Computational Tools for the Clinical Researcher

REDCap 101

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Scientific Computing, Research Data Services

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Icahn School of Medicine at Mount Sinai

Introduction – Team Members

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Applications Support Analyst

Scientific Computing and Data Science Mission

To enable and accelerate biomedical discovery through collaborative research using high performance computing, biomedical informatics and data science.

- Scientific Computing
  - High Performance Computing
  - Mount Sinai Data Warehouse
  - Research Data Services

- Unlike other computing resources, Scientific Computing stakeholders are also actively engaged in research projects

- We work with investigators to create a robust research environment at Mount Sinai, expand our profile in national research efforts, and partner for grant funding success

REDCap at Mount Sinai

- Research Electronic Data Capture – a platform developed by Vanderbilt University as a proper replacement for pen and paper data collection
- We are working towards 21 CFR Part 11 compliance – joint effort by Scientific Computing, IT Security, IRB and Privacy Offices
- Data resources and integration between many existing systems with more to come
  - Import clinical data into REDCap from Epic
  - –Basic Demographics
  - –Condition/Problem list
  - –Medications
  - –Vital signs
  - –Laboratory
- We host more than 11,000 databases with over 20,000 active users
- Services for project building, data protection, support, and training

REDCap at Mount Sinai

- Useful as a tool for different stages of research and operations
  - Industry sponsored studies
  - Private and Government grant funded research projects and programs
  - Hospital Quality Improvement initiatives
  - Flexible platform that is finding uses in new contexts
- Easily accessible and well-rounded open-source learning materials
  - Training and Presentation Materials Repository
  - Language Center translation sharing
  - Plugin and Hook Libraries
  - External Modules
  - Survey Library
- Collaborative platform that reduces barriers for research

Digital Concierge Service

- Virtual REDCap Office Hours: Wednesdays at 3:30pm to 4:30pm
  - Open to all users
  - Get help with specific project questions

  https://zoom.us/my/digitalconcierge

Overview

Project Setup
- -Templates
- -Project page
- -Online Designer
  - -Surveys
  - -Variables
- -Obtaining Data
- -Longitudinal Studies

Managing Users

Project Life Cycle

Data Management

REDCap Access for Mount Sinai Users

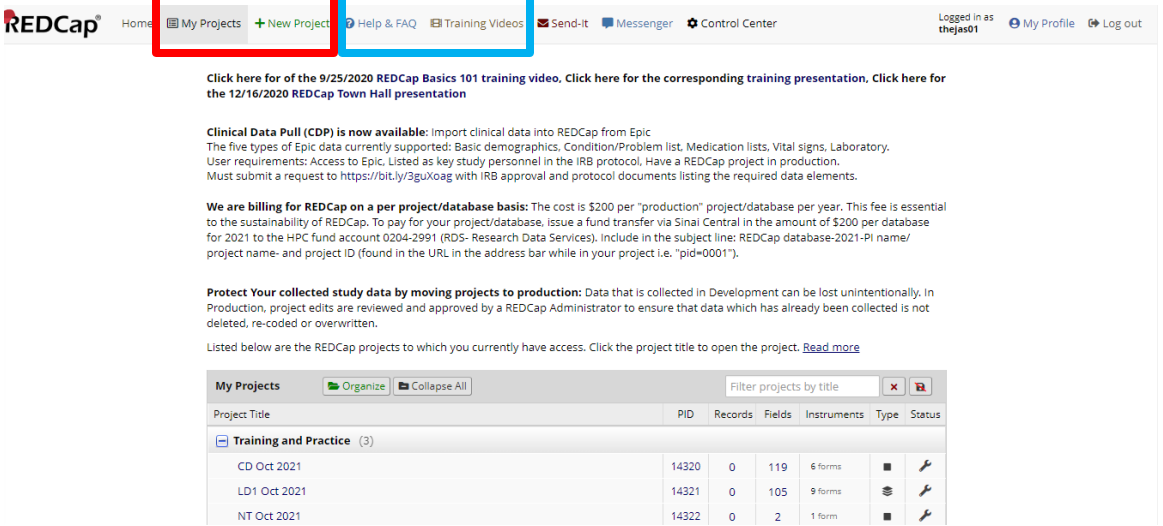
Ensure that you're able to log into REDCap

- Mount Sinai faculty, students and staff can log into REDCap using their regular Mount Sinai username and password here: https://redcap.mountsinai.org

- Users new to Mount Sinai's REDCap instance will need to verify their email. After email verification, you can log in to create new projects or be added to existing ones.

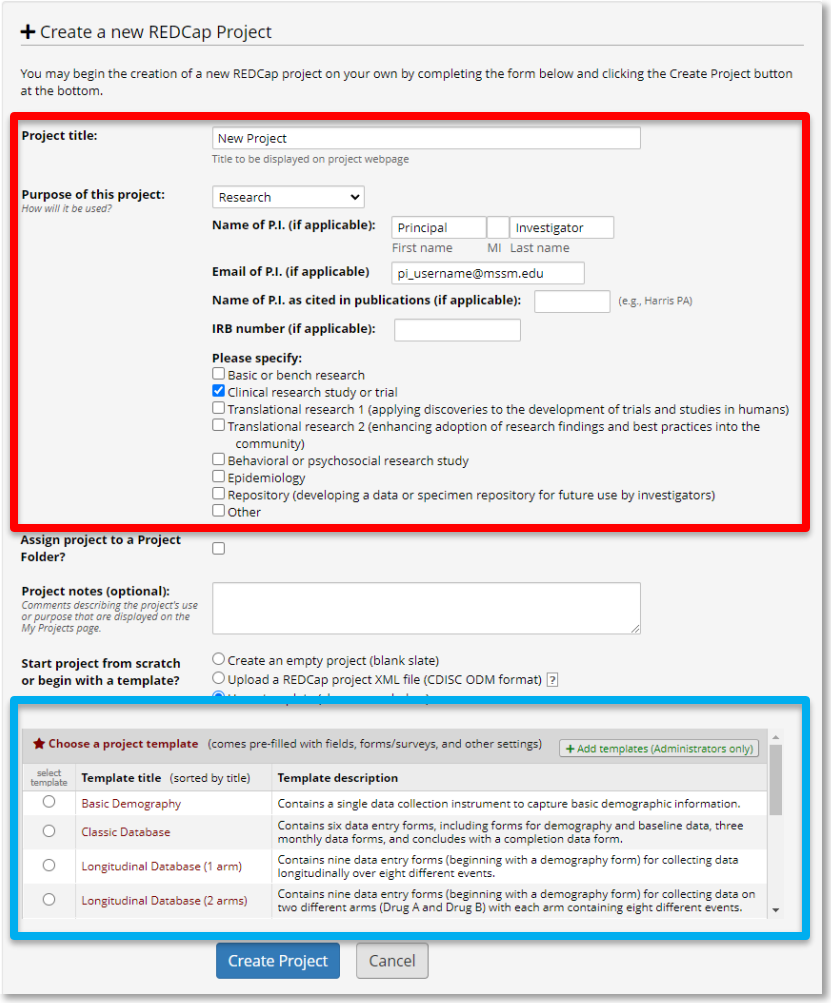
REDCap Homepage

- Mount Sinai REDCap: https://redcap.mountsinai.org
- Users can find the projects they have access to under **My Projects** at the top of the page. These are projects they've been added to or have created.
- To create a project, click on the adjacent **New Project** button.
- Along the top bar, users will also find great resources under **Help & FAQ** as well as **Training Videos** for learning to use REDCap.



Creating a New Project Cont'd

- When creating a new project, users can fill out **project details** and the type of research that will be conducted
- On the same page are **templates** for getting started on a new project

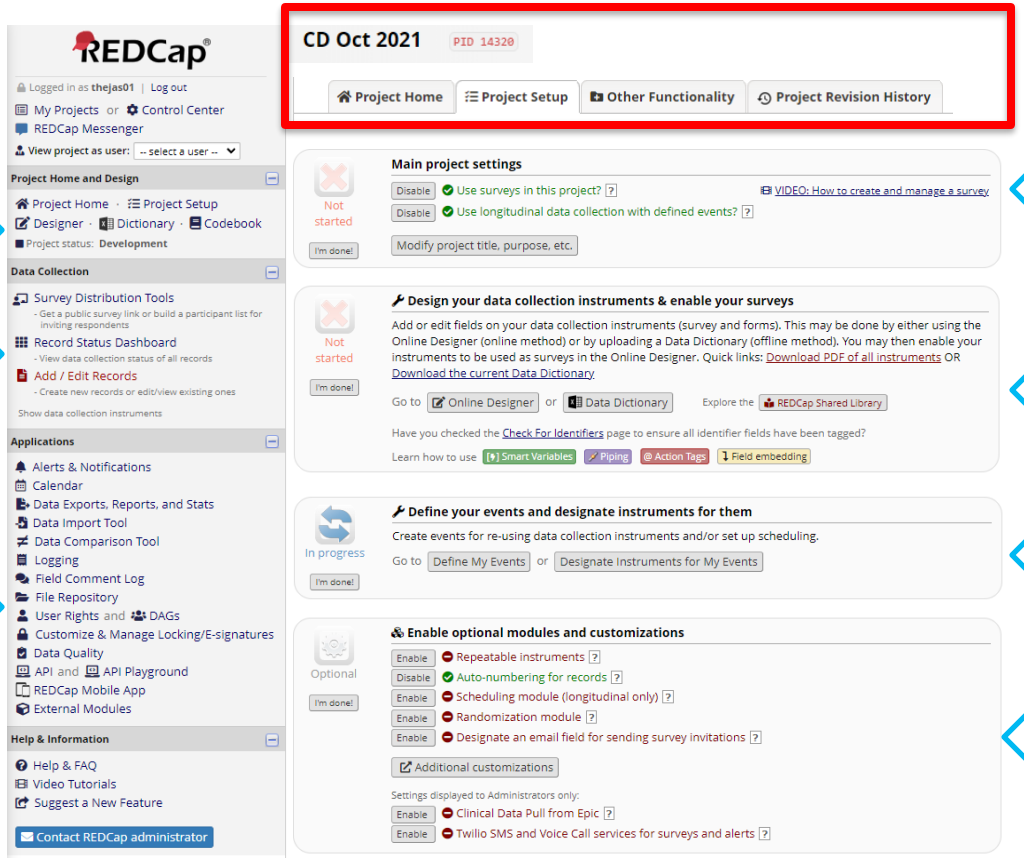


Getting Familiar with the Project Page

- Manage a project

- Check and edit participants' records, share survey invitation links and QR code

- Import, Export, and run Reports on collected data
- Modify User Access
- Configure External Modules



- Modify project title, PI, and descriptions
- Enable Longitudinal data collection

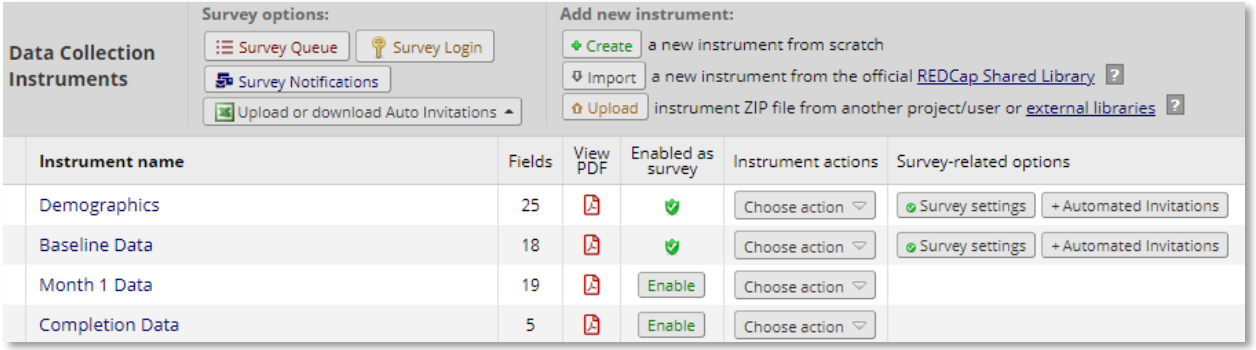
- Access the Online Designer
- Access/download the data dictionary
- Find information on unique REDCap functions

- Define how a longitudinal study is structured

- Extended customizations and modules options

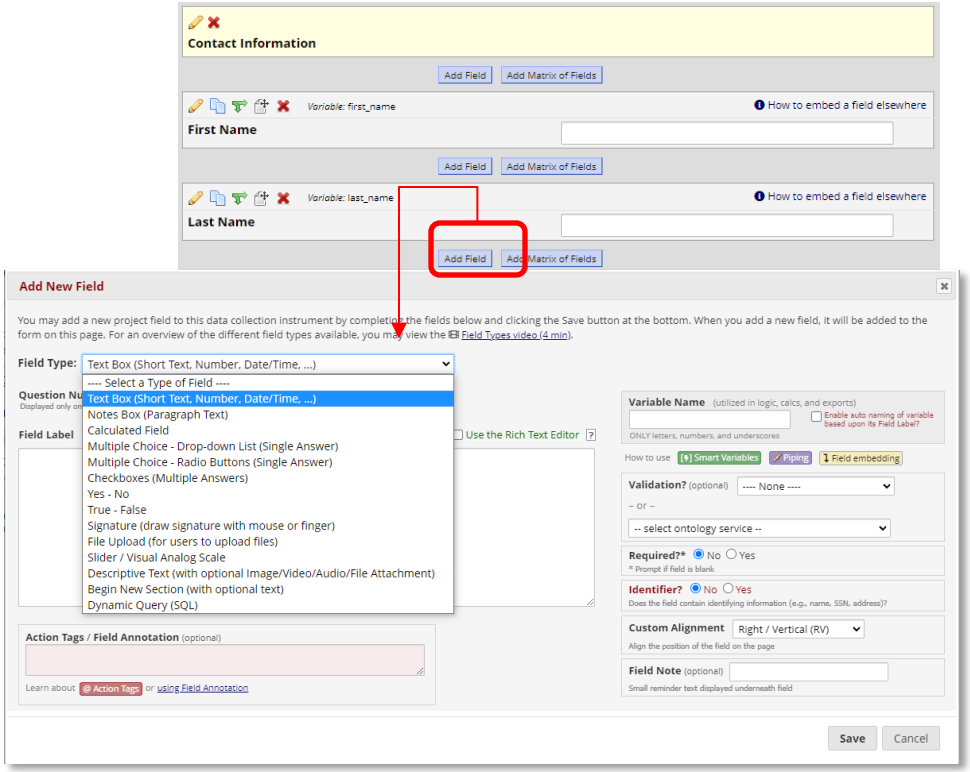
Online Designer – Instruments/Surveys

- Create, Import, and Manage data collection forms
- Enable instruments as surveys
- Edit data collection instruments and variables
- Define how participants can get automated invitations by email



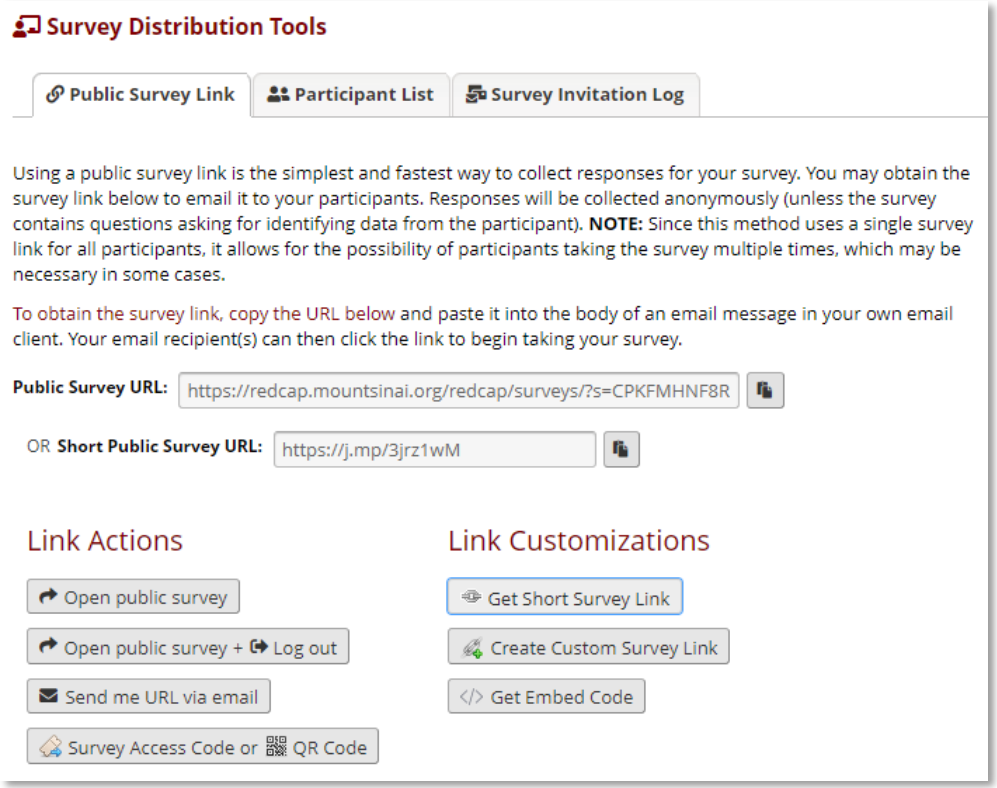
Online Designer – Variables

- Variables allow users to define discrete data points for collection
- Short, simple, and identifiable names for variables are preferred
- Choose the field type that best fits the data point



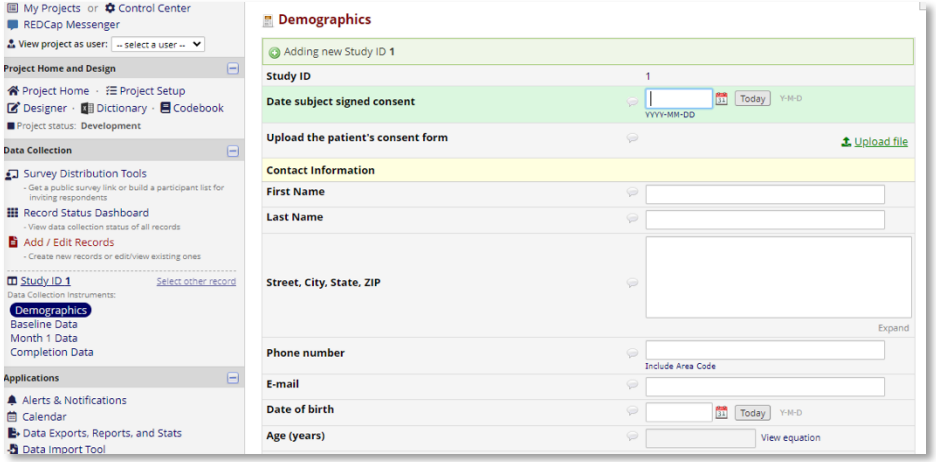
Obtaining Data

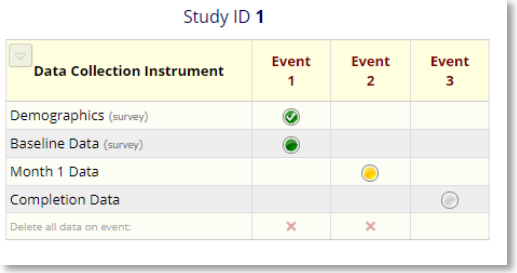
- Invite participants to take a survey by sharing Public Survey URLs or QR codes
- Monitor follow-up surveys and previously sent invitations, manage the survey's participants list



Obtaining Data – Data Entry Form

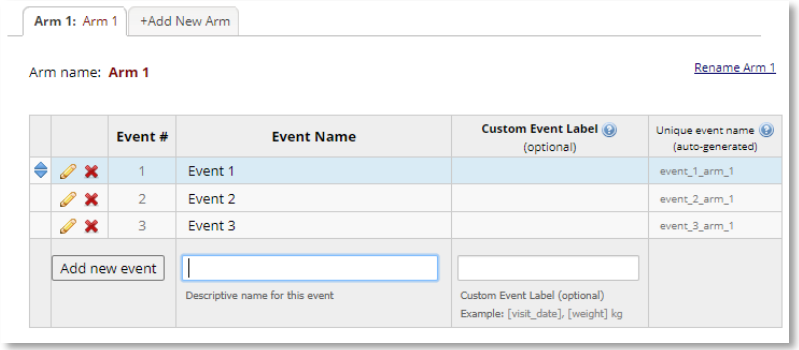
- For data points that are not collected during the surveys, they can be entered in the **Record Home Page**
- Can enter new data, overwrite data, or make notes on data for the record

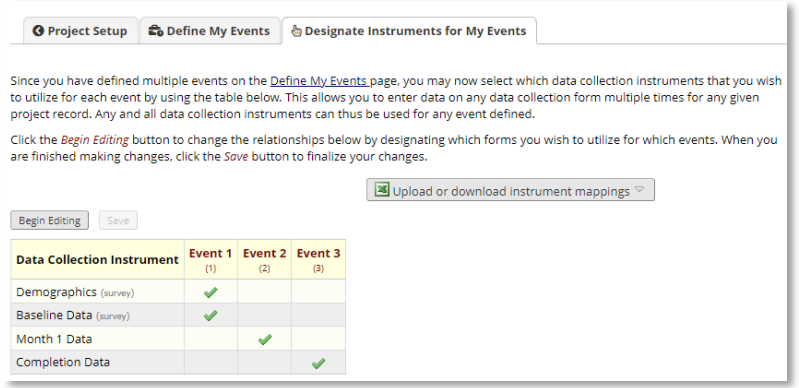




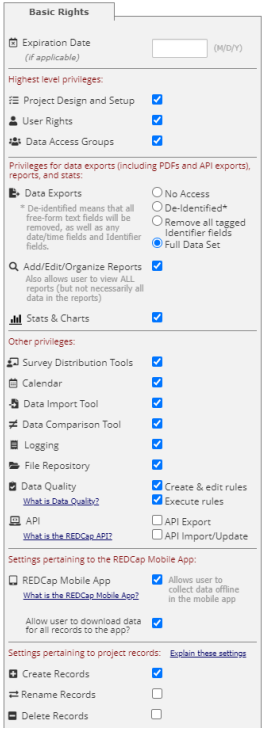
Longitudinal Studies

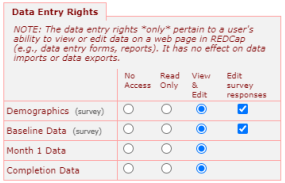
- With longitudinal studies, additional options are available
- Define each of the study **Arms** and **Events** for those Arms
- Designate Instruments for each Arm and Event

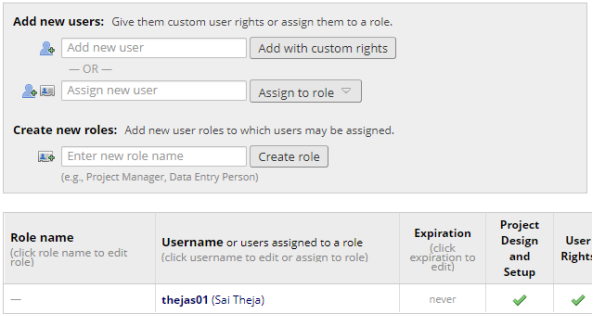




Managing Project Users



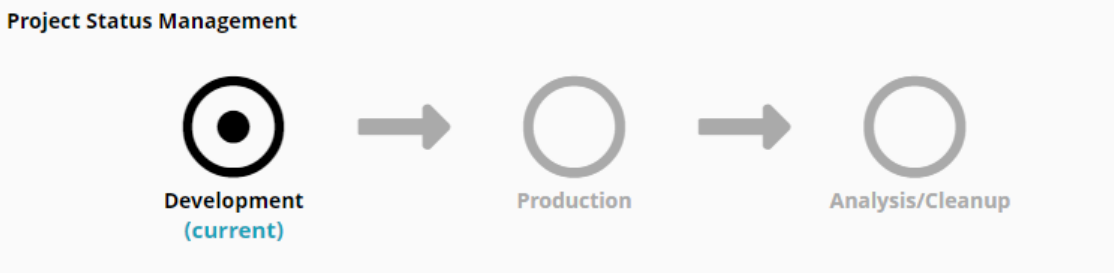




- Users with accounts can be added to a project in the **User Rights** section of your project
- When adding or modifying existing users, a long checkbox section will appear to manage their access
- It is important to properly manage user rights to protect data and PHI, control project design and life cycle, and maintain accountability

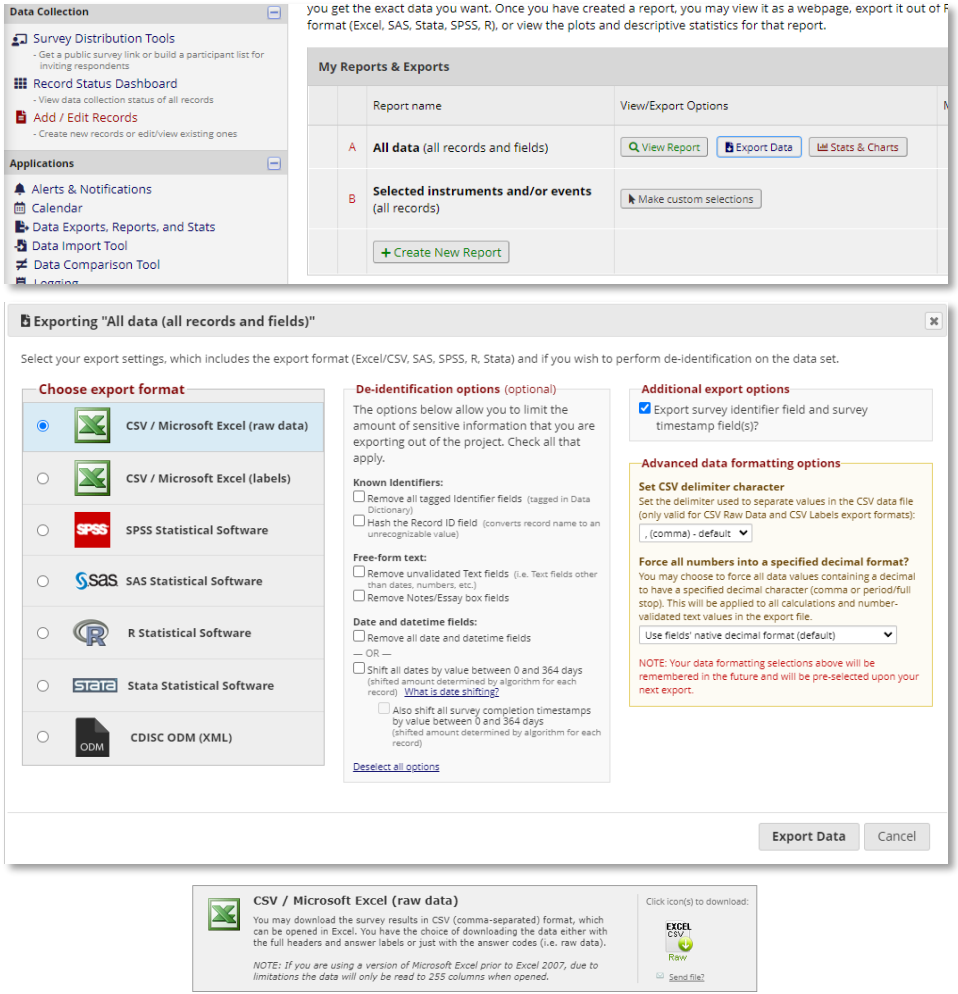
Project Life Cycle

- **Development** phase of the project is best for creating and testing a project. Avoid entering real data if changes still need to be made.
- **Production** phase protects collected data by flagging project changes for data loss review. The bulk of data collection should be performed in this phase if feasible.
- **Analysis/Cleanup** phase for finalizing analysis and ending a study.



Data Management

- **Data Exports, Reports, and Stats** contain methods to export collected data in various formats
- Custom selections can be made to isolate data of interest from larger project databases



Part A: To be able to create a web-based survey form with a link that can be emailed to the subjects.

- Modified BDI questions
- **Field label & Variable name:** Q1
  - **Choices:**
  - 0, I do not feel sad.
  - 1, I feel sad
  - 2, I am sad all the time and I can't snap out of it.
  - 3, I am so sad and unhappy that I can't stand it.
- Q2
  - 0, I am not particularly discouraged about the future.
  - 1, I feel discouraged about the future.
  - 2, I feel I have nothing to look forward to.
  - 3, I feel the future is hopeless and that things cannot improve. cannot improve.
- Q3
  - 0, I do not feel like a failure.
  - 1, I feel I have failed more than the average person.
  - 2, As I look back on my life, all I can see is a lot of failures.
  - 3, I feel I am a complete failure as a person.
- Q4
  - 0, I get as much satisfaction out of things as I used to.
  - 1, I don't enjoy things the way I used to.
  - 2, I don't get real satisfaction out of anything anymore.
  - 3, I am dissatisfied or bored with everything.

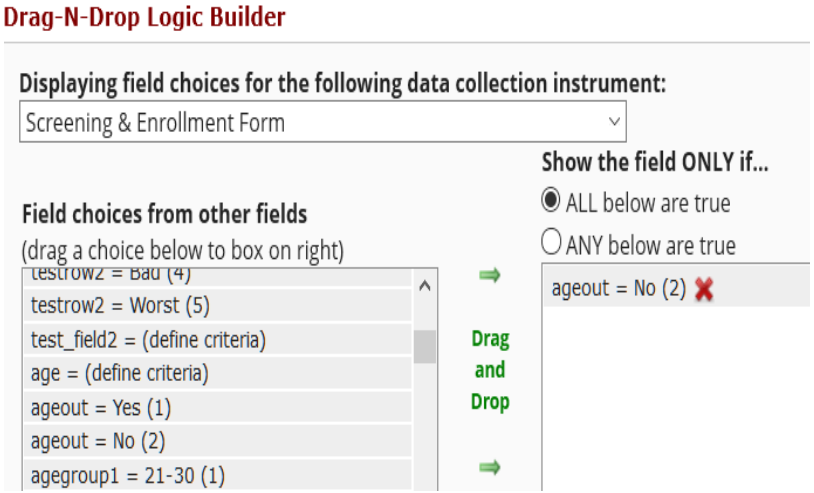
Database vs Longitudinal

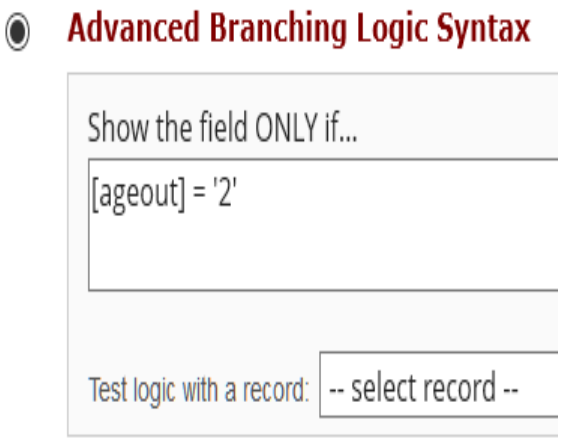
1. Classic Database – Each form can only be completed once. One record per subject.

2. Longitudinal –
   - Data collected multiple times per subject
     - Fixed number of collection points that correspond to pre-defined events (e.g. initial evaluation, 3mo. follow-up, 6mo. follow-up, 1yr follow-up)
   - Optional scheduling via a project calendar
   - Can have multiple study arms

Building Forms: Branching Logic

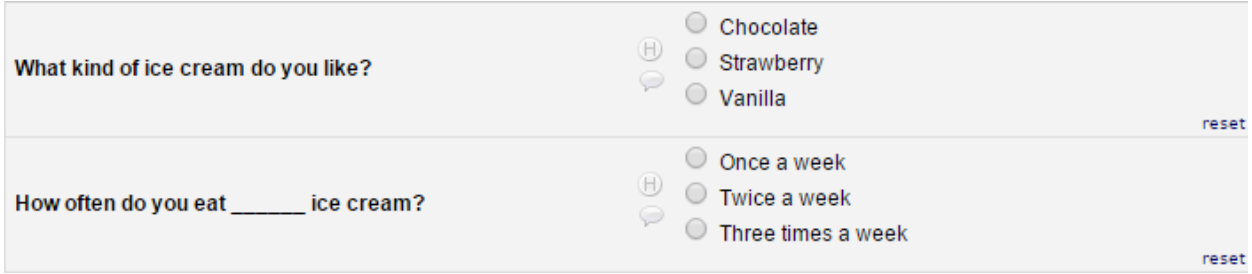
- You can use a *Drag-N-Drop Logic Builder* or *Advanced Branching Logic Syntax*
- You can use fields on the current data entry form OR other forms
- If fields from different events are used in branching logic, the field name needs to be preceded by an event name, e.g. [screening_arm_1][field1]
  - Event names can be found in 'Define My Events' page



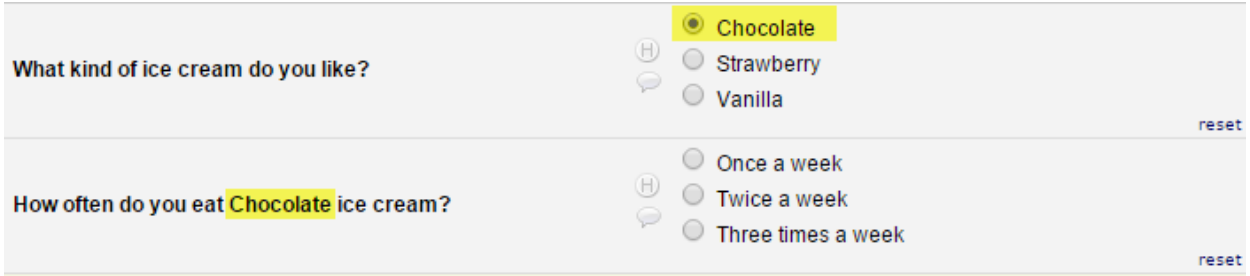


Building Forms: Piping

Without Piping:



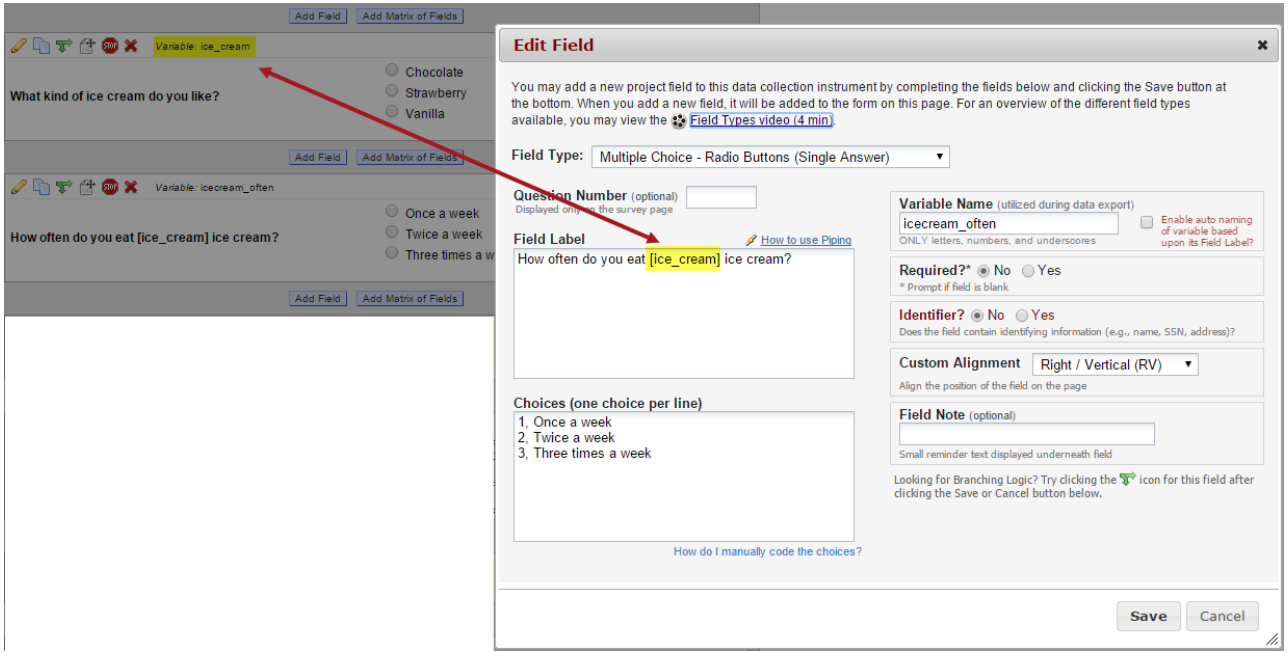
With Piping:



Building Forms: Piping

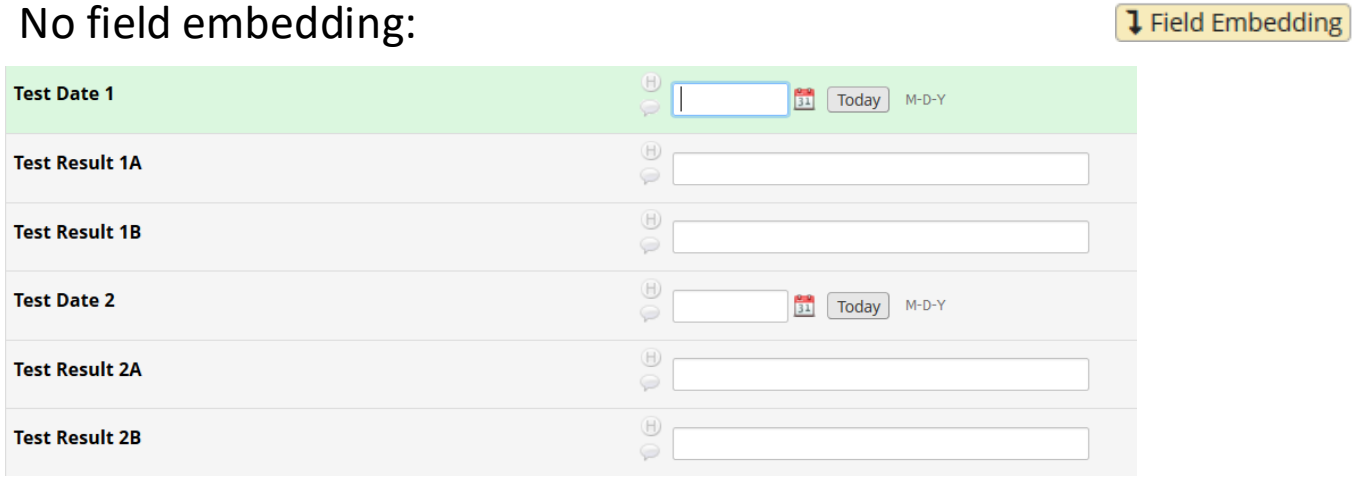
REDCap FAQ
Features-
Basic

How to use piping:

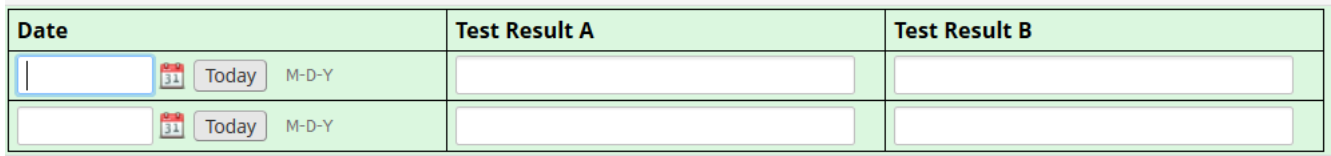


Building Forms: Field Embedding

No field embedding:



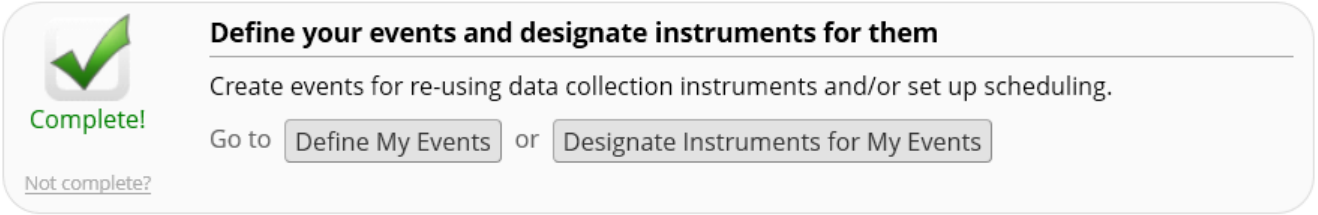
With field embedding:



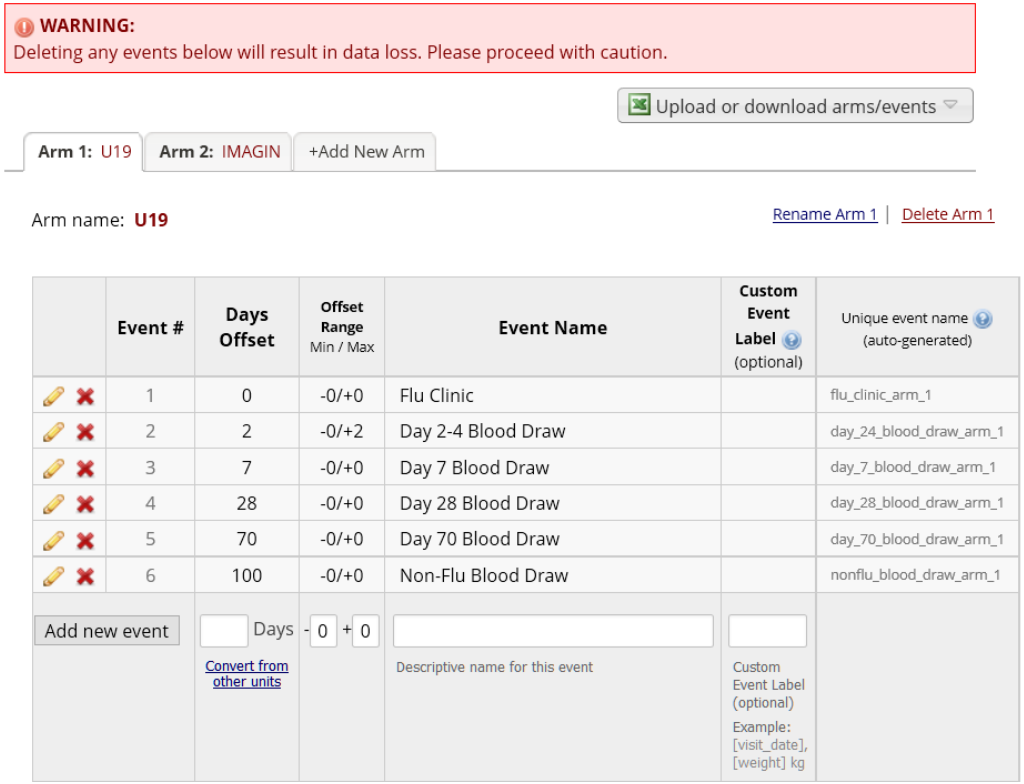
Defining Events
Longitudinal Projects

REDCap FAQ
Project
Design

- Defining Events allows you to:
  - Use data collection forms multiple times for any given project record.
  - Generate new schedules to display on the Calendar.



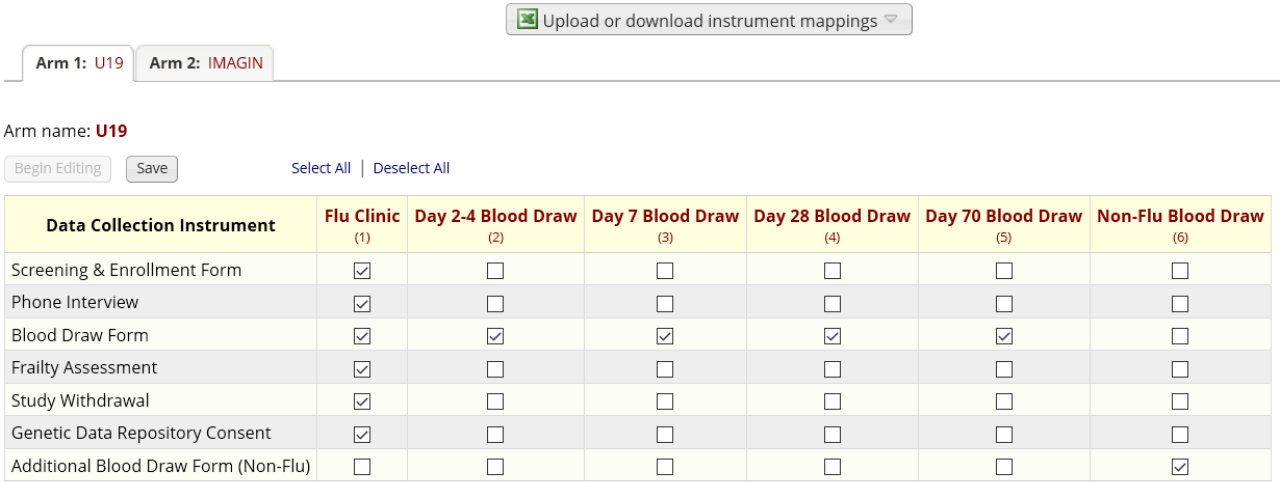
How to Define Events



Unique event name is auto-generated.

This is where you will find the event names for use in branching logic.

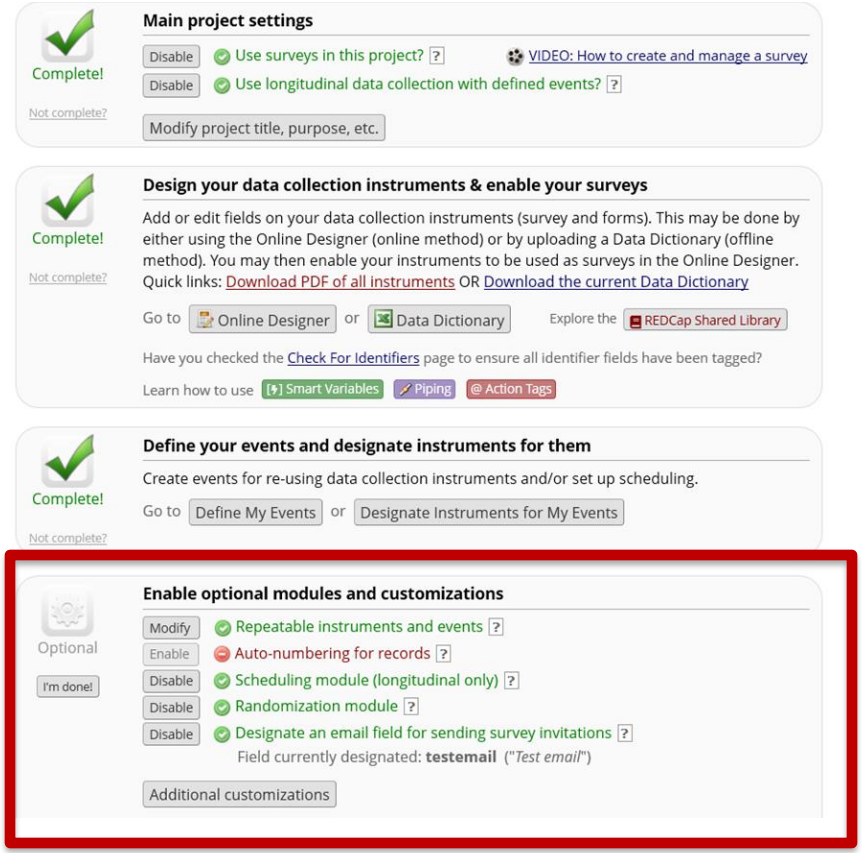
How to Designate Instruments to Events



Data Collection Instrument	Flu Clinic (1)	Day 2-4 Blood Draw (2)	Day 7 Blood Draw (3)	Day 28 Blood Draw (4)	Day 70 Blood Draw (5)	Non-Flu Blood Draw (6)
Screening & Enrollment Form	☑	☐	☐	☐	☐	☐
Phone Interview	☑	☐	☐	☐	☐	☐
Blood Draw Form	☑	☑	☑	☑	☑	☐
Frailty Assessment	☑	☐	☐	☐	☐	☐
Study Withdrawal	☑	☐	☐	☐	☐	☐
Genetic Data Repository Consent	☑	☐	☐	☐	☐	☐
Additional Blood Draw Form (Non-Flu)	☐	☐	☐	☐	☐	☑

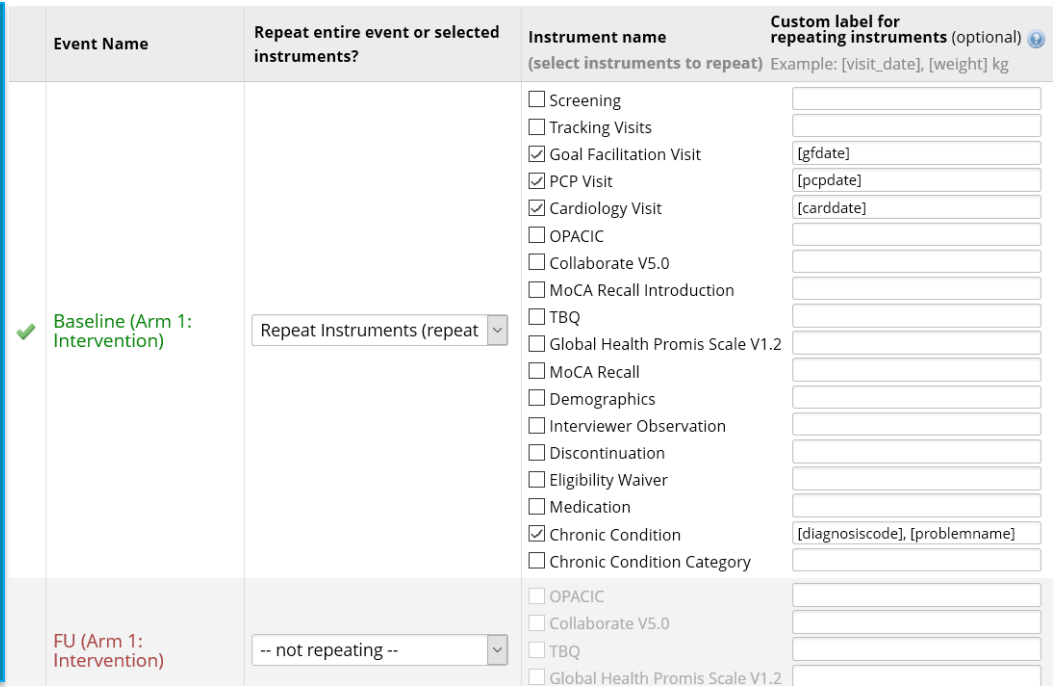
The event list and instrument mappings can be downloaded from one project and uploaded to another project.

How to Set Up your Project



Optional Modules: Repeatable Instruments

REDCap can repeat a data collection instrument or an entire event an unlimited number of times without having to pre-specify the frequency.



Optional Modules: Repeatable Instruments

REDCap FAQ
Project
Design

- Repeatable instruments shown on record home page:

Repeating Instruments

Goal Facilitation Visit
Baseline (Arm 1: Intervention)

1		08-03-1966
2		08-10-1966
4		11-24-1966

+ Add new

PCP Visit
Baseline (Arm 1: Intervention)

1		10-10-1966
2		01-24-1967
3		03-20-1967
4		04-12-1967
5		04-27-1967
6		05-25-1967

+ Add new

Chronic Condition
Baseline (Arm 1: Intervention)

1		F32.9, Depression
2		I10, Hypertension
3		K21.9, Esophageal reflux
4		Z00.00, Encounter for preventive health examination
5		G20, Parkinson's disease
6		M54.6, Pain, upper back
7		I49.3, Premature ventricular contractions

Questions?