

Navigation Sheet – REDCap Randomization Module

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Introduction

This guide gives an overview of REDCap's randomization module. By defining your parameters for randomization, REDCap creates a template allocation table which can then be adapted for your project and imported back into REDCap.

Please note that **REDCap does not generate complete randomization tables for you**, the final allocation table has to be created outside of REDCap and later imported. We recommend consulting with your statistician or data analyst when setting up the randomization module in REDCap.

Setting up randomization within REDCap requires access to specific user rights. For more detailed information about REDCap's *User Rights* menu please refer to our navigation sheet about "User Rights & DAGs" on the [staff portal](#).

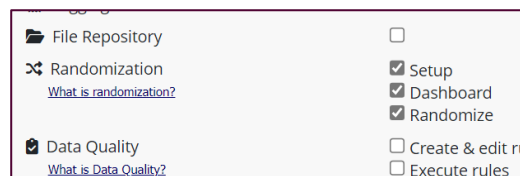
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Randomization User Rights

As can be seen in the *User Rights* section, there are three levels of access to randomization within REDCap:

- Setup (set up the randomization)
- Dashboard (view allocation dashboard)
- Randomize (perform randomization of participants)



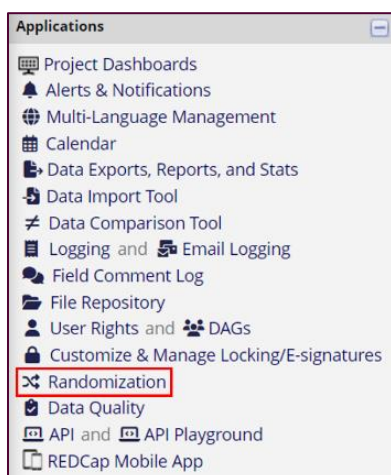
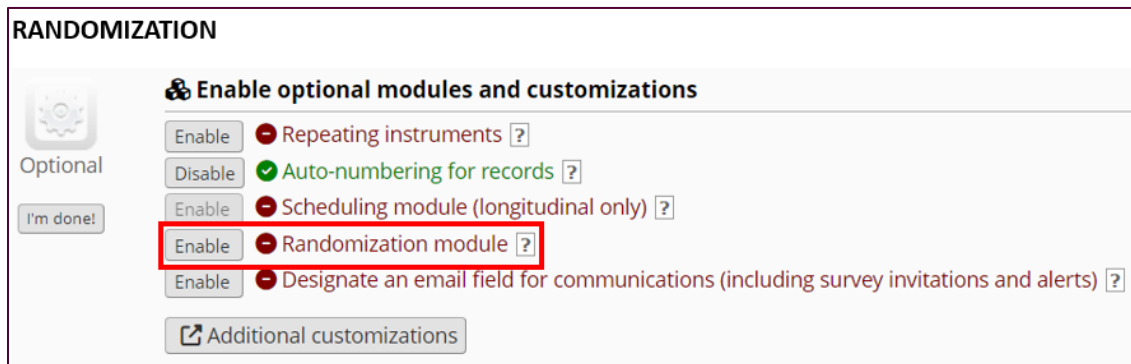
Setup: The user has access to the Setup tab in the *Randomization* menu on the left-hand side. This allows the user to define the randomization by setting up relevant parameters and to upload allocation tables. It is recommended to involve your statistician/data analyst in this process.

Dashboard: The user has access to the allocation *Dashboard* tab in the *Randomization* menu. This tab shows the allocations for participants / records who have been randomized within REDCap.

Randomize: Users with this access will see the “randomize” button in the chosen instrument and are able to perform randomizations within REDCap.

Activating the Randomization Module

The randomization module can be activated on the *Project Setup* page in your project. Click on “Enable” to activate the module.



Any user who has been given access to randomization features in their user rights will now be able to see the *Randomization* menu on the left-hand side of the screen.

Setting up the Randomization

To set up and define the randomization, go to the *Setup* tab in the *Randomization* menu (left-hand side of the screen).

🔗 Randomization

Randomization is a process that assigns participants/subjects by chance (rather than by choice) into specific groups for research and clinical trials. The randomization module in REDCap will help you implement a defined randomization project, allowing you to randomize your subjects (i.e. records in your project). In this module, you first define the randomization parameters. Based on the defined parameters, the module creates a template allocation table, which you can then use to create a randomization table you will import. The module also monitors the overall allocation progress and assignment of randomization subjects. **Note: It is recommended that only people with experience in randomization set up the Randomization module.**

Setup Dashboard

STEP 1: Define your randomization model

This step will allow you to define the randomization model you will be implementing and all its parameters, which includes defining strata (if applicable) and optionally randomizing subjects per group/site (if a multi-site study).

Step 1: Define Randomization Model

First, the parameters for the randomization module need to be set up.

STEP 1: Define your randomization model

This step will allow you to define the randomization model you will be implementing and all its parameters, which includes defining strata (if applicable) and optionally randomizing subjects per group/site (if a multi-site study).

A) Use stratified randomization?

It is often necessary to ensure equal treatment among a number of factors. Stratified randomization is the solution to achieve balance within one or more subgroups, such as gender, race, diabetics/non-diabetics, etc. By choosing strata (multiple choice criteria fields), you may then be able to ensure balance within those subgroups. [Tell me more](#)

B) Randomize by group/site?

If this is a multi-center/multi-site project (or something similar), you may want to stratify the randomization by each group/site. You can select an existing multiple choice field that represents the groups/sites, OR you can use Data Access Groups to stratify by group/site.

C) Choose your randomization field

This is the field where the allocated randomization (treatment) group will be saved and stored, and is where the Randomize button will appear on your data collection form.

- select a field - ▾

Save randomization model Erase randomization model

You can choose stratified randomization or randomization by group/site.

A) Stratified randomization

Stratified randomization aims to balance different randomization groups by taking into account specific variables (e.g. age). How to balance the groups is determined in the allocation table by adding one or more stratification variables from your instruments. Increasing the number of stratification variables will lead to fewer subjects per stratum.

A) Use stratified randomization?

It is often necessary to ensure equal treatment across groups. To achieve balance within one or more subgroups, select multiple criteria fields (multiple choice criteria fields), you may then be able to stratify by these fields.

Choose strata (criteria fields used for stratification)

- select a field - v

- select a field - v

Add another stratum

B) Randomize by group/site

B) Randomize by group/site?

If this is a multi-center/multi-site project (or something similar), you can stratify by group/site. You can select an existing multiple choice field from your instruments to stratify by group/site.

- Use Data Access Groups to designate each group/site
- Use an existing field to designate each group/site

- select a field - v

This option allows you to randomize by either Data Access Groups or by a REDCap drop-down list of different sites (found in your instruments). This option is useful in, for example, multicentre studies.

In addition, you have to **choose a randomization field (C)** in one of your forms/instruments. This is the field where the allocated randomization group (treatment/control/etc.) will be saved; it is also where the “Randomize” button will appear on your data collection form when creating new records via *Add/Edit*

B) Randomize by group/site?

If this is a multi-center/multi-site project (or something similar), you can stratify by group/site. You can select an existing multiple choice field from your instruments to stratify by group/site.

- Use Data Access Groups to designate each group/site
- Use an existing field to designate each group/site

hospital_sites (Participating Hospital Sites) v

C) Choose your randomization field

This is the field where the allocated randomization group (treatment/control/etc.) will be saved; it is also where the “Randomize” button will appear on your data collection form.

randomization_button (Randomization) v

Save randomization model

Erase randomization model

Records. (Note that the “Randomize” button will not appear in *Designer* even after setting up and saving your randomization model, it will only appear when creating new records)

Adding new Record ID 1.

Record ID

1

Participating Hospital Sites

Hospital A v

Randomization

Randomize

Don't forget to click on “save randomization model” when you are done defining your model.

Step 2: Create Allocation Tables

Once you defined your randomization and saved the model, REDCap generates several different template allocation tables which contain the raw coded values for the fields you included in step 1.

STEP 2: Download template allocation tables (as Excel/CSV files)

Below are some example files that you may download to get a general idea for how you may structure your own randomization table. You do not have to use any of these. In fact, **we recommend that you NOT use these exact templates** but instead recommend that you merely use them as an example or baseline to start from in order to create your own custom allocation file. After uploading your allocation table in Step 3 below, it will then be used as a lookup table to perform assignments when subjects are being randomized. **NOTE:** Record names (e.g., study ID) should NOT be included as a column in your allocation table, but only the fields listed in the example files below. [More details](#)

Example #1 (basic)

Example #2 (all possible combos)

Example #3 (5x all possible combos)

Choose the table that best suits your project and start adding your allocations. **Note:** Ideally, this step should be performed by a statistician while the rest of the study team remains blind to the allocations.

Step 3: Upload Allocation Tables

Once both allocation tables have been created, you may import them back into REDCap and start testing your randomization module.

STEP 3: Upload your allocation table (CSV file)



Not
uploaded
yet

Upload allocation table (CSV file) for use in DEVELOPMENT status

Choose File No file chosen

Upload File



Not
uploaded
yet

Upload allocation table (CSV file) for use in PRODUCTION status

Choose File No file chosen

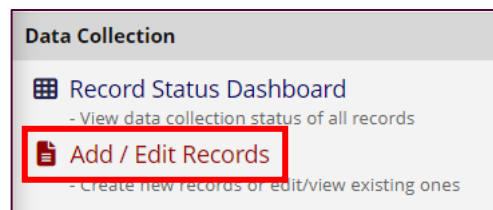
Upload File

The first table is for testing your project (Development) and should not be the same as the one you will use to recruit actual participants (Production). Make sure to test your randomization module while the project is in Development by adding test records.

Randomizing a Record

Any user who has been given access to “randomize” in *User Rights* is now able to create a new record and randomize participants.

The chosen randomization field ([Step 1, C](#)) will now display a “Randomize” button in the relevant instrument/form when creating a new record.

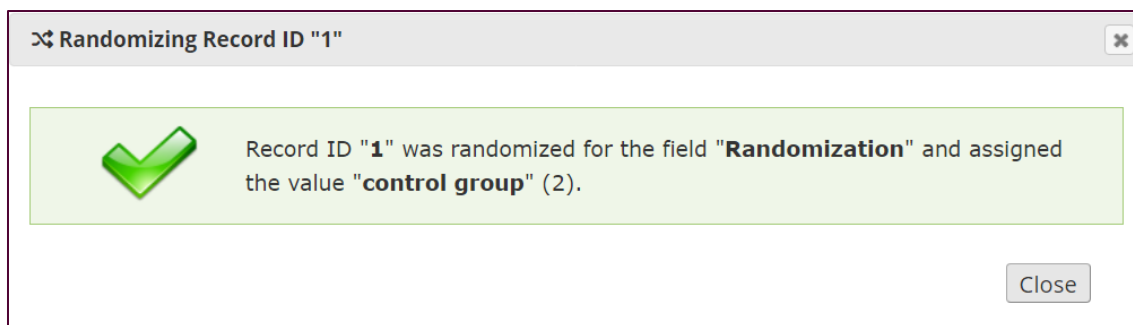


The screenshot shows a form titled 'Randomization Demo' for 'PID 2641'. At the top, there are action buttons: 'Modify instrument' and 'Download PDF of instrument(s)'. Below this is a section for 'Form 1' with a green header 'Adding new Record ID 1.'. The form fields are: 'Record ID' (value: 1), 'Participating Hospital Sites' (dropdown: Hospital B), 'Randomization' (button: Randomize, highlighted with a red box), 'Form Status' (empty), and 'Complete?' (dropdown: Incomplete).

When clicking on the “Randomize” button, a pop-up window will appear where the user can double-check relevant parameters and confirm the randomization.

The screenshot shows a pop-up window titled 'Randomizing Record ID "1"'. It contains the following text: 'Below you may perform randomization for Record ID "1" on the field **Randomization** (*randomization_button*). Please note that the fields below will become permanently locked and uneditable on the data entry form once this record has been randomized.' Below this is a blue instruction bar: 'Provide any missing values below for Record ID 1, then click the Randomize button below.' The 'Participating Hospital Sites' dropdown is set to 'Hospital B'. A yellow reminder box states: 'REMINDER: This project is still in development status, so you should NOT be randomizing real subjects yet. You should only be randomizing real subjects after moving the project into in production status.' At the bottom are 'Randomize' and 'Cancel' buttons.

After randomizing a record, another pop-up window appears showing which group the participant was assigned to.



In addition, the randomization is locked into the randomization field and the field becomes read-only and can no longer be changed.

The screenshot shows a web form titled "Randomization Demo" with a "PID 2641" label. Below the title, there are action buttons: "Modify instrument" and "Download PDF of instrument(s)". A video link "Video: Basic data e" is also visible. The form is labeled "Form 1" and contains several sections:

- A green bar with a plus icon and the text "Adding new Record ID 1."
- A "Record ID" field with the value "1".
- A "Participating Hospital Sites" section with a dropdown menu set to "Hospital B".
- A "Randomization" section, highlighted with a red border, containing the text "Already randomized" and two radio button options: "experimental group" (unselected) and "control group" (selected).
- A "Form Status" section with a yellow background.
- A "Complete?" field with a dropdown menu set to "Incomplete".

The Allocation Dashboard

The *Dashboard* tab in the “Randomization” menu shows a list of all available and used allocations based on the allocation table you uploaded.

Randomization Demo PID 2641

🔗 Randomization

Randomization is a process that assigns participants/subjects by chance (rather than by choice) into specific research and clinical trials. The randomization module in REDCap will help you implement a defined randomization project, allowing you to randomize your subjects (i.e. records in your project). In this module, you first define various parameters. Based on the defined parameters, the module creates a template allocation table, which you will import as a randomization table you will import. The module also monitors the overall allocation progress and assigns subjects. *Note: It is recommended that only people with experience in randomization set up the Randomization module.*

Setup **Dashboard**

The table below displays the allocation dashboard for use in DEVELOPMENT status. All assignments are counted as a count of records that have been randomized for each row (i.e. combinations). Assignments that have been randomized are shown in the 'Used' column while those that are still unallocated will get counted in the 'Not Used' column. Once all allocations for a given row/combination, it will display a checkmark icon in its row. The headers in the table may be clicked to sort the data either in ascending or descending order.

	Used	Not Used	Allocated records	Randomization (randomization_group)	Participating Hospital Sites (hospital_sites)
	0	1		experimental group (1)	Hospital A (1)
	0	1		experimental group (1)	Hospital C (3)
	1	0	1	control group (2)	Hospital B (2)

Here, you can get a snapshot of the status of your allocation table. REDCap groups allocations of the same type (with the same combinations of parameters) together in one row:

- “Used”: shows how many allocations of this type have already been assigned.
- “Not Used”: shows how many allocations of this type have not yet been assigned.
- “Allocated records”: shows how many records have been assigned to this allocation group.
- Second to last column (here “Randomization”): shows to which randomization group records with this type of allocation were assigned to (based on the randomization field you set in [Step 1](#) above).

- last column (here “Participating Hospital Sites”): shows which group/site this type of allocation is part of (based on the field you defined in [Step 1](#) above).
- First column on the left: shows a green checkmark when all allocations from that row/allocation group have been assigned.

It is possible to click on the headers in the table to change the order of the displayed allocation groups.

Tips & Best Practices

Randomization can only be set up while the project is in Development. Once a project is moved to Production, the randomization setup tab is locked and randomization settings can no longer be modified.

Make sure to include more allocations in your table than you think you will need to accommodate, for example, drop-outs and to enable the possibility to randomize additional participants.

Always prepare two different allocation tables. One to test your project (Development) and one for the actual recruitment of participants (Production). These two allocation tables must not be the same.

Ideally, the allocation table should be created by a statistician. The rest of the study team should remain blinded to the allocations.

Remember to limit access to randomization features in the *User Rights* section.

Make sure to test your randomization module before moving your project to Production and starting recruitment.

REDCap follows the allocation table from top to bottom, choosing the next possible match in the table based on the defined criteria.