Randomization in Redcap

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1. Get the following **user rights** for the project within Redcap:
   1. Randomization – setup, dashboard, randomize (3 separate check boxes)
   2. If you don’t see the “user rights” button under “Applications” on the left-hand side of the project dashboard, you don’t have access to change your user rights. Contact the PI/person in charge of the project’s redcap.
2. Click **Randomization** under “Applications” on the left-hand side of the project dashboard.
   1. Step 1: define the randomization model
      1. Choose the stratification variables –i.e age, sex. These must be already defined within the redcap database. If not, you need to create them.
      2. Choose your randomization field – i.e. treatment group. This must be already defined within the redcap database, if not create it.
      3. If these variables are not in redcap, you need to create them (see step 3)
   2. Step 2 (optional): download template allocation tables
      1. Download one of these tables as an example. We recommend using R or SAS to create your own allocation table, as shown by Claire during the demo.
      2. Templates are helpful to see the exact variable names and labels to use in the allocation table that you create
   3. Step 3: upload allocation table
      1. After creating the allocation table (as shown by Claire in the demo), upload the development table here
      2. Do not upload the production that until you test the development table by creating dummy patients (see Step 4)
3. (optional): If any the stratification variables or treatment group variable are NOT already in redcap, **create variables**:
   1. Go to Project Home → Project Setup (tab)
   2. Under “Design your data collection instruments”, click “Online Designer”
   3. Select the instrument where you want to add variables, probably the first instrument
   4. Click “Add Field” and select “Multiple Choice – Radio Buttons (Single Answer)” and pick a label, choices, etc.
4. Test out the randomization:
   1. Once you have uploaded the allocation table in DEVELOPMENT, create some dummy patients (add/edit records)
   2. Choose values for the required stratification variables, push randomize, and compare treatment group to the allocation table
5. Upload production table:
   1. Once you are satisfied with the testing, create a NEW allocation table using a **different random seed**, and upload under Randomization → STEP 3: Upload your allocation table

Tips:

* The Setup tab of the randomization page is **ONLY AVAILABLE DURING DEVELOPMENT** stage. Thus, all of this needs to be done before the project is moved to production‼
* Keep copies of the development and production allocation tables in a safe project folder
  + Make sure to have different tables for development and production
* Be sure to create LOTS of extra rows in your allocation table – it doesn’t hurt to have too many.
  + If more patients are enrolled than expected, and there aren’t enough rows, you will need to upload an additional production table
  + This requires contacting the redcap support team, and may mess up your randomization
* Make sure the entire research team understands how the randomization works:
  + Once the user pushes “randomize”, that patient is in the study and should be used to ensure equal allocations
* How it works:
  + “When the user randomizes the subject, REDCap will check the allocation table and assign that subject's randomization field value, which will be derived from the next match in the table based upon the criteria (e.g., 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.”