

## Building an E-Consent Documentation Tool using REDCap

Use this tip sheet as a guide to help you build a REDCap e-Consent project.

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### What is e-Consent?

E-Consent is a technology-driven process that allows an investigator or study team member and prospective research participant to accept and sign an informed consent document electronically.

There are two types of e-Consent:

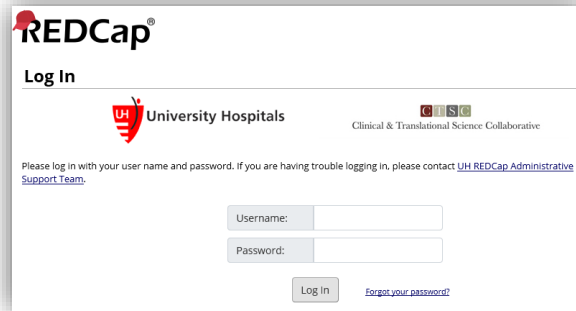
1. **Same location** (i.e., consenter and participant are in the location, but using technology to facilitate the informed consent process and electronic signing of the informed consent form)
2. **Not in the same location** (i.e., consenter and participant are not in the same location and are using technology to facilitate the informed consent process and electronic signing of the informed consent form).

**NOTICE:** if you are collecting data for the purposes of human subjects research, the UH Institutional Review Board requires review and approval of the project **prior** to the collection of the data.

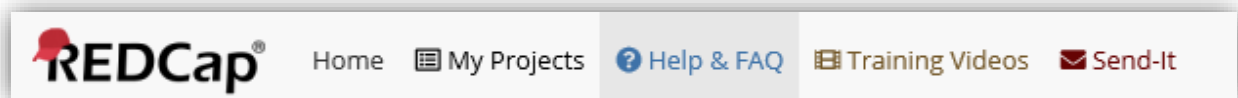
## Getting Started with REDCap

**\*\*Please note: REDCap is NOT 21 CFR 11 compliant.**

1. If you are interested in using REDCap to facilitate the e-consent process for your study, please complete the following form to request a new project [HERE](#).
2. Log into REDCap with your UH user name and password [HERE](#).



3. To request a demo or initial consultation, please email: [REDCap@UHhospitals.org](mailto:REDCap@UHhospitals.org)
4. To view training videos, click [HERE](#).
5. For help and FAQs, click [HERE](#).



## Building an e-consent in REDCap

1. To request a copy of the project from the REDCap Administrator:
  - a. Submit a [new project request](#).
  - b. Complete all fields in the form.
  - c. To the question that asks “**Would you like this project to be an Empty New Project, a Copy of Existing Project, or based off a Template?**” select **Copy**
    - a. Title of the project you will want a copy of is: “**UH e-consent Template**”
  - d. In the “**Provide any additional information here**” section, copy and paste the following language:

I am requesting a copy of the “UH e-consent Template” project with no existing users or data carried over. Please enable the external module for Multi-Signature Consent and retain the settings for the project.

2. After you have received your requested project copy from REDCap Administrator, [log in to REDCap](#) and select the new project from **My Projects**.
  - a. The **Project Setup** page will open with a menu ribbon on the left.
    - i. Project status will reflect “**Development**”. Completed steps status will reflect “**0**”.
  - b. From the Project Setup tab, you will be able to add users to the project and assign rights and permissions, test your project, and move your project to production status so that data may be collected.

c. Start with **Modify project title, purpose, etc.** Complete the fields below:

Project status: Development Completed steps 0 of 8

**Main project settings**

Not started

Use surveys in this project? [VIDEO: How to create and manage a survey](#)

Use longitudinal data collection with defined events?

d. In the pop-up, enter the PI name, IRB number, and project short name in the **Project title** field.

Modify Project Settings ✕

**Project title:**

**Project's purpose:**  
*How will it be used?*

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

e. Select **Research** from the **Purpose of this project** dropdown.

i. **Tip:** Complete ALL fields with the exception of the field for publications unless it is known. REDCap administrators will find the information helpful in locating the proper project if trying to resolve any issues you might encounter down the road.

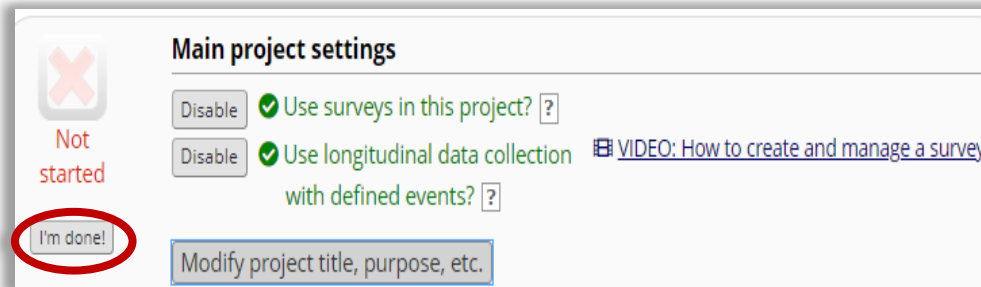
ii. When you are done, Click **Save** to return to the **Project Setup** page.

3. Click on **Enable** next to **Use surveys in this project?** to Enable surveys

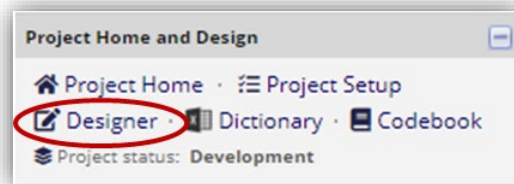
**Main project settings**

Use surveys in this project?

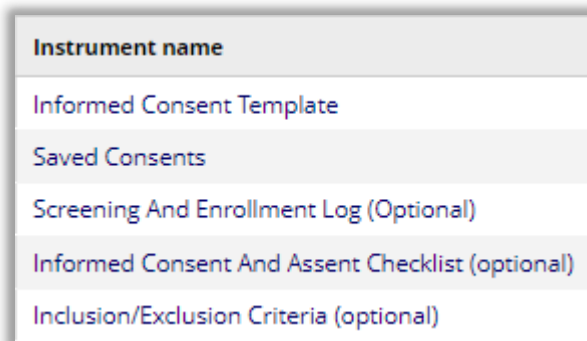
- a. If you are ready, click **I'm done!** to move on to the next item.
- 4. If part of the IRB approved plan states that the consentor will not be in the same place as the participant during consent, then under **Applications** select **External Modules**
  - a. Confirm that the **Multi Signature Consent** module is in the project (configuration will occur after the consent form is ready for approval)



- 5. Select the **“Online Designer”** tab under **“Project Home and Design”** tab on the left to begin designing your data collection instruments



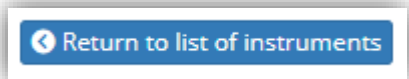
- a. You will notice that there are two main forms listed as instruments, three additional instruments are optional:



i. **Main Instruments**

- 1. **Informed Consent Template:** Main instrument you will use for your project. Ensure that it is enabled as a survey (green shield with a checkmark).
  - a. Once your study and informed consent form are approved copy and paste all text from your paper form into the Informed Consent instrument.

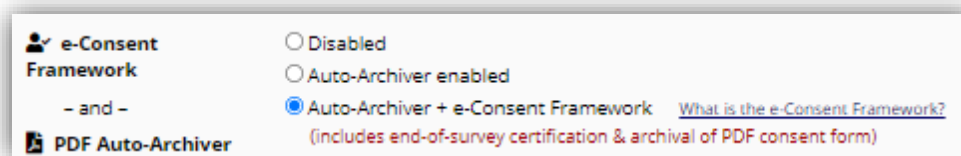
- b. Section headers are in yellow
  - c. Corresponding information sections are in a greyish/brown box
  - d. Remove any information that is not approved by the IRB in the paper consent form
  - e. You will notice that numerous signature types are present in the form, if they are not approved in your paper consent document, select the red “X” to delete inapplicable signature, corresponding printed names, and date/time lines.
2. **Saved Consents:** Important depending on the type of e-consent you are doing.
    - a. **Note:** Paper version of the informed consent form must be approved before inputting electronically.
- ii. **Optional Instruments**
    1. **Pre-Screening Log:** Helps design screening and enrollment log.
    2. **Informed Consent and Assent Checklist** (also available in the Clinical Research Toolbox)
    3. **Inclusion/Exclusion Criteria** (also available in the Clinical Research Tool box)
- b. Open the instrument titled “**Informed Consent Template**” and the approved pdf version of the paper consent document
6. Copy the information verbatim from the approved paper informed consent document into the appropriate section
    - a. **Note:** Only keep signature fields that have been approved by the IRB on the original Informed Consent Document
  7. Once all of the information has been input to the informed consent template, select “**Return to List of Instruments**”



- a. Check to ensure the informed consent instrument is enabled as a survey. Click “**Survey Settings**” for Initial Informed Consent document



- b. Next, scroll down until you see “**e-Consent Framework**” and “**PDF Auto-Archiver**”
  - i. Ensure that the third radio button next to “**Auto-Archiver | e-Consent Framework**” is selected



- c. Under “**e-Consent Framework Options**” update “**e-Consent version**” the first time you set up the e-consent document and each time you submit a continuing review or need a new version of your consent form
  - i. In “**First name field**” select “**Printed Name of Participant**” in “**Consent**”

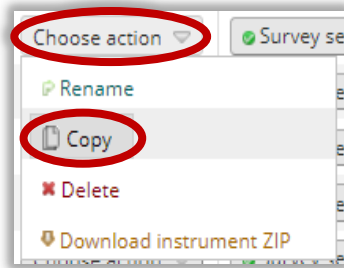
- ii. First and last name are saved in the same field so you do not need to complete the “Last name field”
- iii. The “Allow e-Consent responses to be edited by users should never be checked/turned on

- d. Under the section titled “**Optional fields (these are not always necessary for e-Consent)**” within the e-consent framework and PDF archive settings:
  - i. “**e-Consent type**” it is not required for the e-consent framework to work in REDCap however it is strongly recommended to help to clarify the documents in the file repository (if it is the consenter’s form type in “consenter”, or participant’s form type “participant”)
    - 1. This section is recommended to be filled out when e-consent is being conducted completely virtual and multiple instruments are being used for individual signatures.

- e. “**Force signature field(s) to be erased if participant clicks Previous Page button while on the certification page?**” - Select the signature field associated with the consent and the printed name field. In the general consent, multiple signature fields can be selected
  - i. **Note:** This is strongly recommended to be used.
- 8. Next to “**Send confirmation email?**” select “**Yes**”
  - a. Check the box in front of “**Include PDF of completed survey as attachment**” so the participant will receive a copy of their signed consent.
  - b. Make sure to select the appropriate person to whom the email will be sent from
  - c. **Save** changes
  - d. Template for after consent is signed:
 

“This completes the informed consent e-signature process. Please download a copy of your signed version of the consent for your records.”
- 9. Once the Main Consent Template is complete, if you are going to consent completely virtually, copy the main consent template for each type of signature that is present (consenter, participant, possibly witness/lar, etc.)

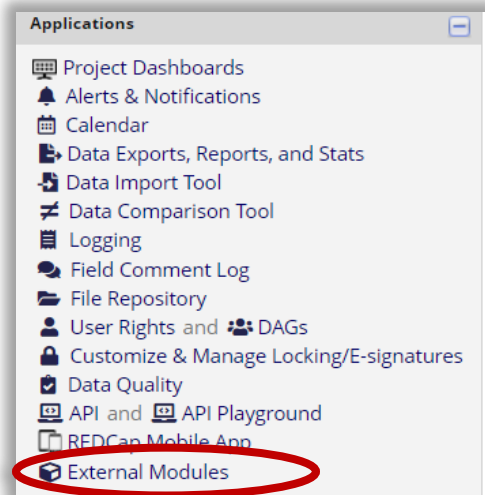
- a. To copy the template select “**Choose action**” drop down and then copy



- i. The new instrument name should reflect the type of signature that will be present on the document
- ii. For the “**suffix appended to variable names:**” also add the consent signature type in the instrument
- iii. Select **Copy Instrument**
- iv. Enter the new instrument and delete all but the signature and date/time lines from the instrument
- v. Repeat steps i-iv for each type of signature (i.e. participant, consenter, etc.) specific consent that is required
- vi. In the Consenter and Witness/LAR REDCap forms - if the consent document contains check boxes, in the corresponding REDCap form field add the Action Tag “@HIDDEN-SURVEY” and mark as not required. This hides the option for the Consenter and Witness/LAR. (The Participant should be the only person making a selection of options in the consent form.). Only the participant should be making a selection of options in the consent form.

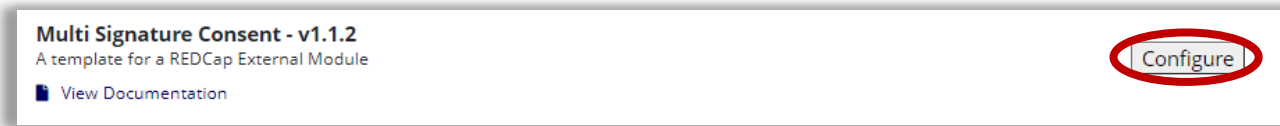


- b. Once all consent documents have been copied in and completed, configure the external module



i. Open the External Module under **Applications**

1. Click **Configure** to the right of the screen



2. Select the instruments to merge (each single signature-specific consent should be selected as its own form)
3. The **File** field will be the field in the saved consents form that the document will be merged into
4. Notice the logic must be filled out before this will work (this is why the consenter must always be the last to sign)

The logic will be:

`(([name of participant informed consent instrument_complete] = "2") AND ([name of consenter informed consent instrument_complete] = "2"))`

**Update Logic**  
When this logic is true and one of the above forms is saved, then create the PDF. This logic should not be true until all forms are complete:  
*\* must provide value*

```
[[informed_consent_template_consente  
r_version_1_appr] = "2") AND  
[[informed_consent_template_participa  
nt_version_1_ap] = "2")
```

- i. This generally states that the documents will be merged once the consenter survey is marked as complete AND the participant survey is marked complete. If you do not know the name of the consenter survey, open the data dictionary which will have the name of the survey that you want to place in brackets
- b. Make sure that these boxes are checked:
  - i. **Keep Page Breaks**
  - ii. **Keep Record ID Field Row**
  - iii. **Save in File Repository- this is required to use this e-consent template at University Hospitals**

<b>Keep Page Breaks</b> Normally page breaks between forms are removed. Check here to keep each form on a separate page in the PDF:	<input checked="" type="checkbox"/>
<b>Keep Record ID Field Row</b> The record id is always in the header, but if you check this it will also be part of the PDF if on the first instrument:	<input checked="" type="checkbox"/>
<b>Save in File Repository</b> Check to save a permanent copy in the local file repository:	<input checked="" type="checkbox"/>
<b>Save to External Storage</b> Check to save a permanent copy in the external storage (the same location that is configured for the econsent module):	<input checked="" type="checkbox"/>



- c. Make sure “**Save as This Survey In File Repository**” is selected and marked as the instrument titled “**Saved Consents**”

**Custom Header**

This header will appear in the upper-right corner of the PDF:

combined consent

- d. A custom header can be used, but not required

**Save As This Survey In File Repository**

If you check the previous option, set which survey you want this to appear as in the File Repository. If you are using the eConsent Framework on one of the surveys in this config, then be sure to select a different survey as you can only have one entry per record, per survey id in the File Repository. Will default to first form otherwise:

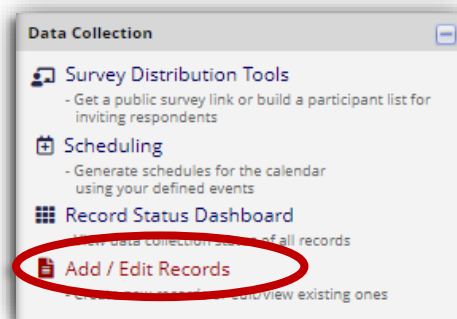
saved\_consent

## How to Consent Using the REDCap e-consent - Completely Virtual

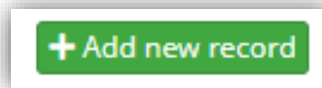
- The steps below must be followed in order, or the e-consent will not merge properly in the end.
- Remember, the REDCap project **instruments must be IRB approved** to use the REDCap e-consent prior to consenting participants with it.
- **Note:** Consenting using e-consent is no different from consenting using a paper version. The same Informed Consent process applies!
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### Consenting using REDCap's e-consent project

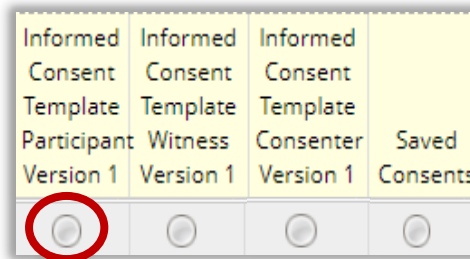
10. Open the e-consent project in REDCap once you are in a quiet space to discuss the consent with the potential participant.
11. Create a new record in REDCap:
  - a. Under the **Data Collection Tab** on the left side of the screen select **Record Status Dashboard** or **Add/Edit Records**.



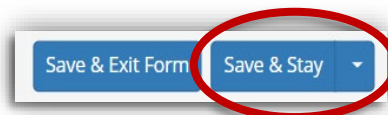
- b. Select the green button labeled “Add new record”



12. Select the radio button next to Informed Consent for Participants to sign.



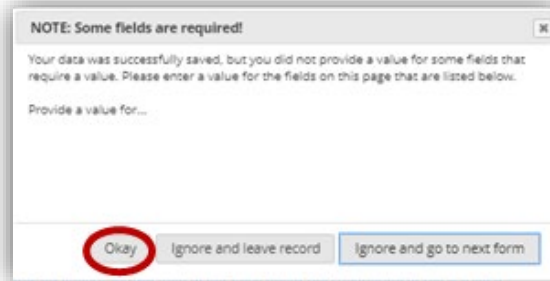
13. Scroll down and enter in the **Contact Information** of the person obtaining consent.
14. Select “Save & Stay”



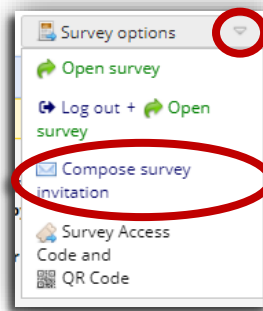
- c. If the “Save & Stay” option does not appear select the pull-down arrow and the option will be available

15. Then click **“Okay”** to the pop-up dialog box.

- d. This pop-up signifies that one or more required fields do not have a response filled in. These fields should only be filled out by the participant, NOT the consentor, and should be left blank for when the participant fills and signs the consent



16. At the top, click **“Survey Options”** and select **“Compose survey invitation”**



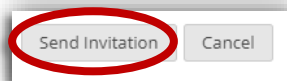
17. Fields:

- e. Type in the **participant’s email address**,
- f. Select **who the email will be coming from**,
- g. **Subject and body**: IRB approved subject and email body.

**Template for initially sending the redcap e-consent survey to a potential participant:**

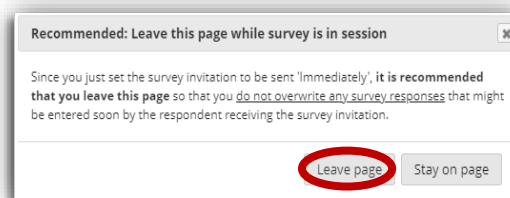
“Please open the informed consent document for the study (INSERT SHORT TITLE) using the link below.”

18. Click **“Send Invitation”**



19. A dialog box will appear, select **“Leave Page”**

- h. The participant cannot sign the survey if you are still on the page.



- i. Then the consentor should open the consent from the survey invitation.

20. The consentor should open the pdf version of the consent form to review the consent form with the participant.
21. Once the consentor has read over and reviewed the consent with the patient, the patient can be asked if they would like to sign the consent to become a participant in the study.
22. Once the participant is ready to sign, have them sign their informed consent document (REDCap survey) first.
  - j. Check REDCap (refresh the page) to ensure the survey was completed (a green check mark will appear next to the instrument)
23. After the participant has completed the survey signature, the person obtaining consent can sign the consent. Refresh the main redcap page and confirm a green check mark is in the participant radio button prior to the consentor signing the consent form.



- k. It is important that the person obtaining consent signs the consent last, otherwise the document will not save properly with both signatures.
24. Complete steps 13- 21 above but using the person obtaining consent's email address.
25. A merged copy of the consent with both signatures will populate under the "Saved Consent" Instrument and in the file repository in the PDF survey archive tab.
26. Review the consent to ensure it was properly signed/merged and send a copy to the participant.
27. Mark the saved consent form as complete

### **What if I need a Witness or LAR to sign?**

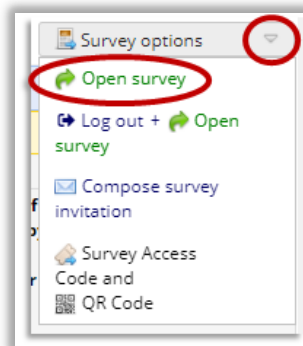
28. Select the informed consent designated for the Witness or LAR to sign.
29. Complete Steps 6-10 above using the Witness's or LAR's email address to send the consent (survey) to.
30. The Witness or LAR should sign the consent after the participant, but before the person obtaining consent signs.
  - l. Always make sure the survey is completed in REDCap before instructing each person to sign the consent.

## How to Consent Using the REDCap e-consent - In Person Using REDCap to Consent

31. Open the e-consent project in REDCap once you are in a quiet space to discuss the consent with the potential participant.
  - a. Create a new record in REDCap:
    - i. Under the **Data Collection** Tab on the left side of the screen select **Record Status Dashboard** or **Add/edit Records**
32. Select the radio button next to the Pre-screening information and input the “**Pre-Screening Log**”, if applicable
33. Select the radio button **Informed Consent for Participants to sign**.
34. Select “**Save & Stay**”



- m. If the “save and stay” option does not appear select the down arrow and the option will be available



35. At the top, click “**Survey Options**” and select “**Open survey**” on the computer you are using
36. Parties that are required to sign can now pass the computer/mouse back and forth to sign the consent document.
37. **Versioning-** all of the following should be changed at every approved version regardless of the changes that were or were not made

<b><u>Where</u></b>	<b><u>What needs changed</u></b>
<u>Survey Settings</u>	e-Consent version:
<u>Copying a survey</u>	Version
<u>Within the new instrument</u>	Version date/Approval date/expiration date
<u>Within the new instrument</u>	Version number
<u>Within the new instrument</u>	Any verbiage changes that have been IRB approved
<u>In saved consents instrument</u>	Create a new field for the new merged surveys to be saved to
<u>In the external module</u>	New field needs to be selected to save the merged copy

38. Once the versioning has been updated, create a copy of the informed consent document and keep only the signature fields for the consenter and participant version of the form

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For additional assistance, contact [ClinicalResearch@UHhospitals.org](mailto:ClinicalResearch@UHhospitals.org)