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NHS Foundation Trust

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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	2	27/04/2020	27/04/2023
Author: **Name and Job Title**	Mona Hassan Research Quality & Safety Manager		
Authorised by: **Name and Job Title:**	Rajinder Sidhu Deputy Director of Research Support		
Target Audience	UCLH/UCL Joint Research Office; UCL/UCLH Chief Investigators		
Please check with the Research Quality & Safety Manager that this is the latest version of this SOP.			

Revision Chronology			
Version	**Effective Date**	**Reasons for Change**	**Author**
1	17/08/2015	Initial SOP following the finalization of the peer review process developed by the peer review working group.	Suzanne Binks
2	27/04/2020	SOP updated to latest JRO template. References to Research Governance Framework for Health and Social Care Research (2nd edition) replaced with the U.K. Policy Framework for Health and Social Care Research (3rd edition). JRO job titles updated. Additional peer review requirements added regarding studies going through NIHR portfolio adoption. References and links updated.	Mona Hassan, Research Quality & Safety Manager

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
QA	Quality Assurance
R&D	Research & Development
RGM	Research Governance Manager
RM (ATIMP)	Regulatory Managers (ATIMP)
RM&G	Research Management & Governance
SO	Sponsorship Officer
SOP	Standard Operating Procedure
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 U.K Policy Framework for Health and Social Care Research 2017 (3rd edition, v3.3 07/11/2017) and its subsequent amendments, and Good Clinical Practice as outlined by the EU Clinical Trials Regulation 2001/20/EC.

4. BACKGROUND

As per the U.K Policy Framework for Health and Social Care Research (and subsequent amendments) and Research Ethics Committees, it is a 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 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 SOP 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 SO/RGM/SRA/RM (ATIMP)	• 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 SO/RGM/SRA/RM (ATIMP) should follow the decision tree (Appendix 1) to determine whether peer review is required and, if so, the level required.

The SO/RGM/SRA/RM (ATIMP) should request peer review (if required) from the CI, providing a copy of the 'Peer Review visio: 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[1].

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

[1] U.K Policy Framework for Health and Social Care Research, Section 9.2: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

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 signature log as a record of acknowledgement.

9. PUBLICATION & COMMUNICATION

This latest version of this SOP is authorised and published on the JRO Website: www.ucl.ac.uk/joint-research-office. The electronic versions maintained here are the controlled copies; therefore, staff are encouraged to frequently review that they have the most up to date copies.

The original fully signed master copy is stored in a designated binder within the JRO and maintained by the Research Quality & Safety Manager.

10. TEMPLATES ASSOCIATED WITH THIS DOCUMENT

	Document	Stored
1.	Guidance for Researchers: JRO Peer Review Requirements for UCL/UCLH Sponsorship	JRO website R&D shared drive
2.	JRO SOP 2: Granting UCL and UCLH sponsorship for Observational Studies	R&D shared drive
3.	JRO SOP 3: Granting UCL Sponsorship for Interventional Trials (excluding Clinical Trials of Investigational Medicinal Products and Device Trials)	R&D shared drive
4.	JRO/SPON/S07/04: SOP for granting UCL sponsorship for Clinical Trials of Investigational Medicinal Products (CTIMPs)	JRO Clinical Trials Team (UCL S drive)

11. REFERENCES

Health Research Authority:
https://www.hra.nhs.uk/

International Conference on Harmonisation Good Clinical Practice: E6 (R2)
http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf

JRO Website:
http://www.ucl.ac.uk/joint-research-office

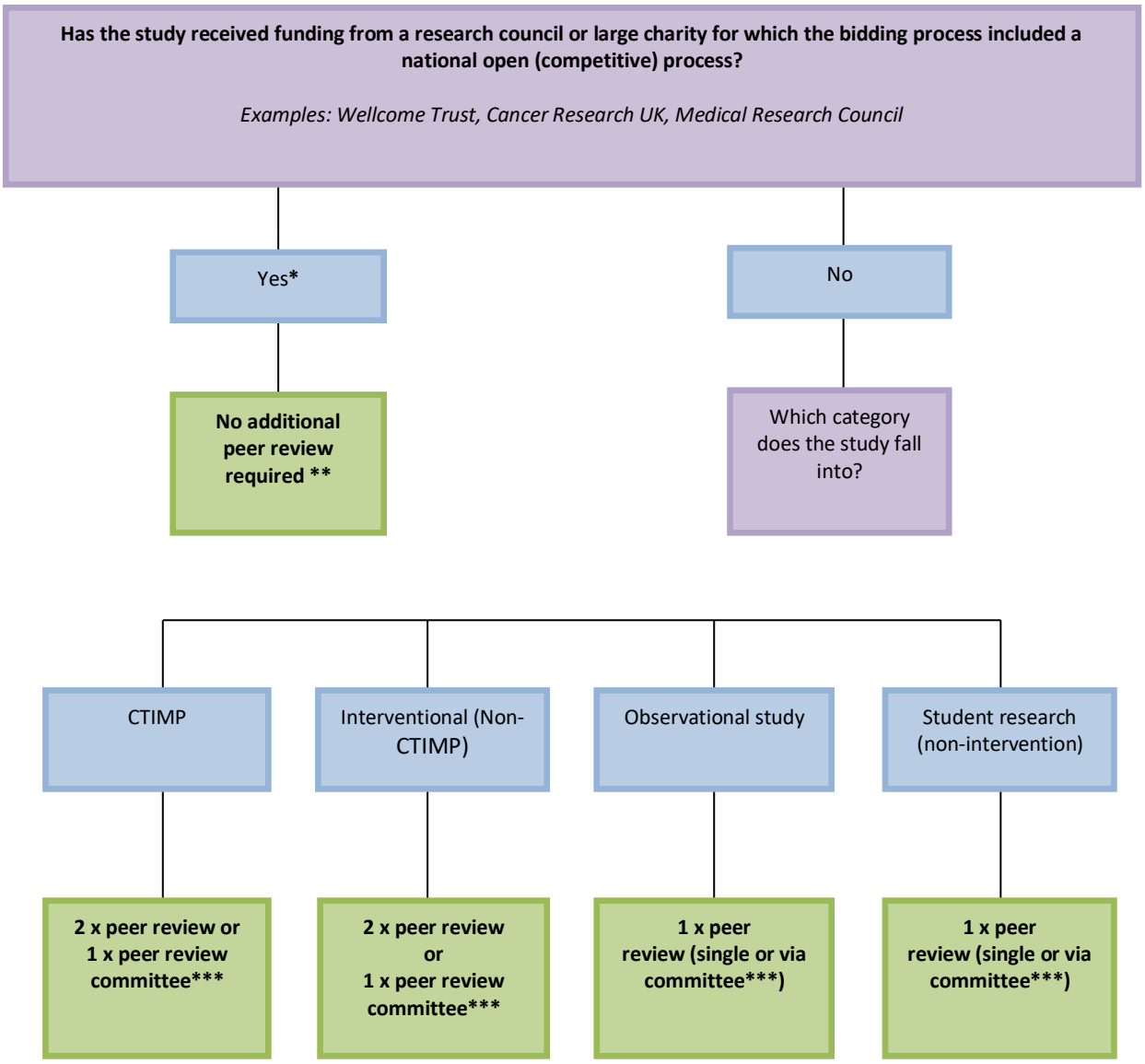
NIHR Eligibility Criteria for NIHR Clinical Research Support and NIHR non-commercial Partner List:
https://www.nihr.ac.uk/documents/nihr-non-commercial-partner-list/11458

Peer/Scientific review of research and the role of NRES Research Ethics Committees (RECs):
https://www.hra.nhs.uk/documents/60/peer-scientific-review-of-research-and-the-role-of-nres-research-ethics-committees-.pdf

U.K Policy Framework for Health and Social Care Research (V3.3, 07/11/2017 Edition):
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

12. APPENDICES

Appendix 1: Decision tree for peer review requirements



*Funders' peer reviews are acceptable but it may not be sufficient for sponsorship, as both consider different aspects in different levels of detail; the funder may have only submitted a skeleton protocol on which funding was awarded, therefore the sponsor should consider whether additional peer reviews are required.

For studies applying for LCRN Portfolio Adoption that are **not on the NIHR's Partner funding list (https://www.nihr.ac.uk/documents/nihr-non-commercial-partner-list/11458), the LCRN request evidence of **two** peer reviews per project proposal. The NIHR portfolio team will ask the sponsor to confirm independent, expert and propionate peer reviews have been carried out.

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

13. SIGNATURE PAGE

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Authorised by: Name / Job Title	Rajinder Sidhu Deputy Director of Research Support	
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