SOP number	**52.017**	Version	**1.0**
Title	**Process for Local Review of Non-Commercial, Hosted, Multi-Centre and Single-Centre PR Studies with NHS Staff as Participants**		

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

Staff Category	**R**	**A**	**C**	**I**
Systems & Operations Manager		X		
Senior Research Administrator	X			
Information Officer	X			
Research Co-ordinator				X
Research Facilitator				X
Research Administrator				X

1 Scope

This procedure applies to Non-Commercial, Hosted Proportionate Review (PR) research studies which involve NHS staff as participants, within NHS Greater Glasgow and Clyde (NHSGGC).

2 Purpose

To describe the process for local review of Non-commercial, Hosted PR research projects which involve staff as participants (both multi-centre and single-centre studies) and how to define when local review is required.

3 Procedures

3.1 Notification of a New Study

3.1.1 Multi-Centre Studies

The Senior Research Administrator (SRA) receives notification from the National Research Scotland Permissions Coordinating Centre (NRS PCC) via the NHSGGC Information Officer (IO) about a new multi-centre, hosted, staff-only study. The SRA will then set-up the email folder and study e-folder (as per SOP 50.011) and file all relevant study documents from SREDA in the study folders.

If NHSGGC is assigned the Scotland-wide Generic Review (SWR), this will be completed following the standard national process. If local review/approval is not required (see step 3.2 below), the SRA will email the Chief Investigator (CI) to confirm that SWR is complete and they can proceed in Scotland as local R&I approval from the participating health boards is not required. If the study does require local R&I review/approval, the SRA will email NRS PCC to inform them SWR has been completed and local health boards should do their own local reviews before the study can start at those participating health boards.

3.1.2 Single-Centre Studies

The SRA is notified of a new single-centre study directly from the lead study team/CI and provided with all relevant study documents. They will then assign this project an R&I reference number (as per SOP 50.009) and set-up a new SReDA profile using the information/documents received. The SRA will also set-up the email folder and study e-folder and upload the study documents to SReDA (as per SOP 50.010).

3.2 Local Review Process

A full local review is required (as per SOP 52.001) if:-

- There are any NHSGGC resource involved (e.g. NHSGGC staff involved in running the study locally or study activities happening on NHSGGC premises such as informed consent etc.)

NB: *If the local activity involves putting up posters/circulating flyers, this does not constitute a research activity and would not require R&I approval. (NRS-CUI-015 – Guidance for the Initiation of PIC Sites)*

No NHSGGC local review required if:-

- There are no NHSGGC resource at all (e.g. no NHSGGC staff involved in running the study, no study activities taking place on NHSGGC premises, no processing of NHSGGC patient data)
- Everything is done virtually/remotely including advertising, promoting, consenting and all study activities

Where no NHSGGC local review is required, the SRA will email the CI to confirm that the study does not meet the requirement for a local review so they can proceed at NHSGGC.

NB: *this step is required for both single-centre studies and some multi-centred studies (The Health Board which completed the SWR should inform the CI that no local review is required – check completed assessment tool)*

In the instance when a NHSGGC Local Collaborator (LC) informs staff of a study but involvement is on a self-referral basis (i.e. the LC role is limited to circulating information and has no involvement in the day to day running of the study) the SRA will conduct a governance check to confirm that all standard documents are present and completed (e.g. protocol, Patient Information Sheet (PIS), Informed Consent Form (ICF), interview schedules/topic guides, Organisation Information Document (OID), insurance certs, CVs – research ethical approval is not required for staff only studies).

The SRA will ask the CI to provide correspondence with the NHSGGC collaborator stating they have agreed to participate. In this scenario, no OID appendix or Head of Department (HoD)approval is required. The SRA will complete pages 1-6 of the OID agreement with the CI in the absence of a Principal Investigator (PI), ensuring the appropriate appendices are selected to form an agreement. For these studies, the OID will be signed off by both the Sponsor and NHSGGC and a standard approval letter issued.

3.3 Updating SReDA

3.3.1 Local Information Tab

If a full review or governance check is required the 'Project Status' & 'Location status' will be updated to 'active' on SReDA by the SRA as per (SOP 50.010). Where no local review is required at all, the SRA will update the fields to "No local review required" in both 'Project Status' & 'Location Status' tabs.

3.3.2 Local Clocks

If a full local review or governance check is undertaken, the local clocks will be started/stopped on SReDA by the SRA as per SOP 50.010. If no local review is required, the local clocks will not be started/stopped.

4 Referenced Documents

- SOP 50.009 – Project Numbering
- SOP 50.010 – Project Data Entry on SReDA
- SOP 50.011 – Setting up and Maintaining Research and Innovation project files (for R&I office approvals)
- SOP 52.001 – Obtaining NHS Management Approval, Non-Commercial Research
- NRS-CUI-015 – Guidance for the Initiation of PIC Sites

5 Related Documents

- UK Policy Framework for Health and Social Care

6 Document History

Version	Date	Description
1.0	09/09/2025	Release of First Version