

# **The Leeds Teaching Hospitals NHS Trust**

## **Department of Research & Development**

### **Policy for the Management of Industry Funded Research**

#### **1 Introduction**

The Trust recognises the role that industry sponsored research can play in contributing to the provision of high quality patient care. Such activity can offer Trust clinicians early access to the latest technologies for diagnosing and treating disease and is essential for the development of new medicines and healthcare technologies.

The Trust supports the conduct of high quality industry funded research by NHS staff, including honorary contract holders, on NHS premises. However, as a teaching hospital, the Trust places priority on peer-reviewed research, sponsored by quality external non-commercial agencies that is of strategic importance to the NHS and of high standing. NHS R&D support funding can not be used to support or subsidise industry sponsored R&D.

It is essential that all industry sponsored research is carried out to recognised international quality standards (e.g. ICH). It must be fully financed to ensure it does not incur a cost to the NHS. The interests and safety of patients must be ensured by appropriate insurance and indemnity arrangements.

#### **2 Governance of Industry Sponsored Research**

The Trust has responsibility to ensure that there are appropriate governance arrangements in place for any industry sponsored research, thus ensuring that:

- all trials are fully costed and that the costs are properly recovered;
- maximum benefit is provided to the investigator and the Trust;
- the interests of both the investigator and the Trust are protected in the event of Intellectual Property arising out of research;
- the interests and safety of patients enrolled in trials are protected in all eventualities;
- any external regulatory, ethical and financial approvals are obtained;
- any risks (liabilities) are properly considered and minimised;
- the Trust presents a thoroughly professional approach in its dealings with industry.

In order to ensure that these areas are covered, all activity must be negotiated and/or authorised by the Trust's R&D office or Divisional Finance Managers. Only protocols and trials registered with the R&D office will be covered by the appropriate insurance or NHS indemnity arrangements. Investigators must be aware that the Trust will not accept liability for any activity that has not been properly registered and managerially approved.

#### **3 Ownership of Data & Intellectual Property Rights**

The arrangements for the ownership of data and intellectual property rights (IPR) should be agreed at the onset of the study, as part of the contract negotiation process.

The ownership of data and IPR is dependent on the type and nature of the study. For contract research, led by the sponsor and with limited academic value to the Trust, the data generated and IPR are retained by the sponsor. For other projects that may be of academic value to the Trust, such as collaborative research agreements, IPR may be shared. Further information is provided in a separate Trust policy on IPR.

#### **4 Costing and Pricing Industry Sponsored Research**

The 1996 NHS R&D Directive states that all industry sponsored research should be fully costed. The full cost of a research project should include the direct staff costs, costs for any contracted service (such as pathology, radiology and pharmacy) and appropriate indirect costs.

Indirect costs cover infrastructure costs such as finance, research administration, personnel and property services. The level of indirect cost is determined by the benefit gained by the sponsor from the study, in terms of ownership of data and intellectual property, but will be no less than a minimum baseline as directed by the Director of Finance.

Payments by sponsors can only be made to Trust exchequer funds or to the University of Leeds. The 1996 Charities Commission ruling does not permit income from industry sponsored research projects or programmes to be paid into Charitable Trust Funds held by or on behalf of the investigator. All financial details should be incorporated within a financial agreement. This may comprise part of the formal clinical trial agreement.

#### **5 Insurance**

The Trust can not, in law, take out insurance policies to cover negligent or non-negligent harm to patients. The Trust will only extend NHS indemnity cover to its employees taking part in studies that have been approved and registered. In the case of contract clinical research, the Trust would expect the sponsoring company to obtain insurance cover with ABPI (no fault) indemnity or its equivalent and approval by a Research Ethics Committee. Informed patient consent is of paramount importance in the approval of any clinical research projects being undertaken in the Trust or involving the Trust in any way.

#### **6 Establishing Formal Contractual Arrangements**

Any arrangements must be fully documented in the form of a formal contract (CTA) and signed off by an approved signatory on behalf of the Trust. The Associate Director of R&D will be the Trust's legal signatory for all such agreements. All legal agreements must be governed by the laws of England.

Further guidance can be obtained from the Trust's R&D Department.

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