SOP number	**SOP 50.026**	Version	**4.0**
Title	**Internal QC checks of Scottish Research Database Application (SReDA)**		

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Released by Signature	Julie Brittenden	Date

SOP category	NHS GG&C General
Staff category	

Staff Category	**R**	**A**	**C**	**I**
Research Information Officer (IO)	X			
Research & Innovation Systems & Operations Manager		X		
Research Administrators			X	
Research Facilitators			X	
Research Co-ordinators			X	
NRS Performance Manager			X	

1. Scope

This procedure details the internal quality check process that applies to Research projects recorded on SReDA, our research database.

2. Purpose

This SOP defines the process of planning, managing and implementing quality checks of SReDA data entry. All research activity in NHS Research Scotland is captured on SReDA for project management and reporting purposes.

A number of national and local procedures apply when this information is added to the database. Compliance of the R&I department to these procedures will be audited locally and nationally. The types of procedures will include (although this list is not exhaustive):

1. NRS-GUI-003, ReDA 3 Minimum Dataset
2. NRS-GUI-001, NRS Clocks Guidance
3. SOP 50.010, Project Data Entry on SReDA

3. Procedures

Internal database checks will be conducted regularly and routinely throughout the year following the processes within this SOP. A list of checks will be defined and any actions from this will be sent to Portfolio team contacts and any escalation will be reported via the System's Team R&I Committee meeting. QC checks undertaken jointly with Research Governance Team (limited to Co-sponsored CTIMPs) will be split into two sections – remote and paper-based.

3.1. QC schedule

An annual QC schedule will be prepared by the IO, detailing month and description of check, recipient and staff involved. Unplanned QC checks will be recorded by the IO and will be conducted when commissioned by Senior Managers and Directors on an ad hoc basis (e.g. checks of NRS finance system). This annual schedule will be retained on the common drive.

5.2 Preparation of QC checks

In preparation of the QC checks, the IO will contact the Research Portfolio team staff and Systems Manager. The purpose of the QC check and the timeline for conclusion of actions will be clearly communicated at the time the report is released.

5.3 Selecting projects for audit

The IO will confirm criteria required for QC checks. Using SReDA (Scottish Research Database Application) the IO will run an advanced report, refer to NRS-GUI-003, and select the relevant fields (study/investigator/funder/sponsor) for the report formula. The QC report will include one or more selected fields and all projects selected will be QC checked e.g. missing 'Portfolio id' for all Eligible projects active between chosen dates.

The criteria used to check against are:

- Missing data fields
- Funder source, type and correct allocation of funding (e.g. Eligible, Extended review, NEF etc)
- Commercial Sponsor
- Start & end dates
- RGL data fields

5.4 Conducting QC checks

In the course of carrying out the QC checks, any identified non-compliances will be managed by the IO.

Issues of non-compliance will be graded using the following system:

Category	Issue	Description
1	Minor	Minor admin or technical issues are detected that do not comply with the required control objectives
2	Major	Major/serious issues are detected that show a significant system weakness, which impact or frequency presents risks to the required control objectives
3	Critical	Critical issues are detected that show significant system weakness, which presents unacceptable risk to the control objectives and required urgent attention

The majority of findings in a database QC are likely to be assigned to category 1. The IO will discuss category 2 and 3 findings with the NRS Portfolio Manager, details of discussion and action will be recorded on the relevant QC report. If any issues are deemed to be of a sufficiently severe nature they will be escalated as Non-Compliances to the Research Governance Manager/Lead Pharmacist Clinical Trials R&I as per SOP 51.008. If the recipient of the report doesn't respond within 1 week this can be escalated to the System & Operations Manager.

The IO will identify the corrective actions and release this report to the relevant staff members. At this time a time frame to respond and correct each action will be given. A summary of the completeness of this will be presented to the System's Team R&I committee.

5.5 Closure of QC report checks

The QC checks can be closed when all actions are met, the IO will enter date the report was closed with all actions having been completed. This will be saved centrally for future reference.

The IO will:

- Discuss any relevant preventative actions with relevant staff groups and Systems & Operations Manager (if required). Preventative actions may include staff training sessions which will be organised by the IO.

5.6 CAS not addressed

If CAS have not been addressed the IO will escalate unconcluded actions to the NRS Portfolio Manager.

4. Referenced documents

- NRS-SUI-001 - NRS Clocks Guidance
- SOP 50.010 - Project Data Entry on SReDA
- NRS-GUI-003 - ReDA 3 Minimum Dataset

5. Related documents

Internal Database Audit Process Map

6. Document history

Version	Date	Description
1.0	16/05/12	Release of SOP
2.0	15/07/2016	Updated to template v1.4 and new author
3.0	28/04/2020	"Prepared, approved and released by" all updated. Remit of SOP changed from audits to QC checks. Version updated.
4.0	03/05/2024	R&D to R&I updates. Update to Referenced Documents. Clarification on the escalation process and the inclusion criteria for the QC report. Change of number.