

Randomization

Randomization is the process of assigning participants to groups by chance (e.g. treatment vs. control groups in a clinical research project). The **REDCap Randomization Module** allows you to implement a defined randomization model in your project, using an uploaded .csv file (“allocation table”) where REDCap will look up and find group assignments.

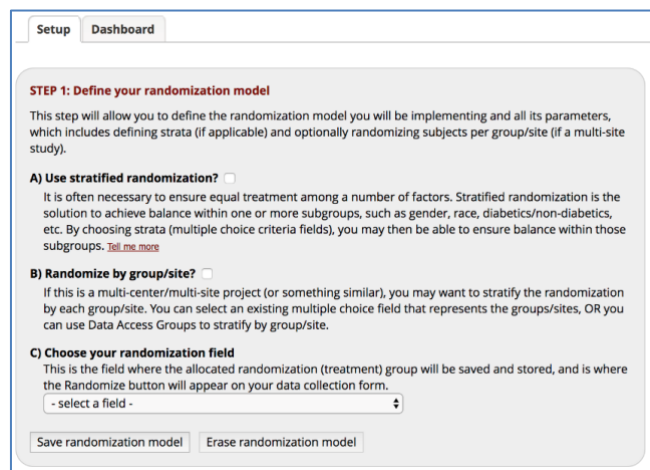
REDCap does not create the allocation table for you. Creating the allocation table usually requires a statistician, who will create the table using R, Stata, or another stats package, and then collaborate with the REDCap admin team to create the .csv files.

Setting up randomization in the CHOP REDCap **always requires the assistance of the REDCap admin team.** Meeting with the REDCap team will ensure your allocation table and randomization module are set up correctly. We can also help plan your workflow depending on the blinding requirements of your study. Please allow adequate time for randomization setup and testing when creating your project.

Methods:

Once a study team approaches REDCap team with request to enable randomization module:

1. The REDCap admin will ask the study team to clarify their randomization scheme with their statistician and/or Principal Investigator. This will include identifying any stratifying categorical variables like biological sex or group/site, and specifying the REDCap field to be used for randomization (i.e. the randomization button). This is typically a multiple choice drop-down field with each allocation listed (e.g. 1, Treatment A | 2, Treatment B | 3, Standard of Care). The REDCap admin uses this information to define the randomization model within REDCap:



The screenshot shows the 'Setup' tab of the REDCap interface. At the top, there are two tabs: 'Setup' and 'Dashboard'. Below the tabs, the page is titled 'STEP 1: Define your randomization model'. The text explains that this step allows defining the randomization model and its parameters, including strata and randomizing subjects per group/site. There are three main sections: A) 'Use stratified randomization?' with a checkbox and explanatory text; B) 'Randomize by group/site?' with a checkbox and explanatory text; and C) 'Choose your randomization field' with a text box and a dropdown menu. At the bottom, there are two buttons: 'Save randomization model' and 'Erase randomization model'.

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).

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

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2. The REDCap admin saves the randomization model, which allows REDCap to automatically generate allocation table templates. REDCap admin will download one of the templates and provide it to the study team, including any statisticians, who will confirm it looks correct.
3.
 - a. If the project requires **simple randomization without stratification and does not have a statistician** to create the allocation tables, the REDCap team can generate allocation tables. Involving a study team statistician is **always** preferred, however.
 - b. If the project **requires more complex randomization like stratification**, a statistician from the project team will create the allocation tables and return them to the REDCap team. The REDCap admin will provide the template to the study team's statistician with the request that the statistician:
 - i. Use the template to generate two separate allocation tables: one for development mode and one for production mode,
 - ii. Return those two allocation tables to the REDCap administrators only, and
 - iii. Never share the allocation templates with the study team (study staff should never be cc'd). This is in order to maintain concealed allocation, aka the concept of the "sealed envelope." Concealed allocation prevents selection bias by preventing study staff from knowing which allocation will come next. This procedure is separate and apart from blinding- study staff may not be blinded to the subject's allocation, but they still should not know which allocation to anticipate next. **Sharing the allocation template with the study team would violate this principle and could result in selection bias.** This is also the reason why two allocation templates exist: one for development mode and a different one for production mode, so staff can practice the workflow of randomization without knowing which allocation comes next.

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4. After the REDCap admin receives the allocation tables from the statistician or has generated the tables themselves, they will upload them into the randomization model:

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.



Already uploaded

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

[Delete allocation table?](#)



Already uploaded

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

[Delete allocation table?](#)

5. The REDCap admin will test the randomization with 2-3 records, then will pass to the study team for testing and practicing the randomization workflow.