

**INSTALLATION / OPERATIONAL QUALIFICATION PROTOCOL
FOR
VANDERBILT RESEARCH ELECTRONIC DATA CAPTURE (REDCAP)
INFORMED CONSENT MODULE
SERVING**





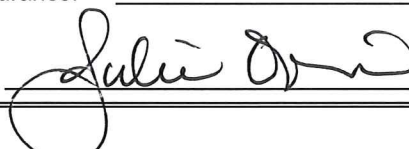
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Vanderbilt Research Electronic Data Capture (REDCap) Informed Consent Module Installation / Operational Qualification Protocol		Doc. #: IOQ-REDCap-Part11-001 Rev. #: 0
Department VICTR	Author Russell Barbare	Page 2 of 22

SIGNATURES

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Vanderbilt Research Electronic Data Capture (REDCap) Informed Consent Module Installation / Operational Qualification Protocol		Doc. #: IOQ-REDCap-Part11-001 Rev. #: 0
Department VICTR	Author Russell Barbare	Page 3 of 22

TABLE OF CONTENTS

1.?	INTRODUCTION.....	4?
1.1.?	Objectives	4?
1.2.?	Scope.....	4?
1.3.?	Assumptions	4?
1.4.?	Exclusions	4?
2.?	ACRONYMS AND REFERENCES.....	5?
2.1.?	Acronyms and Definitions.....	5?
2.2.?	References	5?
3.?	RESPONSIBILITIES	5?
3.1.?	System Owner	5?
3.2.?	Ofni Systems Validation Representative	5?
4.?	SYSTEM DESCRIPTION.....	6?
5.?	PROCEDURE TEST PLAN	6?
5.1.?	General	6?
5.2.?	Documentation	6?
5.3.?	Equipment/Materials	7?
5.4.?	Exclusions	7?
6.?	OPERATIONAL TESTS	8?
6.1.?	Test Case #1: Procedural Controls	8?
6.2.?	Test Case #2: Informed Consent Creation	?
6.3.?	Test Case #3: Administrative Controls	15?

Vanderbilt Research Electronic Data Capture (REDCap) Informed Consent Module Installation / Operational Qualification Protocol		Doc. #: IOQ-REDCap-Part11-001 Rev. #: 0
Department VICTR	Author Russell Barbare	Page 4 of 22

1. Introduction

1.1. Objectives

This is the Installation and Operational Qualification Protocol for the Research Electronic Data Capture (REDCap) (IOQ-REDCap-Part11-001), for use by VICTR at Vanderbilt University (Nashville, TN). The Research Electronic Data Capture (REDCap), hereafter referred to as REDCap, is used to collect electronic data online. REDCap is a proprietary and has been categorized as a Category 5 GxP system.

The Installation and Operational Qualification Protocol for the Research Electronic Data Capture (REDCap) describes the testing methodology and test cases that will provide the necessary documented evidence to assure that REDCap have been properly installed and operates in accordance with defined system and regulatory requirements and Vanderbilt University procedures.

1.2. Scope

This Installation and Operational Qualification Protocol applies to the Research Electronic Data Capture (REDCap). The IOQ verifies the system installation and operation requirements outlined in the Functional Requirement Specification for the Research Electronic Data Capture (REDCap) Informed Consent Module (FRS) and design specifications outlined in the Software Design Specification for the Research Electronic Data Capture (REDCap) Informed Consent Module (SDS).

The validation project was outlined in the Validation and Compliance Plan for the Research Electronic Data Capture (REDCap) Informed Consent Module (VCP-REDCap-Part11-001). The validation project will be summarized in the Validation Summary Report for the Research Electronic Data Capture (REDCap) Informed Consent Module (VSR-REDCap-Part11-001).

1.3. Assumptions

Vanderbilt University has contracted with Ofni Systems to create the validation package and perform validation testing.

The initial validation will be limited to 21 CFR Part 11 requirements and the functions of the informed consent module, but not to project-specific user or institutional requirements. Additional validations may be performed under this validation plan.

21 CFR 11 requirements cannot be met entirely by software - procedural controls are also necessary. This validation will indicate what procedural controls are necessary. Procedural controls that Vanderbilt has in place will be documented; procedural controls that users should have in place will be identified.

21 CFR 11 requires controls for both the developers and the users/administrators of electronic systems. Since REDCap is used both by Vanderbilt personnel and by other persons, businesses, and institutions not affiliated with Vanderbilt University, this validation will indicate which controls are the responsibility of the developers and which are the responsibility of the other users. Both internal and external users of REDCap must ensure that they meet the user responsibilities in order to meet have 21 CFR 11 compliance.

REDCap is configurable; some of the possible configurations will not meet 21 CFR 11 requirements unless specific settings are used or additional testing is performed. The initial validation will identify which settings are needed; system administrators or equivalent must ensure that individual instances have the appropriate settings.

1.4. Exclusions

This validation applies to the REDCap informed consent module, and not the workstation or

Vanderbilt Research Electronic Data Capture (REDCap) Informed Consent Module Installation / Operational Qualification Protocol		Doc. #: IOQ-REDCap-Part11-001 Rev. #: 0
Department VICTR	Author Russell Barbare	Page 5 of 22

computer environment.

2. Acronyms and References

2.1. Acronyms and Definitions

CFR - Code of Federal (US) Regulations

GxP - Abbreviation which includes current Good Manufacturing, Clinical and Laboratory Practices

Informed Consent (form) - A document for recording informed consent as defined in ICH E6(R1)

FRS - Functional Requirement Specification

GUI - Graphical User Interface

IOQ - Installation/Operational Qualification

Informed Consent - The process as defined by ICH E6(R1) whereby a subject is informed about a clinical trial and consents to it.

Open System - An environment in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system.

SDS - Software Design Specification

SOP - Standard Operating Procedure

VICTR - Vanderbilt Institute for Clinical and Translational Research

2.2. References

21 CFR Part 11 "Electronic Records; Electronic Signatures"

GAMP 5, A Risk-Based Approach to Compliant GxP Computerized Systems

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, Guideline for Good Clinical Practice E6(R1)

FRS-REDCap-Part11-001, Functional Requirement Specification for the Research Electronic Data Capture (REDCap)

SDS-REDCap-Part11-001, Software Design Specification for the Research Electronic Data Capture (REDCap)

VCP-REDCap-Part11-001, Validation and Compliance Plan for the Research Electronic Data Capture (REDCap)

3. Responsibilities

3.1. System Owner

3.1.1. Supplies all procedures, data, manuals, drawings and documentation necessary for the generation of protocols and the completion of final reports.

3.1.2. Reviews test data, including deviation resolutions.

3.2. Ofni Systems Validation Representative

3.2.1. Reviews and pre-approves this protocol.

3.2.2. Coordinates protocol execution upon pre-approval.

3.2.3. Executes approved protocol.

3.2.4. Notifies System Owner of issues or deviations rising during protocol execution.

Vanderbilt Research Electronic Data Capture (REDCap) Informed Consent Module Installation / Operational Qualification Protocol		Doc. #: IOQ-REDCap-Part11-001 Rev. #: 0
Department VICTR	Author Russell Barbare	Page 6 of 22

4. System Description

REDCap is a proprietary web server system used to collect electronic data online. REDCap is considered to be an Open System, as defined in 21 CFR 11.3(9). REDCap is accessible through any web-connected device that meets the minimum requirements. The system has a flexible user / group / permission structure to control user rights. Users entering data into the data collection forms can be controlled by a variety of methods. The REDCap informed consent module does not interact with any other validated computer systems beyond those described in this document.

5. Procedure Test Plan

5.1. General

This IOQ protocol will provide the necessary documented verification that all key aspects of the REDCap system have been properly tested. The following items apply to all test steps in this Installation/Operational Qualification Protocol:

- 5.1.1. Read each test case prior to performing the test.
- 5.1.2. The qualification entries should be completed using GxP documentation practices.
- 5.1.3. Follow the test steps listed in each test case.
- 5.1.4. For each test instruction, documents the results in the actual results column.
- 5.1.5. Records Pass or Fail for each step in the test.
- 5.1.6. Record the initials/date of each person performing the test under the Performed By/Date Column.
- 5.1.7. Any event where there is an inability to meet the approved protocol requirements shall be addressed on the Deviation Log.
- 5.1.8. Adhere to all Ofni Systems (Raleigh, NC) site emergency response and safety procedures.
- 5.1.9. The testing included in this Installation/Operational Protocol must meet or exceed all criteria listed in the individual test procedures. Each individual test provides evidence that:
 - 5.1.9.1. The acceptance criteria for each individual test procedure have been met and all required documentation in this protocol has been properly executed.
 - 5.1.9.2. All test procedures have been executed and corresponding test tables are complete.
 - 5.1.9.3. All deviations have been recorded on the appropriate Deviation Log. All deviations have been addressed, resolved and approved.
- 5.1.10. Testing should be performed so all alerts, including aural alerts, are visible to the tester.

5.2. Documentation

Ofni Systems uses FastVal to document the results of software testing and ensure that protocol documentation follows established good documentation practices. The following documentation practices apply to this Installation/Operational Protocol:

- 5.2.1. All qualification reviews, inspections and verifications must be documented at the time they are performed.

Vanderbilt Research Electronic Data Capture (REDCap) Informed Consent Module Installation / Operational Qualification Protocol		Doc. #: IOQ-REDCap-Part11-001 Rev. #: 0
Department VICTR	Author Russell Barbare	Page 7 of 22

- 5.2.2. Perform all qualification work required by this IOQ Protocol.
- 5.2.3. Upon completion and approval of the fieldwork, a Summary Report will be prepared that documents the validation efforts for the system.
- 5.2.4. When applicable, all deviations encountered during the execution of this protocol are documented on the appropriate Deviation Log.

5.3. Equipment/Materials

No additional materials besides a workstation capable of running a browser that REDCap will work on and this protocol are required.

5.4. Exclusions

- 5.4.1. Hardware Identification: The only hardware associated with the system are Vanderbilt host servers.
- 5.4.2. Environment: REDCap is accessed by PCs used in ambient office environments via the web. There will be no verification of the environment.

Vanderbilt Research Electronic Data Capture (REDCap) Informed Consent Module Installation / Operational Qualification Protocol		Doc. #: IOQ-REDCap-Part11-001 Rev. #: 0
Department VICTR	Author Russell Barbare	Page 8 of 22

6. Operational Tests

6.1. Test Case #1: Procedural Controls

6.1.1. Purpose

To document procedural controls

6.1.2. Test Prerequisites

None

6.1.3. Test Criteria

REDCap is backed up.

Vanderbilt has appropriate hiring procedures for REDCap developers.

6.1.4. Test Results and Conclusions:

Step	Procedure	Expected Results	Actual Results	Pass /Fail	Verified By/Date
Data Backup/Recovery (21 CFR 11.10(c))					
1	Verify that REDCap is backed up.	REDCap is backed up.	REDCap _____ backed up.		
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 _____ minimum qualification requirements.		
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 _____ been executed. All deviations occurring during this test case _____ been documented.		

Vanderbilt Research Electronic Data Capture (REDCap) Informed Consent Module Installation / Operational Qualification Protocol		Doc. #: IOQ-REDCap-Part11-001 Rev. #: 0
Department VICTR	Author Russell Barbare	Page 9 of 22

6.2. Test Case #2: Informed Consent Creation

6.2.1. Purpose

To verify Informed Consent creation

6.2.2. Test Prerequisites

None

6.2.3. Test 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.

6.2.4. Test Results and Conclusions:

Step	Procedure	Expected Results	Actual Results	Pass /Fail	Verified By/Date
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 _____		

Vanderbilt Research Electronic Data Capture (REDCap) Informed Consent Module Installation / Operational Qualification Protocol		Doc. #: IOQ-REDCap-Part11-001 Rev. #: 0
Department VICTR	Author Russell Barbare	Page 10 of 22

Step	Procedure	Expected Results	Actual Results	Pass /Fail	Verified By/Date
2	Log out of REDCap. Using the documented survey URL, open the survey.	The survey opens.	The survey _____.		
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 _____ when the user enters an invalid date.		
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 _____ enter a list item that is not on the list.		
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 _____ documented. _____ _____ _____ ...		
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 _____ a list of all of the missing required fields.		

Vanderbilt Research Electronic Data Capture (REDCap) Informed Consent Module Installation / Operational Qualification Protocol		Doc. #: IOQ-REDCap-Part11-001 Rev. #: 0
Department VICTR	Author Russell Barbare	Page 11 of 22

Step	Procedure	Expected Results	Actual Results	Pass /Fail	Verified By/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 _____ documented.</p> <p>First Name: _____</p> <p>Last Name: _____</p> <p>Date of Birth _____</p> <p>Date of Consent: _____</p> <p>Consent Forms reviewed: _____</p> <p>Consent Version _____</p> <p>Language of Consent Reviewed: _____</p> <p>Study Staff Member Conducting Consent Form Discussion: _____</p> <p>Was time allowed to ask/answer questions? _____</p> <p>Was/Were the Consent Form(s) signed prior to initiation of study procedures? _____</p> <p>Was a copy of the signed Consent Form(s) provided to the study subject? _____</p> <p>Additional Notes: _____</p>		
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 _____ identical to the information previously documented		
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: _____		

Vanderbilt Research Electronic Data Capture (REDCap) Informed Consent Module Installation / Operational Qualification Protocol		Doc. #: IOQ-REDCap-Part11-001 Rev. #: 0
Department VICTR	Author Russell Barbare	Page 12 of 22

Step	Procedure	Expected Results	Actual Results	Pass /Fail	Verified By/Date
10	Check the certification. Verify that the Submit button enables.	Checking the certification enables the Submit button.	Checking the certification _____ the Submit button.		
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 _____ displayed.		
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 _____ saved as a product of validation.		
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 _____ identical to the information previously documented		
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 _____ saved as a product of validation.		
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 _____ displayed.		
The audit trail is secure.					

Vanderbilt Research Electronic Data Capture (REDCap) Informed Consent Module Installation / Operational Qualification Protocol		Doc. #: IOQ-REDCap-Part11-001 Rev. #: 0
Department VICTR	Author Russell Barbare	Page 13 of 22

Step	Procedure	Expected Results	Actual Results	Pass /Fail	Verified By/Date
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 _____ have the option to delete or rename the completed surveys.		
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 _____ be downloaded.		
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 _____ human readable and _____ be opened by a standard pdf viewer.		
The audit trail is computer generated.					
19	Verify that the audit trails are 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 _____ automatically generated.		
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 _____ an accurate time/date stamp.		
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 _____ the survey answers.		
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 _____ overwrite the prior survey.		

Vanderbilt Research Electronic Data Capture (REDCap) Informed Consent Module Installation / Operational Qualification Protocol		Doc. #: IOQ-REDCap-Part11-001 Rev. #: 0
Department VICTR	Author Russell Barbare	Page 14 of 22

Step	Procedure	Expected Results	Actual Results	Pass /Fail	Verified By/Date
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 _____ the printed name of the singer.		
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 _____ the date and time the form was signed.		
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 _____ identified as a consent form.		
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 _____ been executed. All deviations occurring during this test case _____ been documented.		

Vanderbilt Research Electronic Data Capture (REDCap) Informed Consent Module Installation / Operational Qualification Protocol		Doc. #: IOQ-REDCap-Part11-001 Rev. #: 0
Department VICTR	Author Russell Barbare	Page 15 of 22

6.3. Test Case #3: Administrative Controls

6.3.1. Purpose

To verify administrative controls

6.3.2. Test Prerequisites

None

6.3.3. Test 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.

6.3.4. Test Results and Conclusions:

Step	Procedure	Expected Results	Actual Results	Pass /Fail	Verified By/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 _____ to https://redcap.vanderbilt.edu/ .		
Access to REDCap project design, settings, or controls requires an active user ID and password.					

Vanderbilt Research Electronic Data Capture (REDCap) Informed Consent Module Installation / Operational Qualification Protocol		Doc. #: IOQ-REDCap-Part11-001 Rev. #: 0
Department VICTR	Author Russell Barbare	Page 16 of 22

Step	Procedure	Expected Results	Actual Results	Pass /Fail	Verified By/Date
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 _____ informed they have entered an invalid user name or password. Date/Time: _____		
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 _____ informed they have entered an invalid user name or password.		
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 _____ informed they have entered an invalid user name or password.		
5	Enter the administrator user ID and the correct password. Click Log in.	The user ID logs in.	The user ID _____ in.		
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 _____ documented.		

Vanderbilt Research Electronic Data Capture (REDCap) Informed Consent Module Installation / Operational Qualification Protocol		Doc. #: IOQ-REDCap-Part11-001 Rev. #: 0
Department VICTR	Author Russell Barbare	Page 17 of 22

Step	Procedure	Expected Results	Actual Results	Pass /Fail	Verified By/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 _____ documented.		
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 _____ be assigned to a role. The role's permissions _____ the user's permissions.		
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 _____ be deleted.		
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 _____ disabled.		

Vanderbilt Research Electronic Data Capture (REDCap) Informed Consent Module Installation / Operational Qualification Protocol		Doc. #: IOQ-REDCap-Part11-001 Rev. #: 0
Department VICTR	Author Russell Barbare	Page 18 of 22

Step	Procedure	Expected Results	Actual Results	Pass /Fail	Verified By/Date
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 _____ be removed from a role.		
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 one 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 _____ be changed when the user is not assigned to a role.		
13	Delete the test role.	Roles can be deleted.	Roles _____ be deleted.		
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 _____ be created.		
15	Assign the test user to the Data Access Group.	Users can be assigned to Data Access Groups.	Users _____ be assigned to Data Access Groups.		
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 _____ be transferred to different Data Access Groups.		
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 with and without users _____ be deleted.		

Vanderbilt Research Electronic Data Capture (REDCap) Informed Consent Module Installation / Operational Qualification Protocol		Doc. #: IOQ-REDCap-Part11-001 Rev. #: 0
Department VICTR	Author Russell Barbare	Page 19 of 22

Step	Procedure	Expected Results	Actual Results	Pass /Fail	Verified By/Date
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) <input type="checkbox"/> Save the download as a product of validation.	The event log is saved as a product of validation.	The event log _____ saved as a product of validation.		
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 _____ in CSV format. The log _____ changes to the user accounts, downloads, and form changes.		
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 _____ a required signature field.		
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 _____ a required birthday field.		

Vanderbilt Research Electronic Data Capture (REDCap) Informed Consent Module Installation / Operational Qualification Protocol		Doc. #: IOQ-REDCap-Part11-001 Rev. #: 0
Department VICTR	Author Russell Barbare	Page 20 of 22

Step	Procedure	Expected Results	Actual Results	Pass /Fail	Verified By/Date
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 _____ a required field asking for the last four digits of the user's SSN.		
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 _____ in the form and _____ required fields.		
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 _____ saved as a product of validation.		
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 _____ set auto-upload and cloud storage options.		

Vanderbilt Research Electronic Data Capture (REDCap) Informed Consent Module Installation / Operational Qualification Protocol		Doc. #: IOQ-REDCap-Part11-001 Rev. #: 0
Department VICTR	Author Russell Barbare	Page 21 of 22

Step	Procedure	Expected Results	Actual Results	Pass /Fail	Verified By/Date
26	<p>Verify that REDCap project managers can set external storage settings for the e-consent framework. Record a screen shot of the external storage settings.</p> <p>Note: Verify the options are available on-screen. Verification of actual file transfer is outside the scope of this protocol.</p>	REDCap project managers can set external storage settings for the e-consent framework.	REDCap project managers _____ set external storage settings for the e-consent framework.		
REDCap passwords expire.					
27	<p>The following steps require help from Vanderbilt personnel.</p> <p>Verify that REDCap passwords expire. Record a screenshot of the expiration setting.</p>	REDCap passwords expire.	REDCap passwords _____.		
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 _____ minimum complexity requirements.		
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 _____ set to lock out after a number of invalid login attempts.		
Invalid login attempts are logged.					

Vanderbilt Research Electronic Data Capture (REDCap) Informed Consent Module Installation / Operational Qualification Protocol		Doc. #: IOQ-REDCap-Part11-001 Rev. #: 0
Department VICTR	Author Russell Barbare	Page 22 of 22

Step	Procedure	Expected Results	Actual Results	Pass /Fail	Verified By/Date
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 _____ invalid login attempts.		
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 _____ after a period of inactivity.		
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 _____ been executed. All deviations occurring during this test case _____ been documented.		