

Advanced REDCap Training Session

Parya Zareie, MS University of Tennessee REDCap Administrator Informatics Architect

Learning Objectives

- Survey Dissemination
- Randomization Build
- Piping



Survey **Dissemination**

Surveys in REDCap

- A survey is a version of a data form that is completed by a study participant without logging into the REDCap system
- REDCap offers two survey options: Public and Private

Type of Survey	Use
Public	Responses are anonymous
Private	Responses can be identified



Public vs Private

Public	Private
Must be the first form	Doesn't need to be the first form
New record for each survey submission	New record before survey submission
One survey link for all participants	Survey links specified for each participants





- Create an instrument in your longitudinal project for "Randomization"
- Create a text box field for the date of randomization
- Insert necessary fields
 - Field label
 - Variable name
 - Validation
 - Action Tag/Field Annotation
 - Automate the date to the date of randomization
 - @TODAY, today's date to be automatically inserted

Edit Field

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button at the bottom. When you add a new field, it will be added to the form on this page. For an overview of the different field types available, you may view the 🖽 Field Types video (4 min).

Field Type: Text Box (Short Text, Number, Date/Time, ...) ▼

		Variable Name (utilized in logic, calcs, and exports)
Date of Randomization		randomization_date variable based upon it
		ONLY letters, numbers, and Field Label?
		underscores
		How to use Crismart variables / Piping
		Validation? (optional) Date (M-D-Y)
		Minimum:
		Maximum:
Action Tags / Field Annotation ((optional)	- or -
@TODAY @READONLY		select ontology service 🔻
Learn about Action Tags or <u>using Field Annotation</u>	Field Annotation	Required?* ONO • Yes
		Identifier? No Yes
		Does the field contain identifying information (e.g., name, SSN, address)?
		Custom Alignment Right / Vertical (RV)
		Align the position of the field on the page
		Field Note (optional)
		rielu Noce (optional)

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- Create a "Multiple Choice-Radio Button" field for the treatment arms
- Insert necessary fields
 - Field Label
 - Variable Name
 - Choices
 - For "Blinded" studies, use numeric values instead of text
 - Means having an allocation table where only the biostatistician is aware of the numeric/text value correlation

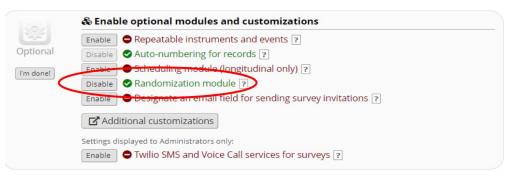
Edit Field

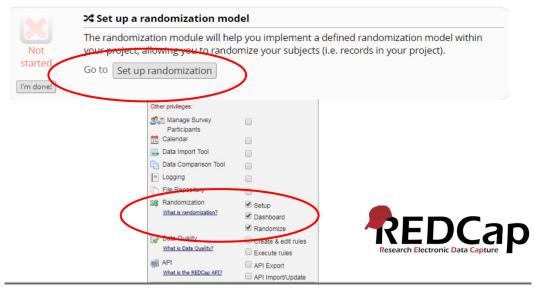
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Field Type: Multiple Choice - Radio Buttons (Single Answ 🔻 Field Label Use the Rich Text Editor ? Variable Name (utilized in logic, calcs, and exports) Enable auto naming of Randomized Treatment Arm randomized treatment arm variable based upon its Field Label? ONLY letters, numbers, and underscores How to use [9] Smart Variables 🖉 Piping Required?* ONO Yes * Prompt if field is blank Identifier?
No Ves Does the field contain identifying information (e.g., name, SSN, address)? Choices (one choice per line) Copy existing choices 1, Usual Care Custom Alignment Right / Vertical (RV) . 2, Intervention Align the position of the field on the page Field Note (optional) Small reminder text displayed underneath field How do I manually code the choices? Action Tags / Field Annotation (optional) Learn about @ Action Tags or using Field Annotation Save Cancel

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- On the project setup page, ensure that the randomization module is enabled
- Edit the REDCap users' right to include randomization setup privilege
- Next, project setting page select set up randomization





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- You will be redirected to the Randomization Setup page
- **Step 1**, make the appropriate selections based on discussion with your PM/PI for stratified randomization or randomization by group/site
- Select the dropdown on the left for "Choose Your Randomization Field"
- Select the "Field Name" designated in your randomization instrument, in the field for treatment arm designation
- Select the dropdown menu on the right under "Choose Your Randomization Field"
- Select the appropriate event where randomization instrument is categorized
- Select "Save Randomization Model"

Randomization

Randomization is a process that assigns participants/subjects by chance (rather than by choice) into specific groups, typically for clinical research and clinical trials. 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. Note: It is recommended that only people with experience in randomization set up the Randomization module. More details

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/hon-diabetics, etc. By choosing strata (multiple choice criteria fields), you may then be able to ensure balance within those subgroups. Tell memore

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 group/sites, OR you can use Data Access Groups to stratify by group/site.

C) Choose your randomization field

	- select a field -	•	for Enrolment •	
C	- select a field - ethnicity (Ethnicity) race (Race) sex (Gender) given_birth (Has the patient given birth before?) dialysis_unit_phone (Confirmed?) subject_comments (Confirmed?) randomized_treatment_arm (Randomized_Treatment Arm).			icture your own
loc sh be	pmq1 (On average, how many pills did you take each day last w pmq2 (Using the handout, which level of dependence do you fee pmq3 (Would you be willing to discuss your experiences with a p pmq4 (How open are you to further testing?) vbw6 (Blood draw shift?) vbw6 (Level of patient anxiety) vbw9 (Patient scheduled for future draws?) vbb1 (nervous?)	ýO	u are currently at?)	from in order to It then be used as a s (e.g., study ID) nple files



• Step 2 allows you to download a sample allocation table

This should be used only for practice/testing

- Your project biostatistician should provide you with an official allocation table
- **Step 3**, click "Choose File" to locate an official or practice allocation table

A project should NOT be moved into production with a practice allocation table in place

- Once the appropriate file is selected, click "Upload File"
- Once your file is successfully uploaded, you will see a green checkmark appear
- You may delete your allocation table by selecting "Delete Allocation Table?"
- You may download and view your allocation table by selecting "Download Table"
- To start the process over, select "Erase Randomization Model" in Step 1

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. <u>More details</u>

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

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.

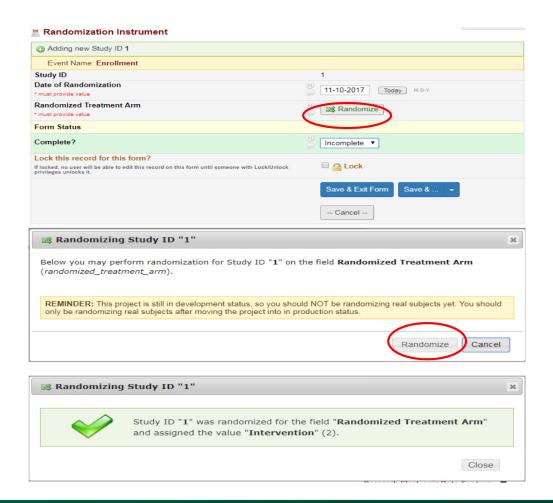
Reminders:

- 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.



- Add a record to test your randomization instrument
- You will now see a "Randomize" button on the form
- Click "Randomize"
- A pop-up box will appear, to proceed with randomization, click "Randomize"
- An additional pop-up box will appear indicating successful randomization and displaying the assigned treatment arm for that participant

When moving your project into production, all test randomizations will be erased





Piping

- Piping is a feature in REDCap that allows you to place previously collected data into fields in other forms or surveys
- Piping does not need to be enabled as a "project setting"
- Information can be piped in a few different ways:
 - Across events by inserting the original event name in front of the piped variable
 - Ex. [Baseline_data][first_name]
 - Create customizability in survey invitations and survey completion text
 - Ex. "Thank you, [first_name] for completing the survey."

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Where can piping be used?

- Field Label
- Field Note
- Section Headers
- Alerts & Notifications
- Option labels for multiple choice fields
- Survey Instructions
- Survey Completion Text
- Survey invitation emails
- Custom text displayed at top of Survey Queue
- Inside the URL for a survey's 'Redirect to a URL' setting You can pipe *from* all fields EXCEPT checkboxes
- Multiple answers cannot be piped at one time



Piping

- To pipe within the same event, between forms, or within the same form, put the variable name in brackets in the desired field
 - Ex. [first_name]
- To pipe data **between events**, ensure the event name you are piping from precedes the variable name in the desired field
 - Ex. [enrollement_arm_1][first_name]

Add	New	Fiel	d

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Field Type: Descriptive Text (with optional Image/Video/, 🔻

Hello [enrollment_arm_1][first_name]	first_name_morale_quest Enable auto naming o ONLY letters, numbers, and underscores Field Label?
	How to use [] Smart Variables Piping
	Optional file attachment, image, audio, or video:
	Embed an external video (provide video URL) ?
Action Tags / Field Annotation (optional)	e.g. https://youtube.com/watch?v=E1cCuWMupz0, https://vimeo.com/62730281, http://example.com/movie.mp4
Learn about @ Action Tags or <u>using Field Annotation</u>	Display format of video: O Inline Inside popup
	Attach an image, file, or embedded audio O Upload document
	Display format of attachment on page: Unk
	 Inline image Audio file (play in embedded player on page) <u>Compatibility notice for embedded audio</u>
	(Images wider than 600 pixels will be downsized to fit page.)



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Questions / Comments

