SOP number	**52.009**	Version	**4.0**
Title	**Validation of Project Submissions for R&I Management Approval: NHS**		

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

Staff Category	R	A	C	I
Research & Innovation Systems Manager		X		
Commercial Research Co-ordinators	X			
Research Facilitators	X			
Senior Research Administrators	X			
Research Administrators	X			
Information Officer	X			

1. Scope

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

2. Purpose

Board Approval/Permission (SOP 52.001 and SOP 52.002) is required for all research projects undertaken within NHSGGC. Researchers must provide a valid document set to enable the Board Approval/Permission process to proceed. The purpose of this SOP is to describe the process for obtaining, validating and storing the project document set.

3. Procedures

3.1. New Study Submission

NHSGGC R&I department 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. Notifications from NRSPCC will be sent to the Information Officer (IO) who will then allocate the study with an R&I reference and assign the study to the appropriate portfolio team. The Research Administrator (RA)/Senior Research Administrator (SRA) then creates an electronic folder for storage of all study documentation. The electronic folder should be set up according to the template e-file (Form 52.009C). In addition, the RA/SRA should initiate the Project e-file Checklist (Form 52.009D). In addition to storing the documents electronically, the master copies must be printed and stored within the TMF as per SOP 51.016.

3.2. Submission of valid document set

The process of requesting/receiving a valid document set will differ depending if the study is single centre or multi centre.

3.2.1. Process for a single centre study

Following initial notification of a clinical research proposal, the RA/SRA sends a checklist (Form 52.009A) of the documents required for R&I submission to the Principal Investigator (or their designee). The template email (Form 52.009B) may be used.

NB: It is not always essential to issue the checklist (Form 52.009B) to the PI or designee as the study team may have already provided these documents directly to the RA/SRA. Completeness is verified by following the steps in section 3.3.

3.2.2. Process for a multi-centre study

Documents for multi-centre studies will be submitted directly to R&I via email from NRSPCC. NRSPCC will declare when a full document set is received.

3.3. Incomplete/Inaccurate submissions

For any document sets which are either incomplete or inaccurate, the SRA/RA must follow up with the PI or NRSPcc (for multi-centre studies) until the document set is complete and valid.

3.4. Review of submission

On receipt of the returned submission, the RA/SRA performs the following checks to ensure the application is valid:

- Check that the document set is complete
- Check that the IRAS application is signed appropriately
- Check that copies of approval letters (e.g. Ethics, MHRA) and correspondence relating to the latest version of study documents are provided.

Once the RA/SRA has verified that the submitted documents are complete and accurate then the Project e-file Checklist (Form 52.009D) must be updated to document the date of a valid submission. The Research Facilitator or Co-ordinator will then be informed by the RA/SRA that the project is valid for review for Board Approval/Permission. For any lower risk studies which fall under the Proportionate Review (PR) team (i.e. Basic science and below on the IRAS form) the SRA will provide review and Approval/Permission on behalf of the PR team.

Once the reviewer has completed their review, then the board approval process should be followed (refer to SOP 52.001/52.002).

4. Referenced documents

- SOP 51.016 - Preparation and Maintenance of a Trial Master File
- SOP 52.001 - Obtaining NHS Management Approval Non-commercial
- SOP 52.002 - Obtaining NHS Management Approval for Commercial Studies
- Form 52.009A - Checklist of documents required for R&I submission
- Form 52.009B - Template email to investigator
- Form 52.009C - Template e-file
- Form 52.009D - Project file checklist

5. Related documents

- None

6. Document history

Version	Date	Description
1.0	11/07/13	Release of first version
2.0	14/07/2016	Updated to template v1.4 and new author
3.0	18/03/2020	Temp. change to Author and "Approved by". "Released by" changed. Staff category updated. Minor typographical changes to reflect process. Reference to Database Assistant tasks removed. Version updated.
4.0	06/09/2023	Change of author and approver, version updates, minor admin changes (changes from R&D to R&I, procedures broken down into sections, separation of process for single centre and multi-centre studies, addition of information in section 5.1)