

# **REDCap “Project/Record Lock”**

## **Performance Qualification Protocol**

University of Vanderbilt  
Medical Center  
(VUMC)

Document Version: 1.0

Document Date: 22-JUN-2020



Record Lock Performance Qualification Test  
Protocol and Test Script

Document Version: 1.0

## 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:**   
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**Title:** Compliance Consultant

**Company:** JAF Consulting Inc.

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Gaurav Kumar

Sr. Validation Consultant, JAF Consulting, Inc

### Reviewed and Approved by:

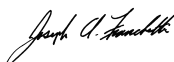
I have reviewed the contents of this document and accept and approve of the provisions as stated herein are appropriate and consistent with current regulatory expectation for computer validation, internal policies and procedures and available FDA industry Guidance and I tender it for approval.

**Signature:**   
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Rob Taylor, Technical Owner, VUMC



**Record Lock Performance Qualification Test  
Protocol and Test Script**

**Document Version: 1.0**

**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.

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Colleen Lawrence, System Owner

Joseph Franchetti, Quality Assurance Representative, JAF  
Consulting, Inc

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Rob Taylor, Technical Owner, VUMC

**Revision History**

Date	Version	Description
22-JUN-2020	01	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 record locking functionality 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 record lock 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 Development 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 URS.

**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 Record Lock Validation Master Plan (VMP)
REDCap Record Lock User Requirements Specifications (URS)
REDCap Record Lock Installation Qualification Protocol
REDCap Record Lock Operation SOP
REDCap Record Lock 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 record lock 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 record lock 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 record lock 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



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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 record lock functionality of the REDCap system at University of Vanderbilt. Record lock is a core REDCap functionality, that enables a user in administrator and / or Principle Investigator role to lock and unlock records for all instruments. Upon locking system renders a PDF copy which is reviewed by the PI and then backed up in a secured SFTP vault for retention and archival. 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 record lock functionality in REDCap system.

### 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.



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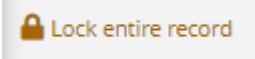
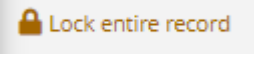

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### Prerequisites:

1. User Role 1 with Data Entry Analyst Permission: \_\_\_\_\_
2. User Role 2 with Study Coordinator Permission: \_\_\_\_\_
3. User Role 3 with Administrator Permission: \_\_\_\_\_
4. User Role 4 with Principle Investigator Permission: \_\_\_\_\_
5. Link to REDCap Development Environment: \_\_\_\_\_
6. PDF file 1 (Less than 50 mb file size): \_\_\_\_\_
7. E-mail ID: \_\_\_\_\_
8. Test Computer: \_\_\_\_\_  
(information about the machine on which testing will be performed)
9. Adobe Acrobat PDF reader version: \_\_\_\_\_

### System Test: PQ Record Lock

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail	Initials / Date
1.	Login to the redcap using <User role 1> using Link for redcap Development 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 Record Locking Validation Testing Project from the Prerequisites  Print, Label and Attach a screen print	Part 11 Record Locking project is successfully opens.  Screen print Attached	Part 11 Record Locking project is _____  Attachment: _____	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail	Initials / Date
3.	<p>Expand the Project Home and Data Collection tab.</p> <p>Verify Record Status Dashboard and Add / Edit Records are available</p> <p>Create new Study ID under Basic Demography Form Instrument type</p> <p>Upload PDF File 1 in File Upload 2</p> <p>Record the new study id number in Actual Results</p> <p>Print, Label and Attach a screen print</p>	<p>Record Status Dashboard and Add / Edit Records are available</p> <p>Study ID successfully created and Studi ID number recorded</p> <p>Screen print Attached</p>	<p>Record Status Dashboard and Add / Edit Records _____ available</p> <p>Study ID _____ created</p> <p>Study ID #: _____</p> <p>Attachment: _____</p>	<input type="checkbox"/> Pass  <input type="checkbox"/> Fail	
4.	<p>Create new record for eDocs Instrument type</p> <p>Upload PDF File 1</p> <p>Select the status of the form to be complete.</p> <p>Save and Exit the record.</p> <p>Print, Label and Attach a screen print</p>	<p>New record for eDocs is successfully created with Complete status.</p> <p>Screen print Attached</p>	<p>New record for eDocs is _____</p> <p>_____ with Complete status.</p> <p>Attachment: _____</p>	<input type="checkbox"/> Pass  <input type="checkbox"/> Fail	
5.	<p>Complete the 'Test' Data Collection Instrument.</p>	<p>'Test' data collection instrument completed.</p>	<p>'Test' data collection instrument _____</p>	<input type="checkbox"/> Pass  <input type="checkbox"/> Fail	
6.	<p>Open the Basic Demography Form</p> <p>Verify  icon is not available.</p> <p>Print, Label and Attach a screen print.</p>	<p> is not present.</p> <p>Screen print Attached</p>	<p> _____</p> <p>Attachment: _____</p>	<input type="checkbox"/> Pass  <input type="checkbox"/> Fail	
7.	<p>Logout of the system.</p>	<p>Logout successful.</p>	<p>Logout _____</p>	<input type="checkbox"/> Pass  <input type="checkbox"/> Fail	





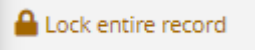


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Step	Test Instruction	Expected Result	Actual Result	Pass / Fail	Initials / Date
8.	Login to the redcap using <User role 2> using Link for redcap Development Environment  Print, Label and Attach a screen print	<User role 2> successfully logged in.  Screen print Attached	<User role 2> _____ logged in.  Attachment: _____	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
9.	Navigate and open the study id created on step 3.  Open the Basic Demography Form Select the Lock icon. Save & Exit Form  Record the date and time in DDMMYYYY and HHMM (24 hrs.) format.	The status icon next to Basic Demograhay Form has a Lock icon.  Date and Time recorded in Actual Results.	The status icon next to Basic Demograhay Form _____ Lock icon. Date: _____ Time: _____	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
10.	Open the eDocs form Select the Lock icon. Save & Exit Form	The status icon next to eDocs form has a Lock icon.	The status icon next to eDocs form _____ Lock icon.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
11.	Open the Test form Select the Lock icon. Save & Exit Form  Print, Label and Attach a screen print	The status icon next to Basic Demograhay Form has a Lock icon.  The status icon next to eDocs form has a Lock icon.  The status icon next to test form has a Lock icon.  Screen print Attached	The status icon next to Basic Demograhay Form _____ Lock icon.  The status icon next to eDocs form _____ Lock icon.  The status icon next to test form _____ Lock icon.  Attachment: _____	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail	Initials / Date
12.	<p>Open the Basic Demography Form</p> <p>Verify  icon is not available.</p> <p>Print, Label and Attach a screen print.</p>	<p> Lock entire record is not present.</p> <p>Screen print Attached</p>	<p> Lock entire record</p> <p>Attachment: _____</p>	<p><input type="checkbox"/> Pass</p> <p><input type="checkbox"/> Fail</p>	
13.	<p>Navigate to the logging tab.</p> <p>Verify the entries are captured under List of Data Changes OR Fields Exported column</p> <p>Action: Lock instrument Record: Study Id from step 3 Form: Basic Demography Form The date and time of this action matches with date and time recorded on step 9</p> <p>Action: Lock instrument Record: Study Id from step 3 Form: eDocs</p> <p>Action: Lock instrument Record: Study Id from step 3 Form: Test</p>	<p>The entries are captured under List of Data Changes OR Fields Exported column</p> <p>Action: Lock instrument Record: Study Id from step 3 Form: Basic Demography Form The date and time of this action matches with date and time recorded on step 9</p> <p>Action: Lock instrument Record: Study Id from step 3 Form: eDocs</p> <p>Action: Lock instrument Record: Study Id from step 3 Form: Test</p>	<p>The entries _____ captured under List of Data Changes OR Fields Exported column</p> <p>Action: Lock instrument Record: Study Id from step 3 Form: Basic Demography Form The date and time of this action matches with date and time recorded on step 9.</p> <p>Action: Lock instrument Record: Study Id from step 3 Form: eDocs</p> <p>Action: Lock instrument Record: Study Id from step 3 Form: Test</p>		
14.	<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>	



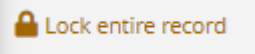
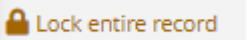
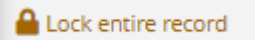
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Step	Test Instruction	Expected Result	Actual Result	Pass / Fail	Initials / Date
15.	Login to the redcap using <User role 3> using Link for redcap Development Environment  Print, Label and Attach a screen print	<User role 3> successfully logged in.  Screen print Attached	<User role 3> _____ logged in.  Attachment: _____	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
16.	Navigate and open the study id created on step 3.  Open the Basic Demography Form Select the Unlock form button. Select Unlock on the popup window. Save & Exit Form	The status icon next to Basic Demograhay Form does not have Lock icon.	The status icon next to Basic Demograhay Form _____ Lock icon.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
17.	Open the eDocs form Select the Unlock form button. Select Unlock on the popup window. Save & Exit Form	The status icon next to eDocs form does not have Lock icon.	The status icon next to eDocs form _____ Lock icon.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
18.	Open the Test form Select the Unlock form button. Select Unlock on the popup window. Save & Exit Form  Print, Label and Attach a screen print	The status icon next to Basic Demograhay Form does not have Lock icon.  The status icon next to eDocs form does not have Lock icon.  The status icon next to test form does not have Lock icon.  Screen print Attached	The status icon next to Basic Demograhay Form _____ Lock icon.  The status icon next to eDocs form _____ Lock icon.  The status icon next to test form _____ Lock icon.  Attachment: _____	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail	Initials / Date
19.	<p>Open the Basic Demography Form</p> <p>Verify  icon is not available.</p> <p>Print, Label and Attach a screen print.</p>	<p> is not present.</p> <p>Screen print Attached</p>	<p></p> <p>Attachment: _____</p>	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
20.	<p>Navigate to the logging tab.</p> <p>Verify the entries are captured under List of Data Changes OR Fields Exported column</p> <p>Action: Unlock instrument Record: Study Id from step 3 Form: Basic Demography Form</p> <p>Action: Unlock instrument Record: Study Id from step 3 Form: eDocs</p> <p>Action: Unlock instrument Record: Study Id from step 3 Form: Test</p>	<p>The entries are captured under List of Data Changes OR Fields Exported column</p> <p>Action: Unlock instrument Record: Study Id from step 3 Form: Basic Demography Form</p> <p>Action: Unlock instrument Record: Study Id from step 3 Form: eDocs</p> <p>Action: Unlock instrument Record: Study Id from step 3 Form: Test</p>	<p>The entries _____ captured under List of Data Changes OR Fields Exported column</p> <p>Action: Unlock instrument Record: Study Id from step 3 Form: Basic Demography Form</p> <p>Action: Unlock instrument Record: Study Id from step 3 Form: eDocs</p> <p>Action: Unlock instrument Record: Study Id from step 3 Form: Test</p>	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
21.	<p>Logout of the system.</p>	<p>Logout successful.</p>	<p>Logout _____</p>	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
22.	<p>Login to the redcap using &lt;User role 4&gt; using Link for redcap Development Environment</p> <p>Print, Label and Attach a screen print</p>	<p>&lt;User role 4&gt; successfully logged in.</p> <p>Screen print Attached</p>	<p>&lt;User role 4&gt; _____ logged in.</p> <p>Attachment: _____</p>	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	



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Step	Test Instruction	Expected Result	Actual Result	Pass / Fail	Initials / Date
23.	Navigate and open the study id created on step 3.  Open the Basic Demography Form Select the Lock icon. Save & Exit Form	The status icon next to Basic Demograhya Form has a Lock icon.	The status icon next to Basic Demograhya Form  _____ Lock icon.	<input type="checkbox"/> Pass  <input type="checkbox"/> Fail	
24.	Open the eDocs form Select the Lock icon. Save & Exit Form	The status icon next to eDocs form has a Lock icon.	The status icon next to eDocs form  _____ Lock icon.	<input type="checkbox"/> Pass  <input type="checkbox"/> Fail	
25.	Open the Test form Select the Lock icon. Save & Exit Form  Print, Label and Attach a screen print	The status icon next to Basic Demograhya Form has a Lock icon.  The status icon next to eDocs form has a Lock icon.  The status icon next to test form has a Lock icon.  Screen print Attached	The status icon next to Basic Demograhya Form  _____ Lock icon.  The status icon next to eDocs form  _____ Lock icon.  The status icon next to test form  _____ Lock icon.  Attachment: _____	<input type="checkbox"/> Pass  <input type="checkbox"/> Fail	






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Step	Test Instruction	Expected Result	Actual Result	Pass / Fail	Initials / Date
26.	<p>Navigate to the logging tab.</p> <p>Verify the entries are captured under List of Data Changes OR Fields Exported column</p> <p>Action: Lock instrument Record: Study Id from step 3 Form: Basic Demography Form</p> <p>Action: Lock instrument Record: Study Id from step 3 Form: eDocs</p> <p>Action: Lock instrument Record: Study Id from step 3 Form: Test</p>	<p>The entries are captured under List of Data Changes OR Fields Exported column</p> <p>Action: Lock instrument Record: Study Id from step 3 Form: Basic Demography Form</p> <p>Action: Lock instrument Record: Study Id from step 3 Form: eDocs</p> <p>Action: Lock instrument Record: Study Id from step 3 Form: Test</p>	<p>The entries _____ captured under List of Data Changes OR Fields Exported column</p> <p>Action: Lock instrument Record: Study Id from step 3 Form: Basic Demography Form</p> <p>Action: Lock instrument Record: Study Id from step 3 Form: eDocs</p> <p>Action: Lock instrument Record: Study Id from step 3 Form: Test</p>	<p><input type="checkbox"/> Pass</p> <p><input type="checkbox"/> Fail</p>	
27.	<p>Navigate and open the study id created on step 3.</p> <p>Open the Basic Demography Form Select the Unlock form button. Select Unlock on the popup window. Save &amp; Exit Form</p>	<p>The status icon next to Basic Demograhpy Form does not have Lock icon.</p>	<p>The status icon next to Basic Demograhpy Form _____ Lock icon.</p>	<p><input type="checkbox"/> Pass</p> <p><input type="checkbox"/> Fail</p>	
28.	<p>Open the eDocs form Select the Unlock form button. Select Unlock on the popup window. Save &amp; Exit Form</p>	<p>The status icon next to eDocs form does not have Lock icon.</p>	<p>The status icon next to eDocs form _____ Lock icon.</p>	<p><input type="checkbox"/> Pass</p> <p><input type="checkbox"/> Fail</p>	

Step	Test Instruction	Expected Result	Actual Result	Pass / Fail	Initials / Date
29.	<p>Open the Test form</p> <p>Select the Unlock form button.</p> <p>Select Unlock on the popup window.</p> <p>Save &amp; Exit Form</p> <p>Print, Label and Attach a screen print</p>	<p>The status icon next to Basic Demograhya Form does not have Lock icon.</p> <p>The status icon next to eDocs form does not have Lock icon.</p> <p>The status icon next to test form does not have Lock icon.</p> <p>Screen print Attached</p>	<p>The status icon next to Basic Demograhya Form</p> <p>_____ Lock icon.</p> <p>The status icon next to eDocs form</p> <p>_____ Lock icon.</p> <p>The status icon next to test form</p> <p>_____ Lock icon.</p> <p>Attachment: _____</p>	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
30.	<p>Open the Basic Demography Form</p> <p>Verify  Lock entire record icon is available.</p> <p>Print, Label and Attach a screen print.</p>	<p> Lock entire record is available.</p> <p>Screen print Attached</p>	<p> Lock entire record</p> <p>_____</p> <p>Attachment: _____</p>	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
31.	<p>Select Lock entire record icon.</p> <p>Download the PDF rendition of record id created on step 3 from the pop up window.</p>	<p>PDF rendition of record id created on step 3 successfully downloaded from the pop up window.</p>	<p>PDF rendition of record id created on step 3</p> <p>_____ downloaded from the pop up window.</p>	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	

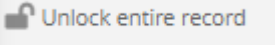
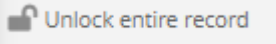


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Step	Test Instruction	Expected Result	Actual Result	Pass / Fail	Initials / Date
32.	<p>Open the PDF in from step 3 and verify the following is displayed and / or listed:</p> <p>&lt;Project Name&gt; Study ID number from step 3 [document] listed next to File Upload 2 implying that a file is uploaded on file upload 2 field. Locked by &lt;User role 2&gt; Date and Time of locking matches with the date and time entries listed on step 9.</p> <p><b>NOTE:</b> Due to server delays and latency issues the time difference between action being performed and system recording can be up to +5 minutes.</p>	<p>The following is displayed and / or matches:</p> <p>&lt;Project Name&gt; Study ID number from step 3 [document] listed next to File Upload 2 implying that a file is uploaded on file upload 2 field. Locked by &lt;User role 2&gt;. Date and Time of locking matches with the date and time entries listed on step 9.</p>	<p>The following _____ displayed and / or matches:</p> <p>&lt;Project Name&gt; Study ID number from step 3 [document] listed next to File Upload 2 implying that a file is uploaded on file upload 2 field. Locked by &lt;User role 2&gt;. Date and Time of locking matches with the date and time entries listed on step 9.</p>	<p><input type="checkbox"/> Pass</p> <p><input type="checkbox"/> Fail</p>	
33.	<p>Select the checkbox next to I approve the data that is contained in this record.</p> <p>Select Lock entire record.</p> <p>Record the date and time in DDMMYYYY and HHMM (24 hrs.) format.</p>	<p>System displays the following status:</p> <p></p> <p>Date and Time recorded in Actual Results.</p>	<p>System _____ the following status:</p> <p></p> <p>Date: _____</p> <p>Time: _____</p>	<p><input type="checkbox"/> Pass</p> <p><input type="checkbox"/> Fail</p>	
34.	<p>Navigate to Record Status Dashboard.</p> <p>Select Study ID from step 3.</p> <p>Select PDF of record data for all instruments.</p>	<p>PDF rendition of record from step 3 successfully downloaded.</p>	<p>PDF rendition of record from step 3 _____ downloaded.</p>	<p><input type="checkbox"/> Pass</p> <p><input type="checkbox"/> Fail</p>	





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Step	Test Instruction	Expected Result	Actual Result	Pass / Fail	Initials / Date
35.	Verify the following information matches between the downloaded PDF on previous step and PDF from step 31. <Project Name> Study ID number from step 3 [document] listed next to File Upload 2 implying that a file is uploaded on file upload 2 field. Locked by <User role 2> Date and Time of locking matches with the date and time entries listed on step 9.	The following information matches:  <Project Name> Study ID number from step 3 [document] listed next to File Upload 2 implying that a file is uploaded on file upload 2 field. Locked by <User role 2>. Date and Time of locking matches with the date and time entries listed on step 9.	The following information _____:  <Project Name> Study ID number from step 3 [document] listed next to File Upload 2 implying that a file is uploaded on file upload 2 field. Locked by <User role 2>. Date and Time of locking matches with the date and time entries listed on step 9.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
36.	Navigate to the logging section and verify the following entries are captured under List of Data Changes OR Fields Exported column.  <ul style="list-style-type: none"><li>Action: Lock entire record</li><li>Record: Study Id from step 3</li><li>(PDF of locked record was stored in File Repository)</li></ul> Date and Time matches with date and time recorded on step 33  <User role 4> is listed under Username.  <b>NOTE:</b> Due to server delays and latency issues the time difference between action being performed and system recording can be up to +5 minutes.	The following entries are captured under List of Data Changes OR Fields Exported column.  <ul style="list-style-type: none"><li>Action: Lock entire record</li><li>Record: Study Id from step 3</li><li>(PDF of locked record was stored in File Repository)</li></ul> Date and Time matches with date and time recorded on step 33  <User role 4> is listed under Username.	the following entries _____ captured under List of Data Changes OR Fields Exported column.  <ul style="list-style-type: none"><li>Action: Lock entire record</li><li>Record: Study Id from step 3</li><li>(PDF of locked record was stored in File Repository)</li></ul> Date and Time matches with date and time recorded on step 33  <User role 4> is listed under Username.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
37.	Coordinate with VUMC IT department and restore the PDF rendition for study id from step 3 from the Vault storage.	PDF rendition for study id from step 3 successfully recovered from the Vault storage.	PDF rendition for study id from step 3 _____ from the Vault storage.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	



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Step	Test Instruction	Expected Result	Actual Result	Pass / Fail	Initials / Date
38.	Verify the restored PDF matches with PDF downloaded on step 34.	The restored PDF matches with PDF downloaded on step 34.	The restored PDF _____ PDF downloaded on step 34.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
39.	Open the Basic Demographic form of Study Id from step 3.  Select Unlock entire record icon.  Select Unlock entire record button on the pop-up window  Print, Label and Attach a screen print.	Study Id from step 3 gets successfully unlocked.  Screenshot attached.	Study Id from step 3 gets successfully unlocked.  Attachment: _____	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
40.	Remove the PDF from File Upload 2 and upload the < PDF file 1> on File Upload 1.  Enter "Validation test of Record Lock function" in File Description 1,2,3,4 and 5. Select Complete from the dropdown list. Select Lock icon. Save & Exit Form.	Basic Demography Form has been successfully updated test instructions provided on this step.	Basic Demography Form _____ successfully updated test instructions provided on this step.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
41.	Open the Basic Demography Form. Select Lock entire record.  Download the updated rendered PDF from Review record data before locking record.	Updated rendered PDF is successfully downloaded.	Updated rendered PDF is _____ downloaded.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	

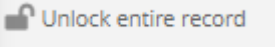
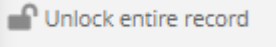


## Performance Qualification Protocol

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Step	Test Instruction	Expected Result	Actual Result	Pass / Fail	Initials / Date
42.	Select the checkbox next to I approve the data that is contained in this record.  Select Lock entire record.  Record the date and time in DDMMYYYY and HHMM (24 hrs.) format.	System displays the following status:    Date and Time recorded in Actual Results.	System _____ the following status:    Date: _____ Time: _____	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
43.	Navigate to Record Status Dashboard.  Select Study ID from step 3.  Select PDF of record data for all instruments.	PDF rendition of record from step 3 successfully downloaded.	PDF rendition of record from step 3 _____ downloaded.	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
44.	Verify the following information matches between the downloaded PDF on previous step and PDF from step 41. <Project Name> Study ID number from step 3 [document] listed next to File Upload 1 implying that a file is uploaded on file upload 1 field. Locked by <User role 2> Date and Time of locking matches with the date and time entries listed on step 42	The following information matches:  <Project Name> Study ID number from step 3 [document] listed next to File Upload 1 implying that a file is uploaded on file upload 1 field. Locked by <User role 2> Date and Time of locking matches with the date and time entries listed on step 42	The following information _____:  <Project Name> Study ID number from step 3 [document] listed next to File Upload 1 implying that a file is uploaded on file upload 1 field. Locked by <User role 2>  Date and Time of locking matches with the date and time entries listed on step 42	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	



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Step	Test Instruction	Expected Result	Actual Result	Pass / Fail	Initials / Date
45.	<p>Navigate to Record Home Page for study id created on step 3</p> <p>Select Chose action for record dropdown list.</p> <p>Select Delete Record (all forms)</p> <p>Select Delete Record on the pop window.</p> <p>Print, Label and Attach a screen print</p> <p><b>NOTE:</b> Deletion test feature will never be enabled for any user in the Production system. This function is enabled for test purposes only. If any record will be removed from the system, PHI of the patient shall be properly handled and managed prior to doing so.</p>	<p>System gives a pop-up window displaying the following message: Study ID "from step 3" was successfully deleted.</p> <p>Screen print Attached</p>	<p>System _____ pop up window displaying the following message: Study ID "from step 3" was successfully deleted.</p> <p>Attachment: _____</p>	<p><input type="checkbox"/> Pass</p> <p><input type="checkbox"/> Fail</p>	
46.	<p>Coordinate with VUMC IT department and restore the PDF rendition for study id from step 3 from the Vault storage.</p>	<p>PDF rendition for study id from step 3 successfully recovered from the Vault storage.</p>	<p>PDF rendition for study id from step 3 _____ from the Vault storage.</p>	<p><input type="checkbox"/> Pass</p> <p><input type="checkbox"/> Fail</p>	
47.	<p>Verify the restored PDF matches with PDF downloaded on step 43.</p>	<p>The restored PDF matches with PDF downloaded on step 43.</p>	<p>The restored PDF _____ PDF downloaded on step 43.</p>	<p><input type="checkbox"/> Pass</p> <p><input type="checkbox"/> Fail</p>	
48.	<p>Coordinate with VUMC IT department and restore the &lt;PDF file 1&gt; associated with study id from step 3, from the Vault storage.</p>	<p>&lt;PDF file 1&gt; associated with study id from step 3 successfully recovered from the Vault storage.</p>	<p>&lt;PDF file 1&gt; associated with study id from step 3 _____ from the Vault storage.</p>	<p><input type="checkbox"/> Pass</p> <p><input type="checkbox"/> Fail</p>	



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Step	Test Instruction	Expected Result	Actual Result	Pass / Fail	Initials / Date
49.	Navigate to the logging section select Export all Logging (CSV).  Open the spreadsheet put a filter pertaining to study id from step 3	Following events associated with to study id from step 3 are listed. <ul style="list-style-type: none"><li>• Creation</li><li>• Modification</li><li>• Update</li><li>• Deletion</li></ul>	Following events associated with to study id from step 3 _____ listed. <ul style="list-style-type: none"><li>• Creation</li><li>• Modification</li><li>• Update</li><li>• Deletion</li></ul>	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	
50.	Logout of the system.	Logout successful.	Logout _____	<input type="checkbox"/> Pass <input type="checkbox"/> Fail	



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**PQ**

**Test Summary**

**Comments/Additional Information:**

☐ **Pass** All tests/verifications were successfully completed.

☐ **Fail** Some tests/verifications were not successfully completed.

**Validation Non-Conformance  
Report No.:**

**Date Test Execution Started**

**Date Test Execution  
Completed**

**Number of Attachments:**

**Recorded By:** I performed the above testing and have accurately recorded the results.

**Reviewed By:** I have reviewed the results of the testing and they are correctly recorded. All failures are documented, and problem reports have been generated.

**Signature**

**Date**

**Signature**

**Date**











# 04 - REDCap Project-Record Lock PQ 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:	CBJCHBCAABAATA9PgSS6LaEzfcxTn64O8VX5v7jXPdZ

## "04 - REDCap Project-Record Lock PQ Test Protocol VUMC v1.0" History

-  Document created by Joseph Franchetti (jfranchetti@jafconsulting.com)  
2020-06-23 - 3:02:14 AM GMT- IP address: 73.196.185.110
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2020-06-23 - 3:03:05 AM GMT
-  Document emailed to Rob Taylor (rob.taylor@vumc.org) for signature  
2020-06-23 - 3:03:06 AM GMT
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2020-06-23 - 3:03:06 AM GMT
-  Document emailed to Joseph Franchetti (jfranchetti@jafconsulting.com) for signature  
2020-06-23 - 3:03:06 AM GMT
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Signature Date: 2020-06-23 - 3:03:13 AM GMT - Time Source: server- IP address: 73.196.185.110
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2020-06-23 - 3:09:41 AM GMT- IP address: 68.34.206.236
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Signature Date: 2020-06-23 - 4:29:37 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 - 10:33:50 AM GMT- IP address: 68.72.133.103



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

2020-06-23 - 1:37:01 PM GMT



Adobe Sign