| SOP number | **51.010** | Version | **5.0** |
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| Title | **Preparation and Review of Grant Applications and Costs** | | |

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| Prepared by<br>Signature | Pamela Sandu<br>Date |
| Approved by<br>Signature | Melissa Robert<br>Date |
| Released by<br>Signature | Julie Brittenden<br>Date |

| SOP category | NHSGGC Sponsor R&I |
|---|---|
| Staff category | |

| **Staff Category** | **R** | **A** | **C** | **I** |
|---|---|---|---|---|
| R&I Systems Manager | | X | | |
| Sponsor Research Co-Ordinators | X | | | |
| R&I Innovation Contracts Manager/Coordinator | X | | | |
| Research Facilitators | X | | | |
| Project Managers | X | | | |
| Senior Research Administrators/Research Administrators | X | | | |
| R&I Finance accountants | X | | | |
| University of Glasgow Head of Research Regulation and Compliance and Research | | | X | |
| R&I Pharmacy | | | X | |
| R&I Governance | | | X | |
| Bio-Repository Staff | | | X | |
| CRIF Staff | | | X | |
| Any other staff to provide costing | | | X | |

## 1. Scope

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

## 2. Purpose

To describe the processes involved in preparation and review of grant applications involving NHS staff, patients and/or facilities, for:

- studies Sponsored by NHSGGC, or Co-Sponsored with University of Glasgow (UoG) (SOP 51.007 Identification of Sponsor Organisation)
- studies where NHSGGC investigators are co-applicants/co-investigators or collaborators on grants sponsored by other organisations (i.e. where study would be hosted by NHSGGC if funded, or involves NHSGGC staff for consultation/advice only)

Applications fall into 4 funding categories

1. NEF (Non-eligible funding) – all project costs and staff time must be covered by departments supporting/delivering the study protocol. (Eligible Funders)
2. Fully eligible – AcoRD funding rules apply. Costs are identified, reviewed and attributed as either Research, Support or Treatment. (AcoRD Guidance)

3. Mixed model of charity/government funding and industry support – AcoRD funding rules apply as above. Sponsor staff salaries paid by Infrastructure funds should not be included for this study type.
4. Investigator-initiated fully funded by Pharmaceutical company(s) – AcoRD funding rules may **NOT** apply. The study should be fully costed and funded as research and additionally for this scenario all sponsor costs, including staff time for Sponsor representatives, research administrator and Management (as per working instructions WI 51.010A) should be included. In addition, a Board overhead may be applied to NHS costs.

The application review is intended to ensure that applications:

- have been clearly written and have considered if feasible
- that all costs have been identified and attributed as per category of study described above
- that in studies that are fully eligible or mixed model type any excess treatment costs have been identified

## 3. Procedures

### 3.1. Background

In order for Researchers to succeed not only in obtaining grant funding, but in completing the resulting study in a timely manner, applications require to be clearly written, contain input from appropriate experts, and to be feasible in terms of the resources required (including participants and finance).

Where the application is led by NHSGGC the Sponsor Research Co-Ordinator or Innovation Co-Ordinator, in conjunction with the finance accountant, will organise input from all partners and support departments required to both develop the application e.g. Pharmacy, Governance, Project Management, Research Imaging, Biorepository etc, and to ensure that all required resources and costs are identified and attributed correctly. Form 51.010E should be used to identify the appropriate departments and other third parties involved.

Where the application is led by another organisation the Research Facilitators will liaise with the Investigators and R&I Finance to identify and attribute NHS costs as above. These will be forwarded to the Investigator to provide to the lead organisation for inclusion in the application.

A copy of the completed application should be requested by the Sponsor Research Co-Ordinator, Innovation Co-Ordinator or Research Facilitator for the study file.

Researchers are requested to contact R&I as early as possible when wishing to submit a grant application, especially if the study to be costed is large, complex, multi-centered, or an investigator initiated study to be funded by a commercial company, as these may involve e.g. obtaining quotes from external companies and involvement of multiple support departments. Industry funded investigator initiated studies will need to be considered for the inclusion of additional costs for staff employed via infrastructure budgets as outlined above. (Sponsor team associated costs should be calculated using WI 51.010A).

Study contracts need to be reviewed for IP and potential royalties for NHS consideration and will likely require review and approval by CLO.

Where the application is led by University of Glasgow, Investigators should also contact the University grants team for non-NHS costs, and factor in time for submission to the College Operations Group (COG). The Project Manager, where the study will have one, Sponsor Research Co-Ordinator,

Innovation Co-Ordinator, and Research Facilitator will assist the Investigator, where possible, to complete the Grant application form (Form 51.010A). The completed form must be discussed and agreed with the Sponsor Research Co-Ordinator, Innovation Co-Ordinator or Research Facilitator before it can be submitted to R&I Finance for approval. R&I Finance requires at least 10 working days for review and sign off before the earlier of grant deadline or institutional approval deadline e.g. COG. Designated members of staff working across Cancer Research UK Clinical Trials Unit (CRUK CTU, Glasgow) will prepare and review this form as per this SOP and relevant CRUK CTU SOPs.

### 3.2. Initial phase of application

Grant application requests should be sent to the R&I grant email inbox: (ggc.randigrantapplications@ggc.scot.nhs.uk ). The Senior Research Administrator (SRA) forwards this request to the appropriate Sponsor Research Co-Ordinator, Innovation Co-Ordinator or Research Facilitator, allocates the R&I reference number (Ref no.) to the Grant and registers the Grant on SReDA (R&D Research database) (SOP 50.009). The Ref no. will be forwarded to the Investigator for future reference. If the application is successful this allocated number will be assigned to the study.
When Sponsor Research Co-Ordinators, Innovation Co-Ordinators or Research Facilitators are informed of a grant application to be prepared involving NHSGGC e.g. by the researcher, GU, other Sponsor organisation or NHS R&I finance, then identification of activities with an associated cost, the attribution and review of the application, where appropriate, are initiated in parallel.

When an individual (e.g. Sponsor Research Co-Ordinator, Innovation Co-Ordinator or Research Facilitator) is contacted regarding a grant application they will forward a copy of the Grant Application Form (Form 51.010A) to the Investigator or their nominated contact.

The Form 51.010A is populated by the investigator or their nominated contact and sent back to the Sponsor Research Co-Ordinator, Innovation Co-Ordinator or Research Facilitator for review. The Sponsor Research Co-Ordinator or Innovation Co-Ordinator may use the study specific strategic plan (Form 51.010E), work instruction WI 51.010A (if applicable) and also contact all partners and support departments involved (e.g. Pharmacy, Governance, Project Management, Research Imaging, Biorepository etc) to provide the time required to cover their corresponding activities and/or any additional costs.

The provisional arrangements and costings for archiving the Trial Master Files for CTIMPs/CIMDs will take into account the legal requirements for the CTIMP/CIMD trials retention period (SOP 51.024) and will be discussed with the CI during the initial Sponsor/Co-sponsors review process. Costs for archiving are the responsibility of the CI and must be included in the application for funding. As archiving period for CTIMPs/CIMDs is expected to be increased in the near future and for this type of trials it is recommended to secure archiving costs for 25 years.

Once all information is received and included in the Form 51.010A, the Sponsor Research Co-Ordinator, Innovation Co-Ordinator or Research Facilitator sends the completed application to the Generic R&I finance email (ggc.randifinancegrants@ggc.scot.nhs.uk ). The R&I reference number should be stated first in the subject field of the email.

A copy of the draft Funder's application form will also be requested at this point by the Sponsor Research Co-Ordinator, Innovation Co-Ordinator or Research Facilitator.

As mentioned previously, designated members of staff working across Cancer Research UK Clinical Trials Unit (CRUK CTU, Glasgow) will prepare and review grant applications and costs as per this SOP and/or relevant CRUK CTU SOPs.

The form and any associated documents (e.g. draft protocol, Schedule of Events) will provide the information which will allow the Project Manager, Sponsor Research Co-Ordinator, Innovation Co-Ordinator or Research Facilitator, with the R&I accountant to:

- Identify the Sponsor (SOP 51.007: Identification of Sponsor Organisation)
- Identify the appropriate departments and other third parties involved and assess the feasibility of conducting the study (Form 51.010E)
- Identify the category of funding organisation (Guideline 51.010A) and deadline for submission (if applicable)
- Determine the staff time for Sponsor representatives, research administrator and Management (WI 51.010A) (if applicable)
- The Stage of the grant submission e.g. Outline or full application
- Whether a SoECAT (Schedule of Events Cost Attribution Template) form is required (SoECAT Guidance) and if required, whether there are any Excess Treatment Costs (ETCs) identified (Use work instructions WI 51.010B to inform on how to complete the SoECAT and ETC processes)
- 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
- The extent of NHSGGC involvement
- Identify departments/organisations within the Glasgow CTU/ CRUK CTU Glasgow that may be required to contribute to the development/review of the application and/or the identification and attribution of costs

### 3.3. Development phase of application

The Project Manager, Sponsor Research Co-Ordinator, Innovation Co-Ordinator or Research Facilitator will then:

- With the R&I accountant, forward the relevant information to the appropriate groups/departments /other organisations for input and costing
- Use the Form 51.010E to understand the study strategy plan and identify the appropriate departments and other third parties required as well as assessing the feasibility of conducting the study at the local participating site.
- Collect and forward input from all groups/departments to the researcher and, when a Co-/Sponsored study, where appropriate, assist with editing the application.
- Work with the R&I accountant and other departments/organisations involved to finalise costs as per each department/organisations standard procedures.
- When the study involves a medical device, Form 51.010D should be completed
- When the study involves imaging using NHSGGCC CRF facilities, Form 58.004B should be completed and approved by the Research Imaging team.
- For NHSGGC Biorepository support with tissue collection or storage form 60.804 should be completed and approved along with the costs provided by the Biorepository team.
- Receive a copy of the R&I Finance approved calculated costs (in locked pdf format) based on Form 51.010A with the costs listed and attributed, as described in section 4 above. The locked pdf NHS costs approved by R&I Finance will be forwarded to the researcher to include in the application.

- Arrange for the appropriate NHS sign off on the application form(s) and, if required, letters of support or Sponsorship in principle. N.B. confirmation that department will meet any excess treatment costs identified up to the Boards pre-subvention limit, or for the entire study should an application for subvention not be successful, from the appropriate NHS manager, either from a signature on the application form or by email to the Sponsor Research Co-Ordinator or Innovation Co-Ordinator, must be obtained before an application can be signed off.
- If a SoECAT is needed at the grant application stage, the SoECAT should be sent for review to R&I Finance along with the grant application form at: ggc.randifinancegrants@ggc.scot.nhs.uk. (as per WI 51.010B)

Where the grant application guidelines require submission of a SoECAT the Sponsor Research Co-Ordinator or Innovation Co-Ordinator will forward the link to this form (see referenced documents) and the guidance on completion to the Project Manager and/or Researcher to complete a draft of this form, with the help of the Sponsor Research Co-Ordinator or Innovation Co-Ordinator. The Sponsor Research Co-Ordinator or Innovation Co-Ordinator forwards the completed SoECAT to R&I finance ( ggc.randifinancegrants@ggc.scot.nhs.uk) for review, finalisation and sign off by one of the Boards AcoRD Specialists.
If Excess Treatment Costs are identified in the SoECAT of a NHSGGC sponsored study with additional English or Welsh sites, the Sponsor Research Co-Ordinator or Innovation Co-Ordinator will follow the processes detailed in the working instruction WI 51.010B. Researchers are required to forward a copy of the submitted version of the application to the Co-Ordinator, together with an estimate of the date that the awards will be announced (for each round).

A process will then be initiated by the Research Administrator and R&I Information Officer to check with the researcher on the outcome of the application, and what future steps (if any) will be required.

## 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
- WI 51.010A - Summary of Sponsor team relating costs (Investigator initiated industry funding)
- WI 51.010B - Working instruction on how to complete a SoECAT and when Excess Treatment Costs (ETCs) are identified as part of SoECAT completion for Sponsored, Non-Commercial Studies.
- Eligible Funders - Chief Scientist's Office- list of 'eligible' organisations
- AcoRD Guidance - Attributing the costs of Health and Social Care Research and Development- Scotland
- SoECAT Guidance - NIHR Schedule of Events Cost Attribution Template (SoECAT) Guidanc

## 5. Related documents

- SOP 50.010 - Project Data Entry on SReDA

## 6. Document history

| Version | Date | Description |
|---|---|---|
| 1.0 | 06/09/13 | Release of first version |
| 2.0 | 14/07/2016 | Updated to template v1.4. |
| 3.0 | 11/12/19 | "Released by" amended. Staff category updated. Generic updates to process to reflect current practice. |
| 4.0 | | Title updated to include the word "costs".<br>Ref to R&D updated to R&I<br>Staff Categories expanded to include Innovation staff<br>Clarification of process for grant applications for 'hosted' studies<br>All funding categories included and a description of each added.<br>Detail re Industry funded- Investigator Initiated Study applications added<br>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<br>Addition of generic R&I Finance, and systems team grant applications emails added<br>Reference to, and link to SoECAT forms included<br>Refs and links updated |

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| | | Form 51.010A updated to include more detailed guidance<br>Form 51.010B deleted<br>Update of form 51.010C<br>Form 51.010D re Grants involving a Medical Device<br>Guideline 51.010A – links updates |
| 5.0 | 24/07/2023 | 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<br>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<br>Updated R&I Finance email address for grant applications<br>Form 51.010A updated to include clarifications on review and approval of proposed NHS costs<br>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<br>Form 51.010C deleted - Feasibility Form – the relevant information is now part of Form 51.010E<br>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<br>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.<br>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. |