Standard Operating Procedure (SOP)
Applying for Sponsorship Non-CTIMPs

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

SOP Chronology		
SOP Version Number:	**Reason for Change:**	**Author:**
V1.0	New SOP	Lisa Clutterbuck
V2.0	New Logo and change of title from CRGM to HRG	Lucy Parker
V3.0	Updated with incorporation of HRA processes in England	Deborah McCartney
V4.0	Updated to include EDGE and incorporate minor amendments	Debbie Rolfe
V5.0	Update to JREO to JRES and associated JRES documents table. Update to Scope to include conditions for sponsorship.	Georgia Bullock
V6.0	Minor updates to include additional considerations in light of the COVID-19 pandemic. Update to include Research DPIA. Update to reflect changes in NIHR CRN Portfolio adoption process.	Joe Montebello

Associated JRES documents

SOPs	WPDs	Docs	LOGs
JRESGOVSOP0021 Peer Review JRESGOVSOP0017 The Confirmation of Capacity and Capability for St George's Hosted Research JRESGOVSOP0054 eConsent	JRESWPD0022 Sponsor Review Checklist Non-CTIMPs JRESWPD0023 General Research Definitions	JRESDOC0002 Non-Interventional Protocol Template JRESDOC0014 DDSA Non-CTIMPs JRESDOC0123: St George's Research DPIA	

Contents

1. Background

The UK Policy Framework for Health and Social Care Research 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 health research should have a Sponsor. The Sponsor is defined as 'the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project'.

A Sponsor's responsibilities include (but are not necessarily limited to):

- Taking responsibility for putting and keeping in place arrangements to initiate, manage and fund the study.
- Ensuring that that the research protocol, research team and research sites are suitable.
- Ensuring that the study has HRA and ethical approval (where appropriate) before it begins.
- Ensuring that arrangements are kept in place for good practice in conducting the study, and for monitoring and reporting, including the prompt reporting of SUSARs.
- Implementing and maintaining quality assurance and quality control systems including written Standard Operating Procedures (SOPs), to ensure that studies are conducted, and data generated, documented and reported, in compliance with the protocol and the applicable regulatory requirements.
- 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 and inspection by regulatory authorities.

All research must be adequately funded to ensure that the research can be set-up and conducted in accordance with current legislation.

The grant awarded for a study sponsored by SGHFT or SGUL must be held by either SGHFT or SGUL, to ensure adequate, and continued, financial oversight and financial risk control.

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 St George's 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 (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 the role of the JRES in the review process for all non-CTIMP research that is to be considered for sponsorship by St George's.

For studies that are being conducted as part of an educational qualification, only SGUL students will have their studies sponsored by St George's. If the course is with another educational establishment, that organisation must act as Sponsor.

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 e.g. NMC, GMC, BDS.
- Study has sufficient funding and central resource to ensure safe and compliant management.

4. Definitions

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

Non-CTIMP:

Trials that do not involve an Investigational Medicinal Product (IMP) as defined by the MHRA, and therefore do not fall within the scope of the Medicines for Human Use (Clinical Trials) Regulations 2004.

5. Responsibilities

This SOP is to be followed by the JRES Research Governance team (RGFO): Head of Research Governance and Delivery (HRGD), Research Development and Governance Manager (RDGM), Research Development and Delivery Manager (RDDM), Clinical Research Associates (CRA) and Research Governance and Facilitations Officer (RGFO).

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

It is the responsibility of the Chief Investigator (CI) to ensure that the completed requested documentation is submitted to the JRES for review.

It is the responsibility of the assigned member of the RGFO to ensure review of all relevant documents in accordance with this SOP prior to Sponsorship being confirmed.

6. Procedure

If an Investigator would like St George's to act as the research sponsor then they should approach the JRES at an early stage to discuss the requirements of the project. Ideally this should be performed while the protocol and/or grant is in development so that the RGFO team can provide advice on the governance and delivery issues of running the project.

St George's sponsorship must be confirmed prior to making a submission to a Research Ethics Committee (REC) and to the Health Research Authority (HRA).

6.1 Sponsor Allocation

St George's will only sponsor research originating from either organisation. The CI must be substantively or clinically employed by St George's University of London or St George's University

Hospitals NHS Foundation Trust. The substantive employment contract of the CI will indicate whether the University or NHS Trust will be named as the Sponsor. St George's University of London should not act as a sponsor for research related to an educational qualification for another academic organisation and should always act as sponsor for student qualifications for SGUL.

6.2 Submitting a Project for Review

All requests for research sponsorship are reviewed by a member of the RGFO within the JRES. In order for a submission to be reviewed, the following documents must be emailed to researchgovernance@sgul.ac.uk, BEFORE the review can commence:

- Draft completed IRAS/Ethics form.
- Draft Protocol on a St George's template.
- CV of Chief Investigator.
- Draft Patient Information Sheet (PIS) , Consent Form (PCF), GP letter.
- Draft SoECAT (required for all non-commercial studies to be based within the NHS/Health sector regardless of funding – please consult a JRES Funding Officer).
- Details of study level funding.
- Draft Research Data Protection Impact Assessment (DPIA)

6.3 Sponsorship Review

All studies where sponsorship is requested in accordance with above will be added to EDGE by the assigned member of the RGFO.

The RGFO member will review the project to ensure that:

- A suitable Chief Investigator has been identified for the study.
- A suitable deputy PI has been identified by the CI, to ensure appropriate study participant clinical management in the absence of the CI.
- The IRAS Project Filter questions have been completed accurately and all relevant sections of the form, according to study type, have been completed.
- The draft IRAS form and relevant protocol template are completed and consistent with each other.
- Consideration has been given to allow for remote recruitment, consent and study activity where possible

- Approval from the Clinical Care Group Lead has been sought for research-specific visits at site
- The Protocol (and PIS where applicable) includes an appropriate COVID-19 risk statement
- Correct insurance arrangements are described within the documents according to substantive employer of the CI (either SGHT/SGUL).
- SGUL/SGHT insurance requirements for the study are adequate and indemnify participants and staff involved in the study. **Please note:**
    - SGHT insurance is automatic and certificates are not provided. SGHT insurance covers the UK only and is not for non-UK research.
    - The SGUL insurance company provides a generic certificate for studies with conditions. If the study breaches any of these conditions then the insurance company will need to review the protocol, PIS and insurance questionnaire.
- The study complies with relevant regulatory requirements, according to the study type. Review against the Sponsorship Checklist - JRESWPD0022.
- The correct funding arrangements for the study have been assessed (this may need liaison with the JRES Grants team). If funding has been awarded as part of an open, peer reviewed competition, the study may be eligible for support from the NIHR: https://www.nihr.ac.uk/researchers/collaborations-services-and-support-for-your-research/run-your-study/crn-portfolio.htm https://www.nihr.ac.uk/researchers/collaborations-services-and-support-for-your-research/run-your-study/crn-portfolio.htm
    - If the study is deemed to be eligible for NIHR CRN Portfolio Adoption, the Investigator must select “Yes” as a response to Question 5b in the IRAS Project Filter
    - The pertinent information from the IRAS will be submitted to CPMS to determine CRN Portfolio Adoption eligibility once the IRAS is submitted to the REC and HRA
    - **Note:** it is the JRES Policy to submit all potentially eligible studies for NIHR adoption
- Adequate Peer Review has been undertaken for the study where required, and if not, a Peer Review form (see JRESGOVSOP0021) must be completed. Please note that if the study is being undertaken as an educational project up to Master’s level, it is understood that adequate peer review has been undertaken by the academic

supervisor of the student. The review or critique should be given to the JRES to place on file.

- Monitoring and other associated documents (insurance statement, patient contacts) have been completed.
- A Research DPIA has been drafted, reviewed and signed-off by the Senior Clinical Research Facilitator

Sponsorship requests for studies that have undergone scientific peer review and are in in receipt of study grant funding will be reviewed within 10-15 working days. Due to the timelines on public and charity funded projects, these will be prioritised.
All non-funded research studies requesting sponsorship will be reviewed within a minimum of 20 working days.
Timelines may be extended in times of a high volume of requests.

Once the review is complete, a RGFO member will respond via email with their feedback. Only when all queries have been addressed will sponsorship be confirmed, on the condition that the study obtains all relevant research approvals before proceeding. St George's does not issue sponsorship in principle unless requested by a funder or 3rd party.

It must be noted that confirmation of research sponsorship is not the same as confirmation of St George's (or any site/Trust) Capacity and Capbility (previously Trust R&D approval). This is a seperate process confirmed AFTER the HRA has issued their final approval.

When sponsorship has been confirmed the request for electronic authorisation of the IRAS Form can be sent through to the reviewing member of RGFO to authorise on behalf of the HRGD who is the offical Sponsor's Representative . Only designated individuals confirmed by the HRGD to the HRA can authorise the IRAS form. The HRA can reject any application not signed off by an appopriate member of the JRES RGFO.
At this point a arrangements can be made for ethical review by an appropriate NHS REC and or assessment by the HRA (please see HRA's central booking https://www.hra.nhs.uk/about-us/committees-and-services/central-booking-service/).

6.4 Sponsor Risk Assessment

There are research funders that require the confirmation of a research sponsor on the initial grant application in order for the application to be valid. As such, St George's may be requested

to act as research sponsor based on the limited information in the grant proposal. Under such circumstances, St George's may provisionally agree to take on this role subject to the study obtaining adequate funding, a positive scientific review and the necessary research approvals. It is the CI's responsibility to ensure that these conditions are met and the JRES reserve the right to withdraw research sponsorship if they are not.

Investigator Procedure

a) On request from the assigned Research Governance Officer (RGFO), the CI or delegated research team member, will submit dcouments as per 6.2
b) All documents submitted must have a version number and date to ensure that both parties are reviewing the same documentation.
c) The CI or delegated research team member will respond to an RGFO member request for any further documentation or amendments if applicable within 20 working days of the email request date.
d) The CI, or delegated research team member is authorised to submit the application to the HRA/REC via IRAS.

JRES Procedure

a) Upon notification of a proposed non-CTIMP for Sponsorship to the generic inbox– the relevant RGFO will be notified (by any member of the team reviewing the inbox) according to the clinical division of the CI.
b) The assigned RGFO will inform the Investigator and/or delegated research team member of the documentation to be completed and submitted for Sponsorship review.

Please note: it may be deemed on receipt of study details that the study does not fall under the definition of research. In which case, the study document(s) should be forwarded to the HRGD or Research Development and Governance Manager (RDGM) for review to determine whether the study is service evaluation or audit. When initially approached regarding the proposed research the RGFO should ask the Investigator to confirm if the project falls under the definition of research using the HRA's Defining Research Table (http://www.hra-decisiontools.org.uk/research/). If the proposed work is deemed to be a service evaluation or audit, then the researcher should be referred to the trust service evaluation and audit team (Adam.Lewarne@stgeorges.nhs.uk).

The RGFO should also provide the Investigator with a link to the University website containing relevant template's, SOP's and logs needed for the management and running of the research. St George's templates must be used for all documents.

It may also be deemed that the study type may not require REC review, as in the case of staff questionnaire studies. In this case the IRAS form does not need to be submitted (see JRES SOP0040 Applying for NHS Ethics).

c) On receipt of a complete and valid Sponsorship submission as per 6.2;

The RGFO will register the project on the internal JRES database, EDGE And generate an JRES reference number via the R&D Number Generator access

d) An electronic sponsor R&D folder (eTMF) will be created by the RGFO within EDGE
e) The RGFO will review the valid Sponsorship submission, in accordance with the timelines and criteria in 6.3.
f) The RGFO will respond to the CI and/or delegated research team member via email with any recommended changes and/or request further information, documentation or amendments to the submitted initial documentation.
g) Once the RGFO is satisfied that the application meets the principles and good practice as described in the UK Policy Framework for Health and Social Care 2017, Good Clinical Practice requirements, relevant regulatory requirements, the CI will be told to check the IRAS form and attach all relevant documents to the Checklist. The CI can then request Sponsor authorisation of the form within IRAS. Once the named RGFO has electronically authorised the form(s) the applicant should sign/authorise the form him/herself and follow the instructions to e-submit. The CI will now book the study into an appropriate Research Ethics Committee for review (if applicable) and proceed to e-submit the application to the HRA/REC via IRAS.
h) The RGFO should sent the CI a copy of the DDSA for Non-CTIMPs (JRESDOC0014), outlining their delegated responsibilities for study conduct and management.
i) Relevant correspondence/documentation should be filed in the study e-folder as applicable.
j) Once Sponsorship has been confirmed (on signature of the IRAS form), and final HRA approval is received, the RGFO should request the final list of documents as listed on the HRA/REC approval letter, in case the HRA/REC required amendments. If the research will be carried out at SGHT, the RGFO should start the process of St George's Confirmation of Capacity and Capability (JRESGOVSOP0017).
k) For Multi Centre studies the RGFO will inform the CI that an initial assessment pack will need to be constructed to send out to any participating site R&D departments in accordance with current HRA guidance (https://www.hra.nhs.uk/planning-and-

improving-research/best-practice/nhs-site-set-up-in-england/). The RGFO must issue Greenlight for any host site's before research activity can begin.

For further advice on approvals needed for research, consult the current HRA guidance: https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/

a) Investigators should be instructed to submit the protocol, IRAS form and associated documents as part of the valid Sponsorship submission and follow the same process as above, but not submit the IRAS form to the REC.
b) Investigators should submit the IRAS form together with the support documents to the HRA.

7. References

IRAS (Integrated System Application System) - www.myresearchproject.org.uk

EDGE- www.edge.nhs.uk

HRA https://www.hra.nhs.uk/

UK Policy Framework For Health and Social Care 2017 (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/)

IRAS – template documents https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx

ICH Good Clinical Practice - ichgcp.net/

8. Appendices

None associated with this SOP.