| SOP number | **50.010** | Version | **7.0** |
|---|---|---|---|
| Title | **Project Data Entry on SReDA** | | |

| | |
|---|---|
| Prepared by<br>Signature | Radoslaw Penar<br>Date |
| Approved by<br>Signature | Melissa Robert<br>Date |
| Released by<br>Signature | Jesse Dawson<br>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 | | | |
| CRIF Project Assistant and Administrator | X | | | |

## 1. Scope

This procedure covers entry of research data into SReDA (Scottish Research Database Application). Research activity in NHS Research Scotland (NRS) 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 Coordinating Centre (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. For feasibilities refer to the working instruction WI 50.010A for the minimum dataset.

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 50.024 - Management of the Central Portfolio Management System
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.

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 /<br>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 NHSGGC 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: Finance > Funding > Finance Funding

| FIELD | SOURCE | Com | Eligible | NEF |
|---|---|---|---|---|
| Local Financial Agreement | Edit the existing funder(s) and tick the checkbox if applicable. For new funders click on 'Add Funder' first and update. | ✓ | ✓ | ✓ |

18. Tab: Imaging > Scanning

| FIELD | SOURCE | Com | Eligible | NEF |
|---|---|---|---|---|
| Facility | Protocol, IRAS form or Imaging Support Form (58.004A). This field is completed by the CRIF Project Assistant and Administrator | ✓ | ✓ | ✓ |
| 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 | ✓ | ✓ | ✓ |

19. 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 | ✓ | ✓ | ✓ |
| R&I-managed endowment funding secured | Record the date when R&I managed endowment funding has been secured | | ✓ | ✓ |
| R&I-managed endowment funded study | Tick the checkbox for relevant studies | | ✓ | ✓ |

20. Sponsor additional minimum data set

Applicable to Eligible and NEF studies

| Tabs | FIELD | SOURCE |
|---|---|---|
| Study Details > Local information > Local information custom fields | Ethics Approval Date * | Add ethics approval date |
| Pharmacy/Custom | Grant Award Date* | Add the date the Grant was awarded. |
| Pharmacy/Custom | Grant Activation Date* | Add the date the Grant was activated. |
| Pharmacy/Custom | Co-sponsor agreement* | Click the drop down box. Click yes if co-sponsor agreement in place. Tick N/A if there is no co-sponsor agreement. |
| Pharmacy/Custom | Date co-sponsor agreement signed* | If yes to the co-sponsor agreement add the date the co-sponsor agreement as signed. |
| Pharmacy/Custom | Date funder agreement signed* | Add the date the funder agreement is signed. |
| Pharmacy/Custom | Funder milestone Specified* | Click the drop down box and click yes if funder miles stone specified. Click no if no funder milestones specified. |
| Pharmacy/Custom | Milestone Target* | If funder milestone specified add the target date. |
| Pharmacy/Custom | Milestone comments* | Add what the funder milestone is In the comment box |
| Pharmacy/Custom | Milestone Achieved* | Add the date when the funder milestone was achieved. |
| Pharmacy/Custom | Multicentre study* | Click the drop down box and click yes if the study is multi-centre. Click no if it is a single centre study. |
| Pharmacy/Custom | Total number of sites* | If the yes to multicentre study add the total number of sites. |
| Study Details > Local information > Local information custom fields | Biorepository* | Click the tick box if biorepository is required. Leave black if Biorepository was not required. |
| Study Details > Local information > Local information custom fields | Safehaven* | Click the tick box if Safehaven is required. Leave black if Safehaven was not required. |
| Pharmacy/Custom | Final report requested* | Add the date when the final report was requested. |
| Pharmacy/Custom | MHRA Acknowledgement of end of study* | Add the date which MHRA acknowledges the end of trial. |

### 3.1. Hosted & Sponsor Grant Applications Minimum Dataset

Applicable to Eligible and NEF studies

| Tabs | FIELD | SOURCE |
|---|---|---|
| Study Details > Project Information > General Information | Short Title * | NHS project costs template for grants – Project title<br><br>Enter 'GRANTS:' before entering short title |
| Study Details > Project Information > General Information | Research Title * | NHS project costs template for grants – Project title<br><br>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 *<br><br>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

- **Form 50.010B - Confirmation of Grant Status**
- **WI 50.010A - Recording Feasibilities**
- **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 - Management of the Central Portfolio Management System**
- **SOP 50.025 – Quality Checks of Project Entries on SReDA**
- **Form 58.004A – CRIF Support Form**

## 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<br>Change of author and releaser<br>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<br>Inclusion of minimum dataset for hosted and sponsored grant applications<br>Procedure for uploading sponsored studies minimum dataset<br>Procedure for withdrawing/progressing grant applications after confirmation of successful/unsuccessful funding. |
| 6.0 | | 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. |
| 7.0 | 22/04/2025 | Update of the Imaging field and source. Update to the Referenced Documents. Addition of CRIF Project Assistant and Administrator to Staff Category table. Sponsor additional minimum data set. Addition of a reference to 'Recording Feasibilities'. Addition of a Local Financial Agreement checkbox. Addition of R&I - managed endowment funded studies fields. |