University of
Massachusetts
UMASS Medical School

Appendix 3: Deviation Report

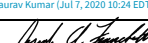This Report will be used to document Deviations. Make copies of this page as necessary.

Deviation Number:	VUMC-Record Lock-PQ-002	Script ID (s):	N/A	Script Step Number (s):	37
Test Cycle Number:	01	Execution Instance:	Development		

Complete description of the Deviation:			
During execution of REDCap "Project / Record Lock" Performance qualification protocol, the instruction on step 37 was to restore the PDF rendition of all instruments from step 37 and verify it matches with the REDCap generated PDF. The IT Department ADMIN is the only role that has the capability to delete the record from the database and this was done solely for the purpose of the testing, although in error. The step was marked as FAIL and the testing was halted.			
Recorded By:	*Gaurav Kumar (Jul 7, 2020 10:24 EDT)*	Date:	Jul 7, 2020

Corrective Action Plan:	
The root cause of this deviation is document requesting and processing error as the study id was deleted in confusion, as the rendered PDF was requested to be restored, however there were no instructions on deleting study id 9 prior to restoration. This happened by the IT department during system testing of record lock functionality in the development environment. Create a new study id as a part of pre-requisites and re-execute from step 37 and finish the testing per deviation. Make a reference of the deviation on step 37 of the PQ protocol. There will be a process defined that will instruct the IT Department ADMIN to never delete any records from the database.	

Test Re-execution required ☒ **YES** ☐ **NO**
If **YES**, specify Test Script #, Step(s) including Login/Logout and Run #:

Impact (High, Med, Low)	High	Criticality (High, Med, Low)	High
Recorded By:	*Gaurav Kumar (Jul 7, 2020 10:24 EDT)*	Date:	Jul 7, 2020
Approval to Proceed:	*Joseph A. Fanciulli*	Date:	Jul 7, 2020

Corrective Action Verification:			
Testing of REDCap "Project / Record Lock" Performance qualification protocol shall commence with a new study id as pre-requisite, from step 37. A reference of this deviation will be made to step 37.			
Recorded By:	*Gaurav Kumar (Jul 7, 2020 10:24 EDT)*	Date:	Jul 7, 2020
Technical Review:	*Rob Taylor (Jul 7, 2020 09:45 CDT)*	Date:	Jul 7, 2020
Approval:	*Joseph A. Fanciulli*	Date:	Jul 7, 2020

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VUMC-Record Lock-PQ-DEVIATION-002

Final Audit Report   2020-07-07

Created:	2020-07-07
By:	Gaurav Kumar (gkumar@jafconsulting.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAKS6QUG6CE--hJxmrcNCDIckM3jn7NY_y

"VUMC-Record Lock-PQ-DEVIATION-002" History

🗂 Document created by Gaurav Kumar (gkumar@jafconsulting.com)
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Signature Date: 2020-07-07 - 2:24:14 PM GMT - Time Source: server- IP address: 96.230.160.12

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