Standard Operating Procedure (SOP)

Delegation of Sponsorship Duties for CTIMPs

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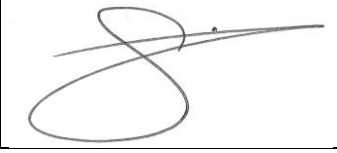
Signature of Authorisor			

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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	JRESDOC0013 DDSA for CTIMPs	

Contents

1. Background

A Sponsor is defined as: 'An individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial'.

The UK Clinical Trial Regulations define the legal responsibilities that the Sponsor must arrange to carry out. These legal responsibilities should not be confused with liability for the harm of a subject.

St George's, as a Sponsor, must define and allocate the trial-related duties and functions that need to be delegated before initiating a trial. St George's remains accountable for all aspects of sponsorship whether delegated or not.

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 SOP will describe the main principles and procedures for delegation of sponsor duties for CTIMPs sponsored by St George's. Specific details will be detailed in legal agreements or delegation logs where applicable.

Specific delegation of activities/duties to the CI is covered in the DDSA_CTIMP Document (JRESDOC0013).

4. Definitions

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

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 trial.

6. Procedure

6.1 Principles of Delegation

Whilst St George's, as Sponsor, is legally responsible for the overall conduct of a trial, the regulations allow for certain functions to be shared or delegated by written agreement. Before the trial starts, St George's will assess, agree and record which functions it is appropriate to delegate to other organisations. This will be documented in the model agreement.

6.2 Decision to Delegate

Decisions to delegate accountability for specific functions will be made by the Head of Research Governance and Delivery (HRGD) or their designee, in conjunction with the CI and the organisation/s, depending on the resources required and available for the trial, level of experience and related training acquired.

The rationale for delegation and description of duties will be discussed by the HRGD, Research Development and Governance Manager (RDGM), Clinical Research Associate (CRA), CI, and others as needed for the trial. This must take place in advance of applying for regulatory approvals.

6.3 Vendor Assessment

The Sponsor will assess the capability and capacity of the other party to undertake the function. This will include a combination of the following:

- Confirming staff qualifications, clinical research experience, medical licences, CVs and training records, and other relevant documentation to assure suitability to lead or participate in the trial.
- Reviewing accreditation certificates (eg: Medicines and Healthcare products Regulatory Agency (MHRA) Phase1 unit accreditation, or applicable trial investigator accreditations).
- Enquiring about capacity and capability.
- Confirming that the Quality Management System and SOPs, forms and templates are appropriate.

- Reviewing any recent applicable audit/inspection findings.
- Requesting any other applicable additional information or evidence of expertise.

The Sponsor and other party will then agree the functions to be delegated, in person or via correspondence, and then will clearly define them in the model agreement between the parties.

Vendor selection must also incorporate formal organisations procurement requirements.

6.4 Delegation Oversight

For St George's to retain oversight of the delegated function(s), the requirements below must be agreed to by the delegated party:

- To copy in the St George's assigned JRES member on all correspondence.
- To provide status reports at an agreed frequency.
- To provide assurance that SOPs, templates, forms which are to be used are compliant with the relevant regulations and policies.
- To attend research team meetings where applicable.
- To provide copies of meeting minutes, and key correspondence.
- To permit Quality Assurance audit(s) by a St George's representative.
- To ensure a mechanism is in place to feed any breaches back to the Sponsor and report to the MHRA.
- To share, for Sponsor review and sign off, study documentation (eg: Monitoring Visit Reports, Data Management Plans, Statistical Analysis Plans, review of deviation logs, audit trails etc.).
- To agree to shared monitoring visits where requested.

7. References

https://www.hra.nhs.uk/planning-and-improving-research/research-planning/roles-and-responsibilities/

8. Appendices

None associated with this SOP.