Standard Operating Procedure			**51.011**
University of Glasgow and NHS Greater Glasgow and Clyde Co-Sponsorship Agreement			
Version	**4.0**		
Prepared by	Emma McDonough	Signature	Date
Approved by	Caroline Watson	Signature	Date
Released by	Julie Brittenden	Signature	Date

1. SOP Category

NHS GG&C Sponsor R&I

2. Staff Category

Research and Innovation (R&I)

- NHS GG&C Sponsor Co-ordinators
- NHS GG&C Governance
- University of Glasgow Research Governance

3. Scope

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

4. Purpose

The purpose of this SOP is to define the process of initiation, preparation and execution of the Co-Sponsorship Agreement when NHS GG&C and University of Glasgow (GU) Co-Sponsor a Clinical Trial of Investigational Medicinal Product (CTIMP).

5. Procedures

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 NHS GG&C and GU Co-Sponsor a CTIMP (SOP 51.007) the legal responsibilities defined in the regulations are allocated between the organisations through the execution of the Co-Sponsorship Agreement. NHS GG&C and GU have agreed to take on each of the following set of Sponsorship responsibilities: (see appendix 1 for titles)

> GU, as Co-Sponsor, is responsible for Part 3 of the regulations. Part 3 encompasses protocol concept/design, submission to Research Ethics Committee and Medicines for Healthcare products Regulatory Agency (or other appropriate regulatory body).
>
> NHS GG&C, as Co-Sponsor, is responsible for Parts 4, 5, 6 and 7 of the regulations. Parts 4, 5, 6 and 7 encompass the conduct of the CTIMP to GCP, monitoring, pharmacovigilance, manufacture (the drug is usually manufactured by the licence

holder/Pharmaceutical company) and labelling of Investigational Medicinal Products (IMPs).

There are three models of the Co-Sponsorship agreement (templates are stored in the R&I department common drive (\\northnet-11\wg-research\common\1.Systems\STANDARD DOCUMENTS\Contracts):

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

5.1. Preparation of Co-Sponsorship Agreement

An agreement must be prepared for each NHS GG&C and GU Co-Sponsored CTIMP.

The Research Co-ordinator will prepare and review the Co-Sponsorship Agreement as follows:

- Contact GU Senior Contracts Manager or GU Research Governance Officer to initiate preparation of the appropriate Co-Sponsorship Agreement.
- Review the Co-Sponsorship Agreement to ensure that the trial details are correct.
    - Clauses within the agreement cannot be amended unless prompted for trial-specific information.
- Review the appended Schedules, these must contain the required document or populated with the appropriate information:
    - **Schedule 1** (Study Protocol) – insert the final Sponsor approved protocol which the trial will start on.
    - **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) - finance details if funding is to be transferred from GU to NHS GG&C
    - **Schedule 5** (Study Risk Assessment Methodology) - insert signed final copy of The Risk Assessment Tool (Form 51.004A)
        - The Research Co-ordinator must ensure that the main actions identified in The Risk Assessment Tool must be completed prior to signing of the Co-Sponsorship agreement
    - **Schedule 6** (Services provided by the University) - Robertson Centre for Biostatistics (RCB) or CRUK will complete to detail trial support.
    - **Schedule 7** (Services provided by the Board) – Research Co-ordinator 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.
- Completion of Letter to Third Party CI Employer in trials where Third-party Chief Investigator Co-Sponsorship Agreement is used (Form 51.011A).

The Sponsor Co-ordinator, in liaison with GU Research Governance Officer, must determine on behalf of the Co-Sponsors when the Co-Sponsorship agreement can be signed, the agreement must be fully executed prior to provision of the regulatory green light.

The Co-Sponsorship Agreement must be signed by NHS GG&C and GU authorised signatories.

The executed Co-Sponsorship Agreement must be accompanied by the completion of 'Responsibilities delegated to the Chief Investigator for Trials Co-Sponsored by the University of Glasgow and NHS Greater Glasgow and Clyde' (Form 51.007D)

5.2. 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 Sponsor file.

6 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

7 Related documents

SOP 51.004 – Clinical Trial Risk Assessment: NHS

8 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 51.011C is now obsolete, activities in this form are now covered in other forms or procedures. Version updated.

Appendix 1

Part 3 - Authorisation for clinical trials and ethics committee opinion
Part 4 - Good clinical practice and the conduct of clinical trials
Part 5 – Pharmacovigilance
Part 6 - Manufacture and importation of investigational medicinal products
Part 7 - Labelling of investigational medicinal products