Standard Operating Procedure		**52.001**	
Obtaining NHS Management Approval Non-commercial			
Version	3.0		
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1. SOP Category

NHS GG&C Hosted R&D

2. Staff Category

- Research Co-ordinators
- Research Facilitators
- Senior Research Administrators
- Research Administrators
- R&D Finance Accountants

3. Scope

This procedure applies to the Research and Development functional unit of Glasgow Clinical Trials Unit.

4. Purpose

To describe the process of how to review submissions and approve research projects applying to take place within NHS Greater Glasgow and Clyde Health Board (GG&C HB).

5. Procedures

5.1 Confirmation of sponsor

Sponsor details will be contained within study documents e.g. IRAS, study protocol etc. The process to identify a sponsor organisation is detailed in SOP 51.007

5.2 Submission of documents

GG&C HB Office can receive notification of a new research study submission from multiple different sources. Notification may be directly from the local investigator, via NHS Research Scotland Permissions Co-ordinating Centre (NRSPCC), HRA or Clinical Trials unit staff. Submission(s) will be dealt with, and routed to, the appropriate portfolio team (i.e. disease specific, for example Oncology); a list of research areas that each portfolio team covers is detailed on the R&D website (**http://www.nhsggc.org.uk/about-us/professional-support-sites/research-development/**).

The Research Administrator will ensure that the notification of the study is not a duplicate by performing a search on the R & D database SReDA. Thereafter, a R & D reference will be issued. Research Administrator will create an electronic file. .

Research Administrator will liaise with NHS Greater Glasgow and Clyde Principle Investigator (PI) regarding submission of documents. PI will receive an email with a R & D checklist, instructions on how to save their IRAS application in xml format and a R & D reference number, starting with GN. Refer to Form 52.001A, Project Checklist. The checklist covers submission for all study types (Requirements for local submission are dependent on the study type).

During submission of documents the Research Administrator of the appropriate portfolio team will be the main contact. The Research Administrator will identify if a research passport may be required for a member of the research team from review of local documentation. Research Administrator will liaise with his/her Research Co-ordinator or Facilitator to determine if the research passport system should be applied (e.g. if the investigator is a University employee without an honorary clinical contract and will have direct patient contact). The Research Administrator completes a Project checklist for each study submitted for approval and tracks receipt of documents and internal authorisations using Form 52.001A.

5.3 Review of submission

Once the Research Administrator has verified that the submitted documents are complete and accurate the study is passed to the Research Facilitator or Co-ordinator for review. The Senior Research Administrator, Research Facilitator and Research Co-ordinator will be the main point of contact for the research team during the review. The Senior Research Administrator, Research Facilitator and Research Co-ordinator must review all documents to ensure compliance with UK Policy Framework for Health and Social Care Research and other applicable regulatory requirements, The Medicines for Human Use (Clinical Trials) Regulations 2004 as amended. Senior Research Administrator, Research Facilitator and Research Co-ordinator must ensure that the Board is able to support the study at the required site(s). To confirm this all relevant departments must confirm their ability to deliver trial activity.

5.3.1 Peer Review

Each Non-commercially sponsored submission should have evidence of peer review to support that the study design and study objective(s) are of appropriate quality. Eligibly funded studies, adopted (more recently referred to as "extended review" studies) do not require additional evidence as the grant application or protocol would have undergone stringent peer review. The responsibility for initiating and ensuring that peer review has been concluded is a Sponsor responsibility. The peer review process is detailed in SOP 51.003.

5.3.2 Review of local information

The Organisational Information Document (OID)is the key document used to assess local project activity. The agreement of all local activity is now collated in a collaborative manner and involves input from Sponsor, local R&D, and local research team. The Senior Research Administrator, Research Facilitator and Research Co-ordinator must assess that the researcher is appropriately trained and qualified to participate in the study. If appropriate further training can be recommended by the Senior Research Administrator, Research Facilitator and Research Co-ordinator (for example, GCP training for CTIMPs or non-CTIMPs). Members of a research team may require letters of access or honorary research contracts (SOP 52.005).

The OID must be an accurate reflection of the NHS resource that will be used for that project. Investigator time, Research Nurse times and all project activities should be captured in the local documents. Local documents collectively are referred to a a Local Information Pack (LIP). Head

of department authorisation(s) and support department approval(s) will be requested following SOP 52.007.

5.3.3 Finance Review

Study documents (e.g. Protocol, IRAS, OID and OID appendix (local document used specifically by GG&C) are used to complete the Study-specific finance form. This form is retained in the central common drive of the Systems folders. This information generates an overall costs for project. Once complete, a updated form is saved in the study-specific Portfolio team folder and an update to finance form is completed to "flag" to finance that project costs have been confirmed. The update to finance form is completed on a weekly basis. A completed Study-specific finance form form part of the overall R&D review which contributes to an Approval letter being issued.

For multi centre projects a completed Schedule of Events Attribution Tool (SoECAT) will be available for each project. When we are the lead (i.e. Sponsor for a project) we generate the SoECAT and share this with other participating Boards and Trust. Study-specific finance forms and SoECAT documents are saved in the electronic study folder for R&D Finance Accountants to access.

5.3.4 Trial Agreements

Site Agreements may be supplied by the Sponsor. A site agreement is required for all studies that fall under regulations for clinical trials for investigational medicinal products. Almost all research project submission are now accompanied by a study contract. For all studies that involve the transfer of funds, patient samples and/or patient data a study contract will be a requirement. In addition, there is now a separate agreement which governs the contracting associated with Patient Identification Centres. This is a standard template. Some sponsor organisations insist on the use of their own specific trail agreements. From a contract negotiation view point use of the standard national agreements is always encouraged and should contribute to more efficient negotiation timelines. Senior Research Administrator, Research Facilitator and Research Co-ordinator must review non-model agreement templates to ensure that all appropriate clauses are included. Standard templates also need to be reviewed for 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 System and Governance Managers where appropriate and independent legal advice can be sought from the Central Legal Office (CLO). If required. Site agreements can only be signed by an authorised signatory of the Board; authorised signatories are R & D Systems & Operations Manager, Lead for Sponsor R&D Pharmacy, Senior R & D Manager and R&D Director.

5.4 Board Approval

Once the Senior Research Administrator, Research Facilitator or Research Co-ordinator has completed his/her review the Research Administrator will complete the Project Checklist (Form 52.001A) and prepare the Board Approval letter. The letter will be signed by the study reviewer and is confirmation, that from a R&D perspective, distribution of study-related documentation and/or patient recruitment can commence. .

The approval letter will be addressed to the PI. The PI will receive the original letter and a copy will be sent by email to 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). Other individuals may require copies of the Board approval letter. Distribution of the approval letter can be expanded on request.

6. Referenced documents

UK Policy Framework for Health and Social Care Research

The Medicines for Human Use (Clinical Trials) Regulations 2004 as amended
SOP 51.003 Peer Review
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

7. Related documents

None

8. 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".