

# **REDCap Record Lock Functionality Requirements Traceability Matrix**

**Vanderbilt University  
Medical Center**

**Document Version: 1.0**

**Document Date: 21-Aug-20**

## 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.

  
Gaurav Kumar (Aug 21, 2020 12:05 EDT)

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Gaurav Kumar

Validation Representative, JAF Consulting, Inc

**Reviewed and Approved by:**

I have reviewed the contents of this document and accept and approve of the provisions as stated 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.



Aug 21, 2020

Joseph Franchetti, Quality Assurance  
Representative, JAF Consulting, Inc

  
Rob Taylor (Aug 21, 2020 11:43 CDT)

Rob Taylor, Technical Owner, UABMC

  
Colleen E. Lawrence (Aug 21, 2020 11:22 CDT)

Colleen Lawrence, System Owner, VUMC

## Revision History

Date	Version	Description
21-Aug-20	1.0	Original Release, New Document

## 1. Purpose

The purpose of this Requirements Traceability Matrix (RTM) is to ensure that all the requirements defined for Record Lock functionality within REDCap system are verified (tested) in the system qualification activities. The RTM is a document to map and trace user requirements with the qualification test cases to ensure adequate level of testing is being achieved. This requirements traceability refers to the ability to follow the life of a requirement, in both forwards and backwards direction, i.e., from its origins, through its development and specification, to its subsequent deployment and use, and through periods of ongoing refinement and iteration.

## 2. Scope

The scope of this document is limited to the association of the user requirements to the test cases executed in the validation activities of REDCap system. The traceability Matrix provides bi-directional traceability from the high-level user requirements to the functional specifications, configuration/design specifications to the test scripts executed during the system qualification activities.

## 3. References

The following reference documents were utilized to generate the Requirements Traceability Matrix.

Title/description	Version	Date of approval
REDCap "Project / Record Lock" User Requirements Specification	V 1.0	15JUN2020
REDCap "Project/Record Lock" Installation Qualification Protocol	V-01	14JUL2020
REDCap "Project/Record Lock" Performance Qualification Protocol	V-01	21AUG2020

## 4. Acronyms and Definitions

TERM	DEFINITION
RTM	Requirement Traceability Matrix
URS	User Requirement Specification

## 5. Requirements

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.

## 6. Traceability Matrix Table

Req#	APPROACH	Priority	Trace to Test or Document	Test Result
<b>3.</b>	<b>N/A</b>	<b>N/A</b>	<b>Section Header</b>	<b>Section Header</b>
3.1	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
<b>4.</b>	<b>N/A</b>	<b>N/A</b>	<b>Section Header</b>	<b>Section Header</b>
<b>4.1</b>	<b>N/A</b>	<b>N/A</b>	<b>Section Header</b>	<b>Section Header</b>
4.1.1	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
4.1.2	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
<b>4.2</b>	<b>N/A</b>	<b>N/A</b>	<b>Section Header</b>	<b>Section Header</b>
4.2.1	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
4.2.2	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
<b>4.3</b>	<b>N/A</b>	<b>N/A</b>	<b>Section Header</b>	<b>Section Header</b>
4.3.1	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
4.3.2	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
4.3.3	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS

# eConsent Requirements Traceability Matrix

Document Date: 21-Aug-20

Document Version: 1.0

Req#	APPROACH	Priority	Trace to Test or Document	Test Result
4.3.4	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
4.3.5	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
4.3.6	P	3	Record Lock Operation and Maintenance SOP	N/A
4.3.7	P	3	Record Lock Operation and Maintenance SOP	N/A
4.3.8	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
4.3.9	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
4.3.10	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
4.3.11	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
4.4	N/A	N/A	Section Header	Section Header
4.4.1	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
4.4.2	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
4.4.3	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
4.5	N/A	N/A	Section Header	Section Header
4.5.1	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
4.5.2	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
4.6	N/A	N/A	Section Header	Section Header
4.6.1	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
4.6.2	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
5.	N/A	N/A	Section Header	Section Header
5.1	N/A	N/A	Section Header	Section Header
5.1.1	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
5.2	N/A	N/A	Section Header	Section Header
5.2.1	V	3	REDCap record lock final validation deliverables	PASS
5.2.2	V	3	Record Lock Operation and Maintenance SOP	PASS
5.2.3	V	3	Record Lock Operation and Maintenance SOP	PASS

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Document Date: 21-Aug-20

Document Version: 1.0

Req#	APPROACH	Priority	Trace to Test or Document	Test Result
5.3	N/A	N/A	Section Header	Section Header
5.3.1	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
5.3.2	V	3	REDCap record lock final validation deliverables	PASS
5.4	N/A	N/A	Section Header	Section Header
5.4.1	T	3	REDCap record lock final validation deliverables – Validation Plan	PASS
5.5	N/A	N/A	Section Header	Section Header
5.5.1	V	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
5.6	N/A	N/A	Section Header	Section Header
5.6.1	T	3	REDCap “Project/Record Lock” Installation Qualification Protocol	PASS
6.	N/A	N/A	Section Header	Section Header
6.1	N/A	N/A	Section Header	Section Header
6.1.1	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
6.1.2	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
6.1.3	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
6.1.4	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
6.1.5	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
6.2	N/A	N/A	Section Header	Section Header
6.2.1	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
6.3	N/A	N/A	Section Header	Section Header
6.3.1	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
6.3.2	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
6.3.3	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
6.3.4	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
6.3.5	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
7.	N/A	N/A	Section Header	Section Header
7.1	T	3	REDCap “Project/Record Lock” Installation Qualification Protocol	PASS
8.	N/A	N/A	Section Header	Section Header

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<b>Req#</b>	<b>APPROACH</b>	<b>Priority</b>	<b>Trace to Test or Document</b>	<b>Test Result</b>
8.1.1	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
8.1.2	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
8.1.3	T	3	PQ protocol section 12: System Test: PQ Record Lock	PASS
<b>9.</b>	<b>N/A</b>	<b>N/A</b>	<b>Section Header</b>	<b>Section Header</b>
9.1	P	3	Record Lock Operation and Maintenance SOP	PASS
<b>9.2</b>	<b>N/A</b>	<b>N/A</b>	<b>Section Header</b>	<b>Section Header</b>
9.2.1	T	3	REDCap "Project/Record Lock" Installation Qualification Protocol	PASS
9.2.2	P	3	REDCap "Project/Record Lock" Installation Qualification Protocol	PASS
9.2.3	T	3	REDCap "Project/Record Lock" Installation Qualification Protocol	PASS
9.2.4	V	3	Record Lock Operation and Maintenance SOP	PASS
9.2.5	V	3	REDCap "Project/Record Lock" Installation Qualification Protocol	PASS











# VUMC REDCap Record Lock Requirements Traceability Matrix- Final V01

Final Audit Report

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