Installation / Operational Qualification Protocol Audit Trail

Qualification Type: OQ

<u>**Section #**</u>   <u>**Test Case**</u> <u>**Title**</u>
6.1.   1   Test Case: Procedural Controls

Test Case # 1. Test Case: Procedural Controls

Step #	**Procedure**	**Audit Trail of Changes**
Data Backup/Recovery (21 CFR 11.10(c))		

1	Verify that REDCap is backed up.	History of changes to this record as of 8/28/2018 10:28:45 AM
		  ActualResult (ExecutedActualResults) changed from 'SOP: _____' to 'See backup schedule documented in the SDS and the attached screenshot.' by Russell Barbare on 8/28/2018 10:28:45 AM
		  PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:28:45 AM
		  Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:28:45 AM
		  ExecutedActualResults changed from 'SOP: _____' to 'See backup schedule documented in the SDS and the attached screenshot.' by Russell Barbare on 8/28/2018 10:28:45 AM

Job Requirements (CFR 11.10(i) and 21 CFR 820.25(b))		

2	Verify that REDCap developers have minimum qualification requirements.	History of changes to this record as of 8/28/2018 10:37:25 AM
		  ActualResult (ExecutedActualResults) changed from 'SOP: _____' to 'REDCap developers are hired per posted job descriptions. The job descriptions are retained. "Application Developer Job Description – VICTR.pdf" saved as a product of validation.' by Russell Barbare on 8/28/2018 10:37:25 AM
		  PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:37:25 AM
		  Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:37:25 AM
		  ExecutedActualResults changed from 'SOP: _____' to 'REDCap developers are hired per posted job descriptions. The job descriptions are retained. "Application Developer Job Description – VICTR.pdf" saved as a product of validation.' by Russell Barbare on 8/28/2018 10:37:25 AM

3	Confirm that for this test case: All test case steps have been executed.	History of changes to this record as of 8/28/2018 10:37:29 AM ActualResult (ExecutedActualResults) changed from 'All test case steps _____ been executed.

Test Case # 1. Test Case: Procedural Controls

Step #	Procedure	Audit Trail of Changes

	All deviations occurring during this test case have been documented.	All deviations occurring during this test case _____ been documented. by Russell Barbare on 8/28/2018 10:37:29 AM
		  PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:37:29 AM
		  Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:37:29 AM
		  ExecutedActualResults changed from 'All test case steps _____ been executed. All deviations occurring during this test case _____ been documented. by Russell Barbare on 8/28/2018 10:37:29 AM

Qualification Type: OQ

Section #	Test Case	Title
6.2.	2	Test Case: Informed Consent Creation

Test Case # 2. Test Case: Informed Consent Creation

Step #	Procedure	Audit Trail of Changes
REDCap has operational checks to ensure informed consents are complete and correct.		

1	Log into REDCap as the project manager. Select the test project. Click Manage Survey Participants. Under the Public Survey Link tab, document the Public Survey URL.	History of changes to this record as of 8/23/2018 11:51:20 PM
		  ActualResult... changed from 'The Public Survey URL _____ documented.' to 'The Public Survey URL is _____' by Russell Barbare on 8/23/2018 11:51:20 PM
		  ActualResultsTemplate changed from 'The Public Survey URL _____ documented.' to 'The Public Survey URL is _____' by Russell Barbare on 8/23/2018 11:51:20 PM
		  ActualResult (ExecutedActualResults) changed from 'The Public Survey URL is _____' to 'The Public Survey URL is https://redcap.vanderbilt.edu/surveys/?s=K3H94M3F77' by Russell Barbare on 8/28/2018 10:39:41 AM
		  PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:39:41 AM
		  Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:39:41 AM
		  ExecutedActualResults changed from 'The Public Survey URL is _____' to 'The Public Survey URL is https://redcap.vanderbilt.edu/surveys/?s=K3H94M3F77' by Russell Barbare on 8/28/2018 10:39:41 AM

2	Log out of REDCap. Using the documented survey URL, open the survey.	History of changes to this record as of 8/28/2018 10:40:11 AM ActualResult (ExecutedActualResults) changed from 'The survey _____.' to 'The survey opens.' by Russell Barbare on 8/28/2018 10:40:11 AM

Step #	Procedure	Audit Trail of Changes
		ExecutedActualResults changed from 'The survey _____.' to 'The survey opens.' by Russell Barbare on 8/28/2018 10:40:11 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:40:27 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:40:27 AM
3	Enter an invalid date in one of the date fields and move the focus (cursor) to a different field. Verify that an error message appears.	History of changes to this record as of 8/28/2018 10:40:48 AM ActualResult (ExecutedActualResults) changed from 'An error message _____ when the user enters an invalid date. by Russell Barbare on 8/28/2018 10:40:48 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:40:48 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:40:48 AM ExecutedActualResults changed from 'An error message _____ when the user enters an invalid date. by Russell Barbare on 8/28/2018 10:40:48 AM
4	Correct or delete the invalid date. In the drop-down list, attempt to enter an item not on the list. Note: Blanks are an allowed list item.	History of changes to this record as of 8/28/2018 10:41:48 AM ActualResult (ExecutedActualResults) changed from 'The user _____ enter a list item that is not on the list. by Russell Barbare on 8/28/2018 10:41:48 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:41:48 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:41:48 AM ExecutedActualResults changed from 'The user _____ enter a list item that is not on the list. by Russell Barbare on 8/28/2018 10:41:48 AM
5	Complete part of the survey - leave at least three required fields blank. Note which required fields were left blank.	History of changes to this record as of 8/28/2018 10:43:52 AM ActualResult (ExecutedActualResults) changed from 'The blank required fields _____ documented. _____ _____ _____ … by Russell Barbare on 8/28/2018 10:43:52 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:43:52 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:43:52 AM ExecutedActualResults changed from 'The blank required fields _____ documented. _____ _____ _____ … by Russell Barbare on 8/28/2018 10:43:52 AM
6	Click Next Page. Take a screen shot of the	History of changes to this record as of 8/28/2018 10:44:35 AM

Test Case # 2. Test Case: Informed Consent Creation

Step #	Procedure	Audit Trail of Changes
	resulting message.	ActualResult (ExecutedActualResults) changed from 'The message _____ a list of all of the missing required fields. by Russell Barbare on 8/28/2018 10:44:35 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:44:35 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:44:35 AM ExecutedActualResults changed from 'The message _____ a list of all of the missing required fields. by Russell Barbare on 8/28/2018 10:44:35 AM
7	Click OK. Fill in all fields in the consent form. Document each value; use a screenshot to document the signature field. Note: For fields that are reformatted automatically, e.g., dates, document the value after the automatic formatting.	History of changes to this record as of 8/28/2018 10:47:10 AM ActualResult (ExecutedActualResults) changed from 'The consent information _____ documented. First Name: _____ Last Name: _____ Date of Birth _____ Date of Consent: _____ Consent Forms reviewed: _____ Consent Version _____ Language of Consent Reviewed: _____ Study Staff Member Conducting Consent Form Discussion: _____ Was time allowed to ask/answer questions? _____ Was/Were the Consent Form(s) signed prior to initiation of study procedures? _____ Was a copy of the signed Consent Form(s) provided to the study subject? _____ Additional Notes: _____ by Russell Barbare on 8/28/2018 10:47:10 AM ExecutedActualResults changed from 'The consent information _____ documented. First Name: _____ Last Name: _____ Date of Birth _____ Date of Consent: _____ Consent Forms reviewed: _____ Consent Version _____ Language of Consent Reviewed: _____ Study Staff Member Conducting Consent Form Discussion: _____ Was time allowed to ask/answer questions? _____ Was/Were the Consent Form(s) signed prior to initiation of study procedures? _____ Was a copy of the signed Consent Form(s) provided to the study subject? _____

Step #	Procedure	Audit Trail of Changes
		Additional Notes: _____ by Russell Barbare on 8/28/2018 10:47:10 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:47:22 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:47:22 AM

8	Document the current date and time. Click Next Page. Verify that the information in the consent form is identical to the information previously documented, included the time-date stamp at the bottom left of the form.	History of changes to this record as of 8/23/2018 11:20:35 PM
		  ActualResult (ExecutedActualResults) changed from 'The information in the consent form _____ identical to the information previosly documented by Russell Barbare on 8/23/2018 11:20:35 PM
		  ExecutedActualResults changed from 'The information in the consent form _____ identical to the information previosly documented by Russell Barbare on 8/23/2018 11:20:35 PM
		  ActualResult (ExecutedActualResults) changed from 'The information in the consent form _____ identical to the information previosly documented by Russell Barbare on 8/23/2018 11:21:56 PM
		  ExecutedActualResults changed from 'The information in the consent form _____ identical to the information previosly documented by Russell Barbare on 8/23/2018 11:21:56 PM
		  ActualResult (ExecutedActualResults) changed from 'The information in the consent form _____ identical to the information previosly documented by Russell Barbare on 8/24/2018 1:00:27 AM
		  ExecutedActualResults changed from 'The information in the consent form _____ identical to the information previosly documented by Russell Barbare on 8/24/2018 1:00:27 AM
		  ActualResult (ExecutedActualResults) changed from 'The information in the consent form _____ identical to the information previously documented by Russell Barbare on 8/28/2018 10:48:19 AM
		  PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:48:19 AM
		  Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:48:19 AM
		  ExecutedActualResults changed from 'The information in the consent form _____ identical to the information previously documented by Russell Barbare on 8/28/2018 10:48:19 AM
		  ActualResult (ExecutedActualResults) changed from 'The information in the consent form is identical to the information previously documented.
		 Current: 08/28/2018 10:47 AM Eastern by Russell Barbare on 8/28/2018 10:49:10 AM
		  ExecutedActualResults changed from 'The information in the consent form is identical to the information previously documented.
		 Current: 08/28/2018 10:47 AM Eastern by Russell Barbare on 8/28/2018 10:49:10 AM

Users signing informed consent have to agree to an accountability clause before signing.

Test Case # 2. Test Case: Informed Consent Creation

Step #	Procedure	Audit Trail of Changes

9	Document the certification statement (can copy it from the browser window).	History of changes to this record as of 8/23/2018 11:54:48 PM
		  ActualResult... changed from 'The certification statement _____ documented. _____ by Russell Barbare on 8/23/2018 11:54:48 PM
		  ActualResultsTemplate changed from 'The certification statement _____ documented. _____ by Russell Barbare on 8/23/2018 11:54:48 PM
		  ActualResult (ExecutedActualResults) changed from 'The certification statement is: _____' to 'The certification statement is: I certify that all the information in the document above is correct. I understand that clicking 'Submit' will electronically sign the form and that signing this form electronically is the equivalent of signing a physical document.' by Russell Barbare on 8/28/2018 10:49:20 AM
		  PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:49:20 AM
		  Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:49:20 AM
		  ExecutedActualResults changed from 'The certification statement is: _____' to 'The certification statement is: I certify that all the information in the document above is correct. I understand that clicking 'Submit' will electronically sign the form and that signing this form electronically is the equivalent of signing a physical document.' by Russell Barbare on 8/28/2018 10:49:20 AM

10	Check the certification. Verify that the Submit button enables.	History of changes to this record as of 8/28/2018 10:49:33 AM
		  ActualResult (ExecutedActualResults) changed from 'Checking the certification _____ the Submit button. by Russell Barbare on 8/28/2018 10:49:33 AM
		  PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:49:33 AM
		  Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:49:33 AM
		  ExecutedActualResults changed from 'Checking the certification _____ the Submit button. by Russell Barbare on 8/28/2018 10:49:33 AM

Subjects can electronically sign an informed consent form.		

11	Click Submit. Verify the survey finalization message is displayed.	History of changes to this record as of 8/28/2018 10:49:55 AM
		  ActualResult (ExecutedActualResults) changed from 'The survey finalization message _____ displayed.' to 'The survey finalization message is displayed.' by Russell Barbare on 8/28/2018 10:49:55 AM
		  PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:49:55 AM
		  Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:49:55 AM
		  ExecutedActualResults changed from 'The survey finalization message _____ displayed.' to 'The survey finalization message is displayed.' by Russell Barbare on 8/28/2018 10:49:55 AM

Step #	Procedure	Audit Trail of Changes
Subjects can complete an informed consent form.		

12	Click Download. Save the downloaded file as a product of validation.	History of changes to this record as of 8/28/2018 10:50:50 AM
		  ActualResult (ExecutedActualResults) changed from 'The downloaded file _____ saved as a product of validation. by Russell Barbare on 8/28/2018 10:50:50 AM
		  PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:50:50 AM
		  Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:50:50 AM
		  ExecutedActualResults changed from 'The downloaded file _____ saved as a product of validation. by Russell Barbare on 8/28/2018 10:50:50 AM

13	Open the downloaded file. Verify that the information in the consent form is identical to the information previously documented, included the time-date stamp at the bottom left of the form. Close the downloaded file.	History of changes to this record as of 8/23/2018 11:20:36 PM
		  ActualResult (ExecutedActualResults) changed from 'The information in the consent form _____ identical to the information previosly documented by Russell Barbare on 8/23/2018 11:20:36 PM
		  ExecutedActualResults changed from 'The information in the consent form _____ identical to the information previosly documented by Russell Barbare on 8/23/2018 11:20:36 PM
		  ActualResult (ExecutedActualResults) changed from 'The information in the consent form _____ identical to the information previosly documented by Russell Barbare on 8/23/2018 11:21:40 PM
		  ExecutedActualResults changed from 'The information in the consent form _____ identical to the information previosly documented by Russell Barbare on 8/23/2018 11:21:40 PM
		  ActualResult (ExecutedActualResults) changed from 'The information in the consent form _____ identical to the information previosly documented by Russell Barbare on 8/24/2018 1:00:28 AM
		  ExecutedActualResults changed from 'The information in the consent form _____ identical to the information previosly documented by Russell Barbare on 8/24/2018 1:00:28 AM
		  ActualResult (ExecutedActualResults) changed from 'The information in the consent form _____ identical to the information previously documented by Russell Barbare on 8/28/2018 10:51:10 AM
		  PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:51:10 AM
		  Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:51:10 AM
		  ExecutedActualResults changed from 'The information in the consent form _____ identical to the information previosly documented by Russell Barbare on 8/28/2018 10:51:10 AM

14	Redo the consent form. Use the exact same information as the prior survey, except for	History of changes to this record as of 8/28/2018 10:53:39 AM ActualResult (ExecutedActualResults) changed from 'The downloaded file _____ saved as a

Step #	Procedure	Audit Trail of Changes
	changing the Additional Notes area. Download the file and save the downloaded file as a product of validation. Note: The signature will not be identical. This is expected and is not a deviation.	product of validation. by Russell Barbare on 8/28/2018 10:53:39 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:53:39 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:53:39 AM ExecutedActualResults changed from 'The downloaded file _____ saved as a product of validation. by Russell Barbare on 8/28/2018 10:53:39 AM
15	Log into REDCap as the project manager. Select the test project. Choose File Repository (left menu) > PDF Survey Archive (tab).	History of changes to this record as of 8/28/2018 10:54:32 AM ActualResult (ExecutedActualResults) changed from 'A list of completed surveys _____ displayed.' to 'A list of completed surveys is displayed.' by Russell Barbare on 8/28/2018 10:54:32 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:54:32 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:54:32 AM ExecutedActualResults changed from 'A list of completed surveys _____ displayed.' to 'A list of completed surveys is displayed.' by Russell Barbare on 8/28/2018 10:54:32 AM
The audit trail is secure.
16	Verify that the project administrator does not have the option to delete or rename the completed surveys.	History of changes to this record as of 8/28/2018 10:54:59 AM ActualResult (ExecutedActualResults) changed from 'The project administrator does _____ have the option to delete or rename the completed surveys. by Russell Barbare on 8/28/2018 10:54:59 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:54:59 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:54:59 AM ExecutedActualResults changed from 'The project administrator does _____ have the option to delete or rename the completed surveys. by Russell Barbare on 8/28/2018 10:54:59 AM ActualResult (ExecutedActualResults) changed from 'The project administrator does does not have the option to delete or rename the completed surveys. by Russell Barbare on 8/28/2018 4:45:25 PM ExecutedActualResults changed from 'The project administrator does does not have the option to delete or rename the completed surveys. by Russell Barbare on 8/28/2018 4:45:25 PM
The audit trail is accessible for agency review and copying.
17	Download the two consent forms previously created in this test case and save them as products of validation.	History of changes to this record as of 8/28/2018 10:56:02 AM ActualResult (ExecutedActualResults) changed from 'The two consent forms previously created in this test case _____ be downloaded. by Russell Barbare on 8/28/2018 10:56:02 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:56:02 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:56:02 AM

Step #	Procedure	Audit Trail of Changes
		ExecutedActualResults changed from 'The two consent forms previously created in this test case _____ be downloaded. by Russell Barbare on 8/28/2018 10:56:02 AM
		ActualResult (ExecutedActualResults) changed from 'The two consent forms previously created in this test case can be downloaded. by Russell Barbare on 8/28/2018 10:56:24 AM
		ExecutedActualResults changed from 'The two consent forms previously created in this test case can be downloaded. by Russell Barbare on 8/28/2018 10:56:24 AM

REDCap informed consent forms can be exported in human-readable and non-proprietary readable electronic format(s).

| 18 | Verify the consent forms are human readable and can be opened by a standard pdf viewer. | History of changes to this record as of 8/28/2018 10:56:31 AM
ActualResult (ExecutedActualResults) changed from 'The consent forms _____ human readable and _____ be opened by a standard pdf viewer. by Russell Barbare on 8/28/2018 10:56:31 AM
PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:56:31 AM
Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:56:31 AM
ExecutedActualResults changed from 'The consent forms _____ human readable and _____ be opened by a standard pdf viewer. by Russell Barbare on 8/28/2018 10:56:31 AM |

The audit trail is computer generated.

| 19 | Verify that the audit trails were automatically generated for both completed surveys.
Note: The pdf copy of the survey serves as the audit trail. | History of changes to this record as of 8/28/2018 10:56:42 AM
ActualResult (ExecutedActualResults) changed from 'The audit trails _____ automatically generated.' to 'The audit trails were automatically generated.' by Russell Barbare on 8/28/2018 10:56:42 AM
PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:56:42 AM
Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:56:42 AM
ExecutedActualResults changed from 'The audit trails _____ automatically generated.' to 'The audit trails were automatically generated.' by Russell Barbare on 8/28/2018 10:56:42 AM
ActualResult (ExecutedActualResults) changed from 'The audit trails were automatically generated.' to 'The audit trails were automatically generated.
Note: The Logging function is also a functional audit trail.' by Russell Barbare on 8/28/2018 10:58:40 AM
ExecutedActualResults changed from 'The audit trails were automatically generated.' to 'The audit trails were automatically generated.
Note: The Logging function is also a functional audit trail.' by Russell Barbare on 8/28/2018 10:58:40 AM |

The audit trail has an accurate time/date stamp.

Test Case # 2. Test Case: Informed Consent Creation	
Step # **Procedure**	**Audit Trail of Changes**

20 Verify that the audit trails have an accurate time/date stamp.	History of changes to this record as of 8/28/2018 10:58:48 AM
	  ActualResult (ExecutedActualResults) changed from 'The audit trails _____ an accurate time/date stamp. by Russell Barbare on 8/28/2018 10:58:48 AM
	  PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:58:48 AM
	  Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:58:48 AM
	  ExecutedActualResults changed from 'The audit trails _____ an accurate time/date stamp. by Russell Barbare on 8/28/2018 10:58:48 AM

The audit trail records actions that create, modify, and delete electronic records.	

21 Verify that the audit trails accurately recorded the survey answers.	History of changes to this record as of 8/28/2018 10:58:54 AM
	  ActualResult (ExecutedActualResults) changed from 'The audit trails accurately _____ the survey answers. by Russell Barbare on 8/28/2018 10:58:54 AM
	  PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:58:54 AM
	  Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:58:54 AM
	  ExecutedActualResults changed from 'The audit trails accurately _____ the survey answers. by Russell Barbare on 8/28/2018 10:58:54 AM

Changes to a record do not obscure previously recorded audit trail information.	

22 Verify that the second consent form did not overwrite the prior survey.	History of changes to this record as of 8/28/2018 10:59:01 AM
	  ActualResult (ExecutedActualResults) changed from 'The second consent form did _____ overwrite the prior survey. by Russell Barbare on 8/28/2018 10:59:01 AM
	  PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:59:01 AM
	  Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:59:01 AM
	  ExecutedActualResults changed from 'The second consent form did _____ overwrite the prior survey. by Russell Barbare on 8/28/2018 10:59:01 AM

Signed informed consent forms will have the printed name of the signer and the date and time the form is signed.	

23 Verify that the consent form has the printed name of the singer.	History of changes to this record as of 8/28/2018 10:59:06 AM
	  ActualResult (ExecutedActualResults) changed from 'The consent form _____ the printed name of the singer. by Russell Barbare on 8/28/2018 10:59:06 AM
	  PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:59:06 AM
	  Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:59:06 AM
	  ExecutedActualResults changed from 'The consent form _____ the printed name of the singer. by Russell Barbare on 8/28/2018 10:59:06 AM

24 Verify that the consent form has the date and time the form was signed.	History of changes to this record as of 8/28/2018 10:59:10 AM ActualResult (ExecutedActualResults) changed from 'The consent form _____ the date and

Step #	Procedure	Audit Trail of Changes
		time the form was signed. by Russell Barbare on 8/28/2018 10:59:10 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:59:10 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:59:10 AM ExecutedActualResults changed from 'The consent form _____ the date and time the form was signed. by Russell Barbare on 8/28/2018 10:59:10 AM

The informed consent is identified as an informed consent.

Step #	Procedure	Audit Trail of Changes
25	Verify the consent form is identified as a consent form.	History of changes to this record as of 8/28/2018 10:59:14 AM ActualResult (ExecutedActualResults) changed from 'The consent form _____ identified as a consent form. by Russell Barbare on 8/28/2018 10:59:14 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:59:14 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:59:14 AM ExecutedActualResults changed from 'The consent form _____ identified as a consent form. by Russell Barbare on 8/28/2018 10:59:14 AM
26	Confirm that for this test case: All test case steps have been executed. All deviations occurring during this test case have been documented.	History of changes to this record as of 8/28/2018 10:59:18 AM ActualResult (ExecutedActualResults) changed from 'All test case steps _____ been executed. All deviations occurring during this test case _____ been documented. by Russell Barbare on 8/28/2018 10:59:18 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 10:59:18 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 10:59:18 AM ExecutedActualResults changed from 'All test case steps _____ been executed. All deviations occurring during this test case _____ been documented. by Russell Barbare on 8/28/2018 10:59:18 AM

Qualification Type: OQ

Section #	Test Case	Title
6.3.	3	Test Case: Administrative Controls

Test Case # 3. Test Case: Administrative Controls

Step #	Procedure	Audit Trail of Changes

Web access to REDCap requires end-to-end encryption.

August 28, 2018

Test Case # 3. Test Case: Administrative Controls

Step #	Procedure	Audit Trail of Changes
1	Log out of REDCap if already logged in. Navigate to http://redcap.vanderbilt.edu/. Verify that the browser redirects to https://redcap.vanderbilt.edu/.	History of changes to this record as of 8/28/2018 11:01:50 AM ActualResult (ExecutedActualResults) changed from 'The browser _____ to https://redcap.vanderbilt.edu/. by Russell Barbare on 8/28/2018 11:01:50 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 11:01:50 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 11:01:50 AM ExecutedActualResults changed from 'The browser _____ to https://redcap.vanderbilt.edu/. by Russell Barbare on 8/28/2018 11:01:50 AM
	Access to REDCap project design, settings, or controls requires an active user ID and password.	
2	Enter a valid login ID but leave the password blank. Click Log in. Document the date and time of the log in attempt.	History of changes to this record as of 8/28/2018 11:03:03 AM ActualResult (ExecutedActualResults) changed from 'The user _____ informed they have entered an invalid user name or password. Date/Time: _____ by Russell Barbare on 8/28/2018 11:03:03 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 11:03:03 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 11:03:03 AM ExecutedActualResults changed from 'The user _____ informed they have entered an invalid user name or password. Date/Time: _____ by Russell Barbare on 8/28/2018 11:03:03 AM
3	Enter a valid login ID but an invalid password. Click Log in. Document the date and time of the log in attempt.	History of changes to this record as of 8/28/2018 11:03:35 AM ActualResult (ExecutedActualResults) changed from 'The user _____ informed they have entered an invalid user name or password. by Russell Barbare on 8/28/2018 11:03:35 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 11:03:35 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 11:03:35 AM ExecutedActualResults changed from 'The user _____ informed they have entered an invalid user name or password. by Russell Barbare on 8/28/2018 11:03:35 AM ActualResult (ExecutedActualResults) changed from 'The user is informed they have entered an invalid user name or password. by Russell Barbare on 8/28/2018 11:06:04 AM ExecutedActualResults changed from 'The user is informed they have entered an invalid user name or password. by Russell Barbare on 8/28/2018 11:06:04 AM
4	Enter an invalid login ID and the correct administrator password. Document the invalid login ID.	History of changes to this record as of 8/28/2018 11:04:09 AM ActualResult (ExecutedActualResults) changed from 'The user _____ informed they have entered an invalid user name or password. by Russell Barbare on 8/28/2018 11:04:09 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 11:04:09 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 11:04:09 AM

Step #	Procedure	Audit Trail of Changes
		ExecutedActualResults changed from 'The user _____ informed they have entered an invalid user name or password. by Russell Barbare on 8/28/2018 11:04:09 AM ActualResult (ExecutedActualResults) changed from 'The user is informed they have entered an invalid user name or password. by Russell Barbare on 8/28/2018 11:06:30 AM ExecutedActualResults changed from 'The user is informed they have entered an invalid user name or password. by Russell Barbare on 8/28/2018 11:06:30 AM
5	Enter the administrator user ID and the correct password. Click Log in.	History of changes to this record as of 8/28/2018 11:04:34 AM ActualResult (ExecutedActualResults) changed from 'The user ID _____ in.' to 'The user ID logs in.' by Russell Barbare on 8/28/2018 11:04:34 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 11:04:34 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 11:04:34 AM ExecutedActualResults changed from 'The user ID _____ in.' to 'The user ID logs in.' by Russell Barbare on 8/28/2018 11:04:34 AM
	REDCap has the ability to control permissions for users with user IDs.	
6	Navigate to the User Rights tab. Identify a user other than the current user whose rights can be edited. Document the user and their current rights (screen shot OK). This user will be called the test user for subsequent steps testing this requirement.	History of changes to this record as of 8/28/2018 11:06:41 AM ActualResult (ExecutedActualResults) changed from 'A user other than the current user whose rights can be edited _____ documented. by Russell Barbare on 8/28/2018 11:06:41 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 11:06:41 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 11:06:41 AM ExecutedActualResults changed from 'A user other than the current user whose rights can be edited _____ documented. by Russell Barbare on 8/28/2018 11:06:41 AM
7	Create a new role. Set the permissions for the role to be different than the test user's permissions - add at least one permission the test user does not have and remove at least one permission the test user has. Document the role and its permissions (screen shot OK). This role will be called the test role for subsequent steps testing this requirement.	History of changes to this record as of 8/28/2018 11:09:39 AM ActualResult (ExecutedActualResults) changed from 'A test role whose permissions are different from the test user _____ documented. by Russell Barbare on 8/28/2018 11:09:39 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 11:09:39 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 11:09:39 AM ExecutedActualResults changed from 'A test role whose permissions are different from the test user _____ documented. by Russell Barbare on 8/28/2018 11:09:39 AM
8	Assign the test user to the test role. Verify the test role's permissions override the user's permissions.	History of changes to this record as of 8/28/2018 11:10:47 AM ActualResult (ExecutedActualResults) changed from 'Users _____ be assigned to a role. The role's permissions _____ the user's permissions. by Russell Barbare on 8/28/2018 11:10:47 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 11:10:47 AM

Test Case # 3. Test Case: Administrative Controls

Step #	Procedure	Audit Trail of Changes
		Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 11:10:47 AM ExecutedActualResults changed from 'Users _____ be assigned to a role. The role's permissions _____ the user's permissions. by Russell Barbare on 8/28/2018 11:10:47 AM
9	Click on the test role name beside the test user name. Attempt to delete the test role. Verify that test roles assigned to users cannot be deleted.	History of changes to this record as of 8/28/2018 11:11:24 AM ActualResult (ExecutedActualResults) changed from 'Test roles assigned to users _____ be deleted.' to 'Test roles assigned to users cannot be deleted.' by Russell Barbare on 8/28/2018 11:11:24 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 11:11:24 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 11:11:24 AM ExecutedActualResults changed from 'Test roles assigned to users _____ be deleted.' to 'Test roles assigned to users cannot be deleted.' by Russell Barbare on 8/28/2018 11:11:24 AM
10	Attempt to change the test user's permissions (click on the user ID). Verify that the only options are removing the test user from the test role or reassigning to another role.	History of changes to this record as of 8/28/2018 11:12:29 AM ActualResult (ExecutedActualResults) changed from 'When a user is assigned a role, individual permission assignments _____ disabled. by Russell Barbare on 8/28/2018 11:12:29 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 11:12:29 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 11:12:29 AM ExecutedActualResults changed from 'When a user is assigned a role, individual permission assignments _____ disabled. by Russell Barbare on 8/28/2018 11:12:29 AM
11	Choose the option to remove the test user from the test role. Note: After removal, a message may appear stating the user's permissions will remain the same as they were within the role. This is expected behavior.	History of changes to this record as of 8/28/2018 11:12:59 AM ActualResult (ExecutedActualResults) changed from 'A user _____ be removed from a role.' to 'A user can be removed from a role.' by Russell Barbare on 8/28/2018 11:12:59 AM ExecutedActualResults changed from 'A user _____ be removed from a role.' to 'A user can be removed from a role.' by Russell Barbare on 8/28/2018 11:12:59 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 11:13:09 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 11:13:09 AM
12	Attempt to change the test user's permissions (click on the user ID). Verify that the user's permissions can be changed by adding at least on permission and removing at least one permission. Document the test user and their current rights (screen shot OK).	History of changes to this record as of 8/28/2018 11:13:52 AM ActualResult (ExecutedActualResults) changed from 'User permissions _____ be changed when the user is not assigned to a role. by Russell Barbare on 8/28/2018 11:13:52 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 11:13:52 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 11:13:52 AM ExecutedActualResults changed from 'User permissions _____ be changed when the user is not assigned to a role. by Russell Barbare on 8/28/2018 11:13:52 AM

Step #	Procedure	Audit Trail of Changes

13	Delete the test role.	History of changes to this record as of 8/28/2018 11:14:17 AM
		  ActualResult (ExecutedActualResults) changed from 'Roles _____ be deleted.' to 'Roles can be deleted.' by Russell Barbare on 8/28/2018 11:14:17 AM
		  PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 11:14:17 AM
		  Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 11:14:17 AM
		  ExecutedActualResults changed from 'Roles _____ be deleted.' to 'Roles can be deleted.' by Russell Barbare on 8/28/2018 11:14:17 AM

14	Navigate to the Data Access Groups tab. Create a Data Access Group and document the name.	History of changes to this record as of 8/28/2018 11:24:29 AM
		  ActualResult (ExecutedActualResults) changed from 'Data Access Groups _____ be created.' to 'Data Access Groups can be created.' by Russell Barbare on 8/28/2018 11:24:29 AM
		  PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 11:24:29 AM
		  Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 11:24:29 AM
		  ExecutedActualResults changed from 'Data Access Groups _____ be created.' to 'Data Access Groups can be created.' by Russell Barbare on 8/28/2018 11:24:29 AM
		  ActualResult (ExecutedActualResults) changed from 'Data Access Groups can be created.' to 'Data Access Groups can be created.
		Group: test_for_val' by Russell Barbare on 8/28/2018 11:24:52 AM
		  ExecutedActualResults changed from 'Data Access Groups can be created.' to 'Data Access Groups can be created.
		Group: test_for_val' by Russell Barbare on 8/28/2018 11:24:52 AM

15	Assign the test user to the Data Access Group.	History of changes to this record as of 8/28/2018 11:25:07 AM
		  ActualResult (ExecutedActualResults) changed from 'Users _____ be assigned to Data Access Groups.' to 'Users can be assigned to Data Access Groups.' by Russell Barbare on 8/28/2018 11:25:07 AM
		  PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 11:25:07 AM
		  Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 11:25:07 AM
		  ExecutedActualResults changed from 'Users _____ be assigned to Data Access Groups.' to 'Users can be assigned to Data Access Groups.' by Russell Barbare on 8/28/2018 11:25:07 AM

16	Create a second Data Access Group and document the name. Reassign the test user to the newly-created group.	History of changes to this record as of 8/28/2018 11:25:47 AM
		  ActualResult (ExecutedActualResults) changed from 'Users _____ be transferred to different Data Access Groups. by Russell Barbare on 8/28/2018 11:25:47 AM
		  PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 11:25:47 AM
		  Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 11:25:47 AM

Step #	Procedure	Audit Trail of Changes
		ExecutedActualResults changed from 'Users _____ be transferred to different Data Access Groups. by Russell Barbare on 8/28/2018 11:25:47 AM
17	Delete the Data Access Group without the user. Delete the Data Access Group with the user. Navigate to the User Rights tab and verify the test user is still listed.	History of changes to this record as of 8/28/2018 11:26:13 AM ActualResult (ExecutedActualResults) changed from 'Data Access Groups with and without users _____ be deleted. by Russell Barbare on 8/28/2018 11:26:13 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 11:26:13 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 11:26:13 AM ExecutedActualResults changed from 'Data Access Groups with and without users _____ be deleted. by Russell Barbare on 8/28/2018 11:26:13 AM ActualResult (ExecutedActualResults) changed from 'Data Access Groups with and without users can be deleted. by Russell Barbare on 8/28/2018 11:35:22 AM ExecutedActualResults changed from 'Data Access Groups with and without users can be deleted. by Russell Barbare on 8/28/2018 11:35:22 AM ActualResult (ExecutedActualResults) changed from 'Data Access Groups without users can be deleted.' to 'Data Access Groups without users can be deleted. Data Access Groups with users cannot be deleted; this is a script error, see the deviation. The step passes by removing 'with and' from the Expected Result.' by Russell Barbare on 8/28/2018 11:41:44 AM ExecutedActualResults changed from 'Data Access Groups without users can be deleted.' to 'Data Access Groups without users can be deleted. Data Access Groups with users cannot be deleted; this is a script error, see the deviation. The step passes by removing 'with and' from the Expected Result.' by Russell Barbare on 8/28/2018 11:41:44 AM
Significant REDCap meta-data can be exported in human-readable and readable non-proprietary electronic format(s).	
18	Click Logging (left menu). Click 'Download entire logging record to Microsoft Excel (CSV)'. Save the download as a product of validation.	History of changes to this record as of 8/28/2018 11:42:35 AM ActualResult (ExecutedActualResults) changed from 'The event log _____ saved as a product of validation. by Russell Barbare on 8/28/2018 11:42:35 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 11:42:35 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 11:42:35 AM ExecutedActualResults changed from 'The event log _____ saved as a product of validation. by Russell Barbare on 8/28/2018 11:42:35 AM
19	Open the log. Verify that it is in CSV format. Verify that it shows the changes to the user account tested previously in this test case, the downloads made previously in this test	History of changes to this record as of 8/28/2018 11:45:44 AM ActualResult (ExecutedActualResults) changed from 'The log _____ in CSV format. The log _____ changes to the user accounts, downloads, and form changes. by Russell Barbare on 8/28/2018 11:45:44 AM

Step #	Procedure	Audit Trail of Changes
	case, and form changes made previously in this test case. Note: The user permissions change event shows that permissions changed, but not exactly which ones changed. This is expected. The log shows additional events also; these do not have to be checked.	PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 11:45:44 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 11:45:44 AM ExecutedActualResults changed from 'The log _____ in CSV format. The log _____ changes to the user accounts, downloads, and form changes. by Russell Barbare on 8/28/2018 11:45:44 AM
	REDCap electronic signatures can use identification components, included those that are designed to be used only by the individual.	

20	Navigate to the informed consent module design form. If a signature field is not already in the informed consent, add one and make it a required field.	History of changes to this record as of 8/28/2018 11:47:31 AM
		  ActualResult (ExecutedActualResults) changed from 'The informed consent design _____ a required signature field. by Russell Barbare on 8/28/2018 11:47:31 AM
		  PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 11:47:31 AM
		  Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 11:47:31 AM
		  ExecutedActualResults changed from 'The informed consent design _____ a required signature field. by Russell Barbare on 8/28/2018 11:47:31 AM

21	If a birthday field is not already in the informed consent, add one and make it a required field.	History of changes to this record as of 8/28/2018 11:47:48 AM
		  ActualResult (ExecutedActualResults) changed from 'The informed consent design _____ a required birthday field. by Russell Barbare on 8/28/2018 11:47:48 AM
		  PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 11:47:48 AM
		  Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 11:47:48 AM
		  ExecutedActualResults changed from 'The informed consent design _____ a required birthday field. by Russell Barbare on 8/28/2018 11:47:48 AM

22	If a field asking for the last four digits of the user's SSN is not already in the informed consent, add one and make it a required field.	History of changes to this record as of 8/28/2018 11:48:21 AM
		  ActualResult (ExecutedActualResults) changed from 'The informed consent design _____ a required field asking for the last four digits of the user's SSN. by Russell Barbare on 8/28/2018 11:48:21 AM
		  PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 11:48:21 AM
		  Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 11:48:21 AM
		  ExecutedActualResults changed from 'The informed consent design _____ a required field asking for the last four digits of the user's SSN. by Russell Barbare on 8/28/2018 11:48:21 AM

23	Log out of the administrator account. Open the informed consent form as a study participant. Verify that the signature,	History of changes to this record as of 8/28/2018 11:50:40 AM ActualResult (ExecutedActualResults) changed from 'The signature, birthday, and SSN fields _____ in the form and _____ required fields. by Russell Barbare on 8/28/2018 11:50:40 AM

Step #	Procedure	Audit Trail of Changes
	birthday, and SSN fields are in the form and are required fields.	PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 11:50:40 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 11:50:40 AM ExecutedActualResults changed from 'The signature, birthday, and SSN fields _____ in the form and _____ required fields. by Russell Barbare on 8/28/2018 11:50:40 AM
24	Complete the informed consent, submit it, and save it as a product of validation.	History of changes to this record as of 8/28/2018 11:51:23 AM ActualResult (ExecutedActualResults) changed from 'The completed form _____ saved as a product of validation. by Russell Barbare on 8/28/2018 11:51:23 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 11:51:23 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 11:51:23 AM ExecutedActualResults changed from 'The completed form _____ saved as a product of validation. by Russell Barbare on 8/28/2018 11:51:23 AM
	REDCap allows project administrators to enter a server to automatically archive informed consents to.	
25	Log into REDCap as a project administrator. Verify that REDCap project managers can set auto-upload and cloud storage options. Record a screen shot of the storage settings. Note: Verify the options are available on-screen. Verification of actual file transfer is outside the scope of this protocol.	History of changes to this record as of 8/28/2018 11:57:48 AM ActualResult (ExecutedActualResults) changed from 'REDCap project managers _____ set auto-upload and cloud storage options. by Russell Barbare on 8/28/2018 11:57:48 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 11:57:48 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 11:57:48 AM ExecutedActualResults changed from 'REDCap project managers _____ set auto-upload and cloud storage options. by Russell Barbare on 8/28/2018 11:57:48 AM
26	Verify that REDCap project managers can set external storage settings for the e-consent framework. Record a screen shot of the external storage settings. Note: Verify the options are available on-screen. Verification of actual file transfer is outside the scope of this protocol.	History of changes to this record as of 8/28/2018 11:59:19 AM ActualResult (ExecutedActualResults) changed from 'REDCap project managers _____ set external storage settings for the e-consent framework. by Russell Barbare on 8/28/2018 11:59:19 AM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 11:59:19 AM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 11:59:19 AM ExecutedActualResults changed from 'REDCap project managers _____ set external storage settings for the e-consent framework. by Russell Barbare on 8/28/2018 11:59:19 AM
	REDCap passwords expire.	
27	The following steps require help from Vanderbilt personnel. Verify that REDCap passwords expire. Record a screenshot of the expiration setting.	History of changes to this record as of 8/28/2018 12:12:46 PM ActualResult (ExecutedActualResults) changed from 'REDCap passwords _____.' to 'REDCap passwords expire.' by Russell Barbare on 8/28/2018 12:12:46 PM PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 12:12:46 PM Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 12:12:46 PM

Test Case # 3. Test Case: Administrative Controls

Step #	Procedure	Audit Trail of Changes
		ExecutedActualResults changed from 'REDCap passwords _____.' to 'REDCap passwords expire.' by Russell Barbare on 8/28/2018 12:12:46 PM ActualResult (ExecutedActualResults) changed from 'REDCap passwords expire.' to 'REDCap passwords expire. Screenshot from policy "IM SOP - VUMC Password Management"' by Russell Barbare on 8/28/2018 12:14:33 PM ExecutedActualResults changed from 'REDCap passwords expire.' to 'REDCap passwords expire. Screenshot from policy "IM SOP - VUMC Password Management"' by Russell Barbare on 8/28/2018 12:14:33 PM

REDCap passwords have minimum complexity requirements.

| 28 | Verify that REDCap passwords have minimum complexity requirements. Record a screenshot of the settings. | History of changes to this record as of 8/28/2018 12:14:41 PM
ActualResult (ExecutedActualResults) changed from 'REDCap passwords _____ minimum complexity requirements. by Russell Barbare on 8/28/2018 12:14:41 PM
PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 12:14:41 PM
Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 12:14:41 PM
ExecutedActualResults changed from 'REDCap passwords _____ minimum complexity requirements. by Russell Barbare on 8/28/2018 12:14:41 PM
ActualResult (ExecutedActualResults) changed from 'REDCap passwords have minimum complexity requirements. by Russell Barbare on 8/28/2018 12:14:53 PM
ExecutedActualResults changed from 'REDCap passwords have minimum complexity requirements. by Russell Barbare on 8/28/2018 12:14:53 PM |

Repeated successive invalid login attempts will lock out the REDCap user ID.

| 29 | Verify that REDCap user accounts are set to lock out after a number of invalid login attempts. Record a screenshot of the setting. | History of changes to this record as of 8/28/2018 12:33:44 PM
ActualResult (ExecutedActualResults) changed from 'REDCap user accounts _____ set to lock out after a number of invalid login attempts. by Russell Barbare on 8/28/2018 12:33:44 PM
PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 12:33:44 PM
Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 12:33:44 PM
ExecutedActualResults changed from 'REDCap user accounts _____ set to lock out after a number of invalid login attempts. by Russell Barbare on 8/28/2018 12:33:44 PM
ActualResult (ExecutedActualResults) changed from 'REDCap user accounts are set to lock out after a number of invalid login attempts. by Russell Barbare on 8/28/2018 12:34:15 PM
ExecutedActualResults changed from 'REDCap user accounts are set to lock out after a |

Step #	Procedure	Audit Trail of Changes
		number of invalid login attempts. by Russell Barbare on 8/28/2018 12:34:15 PM

Invalid login attempts are logged.

Step #	Procedure	Audit Trail of Changes

30	Verify that the invalid login attempts in the Informed Consent Creation test case were logged. Record a screenshot of the log.	History of changes to this record as of 8/28/2018 12:20:28 PM
		  ActualResult (ExecutedActualResults) changed from 'REDCap _____ invalid login attempts.' to 'REDCap logs invalid login attempts.' by Russell Barbare on 8/28/2018 12:20:28 PM
		  PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 12:20:28 PM
		  Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 12:20:28 PM
		  ExecutedActualResults changed from 'REDCap _____ invalid login attempts.' to 'REDCap logs invalid login attempts.' by Russell Barbare on 8/28/2018 12:20:28 PM

REDCap logs out or locks after a period of inactivity.

Step #	Procedure	Audit Trail of Changes

31	Verify that REDCap logs out or locks after a period of inactivity. Record a screenshot of the setting.	History of changes to this record as of 8/28/2018 12:18:37 PM
		  ActualResult (ExecutedActualResults) changed from 'REDCap _____ after a period of inactivity.' to 'REDCap logs out after a period of inactivity.' by Russell Barbare on 8/28/2018 12:18:37 PM
		  PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 12:18:37 PM
		  Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 12:18:37 PM
		  ExecutedActualResults changed from 'REDCap _____ after a period of inactivity.' to 'REDCap logs out after a period of inactivity.' by Russell Barbare on 8/28/2018 12:18:37 PM

32	Confirm that for this test case:
	 All test case steps have been executed.
	 All deviations occurring during this test case have been documented.
		History of changes to this record as of 8/28/2018 12:34:20 PM
		  ActualResult (ExecutedActualResults) changed from 'All test case steps _____ been executed. All deviations occurring during this test case _____ been documented. by Russell Barbare on 8/28/2018 12:34:20 PM
		  PassFail....... Data Added: Pass by Russell Barbare on 8/28/2018 12:34:20 PM
		  Initials....... Data Added: RRB by Russell Barbare on 8/28/2018 12:34:20 PM
		  ExecutedActualResults changed from 'All test case steps _____ been executed. All deviations occurring during this test case _____ been documented. by Russell Barbare on 8/28/2018 12:34:20 PM