

Locking Data in REDCap Projects

Overview

Data presented as publications and to regulatory/funding agencies should come from studies that are not only planned and conducted properly, but also closed out in accordance with sound data management principles. The time, effort, and resources devoted to study conduct and data collection are wasted if the data accuracy, consistency, and completeness cannot be verified and properly documented. A checklist of the steps involved in the close-out process is shown in Appendix A. Locking data is one component of the close out process.

Locking data removes access to the data for the purposes of adding a data record or changing a data value. This locking process is most often performed at the end of a study to ensure that the final data considered clean and ready for analysis cannot be modified. However, there are situations where all data for a subset of individual study participants or study periods are considered final prior to all study data being considered final. In these situations, it may be prudent to also lock these data to avoid unexpected or inadvertent changes to the data.

Locking data in REDCap effectively means changing user access to a data value from 'edit' to 'read-only'. This change in data access (locking) can occur in REDCap

- at the individual field level across all records,
- at the individual instrument level one record at a time,
- at the individual record level for all instruments, and
- at the full database level.

The data at the individual field level can be locked from certain types of editing, depending upon which Action Tag is associated with the field. The data at the individual instrument and individual record levels cannot be edited when the data are locked. Data locked at the full database level stops the entry of new data records but offers the option to either leave the data editable or make it not editable.

Locking Data at the Individual Field Level

There is currently no way in REDCap to lock an individual field for an individual record. However, by using Action Tags, individual fields can be locked across all records. The four ways in which an individual data field value can be entered and edited in REDCap are: 1) in an imported file, 2) on a survey page, 3) on a data entry form, and 4) in a REDCap mobile app form. Individual data fields cannot be locked from editing by way of an imported file. However, individual fields can be locked from editing on a survey page, data entry form, and/or mobile app by associating an Action Tag with the field. Refer to REDCap Action Tag documentation to see how Action Tags can be associated with a data field via the Online Designer or Data Dictionary.

The Action Tag choices are:

- 1) @READONLY – Locks the data field from editing on the survey page, the data entry form, and in the REDCap mobile app so that its value cannot be changed.
- 2) @READONLY-APP – Locks the data field only on the REDCap Mobile App form so that its value cannot be changed.

- 3) @READONLY-FORM – Locks the data field only on the data entry form so that its value cannot be changed.
- 4) @READONLY-SURVEY – Locks the data field only on the survey page so that its value cannot be changed.

Only individuals with the 'Project Design and Setup' user privilege can assign these Action Tags.

The following is one example of the use of these Action Tags.

- Suppose a form has data values for some fields entered from an import file and values for other fields manually entered on the data entry form. The imported values can be edited with a changed value in a newly imported file, but these values for all records can be locked from manual editing on the data entry form by associating the @READONLY-FORM Action Tag with each of the data fields populated with imported values. In this situation, use of the Action Tag helps to avoid inadvertent editing of the values in the imported fields.

Locking Data at the Individual Instrument and Individual Record Levels

Instrument level locking for a single record and record level locking of all instruments are independent features in REDCap, both governed by separate user access privileges. Individuals must have explicit permission to lock at either of these levels to perform the specific locking action. Record locking is a higher-level form of locking than instrument locking, which means that an entire record may be locked or unlocked even if one or more instruments are currently locked for that record, but an instrument cannot be locked or unlocked while the entire record is locked.

The person(s) with the access privilege to assign user rights is typically also the person(s) with the instrument and record locking privileges and who controls the delegation of these privileges. These individuals are also the only person(s) with access to the NOTES and a brief instruction VIDEO available in the lower left section of the screen where the user rights are identified. However, the 'Locking Records' VIDEO is also accessible to all REDCap users in the 'Special Features within REDCap Projects' section of the REDCap Training Videos.

Individual Instrument Level: All data on an individual instrument for a single record can be locked by any person with the necessary user access privileges. A 'Lock' checkbox appears at the bottom of each instrument immediately following the Form Status Field. The following statement appears to the left of the 'Lock' checkbox:

'Lock this instrument?

If locked, no user will be able to modify this instrument for this record until someone with Instrument Level Lock/Unlock privileges unlocks it.'


Note: The 'Lock' checkbox will only appear for persons with the necessary user access privileges.

There are three Lock/Unlock choices at the Instrument Level for users assigned to this User Rights Role.

- 1) 'Disabled': The default choice which indicates the user has no Instrument Level Lock/Unlock privileges.


- 2) 'Locking/Unlocking': The most common choice which indicates the user has basic Instrument Level Lock/Unlock privileges.
- 3) 'Locking/Unlocking with E-signature authority': The advanced choice which indicates the user has basic Instrument Level Lock/Unlock privileges plus the right to include an optional e-signature as part of the Lock/Unlock process. (Note: Giving a user 'Locking/Unlocking with E-signature authority' privileges will not immediately enable the E-signature functionality on all data collection instruments. To enable the E-signature feature on the desired instruments, click on the 'Customize & Manage Locking/E-signatures' link (under Applications on the left side of the REDCap menu screen) and update the settings on the 'Record Locking Customization' tab, where each instrument is listed with an option to 'Display E-signature Option'. Until these settings are updated, the E-signature option will remain hidden.)

The following appears at the top of each locked instrument page.

 -
 **Instrument locked by <username>** (<first name> <last name>) on <date> <time>
 The instrument "<Form Name>" has been locked for record "<#>". If you have instrument-level locking/unlocking privileges, you may unlock this instrument at the bottom of the page.

 -

If the instrument is locked with E-signature authority, the following also appears at the top of the locked instrument page.

 -
 **E-signed by <username>** (<first name> <last name>) on <date> <time>

 -

The following is one example of when locking data at the individual instrument level for a single record may be appropriate.

- Suppose a project has multiple time periods at which data are collected for a patient and the data collected at each time period are entered on separate REDCap instruments. Suppose the patient's data for the first period (maybe a pre or baseline period) is entered, cleaned, and finalized in REDCap before the collection of the patient's data for a subsequent period (maybe a mid or end of study period) is to occur. The instrument on which the patient's first period data are final can be locked via the individual instrument level locking approach to avoid inadvertent editing of these data as the patient's data from subsequent time periods are processed. Each patient's period data can be locked similarly as the study proceeds.

Individual Record Level: All data across all instruments for a single record can be locked by any person with the necessary user access privileges. Users must first identify the individual record with the data to be Locked/Unlocked by selecting the record either from the Record Status Dashboard or the Add / Edit Records links on the left side of the REDCap menu screen. The selected record's Record Home Page will then appear with a 'Choose action for record' box near the top of the page. When users click on this box

they will be presented with a drop-down menu, one choice of which is 'Lock entire record'. When this choice is selected, the following 'Lock Entire Record' box will appear.

'Do you wish to LOCK record "#"? This will lock the ENTIRE record, not just a single instrument. After doing this, no one will be able to edit this record until it is unlocked by someone with Lock/Unlock privileges.'

Lock entire record Cancel

Similarly, if the record is already locked and the intent is to unlock the record, the drop-down menu will include the 'Unlock entire record' choice. When this choice is selected the following 'Unlock Entire Record' box will appear.

'Do you wish to LOCK record "#'?'

Unlock entire record Cancel

The following appears at the top of each instrument page of a locked record.



The entire record was locked by <username> (<first name> <last name>) on <date> <time>
Only users with record-level locking/unlocking privileges may unlock this record in order to modify any of this record's data.

The following is one example of when locking data at the individual record level for all instruments may be appropriate.

- Suppose all data for a patient are entered, cleaned, and finalized on all instruments. All data for this patient can then be locked via the individual record level locking approach to avoid inadvertent editing of these data while the data for other patients are being processed.

Locking Data at the Full Database Level

Locking data at the full database level in REDCap can occur at multiple stages. Typically, these stages only begin once all data for the project has been collected. Only those individuals with the necessary user access privileges can lock the data at the full database level for any of the stages.

In the first stage, entry of new data records is no longer permitted, but the entered data remain editable. Also, many REDCap features typically used during data collection are disabled, such as Surveys, Alerts & Notifications, Automated Survey Invitations, etc. Moving the REDCap project from Production status to Analysis/Cleanup status triggers this stage. This move is achieved when the 'Other Functionality' link at the top of the REDCap Project Home page is selected, followed by the selection of the 'Move to Analysis/Cleanup Status' link on the Project Management Status page. The data typically reside in this stage while the data undergo a final review for accuracy, consistency, and completeness, as

well as a possible preliminary analysis. Data errors that arise during this stage can then be resolved in the database.

Once the database has been moved to Analysis/Cleanup status and all data are considered accurate, consistent, and complete (clean), the second stage of the full database level lock can be achieved by clicking on the 'Modify' button in the box at the top of any of the 'Project Home', 'Project Setup', or 'Other Functionality' pages. In the second stage, not only is the entry of new data records no longer permitted and features typically used during data collection disabled, but also the data are no longer editable, effectively locking all data across all instruments for all records. However, all data remain accessible and REDCap reporting and export feature remain operable.

Once all data collection, cleaning, and analysis are complete, the third and final stage can be achieved by clicking the 'Mark Project as Complete' button on the 'Other Functionality' page. This action moves the REDCap project from Analysis/Complete status to Completed status making the data no longer accessible to project users. Moving the project to Completed status should be done when access to the project is no longer needed. The project is taken offline and removed 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. No one, except REDCap administrators, can access the data or any aspect of the project.

Note: The status of a project can be found in the Project Home and Design section on the left side of the REDCap menu screen. Projects are identified either in Development, Production, or Analysis/Cleanup status. Databases at the first stage of a full database level lock will be identified by the phrase "Analysis/Cleanup". Databases at the second stage will be identified by the phrase "Analysis/Cleanup" accompanied by a LOCK icon. Databases at the third stage, with the Completed status, are not accessible.

The checklist presented in Appendix A (Database Close-Out Process) provides one example of how the full database lock process could be incorporated in the closing out of a REDCap project.

Locking Data By Controlling User Rights

Locking data using the Individual Instrument, Individual Record, and Full Database levels are the preferred approaches. However, using these approaches may be quite laborious, if not impossible, if the need is to:

- 1) Lock all data on a subset of instruments for all records,
- 2) Lock all data on a subset of instruments for a subset of records, or
- 3) Lock all data on all or a subset of instruments for a subset of users.

Using the preferred approaches to achieve the first two data locking needs is only possible by locking the data at the instrument level one record at a time. If the project consists of several instruments and contains many records, locking each instrument one record at a time could become quite laborious. A somewhat less laborious approach is to edit user Data Viewing Rights within the REDCap User Rights application.

The possible Data Viewing access levels are 'No Access', 'Read Only', and 'View & Edit'. Users will have been assigned to Roles with access at the 'View & Edit' level for the instruments for which they have responsibility to enter and edit data during the project. At any point in the project, changing the Data Viewing rights for these Roles to 'Read Only' locks these users from entering and editing the data for the instruments selected, making it possible to effectively lock data for a subset of instruments for all records (#1 above). However, at this time, the more laborious approach must be taken to lock data for a subset of instruments for a subset of records (#2 above).

The consequences of locking data using the preferred approaches affect every user on the project, regardless of Role. If the project need is to lock all data on all or a subset of instruments for a subset of users (#3 above), the User Rights application can again be used. Ensure that the users for whom the data are to be locked are assigned to a Role with the Data Viewing right of 'Read Only'. This may or may not require creating a new Role or Roles for these users. Of course, DAGs should be used to lock a subset of users from any access to data for a subset of records.

The following are a couple examples of when locking data by controlling user rights may be appropriate.

- Suppose in the individual instrument level example presented above, it is impractical to lock individual instruments one record at a time. This situation may occur when the data from a period are entered on multiple instruments and the data for all patients are finalized in about the same time frame. Changing the Data Viewing Rights to 'Read Only' for the users who had 'View & Edit' rights for the instruments containing the finalized data is the more efficient approach to locking the data on these instruments.
- Suppose all expected data have been received and processed and stage 1 of the full database lock approach has been executed. At stage 1 no additional records can be added to the database, but the existing data remain editable. At this point it may be appropriate to limit the users who can edit the data to key project personnel. Changing the Data Viewing Rights for all instruments to 'Read Only' for the users for whom 'View & Edit' rights are no longer required locks these users from editing the data while key personnel retain their rights to edit the data.

APPENDIX A

Database Close-Out Process

At the culmination of a project, database lock and close-out procedures are imperative to prevent inadvertent or unauthorized data changes prior to, during, and after analysis and reporting. Since data integrity is crucial to the success of a project, well-defined and documented processes for locking, unlocking, and closing databases are necessary. Terminology and procedures vary among different organizations and database systems. The following is a sample checklist of common steps involved in the database close-out process for a REDCap project.

Sample Database Close-Out Process Checklist

1. Study team and stakeholders notified of database close-out process initiation
2. Confirm all expected data received and processed
3. Perform a REDCap full database lock at stage 1*
4. Save an exported version of the full database
5. Identify any outstanding data issues by
 - a) Reviewing Data Quality checks in REDCap and
 - b) Reviewing data check output produced from the exported full database, if applicable
6. Edit database, as necessary, in response to any identified data issues
7. Ensure all data queries have been sufficiently resolved
8. Review REDCap Log to ensure no unexpected database changes occurred since the stage 1 full database lock
If unexpected changes occurred, repeat steps 4 through 8, as necessary
9. Perform a REDCap full database lock at stage 2*
Any database changes at this point require key stakeholder authorization to unlock the database
Once database is unlocked and changes made, repeat checklist steps as necessary
10. Release database for analysis and reporting
11. Ensure all required database processing documentation is complete and final
12. At the request of key stakeholders, perform a REDCap full database lock at stage 3*
13. Archive database documentation

* Stage Definitions

1. The project is in Analysis/Cleanup status with entry of new data records no longer permitted, entered data remaining editable, and many REDCap Features typically used during data collection disabled (e.g., Surveys, Alerts & Notifications, Automated Survey Invitations, ...).
2. The project is in Analysis/Cleanup status with entry of new data records no longer permitted, entered data no longer editable, and many features typically used during data collection disabled.
3. The project is in Complete status with the data records only accessible to REDCap administrators.