University College London Hospitals NHS Foundation Trust

Joint Research Office

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Standard Operating Procedure for Peer Review for Studies Sponsored by UCL and UCLH
JRO SOP 15

SOP ID Number	Version Number	Effective Date	Review Date
JRO SOP 15	1	17/08/2015	17/08/2018
Author: Name and Job Title	Suzanne Binks, Quality Assurance Manager		
Reviewed by Date:	Peer Review Working Group		
Target Audience	Joint Research Office		
Please check this is the latest version of the SOP on the Joint Research Office website: www.ucl.ac.uk/jro			

Revision Chronology			
Version	**Effective Date**	**Reasons for Change**	**Author**
1		Initial SOP following the finalization of the peer review process developed by the peer review working group.	Suzanne Binks

1. ACRONYMS

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
JRO	Joint Research Office
PC	Portfolio Coordinator
QA	Quality Assurance
R&D	Research & Development
RM&G	Research Management & Governance
SOP	Standard Operating Procedure
SPC	Senior Portfolio Coordinator
SRA	Sponsor Regulatory Advisor
UCL	University College London
UCLH	University College London Hospitals NHS Foundation Trust

2. DEFINITIONS

Interventional study	A trial which is affecting the clinical care that the patient is receiving. Interventional trials fall into one of the following categories: a. CTIMP b. trial of a medical device c. surgical trial d. mechanistic study e. other intervention using randomised methods.
Observational study	A study involving tests or other methods in order to investigate a research question, where there is no intervention or treatment altering clinical care involved.
Peer review	The means by which the validity, significance and sometimes originality of a study are reviewed by another scientific or clinical expert within the field of study before the project is made public.

3. JRO POLICY

Standard Operating Procedures (SOPs) are written working practice documents detailing routine procedures that must be followed to perform a given task.

All SOPs produced from the JRO must be used in conjunction with local NHS Trust and UCL policies and procedures.

The JRO represents UCL and UCLH as the Sponsor and UCLH as a participating site. The JRO is responsible for research management and governance processes as sponsor and host site representative. The JRO SOPs will provide the quality system to fulfil these requirements.

This SOP complies with the Research Governance Framework for Health and Social Care 2005 (2nd edition) and Good Clinical Practice as outlined by the Clinical Trial Regulations.

4. BACKGROUND

It is a Health Research Authority requirement for sponsors to have in place adequate peer review systems proportionate to the research activity. Peer review would generally focus upon:

a. The relative merit of the research
b. The design and methods
c. The feasibility of the research
d. The presentation of the application
e. Scientific validity

The level of peer review will differ depending on the type of study. Some studies received by the JRO for sponsorship also may have already been through a process of review, which could be considered a suitable peer review requiring no further assessment. It is the Chief Investigator's responsibility to ensure sufficient peer review is in place for a study before sponsorship is agreed.

5. PURPOSE AND SCOPE

This SOP describes the requirements for peer review for UCL and UCLH sponsored studies. This however does **not** cover requirements for studies adopted by a UCL Clinical Trials Unit.

Specifically, this SOP provides information on:

a. The level of peer review required for different types of study
b. The main points that should be considered when conducting a peer review
c. Who should conduct peer review
d. How evidence of peer review should be provided to the JRO

6. RESPONSIBLE PERSONNEL AND THEIR DUTIES

	Responsible Person	Summary of duties
1	JRO PC/SPC/SRA	• Conducts review for UCL or UCLH sponsorship. • Advises CI on peer review requirements. • Receives evidence of peer review.
2	Chief Investigator	• Ensures adequate peer review is in place. • Provides evidence of peer review to the JRO.

7. PROCEDURE

7.1. Assessing the level of peer review required

The PC/SPC/SRA should follow the decision tree (appendix 1) to determine whether peer review is required and, if so, the level required.

The PC/SPC/SRA should request peer review (if required) from the CI, providing a copy of the 'Peer Review: Guidance for Researchers' (section 10).

7.2. Points that should be considered during a peer review

a. The relative merit of the research: The aims, research questions and hypothesis should build on and address gaps in existing knowledge. The research should address a health issue that is important for health and /or society.

b. The design and methods: consideration of the quality of study design and the robustness of the methods used. This may include methodology, a description of sample recruitment and characteristics (including number, gender and ethnicity where relevant) and proposed methods of data analysis. An indication of timelines for the research should be included.

c. The feasibility of the research: consideration of whether the overall strategy, methodology and analyses are well reasoned and appropriate to achieve the specific aims of the project. The review will determine whether the research has the likelihood, on balance, of improving scientific knowledge, concepts, technical capacity or methods in the research field.

d. The presentation of the application: consideration of the overall presentation including structure, 'understandability' clarity and readability of the research application. Presentation is a strong determinant of whether the research will be fundable and whether it will be done at all.

e. Scientific validity:
    i. Credibility of the research; are the design and methodology appropriate?
    ii. Significance/importance of the finding
    iii. Originality of the proposal
    iv. Does the paper refer properly to work done by others?
    v. Should the paper be published, improved or rejected (usually to be submitted elsewhere).

7.3. Who should conduct peer review

It is the responsibility of the Chief Investigator to arrange for peer review.

There are existing peer review groups established within various divisions throughout UCL and UCLH. These peer review groups are suitable to conduct peer review for both interventional and observational studies.

Where a peer review group is not available, the CI should ensure the peer review is conducted by a suitably experienced person within the area of study (research or clinical). The person(s) must be independent and have no involvement in the funding, set-up or running of the proposed study. A Head of research department/division is an acceptable example.

7.4. Evidence of peer review

The JRO should receive a letter or email from the peer reviewer(s) as evidence of peer review detailing:

a. The level of peer review that has been conducted

b. Any comments (using the list provided in 7.3 above where possible).
c. Name, occupation and contact details of peer reviewers

8. IMPLEMENTATION & TRAINING

Staff following this SOP shall confirm they have read and understood the procedures outlined above by completing their relevant training log as a record of acknowledgement. It may be necessary to ensure staff are trained in using specific SOPs.

9. PUBLICATION & COMMUNICATION

This SOP is authorised and published on the JRO website: http://www.ucl.ac.uk/jro. The latest version of the SOP will be made available on the JRO website. The original fully signed master copy is stored in a designated binder within the JRO and maintained by the QA Manager. An electronic copy of the SOP is available on the ReDA SOP store.

10. TEMPLATES ASSOCIATED WITH THIS DOCUMENT

	Document	Latest version
1.	Peer review: guidance for researchers	ReDA SOP store

11. REFERENCES

Research Governance Framework 2005 (2nd edition)
https://www.gov.uk/government/publications/research-governance-framework-for-health-and-social-care-second-edition

JRO SOP 2 Granting UCL and UCLH sponsorship for Observational Studies
www.ucl.ac.uk/jro/standardoperatingprocedures and ReDA SOP store

JRO SOP 3 Granting UCL Sponsorship for Interventional Trials (excluding Clinical Trials of Investigational Medicinal Products and Device Trials)
www.ucl.ac.uk/jro/standardoperatingprocedures and ReDA SOP store

Scientific Peer Review, Dunedin School of Medicine
http://dnmeds.otago.ac.nz/research/pdf/peer-review-dept-guidelines.pdf

12. APPENDICES

Appendix 1: Decision tree for peer review requirements

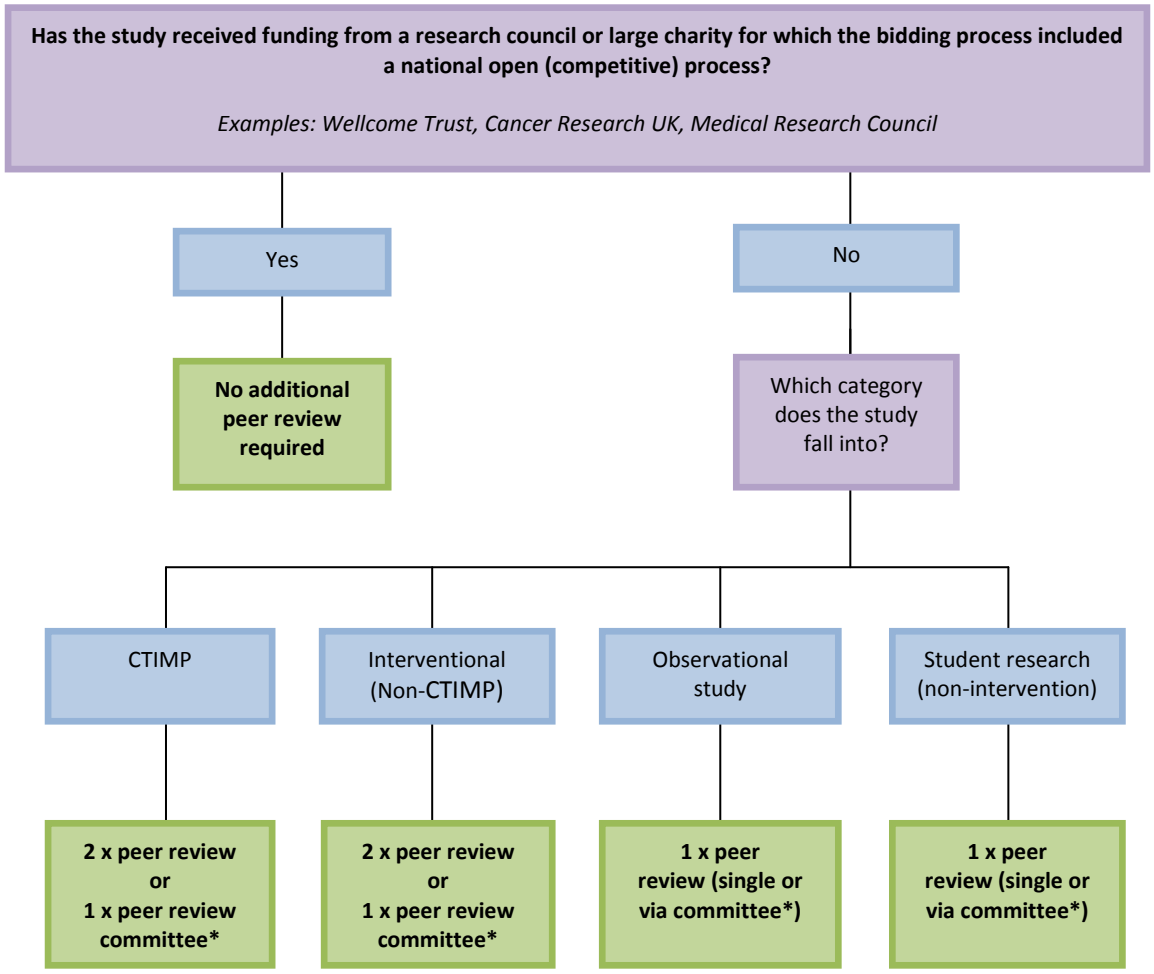
13. SIGNATURE PAGE

Author: Name / Job Title		
Signature / Date:		

Reviewed by: Name / Job Title		
Signature / Date:		

Authorised by: Name / Job Title		
Signature / Date:		

Appendix 1: Decision tree for peer review requirements



*Peer review committee: A group constituting of at least **three** individuals qualified to conduct peer review