King's College Hospital NHS
NHS Foundation Trust

KCH Peer Review

Purpose of Peer Review

The Research Governance Framework states that 'Every proposal for health and social care research must be subjected to review by experts in the relevant fields able to offer independent advice on its quality' (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/139565/dh_4122427.pdf). The aim of the peer review process is to ensure research is well designed and viable.

NRES states that it should be satisfied that the review already undertaken is adequate for the nature of the proposal under consideration. Under RGF and NRES regulations it is the sponsor's responsibility to ensure appropriate review is undertaken. Although it should be noted that this is a highly contested point and in practice many RECs adopt the position that if a study is not scientifically sound then it is not ethical to issue approval and thus the science is also a proper topic for REC consideration, and as such an integral responsibility of ethical review.

Definitions and references of peer review vary among three key regulatory bodies and/or documents (see appendix 1), but all agree that peer review should comprise of the following key elements:

- be independent – reviewers should be outside the direct study team;
- be expert – reviewers should have relevant knowledge to be able to properly assess study design and methodology;
- be proportionate - conducted so that the review is commensurate with the scale and nature of the research.

In sum the scientific review should provide judgement on the value or harm to all parties if the research is blocked, and if the research goes ahead. It can do this by addressing the following:

- is there evidence of prior research?
- has the question been answered already?
- is there a need for this research?
- will it add to current knowledge and treatment?
- will patients or communities benefit?
- will the proposal answer the question it sets itself given proposed design, and is this a relevant question?

Together with an understanding of what is normal care and research will impact on this:

- is research in this area needed?
- what is the context of this work and how will it affect care?

Plus an assessment of the risks from someone with expertise of the field:

- does it withhold proven therapy or is it researching treatment that prior research has demonstrated is inferior?
- does it expose participants to risk?

Although part of peer review should consider feasibility in general, KCH peer review should be distinguished from KCH specialty feasibility review via the local governance process. General feasibility issues as part of peer review concern:

- is it likely this research team will be able to successfully conduct and conclude the research?
- is there similar or complementary research underway elsewhere?
- is the cost of the research viable for KCH/the clinical specialty? (in terms of use of KCH resources and costs to KCH actual and 'in kind')

When is KCH Peer Review Required?

When a study is sponsored by KCH and is not subject to independent review as a result of a peer reviewed grant application, an internal KCH peer review is required. If a grant application is subsequently rejected during the processing of a submission, then the requirement for peer review must be considered before final R&D approval is issued: determination in first instance to be made by R&D Manager/KCH sponsor.

Student studies which are sponsored by KCH are exempt from this requirement, as it is understood that student studies have been reviewed appropriately under the supervising university's usual quality assurance and supervision arrangements.

The KCH peer review should be undertaken prior to sponsor authorisation (e.g. for REC or R&D submissions). This is to ensure that only robust and finalised protocols are sponsored and submitted to external bodies such as RECs for further review.

Peer review process in KCH

Peer review is managed via each clinical specialty research area.

R&D dept Facilitators assist R&D Leads to implement the peer review process derived from a standard set of proformas and this procedural guide.

The proformas consist of a) science summary; b) resource summary; c) reviewers' comments form; and d) outcome/approval letter.

Applications by researchers should consist of profomas a) and b) together with a full protocol.

Step by step guide:

1. Applicant researcher contacts the R&D Facilitator for the clinical specialty to confirm requirement for peer review.
2. Facilitator issues proformas for completion by the research applicant. (email)
3. Facilitator fields applications to the R&D Lead.
4. R&D Lead is responsible for identifying suitable reviewers.
5. Facilitator contacts reviewers to confirm their assistance and then issues reviewer's comment proforma and applicant's completed forms for review. Facilitator confirms deadline for receipt of review. (email)
6. Facilitator liaises with Lead and reviewers to ensure suitable reviewers are appointed and feedback in a timely manner (maximum 4 weeks). (email reminders sent to reviewers 1 week prior to review deadline).
7. Reviews are expected to either be handled via the agenda of the next available specialty R&D meeting (RGB) or, if appropriate, outside of meeting via chair's action.
8. RGB or R&D Lead assess reviews and issue outcome decision (approval, conditional approval or rejection).
9. Facilitators follow up to secure completed review forms, confirm outcome decision with R&D Lead/RGB and issue outcome letter to research applicant on behalf of the R&D Lead.
10. The Facilitators ensure all paperwork for each review is filed in a study folder on R&D 'u' drive (Facilitation/Peer Review/study name folder).
11. Where an applicant is the R&D Lead, the Facilitator will work with a suitable deputy within the RGB to administrate to ensure independent review.
12. In circumstances where it is not possible to provide independent review for instance due to lack of suitable independent reviewers within the KCH clinical specialty (nor via external local contacts with the specialty), then the Facilitator will refer the review request to the Trust-wide Conduct and Research Oversight Committee (CROC). CROC will then be responsible for organising the required peer review.

Appendix 1 – Peer Review Proformas
see below:

1. Research Applicant Proposal Summary form
2. Resource and Costings form
3. Reviewer Comments from
4. Review Outcome Letter