

REDCap eDocs Module Installation Qualification

**University of Vanderbilt Medical
Center**

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Document Date: 16-Feb-2020

1. Pre-Approval 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.

Signature: *Gaurav Kumar*
Gaurav Kumar (Feb 16, 2020)

Email: gkumar@jafconsulting.com

Title: Validation Consultant

Company: JAF Consulting, Inc.

Gaurav Kumar

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 (Feb 17, 2020)

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Company: Vanderbilt University Medical Center (VUMC)

Signature: *Joseph A. Franchetti*

Email: jfranchetti@jafconsulting.com

Title: QA Representative

Company: JAF Consulting Inc

Colleen Lawrence, System Owner

Joseph Franchetti, Quality Assurance Representative, JAF Consulting, Inc

Signature: *Rob Taylor*
Rob Taylor (Feb 17, 2020)

Email: rob.taylor@vumc.org

Title: Mgr of Application Development

Company: VUMC

Rob Taylor, Technical Owner, VUMC

2. 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

3. Revision History

Date	Version	Description
16-Feb-2020	1.0	Original Release, New Document

4. System Description

University of Vanderbilt will utilize a REDCap-based electronic documents (eDocs) Module that will allow the users to upload files in a data collection instrument. The user will select the specific document to upload as part of the data collection instrument and go through the verification process by entering the user id and password for every upload. Documents can also be replaced in the data collection instrument, which is stored in the REDCap database, while still retaining the original record, which is stored on the secured vault portion of the Vanderbilt network. If a file is deleted from the data collection instrument, the record will still be maintained in the vault where it can be retained and viewed for the required retention period. There is a complete audit trail of the records in the data instrument's history log.

5. 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 REDCap eDocs module environment to perform 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 electronic documents (eDocs) as a module of the REDCap system is installed and configured per User Specifications.

Test Method:

The test strategy will incorporate verification of installed configuration for the eDocs module 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 of the eDocs module prior to execution of IQ-eDocs

- 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

6. Installation Qualification Steps

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail
1.	Request VM Setup = 250Gb / 4Gb RAM; Hostname - HHVRIREDCP01; Run CentOS 6.5 Base Webserver Install; Add MySQL, PHP5, MySQL PHP module Append screenshot evidence of install.	VM Setup = 250Gb / 4Gb RAM Hostname - HHVRIREDCP01 Run CentOS 6.5 Base Webserver Install: Add MySQL Install: PHP5 Install: MySQL PHP module Screenshot attached	VM Setup = ____ Gb / ____ Gb RAM Hostname - _____ Run CentOS 6.5 Base Webserver Install: _____ Install: _____ Install: _____ Attachment ID #: _____	<input type="checkbox"/> Pass <input type="checkbox"/> Fail

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail
2.	<p>Configure MySQL Server – run through the secure setup for MySQL</p> <p>Append the execution results (screen shot or report) as evidence of the completed installation and setup.</p> <p>Make sure evidence provides any necessary details of the configuration of the product for use with REDCap eDocs module.</p>	<p>MySQL Server – run through the secure setup for MySQL</p> <p>Screenshot attached</p>	<p>MySQL Server – run through the secure setup for MySQL</p> <p>Attachment ID #: _____</p>	<p><input type="checkbox"/> Pass</p> <p><input type="checkbox"/> Fail</p>
3.	<p>REDCap Setup: Download REDCap 9.4.1 Standard Release or higher.</p>	<p>REDCap 9.4.1 Standard Release or higher is successfully setup.</p>	<p>REDCap 9.4.1 Standard Release or higher is _____ setup.</p>	<p><input type="checkbox"/> Pass</p> <p><input type="checkbox"/> Fail</p>

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail
4.	<p>Official REDCap Installation Instructions.</p> <p>1.) In the installation package zip file, unzip its contents and copy the "redcap" folder from the zip file onto your web server at the file location that you wish to serve it from over the web (i.e., anywhere under your web root).</p> <p>2.) Now that the "redcap" folder is on your web server, try to access the REDCap Install Module from a web browser by pointing your browser to the "install.php" page inside the "redcap" folder (For example: https://www.mc.VUMC.edu/apps/redcap/install.php). Once you have loaded the REDCap installation page in your web browser, it will provide you with the rest of the instructions you will need for completing the installation of REDCap.</p> <p>Append the execution results (screen shot or report) as evidence of the completed installation.</p>	<p>Following Test Instructions REDCap successfully installed.</p>	<p>Following Test Instructions REDCap _____ installed.</p>	<p><input type="checkbox"/> Pass</p> <p><input type="checkbox"/> Fail</p>
5.	<p>Setup LDAP Authentication, SSL Certificate, and REDCap - Email Outside</p> <p>Append evidence (screen shot or report) as evidence of the completed installation and evidence of encryption/security controls.</p>	<p>LDAP Authentication, SSL certificate, and REDCap – Email Outside is setup successfully.</p>	<p>LDAP Authentication, SSL certificate, and REDCap – Email Outside is _____ successfully.</p>	<p><input type="checkbox"/> Pass</p> <p><input type="checkbox"/> Fail</p>



Step	Test Instruction	Expected Result	Actual Result	Pass / Fail
6.	All versions of the files will be maintained within the project “vault.” Append the execution results (screen shot or report) as evidence of the completed installation and setup. Make sure evidence provides any necessary details of the configuration of the product for use with REDCap eDocs module.	“Vault” will maintain all versions of document in REDCap.	“Vault” _____ all versions of document in REDCap.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
7.	If a file is deleted from the data collection instrument, the record will be maintained in the vault where it can be retained and viewed for the required retention period. Append the execution results (screen shot or report) as evidence of the completed installation and setup. Make sure evidence provides any necessary details of the configuration of the product for use with REDCap eDocs module.	Vault will retain deleted files can be viewed.	Vault _____ retain deleted files can be viewed.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
8.	An appropriate “vault” will be set-up for each project. Append the execution results (screen shot or report) as evidence of the completed installation and setup. Make sure evidence provides any necessary details of the configuration of the product for use with REDCap eDocs module.	Vault is setup for eDocs module.	Vault _____ for eDocs module.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail
9.	<p>eDocs will not interface with any other systems directly other than the storage SFTP or “vault.”</p> <p>Append the execution results (screen shot or report) as evidence of the completed installation and setup.</p> <p>Make sure evidence provides any necessary details of the configuration of the product for use with REDCap eDocs module.</p>	<p>eDocs is interfaced with SFTP server.</p>	<p>eDocs is interfaced _____ SFTP server.</p>	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
10.	<p>eDocs will interface with an SFTP storage location.</p> <p>Append the execution results (screen shot or report) as evidence of the completed installation and setup.</p> <p>Make sure evidence provides any necessary details of the configuration of the product for use with REDCap eDocs module</p>			<input type="checkbox"/> Pass <input type="checkbox"/> Fail
11.	<p>The Vault will have limited access only to administrators of the Local Network with write once read many configurations.</p> <p>Append the execution results (screen shot or report) as evidence of the completed installation and setup.</p> <p>Print out the list of user permissions needed to access the Vault.</p>	<p>The Vault has limited access only to administrators of the Local Network with write once read many configurations.</p>	<p>The Vault _____ limited access only to administrators of the Local Network with write once read many configurations.</p>	<input type="checkbox"/> Pass <input type="checkbox"/> Fail

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail
12.	<p>The Vault environment will be backed up daily. Append the execution results (screen shot or report) as evidence of the completed installation and setup. Make sure evidence provides any necessary details of the configuration of the product for use with REDCap eDocs module.</p>	<p>Vault for eDocs will be backed up daily</p>	<p>Vault for eDocs _____ backed up daily</p>	<p><input type="checkbox"/> Pass <input type="checkbox"/> Fail</p>
13.	<p>The Vault will have data encryption enabled. Append the execution results (screen shot or report) as evidence of the completed installation and setup. Make sure evidence provides any necessary details of the configuration of the product for use with REDCap eDocs module.</p>	<p>The Vault has data encryption enabled.</p>	<p>The Vault _____ data encryption enabled.</p>	<p><input type="checkbox"/> Pass <input type="checkbox"/> Fail</p>
14.	<p>Open REDCap application in Web Browser. Select the Key in the address bar. Verify the connection to REDCap server is secured and encrypted.</p>	<p>Connection to REDCap server is secured and encrypted.</p>	<p>Connection to REDCap server _____ secured and encrypted.</p>	<p><input type="checkbox"/> Pass <input type="checkbox"/> Fail</p>

Test Summary			
Comments/Additional Information:			
<input type="checkbox"/> Pass All tests/verifications were successfully completed.		<input type="checkbox"/> 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.	
<i>Signature</i>	<i>Date</i>	<i>Signature</i>	<i>Date</i>

REDCap eDocs IQ Test Protocol - v1

Final Audit Report

2020-02-17

Created:	2020-02-17
By:	Joseph Franchetti (jfranchetti@jafconsulting.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAhQgQshq0HPly0W3cqwoj17ejWz2sCbP

"REDCap eDocs IQ Test Protocol - v1" History

-  Document created by Joseph Franchetti (jfranchetti@jafconsulting.com)
2020-02-17 - 1:25:36 AM GMT- IP address: 73.196.185.110
-  Document emailed to Gaurav Kumar (gkumar@jafconsulting.com) for signature
2020-02-17 - 1:26:21 AM GMT
-  Email viewed by Gaurav Kumar (gkumar@jafconsulting.com)
2020-02-17 - 2:03:08 AM GMT- IP address: 96.10.88.42
-  Document e-signed by Gaurav Kumar (gkumar@jafconsulting.com)
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-  Document emailed to Colleen E. Lawrence (colleen.lawrence@vumc.org) for signature
2020-02-17 - 2:03:59 AM GMT
-  Email viewed by Colleen E. Lawrence (colleen.lawrence@vumc.org)
2020-02-17 - 5:05:00 AM GMT- IP address: 68.72.133.103
-  Document e-signed by Colleen E. Lawrence (colleen.lawrence@vumc.org)
Signature Date: 2020-02-17 - 2:20:14 PM GMT - Time Source: server- IP address: 160.129.251.190
-  Document emailed to Joseph Franchetti (jfranchetti@jafconsulting.com) for signature
2020-02-17 - 2:20:16 PM GMT
-  Document e-signed by Joseph Franchetti (jfranchetti@jafconsulting.com)
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-  Document emailed to Rob Taylor (rob.taylor@vumc.org) for signature
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 Signed document emailed to Gaurav Kumar (gkumar@jafconsulting.com), Rob Taylor (rob.taylor@vumc.org), Joseph Franchetti (jfranchetti@jafconsulting.com), and Colleen E. Lawrence (colleen.lawrence@vumc.org)

2020-02-17 - 2:50:04 PM GMT