NORTH STAFFORDSHIRE R&D CONSORTIUM

NORTH STAFFORDSHIRE HOSPITAL NHS TRUST
NORTH STAFFORDSHIRE COMBINED HEALTHCARE TRUST

RESEARCH AND DEVELOPMENT DEPARTMENT

POLICY ON RESEARCH GOVERNANCE

| POLICY NO: G02 | DATE OF ISSUE:  
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|               | REVIEW DATE:  
|               | (1 year from date of ratification) |
| LEAD DIRECTOR:  
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| Director of Research and Development | DIRECTORATE CONTACT: 
| Research and Development Manager |
Introduction

Since the Culyer Report in 1994 the NHS Executive has initiated a range of measures to manage R&D within the NHS. More recently with the advent of Clinical Governance which covers the delivery of services in the NHS, the concept of Research Governance has emerged. Proper governance of research is essential to ensure that the public have confidence in, and benefit from quality research in the NHS. The North Staffordshire R&D Consortium has been proactive in developing a research governance framework. In March 2001 the NHS R&D directorate issued a long awaited Research Governance Framework. Therefore it is appropriate that the consortium defines its policy in relation to Research Governance which brings together work already done, but which also reflects this national Research Governance Framework.

This paper attempts to outline the approach to Research Governance within the North Staffordshire R&D Consortium. The approach has been designed to ensure proper management of research within the hospital and contains within it a requirement that all employees follow the procedures laid down within it both for the protection of employee and, where applicable, patient.

Policy Statement

The North Staffordshire R&D Consortium believes that Research and Development are essential to the successful promotion of health and well being and the development of more effective treatments. The consortium supports and will comply with the ‘standards for a quality organisation undertaking research’ as defined in The Department of Health Research Governance Framework for Health and Social Care March 2001. These standards are grouped under five domains of: -

- Quality Research Culture
- Ethics
- Science
- Information
- Finance

Quality Research Culture

The organisation supports and promotes high quality research as part of a service culture receptive to the development and implementation of best practice in the delivery of care. There is strong leadership of research and a clear strategy linking research to national priorities and needs, the organisation’s business, and to clinical governance. The organisation’s research strategy values diversity in its patients or users and its staff and promotes their active participation in the development, undertaking and use of research.

Ethics

All research which involves patients, users or care professionals, or their organs, tissue or data is referred to independent ethical review to safeguard their dignity, rights, safety and well-being of the participants.
Research is pursued with the active involvement of service users and carers including, where appropriate, those from hard to reach groups such as the homeless. If organs or tissue are used following post mortems, informed consent is obtained from relatives, and there is a commitment to respectful disposal of material.

If animal use is unavoidable the highest standards or animal husbandry are maintained under veterinary supervision.

Science
There is commitment to the principle and practice of independent peer review, with scrutiny of the suitability of protocols and research teams for all work in the organisation.

There is close collaboration with partner organisations in higher education and care to ensure quality and reference of joint work and avoidance of unnecessary duplication of functions.

The organisation’s human resource strategy includes commitment to support research careers (full and part-time) by earmarking funds specifically for R&D training across the professions. The organisation plays its role in developing research capacity with appropriate training and updating. This includes taking action to ensure that the diversity of the workforce reflects society and developing the capacity of consumers to participate.

The organisation promotes a high standard of health and safety in laboratory work.

Systems are in place to monitor compliance with standards and to investigate complaints and deal with irregular or inappropriate behaviour in the conduct of research.

The organisation assesses its research outputs and their impact and value for money.

Information
Information is available on all research being undertaken in the organisation. This is held on a database, which contains details of funding, intellectual property rights, recruitment, research outputs and impact.

The organisation ensures that patients, users and care professionals have easy access to information on research. Special arrangements are made to ensure access to information for those who are not literate in English or who may need information in different formats because of disability e.g. braille.

Those agreeing to be involved in research (including the relatives of deceased patients who have consented to the use of organs or tissue in the research) are informed of the findings at the end of the study.

An information service provides access from a single point to all up-to-date regulatory and advisory documentation pertaining to research governance, together with procedural guidance, for example, for applications to research ethics committees.

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There is a research dissemination strategy which addresses different media and writing styles for different audiences.

**Finance**
The organisation is aware of the activity involved in supporting research and of what it costs. Research expenditure is planned and accounted for.

The organisation demonstrates financial probity and compliance with the law and rules laid down by H M Treasury. It complies with all audit required by external funders or sponsors and has systems in place to deter, detect and deal with fraud.

When research findings have commercial potential the organisation takes action to protect and exploit them, in collaboration with its research partners and – when appropriate – commercial organisations.

In order for the trust to adhere to these standards any employee of the trust undertaking research, or an individual undertaking research on Trust premises, or involving trust staff or patients must follow the procedures outlined in Appendices 1 and 2.

**Scope**
An employee for the purposes of this policy will be regarded as:

- An individual holding a contract of employment directly with the trust, including those holding a joint contract with another organisation (e.g. a University).
- An individual holding a contract with another organisation but holding an honorary contract with the Trust.
- Students of a university working on Trust property.
- Academic staff from a university on sabbatical working on Trust property.

**Responsibilities**
Both the North Staffordshire Hospital and Combined Healthcare Trusts have delegated responsibility for the management of R&D to the R&D Consortium. However, there are a number of individuals and other organisations who have responsibilities under a research governance framework for the proper conduct of a study.

**Principal Investigator and other researchers**
Developing proposals that are ethical and seeking research ethics committee approval

- Conducting research to the agreed protocol and in accordance with legal requirements and guidance e.g. on consent
- Ensuring participant welfare while in the study

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- Feeding back results of research to participants

**Research Ethics Committee**
- Ensuring that the proposed research is ethical and respects the dignity, rights, safety and well-being of participants.

**Sponsor**
- Assuring the scientific quality of proposed research
- Ensuring research ethics committee approval obtained
- Ensuring arrangements in place for the management and monitoring of research

**Employing organisation**
- Promoting a quality research culture
- Ensuring researchers understand and discharge their responsibilities
- Taking responsibility for ensuring the research is properly managed and monitored where agreed with sponsor

**Care organisation**
- Ensuring that research using their patients, users,

**Responsible Care Professional**
- Carers or staff meets the standard set out in the research governance framework (drawing on the work of the research ethics committee and sponsor)
- Ensuring research ethics committee approval obtained for all research
- Retaining responsibility for research participants’ care
- The Department of Health Research Governance Framework for Health and Social Care should be consulted for further details of the responsibilities of individuals and organisations.
Bibliography/Further Reading

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*All the above are available on [www.doh.gov.uk](http://www.doh.gov.uk)*

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*http://www.mrc.ac.uk*