

The Leeds Teaching Hospitals NHS Trust

Research & Development Department

Research Governance Policy

1 Background

Research in Medicine and Health is both a corporate and individual activity. At a corporate level it must be managed appropriately to ensure (i) patient safety and dignity, (ii) research of high quality and relevance is undertaken and (iii) a balanced spectrum of research activity is being pursued and (iv) financial probity. Within this framework the importance of ideas from individuals is crucial; it is these new and innovative ideas, which will form the cornerstone to research, which is seeking to resolve clinical problems.

2 Research Governance within the Trust Research Strategy

The Trust's policy on Research Governance seeks to provide a framework for research, which complies with good practice in research, without restricting the freedom of individual researchers to develop ideas, which can improve clinical care. The policy is a component of the Trust Strategy for Research & Development.

The implementation of the policy builds on existing partnerships with Universities and, where possible, is pursued jointly.

The bureaucracy associated with research governance can be minimised by adopting common approaches within the Clinical Management Teams (CMTs) of the Trust and with research partners.

3 Research Governance Framework

The components of the policy on research governance are presented in this document under five headings which match Department of Health guidance. In many cases the implementation of the policy is aided by the partnerships the Trust has with other institutions; for example, universities which have processes already in place to support research governance. Similarly, the procedures of high quality external funding bodies, for example, independent peer review, project monitoring, ethical approval, also support the implementation of the policy.

(a) General Management Arrangements

- (i) The Trust should be notified of, and approve, all research which is proposed to be undertaken in the Trust. The progress of research projects will be monitored. Within each CMT, or designated clinical area, the designated research lead is responsible for prior approval of all R&D activity. The

responsibilities of the CMT research lead are described in the R&D Handbook.

- (ii) There should be clear documented agreements with research partners about the allocation of responsibilities for research.
- (iii) Staff should be made aware and kept informed of the Research Governance framework.
- (iv) Adverse events associated with research should be recorded.
- (v) Systems should be set in place to detect and deal with research misconduct and fraud.
- (vi) Research governance is a component of the wider issue of clinical governance and appropriate links should be set in place to ensure compatibility.
- (vii) Honorary contracts should be awarded to non-NHS researchers involved in research within the Trust. Employment contracts and honorary contracts should include compliance with the Research Governance Framework.

(b) Ethics

- (viii) All research should have research ethics committee approval, where appropriate.
- (ix) Arrangements should be set in place to monitor that the procedures in the protocol approved by the research ethics committee, for example informed consent, are being adhered to.

(c) Science

- (x) The 'sponsor' of research should be explicitly stated. This can include externally funded research, research funded by the Trust and research which is indirectly sponsored by another agency.
- (xi) Clinical trials research should be conducted in accordance with the principles of good clinical practice (GCP).
- (xii) Clinical trials involving Investigational Medicinal Products (IMPs) must comply with the Medicines for Human Use (Clinical Trials) Regulations 2004
- (xiii) Prospective research project should be subjected to expert independent review.
- (xiv) Appropriate consumer involvement should be sought at various stages in the development and execution of research projects.

(d) Information

- (xv) Systems should be set in place to ensure that all researchers are aware of the Data Protection Act and other guidance related to handling information.

- (xvi) Research should be both published in peer reviewed academic journals and appropriately disseminated to the relevant target audiences.

(e) Finance

- (xvii) There should be written agreements with sponsors for all funded work in the Trust. In many cases this will be with a University partner on behalf of the Trust.
- (xviii) There should be systems to ensure the appropriate costing and financial management of research.
- (xix) Intellectual property arising from research should be identified and registered with appropriate agreements for ownership, exploitation and income of arising from that intellectual property.