St George's, University of London	
Guidance on Databases for Research Projects	
Version:	3.0
Date:	17/01/2024
Review Date:	17/01/2025

Abbreviations / Definitions

CTIMP	Clinical Trial of an Investigational Medicinal Product
DPIA	Data Protection Impact Assessment
JRES	Joint Research and Enterprise Services
MHRA	Medicines and Healthcare products Regulatory Agency
REDCap	Research Electronic Data Capture
SGREC	St George's Research Ethics Committee
SGHFT	St George's University Hospitals NHS Foundation Trust
SGUL	St George's, University of London

Secure data collection and storage is an essential aspect of all research projects and it is important that all data is collected, stored, analysed and reported according to current Data Protection legislation, clinical trial legislation and local policies.

St George's, University of London (SGUL) has a number of options for the collection and storage of research data. The system/software selected for individual projects will depend on the type of study and the requirements of each study protocol.

Some of the SGUL options are listed here: [Research Data Management (sgul.ac.uk)](https://www.sgul.ac.uk)

However, Investigators should be aware of the following guidance/requirements when selecting a database for an SGUL research project:

CTIMPs / Medical Device Trials

Interventional, regulated clinical trials (ie: drug trials and medical device investigations which need MHRA approval) must use a **validated** database for data collection/storage, in order to be compliant with the relevant regulations and Good Clinical Practice (GCP). A validated database requires documented evidence that controls of the system are in place and that the system is fit for purpose and performs accurately, reliably and as intended.

For this reason, **SGUL's REDCap instances cannot currently be used for these trials.**

There are validated databases available which can be used for these trials. There is a cost implication for these and the costs will need to be factored into any grant application.

Some examples of these databases are:

http://ctu.co.uk/ecrf-database/

https://www.capterra.co.uk/software/133931/clincapture

Investigators are responsible for obtaining quotes from providers, in line with the requirements of SGUL's Procurement Policy Procurement Policy & Guidance (sgul.ac.uk).

The JRES can provide further advice on this (sponsor@sgul.ac.uk).

REDCap

Restrictions

REDCap is currently only available for SGUL-based research projects for Investigators with an SGUL employment contract.

Other Investigators, including those employed by SGHFT, will need to use an alternative database for their studies or may have to pay an external supplier to provide REDCap.

REDCap **cannot** be used for any data which may allow for the identification of a study participant. Only anonymised data can be entered and stored in REDCap.

REDCap Costs

REDCap is set up as an 'instance' (a virtual server) and pricing is based on the 'size' of the instance needed, ie: the disk space required. Guidance on exact costs and individual requirements should be discussed with Information Services, however some basic guides to size and cost are as follows:

- A 'standard' REDCap instance is £50 per month.
- 'On server' backup is free.
- 'Off server' backup is an additional £10 per month.

A 'standard' REDCap instance is defined as:

- Being used to collect a total of < 10m individual data points.
- No document upload/storage (such as PDF/Excel/Word). Document upload in a project consumes disk space extremely quickly.
- Occasional data exports.

'On' vs 'Off' server backup:

- 'On server' backup – a copy of the MySQL database hosting the study's REDCap data is made in another location on the same server's disks. This mainly helps in restoring REDCap in the case of database corruption.
- 'Off server' backup – a copy of the MySQL database hosting the study's REDCap data is copied to another secure server where it is then backed up to tape. As well as helping in the case of database corruption, this allows REDCap to be restored in the case the server is compromised, data deleted or seized in a ransomware attack.

- In both cases, restoration will be to the point the last backup was taken, which is usually the previous night, Monday– Friday, unless specified otherwise.

The approximate total number of data points can be calculated thus:

- Sum of number of data points on each form collected for a study participant multiplied by the number of participants.

Example:

So if there was only 1 form with 20 pieces of data collected for each study participant. But the form was used 3 times over the course of the study for each participant and there were 200 participants, then the total number of data points can be calculated:

(3 x 20) x 200 = 12,000

If researchers feel that their project may require a larger amount of server disk space (a higher number of total data points, file uploads are required, or frequent downloads of the data are envisaged), Information Services can prepare a custom quote for them.

Notes:

- Prices charged cover the cost of St. George's providing the infrastructure and setup of software and services used by the REDCap software. The REDCap software is provided free of charge by Vanderbilt University to non-profit institutions who are members of the REDCap Consortium.

REDCap Set-Up

Where REDCap can be used, it has to be set up for Investigators by the SGUL Information Services. For research studies, they will only set up REDCap once they have been given the 'green light' to do so from the JRES governance team.

Investigators must follow this process in order for REDCap to be set up:

- The JRES will request a draft protocol as part of the sponsorship process for all studies. Both the interventional and non-interventional JRES protocol templates include a Data Protection Impact Assessment (DPIA) which must be completed as part of the protocol.

  Please note: studies which go through the SGREC use a different protocol template and so will require a Research DPIA form to be completed separately, where REDCap is to be used. Applicants should contact sgulrec@sgul.ac.uk

- The JRES will confirm with Information Services by email that REDCap can be set up when they have reviewed the DPIA and are satisfied with the study from a governance perspective.
- A copy of the DPIA must be provided to Information Services.
- The Investigator should then work directly with Information Services to set up REDCap, including agreeing pricing and providing budget codes.
- Information Services will set up the instance and release it to the Investigator for use.

- Whilst Information Services will provide 'best efforts' to support the infrastructure required and the REDCap installation, it does not provide support for use of REDCap itself.
- Investigators are responsible for ensuring that they and their study team are familiar with the use of REDCap. Training modules on the use of REDCap can be found on the REDCap website: https://projectredcap.org/resources/videos/

REDCap Responsibilities

The Investigator responsible for the study is responsible for the data entered and stored in REDCap.

Users who are required to input data at external sites can be given access as appropriate to their role, but the SGUL Investigator will be responsible for the data that has been entered.

The Investigator is responsible for informing Information Services once a project has finished and/or an instance is no longer required.

Investigators with REDCap projects who are leaving SGUL, must inform Information Services of a change of ownership for their REDCap project(s), or must request to close the instance.

Information Services is responsible for closing instances when they are no longer needed.

Information Services will check with Investigators on an annual basis that instances are still in use. Instances that are no longer required will be closed, with any data held for a further 6 months and then deleted.

References / Further Information

JRES:	Joint Research and Enterprise Services (sgul.ac.uk)
Information Services:	Information Services (sgul.ac.uk)
Research Data Management:	Research Data Management (sgul.ac.uk)
REDCap:	https://projectredcap.org/
JRES Documents:	Policies, Standard Operating Procedures and Templates (sgul.ac.uk) JRESGOVSOP0038 Data Management JRESDOC0001 Interventional Study Protocol Template JRESDOC0002 Non-interventional Protocol Template JRESDOC0123 St George's Research DPIA SGREC Protocol Template: https://www.sgul.ac.uk/research/research-ethics/ethical-review-process
SGUL Policies:	SOP_ManagingLeaversRecordsProcedure (sgul.ac.uk)