Standard Operating Procedure:
REDCap Validation

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Department/System:	Digital Solutions – Data Management /REDCap

DOCUMENT HISTORY

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1	New Document	December 16, 2020

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 Research 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 Research Data Management (DM) Team, Digital Solutions Change Approval Board (CAB), and FoM Associate Director, Research & Digital Technologies.

2.2. FoM Research REDCap validation approach utilizes specifications and testing materials developed by the BC Children's Hospital (BCCH) Research DM Team and Vanderbilt University. Additional documents (section 4 below) outline the comprehensive validation activities carried out at each software major upgrade.

3. RESPONSIBITILES

3.1. FoM Research DM Team is responsible for designing and approving the FoM Research REDCap validation plan.

3.2. FoM Research 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 Research DM Team are responsible for reviewing and approving the test scripts.

4. RELATED SOPS/DOCUMENTS

4.1. UBC IT Change Management Process

4.2. Test Script Template

4.3. FoM Research REDCap Validation Plan

4.4. FoM Research REDCap Functional Requirements

4.5. FoM Research REDCap Feature List

4.6. FoM Research REDCap Validation Traceability Matrix

4.7. FoM Research REDCap Validation Certificate

4.8. FoM Research DM SOP 111 Bug Management

4.9. FoM Research DM SOP 115 REDCap Software Upgrade

4.10. FoM REDCap User Testing Checklist

4.11. 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 QI/Project Lead but are generally directly supervised by the PA.

5.2. **FoM Research 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 Test Instance**: REDCap installation/server used for testing, virtually identical as 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 correct behavior.

5.7. **Test Script:** A set of conditions or variables 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. **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. FoM REDCap 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 Research DM Team delays moving to the new LTS Branch until 6 -8 weeks after the LTS Branch is released by the consortium to investigate the new functionalities, update documentation, write test scripts, and perform 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 Research DM Team maintains two instances of the REDCap application. The Production Instance is the live system holding ongoing projects and data. The Test 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 Research DM Team provides Research/Project Teams the opportunity to perform User Acceptance Testing (UAT) on their individual projects. DM Team provides a REDCap User Testing Checklist that guides Research/Project Teams through the necessary steps to validate and test their projects.

7. PROCEDURE

7.1. FoM Research DM Team categorize the new features released in the LTS Branch into the FoM Research REDCap Core Functional Requirements document.

  7.1.1. New Functionalities are categorized as core or ancillary functionality.

7.2. FoM Research 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 Test Instance.

7.3. Once REDCap Core Functional Requirement documents is approved, the FoM Research DM Team updates, and if necessary, 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 Research 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 Research DM Team contacts REDCap consortium to report the bug (see FoM Research DM SOP 110 Bug Management).

7.5. Once script execution is complete, the DM Lead discusses the results with FoM Associate Director, Research & Digital Technologies to seek approval.

  7.5.1. Once validation and functional testing of new LTS upgrade is approved, The DM Scientific Analyst engages with DS Systems Team and starts the Redcap upgrade process following UBC IT Change Management Process (see FoM Research DM SOP 115 Software Upgrade).

7.6. Upon approval, FoM Associate Director, Research & Digital Technologies signs the Validation Certificate to mark the completion of validation process.

7.7. FoM Research 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 Research REDCap Functional Requirements, the FoM Research REDCap Validation Traceability Matrix and the FoM Research REDCap Features List.

8. **REFERENCES**

   8.1. REDCap Consortium Regulatory and Software Validation Committee.

   https://redcap.vanderbilt.edu/community/post.php?id=42432&comment=239

   8.2. UBC IT Change Management Procedure
   https://shareit.it.ubc.ca/itservicemanagement/change-management/Pages/default.aspx

   8.3. Network of Networks (N2) resources - Network of Networks (N2) Standard Operating Procedures, Version 8. Effective May 2019.