St George's University of London

St George's University Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure (SOP)

SOP ID number:	JREOSOP0031	**Effective Date:**	30/01/17
Version number and date:	V3 31/12/16	**Review Date:**	01/12/19
Author:	Debbie Rolfe	**Title:**	Acting Head of Research Governance
Approved by:	Mark Cranmer	**Date:**	27.1.17
Signature of Authorisor			

Standard Operating Procedure (SOP)

Escalation Procedure

SOP Chronology

SOP Version Number:	Reason for Change:	Author:
V1	Original Version	Lucy H H Parker
V2	All research conducted at St George's to be included	Debs Rolfe
V3	TROIKA role in between RGC scheduled meetings	Debbie Rolfe

1. Background

All research conducted at St George's will be in accordance with the key principles of ICH GCP to ensure that

- The rights and well-being of the human subjects are protected
- The reported trial data are accurate, complete, and verifiable from source documents
- The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with the applicable regulatory requirements.

Investigators will have agreed to follow and abide by the approved protocol, Sponsor standard operating procedures (SOPs) and the Research Governance policies of St George's at the point of receiving St George's Host Site approval and/or Sponsorship by St George's.

Monitoring is an integral role in the Quality Control (QC) of a clinical trial and is designed to verify the quality of the study. Should the findings detailed in the monitoring report not be corrected, this could have an impact on the QC of a study. Therefore, it is important to have in place, an escalation procedure should there be non-compliance in relation to monitoring reports.

The Research Governance team of the JREO have an annual target of auditing 10% of all research studies hosted and/or Sponsored by St George's. The aims of this activity are to measure compliance with applicable regulations, assure safe patient management and appropriate use of data. Each audit finding will be referenced against the regulation and suggestions made for remedial actions.

Collective data from the Research Governance audits can collectively inform the Research Governance team of any areas of concern which may shape future training sessions, highlight non-supportive Sponsor organisations or research teams that may need support in terms of correct skill-mix or institutional failings – where practice generally may need to change or adjust appropriately. The investigators will be expected to respond to any audit findings highlighted within 1 month of receipt of the audit report. Failure to do so will be seen as non-compliance.

Investigators may be contacted by members of the Joint Research and Enterprise Office from time to time throughout the lifetime of the study and documentation or evidence of required documentation, study progress updates can be requested. Following receipt of such requests the Investigator will be expected to respond within an acceptable time frame dependent on urgency of the request.

2. Joint Research and Enterprise Office (JREO) Policy

All JREO SOPs will be produced and approved in accordance with the JREO SOP on SOPs and must be used in conjunction with local NHS Trust and St George's policies and procedures.

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

3. Scope

This SOP covers the escalation procedure of non-compliant studies that are hosted and/or Sponsored by St George's.

This SOP does not cover the escalation process of serious breaches of Good Clinical Practice (which is covered in JREOSOP0032) and does not cover complaints made by participants of studies (JREOSOP0026 should be followed for participant complaints.)

4. Definitions

None needed for this SOP.

5. Responsibilities

This SOP should be read and followed by the Principal Investigator and their team. It should also be read and followed by the Research Governance Team of the JREO and the Research Governance Committee (RGC).

6. Procedure

6.1 Investigator Procedure

It is important that the investigator and their team respond to any communications from the Joint Research and Enterprise Office Research Governance Team in a timely manner and within any given deadlines which may be set by the requestor following previous failed attempts.

If the investigator persistently does not respond to requests from the JREO or correct findings from previous monitoring visits or respond to Audit findings, this could bring doubt on the reliability of the data produced , the possible safety of participants ; the ability of the Investigator to manage his/her agreed responsibilities which could increase the risk borne by St George's, therefore it is vital that investigators respond to written requests by the JREO in a timely fashion.

Should the JREO decide that the study is to be closed to new recruitment (see section 6.2),

St George's Sponsored Research

It is the investigator's responsibility to complete a substantial amendment form and send it to the JREO for approval. The amendment form will be to suspend the study to new recruitment until the findings have been corrected. The investigator will then be authorised by the JREO to complete another substantial amendment reopening the study to new recruitment.

Hosted Research not Sponsored by St George's

The JREO will inform the Sponsor/Clinical Research Organisation of the decision to suspend recruitment and the related circumstances. The JREO may be required to assist the Sponsor in the identification of an alternative PI.

The study team should endeavour to communicate efficiently with the JREO Research Governance team and respond quickly to any request or query.

If the study team are still not communicating or responding within the given timelines, then the investigator will be expected to appear before the Research Governance Committee (RGC) or TROIKA in order to discuss the future of the study. Researchers must be aware that Sponsorship and/or host site approval maybe revoked by the committee for non compliance.

If there are issues which result in the requests being unanswered/unresolved within the given time frame, the researcher must discuss this with their assigned JREO Research Governance contact **as soon as possible.**

6.2 JREO Procedure

The JREO Research Governance team member should discuss any concerns regarding audit findings or Monitoring report findings or consistent communication problems by a study team with the Regulatory Assurance Manager (RAM) or Head of Research Governance (HRG) detailing the given deadline for expected resolution.

The JREO Research Governance team member will repeat the written request for resolution of outstanding issue(s) addressed to the Principal Investigator. Reference to this escalation procedure JREOSOP0031 will be made and the date when the response is required– this will dependant on the possible perceived risk to Patients / trial data/institution. Ensure the RAM or HRG is cc'd into the communication. Clearly state that the study will be suspended to new recruitment if a satisfactory response is not received by the date stated.

If the study team fails to respond adequately within the requested timeline, the study will be suspended to new recruitment until the RAM/HRG is satisfied the study is compliant. The suspension will be notified to the REC and to the MHRA (where applicable) by completion of a substantial amendment form. Support departments such as pharmacy and any participating sites (if a St George's Sponsored study) will also be informed that the study is suspended to new recruitment until further notice.

Recruitment following suspension will constitute a Serious Breach of GCP.

When the CI states that the study audit or monitoring findings have been corrected, the assigned Research Governance team member will perform a visit to assess whether the corrections are appropriate. If they are –the JREO Sponsor Representative will notify the REC and MHRA (where applicable) that the study is reopened through submitting an amendment, (see JREOSOP0011 Management of Amendments) Support departments such as pharmacy and all participating sites will be told that the study is re-opened to new participants.

If the study is still not compliant within one calendar month of suspension, this will be escalated, within 2 working days of the deadline passing, to the Research Governance Committee (RGC) or TROIKA (where awaiting RGC scheduled meeting would be impractical) for possible revoking of St George's Sponsorship and insurance for St George's Sponsored studies, or in the case of hosted studies, revoking host site approval.

If closing the study at St George's or revoking Sponsorship would pose a risk or adveresly affect the ongoing patient management then identifying an alternative Principal Investigator should be considered. All responsibilities by the non-compliant team members should be revoked. The Delegation of Responsibilities log should be updated with end dates for those team members. A simple report of reasons leading to escalation procedure – actions taken by whom should be placed in the Site file. Sponsors in the case of hosted studies, and funders in the case of St George's Sponsored studies should be kept fully informed at each stage of the process.

When TROIKA have been consulted between scheduled RGC meetings the membership will ensure a summary of the consultation/escalation circumstances and any actions taken are summarised for discussion at the next scheduled RGC meeting.

The RGC will include in the committee minutes the subjected study JREO database reference, the study team member(s), the issues raised and the recommended actions. The RGC will also note details of the issue raised and members will be invited to vote on any further action to be taken. The RGC should also consider risk to any other research studies noted as active on the JREO database and possible actions to be taken . TROIKA will be contacted in between scheduled RGC meetings to raise issues or to communicate follow up actions.

The Research Governance team will add a note on the governance database against the Investigator entry *of non-compliance with St George's policies and procedures.*

RGC opinion should be sought to allow future research activity for non-compliant Investigators.

7. References

JREOSOP0009 – Monitoring of CTIMPS Sponsored by St George's
JREOSOP0011 - Management of Amendments
JREOSOP0026 - Handling of Research Participant Complaints
JREOSOP0032 – Reporting Serious Breaches of GCP or Trial protocol
JREOWPD0006 - Audit Programme

8. Appendices

No appendices are associated with this SOP