SOP number	**51.020**	Version	**4.0**
Title	**Sponsor Regulatory Green Light and Trial Oversight**		

Prepared by Signature	Pamela Sandu Date
Approved by Signature	Caroline Watson Date
Released by Signature	Julie Brittenden Date

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

Staff Category	R	A	C	I
Governance Manager		X		
R&I Systems Manager	X			
Sponsor Research Co-Ordinators	X			
R&I Innovation Contracts Manager/Coordinator	X			
R&I Pharmacy	X			
University of Glasgow Head of Research Regulation and Compliance and Research			X	
Project Managers				X
R&I Monitoring				X
R&I Pharmacovigilance				X
Chief Investigator				X

1. Scope

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

2. Purpose

The purpose of this SOP is to define the process for issuing Sponsor Regulatory Green Light (RGL) for Clinical Trials of Investigational Medicinal Products (CTIMPs) Sponsored by NHSGGC or Co-Sponsored with University of Glasgow (UoG) (SOP 51.007) and oversight of the Trial throughout its lifecycle.

3. Procedures

3.1. Pre Regulatory Green Light

The Sponsor Oversight Checklist for issuing RGL (Form 51.020B) outlines the Sponsor actions required to be completed for each NHSGGC Sponsored or co-Sponsored CTIMP and documents evidence of Sponsor/Co-sponsors oversight ahead of issuing Sponsor Regulatory Green Light (RGL). Sponsor RGL, for the purposes of this SOP, is defined as the approval confirming that all necessary trial (country-level) documents have been approved by the Sponsor/Co-Sponsors and regulatory requirements under GCP are in place. To clarify, the process of issuing site-specific 'Green for Go' is covered in a separate SOP (SOP 56.001). Sponsor Green for Go relates specifically to the activation of a participating site.

Form 51.020B which lists the minimum requirements for issuing RGL, is started at the funding application stage and the Research Co-ordinator or their designee will populate each section as actions are completed. The Sponsor Pharmacy representative will complete and sign sections relating to pharmacy review. This document must be updated throughout the life cycle of initiating a trial and not left until the point of issuing RGL as this will cause delays in the process.

Once completed, Form 51.020B should be wet ink signed by Sponsor Pharmacy representative (to confirm pharmacy RGL is issued) and by the Research Co-ordinator (to confirm all activities relating to Sponsor RGL have been completed). The Research Co-ordinator will send a Sponsor CTIMP RGL letter (Form 51.020A) to the following:

- Chief Investigator
- Sponsor Pharmacist Pharmacovigilance Manager
- Clinical Trial Monitor
- Data Centre
- Study Project Manager
- University of Glasgow Head of Research Regulation and Compliance and Research (only for co-Sponsored CTIMPs))

The distribution of the RGL letter can be expanded on request.

Copies of the RGL letter and completed Form 51.020B will be saved electronically in the trial eFolder and in paper in the relevant section of the Trial Master File (TMF) (SOP 51.016). Once Sponsor RGL has been issued, submission to national co-ordinating centres for R&D permissions can proceed.

Any request for RGL to be issued when the Sponsor Oversight Checklist for issuing RGL (Form 51.020B) is not complete should be escalated through Governance Management staff and via Governance group if required. This escalation should be in advance of issuing RGL.

3.2. Continue Oversight Post Regulatory Green Light

It is required for the Sponsor to maintain oversight of a trial and its activities post RGL and be able to evidence this oversight. A number of activities will continue for a trial past the point of RGL, oversight of these activities is detailed in Appendix 1 of Form 51.020B.

4. Referenced documents

- SOP 51.007 - Identifying a Sponsor Organization
- SOP 51.016 - Preparation and Maintenance of a Trial Master File
- SOP 56.001 - Site Set Up – Green for Go Process
- Form 51.020A - Sponsor CTIMP Regulatory Green Light Letter
- Form 51.020B - Sponsor Oversight Checklist for issuing RGL

5. Related documents

- SOP 51.001 - Protocol Development
- SOP 51.002 - Patient Information Sheet and Consent Forms: Design and Approval
- SOP 51.004 - Clinical Trial Risk Assessment
- Form 51.004A - Risk Assessment Tool
- SOP 51.011 - University of Glasgow and NHS Greater Glasgow and Clyde Co-Sponsorship Agreement
- SOP 51.014 - Preparation and submission of IRAS forms.
- SOP 51.015 - Assessment of Vendors
- SOP 51.017 - Registration of research projects on public databases
- SOP 52.004 - R&D Contract Development and Review
- SOP 21.012 - R&D Pharmacy review of sponsored clinical trials
- SOP 53.004 - Monitoring Clinical Trials

6. Document history

Version	Date	Description
1.0	25/11/13	Release of first version.
2.0	14/07/2016	Updated to template v1.4. Change of Author
3.0	02/03/2020	Temp. Author change. “Released by” changed. Staff category updated. Minor typographical changes to “Purpose” and “Procedures”. Version updated.
4.0	29/04/2024	Author changed, Staff category updated to include RACI matrix Text updated to reflect current Sponsor processes. Form 51.020B added which includes the minimum requirements for issuing RGL.