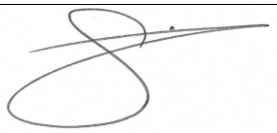
Standard Operating Procedure (SOP)
Escalation Procedure

SOP ID Number:	JRESGOVSOP0031	**Effective Date:**	12/01/2022
Version Number and Date:	Version 4.0 22/04/2021	**Review Date:**	12/01/2024
Author:	Georgia Bullock	**Title:**	Research Development and Governance Manager
Approved by:	Subhir Bedi	**Date:**	11/01/2022
Signature of Authorisor			

This is a controlled document.
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 purpose

SOP Chronology		
SOP Version Number:	**Reason for Change:**	**Author:**
V1.0	Original Version	Lucy H H Parker
V2.0	All research conducted at St George's to be included	Debs Rolfe
V3.0	TROIKA role in between RGC scheduled meetings	Debbie Rolfe
V4.0	Updated escalation procedure in Section 6. Administrative changes to text. Addition of associated JRES documents. Update to procedure to reflect current practice.	Georgia Bullock

Associated JRES documents

SOPs	WPDs	Docs	LOGs
JRESGOVSOP0009 Site Initiation, Monitoring and Close-Out for CTIMPs Sponsored by St George's JRESGOVSOP0026 Handling Research Participant Complaints JRESGOVSOP0032 Reporting of Serious Breaches JRESGOVSOP0035 Auditing	JRESDOC0023 General Research Definitions		

Contents

1. Background

All research conducted at St George's will be in accordance with the key principles of ICH Good Clinical Practice (GCP) to ensure that:

- The rights, safety and well-being of the human subjects are protected.
- The reported trial data is accurate, complete, and verifiable from source documents.
- The conduct of the trial is compliant with the current approved protocol and the applicable regulatory requirements.

Investigators must agree to follow and abide by the approved protocol, the JRES (Sponsor) Standard Operating Procedures (SOPs) and the Research Governance policies of St George's, for all research studies/trials sponsored by and/or hosted at St George's.

The Sponsor is ultimately responsible for the quality of a study/trial. Monitoring and audit play a key role in the quality management of a clinical trial/study, to ensure compliance with applicable regulations, assure safe patient management and appropriate use of data. Findings from audits or routine monitoring visits must be appropriately actioned by the Investigator and their team, according to the agreed timelines specified in the audit/monitoring report. Data collected from monitoring visits and audits can highlight any areas of concern to the Research Governance team and can identify training needs or a need for the change in research practice.

An escalation procedure must be in place for any non-compliance in relation to the resolution of issues documented in monitoring/audit reports. Persistent non-compliance with the Sponsor's requirements, study requirements and/or regulatory requirements may trigger further actions, eg: additional monitoring visits, auditing or the suspension of patient recruitment until the issues have been addressed.

An escalation procedure is also required for any concerns raised about the conduct of hosted studies/trials, by external Sponsors.

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 both institutions acting as clinical trials Sponsor.

3. Scope

This SOP covers the escalation procedure for non-compliance on studies that are hosted and/or sponsored by St George's.

This SOP does not cover the process for reporting serious breaches of GCP or the protocol (see JRESGOVSOP0032) and does not cover complaints made by participants of studies (see JRESGOVSOP0026).

4. Definitions

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

5. Responsibilities

Investigators and their research teams are responsible for following the procedures outlined in this SOP.

The Research Governance Team of the JRES and the St George's Research Governance Committee (RGC) are also responsible for following the procedures outlined in this SOP.

The JRES Research Governance Team responsible for Research Compliance comprises of: the Head of Research Governance and Delivery (HRGD), Research Development and Governance Manager (RDGM); Research Governance and Facilitation Officers (RGFOs); Clinical Research Associates (CRAs); Clinical Research Auditor.

6. Procedure

Studies Sponsored by St George's

- PIs and research teams must respond to any JRES requests, relating to monitoring or audit findings and required actions, in a timely manner and within any set deadlines.
- A persistent lack of correspondence or co-operation from an Investigator/team member relating to findings/actions from monitoring visits or audits will be escalated by the assigned CRA or Auditor to the RDGM.
- The RDGM will escalate any issues to the HRGD if deemed necessary and to the Research Governance Committee (or its sub-committee) if required.
- Investigators must be aware that non-compliance may lead to recruitment being suspended until the issues are resolved or may affect their role on future studies sponsored by St George's. In serious cases, the sponsorship of the study may be revoked.
- Serious non-compliance issues, where sponsorship could be revoked, will be escalated to, and reviewed by, the Research Governance Committee (RGC).

Studies Hosted (but not sponsored) by St George's

- PIs and research teams must respond to any JRES requests or queries in a timely manner and within any set deadlines.
- The Sponsor/CRO must be kept informed of any non-compliance issues at the St George's site and related actions.
- Any research governance findings/concerns identified during Sponsor monitoring visits or audits at the St George's site must be provided to the HRGD and/or RDGM by either the Sponsor or the Research Governance and Facilitation Officers within the JRES.
- Where applicable, the JRES will follow up with the study team or department to ensure oversight of any corrective and preventative actions (CAPA) that have been, or need to be, implemented and to assess any additional training that may be required.
- Investigators must be aware that persistent or serious non-compliance issues may lead to recruitment at the site being suspended until the issues are resolved or host approval being revoked by the RGC. if deemed necessary issues can be escated to the Research Governance Committee (or its sub-committee)

Suspension of a Study to Recruitment

- The study team will be notified that the study will be suspended to new recruitment if non-compliance findings are not actioned during the set timelines, until the JRES are satisfied that the study is compliant. Timelines must take into account any possible perceived risk to the study participants, data or to the institution.

- The JRES will inform the Sponsor/Clinical Research Organisation for hosted studies of the decision to suspend recruitment and the related circumstances.
- The suspension will be notified to the REC and to the MHRA (where applicable) immediately or at least within 15 days, by the completion and submission of a substantial amendment. For hosted studies, the Sponsor will be notified and they will be responsible for doing this. Support departments such as the 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.
- **Please note:** any recruitment undertaken during suspension constitutes a Serious Breach of GCP and must be reported as such.
- When the CI or PI states that the findings have been corrected, the assigned Research Governance team member will perform a visit to assess whether the corrections are appropriate and complete.
- Once the JRES are satisfied that the findings have been actioned appropriately, the REC and MHRA (where applicable) will be notified that the study is re-opened through submitting a substantial amendment. For hosted studies, the Sponsor will be notified. Support departments such as pharmacy and all participating sites must be informed when the study recruitment has re-commenced./
- If a study is not compliant within one calendar month of suspension, this will be escalated, within 2 working days after the deadline, to the RGC for possible revoking of St George's sponsorship or host site approval.

Revoking Sponsorship or Host Approval

- If closing the study at St George's or revoking the sponsorship would pose a risk or adversely affect the ongoing patient management/care, then identifying an alternative Principal Investigator (PI) should be considered. The JRES may be required to assist the Sponsor in the identification of an alternative PI for hosted studies.
- All responsibilities by the non-compliant team members should be revoked. The Delegation of Duties log should be updated with end dates for those team members.
- A simple report of reasons leading to the decision and the actions taken and 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.

RGC / Sub-RGC

- The RGC (or sub-RCG where appropriate, to avoid any delays) will include in the committee meeting minutes the subjected study JRES 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 JRES database and possible actions to be taken.

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

7. References

https://www.hra.nhs.uk/approvals-amendments/amending-approval/

https://www.gov.uk/guidance/clinical-trials-for-medicines-manage-your-authorisation-report-safety-issues#suspend-or-terminate-a-trial

8. Appendices

None associated with this SOP.