SOP number	**52.018**	Version	**1.0**
Title	**NHSGGC R&I Process for Research Database**		

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SOP category	NHS GG&C Sponsor R&I

Staff category

Staff Category	**R**	**A**	**C**	**I**
Systems and Operations Manager		X		
Database Owner	X			
Sponsor Research Co-ordinators	X			
Sponsor Research Facilitator	X			
Senior Research Administrators	X			

1 Scope

This procedure applies to Research Databases managed by or Hosted within NHS Greater Glasgow and Clyde (NHSGGC). For clarity, NHSGGC do not Sponsor Research Databases, the capacity for NHSGGC is to acknowledge the Research Database. It does not apply to databases used exclusively for a single research project (Study Databases).

2 Purpose

To describe the process for Sponsor team involvement during the development and management of a Research Database when NHSGGC are the named establishment.

3 Procedure

3.1 Abbreviations/Definitions

DAC	Data Access Committee
DPO	Data Protection Officer
HRA	Health Research Authority
IRAS	The Integrated Research Application System
NHSGGC	NHS Greater Glasgow and Clyde
PIS	Patient Information Sheet
SOP	Standard Operating Procedure
RC	Research Coordinator
REC	Research Ethics Committee
RF	Research Facilitator

3.2 Background

A Research Database is a structured collection of individual-level patient data. The storage of data in a Research Database is kept beyond the lifespan of a single Research Project. Research Databases offer storage of individual-level patient data that can be retrospectively analysed by researchers that did not collect or store the data. These external researchers can apply for use of data in a Research Database via the Research Database's Data Access Committee (DAC).

A Study Database is a collection of individual level data that is collected for the sole purpose of a single research project. These are governed by the approvals (REC and otherwise) granted for the specific project and are not covered in this SOP.

Research Databases can include any of the following:

- Databases originally established for research purposes
- Databases that have been established for reasons other than research where there is a subsequent intention to use the database for research purposes. For example databases originally established for:
    - Delivery of care
    - Audits and service evaluation
- Databases established for multiple purposes, such as disease registers, where research is one of the intended purposes

The Database owner will contact the R&I Department and the appropriate RF/RC will provide them the following link for them to decide if Research Database is appropriate - https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-tissue-banks-and-research-databases/

3.3 Stage 1 Grant Costing and Adding to SReDA

The RF or RC will request the documents from the Database Owner for the proposed database. This is to inform of any costs associated with the Research Database. The RF/RC will work with the Database Owner to determine any NHSGGC Costs associated with the Research Database, including long-term data storage and management costs if applicable and complete the Cost Template Form R&I Finance Following SOP 51.010.

An R&I Reference Number will be given to the Research Database and the information added to SReDA according to SOP 50.009 and SOP 50.010.

3.4 Stage 2 Information Governance

All study documents for Research Databases will be reviewed by RF/RC. These documents may include IRAS Application, Research Database Protocol Document, Participant Information Sheets, Consent Forms and any other regulatory documents required. The Database Protocol must include purpose, governance, access policies and retention period.

The Authorisation of the Research Database is completed by the Data Protection Officer in NHSGGC Information Governance Team.

3.5 Stage 3 R&I Local Approval

Local R&I acknowledgement will be provided by the Senior Research Administrator. SReDA will be updated and Database Owner provided with an acknowledgement email.

3.6 Stage 4 Contracting and Amendments

3.6.1 Contracts

The RF/RC will contract with external researchers wishing to have access to data within the Research Database. Once an application has been approved by the Data Access Committee, the Data Access Committee will inform the RF/RC that a contract is needed.

All other contracting will be handled by the RF/RC for Research Databases.

3.6.2 Modifications

All Substantial Modifications will have a notice of substantial modification completed by the Database Owner and will be authorised by those who authorised the IRAS Application (Data Protection Officer).

Non-Substantial Modifications do not need to be notified to REC; however, if the Database Owner wishes to do this they can do so via email.

Modifications will be processed by the Information Governance Team who will inform R&I that a modification has been processed. Once Approved the R&I Senior Research Administrator will Acknowledge the Modification and update SReDA.

3.7 Stage 5 End of Research Database

At the end of the Research Database Information Governance will communicate to R&I that the Research Database is closing and the End of Study process will be completed following SOP 51.005.

4 Referenced Documents

- SOP 50.009 – Project Numbering
- SOP 50.010 – Project data entry on SReDA
- SOP 51.005 – End of Study Procedures
- SOP 51.010 – Preparation and Review of Grant Applications and Costs

5 Related Documents

- N/A

6 Document history

Version	Date	Description	Retrospective Implementation
1.0	06/11/2025	First Release	No