SOP number	**51.022**	Version	**4.0**
Title	**Research & Innovation Data & Administration tasks**		

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SOP category	NHS GG&C 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	
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 SOP provides instructions for staff working in the R&I team in relation to SReDA (Scottish Research Database Application) data and administration tasks associated with this. 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. 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 'GRANT' sub folder and name according to the project ID.
ii. Create project record on SReDA following SOP 50.009 and SOP 50.010.
iii. Enter 'GRANT' as prefix at the start of Short Title and Research Title field.
iv. Enter all data from grant application – project title, CI, PI, Sponsor and potential funder. Refer to SOP 50.010 for the grant applications minimum dataset.
v. Create project e-folder, on 'Common' drive, saving as 'GRANT' then project ID.

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

3.2.1. Notification of 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.
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 amendments; download the amendment documents, save Ethics Acknowledgment/Favourable Opinion letters into **Ethics Amendment before approval** sub-folder, all project documents for amendment(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 NHS GG&C Sponsored CTIMPs.
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 permission within 3 days. If notified of a new study with MUSKETEER in the title, make this high priority following the above steps.

3.2.2. 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 NHS GG&C Sponsored CTIMPs.
v. Update the clocks on the governance tab if necessary (e.g. when we receive the OID or Full Document Set). Refer to NRS-GUI-001 for the clocks process.

3.2.3. 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 NHS GG&C Sponsored CTIMPs.
v. Upload Health Board documents to the local folders on SReDA (green) e.g. local documents, PI CV and Management Approval letters.
vi. Generate QC Report following SOP 52.011.
vii. Permanently stop local clock (Refer to NRS-GUI-001).

3.2.4. Notification of amendment

i. Create amendment e-folder, saving as the amendment reference, date and category (e.g. NSA01 20.04.2023 (Cat A)).
ii. Create amendment email folder within the 'Amendments' sub folder saving as the amendment reference, date and category.
iii. Download all amendment documents from SReDA project record and save in amendment e-folder.
iv. Move any previous versions of documents to the superseded folder (NB: This is not relevant for all portfolio teams).
v. Record amendment on 'Post Approval' tab (Refer to SOP 52.003).
vi. Review/arrange review of amendment and issue local approval once all approvals and documentation is in place.
vii. File all emails in the amendment email folder.
viii. If applicable, QC the amendment to ensure SReDA has been updated correctly following SOP 52.011.

3.2.5. Notification of R&I acknowledgement for an amendment

i. Update 'Post Approval' tab with amendment permission date.
ii. Upload amendment approval to SReDA local folder (green).
iii. Move amended project documents to **Protocol** e-folder and appropriate sub-folders. Move any previous versions to the superseded folders (NB: This is not relevant for all portfolio teams).
iv. Amendment documents should also be kept within the relevant amendment sub folders, with exception to the Commercial costing template & distribution amendments – these should be saved in the finance folder and CTA amendments in the CTA folder (Refer to SOP 52.003).
v. Delete any documents attached to emails saved in the email folders, excluding NHS GG&C Sponsored CTIMPs.

3.2.6. Notification of R&I acknowledgement for a GG&C Sponsored CTIMP amendment

i. Update 'Post Approval' tab with amendment permission date.
ii. Upload amendment approval to SReDA local folder (green).
iii. Update approval date and upload date on sponsor amendment checklist.
iv. Move amended 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 lever arch folder (sponsored CTIMPs and device studies only).

3.2.7. Notification of recruitment closure for GG&C

i. Update recruitment information on the 'Target and Dates' tab 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' tab on SReDA – Update 'Recruitment End' tab to reflect the final date of recruitment.
iii. Update study information on the 'Local Information' tab 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 and extended review/adopted studies, contact the local study team/PI to confirm the recruitment number for GGC locations and forward the response to the Information Officer to ensure we have the correct figures on SReDA and CPMS.

3.2.8. Notification of end of study

i. Check for any information in email folders.
ii. Mark study complete on SReDA and record the end date according to the end of study form (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 NHS GG&C Sponsored CTIMPs.

3.3. SINGLE CENTRE STUDIES

3.3.1. Notification of 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.
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 50.011A if documents have unsuitable titles.
vi. Check for any amendments; download the amendment documents, save Amendment tool, documents and Ethics into **Ethics Amendment before approval** sub-folder, all project documents for amendment(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 NHS GG&C Sponsored CTIMPs.
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.

3.3.2. 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 NHS GG&C Sponsored CTIMPs.
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 (e.g. when we receive the OID or Full Document Set). Refer to NRS-GUI-001.

3.3.3. 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. Generate QC Report following SOP 52.011.
vii. Permanently stop local clock on 'Governance' tab (Refer to NRS-GUI-001).

3.3.4. Notification of Amendment

i. Create amendment e-folder.
ii. Create amendment email folder within the 'Amendments' sub folder saving as the amendment reference, date and category.
iii. Download all amendment documents from email folders and save in amendment e-folder.
iv. Move any previous versions to the superseded folder (NB: This is not relevant for all portfolio teams).
v. Upload amendment documents to SReDA.
vi. Record amendment on 'Post Approval' tab (Refer to SOP 52.003).
vii. Review/arrange review of amendment and issue local approval once all approvals and documentation is in place.
viii. Once the amendment has been approved, upload the amendment approval email to SReDA.
ix. If applicable, QC the amendment to ensure SReDA has been updated correctly following SOP 52.011.

3.3.5. Notification of R&I acknowledgement for an amendment

i. Update 'Post Approval' tab with amendment permission date.
ii. Upload amendment approval to SReDA folder (yellow).
iii. Move amended project documents to **Protocol** and appropriate sub-folders. Move any previous versions to the superseded folder (NB: This is not relevant for all portfolio teams).
iv. Delete any documents attached to emails saved in the email folders, excluding NHS GG&C Sponsored CTIMPs.
v. If applicable, QC the amendment to ensure SReDA has been updated correctly following SOP 52.011.

3.3.6. Notification of recruitment closure

i. Update recruitment information on the 'Target and Dates' tab 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' tab on SReDA – Update 'Recruitment End' tab to reflect the final date of recruitment.
iii. Update study information on the 'Local Information' tab 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 and extended review/adopted studies, contact the local study team/PI to confirm the recruitment number and forward the response to the Information Officer to ensure we have the correct figures on SReDA and CPMS.

3.3.7. Notification of end of study

i. Check for any information in email folders.
ii. Mark study complete on SReDA and record end date according to the end of study form (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 NHS GG&C Sponsored CTIMPs.

3.3.8. NHS Greater Glasgow & Clyde Sponsored CTIMP lever arch

i. Obtain lever arch folder and dividers.
ii. Create CTIMP label using template on common drive.
iii. Following SOP 51.016, print Trial Master File Index (Form 51.016A) 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 a NHS GG&C sponsored CTIMP 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.

3.4. Scanning of documents

For contracts which have been signed using wet ink, scan documents and save into relevant project e-folder e.g. Legal. For GG&C Sponsored CTIMPs, ensure these documents are printed and filed as per the TMF.

3.5. 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 studies past end date refer to SOP 51.005.

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 51.016 - Preparation and Maintenance of a Trial Master File
- SOP 51.021 - Sponsor Review and Approval of Amendments
- SOP 52.003 - R&I Review of Amendments
- SOP 52.011 - Quality Check of Project Entries on SReDA
- Form 50.011A - E-Folder Index
- Form 51.016A - Trial Master File Index
- Form 51.016J - TMF Cover Sheet
- Form 52.009D - Project e-File Checklist
- NRS-GUI-001 - Guidance for Measuring NRS Approval Times
- Guideline 51.022A - SReDA End Date Process

5. Related documents

- None

6. Document history

Version	Date	Description
Version 1	20/03/2015	Release
2.0	14/07/2016	Renumbered
3.0	11/12/2019	Author, content, staff category, released by updated. Text updated to reflect current process. Version updated
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.