

# **Newcastle REDCap Data Security**

**NJRO-INF-SOP-002**

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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). The NuTH Research Informatics Team administrates Newcastle REDCap which is hosted by ARO on secure cloud servers based in Liverpool, UK **(7.1)**.

## **2. Purpose**

To describe the responsibilities of NuTH, Newcastle REDCap Administrators and all Newcastle REDCap users to ensure the secure collection and storage of data within Newcastle REDCap.

## **3. Scope of Document**

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

## **4. Definitions**

2FA – Two-Factor Authentication  
CI – Chief Investigator  
DAG – Data Access Group  
eCRF – Electronic Case Report Form  
PI – Principal Investigator  
User – Individual accessing Newcastle REDCap

## **5. Roles & Responsibilities**

It is the responsibility of all Newcastle REDCap users to ensure data is collected and held securely.

## **6. Procedures**

### **6.1. Access**

- Newcastle REDCap can be accessed via the internet and as such, users must remain vigilant as to their surroundings and lock their machine or device when not in active use.
- All Newcastle REDCap users must agree to use Two-Factor Authentication (2FA) when logging in to a REDCap project containing patient or participant data. This is performed either via e-mail address or an authenticator app (e.g. Google Authenticator). A successful Two-Factor Authentication is valid for 12 hours on a per-machine basis. Two-Factor Authentication is not required for users connected to the NuTH internal network.

### **6.2. User accounts**

- Project access for Newcastle REDCap users must be authorised by the PI, CI or delegated individuals associated with the project. The typical level of access is 'data entry' however further privileges can be requested if required.
- All Newcastle REDCap users must provide the Research Informatics Team ([nuth.research.informatics@nhs.net](mailto:nuth.research.informatics@nhs.net)) with an institutional (e.g. NHS or academic) e-mail address for the account creation process. Publicly available e-mail addresses cannot be used unless all other options are exhausted.
- For multi-site studies, users must additionally provide their site name to ensure Data Access Groups (DAGs) are correctly set up to segregate data.
- When accessing the system for the first time, users will be required to set a password. Passwords must be a minimum length of 9 characters and must utilise a mix of lowercase and uppercase letters and numbers.
- The PI, CI or delegated individuals associated with the project must inform the Research Informatics Team ([nuth.research.informatics@nhs.net](mailto:nuth.research.informatics@nhs.net)) of staff changes associated with REDCap users who have access to their project. Users who have not accessed the system at any time within a consecutive 12-month period will be automatically suspended.

### 6.3. Local approvals

- The following must be submitted and approved prior to data collection in Newcastle REDCap:
  - All usual approvals associated with a project (e.g. ethical approval, Caldicott, DPIA, etc.)
  - All usual approvals associated with non-NHS staff (e.g. research passport/letter of access)
- Users at non-NuTH sites must have obtained appropriate local approvals (e.g. Data Sharing Agreement) prior to collecting or storing data in Newcastle REDCap.

### 6.4. Identifiable information

- Identifiable information must only be captured when essential to the nature of the project.
- All potentially identifiable fields must be marked as an 'identifier' within Newcastle REDCap during the initial design of the project. This will be checked by the Research Informatics Team when projects are submitted to production and when project changes are made.
- Identifiable information cannot be exported from REDCap by normal users. If this information is justifiably required, it should be requested via the Research Informatics Team ([nuth.research.informatics@nhs.net](mailto:nuth.research.informatics@nhs.net)) and sent securely via NHSmail.

#### 6.5. Data recovery

- Newcastle REDCap servers are backed up at 00:05 and 07:05 every day.
- Data recovery can be requested via the Research Informatics Team ([nuth.research.informatics@nhs.net](mailto:nuth.research.informatics@nhs.net)) in the event of severe data loss.

### 7. References

#### 7.1. [ARO Private Cloud Design and Implementation](#)