



Setting Up the Randomization Module in REDCap – How-To Guide

REDCAP Randomization Module

Randomization is a process that assigns participants/subjects by chance (rather than by choice) into specific groups, typically for clinical research and clinical trials. Example: each subject assigned to receive either the new treatment or the control (placebo) treatment.

The randomization module in REDCap will help you implement a defined randomization model within your project, allowing you to randomize your subjects (i.e. records in your project). In this module, you first define the randomization model with various parameters. Based on the defined parameters, the module creates a template allocation table, which you can use to structure the randomization table you will import. The module also monitors the overall allocation progress and assignment of randomized subjects.

REDCap Helps you implement a defined randomization model within your REDCap project, by allowing you to

1. Define all of the randomization parameters;
2. Create and upload your custom randomization table (i.e., allocation list). The table serves as a lookup table for deciding how to randomize subjects/records

REDCap does not support dynamic randomization. REDCap DOES NOT create the randomization table for you. This table must be generated outside of REDCap using other software (e.g. SAS, Stata, R), most likely by the statistician/data analyst involved in your project.

By letting you create your own allocation table outside of REDCap, it lets you and your team choose exactly how you wish to structure your allocations and assignments. Examples: block sizes, permutations, and stratification balancing.

Goals of Randomization

- To produce groups that are comparable (i.e., balanced) with respect to known or unknown risk factors.
- To remove bias (selection bias and accidental bias).
- To guarantee the validity of statistical tests.
- To balance treatment groups, stratification factors, or both.

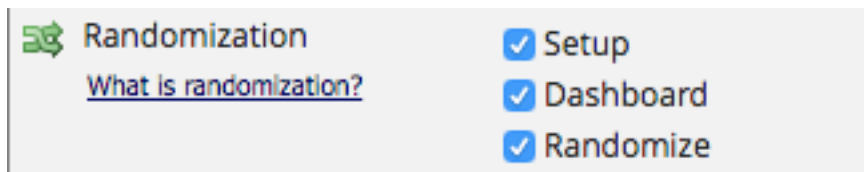
User Privileges

There are 3 different user randomization privileges:

1. Setup (setup the randomization)
2. Dashboard (view the allocation dashboard)
3. Randomize (perform the randomization of participants)

Be sure the user designated to setup the randomization can be *unblinded* to the randomization. This is usually a statistician or data analyst involved in the project, not the PI or coordinator. Your protocol may specify which staff are blinded and unblinded.

If someone is given 'Randomize' privileges, they will be able to view and modify any existing data already collected for the randomization strata fields (if stratification is used) when they are performing the randomization, even if they do not specifically have form-level rights to view the form on which a strata field exists. Thus, Randomize rights trumps form-level rights in this way, but only for the randomization strata fields.



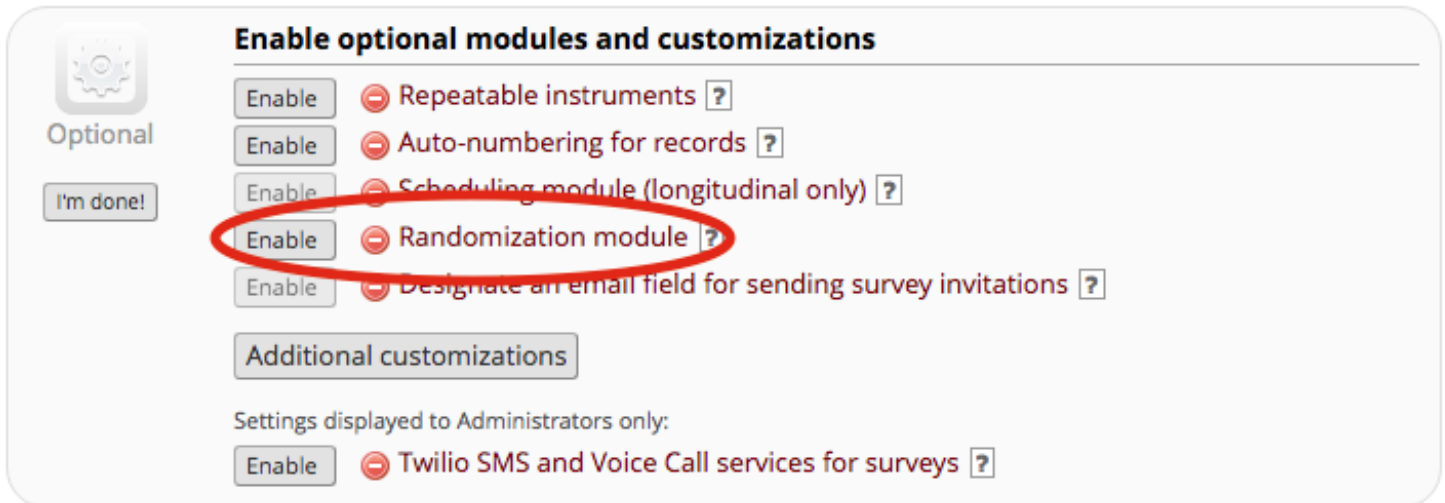
Setup: user will see the Setup tab on the Randomization page, which will allow the user to define the randomization model and all its parameters, as well as upload the custom allocation table(s). The user is usually a statistician/data analyst.

Dashboard: user will see the (Allocation) Dashboard tab on the Randomization page, in which you may view the overall allocation progress and assignments for subjects that have been randomized. User is usually the PI or Project Manager

Randomize: user will be able to view the Randomize button on the data collection form/survey that contains the randomization field, thus allowing the user to perform the randomization on the subject/record they are viewing. The user is usually a Research nurse/Study coordinator.

Setting Up the Randomization Model



To start the process, click on the "Enable" button under the "Enable optional modules and customizations." under the "Project Setup" tab.







Enable optional modules and customizations



Optional



I'm done!

Enable  Repeatabe instruments 

Enable  Auto-numbering for records 



Enable  Scheduling module (longitudinal only) 

Enable  **Randomization module** 

Enable  Designate an email field for sending survey invitations 

Additional customizations


Settings displayed to Administrators only:

Enable  Twilio SMS and Voice Call services for surveys 

Next, click on the Randomization link under "Applications" on the left side menu.



Applications

- Calendar
- Data Exports, Reports, and Stats
- Data Import Tool
- Data Comparison Tool
- Logging
- Field Comment Log
- File Repository
- User Rights and  DAGs
- Record Locking Customization
- E-signature and Locking Mgmt
- Randomization**
- Data Quality
- API and  API Playground
- REDCap Mobile App
- External Modules
- UF REDCap Service Request



Randomization Setup

The randomization model is defined via the "Setup" tab and consists of three main steps:

1. Define your randomization model
2. Download template allocation tables (as Excel/CSV files)
3. Upload your allocation tables (CSV file). **There will be 2 different allocation tables to upload and the order in which you upload are very important.**

Step 1 – Define your Randomization Model

The first main step in the setup process is to define your 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). In this step, you will define the type of randomization and how the randomization is applied to the subjects. There are two randomization types:

1. Stratified randomization
2. Randomize by group/site

Stratified Randomization

Stratified randomization ensures that different groups are balanced. The balance is specified in the allocation table. Increasing the number of stratification variables will lead to fewer subjects per stratum.

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](#)

The exact balance within the subgroups will be whatever proportion you prescribe, as dictated by the allocation table you create. Increased number of stratification variables or increased number of levels within strata leads to fewer subjects per stratum.

Choose strata (criteria fields used for stratification; may specify up to 14 multiple choice fields)

age_online_use (Are you >= 18 years old and have used online) for Hospital

Add another stratum

IMPORTANT: you may need to add the needed fields to specify the randomization model.

Randomize by Group/Site

If this is a multiple site study, this option allows you to stratify the randomization by each group. When this option is checked, you are given the opportunity to select randomization by data access groups or by a REDCap drop-down list of the sites.

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.

Use Data Access Groups to designate each group/site (2 groups currently exist)

Use an existing field to designate each group/site

site_name (Site) for Hospital

Choose your Randomization Field

This is the field that will receive the randomization group designation.

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.

random_group (Randomization Group) for Hospital

Once all parameters are set, save the randomization model.

Step 2 – Download template allocation tables (as excel/CSV files)

The second main step in the randomization setup is to download the allocation table template.

Template allocation tables contain all the raw coded values for the fields used in the randomization model.

- Will list each multiple-choice option's label corresponding to each raw coded value for all of the fields utilized (e.g. 0=Female, 1=Male for the field 'gender').
- If you are using Data Access Groups to randomize by group, then it will additionally list each group name with its corresponding group ID number.

Does not necessarily matter how you set up your allocation table so long as you structure it correctly.

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)

REDCap creates several example files to download that you may use as a structure when creating your own randomization table. For this example, I have stratified Age Online Use field that has 2 different values and I wish to allocate the participants into 2 groups. My allocation template downloaded from REDCap looks similar to the following:

random_group	age_online_use
1	1
2	1
1	0
2	0
1	1
2	1
1	0
2	0
1	1
2	1
1	0
2	0
1	1
2	1
1	0
2	0

REDCap will randomize the participants according to this table. For example, the first participant that has an "Age >18 Online Use" (corresponding to the value of one) will be allocated to random group one. The second person with "Age>18 Online Use" will be allocated to random group two, etc. Note: Make sure the number of entries in the randomization table is large enough to accommodate all participants in each category.



In order to make the allocation schedule more difficult to predict, a temporary column can be added to the spreadsheet for randomizing the order. The Excel function "=RAND()" creates a random value between 0 and 1. This number can be used as an easy way to populate a third column in the spreadsheet with a unique random value. If the spreadsheet is sorted by this column, the group and age online values will be randomized. For example, after sorting, the spreadsheet may look similar to the following:

random_group	age_online_use	random value
1	1	0.772358888
2	1	0.194570591
1	0	0.332192312
2	0	0.657432834
1	1	0.537347694
2	1	0.011228167
1	0	0.794263123
2	0	0.229805789
1	1	0.719394269
2	1	0.263250085
1	0	0.293855915
2	0	0.571696897
1	1	0.670591148
2	1	0.498096731
1	0	0.029795633
2	0	0.184701453
1	1	0.788695359
2	1	0.920001012
1	0	0.268369569
2	0	0.061326155

After sorting the table by the random value, the column with the rand() function should be removed before to saving the spreadsheet as a CSV file and prior to uploading it as the allocation table into REDCap.

Be sure to include more assignments in your allocation table than you think you will need. This will accommodate possible drop-outs and additional enrolling of subjects.

Step 3 – Upload your Allocation Table (CSV file)

WARNING: You will need 2 different allocation tables.

Table 1 is for DEVELOPMENT status and **should not** be the one you plan to use while your project is in Production. This allocation table is used only for testing of your project. After you upload this one it is imperative to enter test records to ensure your project is working correctly. This allocation table cannot be a duplicate of your “real” (production allocation table, Table 2). After you finish testing and your project works as expected then you upload the PRODUCTION status allocation table.

If you do copy your “real” (production) allocation table to use as your DEVELOPMENT status allocation table, then you must change at least one item on the allocation table so it will not be an exact duplicate of your PRODUCTION allocation table. If you try to use the same allocation table for both the DEVELOPMENT and PRODUCTION uploads the system will not allow you to and you will have to erase your randomization model and start over.

STEP 3: Upload your allocation table (CSV file)

Once you have created your custom allocation table as a CSV file and made sure that you kept the format prescribed in the template files from Step 2 above, you may now upload the file below. It will be checked for any possible errors first before it is accepted and stored in REDCap. Please note that you will need to create two different allocation tables: one to be used for testing while your project is in development status and the other for use when in production status. Below are some important reminders before you begin uploading your allocation tables.

Reminders:

- Once your project is in production status, the allocation tables will become locked and unmodifiable.
- Be sure to include more assignments in your allocation table than you think you will need (to accommodate possible drop-out and drop-in of subjects).
- 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 from Step 2 above.



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

[Delete allocation table?](#)

Download table

Should not be the same allocation table!



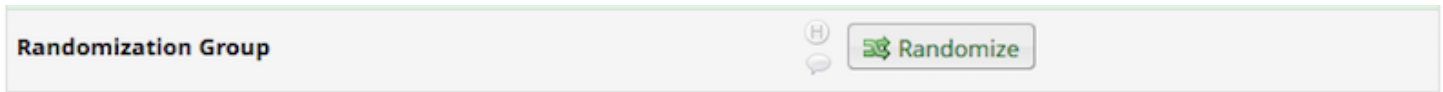
Upload allocation table (CSV file) for use in PRODUCTION status

[Delete allocation table?](#)

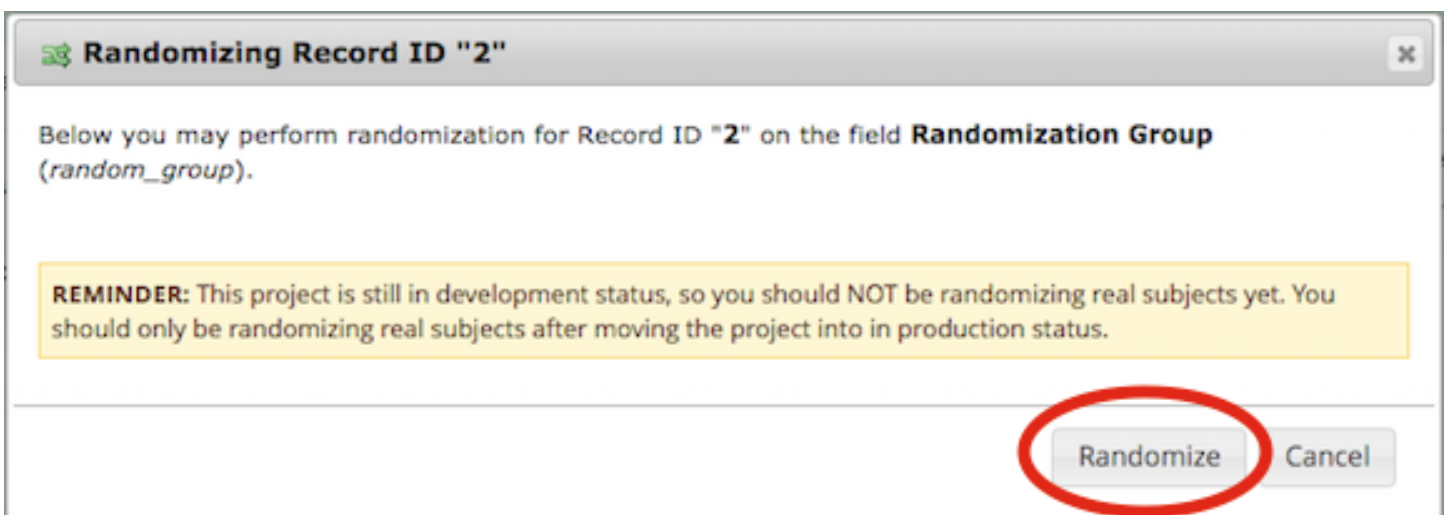
Download table

Randomizing a Record

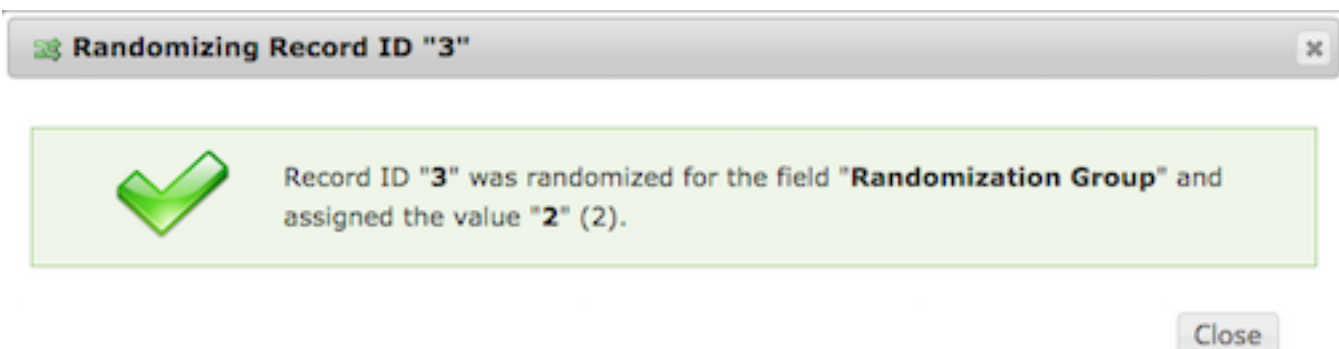
The fields that have been specified for randomization will now display a "Randomize" button in the data entry screen. This will allow you to generate a random value according to the randomization allocation table.



When a user (who has been given appropriate 'Randomize' user privileges) clicks that button, a pop-up box will appear that will allow the user to randomize the subject/record. If any grouping or stratification is being used, the user must provide the group or strata values if any are missing before they can randomize the subject/record. Pressing the "Randomize" button gives you an opportunity to double check the required values that will impact the definition of the resulting randomization group.



When the user randomizes the subject/record, REDCap will check the allocation table and assign that subject's/record's randomization field value, which will be derived from the next match in the table based upon the criteria (eg, strata field values, group). If not using stratified randomization and not randomizing by group/site, then it will simply provide the subject with the very next value in the allocation table. After updating or providing missing values, a dialog of the random group that was assigned is displayed.



In addition, after the value of the random group is assigned, the random group field becomes read-only and the value cannot be changed. The strata fields you have chosen also become read-only and cannot be changed.

Randomization Group	Already randomized
	<input type="radio"/> 1
	<input checked="" type="radio"/> 2

A listing of the records that have been randomized is maintained. To examine those records, click on the Randomization link in the Applications section of the Navigation Pane.



Dashboard

A dashboard displaying the allocated records and the random group assigned are shown below:



The table below displays the allocation dashboard for use in DEVELOPMENT status. All assignments are grouped to show in aggregate the count of records that have been randomized for each row (i.e. combinations). Assignments that have been used will get counted in the 'Used' column while those that are still unallocated will get counted in the 'Not Used' column. Once all assignments have been used 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 table by that column either in ascending or descending order.

	Used	Not Used	Allocated records	Randomization Group (random_group)
✓	1	0	<u>2</u>	1 (1)
✓	1	0	<u>3</u>	2 (2)

IMPORTANT

- How you generate your allocation table should be formal, secure, reproducible, and unpredictable. Best handled by a statistician/data analyst; **NOT** the PI.
- Be sure to include more assignments in your allocation table than you think you will need (to accommodate possible drop-out and additional enrolling of subjects).
- The Setup tab on the Randomization page is **ONLY** available while the project is in Development status.
- Once the project is in Production, the Setup tab will become permanently locked and no randomization settings can be modified, nor can any assignments be undone.
- Test the process of randomizing subjects by entering in test records while in Development status. Delete the test records and then upload the final (production) allocation table before moving the project into Production status.