Standard Operating Procedure (SOP)

Sponsorship and Governance Processes for International Studies at St George's, University of London

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The master document is posted on the JRES website and any print-off will be classed as uncontrolled.

Researchers and their teams are responsible for checking the JRES website for the most recent version. They may print off this document for training and reference purposes.

SOP Chronology		
SOP Version Number:	**Reason for Change:**	**Author:**
V1.0	Original Version	Sarah Burton
V2.0	Updated processes for interventional studies and non-interventional studies. Inclusion of DPIA as a required document. Removal of the need to report all SAEs/AEs to the sponsor, unless classed as a SUSAR.	Georgia Bullock / Sarah Burton

Associated JRES documents

SOPs	WPDs	Docs	LOGs
JRESGOVSOP0003 Sponsorship for CTIMPs JRESGOVSOP0028 Applying for Sponsorship for Non-CTIMPs	JRESWPD0023 General Research Definitions	JRESDOC0013a DDSA for International Studies (no UK sites) JRESDOC0076 UK and International TMF Index JRESDOC0076a International Only Studies (no UK sites) TMF Index JRESDOC0118a Study Registration Questionnaire INTERNATIONAL JRESDOC0119a Risk Assessment Tool International JRESDOC0123 St George's Research DPIA JRESDOC0127 Sponsorship and Governance Checklist International Studies	

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1. Background

A Sponsor takes responsibility for the initiation, management and/or financing (EU Directive 2001/20/EC) of research and clinical trials. It is a legal requirement that all Clinical Trials of Investigational Medicinal Products (CTIMPs) have a Sponsor that is willing and able to take on the responsibilities and liabilities under the current clinical trial legislation.

The Sponsor is usually the company, institution or organisation that is taking responsibility for initiating, financing and/or managing the clinical trial. All trials must be adequately funded to ensure that the trial can be set up and conducted in accordance with the relevant legislation.

The Sponsor has the primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting. This includes the implementation and maintenance of quality systems and written Standard Operating Procedures (SOPs) to ensure that trials are conducted, and data generated, documented and reported, in compliance with the protocol, Good Clinical Practice (GCP) and the applicable regulatory requirements.

It is the expectation that the St George's Research Ethics Committee (SGREC) document templates (e.g. Protocol, Patient Information Sheet, Informed Consent Form) will be used by Investigators for all international studies which are to be considered for sponsorship by St George's.

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 describes the governance process for all international clinical research studies which are sponsored by SGUL. SGHFT is unable to act as sponsor for international studies.

This SOP details the documentation required to allow sponsorship to be issued and the processes that should be followed to ensure appropriate sponsor oversight of the study.

This SOP must be used in conjunction with any relevant SGUL policies and procedures.

4. Definitions

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

DPIA: Data Protection Impact Assessment

5. Responsibilities

This SOP should be read, understood and followed by the Governance/Regulatory JRES team and all those in the research team responsible for the set up and management of any international studies.

6. Overview

International studies should be forwarded to the regulatory governance team (sponsor@sgul.ac.uk) at the earliest opportunity to begin the governance process. The level of review will depend on the type of study (eg: interventional, observational).

All international studies applying for SGUL sponsorship will need to be submitted to the St George's Research Ethics Committee (SGREC) Ethical Review Process (sgul.ac.uk) A Favourable Opinion letter will be required from the SGREC. Queries regarding the SGREC application should be directed to sgulrec@sgul.ac.uk.

This is in addition to the submissions to the country-specific Ethics Committees. It is the responsibility of the CI to know what approvals are needed in each country and to ensure that these are obtained prior to study start. These approvals can include, but are not limited to, site/institution RECs, national RECs, national regulatory bodies and national health boards.

It is a requirement that the JRES maintains oversight of all international studies sponsored by SGUL. The operational management and coordination of the study is the responsibility of the CI/their research team.

Please note: if the trial has **both UK and international sites**, JRESGOVSOP0003 (CTIMPs) and JRESGOVSOP0028 (non-CTIMPs) should be followed for the UK sites and this SOP should be followed for the international sites.

7. Procedure

7.1 CTIMPs/Interventional Studies

1. The research team/CI should inform the regulatory governance team of the study at the earliest opportunity.

2. The CI is responsible for preparing the study documents using the SGREC templates and submitting them to the SGREC for review/approval.
3. The research team/CI will be asked to provide the following to the regulatory team:
    - Protocol
    - Participant Information Sheet / Informed Consent Form
    - Other participant facing documents (diary cards, recruitment posters, questionnaires etc.)
    - EudraCT Registration email (if applicable)
    - Public database registration
    - Funding agreement (when available)
    - Investigator Brochure / SmPCs (if applicable)
4. The research team will be responsible for the creation and maintenance of the Trial Master File (TMF) and any Investigator Site Files (ISF).
5. The Clinical Research Associate (CRA) will create an electronic Sponsor Site File (eSSF) using the relevant template folders.
6. The CRA will assign the study a JRES study reference number (if this has not already been assigned by the SGREC) and inform the research team of this.
7. The CRA will send the following documents to the research team for completion:
    - Delegation of Duties Signed Agreement (DDSA)
    - Study Registration Questionnaire (International)
    - Insurance Enquiry questionnaire (if applicable)
    - St George's Research DPIA
8. The CRA will review the received documents and complete a Risk Assessment based on the responses in the Study Registration Form. The CRA will assign the study a level of risk.
9. The CRA will send the Insurance Request Form, draft protocol and draft PIS to the SGUL insurer for quotes. The CRA will liaise with the research team for any further information required. Quotes will need to be approved by the research team before a policy can be purchased. Insurance invoices should be sent to the JRES Office Manager or equivalent, who will organise a PO number and the payment with accounts. A budget code will be needed for payment. Evidence of payment will need to be provided to the SGUL insurer. The CRA/study team must ensure that the insurance policy (and not just a certificate) has been received prior to the study opening to recruitment.
10. The CRA will forward a copy of the International Trials site agreement for the research team to localise accordingly and forward to the relevant site for review. Any changes need to be in

tracked change and sent back to the JRES for review. The research team cannot approve any agreement deviations without JRES approval. Final agreement approval and authorisation remains a JRES responsibility.

11. When all UK approvals are in place and all required documents listed above have been received by JRES, the Head of Research Delivery and Governance/Research Governance and Development Manager will issue a Final Sponsorship letter.
12. The research team should send the CRA and the SGREC the approvals for all sites/countries conducting the study.
13. The CI/research team should provide the following documents to the CRA before an 'Open to Recruitment' letter will be issued:
    - All approval letters
    - Signed site agreement between the site and SGUL
    - A copy of the Monitoring Plan
    - A copy of the SIV Report
    - Any signed Material Transfer or Data Sharing Agreement (these may be provided during the study but prior to any data/material transfer)
    - The IMP Management Plan (where applicable)
    - Confirmation of receipt of the IMP

14. Throughout the study, the CI/research team should provide the following documents/reports to the CRA, and where required, to the SGREC:
    - SUSAR notifications
    - Copies of the signed monitoring reports
    - Any amendment documentation and updated study documents
    - Annual Progress Reports
    - Minutes from Trial Committee meetings
    - End of trial notification

15. The CI/research team must also comply with the requirements of the SGREC's Favourable Opinion, as listed on the letter.
16. Serious Adverse Events (SAEs) and Adverse Events (AEs) do not need to be reported to the sponsor unless categorised as a SUSAR. All SAE/AEs should be listed in the Annual Progress Report (APR) and reported according to local requirements.

7.2 Non-interventional Studies

1. The research team/CI should inform the regulatory governance team of the study at the earliest opportunity.
2. The CI is responsible for preparing the study documents using the SGREC templates and submitting them to the SGREC for review/approval.
3. The research team will be responsible for the creation and maintenance of the Trial Master File (TMF) and any Investigator Site Files (ISF).
4. The Clinical Research Associate (CRA) will create an electronic Sponsor Site File (eSSF) using the relevant template folders.
5. The CRA will assign the study a JRES study reference number (if this has not already been assigned by the SGREC) and inform the research team of this.
6. Where insurance is required, the CRA will send a draft protocol/PIS to the insurer to obtain a quote. The policy and certificate must be in place prior to the start of the study.
7. The research team/CI will be asked to provide the following to the regulatory team:
    - Protocol
    - Participant Information Sheet / Informed Consent Form
    - Any other participant-facing documents
    - A completed St George's Research DPIA
    - SGREC Favourable Opinion letter
    - Public database registration
    - Funding agreement

8. When all of these documents have been received, the CRA will issue a Final Sponsorship Letter.
9. The CI/research team should provide the following documents to the CRA before an 'Open to Recruitment' letter will be issued (if applicable):
    - Copies of all study approvals (UK and country-specific)
    - Signed site agreement between the site and SGUL
    - Insurance policy/certificate or confirmation that insurance is not required
    - Any signed Material Transfer or Data Sharing Agreement (these may be provided during the study but prior to any data/material transfer)

10. Throughout the study, the CI/research team should provide the following documents/reports to the CRA (the SGREC requirements listed on the Favourable Opinion letter must also be complied with):
    - Any amendment documentation and updated study documents
    - Annual Progress Reports
    - End of study notification

7.3 TMF Management

The CI/research team is responsible for the set-up and maintenance of the TMF (and any ISFs) for international studies sponsored by SGUL. The TMF should follow the International Only Studies TMF Index (JRESDOC0076a).

The TMF may be audited by the sponsor for completeness.

8. References

Policies, Standard Operating Procedures and Templates (sgul.ac.uk)

Ethical Review Process (sgul.ac.uk)

9. Appendices

None.