UNIVERSITY OF ILLINOIS CHICAGO

Randomization

CCTS Biostatistics Core

May 2024

Purpose

The REDCap Randomization module can be used:

- For randomized controlled trials (RCTs) that need to assign study participants to different treatment groups.
  - "An RCT is a prospective study following patients forward in time. After agreeing to participate, patients are randomly allocated to one or more interventions or a control group and are followed until a finite date or the occurrence of one or more outcomes of interest." - Houle S. 2015
- To randomize the survey instruments or data entry forms.

Steps

Outside of REDCap

Plan your randomization method

a. Decide between simple randomization and stratified randomization.
b. Determine the randomization ratio (e.g., 1:1 for equal allocation to treatment and control groups).
c. Determine the number of records to be randomized.

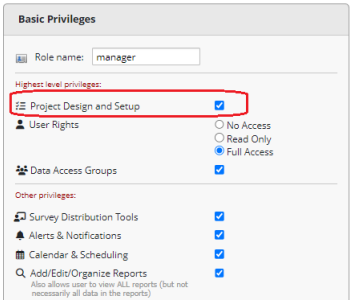
Generate randomization allocation table

a. Create the allocation table outside of REDCap using statistical software in collaboration with your team's data scientist.
b. Ensure the allocation table includes more assignments than the planned sample size to accommodate any unexpected changes or errors.

Within REDCap

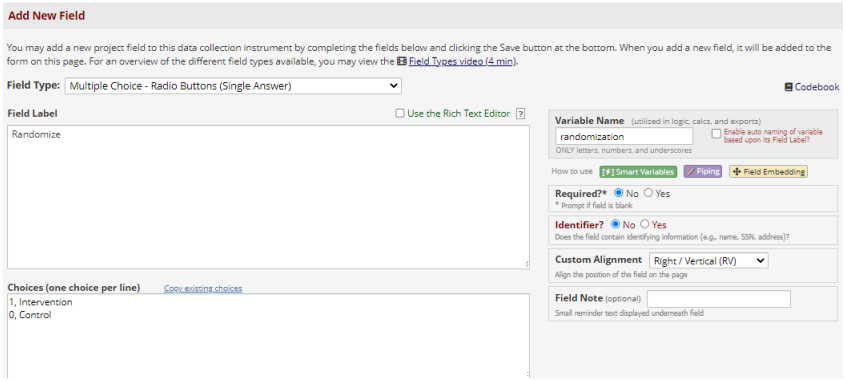
Set up user rights

a. Define user access rights in the REDCap project. Users with access to Project Design and Setup can set up the Randomization module. See the User Rights page form more information.
b. Users accessing the instrument with the randomization field can randomize and view the result. Those requiring blinding should not have access to the instrument.



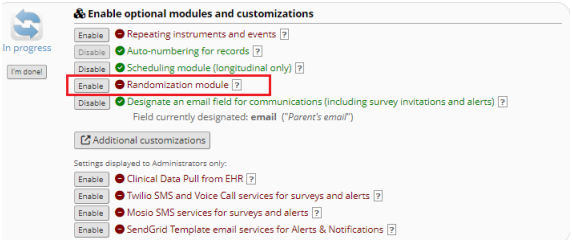
Create fields for randomization in Online Designer

a. Include fields necessary for randomization in your project using the Online Designer.
b. Define inclusion/exclusion criteria used as strata or conditions for randomization using branching logic.
c. Create the randomization result field as a radio button (e.g., 0, Control / 1, Treatment). It is best to create this field in a regular data entry form entered by study staff, not in a screening form or survey instrument.

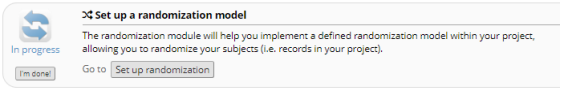


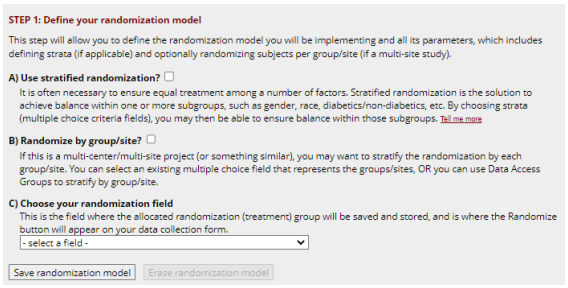
Set up and test Randomization module in Project Setup Perform this setup in development status, as no changes are possible in production status. See this page for more about development and production status.

1. Enable the Randomization module in Project Setup.

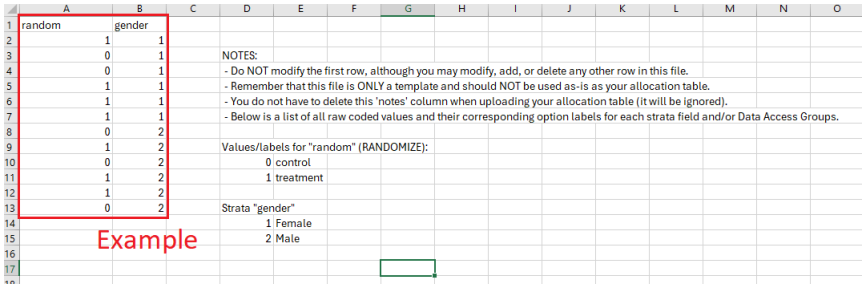


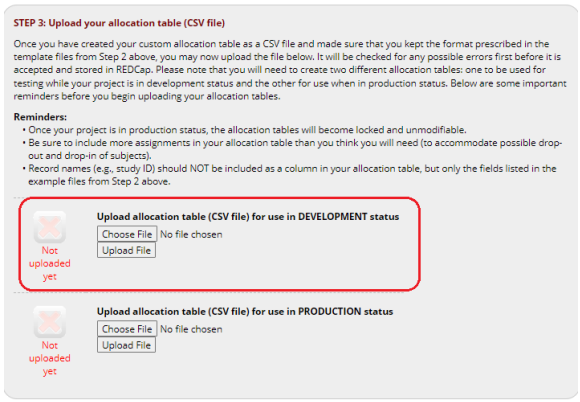
2. Click `Set up randomization` and Complete STEP 1: Define your randomization model.



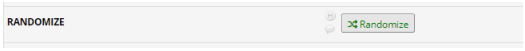


3. Upload your allocation table following the REDCap format. It should contain column headers matching the field names defined in the Online Designer for the randomization and stratification fields, as well as strata and randomization values. The following example randomizes 12 subjects using stratification by gender.



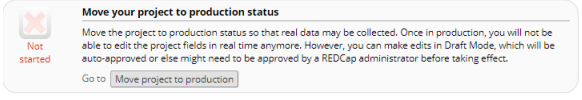


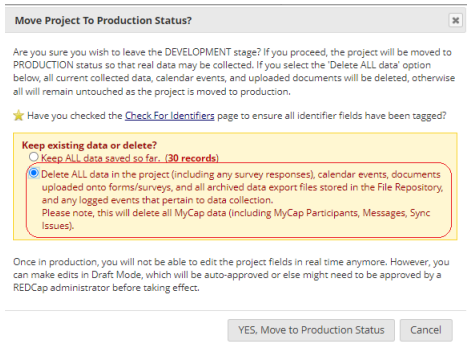
4. Test randomization to ensure proper functionality and verify that branching logic works correctly on the data entry form.



Upload allocation table in production status

1. After successful testing in development, upload the final allocation table again for use in production status.
2. Any test records and the development allocation table should be deleted when you move the project to production.





After Randomization

Using randomization value Randomization results can be used for branching logic, form-skipping logic, Alerts & Notifications, and Automated Survey Invitations.

Modifying or updating the allocation table are restricted Once the “Randomize” button is clicked in production, the randomized result and related values used for stratification will be locked and cannot be modified.

In production status, the uploaded allocation table cannot be modified. However, additional values can be added by the REDCap administrator. To request help, submit a support request.

Handling mistakenly randomized records After randomization, if a record was mistakenly randomized, there should be a process in place to address this issue. This might involve documenting the error and taking corrective action if necessary (e.g., deleting the whole record and re-entering data to randomize again).