

The Leeds Teaching Hospitals NHS Trust
Research & Development Department

PEER REVIEW OF RESEARCH PROJECTS
GUIDANCE NOTES FOR RESEARCHERS

Introduction

Under the DH's national research governance arrangements the Trust is obliged to ensure that all research projects involving patients, their organs, tissue or data undergo appropriate independent expert review through accepted scientific and professional channels. Peer review is seen as a key indicator of quality assurance in research and is an essential process to ensure relevant and scientifically sound research is undertaken within the Trust. The Trust cannot give management approval for projects which do not meet these criteria with the obvious implications for extension of NHS indemnity to researchers and use of Trust facilities for research.

The following guidelines attempt to clarify the process of peer review and show how the requirements can be met with the minimum of bureaucracy.

What is peer review?

Peer review is a system of review for research. Review should be:

- Independent – that are no conflicts of interest
- Expert - in terms of understanding of the clinical and research methodologies and outcomes
- Recorded – clear, written evidence of the review should be available

What doesn't constitute peer review?

- Research Ethics Committee (REC) approval – a project must be peer reviewed **before** it is submitted to the REC.
- Publication in a peer reviewed journal – a project must be peer reviewed **before** it is carried out.

When should peer review take place?

Peer review of a project should be undertaken once the scientific case and protocol or plan have been developed but before any research (including pilot studies) is undertaken. **It should always occur before Research Ethics Committee and Trust management approval are sought.** However grant applications to external funding bodies will receive managerial sign off by the Trust before peer review is undertaken, on the assumption that peer review will take place as part of the grant awarding process. Once the project is funded, full research ethics committee and management approval must be sought before the project can proceed in the Trust.

The REC provides independent advice on the ethical issues of research proposals. The purpose of the REC is to protect the dignity, rights, safety and well being of

research participants. It is not its role or responsibility to undertake peer review of the proposals it reviews. It is however essential that the REC has evidence of the scientific validity of the proposed work given that it is unethical to undertake poor quality research on patients.

The responsibility for approval of projects lies with the Clinical Management Team (CMT) Clinical Director/Research Lead. CMT management approval (see separate guidance) should not be given until appropriate peer review has been undertaken. Once CMT level approval is granted all projects must be submitted to the Trust R&D Department for institutional level approval. The Trust R&D Department will then ensure that all appropriate managerial and ethical approvals have been completed.

What is acceptable peer review?

External Peer Review

Projects that are externally funded and/or sponsored by non-commercial grant giving bodies are subject to external peer review. The following are regarded as appropriately peer reviewed:

- Projects or research activities funded by competitive grants from external non-commercial agencies, for example, Research Councils, major research charities, members of the Association of Medical Research Charities, NHS R&D.
- Multicentre trials run by the MRC and similar bodies with high quality peer review of protocols.
- Activity linked to externally peer reviewed programme grants (MRC, Cancer Research UK etc).
- Other research charities and charitable trusts that have a robust and documented independent peer review process

Commercially funded/sponsored projects

Commercially funded projects carried out purely on behalf of the funder and which have been subject to robust and reliable peer review processes of the sponsor organisations are acceptable to the Trust.

Other commercially funded projects involving significant academic/intellectual input from local researchers are, in effect, research partnerships. Evidence of independent peer review is required for such projects.

Internal Peer Review

Locally organised or pilot projects without external funding and projects funded by external organisations that do not carry out their own peer review must undergo peer review. Peer review must take place **before** the project is submitted to the Local Research Ethics Committee and Central R&D Department for review and approval. Evidence of peer review must be presented to the CMT Clinical Director/Research Lead in order to obtain local management approval of the project (CMT sign off of R&D project approval form). **It is the responsibility of the CMT to ensure that adequate peer review has been undertaken. The type of peer review should be commensurate with the scale and risk of the research project.**

Low Risk Research

Independent internal peer review by the CMT Clinical Director/Research Lead is sufficient for "low risk" studies. These are defined as projects that have only a minimal impact on participants, and where the risk or inconvenience to participants is low for example, pilot, preliminary efficacy, or proof of principle projects. The study

should not involve patients from vulnerable or high risk groups (see High Risk Research below).

Minimal impact research includes:

- collection of small samples of body fluids (blood, tears, saliva, urine),
- collation and review of electronic data/records
- use of tissue or other samples already obtained or obtained as part of the patient's routine care,
- review of case notes
- use of standard questionnaires
- use of structured interviews that do not contain potentially distressing questions

High Risk Research

External peer review must be obtained for high risk studies. Responsibility for co-ordination of the external review lies with the CMT Clinical Director/Research Lead. Individual researchers may nominate external referees. High risk studies are defined as those where invasive interventions form part of the study and/or involve patients from vulnerable groups, for example, children, unconscious patients, participants who have a dependent relationship with the investigator.

Student Research

Undergraduate and postgraduate student research projects should be reviewed by the individual's supervisor only. As with all other research, documentary evidence is required before final management approval will be given.

Please note that in all cases:

- It is crucial that those peer reviewing the project are not co-investigators in the study or members of the same research team. Any Trust researcher or member of staff who is asked to undertake peer review must, of course, declare any conflicts of interest in the project
- There must be clear, written evidence of peer review before the Trust gives final management approval for a study to proceed. A sample review proforma is attached at appendix 1 which experts may wish to use to record their comments.
- The R&D Department will be happy to offer advice on the most appropriate peer review for an individual study.

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