

# REDCap set-up

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This serves as the guidance for the deployment of future REDCap project builds based on the harmonized TB database structure.

## UCT specifics

All projects that utilize REDCap via UCTs instance are required to follow the below steps as detailed on the UCT REDCap website.

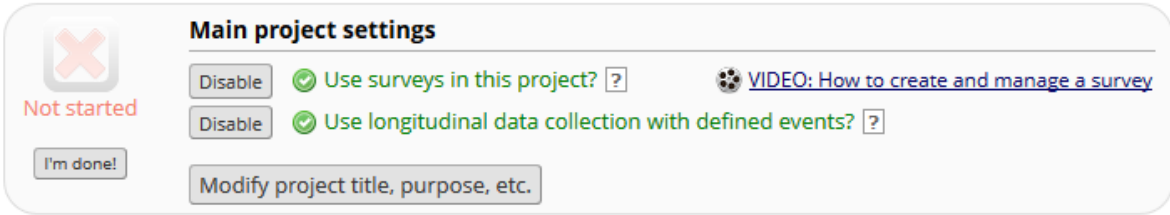
### Procedure for new production projects:

1. When you are ready to start building a real project, [apply for a project to be created](#) and attach at least the study protocol or a FHS020 (Database/Registry) application form.
2. The REDCap admins will then create a new project on the PRD instance, but leave it in development mode.
3. You can then build your project, pilot it and fine-tune instruments, user rights, data access groups and other settings on the PRD instance.
4. Next, save your ethics approval letter in the File Repository of your project
5. Then 'Request move to production' from within your project.
6. One of the REDCap admins will then very briefly review your ethics documents and project settings, and then authorize the project to 'Move to production'.
7. You will receive an email from the system (noreply@uct.ac.za) to notify you that this step has been completed.

Your project will be created and placed in development mode. You will need to upload the data dictionary or XML file and verify some additional project settings before you can start modifying the base elements to suit your study.

## General project settings

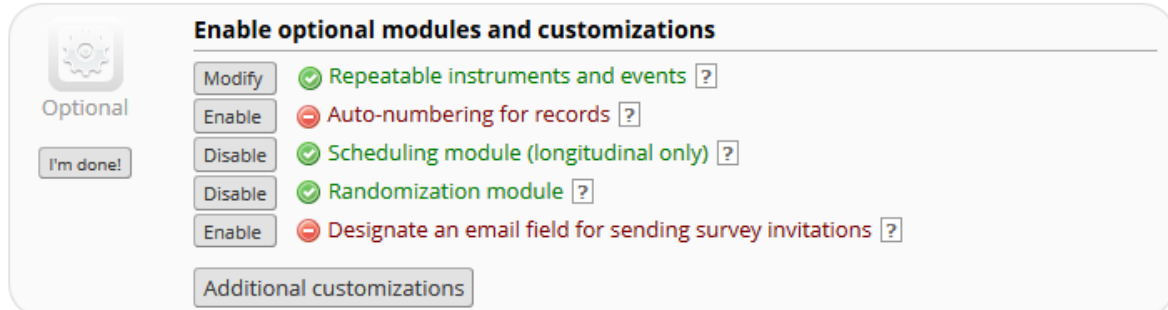
REDCap person will connect the modules as per protocol or investigator instructions. Modules that are not needed can be excluded or deleted.



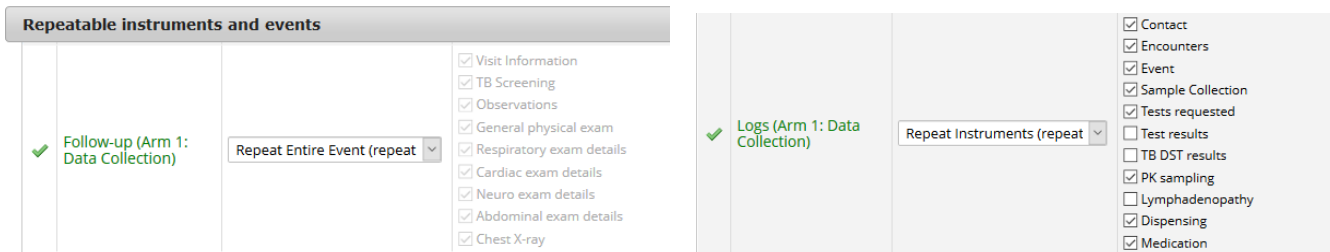
The image shows a screenshot of the 'Main project settings' interface in REDCap. On the left, there is a red 'X' icon and the text 'Not started'. Below this is a button labeled 'I'm done!'. The main area contains several settings: a 'Disable' button, a green checkmark followed by 'Use surveys in this project?' with a help icon, and a video link 'VIDEO: How to create and manage a survey'; another 'Disable' button, a green checkmark followed by 'Use longitudinal data collection with defined events?' with a help icon; and a button labeled 'Modify project title, purpose, etc.'.

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- Use surveys ENABLED
  - This is for the e-consent framework
- Longitudinal data collection ENABLED
  - This is so that we can link forms to events



- Repeatable instruments & events ENABLED
  - This allows for us to repeat entire event or individual instruments



- Scheduling ENABLED
  - This facilitates the use of a data collection schedule & a clinical visit schedule
- Randomization (optional) ENABLED
  - For those studies that require randomization

## Survey settings for e-consent

REDCap now has the ability to manage consent by the e-Consent utility feature. This provides a general mechanism to allow you to administer e-consent to participants. Consent forms can be administered as a REDCap survey via computer, mobile phone, or tablet. Your REDCap person must still create the e-Consent survey with all the relevant questions for your research protocol in it. Remember to include name, surname, date of birth, and how you wish to capture the signatures.

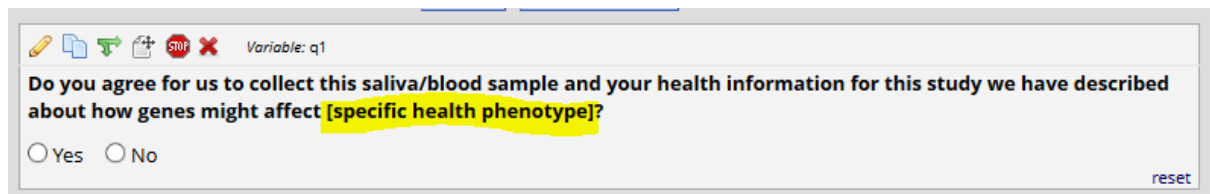
Participants can 'sign' the e-consent by typing their name in the relevant input field or by utilizing REDCap's *signature* field type (i.e., 'wet signature') on the survey. The *Auto-Archiver* option allows a participant to confirm that all information in the document is correct before being saved to the file repository. Clicking the *submit* button marks the end of the consenting process. Thereafter you may print the necessary amount of consent copies that is required by your protocol.

The tool can be adapted to be self-administered or researcher administered.

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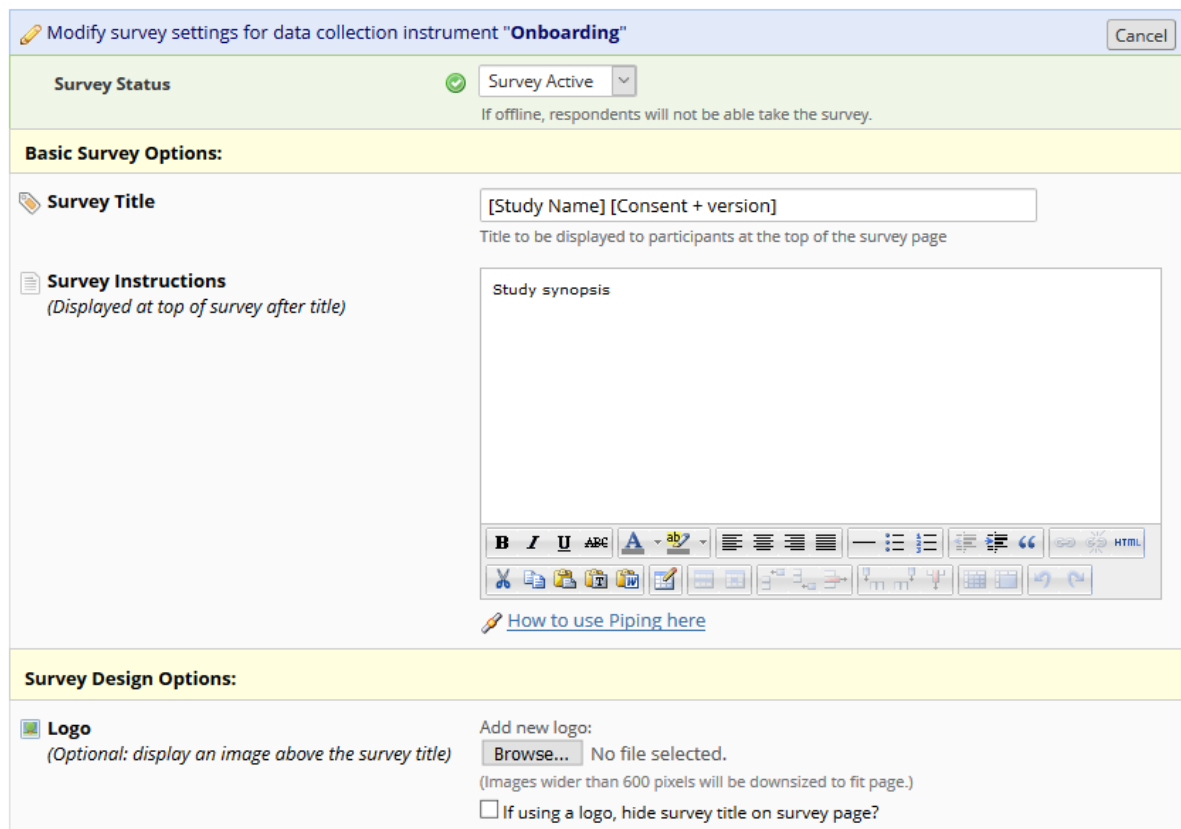
## NOTE!

1. There is specific language in consent data collection instrument that needs to be updated before the tool is used. These sections are currently wrapped in round/square brackets. These updates should be made in the instrument itself via *Online Designer*



A screenshot of a REDCap consent form snippet. At the top, there are icons for edit, copy, paste, and a red 'STOP' sign with an 'X'. To the right, it says 'Variable: q1'. The main text of the consent form is: 'Do you agree for us to collect this saliva/blood sample and your health information for this study we have described about how genes might affect [specific health phenotype]?' The phrase '[specific health phenotype]' is highlighted in yellow. Below the text are two radio buttons: 'Yes' and 'No'. In the bottom right corner, there is a 'reset' button.

2. Additional survey settings, viz. the research study name and study synopsis & consent versioning, should be updated in the survey settings before using the tool.



A screenshot of the 'Modify survey settings for data collection instrument "Onboarding"' interface. The window title is 'Modify survey settings for data collection instrument "Onboarding"' and there is a 'Cancel' button in the top right. The interface is divided into several sections:

- Survey Status:** A green bar with a green checkmark icon, a 'Survey Active' dropdown menu, and the text 'If offline, respondents will not be able take the survey.'
- Basic Survey Options:** A yellow bar.
- Survey Title:** A text input field containing '[Study Name] [Consent + version]' with the description 'Title to be displayed to participants at the top of the survey page'.
- Survey Instructions:** A text area containing 'Study synopsis' with the description '(Displayed at top of survey after title)'. Below the text area is a rich text editor toolbar with icons for bold, italic, underline, text color, background color, bulleted list, numbered list, link, unlink, and HTML. Below the toolbar is a link: 'How to use Piping here'.
- Survey Design Options:** A yellow bar.
- Logo:** A section with a 'Logo' icon, the text '(Optional: display an image above the survey title)', and an 'Add new logo:' section containing a 'Browse...' button, the text 'No file selected.', and the note '(Images wider than 600 pixels will be downsized to fit page.)'. There is also a checkbox labeled 'If using a logo, hide survey title on survey page?'.

A logo can also be added to the consent document if required.

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**Survey Customizations:**

☰ **Question Numbering** Custom numbered

Question numbers will not display correctly if using auto numbering if some questions have branching logic employed. Question auto numbering has been automatically disabled because some of your survey questions use branching logic.

Custom numbering allows you to add descriptive statements in the consent survey, mimicking a regular paper consent form.

Don't forget to add the question numbers to your instrument if you have the option

**Edit Field** ✕

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button at the bottom. When you add a new field, it will be added to the form on this page. For an overview of the different field types available, you may view the [Field Types video \(4 min\)](#).

**Field Type:** Yes - No

**Question Number** (optional) 1  
Displayed only on the survey page

**Field Label**  
Q1  
<i>Screening question</i>

**Choices (not modifiable)**  
1, Yes  
0, No

**Action Tags / Field Annotation** (optional)  
Learn about [@ Action Tags](#) or [using Field Annotation](#)

**Variable Name** (utilized in logic, calcs, and exports)  
scr\_consent\_q1  Enable auto naming of variable based upon its Field Label?  
ONLY letters, numbers, and underscores

How to use [Smart Variables](#) [Piping](#)

**Required?\***  No  Yes  
\* Prompt if field is blank

**Identifier?**  No  Yes  
Does the field contain identifying information (e.g., name, SSN, address)?

**Custom Alignment** Left / Horizontal (LH)  
Align the position of the field on the page

**Field Note** (optional)  
Small reminder text displayed underneath field

Save Cancel

Don't forget to add the necessary question numbers to your consent questions in instrument.

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**PDF Auto-Archiver**  
Upon survey completion, a compact PDF copy of the survey response will be automatically stored in the project's File Repository, from which the archived PDFs can be downloaded at any time.

Disabled  
 Auto-Archiver enabled  
 Auto-Archiver + e-Consent Framework [What is the e-Consent Framework?](#)  
(includes end-of-survey certification & archival of PDF consent form)

**e-Consent Framework Options:** For e-Consent it is sometimes required to include the consenting participant's name (and date of birth in some cases) on the final consent form as extra documentation of their identity. Below you may select fields used to capture that info. You may also enter the current e-Consent version and e-Consent type for this form. The values for the fields below will be automatically inserted into the footer of the PDF consent form that the participant will review at the end the survey, after which that PDF 'hard-copy' will be archived in the File Repository. [Read more](#)

e-Consent version:  e.g., 4

First name field:  in

Last name field:  in

Note: If you are using a single field to capture whole name, you may select it for either first/last name above while leaving the other name field unselected.

Optional fields (these are not always necessary for e-Consent):

e-Consent type:  e.g., Pediatric

Date of birth field:  in

Your REDCap person can adjust e-consent framework options depending on your regulatory requirements. These options populate the footer of the consent document.

Special inclusions have been made to cover the contractual nature of a consent form. The language used can be adapted according to your consent procedures processes.

Variable: validation

\* must provide value

I understand that signing this form electronically is the equivalent of signing a physical document

The survey should be accessed via REDCap survey launch options.

Survey options

- Open survey
- Log out + Open survey
- Compose survey invitation
- Survey Access Code and QR Code

Option 1 or Option 4 are the normal use cases.

An example of option 4:

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**Enter the Survey Access Code**

Start the survey by following the steps below.

1.) Go to this web address:


<https://trn-redcap.uct.ac.za/surveys/>

2.) Then enter this code:

**C3DFRE333**

**Scan the QR Code**

Alternatively, if you have a device that has an app capable of reading QR codes, you may scan the QR code below, which should take you directly to the survey in a web browser.



DO NOT capture directly into the data collection instrument, this limits unauthorised access to the database.

The participant signature can be captured electronically, or the document can be printed out if you require ink signatures.

## Participant signature



A demographics section has been included after the consent section, in the same survey. This allows clinical staff to download and print the consent form to give to the participant and keep a physical print of the demographics on site, if so required.

A PDF with all the information is automatically stored in the file repository under the PDF survey archive for that REDCap project, provided that the correct survey settings were enabled.

Survey Completion Time	Record	Survey	Event	Repeat Instance	Identifier (Name, DOB)	IP Address	Version	Type	Download
23/07/2019 11:11	<a href="#">11</a>	Consent	Consent   Assent		,	41.56.28.54	0.1	Adult	
12/07/2019 11:46	<a href="#">4</a>	Consent	Enrolment		,	196.47.234.185	0.1	Adult	
12/07/2019 11:44	<a href="#">3</a>	Consent	Enrolment		,	196.47.234.185	0.1	Adult	
12/07/2019 11:42		Consent	Enrolment		,	196.47.234.185	0.1	Adult	
12/07/2019 11:41	<a href="#">1</a>	Consent	Enrolment		,	196.47.234.185	0.1	Adult	















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## Schedule structures

Note that this schedule has been created for data collection only. All data should be captured against the relevant visit structure in "Arm 1".

Arm 1: Data Collection
Arm 2: Clinical Visits
+Add New Arm











Arm name: **Data Collection**
[Rename Arm 1](#) | [Delete Arm 1](#)

	Event #	Days Offset	Offset Range Min / Max	Event Name	Custom Event Label (optional)	Unique event name (auto-generated)
 	1	0	-0/+0	Screening		screening_arm_1
 	2	1	-0/+0	Enrolment		enrolment_arm_1
 	3	2	-0/+0	Follow-up		followup_arm_1
 	4	3	-0/+0	Unscheduled		unscheduled_arm_1
 	5	4	-0/+0	Pharmacokinetics		pharmacokinetics_arm_1
 	6	5	-0/+0	Logs		logs_arm_1
 	7	6	-0/+0	Study exit		study_exit_arm_1

*Any changes to the data collection framework must be thoroughly considered before implementation. Please consult your REDCap person.*

If a clinical visit scheduling component is required for the research project, add a second "arm", including days offset and offset range, according to protocol SOE. If the project requires multiple arms e.g. for randomization, these can also be added accordingly.


Arm name: **Clinical Visits**
[Rename Arm 2](#) | [Delete Arm 2](#)

	Event #	Days Offset	Offset Range Min / Max	Event Name	Custom Event Label (optional)	Unique event name (auto-generated)
 	1	0	-0/+0	Enrolment		enrolment_arm_2
 	2	14	-7/+7	Week2		week2_arm_2
 	3	28	-7/+7	Week 4		week_4_arm_2
 	4	84	-14/+14	Week12		week12_arm_2
 	5	100	-3/+3	Study exit		study_exit_arm_2
<input type="button" value="Add new event"/>		<input type="text"/> Days	<input type="text"/> - <input type="text"/> + <input type="text"/>	<input type="text"/>	<input type="text"/>	
		<a href="#">Convert from other units</a>		Descriptive name for this event	Custom Event Label (optional) Example: [visit_date], [weight] kg	

# REDCap set-up

## Map instruments to events

Data collection instruments are connected to specific events under the *Designate instruments for my Events* in the REDCap *Project Setup Page*.



**Define your events and designate instruments for them**

Create events for re-using data collection instruments and/or set up scheduling.

In progress

Go to  or

Data collection instruments should be linked on “Arm 1” only. You select what is required for the specific study by mapping the instruments to the corresponding events.

Data Collection Instrument	Consenting (1)	Screening (2)	Enrolment (3)	Follow-up (4)	Pharmacokinetics (5)	Unscheduled (6)	Logs (7)	Study exit (8)
PID assignment								
Screening Checklist	✓							
Enrolment checklist								
Screening consent (survey)	✓							
Main consent (survey)	✓							
Participant information	✓							
Participant Tracking Information	✓							
Visit Information		✓	✓	✓	✓	✓		✓
Randomization								
TB Symptoms		✓	✓	✓	✓	✓		

## Randomization

Randomization in REDCap works by allowing you to create your custom allocation list, which will serve as a lookup table for deciding how to randomize subjects. This table must be generated outside of REDCap using other software (e.g., SAS, Stata, R, excel), most likely by the statistician/data analyst involved in your project (preferably someone that is unblinded or not directly involved with the study).

## External Modules

Although the database functions as a standalone build. The following external modules are highly recommended and can be installed by a UCT REDCap administrator, set-up by a REDCap superuser.

- Email alerts
- Auto scheduling
- Dashboards