SOP number	**52.001**	Version	**4.0**
Title	**Obtaining NHS Management Approval Non-commercial**		

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SOP category	NHS GG&C Hosted R&I
Staff category	

Staff Category	R	A	C	I
Research & Innovation Systems & Operations Manager		X		
Research Facilitators	X			
Senior Research Administrators	X			
Research Administrators	X			
R&I Finance Accountants			X	
Research Governance Manager			X	
Principal Investigators (Hosted Non-Commercial)			X	
Sponsor Research Co-ordinators				X
Innovation Project Managers				X
Pharmacy Administrator				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 non-commercially sponsored research studies hosted by NHSGGC.

3. Procedures

3.1. Study wide Review

When NHSGGC R&I Office has been identified as the Scottish Study Wide Reviewer, or Lead nation reviewer, for the study, all documents must be reviewed following NRS-SOP-004 - Procedure for Study Wide Review, 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 Research Facilitator or Senior Research Administrator will 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 NRS-GUI-001 'Guidance for Measuring NRS Approval Times', using 'UK_SW_Criteria' as guidance. The Study Wide Review will be completed through the HRA Assessment Review Portal (HARP). The Assessment Tool as well as a list of the documents reviewed to complete it must be emailed to NRSPCC as per NRS-SOP-004 to complete the study wide review.

3.2. Local Review

The Research Facilitator or Senior Research Administrator must ensure that the Health Board is able to support the study at the required site(s) by undertaking an assessment of local site capacity. The Governance Report will be reviewed for any comments which will assist with the local review.

The 'Organisation Information Document' (OID) is the key document used to assess local project activity. The agreement of all local activity is collated in a collaborative manner and involves input from Sponsor, local R&D (as described in this document), and local research team. The OID will be emailed to the local Principal Investigator (PI) or Local Collaborator, along with the OID Appendix (Form 52.001B). If any imaging scans will be taking place as part of the study, including standard of care, the CRIF Imaging Support Form (Form 58.004A) will also be sent to the PI to be completed.

Where the local site is designated as the Beatson West Of Scotland Cancer Centre (the Beatson) , the Regulatory Administrators will send the OID appendix and Head of Department (HOD) approval (see SOP 52.007) directly to the research Facilitator for the study. For all studies, the R&I Officer will ensure that the PI works in the appropriate field, with the expertise and capacity required to lead the study in question locally.

The OID and OID Appendix must be accurate reflections of the NHS resources that will be used for that project. Relevant study dates, target recruitment, Investigator time, Research Nurse time and all project activities must be captured in the local documents. Local documents collectively are referred to a Local Information Pack (LIP). Once this information is obtained, the local review clock will be started in accordance with NRS–GUI– 001. Any queries to the Sponsor, for additional information or agreement review and signing, allow the local review clock to be paused.

Using the information provided in the OID, OID Appendix, and CRIF Imaging Support Form (where applicable), the Research Facilitator, Senior Research Administrator or Research Administrator will request head of department authorisation(s) and support department approval(s) following SOP 52.007 'Authorisations for NHS resource use in R&D submissions'. If the study will be located at the Beatson, the Regulatory Administrators will have already sent the HOD approvals within their original email. R&I Finance and R&I Pharmacy approval must also be sought and obtained where necessary, the details of which are also laid out in SOP 52.007 and WI 52.001A 'Process for Assessing the Acceptability of Excess Treatment costs for Hosted Studies'.

Members of a research team who are not employed by NHSGGC may require letters of access or honorary research contracts, to be completed as described in SOP 52.005 'Review of Research Passport and issuing of Honorary Research Contracts/Letters of Access'.

For Clinical Trials of an Investigative Medicinal Product (CTIMP), a Risk Assessment must be performed by the Research Facilitator or the Senior Research Facilitator using Form 51.004C 'Hosted Non-Commercial CTIMP Risk Assessment'. The Risk Assessment can be completed using a combination of the local documentation and the protocol. This will be saved in the eFolder for the study, and the online database, SReDA, will be updated with the result of the Risk Assessment.

3.2.1. Site Agreements

An agreement is required for all research studies wishing to open in NHSGGC. There are three template, standard agreements for non-commercial studies: the OID, the 'UK Model Agreement for Non-Commercial Research' (mNCA) and the 'Model Non-Commercial Participant Identification Centre Agreement' (mNCA-PICA). The Suitability of the OID and the mNCA for different study types is laid out in NRS-SOP-025 'NRSPCC – Local Information Pack'. The mNCA-PICA will be put in place when NHSGCC is acting as a Participant Information Centre (PIC) only.

The Site Agreement will be provided by the Sponsor. If the sponsor is using one of the standard agreements, this will be reviewed for any changes by the Research Facilitator or Senior Research Administrator. Special attention should be payed to the responsibilities of each of the parties and the governing law. Care should be taken that the appropriate schedules are included in the agreement (relevant to the study), and that the financial arrangements are acceptable to the Health Board.

While it is preferred that Sponsors utilise the standard agreements, some insist on using a bespoke contract. These must be carefully reviewed by the Research Facilitator, paying special attention to the wording around responsibilities of the Health Board, the governing law, data and material transfer, and GDPR. Care should be taken that all relevant clauses are included, and that any financial compensation is agreed in Pounds Sterling. It is the responsibility of the Research Facilitator to negotiate any changes.

Significant changes to standard contract clauses can be discussed with peers via the R&D committee meeting. These can also be escalated to the Systems and Operations Manager and the Research Governance Managers where appropriate and independent legal advice can be sought from the Central Legal Office (CLO) if required.

The Research Facilitator or Senior Research Administrator will update all of the NHSGGC specific information in the contract and ensure it is correct and relevant to the study. These include the Health Board's legal address, the PI's name and address, the target recruitment, archiving details and payment details for any invoices. The R&I Officer will then organise signatures. Site agreements can only be signed by an authorised signatory of the Board; authorised signatories are R&I Systems & Operations Manager, Lead for Sponsor R&I Pharmacy, Senior R&I Manager and R&I Director.

If a third party (not a joint/co-sponsor) will be involved in the study it is sometimes necessary to set up a secondary agreement between NHSGGC and this party, which could cover a transfer of funds, data or materials. Some examples of such agreements are bespoke Data Sharing Agreements or Shared Award letters.

3.3. R&I Management Approval

Once the Senior Research Administrator or Research Facilitator has completed their review, the Research Administrator or Senior Research Administrator will complete the E-Folder Index (Form 50.011A) and prepare the Management Approval Letter (Form 52.001C). The letter will be signed by the study reviewer and is confirmation, that from an R&I perspective, distribution of study-related documentation and/or patient recruitment can commence.

The approval letter will be addressed to the PI. The letter will be sent by email to the PI, copying in the Sponsor, NRSPCC (if involved), Pharmacy Administrator (if pharmacy is involved) and the Regulatory Administrator (only for studies hosted at Beatson West of Scotland Cancer Centre). For the Beatson studies, the Regulatory Administrators should also receive a copy. Other individuals may require copies of the Management Approval Letter. Distribution of the approval letter email can be expanded on request. Once this is issued the local review clock can be permanently stopped.

3.3.1. Non-Commercial Finance Review

Once Management Approval has been issued, the R&I Finance department must be updated accordingly, using Form 52.001A 'Non-Commercial Finance Template'. The Research Facilitator or Senior Research Administrator will use the study documents (e.g. Protocol, IRAS, OID and OID appendix and SoECAT) to complete the Form 52.001A. Using staff times and research activities carried out, this form lays out an estimate for overall costs for the trial.

Once completed, an updated form is saved in the study-specific Portfolio team folder and a copy saved in the Finance folder. R&I Finance must be informed of this using the weekly 'Update to Finance' sheet in the Finance folder.

3.4. Multiple NHSGGC Principal Investigators

Each PI listed in the IRAS form for a study in NHSGCC, or added through an amendment requires separate local set up. For each PI there will be a separate, dedicated OID, OID appendix, Head of department and support department approvals, Management Approval Letter and Non-commercial Finance review.

4. Referenced documents

- Form 52.001A - Non-Commercial Finance Template
- Form 52.001B - OID Appendix
- Form 52.001C - Management Approval Letter
- WI 52.001A - Process for Assessing the Acceptability of Excess Treatment costs for Hosted Studies.
- SOP 52.005 Review of Research Passport and issuing of Honorary Research Contracts/Letters of Access
- SOP 52.007 Authorisations for NHS resource use in R&D submissions
- Form - 50.011A - E-folder Index
- Form - 51.004C Hosted Non-Commercial CTIMP Risk Assessment
- Form - 58.004A CRIF Imaging support Form
- NRS-SOP-004 - Procedure for Study-Wide Review
- NRS-GUI-001 - Guidance for Measuring NRS Approval Times
- NRS-SOP-025 - NRSPCC – Local Information Pack
- UK Policy Framework for Health and Social Care Research
- The Medicines for Human Use (Clinical Trials) Regulations 2004 as amended
- UK_SW_Criteria
- UK Model Agreement for Non-Commercial Research
- Model Non-Commercial Participant Identification Centre Agreement

5. Related documents

- None

6. Document history

Version	Date	Description
1.0	17/07/2012	Release of first version
2.0	14/07/2016	Updated to template v1.4. Updated to reflect changes to R&D review structure and processes.
3.0	18/03/2020	Staff category updated. Procedures sections updated to reflect national changes in document nomenclature and staff groups involved in processing R&D approval. Version updated. "Released by updated".
4.0	27/06/2025	Complete overhaul of the document to remove and Sponsor processes, increase clarity and include further guidance and documentation, as well as update all instances of 'R&D' to 'R&I'