

REDCap eDocs Module

Performance Qualification Protocol

University of Vanderbilt Medical Center

Document Version: 1.0

Document Date: 16-Feb-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
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)
Email: colleen.lawrence@vumc.org
Title: Manager, Translational Research
Company: Vanderbilt University Medical Center (VUMC)

Signature: Joseph A. Franchetti
Email: jfranchetti@jafconsulting.com
Title: QA Rep
Company: JAF Consulting Inc

Colleen Lawrence, System Owner

Joseph Franchetti, Quality Assurance Representative, JAF Consulting, Inc

Signature: Rob Taylor
Rob Taylor (Feb 16, 2020)
Email: rob.taylor@vumc.org
Title: Mgr of Application Development
Company: VUMC

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
16-FEB-2020	001	Original Release, New Document

1. Purpose

The purpose of this Performance Qualification (PQ) protocol is to describe the procedures to be followed that will produce documented evidence the redcap eDocs Module performs as specified and in accordance with VUMC procedures and User Requirements Specifications (URS).

2. Scope

The scope of this PQ protocol is limited to testing activities that will verify the system against documented specifications and user requirements.

3. System Description

Refer to the redcap eDocs Validation Plan for details.

4. Testing Approach

Test scripts will detail the steps to be followed to verify the system functions correctly and consistently and to document the execution of the tests.

Testing will be conducted in the Production environment by the JAF Consulting Validation Consultants, VUMC, and/or redcap Users and System Owner will verify the system performs according to user expectations (intended use) as outlined in the RS.

5. References

Listed below are the supporting documents applicable to the preparation of this protocol, as well as procedures to follow during execution of the protocol.

5.1 Internal References

Title/Description
REDCap eDocs Validation Master Plan (VMP)
REDCap eDocs User Requirements Specifications (URS)
REDCap eDocs Installation Qualification Protocol
REDCap eDocs Operation SOP
REDCap eDocs Administration SOP

5.2 External References

Document ID	Title/Description
21 CFR part 11	Electronic Records, Electronic Signatures: Final Rule"; Federal Register; Vol. 62, No. 54, 13429, March 20, 1997
21 CFR Part 820	Quality System Regulation (QSR) for medical devices
ISO 13485	Medical devices – Quality management systems
GAMP 5	Good Automation Manufacturing Practice, (ISPE), 2008

5.3 Acronyms and Definitions

Refer to the REDCap eDocs Validation Plan for details.

6. Responsibilities

It is the responsibility of the Technical Owner or designate (including the vendor) to execute this protocol and the Validation Representative, System Owner to approve the executed results.

Individuals executing the test scripts are responsible for ensuring appropriate documentation is created and identified.

7. Execution Materials and Equipment

- None

8. Protocol Execution Procedure

Testing will be performed by executing the test scripts in Testing Procedures (section 12) according to the directions contained within the script. Note the test instructions (i.e. Mouse clicks, menus) provided do not serve as definitive directions but as a guide to achieve the expected results. Alternate pathways are acceptable provided the expected results and purpose of the test are fulfilled.

Additional procedures for the execution of this protocol is contained in Appendix 1 of the redcap eDocs Module Validation Plan and includes general information on how to document the execution and review of test scripts, and how to handle deviations / exceptions to the process.

The validation plan also describes the general documentation requirements that must be followed for all testing activities. Recording of data or other required information in any test document must be done per Good Documentation Practices (GDP). Blue or Black ink must be used (no pencil). If an error is made in the documentation, use one line to line out the error and write in the correct information along with a reason for the change and initial and date the correction.

8.1 Signature Log

All participants must complete the log in Appendix 4 of the redcap eDocs Module Validation Plan.

9. Acceptance Criteria

All required testing as specified in the Testing Procedures section (12) have been successfully performed.

All validation deviations resulting from the execution must be documented on a Deviation Report, adequately resolved, and approved.

Where expected results are specified, the actual results must match the expected results. Where minimum requirements are specified, the actual results must meet or surpass the minimum requirements.

10. Protocol Deviations

All errors deemed protocol deviations must be documented using the forms in Appendices 2 and 3 of the redcap e-Consent Module Validation Plan.

11. Validation Results

After completion of test execution, a validation summary report (VSR) will be generated. The report, described in the Validation Plan, will summarize the actual results including any deviations incurred during testing. The document will indicate whether the system is suitable for its' intended use and is acceptable in the production environment.

12. Testing Procedures

Testing Scripts to follow



Performance Qualification Protocol

Title: **Test Script - 001**

Revision: **001**

Page: 6 of 25

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

Test Browser & Version: _____

OS & Version: _____

Test Purpose:

The purpose of this test is to validate electronic documents (eDocs) as a module of the REDCap system at University of Vanderbilt. 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.

The following Functional Requirements will be tested in this script:
All of the Technical Requirements from URS is tested in Test Script – 001.

Test Method:

The test strategy will incorporate positive, negative and boundary testing for all critical core functionality of eDocs Module. This test will also validate Administrator User Role, 21 CFR Part 11 functionality for eDocs module.

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.



Performance Qualification Protocol

Title: Test Script - 001

Revision: 001

Page: 7 of 25

Prerequisites:

1. User Role 1 with Data Entry Analyst Permission: _____
2. User Role 2 with Administrator Permission: _____
3. Link to REDCap Test Environment: _____
4. PDF file (less than 50 mb file size): _____
NOTE: Obtain a print out of the PDF for manual verification during execution of this script.
5. PDF file 1 (More than 50 mb file size): _____
6. E-mail ID: _____
7. Test Computer: _____
(information about the machine on which testing will be performed)
8. PDF file 2 (less than 50 mb file size): _____
9. PDF file 3 (less than 50 mb file size): _____
10. Create and Record the Study ID number with 'Validation Testing' entered in the Comment Section of File Upload and Comment Section (Study ID with comments): _____

System Test: PQ eDocs

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail
1.	Login to the redcap using <User role 1> using Link for redcap Test Environment Print, Label and Attach a screen print	<User role 1> successfully logged in. Screen print Attached	<User role 1> _____ logged in. Attachment: _____	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
2.	Select My Projects tab Open Part 11 Any File Upload (eDocs) Validation Testing Project from the Prerequisites Print, Label and Attach a screen print	Open Part 11 Any File Upload (eDocs) Validation Testing Project page from the Prerequisites section is successfully opened. Screen print Attached	Open Part 11 Any File Upload (eDocs) Validation Testing Project page from the Prerequisites section is _____ Attachment: _____	<input type="checkbox"/> Pass <input type="checkbox"/> Fail



Performance Qualification Protocol

Title: Test Script - 001

Revision: 001

Page: 8 of 25

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail
3.	Expand the Project Home and Data Collection tab. Verify Record Status Dashboard and Add / Edit Records are available Create new Study ID Record the new study id number in Actual Results Print, Label and Attach a screen print	Record Status Dashboard and Add / Edit Records are available Study ID number recorded Screen print Attached	Record Status Dashboard and Add / Edit Records _____ available Study ID #: _____ Attachment: _____	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
4.	Select File Upload 1 Select Choose File Browse and select <PDF file 1> Select Upload file Enter User Name and Password	System prohibits file uploads of more than 50 mb	System _____ file uploads of more than 50 mb	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
5.	Select File Upload 1 Select Choose File Browse and select <PDF file> Select Upload file Verify the system prompts for entering User Name and Password	System prompts for entering User Name and Password	System _____ entering User Name and Password	<input type="checkbox"/> Pass <input type="checkbox"/> Fail



Performance Qualification Protocol

Title: Test Script - 001

Revision: 001

Page: 9 of 25

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail
6.	<p>Complete the e-signature by</p> <p>Entering Username Entering Password Understanding and Agreeing to Meaning of signature</p> <p>Close the pop up window</p> <p>Complete Form Status section Select Save & Exit Form</p>	<p>New Study ID has been created</p> <p>Study ID number matches from Study ID created on step 3</p>	<p>New Study ID _____ been created</p> <p>Study ID number _____ from Study ID created on step 3</p>	<p><input type="checkbox"/> Pass</p> <p><input type="checkbox"/> Fail</p>
7.	<p>Navigate to Record Status Dashboard</p> <p>Click on the status next to study id created on step 3 Modify the record by performing the following:</p> <p>Uploading PDF in File Upload 2</p> <p>Record the Date and Time 1 in Actual Results</p> <p>Removing PDF from File Upload 1</p> <p>Record the Date and Time 2 in Actual Results</p>	<p>Study ID from step 3 successfully updated.</p> <p>Date and Time 1, and 2 are recorded.</p>	<p>Study ID from step 3 _____ updated.</p> <p>Date and Time 1: _____</p> <p>Date and Time 2: _____</p>	<p><input type="checkbox"/> Pass</p> <p><input type="checkbox"/> Fail</p>
8.	<p>Check the Lock check box next to "Lock this record for this form?" field Select E-signature checkbox</p> <p>Save & Exit form</p> <p>Enter Username and Password</p> <p>Select Save</p> <p>Record the Date and Time 3 in Actual Results</p>	<p>Study ID locked</p> <p>Date and Time 3 are recorded.</p>	<p>Study ID _____</p> <p>Date and Time 3: _____</p>	<p><input type="checkbox"/> Pass</p> <p><input type="checkbox"/> Fail</p>



Performance Qualification Protocol

Title: Test Script - 001

Revision: 001

Page: 10 of 25

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail
9.	<p>Open the Study ID from previous step</p> <p>Select Unlock Form Select Unlock and Select Close NOTE: If the Send it option is not enabled, refresh the webpage</p> <p>Select Send-It icon next in File Upload 1 section. Enter <E-mail ID> in To: (recipient emails) box</p> <p>Select Send It! and record the Date and Time 4 in Actual Results</p> <p>Open the Email Inbox of the <E-mail ID></p> <p>Verify the email contains the following:</p> <ul style="list-style-type: none"> Subject Line Contains: [REDCap Send-It] File available for download Link to access the PDF One Time Password (OTP) for download of the PDF. 	<p>Date and Time 4 is recorded.</p> <p>Email contains the following:</p> <ul style="list-style-type: none"> Subject Line Contains: [REDCap Send-It] File available for download Link to access the PDF One Time Password (OTP) for download of the PDF. 	<p>Date and Time 4: _____</p> <p>Email _____ the following:</p> <ul style="list-style-type: none"> Subject Line Contains: [REDCap Send-It] File available for download Link to access the PDF One Time Password (OTP) for download of the PDF. 	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
10.	<p>Navigate to logging section</p> <p>Verify Date and Time1, 2, 3 and 4 from steps 7, 8 and 9 are recorded into logging section..</p>	<p>Date and Time1, 2, 3 and 4 from 7, 8 and 9 are recorded into logging section..</p>	<p>Date and Time1, 2, 3 and 4 from steps 7, 8 and 9 _____ recorded into logging section..</p>	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
11.	<p>Coordinate with IT department and ensure Study ID created on step 3 moves to the SFTP vault.</p>	<p>Study ID created on step 3 successfully moves to the SFTP vault.</p>	<p>Study ID created on step 3 _____ to the SFTP vault.</p>	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
12.	<p>Logout of the System</p>	<p>Logout successful</p>	<p>Logout _____</p>	<input type="checkbox"/> Pass <input type="checkbox"/> Fail



Performance Qualification Protocol

Title: Test Script - 001

Revision: 001

Page: 11 of 25

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail
13.	Login to the application as <User Role 2>	Login Successful	Login _____	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
14.	Obtain a copy of Study ID from the vault and match it with the Study ID from step 3	Study ID from the vault matches with Study ID from step 3	Study ID from the vault _____ with Study ID from step 3	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
15.	Open Study ID from step 3 Update the File Description field Select Save & Exit	System gives the following options: Save Changes and Leave Leave without saving changes Stay on Page	System _____ following options: Save Changes and Leave Leave without saving changes Stay on Page	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
16.	Select "Save Changes and Leave" Select Record Status Dashboard Using the link, select the Study ID from step 3 From 'Choose action for record' drop down list,	System provides following options: <ul style="list-style-type: none"> Download PDF for record data for all instruments Download PDF for record data for all instruments (compact)	System _____ following options: <ul style="list-style-type: none"> Download PDF for record data for all instruments Download PDF for record data for all instruments (compact)	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
17.	Download the PDF file from steps 5 and 6 from study id created on step 3	PDF file of study id from step 3 successfully downloaded.	PDF file of study id from step 3 successfully downloaded.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
18.	From 'Choose action for record' drop down list, select Delete record (all forms)	System prompts following message stating: DELETE RECORD "STUDY ID"? Are you sure you wish to PERMANENTLY delete this record and its data? This will delete ALL DATA for ALL INSTRUMENTS for this record. This process is permanent and CANNOT BE REVERSED.	System _____ following message stating: DELETE RECORD "STUDY ID"? Are you sure you wish to PERMANENTLY delete this record and its data? This will delete ALL DATA for ALL INSTRUMENTS for this record. This process is permanent and CANNOT BE REVERSED.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail



Performance Qualification Protocol

Title: Test Script - 001

Revision: 001

Page: 12 of 25

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail
19.	Select DELETE RECORD	System prompts a message stating: Study ID "Study ID" was successfully deleted.	System _____ a message stating: Study ID "Study ID" was successfully deleted.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
20.	Select Close	Study ID from step 3 is successfully deleted from REDCap system.	Study ID from step 3 _____ deleted from REDCap system.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
21.	Navigate to the logging section and verify the following: Date and Time of deletion of Study ID from step 3 is retained Reason for deletion of Study ID from step 3 is retained User name performing the action	Date and Time of deletion of Study ID from step 3 is retained Reason for deletion of Study ID from step 3 is retained User name performing the action	Date and Time of deletion of Study ID from step 3 is _____ Reason for deletion of Study ID from step 3 is _____ User name performing the action	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
22.	Coordinate with IT department and verify Study ID from step 3 is retained in the vault.	Study ID from step 3 is retained in the vault.	Study ID from step 3 is _____ in the vault.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
23.	Restore the Study ID from step 3	Study ID from step 3 successfully restored from Vault to REDCap application.	Study ID from step 3 _____ from Vault to REDCap application.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
24.	Logout of the system	Logout successful	Logout _____	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
25.	Login to REDCap as <User Role 1>	Login Successful	Login _____	<input type="checkbox"/> Pass <input type="checkbox"/> Fail



Performance Qualification Protocol

Title: Test Script - 001

Revision: 001

Page: 13 of 25

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail
26.	Create a new Study ID Exit the Study ID page without saving the Study ID System gives the following message: Study ID <System Assigned ID> data entry cancelled - not saved Print, Label and Attach a screen print	New Study ID not created in the system System gives the following message: Study ID <System Assigned ID> data entry cancelled - not saved Screen print attached	New Study ID _____ System _____ the following message: Study ID <System Assigned ID> data entry cancelled - not saved Attachment ID # : _____	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
27.	Export entire data collection instrument into a CSV file format.	System allows export of entire data collection instrument into a CSV file format.	System _____ export of entire data collection instrument into a CSV file format.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
28.	Open the restored study id from step 3. Update the file description and exit the record without system. Verify system gives a notification message asking the user to save the changes or leave without saving the changes or stay on the page	System gives a notification message asking the user to save the changes or leave without saving the changes or stay on the page	System _____ a notification message asking the user to save the changes or leave without saving the changes or stay on the page	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
29.	Close the message and logout of the system	Logout successful	Logout _____	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
30.	Login to the REDCap as <User Role 2>	Login Successful.	Logout _____	<input type="checkbox"/> Pass <input type="checkbox"/> Fail



Performance Qualification Protocol

Title: Test Script - 001

Revision: 001

Page: 14 of 25

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail
31.	Select User Rights Verify the following permissions are enabled for Study Coordinator role: Create Records Logging Lock/Unlock Records Reports and Report Builder Verify the following permissions are disabled for Study Coordinator role: Rename Records Delete Records	Following permissions are enabled for Study Coordinator role: Create Records Logging Lock/Unlock Records Reports and Report Builder Verify the following permissions are disabled for Study Coordinator role: Rename Records Delete Records	Following permissions _____ for Study Coordinator role: Create Records Logging Lock/Unlock Records Reports and Report Builder Verify the following permissions are disabled for Study Coordinator role: Rename Records Delete Records	<input type="checkbox"/> Pass <input type="checkbox"/> Fail



Performance Qualification Protocol

Title: Test Script - 001

Revision: 001

Page: 15 of 25

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail
32.	<p>Verify the following permissions are enabled for Data Entry Analyst role:</p> <p>Create Records Logging Reports and Report Builder</p> <p>Verify the following permissions are disabled for Study Coordinator role:</p> <p>Rename Records Delete Records Lock/Unlock Records</p> <p>Verify the following permission(s) are enabled for Monitor / Auditor role:</p> <p>Read Only access to eDocs</p> <p>Verify the following permissions are disabled for Study Coordinator role:</p> <p>Every other permission is disabled</p>	<p>Following permissions are enabled for Data Entry Analyst role:</p> <p>Create Records Logging Reports and Report Builder</p> <p>Verify the following permissions are disabled for Study Coordinator role:</p> <p>Rename Records Delete Records Lock/Unlock Records</p> <p>Following permission(s) are enabled for Monitor / Auditor role:</p> <p>Read Only access to eDocs</p> <p>Verify the following permissions are disabled for Study Coordinator role:</p> <p>Every other permission is disabled</p>	<p>Following permissions _____ for Data Entry Analyst role:</p> <p>Create Records Logging Reports and Report Builder</p> <p>Verify the following permissions are disabled for Study Coordinator role:</p> <p>Rename Records Delete Records Lock/Unlock Records</p> <p>Following permission(s) _____ for Monitor / Auditor role:</p> <p>Read Only access to eDocs</p> <p>Verify the following permissions are disabled for Study Coordinator role:</p> <p>Every other permission is disabled</p>	<p><input type="checkbox"/> Pass</p> <p><input type="checkbox"/> Fail</p>



Performance Qualification Protocol

Title: Test Script - 001

Revision: 001

Page: 16 of 25

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail
33.	<p>Verify the following permissions are enabled for Administrator role:</p> <p>Create Records Logging Reports and Report Builder Project Design and Setup User Rights Data Access Group File Repository</p> <p>Verify the following permissions are disabled for Study Coordinator role:</p> <p>Rename Records Delete Records Lock/Unlock Records</p>	<p>Following permissions are enabled for Administrator role:</p> <p>Create Records Logging Reports and Report Builder Project Design and Setup User Rights Data Access Group File Repository</p> <p>Verify the following permissions are disabled for Study Coordinator role:</p> <p>Rename Records Delete Records Lock/Unlock Records</p>	<p>Following permissions _____ for Administrator role:</p> <p>Create Records Logging Reports and Report Builder Project Design and Setup User Rights Data Access Group File Repository</p> <p>Verify the following permissions are disabled for Study Coordinator role:</p> <p>Rename Records Delete Records Lock/Unlock Records</p>	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
34.	<p>Disconnect the internet on <Test Computer> Attempt to access REDCap application</p>	<p>REDCap system cannot be accessed.</p>	<p>REDCap system _____ be accessed.</p>	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
35.	<p>Login to REDCap as <User Role 1> using <Link to REDCap Test Environment></p> <p>Navigate to Project Setup tab</p> <p>Verify Project Status is in Development Environment. Verify 'Move project to production' option is available</p>	<p>Project Status is in Development Environment</p> <p>Move project to production' option is available</p>	<p>Project Status _____ Development Environment</p> <p>Move project to production' option _____ available</p>	<input type="checkbox"/> Pass <input type="checkbox"/> Fail



Performance Qualification Protocol

Title: Test Script - 001

Revision: 001

Page: 17 of 25

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail
36.	<p>Verify page specific training link (icon below) is available on each page of eDocs module.</p> <p> VIDEO: I</p> <p>Print, Label and Attach a screen print</p>	<p>Page specific training link is available on each page of eDocs module.</p> <p>Screen print attached</p>	<p>Page specific training link _____ available on each page of eDocs module.</p> <p>Attachment ID # _____</p>	<p><input type="checkbox"/> Pass</p> <p><input type="checkbox"/> Fail</p>
37.	<p>Create a new Study ID by performing the following steps:</p> <p>Upload PDF files in File Upload 1, File Upload 2, File Upload 3, File Upload 4 and File Upload 5 using <PDF File></p> <p>Fill out the file descriptions for File Description 1, File Description 2, File Description 3, File Description 4 and File Description 5.</p> <p>Enter Comments in the Comment field</p> <p>Select Complete from Complete? Dropdown</p> <p>Select Save & Exit Form</p> <p>Record Study ID in Actual Results.</p>	<p>New Study ID created.</p> <p>Study ID number recorded.</p>	<p>New Study ID _____</p>	<p><input type="checkbox"/> Pass</p> <p><input type="checkbox"/> Fail</p>
38.	<p>Logout of the system</p>	<p>Logout Successful</p>	<p>Logout _____</p>	<p><input type="checkbox"/> Pass</p> <p><input type="checkbox"/> Fail</p>



Performance Qualification Protocol

Title: Test Script - 001

Revision: 001

Page: 18 of 25

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail
39.	Login to REDCap as <User Role 2> using <Link to REDCap Test Environment> Open the Study ID from step 37. Upload <PDF File 2> in File Upload 1 Manifest electronic signature of <User Role 2> Record the Current Data and Time 5 in Actual Results Upload <PDF File 3> in File Upload 2 Manifest electronic signature of <User Role 2> Record the Current Data and Time 5 in Actual Results Select Complete from Complete? Dropdown Select Save & Exit Form	Study ID from step 37 successfully updated. Date and Time 5 and 6 recorded	Study ID from step 37 _____ updated. Date and Time 5: _____ Date and Time 6: _____	<input type="checkbox"/> Pass <input type="checkbox"/> Fail

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail
40.	<p>Open the Study ID from step 37 and open the View Data History by selecting the  icon next to File Upload 1.</p> <p>Verify the following entries are listed:</p> <p>Date/Time of Upload includes Date and Time 5</p> <p><User Role 2> is listed under User column</p> <p><PDF file 2> is listed under File Uploaded column</p> <p><PDF file 2> is version V2</p> <p>Download and Delete icon is listed under Information / Action column.</p> <p>Print, Label and Attach a screen print</p> <p>NOTE: Due to time delay in recording and server delays +2 minutes is acceptable</p>	<p>Following entries are listed</p> <p>Date/Time of Upload includes Date and Time 5</p> <p><User Role 2> is listed under User column</p> <p><PDF file 2> is listed under File Uploaded column</p> <p><PDF file 2> is version V2</p> <p>Download and Delete icon is listed under Information / Action column.</p> <p>Screen print attached</p>	<p>Following entries _____ listed:</p> <p>Date/Time of Upload includes Date and Time 5</p> <p><User Role 2> is listed under User column</p> <p><PDF file 2> is listed under File Uploaded column</p> <p><PDF file 2> is version V2</p> <p>Download and Delete icon is listed under Information / Action column.</p> <p>Attachment ID # _____</p>	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
41.	<p>Download V1 <PDF File> and match it with the print out from pre-requisite section</p>	<p>V1 <PDF File> successfully downloaded and matches with the print out from pre-requisite section</p>	<p>V1 <PDF File> successfully downloaded and _____ with the print out from pre-requisite section</p>	<input type="checkbox"/> Pass <input type="checkbox"/> Fail



Performance Qualification Protocol

Title: Test Script - 001

Revision: 001

Page: 20 of 25

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail
42.	<p>Delete V1 <PDF File> by performing the following instructions:</p> <p>Select the Delete Icon under Information / Action column.</p> <p>Enter "Validation Test" in the Delete File? Pop up window Selet Yes, delete it</p> <p>Record the Date and Time 7</p>	<p>V1 <PDF File> deleted</p> <p>Date and Time 7 recorded</p>	<p>V1 <PDF File> _____</p> <p>Date and Time 7: _____</p>	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
43.	<p>Verify the Data History pop up window for File Upload 1 includes Date and Time 6 next to V1 <PDF file></p> <p>NOTE: Due to time delay in recording and server delays +2 minutes is acceptable</p>	<p>Data History pop up window for File Upload 1 includes Date and Time 6 next to V1 <PDF file></p>	<p>Data History pop up window for File Upload 1 _____ Date and Time 6 next to V1 <PDF file></p>	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
44.	<p>Coordinate with IT department and restore Study ID created on step 37 from Vault to REDCap instance.</p>	<p>Study ID created on step 37 is resotred from Vault to REDCap server</p>	<p>Study ID created on step 37 _____ from Vault to REDCap server</p>	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
45.	<p>Open the Study ID from step 37 and open the View Data History by selecting the  icon next to File Upload 1.</p> <p>Verify V1 <PDF File> is retained</p>	<p>V1 <PDF File> is retained</p>	<p>V1 <PDF File> _____ retained</p>	<input type="checkbox"/> Pass <input type="checkbox"/> Fail



Performance Qualification Protocol

Title: Test Script - 001

Revision: 001

Page: 21 of 25

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail
46.	<p>Close the popup window and Navigate to Logging section.</p> <p>Verify the following entries are listed:</p> <p>Time / Date includes Date and Time 5</p> <p>Document upload was confirmed with password (field = 'file_upload_1') is listed under List of Data Changes OR Fields Exported column</p> <p><User Role 2> is listed under Username column</p> <p>Updated Record Study ID from step 37 is listed under Action section</p> <p>NOTE: Due to time delay in recording and server delays +2 minutes is acceptable</p>	<p>Following entries are listed:</p> <p>Time / Date includes Date and Time 5</p> <p>Document upload was confirmed with password (field = 'file_upload_1') is listed under List of Data Changes OR Fields Exported column</p> <p><User Role 2> is listed under Username column</p> <p>Updated Record Study ID from step 37 is listed under Action section</p>	<p>Following entries are listed:</p> <p>Time / Date _____ Date and Time 5</p> <p>Document upload was confirmed with password (field = 'file_upload_1') _____ under List of Data Changes OR Fields Exported column</p> <p><User Role 2> _____ under Username column</p> <p>Updated Record Study ID from step 37 _____ under Action section</p>	<p><input type="checkbox"/> Pass</p> <p><input type="checkbox"/> Fail</p>



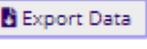
Performance Qualification Protocol

Title: Test Script - 001

Revision: 001

Page: 22 of 25

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail
47.	<p>Verify the following entries are listed:</p> <p>Time / Date includes Date and Time 7</p> <p>file_upload_1 (V1) is listed under List of Data Changes OR Fields Exported column</p> <p>Deleted Document Updated Record Study ID from step 37 is listed under Action section</p> <p><User Role 2> is listed under Username column</p> <p>NOTE: Due to time delay in recording and server delays +2 minutes is acceptable</p>	<p>The following entries are listed:</p> <p>Time / Date includes Date and Time 7</p> <p>file_upload_1 (V1) is listed under List of Data Changes OR Fields Exported column</p> <p>Deleted Document Updated Record Study ID from step 37 is listed under Action section</p> <p><User Role 2> is listed under Username column</p>	<p>The following entries are listed:</p> <p>Time / Date _____ Date and Time 7</p> <p>file_upload_1 (V1) _____ under List of Data Changes OR Fields Exported column</p> <p>Deleted Document Updated Record Study ID from step 37 _____ under Action section</p> <p><User Role 2> _____ under Username column</p>	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
48.	<p>Verify the following entries are listed:</p> <p>Time / Date includes Date and Time 7</p> <p>Reason for document deletion (field = 'file_upload_1' - V1): Validation Test is listed under List of Data Changes OR Fields Exported column</p> <p>Updated Record Study ID from step 37 is listed under Action section</p> <p><User Role 2> is listed under Username column</p> <p>NOTE: Due to time delay in recording and server delays +2 minutes is acceptable</p>	<p>The following entries are listed:</p> <p>Time / Date includes Date and Time 7</p> <p>Reason for document deletion (field = 'file_upload_1' - V1): Validation Test is listed under List of Data Changes OR Fields Exported column</p> <p>Updated Record Study ID from step 37 is listed under Action section</p> <p><User Role 2> is listed under Username column</p>	<p>The following entries are listed:</p> <p>Time / Date _____ Date and Time 7</p> <p>Reason for document deletion (field = 'file_upload_1' - V1): Validation Test _____ under List of Data Changes OR Fields Exported column</p> <p>Updated Record Study ID from step 37 _____ under Action section</p> <p><User Role 2> _____ under Username column</p>	<input type="checkbox"/> Pass <input type="checkbox"/> Fail

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail
49.	<p>Navigate to 'Data Exports, Reports, and Stats' tab</p> <p>Select  icon</p> <p>Select  for all records in the system</p> <p>Print, Label and Attach a screen print</p>	<p>System generates a report for all records in the system.</p> <p>Screen print attached</p>	<p>System _____ report for all records in the system.</p> <p>Attachment ID # _____</p>	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
50.	<p>Select  icon</p> <p>Select CSV / Microsoft Excel (raw data)</p> <p>Select Export Data</p> <p>Select the Excel CSV icon</p>	<p>A report in excel format is downloaded on <Test Computer></p>	<p>A report in excel format _____ downloaded on <Test Computer></p>	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
51.	<p>Open the excel spreadsheet and verify the report includes:</p> <ul style="list-style-type: none"> All Study ID's All fields mapped from eDoc form <p>Print the spreadsheet and attach it with this test protocol.</p>	<p>Report includes the following:</p> <ul style="list-style-type: none"> All Study ID's All fields mapped from eDoc form <p>Excel printout attached</p>	<p>Report _____ the following:</p> <ul style="list-style-type: none"> All Study ID's All fields mapped from eDoc form <p>Attachment ID # _____</p>	<input type="checkbox"/> Pass <input type="checkbox"/> Fail



Performance Qualification Protocol

Title: Test Script - 001

Revision: 001

Page: 24 of 25

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail
52.	Select Data Import Tool In CSV Import file, Select Chose File Select the Downloaded excel file from step 50 Select Upload File Select Import Data	System gives the following message: Import Successful! <Current Study ID's in the system> records were created or modified during the import. The data you uploaded from the file was successfully imported into the project. If you wish to import more data, you may use the box above to select another file on your computer.	System _____ the following message: Import Successful! <Current Study ID's in the system> records were created or modified during the import. The data you uploaded from the file was successfully imported into the project. If you wish to import more data, you may use the box above to select another file on your computer.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
53.	Open the record status Dashboard and verify All version of the Study ID's are listed	All version of the Study ID's are listed in the Record Status Dashboard.	All version of the Study ID's _____ in the Record Status Dashboard.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
54.	Navigate to File Comment Log Select Export Entire Log Ensure system downloads an excel file on Local Drive Verify the Excel Sheet contains the < Study ID with comments> record number with Validation Testing listed as Comment	Excel Sheet contains the < Study ID with comments> record number with Validation Testing listed as Comment	Excel Sheet _____ the < Study ID with comments> record number with Validation Testing listed as Comment	<input type="checkbox"/> Pass <input type="checkbox"/> Fail
55.	Logout of the system	Logout Successful	Logout _____	<input type="checkbox"/> Pass <input type="checkbox"/> Fail



Performance Qualification Protocol

Title: Test Script - 001

Revision: 001

Page: 25 of 25

PQ			
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>