St George's University Hospitals NHS
NHS Foundation Trust

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They may print off this document for training and reference purposes.

Standard Operating Procedure (SOP)
Transferring Sponsorship

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

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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 Products (CTIMPs) have a Sponsor that is willing and able to take on the responsibilities and liabilities under the Medicines for Human Use (Clinical Trial) Regulations 2004 SI 1031 and subsequent amendments (The Regulations)

The Research Governance Framework for Health and Social Care (2nd Edition, 2005) sets out the principles and requirements of good governance for all research within the remit of the Secretary of State. According to the Framework, all research should have a Sponsor. The Sponsor is defined as an 'individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study.'

The Sponsor is usually the company, institution or organisation that is taking responsibility for initiating, financing and/or managing the research or Clinical trial.
The Sponsor has the primary responsibility for ensuring that the design of the study meets appropriate standards and that the arrangements are in place to ensure appropriate conduct and reporting.
A Sponsor is required for all NHS research in the UK, including:

- Research concerned with the protection and promotion of public health
- Research undertaken in or by the Department of Health, its non-departmental public bodies and the NHS
- Research undertaken by or within social care agencies
- Clinical and non-clinical research
- Research undertaken by the NHS or social care staff using the resources of health and social care organisations
- Research undertaken by industry, charities, research councils and universities within the health and social care systems that might have an impact on the quality of those services. (Research Governance Framework for Health and Social Care 2nd edition 2005, section 1.2)

The Sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written standard operating procedures (SOPs) to ensure that trials are conducted, data generated, documented (recorded) and reported in compliance with the protocol, Good Clinical Practice (GCP) and the applicable regulatory requirements.

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The Sponsor is responsible for securing agreement from all involved parties to ensure direct access to all research related sites, source data/documents, and reports for the purpose of monitoring and auditing by the Sponsor and inspection by regulatory authorities.

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 outlines how the Sponsorship of studies can be transferred to or from St George's.

4. Definitions

None applicable to this SOP

5. Responsibilities

This SOP is to be followed by the JREO Governance and Approvals team: Head of Research Governance (HRG), Regulatory Assurance Manager (RAM), Research Governance Officers (RGOs) and Clinical Trial Monitors (CTMs)

It is the responsibility of the HRG to ensure that the SOP is updated and audited where necessary.

It is the responsibility of the Chief Investigator (CI) to ensure that the transfer of Sponsorship is done with the full knowledge of both organisations involved

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6. Procedure

6.1 Investigator Procedure

The transfer of Sponsorship is split into studies transferring into St George's (section 6.1.1) and studies transferring to an organisation outside St George's (section 6.1.2).

In addition to this SOP, researchers interested in transferring their study, should also refer to the following SOP, JREOSOP0029 Change management.

Section 6.1.1 Studies Transferring into St George's

a) Once the CI has decided they would like to transfer a study to St George's, they should contact the JREO as soon as possible to see whether the transfer is possible.
b) Once the JREO 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.
c) If the study is a CTIMP where IMP supply may need relabelling, the Research Pharmacy may need to be consulted- consult the RAM. Relabelling of IMP may have cost implications
d)Once the written confirmation has been received, the CI must then modify all their existing ethically approved documents to reflect change in Sponsorship. For example, changing the insurance statement in the patient information sheet to the St George's standard statement. The CI must also produce a substantial amendment form reflecting the change in Sponsor. These documents must be submitted to the JREO and the existing Sponsor for approval.
e) Once the JREO has approved these documents, the JREO will then issue a confirmation of transfer of Sponsorship letter (JREODOC0092).
f) The CI must then obtain the signature of the existing Sponsor and submit the amendment to REC and to the MHRA (if applicable).
g) Once the amendment has been approved, the JREO should be notified.
h) If the study is a not a Clinical Trial of an Investigational Medicinal Product (CTIMP), then the CI will be responsible for informing all sites where the study is active of the change in Sponsor.

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i) If the study is a CTIMP – the CI must liaise with the Regulatory Assurance Manager and their assigned Clinical Trials Monitor (CTM) to notify all sites and to arrange suitable monitoring plans and pharmacovigilance reporting framework.

Section 6.1.2 St George's Studies transferring to a different organisation.

a) Once the CI has decided they would like to transfer an active St George's study to a different organisation, they should contact the JREO as soon as possible to see whether the transfer is possible.
b) Once the JREO has confirmed it is willing in principle to accept the transfer of Sponsorship, the CI must obtain written confirmation from the proposed Sponsor that they are willing to take on Sponsorship. This letter should include any financial arrangements where applicable, such as the transfer of the study grant.
c) Once the written confirmation has been received, the CI must then modify all their existing ethically approved documents to reflect change in Sponsorship. For example, changing the insurance statement in the patient information sheet to their new Sponsor's standard statement.
d) Safety reporting/pharmacovigilance procedures must be updated within the protocol to facilitate a seamless service to the participating sites.
e) Consideration may also need to be given to the relabelling of IMP packaging to reflect change of Sponsorship together with any 24 hour participant cards- this may have a cost implication and Research pharmacy will need to be consulted.
f)The CI must also produce a substantial amendment form reflecting the change in Sponsor. These documents must be submitted to the JREO and the proposed new Sponsor for approval.
g) Once the JREO has approved these documents, the JREO will then issue a confirmation of transfer of Sponsorship letter (JREODOC0092).
h) The CI must then obtain the signature of the JREO Sponsor representative and submit the amendment to REC and to the MHRA (if applicable).

6.2 JREO Procedure

The transfer of Sponsorship is split into studies transferring into St George's (section 6.2.1) and studies transferring to an organisation outside St George's (section 6.2.2).

Section 6.2.1 Studies Transferring into St George's

a) Once the CI has contacted the JREO, the assigned JREO Governance contact will liaise

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with the different sections of the JREO as applicable to ensure that St George's is able to take on the responsibility of Sponsorship – (follow Sponsorship Working Practice Document JREOWPD0007 or JREOWPD0013 Issuing Sponsorship for non CTIMPs

b) Once the JREO 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.

c) Once the change in Sponsorship letter has been received and all the amendment documents, the JREO Governance contact must review them as per standard Sponsorship process. Any trial related document must be reviewed by the JREO Governance contact and approval gained from other sections of the office.

d) Once the JREO has approved the documents, the JREO will then issue a confirmation of transfer of Sponsorship letter (JREODOC0092). At this stage, the Governance team contact will also inform the investigator what other changes will need to be done eg issuing of new contracts to reflect the new Sponsor.

e) The CI must then obtain the signature of the existing Sponsor and submit the amendment to REC and to the MHRA (if applicable).

f) Once the amendment has been approved, the JREO should be notified.

g) If the study is a not a clinical trial of an investigational medicinal product (CTIMP), then the CI will be responsible for informing all sites where the study is active of the change in Sponsor.

h) If the study is a CTIMP – the CI must liaise with the Regulatory Assurance Manager and their assigned Clinical Trials Monitor (CTM) to notify all sites and to arrange suitable monitoring plans and confirm the safety reporting framework

Section 6.2.2 St George's Studies transferring to a different organisation.

a) Once the CI has contacted the JREO, the assigned JREO Governance contact will liaise with the different sections of the JREO as applicable to ensure that St George's is able to transfer on the responsibility of Sponsorship – (follow Sponsorship Working Practice Document JREOWPD0007 or JREOWPD0013 for non CTIMPs)

b) Once the JREO has confirmed it is willing in principle to accept the transfer of Sponsorship, the CI must obtain written confirmation from the proposed new Sponsor that they are willing to take on Sponsorship from St George's. This letter should include any financial arrangements where applicable, such as the transfer of the study grant.

c) Once the change in Sponsorship letter has been received and all the amendment documents, the JREO Governance contact must review them as per standard

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Sponsorship process. Any trial related document must be reviewed by the JREO Governance contact and approval gained from other sections of the office.

d) Once the JREO has approved the documents, the JREO will then issue a confirmation of transfer of Sponsorship letter (JREODOC0092). At this stage, the Governance team contact will also inform the investigator what other changes will need to be done eg issuing of new contracts to reflect the new Sponsor.

e) The CI must then obtain the Sponsor representative signature from the assigned Governance contact and submit the amendment to REC and to the MHRA (if applicable).

f) Once the amendment has been approved, the JREO should be notified.

7. References

www.myresearchproject.org.uk

Transfer of Sponsorship letter JREODOC0092

Sponsorship WPD JREOWPD0007

Sponsorship WPD for non CTIMP JREOWPD0013

8. Appendices

None associated with this SOP.

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