| SOP number | **51.010** | Version | **6.0** |
|---|---|---|---|
| Title | **Preparation and Review of Grant Applications and Costs** | | |

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|---|---|
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| SOP category | |
|---|---|
| Staff category | |

| **Staff Category** | **R** | **A** | **C** | **I** |
|---|---|---|---|---|
| R&I Systems & Operations Manager | | X | | |
| Sponsor Research Co-ordinators | X | | | |
| Innovation Sponsor Co-ordinator | X | | | |
| Sponsor Research Facilitator | X | | | |
| Project Managers | X | | | |
| Senior Research Administrators | X | | | |
| R&I Finance Accountants | X | | | |
| University of Glasgow Research Regulation and Compliance Team | | | X | |
| R&I Pharmacy | | | X | |
| R&I Governance | | | X | |
| Monitoring | | | X | |
| Bio-Repository Staff | | | X | |
| CRF Staff | | | X | |
| CRIF Staff | | | X | |
| Any other staff to provide costing | | | X | |

## 1. Scope

This procedure applies to all staff within NHS Greater Glasgow & Clyde (NHSGGC) involved in the preparation, review, costing and approval of grant applications.

## 2. Purpose

To describe the process for the preparation, review and approval of grant applications involving NHS staff, patients and/or facilities where NHSGGC is:

- Sponsor or Co-Sponsor with University of Glasgow (UoG) (see SOP 51.007)
- A collaborator on grants where the study is led by another Sponsor
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This SOP ensures that:

- grant applications are feasible, deliverable and appropriately resourced
- all costs are identified, attributed and justified
- Sponsor responsibilities for oversight and resource assurance are fulfilled and evidence is retained.

## 3. Procedures

### 3.1. Background

To support successful grant applications and timely study delivery, applications must be clearly written, informed by appropriate expert input and demonstrably feasible in terms of required resources, including participant recruitment, staff capacity and financial provision.

#### 3.1.1. Funding Categories

All grant applications and studies involving NHSGGC must be classified into one of the following categories to determine the applicable costing framework and required level of Sponsor review:

| Category | Definition | Key Requirements |
|---|---|---|
| Eligible funding | Funding from CSO-recognised eligible funders: NRS CSO Eligible Funders List 19 February 2025.pdf | • AcoRD applies - costs attributed as Research, Support or Treatment AcoRD Guidance<br>• core-funded staff costs must not be included |
| Non-eligible funding (NEF) | Funding from organisations not listed on CSO Eligible Funder list | • All costs must be fully covered<br>• infrastructure support not absorbed through CSO-funded mechanisms |
| investigator initiated industry-funded studies | Studies initiated by investigators but funded by commercial companies | • All costs must be fully covered<br>• Core-funded staff to be costed (e.g. Sponsor representatives and management time) as per WI 51.010A Board overheads may apply |
| Mixed funding (Eligible + NEF/ commercial) | Combination of eligible and Funding from organisations not listed on CSO Eligible Funder list / commercial support | • AcoRD applies<br>• core-funded staff costs must not be included |

Further guidance on these categories is provided in GUI 51.010A: Guidelines for Identifying Category of Research Funding Organisation. The selected funding category must be documented in Form 51.010E.

### 3.2. Requesting NHS Costs for Grant Application

Chief Investigators (CIs) or their delegate must contact R&I at the earliest opportunity when preparing a grant application, **allowing at least 20 working days before the earliest deadline;** 10 working days for the Sponsor Research Co-ordinator, Sponsor Research Facilitator or Innovation Sponsor Co-ordinator (collectively referred to as Grant Co-ordinator in this SOP), and a further 10 working days for R&I Finance. Early engagement is particularly important for large, complex or multi-centre studies, or investigator-initiated studies funded by commercial organisations, since input from multiple departments and external providers may be required (e.g. obtaining external quotes).

Cost requests for grant applications must be sent by the CI or delegate to the R&I grant email inbox: ggc.randigrantapplications@nhs.scot.
The cost request should include:

- Form 51.010A: the NHS Project Costs for Non-Commercial Research, completed as fully as possible
- A draft application, proposal or protocol

Once this has been received, the Senior Research Administrator (SRA) will:

- Allocate an R&I reference number as per SOP 50.009 (this will remain the R&I reference number if the application is successful)
- Register the grant on SReDA as per SOP 50.010
- Forward the request to the appropriate Grant Co-ordinator
- Create an email folder and e-file and save the relevant documents within
- Add to study to the Finance Meeting spreadsheet
- Inform the CI of the R&I reference number for future reference

Where a Grant Co-ordinator is contacted directly regarding a grant application, they will inform the SRA so they are able to proceed with the above and request the CI to send a completed Form 51.010A and a draft application, proposal or protocol.

#### 3.2.1. Grant Allocation

Grants are allocated to either the Systems or Innovation team in line with the criteria set out in Appendix 1. Where a study does not clearly align to a single team, allocation will be agreed following discussion between both teams.

Within the Systems team, grant applications will be assigned to a Grant Co-ordinator based on agreed therapy areas, as detailed on the R&I website: https://www.nhsggc.scot/staff-recruitment/staff-resources/research-and-innovation/ri-management-office/. Where a study spans multiple therapy areas, allocation will be based on the primary specialty of the CI.

Studies classified as low risk will be managed by the Proportionate Review (PR) team. This includes studies falling within the following IRAS categories:

- Research involving questionnaires or interviews (quantitative or mixed methods)
- Qualitative research studies
- Studies limited to the use of human tissue (or other human biological samples) and associated data (specific project only)
- Studies limited to the use of data only (specific project only)
- Tissue banks
- Research databases

Where classification is unclear, this must be escalated for discussion amongst the Sponsor Systems team for a decision to be made.

### 3.3. Costing Review

Upon notification of a grant application involving NHSGGC, the Grant Co-ordinator must initiate cost identification, costing review and feasibility assessment at the earliest stage of application development.

The Grant Co-ordinator will provide the Chief Investigator (CI) with relevant guidance, including R&I SOPs. For non-CTIMP studies, a link to GUI 51.010B: Handbook for Researchers involved in non-CTIMPs must also be provided.

#### 3.3.1. Information Gathering and Feasibility

The Grant Co-ordinator will ask CI to complete Form 51.010E: The Study Specific Strategic Plan. For more complex studies, it is advised the CI meets with the Grant Co-ordinator to discuss the study and review Form 51.010E. The Grant Co-ordinator will then use Form 51.010E to identify the appropriate departments (e.g. Pharmacy, Governance, Project Management, Research Imaging, Biorepository, CRF etc.) and other third parties required for the time required to cover their corresponding activities and/or any additional costs as per Appendix 2, as well as assessing the feasibility of conducting the study at the local participating study location(s) and forward the relevant information to the appropriate departments or organisations for input and costing.

#### 3.3.2. Costing Development and Co-ordination

The CI or their delegate will complete Form 51.010A: NHS Project Costs for Non-Commercial Research, which will be submitted to the Grant Co-ordinator for review. The Grant Co-ordinator is responsible for collating all internal NHSGGC costs for the study.
For applications where NHSGGC will be the administering Institution (i.e. NHSGGC will hold the funds if awarded), the Grant Co-ordinator will also organise input from all relevant external parties to ensure that all activities, resources and costs involved in the study are identified and added directly to Form 51.010A. Where this is the case, the Grant Co-ordinator will also review the grant application as per Section 3.7.

Where the application is led by another organisation, such as the University of Glasgow, CIs will be responsible for contacting the Lead organisation's grants team for non-NHS costs, and must factor in the Lead organisation's internal deadlines for review and submission.

All costings and supporting correspondence obtained by the Grant Co-ordinator must be retained within the study e-file.
The Grant Co-ordinator will support the CI in incorporating confirmed costs into Form 51.010A, ensuring that each department's costing is clearly documented. It is recommended that costings are organised with a separate tab for each contributing department or cost element on Form 51.010A. Once all information is received and included in the Form 51.010A and the CI has confirmed the information is correct, the Grant Co-ordinator will send the completed Form 51.010A to the Generic R&I finance inbox: ggc.randifinancegrants@nhs.scot, with the R&I reference and deadline stated in the subject and copy in the CI. They will then update the Finance Meeting spreadsheet

Form 51.010A will provide R&I Finance the information required to:

- Identify the Sponsor (as per SOP 51.007)
- Identify the appropriate departments and other third parties involved
- Identify the funding call, category of funding organisation (Guideline 51.010A), stage of submission and deadline for submission (if applicable)

- Identify relevant departments/organisations costs associated with the study (some considerations can be seen in Appendix 3)
- Identify whether a SoECAT (Schedule of Events Cost Attribution Template) is required (see WI 51.010B and Online SoECAT Guidance | NIHR for guidance)
- Obtain basic information on the study e.g. the type and size of the study, number of participants, single/multi-centre, inter/national, duration, potential risk/need for additional insurance etc.
- Identify the extent of NHSGGC involvement

The Grant Co-ordinator will work with the R&I accountant, CI and other departments/organisations involved to resolve any queries and finalise costs that arise during finance review. **R&I Finance requires at least 10 working days for review and sign off before the earliest grant deadline or institutional approval deadline.**

### 3.4. SoECAT

Where the grant application guidelines require submission of a SoECAT, this should be submitted for review to R&I Finance at the same time as Form 51.010A (as per WI 51.010B).

The Grant Co-ordinator will send the link to create an online SoECAT and the guidance for completion to the CI or delegate to complete. The CI should add the Grant Co-ordinator to the completed SoECAT to permit review. The Grant Co-ordinator will then confirm the SoECAT is ready for the CI to submit to NHSGGC's Boards AcoRD Specialists within R&I Finance for review, finalisation and authorisation.

If Excess Treatment Costs (ETCs) are identified in an NHSGGC-sponsored study, where NHSGGC is not the only site, the SoECAT is required before study approval.

### 3.5. Receiving R&I Finance Costs

The Grant Co-ordinator and CI (if originally copied in the submission), will receive a copy of the R&I Finance approved calculated costs via email in locked PDF format. The calculated cost are based on the submitted Form 51.010A with the costs listed and attributed. The Grant Co-ordinator will ensure the CI has a copy of the locked PDF R&I Finance approved NHS costs, for inclusion in the grant application, and will update the Finance Meeting spreadsheet.

### 3.6. Application Review

Where the application is being led by NHSGGC, the Grant Co-ordinator will review the grant application to ensure:

- the application has been clearly written and feasibility has been considered
- the application is consistent with Form 51.010A and Form 51.010E
- that all costs have been identified and attributed as per R&I Finance approved NHS costs
- any ETCs have been identified for fully eligible or mixed model funding grants

### 3.7. Submission of Application

The Grant Co-ordinator will arrange for the appropriate NHS sign off on the application form(s) and, if required, letters of support or Sponsorship in principle. For studies involving Excess Treatment Costs (ETCs), approval must be received from the appropriate NHS manager confirming that the department will meet ETCs up to the Board's subvention threshold and, if subvention funding is not awarded, any remaining ETCs associated with the study. This confirmation must be documented by signature or email prior to application sign-off.

A copy of the completed application must be obtained by the Grant Co-ordinator and filed in the study e-file as per SOP 50.011. For successful grants of regulated trials (CTIMP/CIMDs), this will be filed in the TMF as per SOP 51.021.

### 3.8. Grant Outcome

The Information Officer (IO) and SRA will keep track of the outcome of the application, and what future steps (if any) will be required. If a grant has been unsuccessful, this will be withdrawn from SReDA by the SRA until another funding call is identified.

## 4. Referenced Documents

- SOP 50.009 - Project Numbering
- SOP 51.007 - Identification of Sponsor Organisation
- SOP 51.024 - Archiving Essential Documents from Clinical Research – Process for a Sponsored Clinical Trial of an Investigational Medicinal Product (CTIMP)
- Form 51.010A - NHS Project Costs for Non-commercial Grants
- Form 51.010D - Grant with Potential non CA/CE marked Medical Device - Checklist
- Form 51.010E – R&I Study Strategic Plan
- Form 58.004B - Research Imaging Support Form
- Form 60.804 - Biorepository/Pathology Engagement Form for Research
- Guideline 51.010A - Guidelines for identifying category of research funding organisations
- Guideline 51.010B - Handbook for Researchers involved in Non-CTIMPs NHSGGC
- Guideline 51.010C - Non-Commercial Nurse Intensity Tool
- WI 51.010A - Summary of Sponsor team relating costs (Investigator initiated industry funding)
- WI 51.010B - Completion and Review of SoECAT
- WI 51.010C - DPIA and SSP Working Instruction
- Eligible Funders - https://www.nhsresearchscotland.org.uk/uploads/tinymce/NRS%20CSO%20Eligible%20Funders%20List%2019%20February%202025.pdf
- AcoRD Guidance - https://www.nhsresearchscotland.org.uk/uploads/tinymce/AcoRD-Guidance-Scotland.pdf
- SoECAT Guidance - https://www.nihr.ac.uk/support-and-services/support-for-delivering-research/online-soecat-guidance

## 5. Related documents

- SOP 50.010 - Project Data Entry on SReDA

## 6. Document history

| Version | Date | Description |
|---|---|---|
| 1.0 | 06/09/2013 | Release of first version |
| 2.0 | 14/07/2016 | Updated to template v1.4. |
| 3.0 | 11/12/2019 | “Released by” amended. Staff category updated. Generic updates to process to reflect current practice. |
| 4.0 | 26/10/2022 | Title updated to include the word “costs”. Ref to R&D updated to R&I. Staff Categories expanded to include Innovation staff. Clarification of process for grant applications for ‘hosted’ studies. All funding categories included and a description of each added. Detail re |

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| | | Industry funded- Investigator Initiated Study applications added. Background information updated to include more detail of the process, types of studies, departments and organisations that may need to be involved in costing, as well as additional costs relating to Industry funded-Investigator Initiated Studies. Addition of generic R&I Finance, and systems team grant applications emails added. Reference to, and link to SoECAT forms included Refs and links updated Form 51.010A updated to include more detailed guidance, Form 51.010B deleted, Update of form 51.010C, Form 51.010D re Grants involving a Medical Device, Guideline 51.010A – links updates |
| 5.0 | 09/06/2023 | Initial/Development phase of application updated to clarify the role of the Sponsor Research Co-Ordinator, Innovation Co-Ordinator or Research Facilitator in the review and completion of the Form 51.010A as well as forwarding all information to R&I Finance. Updated to include the use of Form 58.004B when NHSGGC Research Imaging department is involved and Form 60.804 when support from NHSGGC Biorepository is required. Updated R&I Finance email address for grant applications. Form 51.010A updated to include clarifications on review and approval of proposed NHS costs. Form 51.010B - List of CTU Groups and Support Departments - deleted – due to the fact that points of contact are changing regularly, it is difficult to keep the list updated. Form 51.010C deleted - Feasibility Form – the relevant information is now part of Form 51.010E. Form 51.010E - R&I Study strategic plan - New Form - includes the feasibility of conducting the study, checklist to identify the appropriate departments and other third parties required and understand participant pathway/data flow/materials/ contractual arrangements. WI 51.010A "Summary of Sponsor team relating costs (Investigator initiated industry funding)" - New Working Instructions – to help identify sponsor team associated costs for non-commercial, investigator initiated industry funded studies. WI 51.010B – New Working Instructions on how to complete a SoECAT and sponsor actions when Excess Treatment Costs (ETCs) are identified as part of SoECAT completion for Sponsored, Non-Commercial Studies." - includes instructions on how to complete a SoECAT as well as activities related to ETCs in Scotland, England and Wales. |
| 6.0 | 01/09/2026 | • Comprehensive review and restructuring of the SOP to improve clarity and align with current practice. |

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| | | • Updated staff categories, roles and responsibilities.<br>• Revised funding category guidance, costing processes and SoECAT requirements.<br>• Added grant allocation criteria, feasibility assessment requirements and cost consideration guidance (Appendices 1 and 2).<br>• Added reference to GUI 51.010B: Handbook for Researchers involved in Non-CTIMPs NHSGGC.<br>• Updated email addresses, document references and external guidance links. |

**Appendix 1 – Systems and Innovation Split**

| Feature | Innovation Sponsor | Systems Sponsor | Examples | Project further information | Conclusion |
|---|---|---|---|---|---|
| Combined trial of an investigational medicinal product (IMP)and an investigational medical device (IMD) (1) | | X | SUBCUT2 R&I ref GN18CA193 | Involves a medicine/pharmacy Regulated trial | Systems team sponsor due to medicine involvement |
| Clinical Trial of an Investigational Medicinal Product (CTIMP) (2) | | X | EMPRESS-MI R&I ref GN21CA051 | Involves a medicine/pharmacy Regulated trial | Systems team sponsor due to medicine involvement |
| Non-CTIMP drug study (3) | | X | Viktories R&I ref GN15RE696 | Involves a medicine/pharmacy | Systems team sponsor due to medicine involvement |
| Hosted projects with no integration into NHS systems | | X | Impact of AI on Stroke Diagnosis and Treatment R&I Ref GN24ST101 | | R&I approval only No Innovation contracts manager +/- PM, no eHealth |
| Hosted project with integration into NHS systems (Research team looking for support and guidance from WoS Hub and eHealth) | X | | ACCEPT R&I ref INGN22AE383 | | Innovation contracts manager light touch + PM + eHealth |
| Commercially sponsored and funded | | X | | | R&I approval only No Innovation contracts manager +/- |

| | | | | | |
|---|---|---|---|---|---|
| | | | | | PM, no eHealth |
| Commercially sponsored and funded with eHealth requirements/NHS integrations | X | | RealZE (sponsored by GSK) R&I ref GC23ON556 | | Innovation sponsor and contracts + PM +/- eHealth |
| Creating a product co-developed with NHS | X | | DYNAMIC-AI R&I ref INGN20RM641 | | Innovation sponsor and contracts + PM + eHealth |
| Product developed in isolation and tested in GGC test bed | X | | PARS – class 1 MD to monitor respiratory rate R&I ref INGN22RM471P | | Innovation sponsor and contracts + PM +/- eHealth |
| Actively involved in funding call (SBRI/CivTech etc) to work up innovation project | X | | Diabetes challenge R&I ref INGN23DI405 | | Innovation sponsor and contracts + PM +/- eHealth |
| Innovation Funder e.g. Innovate UK, NHS England, CanDo For specific device/digital/data science & AI funding calls | X | | AIVAL – development of AI assessment platform R&I ref INGN23HS395 | | Innovation sponsor and contracts + PM +/- eHealth |
| Investigator Initiated Industry funded projects (not meeting criteria for 1, 2 or 3) | X | | Propel - R&I ref INGN24NE003 | | Innovation sponsor and contracts + PM +/- eHealth |
| Continuation work i.e. Device studies/ trials which have gone from early | X | | Medtronic MOU R&I ref INGC24RM102P | | Innovation sponsor and contracts + |

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| development to testing, or from MOA / MOU to a project | | | | | PM +/- eHealth |
| Device studies/ trials - Real world evaluation of a UKCA/CE marked device | X | | RADICAL R&I ref INGN23RM028 | | Innovation sponsor and contracts + PM +/- eHealth |
| Service Evaluation of an Innovation involving integration into NHS systems | X | | vCREATE R&I ref INGN20NE367 | | Innovation sponsor and contracts + PM +/- eHealth |
| CE marked device projects<br>• Device is focus of research<br>• Device is NOT focus of the research | X | X | PHOENIX R&I ref INGN24MG113<br>*Potentially R&I ref GN23ON397* | | Innovation sponsor and contracts + PM +/- eHealth<br>No Innovation contracts manager +/- PM, no eHealth |
| AI Projects<br>• AI is the focus of the research<br>• AI is not the focus of the research | X | X | RADICAL R&I ref INGN23RM028<br>Tartan-HF R&I ref GN22CA228 | | Innovation sponsor and contracts + PM +/- eHealth<br>No Innovation contracts manager +/- PM, no eHealth |

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|---|---|---|---|---|---|
| Novel devices or regulated devices modified under healthcare exemption (MDU or UKAS accredited labs) | X | | Pafdadi R&I ref GN22ST004 | | Innovation sponsor and contracts + PM +/- eHealth |

**Appendix 2: Cost Considerations and Required Documents**

| Scenario / Trigger | Items to Consider Costing | Team to provide costs/time | Additional Documents Required |
|---|---|---|---|
| DPIA/SSP required (see WI 51.010C) | Information Governance & Cyber security staffing | Cost as per WI 51.010C | DPIA/SSP + Risk Register, Notify Innovation Programme Manager (if successful) |
| Unconsented data / Data linkage / national datasets / Safehaven data access | eDRIS / Research Data Scotland / Safehaven | RAS Approval Pathway pricing \| Research Data Scotland / Safehaven | Caldicott / PBPP / CAG applications (if successful) |
| Site archiving | 1 box per site | R&I Finance | |
| Sponsor archiving (CTIMP / CIMD only) | Sponsor Archiving Costs | R&I Finance | |
| CTIMP /CIMD - Regulatory | MHRA fees (10 modifications, application fee, safety report per year) | Current MHRA fees - GOV.UK | |
| Studies involving a medicine or device | Pharmacovigilance support | Pharmacovigilance | |
| Studies involving a medicine | Pharmacy support | Sponsor Pharmacy | |
| Studies involving a device | device acquisition, set-up, training, clinical use, maintenance | Manufacturer | Form 51.010D should be completed |
| International studies | Ethics applications, insurance, translation of documents | | |
| Studies with Imaging | CRIF costs, external scans | CRIF / external imaging department, | Imaging using NHSGGC CRIF facilities, Form 58.004B should be completed and approved by CRIF. |
| Administration of radioactive substances | ARSAC/ Radiation Assurance (IR(ME)R / CRE & MPE review) | How and when to submit research applications to ARSAC - GOV.UK<br><br>Applying for Radiation Assurance - Health Research Authority | |
| Studies with research samples, eg blood or tissue | Consumables (tubes, kits), Equipment, tissue collection, processing, analysis, | Labs, R&I Finance and Biorepository (if involved). | For NHSGGC Biorepository support, Form 60.804 should be completed |

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| | transport, Long-term storage, Couriers | | and approved by Biorepository |
| Staff time | NHS staff time (e.g. CI, PI per site, nurse time, support staff) | CI, Grant co-ordinator and CRF (if involved), | GUI 50.010A can be used to estimate research nurse time |
| Project Management (required for CTIMPs, recommended for all multi-site studies) | Staff time, consumables | Project Management | |
| Monitoring (required for CTIMPs, recommended for all complex, interventional studies) | Staff time, travel costs and expenses | Monitoring | |
| Consumables & equipment | Study-specific equipment and consumables | Provider and R&I Finance for NHS supplies | |
| Additional languages | Translation costs | Estimated from recent quotes | |
| Additional insurance for high-risk populations/devices/trials | Insurance | Insurance purchaser (e.g. UoG) | Criteria listed on Form 51.010E |
| Contributions in kind | | | Email confirmation required from the relevant HoD or Service Manager |