

# Greater Manchester Primary Care Research Governance Partnership (ReGroup)



# POLICY

## Research Governance Policy

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Scope of document	
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Authorised by: .....  
(Chief Executive on behalf of the Association of Greater Manchester PCTs)

Date: .....

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## SECTION 1. INTRODUCTION

*The Department of Health Research Governance Framework for the Health & Social Care (DoH 2001)* and subsequent editions aims to bring together general principles of good practice.

It is necessary for the PCT's to have a working policy relating to the way that research is undertaken in the Trusts. The Greater Manchester Primary Care Research Governance Partnership (ReGrouP) central office sets in place systems and processes which ensure that all research is safe, of a high quality and contributes to improving the treatment and care of patients.

## SECTION 2. PURPOSE

The purpose of this policy is to;

- Inform staff of the appropriate procedures regarding the conduct of research within the Trust
- ensure all research undertaken by the Trust complies with statutory legislation and guidance
- provide a framework for the development of a robust research governance process across the Trust and its partner organisations
- clearly define accountability and responsibility for research governance
- to ensure any incidents, hazards or risks arising from research governance are identified and managed in accordance with Trust policies
- promote good practice across the Trust
- to enhance ethical and scientific standards and quality

## SECTION 3. POLICY STATEMENT

This policy aims to reflect the requirements of the Department of Health's Research Governance Framework in order to develop and maintain a research culture of excellence within the PCT

## SECTION 4. DEFINITIONS

### **Research**

The attempt to derive new knowledge by addressing clearly defined questions with systematic and rigorous methods

### **Research Governance**

This applies to all research concerned with the protection and promotion of public health, research undertaken in or by the Department of Health, its non Departmental Public Bodies and the NHS, and research undertaken by or within social care agencies. It includes clinical and non-clinical research; research undertaken by NHS or social care staff using the resources of health and social care organisations; and any research undertaken by industry, charities, research councils and universities within the health and social care systems that might have an impact on the quality of those services.

## SECTION 5. STATEMENT OF PRINCIPLES

The Trust requires all members of the Trust, including staff (whether full-time or part-time, salaried or honorary) and students, and those who are not members of the Trust but who are authorised to conduct research in the Trust or to use Trust facilities, to observe the highest standards in the conduct of their research. In pursuing such high standards, it is expected that they shall:

- take all due steps to acquaint themselves with available guidance as to ‘best practice’ in matters of research policy, finance and safety relevant to their area of research, as contained, for example, in the Department of Health’s Research Governance Framework for Health and Social Care and related documents, and other such documents;
- observe such legal and ethical requirements as are laid down by the Trust or such other properly appointed bodies as are involved in their field of research;
- take steps to secure the safety of those associated with the research;
- report any conflict of interest, whether actual or potential, to the appropriate authority;
- observe fairness and equity in the conduct and publication of their research.

## **SECTION 6. PERSONNEL ISSUES**

### **Chief Executive**

Each PCT Chief Executive has the overall responsibility for research governance in their PCT.

### **ReGrouP Central office**

The ReGrouP central office have delegated responsibility for ensuring all research projects comply with the Research Governance Framework and the necessary legislation and guidance before approving research studies. The Central Office is also responsible for establishing systems of research governance including the monitoring of research activity. It will hold the central database of GM primary care research activity.

### **PCT R&D Leads**

PCT R&D Leads are responsible for assessing the impact of a research study on their local services.

### **Chief Investigators & Researchers are responsible for:**

- Developing proposals that are scientifically sound and ethical.
- Submitting the design for independent expert review.
- Submitting the study (or proposal) for independent ethical review.
- Conducting a study to the agreed protocol (or proposal), in accordance with legal requirements, guidance and accepted standards of good practice.
- Preparing and providing information for participants
- Ensuring participants’ welfare while in the study.
- Arranging to make findings and data accessible following expert review.
- Feeding back results of research to participants
- To report adverse incidents
- Comply with audit/monitoring requirements
- To obtain Research Ethics Committee approval, honorary contracts (where necessary) and R&D management approval for any research they are planning to undertake.

### **Research Funders**

- Assessing the scientific quality of the research as proposed.

- Establishing the value for money of the research as proposed.
- Considering the suitability of the research environment in which the research will be undertaken, particularly the experience and expertise of the chief investigator, principal investigator(s) and other key researchers involved.
- Requiring that a sponsor takes on responsibility before the research begins.

**Research Sponsors are responsible for:**

- Confirming that everything is ready for the research to begin:
  - Taking on responsibility for putting and keeping in place arrangements to initiate, manage and fund the study;
  - Satisfying itself the research protocol, research team and research environment have passed appropriate scientific quality assurance;
  - Satisfying itself the study has ethical approval before it begins;
  - For clinical trials involving medicines, seeking a clinical trial authorisation and making arrangements for investigational medicinal products.
  - Adequate indemnity arrangements are in place.
- Satisfying itself that arrangements are kept in place for good practice in conducting the study, and for monitoring and reporting, including prompt reporting of suspected unexpected serious adverse events or reactions.

**Employing Organisation are responsible for:**

- Promoting a quality research culture.
- Ensuring researchers understand and discharge their responsibilities.
- Ensuring studies are properly designed and submitted for independent review.
- Ensuring studies are managed, monitored and reported as agreed, according to the protocol.
- Providing written procedures, training and supervision.
- Taking action if misconduct or fraud is suspected.

**Organisation providing care/ Responsible care professional are responsible for:**

- Arranging for an appropriate person to give permission for research involving their patients, service users, carers or staff, before the research starts
- Ensuring any such research is conducted to the standards set out in this research governance framework
- Requiring evidence of ethical review before recruitment to any research that affects their duty of care
- Before recruitment to trials with medicines, requiring evidence of a positive ethical opinion and a clinical trials authorisation
- Retaining responsibility for the care of participants to whom they have a duty

**All staff are responsible for:**

Research governance is of direct relevance to all those who host, conduct, participate in, fund and manage health and social care research. It is not just for investigators, managers or any one professional group. All service and academic staff, no matter how senior or junior, have a role to play in the conduct of research. Participants in research and the public in general can also help to ensure that standards are understood and met.

**SECTION 7. TRAINING**

Training needs relating to the research governance policy will be identified, provided or commissioned by the central office on behalf of Greater Manchester PCT's.

## **SECTION 8. GENERAL OR SPECIFIC RELATED ISSUES**

The Research Governance Framework sets out standards to establish and manage a quality research culture. One requirement is to have written agreements describing clearly the allocation of responsibilities and rights with partner organisations.

The 5 domains of the Research Governance Framework are:

### **Ethics**

- All research involving patients, service users, carers or care professionals and other staff, or their organs, tissue or data, is referred for independent ethical review to safeguard their dignity, rights, safety and well-being.
- Consent is sought in the way agreed during ethical review.
- Research is pursued with the active involvement of service users and carers including, where appropriate, those from hard to reach groups such as homeless people.
- 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 using animals is unavoidable, the highest standards of animal husbandry are maintained under veterinary supervision.

### **Science**

- There is commitment to the principle and practice of scientific review by independent experts, with scrutiny of the suitability of protocols or proposals and research teams for all work in the organisation.
- Data collected in the course of research must be retained for an appropriate period as defined in research protocol/ethics submission as defined in the research protocol.
- There is close collaboration with partner organisations in higher education and care to ensure quality and relevance of joint work and avoidance of unnecessary duplication of functions.

### **Information**

- Information is available on all research being undertaken in the organisation. It is held on a database containing details of research providers, funding, intellectual property rights, recruitment, research outputs and impact
- The organisation ensures patients, service users and carers, care professionals and other staff have easy access to information on research. Where necessary, special arrangements are made to ensure access to information for those who do not have English as a first language, cannot read, or may need information in different formats because of a disability e.g. Braille.
- There is a strategy for making research findings accessible. It addresses different media and writing styles for different audiences. Unless the research ethics committee agrees otherwise, those consenting to be involved in a study (including the relatives of deceased patients who have consented to the use of organs or tissue in the research) have ready access to 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 for ethical approval.
- When established, findings (including negative findings) are published in ways that allow critical review and dissemination to those who could benefit from them. Other researchers have access to the data on which the findings are based.

## Health and Safety

- Research may involve the use of potentially dangerous or harmful equipment, substances or organisms. The safety of participants and of research and other staff must be given priority at all times, and health and safety regulations must be strictly observed – including the provision of information, containment, shielding and monitoring as required.

## 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 set out by HM Treasury. It complies with all audit required by external funders or sponsors and has systems to deter, detect and deal with fraud.
- Organisations employing researchers must be in a position to compensate anyone harmed by their negligence. If any organisation offers to compensate participants in the event of non-negligent harm, it must be in a position to do so.
- When research findings have commercial potential the organisation takes action to protect and exploit them (intellectual property), in collaboration with its research partners and – when appropriate – commercial organisations.
- Completion of NRR returns
- Completion of Annual R&D report

## SECTION 9. METHOD OF MONITORING COMPLIANCE with Timescales

The ReGroupP central office monitor as a minimum 10% of all research projects per year. Should any misconduct/fraud be identified, it will follow the process set out in the Fraud & Misconduct Policy and procedure.

## SECTION 10. BREACHES OF POLICY

Misconduct in research may be grounds for disciplinary action, and if serious, for dismissal or expulsion.  
Each organisation will be responsible for undertaking the disciplinary action.

## SECTION 11. RELATED PROCEDURES, POLICIES AND PROTOCOLS

Approval of Research Procedure  
Research Misconduct & Fraud Policy  
Research Misconduct and Fraud Investigation Procedure  
Intellectual Property Policy

## SECTION 12. RELATED DOCUMENTS

Memorandum of Understanding - University of Manchester (date)  
Memorandum of Understanding – Manchester Metropolitan University (date)  
Memorandum of Understanding – Liverpool John Moores University (date)  
Memorandum of Understanding - University of Salford (date)

## SECTION 13. BIBLIOGRAPHY/RELATED DOCUMENTS

1. Department of Health, 2005. 'Research Governance Framework for Health and Social Care', Second Edition
2. Medical Research Council Policy and Procedure for Inquiring into Allegations of Scientific Misconduct December, 1997 London
3. General Medical Council *Good Practice in Medical Research* January 2002 London

#### **SECTION 14. FURTHER INFORMATION**

Further details of the governance of research can be obtained from the Department of Health website, the PCT R&D lead and the ReGrouP Central Office.

#### **SECTION 15. SUMMARY**

The Department of Health's Research Governance Framework sets out the standards with which a quality research culture can be established and managed within the NHS and social care. It is of direct relevance to all levels of staff involved.

#### **SECTION 16. APPENDICES**



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