VALIDATION AND COMPLIANCE PLAN
FOR THE
VANDERBILT RESEARCH ELECTRONIC DATA CAPTURE (REDCAP)
INFORMED CONSENT MODULE
SERVING

VICTR DEPARTMENT
VANDERBILT UNIVERSITY
NASHVILLE, TN

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SIGNATURES

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REVISION HISTORY

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0	Initial Issue.	26 August 2018

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1. Introduction

1.1. Objectives

This is the Validation and Compliance Plan (VCP-REDCap-Part11-001) for the Research Electronic Data Capture (REDCap) system informed consent module, for use by VICTR at Vanderbilt University (Nashville, TN). The Research Electronic Data Capture (REDCap) system, hereinafter referred to as REDCap, is used to collect electronic data online. The informed consent module collects informed consent forms. REDCap is a proprietary web server system and has been categorized as a GAMP Category 5 GxP system.

The Validation and Compliance Plan for the Research Electronic Data Capture (REDCap) defines the methodology, deliverables, and responsibilities for the validation of the REDCap informed consent module. The Validation and Compliance Plan will also describe criteria for final acceptance of validation deliverables and the controls that Vanderbilt University has in place to maintain the REDCap informed consent module in a validated state.

1.2. Scope

This Validation and Compliance Plan applies to the Research Electronic Data Capture (REDCap) informed consent module. The VCP will define the strategy project deliverables and acceptance criteria for the validation of the REDCap informed consent module.

1.3. 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 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 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; project administrators or equivalent must ensure that individual instances have the appropriate settings.

2. Acronyms and References

2.1. 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

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

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.

RTM - Requirement Traceability Matrix

SDS - System Design Specification

SOP - Standard Operating Procedure

VCP - Validation and Compliance Plan

VICTR - Institute for Clinical and Translational Research

VSR - Validation Summary Report

2.2. References

21 CFR Part 11 "Electronic Records; Electronic Signatures"

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

3. Responsibilities

3.1. System Owner

This is a Vanderbilt role.

3.1.1. Provides technical expertise related to system and database design, including specific guidance relative to approach, methodology, etc. as requested.

3.1.2. Assists in development and execution of training required by the validation project.

3.1.3. Manages the development of system process SOPs and maintains SOPs as appropriate.

3.1.4. Reviews and approves of key project deliverables.

3.1.5. Performs validation periodic reviews of the validated computer system to ensure it is operated in compliance with all Policies, SOPs, and regulatory requirements and is being maintained in a controlled manner

3.1.6. Assists in testing as needed to ensure the system is tested properly.

3.1.7. Reviews and approves all computer validation and training documentation to ensure that the information is accurate and complete from the business process perspective.

3.2. Validation Manager

This is an Ofni Systems role.

3.2.1. Manages overall project resources and is the point contact for the project.

3.2.2. Leads the Validation sub-team in developing validation deliverables, including this Validation Plan and Validation Summary Report

3.2.3. Provides specific guidance relative to approach, methodology, etc.

3.2.4. Monitors project progress per validation plan.

3.2.5. Reviews and approves of key project deliverables.

3.3. Validation Resources

This is an Ofni Systems role.

3.3.1. Provides subject matter expertise on all aspects of the validation project, as required.

3.3.2. Provides assistance on creation of specifications, test protocols, and summary reports, as required.

3.3.3. Provides assistance on execution of test protocols, as required.

3.3.4. Provides technical assistance on FastVal, as required.

3.4. Quality Assurance

This is a Vanderbilt role.

3.4.1. Provides an independent review and approval on all validation documents and policy and procedures for completeness and consistency

3.4.2. Provides independent quality assurance that the system is validated to meet regulatory compliance standards

3.4.3. Ensures that Standard Operating Procedures are in place for user operations.

3.5. Project Personnel

For this validation project, the following personnel will fulfill these identified responsibilities:

Role	Name
System Owner	Lindsay O'Neal
Validation Manager	Russell Barbare
Validation Resources	Ofni Systems personnel as needed

Quality Assurance

4. System Description

The Research Electronic Data Capture (REDCap) is a proprietary web server system designed to collect clinical data over the web. Its primary instance is hosted by Vanderbilt University. This system can be accessed from any computer with the necessary minimum web capabilities given the user has the privileges to access the system. REDCap is considered to be an Open System, as defined in 21 CFR 11.3(9). REDCap was determined to be GxP category 5 (highly-configurable) system based upon its functionality.

5. Validation Strategy and Overview

5.1. Validation Testing Strategy

Validation testing will occur in the current REDCap system using test projects created for the validation. Validation testing will be primarily "black box" testing, focusing on functionality defined in the Functional Specification. The REDCap informed consent module will be specifically tested to demonstrate compliance with 21 CFR 11.

After test protocols have been reviewed and approved, test protocols will be executed electronically with FastVal. Validation documents will be exported as Word or PDF files and

preserved in the validation package.

During validation activities, changes to the modules/functions of the REDCap informed consent module being validated or to controlled documentation must be made through the defined change control process.

5.2. Validation Documents

In addition to this Validation Plan, the completed validation package for the REDCap informed consent module will include:

5.2.1. FRS-REDCap-Part11-001, Functional Requirement Specification for the Research Electronic Data Capture (REDCap) Informed Consent Module

The FRS will address what functions the REDCap informed consent module must be able to perform to successfully meet 21 CFR 11 requirements. The focus is on what the system must do. The FRS will be reviewed and signed by the System Owner, the Author or Validation Manager, and Quality Assurance.

5.2.2. SDS-REDCap-Part11-001, Software Design Specification for the Research Electronic Data Capture (REDCap) Informed Consent Module

The SDS will describe the system elements, functions, and configurations necessary to properly operate the system within functional requirements outlined in FRS. The FRS must be approved before the SDS can be approved. The SDS will be reviewed and signed by the System Owner, the Author or Validation Manager, and Quality Assurance.

5.2.3. IOQ-REDCap-Part11-001, Installation/Operational Protocol for the Research Electronic Data Capture (REDCap) Informed Consent Module

The IOQ will provide the instructions to verify the installation and operation of the REDCap informed consent module. The FRS must be approved before the IOQ can be approved. The IOQ will be reviewed and signed by the System Owner, the Author or Validation Manager, and Quality Assurance. The IOQ must be approved before the IOQ can be executed.

5.2.4. Requirement Traceability Matrix

The RTM will document that all requirements outlined in the FRS are properly described in the SDS and tested in the IOQ.

5.2.5. VSR-REDCap-Part11-001, Validation Summary Report for the Research Electronic Data Capture (REDCap) Informed Consent Module

The VSR summarizes the results obtained during the execution of the Installation/Operational Protocol for the REDCap informed consent module (IOQ-REDCap-Part11-001). This Validation Summary Report will document if the REDCap informed consent module performed in accordance with its intended use as described in the Functional Requirement Specification and the Software Design Specification. The VSR will be reviewed and signed by the System Owner, the Author or Validation Manager, and Quality Assurance.

5.2.6. Responsibilities Matrix

The Responsibilities Matrix will delineate the parts of 21 CFR 11 that are fulfilled by REDCap, the parts that are fulfilled by Vanderbilt University VICTR department, and the parts that must be fulfilled by the users of REDCap in order to fully comply with 21 CFR 11.

5.3. Compliance Objectives

The REDCap informed consent module will be compliant with 21 CFR 11. In order to meet these requirements, Vanderbilt University will meet the following requirements of 21 CFR 11:

5.3.1. 21 CFR 11.10(a) Validation

Validation is a responsibility shared between Vanderbilt and the administrators of the projects. The initial validation will document that the system can be 21 CFR 11 compliant; project administrators must perform additional validation on specific projects. Partition of responsibilities will be documented in the FRS and the Responsibilities Matrix. The validation documents themselves and any products of validation demonstrate Vanderbilt's validation of the system.

5.3.2. 21 CFR 11.10(b) Accurate Record Generation

Verification of accurate record generation is a responsibility shared between Vanderbilt and the administrators of the projects. The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the FDA will be demonstrated for applicable functions tested in the initial validation. System administrators must verify accurate record generation on specific projects. Partition of responsibilities will be documented in the FRS and the Responsibilities Matrix; functions tested in the initial validation will be detailed in the SDS and tested in the IOQ.

5.3.3. 21 CFR 11.10(c) Protection of Records

Vanderbilt University has adequate procedures to ensure that all records in the REDCap informed consent module are accurate and can be readily retrieved. Compliance with the requirement for protection of records will be tested by verifying that Vanderbilt University has adequately defined procedures for data backup and recovery, data archiving and business continuity. Individual project administrators are responsible for determining the retention period for records and retaining them for that period.

5.3.4. 21 CFR 11.10(d) Limiting System Access

Limiting system access is a responsibility shared between Vanderbilt and the project administrators. Administrator access to REDCap requires a defined user ID and password. User ID and password controls will be verified in the IOQ. User/patient access can be controlled in an equivalent manner - this will be verified as part of the initial validation. System administrators must verify that the proper controls are placed on specific projects. Partition of responsibilities will be documented in the FRS and the Responsibilities Matrix; functions tested in the initial validation will be detailed in the SDS and tested in the IOQ.

5.3.5. 21 CFR 11.10(e) Audit Trails

In cases where users alter data, REDCap will use secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for FDA review and copying. Partition of responsibilities will be documented in the FRS and the Responsibilities Matrix; functions tested in the initial validation will be detailed in the SDS and tested in the IOQ.

5.3.6. 21 CFR 11.10(f) Operational System Checks

Verifying operational system checks is a responsibility shared between Vanderbilt and

the administrators of the projects. The initial validation will verify that the REDCap informed consent module uses appropriate system-level operational system checks to enforce permitted sequencing of steps and events. System administrators must verify that the proper operational system checks are placed on specific projects. Partition of responsibilities will be documented in the FRS and the Responsibilities Matrix; functions tested in the initial validation will be detailed in the SDS and tested in the IOQ.

5.3.7. 21 CFR 11.10(g) Authority Checks

Verifying permissions structures is a responsibility shared between Vanderbilt and the administrators of the projects. The initial validation will verify that REDCap has system-level permission checks and a flexible permission control structure. System administrators must verify that the proper permission controls are placed on specific projects. Partition of responsibilities will be documented in the FRS and the Responsibilities Matrix; functions tested in the initial validation will be detailed in the SDS and tested in the IOQ.

5.3.8. 21 CFR 11.10(h) Device/Terminal Checks

Beyond use of the keyboard, touchscreen, and mouse for data input, it is not anticipated that REDCap will use devices and/or terminals so this requirement is not applicable.

5.3.9. 21 CFR 11.10(i) Training Systems

Vanderbilt University will determine that persons who develop or maintain REDCap have the education, training, and/or experience to perform their assigned tasks. System administrators must verify any necessary education, training, and/or experience for users of specific projects. Partition of responsibilities will be documented in the FRS and the Responsibilities Matrix.

5.3.10. 21 CFR 11.10(j) Policies for Electronic Signatures

The REDCap informed consent module will require users to agree to electronic signature terms and conditions before applying electronic signatures. These terms and conditions will include acknowledging that the electronic signature is the legal equivalent of their physical signature. Signature functions tested in the initial validation will be outlined in the FRS, detailed in the SDS, and tested in the IOQ.

5.3.11. 21 CFR 11.10(k) Control over System Documentation

Vanderbilt University has a system to control internal SOPs and documents that require approval. The existence of the system will be verified as part of the initial validation. If there are SOPs and documents that require approval related to specific projects, project administrators must verify that similar controls are placed on specific projects.

5.3.12. 21 CFR 11.30 Controls for Open Systems

REDCap is considered to be an open system, as defined in 21 CFR 11.3(9). The initial validation will verify that REDCap uses end-to-end encryption for security.

5.3.13. 21 CFR 11.50 Signature Manifestations

Electronic signatures in the REDCap informed consent module will have the printed name of the signer, date and time when the signature was executed and the meaning of the signature. All three elements of the electronic signature will be included on human readable and electronic versions of the records. The appearance and content of electronic signatures will be defined in FRS and SDS and then verified in IOQ.

5.3.14. 21 CFR 11.70 Signature/Record Linking

REDCap applies an electronic signature to a record, the electronic signature will linked to its respective electronic record to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means. This will be a requirement in FRS, explained in SDS and verified in IOQ.

5.3.15. 21 CFR 11.100 General Requirements for Electronic Signatures

Verifying general requirements for electronic signatures is a responsibility shared between Vanderbilt and the administrators of the projects - Vanderbilt will ensure that the REDCap informed consent module can fulfill the requirements with the correct settings and project administrators should then verify and test those settings for individual instances. The necessary settings will be documented in the SDS and tested in the IOQ.

5.3.16. 21 CFR 11.200 Electronic Signature Components and Controls

Verifying components and controls for electronic signatures is a responsibility shared between Vanderbilt and the administrators of the projects - Vanderbilt will ensure that the REDCap informed consent module can fulfill the requirements with the correct settings and project administrators should then verify and test those settings for individual instances. The necessary settings will be documented in the SDS and tested in the IOQ.

5.3.17. 21 CFR 11.300 Controls for Identification Codes/Passwords

Verifying controls for identification codes is a responsibility shared between Vanderbilt and the administrators of the projects. Vanderbilt will ensure that core REDCap systems meet the controls and that the configurable systems can meet the controls with proper settings; project administrators should then verify and test those settings for individual instances. The necessary settings will be documented in the SDS and tested in the IOQ.

5.4. Deviation Resolution Process

When validation testing identifies a difference between expected results and actual results, this will be documented as a deviation. The Validation Resource will classify the severity and category of the nonconformance. Script deviations, deviations where the validation script has a typo or other error, will be corrected during testing. Tester deviations, deviations where the tester did not follow instructions outlined in the validation procedure will be noted and test cases re-executed as required. Documentation deviations, deviations were requirements were incorrectly documented will recorded as open deviations until the appropriate specification is updated. Program deviations will be reported to Vanderbilt University and a determination will be made about when the issues can be resolved.

5.5. Other Validation Requirements

The REDCap informed consent module validation effort will be controlled via Change Control procedures.