St George's University of London

St George's University Hospitals NHS
NHS Foundation Trust

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

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	Deputy PI to be nominated to cover CI absence. HRA requirements and provision of STG letter to document Service Evaluation/Clinical Audit for benefit of external R&D/publishers	Debbie Rolfe

1. Background

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

- Confirming that everything is ready for the research to begin:
  - taking on responsibility for putting and keeping in place arrangements to initiate, manage and fund the study;
  - satisfying itself that the research protocol, research team and research environment have passed appropriate scientific quality
  - satisfying itself the study has HRA and ethical approval (where appropriate) before it begins;
- Satisfying itself that arrangements are kept in place for good practice in conducting the study, and for monitoring and reporting, including prompt reporting of suspected unexpected serious adverse incidents.

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 studies are conducted, data generated, documented (recorded) and reported in compliance with the protocol, Good Clinical Practice (GCP) and the applicable regulatory requirements.

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

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 the role of the JREO in the review process for all non-CTIMP research that is to be considered for Sponsorship by St George's and the subsequent issuing of 'Sponsorship'.

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

4. Definitions

4.1 Research

Research can be defined as the attempt to derive generalisable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them. (www.hra.nhs.uk)

4.2 Non-CTIMP (Non-Clinical Trial of an Investigational Medicinal Product)

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.

4.3 Sponsorship in principle

St George's is prepared, in principle, to act as Sponsor based on the information presented by the applicant. It is recognised that Sponsors cannot give a final confirmation of their ability to sponsor a study until further confirmation that all arrangements for the study have been made. Once Sponsors have declared that they agree in principle to act as a Sponsor, the Sponsor is expected to make clear in writing to all parties if it no longer agrees to sponsor a study at any stage. It is therefore reasonable for all parties to assume that an organisation that has agreed in principle to 'act as Sponsor' is the final Sponsor unless the organisation clarifies in writing that it is no longer the Sponsor.

5. Responsibilities

This SOP is to be followed by the JREO Research Governance team: Head of Research Governance (HRG), Research Governance Officers (RGOs) and, if applicable in some cases, Regulatory Assurance Manager (RAM), 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 completed requested documentation is submitted to the assigned member of the Research Governance Team (RGT)

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

6. Procedure

6.1 Investigator Procedure

a) On request from the assigned Research Governance Officer (RGO), the CI or delegated research team member, will submit;
   - DRAFT IRAS form
   - The non-CTIMP protocol (investigators may use one of the non-CTIMP protocol templates- JREODOC0002, JREODOC0091, JREODOC0096 or JREDOC0102)
   - Associated documents - Informed Consent Form, Patient Information Sheet and GP Letter if applicable and any other participant or public facing information.
   - For adopted (or likely to be adopted) multi-site studies the Health Research Authority (HRA) Schedule of Events and Statement of Activities must be completed by the CI (with assistance by the network study support team &/ or agreed by the Network and returned to the JREO.
   - For non-adopted multi-site studies, the HRA Schedule of Events and Statement of Activities must be completed.

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 RGT member request for any further documentation or amendments if applicable within 20 working days of the email request date.

d) Following receipt of confirmation of Sponsorship and insurance, the CI, or delegated research team member, is then authorised to submit the application to the HRA/REC via IRAS.

6.2 JREO Procedure

a) Upon notification within the Research Governance Team (RGT) of a proposed non-CTIMP for Sponsorship – the RGT member will inform the relevant RGO according to the clinical division of the CI.

b) The assigned RGO 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 HRG for review to determine whether the study is service evaluation or audit. If the proposed work

is deemed to be service evaluation or audit, then the researcher must check with the host NHS organisation as to the correct process for registering these types of project. If the project is an audit and is taking place at SGHT, the study must be registered with the Clinical Audit Office. If the project is deemed to be a service evaluation, it must have the approval of the relevant Care Group Lead. A letter confirming R & D review and study type (Service Evaluation/ Clinical Audit) should be provided to the Investigator to produce upon request at external host R&D departments or prospective publishers. A copy of the letter together with the Project Docs should be saved in the 'service Evaluation' e-folder.

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 JREOSOP0040 Applying for NHS Ethics).

c) On receipt of a complete and valid Sponsorship submission;
    - DRAFT IRAS form
    - Protocol (investigators may use an appropriate JREO non-CTIMP protocol templates- e.g. JREODOC0002, JREODOC0091, JREODOC0096 or JREDOC0102)
    - Associated documentation - Informed Consent form, Patient Information Sheet, GP Letter etc.,
    - For multi-site studies a completed Statement of Activities for each site type (e.g. PIC, Recruiting site) and Schedule of events

The RGO will register the project on the internal JREO database, ReDA (www.reda.org.uk/reda3) as a new project with a successive project ID number, known as the JREO R&D Reference, (last 2 digits of the year.xxxx) and complete the data set as required. The EDGE database will also require the full Minimum Dataset to be completed..

d) An electronic folder (eTMF) will be created by the RGO within the internal JREO shared drive in accordance with the e-file templates under Investigator\5.Governance\ReDA Ref_ study acronym.
e) The RGO will review the valid Sponsorship submission, within 5 working days of receipt, ensuring the following (but not limited to) is conducted:
    - Ensure a suitable Chief Investigator has been identified for the study.

- The CI will need to identify a suitable deputy PI to ensure appropriate study participant clinical management in the absence of the CI.
- IRAS Project Filter questions are accurately completed and all relevant sections of the form, according to study type, have been completed
- Draft IRAS form and non-CTIMP protocol are consistent with each other
- 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 (this may need liaison with the HRG and/or other suitable personnel such as the JREO Legal team.
- Ensure that study complies with relevant regulatory requirements, according to study type, including but not limited to the Human Tissue Act, the Data Protection Act 1998, the Mental Capacity Act 2005, IRMER (2000).
- Assess funding arrangements for the study (this may need liaison with the JREO cost accountant and the Grants team) and request funding award letter if applicable and confirmation of the Agresso code. If funding has been awarded as part of an open, peer reviewed competition, the study may be eligible for support from the NIHR (see JREOSOP0044 Applying for NIHR adoption). It is recommended that this procedure is followed and the associated PAF is submitted BEFORE submitting project to HRA/REC for approval.
- Assess whether adequate Peer Review has been undertaken for the study and if not, request a Peer Review form (see JREOSOP0021 Peer Review) to 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 JREO to place on file.
- Other: monitoring, archiving, associated documents (insurance statement, patient contacts) and the required Statement of Activities and Schedule of Events for multi-site studies have been completed (and approved by the Local Network where the study is likely to be portfolio-adopted).

f) The RGO will respond to the CI and/or delegated research team member, within 5 working days, via email with any recommended changes and/or request further information, documentation or amendments to the submitted initial documentation.

g) Once the RGO is satisfied that the application meets the principles and good practice as described in the Research Governance Framework (2nd Edition, 2005), 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 RGO 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. (see JREOSOP0040 on applying to NHS ethics)

h) Relevant correspondence/documentation should be filed in the study e-folder as applicable.

i) Once Sponsorship has been confirmed (on signature of the IRAS form), and final HRA approval is received, the RGO should request the final list of documents as listed on the REC approval letter, in case the REC required amendments. If the research will be carried out at SGHT, the RGO should start the process of St George's Confirmation of Capacity and Capability (JREOSOP0017), formerly known as Trust Approval. The RGO should inform supporting departments (Radiology, Pathology, CRF), legal team, if applicable, of the study and provide advice on their requirements and documents as necessary.

j) The RGO will inform the CI that an initial assessment pack will need to be constructed to send out to any participating site R&D departments. The initial assessment pack will consist of HRA initial assessment letter, Protocol, PIS, ICF and Schedule of Events, Statement of Activities and any other documents that would facilitate host site R&D assessment.

For studies not requiring REC review:

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

ReDA – www.reda.org.uk

EDGE- www.edge.nhs.uk

HRA – studies not requiring REC review www.hra.nhs.uk

Research Governance Framework (2nd Edition, 2005) - www.gov.uk/government/uploads/system/uploads/attachment_data/file/139565/dh_4122427.pdf

http://www.hra.nhs.uk/resources/hra-approval-applicant-guidance/statement-activities-hra-approval/

ICH Good Clinical Practice - ichgcp.net/

Data Protection Act 1998 - www.legislation.gov.uk/ukpga/1998/29/contents

Human Tissue Act 2004 - www.legislation.gov.uk/ukpga/2004/30/contents

Mental Capacity Act 2005 - www.legislation.gov.uk/ukpga/2005/9/contents

IRMER (2000) - www.legislation.gov.uk/uksi/2000/1059/contents/made

8. Appendices

No appendices associated with this SOP.