# Standard Operating Procedure (SOP)
# Transferring Sponsorship

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| **SOP ID Number:** | JRESGOVSOP0046 | **Effective Date:** | 04/11/2021 |
| **Version Number and Date:** | Version 3.0<br>26/04/2021 | **Review Date:** | 04/11/2023 |
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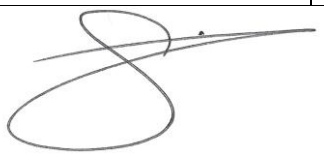
| **Signature of Authorisor** |  | | |

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

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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 | New Logo and Trust name, change of title from CRGM to HRG | Lucy H H Parker |
| V3.0 | Updates from JREO to JRES. Updated Associated JRES documents table. Updated procedure for studies being transferred into St George's. | Georgia Bullock |

Associated JRES documents

| SOPs | WPDs | Docs | LOGs |
|---|---|---|---|
| JRESGOVSOP0011 Management of Amendments for Studies Sponsored by St George's<br><br>JRESGOVSOP0003 Sponsorship for CTIMPs<br><br>JRESGOVSOP0028 Applying for Sponsorship for Non-CTIMPs | JRESWPD0023 General Research Definitions<br><br>JRESWPD0007 Issuing Sponsorship – CTIMPs<br><br>JRESWPD0013 Issuing Sponsorship – Non-CTIMPs | | |

# Contents

## 1. Background

A Sponsor takes responsibility for the initiation, management and/or financing of research and clinical trials. All health and social care research should have a Sponsor. It is a legal requirement for Clinical Trials of Investigational Products (CTIMPs) to have a Sponsor that is willing and able to take on the responsibilities and liabilities outlined in the Clinical Trials Regulations. The UK Policy Framework for Health and Social Care Research states that all research should have a Sponsor. The Framework defines the Sponsor as an 'individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study.'

The responsibilities of a Sponsor, for all research, including CTIMPs, are set out here: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/roles-and-responsibilities/

For CTIMPs and regulated Medical Device trials, St George's will only act as Sponsor where the:

- CI is substantively employed at either St George's, University of London or St George's University Hospitals NHS Foundation Trust.
- CI Is at medical consultant level within a relevant speciality to the patient group.
- CI is currently GMC/BDS registered with no restrictions.
- Study has sufficient funding and central resource to ensure safe and compliant management.

For non-CTIMP studies, St George's will only act as Sponsor where the:

- CI is substantively employed at either St George's, University of London or St George's University Hospitals NHS Foundation Trust.
- CI is suitably qualified and experienced within a relevant speciality to the patient group.
- CI has no professional restrictions and where applicable is registered with a professional body.
- Study has sufficient funding and central resource to ensure safe and compliant management.

## 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 outlines how the sponsorship of trials/studies can be transferred to or from St George's.

This SOP is to be followed by the JRES Governance team and the Chief Investigator (CI) of the trial/study.

## 4. Definitions

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

## 5. Responsibilities

It is the responsibility of the CI to ensure that the transfer of sponsorship is completed with the full knowledge of both organisations involved.

## 6. Procedure

**Investigator Procedure:**

### 6.1 Studies Transferring into St George's

- Once the CI has decided they would like to transfer a study to St George's, they should contact the JRES as soon as possible to see whether the transfer is possible.
- Once the JRES has confirmed it is willing in principle to accept the transfer of sponsorship, the CI must obtain written confirmation from the existing Sponsor that they are willing to

transfer sponsorship to St George's. This letter should include any financial arrangements where applicable, such as the transfer of the study grant.

- The study should be treated as a “new” project for a sponsorship request. If the study is a CTIMP, JRESGOVSOP0003 Sponsorship for CTIMPs should be followed, if the study is a non-CTIMP, JRESGOVSOP0028 Applying for Sponsorship for Non-CTIMPs should be followed.
- Once the written confirmation of JRES acceptance has been received, the CI must then modify all their existing ethically-approved documents to reflect the change in sponsorship. The CI must also produce a substantial amendment form reflecting the change in Sponsor. These documents must be submitted to the JRES and the existing Sponsor for approval.
- Once the JRES has approved these documents, the JRES will then confirm sponsorship in line with relevant Sponsorship SOP.
- The JRES governance team will update the EDGE study entry and retain all correspondence and documents in the Investigator study (e-)folder.
- The CI must then obtain authorisation from the existing Sponsor and complete the amendment submission to the REC and HRA, ensuring that the relevant governance team contact within the JRES is included in all correspondence.
- Where applicable, any amendment submission to the MHRA will be co-ordinated by the original sponsor as part of the transfer.
- The CI must retain the MHRA (if applicable), REC and HRA approvals in the Trial Master File. The JRES will update the Investigator (e-)folder and the EDGE database.
- If the study is a not a CTIMP, then the CI will be responsible for informing all sites, where the study is active, of the change in Sponsor.
- If the study is a CTIMP, the CI must liaise with the JRES to notify all sites to ensure Sponsor oversight activities are initiated.
- JRES approval for amendments will be in accordance with JRESGOVSOP0011.

### 6.2 St George's Studies Transferring to a Different Organisation

- Once the CI has decided they would like to transfer sponsorship of an active St George’s study to a different organisation, they should contact the JRES as soon as possible to see whether the transfer is possible.
- Once the JRES has confirmed it is willing in principle to accept the transfer of sponsorship to another organisation, the CI must obtain written confirmation from the proposed Sponsor that they are willing to take on the responsibility. This letter should include any financial arrangements where applicable, such as the transfer of the study grant.

- Once the written confirmation has been received, the CI will need to work with the new sponsor and their SOPs to update any study documentation.
- The CI must also produce a substantial amendment form reflecting the change in Sponsor. These documents must be submitted to the proposed new Sponsor for approval.
- Once approved, the CI must then obtain the signature of the Sponsor representative and submit the amendment to the MHRA, REC and HRA.
- Where applicable the JRES will be required to co-ordinate the Amendment to the CTA notification. Upon receipt of acknowledgement the JRES will forward any correspondence to the CI and retain copies in the Investigator e-folder.

## 7. References

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

## 8. Appendices

None associated with this SOP.