SOP number	**56.001**	Version	**8.0**
Title	**Site Set up – Green for Go Process**		

Prepared by Signature	Lynsey Gillespie Date
Approved by Signature	Lynn Prentice Date
Released by Signature	Julie Brittenden Date

SOP category	NHSGGC Project Management Unit
Staff category	

Staff Category	**R**	**A**	**C**	**I**
GCRF Clinical Research Manager		X		
Research & Innovation Systems & Operations Manager	X			
Research Governance Manager	X			
Sponsor Research Coordinator	X			
Project Managers	X			
Chief Investigator			X	
Principal Investigator				X
Sponsor Pharmacy Team				X

1. Scope

This procedure applies to the Project Management Unit (PMU) staff, study specific Project Manager's (PM) external to the PMU. This SOP does not cover oncology CTIMP studies coordinated by the Glasgow Oncology Clinical Trials Unit.

2. Purpose

To describe the Green for Go process for all studies sponsored by NHSGGC or co-sponsored NHSGGC with University of Glasgow (GU), and supported by either PMU or a study specific PM.

For the purpose of this SOP the site set up Green for Go process is defined as a quality assurance process to ensure that all regulatory and operational components are in place for individual participating sites prior to start of recruitment and treatment.

3. Procedures

3.1. Pre-site Green for Go approval

3.1.1. Trigger of process

The Sponsor Research Co-ordinator will notify the PM that all regulatory approvals are in place (e.g Ethics, MHRA etc.). This will act as the trigger for the PM to send out a cover email (Form 56.001G) which contains information on the Green for Go process along with the Local Information Pack (LIP) to study sites that have been identified as part of the site capability assessment process (SOP 56.007). This email will detail the actions required before Green for Go can be issued.

The PM will prepare and forward study site files using the relevant NHSGGC Principal Investigator Site File index [Form 51.016C (for CTIMPs and CIMDs) and Form 56.001H (for other research studies)].

3.1.2. Completion of Green For Go checklist

The PM will work with the site team to ensure that all requirements listed in the Green for Go Checklist (Form 56.001B) are in place. The PM will complete the Green For Go checklist based upon documents received and confirmations provided by the local participating site research team. The checklist must also detail confirmation of requirements being in place from Sponsor Research & Innovation stakeholders (R&I), the Data Centre (DC) and the Chief Investigator (CI).

Form 56.001E Protocol Approval Page should be signed by the Local PI as part of the Green for Go process to acknowledge the current approved protocol.

Once all requirements listed in the Green For Go Checklist (Form 56.001B) are met, the PM will sign and date the checklist to confirm.

3.2. Site Initiation Visit (SIV)

A Site Initiation Visit (SIV) will be carried out by the PM/study research team. This should involve relevant staff members of the local study team. SIVs will be performed as close as possible to local R&I permission being granted or shortly thereafter. Confirmation of attendance at SIV will be documented using the training log (Form 56.002F) and filed in the relevant section of the ISF along with a copy of the SIV training materials.

3.3. Issuing Site Green For Go

Once the Green for Go checklist is complete:

- For CTIMPs the PM will generate the IMP release email to the Sponsor R&I Clinical Trial Pharmacist (Form 56.001C).
- PM/study team will ensure delivery (if not already done so) of study specific equipment / consumables, if required.
- Generate the Green for Go email (Form 56.001D).

The Green for Go email will be sent to the Principal Investigator and to any relevant staff listed below, as well as printed and filed in the ISF:

- All local participating study staff listed on the delegation log
- Site pharmacy staff (for CTIMPs)
- Site R&I contact
- CI
- Sponsor R&I Coordinator
- Sponsor R&I Clinical Trial Pharmacy staff (for CTIMPs)
- Sponsor R&I Pharmacovigilance Manager (where applicable)
- Data Centre/Case Report Form provider (where applicable)
- Sponsor R&I Monitors (where applicable)
- University of Glasgow Head of Research Regulation and Compliance (when co-sponsored)
- Any other staff as deemed appropriate.

4. Referenced documents

- SOP 56.007 - Site Capability Assessment
- Form 51.016C – PI Site File Index
- Form 56.001B – Green for Go Checklist Template
- Form 56.001C - IMP Release Email Template
- Form 56.001D - Green for Go Email Template
- Form 56.001G – LIP Email Template
- Form 56.001H – PI Site File Index (non-CTIMP)
- Form 56.001E – Protocol Approval Page Template
- Form 56.002F – Site Clinical Trial Training Log Template

5. Related documents

None

6. Document History

Version	Date	Description
1.0	28/06/13	Release of first version
2.0	04/11/15	Changes made to clarify process and address MHRA finding 3.1.1 and 3.4.4
3.0	15/07/2016	Restructure of SOPs Removed former section 5.3 now covered in Form 56.001B Minor admin changes Change number from 05.001 to 56.001 Addition of Sponsor Monitor signature
4.0	17/10/2016	Change of staff category Addition of Protocol Signature Form Removal of site set-up letter to SOP 56.002
5.0	17/12/2018	Staff category updated
6.0	29/08/2019	Changes made to clarify process green for go sign off and documentation of SIV attendance
7.0	23/01/2020	Minor admin change: Site Set Up Letter – Form number – change from 56.001A to 56.002J Changes made to clarify process for Green For Go checklist
8.0	22/05/2024	Expanded to include all sponsored studies, previously CTIMP only Other changes for clarification Addition of FORM 56.001G and FORM 56.001H