

REDCap “Project/Record Lock” Installation Qualification Protocol

**University of Vanderbilt
Medical Center
(VUMC)**

**Document Version: 1.0
Document Date: 22-JUN-2020**

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

Email: gkumar@jafconsulting.com

Title: Compliance Consultant

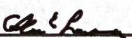
Company: JAF Consulting Inc.

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.

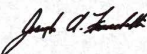
Signature: 
Colleen E. Lawrence (Jun 23, 2020 09:51 CDT)

Email: colleen.lawrence@vumc.org

Title: Manager, Translational Research

Company: Vanderbilt University Medical Center

Colleen Lawrence, System Owner

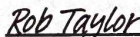
Signature: 

Email: jfranchetti@jafconsulting.com

Title: President

Company: JAF Consulting Inc

Joseph Franchetti, Quality Assurance Representative, JAF Consulting, Inc

Signature: 
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 E. Lawrence (Jul 14, 2020 06:05 CDT)

Colleen Lawrence, System Owner

Joseph Franchetti, Quality Assurance Representative,
JAF Consulting, Inc

Rob Taylor (Jul 13, 2020 21:45 CDT)

Rob Taylor, Technical Owner, VUMC

Revision History

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

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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.

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Redcap Version: 10.1.0 Environment: (Development ☒ / Test ☐ / Production ☐) (Check Applicable Instance Box)

Test Browser & Version: typographical error 9m 245UN20 OS & Version: 83.0.44 83.0.4103.116

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



Record lock Installation Qualification Test Protocol

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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 <u>met and exceeded</u> 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: <u>ori110071p</u> Attachment ID #: <u>001</u>	☒ Pass ☐ Fail	<u>gh</u> <u>24JUN20</u>
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 <u>was</u> installed and configured for MySQL Attachment ID #: <u>002</u>	☒ Pass ☐ Fail	<u>gh</u> <u>24JUN20</u>



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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 <u>is</u> running on version 9.0.2 Standard Release or higher. Attachment ID #: <u>003</u>	☒ Pass ☐ Fail	<u>gn</u> <u>24JUN20</u>
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 <u>setup</u> successfully. Attachment ID #: <u>004</u>	☒ Pass ☐ Fail	<u>gn</u> <u>24JUN20</u>
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 <u>successfully</u> confirms Installation and Setup of record lock functionality within REDCap application Attachment ID #: <u>005</u>	☒ Pass ☐ Fail	<u>gn</u> <u>24JUN20</u>
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 <u>in attachment 006</u> printed, labeled, and attached.	☒ Pass ☐ Fail	<u>gn</u> <u>24JUN20</u>



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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 <u>was</u> setup to store / archive PDF renditions of locked records.	☒ Pass ☐ Fail	gh 24JUN20
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 <u>stores</u> read only PDF copies of completed locked records.	☒ Pass ☐ Fail	gh 24JUN20
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 <u>has</u> an option of moving to Production server. Attachment ID #: <u>007</u>	☒ Pass ☐ Fail	gh 24JUN20
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 <u>are</u> maintained within the project "vault." Attachment ID #: <u>008</u>	☒ Pass ☐ Fail	gh 24JUN20

	Record lock Installation Qualification Test Protocol	Document Version: 1.0
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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 <u>has</u> limited access only to administrators of the Local Network with write once read many configurations. Attachment ID #: <u>009</u>	☒ Pass ☐ Fail	<u>ga</u> <u>24JUN20</u>
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 <u>is</u> configured to be backed up daily. <u>Attachment: 010</u>	☒ Pass ☐ Fail	<u>ga</u> <u>24JUN20</u>



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Test Summary

Comments/Additional Information:

N/A gm
24JUN20

☒ Pass All tests/verifications were successfully completed.

☐ Fail Some tests/verifications were not successfully completed.

Validation Non-
Conformance Report
No.:

N/A gm 24JUN20

Date Test Execution
Started

24JUN20

Date Test Execution
Completed

24JUN20

Number of
Attachments:

010

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]

Signature

24JUN20

Date

Signature

Date

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

Final Audit Report

2020-06-23

Created:	2020-06-23
By:	Joseph Franchetti (jfranchetti@jafconsulting.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAEeJhrcNM-zxgvr04sezV7U5vm8RzsxC8

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

-  Document created by Joseph Franchetti (jfranchetti@jafconsulting.com)
2020-06-23 - 3:00:37 AM GMT- IP address: 73.196.185.110
-  Document emailed to Gaurav Kumar (gkumar@jafconsulting.com) for signature
2020-06-23 - 3:01:28 AM GMT
-  Document emailed to Rob Taylor (rob.taylor@vumc.org) for signature
2020-06-23 - 3:01:28 AM GMT
-  Document emailed to Colleen E. Lawrence (colleen.lawrence@vumc.org) for signature
2020-06-23 - 3:01:28 AM GMT
-  Document emailed to Joseph Franchetti (jfranchetti@jafconsulting.com) for signature
2020-06-23 - 3:01:28 AM GMT
-  Document e-signed by Joseph Franchetti (jfranchetti@jafconsulting.com)
Signature Date: 2020-06-23 - 3:01:37 AM GMT - Time Source: server- IP address: 73.196.185.110
-  Email viewed by Rob Taylor (rob.taylor@vumc.org)
2020-06-23 - 3:09:41 AM GMT- IP address: 68.34.206.236
-  Email viewed by Gaurav Kumar (gkumar@jafconsulting.com)
2020-06-23 - 4:21:27 AM GMT- IP address: 103.106.28.250
-  Document e-signed by Gaurav Kumar (gkumar@jafconsulting.com)
Signature Date: 2020-06-23 - 4:26:00 AM GMT - Time Source: server- IP address: 103.106.28.250- Signature captured from device with phone number XXXXXXXX2886
-  Email viewed by Colleen E. Lawrence (colleen.lawrence@vumc.org)
2020-06-23 - 10:33:44 AM GMT- IP address: 68.72.133.103



Adobe Sign

 Document e-signed by Colleen E. Lawrence (colleen.lawrence@vumc.org)

Signature Date: 2020-06-23 - 1:31:07 PM GMT - Time Source: server- IP address: 160.129.251.127

 Document e-signed by Rob Taylor (rob.taylor@vumc.org)

Signature Date: 2020-06-23 - 1:35:51 PM GMT - Time Source: server- IP address: 160.129.251.127

 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)

2020-06-23 - 1:35:51 PM GMT



Adobe Sign

Document No.: N/A

Document Version: 01

Run: 01

Initials: gk

IQ Section Number: 6

Step No.: 1

Date: 24JUN2020

Attachment: 001

```
[oriapp@oril007lp: ~]$  
[oriapp@oril007lp: ~]$  
[oriapp@oril007lp: ~]$  
it [oriapp@oril007lp: ~]$  
[oriapp@oril007lp: ~]$  
[oriapp@oril007lp: ~]$  
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[oriapp@oril007lp: ~]$  
[oriapp@oril007lp: ~]$  
[oriapp@oril007lp: ~]$  
[oriapp@oril007lp: ~]$  
[oriapp@oril007lp: ~]$ hostnamectl  
  
Static hostname: oril007lp  
    icon name: computer-vm  
    Chassis: vm  
    Machine ID: 54a593597f674854b84ac898b9f86338  
    Boot ID: c9bdf42d55e241a89813594b04330a5d  
    Virtualization: vmware  
Operating System: Red Hat Enterprise Linux  
    CPE OS Name: cpe:/o:redhat:enterprise_linux:7.7:GA:server  
    Kernel: Linux 3.10.0-1062.9.1.el7.x86_64  
    Architecture: x86-64  
[oriapp@oril007lp: ~]$ df -h /app001/  
Filesystem                Size      Used Avail Use% Mounted on  
/dev/mapper/vg01-lvapp001 65G       21G     45G   32% /app001  
[oriapp@oril007lp: ~]$ free -g  
total        used            free      shared  buff/cache   available  
Mem:          23             1              0           1           21           20
```

	Title: Record lock Installation Qualification Test Protocol	Page 2 of 2
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[Home](#)
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[New Project](#)
[Send-It](#)
[Messenger](#)
[Control Center](#)
Logged in as **taylor4**
[My Profile](#)
[Log out](#)
[More](#)

Control Center Home

- Notifications & Reporting
- To-Do List 10
- Enter PID to go to project

Administrator Resources

- REDCap Community
- Project REDCap website
- REDCap Training Materials
- URL Shortener

Dashboard

- System Statistics
- Activity Log
- Activity Graphs
- Map of Users

Projects

- Browse Projects
- Edit a Project's Settings
- Survey Link Lookup

Users

- Browse Users
- Add Users (Table-based Only)
- User Whitelist
- Email Users
- API Tokens
- Administrators & Acct Managers

Technical / Developer Tools

- External Modules
- API Documentation
- Plugin, Hook, & External Module Documentation
- MySQL Dashboard
- MySQL Simple Admin

Miscellaneous Modules

- Clinical Data Interoperability Services
- Dynamic Data Pull (DDP) - Custom
- Custom Application Links
- Publication Matching
- Find Calculation Errors in Projects

System Configuration

- Configuration Check
- General Configuration
- Security & Authentication
- User Settings
- File Upload Settings
- Modules/Services Configuration
- Field Validation Types
- Home Page Settings
- Project Templates
- Default Project Settings
- Footer Settings (All Projects)
- Cron Jobs

External Modules

- Admin Dashboard
- Epic Participant Updater
- Example Module Control Center Page
- Generate External Module Template
- Manage User Roles
- MyCap Administration
- Tableau Connector Instructions

Configuration Check

This page will test your current REDCap configuration to determine if any errors exist that might prevent it from functioning properly.

Basic tests

TEST 1: Establish basic REDCap file structure
Search for necessary files and folders that should be located in the main REDCap folder (i.e. "/app001/www/redcap").

✓ **SUCCESSFUL!** - All necessary files and folders were found.

TEST 2: Connect to the table named "redcap_config"

✓ **SUCCESSFUL!** - The table "redcap_config" in the MySQL database named **redcap** was accessed successfully.

TEST 3: Check REDCap database table structure

✓ **SUCCESSFUL!** - Your REDCap database structure is correct

TEST 4: Check if PHP cURL extension is installed

✓ **SUCCESSFUL!** - The cURL extension is installed.

TEST 5: Checking communication with REDCap Consortium server
(<https://redcap.vanderbilt.edu/consortium/>)
(used to report weekly site stats and connect to Shared Library)

✓ **SUCCESSFUL!** - Communicated successfully with the REDCap Consortium server. You WILL be able to use the "automatic reporting" method to report your site stats, as well as use the REDCap Shared Library.

TEST 6: Check if REDCap Cron Job is running

✓ **SUCCESSFUL!** - REDCap Cron Job is running properly.

Secondary tests

✓ Using SSL

✓ Using PHP 5.5.0 or higher

✓ Using MySQL 5 or higher

✓ GD library (version 2 or higher) is installed

✓ PHP Fileinfo extension is installed

✓ REDCap is able to send emails

✓ The REDCap web server's temp directory is writable
Location: /app001/tmp

✓ "temp" directory is writable
Location: /app001/www/redcap/temp/

✓ File upload directory is writable
Location: /ori/redcap_edocs/

✓ "modules" directory is writable
Location: /app001/www/redcap/modules/

External Service Check: Checking communication with Twilio telephony API services

✓ **SUCCESSFUL!** - Communicated successfully with the Twilio API server (<https://api.twilio.com>).

External Service Check: Checking communication with PROMIS assessment API services

✓ **SUCCESSFUL!** - Communicated successfully with the PROMIS API server (https://www.redcap-cats.org/promis_api/).

External Service Check: Checking communication with BioPortal biomedical ontology API services

✓ **SUCCESSFUL!** - Communicated successfully with the BioPortal API server (<http://data.bioontology.org>).

External Service Check: Checking communication with Bit.ly URL shortening API services

✓ **SUCCESSFUL!** - Communicated successfully with the Bit.ly API server (<http://api.bit.ly>).

External Service Check: Checking communication with IS.GD URL shortening API services

✓ **SUCCESSFUL!** - Communicated successfully with the IS.GD API server (<https://is.gd>).

External Service Check: Checking communication with Google reCAPTCHA API services

✓ **SUCCESSFUL!** - Communicated successfully with the Google reCAPTCHA server (<https://www.google.com/recaptcha/api/siteverify>).



Title: Record lock Installation Qualification Test Protocol

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Document No.: N/A

Document Version: 01

IQ Section Number: 6

Attachment: 002

Run: 01

Step No.: 2

Initials: gk

Date: 24JUN2020

The screenshot displays the phpMyAdmin web interface. On the left, a sidebar shows the database structure with 'information_schema' and 'redcap' databases. The 'redcap' database is expanded, showing a list of tables including 'core_shm_glucose_data', 'ctsa_committee_link', 'ctsa_site', 'ddp_fhir_missing_loinc_mappings', 'mycap_messages', 'mycap_projectfiles', 'mycap_projects', 'mycap_syncissuefiles', 'mycap_syncissues', 'redcap_actions', 'redcap_alerts', 'redcap_alerts_recurrence', 'redcap_alerts_sent', 'redcap_alerts_sent_log', 'redcap_auth', 'redcap_auth_history', 'redcap_auth_questions', 'redcap_config', 'redcap_consortium_app_codes', 'redcap_consortium_app_logins', 'redcap_consortium_module_downloads', 'redcap_consortium_module_downloads_s', and 'redcap_consortium_sites'. The main panel shows the 'Server: REDCap PROD (ori31lp)' configuration. The 'General settings' section includes 'Change password', 'Server connection collation' set to 'utf8mb4_unicode_ci', and 'Appearance settings' with 'Theme' set to 'pmahomme' and 'Font size' set to '78%'. The 'Database server' section, highlighted with a red border, lists the following details: Server: REDCap PROD (ori31lp) (redcap-db.app.vumc.org via TCP/IP), Server type: MariaDB, Server connection: SSL is used without certification authority, Server version: 5.5.64-MariaDB - MariaDB Server, Protocol version: 10, User: taylorr4@ori1020lp.hs.it.vumc.io, and Server charset: cp1252 West European (latin1). The 'Web server' section lists: Apache, Database client version: libmysql - mysqlnd 5.0.12-dev - 20150407 - \$Id: 7cc7cc96e675f6d72e5cf0f267f48e167c2\$, PHP extension: mysqli, curl, mbstring, and PHP version: 7.3.11. The bottom section, 'phpMyAdmin', provides version information (4.9.4) and links to documentation, official homepage, contribute, get support, and list of changes.

	Title: Record lock Installation Qualification Test Protocol		Page 1 of 1
	Document No.: N/A Document Version: 01 IQ Section Number: __6_ Attachment: _____003_____	Run: 01 Step No.: __3__	Initials: gk Date: _24JUN2020_

My Projects Organize Collapse All Filter projects by title × 						
Project Title		Records	Fields	Instruments	Type	Status
JAF Sample eCosnent	□	80	33	1 survey	■	⚙
JAF Sample eConsent_w/Coordinator Attestation	□	13	42	3 surveys	■	⚙
Part 11 Any File Upload demo		19	17	3 forms	■	⚙
Part 11 Record Locking		8	17	3 forms	■	⚙

The projects listed below are public and are accessible by anyone. No authentication (i.e. username/password) is required to access them directly.

Public Projects
Conditional Knockout Mouse Study
Example Survey
Human Cancer Tissue Biobank example
Key Driver Diagram Delphi Process Template
Project Tracking Example
REDCap Demo Database
REDCap Demo Database (Longitudinal + Scheduling)
REDCap Demo Database (Longitudinal) - Drug Trial
REDCap Demo Database (Scheduling Only)

	Title: Record lock Installation Qualification Test Protocol	Page 1 of 1
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LDAP Troubleshooter for REDCap

[Reload page](#)
[Go back to REDCap](#)

Authentication Successful!

Logging Output:

AUTH_LOG_INFO level messages:

6: AUTH: Successful login.
6: AUTH: Session OK.

AUTH_LOG_DEBUG level messages:

7: AUTH: Auth::start() called.
7: AUTH: Auth::assignData() called.
7: AUTH: Auth::checkAuth() called.
7: AUTH: No login session.
7: AUTH: Auth::login() called.
7: AUTH: Loaded storage container (LDAP)
7: AUTH: Auth_Container_LDAP::fetchData() called.
7: AUTH: Auth_Container_LDAP::_connect() called.
7: AUTH: Connecting with URL
7: AUTH: Successfully connected to server
7: AUTH: Switching to LDAP version 3
7: AUTH: Switching LDAP referrals to true
7: AUTH: Binding with credentials
7: AUTH: Binding was successful
7: AUTH: Auth_Container_LDAP::_getBaseDN() called.
7: AUTH: UTF8 encoding username for LDAPv3
7: AUTH: Searching with ldap_search and filter (&(uid=taylorr4)(objectClass=posixAccount)) in ou=people,dc=vanderbilt,dc=edu
7: AUTH: User(s) found
7: AUTH: Bind as uid=taylorr4,ou=people,dc=vanderbilt,dc=edu
7: AUTH: Bind successful
7: AUTH: Authenticated
7: AUTH: Auth_Container_LDAP::_disconnect() called.
7: AUTH: disconnecting from server
6: AUTH: Successful login.
7: AUTH: Auth::setAuth() called.
7: AUTH: Auth::checkAuth() called.
6: AUTH: Session OK.

LDAP Configuration being used:

Using the `ldapsn` array from the LDAP config file at
`/app001/www/redcap/webtools2/ldap/ldap_config.php`

```
Array
(
    [url] => ldaps://ldap.vunetid.mc.vanderbilt.edu
    [port] => 636
    [version] => 3
    [binddn] => uid=taylorr4,ou=people,dc=vanderbilt,
    [basedn] => ou=people,dc=vanderbilt,dc=edu
    [bindpw] => [REDACTED]
    [enableLogging] => 1
)
```

	Title: Record lock Installation Qualification Test Protocol	Page 1 of 1
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Control Center Home	
• Notifications & Reporting	
• To-Do List 10	
Enter PID to go to project	
Administrator Resources	
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• Project REDCap website	
• REDCap Training Materials	
• URL Shortener	
Dashboard	
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Projects	
• Browse Projects	
• Edit a Project's Settings	
• Survey Link Lookup	
Users	
• Browse Users	
• Add Users (Table-based Only)	
• User Whitelist	
• Email Users	
• API Tokens	
• Administrators & Acct Managers	
Technical / Developer Tools	
• External Modules	
• API Documentation	
• Plugin, Hook, & External Module Documentation	
• MySQL Dashboard	
• MySQL Simple Admin	
Miscellaneous Modules	
• Clinical Data Interoperability Services	
• Dynamic Data Pull (DDP) - Custom	
• Custom Application Links	
• Publication Matching	
• Find Calculation Errors in Projects	
System Configuration	
• Configuration Check	
• General Configuration	
• Security & Authentication	
• User Settings	
• File Upload Settings	
• Modules/Services Configuration	
• Field Validation Types	
• Home Page Settings	
• Project Templates	
• Default Project Settings	
• Footer Settings (All Projects)	
• Cron Jobs	
External Modules	
• Admin Dashboard	
• Epic Participant Updater	
• Example Module Control Center Page	
• Generate External Module Template	
• Manage User Roles	
• MyCap Administration	
• Tableau Connector Instructions	

Configuration Check

This page will test your current REDCap configuration to determine if any errors exist that might prevent it from functioning properly.

Basic tests

TEST 1: Establish basic REDCap file structure Search for necessary files and folders that should be located in the main REDCap folder (i.e. "/app001/www/redcap"). ✓ SUCCESSFUL! - All necessary files and folders were found.
TEST 2: Connect to the table named "redcap_config" ✓ SUCCESSFUL! - The table "redcap_config" in the MySQL database named redcap was accessed successfully.
TEST 3: Check REDCap database table structure ✓ SUCCESSFUL! - Your REDCap database structure is correct
TEST 4: Check if PHP cURL extension is installed ✓ SUCCESSFUL! - The cURL extension is installed.
TEST 5: Checking communication with REDCap Consortium server (https://redcap.vanderbilt.edu/consortium) (used to report weekly site stats and connect to Shared Library) ✓ SUCCESSFUL! - Communicated successfully with the REDCap Consortium server. You WILL be able to use the "automatic reporting" method to report your site stats, as well as use the REDCap Shared Library.
TEST 6: Check if REDCap Cron Job is running ✓ SUCCESSFUL! - REDCap Cron Job is running properly.

Secondary tests

✓ Using SSL
✓ Using PHP 5.5.0 or higher
✓ Using MySQL 5 or higher
✓ GD library (version 2 or higher) is installed
✓ PHP Fileinfo extension is installed
✓ REDCap is able to send emails
✓ The REDCap web server's temp directory is writable Location: /app001/tmp
✓ "temp" directory is writable Location: /app001/www/redcap/temp/
✓ File upload directory is writable Location: /ori/redcap_edocs/
✓ "modules" directory is writable Location: /app001/www/redcap/modules/
External Service Check: Checking communication with Twilio telephony API services ✓ SUCCESSFUL! - Communicated successfully with the Twilio API server (https://api.twilio.com).
External Service Check: Checking communication with PROMIS assessment API services ✓ SUCCESSFUL! - Communicated successfully with the PROMIS API server (https://www.redcap-cats.org/promis_api/).
External Service Check: Checking communication with BioPortal biomedical ontology API services ✓ SUCCESSFUL! - Communicated successfully with the BioPortal API server (http://data.bioontology.org).
External Service Check: Checking communication with Bit.ly URL shortening API services ✓ SUCCESSFUL! - Communicated successfully with the Bit.ly API server (http://api.bit.ly).
External Service Check: Checking communication with IS.GD URL shortening API services ✓ SUCCESSFUL! - Communicated successfully with the IS.GD API server (https://is.gd).
External Service Check: Checking communication with Google reCAPTCHA API services ✓ SUCCESSFUL! - Communicated successfully with the Google reCAPTCHA server (https://www.google.com/recaptcha/api/siteverify).



Title: Record lock Installation Qualification Test Protocol

Page 1 of 1

Document No.: N/A

Document Version: 01

IQ Section Number: __6_

Attachment: _____006_____

Run: 01

Step No.: __6, 7_

Initials: gk

Date: _24JUN2020_

REDCap
Logged in as taylorr4 | Log out
My Projects or Control Center
REDCap Messenger
View project as user: -- select a user --
Project Home and Design
Project Home · Project Setup
Designer · Dictionary · Codebook
Project status: Development
Data Collection
Record Status Dashboard
- View data collection status of all records
Add / Edit Records
- Create new records or edit/view existing ones
Show data collection instruments
Applications
Alerts & Notifications
Calendar
Data Exports, Reports, and Stats
Data Import Tool
Data Comparison Tool
Logging

Part 11 Record Locking
Project Home
Project status: Development
Main
Not started
I'm done!
Modif
Des
Add or (online
instru
Go to
Have y
Learn h
Ena

Additional customizations
Keep it displayed
☒ **Enable the Record-level Locking Enhancement: PDF confirmation & automatic external file storage?**
If enabled, users will receive a prompt when locking an entire record (i.e., when performing record-level locking but not instrument-level locking), in which they will be asked to review a PDF copy of the entire record to confirm it is the correct record and/or file. Once the PDF has been reviewed and confirmed, the record will be locked, after which a copy of the record's PDF file will be stored in the project's File Repository. This feature has been specifically created for projects wishing to be compliant for specific regulations, such as 21 CFR Part 11 compliance for FDA trials. Note: When this feature is enabled, all records that are locked using record-level locking will have a duplicate copy of the PDF file automatically stored on a secure file server outside of REDCap (please contact your REDCap administrator regarding any questions or details of this external server).
☒ **Missing Data Codes: Set up your missing data codes for this project**
Fields that have a blank/missing value may be marked with a custom 'Missing Data Code' to note why the value is blank. These missing codes may be used to aid in data analysis by specifying why a field lacks a value. To enable this feature below, enter both the codes AND their labels for all the categories of missing data that you wish to use in this project. The missing codes should be coded just like the choices of a multiple choice field with *code + comma + label*, in which the codes can only have letters, numbers, dots, dashes, and underscores (e.g., '999, Not asked' or 'UNK, Unknown'). If no codes are entered, this feature will remain disabled.
[Read more detailed instructions.](#)
Missing Data Codes
Add code from standardized list of missing data codes (optional suggestions):
Add NI No information
Add INV Invalid
Add UNK Unknown

	Title: Record lock Installation Qualification Test Protocol	Page 1 of 2
	Document No.: N/A Document Version: 01 IQ Section Number: <u> 6 </u> Attachment: <u> 007 </u>	Run: 01 Step No.: <u> 9 </u> Initials: gk Date: <u> 24JUN2020 </u>



Logged in as **gkumar@jafconsulting.com**
 Log out
 My Projects
 REDCap Messenger !

Project Home and Design

Project Home · Project Setup
 Designer · Dictionary · Codebook
 Project status: **Development**

Data Collection

Record Status Dashboard
 - View data collection status of all records
 Add / Edit Records
 - Create new records or edit/view existing ones
 Show data collection instruments

Applications

Alerts & Notifications
 Calendar
 Data Exports, Reports, and Stats
 Data Import Tool
 Data Comparison Tool
 Logging
 Field Comment Log
 File Repository
 User Rights and DAGs
 Customize & Manage Locking/E-signatures
 Data Quality
 External Modules

Help & Information

Help & FAQ
 Video Tutorials
 Suggest a New Feature

Part 11 Record Locking PID 112419

[Project Home](#)
[Project Setup](#)
[Other Functionality](#)
[Project Revision History](#)

Project status: 🔧 Development Completed steps **0** of **7**



Not started

I'm done!

Main project settings

● Use surveys in this project? ?
[VIDEO: How to create and manage a survey](#)

● Use longitudinal data collection with defined events? ?



Not started

I'm done!

🔧 Design your data collection instruments

Add or edit fields on your data collection instruments. This may be done by either using the Online Designer (online method) or by uploading a Data Dictionary (offline method). Quick links: [Download PDF of all instruments](#) OR [Download the current Data Dictionary](#)

Go to or Explore the

Have you checked the [Check For Identifiers](#) page to ensure all identifier fields have been tagged?

Learn how to use



Optional

I'm done!

⚙️ Enable optional modules and customizations

● Repeatable instruments ?
 ✔️ Auto-numbering for records ?
 ● Scheduling module (longitudinal only) ?
 ● Randomization module ?
 ● Designate an email field for sending survey invitations ?
 ● Clinical Data Pull from eStar ?
 ● Twilio SMS and Voice Call services for surveys and alerts ?



Title: Record lock Installation Qualification Test Protocol

Page 2 of 2

Document No.: N/A

Document Version: 01

IQ Section Number: __6__

Attachment: _____007_____

Run: 01

Step No.: __9__

Initials: gk

Date: _24JUN2020_

Contact REDCap administrator



Optional

I'm done!

Set up project bookmarks (optional)

You may create custom bookmarks to webpages that exist inside or outside of REDCap. These bookmarks will be seen as links on the left-hand project menu and can be accessed at any time by users who are given privileges to do so. Every project bookmark has custom settings that allow one to control its appearance and behavior.

Go to [Add or edit bookmarks](#)



Optional

I'm done!

User Rights and Permissions

You may grant other users access to this project or edit the user privileges of current users on this project by navigating to the User Rights page. Additionally, if you wish to limit user access to certain records/responses for this project, you may want to use Data Access Groups, in which only users within a given Data Access Group can access records created by users within that group.

Go to [User Rights](#) or [Data Access Groups](#)



Not started

I'm done!

Test your project thoroughly

It is important to test the essential components of your project before moving it into production. Try creating a few test records and entering some data for each to ensure that your data collection instruments look and behave how you expect, especially branching logic and calculations. Then review your test data by creating reports and exporting your data to view in Excel or a statistical analysis package. If you have surveys, complete the surveys as if you were a participant by using the Public Survey Link or Participant List by sending a survey invitation to yourself. If other project modules will be used regularly, test them out a bit too. The best way to test your project is to use it as if you were entering real production data, and it is always helpful to have colleagues (especially team members) take a look at your project to get a fresh set of eyes looking at it.



Not started

Move your project to production status

Move the project to production status so that real data may be collected. Once in production, you will not be able to edit the project fields in real time anymore. However, you can make edits in Draft Mode, which will be auto-approved or else might need to be approved by a REDCap administrator before taking effect.

Go to [Move project to production](#)

```

total 3758339
--w----- 1redcap redcap      52928 Jun  4  2019
01-01-1990_pid92821_formE-Consent_parental_consent_id10_2019-06-04_084411.pdf
--w----- 1redcap redcap      51320 Apr 23  2019
03-14-2019_pid92821_formE-Consent_parental_consent_id1_2019-04-23_102637.pdf
--w----- 1redcap sftponly    37189 Oct 25 07:25
0_pid78119_formTEST_id73_2019-10-25_072536.pdf
--w----- 1redcap users      89898 Feb 21 18:48
10_pid88111_formDiabetes_Financial_Incentive_Survey_id10_2020-02-21_184814.pdf
--w----- 1redcap redcap      42985 Feb 16  2019
1_1_pid90414_formExample_Survey_id1_2019-02-16_033053.pdf
--w----- 1redcap redcap      60837 Jun 27  2019
11_pid95132_formNEW_Health_Sciences_Consent_-_Template_rev_12119_id9_2019-06-27_201
928.pdf
--w----- 1redcap redcap      99515 Jun 25  2019
1234_pid95132_formNEW_Health_Sciences_Consent_-_Template_rev_12119_id5_2019-06-25_1
04747.pdf
--w----- 1redcap redcap      69847 Jun 28  2019
12387qr_pid95132_formNEW_Health_Sciences_Consent_-_Template_rev_12119_id13_2019-06-
28_094602.pdf
--w----- 1redcap redcap      65241 Feb  7  2019
1645_pid89310_formConsent_id4_2019-02-07_132752.pdf
--w----- 1redcap redcap      38633 Apr  9  2018
1956-10-16_pid70870_formConsent_idBP2-008_2018-04-09_101118.pdf
--w----- 1redcap redcap      45135 Apr  8  2018
1970-01-27_pid70870_formConsent_idBP2-001_2018-04-08_121244.pdf
--w----- 1redcap redcap      38272 Apr  9  2018
1983-04-01_pid70870_formConsent_idBP2-012_2018-04-09_114255.pdf
--w----- 1redcap redcap      48291 Jul 22  2019
1986-05-14_pid79529_formInformed_Consent_Behavioral_id1_2019-07-22_104341.pdf
--w----- 1redcap redcap      79043 Nov 15  2018
1_Meaghan_pid85794_formSurvey_id1_2018-11-15_163648.pdf
--w----- 1redcap users      41357 Jan  3 14:56
1_pid104665_formDuic_Behavioral_Assessment_Base_id1_2020-01-03_145645.pdf
--w----- 1redcap users      37870 Jan  3 14:39
1_pid104665_formPremarijuana_Drug_Effect_Questionnaire_Mjdeq_id1_2020-01-03_143921.p
df
--w----- 1redcap redcap      51978 Jan 15  2019
1_pid88724_formInformed_Consent_Document_id5_2019-01-15_095015.pdf
--w----- 1redcap redcap      65757 Jul 31  2019
2003-09-06_pid96470_formConsent_Assent_Form_id1_2019-07-31_234323.pdf
--w----- 1redcap redcap      65640 Jul 15  2019
2004-07-06_pid96470_formConsent_Assent_Form_id4_2019-07-15_214542.pdf
--w----- 1redcap redcap      61487 Jul  9  2019
2010-07-09_pid96470_formConsent_Assent_Form_id2_2019-07-09_145817.pdf
--w----- 1redcap redcap      35157 Apr 11  2019
2019-04-11_pid92758_formPre-Screening_Survey_id1_2019-04-11_195012.pdf
--w----- 1redcap redcap      35723 Apr 11  2019
2019-04-11_pid92758_formPre-Screening_Survey_id2_2019-04-11_195127.pdf
--w----- 1redcap redcap      44398 Aug  2  2019

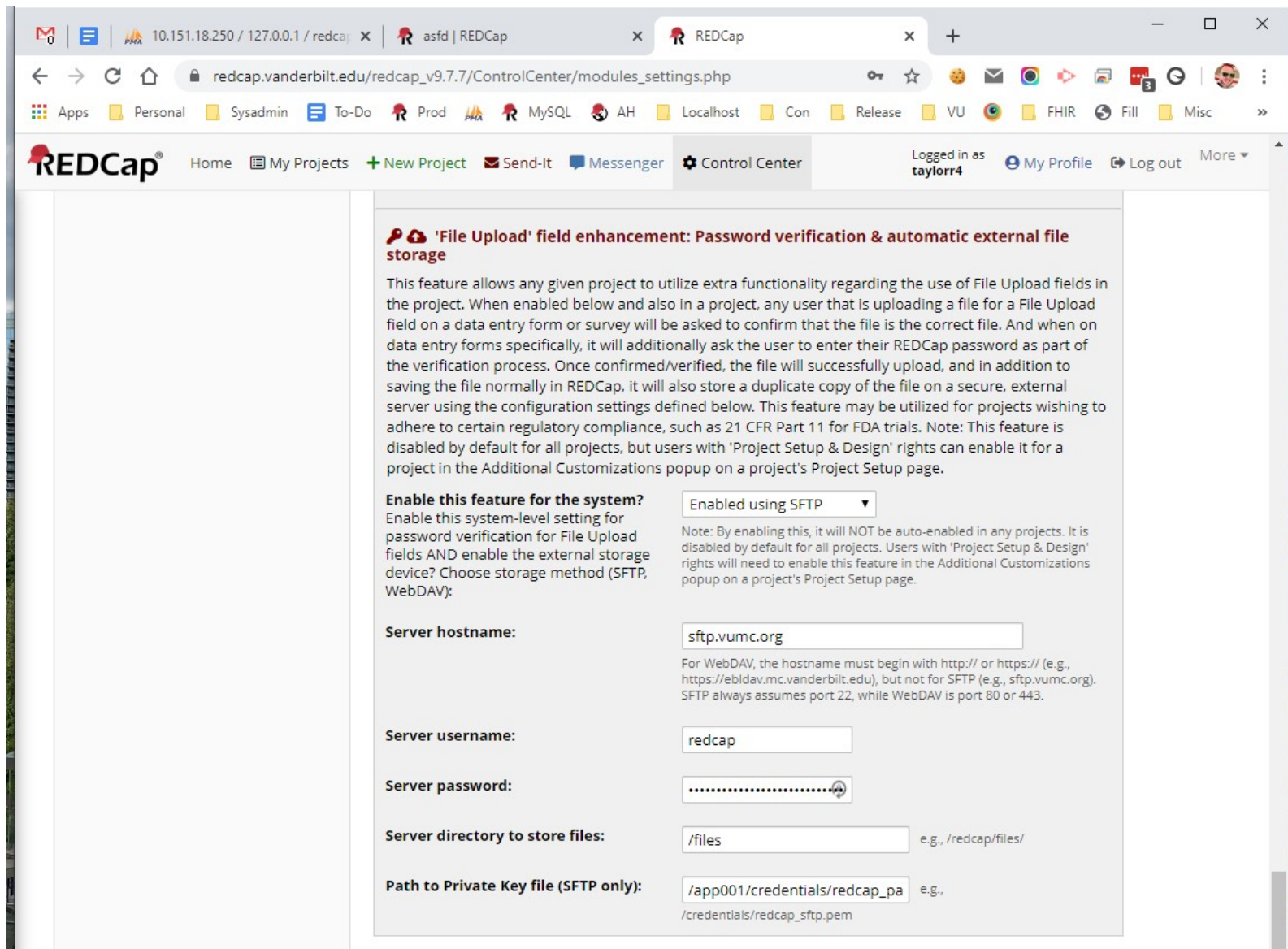
```

JK 24 JUN 2020

--w----- 1redcap sftponly 60270 Dec 2 12:11
Zeen_Zeen_pid85118_formInvestigating_Social_Competence_in_Youth_with_ASD_a_Multisite
_RCT_Consent_Document_for_Research_Study_id1_2019-12-02_121136.pdf
--w----- 1redcap sftponly 60262 Dec 2 12:12
Zeen_Zeen_pid85118_formInvestigating_Social_Competence_in_Youth_with_ASD_a_Multisite
_RCT_Consent_Document_for_Research_Study_id1_2019-12-02_121205.pdf
--w----- 1redcap sftponly 55173 Dec 4 00:18
Zeiger_pid97204_formE-Consent_Form_id2191_2019-12-04_001830.pdf
--w----- 1redcap redcap 44530 Mar 16 2019
Zhenya_Bolotin_pid91223_formParticipant_Informed_Consent_id15_2019-03-16_191526.pdf
--w----- 1redcap redcap 54202 Sep 3 09:43
Zhijun_Yin_pid98278_formRA_Survey_Responses_id0109612_2019-09-03_094320.pdf
--w----- 1redcap redcap 55382 Aug 28 15:09
Zhipeng_Cao_pid98278_formRA_Survey_Responses_id0114966_2019-08-28_150904.pdf
--w----- 1redcap redcap 55403 Aug 30 22:26
Zhipeng_Cao_pid98278_formRA_Survey_Responses_id0114966_2019-08-30_222636.pdf
--w----- 1redcap redcap 55403 Aug 30 22:26
Zhipeng_Cao_pid98278_formRA_Survey_Responses_id0114966_2019-08-30_222648.pdf
--w----- 1redcap redcap 55399 Aug 31 18:24
Zhipeng_Cao_pid98278_formRA_Survey_Responses_id0114966_2019-08-31_182441.pdf
--w----- 1redcap redcap 55399 Aug 31 18:24
Zhipeng_Cao_pid98278_formRA_Survey_Responses_id0114966_2019-08-31_182453.pdf
--w----- 1redcap redcap 65501 May 28 2019
Zion_Williams_2006-11-13_pid84413_formAssent_Ages_12-17_Control_id26_2019-05-28_1426
22.pdf
--w----- 1redcap sftponly 56023 Dec 3 16:57
Zirges_pid97204_formE-Consent_Form_id2107_2019-12-03_165702.pdf
--w----- 1redcap redcap 61520 Apr 30 2019
Zi_Wei_Liao_pid91464_formDaily_Sleep_and_PTSD_Consent_id10_2019-04-30_123453.pdf
--w----- 1redcap sftponly 53648 Dec 3 09:57
Zucchelli_pid97204_formE-Consent_Form_id2001_2019-12-03_095739.pdf
--w----- 1redcap redcap 54143 Dec 28 2018
Zulma_Pegel_Zulma_Pegel_pid62282_formConsent_id72_2018-12-28_112433.pdf

JK 24 JUN 2020

	Title: Record lock Installation Qualification Test Protocol	Page 1 of 3
	Document No.: N/A Document Version: 01 IQ Section Number: __6_ Attachment: _____009_____	Run: 01 Step No.: 11



The screenshot shows the REDCap Control Center interface. The top navigation bar includes links for Home, My Projects, New Project, Send-It, Messenger, and Control Center. The user is logged in as 'taylor4'. The main content area is titled "'File Upload' field enhancement: Password verification & automatic external file storage". It provides a detailed explanation of the feature, which allows for password verification and automatic external storage of uploaded files. The settings are currently enabled using SFTP. The configuration fields are as follows:

Enable this feature for the system? Enable this system-level setting for password verification for File Upload fields AND enable the external storage device? Choose storage method (SFTP, WebDAV):	Enabled using SFTP
Server hostname:	sftp.vumc.org
Server username:	redcap
Server password:	
Server directory to store files:	/files e.g., /redcap/files/
Path to Private Key file (SFTP only):	/app001/credentials/redcap_pa e.g., /credentials/redcap_sftp.pem

A note at the bottom states: "Note: By enabling this, it will NOT be auto-enabled in any projects. It is disabled by default for all projects. Users with 'Project Setup & Design' rights will need to enable this feature in the Additional Customizations popup on a project's Project Setup page."

	Title: Record lock Installation Qualification Test Protocol	Page 2 of 3
	Document No.: N/A Document Version: 01 Run: 01 IQ Section Number: __6_ Step No.: 11 Attachment: _____009_____	Initials: gk Date: _24JUN2020_

```
##
## sftp.vumc.org
##

## redcap sftp account permissions
Accounts with read: root
Accounts with write: root, redcap

## sftp-server chroot configuration in /etc/ssh/sshd_config
Subsystem      sftp    internal-sftp -l VERBOSE

Match user redcap
  AuthorizedKeysFile /sftp/%u/home/.ssh/authorized_keys
  ChrootDirectory /sftp/%u
  AllowTcpForwarding no
  ForceCommand internal-sftp -l VERBOSE -u 0577 -P setstat,fsetstat
  X11Forwarding no
```

	Title: Record lock Installation Qualification Test Protocol	Page 3 of 3
	Document No.: N/A Document Version: 01 IQ Section Number: __6_ Attachment: _____009_____ Run: 01 Step No.: 11	Initials: gk Date: _24JUN2020_

Step 11 was addressed by the file I sent you named "redcap_sftp.txt". I've reattached it here for your convenience. Notice inside it is states the following:

```
## redcap sftp account permissions
Accounts with read: root
Accounts with write: root, redcap
```

This implies that "root" user can read/write, and "redcap" user can only write. This is what you asked for in step 11. Let me know if somehow we've misunderstood that.

Regarding Steps 8,9,10,13, they are also addressed by the same file. Inside it lists the text below. This is as close to an "objective evidence of the configuration" that we'll get. There is no user interface to get screenshots through; there is only command line information, thus everything is provided as text. Below lists the configuration, in which it clarifies that the vault is set up as an internal SFTP subsystem and can only be accessed by authorized users, as evidenced by the SSH AuthorizedKeysFile, along with the two noted users above. **This is the vault configuration you asked for. Let me know if you have any questions.**

```
## sftp-server chroot configuration in /etc/ssh/sshd_config
Subsystem sftp internal-sftp -l VERBOSE
```

```
Match user redcap
AuthorizedKeysFile /sftp/%u/home/.ssh/authorized_keys
ChrootDirectory /sftp/%u
AllowTcpForwarding no
ForceCommand internal-sftp -l VERBOSE -u 0577 -P setstat,fsetstat
X11Forwarding no
```

	Title: eDocs Installation Qualification Test Protocol and Test Script	Page 1 of 1
	Document No.: N/A Document Version: 01 IQ Section Number: __6_ Attachment: _____010_____	Run: 01 Step No.: 12 Initials: gk Date: _24JUN2020_

SnapshotIQ

Snapshots

Snapshot Schedules

Settings

Schedules

[+ Create a Schedule](#)

Bulk actions

☐	Next Run	Schedule Name	Path	Schedule	Actions
☐	2020-03-07 01:05 (CST)	APPS_45DAYS_I10FILE...	/ifs/i10file/apps	Every 1 days at 01:05 AM	View / Edit Delete

Record Lock Executed IQ

Final Audit Report

2020-07-14

Created:	2020-07-14
By:	Gaurav Kumar (gkumar@jafconsulting.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAiasLmdXlhjgaqRk10Uk9zadmkmjE-iZ

"Record Lock Executed IQ" History

-  Document created by Gaurav Kumar (gkumar@jafconsulting.com)
2020-07-14 - 2:42:35 AM GMT- IP address: 96.230.160.12
-  Document emailed to Rob Taylor (rob.taylor@vumc.org) for signature
2020-07-14 - 2:43:48 AM GMT
-  Email viewed by Rob Taylor (rob.taylor@vumc.org)
2020-07-14 - 2:45:08 AM GMT- IP address: 68.34.206.236
-  Document e-signed by Rob Taylor (rob.taylor@vumc.org)
Signature Date: 2020-07-14 - 2:45:58 AM GMT - Time Source: server- IP address: 68.34.206.236
-  Document emailed to Colleen E. Lawrence (colleen.lawrence@vumc.org) for signature
2020-07-14 - 2:46:01 AM GMT
-  Email viewed by Colleen E. Lawrence (colleen.lawrence@vumc.org)
2020-07-14 - 9:11:38 AM GMT- IP address: 68.72.133.103
-  Document e-signed by Colleen E. Lawrence (colleen.lawrence@vumc.org)
Signature Date: 2020-07-14 - 11:05:09 AM GMT - Time Source: server- IP address: 68.72.133.103
-  Document emailed to Joseph Franchetti (jfranchetti@jafconsulting.com) for signature
2020-07-14 - 11:05:14 AM GMT
-  Email viewed by Joseph Franchetti (jfranchetti@jafconsulting.com)
2020-07-14 - 1:48:11 PM GMT- IP address: 73.196.185.110
-  Document e-signed by Joseph Franchetti (jfranchetti@jafconsulting.com)
Signature Date: 2020-07-14 - 1:48:59 PM GMT - Time Source: server- IP address: 73.196.185.110
-  Signed document emailed to Gaurav Kumar (gkumar@jafconsulting.com), Colleen E. Lawrence (colleen.lawrence@vumc.org), Joseph Franchetti (jfranchetti@jafconsulting.com), and Rob Taylor (rob.taylor@vumc.org)
2020-07-14 - 1:48:59 PM GMT