



# University Hospitals of North Midlands **NHS**

NHS Trust

## R&I STANDARD OPERATING PROCEDURE FOR PEER REVIEW

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AUTHOR:	Dr Simon Lea
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Sign	Date
AUTHOR: Dr Simon Lea (name, job title) Academic Development Officer  Signature 	20/12/2019.
APPROVED BY: Robert Bowler, R&I QA Manager  Signature 	19/12/2019

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## 1. PURPOSE

The purpose of this SOP is to describe the peer review process for studies seeking UHNM sponsorship. It is a HRA requirement for sponsors to have in place adequate peer review systems proportionate to the research activity. Peer review would generally focus upon the following study elements:

- 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. The scientific and clinical validity

The level of peer review will differ depending on the type of study.

It is the Chief Investigator's responsibility to ensure sufficient peer review is in place for a study before sponsorship is agreed.

This SOP provides information on:

- a. When peer review is required
- b. The peer review process
- c. The main points that should be considered when conducting a peer review
- d. Who should conduct a peer review
- e. The outcomes of the peer review process

## 2. SCOPE

Studies seeking UHNM sponsorship which have not already received peer review by the funder or where no funding has been applied for, or where the level of peer review already gained has been deemed not adequate by the COG.

This SOP does not apply to studies hosted by UHNM.

## 3. RESPONSIBILITIES

ADT	Advises CI on peer review requirements Receives evidence of peer review
CI	Ensures adequate peer review is in place Provides evidence of peer review to R&I Office
COG	Make final decision on sponsorship of studies

## 4. PROCEDURE

### 4.1 When is peer review required?

All research projects seeking UHNM sponsorship,

- that have not already received peer review by the funder, or
- where no funding has been applied for, or
- where the level of peer review already received has been deemed by the COG not to be sufficient

will require peer review.

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The ADT can use the decision tree (Appendix A) to determine whether 1 or 2 reviewers are required.

#### 4.2 The peer review process

If Peer Review is required:

- The CI should complete the Peer Review Application form (Doc Ref 044) and forward this to the ADT.
- The ADT will identify up to two potentially suitable reviewers (either from their approved reviewers list or identified as someone from the CI's clinical field of work) and ask them if they will perform peer review of the study. If they agree, the ADT will forward to the reviewer
  - the completed Peer Review Application Form (Doc Ref 044) and
  - a Peer Review Feedback Form (Doc Ref 045).
- The reviewer should be asked to return their review within 2 weeks of date of receipt of the documents. If this is not possible, the ADT should consider the need to identify a different reviewer.

#### 4.3 Points that should be considered during a peer review

- a. The relative merit of the research: The aim(s), research question(s) and hypothesis should bridge gaps in existing knowledge. The research should address an issue that is important for improving health or improving the management of health conditions.
- 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 of participants where relevant) and proposed methods of data analysis (including who will perform the analysis and their qualifications for doing so). 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 aim(s) of the project. The review will help to determine whether the research has the potential to improve scientific knowledge, concepts, technical capacity or treatment / management methods in the field.
- d. The presentation of the application: consideration of the overall presentation including structure, clarity and readability of the research application.
- e. Scientific and clinical validity:
  - i. Credibility of the research; are the design and methodology appropriate?
  - ii. Significance/importance of the finding(s)
  - iii. Originality of the proposal
  - iv. Does the paper refer properly to work done by others?
  - v. Is the work clinically / scientifically important or relevant?

#### 4.4 Who should conduct peer review?

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UHNM's peer reviewers are experienced clinicians from a variety of specialties throughout UHNM. This group are suitable to conduct peer review for both interventional and observational studies.

R&I will identify the most appropriate reviewers for the project, ensuring the person or persons, are suitably experienced within the area of study (research or clinical). The person(s) conducting the peer review must be independent and have no involvement in the funding, set up, or running of the proposed study.

#### 4.5 Outcomes of peer review

R&I should receive the completion of a Peer Review Feedback form (Doc Ref 045) which asks the reviewer to give an overall grade to the project:

1. Grade 1: Application is approved and may proceed to COG for sponsorship decision
2. Grade 2: The application requires minor amendments or further information. Application to be revised and re-assessed by reviewer(s) prior to proceeding to COG.
3. Grade 3: The application requires major revision. Application to be revised and reassessed by reviewer(s) prior to proceeding to COG.
4. Grade 4: Reject on the basis that the project has major scientific / clinical flaws.

The feedback will be anonymised and sent back to the CI. The feedback given to the CI will take one of the following forms:

Feedback Grade 1: The CI will be contacted with a Favourable Peer Review Opinion letter stating that the project will now be reviewed at COG.

Feedback Grade 2-3: The CI will be required to address the comments raised by the reviewers and resubmit their Peer Review Form with the changes tracked in the document and a supporting letter / email outlining changes made or reasons for not making changes. The investigator's responses will be returned to the reviewers who may adjust their recommendation as appropriate.

Feedback Grade 4: The CI will be contacted to explain why their project has been rejected.

Where the two reviewers disagree on the recommendation for the study, a third review will be sought.

The feedback from the Peer Review process will be used by the COG to inform the study sponsorship decision.

#### 5. ABBREVIATIONS & DEFINITIONS

ADT	Academic Development Team
CI	Chief Investigator
COG	Clinical Oversight Group
HRA	Health Research Authority
R&I	Research and Innovation
UHNM	University Hospitals of North Midlands

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## 6. ASSOCIATED DOCUMENTS & REFERENCES

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI Ethical Principles for Medical Research Involving Human Subjects.

Medicines for Human Use (Clinical Trials) Regulations 2004. *It is assumed that by referencing the principal regulations, all subsequent amendments made to the principal regulations are included in this citation.*

Doc Ref 044 UHNM R&I Internal Peer Review Application Template

Doc Ref 045 UHNM R&I Internal Peer Review Feedback Form

### References

1. UK Policy Framework for Health and Social Care Research v3.3 (accessed 19/04/18). <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>
2. National Institute for Health Research, Research Governance Guidelines (accessed 20/04/18). [https://www.nihr.ac.uk/funding-and-support/documents/current-funding-opportunities/phr/NETSCC\\_TSC\\_SSC-Guidance\\_April-2016.pdf](https://www.nihr.ac.uk/funding-and-support/documents/current-funding-opportunities/phr/NETSCC_TSC_SSC-Guidance_April-2016.pdf)

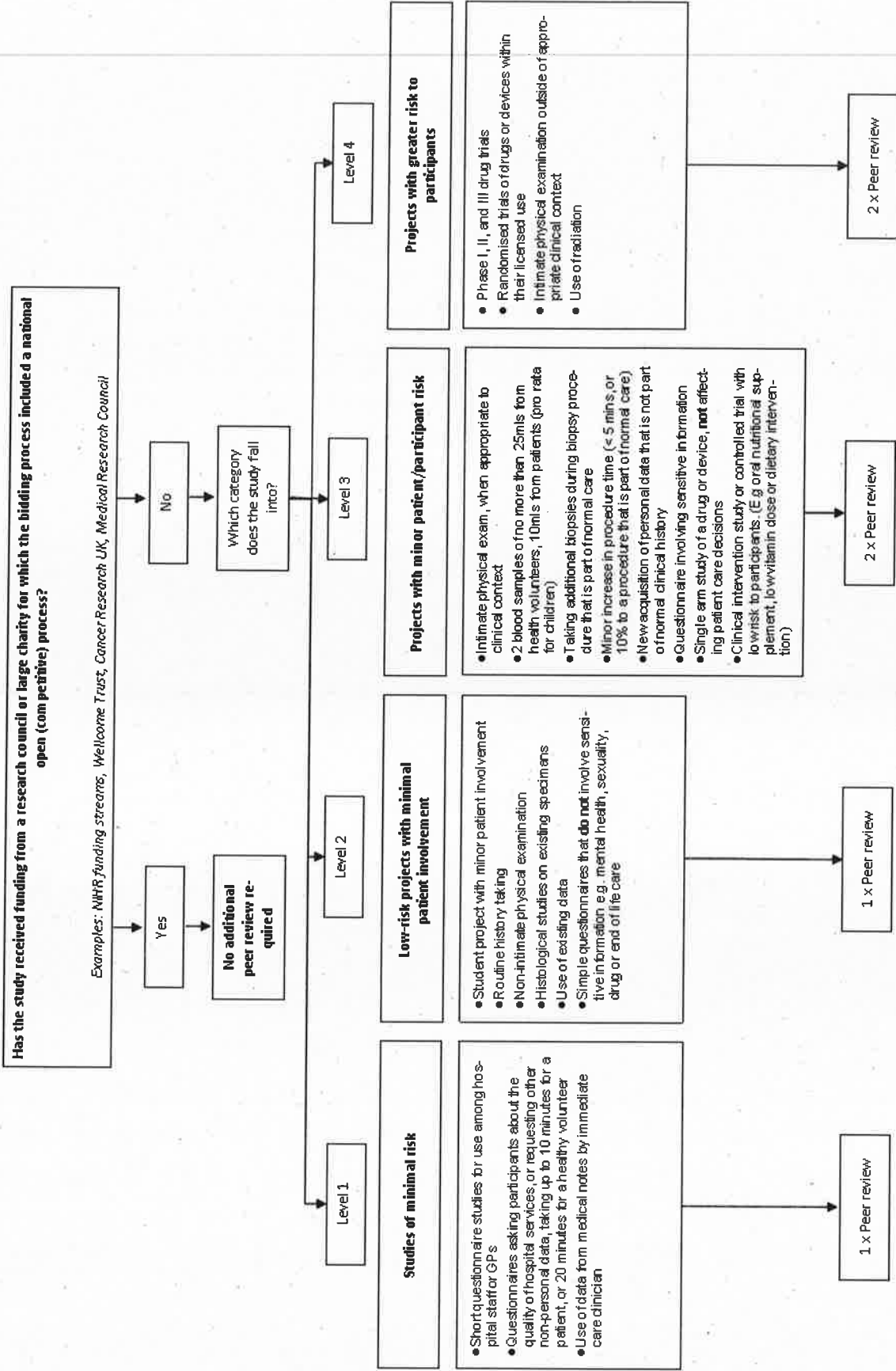
## 7. DOCUMENT HISTORY

Following an Independent Audit in 2017 it was determined with Research and Development Senior team that the Quality Management System was to be re-written using a new system of reference numbers and where some Standard Operating Procedures would have different names. Therefore in the Document History under "version number" the previous SOP reference number has been included for previous versions.

Version Number	Reviewed By (name, job title)	Effective Date	Reason for Change
RG023 1.0	Dr. S Lea,	November 2019	New procedure that outlines the process to describe the requirements for peer review for UHNM sponsored studies.

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Appendix A



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SOP Reading Log (DocRef005) must be completed fully and the SOP listed & signed by the staff member as evidence of the review and understanding of the SOP. The knowledge check is required to be stored in your Personal R&I Training Record. If the staff member does not attain 4/4 - their manager should reiterate the main points of the SOP to confirm knowledge and understanding of the SOP.

**QMS**  
**SOP (RG023) KNOWLEDGE CHECK**

<p><b>QUESTION 1:</b></p> <p>For whom is peer review a requirement?</p>	<p><b>ANSWER:</b></p> <p>A: Research and Innovation Department <input type="checkbox"/></p> <p>B: Health Research Authority <input type="checkbox"/></p> <p>C: University Hospitals of North Midlands NHS Trust <input type="checkbox"/></p>
<p><b>QUESTION 2:</b></p> <p>Name the 3 purposes of peer review?</p>	<p><b>ANSWER:</b></p> <p>A: To assess the skills of the researcher, the supervisor and the cost of the project <input type="checkbox"/></p> <p>B: To assess whether the project can be supported through the relevant clinical department, Research &amp; Innovation and the Trust <input type="checkbox"/></p> <p>C: To assess the merit, scientific validity and methodology of project <input type="checkbox"/></p>
<p><b>QUESTION 3:</b></p>	<p><b>ANSWER:</b></p>

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<p>To which group are conflicting peer review assessments escalated?</p>	<table border="1"> <tr> <td data-bbox="231 280 327 1265">A: Research and Innovation Clinical Oversight Group</td> <td data-bbox="231 172 327 280"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="327 280 470 1265">B: To a 3<sup>rd</sup> independent reviewer</td> <td data-bbox="327 172 470 280"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="470 280 582 1265">C: To Keele University</td> <td data-bbox="470 172 582 280"><input type="checkbox"/></td> </tr> </table>	A: Research and Innovation Clinical Oversight Group	<input type="checkbox"/>	B: To a 3 <sup>rd</sup> independent reviewer	<input type="checkbox"/>	C: To Keele University	<input type="checkbox"/>
A: Research and Innovation Clinical Oversight Group	<input type="checkbox"/>						
B: To a 3 <sup>rd</sup> independent reviewer	<input type="checkbox"/>						
C: To Keele University	<input type="checkbox"/>						
<p><b>QUESTION 4:</b></p> <p>How many reviewers are required when the project has minor patient or participant risk?</p>	<p><b>ANSWER:</b></p> <table border="1"> <tr> <td data-bbox="678 280 805 1265">A: 1 internal reviewer</td> <td data-bbox="678 172 805 280"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="805 280 949 1265">B: 1 external reviewer</td> <td data-bbox="805 172 949 280"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="949 280 1077 1265">C: 2 internal reviewers</td> <td data-bbox="949 172 1077 280"><input type="checkbox"/></td> </tr> </table>	A: 1 internal reviewer	<input type="checkbox"/>	B: 1 external reviewer	<input type="checkbox"/>	C: 2 internal reviewers	<input type="checkbox"/>
A: 1 internal reviewer	<input type="checkbox"/>						
B: 1 external reviewer	<input type="checkbox"/>						
C: 2 internal reviewers	<input type="checkbox"/>						
<p><b>Staff Member Signature:</b></p>	<p><b>Date:</b> ..... / 4</p>						
<p><b>Manager Signature:</b></p>	<p><b>Date:</b></p>						

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