





ECTU Central Office SOP ECTU_REDCap_05: Study Database Release

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Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	25-Nov-2015	<ul style="list-style-type: none"> Initial creation/new document
2.0	26-May-2016	<ul style="list-style-type: none"> Change to SOP name as separate naming convention allocated to REDCap SOP/WPDs
3.0	21-Nov-2016	<ul style="list-style-type: none"> Additional instructions added to section 3.2.2 (subsections d and e) regarding events. Section 4 added for definition of an event Formatting and numbering altered and simplified for ease of use Location of relevant documents added in section 5
4.0	12 Aug 2024	<ul style="list-style-type: none"> Document moved to new template Extensive changes to entire document to reflect process more clearly

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1.0 PURPOSE

Study Database Release is the process of moving a database from the training environment (Development mode) to a live environment (Production mode) on the REDCap server.

The SOP describes the process of releasing an individual study database. In cases where more than one database is applicable for the study (for example, main study database and Screening Log database), this procedure applies to each database.

2.0 SCOPE

This SOP applies to staff in the following roles within the ECTU Data Management Team as REDCap study database developers:

- Data Manager
- Assistant Data Manager
- Data Management and Programming Architect

3.0 RESPONSIBILITIES

The database developer is responsible for the following:

- Ensuring all pre-release documentation is in place as required
- Releasing the database to the live environment
- Completion of any post-release documentation
- Sending notification of release to the appropriate study and Sponsor staff

4.0 PROCEDURE

Definitions:

- **Data Dictionary:** The Data Dictionary is the structural map of the database. This includes all events, instruments and fields included in the database
- **Development mode:** All **training** versions of REDCap databases are held in this mode on the server
- **Production mode:** All **live** versions of REDCap databases are held in this mode on the server

4.1 Pre-Release Checks and Documentation

4.1.1 At a minimum, the following is required before a database can be released. This applies to all studies:

- All instrument and functionality validation must have passed and all validation documentation must be signed by appropriate parties.
- Database review and approval has been given by the Trial Statistician or appropriate study designee. This should be confirmed in writing (e.g., email).
- Database review and approval has been given by the Trial Manager or appropriate study designee. This should be confirmed in the writing (e.g., email).

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4.1.2 In addition, if the study is a CTIMP or risk-assessed study sponsored by ACCORD, the following is also required:

- Database review and approval has been given by the Trial Monitor. This should be confirmed in writing (e.g., email).
- Database and documentation review and approval by the ACCORD QA team. All completed and signed validation documentation should be sent to the team once all other approvals are in place. The team will complete the Computer Systems Validation Checklist and confirm via email once the database is approved for release.

4.1.3 If the study is sponsored by a different Sponsor than ACCORD, please check their guidance for any additional requirements prior to database release.

4.1.3 The above requirements apply to the initial database release and all subsequent releases after a database update.

4.2 Database Release

4.2.1 The database is initially built in Development mode and serves as a training version of the database.

4.2.2 For initial database release, a copy of this database is taken and moved to the Production server, where it moves to a live status.

4.2.2 The training version of the database is retained in Development mode and is used for both training purposes and for subsequent updates and changes that are made to the database. The training version is used to test and validate any changes by the same process as for initial release.

4.2.3 For subsequent releases, the updated Data Dictionary is downloaded from the training database and uploaded to live version of the database in order to implement the changes.

4.2.4 To release the database to a live status, follow the instructions outlined in ECTU Central Office WPD ECTU_REDCap_W1 Database Release Procedure.

4.3 Release Specification

4.3.1 Once the database is released, the database developer will complete the Release Specification using RC009 REDCap Study Database Release Specification Template.

4.3.2 The Release Specification documents the specification that was in place at the time of database release as well as the validation and approval process.

4.3.3 If the database release has been approved by ACCORD QA team, the database developer will provide a copy of the signed Release Specification to the team as confirmation of the release.

5.0 RELEVANT DOCUMENTS AND REFERENCES

[ECTU Website](#)

- ECTU Central Office WPD ECTU_WPD_REDCap_W1 Database Release Procedure

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[ECTU Templates](#)

- RC009 REDCap Study Database Release Specification Template

[ACCORD Website](#)

- POL007 Computer System Validation

For studies with a different Sponsor, please refer to local guidance as required

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ECTU REDCap SOP 05 and W1

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