

Installation / Operational Qualification Protocol

Qualification Type: OQ

Section # **Test Case #** **Title**
6.1. 1 Test Case: Procedural Controls

Purpose

To document procedural controls

Acceptance Criteria

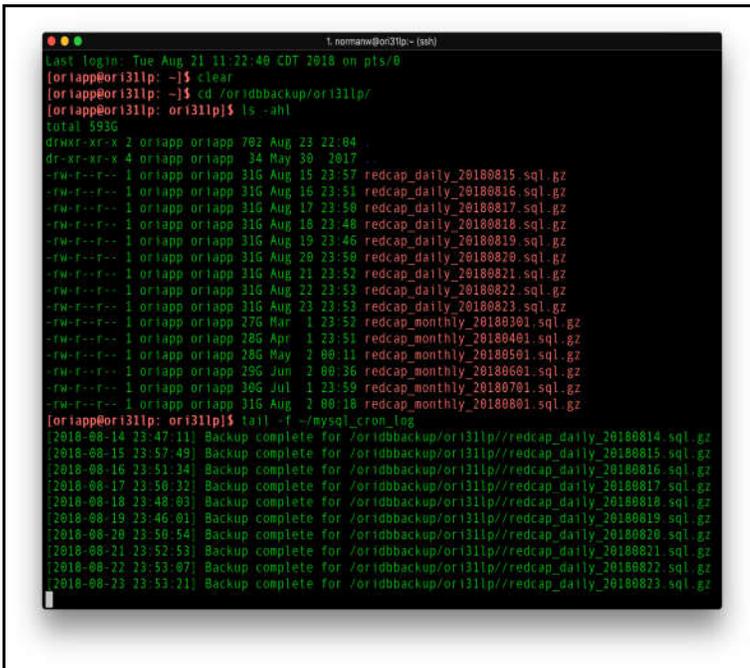
REDCap is backed up.

Vanderbilt has appropriate hiring procedures for REDCap developers.

Test Case 1. Test Case: Procedural Controls

Step #	Procedure	Expected Result	Actual Result	P / F	Init.	Date
Data Backup/Recovery (21 CFR 11.10(c))						
1	Verify that REDCap is backed up.	REDCap is backed up.	See backup schedule documented in the SDS and the attached screenshot.	Pass	RRB	28-Aug-18

Snapshot from test step #1



Test Case 1. Test Case: Procedural Controls

Step #	Procedure	Expected Result	Actual Result	P / F	Init.	Date
Job Requirements (CFR 11.10(i) and 21 CFR 820.25(b))						
2	Verify that REDCap developers have minimum qualification requirements.	REDCap developers have minimum qualification requirements.	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.	Pass	RRB	28-Aug-18
3	Confirm that for this test case: All test case steps have been executed. All deviations occurring during this test case have been documented.	All test case steps have been executed. All deviations occurring during this test case have been documented.	All test case steps have been executed. All deviations occurring during this test case have been documented.	Pass	RRB	28-Aug-18

Qualification Type: OQ

<u>Section #</u>	<u>Test Case #</u>	<u>Title</u>
6.2.	2	Test Case: Informed Consent Creation

Purpose

To verify Informed Consent creation

Acceptance Criteria

REDCap has operational checks to ensure informed consents are complete and correct.

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

Subjects can electronically sign an informed consent form.

Subjects can complete an informed consent form.

The audit trail is secure.

The audit trail is accessible for agency review and copying.

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

The audit trail is computer generated.

The audit trail has an accurate time/date stamp.

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

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

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

The informed consent is identified as an informed consent.

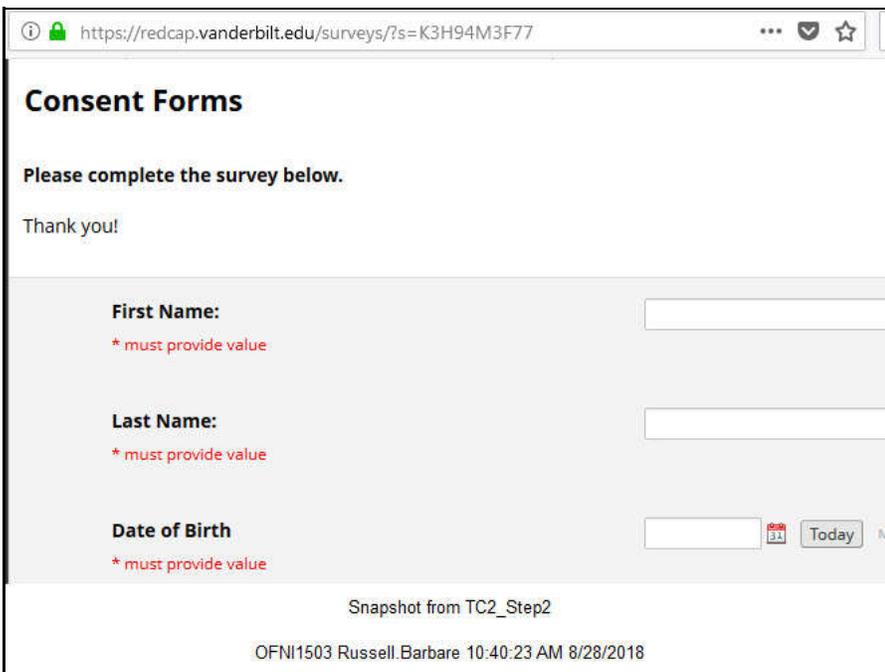
Test Case 2. Test Case: Informed Consent Creation

<u>Step #</u>	<u>Procedure</u>	<u>Expected Result</u>	<u>Actual Result</u>	<u>P / F</u>	<u>Init.</u>	<u>Date</u>
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.	The Public Survey URL is documented.	The Public Survey URL is https://redcap.vanderbilt.edu/surveys/?s=K3H94M3F77	Pass	RRB	28-Aug-18
2	Log out of REDCap. Using the documented survey URL, open the survey.	The survey opens.	The survey opens.	Pass	RRB	28-Aug-18

Test Case 2. Test Case: Informed Consent Creation

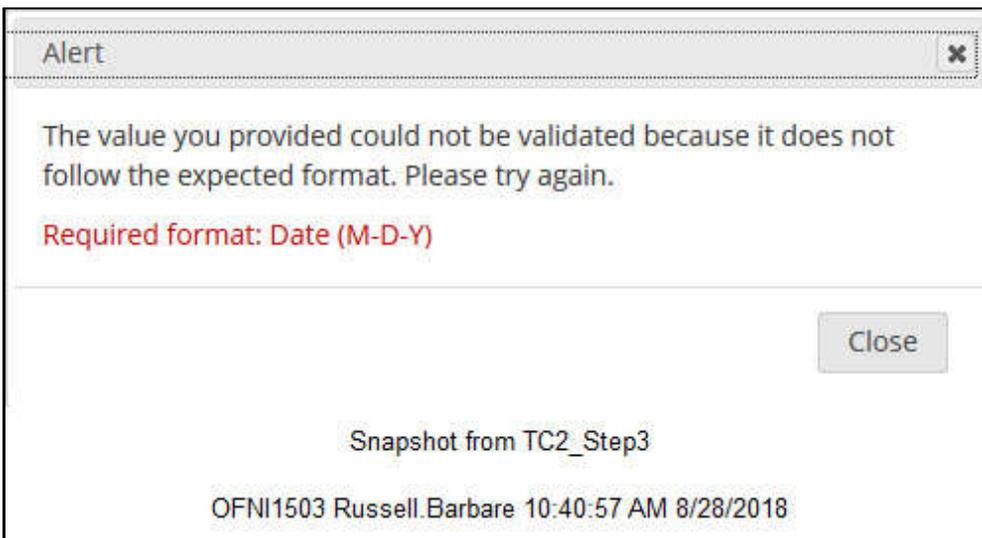
Step #	Procedure	Expected Result	Actual Result	P / F	Init.	Date
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Snapshot from test step #2



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.	An error message appears when the user enters an invalid date.	An error message appears when the user enters an invalid date.	Pass	RRB	28-Aug-18
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Snapshot from test step #3

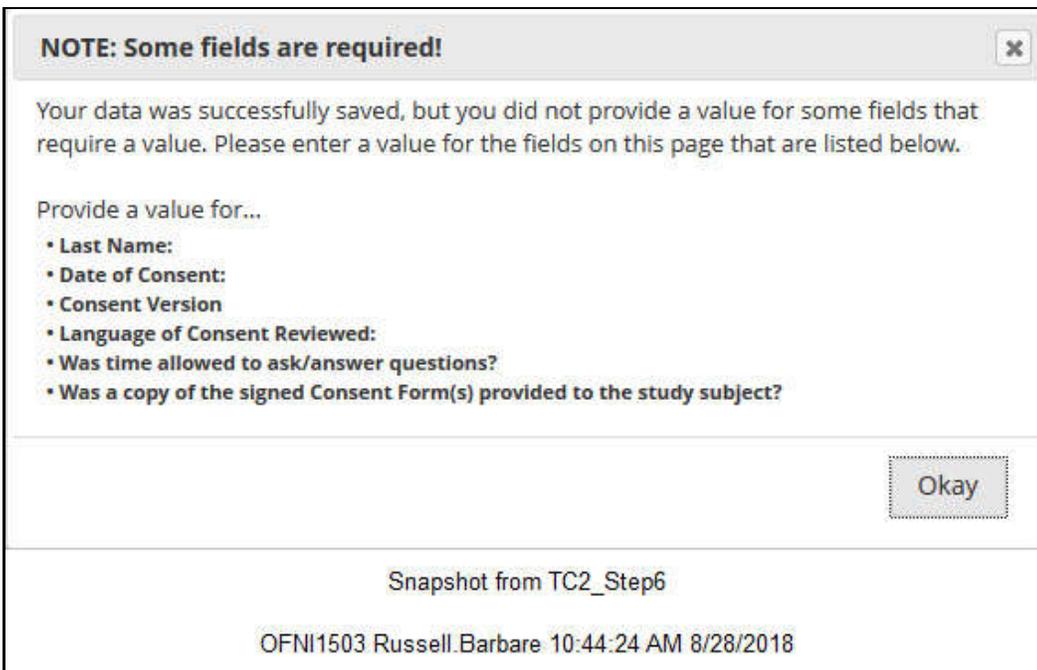


4	Correct or delete the invalid date. In the drop-down list, attempt to enter an item not on the list. Note: Blanks are an allowed list item.	The user cannot enter a list item that is not on the list.	The user cannot enter a list item that is not on the list.	Pass	RRB	28-Aug-18
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Test Case 2. Test Case: Informed Consent Creation

Step #	Procedure	Expected Result	Actual Result	P / F	Init.	Date
5	Complete part of the survey - leave at least three required fields blank. Note which required fields were left blank.	The blank required fields are documented.	The blank required fields are documented. Last Name Date of Consent Consent Version Language of Consent Reviewed Was time allowed to ask/answer questions? Was a copy of the signed Consent Form(s) provided to the study subject? ...	Pass	RRB	28-Aug-18
6	Click Next Page. Take a screen shot of the resulting message.	The message displays a list of all of the missing required fields.	The message displays a list of all of the missing required fields.	Pass	RRB	28-Aug-18

Snapshot from test step #6



Test Case 2. Test Case: Informed Consent Creation

Step #	Procedure	Expected Result	Actual Result	P / F	Init.	Date
7	<p>Click OK. Fill in all fields in the consent form. Document each value; use a screenshot to document the signature field.</p> <p>Note: For fields that are reformatted automatically, e.g., dates, document the value after the automatic formatting.</p>	The consent information is documented.	<p>The consent information is documented.</p> <p>First Name: Joe Last Name: Average Date of Birth 08-20-1980 Last 4 digits of the participant Social Security Number 5555 Date of Consent: 08-28-2018 Consent Forms reviewed: Main Study Consent Form Consent Version 1.0 Language of Consent Reviewed: English Study Staff Member Conducting Consent Form Discussion: Kendra Malone Was time allowed to ask/answer questions? Yes Was/Were the Consent Form(s) signed prior to initiation of study procedures? Yes Was a copy of the signed Consent Form(s) provided to the study subject? Yes Additional Notes: None Signature documented by screen shot.</p>	Pass	RRB	28-Aug-18

Test Case 2. Test Case: Informed Consent Creation

Step #	Procedure	Expected Result	Actual Result	P / F	Init.	Date
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Snapshot from test step #7

Signature for Consent
* must provide value



[signature_2018-08-28_0942.png \(0.01 MB\)](#)

Snapshot from TC2_Step7

OFNI1503 Russell.Barbare 10:47:18 AM 8/28/2018

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.	The information in the consent form is identical to the information previously documented	The information in the consent form is identical to the information previously documented. Current: 08/28/2018 10:47 AM Eastern Note: The time stamp is in Central time. This is expected due to the location of REDCap servers.	Pass	RRB	28-Aug-18
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Snapshot from test step #8

08/28/2018 9:47am Joe Average, 1980-08-20, Version: 1, Type: Testing 

Snapshot from TC2_Step8

OFNI1503 Russell.Barbare 10:48:30 AM 8/28/2018

Test Case 2. Test Case: Informed Consent Creation

Step #	Procedure	Expected Result	Actual Result	P / F	Init.	Date
Users signing informed consent have to agree to an accountability clause before signing.						
9	Document the certification statement (can copy it from the browser window).	The certification statement is documented.	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.	Pass	RRB	28-Aug-18
10	Check the certification. Verify that the Submit button enables.	Checking the certification enables the Submit button.	Checking the certification enables the Submit button.	Pass	RRB	28-Aug-18

Snapshot from test step #10

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.

If any information above is not correct, you may click the 'Previous Page' button to go back and correct it.

<< Previous Page

Submit

Snapshot from TC2_Step10

OFNI1503 Russell.Barbare 10:49:42 AM 8/28/2018

Subjects can electronically sign an informed consent form.

11	Click Submit. Verify the survey finalization message is displayed.	The survey finalization message is displayed.	The survey finalization message is displayed.	Pass	RRB	28-Aug-18
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Test Case 2. Test Case: Informed Consent Creation

Step #	Procedure	Expected Result	Actual Result	P / F	Init.	Date
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Snapshot from test step #11

Close survey

Thank you for taking the survey.

Have a nice day!

Download your survey response (PDF): Download

Snapshot from TC2_Step11

OFNI1503 Russell.Barbare 10:50:09 AM 8/28/2018

Subjects can complete an informed consent form.

12	Click Download. Save the downloaded file as a product of validation.	The downloaded file is saved as a product of validation.	The downloaded file is saved as a product of validation. File: ConsentForms_EC onsentPart11Cer_2 018-08- 28_0950.pdf	Pass	RRB	28-Aug-18
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.	The information in the consent form is identical to the information previously documented	The information in the consent form is identical to the information previously documented	Pass	RRB	28-Aug-18
14	Redo the consent form. Use the exact same information as the prior survey, except for 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.	The downloaded file is saved as a product of validation.	The downloaded file is saved as a product of validation. File: ConsentForms_EC onsentPart11Cer_2 018-08- 28_0953.pdf	Pass	RRB	28-Aug-18

Test Case 2. Test Case: Informed Consent Creation

Step #	Procedure	Expected Result	Actual Result	P / F	Init.	Date
15	Log into REDCap as the project manager. Select the test project. Choose File Repository (left menu) > PDF Survey Archive (tab).	A list of completed surveys is displayed.	A list of completed surveys is displayed.	Pass	RRB	28-Aug-18

Snapshot from test step #15

File Repository

This page may be used for storing and retrieving files and documents used for this project. You may upload files here to save for retrieval later, or you may download previously uploaded files in the file list below. Whenever a data export is performed, the resulting data and syntax files are stored here also.

[User Files](#)
[Data Export Files](#)
[PDF Survey Archive](#)
[Upload New File](#)

Displayed below are PDF files that have been automatically captured and stored by the PDF Auto-Archiver setting, which has been enabled by one or more surveys on their Survey Settings page. Only users with 'Full data set' data export privileges will be able to download the archived files. Note: The PDFs below are archived when a participant completes a survey, which means they might be different from other downloadable PDFs in the project that are generated on demand using the current data.

Show entries

Survey Completion Time	Record	Survey	Identifier (Name, DOB)	IP Address	Version	Type	Download
08/28/2018 9:52am	11	Consent Forms	Joe Average, 1980-08-20	99.32.253.114	1	Testing	
08/28/2018 9:49am	10	Consent Forms	Joe Average, 1980-08-20	99.32.253.114	1	Testing	

Snapshot from TC2_Step15

OFNI1503 Russell.Barbare 10:54:50 AM 8/28/2018

The audit trail is secure.

16	Verify that the project administrator does not have the option to delete or rename the completed surveys.	The project administrator does not have the option to delete or rename the completed surveys.	The project administrator does not have the option to delete or rename the completed surveys.	Pass	RRB	28-Aug-18
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Test Case 2. Test Case: Informed Consent Creation

Step #	Procedure	Expected Result	Actual Result	P / F	Init.	Date
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.	The two consent forms previously created in this test case can be downloaded.	The two consent forms previously created in this test case can be downloaded. Files: Joe_Average_1980-08-20_pid76359_form Consent_Forms_id 10_2018-08-28_094951.pdf, Joe_Average_1980-08-20_pid76359_form Consent_Forms_id 11_2018-08-28_095256.pdf	Pass	RRB	28-Aug-18
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.	The consent forms are human readable and can be opened by a standard pdf viewer.	The consent forms are human readable and can be opened by a standard pdf viewer.	Pass	RRB	28-Aug-18
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.	The audit trails were automatically generated.	The audit trails were automatically generated. Note: The Logging function is also a functional audit trail.	Pass	RRB	28-Aug-18
The audit trail has an accurate time/date stamp.						
20	Verify that the audit trails have an accurate time/date stamp.	The audit trails have an accurate time/date stamp.	The audit trails have an accurate time/date stamp.	Pass	RRB	28-Aug-18
The audit trail records actions that create, modify, and delete electronic records.						
21	Verify that the audit trails accurately recorded the survey answers.	The audit trails accurately recorded the survey answers.	The audit trails accurately have the survey answers.	Pass	RRB	28-Aug-18

Test Case 2. Test Case: Informed Consent Creation

Step #	Procedure	Expected Result	Actual Result	P / F	Init.	Date
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.	The second consent form did not overwrite the prior survey.	The second consent form did not overwrite the prior survey.	Pass	RRB	28-Aug-18
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.	The consent form has the printed name of the singer.	The consent form has the printed name of the singer.	Pass	RRB	28-Aug-18
24	Verify that the consent form has the date and time the form was signed.	The consent form has the date and time the form was signed.	The consent form has the date and time the form was signed.	Pass	RRB	28-Aug-18
The informed consent is identified as an informed consent.						
25	Verify the consent form is identified as a consent form.	The consent form is identified as a consent form.	The consent form is identified as a consent form.	Pass	RRB	28-Aug-18
26	Confirm that for this test case: All test case steps have been executed. All deviations occurring during this test case have been documented.	All test case steps have been executed. All deviations occurring during this test case have been documented.	All test case steps have been executed. All deviations occurring during this test case have been documented.	Pass	RRB	28-Aug-18

Qualification Type: OQ

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

Purpose

To verify administrative controls

Acceptance Criteria

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

Access to REDCap project design, settings, or controls requires an active user ID and password.

Significant REDCap meta-data can be exported in human-readable and readable non-proprietary electronic format(s).

REDCap electronic signatures can use identification components, included those that are designed to be used only by the individual.

REDCap allows project administrators to enter a server to automatically archive informed consents to.

REDCap has the ability to control permissions for users with user IDs.

REDCap passwords expire.

REDCap passwords have minimum complexity requirements.

Invalid login attempts are logged.

Test Case 3. Test Case: Administrative Controls

Step #	Procedure	Expected Result	Actual Result	P / F	Init.	Date
Web access to REDCap requires end-to-end encryption.						
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/ .	The browser redirects to https://redcap.vanderbilt.edu/ .	The browser redirects to https://redcap.vanderbilt.edu/ .	Pass	RRB	28-Aug-18

Snapshot from test step #1



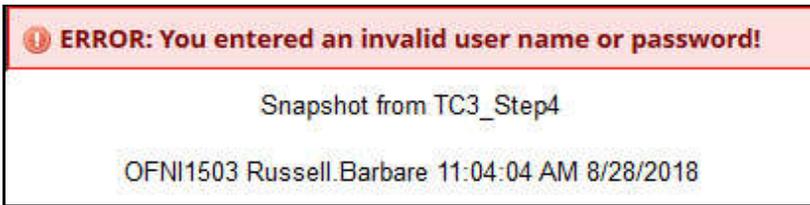
Test Case 3. Test Case: Administrative Controls

Step #	Procedure	Expected Result	Actual Result	P / F	Init.	Date
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.	The user is informed they have entered an invalid user name or password.	The user is informed they have entered an invalid user name or password. Date/Time: 08/28/2018 11:02 AM Eastern	Pass	RRB	28-Aug-18
<p><u>Snapshot from test step #2</u></p> <div style="border: 1px solid black; padding: 5px;"> <p>❗ ERROR: You entered an invalid user name or password!</p> <p style="text-align: center;">Snapshot from TC3_Step2</p> <p style="text-align: center;">OFNI1503 Russell.Barbare 11:02:43 AM 8/28/2018</p> </div>						
3	Enter a valid login ID but an invalid password. Click Log in. Document the date and time of the log in attempt.	The user is informed they have entered an invalid user name or password.	The user is informed they have entered an invalid user name or password. Date/Time: 08/28/2018 11:02 AM Eastern	Pass	RRB	28-Aug-18
<p><u>Snapshot from test step #3</u></p> <div style="border: 1px solid black; padding: 5px;"> <p>❗ ERROR: You entered an invalid user name or password!</p> <p style="text-align: center;">Snapshot from TC3_Step3</p> <p style="text-align: center;">OFNI1503 Russell.Barbare 11:03:30 AM 8/28/2018</p> </div>						
4	Enter an invalid login ID and the correct administrator password. Document the invalid login ID.	The user is informed they have entered an invalid user name or password.	The user is informed they have entered an invalid user name or password. Date/Time: 08/28/2018 11:03 AM Eastern	Pass	RRB	28-Aug-18

Test Case 3. Test Case: Administrative Controls

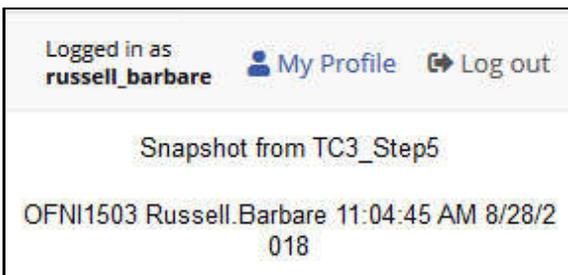
Step #	Procedure	Expected Result	Actual Result	P / F	Init.	Date
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Snapshot from test step #4



5	Enter the administrator user ID and the correct password. Click Log in.	The user ID logs in.	The user ID logs in.	Pass	RRB	28-Aug-18
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Snapshot from test step #5



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.	A user other than the current user whose rights can be edited is documented.	A user other than the current user whose rights can be edited is documented.	Pass	RRB	28-Aug-18
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Snapshot from test step #6

Username or users assigned to a role <small>(click username to edit or assign to role)</small>	Expiration <small>(click expiration to edit)</small>	Data Access Group <small>(click DAG to assign user)</small>	Project Design and Setup	User Rights	Data Access Groups	Data Export Tool	Reports & Report Builder	Graphical Data View & Stats	Manage Survey Participant	Calendar	Data Import Tool	Data Comparison Tool	Logging	File Repository	Record Locking Customization	Lock/Unlock Records	Data Quality (create/edit rules)	Data Quality (execute rules)	API	REDCap Mobile App	Create Records	Rename Records
alyssa_abramsky (Alyssa Abramsky)	never	test2	✓	✓	✓	De-Identified	✓	✓	✓	✓	✓	✗	✗	✓	✗	✗	✗	✗	✗	✗	✓	✗

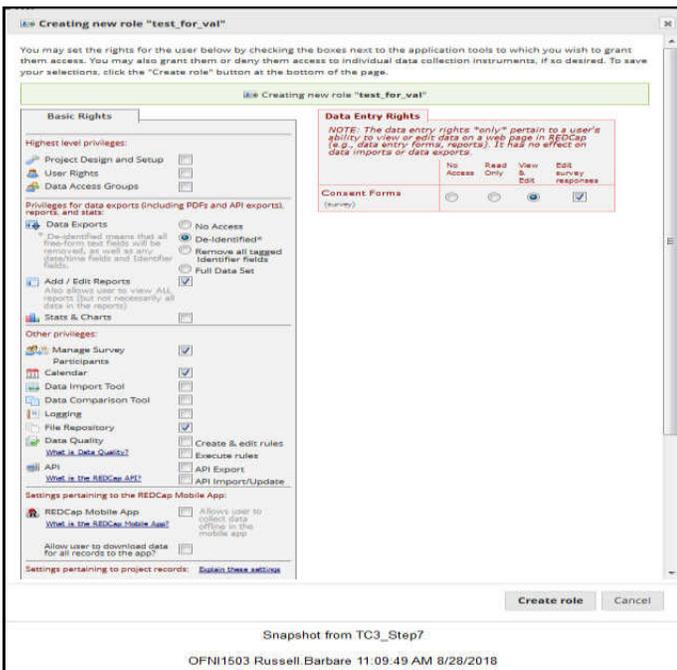
Snapshot from TC3_Step6

OFNI1503 Russell.Barbare 11:07:53 AM 8/28/2018

Test Case 3. Test Case: Administrative Controls

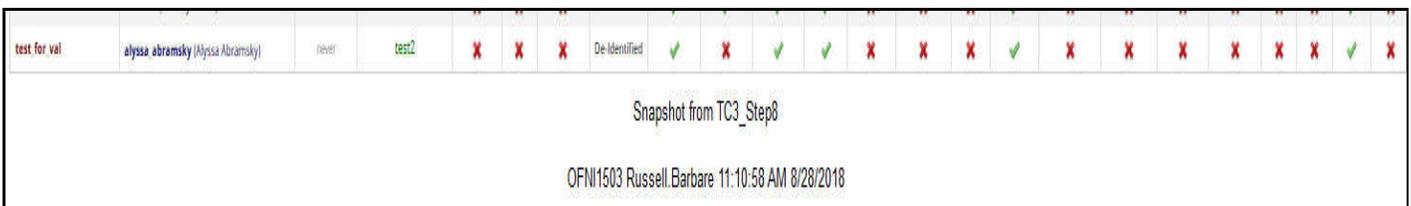
Step #	Procedure	Expected Result	Actual Result	P / F	Init.	Date
7	Create a new role. Set the permissions for the role to be different than the test user's permissions - add at least one permission the test user does not have and remove at least one permission the test user has. Document the role and its permissions (screen shot OK). This role will be called the test role for subsequent steps testing this requirement.	A test role whose permissions are different from the test user is documented.	A test role whose permissions are different from the test user is documented. Role: test_for_val	Pass	RRB	28-Aug-18

Snapshot from test step #7



8	Assign the test user to the test role. Verify the test role's permissions override the user's permissions.	Users can be assigned to a role. The role's permissions override the user's permissions.	Users can be assigned to a role. The role's permissions override the user's permissions.	Pass	RRB	28-Aug-18
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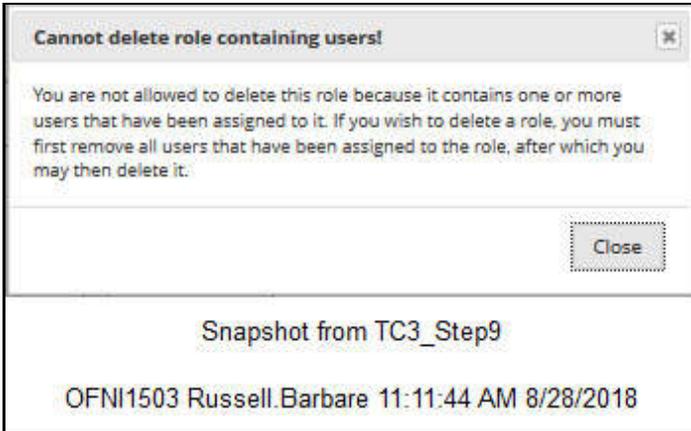
Snapshot from test step #8



Test Case 3. Test Case: Administrative Controls

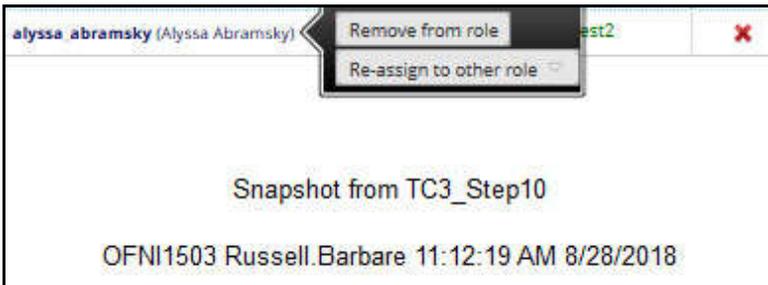
Step #	Procedure	Expected Result	Actual Result	P / F	Init.	Date
9	Click on the test role name beside the test user name. Attempt to delete the test role. Verify that test roles assigned to users cannot be deleted.	Test roles assigned to users cannot be deleted.	Test roles assigned to users cannot be deleted.	Pass	RRB	28-Aug-18

Snapshot from test step #9



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.	When a user is assigned a role, individual permission assignments are disabled.	When a user is assigned a role, individual permission assignments are disabled.	Pass	RRB	28-Aug-18
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Snapshot from test step #10



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.	A user can be removed from a role.	A user can be removed from a role.	Pass	RRB	28-Aug-18
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Test Case 3. Test Case: Administrative Controls

Step #	Procedure	Expected Result	Actual Result	P / F	Init.	Date
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Snapshot from test step #11

Snapshot from TC3_Step11

OFNI1503 Russell.Barbare 11:13:05 AM 8/28/2018

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).	User permissions can be changed when the user is not assigned to a role.	User permissions can be changed when the user is not assigned to a role.	Pass	RRB	28-Aug-18
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Snapshot from test step #12

Snapshot from TC3_Step12

OFNI1503 Russell.Barbare 11:14:01 AM 8/28/2018

13	Delete the test role.	Roles can be deleted.	Roles can be deleted.	Pass	RRB	28-Aug-18
14	Navigate to the Data Access Groups tab. Create a Data Access Group and document the name.	Data Access Groups can be created.	Data Access Groups can be created. Group: test_for_val	Pass	RRB	28-Aug-18

Test Case 3. Test Case: Administrative Controls

Step #	Procedure	Expected Result	Actual Result	P / F	Init.	Date
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Snapshot from test step #14

Data Access Groups	Users in group	Number of records in group	Unique group name (auto-generated)	Group ID number	Delete group?
test_for_val		0	test_for_val	63398	✗

Snapshot from TC3_Step14
OFNI1503 Russell.Barbare 11:24:42 AM 8/28/2018

15	Assign the test user to the Data Access Group.	Users can be assigned to Data Access Groups.	Users can be assigned to Data Access Groups.	Pass	RRB	28-Aug-18
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Snapshot from test step #15

Data Access Groups	Users in group	Number of records in group	Unique group name (auto-generated)	Group ID number	Delete group?
test_for_val	alyssa_abramsky (Alyssa Abramsky)	0	test_for_val	63398	✗

Snapshot from TC3_Step15
OFNI1503 Russell.Barbare 11:25:17 AM 8/28/2018

16	Create a second Data Access Group and document the name. Reassign the test user to the newly-created group.	Users can be transferred to different Data Access Groups.	Users can be transferred to different Data Access Groups.	Pass	RRB	28-Aug-18
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Snapshot from test step #16

Data Access Groups	Users in group	Number of records in group	Unique group name (auto-generated)	Group ID number	Delete group?
test_for_val		0	test_for_val	63398	✗
test_for_val_2	alyssa_abramsky (Alyssa Abramsky)	0	test_for_val_2	63399	✗

Snapshot from TC3_Step16
OFNI1503 Russell.Barbare 11:25:58 AM 8/28/2018

Test Case 3. Test Case: Administrative Controls

Step #	Procedure	Expected Result	Actual Result	P / F	Init.	Date
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.	Data Access Groups with and without users can be deleted.	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.	Pass	RRB	28-Aug-18

Snapshot from test step #17

ERROR:
 The group could not be deleted because users or roles are still assigned to it. Unassign all users and roles first, and then you can then delete the group.

Snapshot from TC3_Step17

OFNI1503 Russell.Barbare 11:36:13 AM 8/28/2018

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.	The event log is saved as a product of	The event log is saved as a product of validation. File: EConsentPart11CertificationOfn_Logging_2018-08-28_1042.csv	Pass	RRB	28-Aug-18
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 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.	The log is in CSV format. The log shows changes to the user accounts, downloads, and form changes.	The log is in CSV format. The log shows changes to the user accounts, downloads, and form changes.	Pass	RRB	28-Aug-18

Test Case 3. Test Case: Administrative Controls

Step #	Procedure	Expected Result	Actual Result	P / F	Init.	Date
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.	The informed consent design has a required signature field.	The informed consent design has a required signature field.	Pass	RRB	28-Aug-18

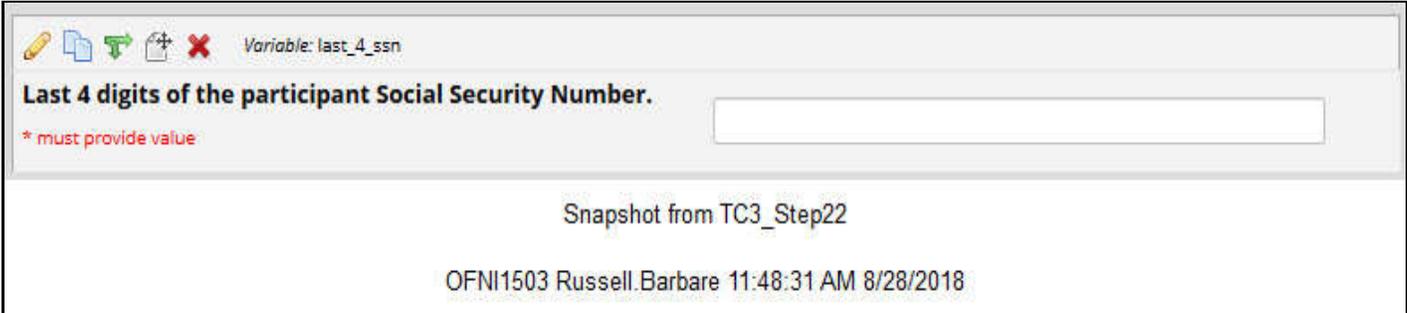
Snapshot from test step #20

21	If a birthday field is not already in the informed consent, add one and make it a required field.	The informed consent design has a required birthday field.	The informed consent design has a required birthday field.	Pass	RRB	28-Aug-18
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Snapshot from test step #21

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.	The informed consent design has a required field asking for the last four digits of the user's SSN.	The informed consent design has a required field asking for the last four digits of the user's SSN.	Pass	RRB	28-Aug-18
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Test Case 3. Test Case: Administrative Controls

Step #	Procedure	Expected Result	Actual Result	P / F	Init.	Date
Snapshot from test step #22						
						
Snapshot from TC3_Step22 OFNI1503 Russell.Barbare 11:48:31 AM 8/28/2018						

23	Log out of the administrator account. Open the informed consent form as a study participant. Verify that the signature, birthday, and SSN fields are in the form and are required fields.	The signature, birthday, and SSN fields are in the form and are required fields.	The signature, birthday, and SSN fields are in the form and are required fields.	Pass	RRB	28-Aug-18
24	Complete the informed consent, submit it, and save it as a product of validation.	The completed form is saved as a product of validation.	The completed form is saved as a product of validation. File: ConsentForms_EC onsentPart11Cer_2 018-08- 28_1050.pdf	Pass	RRB	28-Aug-18

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.	REDCap project managers can set auto-upload and cloud storage options.	REDCap project managers can set auto-upload and cloud storage options.	Pass	RRB	28-Aug-18
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Test Case 3. Test Case: Administrative Controls

Step #	Procedure	Expected Result	Actual Result	P / F	Init.	Date
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Snapshot from test step #25

PDF Auto-Archiver
 Upon survey completion, a compact PDF copy of the survey response will be automatically stored in the project's File Repository, from which the archived PDFs can be downloaded at any time.

Disabled
 Auto-Archiver enabled
 Auto-Archiver + e-Consent Framework [What is the e-Consent Framework?](#)
 (includes end-of-survey certification & archival of PDF consent form)

e-Consent Framework Options: For e-Consent it is sometimes required to include the consenting participant's name (and date of birth in some cases) on the final consent form as extra documentation of their identity. Below you may select fields used to capture that info. You may also enter the current e-Consent version and e-Consent type for this form. The values for the fields below will be automatically inserted into the footer of the PDF consent form that the participant will review at the end the survey, after which that PDF 'hard-copy' will be archived in the File Repository. [Read more](#)

e-Consent version: e.g., 4

First name field: "First Name:"

Last name field: "Last Name:"

Note: If you are using a single field to capture whole name, you may select it for either first/last name above while leaving the other name field unselected.

Optional fields (these are not always necessary for e-Consent):

e-Consent type: e.g., Pediatric

Date of birth field: "Date of Birth"

Snapshot from TC3_Step25

OFNI1503 Russell.Barbare 11:58:05 AM 8/28/2018

26	Verify that REDCap project managers can set external storage settings for the e-consent framework. Record a screenshot 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.	REDCap project managers can set external storage settings for the e-consent framework.	REDCap project managers can set external storage settings for the e-consent framework.	Pass	RRB	28-Aug-18
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Test Case 3. Test Case: Administrative Controls

Step #	Procedure	Expected Result	Actual Result	P / F	Init.	Date
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Snapshot from test step #26

e-Consent Framework: PDF External Storage Settings (for all projects)

If the 'e-Consent Framework' option is enabled for the PDF Auto-Archiver setting on any survey, the e-Consent PDF files that are archived in the File Repository can additionally be stored on an external file server if enabled using the settings below. This might be desirable for certain regulatory compliance requirements, such as 21 CFR Part 11 studies where the PDFs must be stored in a Part 11 compliant environment. Note: If enabled, then *all* surveys in this entire REDCap installation that have the 'e-Consent Framework' option enabled will automatically have those PDFs stored on the external server whose credentials/settings are defined below.

Enable the external storage device and choose storage method (SFTP, WebDAV): SFTP

Server hostname:
For WebDAV, the hostname must begin with http:// or https:// (e.g., https://ebdav.mc.vanderbilt.edu), but not for SFTP (e.g., sftp.vumc.org). SFTP always assumes port 22, while WebDAV is port 80 or 443.

Server username:

Server password:

Server directory to store files: e.g., /redcap/files/

Path to Private Key file (SFTP only): e.g., /credentials/redcap_sftp.pem

REDCap passwords expire.

27	The following steps require help from Vanderbilt personnel. Verify that REDCap passwords expire. Record a screenshot of the expiration setting.	REDCap passwords expire.	REDCap passwords expire. Screenshot from policy "IM SOP - VUMC Password Management"	Pass	RRB	28-Aug-18
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Test Case 3. Test Case: Administrative Controls

Step #	Procedure	Expected Result	Actual Result	P / F	Init.	Date
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Snapshot from test step #27

I. Purpose:
To define acceptable methods for creation and management of passwords at VUMC.

II. Process:

A. Password Complexity:

1. Passwords must meet the following complexity requirements:
 - a. Must contain at least eight (8) characters.
 - b. Must contain characters from at least three (3) of the following character sets:
 - i. Lower Case Letters: abcdefghijklmnopqrstuvwxyz
 - ii. Upper Case Letters: ABCDEFGHIJKLMNOPQRSTUVWXYZ
 - iii. Numbers: 0123456789
 - iv. Special Characters: ~!@#\$%^&*()_+~;:/[]{}<>.,/?
 - c. Cannot contain three (3) consecutive characters from the user ID.
 - d. Cannot contain the user ID in reverse.
 - e. Cannot be a password included on organizational blacklist.

B. Changing Passwords:

1. Passwords must be changed at least annually and no more than once per day.
2. When changing a password the new password cannot match any of your previous ten (10) passwords.

C. Storage/Transmission:

1. Passwords must never be stored or transmitted in clear text.

REDCap passwords have minimum complexity requirements.

28	Verify that REDCap passwords have minimum complexity requirements. Record a screenshot of the settings.	REDCap passwords have minimum complexity requirements.	REDCap passwords have minimum complexity requirements. See screenshot for step 27.	Pass	RRB	28-Aug-18
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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.	REDCap user accounts are set to lock out after a number of invalid login attempts.	REDCap user accounts are set to lock out after a number of invalid login attempts. Note: Sixth attempt.	Pass	RRB	28-Aug-18
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Test Case 3. Test Case: Administrative Controls

Step #	Procedure	Expected Result	Actual Result	P / F	Init.	Date
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Snapshot from test step #29

ACCESS DENIED!

For security purposes, your REDCap user account has been temporarily disabled because it has exceeded the maximum amount of failed login attempts that are allowed within a set period of time (**15 minutes**). After that time, your account will become active again, after which you may return and log in.

If you believe someone other than you is attempting to log in to REDCap using your username without your permission, immediately contact your REDCap administrator: [REDCap Administrator](#).

Snapshot from TC3_Step29

OFNI1503 Russell.Barbare 12:33:52 PM 8/28/2018

Invalid login attempts are logged.

30	Verify that the invalid login attempts in the Informed Consent Creation test case were logged. Record a screenshot of the log.	REDCap logs invalid login attempts.	REDCap logs invalid login attempts.	Pass	RRB	28-Aug-18
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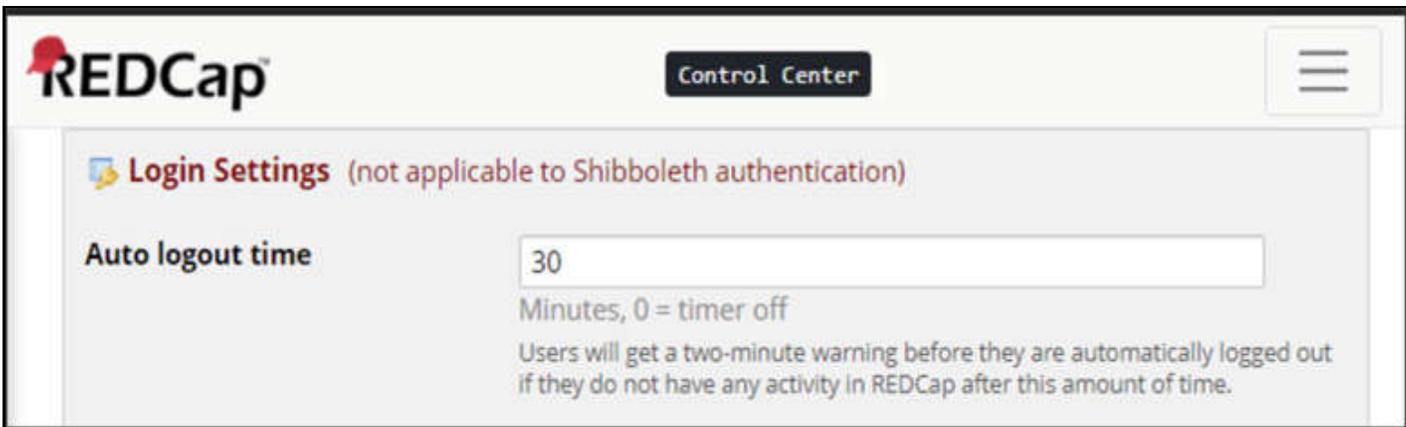
Snapshot from test step #30

time_of_event	user	event	ip	full_url
2018-08-28 10:03:50	alyssa_abramsky	LOGIN_FAIL	99.32.253.114	https://redcap.vanderbilt.edu/
2018-08-28 10:03:14	alyssa_abramsky	LOGIN_FAIL	99.32.253.114	https://redcap.vanderbilt.edu/
2018-08-28 10:02:27	alyssa_abramsky	LOGIN_FAIL	99.32.253.114	https://redcap.vanderbilt.edu/

REDCap logs out or locks after a period of inactivity.

31	Verify that REDCap logs out or locks after a period of inactivity. Record a screenshot of the setting.	REDCap after a period of inactivity.	REDCap logs out after a period of inactivity.	Pass	RRB	28-Aug-18
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Snapshot from test step #31



Test Case 3. Test Case: Administrative Controls

Step #	Procedure	Expected Result	Actual Result	P / F	Init.	Date
32	Confirm that for this test case: All test case steps have been executed. All deviations occurring during this test case have been documented.	All test case steps have been executed. All deviations occurring during this test case have been documented.	All test case steps have been executed. All deviations occurring during this test case have been documented.	Pass	RRB	28-Aug-18