



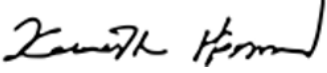

Standard Operating Procedure: REDCap Validation

SOP Number:	113
Version Number:	2.0
Approved Date:	May 24, 2024
Department/System:	Digital Solutions – Data Management /REDCap

DOCUMENT HISTORY

Version Number:	Summary of Changes Made:	Effective Date
1	New Document	December 16, 2020
2	<ul style="list-style-type: none"> • Branding • Procedure updates and other minor wording changes 	May 24, 2024

APPROVALS

Approver Name	Approver Signature	Date
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1. PURPOSE

- 1.1. To define the procedure used for validation of the UBC Faculty of Medicine (FoM) REDCap application. As outlined in the FoM REDCap Validation Plan, REDCap validation focuses on core functionalities and does not cover project-specific validation.



2. SCOPE

- 2.1. This procedure applies to the FoM Data Management (DM) Team, Digital Solutions Change Approval Board (CAB), and Manager, Research Data Services.
- 2.2. FoM REDCap validation approach utilizes specifications and testing materials developed by Vanderbilt University. Additional documents (section 4 below) outline the comprehensive validation activities carried out at each software major upgrade.

3. RESPONSIBILITIES

- 3.1. FoM DM Team is responsible for designing and approving the FoM REDCap validation plan.
- 3.2. FoM DM Team is responsible for creating and executing the test scripts for a set of defined core functionalities of the REDCap application released in the Long-Term Support (LTS) branch by REDCap consortium (Vanderbilt University).
- 3.3. FoM DM Team are responsible for reviewing and approving the test scripts.

4. RELATED SOPS/DOCUMENTS

- 4.1. MDITSYS SOP0023 IT Change Management Plan
- 4.2. FoM DM SOP 111 Bug Management
- 4.3. FoM DM SOP 115 REDCap Software Upgrade
- 4.4. FoM REDCap Validation Plan
- 4.5. FoM REDCap Functional Requirements vX.x
- 4.6. FoM REDCap Features List
- 4.7. FoM REDCap Validation Certificate
- 4.8. FoM REDCap User Acceptance Testing Checklist
- 4.9. FoM REDCap Core Features Checklist

5. DEFINITIONS

- 5.1. **Research/Project Team:** Research/project assistants, nurses, data entry and other personnel involved with and granted access to the REDCap project. The Team members report to the PI/Project Lead but are generally directly supervised by the PA.
- 5.2. **FoM Data Management (DM) Team:** Team Lead, Scientific Analyst and other FoM DM individuals responsible for managing projects in REDCap and assisting Research/Project Teams in conducting research studies or projects.



- 5.3. **REDCap Project:** A set of data entry forms, surveys, schedules and other data management tools pertaining to a specific research study or project.
- 5.4. **REDCap Long Term Support (LTS) Branch:** Long Term Support is a major release by REDCap consortium and is supported with patches only (i.e. new features are not added) for an extended period of 6 months.
- 5.5. **FoM REDCap Development (Dev) Instance:** REDCap installation/server used for testing, virtually identical to the production or live installation/server.
- 5.6. **Manual Testing:** This is the process of manually testing software for defects. It requires a tester (DM Senior Programmer or Coordinator) to play the role of an end user and exercise selected features of the application to ensure expected behavior.
- 5.7. **Test Script:** A set of conditions, variables or steps under which a tester will determine whether a system under test satisfies requirements or works correctly.
- 5.8. **Bug:** Industry term for error or failure.
- 5.9. **FoM Digital Solutions (DS) Systems Team:** Team responsible for the configuration, operation and maintenance of the FoM servers and underlying platforms.
- 5.10. **Digital Solutions Change Approval Board (CAB):** A fixed group of managers to oversee and approve/deny changes on the software application.
- 5.11. **FoM DM REDCap LTS X.x Validation Tracking project:** A REDCap project designated with the corresponding LTS version used by the DM Team to track validation testing.

6. SET-UP

- 6.1. Every six months, the REDCap consortium releases a new LTS Branch with new features. FoM REDCap is upgraded on a 6-8-month cycle (LTS Release). The FoM DM Team moves to the new LTS Branch 1-2 months after the LTS Branch is released by the consortium. During this time, the FoM DM Team investigates the new functionalities, updates documentation, writes test scripts, and performs validation activities. After the new LTS Branch is running as the active REDCap version, it is supported by bug fixes and patches which are applied as necessary.
- 6.2. FoM DM Team maintains two instances of the REDCap application. The Production Instance is the live system holding ongoing projects and data. The Dev Instance is used for testing and validating new LTS releases and is identical to the Production instance with the exception that it does not contain live projects and/or data.
- 6.3. Project-specific validation is the responsibility of the Research/Project Team. The FoM DM Team provides Research/Project Teams the opportunity to perform User Acceptance Testing (UAT) on their individual projects. FoM DM Team provides a



REDCap User Acceptance Testing Checklist that guides Research/Project Teams through the necessary steps to validate and test their projects.

7. PROCEDURE

- 7.1. FoM DM Team categorizes the new features released in the LTS Branch into the FoM REDCap Core Functional Requirements document.
 - 7.1.1. New Functionalities are categorized as core or ancillary functionality.
- 7.2. FoM DM Team sends notification to active REDCap users approximately one month prior to upgrade with instructions on how to test their individual REDCap project/study in the Development Instance should they choose to (see FoM DM SOP 115 REDCap Software Upgrade).
- 7.3. Once REDCap Core Functional Requirement document is approved, the FoM DM Team updates, and if necessary, updates or creates new test scripts for the updated core functionalities. Updated scripts are uploaded to the FoM REDCap LTS X.x Validation Tracking project.
- 7.4. The FoM DM Teams executes the test scripts on the REDCap Development Instance and tracks results on the FoM DM REDCap LTS X.x Validation Tracking project.
 - 7.4.1. If a bug is found while executing the test scripts, the FoM DM Team contacts REDCap consortium to report the bug (see FoM DM SOP 110 Bug Management).
- 7.5. Once script execution is complete, the DM Team Lead discusses the results with the Manager, Research Data Services to seek approval.
- 7.6. Once validation and functional testing of new LTS upgrade is approved, The DM Scientific Analyst engages with FoMDS Systems Team and begins the REDCap upgrade process following UBC IT Change Management Plan (see MDITSYS SOP0023 IT Change Management Plan and FoM DM SOP 115 Software Upgrade).
- 7.7. Upon approval, the Manager, Research Data Services signs the Validation Certificate to mark the completion of validation process.
- 7.8. FoM DM Team adds the approved test scripts to the FoM DM REDCap LTS X.x Validation Tracking project, *Instructions and Documentation* form which also includes the FoM REDCap Functional Requirements and the FoM REDCap Features List.

8. REFERENCES

- 8.1. REDCap Consortium Regulatory and Software Validation Committee:
<https://redcap.vanderbilt.edu/community/post.php?id=42432>