

REDCap Record Lock Functionality Validation Summary Report

**Vanderbilt University Medical
Center**

Document Version: 1.0

Document Date: 25-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 25, 2020 17:32 EDT)

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.

We also release the system for Production use.



Colleen E. Lawrence (Aug 25, 2020 16:41 CDT)

Colleen Lawrence, System Owner VUMC

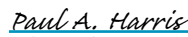


Joseph Franchetti, Quality Assurance Representative,
JAF Consulting, Inc



Rob Taylor (Aug 25, 2020 16:37 CDT)

Rob Taylor, Technical Owner, UABMC



Paul A. Harris (Aug 25, 2020 21:32 CDT)

Paul Harris, Management, VUMC

Revision History

Date	Version	Description
25-Aug-20	1.0 (draft)	Original Release, New Document

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1 Introduction

1.1 Overview

University of Vanderbilt will utilize a REDCap-record locking feature that will allow the users to lock the records individually and project level. This is compliance feature which will be which will prevent records from being edited after review and approval. This functionality will require an elevated permission which will enable the locked records to be archived. A complete audit trail of the locked / unlocked records in the data instrument's history log.

1.2 Objective

This Validation Summary Report (VSR) serves as the summary of the validation execution effort providing an understanding of the inventory of documents created during the validation effort, Team Roles involved in the effort, any deviations encountered during testing and any requirements deferred from the planned release.

2 Validation Deliverables and Documentation

2.1 Table of Validation Deliverables

Document/Deliverable	Version	Completion
REDCap "Project/Record Lock" Validation Master Plan	1.0	16JUN2020
REDCap "Project / Record Lock" User Requirements Specification	1.0	16JUN2020
REDCap "Project / Record Lock" Installation Qualification protocol – pre execution approval	1.0	23JUN2020
REDCap "Project / Record Lock" Installation Qualification protocol -post execution approval Run 01	1.0	14JUL2020
REDCap "Project / Record Lock" Installation Qualification protocol -post execution approval Run 02	1.0	24AUG2020
REDCap "Project / Record Lock" Performance Qualification protocol – pre execution approval	1.0	23JUN2020
REDCap "Project / Record Lock" Performance Qualification protocol – post execution approval	1.0	24AUG2020
Traceability Matrix	1.0	21AUG2020
REDCap Record Lock Operation and Administration SOP	1.0	21AUG2020
Training	N/A	https://redcap.vanderbilt.edu/

3 Team Roles

The following table outlines the personnel who played roles with the REDCap eConsent validation effort.

Name	Role	Dates on Validation project
Gaurav Kumar	Validation Lead	June 2020 – Present
Joe Franchetti	Quality Assurance Representative	June 2020 – Present
Rob Taylor	IT Representative, SME	June 2020 – Present
Colleen Lawrence	System Owner	June 2020 – Present
Paul Harris	System Management	June 2020 – Present

4 Validation Test Execution Summary

4.1 Methodology

The methodology used for the validation of regulated computer systems is outlined in the approved Validation Plan.

The Validation deliverables and documentation based on the validation methodology are outlined in the following subsections:

4.1.1 User Requirement Documents

A document titled “REDCap “Project / Record Lock” User Requirements Specification” was created and approved on 16JUN2020 as version 1.0. This document was used in the creation of the Installation Qualification, Performance Qualification protocols, standard operating procedures and Requirements Traceability Matrix (RTM).

4.1.2 Requirements Traceability Matrix

The RTM was approved on 21AUG2020. This document will provide traceability between the Requirements and Testing.

4.1.3 Qualification Activities

There was an IQ Plan Developed and approved pre-execution. The document is titled REDCap “Project / Record Lock” Installation Qualification protocol. This IQ was a verification of the installation of the REDCap instance and was not a prospective installation qualification.

There was an initial Performance Qualification Plan and test scripts developed “REDCap “Project / Record Lock” Performance Qualification protocol”. The executed version of the protocol was post-execution approved on 24AUG2020.

The executed test scripts were executed in development environment which is a duplicate of the production environment.

The test scripts from the *IQ and PQ protocols* were executed between 14JUN2020 and 20JUL2020. Testing was completed following the methodology and qualification instructions of the Validation Plan document. Executed Test Scripts are part of the Validation evidence. Supporting evidence (e.g., reference documents, screen printouts, graphs and reports) are attached to each of the representative test scripts.

4.1.3.1 Execution of the Test Plans and Evaluation of Test Results

A printed copy of the pdf version of the approved Test Scripts were used as the execution copy for both IQ and PQ. All test results will be documented, reviewed, and evaluated according to the acceptance criteria. The completed validation test result pages, and supporting documentation, were collected during execution of the plan and are attached and labeled accordingly.

4.1.3.2 Summary of each Test Script

Test Case ID	Acceptance Criteria	Conclusion
IQ Test Case	All Test Results must pass	All Test acceptance criteria have been met after resolution of deviation UMass-IQ-001. Actual Results for each test step satisfied the PASS requirements.
PQ Test script-001	All Test Results must pass.	All Test acceptance criteria have been met. Actual Results for each test step satisfied the PASS requirements.

4.1.3.3 Operational and Administration SOP

The procedure is approved and Effective and will be used as a guideline in the operation and administration of the record lock functionality. Following are the in-scope items in the SOP:

- User Permissions and management.
- Record Lock Operation.

4.2 Deviation

There were 3 deviations that occurred during the execution of the Test Protocols and all were successfully reconciled (see below for details). Execution of the test protocols verified the system will completely and accurately operate and perform according to predetermined specifications within the user environment.

The following table describes number of deviations, Types of deviations which were summarized with their impact and criticality and finally Disposition of the deviations.

The individual deviations are attached as part with the executed IQ and PQ protocols.

Deviation Number	Summary of Deviation	Impact	Criticality	Disposition
VUMC-Record Lock-PQ-001	During execution of REDCap "Project / Record Lock" Performance qualification protocol, step 32 the following expected results didn't match with Actual Results. <ul style="list-style-type: none"> • Locked by <User role 2>. • Date and Time of locking matches with the date and time entries listed on step 9 Step 32 was marked as fail and testing was halted.	Med	Med	Closed

REDCap Record Lock Validation Summary ReportDocument Date: **25-Aug-20**

Document Version: 1.0

Deviation Number	Summary of Deviation	Impact	Criticality	Disposition
VUMC-Record Lock-PQ-002	<p>During execution of REDCap "Project / Record Lock" Performance qualification protocol, the instruction on step 37 was to restore the PDF rendition of all instruments from step 37 and verify it matches with the REDCap generated PDF. The IT Department ADMIN is the only role that has the capability to delete the record from the database and this was done solely for the purpose of the testing, although in error. The step was marked as FAIL and the testing was halted.</p>	High	High	Closed
VUMC-Record Lock-PQ-DEV-003	<p>Per corrective action of deviation 'VUMC-Record Lock-PQ-002', tester was instructed to create a new study id, exactly similar as study id 9, which was deleted from the system by the IT department. While creating that new study id, REDCap system didn't allow the user to create a new record id renumbered as study id 9. This issue was communicated with the IT and QA team and the following justification was provided by the IT department:</p> <p>If a record has been locked at the record level and then the record is deleted and another record is created with the same name, the new record will mistakenly be initially locked after creation and have the same lock status and lock time as the original record bearing its name.</p> <p>This fix was deployed in the system with a new version number of the application without any communication to the validation team along with no appropriate change management process.</p>	Med	High	Closed

4.3 Deferrals

No issues identified during the testing were deferred for a future release.

5 Personnel Qualifications / Training

Each individual participating in the execution of the computer validation effort was qualified to perform their associated validation task. The Consulting Firm of JAF Consulting, Inc, was utilized as the contractor in this validation effort. Gaurav Kumar was the validation lead responsible for validation of the record lock functionality in REDCap system.

All users to the system were trained in the SOPs and / or Work Instructions. This training documentation will be maintained as part of the individual users Training Dossier / file.

6 Signature Identification Log

The signature identification log has identified all the individuals, who signed or initialed any validation page executed under the Validation plan. The identifications were recorded on the Original Approved Signature Identification log of the Validation Plan and the final is attached to this Summary in Attachment #1.

7 Validation Package/System Release

The Validation Package consists of approved and executed plans, test scripts and test results, reports and supporting documentation as defined in the Validation Master Plan. All approved hardcopy Validation documents will be scanned and kept in a controlled access area.

A Quality Assurance Representative will review the full Validation package after completion to assure that all validation activities have been successfully completed and that documented evidence exists to substantiate the declaration that the Validation has been completed.

Release of the system will be documented and communicated to the System Owner and System Management, who will make sure that users are appropriately trained on the use of the system prior to gaining access and any necessary procedures for the new system documented and released as effective.

8 Validation Conclusion

The planned validation activities have successfully been executed according to REDCap record lock functionality Validation Plan as referenced above and the REDCap eConsent Module is recommended for release by the System Owner.

The system status will become validated upon final approval of this Validation Summary Report by the System Owner and Quality Assurance.

All Phases of the Validation defined in the REDCap record lock functionality Validation Plan have been performed, and test results were as expected. The REDCap eConsent module is considered to be acceptable for use in the production environment.

8.1 System Restriction / Limitations

There are no restrictions in the use of the record lock functionality.

8.2 Recommendations, Regulatory and Quality Statements

Based on a review of the validation documents and test executions, the REDCap record lock functionality implementation has successfully met the requirements for Computerized System Validation.

Signed acceptance of this document and all supporting relevant documentation will denote that the System can be placed in production for regulated activities except for the restrictions defined in section 10.1 of this report.

9 Regulatory References

List of regulations that will need to be considered or met related to the system:

- HIPAA (Health Insurance Portability and Accountability Act of 1996)
- FDA, 21 CFR Part 50, "Protection of Human Subjects (Informed Consent)"
- FDA, 21 CFR Part 11, "Electronic Records; Electronic Signatures; Final Rule." Federal Register Vol. 62, No. 54, 13429, March 20, 1997FDA, 21 CFR Part 11, "Electronic Records; Electronic Signatures; Final Rule." Federal Register Vol. 62, No. 54, 13429, March 20, 1997
- Guidance Document – Use of Electronic Informed Consent in Clinical Investigations – Questions and Answers, Guidance for Institutional Review Boards, Investigators and Sponsors, December 2016

Attachment 1 – Signature Log



Project / Record Lock Validation Master Plan

Document Date : 11-Feb-2020

Document Version: 1.0

Appendix 4: Validation Signature Log

All Participants in this validation effort must complete the following information:

Name (Printed)	Title / Responsibility	Signature	Initials	Date
Gaurav Kumar	Validation Consultant JAF Consulting Inc.		GK	21 Aug 2020
Joseph Frenschke	Quality Assurance JAF Consulting, INC		JF	21 Aug 2020
Reviewed By / Date:	 21 Aug 2020			

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Attachment 2- Attachment reconciliation log

Protocol Number / Run Number / Reference Section and Step	Attachment Number	Total Page Count
Record lock IQ test protocol / 01 / section 6 step 1	001	2
Record lock IQ test protocol / 01 / section 6 step 2	002	1
Record lock IQ test protocol / 01 / section 6 step 3	003	1
Record lock IQ test protocol / 01 / section 6 step 4	004	1
Record lock IQ test protocol / 01 / section 6 step 5	005	1
Record lock IQ test protocol / 01 / section 6 step 6, 7	006	1
Record lock IQ test protocol / 01 / section 6 step 9	007	2
Record lock IQ test protocol / 01 / section 6 step 10	008	535
Record lock IQ test protocol / 01 / section 6 step 11	009	3
Record lock IQ test protocol / 01 / section 6 step 12	010	1
Record lock PQ test protocol / 01 / section 12 step 1	001	1
Record lock PQ test protocol / 01 / section 12 step 2	002	1
Record lock PQ test protocol / 01 / section 12 step 3	003	1

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Protocol Number / Run Number / Reference Section and Step	Attachment Number	Total Page Count
Record lock PQ test protocol / 01 / section 12 step 4	004	1
Record lock PQ test protocol / 01 / section 12 step 6	005	1
Record lock PQ test protocol / 01 / section 12 step 8	006	1
Record lock PQ test protocol / 01 / section 12 step 11	007	1
Record lock PQ test protocol / 01 / section 12 step 12	008	1
Record lock PQ test protocol / 01 / section 12 step 16	009	2
Record lock PQ test protocol / 01 / section 12 step 18	010	1
Record lock PQ test protocol / 01 / section 12 step 19	011	1
Record lock PQ test protocol / 01 / section 12 step 22	012	1
Record lock PQ test protocol / 01 / section 12 step 25	013	1
Record lock PQ test protocol / 01 / section 12 step 29	014	1
Record lock PQ test protocol / 01 / section 12 step 30	015	1
Record lock PQ test protocol / 01 / section 12 step 39	016	1
Record lock PQ test protocol / 01 / section 12 step 45	017	1

Attachment 3- Deviations

Project / Record Lock Validation Master Plan



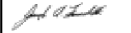


Document Date: 15-JUN-2020

Document Version: 1.0



Appendix 3: Deviation Report

This Report will be used to document Deviations. Make copies of this page as necessary.

Deviation Number:	VUMC-Record Lock-PQ-001	Script ID (s):	N/A	Script Step Number (s):	32
Test Cycle Number:	01	Execution Instance:	Development		
Complete description of the Deviation:					
<p>During execution of REDCap "Project / Record Lock" Performance qualification protocol, step 32 the following expected results didn't match with Actual Results.</p> <ul style="list-style-type: none"> Locked by <User role 2>. Date and Time of locking matches with the date and time entries listed on step 9 <p>Step 32 was marked as fail and testing was halted.</p>					
Recorded By:	 Gaurav Kumar (Jul 1, 2020 20:08 EDT)	Date:	Jul 1, 2020		
Corrective Action Plan:					
<p>The root cause of this deviation is a protocol generation error as Study ID 9 was unlocked on step 29 so the Locked by and the Date and Time of locking would not be displayed on the rendered PDF. This deviation will also be encountered on steps 35 and 44. The corrective action plan of this deviation is to execute steps 32, 35 and 44 without the following expected results as Study ID 9 is unlocked. Refer this deviation on steps 32, 35 and 44. There is no impact of this deviation on intended system functionality.</p> <p>For steps 32 and 35:</p> <p>The following is displayed and / or matches:</p> <p><Project Name> Study ID number from step 3 [document] listed next to File Upload 2 implying that a file is uploaded on file upload 2 field.</p> <p>For step 45:</p> <p>The following is displayed and / or matches:</p> <p><Project Name> Study ID number from step 3 [document] listed next to File Upload 2 implying that a file is uploaded on file upload 1 field.</p>					
Test Re-execution required <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO					
If YES, specify Test Script #, Step(s) including Login/Logout and Run #:					
Impact (High, Med, Low)	Med	Criticality (High, Med, Low)	Med		
Recorded By:	 Gaurav Kumar (Jul 1, 2020 20:08 EDT)	Date:	Jul 1, 2020		
Approval to Proceed:	 Jul 1, 2020	Date:	Jul 1, 2020		
Corrective Action Verification:					
Steps 32, 35 and 44 were re-executed with updated expected results from corrective action plan of this deviation. A reference of this deviation was made on steps 32, 35 and 45.					
Recorded By:	 Gaurav Kumar (Jul 1, 2020 20:08 EDT)	Date:	Jul 1, 2020		
Technical Review:		Date:			
Approval:	 Joseph Franchetti	Date:	Jul 1, 2020		

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Project / Record Lock Validation Master Plan



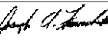


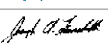
Document Date: 15-JUN-2020

Document Version: 1.0



Appendix 3: Deviation Report

This Report will be used to document Deviations. Make copies of this page as necessary.

Deviation Number:	VUMC-Record Lock-PQ-002	Script ID (s):	N/A	Script Step Number (s):	37
Test Cycle Number:	01	Execution Instance:	Development		
Complete description of the Deviation:					
<p>During execution of REDCap "Project / Record Lock" Performance qualification protocol, the instruction on step 37 was to restore the PDF rendition of all instruments from step 37 and verify it matches with the REDCap generated PDF. The IT Department ADMIN is the only role that has the capability to delete the record from the database and this was done solely for the purpose of the testing, although in error. The step was marked as FAIL and the testing was halted.</p>					
Recorded By:	 Graham Kuerste (Jul 7, 2020 10:24 EST)	Date:	Jul 7, 2020		
Corrective Action Plan:					
<p>The root cause of this deviation is document requesting and processing error as the study id was deleted in confusion, as the rendered PDF was requested to be restored, however there were no instructions on deleting study id 9 prior to restoration. This happened by the IT department during system testing of record lock functionality in the development environment.</p> <p>Create a new study id as a part of pre-requisites and re-execute from step 37 and finish the testing per deviation.</p> <p>Make a reference of the deviation on step 37 of the PQ protocol.</p> <p>There will be a process defined that will instruct the IT Department ADMIN to never delete any records from the database.</p>					
Test Re-execution required <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO					
If YES, specify Test Script #, Step(s) including Login/Logout and Run #:					
Impact (High, Med, Low)	High	Criticality (High, Med, Low)	High		
Recorded By:	 Graham Kuerste (Jul 7, 2020 10:24 EST)	Date:	Jul 7, 2020		
Approval to Proceed:	 Joseph A. Smith	Date:	Jul 7, 2020		
Corrective Action Verification:					
<p>Testing of REDCap "Project / Record Lock" Performance qualification protocol shall commence with a new study id as pre-requisite, from step 37.</p> <p>A reference of this deviation will be made to step 37.</p>					
Recorded By:	 Graham Kuerste (Jul 7, 2020 10:24 EST)	Date:	Jul 7, 2020		
Technical Review:	 Rob Taylor (Jul 7, 2020 10:45 CDT)	Date:	Jul 7, 2020		
Approval:	 Joseph A. Smith	Date:	Jul 7, 2020		

Project / Record Lock Validation Master Plan

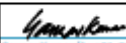



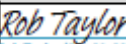
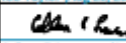
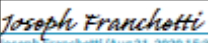
Document Date: 15-JUN-2020

Document Version: 1.0



Appendix 3: Deviation Report

This Report will be used to document Deviations. Make copies of this page as necessary.

Deviation Number: 003	VUMC-Record Lock-PQ-DEV-003	Script ID (s):	PQ	Script Step Number (s):	32
Test Cycle Number:	01	Execution Instance: Dev	Development		
<p>Complete description of the Deviation:</p> <p>Per corrective action of deviation 'VUMC-Record Lock-PQ-002', tester was instructed to create a new study id, exactly similar as study id 9, which was deleted from the system by the IT department. While creating that new study id, REDCap system didn't allow the user to create a new record id renumbered as study id 9. This issue was communicated with the IT and QA team and the following justification was provided by the IT department:</p> <p>If a record has been locked at the record level and then the record is deleted and another record is created with the same name, the new record will mistakenly be initially locked after creation and have the same lock status and lock time as the original record bearing its name.</p> <p>This fix was deployed in the system with a new version number of the application without any communication to the validation team along with no appropriate change management process.</p>					
Recorded By:	 Gaurav Kumar (Aug 21, 2020 11:45 EDT)	Date:	Aug 21, 2020		
<p>Corrective Action Plan:</p> <p>The corrective actions of this deviation are the following:</p> <ol style="list-style-type: none"> 1. Print out release logs for REDCap application from release 1 and ,evaluate the change logs to assess impact on current validation of the system. 2. Establish a procedural change management process for the validated instance. This process will also ensure that compliance is maintained for future software releases. 3. Ensure REDCap system administrators are trained on the change management process. 4. Verification of training will be by email read and understand statement. 5. Re-execute the IQ to capture new version of REDCap. 					
<p>Test Re-execution required? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>If YES, specify Test Script #, Step(s) including Login/Logout and Run #: N/A</p>					
Impact Med (High, Med, Low)	Med	Criticality (High, Med, Low)	High		
Recorded By:	 Gaurav Kumar (Aug 21, 2020 11:47 EDT)	Date:	Aug 21, 2020		
Approval to Proceed:	 Yes	Date:	21AUG20 Aug 21, 2020		
<p>Corrective Action Verification:</p> <p>The new change management process will be identified in the Administration SOP for REDCap system, with training type set as, Read and Understand. The verification of the training shall be done through an email verification with a list of users trained.</p>					
Recorded By:	 Colleen E. Lawrence (Aug 21, 2020 11:49 CDT)	Date:	Aug 21, 2020		
Technical Review:	 Rob Taylor (Aug 21, 2020 11:43 CDT)	Date:	Aug 21, 2020		
System Owner	 Colleen E. Lawrence (Aug 21, 2020 11:59 CDT)	Date:	Aug 21, 2020		
Approval:	 Joseph Franchetti (Aug 21, 2020 15:36 EDT)	Date:	21AUG20 Aug 21, 2020		











08 - VUMC Record Lock Validation Summary Report - Final v 1.0

Final Audit Report

2020-08-26

Created:	2020-08-25
By:	Gaurav Kumar (gkumar@jafconsulting.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAaZLI_QHZcS87qiaU8Tgq5hK1VZdloEAq

"08 - VUMC Record Lock Validation Summary Report - Final v 1.0" History

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2020-08-26 - 2:32:44 AM GMT



Email viewed by Joseph Franchetti (jfranchetti@jafconsulting.com)

2020-08-26 - 12:50:38 PM GMT- IP address: 12.105.143.243



Document e-signed by Joseph Franchetti (jfranchetti@jafconsulting.com)

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Signed document emailed to Paul A. Harris (paul.a.harris@vumc.org), Joseph Franchetti (jfranchetti@jafconsulting.com), Gaurav Kumar (gkumar@jafconsulting.com), Colleen E. Lawrence (colleen.lawrence@vumc.org), and 1 more

2020-08-26 - 12:51:05 PM GMT



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