SOP number	**51.011**	Version	**5.0**
Title	**University of Glasgow and NHS Greater Glasgow and Clyde Co-Sponsorship Agreement**		

Prepared by Signature	Maureen Travers	Date
Approved by Signature	Melissa Robert	Date
Released by Signature	Jesse Dawson	Date

SOP category	NHS GG&C Sponsor R&I

Staff category

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

1. Scope

This procedure applies to NHS Greater Glasgow and Clyde (NHSGGC) R&I Department and University of Glasgow Research Governance staff.

2. Purpose

The purpose of this SOP is to define the process of initiation, preparation and execution of the Co-Sponsorship Agreement when NHSGGC and University of Glasgow (GU) Co-Sponsor a Clinical Trial of Investigational Medicinal Product (CTIMP) or Clinical Investigation of Medical Device (CIMD)

3. Procedures

3.1. Background

The Medicines for Human Use (Clinical Trials) Regulations 2004 (regulations) and amendments state that the Sponsor of a CTIMP shall put and keep in place arrangements for the purpose of ensuring, in regard to that trial, that the conditions and principles of Good Clinical Practice (GCP) are satisfied and adhered to.

In the scenario where NHSGGC and GU Co-Sponsor a CTIMP/CIMD (SOP 51.007) the legal responsibilities defined in the regulations are allocated between the organisations through the execution of the Co-Sponsorship Agreement. NHSGGC and GU have agreed to take on each of the following set of Sponsorship responsibilities:

Section	Responsibility	Party Responsible
Part 3	Authorisation for clinical trials and ethics committee opinion	GU
Part 4	Good clinical practice and the conduct of clinical trials	NHSGGC
Part 5	Pharmacovigilance	NHSGGC
Part 6	Manufacture and importation of investigational medicinal products	NHSGGC
Part 7	Labelling of investigational medicinal products	NHSGGC

There are three models of the Co-Sponsorship agreement:

- Single-site Co-Sponsorship Agreement
- Multi-centre Co-Sponsorship Agreement
- Third-party Chief Investigator Co-Sponsorship Agreement

These templates can be obtained from GU by emailing the GU Co-Sponsor representative who will liaise with GU legal

3.2. Preparation of Co-Sponsorship Agreement

An agreement must be prepared for each NHSGGC and GU Co-Sponsored CTIMP/CIMD.

GU will prepare and forward the draft Co-Sponsorship Agreement to NHSGGC RC for review as follows:

- Review the Co-Sponsorship Agreement to ensure that the trial details are correct.
- Clauses within the agreement, these cannot be amended unless prompted for trial specific information.
- Ensure that the draft agreement includes the completed following schedules:
    - **Schedule 1**: Study Protocol – insert current version of the protocol.
    - **Schedule 2**: The Study Related Duties of The University – text not to be amended
    - **Schedule 3**: The Study Related Duties of The Board – text not to be amended
    - **Schedule 4**: The Budget and Payment Schedule – include finance details and arrangement with reference to other contract (as applicable)
    - **Schedule 5**: Study Risk Assessment Methodology - insert signed copy of initial Risk Assessment Tool (Form 51.004A).
    - **Schedule 6**: Services provided by the University – Request Robertson Centre for Biostatistics (RCB) or GO CTU will complete to detail trial support (as applicable).
    - **Schedule 7**: Services provided by the Board – RC will complete this if additional services are to be documented.
    - **Schedule 8**: Trial Sites – this schedule will only be completed for the Multi-centre Co-Sponsorship Agreement. Trial sites should be listed and may need to be updated after signing of the agreement.
- Send template letter (Form 51.011A) to Third Party CI Employer in trials where Third-party CI Co-Sponsorship Agreement is used.

When all appendices have been added, 'Responsibilities delegated to the Chief Investigator for Trials Co-Sponsored by the University of Glasgow and NHS Greater Glasgow and Clyde' Form 51.011C will be sent to GU Research Regulation and Compliance Team (RRCT) for completion.

The Sponsor RC will confirm with GU RRCT that the Co-Sponsorship agreement can be signed, the Co-Sponsors will then be sent for signature by authorised signatories. The agreement must be fully executed prior to provision of the regulatory green light.

3.3. Storage of Documents

Original signed versions of the co-Sponsorship agreement, Form 51.011A (where applicable), Form 51.007B, Form 51.007D and Form 51.011C must be filed in the TMF according to SOP 51.016.

4. Referenced documents

- SOP 51.007 – Identifying a Sponsor organisation.
- Form 51.007B – Co-Sponsor Letter
- Form 51.007D – Responsibilities delegated to the Chief Investigator for CTIMP Trials Co-Sponsored by the University of Glasgow and NHS Greater Glasgow & Clyde
- Form 51.004A – Risk Assessment Tool
- Form 51.011A – Short Form CTA Letter CI employer

5. Related documents

- SOP 51.004 – Clinical Trial Risk Assessment: NHS

6. Document *History*

Version	Date	Description
1.0	05/02/2013	Release of first version
2.0	14/07/2016	Updated to template v1.4, renumbered and new author
3.0	24/05/2018	Authorship and released by changed
4.0	04/10/2021	Change in author, updated staff category and updated referenced and related documents to reflect changes in other SOPs. Form 51.011B is now obsolete, activities in this form are now covered in other forms or procedures. Version updated.
5.0	20/10/2025	Updated RACI Matrix; clarification re medical devices; replaced text with table for responsibilities or Parties; removed duplication.