SOP number	**51.007**	Version	6.0
Title	**Identifying a Sponsor Organisation**		

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

Staff Category	**R**	**A**	**C**	**I**
Systems & Operations Manager		X		
Sponsor Research Co-ordinators	X			
University of Glasgow Research Regulation & Compliance team			X	
Chief Investigators	X			
Innovation Contracts Manager (Innovation Coordinator)	X			

1. Scope

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

2. Purpose

To describe NHSGGC process to identify a Sponsor for all Research and Innovation projects.

Research and Innovation project, for the purpose of this SOP, is defined as a study where the research will involve human participants, their organs, tissue or data and the project will seek to obtain an opinion from an NHS Research Ethics Committee (Staff only studies are now excluded from this requirement)

3. Procedures

3.1. Background

A Sponsor is defined as 'the individual or organisation responsible for the initiation, management and finance of research projects' outlined in the UK Policy Framework for Health & Social Care Research) or other appropriate legislation (e.g. The Medicines for Human Use (Clinical Trials) Regulations 2004 (Statutory Instrument (SI) 2004/1031) and the Medical Devices Regulations 2002 (SI 2002 No 618, as amended (regulations).

A Sponsor should hold appropriate insurance to indemnify Research and Innovation projects, implement plans to mitigate risks to the research participants and organisation and implement processes to manage oversight of all aspects of the research project. Sponsor responsibilities may be assigned to a single organisation or may be shared between organisations as long as this relationship is formalised in the form of a contract.

NHSGGC may sole Sponsor research projects or, where applicable (see section 3.3.1), may co-Sponsor CTIMPs and Medical Device Trials and related technologies (such as in vitro Medical Devices, Software Packages and Health Smartphone applications) with The University of Glasgow (GU).

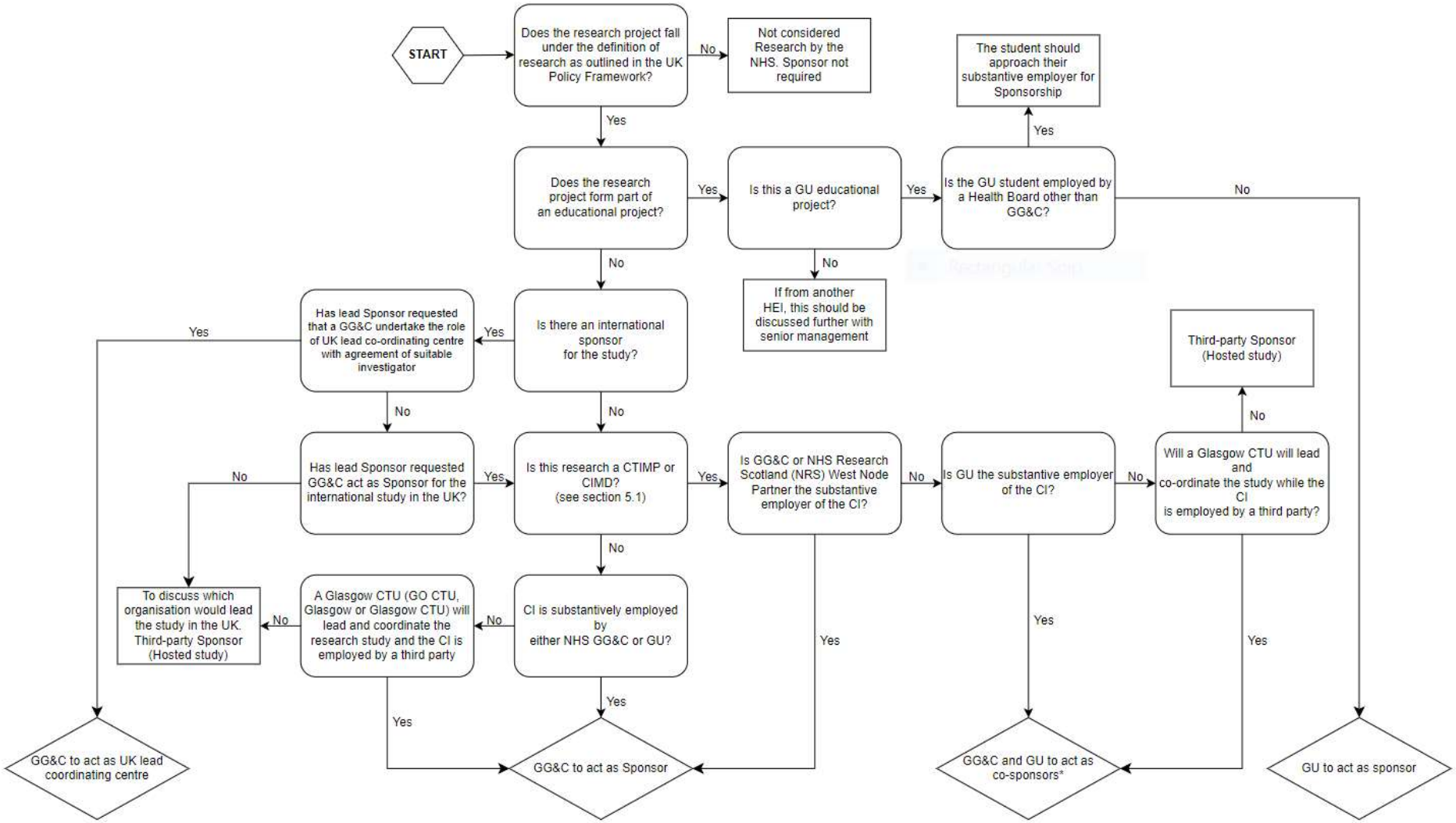
Research projects can be organised as follows:

- Clinical Trials of Investigational Medicinal Products (CTIMPs)
    - Studies governed by The Medicines for Human Use (Clinical Trials) Regulations 2004 (Statutory Instrument (SI) 2004/1031), as amended
- Clinical Investigation or other study of a Medical Device (CIMDs)
    - Studies governed by the Medical Devices Regulations 2002 (SI 2002 No 618, as amended, including Medical Device Trials and related technologies, such as in vitro Medical Devices, Software Packages and Health Smartphone Applications
- Research studies
    - Studies not governed by specific UK regulations but are defined as research by the UK Policy Framework for Health and Social Care Research.

3.2. How do you identify a Sponsor?

Investigators or a member of a research team will make contact with NHSGGC R&I with a study proposal or grant application. If this involves a digital solution or medical device the contact should be made to the West of Scotland Innovation Hub (WoSIH). Prior to review of submitted documents, the R&I Co-ordinator will determine which organisation and team has been identified to act as Sponsor.

If no Sponsor has been identified the following flowchart can be used by the R&I Co-ordinator as guidance to determine the project's Sponsor:



*Co-Sponsorship of CIMDs is agreed with GU on a case-by-case basis.

3.3. Studies with UK sites only

3.3.1. NHSGGC as Sole Sponsor

NHSGGC will act as sole Sponsor if any of the following criteria are confirmed:

- CTIMPs:
  - The CI is substantively employed by NHSGGC or NHS Research Scotland (NRS) West Node Partners (is not substantively employed by any of the Glasgow-based Universities).
- CIMDs:
  - The CI is substantively employed by NHSGGC and a Collaboration Agreement is in place to cover the Manufacturer's obligations.
- Research Studies:
  - The CI is substantively employed by either NHSGGC or GU
  - A Glasgow CTU (GO CTU, Glasgow or Glasgow CTU) will lead and co-ordinate the research study and the CI is employed by a third party.

Substantive employer – the organisation that holds the employment contract with that individual e.g. NHSGGC, Affiliated Health Boards or GU.

NHS Research Scotland (NRS) West Node Partners – Health Boards within the NRS West region (NHS Ayrshire and Arran, NHS Lanarkshire, NHS Dumfries and Galloway and NHS National Waiting Times Centre Board are the Boards affiliated with NHSGGC via the West Node Partnership arrangements)

3.3.2. GU as Sole Sponsor

The decision for GU to be sole Sponsor is made by the GU Head of Research Regulation & Compliance and/or Officers provided the following criteria are met:

- Research Studies:
  - The study is a GU student's educational project

Others may be considered on a case-by-case basis.

3.3.3. NHSGGC and GU Co-Sponsorship

The decision to Co-Sponsor is made jointly by the NHSGGC R&I and GU R&C. For projects involving the WoSIH (see section 3.2), the decision will be made by the Innovation Lead and the GU Head of Research Regulation & Compliance and/or Officers. For all other research projects the decision will be made by the Sponsor Research Co-ordinator and the GU Head of Research Regulation & Compliance and/or Officers. For all co-sponsored projects, the division of responsibilities is documented in a Co-Sponsorship Agreement.

NHSGGC and GU will Co-Sponsor studies if any of the following criteria are met:

- CTIMPs:
  - The CI is substantively employed by GU
  - A Glasgow CTU will lead and co-ordinate the study and the CI is employed by a third party. Co-Sponsorship involving Glasgow CTUs is agreed with GU on a case-by-case basis.
- CIMDs:
  - The CI is substantively employed by GU and a Collaboration Agreement (s) is in place to cover the Manufacturer's obligations. Co-Sponsorship of Device Trials is agreed with GU on a case-by-case basis.

3.3.4. Third-Party Sponsor (Hosted studies)

A third-party (i.e. not NHSGGC or GU) will undertake the role of Sponsor when any of the following criteria are met:

- The CI is not substantively employed by NHSGGC or GU and the research project is not being co-ordinated by a Glasgow CTU.
- The research project will form part of an educational qualification with an academic institution other than GU and the academic institution has confirmed that they will undertake the role of Sponsor.
- The research project is a student project and the student is registered with GU but is employed by a Health Board other than NHSGGC.
- The research project protocol has been developed by a commercial organisation and will be fully funded and managed by the commercial organisation.
- The third-party organisation has requested that a GU or NHSGGC employee will undertake role of CI and does not require NHSGGC sole Sponsorship or NHSGGC/GU Co-Sponsorship.

3.4. NHSGGC Sponsored and Co-Sponsored Studies with International Sites

NHSGGC are unable to act as Sponsor/Co-Sponsor at sites outside of the UK. In this scenario, NHSGGC and, where applicable, GU may act as lead Sponsor/Co-Sponsors and a legal entity within each host country, with sites out with the UK, must accept the role of Sponsor. The NHSGGC R&I Co-ordinator will assess Sponsor suitability by requesting completion of the International Site Questionnaire (Form 51.007A) and Sponsorship arrangements will be detailed in a contract.

3.5. Studies with Lead International Sponsor

Multicentre Research projects may have international sites out with the UK. The lead Sponsor of the study may request that NHSGGC and, where applicable, GU undertake the role of UK Sponsor or that NHSGGC is the lead co-ordinating centre for the UK for this study type.

3.5.1. International Lead Sponsor – UK Sponsorship Request

3.5.1.1. NHSGGC as UK Sponsor in International Multi-Centre Studies

NHSGGC will act as sole Sponsor if any of the following criteria are met:

- CTIMPs:
  - The CI is substantively employed by NHSGGC or NRS West Node Partner Boards.
- CIMDs:
  - The CI is substantively employed by NHSGGC.
- Research Studies:
  - The CI is substantively employed by either NHSGGC or GU
  - A Glasgow CTU will lead and co-ordinate the research study and the CI is employed by a third party organisation (Sponsorship for this study type is considered on a case-by-case basis).

Sponsorship responsibilities will be defined in a contract between NHSGGC and the Lead International Sponsor. The lead Sponsor must hold appropriate clinical trials insurance to indemnify all host sites/nations for study design if the study is a CTIMP/CIMD.

3.5.1.2. NHSGGC / GU as UK Co-Sponsors in International Multi-Centre Studies

The decision to Co-Sponsor is made jointly by the NHSGGC R&I Co-ordinator and the GU Head of Research Regulation & Compliance and/or Officers and responsibilities of each party are detailed in a Co-Sponsorship Agreement.

NHSGGC and GU (where appropriate) will undertake the role of UK Co-Sponsors if either of the following criteria are met:

- CTIMPs:
  - The CI is substantively employed by GU
  - A Glasgow CTU will lead and co-ordinate the research study and the CI is employed by a third party.
- CIMDs:
  - The CI is substantively employed by GU.

Sponsorship responsibilities should be defined in a contract between NHSGGC, GU and the Lead International Sponsor. The lead Sponsor must hold appropriate clinical trials insurance to indemnify all host sites/nations for study design if the study is a CTIMP.

3.5.2. NHSGGC as UK Co-ordinating Centre

For CTIMPs and Medical Device Trials and related technology studies with a single European Sponsor, NHSGGC will undertake the role of UK co-ordinating centre if the following criteria are met:

- CTIMPs/CIMDs:
  - The CI is substantively employed by NHSGGC or GU
  - A Glasgow CTU will lead and co-ordinate the research study and the CI is employed by a third party

The lead EU Sponsor should retain Sponsor responsibilities across the EU and this is formally documented in a contract. The lead Sponsor must hold appropriate clinical trials insurance to indemnify all host sites/nations for study design if the study is a CTIMP.

3.6. Confirmation of Sponsor

Once NHSGGC has accepted the role of Sponsor/Co-Sponsor, in principle, Sponsorship will be confirmed by NHSGGC R&I Co-ordinator. For studies defined as CTIMP/CIMD this will be formalised in a letter which will be issued prior to any regulatory submission. Confirmation of agreement to Sponsor can be conveyed in a number of ways e.g. signing a grant application or submission documents as the Sponsor representative, if a formal letter is required for non-CTIMP studies, this can be provided on request. Formal sign off on regulatory and Ethics submissions will also be concluded. If the study is to be Co-Sponsored by NHSGGC and GU the NHSGGC R&I Co-ordinator will also complete this on behalf of GU after confirmation of University of Glasgow sponsorship by University Governance.

Any scenarios where NHSGGC has been requested to undertake the role of Sponsor or Co-Sponsor that is not covered will be presented to the R&I committee meeting and a final decision will be made, and documented, by this group.

For sole sponsored CTIMP and/or CIMDs a letter confirming sponsorship in principle (Form 51.007C) will be sent to the Chief Investigator (CI) by the NHSGGC R&I coordinator as soon as possible after the study protocol and/or successful funding application has been reviewed (if appropriate). At this stage, the CI will also be asked to read and sign Form 51.007E: 'Responsibilities delegated to the Chief Investigator for CTIMP Trials Sponsored by NHSGGC'.

They will be expected to read, comprehend and stay up to date with all relevant SOPs for the duration of the trial. This will be managed through Q-Pulse and the CI will receive notifications of new and updated SOPs they are expected to read and acknowledge.

For Co-Sponsored CTIMPs and/or CIMDs, a letter confirming co-sponsorship in principle (Form 51.007B) signed jointly by the NHSGG&C R&I coordinator and a member of the University of Glasgow Research Regulation & Compliance team, will be sent to the CI as soon as possible after the study protocol and/or successful funding application has been reviewed by both organisations (if appropriate). At this stage, the CI will also be asked to read and sign Form 51.007D: 'Responsibilities delegated to the Chief Investigator for CTIMP Trials Co-Sponsored by the University of Glasgow and NHSGGC'. They will be expected to read, comprehend and stay up to date with all relevant SOPs for the duration of the trial.

SOP records are now held in Q-Pulse and by signing form 51.007D or 51.007E, CIs agree they have read and understood all of the SOPs. R&I Co-ordinators should then send the signed forms onto the Quality Assurance team to update their training record in Q-Pulse.

4. Referenced documents

- UK Policy Framework for Health & Social Care Research.
- The Medicines for Human Use (Clinical Trials) Regulations 2004 (Statutory Instrument 2004/1031), as amended.
- Glasgow Health Science Partnership Board – Sponsor/Co-Sponsorship arrangements; May 2008
- Form 51.007A – International Site Questionnaire
- Form 51.007B – NHSGGC and University of Glasgow Co-Sponsor Letter
- Form 51.007C – NHSGGC Sponsor Letter
- Form 51.007D – Responsibilities delegated to the Chief Investigator for CTIMP Trials Co-Sponsored by the University of Glasgow and NHSGGC
- Form 51.007E - Responsibilities delegated to the Chief Investigator for CTIMP Trials Sponsored by NHSGGC

5. Related documents

- University of Glasgow Policy on Sponsorship and Co-Sponsorship Arrangements with NHS Greater Glasgow & Clyde

6. Document History

Version	Date	Description
1.0	13/12/2012	Release of 1st Version
2.0	14/07/2016	Updated to template v1.4.
3.0	11/12/2019	"Released by" amended. Staff category updated. Governance framework reference updated. General updates to process to reflect current practice. GHSP Board referenced.
4.0	18/03/2020	Addition of CTIMP co-sponsorship in principle letters Processes and procedures updated SOP version updated Staff category updated
5.0	25/08/2021	Updated to R&I from R&D and to include Medical Device Trials and related technologies, such as Invitro Medical Devices, Software Packages and Health Smartphone Applications

		Clarified the process in section 5 and added a reference to the CI delegation of responsibility and included four forms, Forms 51.007 B,C,D and E. SOP version updated
6.0	09/01/2025	Flowchart added to clarify decision process. CRUK CTU updated to GO CTU. Updated to reflect GU student projects will now be sponsored by GU. WoSIH roles have also been included. Associated forms referenced and SOPs updated in forms D and E.