







ECTU Central Office WPD ECTU_REDCap_W3: Database Lock and Unlock Procedures

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1. INTRODUCTION

This WPD provides instruction on the mechanisms that can be used to lock and unlock a REDCap study database by an ECTU REDCap database developer with appropriate user access. Depending on the type of lock required, the database developer can utilise any appropriate method to ensure the relevant data is inaccessible.

2. INSTRUCTIONS and GUIDANCE

2.1 Lock Method 1 – Full Database Lock

2.1.1 This method involves the removal or disabling of accessibility rights via the user roles and constitutes a full database lock. This would commonly be performed at end of study.

2.1.2 For all user roles disable or remove all Basic Privileges, ensuring the following:

- 'Create Records' must be disabled for all user roles
- 'Rename Records' must be disabled for all user roles
- 'Delete Records' must be disabled for all user roles
- 'Data Import Tool' must be disabled for all user roles
- If delegated to a 'Trial Office' or equivalent role, 'User Rights' can remain enabled (see 2.1.6)
- If delegated to a 'Statistician' or equivalent role(s), 'Add/Edit/Organise Reports' and 'File Repository' can remain enabled

2.1.3 For all user roles ensure Data Viewing Rights is set to 'Read Only' for all instruments

2.1.4 For all user roles except 'Statistician' or equivalent role(s), ensure Data Export Rights is set to 'No Access' for instruments.

2.1.5 The 'Statistician' or equivalent role(s) will require 'Full Data Set' export access to all instruments in order to complete the final analysis. If there is a blinded role where export access has been limited on some instruments, the database developer will confirm with the Trial Statistician if this should now be extended to full export access for this role.

2.1.6 Individual user access will not be removed by the database developer as part of the database lock. Where 'User Rights' has been delegated to 'Trial Office' or equivalent role, this will remain enabled to allow removal of individual access as required and to facilitate any further access requirements in the event of a database unlock.

2.2 Lock Method 2 – Individual Record Lock

2.2.1 This method involves locking an individual record on the database and constitutes a partial database lock. This may be applicable for certain circumstances such as interim analysis of a limited proportion of the participants recruited.

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- 2.2.2 The ability to individually lock a record is a built-in feature of REDCap. To complete the lock, access the required record and select 'Lock entire record' from the 'Choose action for record' drop-down.
- 2.2.3 Once locked, a notification that the record has been locked will appear on each instrument within that record. All instruments in that record will be inaccessible for further editing.
- 2.2.4 This method only removes accessibility for that individual record and can only be implemented on a per record basis. This method does not change any accessibility at a user role level and any unlocked records will remain open to all applicable users.
- 2.2.5 Although each individual record could be locked at the end of study, this is not recommended as it can potentially be a lengthy process and the full lock implemented (as described in Lock Method 1) would remove accessibility anyway.

2.3 Lock Method 3 – Individual Instrument Lock

- 2.3.1 This method involves locking an instrument within a record and constitutes a partial database lock. This may be applicable for certain circumstances such as interim analysis of a limited proportion of the participants recruited.
- 2.3.2 The ability to individually lock an instrument is a built-in feature of REDCap. To complete the lock, access the instrument within the required record and check the 'Lock' option at the bottom of the page. Once the page is saved, the instrument will be locked.
- 2.3.3 Once locked, a notification that the instrument is locked will appear at the top of the instrument within that record only. The individual instrument will be inaccessible for further editing.
- 2.3.4 This method only removes accessibility for that individual instrument within a specific record and can only be implemented on a per instrument basis. This method does not change any accessibility at a user role level or accessibility to that instrument on other records. All other instruments within the record and this instrument in other records will remain open to all applicable users.
- 2.3.5 As with Lock Method 2, it is not recommended that this method is used as part of a full database lock.

2.4 Unlock Method 1 – Unlock after full database lock

- 2.4.1 If a request is received to unlock the database lock as described in Lock Method 1, it is not recommended that the entire database is unlocked and the removed or disabled functionality is restored.
- 2.4.2 In order to preserve existing data and minimise the risk of cleaned data being further altered after unlock, only the required sections of the database that need to be amended should be unlocked. This should be clearly specified on the unlock

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request. Refer to ECTU_REDCap_07 Management of Study Database Lock and Unlock Requests

2.4.3 On receipt of the unlock request, the database developer will create a new user role with an appropriate name distinct from those used in the study (e.g.'Unlock User Role DDMMYYYY')

2.4.4 All Basic Privileges will be removed from this role. This role must not be able to:

- 'Create Records'
- 'Rename Records'
- 'Delete Records'
- Access any randomisation instruments if applicable to the study
- Export any data for any instrument

2.4.5 Data Viewing Rights will be set to 'View and Edit' only for the instruments that will require amendment as specified in the request.

2.4.6 Once the user role is in place, users can be allocated to this role for each site as required. This will be completed by users in the 'Trial Office' or equivalent role if User Rights has been delegated to them or by the ECTU Data Management Team.

2.4.7 Once any amendments have been completed and a re-lock request is received, the accessibility will be removed from the 'Temporary Unlock User Role' as per Lock Method 1, returning the database to a fully locked state.

2.4.8 It is recommended that users are removed from the 'Temporary Unlock User Role' after completion of the amendments.

2.5 **Unlock Method 2 – Individual Record Unlock**

2.5.1 This method should only be used if Lock Method 2 has been implemented as described above in section 2.2. To unlock an individual record, access the required record and select 'Unlock entire record' from the 'Choose action for record' drop-down.

2.5.2 Once unlocked, all instruments within the record will be returned to their pre-lock appearance and functionality and will be accessible for amendment to those with appropriate user rights.

2.5.3 As with individual record lock, unlock must be completed on a per record basis and only the selected record will be unlocked.

2.6 **Unlock Method 3 – Individual Instrument Unlock**

2.6.1 This method should only be used if Lock Method 3 has been implemented as described above in section 2.3. To unlock an individual instrument, access the instrument within the required record and click the 'Unlock form' at the bottom of the page.

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2.6.2 Once unlocked the appearance and functionality of the instrument within that record will return to its pre-lock state and will be accessible for amendment to those with appropriate user rights.

2.6.3 As with individual instrument lock, unlock must be completed on a per instrument basis and only the selected instrument within the record will be unlocked.

3. RELEVANT DOCUMENTS AND REFERENCES

[ECTU Website](#)

- ECTU Central Office SOP ECTU_REDCap_07 Management of Study Database Lock and Unlock Requests












ECTU REDCap SOP 07 and W3

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