SOP number	**50.010**	Version	**6.0**
Title	**Project Data Entry on SReDA**		

Prepared by Signature	Radoslaw Penar Date
Approved by Signature	Melissa Robert Date
Released by Signature	Julie Brittenden Date

SOP category	NHS GG&C General
Staff category	

Staff Category	**R**	**A**	**C**	**I**
Systems Manager		X		
Sponsor Research Co-Ordinator	X			
Commercial Research Co-Ordinator	X			
Research Facilitator	X			
Senior Research Administrator	X			
Research Administrator	X			
Research Information Officer	X			
NRS Portfolio Performance Manager	X			
GCRF Information Manager	X			
Innovation Project Manager	X			
Innovation Contract Manager	X			

1. Scope

This procedure covers entry of research data into SReDA (Scottish Research Database Application). Research activity in NHS Research Scotland is recorded on SReDA for project management and reporting purposes.

2. Purpose

This SOP defines the required minimum dataset to facilitate consistent and efficient working of research data in SReDA. For single centre studies and grant applications R&I office staff create the study record and enter the required minimum dataset. For multicentre studies NRS Permissions CC create the study record and enter the project level fields of the required minimum dataset, R&I office staff enter Health Board and local level data.

A number of national and local procedures apply to inserting information into SReDA. NRS SOPs are in the Document Store in SREDA which can be accessed from the home page. The types of procedures will include (although this list is not exhaustive):

1. NRS-SOP-008 - Procedure for Use of SReDA within the NHS Research Scotland Research & Development offices
2. NRS-GUI-001 - NRS Clocks Guidance
3. SOP 52.010 - Registration on the Central Portfolio Management System (CPMS)
4. NRS-GUI-003 - NRS ReDA 3 Minimum Dataset
5. NRS-GUI-020, NRS ReDA – CPMS Recruitment User Guideline
6. NRS-SOP-022, Updating SReDA Recruitment Tab for Non-Commercial Studies

3. Procedures

The following tables detail the required minimum datasets for grant applications and study types that require R&I permission. Studies that do not require R&I permission (Tissue Bank, Research Database studies) have a smaller minimum dataset, the required fields have * in 'FIELD' column. The required minimum dataset should be uploaded to SReDA for all studies (including Grant applications) as soon as the information is made available to R&I office staff. For sponsored studies the senior research administrator/research administrator should request the IRAS XML and upload this to SReDA, completing the minimum dataset as soon as the IRAS becomes available.
The GCRF Information Manager will update the 'Support Department' field for all projects supported by GCRF as soon as the support has been confirmed.
The Innovation Team will follow this SOP for all projects with an IRAS Form, they have a separate Working Instruction for all other Innovation projects.

1. Tab: Study Details > Project Information > General Information

FIELD	SOURCE	Com	Eligible	NEF
Short Title *	IRAS Form – IRAS Project Filter	✓	✓	✓
Research Title *	IRAS Form –Part A, QA1	✓	✓	✓
NRS Study	NRS Permissions Co-ordinating Centre local field (Multi-Centre Only)	✓	✓	✓
NRS Reference	NRS Permissions Co-ordinating Centre local field (Multi-Centre Only)	✓	✓	✓
IRAS Project Code *	IRAS Form – First 5/6 numbers found at the bottom right hand corner of the form	✓	✓	✓
Project ID	Board Determined	✓	✓	✓
Lead Reviewer	NRS PCC to determine Lead Reviewer for multisite studies only	✓	✓	✓
Sponsor Representative *	Select the R&I Research Co-ordinator name from the drop down (For Sponsor studies Only)		✓	✓

2. Tab: Study Details > Project Information> Study Identifiers

FIELD	SOURCE	Com	Eligible	NEF
Portfolio	Completed by the Scottish leading board		✓	
Portfolio ID	CPMS record generated		✓	
Clinical-Trials.gov Reference	IRAS Form - Q5 A5-1 of IRAS form – CTIMPs only	✓	✓	✓
REC No *	REC Approval Letter	✓	✓	✓
Eudract	IRAS Form – Part A, QA5-1 – CTIMPs & combined device trials only	✓	✓	✓
ISRCTN	IRAS Form – Part A, QA5-1 - CTIMPs only	✓	✓	✓
Protocol ID	Commercial – protocol number, version and date. Non-commercial – protocol version and date.	✓	✓	✓

3. Tab: Study Details > Project Information> Study Categorisation

FIELD	SOURCE	Com	Eligible	NEF
Main Ethics Status *	REC Correspondence	✓	✓	✓
Study Type *	IRAS Project Filter Q2	✓	✓	✓
Lead Nation	IRAS Project Filter Q3A	✓	✓	✓
Participating Nations	IRAS Project Filter Q3	✓	✓	✓
UKCRC Health Category	IRAS Form Part A, QA15 (all categories to be included)	✓	✓	✓
Multi Centre	Tick checkbox if the project has more than one UK participating site	✓	✓	✓

4. Tab: Study Details > Project Information> Information Custom Fields

FIELD	SOURCE	Com	Eligible	NEF
Project Type *	Determined by R&I board following CSO guidance	✓	✓	✓
NRS Project Status	NRS Permissions Co-ordinating Centre / Status of Project set up	✓	✓	✓
COVID-19 STUDY	Tick checkbox if the project is Covid-19 related	✓	✓	✓

5. Tab: Study Details > Stakeholders >Personnel

FIELD	SOURCE	Com	Eligible	NEF
Chief Investigator	IRAS Form – Part A, QA3-1/QA3-2	✓	✓	✓
Principal Investigator *	Organisation Information Document/Local Information Pack/IRAS Form	✓	✓	✓
Investigator Name and Role	All local investigators listed in the OID Appendix email/letter	✓	✓	✓

6. Tab: Study Details > Stakeholders> Funders

FIELD	SOURCE	Com	Eligible	NEF
Funder Name	IRAS Form QA65 or Funding Award Letter	✓	✓	✓

7. Tab: Study Details > Stakeholders >Sponsors

FIELD	SOURCE	Com	Eligible	NEF
Sponsor Name	IRAS Form – QA64-1	✓	✓	✓

8. Tab: Study Details > Research

FIELD	SOURCE	Com	Eligible	NEF
Primary Research Question	IRAS Form – Part A, QA10	✓	✓	
Minimum Age of Participants	IRAS A15	✓	✓	
Maximum Age of Participants	IRAS A15 (if no upper age limit indicated then enter 100)	✓	✓	

9. Tab: Study Details > Research> Research Custom Fields

FIELD	SOURCE	Com	Eligible	NEF
Trial Phase	IRAS Form – Part A, QA9 – CTIMPs only (for other projects mark as N/A)	✓	✓	

10. Tab: Study Details > Local Information

FIELD	SOURCE	Com	Eligible	NEF
Project Status *	Health Board determined	✓	✓	✓
R&D Officer *	Enter the R&I officer's name. For Sponsored studies enter the Senior Research Administrator's name	✓	✓	✓
Is lead centre	Tick if your health board is lead centre of the study	✓	✓	
Lead centre name	Enter the name of the lead centre in the UK	✓	✓	
Actual Start Date *	Management Approval date	✓	✓	✓
Actual End Date *	Date study is expected to end or has completed	✓	✓	✓
Location Status	Enter the status of the currently chosen location	✓	✓	✓
Location Start Date	For multiple GG&C locations, enter the R&I approval date for each location. Choose location from the top of the screen drop down list	✓	✓	✓
Location End Date	Date each site is expected to end or has completed. Choose location from the top of the screen drop down list	✓	✓	✓
Primary Care/ GP/ Dental Study	Tick checkbox if appropriate	✓	✓	✓

11. Tab: Study Details > Locations

FIELD	SOURCE	Com	Eligible	NEF
Add Licences/ Locations *	Health Board Determined	✓	✓	✓
Location Type	OID/OID Appendix	✓	✓	✓

12. Tab: Governance > Checklist (Refer to NRS-GUI-001)

FIELD	SOURCE	Com	Eligible	NEF
Full Document Set check (FDS)	Date FDS received	✓	✓	✓
Outline OID	Date OID/OID Appendix received	✓	✓	✓
Local Management Permissions Letter issued check	Date permission letter issued	✓	✓	✓
Start Local Review Clock	Start clock on receipt of FDS and OID/OID Appendix	✓	✓	✓
Stop Local Review Clock	Stop clock on date permission letter issued	✓	✓	✓
Stop Local Review Clock	Withdrawn projects to be updated to 'Application withdrawn or deemed withdrawn'	✓	✓	✓

13. Tab: Recruitment > Targets and Dates > General Recruitment Information

FIELD	SOURCE	Com	Eligible	NEF
Recruitment Status	To be updated for every location (see NRS-GUI-020)		✓	
Date of Status Change	To be updated for every location when the Recruitment Status field is amended (see NRS-GUI-020)		✓	

14. Tab: Recruitment > Targets and Dates > Targets

FIELD	SOURCE	Com	Eligible	NEF
Local Recruitment Target	Local Information Pack (LIP) / Site agreements / contracts or board defined based on site target if multiple locations. Enter the target for every site	✓	✓	

15. Tab: Recruitment>Recruitment Totals> Custom Recruitment Fields

FIELD	SOURCE	Com	Eligible	NEF
CRO	Select the clinical research organisation involved in the study	✓		
Initial Costing Template price per patient	Commercial costing template	✓		
Agreed Costing Template price per patient	Enter the total per patient budget fee	✓		
Set up and Management Costs	Enter the sum of set up fees and management costs in the contract	✓		
Other Costs	Commercial costing template	✓		
Pharmacy Set up Fees	Commercial costing template – CTIMPs only	✓		
Agreed Pharmacy per patient	Enter the total fee associated with pharmacy elements of the protocol for one patient - CTIMPs only	✓		
Current Target Recruitment end	Enter the projected date recruitment to the study is scheduled to end (See NRS SOP 22)	✓	✓	
Recruitment End	Enter the date when recruitment to the study ended or was suspended/withdrawn (this date must be in the past- see NRS SOP 22)	✓	✓	
RGL from Sponsor	The date at which recruitment has opened.	✓	✓	
SIV date	Enter the date of the site initiation visit	✓		
Actual FSI	Enter the date the first patient was recruited into the study	✓		
Final Subject in	Enter the date the last patient was recruited into the study	✓		
Recruitment Source	Non-Commercial - CPMS Record. Commercial – Health Board determined	✓	✓	
Legacy SSC value	Lead site to complete from the data entered in the NRS Finance tool		✓	

16. Tab: Finance > Finance > Support

FIELD	SOURCE	Com	Eligible	NEF
Add New Support*	Enter associated support departments e.g. CRUK, PMU, CRF	✓	✓	✓

17. Tab: Imaging > Scanning

FIELD	SOURCE	Com	Eligible	NEF
Facility	Protocol, IRAS form or Imaging Support Form (58.004B). This field is completed by the research co-ordinator and commercial research co-ordinator (Imaging will QC & correct errors/update as study progresses)	✓	✓	✓
Body Area	As above	✓	✓	✓
No of Scans: (Standard of Care)	As above	✓	✓	✓
No of Scans: (Research)	As above	✓	✓	✓
Type of Imaging	As above	✓	✓	✓
Reporting	As above	✓	✓	✓
Specific Acquisition	As above	✓	✓	✓

18. Tab: Pharmacy/ custom

FIELD	SOURCE	Com	Eligible	NEF
Portfolio *	Select portfolio team assigned to study	✓	✓	✓
Risk Assessment*	Completed by Senior Research Administrator, Research Administrator, Research Coordinator or Commercial Research Coordinator		✓	✓
SReDA updated by Research Administrator *	Tick box once minimum dataset has been completed after R&I approval is issued	✓	✓	✓

3.1. Hosted & Sponsor Grant Applications Minimum Dataset

Tabs	FIELD	SOURCE
Study Details > Project Information > General Information	Short Title *	NHS project costs template for grants – Project title Enter 'GRANTS:' before entering short title
Study Details > Project Information >General Information	Research Title *	NHS project costs template for grants – Project title Enter 'GRANTS:' before entering research title
Study Details > Project Information >General Information	Project ID*	R&I number assigned by the Research information officer or senior research administrator/research administrator using Project ID log
Study Details > Project Information > General Information	Sponsor Representative *	Select the R&I Research Co-ordinator name from the drop down (For Sponsor studies Only)
Study Details > Stakeholders >Personnel	Chief Investigator*	NHS project costs template for grants – Chief Investigator - Name
Study Details > Stakeholders >Personnel	Principal Investigator*	NHS project costs template for grants – Principal investigator - Name
Study Details > Stakeholders >Funders	Funder name *	NHS project costs template for grants – Funder - Name
Study Details > Stakeholders >Sponsors	Sponsor Name*	NHS project costs template for grants – Sponsor & Co-Sponsor (if applicable)
Study Details > Local Information	Project Status*	Select 'Proposed' from drop down list
Study Details > Local Information	R&D Officer*	Enter the R&I officer's name. Assign grant to R&I officer based on Activity area (Activity area split included in project ID log spreadsheet). For Sponsored studies enter the Senior Research Administrator's name
Study Details > Local Information	Location status*	Select 'Grant App' from drop down list
Study Details > Locations	Add Licenses/Locations*	NHS project costs template for grants – Chief Investigator – Location or Administering institution
Pharmacy/Custom	Portfolio (Board) *	Select portfolio team assigned to study
Finance > Finance > Support	Add new support * Please note that hosted grants often do not include PMU support, so can be not applicable	NHS project costs template for grants – detailed in Section 1 Row 24 (NHS Project Manager name and email) as well as Resources Information Section 6 (NHS Staff involved

3.2. Procedure for grant applications – Successful/Unsuccessful funding outcomes

The Senior Research Administrator and Research Administrator will send the 'confirmation of grant status' template email (Form 50.010B) to the chief/principal investigator listed on the grant application, to check on the grant application outcome. The research information officer will provide a report every 3 months of grant applications which are 3 months after their 'SReDA registered date', for the senior research administrator and research administrator to contact.

If the grant application is confirmed as successful, the study email folder will be moved from 'grants' to 'proposed'. The E-file in the common drive must also be updated with the correct template folder (CTIMP or Non-CTIMP). When a grant is awarded the pre-fix 'GRANT' in the short title and research title on SReDA must be removed immediately. The location status will also be changed from 'Grant App' to 'Proposed'. The Senior Research Administrator will also request the IRAS XML for sponsored grant applications, this must be uploaded on to SReDA, with the other fields that constitute the minimum dataset completed as soon as the IRAS becomes available.

If the grant application is confirmed as unsuccessful, the study email folder must be moved from 'grants' to 'withdrawn'. The email confirming that the grant application was unsuccessful shall be saved in the E-file in the common drive. On SReDA the study details, local information tab must be updated, with 'project status' and 'location status' fields updated to 'Withdrawn'. Under the 'Governance' tab, 'Change Status (No Event)' the local review clock will be permanently stopped with the application 'Withdrawn or deemed Withdrawn'. Finally, the 'Study details', 'Study notes' must be updated by the senior research administrator and research administrator to 'add a new comment'. This comment will include the date and details which document the unsuccessful grant outcome.

4. Referenced documents

- **NRS-SOP-008 - Use of SReDA within NRS Research & Development Offices (https://scotland.reda.org.uk/sopstore/default.aspx)**
- **NRS-GUI-001 - NRS Clocks Guidance (https://scotland.reda.org.uk/sopstore/default.aspx)**
- **NRS-GUI-003 - NRS ReDA 3 Minimum Dataset (https://scotland.reda.org.uk/sopstore/default.aspx)**
- **NRS-GUI-020 - NRS ReDA – CPMS Recruitment User Guideline (https://scotland.reda.org.uk/sopstore/default.aspx)**
- **NRS-SOP-022 - Updating SReDA Recruitment Tab for Non-Commercial Studies (https://scotland.reda.org.uk/sopstore/default.aspx)**
- **SOP 50.024 - Registration on the Central Portfolio Management System (CPMS)**
- **Form 50.010B - Confirmation of Grant Status**
- **SOP 50.025 – Quality Checks of Project Entries on SReDA**

5. Related documents

N/A

6. Document history

Version	Date	Description
1.0	27/04/12	Release of SOP
2.0	14/07/16	Updated to template v1.4. change of author
3.0	14/02/2020	Updated to template v3.0 Change of author and releaser Procedures updated to reflect latest version of SReDA
4.0	4/10/2021	R&D to R&I updates. Additional fields on SReDA
5.0	03/02/2023	Updates to staff category Inclusion of minimum dataset for hosted and sponsored grant applications Procedure for uploading sponsored studies minimum dataset Procedure for withdrawing/progressing grant applications after confirmation of successful/unsuccessful funding.
6.0	03/05/2024	Inclusion of the GCRF Information Manager to staff category and a paragraph regarding the field they update. Inclusion of the Innovation Team. Added a new referenced document.