SOP number	52.007	Version	4.0
Title	Authorisations for NHS Resource use in R&I Systems Submissions		

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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		
Commercial Research Co-ordinators	X			
Innovation Co-ordinator	X			
Research Facilitators	X			
Senior Research Administrators	X			
Research Administrators	X			
Principal Investigators			X	
Lead Clinical Trials Pharmacist			X	
Head of R&I Finance			X	
GCRF Clinical Research Manager			X	
Lead Research Radiographer (CRIF)			X	
R&I Innovation Lead			X	
Research Governance Manager				X

1. Scope

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

2. Purpose

Research projects utilise NHS staff, services provided by support departments and other NHS resources. The necessary authorisations from heads of relevant departments to use such resources in research studies must be in place prior to the granting of Board Approval/Permission. This is essential to ensure that the study can be supported and the costs of conducting the research have been identified and are fully covered wherever possible.

This SOP will describe the process of identifying when an authorisation is/is not required and provide guidance on who should provide an authorisation. This SOP is applicable to all research projects undertaken at an NHSGGC location and approved or managed by R&I Systems.

3. Procedures

3.1. Background

An authorisation is required when an activity is conducted in addition to standard of care i.e. specified by the clinical trial or research study protocol and not conducted at all during routine care or conducted at a greater frequency than during routine care for the study participants. An authorisation may be provided by, but not limited to, the following: Clinical Supervisors, Line Managers, Service Managers, Support Department Managers, Pharmacy, Clinical Research Facility Management, Data Controllers, Clinical Research Imaging, R&I Finance, Labs and Medical records depending on the nature of the research.

3.2. Identification of Necessary Authorisations

The submission of study documents to R&I are addressed by SOPs 52.001 and 52.002.

The generic IRAS and local information documents along with the study protocol are key source reference documents for aiding the identification of where trial procedures are conducted additional to routine NHS care or necessitate use of other NHS resources e.g. pharmacy.

The local documents, particularly the Organization Information Document and the 'OID Appendix' (Form 52.001B) detail clinical and non-clinical activities, specifying which are standard of care and which additional activities are to be performed as part of the study, and which departments are involved. It is the responsibility of the PI to let the R&I team know which activities are additional to standard of care.

The 'CRIF Imaging Support Form' (Form 58.004A) should be completed when necessary, by the Research Facilitator or Research Coordinator with assistance from the local research team to determine what imaging is required for the study, where they will be taking place, how many are standard of care and who is responsible for reporting.

The 'Schedule of Events Cost Attribution Template' (SoECAT) and 'UK Model Non-Commercial Participant Identification Centre Agreement' (mNCA) are used to determine what (if any) excess treatment costs could be incurred by the health board during the study.

The Research Facilitator or Research Co-ordinator is responsible for determining what authorisations are required

3.3. Obtaining and Recording Authorisations

The Principal Investigator (PI) should be advised to obtain authorisation from their Line Manager (Clinical Manager e.g. Clinical Director) or Clinical Service Department Manager, and Support Department authorisations, where relevant (see 3.4), in the first instance and prior to R&I submission, as per IRAS guidance.

For all research studies when patients are recruited from a particular Clinical Service, or there will be a significant impact on the Clinical Service, NHS departmental oversight should be obtained. This can be obtained from the Clinical Director, Clinical Lead, Clinical Service Manager or the Consultant whose lists from which patients will be identified.

An authorisation should be at a level of seniority that takes into account Service support across multiple locations within the Board, where relevant. In some cases, it might be necessary to obtain an authorisation from each location where patients/participants are recruited from multiple locations.

The Research Co-ordinator, Facilitator or Senior Research Administrator/Research Administrator can/will provide guidance to the research team on who should be approached to provide the relevant authorisation/s. The investigator should be advised to ask the relevant clinical service department manager/clinical manager aware of the study that will be conducted in their department and to ask the authorising manager to send an email confirming their authorisation directly to the Senior/Research Administrator. R&I staff may also obtain the authorisation directly from a Service or Support department where there are existing arrangements with Service Managers

The number of authorisations should be minimised and restricted to those necessary to achieve oversight, authorise staff time and/or Support department engagement such that the study can proceed without disruption to trial/study procedures.

The email of authorisation(s) should be stored in the study e-folder under 'R&D'.

If an email of authorisation is not obtained from the relevant **Clinical Manager** or **Service Department Manager** (see 3.4) within 10 calendar days of the request for authorisation **and** where **all** the following conditions are also met:

- The study is eligible for NHS Support costs or Commercially Sponsored;
- All additional relevant authorisations (e.g. R&I Pharmacy, R&I Finance, Clinical Research Facility and Imaging) are in place;
- the study does not incur excess treatment costs, or these costs have been approved;
- deemed by the Facilitator or Co-ordinator to have minimal impact on the clinical service;

The Facilitator or Co-ordinator can provide an email of notification to the Clinical Manager or Clinical Service department Manager that the research will take place in their department. The email of notification should include a statement confirming the Board's obligation to approve research in-line with timelines set by Scottish Government. Local documents may be included in this email.

The email of notification should also be stored in the finance and support department subfolder of the study e-folder.

3.4. Service and Support Department Authorisations

Where a study requires exceptional activity on the part of a support department (for example, but not limited to, excess treatment costs, lab tests and procedures not routinely conducted by NHSGGC clinical laboratories), the department should always be consulted and their authorisation sought. All authorisation should be saved in the study e-folder. The PI has a responsibility to engage with all support department before seeking R&I approval, and the R&I systems team has a responsibility to confirm the department's support.

The following lays out which support department approvals ***must*** be in place prior to R&I management approval, and under what circumstances these are necessary:

R&I Pharmacy approval – All Clinical Trials of an Investigational Medicinal Product (*CTIMPs*) i.e. all trials conducted under the Medicines for Human Use (Clinical Trials) Regulations 2004. Pharmacy approval must also be obtained for all substantial modifications for these studies. Other study types may also require pharmacy approval if medicinal products are to be used (refer to protocol and local research team).

If a CTIMP is a Phase 1, FIH study, then it must be sent to the **Phase 1 Committee** for their assessment and approval, and if a CTIMP involves genetically modified organisms (GMOs) it must be sent to the **GMO committee** for their assessment and approval.

Clinical Research Facility (CRF) approval – confirmation should be sought from the CRF managers for any study which requires CRF staff time or use of the CRF facilities. This information can be obtained from the OID appendix.

Clinical Research Imaging Facility (CRIF) approval – CRIF authorisation is required when the CRIF facility will be used for any research imaging or the reporting of any imaging (even if they will be reporting on standard of care images). Form 58.004A will be completed and sent to CRIF management to provide them the necessary information.

R&I Finance approval – All *Eligibly funded, non-commercial studies* which incur *Excess Treatment Costs* (as laid out in the SoECAT) need approval from R&I Finance. Please follow WI 52.001A 'Process for Assessing the Acceptability of Excess Treatment costs for Hosted Studies' for details on seeking this approval.

Prison Governor Approval – For all studies which involve prisoners, governor authorisation must be sought for each participating prison. Scottish Prison Service (SPS) Research Access & Ethics Committee approval (additional to NHS Research Ethics Committee) must also have been obtained by the Sponsor.

In all of the above cases the Research Coordinator/Facilitator or Research Administrators should contact the departments directly to obtain their authorisations.

The above list is not exhaustive and other support department authorisations may be required as deemed necessary by the R&I officers from the paperwork provided. Some support departments may only require a notification email, depending on the circumstances.

Section 3.6 provides guidance on specific instances where an authorisation is not required or notification of the research activity can be made to the relevant department.

For all insufficiently funded non-eligible studies authorisation must be sought from all support departments.

3.5. Studies Taking Place at the Beatson West of Scotland Cancer Centre

All cancer studies taking place at the Beatson West of Scotland Cancer Centre (BWOSCC/Beatson) must be presented at the monthly 'Clinical Trial Executive Committee' (CTEC) meeting. During this meeting all study activities- whether SOC or non-SOC- are considered approved following a Clinical Trials Executive Committee (CTEC) 'A' rating. Where applicable, a designated committee member will also seek Systemic Anti-Cancer Therapy (SACT) approval, which will also be included in the 'A' rating. No further authorisations should be required from Beatson departments.

The only exception is the CRIF approval and the completion of a CRIF ISF form (Form 58.004A), which must still be completed as per standard procedure and in the case of excess treatment costs R&I finance approval.

Additionally, Phase1 committee and GMO committee approval must be sought separately to this committee.

For the BWOSCC, local documents including the Head of Department approval, will be provided by the Regulatory Administration team. Pharmacy approval will be provided at the time of the meeting or afterward and the Pharmacy-Finance Form for Non-Commercial Research (also known as the SSI appendix, Form 22.021A) will follow.

3.6. When is an Authorisation Not Required?

An authorisation is not required under the following circumstances:

Study Type	Applicable to:	Additional Actions
Commercial studies	Routinely available lab tests/procedures (except imaging) provided by the Diagnostics Directorate.	Support departments may need to be approached to confirm costs or to confirm test/procedure is offered within NHSGGC laboratories if not included on UKCRN Industry template. The North Biochemistry list of prices (latest edition 2014) provides a useful guide to assays conducted as routine by Biochemistry
Non-commercial studies Funding from eligible source	Routinely available lab tests/procedures (except imaging) provided by the Diagnostics Directorate.	Consult CSO website for list of eligible sources of grant funding. Additional information as above.
Other studies where funds are available to cover all NHS costs	Routinely available lab tests/procedures (except imaging) provided by the Diagnostics Directorate.	Confirm with finance that costs are covered and are payable. Additional information as above.

3.7. Modifications

Modifications should be reviewed for the use of additional NHS resources (SOP 52.003). Relevant support departments e.g. Pharmacy and Finance should be contacted where a modification may have an impact on the continuing approval of that department, and re-authorisation sought, if required

4. Referenced documents

- SOP 52.001 - Obtaining NHS Management approval: Non-commercial
- SOP 52.002 - Obtaining NHS Management approval for Commercial Studies
- SOP 52.003 - R&I review of Modifications
- Form 52.001B - OID Appendix
- WI 52.001A - Process for Assessing the Acceptability of Excess Treatment costs for Hosted Studies.
- Form 58.004A CRIF Imaging support Form
- UK Model Agreement for Non-Commercial Research
- The Organization Information Document
- IRAS – Integrated Research Application system
- SoECAT – Schedule of Events Cost Attribution Template

5. Related documents

N/A

6. Document history

Version	Date	Description	Retrospective Implementation
1.0	06.11/2013	Release of first version	No
2.0	14/07/2016	Renumbered and new author	No
3.0	18/03/2020	Temp. change to Author and "Approved by". "Released by" updated. Staff category updated. Typographical corrections to procedure. Version updated.	No
4.0	16/07/2026	Change of author/approver/released by. Additional detail regarding service & support department authorisation	No