York and Scarborough Teaching Hospitals NHS Foundation Trust R&I Department
SOP
R&D/S111

REDCAP Project Design and Maintenance

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&I Department's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&I Department SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&I Department website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

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Author:	Liz Johnson
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Approved by:	Name/Position:	Deborah Phillips, Research Advisor
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	Name/Position:	Sarah Sheath, SOP Controller
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This SOP will normally be reviewed at least every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Reviewer	Details of significant changes
1.0	13th May 2026		New SOP

Contents

1 Introduction, Background and Purpose

REDCap is an electronic case report form (eCRF) system which can capture data in a variety of formats. These include service evaluation as well as a variety of research study designs (e.g. longitudinal, qualitative surveys, randomised trials). The Study Management Team and the IT service desk own and maintain REDCap for any Trust Sponsored Studies or Trust audits. This SOP provides information and best practice for setting up a new project on the Trust's REDCap software. It also details best practice for maintaining projects within REDCap.

2 Who Should Use This SOP

This SOP is for anybody who is creating new projects on the Trust's REDCap software. The Study Management Team are responsible for any new projects which are set up – however other staff members of York and Scarborough NHS Teaching Hospital may set up projects on REDCap. In these instances, this must have been requested and agreed with the Study Management Team in advance. Once agreed, the REDCap administrators can provide users with the access to create new projects.

3 When this SOP Should be Used

This SOP should be followed by anybody setting up a new project on REDCap. Once completed, the project should be regularly audited and backed up to protect the data. Additional information and training videos for specific aspects of project design can be found on the REDCap homepage. This SOP should also be used in conjunction with the SOPs and guidance on management of Trust Sponsored studies.

4 Procedure(s)

4.1 Initial authorisation to set up Projects

For Trust Sponsored Studies – the use of REDCap as the data capture software that is being used should be documented in the Protocol and confirmed as part of the study process before the IRAS application is submitted.

If anyone other than the Study Management team wishes to create a project within REDCap – this request must be sent to the study management team as part of this initial study process detailing the project and the access levels required to create it. Requests should be emailed to yhs-tr.research.enquiries@nhs.net. Once approved – the REDCap administrators will create and set up the account so new projects can be created. The REDCap administrators will have access and oversight to the project.

4.2 Project Set Up and Design

A new project can be created in REDCap by selecting the 'New Project' tab. Here you can name and describe your project – complete these sections with as much detail as possible. You can also at this point create your project either as 'Empty Project (blank slate)', or 'Use a template (choose one below)'. Both are acceptable and this will depend on the study design – however for the templates you may still need to edit these for study specific questions.

The new project will then be created in Draft Mode – you can only edit the project when in Draft Mode. On the Project Set-up tab, you should ensure the progress of your design is kept up to date.

In the Designer tab – you can add or edit the forms for data collection (Data Collection Instruments). There will be an Instrument which will initially be created to record 'Record ID' as a data set (or field). This field cannot be deleted and you must incorporate this into the first data collection instrument.

Additional instruments can be created, edited and deleted as appropriate. You can also amend the sequence of these instruments.

The fields of data collected within each instrument can be added by using the 'Add field' button. The type of data field can be selected at this point and can be edited and customized by selecting the 'Use the Rich Text Editor' button. There are a wide variety of types of questions and fields you can use. You can also use the 'branching logic' option to set up rules to only show certain fields based on previous data values.

Wherever possible please keep Patient Identifiable Information to a minimum. For any fields with identifiable information select Yes in the 'Identifier' section. REDCap logs any of these fields as part of the project set up and adds prompts and checks in when exporting this data.

Any changes and edits made to the project need to be submitted to the REDCap administrators for review. This is a double check to ensure the data fields are accurate and in keeping with the study design as per protocol. It is recommended you do as much work as possible before sending these for submission to prevent delays. Please email the administrators to let them know when you plan to submit these changes.

All data collection instruments and fields should be designed in keeping with guidance from R&D/S81 – Case Report Form Design and Completion.

4.3 Data Validation Checks

In order to ensure quality data entry, it is recommended you implement software validation checks within the project. Consider the following steps;

1. Set each field to yes in the 'Required' section to avoid missing data

2. Specify the data type in the 'Validation' section to ensure the correct data type and format is entered. This can help stop typographical errors and can help auto-correct certain data types such as dates.

3. For numerical data, consider entering a minimum and maximum value – to help avoid any incorrect extreme values or outliers.

4. Use the Data Quality auto checks which can run reports to look for data issues, as well as creating bespoke reports if required.

5. Avoid free text boxes where possible. Used radio button drop down options and include all possible options, including answers such as 'N/A' or 'Not Known'.

4.4 Project Testing

Once you have completed your project it is vital to test it thoroughly to ensure the software works as expected before you begin collecting real data. You can add dummy data into the project whilst the project is still in Draft Mode by selecting 'Add/Edit participants'.

Evidence of testing and validation should be documented using R&D/T10 as a guideline. If you are designing the project on behalf of someone else (e.g. Chief Investigator) you must get documented confirmation from them that they are happy the project has been tested and is ready for use.

4.5 Putting the Project into Production

Once all changes have been submitted and approved on the project and you have completed testing, on the Project Set up tab you can 'Move your project to production status'. The project is now live and you can collect and enter project data. Please ensure all other approvals for the study have been completed and you have been given greenlight to begin recruiting before entering any live data. If this is study that involves participant consent, then this must have been received before entering any live data.

4.6 Adding Users

If you need to add any additional users to your project, you should follow the process documented in R&D/S65 – REDCap Database Access. You should ensure all users have been given training on the project and how to use REDCap. They should also have been added to the study delegation log with data entry duties, if applicable to the project.

Please note that if you need to add other users to the project, you should ensure that the REDCap administrators are aware of this requirement. The administrators will also need to set up user's accounts first, before you can assign them to the project

4.7 Ongoing REDCap Maintenance

To protect the data and project integrity, it is advised to export and back up the data from REDCap. This can be done from the 'Data Export, Reports and Stats' tab. Here you can export all data to various file formats and save it to one of the Trusts network drives. Depending on the amount of study data, the frequency of these back-ups will vary but it is recommended to back up ever 1-2 weeks. Ensure you export the 'raw data' into an excel format as a minimum. This will be required if there is any systems failure and the data needs to be imported back onto REDCap. Please ensure that the Trust network drive you save this to is secure and has permissions applied so only the relevant staff can access the data.

If you have other users on the project please ensure that you monitor the access to your project – and remove any users who no longer need access to the account. Please contact the REDCap administrators who can suspend access to REDCap accounts if required.

It is also advisable to check the data entered for consistency and to identify any missing data, typographical errors, or illogical data. Depending on the study design, you can make audited changes to the data, or raise queries within REDCap to other users to perform checks on the data quality. These can be accessed and monitored through the 'Data Quality' tab.

4.8 At the End of the Project

At the end of the study, or when all data has been collected it is advisable to 'lock' the datasets on REDCap. This means that the final dataset can be cleaned and exported without anyone else changing or editing the data on REDCap at the same time.

The data can be exported into various file formats including statistical packages for analysis. A code book for each project is available to list all the fields and variable names which can assist in analysis.

Once all the analysis has been completed, and the study or data can now be archived, please contact the REDCap administrators, The data must be backed up and archived as per R&D/S11 – Archiving of Research Study Documents before the data can be deleted off REDCap – all this must be confirmed and documented.

5 Related SOPs and Documents

REDCap additional training videos and FAQs :
https://redcap01.yorkhospitals.nhs.uk/redcap/index.php?action=training

R&D/S81 – Case Report Form Design and Completion

R&D/S65 – REDCap Database Access

R&D/S29 – Data Management

R&D/S11 – Archiving of Research Study Documents

R&D/T10 – Database Validation Checklist