Standard Operating Procedure:
REDCap Validation

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1. PURPOSE

1.1. To define the procedure used for validation of Health Research BC REDCap application. As outlined in the BCCH Research REDCap Validation Plan, REDCap validation focuses on core functionalities and **does not cover project-specific validation**:

- In summary, BCCH Research REDCap validation approach focuses on the **DM team** validating core functionalities at the platform level and **REDCap users** validating their projects. The DM team runs test scripts for each functionality categorized as core, while research teams perform user acceptance testing on their individual projects as necessary, to test project functionality in parallel.

2. SCOPE

2.1. This procedure applies to the Health Research BC Data Management (DM) team and the Population Data BC Systems Administrator(s) responsible for the upgrade of Health Research BC REDCap software.

2.2. Health Research BC REDCap validation approach utilizes specifications and testing materials developed by the BCCH Research DM team. Additional documents (section 4 below) outline the comprehensive validation activities carried out at each major software upgrade.

3. RESPONSIBILITIES

3.1. The Health Research BC DM team and Population Data BC Systems Administrator(s) are responsible for overseeing the upgrade of Health Research BC REDCap.

3.2. The DM Coordinators are responsible for executing the test scripts for a set of defined core functionalities of the REDCap application released in the Long-Term Support (LTS) branch by the REDCap Consortium (Vanderbilt University).

4. RELATED SOPS/DOCUMENTS

4.1. Health Research BC SOP 108 Software Upgrade

4.2. Health Research BC Validation Certificate

4.3. BCCH Research REDCap Functional Requirements

4.4. BCCH Research REDCap Feature List

4.5. BCCH Research REDCap Validation Traceability Matrix

4.6. BCCH Research REDCap User Testing Checklist

4.7. BCCH Research REDCap Validation Plan

5. DEFINITIONS

5.1. **Research team**: Research assistants/nurses, data entry personnel and other personnel involved in the clinical research study and granted access to REDCap projects. The Research team members report to the PI but are generally supervised by the PA.

5.2. **Health Research BC Data Management (DM) team**: team that is responsible for managing projects in Health Research BC REDCap and assisting research teams in conducting research studies.

5.3. **BC Children's Hospital Research (BCCHR) DM team:** team that is responsible for managing projects in BCCHR REDCap and assisting research teams in conducting research studies.

5.4. **Population Data BC:** Population Data BC (PopData) is a multi-university, data and education resource facilitating interdisciplinary research on the determinants of human health, well-being and development. The Health Research BC REDCap database server is located here.

5.5. **REDCap Long Term Support (LTS) Branch:** Long Term Support is a major release by the REDCap Consortium and is supported with patches only (i.e., new features are not added) for an extended period of six months.

5.6. **REDCap Project:** A set of data entry forms, surveys, schedules and other data management tools pertaining to a specific study or research project.

5.7. **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.

5.8. **Test Script:** A set of conditions or variables under which a tester will determine whether a system under test satisfies requirements or works correctly.

5.9. **Bug:** Industry term for error or failure.

5.10. **Health Research BC 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. Health Research BC REDCap Set Up

6.1. Every six months, the REDCap Consortium releases a new LTS Branch with new features. Health Research BC REDCap is upgraded on a 6-8 month cycle (LTS Release). The Health Research BC DM team delays moving to the new LTS Branch until 6-8 weeks after the LTS branch is released by the Consortium to wait for the BCCHR DM Team to finalize their validation package. 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 by the System Administrator.

6.2. The Health Research BC DM team maintains two instances of the REDCap application. The Production Instance is the live system holding ongoing projects and data. The Development 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 DM team provides research/project teams the opportunity to perform User Acceptance Testing (UAT) on their individual projects per the BCCH Research REDCap User Testing Checklist (https://rc.bcchr.ca/redcap/surveys/?s=KTJHHT8CRD). The Checklist guides research/project teams through the necessary steps to validate/test their projects.

7. PROCEDURE

7.1. Once the BCCHR DM Team has undergone validation of their REDCap installation and finalized their validation package, the Health Research BC DM team requests a copy of the BCCHR REDCap LTS X.X Validation Tracking Project and uses it to create the Health Research BC REDCap LTS X.X Validation Tracking Project.

7.2. Health Research BC DM team sends upgrade email to active REDCap users approximately two weeks prior to upgrade with instructions on how to test their individual REDCap project in the Development Instance should they want to.

7.3. Two DM team coordinators execute the test scripts on the Health Research BC REDCap Development Instance and track results on the Health Research BC REDCap LTS X.X Validation Tracking Project.

- If a bug is found while executing the test scripts, the coordinator contacts the REDCap Consortium to report the bug.

7.4. Once all scripts have been executed and passed testing successfully, the Validation Certificate is signed by the Health Research BC REDCap Leads as a final approval.

7.5. Health Research BC DM team uploads the executed test scripts to the Health Research BC REDCap LTS X.X Validation Tracking Project

7.6. Upon validation approval by the Health Research BC DM team, the upgrade will be scheduled and performed on the production instance by the System Administrator. During the upgrade, the system is taken offline and a message with upgrade information is provided to potential users during the time frame. The software is upgraded following the REDCap Consortium Upgrade Guidelines (*See SOP 108*).

7.7. Health Research BC DM team posts the validation certificate in the appropriate locations so it is available to users.

8. REFERENCES

- REDCap Consortium Regulatory and Software Validation Committee. https://community.projectredcap.org/articles/239/regulatory-software-validation-committee.html