

# **REDCap eDocs Module Validation Plan**

University of Vanderbilt

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## Signature Page

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I have prepared the contents of this document and agree that the provisions contained herein are appropriate and consistent with current regulatory expectation for computer validation, internal policies and procedures and available FDA industry Guidance and I tender it for approval.

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## 1 Introduction

### 1.1 Purpose

University of Vanderbilt will utilize a REDCap-based electronic documents (eDocs) Module that will allow the users to upload files in a data collection instrument. User(s) will select the specific document to upload as part of the data collection instrument and go through the verification process by manifesting their electronic signature for every upload. Documents can also be replaced in the data collection instrument, which is stored in the REDCap database, while retaining the original record, which is stored on the secured vault portion of the Vanderbilt network. If a file is deleted from the data collection instrument, that file will be maintained in the vault where it can be retained and viewed for the required retention period. There is a complete audit trail of the records in the data instrument's history log.

### 1.2 Objective

This Validation Master Plan (VMP) serves as the project overview and lists the tasks and deliverables that will be completed to prospectively validate the eDocs application for REDCap utilizing the as-built configuration with respect to appropriate areas of compliance with internal requirements, health authority expectations and other regulatory requirements, including FDA 21 CFR Part 11. Validation is a process that provides a high degree of assurance that the electronic system and process are reliably performing the functions as they were intended and will continue to do so in a consistent manner. This VMP is the controlling document for the prospective validation and serves to guide project-related activities to validate the system. This VMP defines the roles and responsibilities for development, review, approval, and execution of the validation deliverables and activities.

### 1.3 Rationale

The prospective validation will occur at University of Vanderbilt, located in Nashville, Tennessee (hereafter VUMC). It is the practice of VUMC to assure that all GCP-regulated computerized systems perform according to predetermined specifications in an accurate, reliable and repeatable manner. These activities are designed and executed to ensure the system and related procedures are in compliance with 21 CFR Parts 11, VUMC internal policies and procedures. As the system has been previously installed by VUMC, and VUMC has historical data to demonstrate that the system is working as intended and is fit for purpose to fulfill VUMC's business processes, the retrospective validation effort will focus on system configuration per specifications, system security, data integrity, and system communication with interfaced instrumentation.

This plan encompasses processes, computer software, hardware and procedures and governs those individuals involved in the implementation, support and use of these systems.

### 1.4 In-Scope

The scope of this plan is limited to the Validation of the following:

- a. Abbreviated Installation Qualification – Retrospective – As Built Configuration of REDCap Instance and Vault environment
- b. eDocs applicable software functionality
- c. Verification of communication with interfaced storage locations.
- d. Application security
- e. Data Integrity
- f. Electronic Records and Electronic Signatures

### 1.5 Out of Scope

The following is out of scope for this project:

- a. Core REDCap functionality
- b. Data archival
- c. Backup restore capabilities.

## 2 Assumptions and Exclusions

### 2.1 Assumptions

The following assumptions apply to the implementation of this system:

- Third party software applications (e.g., Microsoft Office Products, Adobe) are considered market-proven by the industry and will not be tested or validated.
- The computing environment is operating properly, relative to the type of testing being performed.
- The test participants have been trained in the validation plan.
- Test participants have been trained in applicable VUMC SOPs.
- All individuals participating in validation activities are appropriately trained and/or have the appropriate experience to perform their respective roles.
- All materials, tools, and data specified must be prepared and provided to the test participants prior to the execution of the test scripts.

### 2.2 Exclusions

The following exclusions apply to the implementation of this system:

- All functions and abilities of the REDCap system that are outside the intended use of the eDocs will not be verified in the testing phase and therefore not validated.

## 3 Responsibilities

The following organizations and individuals will participate in the validation effort.

### 3.1 Management

Management will be responsible for the overall scope and execution of the validation project and review and approval of the validation documents. Management will also approve the system for use.

### 3.2 System Owner

The System Owner is accountable for establishing and maintaining the validated status of the computerized system. This includes ensuring that adequate resources for support and maintenance are in place and ensuring the integrity of the records residing on their computerized system. The System Owner represents the needs of the business users and the Business Process Owners. For this validation project, the System Owner will be responsible for reviewing and approving validation documents, including test scripts and test results and authoring applicable SOPs, if necessary. The System Owner will be required to provide scientific and technical assistance as well as access to the computerized system as required and in coordination with routine business operations, including providing generic user accounts to be used in the development and execution of tests scripts.

The System Owner will also provide scheduling information with respect to study specific and other business needs around the use of the system by the project team.

### 3.3 Quality Assurance Representative

The Quality Assurance Representative will ensure the validation process is in compliance with the regulatory standards identified in this VMP and applicable VUMC SOPs.

The Quality Assurance Representative will also be responsible for reviewing validation documents and performing audits of testing and documentation generated in accordance with this Plan and departmental SOPs. The Quality Assurance Representative will approve the system for use.

### 3.4 Application Manager/IT Representative

The Application Manager/IT Representative, also known as Technical owner, will be responsible for oversight of the day-to-day operation of the computerized system. The Application Manager/IT Representative is the technical expert ensuring the computerized system is installed, configured, secured and managed appropriately (including data archive, backup, restore, disaster recovery and business continuity processes) within the VUMC IT infrastructure environment.

### 3.5 Validation Representative

The Validation Representative will be responsible for management of the validation activities of the project. The Validation Representative will also be primarily responsible for defining the validation strategy and authoring all validation documents required for the validation of the system.

### 3.6 Validation Project Team

The validation project team will consist of the Validation Representative, a Quality Assurance Representative, Management, IT Representative and the System Owner, at minimum. Additional members may be added as needed. This team will be responsible for addressing any project related issues, questions, or concerns.

All Validation Project participants will be expected to adhere to the following:

- All work inputs from these stakeholders are expected to be completed in a timely manner.
- Any changes in availability of personnel or other resources will be proactively conveyed to the Validation Representative as soon as they are identified.
- Training will be provided by the responsible parties, as appropriate, to complete project tasks.
- Physical and logistical access will be provided, as required, to complete project tasks.

These responsibilities are not all inclusive and additional requirements may be placed on the various parties during the course of the validation activities. These additional duties will be agreed to by the Validation Project team. Tasks may be delegated as needed. However, the parties identified above will still be held responsible for seeing to the completion of those tasks unless otherwise specified.

## 4 Project Plan

### 4.1 Organizational Impact

eDocs will provide the file upload with electronic signature capability in any data collection instrument. This system is subject to 21 CFR Part 11 Electronic Records and Electronic Signature requirements.



## 4.2 Training

Training on the use of the system will be drafted in the form of a Guidance document as well as REDCap enabled FAQs as a part of this project and made available to users of the eDocs application.

VUMC and JAF Consulting associates must be trained on the following:

- Good Documentation Practices
- Systems Implementation Lifecycle and Change Control procedures

JAF consultants that participate and/or support in any phase of this plan will provide a copy of their curriculum vitae detailing the education, experience and/or training of the consultant will be included as an attachment to the Validation Summary Report.

Individuals who execute test scripts and/or are required to initial/date test scripts, will be required to sign the Signature Log sheet in Appendix 4.

## 5 Validation Overview

VUMC's validation processes is described in this plan and are designed to support all system life cycle activities on a per-phase basis; notably validation planning, system testing, system release/deployment, system maintenance.

Validation testing is designed and executed in consideration of pre-approved requirements, with the intent of verifying the system's ability to satisfy those requirements. This is to be done by executing test scripts designed to demonstrate the ability of the system to satisfy those requirements. For any requirement that cannot be technically met, procedural solutions will be utilized and verified.

Validation testing documents and associated deliverables are subject to review and approval by the system owner and VUMC Management, both prior to and after execution. Additionally, all validation deliverables are subject to audit by the Quality Assurance Representative, to ensure conformance with VUMC procedures and regulatory requirements.

### 5.1 Validation Testing

Validation testing for the system will be performed by designated, trained VUMC or JAF personnel and/or qualified vendor technicians as part of documented, approved Validation Test Scripts. The test scripts will describe each test purpose, objective and pre-defined testing acceptance criteria. The Validation Test Scripts will be designed in consideration of the approved requirements, with the purpose of verifying that each requirement is satisfied through formal testing or procedure.

### 5.2 Validation Deliverables

The Validation Project Team will ensure that validation deliverables outlined below are developed, reviewed and approved. The following table details the validation project deliverables as well as roles and responsibilities for the project team.

Table 1: Project Deliverable Overview

Deliverable/ Activities	Dependencies	Create / Update	Execute	Review / Approve
Validation Master Plan (VMP)	None	V	N/A	SO, TO, QA, M
Requirements Specification (RS)	None	V / SO	N/A	SO, TO, QA, M

Deliverable/ Activities	Dependencies	Create / Update	Execute	Review / Approve
Test / Qualification Protocols (IQ/OQ/PQ)	VP, RS	V / SO	TO / V/SO	SO, TO, QA
Post Execution Test / Qualification	VP, RS, TP / QP	V	V	SO, TO, QA
Requirements Traceability Matrix (RTM) NOTE: RTM will be incorporated within IQ and PQ.	TP / QP	V	N/A	SO, TO, QA
Validation Summary Report (VSR)	Executed TP / QP	V	N/A	SO, TO, QA, M

**V=Validation, SO=System Owner, TO = Technical Owner, M-Management, QA= Quality Assurance**

## 6 Validation Deliverables

### 6.1 Validation Plan

The eDocs application will be validated utilizing the validation overview as described above and following documenting a set of formal requirements and associated test cases, including regulatory control interpretations as requirements. Once validated to demonstrate the functionality and use, eDocs will be made available for use by VUMC and any associated partners or organizations who request to utilize the application.

The validation will include a standard validation lifecycle including validation planning (this document), requirements, testing strategy, executed testing and a validation summary confirming readiness for production.

### 6.2 User Requirement Specification

A requirement specification will be drafted utilizing the available wireframe design document for eDocs and noted updates based on the working application will be made prior to formal validation test execution.

Note that a wireframe process of design was used for the development and an initial set of requirements for use in the validation was drafted after the design of the application.

The requirements for eDocs will include the following components for system functionality:

- Ability of users to design a basic data collection instrument / form with the uploading of electronic documents capability
- Access granted to research staff who will provide role-based access to the eDocs module
- eDocs will work on any internet connected device.
- Functionality to keep the previous version of file in data history and new uploads are made to the eDocs records as updated versions
- Effective Security of the system and data in the vault environment
- Record retention capabilities in the configured Vault storage area.
- Because of the nature of the record created for research and submission purposes, will be compliant with 21 CFR Part 11

- Data Location: Locally Hosted in an on premises operating environment.

### 6.3 Functional Specification

A functional specification will not be required for this validation as the design of the tool will be based off of the storyboard designed to help with the initial development and flow of the record data associated with the eDocs record.

#### 6.3.1 Interfaces

eDocs is an integrated feature of the REDCap application at University of Vanderbilt Medical Center.

#### 6.3.2 System Diagram

The eDocs System is designed to utilize the functionality of the REDCap file upload which will allow the user to go through the verification process by entering the password for every upload.

#### 6.3.3 Hardware and Software details

The hardware and software information regarding versioning of equipment and software (primary and support) will be documented for the test and eventual production environments via a standard Installation Qualification document.

#### 6.3.4 Physical Location

The environment will be set up in connection with the existing REDCap environment at VUMC.

#### 6.3.5 Security

All encryption and security settings will be documented in the Installation Qualification document and confirmed, as needed, with the formal testing of the system and functionality that will be performed.

#### 6.3.6 Capacity

There are no concurrent user or storage capacity limitations or restrictions for the eDocs application.

#### 6.3.7 Backup

Backups of the eDocs environment will be performed in accordance with REDCap hosting. Backups of the application and the associated completed record form documentation will be done daily.

#### 6.3.8 Availability

The system will be routinely available with the exception of standard maintenance windows defined by the support Service Level Agreement for the IT management of the REDCap and associated eDocs environment.

#### 6.3.9 Recoverability

Based on the backups and associated system installation and configuration documentation, the system will be recoverable. This will be demonstrated with associated formal disaster recovery planning and testing for the REDCap application overall.

#### 6.3.10 System Maintenance

The eDocs application will be maintained for the foreseeable future by University of Vanderbilt Medical Center IT, which will manage ongoing enhancement/upgrades for the application and will also provide software patch / fix support, as necessary.

#### 6.4 Traceability Matrix

A Traceability Matrix document will be created to support the connecting of each requirement to associated executed test case evidence. This will provide demonstrative evidence of the validation of the eDocs software as a service product for VUMC Medical Center and associated research partners. The Traceability Matrix will be available as part of the validation documentation that can be utilized by those using the system.

#### 6.5 Installation Qualification (IQ) Protocol

The eDocs software version associated with the REDCap application has been installed at University Of Vanderbilt Medical Center. An abbreviated Installation Qualification will be executed documenting the installed applications and support software that allows for the eDocs application to run within the REDCap application. The abbreviated IQ information provides for effective installation details to support installations of this version of eDocs REDCap at other entities who wish to have the application installed for use.

Test Scripts within test protocol will be drafted, approved and executed to provide the documented evidence the “as Built” configuration of the installation of the REDCap system and supporting infrastructure are captured.

#### 6.6 Operational Qualification (OQ) Protocol

eDocs has been built according to a storyboard design and leveraging existing form functionality available within REDCap. A set of retrospective requirements have been developed and will be tested in alignment with a Performance Qualification (PQ) formally testing the associated functionality as fit for use.

Test Scripts within test protocol will be drafted, approved and executed to provide the documented evidence of the operation of the REDCap system and supporting infrastructure are captured. Test Scripts will be written to address the defined Requirement Specifications.

#### 6.7 Performance Qualification (PQ) Protocol

The PQ step determines that the system will work as intended with real data to demonstrate satisfactory results. As noted above, a Requirements specification will be created with this validation effort. The requirements, which include 21 CFR Part 11 requirements based off a drafted interpretation document, will be traced to effective performance qualification test cases providing effective evidence in support of the validation of the eDocs software.

#### 6.8 Validation Summary Report

The eDocs Validation Report will summarize the execution of the validation effort. It will provide a clear list of all completed documentation, will summarize the testing effort and document of any testing issues encountered and how they have been addressed and closed out or deferred. The execution will include an independent review of the executed testing, as well as documenting any decisions to defer any issues from the limited development that cannot be closed out. The error and issue resolution processes will be defined and documented in an official Error Log for the project. The process will include an independent review and confirmation for any deferred requirement.

## 6.9 Standard Operating Procedures

All User Operation and Administrative procedures will be developed to ensure they reflect current operation, maintenance and administration of the system.

## 7 Quality Assurance

Quality assurance for the eDocs project will be performed by JAF Consulting, who was hired as subject matter experts in regulated validation processes and will apply that knowledge and experience to the validation and documentation processes for eDocs. JAF is leveraging existing documentation to provide for the expected documentary evidence to support eDocs validation. As noted in the roles, JAF representatives will perform quality review of the documentation for this project.

## 8 Acceptance Criteria

Within each of the test scripts, pre-defined acceptance criteria for each test with a Pass/Fail for each test will be identified. All essential components of the documents must be created, reviewed and approved before overall acceptance completion.

Overall acceptance of the Project will be deemed complete when the following criteria have been accomplished:

- It has been demonstrated that Vendor Assessment of the Empower3 system was performed and has been satisfied.
- It has been demonstrated that the Requirement Specifications have been satisfied where required.
- All Users have been trained in the use of the system.
- All risks identified in this plan have been addressed and/or have been appropriately mitigated.
- It has been demonstrated that testing has been satisfactorily completed and approved, all test results must pass the pre-approved acceptance criteria and all necessary operators trained.
- All discovered deviations have been appropriately documented and resolved.
- Any constraints concerning the completion of the validation effort have been addressed and documented.
- SOPs are in approved state.
- Approval of the Validation Summary Report.
- Any additional items which will be identified within the Validation Summary Report.

## 9 Validation Package/System Release

The Validation Package consists of approved and executed plans, test scripts and test results, reports and supporting documentation as defined in Validation Overview, Table 1.

A Quality Assurance Representative will review the Validation package to assure that all validation activities (elements and components of this plan) have been successfully completed and that documented evidence exists to substantiate the declaration that the Validation has been completed.

Release of the system will be documented and communicated to the signers of the Validation Summary Report via e-mail, a copy of which will be maintained with the Validation Summary Report.

## 10 Deviation Management

All Deviations to this plan will be handled as part of the process described in Appendix 1.

## 11 Documentation Management

### 11.1 Documentation Management

The management of validation documentation provides assurance that the documentation is version controlled, complete, clear, accurate, and intelligible to the intended audience and approved by a Quality Assurance Representative.

### 11.2 Document Approval

Documents will be reviewed and approved according to Validation Overview, Table 1. Document approval will be by wet signature on paper documents. Signature may be scanned or similar representation.

### 11.3 Document Changes

Revisions to documents will be handled following Good Documentation Practices (GDP) and as outlined in VUMC's SOPs. Any significant modifications (typos not considered Significant Modifications) to a document will be approved by the same person(s), or designees, that approved the original document. If a personnel change occurs during the execution of the validation, an individual with the equivalent title and authority may serve as a replacement member of the validation team and approve modifications.

### 11.4 Document Storage

Documents and deliverables listed in this plan, along with any physical media (such as data and application CDs) and archive copies of the hard-copy manuals, constitute the validation documentation for the Project. The validation documentation collection will be stored by VUMC, as per current archiving SOPs and both physical documents and electronic copies will be transferred to VUMC Archives for storage.

### 11.5 Record Retention

VUMC will retain all validation documentation on site in company archives for a defined period.

## 12 Regulatory References

List of regulations that will need to be considered or met related to the system:

- HIPAA (Health Insurance Portability and Accountability Act of 1996)
- FDA, 21 CFR Part 11, "Electronic Records; Electronic Signatures; Final Rule." Federal Register Vol. 62, No. 54, 13429, March 20, 1997
- FDA, 21 CFR Part 11, "Electronic Records; Electronic Signatures; Final Rule." Federal Register Vol. 62, No. 54, 13429, March 20, 1997
- Guidance Document – Use of Electronic Records and electronic signatures in clinical investigations under 21 CFR Part 11–June 2017 Definitions, Acronyms and Abbreviations

## 13 Definitions / Terms / Acronyms

- **21 CFR Part 11** – (FDA Title 21: Food and Drugs - Part 11 - Electronic Records; Electronic Signatures) The regulations in this part set forth the criteria under which the agency considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.
- **ASA** – Application Server Administrator, configures application server including installation and support related problems.

- **DBA** – Database Administrator, perform database-related installation procedures; provide database support; address database-related problems.
- **eDocs/eRecords**– Any combination of text, graphics, data, audio, pictorial or other information in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system.
- **FS** - Functional Specifications - This step defines or creates a document in user understandable format based on URS. This is developed by developer or vendor or service provider.
- **HIPAA** - Health Insurance Portability and Accountability Act (HIPAA) of 1996 - a US law designed to provide privacy standards to protect patients' medical records and other health information provided to health plans, doctors, hospitals and other health care providers.
- **IA** – Internal Audit, assess the project by providing guidance from an audit perspective.
- **IQ** - Installation Qualification – This step provides documented evidence that the system, as installed or modified, comply with the approved design and the manufacturers recommendations.
- **IRB** – Institutional Review Board (IRB) is an committee made of up representatives to provide voting oversight of the clinical research by reviewing the protocol and making sure that the proposed research is sound and beneficial as well as providing for input and oversight of patient safety as the participating sites.
- **IT** – Information Technology, provides support related to any information technology requirement, policy or need.
- **JAF** – JAF Consulting, Inc.
- **OQ** - Operational Qualification – This step provides documented evidence that the systems and sub-systems are capable of consistently operating within established limits and tolerances.
- **PHI** - Protected health information - Under US law (HIPAA), PHI is any information about health status, provision of health care, or payment for health care that is created or collected by a "Covered Entity" (or a Business Associate of a Covered Entity), and can be linked to a specific individual.
- **PM** - Project Manager, responsible for project management and planning
- **PQ** - Performance Qualification - This step is conducted to demonstrate compliance with all requirements under actual process conditions. This includes performance as well as process requirements.
- **PS** – Project Sponsors, provide overall guidance.
- **PU** – Power Users, REDCap users who have advanced application experience and use the application on a daily basis.
- **QA** - Quality Assurance, assists for compliance with regulatory requirements from a quality manager perspective.
- **RA** – Regulatory Affairs, assures compliance to applicable regulatory requirements
- **REDCap** - Research Electronic Data Capture
- **SA** – System Administrator, person(s) who administer the application and are very familiar with the application.
- **VUMC** – University of Vanderbilt



- **URS** - User Requirement Specifications - This step defines what user wants from the system and makes sure that requirement is met
- **VMP** - Validation Master Plan - A VMP will specify all necessary qualification / validation activities for a system validation project. All validation activities are planned using the 'V Model' approach as follows to identify the relationship between the development and testing phases of the project ensuring that appropriate quality assurance and testing takes place throughout the project lifecycle.



## Appendix 1: Test Script Execution Procedure

### 1 General Information

- Copies of the original approved test scripts will be made for execution purposes prior to the commencement of testing. The copies must be labeled or stamped as “Approved for Execution Copy”, initialed and dated on the first page. A copy of the original test script will be used for the initial execution. Iteration number will be documented on re-executed test scripts, if necessary. Unused test script copies will be destroyed at the end of the project.
- All entries to the test scripts and associated documentation will follow the General Documentation Practices in this appendix and must be recorded legibly in permanent blue or black ink (Not Gel or marker).
- Each person involved in executing or reviewing the test scripts (post execution) throughout the validation project must complete a copy of the attached Signature Log page (see Appendix 4). The copies must be labeled or stamped as “Exact Copy”, initialed and dated. The completed copy or copies of the Signature Log page will be filed as part of the Validation Summary Report.
- Two or more persons will participate during the execution of test scripts. One person will act as the “tester” executing the test, documenting the results, entering Pass or Fail. The other will act as the “reviewer” and will review the test results and document the overall execution. Roles may be switched throughout the test execution.
- Date Format: The date format to be used in DDMMYYYY or MM/DD/YYYY
- All screen prints will be paginated and will also include the test script number, test step number, tester’s initials, and date.

#### 1.1 Tester Instructions

- The Tester will execute the test steps in sequential order unless noted.
- The Tester will record the actual results.
- The Tester will note any relevant comments in the Actual Results or Comments field.
- The Tester will print all reports and note the test script number, test step number, initial and date the top page of the report.
- The Tester will sign and date the bottom of each test script executed to indicate that they were the person who executed the test script on that date.
- After completing the entire test script, the Tester will record any deviations in the Test Summary section of the script and record the deviation number from the log next to the deviation on the test script.
- The Tester will take screen prints when indicated, when an unexpected error message is received and when the expected results did not occur.
- The Tester will print the screen prints, note the test script number, test step number, date and initial the top of each page and attach them to the completed test script. They will also number all items in the appendices page X of Y.

- Should any script errors be encountered, the Tester will converse with the author and make a notation in the comment section of the test script.
- Should an additional comment sheet be required, the Tester must note the test script number, date and initial the top page and attach it to the completed test script.

## 1.2 Reviewer Instructions

- The Reviewer will review all test scripts, resulting data, reports and screen prints.
- The Reviewer will sign and date the bottom of each test script executed to indicate that they have reviewed the test results and supporting documentation.

## 2 Documenting Test Execution

All annotations, such as test results, reviews, and hand-written notes (check marks, signatures, problem descriptions, comments, script corrections, etc.) should be recorded in indelible blue or black ink, initialed, and dated. Mistakes must be crossed out with a single line, initialed, and dated with a brief explanation given. Do not use whiteout or other means of masking an error. Comments and significant notes related to the Test Plan or script are to be noted in the Comments section, at the bottom of each page. The tester may make additional notations on an attachment to clarify information relevant to the test. The notations must be documented with the initials of the tester and the date the notation was made. The attachments are filed directly at the end of each corresponding test script. The tester and the reviewer will verify there is an attachment and that it is labeled as described in Section Verification of Screen Prints and Other Output Attachments.

### 2.1 Verification of Screen Prints and Other Output Attachments

During testing, screen prints and other attachments will be generated as required. The testers must collect each attachment during the test and must write the following on the first page of each attachment:

- test script number,
- test script iteration (if applicable),
- test step number,
- page number (in the format x of y),
- tester's initials and date.

The rest of the attachment pages must be numbered only (e.g. Page X of Y).

For example, if a 25-page printout is attached it would be numbered as follows: 1 of 25, 2 of 25, ..., 25 of 25. Each set of attachment(s) is to be signed and dated by the person(s) executing the test script on the day that the test has been completed. The attachments are filed directly at the end of each executed test script. The tester and the reviewer will verify there is an attachment and that it is labeled as described above. Post-dating is unacceptable. Any late entries made to the test script must be initialed and dated by person making the entry followed by a brief explanation why the entry was made.

Supplemental execution documentation requires the same information and page numbering scheme described above.

## 2.2 Taking a Screen Print (other methods may be used)

Steps for taking a screen print using a blank Microsoft WordPad document:

1. Click on the screen being captured.
2. Press ALT and Print Screen.
3. Click at the end of the MS WordPad document.
4. Type the Test Script Number, Test Step Number and the Run Number/Iteration.
5. Press **Ctrl** and **'V'** to paste the captured screen image.
6. If more than one screen print is required for the test script, repeat steps 1 – 5.

## 2.3 Handling Test Changes / Corrections

If, during the course of test script execution, either of these two situations is encountered; there is an acceptable way of making a correction where a Deviation Report is not required. The two situations are:

- An obvious error is identified in a test script requiring a test change
- The tester creates a documentation error, where the tester records data incorrectly (e.g. transposition) or records data in an incorrect place or manner

Follow these steps to make the correction when either of these situations occurs:

1. The word or words that are in error will be crossed-out with a single line
2. The correction for that error will be written above the incorrect word or words
3. A reason for the correction will be written next to the correction (a lengthy explanation for the correction may be placed in that page's "Comments:" section with a corresponding in-line footnote located by the correction which refers to the explanation in the comments section)
4. The tester's initials identifying the person making the correction will be written next to the reason for the correction and the date of the correction will be written next to the testers initials
5. Resume testing at the place where the error was encountered.

Whiteouts, scratch-outs, and overwrites are **not** allowed. This method of test correction will only be done on tests where the error in the test script is easily recognizable as an error, such as an obvious contradiction, and does not change the intent of the test; or where there is a tester documentation error. If the error does not meet these criteria, the tester will follow instructions in Managing and Documenting Deviations.

## 2.4 Documenting Results

If the Expected Results are met, then the test step result is a Pass. If any variation occurs from what is described in the Expected Results, then it is a Fail, even if the problem was not due to the system, but to missing inputs or an incorrect test. (See above for permissible changes to test scripts.) The Actual Results are entered just before the "Pass" or "Fail" indication. Deviations will be noted in the method as follows:

The test will be marked as failed, the step within the test script will be recorded, and a description of the observed test results will be recorded on the test script. If the deviation

was investigated and resolved, the details of the resolution should be included (See Managing and Documenting Deviations).

#### 2.4.1 Tests that meet Acceptance Criteria

When tests meet the Acceptance Criteria, the tester may write one of the following in the actual results column:

- “As Specified” or “A/S” when the actual value is not being recorded, or
- write in the actual value if requested by the test script (e.g., serial number), or
- write in the missing words that are in the Expected Results column and then write the word “Pass” in the “Pass/Fail” Column.

#### 2.4.2 Tests that DO NOT meet Acceptance Criteria

When a test does not meet the Acceptance Criteria, the tester will enter the actual result or a description of that result in the “Actual Results” column. Failure to meet the Acceptance Criteria may be caused by, but not limited to, a test script error (See Handling Test Changes/Corrections), a system failure due to unexpected events impacting testing activities, or tester execution error. In any case, a deviation must be documented.

### 2.5 Managing and Documenting Deviations

Each test script can only have one of two possible statuses for any given test execution: Pass or Fail. If the Expected Results are met, then it is a Pass. If a test does not meet Acceptance Criteria, or any variation occurs from what is described in the Expected Results, then the tester will notify the Validation Representative and wait for further instruction. The test script will not be given a status of Fail until instructed to do so.

#### 2.5.1 Assigning Deviation Severity and Test Suspension

The Validation Representative will review the reported deviation first with the tester to assess if it is a: script error, minor deviation, or major deviation.

If the Validation Representative cannot assess its severity, then the deviation will be raised to the Validation Team to determine the error type and the course of action.

Depending on the outcome of the deviation severity assessment, the Validation Representative will inform the tester to do one of the following:

- If the deviation is determined to be a script or documentation error; the tester will be directed to follow the procedure in Handling Test Changes / Corrections section.
- If the deviation is determined to be a Minor deviation; the tester will be directed to follow the procedure in Minor Deviations Section
- If the deviation is determined to be a Major deviation; the tester will be directed to follow the procedure in the Major Deviations Section.

#### 2.5.2 Minor Deviations

Minor Deviations, include the following occurrences:

- Tester error (tester executed an instruction incorrectly)
- Test script Errors (missing or duplicate test step that do not change the intent of test)
- Aesthetic Deviations on a display label

- Variations in a message text

Manage minor Deviations as follows:

1. The tester will check “Fail” for the test step
2. The Validation Representative will immediately generate a Deviation Report Number. Deviation Report Numbers shall start at #001 and continue up, as needed.
3. A Deviation Log entry will be made by the Validation Representative documenting the Deviation number, Test Script and Script Step numbers, and a brief summary of the deviation. The Deviation Log Entry shall be signed and dated by the tester.
4. The tester (with the help of the Validation Representative) will create a Deviation Report.
5. The Validation Representative will verify that the test script step has a brief description of the error in the Actual Results column with a reference to the comments section of that page. The comments section of the test script on that page will contain a reference to the Deviation Report (DR) number and the failed step number.
6. Any unexecuted test steps on the page where the error occurred will be crossed out and labeled N/A with the reason, the tester’s initials, and the test date.
7. The Validation Representative and / or the Validation Team will detail a resolution, which will include the scope of repeat testing required (specific steps to re-execute). The resolution may be determined by the System Owner, who serves as technical expert. The resolution must be approved by the System Owner before it can be implemented.
8. The resolution is implemented (following change control procedures, if required).
9. The Validation Representative will generate unused page(s) of the original test script where the error occurred and have the tester label the new page(s) as the original page number followed by an ‘A’ (i.e. the first duplicate of page 7 would be Page 7A, the second duplicate of page 7 would be 7B, etc.).
10. Unexecuted test steps on this duplicate page (i.e. page 7A) will be crossed out and labeled N/A with the reason, the tester’s initials, and the test date.
11. Applicable test steps on this page will be executed and documented in the usual manner.
12. This additional page will then be placed behind the original page and notations referring to the additional page for the retest will be made on the original page (e.g. a notation on the original page will indicate to “See page 7A for re-test”).
13. Upon successful completion of the retest, the DR must be completed, reviewed, and the Deviation Log updated. All Deviations must be closed and updated in the Deviation Log maintained by the Validation Representative.
14. Completed DRs will be placed at the end of the test script.

### 2.5.3 Major Deviations

Major Deviations, which cause test execution to be suspended, include the following occurrences:

- Incorrect test environments, database setup or system configuration.
- System/application errors that are attributable to the software, hardware, or system design.
- Network problems or power failures.
- Requirement or design errors.
- Technical errors in the test script.

Manage major Deviations as follows:

1. The tester will check “Fail” for the test step
2. Testing will be suspended.
3. The Validation Representative will immediately generate a Deviation Report Number. Deviation Report Numbers shall start at #001 and continue up, as needed.
4. A Deviation Log entry will be made by the Validation Representative documenting the Deviation number, Test Script and Test Step numbers, and a brief summary of the deviation. The Deviation Log Entry shall be signed and dated by the tester.
5. The tester (with the help of the Validation Representative) will create a Deviation Report.
6. The Validation Representative will verify that the test script step has a brief description of the error in the Actual Results column with a reference to the comments section of that page. The comments section of the test script on that page will contain a reference to the Deviation Report (DR) number and the failed step number.
7. The Validation Team will evaluate the deviation and propose a resolution, which will include the level of repeat testing required and any impact on test execution. The proposed resolution must be approved by the System Owner before it can be implemented.
8. If applicable, any required changes to the code as a result of a system or application error will be performed in the development environment and then migrated to the validation environment after successful testing. Release for retesting shall follow the appropriate Change Control procedures.
9. Any unexecuted test steps in the test script where the error occurred will be crossed out and labeled N/A with the reason, the tester’s initials, and the

test date. A reference to the new test script must be made on the original script (i.e. "See entire script retest; Run 2").

10. Once the resolution is implemented, testing can resume. The Validation Representative will generate an entirely new test script to use for retesting; the new copy of the script will have a reference to the original execution.
11. For retesting, the script "Run" number shall be incremented to the next sequence number, a reference to the original test must be made and the script must be clearly identified as the next run on each page.
12. The retest script will be executed and documented in the usual manner.
13. Upon successful completion of the test script execution, the DR must be completed, reviewed, and the Deviation Log updated. All Deviations must be closed and updated in the Deviation Log maintained by the Validation Representative.
14. Completed DRs will be placed at the end of the test script.

### 3 Deviation Log

1. Each exceptional condition is logged on a copy of the attached Deviation Log (see Appendix 2) leaving the Date Closed and Closed By columns blank until the Deviation has been resolved. The copies must be labeled or stamped as "Approved for USE COPY", initialed and dated. The copy or copies of the log will be used to track all Deviations generated during Validation Testing.
2. Once the Deviation is resolved, reviewed and signed by the Validation Representative, the Validation Representative completes the Date Closed and Closed By columns.
3. The copy or copies of the completed Deviation Log will be filed as an attachment to the Validation Summary Report.

### 4 Deviation Report

1. If the test result does not meet the expected result/acceptance criteria, after confirming that it is not due to a readily correctible test script error, the tester will write "Fail" in the "Pass/Fail" column.
2. The "Deviation Report" (see Appendix 3) will be completed for each deviation that is encountered during the execution of a test script or to document an exceptional condition that is encountered during the execution or review of a test script. The test script will reference each deviation report by number when applicable. Each "Deviation Report" recorded will be assigned a unique deviation report number. The report number will be DV-atn-nnn where "DV" stands for Deviation, "atn" is the asset tag number and "nnn" is a number starting at 001. Deviation reports will be numbered sequentially.
3. Classification of the deviation on the "Deviation Report" must be in accordance with the section of this Plan, "Assigning Deviation Severity and Test Suspension." A blank "Deviation Report" form will be included and approved as part of each individual Test script. Copies of the



blank form will be made and used to document Deviations. The copies must be labeled or stamped as “Approved for USE COPY”, initialed and dated. Deviation reports will be filed with its corresponding Test script.

4. The following field definitions are provided for clarity when completing a report:

Data Field	Description
Deviation Number:	This is the sequential Number assigned to the Deviation as entered within the Deviation Log.
Script ID (s)	The ID’s of all test scripts that are impacted by or associated with the Deviation must be listed here. If multiple are listed, the test script in which the Issue occurred should have a * placed next to it to identify the test script in which the deviation was identified.
Script Step Number(s)	The step Numbers in which the Deviation was encountered. This refers to the Test Steps associated with the Script in which the deviation was identified (although other scripts may be impacted).
Test Run Number	This is the cycle of test script execution in which the deviation was encountered. The Run Number is indicated on the test script and is incremented by one for each execution of the test script.
Execution Instance	Production
Complete description of the Deviation:	The full description of the behavior/actual result that was encountered during testing appears here.
Recorded By & Date:	Signature of the Individual that recorded the deviation description.
Corrective Action Plan:	The actions that are taken to resolve the deviation. This includes updates to the system, documentation and retesting (if required).
Impact (High, Medium, and Low):	The impact dimension gives a measure of the amount of effort that was required to fix the deviation and/or the amount of re-design that was needed to address the Deviation. The impact dimension of a deviation should be classified as <b>Low</b> if addressing the deviation merely requires changing a system setting or if the deviation does not require any changes. These cases do not require a change to the specification document or procedures. The deviation should be classified as <b>Medium</b> if some amount of system redesign or procedural change is involved. In most cases, a change or correction to the specification document will be required. Finally, the deviation should be classified as <b>High</b> on the impact dimension if the system requires considerable re-design, or if the defect could not be fully addressed through re-design.



Data Field	Description
Criticality (High, Medium, and Low):	The criticality dimension gives a measure of the impact on data integrity if the Deviations were not addressed or had not been detected. The criticality dimension is expressed as High, Medium or Low. Deviations classified as <b>High</b> could affect data integrity and the core functionality of the system if not addressed. Deviations classified as <b>Medium</b> affect desired functionality but do not affect data integrity and integrity of procedural enforcements. Finally, those Deviations classified as <b>Low</b> could cause minor inconveniences on the side of the users, or the Deviations were acceptable by the System Owner.
Recorded By & Date:	Signature of the Individual that recorded the corrective action plan.
Approval to Proceed & Date:	Signature of the Individual that is approving the corrective action plan. The System Owner and Technical Owner may approve the corrective action plan.
Corrective Action Verification:	This field captures the verification of the results of the corrective action plan and summarizes the closure of the deviation
Recorded By & Date:	Signature of the Individual that recorded the corrective action verification.
Technical Review Signature & Date:	Signature of the individual responsible for the Implementation of the Changes.
Approval & Date:	Signature of the Representative that has reviewed the documentation, plan and results of the closure of the deviation and is approving closure of the deviation.
Page Number:	Page Numbering is to be expressed in X of Y format. The Deviation report is always page 1 and each attachment to the deviation is sequentially numbered behind the deviation report.

## 5 Test Script Format

A test script may be composed of numerous tests. Each test script may contain numerous test steps. Each test step has a procedure, expected results, actual results and step pass/fail. Following are brief summaries of the test sections if they are included. Some test scripts are to collect information and would not contain all of the sections below.

Data Field	Description
Test Script Number	A sequential number that uniquely identifies each test script.
Acceptance Criteria	A brief description how the overall test script disposition will be determined.
Test Setup	Lists any specific test data sets and, where applicable, test values required for test script execution. "N/A" is used to indicate that there are no additional input data requirements.
Test Script Title	The test script title provides a brief description of the test.

Data Field	Description
Test Objective	The test objective identifies the objective of the test and what is to be accomplished.
Step Number	Uniquely identifies a test step in a test script sequence.
Input Action	Describes actions to be taken by the tester. Examples of this include navigation through an application menu structure, selecting and entering values, printing screen captures, etc. – Not always required.
Test Procedure	There is a test procedure statement for each test step. The test procedure identifies exactly what steps are to be performed. There must be sufficient detail in the test procedure to repeat the test and obtain the same results. The test procedure must identify all inputs. Where that is not possible, space for recording actual inputs must be provided.
Expected Result	The expected results are stated for each test step and are the basis for evaluating system performance against expected results. The overall standard of performance is that no Deviations between expected data and actual data (either displayed or reported) are allowed.
Actual Results	Test observations will be noted in the Observed Results section, as they are made, as evidence for following the defined steps, such as comparisons between Acceptance Criteria and test results, and confirmation that the test has been successful or has failed. Observations can be supported by screen prints or reports, however, observations not supported by screen prints and/or hard copy reports shall be recorded in this section. If additional space is needed for documentation, the Comments section or an additional may be used. Actual test results will be recorded when quantifiable. If the test results are exactly as expected, the tester will document this in the Actual Results indicating that the actual results matched the expected results. If the test results are not exactly as expected the tester will contact the Validation Representative for further instruction. Under no circumstances may the observed results field be left blank.
Step Pass/Fail	This section is for recording the status of an individual test step. The "Pass" checkbox will be checked if all acceptance criteria are met. Testers should not check the "Fail" checkbox until instructed to do so by the Validation Representative. All "Fail" results must be documented in the Comments Section and a deviation form completed.
Comments	If additional space is needed for documentation, the Comments Section of each test script may be used. If the comments section is not used it must be lined out and initialed and dated by the tester. Under no circumstances may the Comments field be left blank. This would provide area for additional data to be added after test execution.



Data Field	Description
Performed By Initials/Date	Provides a space for the initials of the person who executed the test script page and the date. If more than one tester executes a test script, a comment must be included in the test script to clarify which steps were executed by which tester. All testers must include their initials and date at the end of the applicable test script page. The tester(s) initials/date must be included the date when the test script page or steps were executed.
Test Summary Page	At the conclusion of each test script execution, there is a summary page including an overall Pass/Fail box that must be completed appropriately. Write "Pass" when all acceptance criteria are met. Write "Fail" if any test step fails. Typically, if a test fails there is supporting documentation in the form of a Deviation Report.
Test Conclusion	Specifies whether or not all test acceptance criteria have been met and if the test passed or failed. The test script reviewer will indicate "Yes" or "No" and will enter their initials and the date in the "Initials and Date" field. Note: In some circumstances, one or more test steps can fail while still allowing the script to pass. This determination will be made by the reviewer of the test script and documented in the comments area.
Execution Reviewed by/date	Provides a space at the end of the test script for the signature of the person who has reviewed the test script and the date when they signed.

**Appendix 2: Deviation Log**

This log will be used to keep track of issued deviations. Make copies of this page as necessary.

Deviation Number	Test Script Number / Section	Brief Description of Amendment/Deviation	Status	Script Step Number(s)	Test Step	Site	Date Closed	Closed by	Impact	Criticality
Reviewed By/ Date										

Page \_\_ of \_\_

**Appendix 3: Deviation Report**

This Report will be used to document Deviations. Make copies of this page as necessary.

Deviation Number:		Script ID (s):		Script Step Number (s):	
Test Cycle Number:		Execution Instance:			
Complete description of the Deviation:					
Recorded By:		Date:			
Corrective Action Plan:					
Test Re-execution required? <input type="checkbox"/> YES <input type="checkbox"/> NO					
If YES, specify Test Script #, Step(s) including Login/Logout and Run #:					
Impact (High, Med, Low)		Criticality (High, Med, Low)			
Recorded By:		Date:			
Approval to Proceed:		Date:			
Corrective Action Verification:					
Recorded By:		Date:			
Technical Review:		Date:			
Approval:		Date:			

**Appendix 4: Validation Signature Log**

All Participants in this validation effort must complete the following information:

Name (Printed)	Title / Responsibility	Signature	Initials	Date
Reviewed By / Date:				

Page \_\_ of \_\_

**Appendix 5: Attachment Reconciliation Log**

Protocol Number / Run Number / Reference Section and Step	Attachment Number	Total Page Count