St George's University Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure (SOP)

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Signature of Authorisor			

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Standard Operating Procedure (SOP)
Peer Review Process for JREO Sponsored Studies

SOP Chronology		
SOP Version Number:	**Reason for Change:**	**Author:**
V1.0	New SOP	Lucy H H Parker
V2.0	Updated with new Trust Logo and Foundation Trust	Nadia Azzouzi

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1. Background

The purpose of this SOP (Standard Operating Procedure) is to affirm that all research sponsored by St George's should be subject to a process of peer review prior to sponsorship being granted. The standards and processes for peer review are set out, and vary according to the expected risks and burdens the research carries for the Sponsor.

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 applies to all research carried out by staff employed by either SGUL, or SGHT, in the course of their employment, where research is funded or part-funded through a contract held by either organisation (or both), or funded or part-funded from institutional funds, and where St George's is requested to act as Sponsor.

4. Definitions

4.1 Peer Review

Peer review is a cornerstone principle of academic research, a means of assessing the quality of research as presented in proposals, presentations or papers. Proposals and papers are subject to critical evaluation by experts independent of the research, usually appointed by the party to which the work has been submitted (e.g. funding body, journal editors), often taking into account reviewers suggested by the originator. Peer review is increasingly promoted within research organisations as a formal approach for assuring and improving research quality before a proposal is submitted for funding or a paper for publication.

Whilst there are debates on the (cost-) effectiveness, subjectivity and transparency of the peer review process, especially in relation to novel and innovative (including multi- and trans-disciplinary) research, it is generally accepted to be the best available mechanism to assess and affirm the quality of planned research.

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4.2 Good Clinical Practice

Good Clinical Practice (GCP) is an international quality standard that was agreed by the International Conference on Harmonisation (ICH), an international body that defines standards, which governments have transposed into regulations for clinical trials involving human subjects. The European Clinical Trials Directive (EUCTD) 2001/20/EC was transposed into UK law by The Medicines for Human Use (Clinical Trials) regulations 2004 (SI 2004/1031) on 1st May 2004

5. When is peer review required?

All proposed research should be subject to a process of independent scrutiny outside the research team during the development phase. For most research, independent scientific peer review is likely to have been undertaken during the development of the study and therefore will not need to be repeated in order to confirm Sponsorship. This applies to research funded by the Research Councils, major charities (especially members of the Association of Medical Research Councils), National Institute of Health Research (NIHR) and main government agencies, as well as many industry-funded studies, in particular those industry-initiated clinical trials which are adopted onto the NIHR portfolio.

Research which is wholly or largely funded from St George's own funds, studies that form part of a programme grant, investigator-initiated studies funded by industrial partners and studies funded by smaller charities (including those which are considered as 'closed' charities funding research only or mainly at St George's) or education qualification studies below a PhD level are less likely to have been subject to a robust process of external peer review during the development phase and it is this research which this SOP is intended to cover.

If the study is to be put forward for NIHR portfolio adoption, NIHR criteria must be followed. That is, the study must have two peer reviews conducted, with both reviewers external to the host organisation.

Please see Appendix One: Peer Review Algorithm, which should give a definitive answer as to whether a particular study requires formal peer review, by the JREO.

6. Responsibilities

The Chief and/or Principal Investigator is responsible for identifying the peer review process to be used (i.e. externally-organised or internally-organised), factoring this into planning timetables and completing documentation as required, (see Appendix One). CIs/PIs will be expected not to refuse unreasonably to act as reviewers of others' proposals.

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The "Troika" of Associate Medical Director, Research (SGHT), Dean of Research and Enterprise (SGUL) and JREO Director will organise a peer review process where necessary and make decisions or recommendations as a result.

Reviewers must allow adequate time to complete the task, seek to be objective, be aware of the limits of their own competence, and complete the agreed form within **2 weeks** of the request. Peer reviewers' anonymity will be respected at all times unless they express a preference to be identified (by indicating this on Appendix Two) and this request is upheld by the Troika.

The Research Governance Committee will have oversight of the process and will act as the arbitrator of any final decisions relating to the research following peer review.

7. Procedure

7.1 Sponsored CTIMP (Clinical Trial of Investigational Medicinal Product) studies

a) CI liaises with assigned JREO Governance contact to develop budget, protocol etc. The need for peer review will be discussed and the necessary approach identified.
b) If the funder will be undertaking the peer review as part of the funding application, and sponsorship in principle is required prior to the funding application being submitted, this will be recorded in the risk assessment. Otherwise, peer review should normally take place as part of the risk assessment prior to sponsorship being issued.
c) Studies that obtain funding from crowdsourcing will be required to undergo formal peer review to ensure scientific robustness.
d) If funder-organised peer review is used, the CI must complete the cover sheet (Appendix 2) and provide evidence of process if not self-evident, including copies of written feedback from peer reviewers where received.
e) If internal peer review is required, the CI must complete the cover sheet (Appendix 2), attach a draft protocol and provide these to their assigned JREO Governance contact.
f) The assigned JREO Governance contact will liaise with and support the Troika in organising and managing the peer review process.
g) The Troika will determine whether the internal review is sufficient or whether external review is required (where insufficient independent expertise is available within St George's or a possible NIHR portfolio study) and the number of reviewers needed (usually two) and will liaise with reviewers as necessary. Modest fees may be paid to external reviewers if the Troika consider it appropriate.
h) Reviewers to be sent and complete the feedback form (Appendix 3) and return to the assigned JREO Governance contact (preferably within 2 weeks).
i) The Troika will review feedback and decide whether the trial should proceed, with or without amendments to the protocol.
j) The assigned JREO Governance contact will then record information about the peer review process and outcome in the Trial Master File (TMF) and JREO ReDA record.

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7.2 Sponsored non CTIMP studies

a) CI liaises with assigned JREO Governance contact to develop protocol, supporting documents etc. and to complete the ethics application form. This form is known as the IRAS form (Integrated Research Approval System) .The method of peer review will be identified through the IRAS form
b) The CI must check the algorithm to see whether the formal peer review process must be used. (see Appendix 1)
c) If the funder will be undertaking the peer review as part of the funding application, and sponsorship in principle is required prior to the funding application being submitted, Otherwise, peer review should normally take place as part of the risk assessment prior to sponsorship being issued.
d) If funder-organised peer review is used, the CI must complete the cover sheet (Appendix 1) and provide evidence of process if not self-evident, including copies of written feedback from peer reviewers where received.
e) If internal peer review is required, the CI must complete the cover sheet (Appendix 2), attach a draft protocol and provide these to their assigned JREO Governance contact.
f) The assigned JREO Governance contact will liaise with and support the Troika in organising and managing the peer review process.
g) Non CTIMPs generally require a lower level of review and are unlikely to require external review. The assigned JREO governance contact will determine whether the internal review is sufficient or whether external review is required (where insufficient independent expertise is available within St George's or a possible NIHR portfolio study) and the number of reviewers needed (usually two) and to liaise with reviewers as necessary. The study will be referred to the Troika if the assigned JREO governance contact deems it appropriate. Modest fees may be paid to external reviewers if the Troika consider it appropriate.
h) Reviewers to be sent and complete the feedback form (Appendix 3) and return to the assigned JREO Governance contact (preferably **within 2 weeks**).
i) The Troika will review feedback and decide whether the trial should proceed, with or without amendments to the protocol.
j) The assigned JREO Governance contact will then record information about the peer review process and outcome in the ReDA record.

8. References

Research for Patient Benefit Peer/Lay Review Form

9. Appendices

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Appendix 8.1: Peer Review Algorithm

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Appendix 8.2: Peer Review Cover Form

Appendix 8.3: Peer Reviewer Feedback Form

Appendix 8.4: Example of simple Peer Review Form

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Appendix 8.1: Peer Review Algorithm

Study Type	A	Funding	B	NIHR	C	D	E
If you answer **no** to all the questions in Column A, the study does not need a formal peer review through the JREO. It is recommended the study still undergoes a level of peer review – there is an example form in appendix 4. If you answer **yes** to any of the below – move onto column B		If you answer yes to **any** of the below – move to column C. If you answer no to **all** of the below, formal peer review through the JREO is needed.		If you answer yes to **any**, move to column E If you answer no to **all** , move to column D			
A clinical trial of an investigational medicinal product (CTIMP). A clinical investigation or other study of a medical device. Combined trial of an IMP and an investigational medical device. Other clinical trial to study novel intervention or randomised clinical trial to compare interventions in clinical practice. A study that is potentially eligible for NIHR portfolio adoption ^		Funded by a Research Council^^ Funded by NIHR^^ Funded by a major charity^^ Funded by a main Government agency^^ Funded in open competition by an industry partner^^		Study has undergone two independent Peer Reviews. Study is not eligible for NIHR portfolio adoption.		Complete Appendix 2: Peer Review Cover Form. Formal Peer Review through the JREO is required.	Complete Appendix 2: Peer Review Cover Form. Formal Peer Review through the JREO is not needed.
Notes ^ A study is potentially eligible for NIHR portfolio adoption if it is fully funded (from awarded funding)							
^^ The funds must be awarded to the specific study. I.e. not awarded as part of a programme grant.							

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Appendix 8.2: Peer Review Cover Form

Version 2 09/10/2015

Project Title:	
Chief Investigator:	
JREO ReDA no:	

Chief Investigator Questions:

1. Are you intending to use funder-organised peer review as evidence?	YES NO
If yes, please state your funder. If written feedback was given – please attach to this application.	
2. Is further peer review required as per section 5 of the JREO SOP on the Peer Review Process? (JREOSOP0021)	YES NO
3. Are you intending to apply for NIHR portfolio adoption?	YES NO
If yes, please be aware NIHR require two peer reviews external to the host organisation :	

For NIHR studies, the suggested reviewers **must** be external to the host organisation. For all other studies, you may suggest internal reviewers. The JREO may request external reviewers for these if they deem it appropriate

Reviewer One		**Reviewer Two**	
Name of Reviewer:		Name of Reviewer:	
Position:		Position:	
Address:		Address:	

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Email Address:		Email Address:	
Telephone Number:		Telephone Number:	

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Decision	Yes	No	Date
Funder Peer Review Appropriate:			
Referred to Troika:			
External Reviews received			
Peer Review deemed satisfactory			

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Appendix 8.3: Peer Reviewer Feedback Form

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The rows coloured in grey will be removed before the form is fed back to the requesting Chief Investigator (CI). Where you have written a response in a white row – please do not write something that will identify you as this information is going to be fed back to the CI.

If you wish for your feedback form to be identified to the CI as coming from you, please tick the following box, otherwise your anonymity will be respected.

☐ I wish my form **with** identifiers to be given to the CI.

Project Title:	
Chief Investigator:	
Name of Reviewer:	
Position:	
Address:	
Email Address:	
Telephone Number:	

Reviewer Questions:

1. Have you had any involvement in this project?	YES	NO
If yes, please state what your involvement is:		
2. Have you worked in the same organisation as the CI in the last five years?	YES	NO
If yes, please specify:		
3. Please indicate the nature of your expertise in this field:		
4. Are there any conflicts of interest that you would like to declare in relation to this project?	YES	NO
If yes, please specify:		

Please read the proposed protocol and answer the following questions:

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1. RELEVANCE of the proposed research

a) How relevant and important is the proposed research to the priorities and needs of the NHS or healthcare in general. Does it offer a health/healthcare solution with demonstrable benefit to patients or generation of knowledge that is likely to lead to the development of a healthcare intervention?

b) Does the application demonstrate an awareness and understanding of previous relevant research or developments in this area?

c) To what extent does the proposed research add distinct value or provide an advance to what is already known from other work currently in progress or already completed in this area? **(max 300 words)**

2. QUALITY of the proposed work

2a. Research design

a) Is the proposed research of high quality and does it address the stated objectives?

b) How convincing and coherent is the proposed rationale and approach?

c) Is the proposed design and methodology for all elements of the research well defined, appropriate, valid, robust and feasible within the timeframe and resources requested?

d) What are the strengths and weaknesses of the research design as proposed? **(max 300 words)**

2b. Work plan and proposed management arrangements

a) Do the work plan and project management arrangements give confidence that proposed milestones will be met within the specified timeframe?

b) Can you identify any difficulties that the applicants are likely to encounter in meeting their milestones?

c) Have the major ethical, scientific, technical and organisational challenges, as well as any issues around intellectual property rights, been identified and will they be addressed adequately?

d) Are the necessary clinical, academic or organisational links needed to support the research, or help translate it into practice, in place? **(max 300 words)**

3. STRENGTH of the research team

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a) Are the applicants familiar with the methodologies outlined in their application and are they well qualified to undertake the proposed work on the basis of their rack record in relevant areas
b) Does the research team have the necessary breadth and depth of expertise to deliver the planned work?
c) Are the roles of the team members clearly described, and is the overall team well coordinated?
d) If the lead applicant is inexperienced, does he/she have appropriate support (e.g. from their host institution and more senior colleagues) to deliver the work plan? **(max 300 words)**

4. IMPACT of the proposed work
a) Have the applicants outlined an appropriate and adequate approach to disseminating the result of their research (including engaging with healthcare planners and/or policy makers)? Could this be developed further?
b) Considering the plans for dissemination, what is the likelihood of significant changes to general practice or the
potential to contribute to future health gain for patients and the general population?
c) Have the applicants identified any new intellectual property that will be produced during the course of this research and are there plans to protect and exploit it? **(max 300 words)**

5. Additional comments
Do you have any other comments or suggestions for how the proposed research might be improved? If so, please indicate whether you see these as critical factors. **(max 300 words)**

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6. Rating Summary

Considering your answers to the questions above, please rate how well this application addresses each of the criteria using following table:

Criteria	Unsatisfactory	Average	Good	Excellent
Relevance (Q1)				
Quality of Research Design (Q2a)				
Quality of Work Plan (Q2b)				
Strength of Team (Q3)				
Impact of the work (Q4)				

7. Overall Score:

Taking into account your ratings summary above, and the comments you have provided, please give an overall score, using the guide below to help you.

Overall Score :

Guide

Ranking	Meaning
A	Acceptance
B	Revision and review
C	Rejection

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Appendix 8.4: Example of Simplified Peer Reviewer Feedback Form

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Project Title:	
Chief Investigator:	
Name of Reviewer:	
Position:	
Address:	
Email Address:	
Telephone Number:	

Reviewer Questions:

1. Have you had any involvement in this project?	YES NO
If yes, please state what your involvement is:	
2. Have you worked in the same organisation as the CI in the last five years?	YES NO
If yes, please specify:	
3. Please indicate the nature of your expertise in this field:	
4. Are there any conflicts of interest that you would like to declare in relation to this project?	YES NO
If yes, please specify:	

Please read the proposed protocol and answer the following questions:

1. STUDY DESIGN

Strengths:
Weaknesses:
Any other comments:

2. STUDY TEAM

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Strengths: Weaknesses: Any other comments:

3. RELEVANCE OF STUDY

Strengths: Weaknesses: Any other comments:

4. IMPACT OF STUDY

Strengths: Weaknesses: Any other comments:

5. Overall Score:

Taking into account the above and the comments you have provided, please give an overall score, using the guide below to help you.

Overall Score : Comments:

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Guide

Ranking	Meaning
A	Acceptance
B	Revision and review
C	Rejection

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