Standard Operating Procedure (SOP)

Site Feasibility and Selection

SOP ID Number:	JRESGOVSOP0050	**Effective Date:**	04/11/2021
Version Number and Date:	Version 1.0 26/04/2021	**Review Date:**	04/11/2023
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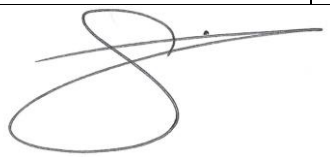
Signature of Authoriser			

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They may print off this document for training and reference purposes.

SOP Chronology		
SOP Version Number:	**Reason for Change:**	**Author:**
V1.0	Original Version	Ali Alshukry / Georgia Bullock

Associated JRES documents

SOPs	WPDs	Docs	LOGs
	JRESWPD0023 General Research Definitions	JRESDOC0083 Site Feasibility Checklist Form	

Contents

1. Background

ICH GCP, and the UK Framework for Health and Social Care Research, outline that it is the Sponsor's responsibility to ensure selected Investigator(s) and study sites are suitable. It is therefore essential that a feasibility assessment is undertaken at each site to ensure that they are able to conduct the research in accordance with the requirements of the protocol, ethical and regulatory requirements, and will be able to recruit to time and target.

A comprehensive, study-specific site feasibility assessment can identify problems that may impact on the site's ability to deliver the trial/study and which need to be addressed. It should be conducted prior to any formal external site selection to allow early identification of delivery issues to enable resources and funding to be targeted appropriately.

Site selection/feasibility for studies sponsored by St George's is assessed using the Site Feasibility Checklist (JRESDOC0083).

2. Joint Research and Enterprise Services (JRES) Policy

All JRES SOPs will be produced and approved in accordance with the JRES SOP on SOPs and must be used in conjunction with local NHS Trust and University policies and procedures.

The JRES acts as the representative of both St George's University of London (SGUL) and St George's University Hospitals NHS Foundation Trust (SGHFT). St George's will be the official name used on all SOPs to represent either institution acting as Sponsor.

3. Scope

This Standard Operating Procedure (SOP) defines the procedure for identifying sites to undertake research studies sponsored by St George's.

It applies to both single and multi-site research studies.

4. Definitions

For general research-related acronyms used in this SOP, refer to the General Research Definitions Working Practice Document (JRESWPD0023).

Feasibility: the process of comprehensive assessment, to include any risk, resource and delivery assessments, to identify whether a site is able to deliver a study protocol.

5. Responsibilities

This SOP is to be followed by the JRES Research Governance and Delivery Team (RGDT) and the Chief Investigator (CI) of the proposed study.

The CI is responsible for:

- Undertaking the site feasibility process for St George's sponsored studies.
- Confirming the site feasibility decision, for non-IMP/Device trials, on behalf of the Sponsor.
- Communicating all feasibility reviews and outcomes to the JRES.
- Ensuring that all Site Feasibility Checklists are filed in the TMF.

The JRES (Sponsor) is responsible for:

- Completing the Sponsor review of site feasibility assessments where applicable.
- Liaising with the CI and recording any discussion about the inclusion of individual sites.
- For IMP/Device trials, reviewing the completed Site Feasibility Checklists and confirming the outcome of an individual site's assessment/suitability.
- For all studies, ensuring that the Sponsor files are updated with Site Feasibility evidence.

6. Procedure

Investigators wishing to undertake research sponsored by St George's must consider the process for site selection during sponsorship review. The application and risk assessment process for sponsorship requires each site to complete to complete a feasibility assessment. Sites will not be added without an assessment.

A site's feasibility assessment can have 3 outcomes:

- Feasible – no further action is required.
- Potentially feasible – there are areas to be addressed/resolved.
- Not feasible at this time.

It is expected that the CI will delegate the site feasibility process to an appropriate individual and collate all responses from the sites to send to the Sponsor.

- The CI will sign-off feasibility for all non-IMP/Device studies on behalf of the Sponsor (this can not be delegated). Confirmation of whether or not a site is viable (based on the form completed by the site) must be communicated to the JRES.

- The Sponsor (JRES) will, for IMP/Device trials, receive the completed Site Feasibility Checklist from each site and will discuss the inclusion of the site with the CI. The CI will inform the PI at the site of the decision, copying the JRES and the R&D department at the site into the email.

For trials involving an IMP, the Pharmacy section of the form must be completed by the site's Pharmacy department. The form must be completed by a suitably qualified individual within the department. A CV should be attached to the assessment to notify the Sponsor that the individual is suitably qualified to complete the form.

It is expected that an individual within each site will be identified to complete the Site Feasibility Checklist for their site. This does not necessarily need to be the Principal Investigator (PI) but should be an individual with appropriate organisational knowledge.

For certain types of studies, the process may include a site selection visit. This can be conducted by the CI/their delegated indvidual and/or a member of the JRES team.

It is recognised that there will be sections of the Site Feasibility Checklist which are not relevant to every study. In these cases, it must be made clear on the form that the protocol does not require these sections to be completed.

All correspondence and the Site Feasibility Checklist must be retained in the site's Investigator Site File, the CI's Trial Master File within the individual site section, and the Sponsor files (physical or electronic).

Selection of a site already known to the Sponsor:

If an Investigator and site has been involved in a St George's sponsored study within the 12 months prior to the intended study start date, the following additional factors must be taken into consideration:

- The site/Investigator's previous recruitment ability
- Protocol compliance record
- Frequency of changes in staff
- The specific requirements of the study protocol

The site must still complete a Site Feasibility Checklist.

7. References

ICH GGP.

UK Policy Framework for Health and Social Care Research

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

8. Appendices

None associated with this SOP.