

Navigation Sheet – REDCap Randomization Module

Compliance & Data Office

Research Support Office

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 a 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)



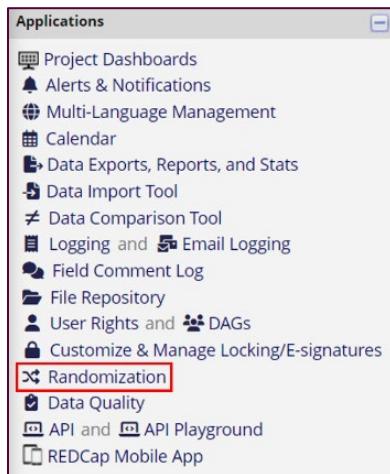
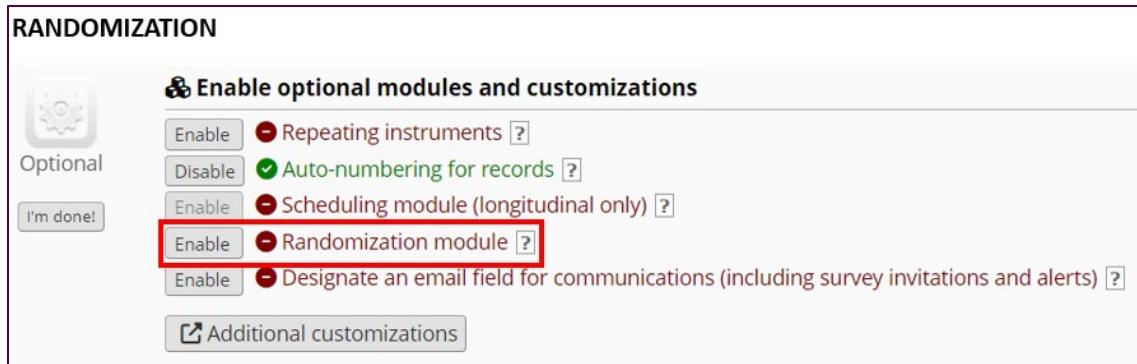
Setup: The user has access to the Setup tab in the *Randomization* menu on the left-hand side. This allows the user to define the randomization by setting up relevant parameters and to upload allocation tables. It is recommended to involve a statistician/data analyst in this process.

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, click on Add new randomization model in the *Randomization* menu (left-hand side of the screen).

Randomization

Randomization is a process that assigns participants/subjects by chance in research and clinical trials. The randomization module in REDCap will help you manage this process, allowing you to randomize your subjects (i.e. records in your database) based on the defined parameters. The module can generate randomization table you will import. The module also monitors the randomization process and provides reports on the status of the subjects. **Note:** It is recommended that only people with experience in randomization should use this module.

[Summary](#)

[+ Add new randomization model](#)

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 sex, 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 "Randomize" button will appear on your data collection form. The type of field you choose (text field vs. single-select multiple choice field) dictates the Allocation Type for this randomization model.

For open randomization:

- Select a single-select (dropdown or radio) field. The randomized **group allocation** will be saved to this field.

For concealed (blinded) randomization:

- Select a text field that does not have field validation. The assigned **randomization number** will be saved to this field.

Note that the randomization number is available through the smart variable `[rand-number]`.

[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 and achieve balance within one or more subgroups, so (multiple choice criteria fields), you may then be

Choose strata (criteria fields used for stratification)

- select a field -

- select a field -

B) Randomize by group/site

B) Randomize by group/site?

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

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

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 Records*.

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For open randomization:

- Select a single-select (dropdown or radio) field. The randomized **group allocation** will be saved to this field.

For concealed (blinded) randomization:

- Select a text field that does not have field validation. The assigned **randomization number** will be saved to this field.

Note that the randomization number is available through the smart variable `[rand-number]`.

(Note that the “Randomize” button will not appear in *Designer* even after setting up and saving your randomization model; to see the randomize button, you need to choose a record and open the relevant instrument for data entry.)

Finally, you can choose whether the randomization field displays the group allocation (see “For open randomization” under Step 1 C) or if a randomization number is saved instead (see “For concealed (blinded) randomization”).

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 <input type="button" value="Choose File"/> No file chosen <input type="button" value="Upload File"/>
 Not uploaded yet	Upload allocation table (CSV file) for use in PRODUCTION status <input type="button" value="Choose File"/> No file chosen <input type="button" value="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. Make sure to test your randomization module while the project is in Development by adding test records.

Step 4: Automatic Triggering Option

Randomization can be automated by defining logic to trigger randomization, for example, when a certain form or survey is saved in REDCap.

Trigger option	<input type="button" value="Trigger logic, for all users (including survey respondents)"/> <input type="button" value="Save trigger option"/>
Instrument	<input type="button" value="Baseline"/>
Trigger logic	<input type="text" value="baseline_complete='2'"/>

1. Decide who can trigger automatic randomization under “Trigger option” (choose between manual trigger, trigger logic for users with permission in user rights, or trigger logic for everyone including survey participants).
2. Choose which instrument should be the trigger under “Instrument” (the randomization field can be placed in the same or a separate instrument; if placed in a survey, the randomization field can be hidden from participants)
3. Add logic to determine exactly when randomization is triggered/activated under “Trigger logic”.

Possible applications of auto-randomization:

- Study participants can complete an initial REDCap survey, automatically be randomized, and then sent on to further surveys based on their allocation group, all without a REDCap user having to get involved.

Manually Randomizing a Record

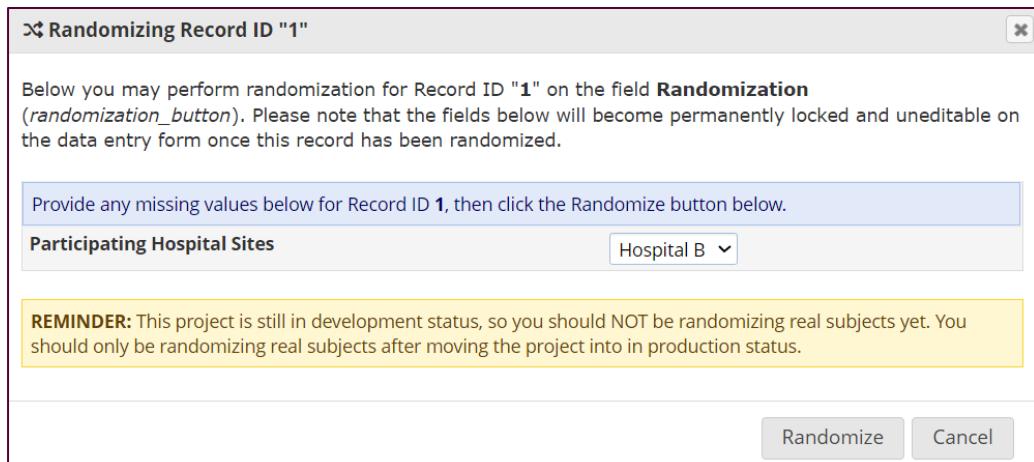
Any user who has been given “randomize” user rights is now able to create a new record and randomize participants.

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

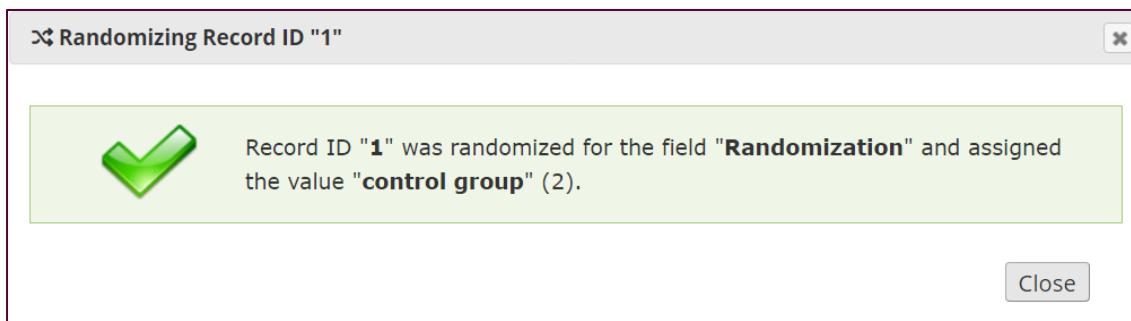


The screenshot shows the 'Randomization Demo' form for PID 2641. It includes sections for 'Actions' (Modify instrument, Download PDF of instrument(s), Video: Bas), 'Form 1' (Adding new Record ID 1), and fields for 'Record ID' (1), 'Participating Hospital Sites' (Hospital B), 'Randomization' (button highlighted with a red box), 'Form Status' (Incomplete), and 'Complete?' (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.



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.

Randomization Demo		PID 2641										
Actions: Modify instrument Download PDF of instrument(s) Video: Basic data entry												
Form 1 <div style="background-color: #e0f2e0; padding: 5px;"> + Adding new Record ID 1. </div> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;">Record ID</td> <td style="width: 85%;">1</td> </tr> <tr> <td>Participating Hospital Sites</td> <td>Hospital B</td> </tr> <tr> <td>Randomization</td> <td style="text-align: right; vertical-align: bottom;"> Already randomized <input type="radio"/> experimental group <input checked="" type="radio"/> control group </td> </tr> <tr> <td>Form Status</td> <td style="background-color: #ffffcc;">Incomplete</td> </tr> <tr> <td>Complete?</td> <td style="text-align: right; vertical-align: bottom;"> <input type="radio"/> Incomplete </td> </tr> </table>			Record ID	1	Participating Hospital Sites	Hospital B	Randomization	Already randomized <input type="radio"/> experimental group <input checked="" type="radio"/> control group	Form Status	Incomplete	Complete?	<input type="radio"/> Incomplete
Record ID	1											
Participating Hospital Sites	Hospital B											
Randomization	Already randomized <input type="radio"/> experimental group <input checked="" type="radio"/> control group											
Form Status	Incomplete											
Complete?	<input type="radio"/> Incomplete											

If automatic randomization is enabled, it is still possible to click on the "Randomize" button instead if the randomization has not yet been triggered.

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 table in your project, allowing you to randomize your subjects (i.e. records in your project). In this module, you first define the randomization table, then import it into the system. The randomization module will then create a template allocation table, which you can use to assign subjects to treatment groups. 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 grouped by randomization type. The table shows the count of records that have been randomized for each row (i.e. combinations). Assignments that have been completed will be listed in the 'Used' column while those that are still unallocated will get counted in the 'Not Used' column. Once all assignments for a given row/combination, it will display a checkmark icon in its row. The headers in the table may be clicked to sort either in ascending or descending order.

	Used	Not Used	Allocated records	Randomization (randomization)	Participating Hospital Sites (hospital_sites)
<input type="radio"/>	0	1		experimental group (1)	Hospital A (1)
<input type="radio"/>	0	1		experimental group (1)	Hospital C (3)
<input checked="" type="radio"/>	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 which 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.

If you want to use the smart variable [rand-number], you must use the concealed (blinded) randomization field type (Step 1C). This could be a useful feature if you, for example, want to inform your survey participant of which group they've been assigned to.