SOP number	**52.019**	Version	**1.0**
Title	**R&I Review Of Hosted, Non-Commercial Research Projects Involving GP Practices**		

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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		
Senior Research Administrator	X			
Research Administrator	X			
Sponsor Research Co-ordinator			X	
Research Facilitator			X	
Innovation Contracts Manager				X
Innovation Research Co-ordinator				X
Innovation Project Manager				X
Information Officer				X

1. Scope

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

2. Purpose

The purpose of this SOP is to define the process of review and approval of hosted, non-commercial research studies which involve GP practices.

3. Procedures

3.1. Background

When a non-commercial research study involves GP practices, the level of R&I governance review can be different to that undertaken for studies which involve NHSGGC resources. For such studies, there are often no NHSGGC staff or premises involved, so the level of review required is less. The NHSGGC Information Governance team has confirmed that although NHSGGC are joint controllers with GPs for the patient records they hold; access to primary care data for research is approved by the GP and not NHSGGC. As such, the R&I team will take a proportionate approach and undertake a *'Governance Check'* to ensure that all regulatory approvals (e.g. REC) are in place, following which a letter will be issued to confirm that this has been completed. The Sponsor will then be directed to set up the study with each participating GP practice directly, including contracting with GP practices.

For studies which ***do*** involve NHSGGC resources (e.g. NHSGGC staff who work in GP practices), the standard R&I review [as per SOP 52.001] will be undertaken. For such studies, it may be that there

are monies going from the sponsor to both the GP practice/s and NHSGGC, in which case the Sponsor should draw up contracts with both NHSGGC *and* the GP practice/s.

3.2. Generic & Local Review Processes For the Following Scenarios:-

3.2.1. Hosted GP Studies with No NHSGGC Resources Involved

Generic Review Process

1. When the study is received from NRS, set it up as usual as per SOP 52.001.
2. If NHSGGC is assigned generic review, undertake this as usual per SOP 52.001. Include in the generic review notes that no local review is required.
3. Email NRS to say that Generic Review is complete and attach the relevant documents.
4. Update SReDA Project Status as 'Generic Review only'.

Local Review Process

1. Ensure that the relevant regulatory approvals have been received (e.g. REC).
2. Issue the NHSGGC Governance Check letter [Form 52.017A] along with a covering email [Form 52.017B] to the study team and Sponsor. This explains that the Sponsor should put contracts in place with participating GP practices directly, and provide a link to the relevant standard template documents they may wish to use.
3. Update SReDA location status as 'Governance Check only'
4. Update Actual Start Date (Board) with date 'Governance Check Letter' issued
5. Update Actual End Date (Board) with end date from IRAS form (if this has passed, ask the sponsor for the end date)
6. Update RGL Sponsor date with date 'Governance Check Letter' issued
7. Add GP locations to SREDA (the CI will email us with these when they come on board)
8. On SReDA, change 'Recruitment Status' to 'Recruiting' with the date of the change.
9. Add the local recruitment target for each location.
10. Enter the CI's email address in 'Key Recruitment Contact'.
11. In the 'Management Information' box add a comment that it's a GP-only study.
12. For 'Recruitment Source', select 'Manual Gathering'.
13. No local clocks required.

3.2.2. Hosted GP Studies When They Are PICS (Both Non-NHSGGC and NHSGGC Trial Location)

Generic Review Process

1. When the study is received from NRS, set it up as usual as per SOP 52.001.
2. If NHSGGC is assigned generic review, undertake this as usual per SOP 52.001. Include in the generic review notes that no local review is required, and a governance check is sufficient.
3. Email NRS to say that Generic Review is complete and attach the relevant documents.

Local Review Process: Hosted GP studies when they are PICs for non-NHSGGC locations

1. Ensure that the relevant regulatory approvals have been received (e.g. REC).
2. Issue the NHSGGC Governance Check letter [Form 52.017A] and edit it to make it clear that the participating locations will be PICs.
3. Send the covering email [Form 52.017B] to the study team and sponsor with the Governance Check letter. This explains that the sponsor should put contracts in place with participating GP practices directly, and provide a link to the relevant standard template PIC Agreement.
4. Update SReDA location status as 'Governance Check only'
5. Update Actual Start Date (Board) with date 'Governance Check Letter' issued
6. Update Actual End Date (Board) with end date from IRAS form (if this has passed, ask the sponsor for the end date)
7. Update RGL Sponsor date with date 'Governance Check Letter' issued
8. No local clocks required.

Local Review Process: Hosted GP studies when they are PICs for the NHSGGC trial location

1. Undertake the usual local R&I review as per SOP 52.001 and wait for relevant regulatory approvals (e.g. REC if single centre). As part of local approval, HoD approval will be the NHSGGC staff member's clinical lead, not the GP.
2. Contact PI / NRSPCRN to establish the contact details for the participating GP practices.
3. Use the 'Trial Site to PIC' Agreement with the GP practice who is acting as the PIC.
4. Update SREDA as for a standard review and the local clock as per SOP 50.010.

3.2.3. Hosted GP Studies Which Involve NHSGGC Employees Based In GP Practices (E.G. Physiotherapists, Podiatrists)

Generic Review Process

1. When the study is received from NRS, set it up as usual as per SOP 52.001.
2. If NHSGGC is assigned generic review, undertake this as usual per SOP 52.001.
3. Email NRS to say that Generic Review is complete and attach the relevant documents.

Local Review Process

1. Undertake the usual local R&I review as per SOP 52.001. (Note: as part of local approval, HoD approval will be the GGC staff member's clinical lead, *not* the GP).
2. Update SReDA and local clocks as usual as per SOP 50.010.

3.2.4. Hosted GP Studies Which Involve both NHSGGC Secondary Care Locations And GP Practices As Locations

Generic Review Process

1. When the study is received from NRS, set it up as usual as per SOP 52.001.
2. If NHSGGC is assigned generic review, undertake this as usual per SOP 52.001.
3. Email NRS to say that Generic Review is complete and attach the relevant documents.

Local Review Process

1. Undertake the usual local R&I review as per SOP 52.001.
2. The sponsor should draw up contracts (if they are required) with both NHSGGC *and* the GP practice/s. R&I has responsibility for the NHSGGC contract/s only.
3. Send out a covering email (Form 52.017C) to study team and sponsor along with the standard management approval letter. This email (Form 52.017C) makes it clear that the approval applies to the NHSGGC locations only, and that contracting should be done separately with the GP locations to set them up).
4. Update SReDA and local clocks as usual as per SOP 50.010.

4. Referenced Documents

- SOP 50.010 - Project Data Entry on SReDA
- SOP 52.001 – Obtaining NHS Management Approval, Non-Commercial Research
- Form 52.019A – NHSGGC Governance Check Letter for GP studies
- Form 52.019B – Covering Email to accompany Governance Check Letter
- Form 52.019C – Covering Email to accompany Management Approval Letter when NHSGGC staff based in GP practices

5. Related Documents

- UK Policy Framework for Health and Social Care

6. Document History

Version	Date	Description	Retrospective Implementation
1.0	23/12/2025	First Release	No