

**Standard Operating Procedure:
Auditing REDCap Usage**

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1. PURPOSE

- 1.1 To define the procedures used by the Health Research BC Data Management (DM) team to audit/monitor Health Research BC REDCap usage.

2. SCOPE

- 2.1 This procedure applies to the Health Research BC DM team responsible for reviewing and implementing the auditing/monitoring tasks on Health Research BC REDCap.
- 2.2 It also applies to the Population Data BC (PopData) IT team involved in the maintenance of REDCap functionality.

3. RESPONSIBILITIES

- 3.1 Health Research BC DM team is responsible for running system-level monitoring tasks.
- 3.2 Health Research BC DM is responsible for notifying PopData IT if an audit produces an unexpected finding.
- 3.3 Health Research BC DM team is responsible for running project-level monitoring tasks.
- 3.4 Health Research BC DM team is responsible for notifying REDCap users and/or Clinical Research Informatics Lead of the audit findings and mitigation strategies where appropriate.

4. RELATED SOPS/DOCUMENTS

- 4.1 SOP 107 – Health Research BC REDCap Project Archiving

5. DEFINITIONS

- 5.1. **Principal Investigator (PI):** Primary individual in charge of and responsible for the proper conduct of a research project.
- 5.2. **Project Administrator (PA):** Person responsible for the development of REDCap data instruments and the overall management of the project data.
- 5.3. **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.
- 5.4. **Health Research BC Data Management (DM) team:** team that is responsible for managing projects in REDCap and assisting research teams in using REDCap for their research studies.
- 5.5. **REDCap Project:** A set of data entry forms, surveys, schedules and other data management tools pertaining to a specific study or research project.

- 5.6. **BC SUPPORT Unit:** Team responsible for determining whether a project is patient-oriented.
- 5.7. **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.
- 5.8. **Project Lifecycle Tool:** An active, internal project used by the Health Research BC DM team to track the lifecycle of projects and to assist in REDCap data management.
- 5.9. **Service Agreement:** The joint contract agreed to by both the Health Research BC DM team and the PI or PA for commencement of work and services related to REDCap project data management as outlined.
- 5.10. **Identifier:** Collected variable that identifies (that is, labels the identity of) a record. The DM Team is using the following keywords as potential identifiers: name, street, address, city, zip, postal, phone, fax, mail, social security, mrn, phn, email, mrid, first_name, firstname, fname, last_name, lastname, familyname, lname, mrn.

6. PROCEDURE

- 6.1. DM team performs auditing/monitoring tasks according to defined frequency or as needed (see Appendix A below).
- 6.2. Audits are logged in an internal tracking system.
- 6.3. If a system-level monitoring task yields an unexpected result:
 - 6.3.1 The DM Team will work with PopData IT/Systems team to notify them of the issue and assist in finding a resolution.
 - 6.3.2 DM team notifies Project team of the resolution, if necessary.
 - 6.3.3 DM team logs results in internal tracking system and resolves the communication.
- 6.4. If a project-level monitoring task yields an unexpected result:
 - 6.4.1 The DM team emails PA or the research/project team, advising them of the required corrective actions.
 - 6.4.2 Once corrective actions are taken and the research/project team has emailed the DM Team that they are complete, the DM team reviews the project to make sure the project is corrected.
 - 6.4.3 DM team logs results in internal tracking system and resolves the communication.

7. REFERENCES

- N/A

APPENDIX A – AUDITING/MONITORING TASKS

Description	Type	Frequency	Responsible DM person	Steps
Audit Failed logins	System-level	Daily	DM team	<ol style="list-style-type: none"> 1. Report is generated detailing failed login attempts. 2. Report is reviewed. 3. Users with more than 5 failed attempts are investigated: <ul style="list-style-type: none"> • Check if IP addresses are outside Canada • Check if user name exists in system 4. If determined a brute-force attack, follow error reporting procedure.
Check CRON Jobs (ie. survey sending, emails etc.) running status	System-level	Quarterly	DM team	<ol style="list-style-type: none"> 1. Go through the backend REDCap database table 'redcap_cron_history'. 2. Check for any errors on cron jobs. 3. Check for any job that took more than 5 hours to complete. 4. If failures are identified, follow error reporting procedure.
Check projects in development with >25 records to ensure they are not collecting real data	Project-level	Quarterly	DM team	<ol style="list-style-type: none"> 1. Flag the following: <ol style="list-style-type: none"> a. projects in development status with >25 records b. projects in Demo REDCap in Production status with >25 records 2. Follow above process for projects requiring action.
Check for Identifiers	Project-level	Quarterly	DM team	<ol style="list-style-type: none"> 1. Identify projects with identifiers using defined keywords (see definition above). 2. Review projects to see which identifiers are approved to be stored.

				<ol style="list-style-type: none"> 3. Flag projects with non-approved identifiers. 4. Follow above process for projects requiring action.
Review projects before moving to Production	Project-level	As necessary	DM team	<ol style="list-style-type: none"> 1. Research/project team selects project to move to production triggering an email to DM team. 2. Project is reviewed according to Move to Production Checklist (see attached document). 3. Follow above process for projects requiring action. 4. Once project passes the checklist successfully, the project is moved to production and Research/project team is notified.
Archiving (Completing) projects	Project-level	Yearly	DM team	<ol style="list-style-type: none"> 1. Identify projects with no activity for >2 years. 2. Actions are taken according to Health Research BC DM SOP 107 REDCap Project Archiving. 3. Follow above process for projects requiring action.