

# **Newcastle REDCap Data Lifecycle**

**NJRO-INF-SOP-006**

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## **1. Background/Introduction**

REDCap is a browser-based Electronic Case Report Form (eCRF) solution to store research data for projects led by The Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH). REDCap can be used throughout the research process, from the design of data capture forms through to the eventual destruction of data.

## **2. Purpose**

To describe the lifecycle of data entered into the Newcastle REDCap system and the responsibilities of those who enter, process and control it.

## **3. Scope of Document**

Applicable to anyone using Newcastle REDCap to collect and/or store research data.

## **4. Definitions**

CI – Chief Investigator

DPIA – Data Privacy Impact Assessment

eCRF – Electronic Case Report Form

PI – Principal Investigator

## **5. Roles & Responsibilities**

It is the responsibility of all Newcastle REDCap users to understand the data lifecycle to ensure they correctly enter and access data, and understand when data will be destroyed.

## **6. Procedures**

### **6.1. Data Specification**

- To obtain a quote, project requirements must be sent to the Newcastle Research Informatics Team in advance of costing/contract and will include as a minimum:
  - Variables
  - Questionnaires (if applicable)
  - Schedule of events
  - Project duration
  - Number of sites
  - Desired processes (e.g. eConsent)

- An online REDCap Agreement will be issued, detailing the services to be provided and the associated costs. This must be signed by the PI, CI or a designated individual.
- Once approvals are in place, the data specification will be revisited and latest versions provided to the Research Informatics Team ahead of project build.
- Substantial changes to the data specification both before the project is considered live and during the project in live status may incur additional costs. These changes should be formally requested to the Research Informatics Team.
- Changes to the project are recorded in the REDCap 'Project Revision History'.

### **6.2. Data Generation & Recording**

- Project data is entered by REDCap users. Access to Newcastle REDCap for specific projects is governed by the Newcastle Research Informatics Team and is detailed in the Newcastle REDCap Data Security SOP (7.1).
- Data is entered into REDCap in plain text format. Where multiple choices are present, data is coded using legible numbering or lettering. A codebook is provided alongside each project to interpret coded data.
- Fields in REDCap will contain standard data validation to ensure data accuracy (e.g. e-mail addresses, decimal places). Specific data validation should be requested in the data specification and will be implemented where possible.
- Fields which are essential to the study will be marked as required. Where possible, missing data codes will be utilised to log the reasoning for unavailability of required data points.
- All data entered is logged via the REDCap 'Logging' tool, alongside the exact date and time the data was entered and which user entered it. This user is responsible for anything recorded against their name and no other user will be granted access to their account.

### **6.3. Data Processing**

- Alterations to existing data in REDCap are logged via Data History alongside the date, time and user who made the alteration. A reason for the alteration must be provided by the user.
- All activity in REDCap is logged including the date, time and user who viewed any page within a project.
- Substantial changes to the specification of a project may cause existing data to lose context or be destroyed. Changes with this effect are flagged by REDCap prior to approval and will be presented to the PI, CI or designated individual to ensure they are aware of consequences and have mitigations in place.

#### **6.4. Data Use**

- Data held in REDCap can be accessed at any time by users with the appropriate permissions to allow for live monitoring of a project.
- Non-identifiable data can be exported from REDCap during a live project for reporting purposes.
- Data may be modified/corrected as per **6.3**.
- Metadata can be referenced via the data history and logging functions of REDCap for study monitoring purposes.
- Where the Data Resolution Workflow is utilised, additional data will be generated to flag and resolve potential issues. This is not considered study data and is not exported as part of analysis.
- Where the Locking function is utilised, additional data will be generated to mark a form as locked or e-signed where appropriate to the project. These forms will no longer be modifiable when in this state. This is not considered study data and is not exported as part of analysis.

#### **6.5. Data Retention**

- Newcastle REDCap studies reaching the recruitment end date will be stored in an Analysis/Cleanup state and further data collection will be prohibited.
- Non-identifiable data can be exported for analysis from a REDCap project in an Analysis/Cleanup state.
  - Data can also be requested from the Newcastle Research Informatics Team, in which case it will be exported and transferred securely by NHSmail. Identifiable information will only be exported and transferred if this is justifiably required.
- Newcastle REDCap studies reaching the study end date will be archived and inaccessible to non-administrative users.
- Archived projects remain in REDCap until the time point requested in the DPIA, at which point it is erased (see **6.7**).

#### **6.6. Data Retrieval**

- Data can be retrieved from projects in a live or analysis/clean-up state.
- A final data extract will be provided before archival. Once archived, requests to unarchive a project and/or retrieve a further extract must be made to the Newcastle Research Informatics Team.

#### **6.7. Data Destruction**

- Archived projects remain in REDCap until the time point requested in the DPIA, at which point it is erased. The CI, PI or designated individual will be notified of this deletion one month prior.

- Erased REDCap projects are irrecoverable.
- After erasure, data becomes subject to the AIMES data destruction policy **(8.1)**

## 7. References

7.1 [NJRO-INF-SOP-002 Newcastle REDCap Data Security SOP](#)

## 8. Appendices

8.1 ARO Data Destruction Policy (available upon request via the [nuth.research.informatics@nhs.net](mailto:nuth.research.informatics@nhs.net) email address)