SOP number	**52.002**	Version	**5.0**
Title	**Obtaining NHS Management Approval for Commercial Studies**		

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SOP category	NHS GG&C Hosted R&I

Staff category

Staff Category	**R**	**A**	**C**	**I**
R&I Systems Manager		X		
Commercial Research Coordinators	X			
Research Facilitators	X			
Research Administrators	X			
Clinical Trials Pharmacist	X			
GCRF Clinical Research Manager			X	
R&I Finance Accountants				X

1. Scope

This procedure applies to NHS Greater Glasgow & Clyde (NHSGGC) R&I department.

2. Purpose

To outline the review and approval process for commercially sponsored research studies hosted by NHSGGC.

3. Procedures

3.1. Review of Documentation

3.1.1. Study Wide Review (SWR)

When NHSGGC R&I Office has been identified as the UK or NRS Study Wide Reviewer for the study, all documents must be reviewed following SOP Procedure for Study Wide Review NRS-SOP-004 and also must ensure compliance with all applicable regulations including, but not limited to:

- UK Policy Framework for Health and Social Care Research
- The Medicines for Human Use (Clinical Trials) Regulations 2004, as amended

3.1.1.1. National Contract Value Review (NCVR)

The Commercial Research Co-Ordinator is responsible for the oversight of the financial budget and financial cost recovery negotiation of all commercial studies within their portfolio.

NRS PCC will indicate whether the Sponsor is using the National Institute for Health and Care Research (NIHR) interactive Costing Tool (iCT) within Central Portfolio Management System (CPMS), which is the preferred option or an alternative budget template. If an alternative budget template has been provided, the Commercial Research Co-ordinator should encourage the Sponsor to use the iCT. Alternative budget templates will only be accepted on a case by case basis. The Commercial Research Co-ordinator should seek acceptance of the alternative budget template at the R&I committee, providing reasons for its use.

NHSGGC may be allocated to complete the National Costing Validation Review (NCVR) if:

1. The CI of the study is based in NHSGGC, or
2. The CI of the study is based in one of the other Scottish Health Boards and NHSGCC is allocated to undertake it by NRSPCC

The Commercial Research Co-Ordinator will review the costs within the Commercial study submission section of the CPMS system in accordance with

- NRS guidelines NRS-GUI-024 – National Contract Value Review Guidance.
- Interactive costing Tool Study Resource Review: Part of the National Contract Value Review process V3 October 2024
- Clinical Trial Costing Guidance for Early Phase and Advanced Therapy Medicinal Products (ATMP) Clinical Trials Version 1 (October 2024)
- NCVR Study Resource Review checklist

The Commercial Research Co-Ordinator will liaise with the CI and any relevant support departments as necessary to ensure accurate costs are captured. Once the review is complete on CPMS, the status must be updated to allow the Sponsor Representative to view the budget and respond to any changes.

The Commercial Research Co-Ordinator will then work with the Sponsor Representative to agree the budget.

Once agreed the Sponsor Representative can enable the budget to be seen by all sites involved in the study.

3.1.1.2. Contract Review

The Commercial Research Co-Ordinator is responsible for the contract negotiation of all commercial studies within their portfolio. As part of the UK study wide review process the contract is reviewed against the national model agreements.

NHSGGC led studies:

- The Commercial Research Co-Ordinator is responsible for reviewing the contract against the appropriate national model agreement. Revisions to the agreement are not allowed, except for the highlighted areas in the template.

All other studies:

- The Commercial Research Co-Ordinator will check that the template received is the one that has been agreed in the SWR.
- The Commercial Research Co-Ordinator will add NSGGC local details to the template, including making sure the Financial Appendix is correctly completed

3.1.1.3. Governance Report

The Commercial Research Co-Ordinator is responsible for the governance review and risk management of all commercial studies within their portfolio in line with:

- UK Policy Framework for Health and Social Care Research
- The Medicines for Human Use (Clinical Trials) Regulations 2004, as amended
- Procedure for Study Wide Review SOP NRS-SOP-004

NHSGGC led studies

The Commercial Research Co-Ordinator is responsible for completing Sections 1-7 in the Assessment Tool in HARP in line with the above and the UK SW Criteria (updated 19.11.2021.pd Version 5 21Nov2021). This forms the UK wide governance report for the study.

NHSGGC as Generic Reviewer for Scotland studies

The Commercial Research Co-Ordinator is responsible for checking Sections 1-7 have been completed and for completing Section 10 of the Assessment Tool in HARP.

- The budget section of Section 10 can be completed when the budget has been submitted in CPMS. The budget does not have to be agreed at this stage.
- The contract section of Section 10 can be completed when the unmodified contract template is received. The contract does not have to be agreed at this stage.

Section 10 forms the Scottish governance report for the study.

When Section 10 is complete the Research Administrator generates the list of documents which have been reviewed and emails the relevant documents to NRS PCC as per NRS-SOP-004 section 4.1.9 to complete the Scottish Generic Review. This must be completed within 10 calendar days of NHS Research Scotland Permissions Coordinating Centre (NRSPCC) being in receipt of the full document set and following Guidance for NRS Clocks NRS-GUI-001.

3.1.2. Local Review

The Commercial Research Co-Ordinator must ensure that the Health Board is able to support the study at the required location(s) by under taking an assessment of staff and support departments involved, study protocol and the budget offered. The Governance Report should be reviewed for any comments which will assist with the local review.

The Research Administrator will contact the Sponsor/Sponsor representative to inform them that the study submission has been received and who will be their R&I contacts for the study.
The Research Administrator will also contact the following as appropriate:

- The Principal Investigator asking them to complete the OID appendix
- The CRF Clinical Research Manager and Lead Nurse asking if the CRF can support the study
- The Head of Department requesting approval for the study to take place within their department
- The pharmacy team informing them of the submission and of generic and/or local review requirement

The Commercial Research Co-Ordinator will aim to provide confirmation that local activity can proceed within 15 calendar days of receipt of local documents, in line with Guidance for NRS Clocks NRS-GUI-001. The Local Clock will start once the R&I office has received the Full document set and the completed OID appendix, which is the confirmation that the PI wishes to take part in the study and also agreement of the declaration statements required to undertake the study.

3.1.2.1. Staff

The Commercial Research Co-Ordinator will review the OID appendix to ensure the following:

- The Principal Investigator (PI) and other study team members are listed and are either employed by, or have a contract with, NHSGGC
- Researcher Access:
    - If the Research Administrator has highlighted that a research passport may be required the Commercial Research Co-Ordinator will review the role that the researcher will have in the study, their role in patient care and advise on required pre-engagement checks. A Letter of Access or Honorary Research Contract will be issued once a valid research passport has been received and verified where appropriate. N.B. Research Passports and Honorary contracts are not issued to staff from the CRO or Pharmaceutical organisation. The Research Passport scheme is specifically designed for Employees of Higher Educational Institutions (HEIs) and government offices. In most scenarios, the application is from an HEI.
- The study procedures/investigations are listed, where they will take place is detailed and how many are standard of care or research specific.

3.1.2.2. Support Departments

The Commercial Research Co-Ordinator will identify all the support departments needed to successfully delivery the study. The study protocol and local documents are reviewed for this purpose. The Commercial Research Co-Ordinator will then obtain support department approval by either e-mail, or the appropriate approval committee (e.g. CTEC for Beatson studies, Phase 1 or GMO committees) as per SOP 52.007 Authorisations for NHS resource use in R&D submissions and SOP 58.004 Clinical Research Involving Imaging

The Pharmacy administrator will be notified of the study as early as possible in the process to ensure that the pharmacy department can collect their paperwork and confirm that they can deliver for each research study involving study medicine.

3.1.2.3. Risk Assessment

The Commercial Research Co-Ordinator will review the Protocol and study documentation to identify the type of study being undertaken. If the study is a GMO and/or a Phase 1 First in Human (FIH) study then they will follow the SOP's below as appropriate to obtain the approval of the relevant committee before Management approval can be given.

- SOP 52.015 - Phase I FIH Committee Review Process
- SOP 52.013 - Process for approving studies and trials involving a Genetically Modified Organism (GMO)

If the study is both a GMO and Phase 1 FIH, the GMO risk assessment process will be completed first. Then only the IMP risk assessment form for Phase I should be submitted to the Chair of the Phase 1 committee, along with the GMO committee approval. The Chair will then review the advice from GM Safety Committee with the IMP risk assessment and decide if it can be approved on this evidence or if a full Phase I risk assessment is required. If not required, the Chair can approve at that time, otherwise a full submission will need to be made according to the above SOP.

3.1.2.4. Local Finance Review

The NCVR agreed budget will have an initial review to check if it has been thoroughly completed and if appropriate for Glasgow. This review will check that the following have been included

Correct Set up fees
Correct Training times
Correct Monitoring times
Pharmacy fees (check with Pharmacy dept if required)
All Procedure costs
Blood sampling and processing are added multiple times at visits (if required)
That NCVR has added all the costs necessary

An appropriate clinical trials Pharmacist will be informed by email by the Research Administrator of a new study for review and they will confirm appropriate drug and Pharmacy costs for the project. The review will be carried out against the Protocol to ensure that all pharmacy elements have been entered correctly, following Pharmacy Review NRS-SOP-PH-003 and Completion of NIHR pharmacy costing template NRS-SOP-PH-002. The Commercial Research Co-Ordinator will review the comments by the clinical trial Pharmacist and use these to check against the NCVR budget.

If a number of items have been missed then a thorough review of the NCVR budget should be undertaken to identify the items that have been missed. The Escalation process NRS-GUI-013 National Contract Value Review Escalation Process Guidance should then be followed to have the missing items added to the budget

The agreed budget will be saved in the study e-folder "7.Finance&Support Departments/Edge" within the common drive.

3.1.2.5. Local Trial Agreements

A Clinical Trial Agreement (CTA) is required for all commercial research projects and each PI will have a separate CTA. CTAs have to be checked to ensure that either the unmodified version has been submitted to the Board or any changes to the CTA have been approved by the UKSWR.

Financial Appendix 4 will include the agreed budget downloaded from the agreed iCT. The fully signed contract will be saved in the study e-folder "9.Legal/Contracts/Participating Site Agreements" within the common drive.

3.2. Management Approval

The Commercial Research Co-Ordinator is responsible for the management approval of all commercial studies within their portfolio. Once the Commercial Research Co-Ordinator has completed their review, the Research Administrator will complete the Project checklist (Form 52.009D) and prepare the Commercial Permission Letter (Form 52.002C) which the Commercial Research Co-Ordinator will sign (electronically).

The Commercial Permission Letter will be addressed to the PI. The PI will be sent an e-mail with the Commercial Permission Letter and the executed contract attached (if required). The permission letter will be copied to the following staff groups:

- CRO/Sponsor,
- CRF Administrator (if involved),
- Pharmacy administrator (if pharmacy is involved)
- Regulatory Administrator (only for studies hosted at Beatson West of Scotland Cancer Centre).

Other individuals may require copies of the Commercial Permission Letter and this will be issued if deemed appropriate by the Commercial Research Co-Ordinator or on request.
The PDF of the signed Commercial Permission Letter will be saved in the study e-folder "6.R&D" within the common drive.

3.3. Post Approval

Once the study has been approved the Commercial Research Co-Ordinator (or their designee) will update the Recruitment tab on SReDA as per Updating SReDA Recruitment Tab for Commercial Studies NRS-SOP-021. CRIF staff will ensure that the imaging tab is successfully updated to reflect study design. The Research Administrator will ensure all other relevant Tabs are completed and accurate as per SOP 50.010 Project Data Entry on SReDA. The Internal costing sheet needs to be completed using the Internal Cost Sheet guideline and sent to the R&I finance department to allow the financial distribution to be done. Once the Financial distribution has been received from the financial department the Commercial Research Co-ordinator will e-mail this along with the income distribution explanation, Form 52.002D, to the PI.

4. Referenced documents

- SOP 50.010 - Project Data Entry
- SOP 52.007 - Authorisations for NHS resource use in R&D submissions
- SOP 52.013 - Process for approving studies and trials involving a Genetically Modified Organism (GMO)
- SOP 52.015 - Phase I FIH Committee Review Process
- SOP 58.004 - Clinical Research Involving Imaging
- Form 52.002C - Commercial Permission Letter
- Form 52.002D – Income Distribution explanation
- Form 52.009D - Project checklist
- NRS-SOP-021 - Updating SReDA Recruitment Tab for Commercial Studies
- NRS-SOP-PH-002 - Completion of NIHR pharmacy costing template
- NRS-SOP-PH-003 - Coordinated Pharmacy Review
- NRS-GUI-001 - Guidance for NRS Clocks
- NRS-GUI-013 - National Contract Value Review Escalation Process
- NRS-GUI-024 – National Contract Value Review Guidance.
- UK Policy Framework for Health and Social Care Research
- The Medicines for Human Use (Clinical Trials) Regulations 2004, as amended
- NRS SOP 004 - Procedure for Study wide Review
- UK_SW_Criteria_updated_19.11.2021.pd Version 5 21Nov2021
- Interactive costing Tool Study Resource Review: Part of the National Contract Value Review process V3 October 2024
- Clinical Trial Costing Guidance for Early Phase and Advanced Therapy Medicinal Products (ATMP) Clinical Trials Version 1 (October 2024)
- NCVR Study Resource Review checklist

5. Related documents

- None

6. Document history

Version	Date	Description	Retrospective Implementation
1.0	13/12/2012	Release of 1st Version	No
2.0	14/07/2016	Updated to template v1.4. renumbered	No
3.0	18/03/2020	Temp. change to Author. “Approved by” temporarily changed and “Released by” changed. Staff category updated. Process for finance updated to reflect process changes. Referenced documents updated. Version updated.	No
4.0	06/09/2023	Inclusion of Commercial Permission Letter	No
5.0	06/11/2025	Re written to incorporate the new process and forms	No