SOP number	**51.003**	Version	**5.0**
Title	**Peer Review of NHSGGC Sponsored and Co-Sponsored Research Studies**		

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SOP category	NHS GG&C Sponsor R&I

Staff category

Staff Category	**R**	**A**	**C**	**I**
Research & Innovation Systems & Operations Manager		X		
Research & Innovation Director			X	
Clinical Research Facility Director			X	
Research Co-ordinators (Sponsor) (SRC)	X			
Research Facilitator (Sponsor) (SRF)	X			
Senior Research Administrators (SRA)	X			
Innovation Contracts Manager (ICM)	X			
Innovation Project Managers	X			

1. Scope

This procedure applies to NHS Greater Glasgow and Clyde (NHSGGC) Research and Innovation (R&I) staff involved in confirming that studies sponsored by NHSGGC, or co-sponsored with the University of Glasgow (UoG), have undergone adequate peer review prior to sponsorship being confirmed.

2. Purpose

The purpose of this SOP is to define when peer review is required for sponsored studies submitted to NHSGGC R&I and to outline the process for obtaining and documenting that peer review.

3. Procedures

The UK Policy Framework for Health and Social Care Research states that the Sponsor is responsible for, among other things, ensuring that research studies are well designed and planned, and scientifically sound, and that this can be demonstrated by independent peer review, to a level proportionate to the study type.

In Scotland the CSO has compiled, and regularly updates, a list of funding organisations that they have deemed eligible for NHS support as their processes align with CSO/NHS requirements, and more specifically, have robust peer review processes. NHSGGC also recognises Association of Medical Research Charities (AMRC) members as organisations providing robust scientific peer review therefore does not require additional peer review by the Board before confirming sponsorship (as per SOP 51.007). When funding is not from CSO-listed or AMRC-member organisations, NHSGGC must obtain peer review in line with national extended review guidance.

Extended review is required when a more thorough evaluation of study documents beyond the standard peer review process is needed and if funding is wholly or partly from:

- Overseas government
- Overseas charity
- Commercial companies as collaborative research or investigator-initiated studies (see section 4.1.2.)

AND is identified as:

- Having undergone high-quality peer review
- Been awarded in open competition
- Meeting the definition of research

4. Procedures

4.1. Confirming Funding Source and Eligibility

Upon receipt of a grant application or a draft protocol, the R&I Research Co-ordinator/ Research Facilitator (Sponsor) will cross check the funder against the CSO eligibility list and the AMRC member list and document the type of funding in Form 51.010E: R&I Study Strategic Plan.

4.1.1. Eligible funders

If the funder is eligible or an AMRC member, no further peer review is required.

4.1.2. Non-Eligible Funders

Where the funder is not CSO-listed or an AMRC member, the Research Co-ordinator/ Research Facilitator (SRC/SRF) will confirm with the funder whether peer review has been undertaken. If peer review has been conducted, the documentation should be obtained and filed appropriately. If peer review has not been conducted, NHSGGC's peer review process will be initiated as per Section 4.2.

4.1.3. Unfunded Studies

For studies without funding, the peer review process must always be undertaken as per Section 4.2.

4.2. Peer Review Process

The SRC/SRF will engage with both the R&I Director and CRF Director, who will identify at least two suitable independent reviewers with relevant expertise and no conflicts of interest. The Senior Research Administrator (SRA) will liaise with the reviewer to ensure they have the relevant documents (marked private and confidential) and set a response deadline of 10 working days.

The reviewers will receive:

- The study protocol
- Any other relevant supporting documentation (e.g. questionnaires)
- The Peer Review Assessment Form (Form 51.003A)

4.3. Peer Review Outcome Management

4.3.1. Expected Timelines

The Chief Investigator (CI) should receive comments back from peer review within 10 working days. If no response is received within this timeframe, the SRA will follow-up with the reviewer. If there is no response after a following 5 working days, then the SRC/SRF will escalate to R&I management at the Sponsor Systems Meeting.

4.3.2. Reviewer Outcomes

The peer reviewer may recommend:

- Approval
- Approval with required amendments (may request resubmission to peer reviewers after revisions)
- Rejection following resubmission (this should be escalated by SRC/SRF to R&I management at Sponsor Systems Meeting)

If recommended changes are not accepted by the CI, this must be documented along with justification

4.4. Providing Peer Review Feedback

The SRA will send anonymised reviewer feedback to the CI and study team and confirm whether resubmission is required. If resubmission is required, comments must be appropriately addressed and sent back to reviewer by SRA. This process will continue until Approval or Rejection is recommended. Where amendments are made, the updated version of the protocol must be provided to the SRC/SRF by the CI or study team before IRAS submission (see SOP 51.001 and 51.014). Two reviews are required before approval.

4.5. Documenting Peer Review

All peer review documents, correspondence, and outcomes must be retained in the Trial Master File (TMF) as per SOP 51.016. Peer review is required for RGL, the peer review section should be updated on the sponsor oversight checklist (Form 51.020B) and strategic plan (Form 51.010E) once obtained.

5. Referenced documents

- UK Policy Framework for Health & Social Care
- SOP 51.001: Protocol Development
- SOP 51.007: Identifying a Sponsor Organisation
- SOP 51.014: Preparation and Initial Submission of Research Studies to the Research Ethics and Regulatory authorities IRAS/Combined Review Forms for Sponsored & Co-sponsored Studies
- SOP 51.016: Preparation and Maintenance of a Trial Master File
- Form 51.003A: Peer Review Assessment Form
- Form 51.010E: R&I Study Strategic Plan
- Form 51.020B: Sponsor Oversight Checklist for issuing RGL

6. Related documents

- NRS Funding Guidance 2019-20 NRS Funding Guidance - 27.09.19.pdf
- Chief Scientist Office Eligible Funder list (Appendix 1)
- AMRC members: https://www.amrc.org.uk/Listing/Category/member-directory?Take=25

7. Document history

Version	Date	Description	Retrospective implementation
1.0	27/11/2012	Release of first version	No
2.0	14/07/2016	Updated to template v1.4.	No
3.0	11/12/2019	"Released by" changed. Staff category updated. General inclusions made to process. Eligible funder list updated.	No
4.0	11/02/2022	Updated to R&I from R&D and to include innovation	No
5.0	26/05/2026	Updated process with new timelines set, recommendation options, responsibilities defined and new process to identify reviewers including the R&I and CRF directors to advise on two suitable reviewers. Updated for GCP requirements and put in new SOP format. Form 51.003A also updated.	No

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Appendix 1 – list of Eligible Funders

A list of eligible funders can be found on the CSO website

https://www.nhsresearchscotland.org.uk/uploads/tinymce/NRS%20CSO%20Eligible%20Funders%20List%2019%20February%202025.pdf