

REDCap “Project / Record Lock” User Requirements Specification

University of Vanderbilt
Medical Center
(VUMC)

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Signature Page

Prepared by:

I have prepared the contents of this document and agree that the provisions contained herein are appropriate and consistent with current regulatory expectation for computer validation, internal policies and procedures and available FDA industry Guidance and I tender it for approval.

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Revision History

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15-JUN-2020	1.0	Original Release, New Document

1 Introduction

1.1 Objective

The purpose of this User Requirements Specification (URS) is to define the various user requirements for the Record Lock feature of REDCap system. The requirements will be tested and/or verified in the execution of the test scripts or implemented by procedure.

Validation is a process that provides a high degree of assurance that the system and / utilities / facilities / process are reliably performing the functions as they were intended and will continue to do so in a consistent manner. This URS is the controlling document for the requirements of the record lock feature of REDCap system and serves to guide validation testing activities needed to retrospectively and prospectively validate the system.

Project specific information such as scope, responsibilities, validation deliverables as well as other project information can be found in the Record Lock Validation Plan.

1.2 Rationale

It is the practice of University of Vanderbilt, located in Nashville, Tennessee to assure that all regulated computerized systems perform according to predetermined specifications in an accurate, reliable and repeatable manner. These activities are designed and executed to ensure that the system and related procedures comply with Good Clinical Regulations, Data Integrity guidelines and 21 CFR Part 11 regulations.

1.3 Requirements

The following requirements apply to the system being retrospectively validated. These requirements include all activities and standards which must be met prior to releasing the system into the production environment. Each requirement will include a proposed verification mechanism. This will be identified in the 'Verification' column below. Verification methods include:

- P - Procedural controls will be verified to satisfy these requirements.
- T - Formal testing will be executed to document that these requirements are satisfied.
- V - Verification will be performed and documented that these requirements are satisfied.
- N/A - Requirement may not be verified in the scope of this project.

Some requirements may have multiple verification methods.

This section shall state the requirements: installation, system, security, regulatory, user/functional, instrument interface and risk mitigation (if necessary). The contents of this section shall define the environment in which the system must operate, the interface, data and reporting, as applicable.

A set of criteria will also be applied resulting in a prioritization of each user requirement on a scale from 1-3.

The priority levels are defined as:

- Priority (3): the user requirement is mandatory and must be implemented in the scope of the project. Essential to business operations; a mandatory function or requirement.
- Priority (2): the user requirement is strongly expected and may be implemented after this project or highly desirable to business operations; would provide significantly enhanced benefit but is not critical.
- Priority (1): the user requirement is "Optional" and may not be implemented nor tested in the scope of the project ("Nice to have" requirement) or for future business operations; nice to have feature or requirement.

Priority 3 requirement is mandatory, and a functional solution must satisfy the requirement. Priority 2 or 1 requirements are optional and do not need to be tested or satisfied in this retrospective validation effort.

The Requirement ID number (Req ID #) number must be unique and user must allow considerable empty numbers for future changes to requirements document.

1.4 System Context

University of Vanderbilt will utilize the record lock feature in the electronic records in REDCap system to ensure compliance to records in the REDCap system. This feature will enable to user to lock records and projects. This feature will be deployed and validated to ensure users with PI level user permissions are able to perform this action, which will ensure Case Report Form (CRF) associated with a patient can be locked and be archived at REDCap webserver along with the SFTP vault, where it will be maintained for the required retention period. There is a complete audit trail of the records in the data instrument's history log.

2 Requirements

The below functional requirements will reflect the functional requirements defined for this release of the eDocs application.

Req#	Requirement	Verification	Priority
3	Data Requirements		
3.1	The system shall provide an ability to lock and unlock records in REDCap system.	T	3
4	Record Functionality 21 CFR Part 11.10 (a) Functional and user requirements will be authorized through the development process. These will be effectively tested to demonstrate the expected accuracy and consistent intended performance of the application.		
4.1	Record Lock functionality		
4.1.1	The system shall provide an ability to lock records on a record level.	T	3
4.1.2	The system shall provide an ability to lock records on an instrument level.	T	3
4.2	Record Unlock functionality		
4.2.1	The system shall provide an ability to unlock records on a record level.	T	3
4.2.2	The system shall provide an ability to unlock records on a instrument level.	T	3
4.3	Record lock review and approval		
4.3.1	The system shall allow a user with record lock / unlock user rights to unlock record on record level.	T	3
4.3.2	The system shall prohibit a user with record lock / unlock user rights to unlock record on instrument level.	T	3
4.3.3	The system shall enforce a mechanism for the user to review rendered PDF of all collected data.	T	3
4.3.4	The system shall enforce a mechanism for the user to confirm to the accuracy of the rendered PDF(s) of all collected data prior to locking.	T	3
4.3.5	The system shall prohibit all users from data collection the records locked on record level.	T	3
4.3.6	The system shall have a mechanism to notify users to re-review records under revision on a record level.	P	3
4.3.7	The system shall have a mechanism to notify users to re-confirm records under revision on a record level.	P	3
4.3.8	The system shall prohibit all users from data collection the records locked on record level.	T	3

Req#	Requirement	Verification	Priority
4.3.9	The system shall have a mechanism to keep a locked / unlocked history log for a record.	T	3
4.3.10	The history log shall capture the following: <ul style="list-style-type: none"> • Date / Time of change • User • Data Changes Made 	T	3
4.3.11	The history log shall capture information in the following fields for locked / unlocked records: <ul style="list-style-type: none"> • Date / Time of change • User • Data Changes Made 	T	3
4.4	Record Lock Configuration		
4.4.1	The system shall allow a user to configure record lock functionality under additional customizations.	T	3
4.4.2	The system shall be able to render PDF file(s) of all record data.	T	3
4.4.3	The system shall be able to enable / disable PDF rendition feature.	T	3
4.5	Locked Record Storage and archival		
4.5.1	The system shall be able to send the rendered PDF of all collected data to the secured vault.	T	3
4.5.2	The vault shall have a mechanism to capture rendered PDFs of only approved / locked records.	T	3
4.6	SFTP storage		
4.6.1	The rendered PDFs will be stored in a secure SFTP vault storage.	T	3
4.6.2	The system shall have an ability to restore the rendered PDFs of the records into REDCap application.	T	3
5	Non-Functional Requirements All non-functional requirements not specified in this document are defined by data and application architectures and SOPs.		
5.1	Regulatory Information		
5.1.1	This system is subject to FDA 21 CFR Part 11, Electronic Records; Electronic Signatures and other global system regulations.	T	3
5.2	Documentation and Training		
5.2.1	REDCap validation documentation will be maintained by Vanderbilt University IT.	V	3
5.2.2	Training for eventual users of the eDocs module will be provided in association with the REDCap training modules.	V	3
5.2.3	There WILL BE training on regulated use of the record lock and unlock feature and configuration considerations necessary for compliant use and control of the product.	V	3
5.3	Accuracy and Reliability		
5.3.1	The system shall have a mechanism to discern invalid / altered (locked) records.	T	3

Req#	Requirement	Verification	Priority
5.3.2	This validation package will provide the basic design and associated functionality and testing to demonstrate that the application performs in an accurate and reliable manner.	V	3
5.4	Availability and Recoverability		
5.4.1	Disaster recovery and business continuity planning along with testing evidence will be developed and executed for the REDCap system and environment, effectively demonstrating the ability to recover and not lose data in the event of an outage or issues with the system or hosting environment.	T	3
5.5	Performance		
5.5.1	There are no known performance risks or limitations with REDCap application. The system supports concurrent users.	V	3
5.6	Installation Considerations		
5.6.1	For all supporting infrastructure or hardware (both for test and production implementation), a formal Installation Qualification including any noted configuration points will be executed to document the infrastructure and associated components necessary to run the application.	T	3
6	FDA 21 CFR Part 11 and Associated Global Regulatory Requirements As planned, eDocs will be a regulated application and the requirements associated with the defined Part 11 interpretation document will be included here to identify the expected controls and for availability to trace those requirements to associated test cases.		
6.1	Security		
6.1.1	21 CFR Part 11 (g) (d) The system will enforce role-based authorization to various parts of the system. Refer to the matrix below for a list of roles supported by the system and the activities that each role is authorized to perform. Roles will have effective checks and balances on use, as well as a process for granting access with appropriate authorization (may be non-testable but confirmed with procedures).	T	3
6.1.2	User Roles and Permissions: Record Lock User Roles are based on Data entry so every user regardless of the roles and permission can view and edit the records.	T	3
6.1.3	The system shall grant locking / unlocking records user permission only to PI user group on a project level.	T	3
6.1.4	The system shall deny locking / unlocking records user permission to a specific user on a project level.	T	3
6.1.5	21 CFR Part 11 (g) (e) Actions performed within the system should be recorded within the audit trail and the role/user performing the action is included within the audit trail record.	T	3
6.2	Records		
6.2.1	21 CFR Part 11 (f) Where employed, the system will include checks and controls to enforce the sequencing of events in support of effective data collection and reporting.	T	3
6.3	Audit Trail		

Req#	Requirement	Verification	Priority
6.3.1	eDocs will leverage the audit trail capabilities of the REDCap application. The attached screenshots demonstrate the basic audit trail functionality of the REDCap application.	T	3
6.3.2	21 CFR Part 11 (e) The system will provide secure, computer-generated audit trails to independently record all changes made to electronic records. The audit trail must contain the date and time of operator entries, the action performed (create, update, delete), the username of the operator performing the action, and the data elements affected. Record changes will not obscure previously recorded information.	T	3
6.3.3	An audit trail record will be created for every data entry in the system.	T	3
6.3.4	Such audit trail documentation will be retained and will be available for review and copying.	T	3
6.3.5	Audit trail can be maintained with the data records for the length of the data retention requirements.	T	3
7	Hardware and Software Requirements		
7.1	A standard installation qualification document, defining the version of the software, the additional software and hardware components (i.e. PDF rendering software, etc.) and versions leveraged for the system to work, will be executed to capture these requirements.	T	3
8	User Groups		
8.1.1	User Groups and accounts are managed per project and utilize record lock functionality associated with the REDCap application. The associated screen shots included here is of the REDCap User Rights module for record lock functionality, which will be utilized for account and role set-up:	T	3
8.1.2	Users in Principle Investigator and System Administrator user role will be having Record Locking and Unlocking permission.	T	3
8.1.3	All other user role shall not be able to lock / unlock records.	T	3
9	Other Requirements		
9.1	There shall be an administrative standard operating procedure that shall define the end to end record lock process.	P	3
9.2	Computing Environment		
9.2.1	There will be a test environment which will be validated.	T	3
9.2.2	The validated environment will be moved to the production environment.	P	3
9.2.3	The configuration of the validated development / test environment will be the same as the production environment.	T	3
9.2.4	Changes to the validated production environment shall be handled through internal quality management system.	V	3
9.2.5	The REDCap Version shall have a minimum version of 9.4.1	V	3

8 Attachments

Attachment A is the storyboard/wireframe that was utilized in the development of the application and this set of requirements for validation/testing purposes.



storyboard_RecordL
ocking_20200504.ppt











02 - REDCap Projct-Record Lock User Requirements Specification VUMC - v1.0


Final Audit Report

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