REDCap Research Data Management Guidance

Introduction

REDCap (Research Electronic Data Capture) is a secure, web-based application designed exclusively to support data capture for research studies. REDCap provides: an intuitive interface for data entry (with data validation), 128 bit encryption between the data entry client and the server (https), audit trails for tracking data manipulation and export procedures, automated export procedures for seamless data downloads to common statistical packages (SPSS, SAS, Stata, R), procedures for importing data from external sources, and advanced features such as branching logic, calculated fields and data quality checks. REDCap is developed and maintained by a team at Vanderbilt University and licensed free of charge to Stellenbosch University (SU) staff and students. The application and data are housed on servers provided by the SU ICT Division.

Using REDCap

REDCap is a tool capturing confidential information which requires planned and careful management in order to protect the participant's personal data. The biggest risk to the protection of personal information is when datasets are exported from REDCap. SU does not provide institutional support for the day to day operational use of REDCap. It is the SU researcher's responsibility to familiarise themselves with how to use the application.

Confidentiality and Security in Exporting Data

Protecting personal information is part of the contract between research participant and researcher and REDCap does allow for this if used correctly. While located within the REDCap platform, data is secured, but once exported, this security no longer protects it. SU advises researchers to avoid, if at all possible, the exporting of data from the platform. But, if it is necessary, then security and confidentiality depends on two processes:

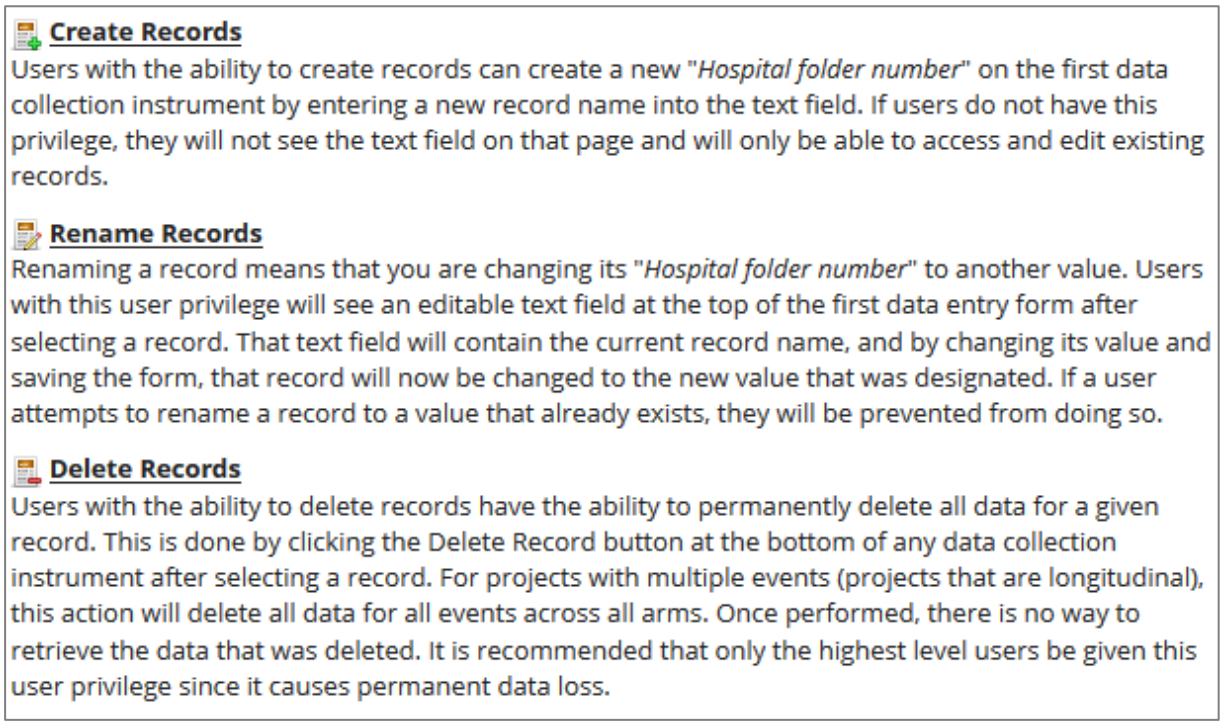
- **Tagging of identifier fields in the data dictionary**: Personal identifier fields can be tagged in the Data Dictionary which is a spreadsheet detailing all the field (variable) names, field types, possible values, etc. Special attention must be paid to Column K where identifier boxes must be marked with a 'y'. This tagging will come into effect during export when only researchers assigned rights to export tagged identifiers will be able to do this (data manager and PI); all other researchers will be able to export only untagged fields.
- **Therefore the correct assigning of user rights** is the second crucial step securing participant confidentiality. This task is carried out by the data manager using the 'roles and responsibilities' spreadsheet as a guide. The PI remains ultimately responsible for any breaches of confidentiality.

The successful implementation of these two processes depends on the correct understanding of the roles and responsibilities of the Principle Investigator and the Data Manager, two key elements to managing the governance of REDCap projects.

Roles and Responsibilities

Project: **PI:** **Database Roles**

Tasks	Items	Data Manager	Study Coordinator	Investigator / Doctor	Data Capturer	Principle Investigator
Database construction & setup	Project design & setup	✓	×	×	×	✓
	Assigning User Rights	✓	×	×	×	✓
	Setup Data Access rights (DAGs)	✓	×	×	×	✓
Data Exports (No Access, De-Identified, Remove all tagged Identifier fields, or Full Data Set)	Data Export Tool	Full Data Set	Remove all tagged Identifier fields	Remove all tagged Identifier fields	No Access	Full Data Set
	Reports & Report Builder	✓	✓	✓	×	
	Graphical Data View & Stats	✓	✓	✓	×	
Technical management	Data Import Tool	✓	×	×	×	
	Data Comparison Tool	✓	×	×	×	
	Logging (view audit trail)	✓	✓	✓	✓	
Shared Files	File Repository	✓	✓	✓	✓	
Data quality	Create / edit quality checks (rules)	✓	✓	×	×	
	Execute quality checks (rules)	✓	✓	✓	✓	
Data Resolution Workflow (data queries)	View queries	✓	✓	✓	✓	
	Open data queries	✓	✓	×	×	
	Respond to queries	✓	✓	✓	✓	
	Close queries	✓	✓	×	×	
API	API Export	✓	×	×	×	
	API Import/Update	✓	×	×	×	
REDCap Mobile App	Collect data offline in the mobile app	✓	✓	✓	✓	
	Download data for all records to the app	✓	✓	✓	✓	
Records rights (see explanation below)	Create/Edit Records	✓	✓	✓	✓	
	Rename Records	✓	✓	✓	✓	
	Delete Records	✓	✓	×	×	
Record Locking	Record Locking setup	✓	×	×	×	
	Lock/Unlock records	✓	✓	×	×	
Data Access rights	Records from own site	✓	✓	✓	✓	
	Records from other sites	n/a	n/a	n/a	n/a	
Form-level Access (View & Edit, Read Only, or No Access)	Enrolment form	Read Only	View & Edit	View & Edit	View & Edit	
	Other forms (List:)	Read Only	View & Edit	View & Edit	View & Edit	
	Exit form	Read Only	View & Edit	View & Edit	View & Edit	



Responsibilities of the various roles for the project

REDCap was specifically designed to enable clinicians and other researchers that have no web application or database development experience, to build high quality, web-based, data collection instruments and surveys themselves. As SU does not provide a REDCap Support Team, users are expected to autonomously create forms, perform data collection and manage the entire project from the conceptual design to the final analysis.

Principle Investigator: Overall and ultimate responsibility for the management of the project and its governance to include data management. This must be consistent with all legislative, regulatory, local and collaborator (to include funding body) requirements. Data management (database construction and set – up) can be delegated to the Data Manager, although the PI still retains responsibility. The data manager must be appropriately qualified and skilled; it is the PI's responsibility to ensure this.

Data Manager: Must understand the requirements of data confidentiality and security and how this is achieved through REDCap. A clear understanding of and ability to assign identifier fields to specific data elements and an understanding of the roles of other project participants such that the data manager can assign their level of privacy and security settings accurately. To have a close enough relationship to the PI to be able to escalate any issues to the PI as soon as they become apparent.

Ethics: Research Ethics Committee (REC) Approval

Ethics approval is required from an appropriate Stellenbosch University REC if working with humans, human material (such as blood or tissue) or their identifiable data including secondary use (this is defined as the reuse in a new project of previously collected data or material) of such materials or data. Please contact the appropriate ethics office if you have not yet applied for ethics clearance. This application will include questions related to how you manage, store and use data including that entered into REDCap and may also require that you submit the data dictionary and assigned roles list along with some information regarding the qualifications of your data manager. Particular attention should to paid to what identifiers you intend to collect and how you will maintain confidentiality if exporting identifiable data.

Adequate and appropriate consent is an essential requisite of REC approval. If you are collecting and storing personal identifiers, this must be reflected in the consent form and if you are intending to share or reuse data/material, then this must be consented to when the material/data is collected otherwise it cannot be shared or used in future research projects.

Using the REDCap Mobile App

When using the REDCap Mobile App please note the following:

Only certain devices are supported.

- iOS - iPad 2 iOS 6.0 or later, iPhone 4 or later
- Android 4.3 or later; tablet or phone

The devices (tablet or phone) used must be secured.

- Automatic locks must be set on mobile devices.
- Not connect to unsecured Wi-Fi networks
- Only download apps from trusted sources

REDCap Mobile App users must report any stolen devices to SU IT and the SU REDCap Administrators.