REDCap "Project/Record Lock" Installation Qualification Protocol

University of Vanderbilt
Medical Center
(VUMC)

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Signature Page Pre-Execution

Prepared by:

I have prepared the contents of this document and agree that the provisions contained herein are appropriate and consistent with 21 CFR Part 58 requirements, internal policies and procedures and available FDA industry Guidance and I tender it for approval.

Signature: *Gaurav Kumar*
Gaurav Kumar (Jun 23, 2020 09:56 GMT+5.5)

Email: gkumar@jafconsulting.com

Title: Compliance Consultant

Company: JAF Consulting Inc.

Gaurav Kumar   Sr. Validation Consultant, 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.

Signature: *Colleen E. Lawrence*
Colleen E. Lawrence (Jun 23, 2020 08:31 CDT)

Email: colleen.lawrence@vumc.org

Title: Manager, Translational Research

Company: Vanderbilt University Medical Center

Signature: *Joseph A. Franchetti*

Email: jfranchetti@jafconsulting.com

Title: President

Company: JAF Consulting Inc

Colleen Lawrence, System Owner   Joseph Franchetti, Quality Assurance Representative, JAF Consulting, Inc

Signature: *Rob Taylor*
Rob Taylor (Jun 23, 2020 08:35 CDT)

Email: rob.taylor@vumc.org

Title: Manager of Application Development

Company: Vanderbilt University Medical Center

Rob Taylor, Technical Owner, VUMC

Post-Approval Signature Page

Reviewed and Approved by:

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

_____

Colleen Lawrence, System Owner

Joseph Franchetti, Quality Assurance Representative, JAF Consulting, Inc

_____

Rob Taylor, Technical Owner, VUMC

Revision History

Date	Version	Description
22-JUN-2020	01	Original Release, New Document

1. Purpose of the Installation Qualification Plan

The Installation Qualification Plan document is to capture the details of the hardware and software components installed to provide for the record lock functionality is installed and performing as intended. The steps included below will document and provide confirmation of the installation as well as providing evidence of a controlled install performing as expected.

Additionally, some of the confirmation steps provided here will provide evidence of control mechanisms such as encryption and other security controls provided by the production environment.

Redcap Version: _____ Environment: (Development ☐ / Test ☐ / Production ☐) (Check Applicable Instance Box)

Test Browser & Version: _____ OS & Version: _____

Test Purpose:
The purpose of this test is to verify record locking functionality of REDCap system is installed and configured per User Requirement Specifications at UMC.

Test Method:
The test strategy will incorporate verification of installed configuration for the record lock functionality within REDCap application

Acceptance Criteria:
All test steps must be executed, and PASS/FAIL designation assigned. In the event of a failure, the test executor must log the Actual Results encountered and capture a screen shot of the result and/or other evidence and include it with an Error Log. Link the Error Log record with the failed test. If Error Log is resolved and appended with the test case as evidence, the step can be considered Passed with the Error Log resolution evidence.

Prerequisites:

Verify the following options are enabled with additional customizations prior to execution of this Installation Qualification Test Protocol:
- Field comment logging
- Data History Pop up
- Enable File version History
- Require reason when making changes.

User Accounts and User Groups have been setup per approved version of URS

2. Installation Qualification Steps

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail	Initials / Date
1.	Coordinate with VUMC IT department and request information on VM Setup Hostname Webserver Install information MySQL MySQL PHP module Record the Hostname in Actual Results. **Print, Label and attach a screen print of install.**	Verify the configuration of the install meets and / or exceed the following specifications: VM Setup = 65 Gb / 23 Gb RAM Run RedHat Enterprise Linux 7 Install: Add MySQL Install: PHPS Install: MySQL PHP module Hostname recorded in Actual Results. Screen print attached	The configuration of the install _____ the following specifications: VM Setup = 65 Gb / 23 Gb RAM Run RedHat Enterprise Linux 7 Install: Add MySQL Install: PHPS Install: MySQL PHP module Hostname: _____ _____ Attachment ID #: _____	☐ Pass ☐ Fail	
2.	Verify MySQL Server is installed and configured for MySQL **Print, Label and attach a screen print.**	MySQL Server is installed and configured for MySQL Screen print attached	MySQL Server _____ installed and configured for MySQL Attachment ID #: _____	☐ Pass ☐ Fail	

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail	Initials / Date
3.	Verify REDCap is running on version 9.0.2 Standard Release or higher. **Print, Label and attach a screen print.**	REDCap is running on version 9.0.2 Standard Release or higher. Screen print attached	REDCap _____ running on version 9.0.2 Standard Release or higher. Attachment ID #: _____	☐ Pass ☐ Fail	
4.	Setup LDAP Authentication, SSL Certificate, and REDCap - Email Outside **Print, Label and attach a screen print.**	LDAP Authentication, SSL certificate, and REDCap – Email Outside is setup successfully. Screen print attached	LDAP Authentication, SSL certificate, and REDCap – Email Outside is _____ successfully. Attachment ID #: _____	☐ Pass ☐ Fail	
5.	Coordinate with the IT department and perform a verification of REDCap Configuration to confirm Successful Installation and Setup. **Print, Label and attach a screen print.**	Configuration Check successfully confirms Installation and Setup of record lock functionality within REDCap application Screen print attached	Configuration Check _____ confirms Installation and Setup of record lock functionality within REDCap application Attachment ID #: _____	☐ Pass ☐ Fail	
6.	Coordinate with IT department and attach screen shots of configuration related to record lock functionality within REDCap system.	Screen shot pertaining to configuration of record lock functionality within REDCap system is printed, labeled, and attached.	Screen shot pertaining to configuration of record lock functionality within REDCap system _____ printed, labeled, and attached.	☐ Pass ☐ Fail	

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail	Initials / Date
7.	Verify encrypted SFTP / vault is setup to store archive PDF renditions of locked records.	Encrypted SFTP / vault is setup to store / archive PDF renditions of locked records.	Encrypted SFTP / vault _____ setup to store / archive PDF renditions of locked records.	☐ Pass ☐ Fail	
8.	Verify SFTP/ Vault secure storage stores read only PDF copies of completed locked records.	SFTP/ Vault secure storage stores read only PDF copies of completed locked records.	SFTP/ Vault secure storage _____ read only PDF copies of completed locked records.	☐ Pass ☐ Fail	
9.	Verify the REDCap application has an option of moving to Production server. **Print, Label and attach a screen print.**	REDCap application has an option of moving to Production server. Screen print attached	REDCap application _____an option of moving to Production server. Attachment ID #: _____	☐ Pass ☐ Fail	
10.	Verify all versions of the locked records will be maintained within the project "vault." **Print, Label and attach a screen print.**	All versions of the locked records will be maintained within the project "vault." Screen print attached	All versions of the locked records _____ maintained within the project "vault." Attachment ID #: _____	☐ Pass ☐ Fail	

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail	Initials / Date
11.	Verify the Vault has limited access only to administrators of the Local Network with write once read many configurations. **Print, Label and attach a screen print.**	The Vault has limited access only to administrators of the Local Network with write once read many configurations. Screen print attached	The Vault _____ limited access only to administrators of the Local Network with write once read many configurations. Attachment ID #: _____	☐ Pass ☐ Fail	
12.	The REDCap production environment is configured to be backed up daily.	The REDCap production environment is configured to be backed up daily.	The REDCap production environment _____ configured to be backed up daily.	☐ Pass ☐ Fail	

Test Summary				
Comments/Additional Information:				
☐ **Pass** All tests/verifications were successfully completed.		☐ **Fail** Some tests/verifications were not successfully completed.		
Validation Non-Conformance Report No.:				
Date Test Execution Started		**Date Test Execution Completed**		**Number of Attachments:**	
Recorded By: I performed the above testing and have accurately recorded the results.			**Reviewed By: I have reviewed the results of the testing and they are correctly recorded. All failures are documented, and problem reports have been generated.**	
Signature		*Date*	*Signature*	*Date*

03 - REDCap Project-Record Lock IQ Test Protocol VUMC v1.0

Final Audit Report   2020-06-23

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Signed document emailed to Gaurav Kumar (gkumar@jafconsulting.com), Joseph Franchetti (jfranchetti@jafconsulting.com), Colleen E. Lawrence (colleen.lawrence@vumc.org), and Rob Taylor (rob.taylor@vumc.org)
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