





ECTU Central Office SOP ECTU_REDCap_04: Study Database Validation

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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	19 Aug 2024	<ul style="list-style-type: none"> Document moved to new template Change to SOP Name Extensive changes to document to include REDCap validation process (updated process from ECTU_SOP_REDCap_03) Reference to REDCap Validation documents now included

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1.0 PURPOSE

Study database validation is the process of testing the content, appearance and functionality of the REDCap database as implemented by the database developer to ensure it meets the specification criteria and collects the data as is required by the study protocol.

The SOP describes the validation process for a REDCap study database, including documentation of the process. 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

This SOP also applies to members of the Trial Management team or appropriate study designee who may be responsible for reviewing, validating and approving the REDCap study database

3.0 RESPONSIBILITIES

The database developer is responsible for preparing all validation documents and ensuring that these are completed and approved by the Trial Manager or appropriate study designee (as designated validator) as applicable.

The Trial Manager or appropriate study designee is responsible for validating the database and completing the validation documents as directed by the database developer.

4.0 PROCEDURE

4.1 Validation Procedure

4.1.1 All study databases must be fully validated prior to release. For new study databases undergoing initial release all core functionality and instruments/features must be validated. For existing study databases undergoing a change, only the core functionality and/or instruments/ features that have changed need to be validated.

4.1.2 The database developer will prepare all validation documentation as specified in section 4.2 below. This will be provided to the Trial Manager and/or appropriate study designee to be completed during the validation.

4.1.3 Validation must not be completed by the database developer. Validation must be delegated to the Trial Manager or appropriate study designee (for example, another member of the Trial Team or Data Management team).

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- 4.1.4** All validation must be completed on the **training** version of the study database using dummy data. The **live** version of the study database (in the case of an existing database) and real study data must not be used for validation.
- 4.1.5** All applicable core functionality and/or instruments/features must have passed the validation checks specified in the documentation before the database can be released (section 4.2).
- 4.1.6** The validator is responsible for completing the validation and determining whether the checks have passed. Any failures should be returned to the database developer for review and repair as necessary so that the validation can be repeated.
- 4.1.7** Once all validation is complete and passed, the completed documentation is returned to the database developer is responsible for verifying all documentation has been completed in full and approved as required.

4.2 Validation Documentation

4.2.1 The following validation documentation will be prepared by the database developer using the ECTU templates (specified in brackets):

- Validation Plan (RC010 REDCap Study Database Validation Plan Template)
- Validation Document for Core Functionality (RC011 REDCap Study Database Validation Document Core Functionality Template)
- Validation Documents for Instruments/Features (RC012 REDCap Study Database Validation Document Template)

4.2.2 The Validation Plan will specify the parameters of the validation process including who will complete validation, preparation, maintenance and retention of documentation and a list of core functionality and instruments/features that will be validated for this database release.

4.2.3 The Validation Plan for the initial release of the database will include all functions and instruments features requiring validation in section 4 on the template. For each subsequent database release, a new version of the Validation Plan will be created and will include only the functions and/or features/instruments that have changed for this release. (Section 4.3)

4.2.4 The Validation Document for Core Functionality will specify the validation parameters for any functions underpinning the database features/instruments. This may include (but is not limited to) the following:

- Events Grid Structure
- Status Alerts (as displayed on multiple instruments)
- Repeating Instruments and Events
- Surveys
- Form Display Logic

Additional core functionality may be included as required depending on the study requirements. See section 4.3 for version control.

4.2.5 The Validation Document for Instruments/Features will include the validation for each feature/instrument built, using a separate document for each. Each document is

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prepared using the Codebook available in the database. Validation will be completed for each field within the instrument by the designated validator. See section 4.3 for version control.

4.3 Validation Document Version Control

- 4.3.1** All validation documentation will initially be versioned as 1.0. Version numbers will increase in whole number increments (for example, v2.0, v3.0) with each update.
- 4.3.2** Version numbers for the validation documentation will increase with each database update. For example, at initial release, the Validation Plan, Validation Document for Core Functionality and all Validation Documents for Instruments/Features will all be version 1.0.
- 4.3.3** Subsequent database releases will increase the version number of the Validation Plan as this must be renewed with each release.
- 4.3.4** The version numbers for Validation Document for Core Functionality and any applicable Validation Documents for Instruments/Features will increase if they have been altered as part of a subsequent release and require revalidation.
- 4.3.5** During the validation process, if a Validation Document is returned to the database developer with a failure, this does not require a version change to the document. The failure should be repaired and returned for revalidation using the existing version no.
- 4.3.6** The database developer is responsible for version control of all validation documentation.

4.4 Document Approval and Retention

- 4.4.1** The Validation Plan will be approved by the Trial Manager or appropriate study designee and the database developer. This should be approved before the validation can begin.
- 4.4.2** The Validation Document for Core Functionality and all Validation Documents for Instruments/Features will be approved by the designated Validator once all validation points have passed. The database developer will further approve these documents to confirm completion.
- 4.4.3** All validation documents must be approved before the database can be released. The database release process is described in ECTU Central Office SOP ECTU_REDCap_05 Study Database Release.
- 4.4.3** The database developer is responsible for retaining the validation documentation during the life-cycle of the study. These will be held electronically in a study-specific folder on the shared drive. Paper copies will be filed in a study-specific data management folder.

5.0 RELEVANT DOCUMENTS AND REFERENCES

[ECTU Website](#)

- ECTU Central Office SOP ECTU_REDCap_05 Study Database Release

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[ECTU Shared Drive](#)

- RC010 REDCap Study Database Validation Plan Template
- RC011 REDCap Study Database Validation Document Core Functionality Template
- RC012 REDCap Study Database Validation Document Instruments Template

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ECTU REDCAP_03, 04, 06 and W2

Final Audit Report

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