e-CRF *w/* **REDCap**
electronic – Case Report Form

SOM CTU CME Series - Clinical Research education series

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Tuesday, October 22, 2024

UNIVERSITY of VIRGINIA

REDCap
Research Electronic Data Capture

Accreditation

The University of Virginia School of Medicine and School of Nursing awards **1.0 contact hour** for nurses who participate in this educational activity and complete the post activity evaluation.

The University of Virginia School of Medicine and School of Nursing awards **1.0 hour of participation** (consistent with the designated number of *AMA PRA Category 1 Credit(s)*^{TM} or ANCC contact hours) to a participant who successfully completes this educational activity. The University of Virginia School of Medicine and School of Nursing maintains a record of participation for six (6) years.

Disclosures

Full Disclosure Policy Affecting CME Activities: As a joint accredited provider, the University of Virginia Office of CME/CE requires attested and signed global disclosure of the existence of all financial interests or relationships with commercial interest from any individual in a position to control the content of a CME activity sponsored by OCME.

Disclosure Summary:

No one in a position to control the content of this educational activity has disclosed a relevant financial interest or relationship with any commercial interest

Activity Code

Activity Code: 24722
Instructions for claiming credits/contact hours can be found here.

Who we are

Research and Clinical Trial Analytics
A multi-disciplinary team of specialists in human subject research data who support the School of Medicine's research community across the globe. Together we work to provide innovative solutions and find the best tools, systems and processes to reach your research goals.

We are a remote team that reports up through the University Health System Analytics and Reporting Team (ART) of the Quality and Performance Improvement (QPI) Department.

Director: Christine Kelly-Fisher
Manager: Deb Green
REDCap Team

- Fauzia Khan
- Dave Guan

Website: Research and Clinical Trials Analytics.

Other applications and services on our team:

- **Advarra EDC**
- **MuSIC**
- **REDCap – Presentation today!**
- **UVA Health Data (Data Requests, Cosmos, Epic Tools, EMERSE, OMOP, TriNetX)**
- **Caisis**
- **Cancer Research Data Mart (CRDM)**
- **CRConnect2/CRC2**

Contents

REDCap
Research Electronic Data Capture

1a. What is REDCap

What is REDCap?

- REDCap (Research Electronic Data Capture) is a secure web application developed by Vanderbilt University in 2004 for building and managing online surveys and databases for clinical research.
- REDCap provides a user-friendly interface that allows users/researchers to quickly build electronic case report forms (eCRFs) with the ability to support features such as public surveys, calendars for scheduling, longitudinal events, repeating forms, randomization module, various levels of access for users, eConsents, and more. It is a great tool for single and multi-site studies.
- No programming, networking or database experience is needed to use REDCap. Simple design interfaces within REDCap handle all of these details automatically.
  - It is recommended that once designed, you have a statistician review your project. It is important to consider the planned statistical analysis before collecting any data. A statistician can help assure that you are collecting the appropriate fields, in the appropriate format necessary to perform the needed analysis.
- Please see the linked document detailing the UVA REDCap Features & Capabilities for more information on the features available. *Disclaimer – we are in the processing of migrating our website content to our new site, links are expected to change in the future*

REDCap at UVA

- Version 14.5.13 as of September 2024
- Version updates every 6-12 months as necessary (sometimes more frequently)
- Health System Network access required!
- Server is located behind the UVA Health System internal firewalls (UVA HS Network)
- Application is publicly available (public surveys)
  - If accessing externally will use DUO (if not already logged into the network)
- Multi-Site research collaboration capable
- Who can access REDCap:
  - Health System users – Those with UVA Health Network account
  - Academic Staff – UVA HS Account Sponsorship required by your supervisor
  - External Users – UVA HS Account creation required (account Sponsorship through REDCap Team)
- Data is backed up and secured daily
  - What this means? System Recovery is possible, but user error recovery isn't possible

REDCap Disclaimer

- The system is **NOT** 21 CFR Part 11 compliant. This means that it should NOT be used IF :
  - your study is FDA regulated AND the data will be submitted as part of a marketing approval application OR
  - your study is FDA regulated AND the study involves e-Consent

- Able to support public surveys
- Able to support e-Consents with approved IRB templates within REDCap during project creation

1b. How to Access REDCap & Resources

How to Access REDCap & Resources

Access

- Application Website - *https://redcap.healthsystem.virginia.edu/*
- Log in with UVA Health System Credentials - REDCap Access Guide - Access & Training
- If you do not have UVA Health System Credentials follow
  - Academic User Instructions (account sponsorship required) – REDCap Access Guide - UVA Academic User Access
- If you are collaborating on a study with an outside institute, please follow these instructions to request access for those external collaborators (Sponsorship through REDCap Team required) – REDCap Access Guide - External Collaborator Request

REDCap Database Development – iTHRIV Research Concierge Portal

The iTHRIV Research Concierge Portal functions as a single online entry point to access essential research resources and information. REDCap has a dedicated resource website currently (to be discontinued in near future)

- REDCap Database Development
- User Guide Documents provided as Attachments on the right side
- Disclaimer – this site and it’s contents will be deprecated in near future. At that time you will be able to access similar documents on our new School of Medicine website: Research and Clinical Trials Analytics

Contact the REDCap Team

- Email → RedCap@uvahealth.org

2. Build Options in REDCap

2a. Self-Service

Self Build option in REDCap

- Review training videos within REDCap before starting
- Build a REDCap project on your own, or with your research team
- No associated cost at this time
- Ask questions to REDCap Team as needed via email (must not exceed more than 1 of support over the development timeline

Other Self-Service Resources

REDCap Resources

- Once you are logged into our REDCap Instance, you can view videos under Help & FAQ / Training Videos 

- Short Videos on the Project REDCap site: https://projectredcap.org/ Resources → Videos
- Google is your friend
- YouTube how-to videos are helpful
- Email the REDCap Team: redcap@uvahealth.org
- REDCap Virtual Office Hours, Every Thursday, 9AM-12PM: Register Here

2b. REDCap full-service Research Database build

REDCap Charged Service

- Full-Service with cost – Current hourly rate will be listed on site: RATES
- UVA School of Medicine Researchers (serve other schools as well i.e. SON, SOE)
- Initial Consultation with REDCap Staff member to gather requirements – 1 free hour
- Cost Estimate developed and approved by your team
- Requirements apply as mentioned earlier (IRB approval, contracts in place, completed CRF for forms development, etc.…)
- Upon approval of Cost estimate, build is prioritized and development begins
- Your team will perform testing after development is complete (User Acceptance Testing)
- Project placed into Production Status, so you can begin entering real data
- Research team is invoiced
- Annual maintenance is provided for minor needs such as occasional instructions, minor updates to forms, various questions your team may have, etc.…
- Your team is expected to handle add/remove users as your project requires. The REDCap team will help provide the instructions if needed. Any new external users must be requested through the REDCap Team.
- Larger modifications to the project will require a new consultation and cost estimate.

You can submit a request for a free Consultation by emailing the REDCap team: redcap@uvahealth.org

Requirements for Full-Service

1. IRB approval/assurance document
2. Research Protocol including a schedule of events
3. Case Report Forms (dataset fields and related requirements)
4. Contractual Agreement if required
   - If you are sharing/gathering research data between UVA and an outside institution, you will need a legal contract to be executed between parties. This could be a clinical trials agreement, a data use agreement, a statement of work, etc. Please work with the School of Medicine Office and Grants & Contracts and/or the Office of Sponsored Programs to negotiate and execute this agreement prior to starting work on the project.
5. If your research involves multi-site collaboration, please reach out to REDCap team to request access for external users (Contractual Agreement(s) required)

2c. Other Service Options

Clinical Data Pulls for research projects

- Epic Data Request
- Import Data into REDCap project
- These both can have a preset frequency or one-time

Application Programming Interface. Data import/export, can be automated –usually requires REDCap Staff services, unless you have internal developers/programmer

3. How to build in REDCap

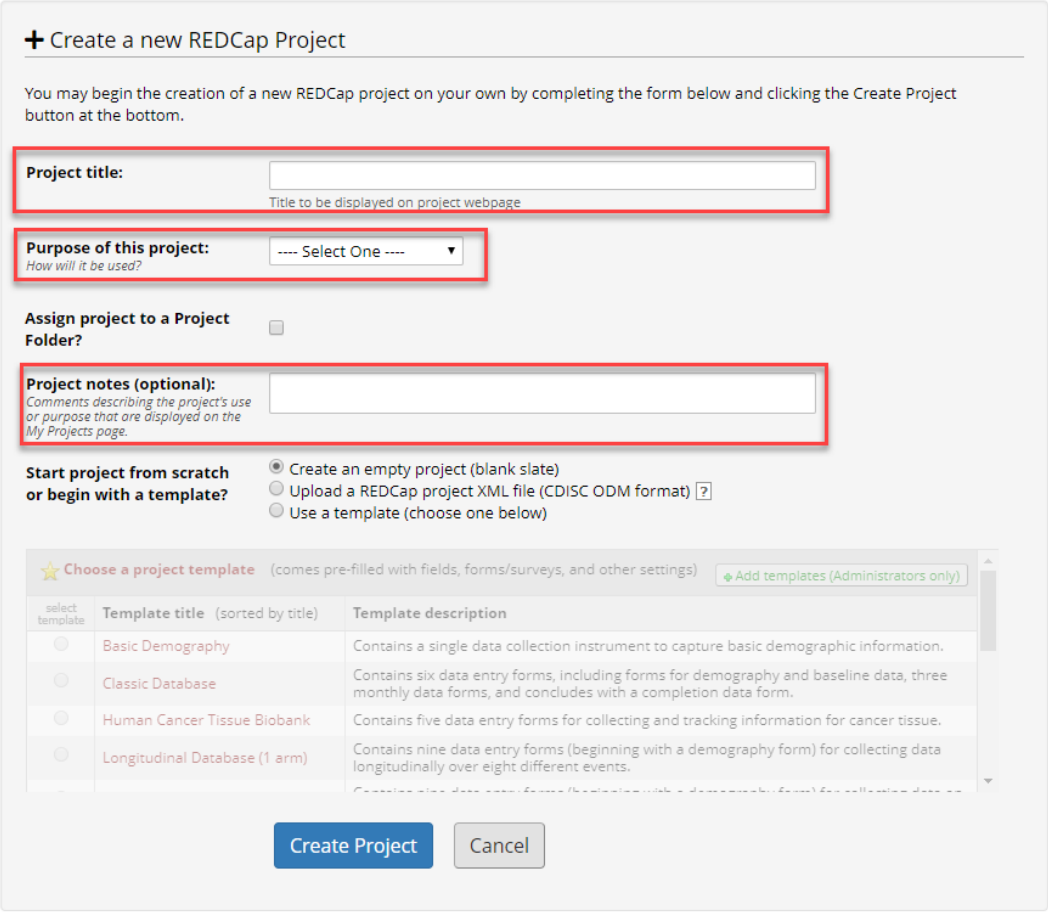
3a. Development & Project Lifecycle

1. Create a new Project
2. Project Setup
    - Events
    - Enable/Disable functionality
    - Additional Customization
    - Steps → I'm Done!
3. Online Designer
    - Instruments → Forms/Questionnaires
        - Data Entry Fields created here
        - Field types, matrix, Field Embedding
4. Production Status & Development Status

3b. *How to build a REDCap e-CRF*

(e-CRF →electronic Case Report Forms)

Create New Project



+ Create a new REDCap Project

You may begin the creation of a new REDCap project on your own by completing the form below and clicking the Create Project button at the bottom.

Project title:

Title to be displayed on project webpage

Purpose of this project:
How will it be used?

---- Select One ----

Assign project to a Project Folder?

Project notes (optional):
Comments describing the project's use or purpose that are displayed on the My Projects page.

Start project from scratch or begin with a template?

- Create an empty project (blank slate)
- Upload a REDCap project XML file (CDISC ODM format) ?
- Use a template (choose one below)

Choose a project template (comes pre-filled with fields, forms/surveys, and other settings) Add templates (Administrators only)

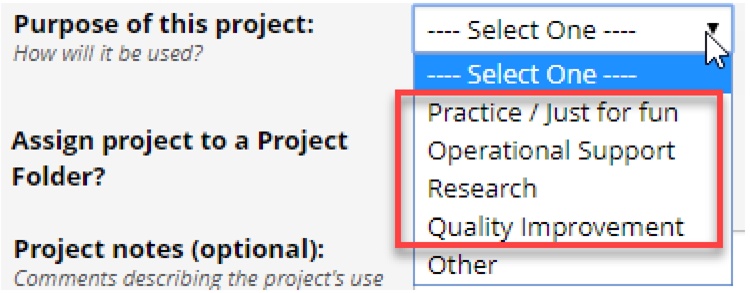
select template	Template title (sorted by title)	Template description
	Basic Demography	Contains a single data collection instrument to capture basic demographic information.
	Classic Database	Contains six data entry forms, including forms for demography and baseline data, three monthly data forms, and concludes with a completion data form.
	Human Cancer Tissue Biobank	Contains five data entry forms for collecting and tracking information for cancer tissue.
	Longitudinal Database (1 arm)	Contains nine data entry forms (beginning with a demography form) for collecting data longitudinally over eight different events.

Create Project Cancel

For Research purpose: need IRB #, PI name, PI email, and description

Please enter a description of your project purpose. Can include details such as project end date and more

Create New Project: Select a Project Type



REDCap Project Development Steps 1-x.
x Depends on modules that have been enabled

Project Home | Project Setup | Other Functionality | Project Revision History | Edit project settings

Project status: Development

Completed steps 7 of 9

Main project settings
Complete!
Not complete?

Disable — Use surveys in this project? [?] VIDEO: How to create and manage a survey

Disable — Use longitudinal data collection with defined events? [?]

Modify project title, purpose, etc.

Design your data collection instruments & enable your surveys
Complete!
Not complete?

Add or edit fields on your data collection instruments (survey and forms). This may be done by either using the Online Designer (online method) or by uploading a Data Dictionary (offline method). You may then enable your instruments to be used as surveys in the Online Designer. Quick links: Download PDF of all instruments OR Download the current Data Dictionary

Go to Online Designer or Data Dictionary   Explore the REDCap Shared Library

Have you checked the Check For Identifiers page to ensure all identifier fields have been tagged?

Learn how to use [$] Smart Variables | Piping | @ Action Tags | Field Embedding

Define your events and designate instruments for them
Complete!
Not complete?

Create events for re-using data collection instruments and/or set up scheduling.

Go to Define My Events or Designate Instruments for My Events

Enable optional modules and customizations
Complete!
Not complete?

- Modify — Repeatable instruments and events [?]
- Enable — Auto-numbering for records [?]
- Disable — Scheduling module (longitudinal only) [?]
- Disable — Randomization module [?]
- Enable — Designate an email field for sending survey invitations [?]

Additional customizations

Settings displayed to Administrators only:

Enable — Twilio SMS and Voice Call services for surveys and alerts [?]

Set up a randomization model
Not started
I'm done!

The randomization module will help you implement a defined randomization model within your project, allowing you to randomize your subjects (i.e. records in your project).

Go to Set up randomization

Set up project bookmarks (optional)
Complete!
Not complete?

You may create custom bookmarks to webpages that exist inside or outside of REDCap. These bookmarks will be seen as links on the left-hand project menu and can be accessed at any time by users who are given privileges to do so. Every project bookmark has custom settings that allow one to control its appearance and behavior.

Go to Add or edit bookmarks

User Rights and Permissions
Complete!
Not complete?

You may grant other users access to this project or edit the user privileges of current users on this project by navigating to the User Rights page. Additionally, if you wish to limit user access to certain records/responses for this project, you may want to use Data Access Groups, in which only users within a given Data Access Group can access records created by users within that group.

Go to User Rights or Data Access Groups

Test your project thoroughly
Complete!
Not complete?

It is important to test the essential components of your project before moving it into production. Try creating a few test records and entering some data for each to ensure that your data collection instruments look and behave how you expect, especially branching logic and calculations. Then review your test data by creating reports and exporting your data to view in Excel or a statistical analysis package. If you have surveys, complete the surveys as if you were a participant by using the Public Survey Link or Participant List by sending a survey invitation to yourself. If other project modules will be used regularly, test them out a bit too. The best way to test your project is to use it as if you were entering real production data, and it is always helpful to have colleagues (especially team members) take a look at your project to get a fresh set of eyes looking at it.

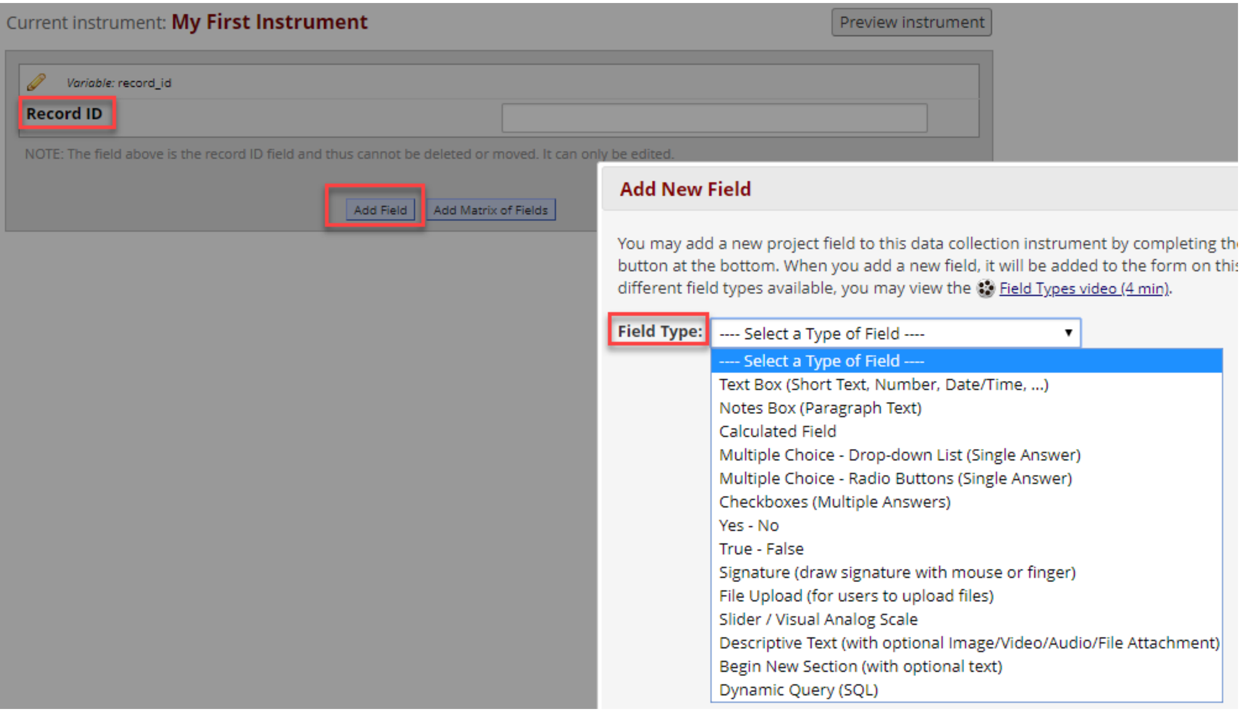
Move your project to production status
Not started

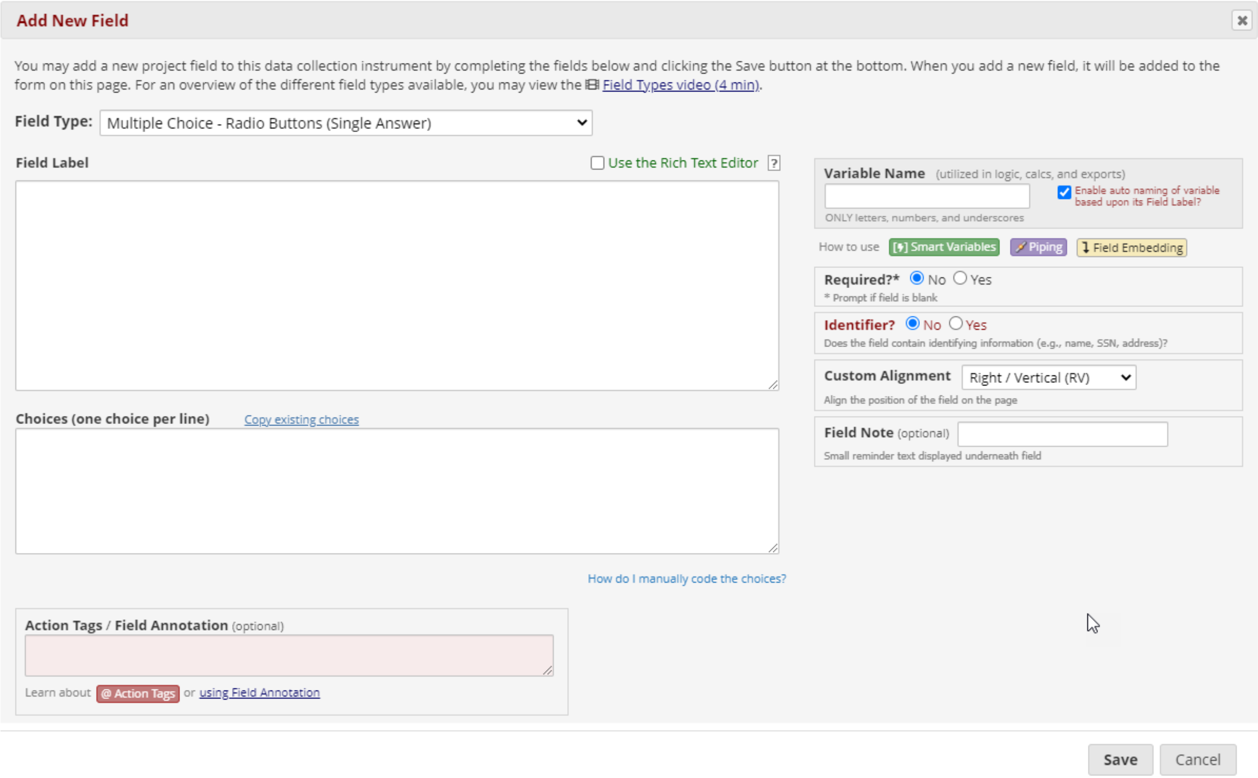
Move the project to production status so that real data may be collected. Once in production, you will not be able to edit the project fields in real time anymore. However, you can make edits in Draft Mode, which will be auto-approved or else might need to be approved by a REDCap administrator before taking effect.

Go to Move project to production

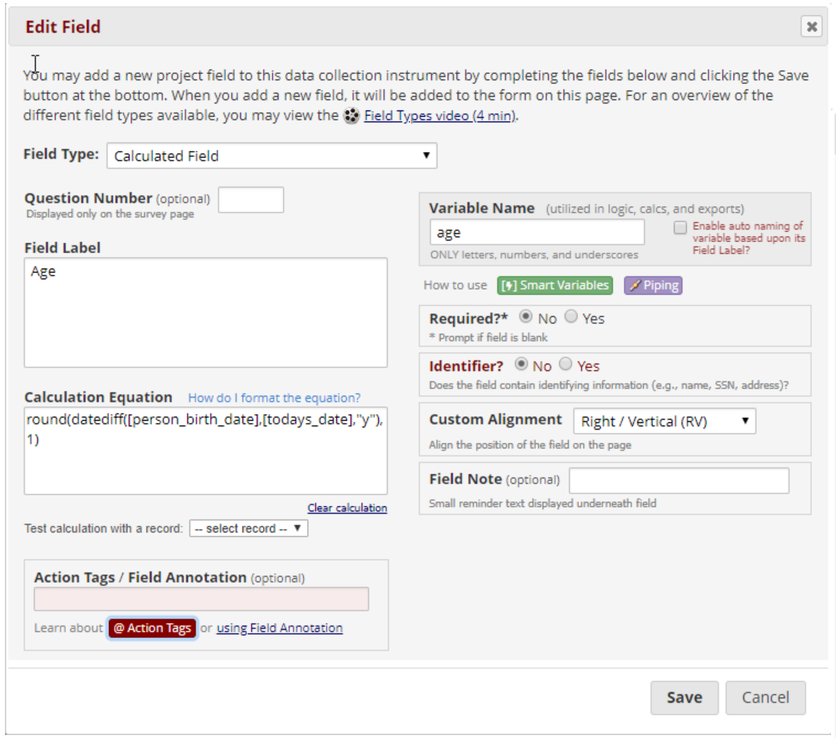
Online Designer: Create a field, select Field Types

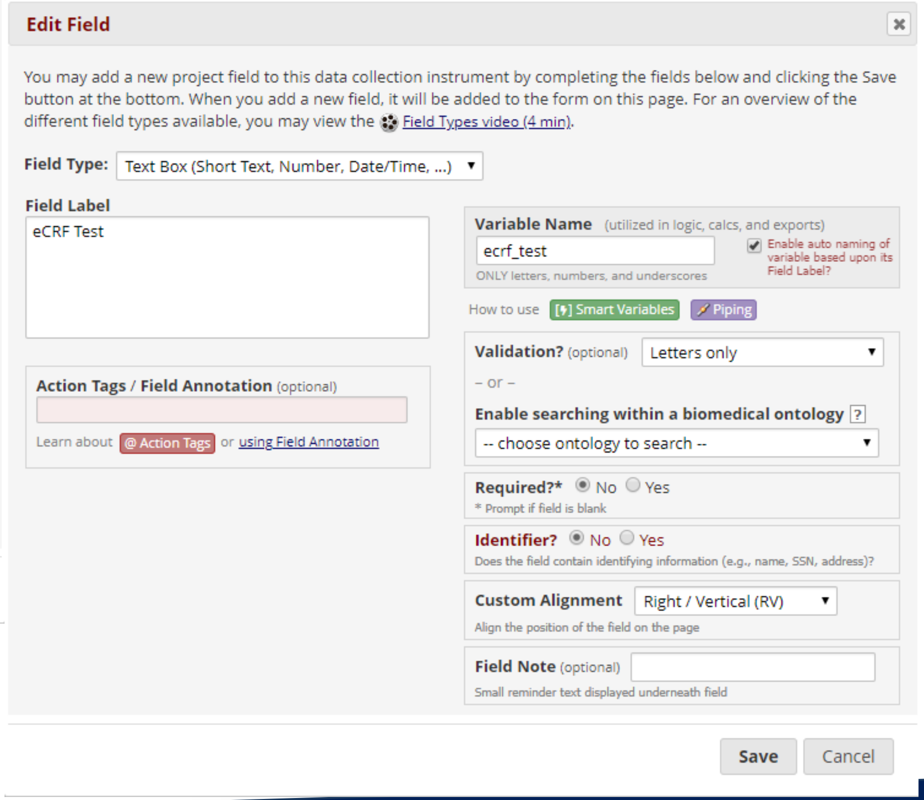
Example: Field Type → Multiple Choice
First Field must always remain record_id on the first instrument





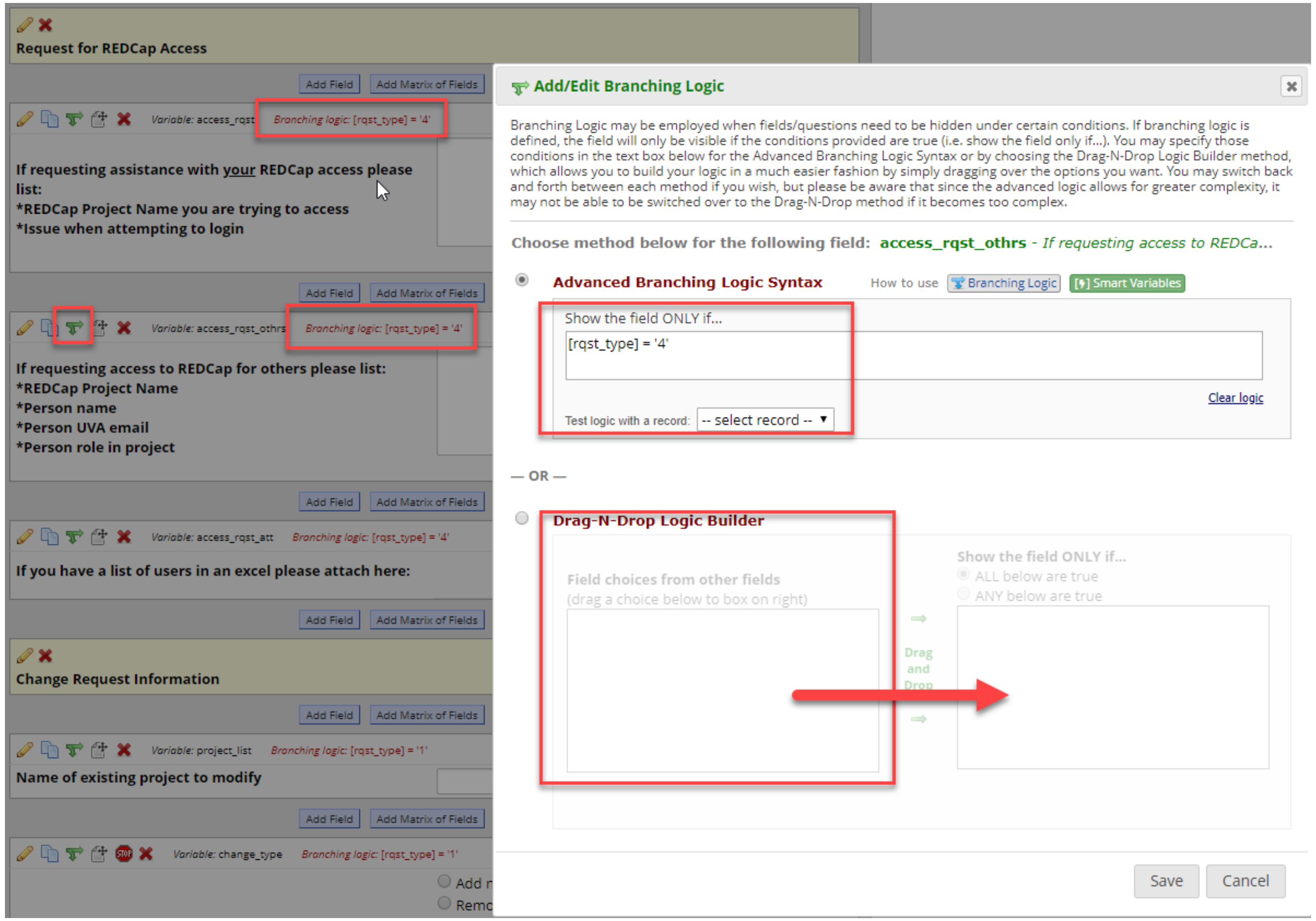
Online Designer: Edit a field





- Field Types
- Field label & Variable Name
- Action Tags
- Required & Identifier designation
- Validation
- Ontology - A special feature that provides auto-suggest functionality for real-time searching within biomedical ontologies such as: CPT, ICD 9 CM, ICD 10 CM & PCS, LOINC, NCFRT, RxNORM, SNOWMED CT, and more

Online Designer: Additional features



- Branching Logic
- Survey (Internal) settings
- Repeat Instruments & Events
- Field Embedding
- Events – Longitudinal
- Enable/Disable functionality
- Additional Customization
- Steps → I'm Done!

Other instrument/from build option methods

Data Dictionary	All instruments at once. Create or Upload (ex: shared by another organization) short video in REDCap provides guidance. Will overwrite all instruments at once.
Instrument Zip file	Only one instrument at a time. Must be careful, if want to upload, must first delete the original after edits; otherwise must be okay with renamed variables for the same duplicate instrument.
XML file	Entire project upload/download (with or without data options)
REDCap Shared Library	A global repository of data collection instruments that can be downloaded and used in your REDCap projects. In the Shared Library, you may view any of the library's instruments on the library web page or as a PDF. It will allow you to import any instrument from the library into your REDCap project. Many instruments have Computer Adaptive Tests (CATs) & Auto-scoring.

Advanced Features in REDCap

- **Field Embedding** - The Field Embedding feature in REDCap is the ultimate way to customize your surveys and data collection instruments to make them look exactly how you want. Field Embedding allows you to reposition fields on a survey or data entry form to embed them in a new location on the same page. Embedding fields gives you greater control over the look and feel of your instrument.
- **Data Imports** - With approval can be performed by project developer
- **API** - Application Programming Interface. Data import, can be automated –usually requires REDCap Staff services, unless you have internal developers/programmer
- **e-Consent framework** - Approved Templates from IRB, for non-FDA Regulated studies

3c. How to prepare for Production Status

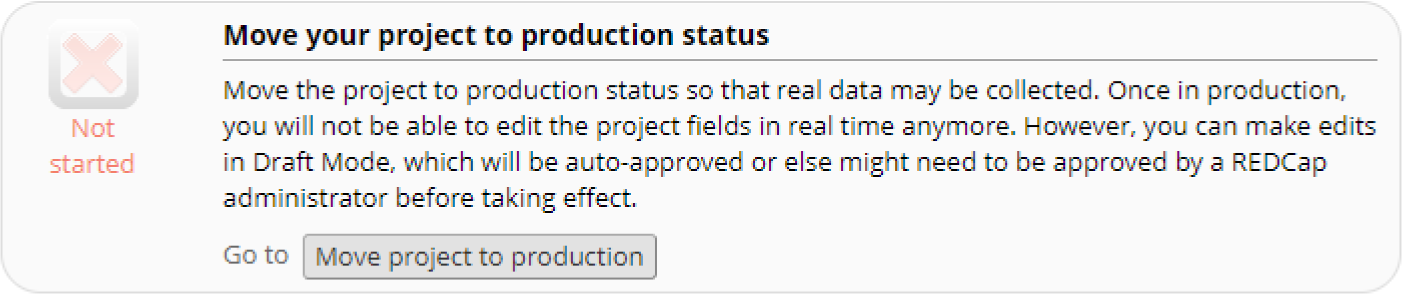
Production Status: how to Prepare

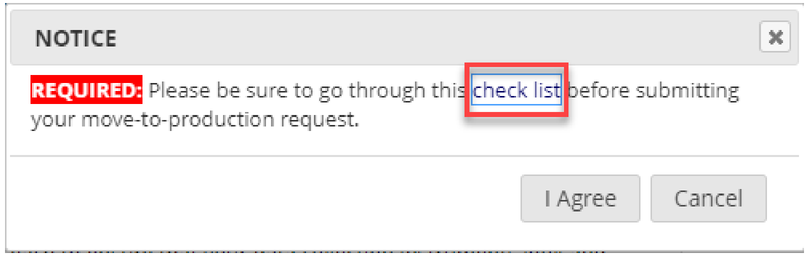
- Production status locks your project down so that forms cannot be modified while live data is being entered. This status also ensures a snapshot of the data dictionary is taken when modifications are made via Draft Mode.
- You can request edits by entering Draft Mode and making modifications. The Admin will approve these changes after first reviewing the modifications you have made. Be mindful of branching logic errors that your mods can cause.
- Ensure you have checked all of your identifiers (PHI) so that you can utilize the de-identified data export capability.
- Have performed thorough testing, to include you internal/external users ability to access and enter data.

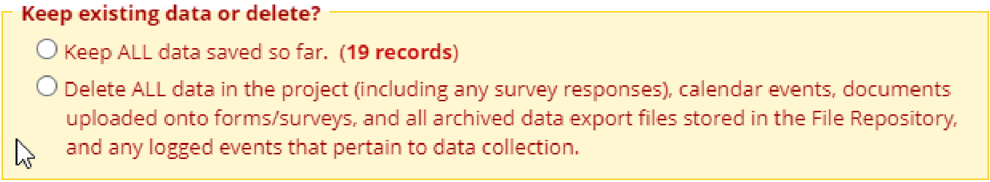
[REDCap User Guide - Production Status Requirements]

Production Status: How to request

- In the very last section of the Project Setup, you will select the **<u>Move project to production</u>** button. A notice will show you a checklist (open the link) to guide you through requirements before PROD Status is granted. You will also be asked to keep or delete the data in the project. If it is test data, then select “Delete ALL data in the project”. If it is real production data from an import for example, select “Keep ALL data saved so far”. then keep.
  - Do not enter data after sending the request until is approved and the project is locked into Production status!
- An email request is generated for the Admin who will review your project before placing into production.







[REDCap User Guide - Production Status Requirements]()

Post PROD Status in REDCap

Project Status Management

Development → **Production** (current) → Analysis/Cleanup

Move to Analysis/Cleanup status →

Move the project to Analysis/Cleanup status if data collection is complete. This will disable most project functionality, although all collected data will remain intact. Once in Analysis/Cleanup status, the project can be moved back to production status at any time.

← Move back to Development status

Moved to production too soon? You may move the project back to development status, if needed. NOTE: Since the project is currently in Draft Mode, all drafted changes will be discarded when moving back to development. So if you do not want to lose the current drafted changes, then first finish making changes to then fields in Draft Mode and then have them submitted for approval before continuing here. **(Administrators Only)**

Mark project as Completed

If you are finished with a project and wish to make it completely inaccessible, you may mark the project as 'Completed'. Doing so will take it offline and remove it from everyone's project list, after which it can only be seen again by clicking the *Show Completed Projects* link at the bottom of the *My Projects* page. Read more

Activity Code

Activity Code: 24722
Instructions for claiming credits/contact hours can be found here.”

University of Virginia

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Questions?

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Research Electronic Data Capture