Kaiser Permanente Colorado

Institute for Health Research

REDCap Protocol
2020

This document provides information regarding the policies and procedures for the use of REDCap within the Institute for Health Research.
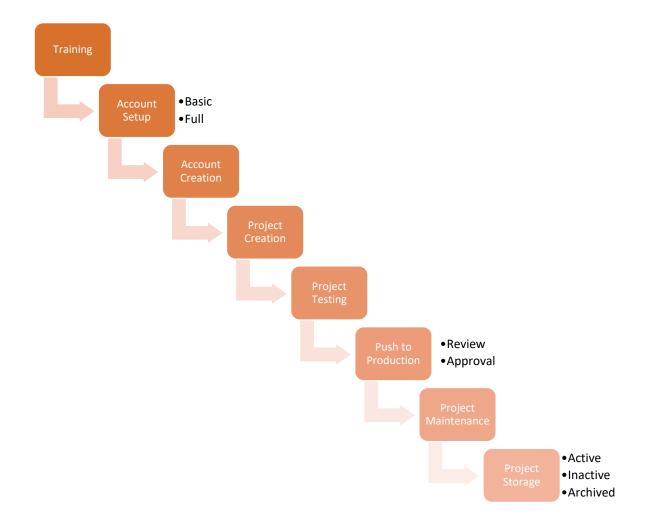
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IHR REDCap Basic Concepts

REDCap = **R**esearch **E**lectronic **D**ata **Cap**ture

- An easy-to-use data entry system, with data validation;
- The ability to import data from external sources;
- Automated exports to the most common statistical packages (SPSS, SAS, R, and Stata);
- Audit trails for tracking data changes and exports;
- Branching logic, calculations, and piping to increase functionality and personalization;
- A sophisticated survey tool for building and managing online surveys.

Training → Account Setup (• Basic • Full) → Account Creation → Project Creation → Project Testing → Push to Production (• Review • Approval) → Project Maintenance → Project Storage (• Active • Inactive • Archived)

Section 1A.   Account Setup - There are 2 types of accounts, Basic and Full. A basic account is designed for people doing data-entry level tasks, a full account for people who need to do project design/management. The functional difference is that the full account gets the "Create Project" feature; however, if someone with a basic account has been given project design or user rights privileges in a project, they will need additional training to get a full account. Administrative staff can suspend the account if they refuse to stop doing high-level tasks without it.

Section 2A.   Training Requirements – New REDCap accounts within the IHR require training without exception.

Basic Training can be found on the IHR REDCap website at this link: https://www.kpredcapihr.org/surveys/?s=FJ4FXDL484.

Full Training can be found on the IHR REDCap website at this link: https://www.kpredcapihr.org/surveys/?s=TWC8PLHLMC

Data-Role Training can be found on the IHR REDCap website at this link: https://www.kpredcapihr.org/surveys/?s=3EXADW3NPD

PI/PM Operational Form Training can be found on the IHR REDCap website at this link: https://www.kpredcapihr.org/surveys/?s=CRP7HD34PR

All users must complete the Training Attestation which can be found on the IHR REDCap website at this link: https://www.kpredcapihr.org/surveys/?s=FPLLLCXACN

Additional REDCap training for full or basic accounts needed at the University of Colorado at Denver can be found at https://redcapinfo.ucdenver.edu/

Section 3A.   Account Creation – Account creation at KPCO IHR goes through the REDCap Admin Team, with the user submitting an account request after completing the appropriate training to Project_REDCap@kp.org. Account requests can be made by directly emailing the REDCap admin team at the above address or accessing the trainings independently on the IHR REDCap website. The administrative team will be notified of training completion, and following administrative approval, users will receive an email prompting them to set up their account. Account users will need to sign in, set up an account password, and send their username to their project manager to be added to the desired project.

Section 4A.   User Levels/Rights/Permissions - Universal REDCap Best Practices provide guidance that users shall only be granted the *minimal* amount of user rights necessary to complete their job duties within REDCap and that defined user roles should be created for each level of access (e.g., Admin, Data Entry, Data Analysis, PI Review).

It is especially important to consider the security of any PHI housed within your project. Only users that must be able to review this PHI should have the ability to view and export this data. If your project users include external collaborators, you **must** consult with your study PI/PM to align these user rights with your study data agreement(s) before granting project rights to external users. If

your project must include these users, but your data agreement(s) are still pending, you **must** restrict data access/exports from these users until your data agreement(s) are fully executed. It is incumbent upon the project PI/PM to exercise discretion when granting user rights within the project. If the PI/PM are not involved directly in the REDCap project build, they **must** be consulted about user rights prior to moving the project into production.

Data Access Groups (DAGs) should be implemented to help segregate users and the data they enter by placing users into "data access groups", after which they will only be able to access records created by someone in their group. This feature is is especially helpful in certain situations, such as for multi-institutional projects where the data entered by one institution should not be accessible or viewable by other institutions with access to that same project.

Beginning in 2020, user roles **must** be created prior to a project being moved into production. Each user within the project must be assigned to the appropriate role for their project duties.

The IHR Admin suggest the following user roles be created within each research project:

1. **Admin** – Full User Rights including:
   a. Project Design & Setup; User Rights; Data Access Groups; Full Data Set Exports; Add/Edit/Organize Reports; Stats & Charts; Survey Distribution Tools; Calendar (if applicable); Data Import Tool; Data Comparison Tool; Logging; File Repository; Data Quality – Create/Edit & Execute; API (if applicable); REDCap Mobile App (if applicable); Create/Rename/Delete Records; Record Locking Customization; Locking/Unlocking w. E-signature Authority (if applicable); View & Edit Data Entry Rights.
      i. Only the REDCap project developers should have this level of access and MUST have full-account training or rights will be revised by REDCap administrative staff.
2. **Data Entry** – Limited User Rights including:
   a. Add/Edit/Organize Reports; Survey Distribution Tools; Calendar (if applicable); Data Import Tool; Create Records; Record Locking Customization; Locking/Unlocking w. E-signature Authority (if applicable).
      i. This is an appropriate level to assign to external users who will be performing data entry.
3. **Data Analysis** - Limited User Rights including:
   a. Data Access Groups; Full Data Set Exports; Stats & Charts; Data Import Tool; Data Comparison Tool; Data Quality – Create/Edit & Execute; API (if applicable).
4. **Data Reviewer** – Limited User Rights including:
   a. Stats & Charts; Read Only Data Entry Rights

Section 5A.   Best Practices – Development – Standards/best practices recommended to all users include, but aren't limited to:

- ✓ The record ID must be the first variable of the first form (Can be changed to study ID, MRN etc.)
- ✓ Keep variable names short, succinct, and meaningful (must be less than 26 characters to avoid truncation)
- ✓ Use multiple choice questions where possible
- ✓ Minimize the use of free response fields
- ✓ Use field notes to help the data enterers enter information correctly
- ✓ When using free text fields, ensure validation of the data type whenever possible (e.g., date, zip)
- ✓ Keep forms short, with similar types of data grouped together
- ✓ Limit the use of calculations and never use stacked calculations (calculations that include other calculated fields)
- ✓ Be consistent in the coding of multiple-choice questions (1, 2, 3, 4 etc.)
- ✓ Use the 1-Yes 0-No/1-True 0-False convention
- ✓ Use large, negative numbers for answer choices like NA, Prefer Not to Answer, or Other (e.g., 00, 999)
- ✓ Minimize the use of required fields in surveys
- ✓ Test projects thoroughly, including all branching logic, calculations, automation, reports and piping; send test surveys both to yourself and to different email domains (e.g., gmail); practice data entry on a longitudinal project; have other team members practice data entry and pulling data from the project to make sure it is functional
- ✓ Ensure variables are broken into appropriately separated fields for analysis (e.g., address, city, state, zip)
- ✓ Set up data quality rules
- ✓ Ensure that all appropriate REDCap forms/instruments are sent to project manager for review by IRB
- ✓ Take frequent snapshots of the data dictionary
- ✓ Be consistent in how questions are framed
- ✓ Use validated instruments from the REDCap Library where possible
- ✓ Be conscious of copyright issues when using pre-existing forms and translate them as exactly as possible from their paper formats; be aware that if they cannot be properly translated, they are no longer validated instruments
- ✓ Flag identifiers and limit who can access and export them (e.g., deidentified vs. full data set)
- ✓ Be consistent in coding your variables (code to recognizable terms) (e.g., phq9 q1, phq9 q2, etc.)
- ✓ Variable name should not be changed once data collection has begun- this will corrupt your data
- ✓ If you have multiple questions that will use the same answer choices, code them all the same

- ✓ Above all, consider carefully how the data you collect will be used in analysis and code variables appropriately. Make sure to consult, if possible, with the data analyst/statistician who will be reviewing data on the back end.
- ✓ Ensure data roles are created and users appropriately assigned with the minimal required rights
- ✓ Consult with Biostatistician for Randomization Setup
- ✓ Utilize File Repository to upload/organize documents
- ✓ Utilize E-consent framework & Auto-archiver for all participant consenting
- ✓ Utilize Auto-archiver for surveys
- ✓ Confirm ALL automated settings PRIOR to moving project into production
- ✓ Ensure any safety alerts are built PRIOR to moving into production
- ✓ Ensure reports that guide workflow are built PRIOR to moving into production
- ✓ Ensure survey settings are finalized PRIOR to moving into production
- ✓ Ensure IRB number is included for any IRB approved projects

Section 6A. **Moving Projects to Production -** All projects _must be moved to production_ before data collection begins. Users wishing to move projects to production must email the administrative team at Project_REDCap@kp.org with the request OR a request will automatically be sent when they attempt to move the project to production. When a user submits a request to move to production, project user roles are reviewed and adjusted if necessary; a copy of the data dictionary will be downloaded; the admin team will run the macro "CheckMate"; lastly the presence of the IRB number will be verified. CheckMate alerts the admin team to likely identifiers and text fields that require validation. A list of any errors requiring correction will be sent to the requesting user. After errors have been corrected, the user will resubmit a request and the admin team will perform another check. The admin team will also verify whether the user would like to keep or delete the data in the project. Once verified, the project is moved to production by the admin team.

Best Practices – Production

Standards/best practices recommended to all users include, but aren't limited to:
- ✓ DO NOT delete/rearrange events once real data exist in your project – this can result in deletion/data scrambling
- ✓ DO NOT alter your existing automations once real data exist in your project – any changes will ONLY apply to new records, not existing records
- ✓ DO NOT rearrange survey questions/answers once real data exist in your project – this can result in deletion/data scrambling/alteration of existing survey responses
- ✓ AVOID making any major structural changes to your project once it is in production (this does not include minor survey question adjustment, aesthetic changes etc.)
- ✓ Utilize Data Quality Rule H to update calculations in instruments
- ✓ New instruments must be assigned to events in longitudinal projects
- ✓ Download your current data set at least monthly AND before any large data imports
- ✓ PRIOR to making any major changes to the structure of your project, make a copy of your project, including the dataset
- ✓ Consult the REDCap Admin Team PRIOR to making any major changes to your project to formulate a sound plan – Admin team must approve any changes that could alter existing data

Section 7A.   Project Maintenance - In general, REDCap project maintenance (adding/removing users, maintaining forms, managing reports and exports, moving to inactive/archived, making sure data quality rules are used where appropriate, etc.) is the responsibility of the project owner/project manager. Changes that could potentially affect data require administrator approval, as does deleting a project. In these instances, the admin team will make certain the user is aware of the consequences before approving the action; the same principle applies for actions like moving forms around in longitudinal projects or deleting events. The admin team also reserves the right to check user rights and adjust when necessary. The admin team is available for any questions at Project_REDCap@kp.org.

Section 8A.   Requirements - Project Storage Following Data Collection Completion – Project "storage" is the responsibility of the study PM/PI. Projects must be moved to "Inactive" status when data collection is completed. This status allows for continued data exportation and analysis, but locks down your current data set, ensuring no additional changes can be made. Projects must be archived when data collection, exportation, and analysis is complete, and the REDCap project no longer needs to be referenced. Project archival and deletion are entirely up to the REDCap project managers, although they cannot delete a production project without administrator approval. It is the responsibility of all REDCap project owners/project managers, to ensure projects are appropriately organized and archived when no longer needed. Please note – projects continue to be accessible in both the inactive/archived state and can be returned to production status with approval of the administrative team.

Section 9A.   Updates/Bug Reporting & Fixes - The KP Center for Health Research (CHR) currently manages/hosts both our REDCap Internal and DMZ instances on secure servers at CHR. CHR primarily sticks to a maintenance/upgrade schedule of every 3rd Sunday of each month. They use the Standard Support updates for system upgrades. These updates are more frequent and provide quicker resolutions to previous bugs and errors within REDCap. Bugs are reported to Vanderbilt as soon as they are discovered, usually through the REDCap consortium.