ECTU Central Office WPD ECTU_REDCap_W1: Database Release Procedure

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Authorship and Approval			
Name and Designation	Author/Reviewer /Approval/ Authorisation	Date	Signature
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Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	12 Aug 2024	• Initial Creation/New document

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1. INTRODUCTION

This WPD provides instruction on how to release a study database built on the REDCap platform. This WPD provides instructions for initial release and any subsequent release after a database update. A study database should only be released once all approvals and signed validation documentation is in place as specified in ECTU Central Office SOP ECTU_REDCap_05 Study Database Release.

2. INSTRUCTIONS and GUIDANCE

2.1 Initial Release

2.1.1 Create a copy of the project and rename it for live status. This can be done by selecting 'Copy' in the 'Other Functionality' tab on the dashboard. The name should be changed using the following convention:

<<STUDY NAME/ACRONYM>> LIVE

2.1.2 The 'Project's purpose' should be 'Research' and specify 'Clinical research study or trial'

2.1.3 In the 'Also copy the following' section, ensure that 'All records' and 'Users and their user rights' are **unchecked.** Users and records/data entered on the training database should not be copied to the live database.

2.1.4 In this section, ensure that 'User roles' is ticked. This ensures that the agreed roles and their functionality will be in place on the live dataset.

2.1.5 Tick any other functionality that may be applicable to the database. This may vary according to each database but the most commonly applicable functions include:

- Reports
- Report folders
- Data quality rules
- Alerts and Notifications
- Survey Queue and Automated Survey Invitation settings
- Form Display Logic settings

It is important to ensure the relevant functionality is ticked as this will ensure that the tested and validated functionality on the training database will be in place on the live database.

2.1.6 Click 'Copy Project' to create the new live version of the database. This version is held on the REDCap Development server. At this point, although the live version has been created, it has not been fully released.

2.1.7 Some functionality is not fully enabled when the database is copied as above. In the new live version of the database, the following functionality should be enabled where applicable:

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Randomisation via the API token – a new API token should be set-up for the new live database. This process is described in ECTU Central Office SOP ECTU_REDCap_12 TBC

Survey Functionality – the 'Automated Invitations' function for surveys will automatically be disabled on the new live database. Ensure that the survey invitation is set to 'Active' at each timepoint.

Alerts and Notifications – all Alerts and Notifications will automatically be disabled on the new live database and will have the logic functionality that existed on the training database. Ensure that each notification logic is updated for the new live database (for example, randomisation alerts use logic based on the DAG number and this number will be different on the live database) and that any initial recipients are included on each alert before the alert is set to 'Active'.

2.1.7   Once all functionality is in place, ensure that the Senior Software Developer has confirmed that the new randomisation via API and any additional external modules (for example Text Alerts) have been made live.

2.1.8   The new live database can now be released. This is done by changing all settings on 'Project Setup' page to an 'I'm done' status and clicking 'Move project to production'. At this point, you should check 'Delete all data' from the options provided. No data should have been copied to the live version of the database but this is a final check to ensure all data is removed.

2.1.9   Once the new live database is on the REDCap Production server the initial release is complete.

2.1.10 Users in the Trial Office and Statistician/Unblinded Statistician roles (as applicable) can now be added to the live database. All other users will be added by the Trial Office users or ECTU Data Management Team as required.

2.1.11 Send a notification email to the relevant trial staff advising that the database is now live.

2.1.12 Complete the Release Specification as per ECTU Central Office SOP ECTU_REDCap_05 Study Database Release.

2.2   Subsequent Releases

2.2.1   Download a copy of the Data Dictionary from the live database and save as a csv file in the 'Additional Requirements' folder on the ECTU shared drive. When saving, add **'ORIGINAL'** to the file name.

2.2.2   Download a copy of the Data Dictionary from the training database and save as a csv file in the Additional Requirements folder on the drive, alongside the live file specified in 2.2.1.

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2.2.3   On the live database, 'Enter Draft Mode' in the Online Designer.

2.2.4   Upload the training database Data Dictionary (as specified in 2.2.2) to the live database in the Dictionary section. Click 'Commit Changes' to import the new dictionary. This will replace the previous data dictionary.

2.2.5   The changes must be reviewed and approved by a REDCap Administrator before they are fully committed to the database. REDCap will highlight the altered fields and highlight any potential data loss. It is important that this is reviewed by the database developer before the change is fully committed.

2.2.6   Once the changes have been approved, the live database will automatically be moved out of 'Draft Mode' and the changes in the Data Dictionary will be implemented.

2.2.7   Not all functionality will update when the new Data Dictionary is committed. Some functions and applications must be updated separately (NOTE: The live database may have to be returned to 'Draft Mode' to implement some changes). If the update includes changes to these functions, check these compared to the training database and amend as required:

- Define My Events and Designate Instruments for My Events – check events and designations are correct
- Optional Modules and Customizations – check repeatable instruments and events are correct
- Designer – Check Instrument Names are correct. The database update can cause minor changes (e.g. from upper to lower case letters)
- Surveys – Check Survey Settings and Automated Invitations are correct
- User Rights and DAGs – Check all User Rights and DAGs are correct as required
- Data Quality – check all Data Quality Rules are correct as required

2.2.8   Once the changes are complete, download a copy of the new Data Dictionary (post-update) from the live database and save as a csv file in the Additional Requirements (or similar applicable folder) folder on the ECTU shared drive. When saving, add **'UPDATED'** to the file name.

2.2.9   In order to verify that the changes have been implemented correctly, use compare software such as Spreadsheet Compare or Notepad ++ to compare the **TRAINING** Data Dictionary (see section 2.2.2) to the **UPDATED** live Data Dictionary (see section 2.2.7). The documents should match except for the title field (i.e. only one difference should be found when comparing).

2.2.10 Save a copy of the spreadsheet compare results (for example, screenshot or download) alongside the downloaded Data Dictionary csv files in the Additional Requirements (or similar applicable folder) folder.

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2.2.11 Send a notification email to the relevant trial staff advising that the database is now live.

2.2.12 Complete the Release Specification as per ECTU Central Office SOP ECTU_REDCap_05 Study Database Release.

3. RELEVANT DOCUMENTS AND REFERENCES

ECTU Website

- ECTU Central Office SOP ECTU_SOP_REDCap_05 Study Database Release
- ECTU Central Office SOP ECTU_SOP_REDCap_12 Using an API token on a REDCap Database

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ECTU REDCap SOP 05 and W1

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