





### Appendix 3: Deviation Report


This Report will be used to document Deviations. Make copies of this page as necessary.


Deviation Number: 003	VUMC-Record Lock-PQ-DEV-003	Script ID (s):	PQ	Script Step Number (s):	32
Test Cycle Number: 1	01	Execution Instance: Dev	Development		
Complete description of the Deviation:					
<p>Per corrective action of deviation 'VUMC-Record Lock-PQ-002', tester was instructed to create a new study id, exactly similar as study id 9, which was deleted from the system by the IT department. While creating that new study id, REDCap system didn't allow the user to create a new record id renumbered as study id 9. This issue was communicated with the IT and QA team and the following justification was provided by the IT department:</p> <p>If a record has been locked at the record level and then the record is deleted and another record is created with the same name, the new record will mistakenly be initially locked after creation and have the same lock status and lock time as the original record bearing its name. This fix was deployed in the system with a new version number of the application without any communication to the validation team along with no appropriate change management process.</p>					
Recorded By: Gaurav Kumar	 Gaurav Kumar (Aug 21, 2020 11:45 EDT)		Date:	Aug 21, 2020	
Corrective Action Plan:					
The corrective actions of this deviation are the following:					
<ol style="list-style-type: none"> <li>1. Print out release logs for REDCap application from release 1 and ,evaluate the change logs to assess impact on current validation of the system.</li> <li>2. Establish a procedural change management process for the validated instance. This process will also ensure that compliance is maintained for future software releases.</li> <li>3. Ensure REDCap system administrators are trained on the change management process.</li> <li>4. Verification of training will be by email read and understand statement.</li> <li>5. Re-execute the IQ to capture new version of REDCap.</li> </ol>					
Test Re-execution required? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO					
If YES, specify Test Script #, Step(s) including Login/Logout and Run #: N/A					
Impact Med (High, Med, Low) Med	Med		Criticality (High, Med, Low)	High	
Recorded By: Gaurav Kumar	 Gaurav Kumar (Aug 21, 2020 11:47 EDT)		Date:	Aug 21, 2020	
Approval to Proceed: Yes	 Joseph A. Franchetti		Date: 21AUG20	Aug 21, 2020	
Corrective Action Verification:					
The new change management process will be identified in the Administration SOP for REDCap system, with training type set as, Read and Understand. The verification of the training shall be done through an email verification with a list of users trained.					
Recorded By: Gaurav Umar	 Colleen E. Lawrence (Aug 21, 2020 11:59 CDT)		Date:	Aug 21, 2020	
Technical Review: Rob Taylor	 Rob Taylor (Aug 21, 2020 11:43 CDT)		Date:	Aug 21, 2020	
System Owner Colleen Lawrence	 Colleen E. Lawrence (Aug 21, 2020 11:59 CDT)		Date	Aug 21, 2020	
Approval: Joe Franchetti	 Joseph Franchetti (Aug 21, 2020 15:36 EDT)		Date: 21AUG20	Aug 21, 2020	

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# VUMC-Record Lock-PQ-DEV-003

Final Audit Report

2020-08-21

Created:	2020-08-21
By:	Joseph Franchetti (jfranchetti@jafconsulting.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAL1yiPHdyy4BgnrFzqFAWpQ0at_t6JRsq

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 Signed document emailed to Gaurav Kumar (gkumar@jafconsulting.com), Colleen E. Lawrence (colleen.lawrence@vumc.org), Gaurav Kumar (gkumar@jafconsulting.com), Joseph Franchetti (jfranchetti@jafconsulting.com), and 2 more

2020-08-21 - 7:36:22 PM GMT