

SOP number	<b>56.001</b>	Version	<b>9.0</b>
Title	<b>Location Set up – Green for Go Process</b>		

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SOP category	NHS GG&C Project Management Unit			
Staff category				
<b>Staff Category</b>	<b>R</b>	<b>A</b>	<b>C</b>	<b>I</b>
GCRF Clinical Research Manager		X		
R&I Systems Manager	X			
Sponsor Research Coordinator	X			
Project Managers	X			
Chief Investigator			X	
Principal Investigator				X
Sponsor Pharmacy				X
Clinical Trial Monitors				X

## 1. Scope

This procedure applies to the Project Management Unit (PMU) staff and 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 with University of Glasgow (GU), and supported by either PMU or a study specific PM.

For the purpose of this SOP, the location 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 locations prior to start of recruitment and treatment.

### **3. Procedures**

#### **3.1. Prior to Green for Go approval**

##### **3.1.1. Trigger of process**

When all relevant 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 locations that have been identified as part of the capability assessment process (SOP 56.007). This email will detail the actions required before Green for Go can be issued. Alternatively one of the templates available from the HRA could be used to share the Local Information Pack with participating locations.

For CTIMP / CIMD: The PM will prepare and forward study investigator site files (ISF) using the NHSGGC Principal Investigator Site File index Form 51.016C (for CTIMPs and CIMDs). If a participating location indicates that they wish to use an electronic ISF in line with their local processes they should be asked to complete and return Form 56.001I. The Sponsor team (Research Co-ordinator, QA Manager or Lead CTM) will use this to ensure that the system used at the participating location meets their requirements.

For all other research studies: The PM will forward the ISF index (Form 56.001H) that the site should use.

##### **3.1.2. Completion of Green for Go checklist**

The PM will work with the local research 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 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). The Sponsor Regulatory Green Light (RGL) must be in place prior to the location level Green for Go being given.

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. Location/ Site Initiation Visit (SIV)**

A Location / Site Initiation Visit (SIV) will be carried out by the PM/study research team. The SIV Checklist (Form 56.001J) should be used to ensure all relevant points are included in preparation of the SIV slide set. The SIV will 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 an attendance sheet provided or 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 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
- Local pharmacy staff (for CTIMPs)
- Local 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 Sponsor Representative (when co-sponsored)
- Any other staff as deemed appropriate.

**4. Referenced documents**

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

**5. Related documents**

- SOP 51.020 Sponsor Regulatory Green Light

**6. Document History**

Version	Date	Description	Retrospective Implementation
1.0	28/06/13	Release of first version	No
2.0	04/11/15	Changes made to clarify process and address MHRA finding 3.1.1 and 3.4.4	No
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	No
4.0	17/10/2016	Change of staff category Addition of Protocol Signature Form Removal of site set-up letter to SOP 56.002	No
5.0	17/12/2018	Staff category updated	No
6.0	29/08/2019	Changes made to clarify process green for go sign off and documentation of SIV attendance	No
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	No
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	No
9.0	03/12/2025	Addition of FORM 56.001I and FORM 56.001J Other changes for clarification Site changed to Location as per change to regulations	No

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