







ECTU Central Office SOP_REDCap_02: Database Specification for Initial 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 name as REDCap allocated separate naming convention to IT
3.0	01-March-2019	<ul style="list-style-type: none"> Document moved to new template Extensive changes to document due to procedural changes REDCap Initial Specification Template implemented and reference added to SOP
4.0	07 Aug 2024	<ul style="list-style-type: none"> Change to document title Extensive changes to document due to procedural changes REDCap Initial Specification Template withdrawn and reference removed Updated to new template v3.0

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1.0 PURPOSE

This SOP describes the documentation and information that must be provided in order in order to build the study database on the REDCap platform. This documentation will form the specification that includes the format, content and functionality of the 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

Within the Data Management team, the Data Management and Programming Architect, Data Managers and Assistant Data Managers are responsible for designing and building study databases on REDCap.

The Trial Manager and Trial Statistician or delegated individuals are responsible for providing documentation and information required by the database developer in order for the developer to draft a database specification ahead of building the database.

4.0 PROCEDURE

4.1 Specification Requirements

4.1.1 In order to create a study database, the following required information:

- **Arm and Event Structure**
A description of the arm structure is only necessary in a multi-arm study. The Event structure is usually based on the visit structure of the study itself.
- **Randomisation***
If randomisation is required, a description of the required functionality will be required, including randomisation groups, allocation variables, minimisation and stratification variables (if applicable)
- **Blinding and Unblinding***
If blinding is required, a description of what is blinded and who is blinded will be required. Unblinding requirements in these cases should also be specified
- **Data Collection Variables**
This includes names of specific CRFs and fields required within these
- **Data Imports**
If data will be collected externally and imported into the study database (for example, sample analysis results completed by an external lab, SAE line-listings provided by the Sponsor), a description of what data is expected and when the import will be required.
- **Surveys and Text Reminders***
If surveys are to be issued to the participant, a description of what surveys are to be included, issuing rules and approved wording for any emails should be

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specified. If Text Reminders are required, issuing rules and approved wording for the text should be specified

- **User Roles**
A list of specific user roles that will be required and what accessibility should be attached to these
- **Data Access Groups (DAGs)**
Number of sites expected to take part in the study and details of these where available
- **Identifier Requirements**
Specify whether a sequential number should be allocated or a custom identifier will be used when adding a record to the study database
- **Notification Requirements**
Specify if any notifications should be sent automatically by the database (for example, randomisation alert email)

* These functions may require additional system build from Senior Software Developer if using an API token connected to an external system. This is detailed in ECTU_SOP_REDCap_12 Using an API token on a REDCap Database

4.1.2 The above information may be provided by various methods and documentation, including the following:

- **Study Protocol**
As a minimum, the study protocol should be provided in order to start the database build. It does not need to be a final version of the protocol but at least a draft that is close to being finalised
- **Study pCRFs/ Data Collection Sheets**
If pCRFs/ Data Collection Sheets have been designed for the study these should be provided
- **Data Collection Variables**
If a pCRF is not required, a list of expected fields can be provided in a document (for example Excel, Word). This should specify, the name of the field, type of field (for example drop-down, free-text), any answer options (in case of multiple choice), and validation ranges

4.1.3 A full specification (as described in section 4.1.1) is not required to begin building the study database. The study protocol usually provides enough minimal information for this to begin.

4.1.4 The database specification will evolve over the course of the build based on changes to the protocol or study requirements or based on feedback from users during testing. The Trial Manager or appropriate study designee is responsible for ensuring the database developer is informed of any required changes.

4.1.5 The database developer will ensure that all documentation received relating to the initial release specification is retained for monitoring and audit purposes. These documents will not be printed but will be retained in the study folder in the REDCap inbox or held electronically in the study folder on the shared drive.

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5.0 RELEVANT DOCUMENTS AND REFERENCES

[ECTU Website](#)

- ECTU_SOP_REDCAP_03 REDCap Database Development
- ECTU_SOP_REDCAP_12 Using an API token on a REDCap Database

[ACCORD Website:](#)

- ACCORD SOP CR004 Recording and Reporting Study Data
- ACCORD SOP CR007 Study Documents
- ACCORD SOP CR013 CRF Design and Implementation

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

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Final Audit Report

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