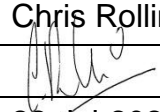


Standard Operating Procedure

Please refer to <https://www.plymouthhospitals.nhs.uk/research-sops> to ensure the latest version of this document is in use. Printed copies are uncontrolled.

Title:	Access and Use of REDCap Community		
Approver	Document No:	P19	
Name:	Chris Rollinson	Version No:	1.0
Signature:		Effective Date:	Jul-2021
Date:	22-Jul-2021	Review Date:	Jul-2024

1. Purpose

To describe the procedure for using the secure web-based application REDCap (Research Electronic Data Capture) Community at University Hospitals Plymouth NHS Trust (UHP).

2. Scope

This SOP applies to individuals at the Trust who wish to use REDCap for building and managing online databases and surveys. The system is suitable for use in participant-based research Sponsored by UHP, such as observational studies, longitudinal studies, and survey-based projects. It should not be used for Clinical Trials regulated by the Medicines and Healthcare products Regulatory Agency (MHRA).

N.B. The Trusts has two versions of REDCap available for use.

3. Responsibilities

Project Owner/ Lead

- Projects are registered with the relevant authority or department.
- Databases are created in accordance with the project proposal or protocol and tested using fictional data.
- At project completion data is retained/ removed.
- Ensure user access to project is accurate.

All Users

- Inform project owner/ lead or the System Administrator if access is no longer required.
- Ensure adequately trained.
- Data entry completed accurately and in a timely manner.

System Administrator (also known as Super User/ System Manager)

- Identify which version of REDCap is more suitable for the user i.e. for internal Trust use only (plym118/redcap) or for external use (redcap.plymouth).
- Manage all tasks within the remit of the role including access control.

R&D Governance/ Research Sponsor Representative

- Review completeness of data.
- Export audit (trail) report and review user access for Research Project.
- Data Sharing Agreements for data transfers are in place.

4. Documents needed for this SOP

- P13_Database management, security, design and validation
- P14_Computerised Systems for Supporting Clinical Trials
- P15_Case Report Form Design
- P16_Data Management & IDMC
- T10_Study Data (Source Data, Medical notes and CRF)
- T4_Case Report Form (CRF) completion

5. Related documents

- System Level Security Policy for REDCap Community
- Data Protection Impact Assessment for REDCap Community on Microsoft Azure
- [REDCap Training Videos](#)
- UHP REDCap Access Request Spreadsheet

6. Acronyms

CRF: Case Report Form

FAQ: Frequently Asked Questions

HRA: Health Research Authority

IDMC: Independent Data Monitoring Committee

MHRA: Medicines and Healthcare products Regulatory Agency

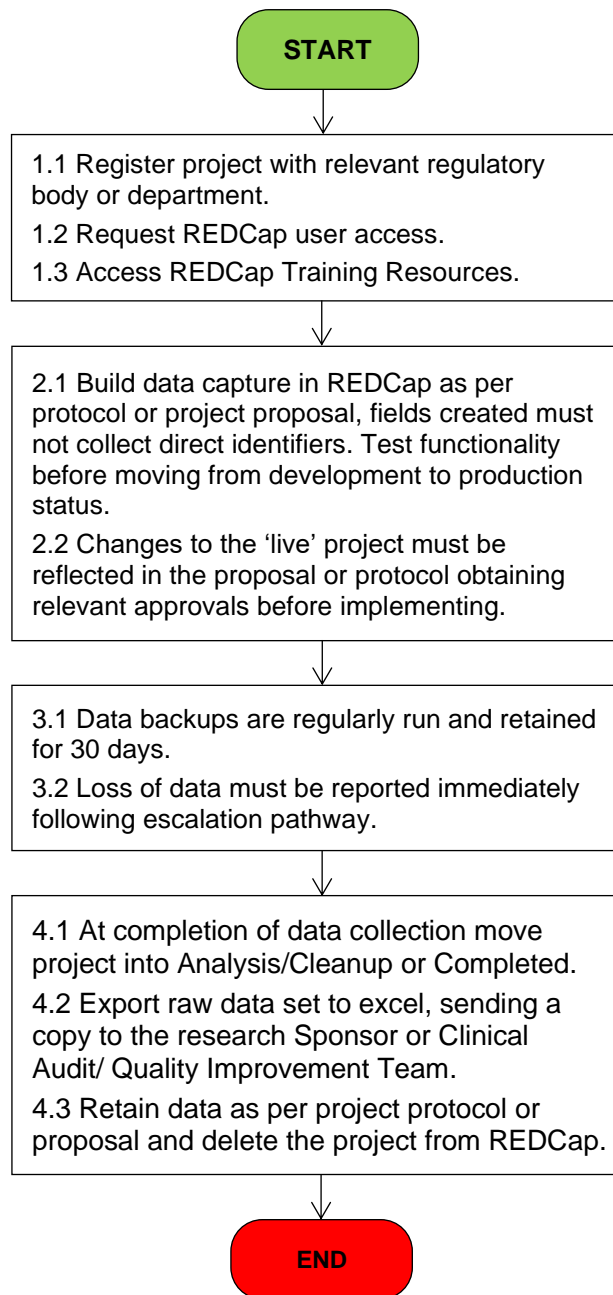
R&D: Research & Development

REC: Research Ethics Committee

SOP: Standard Operating Procedure

UHP: University Hospitals Plymouth NHS Trust

7. Process map(s)/ flow chart(s)



8. Procedure

Step	Action	Responsibility
1	User Account Access and Training	
1.1	Register all projects with the relevant authority or department i.e. Health Research Authority (HRA)/ Research Ethics Committee (REC), UHP's Clinical Audit or Quality Improvement Team.	Individual responsible for/ leading on the project.
1.2	<p>Request access by emailing the R&D Manager (System Administrator). Include reason for access and details of the project confirming registration as mentioned above.</p> <p>If the project owner/ lead wishes to add users to a project who do not have a REDCap account, they should complete the UHP REDCap Access Request excel spreadsheet and submit to the R&D Manager.</p> <p>Setup account password with at least 9 characters in length, consist of at least one lower-case letter, one upper-case letter, and one number.</p> <p>Projects are assigned up to three user roles with predefined user rights:</p> <ol style="list-style-type: none">1. Project Owner/ Lead: high-level user rights, including to create and copy projects, to design and set up projects, to modify project user rights, to view and edit all data, to create and rename records, and to export all data;2. Data Collector: rights to view and edit data, to create and rename records, and to export data;3. Sponsor Oversight (research only): read only access to all data, export all data and logging (audit trail). <p>Project owners (once privileges are set by the Administrator) can create their own user roles, or define customised user rights for each user.</p> <p>User rights should be granted with caution, as permissions to view and export information carry risks relating to participant confidentiality and data protection, while permissions to edit and delete records may affect data integrity.</p> <p>Full list of what User Rights can be granted/ restricted is available in REDCap Help and FAQ .</p>	All individuals requiring access, System Administrator and Sponsor Representative.

Step	Action	Responsibility
1.3	<p>Access the Training Resources page directly through the system where training videos, Help and FAQ and on-screen guidance is available. Users are expected to take responsibility to ensure they are adequately trained before creating a database.</p> <p>The REDCap Consortium also provides access to a Shared Library of data collection instruments and forms that can be downloaded and used.</p> <p>Test the project instruments thoroughly before live data collection commences. Testing must use fictional data only.</p>	Project Owner/Lead.
2	Project Build and Modification	
2.1	<p>Consider if event and arm structure is applicable.</p> <p>Produce ‘Instrument’ and ‘Field’ as per the project proposal or research protocol. Data points created which are not covered in the original proposal or protocol must be approved.</p> <p>Setup participant identifiers in the project, where required through either sequential numbering allocated by REDCap or custom identifier manually entered by the user.</p> <p>Projects ready for data collection, must be moved from development to production status. This can only be authorised by the System Administrator.</p> <div data-bbox="284 1352 1007 1435" style="border: 1px solid black; border-radius: 10px; padding: 5px; text-align: center; margin: 10px 0;"> <p>Is your dataset anonymised or pseudonymised?</p> </div> <p>REDCap is provided solely for anonymised or pseudonymised data. No direct identifiers are to be held on the system and the likelihood of being able to identify an individual by combining any Indirect Identifiers is kept low.</p>	Project Owner/Lead and System Administrator.
2.2	<p>Changes to a project must be amended in the project proposal or protocol, and approval obtained from the relevant authority or department before implementing.</p> <p>‘Entre Draft Mode’ for projects with production status. Most design changes will be automatically implemented. Modifications considered critical by REDCap will be forwarded to the System Administrator for approval. The project owner is responsible for any data loss caused by</p>	Project Owner/Lead and System Administrator.

Step	Action	Responsibility
	making design changes to a project in production.	
3	Data Backup and Loss	
3.1	Backups of REDCap are run regularly and have 30 day retention period.	IM&T Service.
3.2	Report any loss of data initially to the project owner/ lead or System Administrator. If the data cannot be retrieved by the System Administrator or the IM&T Dept, then the data loss should be reported to the Trusts Information Governance team <i>via</i> Datix. If the data is from a research project an additional report must be made to the R&D Governance team (Sponsor Representative) who will report onwards to the appropriate regulatory bodies (within 7 days of becoming aware) and to sites.	Individual impacted or who has observed the data loss and Sponsor Representative.
4	Database Lock, Export and Retention	
4.1	Move the project to Analysis/Cleanup status if data collection is complete, disabling most project functionality. Lock the database by marking the project as 'Completed', doing so will take it offline and remove it from everyone's project list.	Project Owner/ Lead.
4.2	Export the dataset for analysis. REDCap provides automated export procedures for downloading data to common statistical packages such as SPSS, SAS, R and Stata. Send a copy of the exported raw research data to the research Sponsor Representative, or Audit/ Quality Improvement Team for other projects.	Project Owner/ Lead.
4.3	Retain exported data as described in the project proposal or protocol. REDCap is not intended for use as project archive, therefore the project must be removed ('Deleted') in which all its data will be permanently deleted. N.B. Projects are permanently removed from REDCap 30 days after they have been deleted. Until that time, the System Administrator can undelete the project.	Project Owner/ Lead, System Administrator, Sponsor Representative.

8. Changes from last revision

None.