| SOP number | **56.007** | Version | **2.0** |
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| Title | **Project Management Site Capability Assessment** | | |

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| SOP category | 56 NHS GG&C Sponsor Project Management Unit |

Staff category

| **Staff Category** | **R** | **A** | **C** | **I** |
|---|---|---|---|---|
| Project Management Unit | X | | | |
| Heart Failure Project Manager | X | | | |
| Robertson Centre for Biostatistics (RCB) Project Manager | X | | | |
| GCRF Manager | | X | | |
| Head of Clinical Trials for Heart Failure Group (University of Glasgow) | | X | | |
| Director of Operations RCB | | X | | |
| Sponsor Research Coordinator | | | | X |
| Chief Investigator | | | | X |
| R&I Systems Manager | | | | X |
| Senior R&I Manager | | | | X |

## 1. Scope

This procedure applies to Project Management Unit (PMU) staff and study specific Project Managers (PM). Accountability of this SOP differs as detailed in the RACI. This SOP does not cover studies coordinated by Cancer Research UK Clinical Trials Unit, Glasgow.

## 2. Purpose

The purpose of this SOP is to describe the project management procedure for selecting suitable sites to participate in studies sponsored or co-sponsored by NHS GG&C, or for studies of which NHS GG&C is the UK lead centre. It is essential that a site capability assessment is undertaken by each site, including in instances where there is only one site. This is to ensure that sites are able to conduct the study in accordance with the requirements of the protocol, will be able to deliver the recruitment and achieve the national time and target deadlines.

## 3. Procedures

### 3.1. Responsibilities

The site capability assessment process is part of the Project Manager's (PM) role to be undertaken in conjunction with the Chief Investigator (CI) and Sponsor stakeholders.

The CI will identify key sites. The PM is then responsible for liaising with sites to begin the capability assessment process.

The Members of the Trial Management Group (TMG) will be collectively responsible for assessing the capability of the prospective site(s) based on the information provided in the Site Capability Assessment Form (Form 56.007A).

Site capability assessment should be considered at the very early stages of setting up a new trial, although additional sites may be identified at later stages (e.g. after recruitment has commenced) and this procedure still applies.

3.2. Site Selection and Feasibility

Potential sites may be identified by contacting investigators who have previous experience in the therapeutic area, recommendations by colleagues, via publications, professional groups or research networks.

Feedback should be obtained from TMG members as to suitability of potential sites, and any previous issues with the sites and/or investigator identified. Discussion and decision about potential sites should be captured in the TMG meeting minutes.

The PM will forward a Site Capability Assessment Form (Form 56.007A) which will be used to assess the site's suitability to participate against the protocol requirements. This will include their ability to recruit patients and an assessment of available staff resources and facilities. It is expected that an individual within the site team will be identified to complete the Site Capability Assessment Form on behalf of the site. This does not necessarily need to be the Principal Investigator (PI) but should be an individual with appropriate organisational knowledge.

Factors that should be considered during investigator site selection include:

- Interest in the research question
- Experience and qualifications of the investigator
- Ability to comply with the trial protocol
- Sufficient, suitably qualified and experienced staff to conduct the study
- Availability of suitable patient population, including:
    - Anticipated rate of patient recruitment (determined through feasibility assessments)
    - Conflicting studies (competing for the patient population and potentially introducing recruitment bias)
- Adequate time to conduct and oversee the trial
- Suitable facilities, including:
    - Availability of any specialised diagnostic or therapeutic equipment required by the protocol
    - Satisfactory space and storage conditions (including archive)
    - Available resources in NHS support departments
- Track record of recruiting
- Geographic location

It is recognised that there will be sections of the Site Capability Assessment Form that are not relevant to every study and the template should be adapted accordingly.

When undertaking site selection, the preparation of 'reserve' investigator sites should also be considered as part of proactive trial planning (so that the trial may be extended to these sites if recruitment issues arise).

Completed Site Capability Assessment Forms should be returned to the PM and reviewed at Trial Management Group level to determine the site's suitability. The site capability assessment can have 3 outcomes

- Feasible – no future action required
- Potentially feasible – areas to be addressed
- Not feasible at this time

The Project Manager will confirm in writing to the Principal Investigator at each individual site the outcome of the site capability assessment and whether their site has been selected to participate.

Once it is confirmed that the site is deemed suitable to participate, the Green For Go process (SOP 56.001) and Project Management Trial Set-up process (SOP 56.002) can commence.

The Site Capability Assessment Form will also provide information for developing the formal site agreement between the Sponsor and participating site.

If for any reason the participating site is unable to meet the criteria originally provided in the Site Capability Assessment Form, for example; the agreed recruitment target, then this should be discussed at Trial Management Group meetings (SOP 56.003).

The Project Manager will ensure that completed Site Capability Assessment Forms will be retained in the appropriate section of the Trial Master File (TMF). Paperwork for sites kept in reserve or not progressed forward from the feasibility phase will also be stored for reference in this section.

## 4. Referenced documents

- Form 57.007A – Site Capability Assessment Form

## 5. Related documents

- SOP 56.001 Site Set up – Green For Go Process
- SOP 56.002 Project Management Trial Set-Up
- SOP 56.003 Project Management: Managing an Active Trial

## 6. Document history

| Version | Date | Description |
|---|---|---|
| 1.0 | 26/08/2019 | First release |
| 2.0 | | Update to SOP template v2.0<br>Addition of RACI matrix<br>Wording updated |

| Version | Date | Description |
|---|---|---|
| | | Clarification to site selection process added<br>Addition of external PMs as SOP category<br>SIG/SMG changed to TMG in line with other SOP revisions |