

SOP number	51.022	Version	5.0
Title	Research & Innovation Data & Administration tasks		

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SOP category	NHSGGC Sponsor R&I			
Staff category				
Staff Category	R	A	C	I
Systems Research & Innovation Manager		X		
Sponsor Research Administrator	X			
Research Administrator	X			
Sponsor Research Coordinator			X	
Commercial Research Coordinator			X	
Innovation Project Manager			X	
Innovation Sponsor Co-Ordinator			X	
Information Officer			X	
Biorepository Manager				X
Human Tissue Governance Manager				X
Biorepository Administrator				X
West of Scotland Safe Haven Manager				X
West of Scotland Safe Haven Project Manager				X

1. Scope

This procedure applies to NHS Greater Glasgow and Clyde (NHSGGC) Research and Innovation (R&I) staff by providing instructions for Senior Research Administrators (SRAs) and Research Administrators (RAs) undertaking SReDA (Scottish Research Database Application) data management and associated administrative tasks. Biorepository staff should refer to SOP 60.204 for their SReDA data and administration tasks process.

2. Purpose

This SOP provides details on how to complete data on SReDA and conclude the administration tasks associated with this. This activity is completed by the Senior Research Administrators (SRAs) and Research Administrators (RAs) and the Co-ordinator's and Information Officer are consulted as required.

3. Procedures

3.1. Processing a New GRANT Submission

- i. Requests for NHSGGC costing for a grant application are submitted to ggc.randigrantapplications@nhs.scot and the SRA will follow the steps as per SOP 51.010
- ii. Check for information in email folders on Outlook. If there is not an email folder created, then create one in the relevant portfolio folder within the 'GRANTS' sub folder and name according to the project ID.
- iii. Create project a Project ID as per SOP 50.009.
- iv. Record the project on SReDA following SOP 50.010.
- v. Enter 'GRANT' as prefix at the start of Short Title and Research Title field.
- vi. Enter all data from grant application – project title, CI, PI, Sponsor and potential funder, Eligibility, IRAS categorisation & portfolio. Refer to SOP 50.010 for the grant applications minimum dataset.
- vii. Create project e-folder on the 'Common' drive using the project ID.
- viii. For NHSGGC-sponsored studies, study documentation will be filed using the appropriate common drive e-folder template. Two templates are available: One for Clinical Trials of Investigational Medicinal Products (CTIMP)/ Clinical Investigations of Medical Devices (CIMD) studies and one for non-CTIMP studies, in accordance with Form 52.009C.

3.2. Basic Science Support Model for NHSGGC Sponsored Studies

For studies categorised as "Basic Science Study Involving Procedures with Human Participants" on the IRAS categorisation form (also found on the costing sheet), the Proportionate Review (PR) SRAs will provide local review & approval of the studies. This includes the creation and maintenance of the study record within SReDA and the creation of the project e-folder on the Common drive. The Sponsor Senior Research Administrator (SRA) will continue to support Research Coordinators (RCs) with Sponsor-related processes and requirements throughout the study lifecycle.

3.3. Feasibilities

Commercial feasibility activities must be recorded and maintained within SReDA in accordance with WI 50.010A

- i. Check for information in email folders on Outlook. If there is not an email folder created, then create one in the relevant portfolio folder within the 'Feasibility' sub folder and name according to the project ID.
- ii. Create project a Project ID as per SOP 50.009.
- iii. Record the project on SReDA following SOP 50.010.
- iv. Enter 'Feasibility' in the start of Short Title field.
- v. Enter all data from the feasibility form – project title, CI, PI, Sponsor and potential funder, Eligibility, IRAS categorisation & portfolio. Refer to WI 50.01A for the grant feasibility minimum dataset.
- vi. Create project e-folder on the 'Common' drive using the project ID.

3.4. MULTICENTRE STUDIES COORDINATED BY NRS PERMISSIONS COORDINATING CENTRE (NRSPCC)

3.4.1. Notification of a New Study

- i. Check if a project e-folder has been created for the study. If not create project e-folders on 'Common' drive, using e-folder template, in accordance with Form 52.009C.
- ii. Check for information in email folders on Outlook. If there is not an email folder created, then create one in the relevant portfolio folder within the 'Pending' sub folder and name according to the project ID.
- iii. Search for project record on SReDA.
- iv. Click on 'Documents tab'.
- v. Download all available documents from SReDA and save in e-folders.
- vi. Enter as much of the local minimum dataset as possible following SOP 50.010.
- vii. Check SReDA for any modifications; download the modification documents, save Ethics Acknowledgment/Favourable Opinion letters into **Ethics Modification before approval** sub-folder, all project documents for modification(s) into **Protocol** e-folder and if applicable MHRA approval and correspondence into **Regulatory** e-folder.
- viii. Delete any documents attached to emails saved in the email folders, excluding NHSGGC Sponsored studies.
- ix. Update project e-file checklist (Form 52.009D) with the relevant information gathered from the study documents.

NOTE: MUSKETEER studies have to be granted R&I management approval within 3 working days. If notified of a new study with MUSKETEER in the title, make this high priority following the above steps.

3.4.2. Additional project documents received

- i. Download additional documents from SReDA, saving into relevant e-folders and update the project e-checklist.
- ii. Move any previous versions to the superseded folder.
- iii. If documents provide new data, amend the fields in SReDA (e.g. a letter from Ethics with the REC number).
- iv. Delete any documents attached to emails saved in the email folders, excluding NHSGGC Sponsored studies.
- v. Update the clocks on the governance tab if necessary. Refer to NRS-GUI-001 for the clocks process.
- vi.

3.4.3. R&I permission granted

- i. Ensure SReDA minimum dataset is completed (Refer to SOP 50.010).
- ii. Once SReDA has been fully updated, then check the 'SReDA updated by the Research Administrator' box.
- iii. Check all documents have been downloaded and saved in the e-folders.
- iv. Delete any documents attached to emails saved in the email folders, excluding NHSGGC Sponsored studies.
- v. Upload Health Board documents to the local folders on SReDA (green) e.g. local documents, PI CV and Management Approval letters.
- vi. QC Reports will be generated by the Information Officer (IO) following SOP 50.025.
- vii. Permanently stop local clock (Refer to NRS-GUI-001).

- viii. For eligible NHSGGC-led studies funded through the Eligible, Extended Review, or Commercial pathways (e.g. sponsored studies where the Chief Investigator is based in Glasgow), submit the CPMS minimum dataset (Form 50.024A) to the Information Officer (IO). For studies already registered on CPMS, notify the IO of any changes requiring a CPMS status update.

3.4.4. Notification of a Modification

- i. Create modification e-folder, saving as the modification reference, date and category (e.g. SM01 20.04.2023 (Cat A)) as per SOP 52.003.
- ii. Create a modification email folder within the 'Modifications' sub folder saving as the modification reference, date and category.
- iii. Download all modification documents from SReDA project record and save in the modification e-folder.
- iv. Move any previous versions of documents to the superseded folder.
- v. Record the modification on 'Post Approval' tab (Refer to SOP 52.003).
- vi. Review/arrange review of the modification and issue local approval once all approvals and documentation is in place.
- vii. File all emails in the modification email folder.
- viii. If applicable, QC the modification to ensure SReDA has been updated correctly following SOP 50.025.

3.4.5. Notification of R&I acknowledgement for a Modification

- i. Update 'Post Approval' tab with modification permission date (Refer to SOP 52.003).
- ii. Upload modification approval email to SReDA, onto the local folder (green).
- iii. Move modified project documents to Protocol e-folder and appropriate sub-folders. Move any previous versions to the superseded folders.
- iv. Modification documents should also be kept within the relevant modification sub folders, with exception to the Commercial costing template & distribution modification – these should be saved in the finance folder and CTA modifications in the CTA folder (Refer to SOP 52.003).
- v. Delete any documents attached to emails saved in the email folders, excluding NHSGGC Sponsored studies.

3.4.6. Notification of R&I Acknowledgement for a GG&C Sponsored CTIMP/CIMDs Modification

- i. Update 'Post Approval' tab with the modification permission date (Refer to SOP 52.003).
- ii. Upload the modification approval email to SReDA local folder (green).
- iii. Update approval date and upload date on sponsor modification checklist (FORM 51.021C).
- iv. Move modified project documents to Protocol e-folder and appropriate sub-folders. Move any previous versions to the superseded folder.
- v. Print new documents and save to CTIMP/CIMDs lever arch folder (Refer to SOP 51.016)

3.4.7. Notification of recruitment closure for NHSGGC

- i. Update recruitment information on the 'Target and Dates' field on SReDA - Update 'Recruitment Status' to 'No Longer Recruiting' and 'Date of Status Change' to the final date of recruitment (NB: This is for non-commercial studies only and this must be done for all locations that are closing to recruitment).
- ii. Update recruitment information on the 'Recruitment Totals' field on SReDA – Update 'Recruitment End' field to reflect the final date of recruitment.
- iii. Update study information on the 'Local Information' field on SReDA – Update 'Project Status' and 'Location Status' to 'In Follow Up' (NB: This must be done for all locations that are closing to recruitment).
- iv. For all eligible, commercial & extended review studies, contact the local study team/PI to confirm the recruitment number for NHSGGC locations and forward the response to the IO to ensure we have the correct figures on SReDA and CPMS.

3.4.8. Notification of end of study

- i. Check for any information in email folders.
- ii. Mark the study complete by recording on SReDA the 'Actual End Date (Board)' and 'Location End Date' for each location within NHSGGC on SReDA as well as 'Archiving Proposed Destruction Date' (in the Pharmacy/custom tab on SReDA) (Refer to SOP 51.005).
- iii. Save end of study documents in the Ethics section of the e-folder.
- iv. Upload documents to SReDA.
- v. File all emails in email folder.
- vi. Delete any documents attached to emails saved in the email folders, excluding NHSGGC Sponsored studies.
- vii. For eligible NHSGGC-led studies funded through the Eligible, Extended Review, or Commercial pathways (e.g. sponsored studies where the Chief Investigator is based in Glasgow), notify the IO of the end of study date for CPMS.
- viii. For NHSGGC Sponsored studies the SRA will follow SOP 51.019.

3.5. SINGLE CENTRE STUDIES

3.5.1. Notification of a New Study

- i. Check for any information in email folders. If there is not an email folder created, then create one in the relevant portfolio folder within the 'Pending' sub folder and name according to the project ID.
- ii. Create project e-folders on 'Common' drive, using e-folder template, in accordance with Form 52.009C.
- iii. Search for project record on SReDA, if not found create project record following SOP 50.009.
- iv. Enter as much of the SReDA minimum dataset as possible following SOP 50.010.
- v. Download all available documents from email and save in e-folders. Follow Form 52.009A.
- vi. Check for any modifications; download the modification documents, save the Modification tool, documents and Ethics into **Ethics modification before approval** sub-folder, all project documents for modification(s) into **Protocol** e-folder and if applicable MHRA approval and correspondence into **Regulatory** e-folder.
- vii. Delete any documents attached to emails saved in the email folders, excluding NHSGGC Sponsored studies.
- viii. Upload all documents to SReDA 'Documents' tab.
- ix. Update project e-file checklist (Form 52.009D) with the relevant information gathered from the study documents.

3.5.2. Additional project documents received

- i. Download additional documents from email, saving into relevant e-folders. Move any previous versions to the superseded folder.
- ii. Upload documents to SReDA.
- iii. Delete any documents attached to emails saved in the email folders, excluding NHSGGC Sponsored studies.
- iv. If documents provide new data, amend the fields in SReDA (e.g. a letter from Ethics with the REC number).
- v. Update the clocks on the 'Governance' tab if necessary. Refer to NRS-GUI-001.

3.5.3. R&I Permission Granted

- i. Upload approval letter to SReDA.
- ii. Upload Health Board documents to the local folders on SReDA (green) e.g. local documents, and PI CV.
- iii. Check all project documents within e-folder have been uploaded to SReDA.
- iv. Ensure SReDA minimum dataset is completed following SOP 50.010.
- v. Once SReDA has been fully updated, check the 'SReDA updated by the Research Administrator' box.
- vi. QC Reports will be generated by the Information Officer (IO) following SOP 50.025.
- vii. Permanently stop local clock on 'Governance' tab (Refer to NRS-GUI-001).
- ix. For eligible NHSGGC-led studies funded through the Eligible, Extended Review, or Commercial pathways (e.g. sponsored studies where the Chief Investigator is based in Glasgow), submit the CPMS minimum dataset (Form 50.024A) to the Information Officer (IO). For studies already registered on CPMS, notify the IO of any changes requiring a CPMS status update.

3.5.4. Notification of a Modification

- i. Create a modification e-folder, saving as the modification reference, date and category (e.g. SM01 20.04.2023 (Cat A)) as per SOP 52.003.
- ii. Create a modification email folder within the 'Modifications' sub folder saving as the modification reference, date and category.
- iii. Download all modification documents from email folders and save in the modification e-folder.
- iv. Move any previous versions to the superseded folder (NB: This is not relevant for all portfolio teams).
- v. Upload modification documents to SReDA.
- vi. Record modifications on the 'Post Approval' tab (Refer to SOP 52.003).
- vii. Review/arrange review of modifications and issue local approval email once all the approvals and documentation is in place.
- viii. Once the modification has been approved, upload the modification approval email to SReDA.
- ix. If applicable, QC the modification to ensure SReDA has been updated correctly following SOP 50.025.

3.5.5. Notification of R&I Acknowledgement for a Modification

- i. Update 'Post Approval' tab with the modification permission date.
- ii. Upload modification approval email to SReDA folder (yellow).
- iii. Move modified project documents to **Protocol** and appropriate sub-folders. Move any previous versions to the superseded folder.
- iv. Delete any documents attached to emails saved in the email folders, excluding NHSGGC Sponsored studies.
- v. If applicable, QC the modification to ensure SReDA has been updated correctly following SOP 50.025.

3.5.6. Notification of recruitment closure

- i. Update recruitment information on the 'Target and Dates' field on SReDA - Update 'Recruitment Status' to 'No Longer Recruiting' and 'Date of Status Change' to the final date of recruitment (NB: This is for non-commercial studies only and must be done for all locations that are closing to recruitment).
- ii. Update recruitment information on the 'Recruitment Totals' field on SReDA – Update 'Recruitment End' field to reflect the final date of recruitment.
- iii. Update study information on the 'Local Information' field on SReDA – Update 'Project Status' and 'Location Status' to 'In Follow Up' (NB: This must be done for all locations that are closing to recruitment).
- iv. For all eligible, commercial & extended review studies, contact the local study team/PI to confirm the recruitment number and forward the response to the IO to ensure we have the correct figures on SReDA and CPMS.

3.5.7. Notification of end of study

- i. Check for any information in email folders.
- ii. Mark the study complete by recording on SReDA the 'Actual End Date (Board)' and 'Location End Date' for each location within NHSGGC on SReDA as well as 'Archiving Proposed Destruction Date' (in the Pharmacy/custom tab on SReDA) (Refer to SOP 51.005).
- iii. Save end of study documents in Ethics section in e-folder.
- iv. Upload documents to SReDA.
- v. Delete any documents attached to emails saved in the email folders, excluding NHSGGC Sponsored studies.
- vi. For eligible NHSGGC-led studies funded through the Eligible, Extended Review, or Commercial pathways (e.g. sponsored studies where the Chief Investigator is based in Glasgow), notify the IO of the end of study date for CPMS.
- vii. For NHSGGC Sponsored studies the SRA will follow SOP 51.019.

3.6. NHSGGC Sponsored CTIMP/CIMD Trial Master File (TMF)

- i. Obtain lever arch folder and dividers.
- ii. Create CTIMP/CIMD label using template (Form 51.016N)
- iii. Following SOP 51.016, print Trial Master File Index (Form 51.016A), TMF Index Pages (Form 51.016K) on pink paper and TMF Cover Sheet (Form 51.016J) filing appropriately.
- iv. Print all project documents, filing lever arch appropriately.
- v. When further project documents are available for NHSGGC sponsored CTIMP/CIMD study, print off and file appropriately, moving superseded versions to the relevant section.
- vi. Ensure each study folder receives a QC throughout the lifetime of the study as per SOP 51.016.

3.7. Management of Signed & Scanned Documents

For contracts which have been signed using wet ink, scan the fully executed documents and save into relevant project e-folder e.g. Legal. Documents signed electronically should be saved in their original electronic format in the relevant project e-folder as per SOP 50.028. For NHSGGC Sponsored CTIMP/CIMDs, ensure these documents are printed and filed as per the TMF.

3.8. Research Passports/ Letter of Access (LoA)/ Honorary Research Contracts (HRCs)

Research Passports, Letters of Access (LoA) and Honorary Research Contracts (HRCs) must be managed in accordance with SOP 52.005.

- i. Where a Research Passport, LoA or HRC is required, create an email folder and name the researcher/Investigator.
- ii. Create a e-folder on the 'Common' drive, using the name of the researcher/Investigator and all relevant documentation filed accordingly.
- iii. A copy of the Change to Study Team Form and any supporting documentation must be retained within the project e-folder.
- iv. Update any stakeholder information on SReDA.

3.9. Studies past end date

Please see Guideline 51.022A for the process on studies past end date. For further information on end of study procedures and hosted studies past end date refer to SOP 51.005 & for NHSGGC sponsored studies refer to SOP 51.019.

4. Referenced documents

- SOP 50.009 - Project Numbering
- SOP 50.010 - Project Data Entry on SReDA
- SOP 51.005 - R&I - End of Study Procedures
- SOP 51.010 - Preparation and Review of Grant Applications and Costs
- SOP 51.016 - Preparation and Maintenance of a Trial Master File
- SOP 51.019 - Sponsor – End of Study Procedures
- SOP 51.021 - Review and Approval of Modifications for Research Sponsored by NHSGGC or Co-Sponsored by NHSGGC and the University of Glasgow
- SOP 52.003 - R&I Local Review of Modifications
- SOP 52.005 - Review of Research Passport and issuing of Honorary Research Contracts/Letters of Access
- SOP 50.025 - Quality Check of Project Entries on SReDA
- SOP 52.014 - Archiving Essential Documents from Clinical Research – Process for Hosted Research
- SOP 50.028 – Signatures & Approvals Process for Research and Innovation Documents
- SOP 60.204 - Registration of Biorepository Studies on SReDA and CPMS
- Form 51.016A - Trial Master File Index
- Form 51.016K - TMF Index Pages
- Form 51.016N - TMF Spine Label Template
- Form 51.016J - TMF Cover Sheet
- Form 51.021C - Sponsor Review of Modification Checklist
- Form 52.009A - Checklist of documents required for R&I submission
- Form 52.009C - Template e-file
- Form 52.009D - Project e-File Checklist
- Form 50.024A - CPMS Minimum Dataset
- WI 50.010A - Recording Feasibility
- NRS-GUI-001 - Guidance for Measuring NRS Approval Times
- Guideline 51.022A - SReDA End Date Process

5. Related documents

- Form 50.011A - E-Folder Index

6. Document history

Version	Date	Description	Retrospective Implementation
Version 1	20/03/2015	Release	No
2.0	14/07/2016	Renumbered	No
3.0	11/12/2019	Author, content, staff category, released by updated. Text updated to reflect current process. Version updated	No
4.0	29/08/2023	Change of author, version updated. Addition of new sections 3.27 (PCC - Notification of recruitment closure for GG&C), 3.36 (Notification of recruitment closure) and 3.5 (Studies past end date). Addition of processes on local clocks throughout. Minor admin changes (changes from R&D to R&I, updated referenced documents throughout, removal of note stating amendment documents should be deleted from amendment folder once approved, addition of mention of commercial costing template). Removal of mention of Form 51.018A, 52.003A and NRS-GUI-008 and GUI-009. Addition of SOP 50.009, 51.005, 51.021, 52.003, Form 51.016A, 51.016J, NRS-GUI-001 in referenced documents.	No
5.0	19/10/2026	Change of author and released by. Addition of section 3.2, section 3.3 and section 3.6. Minor admin changes (Change of Amendment to Modification, NHS GG&C to NHSGGC) Addition of SOP 51.010, 51.019, 52.005, 52.014, SOP 50.028, Form 52.009C, 51.021C, 52.009A, 51.016N, 51.016K, WI 50.010A, 50.024A	No

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