REDCap
Research Electronic Data Capture

Randomization Module

THE UNIVERSITY OF CHICAGO MEDICINE & BIOLOGICAL SCIENCES

CENTER FOR RESEARCH INFORMATICS

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 (ie, allocation list)
   - Table serves as a lookup table for deciding how to randomize subjects/records

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 (ie, 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.
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When to randomize?
- After determining eligibility
- As close to treatment time as possible (to avoid death or withdrawal before treatment start).

User Privileges
User privileges can be set to allow only certain users to be able to set up the randomization, perform the randomization, or view the allocation dashboard to view progress. 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.

Setting-up a Randomization Model

A randomization model defines how the subjects in the study are randomized. To start the process, click on the "Enable" button under the "Enable optional modules.." under the "Project Setup" tab.
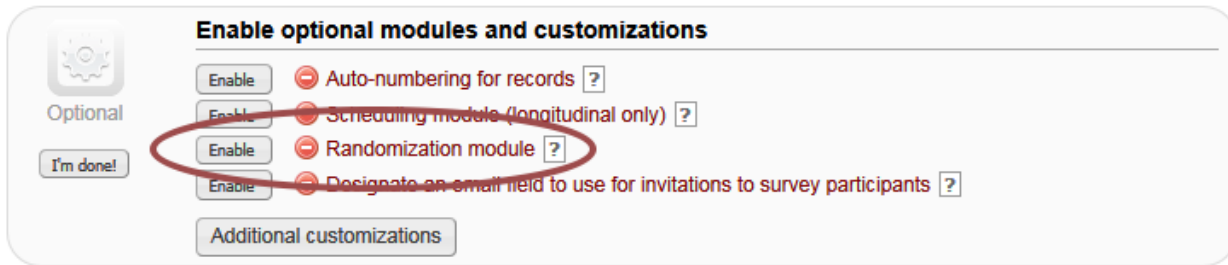
Next, click on the Randomization link under "Applications" on the left side menu.

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 table (CSV file)

Step1 - 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. Use stratified randomization?
2. Randomize by group/site?

Use 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.

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 (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 fields)

hair_color (Hair Color) ⌄

Add another stratum

IMPORTANT: you must revise the data dictionary to include 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 is this 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 (**1** groups currently exist)
◉ Use an existing field to designate each group/site

facility_site (Facility Site) ⌄

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 (Random Group) ⌄

Once all parameters are set, save the randomization model.

Save 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.

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

The template allocation tables will contain all the raw coded values for the fields used in your randomization model. When downloading and opening any of the template allocation tables, you will find some helpful notes in the last column of each file. It will list each multiple choice option's label corresponding to each raw coded value for all the fields utilized (e.g., it will specify 0=Female and 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, which can be used in your allocation table in the same fashion as the raw coded values for your randomization field and strata. The last column with the notes will be ignored when you finally upload your custom allocation table in Step 3.

| Example #1 (basic) | Example #2 (all possible combos) | Example #3 (5x all possible combos) |

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

- Will list each multiple choice option's label corresponding to each raw coded value for all the fields utilized (e.g. it will specify 0=Female and 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 create or set up your allocation table so long as you structure it correctly.

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 a hair color field that has 7 different values and I wish to allocate the participants into 5 groups. My allocation template downloaded from REDCap looks similar to the following:

random_group	hair_color
1	1
2	1
3	1
4	1
5	1
1	2
2	2
3	2
4	2
5	2
1	3
2	3
3	3
4	3
5	3
...	...

REDCap will randomize the participants according to this table. For example, the first participant that has a hair color of "Light Blond" (corresponding to the value of one) will be allocated to random group one. The second person with "Light Blond" 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 "func()" 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 hair color values will be randomized. For example, after sorting, the spreadsheet may look similar to the following:

random_group	hair_color	Random Value
4	4	0.01050529
3	1	0.01424553
2	5	0.02642509
2	4	0.03923845
3	5	0.03996002
5	3	0.04541500
5	6	0.04785563
4	2	0.05979234
5	5	0.06626952
1	4	0.06678536
2	7	0.06803015
5	2	0.06874587
3	2	0.07215219
3	3	0.07640087
2	1	0.07756467
...	...	...

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.

Step 3 - Upload your Allocation Table (CSV file)

The third and final main step in the randomization setup is to upload the allocation table.

Two allocation tables will eventually need to be defined, one for the development stage and a different one for the production stage.

Randomization User Rights

There are several user privileges that can be utilized for randomization, all of which correspond to different roles during the randomization process and can be set on the **User Rights** page.

- **Setup:** will see the **Setup** *tab* on the **Randomization** *page*, which will allow you to define the randomization model and all its parameters, as well as upload your custom allocation table → *Statistician/data analyst*
- **Dashboard:** 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 → *Study's PI*
- **Randomize:** - will be able to view the **Randomize** *button* on the data collection form that contains the randomization field, thus allowing you to perform the randomization on the subject/record you are viewing → *Research nurse/Study coordinator*
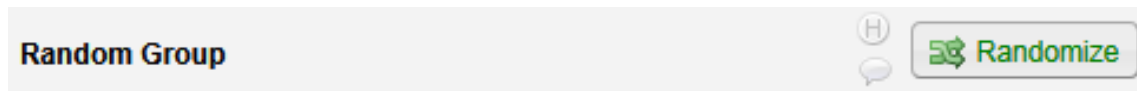
Randomizing a Record

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.
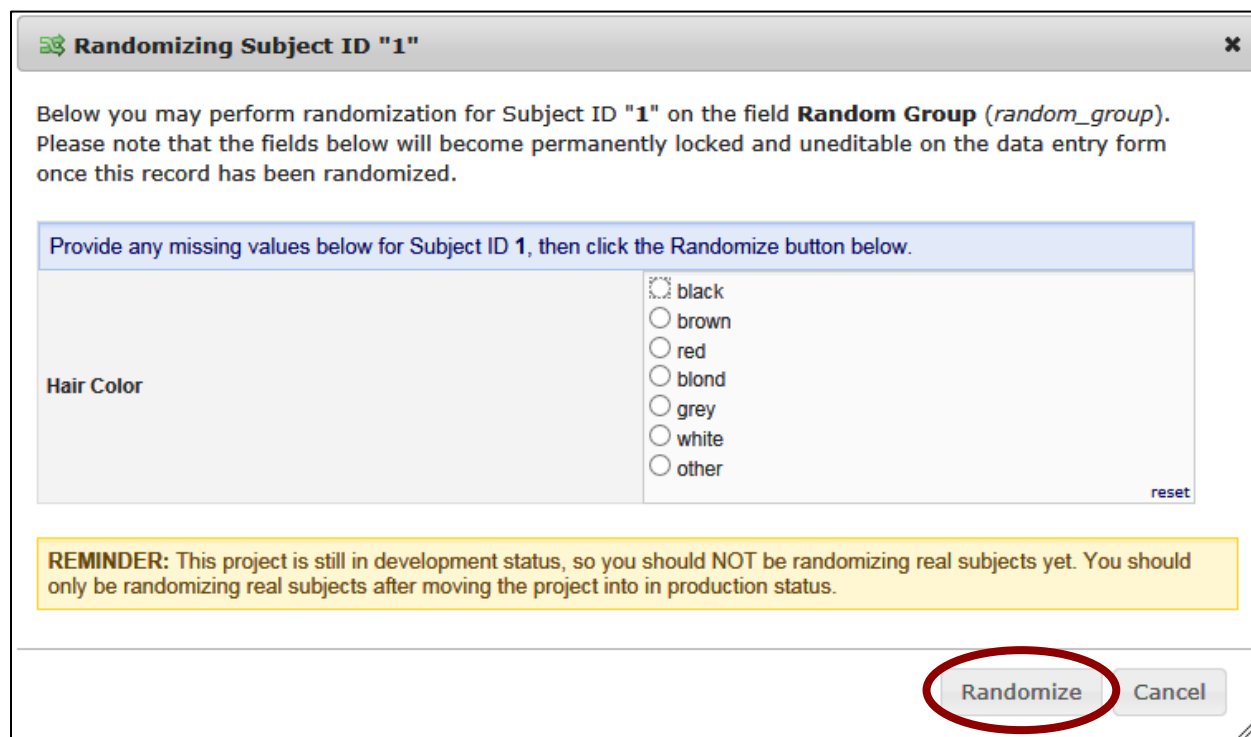
When the user randomizes the subject/record, REDCap will check the allocation table and assign that subject's/record's randomization field value, which will be derived from the next match in the table based upon the criteria (eg, strata field values, group). If not using stratified randomization and 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.
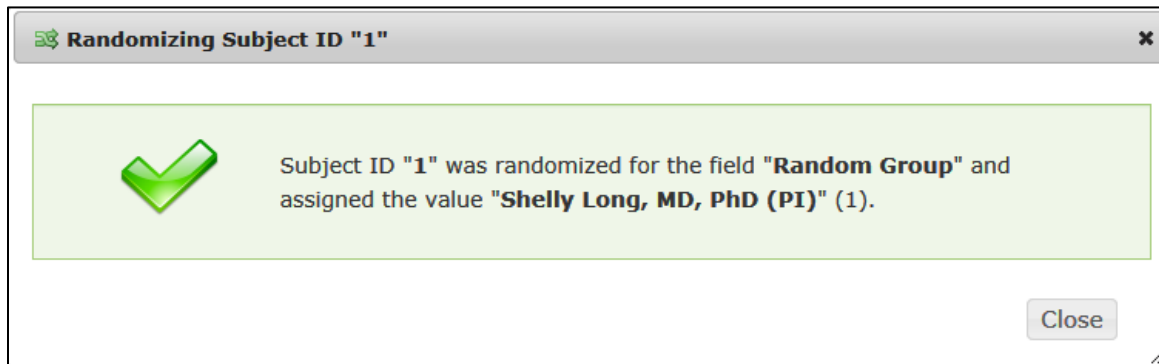

In addition, after the value of the random group is assigned, the random group field becomes read-only and the value cannot be changed.
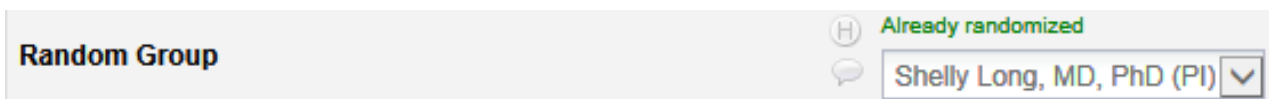
The strata fields you have chosen also become read-only and cannot be changed.
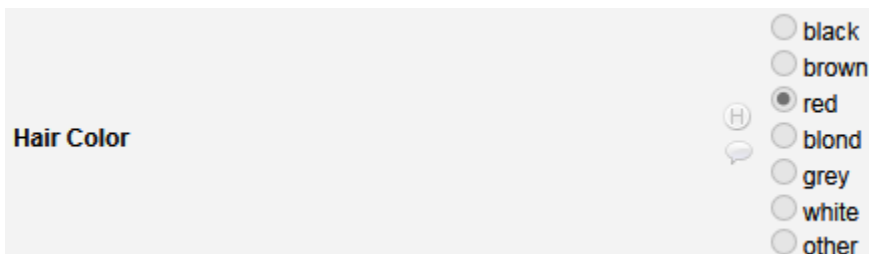
A listing of the records that have been randomized is maintained. To examine those records, click on the Randomization link in the Applications section of the Navigation Pane.
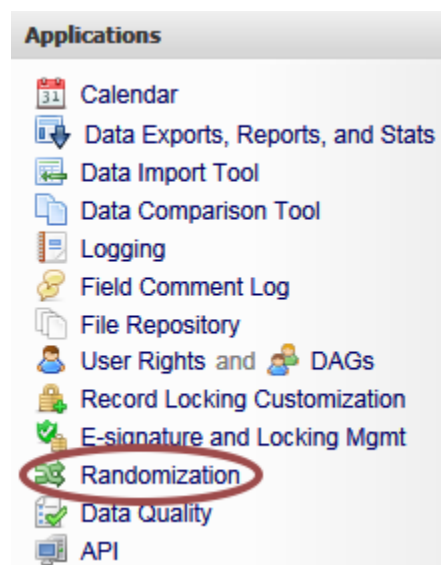
Dashboard

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	Random Group (random_group)	Hair Color (hair_color)
	0	1		Shelly Long, MD, PhD (PI) (1)	black (1)
	0	1		Shelly Long, MD, PhD (PI) (1)	brown (2)
✓	1	0	1	Shelly Long, MD, PhD (PI) (1)	red (3)
	0	1		Shelly Long, MD, PhD (PI) (1)	blond (4)
	0	1		Shelly Long, MD, PhD (PI) (1)	grey (5)
	0	1		Shelly Long, MD, PhD (PI) (1)	white (6)
	0	1		Shelly Long, MD, PhD (PI) (1)	other (7)

IMPORTANT

- How you generate your allocation table should be formal, secure, reproducible, and unpredictable → Best handled by a statistician; **_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 drop-in 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 settings can be modified, nor can any assignments be undone.
- Practice the process of randomizing patients by uploading an allocation table while in **Development** *status* and creating dummy records.
    - Delete the dummy records and upload "final" allocation table before moving to **Production** *status*.