VALIDATION SUMMARY REPORT
FOR
VANDERBILT RESEARCH ELECTRONIC DATA CAPTURE (REDCAP)
INFORMED CONSENT MODULE
SERVING

VICTR DEPARTMENT
VANDERBILT UNIVERSITY
NASHVILLE, TN

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REVISION HISTORY

Rev #	Description	Date Approved
0	Initial Issue.	

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1. Executive Summary

This is the Validation Summary Report for the Research Electronic Data Capture (REDCap) Informed Consent Module (VSR-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 web server system and has been categorized as a GAMP category 5 GxP system.

This Validation Summary Report summarizes the results obtained during the execution of the Installation and Operational Qualification Protocol for the Research Electronic Data Capture (REDCap) Informed Consent Module (IOQ-REDCap-Part11-001). This Validation Summary Report documents that the REDCap informed consent module operates in accordance with requirements described in the Functional Requirement Specification (FRS-REDCap-Part11-001) and the Software Design Specification (SDS-REDCap-Part11-001) and complies with the applicable sections of 21 CFR 11.

All sections of the Installation/Operational Protocol were executed and successfully completed. There was one script deviation that has handled and closed during execution. The Vanderbilt University, Nashville, TN, Research Electronic Data Capture (REDCap) Informed Consent Module functioned in accordance with the approved functional requirements, system specifications, and regulatory requirements. The Research Electronic Data Capture (REDCap) Informed Consent Module is considered validated.

2. Introduction

2.1. Objectives

This is the Validation Summary Report for the Research Electronic Data Capture (REDCap) Informed Consent Module (VSR-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. REDCap is a proprietary web server system and has been categorized as a GAMP category 5 GxP system.

This Validation Summary Report summarizes the results obtained during the execution of the Installation and Operational Qualification Protocol for the Research Electronic Data Capture (REDCap) Informed Consent Module (IOQ-REDCap-Part11-001). This Validation Summary Report documents that the Research Electronic Data Capture (REDCap) was installed and operates in accordance with requirements described in the Functional Requirement Specification (FRS-REDCap-Part11-001) and the Software Design Specification (SDS-REDCap-Part11-001).

2.2. Scope

This Validation Summary Report applies to the Research Electronic Data Capture (REDCap) informed consent module. The scope of this Validation Summary Report is limited to the testing defined in the FRS and 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). Functional requirements for REDCap are detailed in the Functional Requirement Specification for the Research Electronic Data Capture (REDCap) Informed Consent Module (FRS-REDCap-Part11-001). Design requirements for REDCap are detailed in the Software Design Specification for the Research Electronic Data Capture (REDCap) Informed Consent Module (SDS-REDCap-Part11-001). Demonstrating successful installation and operation of these requirements was described in the Installation and Operational Qualification Protocol for the Research Electronic Data Capture (REDCap) Informed Consent Module (IOQ-REDCap-Part11-001).

2.3. Assumptions/Restrictions

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

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 the 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.

3. Acronyms and References

3.1. Acronyms and Definitions

CFR - Code of Federal (US) Regulations

Closed System - An environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.

FRS - Functional Requirement Specification

GUI - Graphical User Interface

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

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

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

IOQ - Installation/Operational Qualification

LAN - Local Area Network

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

3.2. References

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

IOQ-REDCap-Part11-001, Installation/Operational Protocol for the Research Electronic Data

Capture (REDCap)

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

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. Testing Process Summary

5.1. General

The IOQ protocol provided the necessary documented verification that all key aspects of the REDCap system were properly installation and operation. The following items applied to all test steps in this Installation/Operational Qualification Protocol:

5.1.1. Each test case was read prior to performing the test.

5.1.2. Qualification entries were completed using GxP documentation practices.

5.1.3. Test steps were followed as listed in each test case.

5.1.4. For each test instruction, results were documented in the actual results column.

5.1.5. For each test instruction, Pass or Fail was recorded for each step.

5.1.6. The tester recorded their initials/date in the Performed By/Date Column.

5.1.7. Any event where there was an inability to meet the approved protocol requirements was addressed on the Deviation Log.

5.1.8. The tester adhered to all Ofni Systems (Raleigh, NC) site emergency response and safety procedures.

5.1.9. The testing included in this Installation/Operational Protocol met or exceeded all criteria listed in the individual test procedures. For each individual test:

5.1.9.1. The acceptance criteria for each individual test procedure was met and all required documentation in this protocol was properly executed.

5.1.9.2. All test procedures were executed and corresponding test tables were completed.

5.1.9.3. All deviations were recorded on the appropriate Deviation Log. All deviations were addressed, resolved and approved.

5.2. Documentation

The following documentation practices apply to this Installation/Operational Protocol:

5.2.1. All qualification work required by this IOQ Protocol was performed.

5.2.2. When applicable, all deviations encountered during the execution of this protocol were documented on the appropriate Deviation Log.

5.3. Equipment/Materials

No additional materials besides a computer capable of accessing the REDCap application were

required.

5.4. Testing Exclusions

5.4.1. Hardware Identification

No hardware identification was required.

5.4.2. Equipment Installation

No equipment installation was required.

5.4.3. Environment

There was no environmental verification or testing.

6. Test Results, Data Analysis and Non-Conformance Events

6.1. Operational Qualification Tests

6.1.1. Test Case 1, Procedural Controls

Purpose: To document procedural controls

6.1.1.1. Acceptance Criteria

REDCap is backed up.

Vanderbilt has appropriate hiring procedures for REDCap developers.

6.1.1.2. Test Results

This test case met or exceeded the □Expected Results□listed in the individual test procedures. The test passed without reported deviations.

6.1.2. Test Case 2, Informed Consent Creation

Purpose: To verify Informed Consent creation

6.1.2.1. 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.

6.1.2.2. Test Results

This test case met or exceeded the Expected Results listed in the individual test procedures. The test passed without reported deviations.

6.1.3. Test Case 3, Administrative Controls

Purpose: To verify administrative controls

6.1.3.1. 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.

6.1.3.2. Test Results

This test case met or exceeded the Expected Results listed in the individual test procedures with the exception of the following deviations:

6.1.3.2.1. Deviation #1: Script Error in Test Case 3 Step #17

Risk Assessment: N/A

Status: Closed

Category: Validation Error, Script Error

Description: There was an error in the test script. The script says that Data Access Groups with users can be deleted. Only Data Access Groups without users can be deleted.

Root Cause: Script Error

Corrective Action: The script error was corrected during validation by noting the correct script. No further corrective action is needed.

Summary: A script error was corrected during validation. No further corrective action is needed.

Fixed by: Russell Barbare, 8/28/2018

7. Validation Summary

All sections of the Installation/Operational Protocol for the Research Electronic Data Capture (REDCap) were executed and successfully completed. There was one script deviation that has handled and closed during execution. The Vanderbilt University, Nashville, TN, Research Electronic Data Capture (REDCap) Informed Consent Module functioned in accordance with the approved functional requirements, system specifications, and regulatory requirements. The Research Electronic Data Capture (REDCap) Informed Consent Module is considered validated and can be used for its intended use.