Standard Operating Procedure			**52.007**
Authorisations for NHS resource use in R & D submissions			
Version	3.0		
Prepared by	Melissa Robert	Signature	Date
Approved by	Roma Armstrong	Signature	Date
Released by	Julie Brittenden	Signature	Date

1. SOP Category

NHS GG&C Hosted R&D

2. Staff Category

Research and Development (R&D)

- Research Co-ordinators
- Research Facilitators
- Senior Research Administrators
- Research Administrators

2. Scope

This procedure applies to NHS Greater Glasgow & Clyde (NHS GG&C) R&D Department.

4. Purpose

Research projects utilise NHS staff, services provided by support departments and other NHS resources. The necessary authorisations 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.

5. Procedures

5.1 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, and Medical records depending on the nature of the research.

5.2 Identification of necessary authorisations

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

The generic IRAS and local information documents 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. clinic areas.

The local documents detail non-clinical and clinical activity in terms of what activity would be received as part of standard of care and what activity would be additional. Review of the study protocol will also be necessary to identify research activity, and in some cases clarification with the research team may be required as the indicated activity on the local documents may be defined by that pertaining at the lead site, which may differ from the local site.

Review of the patient/participant information sheet may also be useful in helping to identify activity that is additional to standard of care.

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

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 5.7 and 5.8), in the first instance and prior to R&D submission, as per IRAS guidance.

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. 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&D staffmay also obtain the authorisation directly from a Service or Support department where existing arrangements with Service Managers are efficient (e.g Neurology), or through expediency.

The email should contain the R&D reference number in the subject header or body of the email.

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 finance and support department subfolder of the study e-folder.

If an email of authorisation is not obtained from the relevant **Clinical Manager** or **Service Department Manager** (see 5.4) 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. Pharmacy and other Support Departments) are in place;
- the study does not incur excess treatment costs;
- 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 synopsis of the study and a statement confirming the Board's obligation to approve research in-line with timelines set by Scottish Government. (Sample text provided as Form 52.007B) Local documents may be included in this email.

Board Approval/Permission can be provided immediately following the email of notification to the Clinical Manager/Service department Manager. The email of notification should also be stored in the finance and support department subfolder of the study e-folder.

If ONLY one or more requirements external to the Board (For example, but not limited to the following: contract with sponsor for signature; pending confirmation of ARSAC licence; receipt of Research Passport) are not met at the time the email of notification is provided to the Clinical Manager/Service department Manager the local review clock should be temporarily stopped. Board Approval/Permission will be provided when all research governance requirements are met.

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

Patients, staff and facilities authorisations

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.

5.5 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 NHS GG&C clinical laboratories), the department should always be consulted and their authorisation sought.

Clinical trials Pharmacy authorisation is required for all trials conducted under the Medicines for Human Use (Clinical Trials) Regulations 2004, and as amended, and for other studies where the use of medicinal products are directed by the protocol.

Section 5.7 and 5.8 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.

5.6 Studies of low financial impact where only NHS staff participate

In some cases it will not be practical to obtain an authorisation, for example obtaining authorisations from gatekeepers to administer questionnaires to staff groups. Where obtaining an authorisation is not practical, the Board Approval/Permission letter should be amended to note that it is the responsibility of the Principal Investigator to approach relevant managers prior to commencing the study. The first paragraph of the Board approval letter can be replaced by the following text:

*I am pleased to confirm that NHS Greater Glasgow and Clyde is now able to grant **overall governance** and **management Approval** for the above study. However, it is the responsibility of the Investigator to approach individual heads of units to negotiate if staff can participate. Participation is entirely at the discretion of the unit/department head.*

5.7 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 GG&C 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.

5.8 Support departments requiring notification.

Study Type	Applicable to:	Notify by
Commercial studies, Non-commercial studies with funding from an eligible source	All imaging procedures conducted by Radiology or conducted by Research Imaging Facility	For studies not involving CTEC (Beatson Clinical Trial Executive Committee) review the coordinator should forward the completed **Imaging Research Forum Form** (Form 52.007A) by email to the lead radiographer of the Research Imaging Facility. **CTEC studies only:** notification will occur
	Clinical Service and support departments delivering research investigations	Where arrangements with departments permit notification, Co-ordinator to notify by email and attach protocol or summary information. For others provisions of section 5.5 apply. Consult department.

5.9 Amendments

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

6. 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&D review of Amendments
Form 52.007A Imaging Research, Research Trial Imaging Details
Form 52.007B Sample email of notification to Head of Clinical Department or Clinical Service Manager

7. Related documents

N/A

8. Document History

Version	Date	Description
1.0		Release of first version
2.0	14/07/2016	Renumbered and new author
3.0	18/03/2020	Temp. change to Author and "Approved by". "Released by" updated. Staff category updated. Typographical corrections to procedure. Version updated.