SOP number	**52.002**	Version	**4.0**
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 (GG&C) R&I department.

2. Purpose

To outline the review and approval process for commercially sponsored research studies hosted by NHS GG&C.

3. Procedures

3.1. Review of Documentation

3.1.1. Study Wide Review (SWR)

When NHS GG&C R&I Office has been identified as the Scottish 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

The Commercial Research Coordinator should aim to provide a UK Study-Wide Governance Report 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.

3.1.1.1. Generic Financial Review

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.

If NHSGGC has been allocated a study to do the National Costing Validation Review (NCVR) as the CI of the project may be based in Scotland. The Commercial Research Co-ordinator will review the costs (once NRS PCC have indicated that study documents have been downloaded into SREDA) within the Commercial study submission section of the CPMS system in accordance with NRS guidelines NRS-GUI-007 – Guidance for Budget Negotiations on Commercial Research Studies. Once the budget has been agreed the complete button on CPMS should be clicked to allow the budget to be seen by the other sites in the UK.

For studies NHSGGC has been allocated as the SWR for Scotland, a Research Facilitator will be informed by email by the Research Administrator of a new study for review and they will review the Interactive Costing Tool (ICT) within CPMS, once the sponsor has given Glasgow access to this, against the protocol to ensure that all costing elements, procedures, investigations, itemised costs, and set-up costs have been entered correctly, following the NRS guidelines NRS-GUI-007 – Guidance for Budget Negotiations on Commercial Research Studies. If any procedures or investigations are not standard within the ICT then this should be highlighted to the Commercial Research Co-ordinator who will clarify or contact the relevant support department to obtain a price or estimate of time for the procedure.

An appropriate clinical trials Pharmacist will be informed by email by the Research Administrator of a new study for review and they will review 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 and checks performed by the Research Facilitator and the clinical trial Pharmacist and use these to initiate the budget negotiation with the Sponsor and/or CRO. Outcome from the negotiation will be supplied to other participating sites via the UK Study-Wide Governance Report.

3.1.1.2. Contract review

The Commercial Research Co-ordinator is responsible for the contract negotiation of all commercial studies within their portfolio. The Commercial Research Co-ordinator reviews the contract in line with the Model Clinical Trial Agreement and R&I Contract Development and Review SOP 52.004, making sure that the financial appendix with the contract covers all agreed budgets, all the agreed set up fees, screen failure fees, and extra clauses as would be appropriate for GG&C. However the Final approval of the Contract including the Financial appendix will be agreed by the local Board as per NRS-GUI-007 Guidelines Guidance for Budget Negotiations on Commercial Research Studies. Outcome from the negotiation will be supplied to other participating sites via the UK Study-Wide Governance Report.

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. Once the Budget and contract have been agreed and the other supporting documents have been reviewed by the Commercial Research Co-ordinator (including the appropriate Ethics and MHRA approvals) 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

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. The agreed budget should be put into the study e-folder “7.Finance&Support Departments/Edge” within the common drive.

3.1.2. Local Review

The Commercial Research Co-ordinator should ensure that the Health Board is able to support the study at the required site(s) by under taking an assessment of local site activity The Governance Report should be reviewed for any comments which will assist with the local review. The SWR agreed budget should be checked to ensure that there are no local procedures or processes which would need to be added to enable the study to run in Glasgow. The Research Administrator will e-mail the Principle Investigator asking them to complete the OID appendix and also will e-mail the CRF Clinical Research Manager and Lead Nurse asking if the CRF can support the study.

The Commercial Research Co-ordinator should 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 should start once the R&I office has received 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 should review the OID appendix to ensure the following:

- Principle Investigators (PI) are appropriately trained and qualified to participate in that study (based on therapeutic area of the study and the expertise of the PI in that area)
    - if appropriate, further training can be recommended by the Commercial Research Co-ordinator (for example, GCP training for Clinical Trials of Investigational Medicinal Products [CTIMPs] or non-CTIMPs)
- 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.

3.1.2.2. Procedures

Local documents should provide an accurate reflection of the procedures required to fulfil the protocol and indicate if they are either standard of care or research-specific.

3.1.2.3. 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 should then obtain support department costs (if not a standard cost) and approval by either e-mail, or the appropriate approval committee (e.g. CTEC for Beatson studies) 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 should 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.

3.1.2.4. Local FIH Review

The Commercial Research Coordinator will review the Protocol and study documentation to identify if the study is a GMO and/or a Phase 1 First in Human (FIH) study and then they should 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 should be completed and once that has been to committee and approved, the IMP risk assessment form for Phase I only needs completed in addition. Phase I chair will then review the advice from GM Safety Committee with the IMP risk assessment and decide if they want a full Phase I risk assessment completed or not. The Phase I chair can approve at that time if they accept the risk assessment already done is enough.

3.1.2.5. Local Trial Agreements

A Clinical Trial Agreement (CTA) is required for all commercial research projects and each PI should have a separate CTA. Generically reviewed and approved CTAs have to be checked to make sure that the correct GG&C Boards details are included, the target number of patients, Clause 12.4 has the addition sentence "Such notification must be sent to R&DFinance.Contracts@ggc.scot.nhs.uk. To avoid doubt, the timescales in Clauses 12.5 and 12.6 do not commence until such notification has been received" (except for AstraZeneca contracts) and Financial Appendix 5 details are appropriate for GG&C as per R&I Contract Development and Review SOP 52.004. The Agreed and fully signed contract should be put into 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 attached. The permission letter should 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).
- Ross Hall (only for studies using Ross Hall facilities).

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 should be put into 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) should update the Recruitment tab on SReDA as per Updating SReDA Recruitment Tab for Commercial Studies NRS-SOP-021. CRIF staff should ensure that the imaging tab is successfully updated to reflect study design. The Research Administrator should 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 (R&IFinance.GCRF@ggc.scot.nhs.uk) to allow the financial distribution to be done.

4. Referenced documents

- 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
- NRS-SOP-021 - Updating SReDA Recruitment Tab for Commercial Studies
- NRS-SOP-PH-003 - Coordinated Pharmacy Review
- NRS-SOP-PH-002 - Completion of NIHR pharmacy costing template
- NRS-GUI-001 - Guidance for NRS Clocks
- NRS-GUI-007 - Guidelines for Budget Negotiations on Commercial Research
- SOP 50.010 - Project Data Entry
- SOP 52.004 - R&I Contract Development and Review
- 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 52.009D - Project checklist

5. Related documents

- None

6. Document history

Version	Date	Description
1.0	13/12/2012	Release of 1st Version
2.0	14/07/2016	Updated to template v1.4. renumbered
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.
4.0	06/09/2023	Inclusion of Commercial Permission Letter