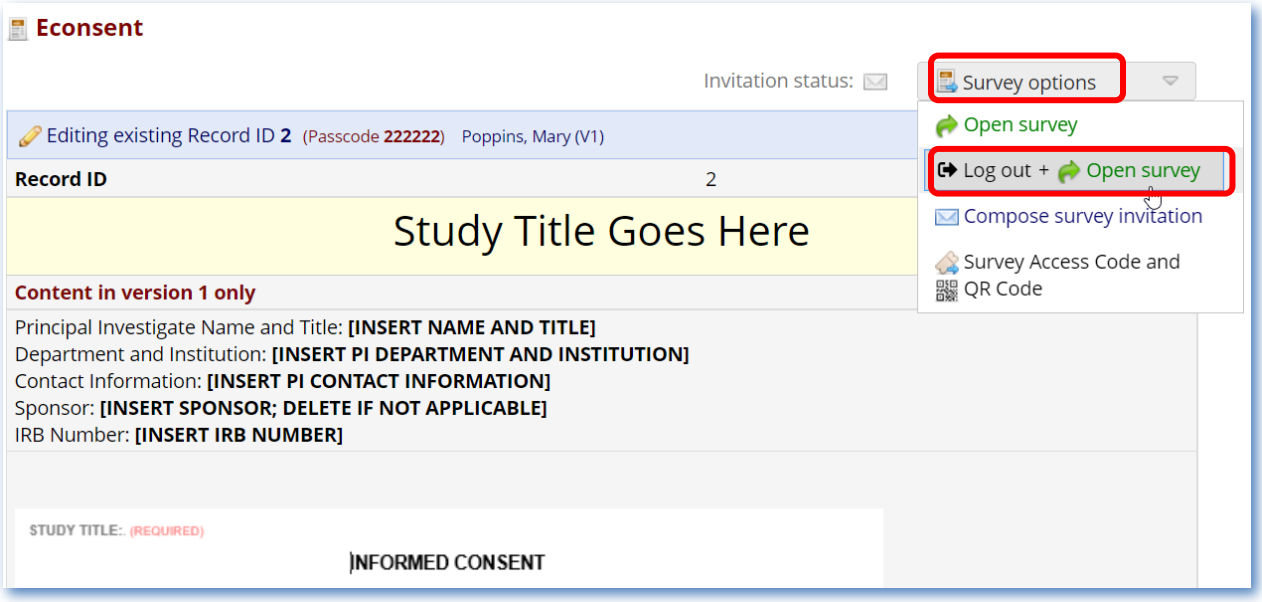
7. ADDITIONAL TIPS

1. For in-person consent using the REDCap eConsent framework:

a. The consenter will open the REDCap project on their device,
b. Complete the **Registration Instrument** for the participant to be consented (**Add new Record**)
c. Enter all required information in the **Registration Instrument (including a unique passcode – *see section 7.b for customization of studies utilizing ONLY in-person consenting*)**
d. Select "**In-Person**" under Status
e. Select **"Identity has been verified"**
f. Select "**Complete**" under Form Status
g. Select "**Save & Go to Next Form"** under Form Status

h. Under the **Survey options** dropdown (upper right, see below), select

i. **Log out + Open Survey**" (the consenter must be logged out prior to having the participant complete the eConsent)



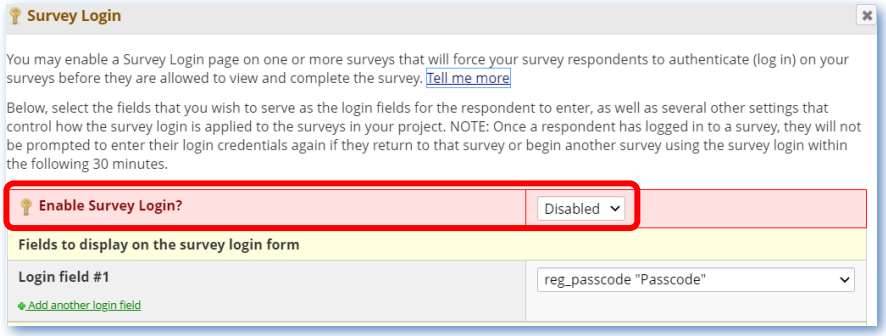
j. The **eConsent** opens as a survey in a new tab
k. **Close the database tab**
l. Enter the participant's unique Passcode to login
m. Ensure **ONLY** the eConsent is accessible and viewable by the participant
n. Review the eConsent with the prospective participant and should the participant choose to participate in the study, the participant will complete the eConsent (sign, review the online eConsent PDF, certify the eConsent, and submit).

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

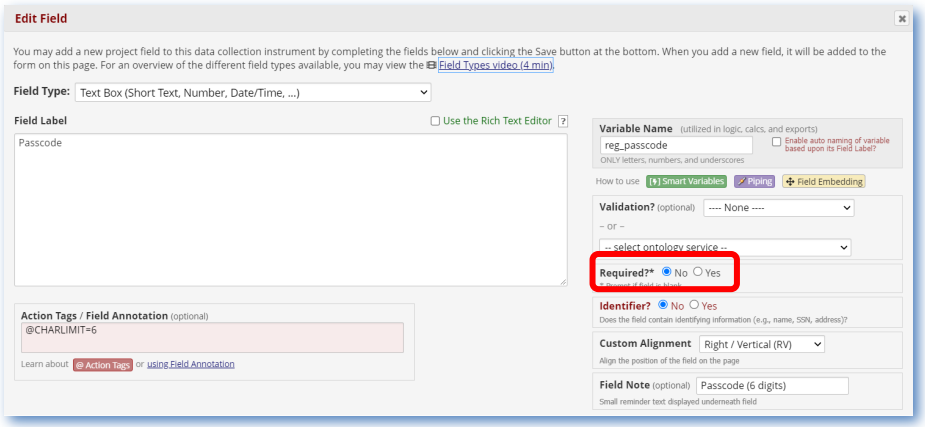
2. Customizing the eConsent template for studies utilizing in person consenting only:

This customization will omit the passcode and survey login features necessary for remote consenting. Use this customization for studies which will exclusively utilize in-person consenting (no remote consenting). All other steps for in person consenting (see section 7.a) remain the same.

a. Disable survey login



b. Change the Passcode field to not Required (Required? = No)



3. Customizing the eConsent template for comprehension and information:

There are other ways you can customize your consent form to ensure participant comprehension and provide additional information.

a. Insert pictures and videos. If there is a procedure or data collection instrument you want participants to understand, inserting pictures and videos can be a good way to increase comprehension.

   i. To insert pictures or videos, use the "Descriptive Text" field with the "Optional file attachment" features.
   ii. Several videos explaining common medical procedures are available from the STRIDE Project for use within the RECap eConsent: https://www.youtube.com/channel/UCKOqWFdtVU7XsxWs2fpfvNQ
   iii. Study-specific videos must be uploaded to the RAMS IRB amendment worksheet for final IRB approval (provide the weblink to the video if it cannot be uploaded).

b. Comprehension Questions: Utilization of REDCap's branching logic may be helpful to create comprehension questions to confirm participant responses, direct participants to the relevant information within the eConsent form and assist study teams in determining participant comprehension or areas which may be more confusing for participants.

c. **REDCap External Modules:** Please contact the Wright Center Informatics team for assistance with these modules.

   i. Inline Descriptive Pop-ups (hover and click): allows additional or supplemental information to be provided to the participant. Words or phrases may be specified within the eConsent form to appear as a highlighted link that will display a pop-up of descriptive text when the cursor moves over the specified word or phrase.
   ii. Analytics module: used to capture metrics about how a participant interacts with the eConsent features.

8. REFERENCES & RESOURCES:

- Lawrence, C., Dunkel, L., McEver, M., Israel, T., Taylor, R., Chiriboga, G., . . . Harris, P. (2020). A REDCap-based model for electronic consent (eConsent): Moving toward a more personalized consent. *Journal of Clinical and Translational Science, 4*(4), 345-353. doi:10.1017/cts.2020.30

- VCU IRB REDCap eConsent settings worksheet: This worksheet is to be completed and included in an IRB submission proposing to use REDCap's eConsent templates.

- VCU IRB Guidance on REDCap for eConsent can be found under the "informed consent" accordion on the HRPP's Policies and Guidance page.

- Several videos explaining common medical procedures are available from the STRIDE Project for use within the RECap eConsent: https://www.youtube.com/channel/UCKOqWFdtVU7XsxWs2fpfvNQ

- For assistance configuring the REDCap eConsent templates, submit a research support request to the Wright Center Informatics team.