Promoting Good Practice in Research

Essentials of RESEARCH GOVERNANCE

Information for Researchers, Students and Support Staff involved in Health & Social Care Research

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**What is Governance?**

"Governance" is an umbrella term that is used to describe management, regulations, systems and processes related to an activity.

**Research governance information**
The information in this leaflet refers to information contained in the Research Governance Framework document and annex, which is available from the Department of Health and can be downloaded from:

www.dh.gov.uk/assetRoot/04/10/89/65/04108965.pdf

**Other useful information**

Data Protection Act (1998)
Information: www.dataprotection.gov.uk

Health and Safety at Work Act (1974)
Information: www.hse.gov.uk
Read the Act: www.healthandsafety.co.uk/haswa.htm

Medicines for Human Use (Clinical Trials) Regulations (2004)
Clinical Trials Toolkit: www.ct-toolkit.ac.uk
MHRA: http://medicines.mhra.gov.uk

Central Office for Research Ethics Committees
COREC: www.corec.org.uk

NHS R&D Forum: www.rdforum.nhs.uk

ESRC Ethics Framework:
www.esrc.ac.uk/ESRCInfoCentre/opportunities/research_ethics_framework/

**University of Manchester**

Ethics:
www.campus.manchester.ac.uk/researchoffice/researchethics/

Governance:
www.campus.manchester.ac.uk/researchoffice/policies/governance/

Data Protection and Freedom of Information:
www.campus.manchester.ac.uk/recordsmanagement/

Intellectual Property:
www.umip.com/
What is Research Governance?

Research and development (R&D) is essential for generating new knowledge to improve services in the NHS and for Social Care. Research Governance describes and consists of all regulations, systems and procedures related to research. These systems allow organisations and individuals to ensure they deliver high quality research. *All research active organisations will have a set of policies and procedures to support good practice in research.*

**Research Governance:**

Sets standards for research conduct

Defines responsibilities of those involved in research

Improves research quality and safeguards the public by:

- Enhancing ethical and scientific quality
- Promoting good practice
- Reducing adverse incidents and ensuring lessons are learned
- Preventing poor performance and misconduct

Is important for all those who:

- Undertake research
- Host research in their organisation
- Act as sponsors of research
- Fund research proposals or infrastructure
- Manage research
- Participate in research

**Like Clinical and Corporate Governance, Research Governance promotes:**

- High quality
- Maintaining specific and high standards of work
- Openness
- Responsibility & accountability
- Incorporating mechanisms for:
  - Implementation
  - Monitoring
- Relevance to EVERYONE
Questions you may ask

Why should I learn about Research Governance?

All research must be conducted to the highest standards. The Research Governance Framework sets out the **standards** and **responsibilities** of research and is designed to help researchers ensure that their work is of high quality. Being a researcher, or somebody helping with research, it is **your responsibility** to ensure that you are aware of the standards you are expected to maintain.

Who does it affect?

All those involved in research. This includes:

- Institutions hosting the research,
- Bodies that fund it,
- Individuals who participate in it and, of course,
- All those involved in conducting it on a day-to-day basis.

How does it affect me?

Research governance ensures that we maintain high standards, that responsibilities are clearly laid out and understood and that there is documentary evidence for this. Your research will also be subject to any auditing arrangements put in place by the host organisation. **Don’t panic!** Research Governance simply brings the components of good research practice under one heading; many systems are already in place and, in most cases, researchers are already working to these standards and expectations.

What should I know?

You should make yourself aware of:

- The standards set out in the Framework;
- Any legislation and regulations that apply to your research;
- Your responsibilities;
- What others’ responsibilities towards you are;
- How the University and your research hosts deliver Research Governance;
- How your research will be monitored.
**Laws? What laws?**

Certain laws apply to the conduct of research; some are general and others are specific. Some important ones that relate to research are:

- **Medicines for Human Use (Clinical Trials) Regulations, 2004** [Translated from the “EU Clinical Trials Directive”]—Conduct of clinical trials of investigational medicinal products (IMPs) within standards described by Good Clinical Practice (GCP) and Good Manufacturing Practice (GMP) Directives

- **Data Protection Act, 1998**—Collection, use and storage of personal identifiable information of living persons; protection of people’s privacy

- **Human Tissue Act, 2004**—Collection, use and storage of human biological samples, tissues, organs and whole bodies

- **Health & Safety at Work Act, 1974**—Assessment and effective management of risks to ensure safety of participants and researchers

- **Freedom of Information Act, 2000**—Public access to research-related information: may be subject to exemptions

*Other legislation and regulations may apply, depending on the type of research; researchers must know what these are and conduct their research accordingly*

**What should I do?**

- Make sure that you are aware of your responsibilities;

- Be sure that the standards and guidelines are adhered to by yourself and all those involved in your research;

- Ensure research is conducted within all relevant legal and regulatory frameworks;

- Talk to the relevant Research Office and your local research administrator at the earliest possible stage of planning your research!

If you are not happy with any aspects of your research, or the way it is conducted, it is essential that you convey any concerns to the appropriate individual or body. THE UNIVERSITY HAS A CODE OF PRACTICE FOR DEALING WITH ALLEGATIONS OF MISCONDUCT IN RESEARCH that details the measures to take in these circumstances.
Standards

Clinical governance aims to continually improve the overall standards of clinical care in the NHS and reduce unacceptable variations in clinical practice.

**Research governance** is aimed at the continuous improvement of standards and the reduction of unacceptable variations in research practice across health and social care. Minimum standards must be met across 5 broad domains:

- Ethics
- Science
- Information
- Health & safety and Employment
- Finance and Intellectual Property

**Ethics**

The dignity, rights, safety and wellbeing of participants must be the primary consideration in any research study.

**Research Ethics Committees (RECs)**

Research ethics committees (RECs) ensure that ethical standards are met with research involving human participants: patients, clients, users, care professionals or volunteers, or their organs, tissue or data. All research must have a favourable opinion from an appropriate REC before it can start.

In the UK, all NHS research ethics committees are managed by the **Central Office for Research Ethics Committees (COREC, www.corec.org.uk)**. There is a standard NHS REC application form that must be completed for all NHS ethics applications, this is available from the COREC website **www.coreform.org.uk**

The University of Manchester REC (and subcommittees) oversees all research involving human participants where it is conducted by staff and / or students of this University.

**Informed consent**

Informed, written consent is at the heart of ethical research. Appropriate arrangements for obtaining consent from all participants must be made; ethics review processes will pay particular attention to these processes.
Confidentiality

Protect participant data. Confidentiality of personal information is essential. All those involved in research must be aware of and administer their legal and ethical duties as set out in the Data Protection Act (1998). Those whose research involves the health or social care sector should also refer to the Caldicott Guidelines.

User/Public Engagement

Where appropriate, every effort should be made to involve research participants (sometimes referred to as “consumers”) and/or their representatives in the design, conduct, analysis & reporting of research.

INVOLVE is an organisation that supports patient and public engagement in research. For more information, see www.involve.org.uk.

Diversity of human culture and conditions

Must also be reflected in the design of research so that the knowledge base is applicable to all the population.

Science

Independent expert (peer) review

Ensures the validity and quality of research proposals. It is now an essential prerequisite for ethics applications and ALL research proposals should undergo some form of independent expert review.

Whilst this procedure usually forms part of the funding process, those conducting unfunded research may have to source independent expert review from other sources such as PReviewNow, a peer review system for health research in the North West of England: www.cmht.nwest.nhs.uk/peer_review/

Authorisation for clinical trials must be obtained from the Medicines & Healthcare Products Regulatory Agency (MHRA). Other authorisations and licensing procedures may also apply.

Retention of data

Data must be retained safely and retrievably for a period of time following the conclusion of a study in the event that reassessment or further analysis is required at a later date. This also supports monitoring of good research practice by regulatory and other authorities. The Records Management, Data Protection and Freedom of Information Office can provide support on the subject of protecting personal information.
**Information**

**Be open**

Information obtained through research must be freely available. This relates to ongoing research as well as the findings of research. Reports must be in a format understandable by the general public taking language and other needs into consideration.

**Dissemination**

Appropriate dissemination of findings following peer review is an essential part of the research process. The next steps in developing better healthcare might not be known if the latest knowledge is unavailable. The findings of research must be opened up to critical review and be made available to all those who will benefit from it.

**Intellectual property**

Commercial development of some research findings is necessary for their benefits to become available to the population at large (e.g. drug developments, medical devices). This will often depend on protection of intellectual property or commercial confidentiality, and the timing of research publication needs to take this into account.

The University of Manchester Intellectual property Limited (UMIP) is our technology transfer and intellectual property commercialisation company. UMIP deals with the ownership, protection and commercialisation of intellectual property and know-how created by employees and students of the University. They also interface with others who may fund or collaborate with the University in the creation of intellectual property and know-how. [www.umip.com](http://www.umip.com)

NHS Trusts also have clear IP policies to protect innovation and exploit ideas to their full potential. Contact the R&D Department or see [www.trustech.org.uk](http://www.trustech.org.uk).

**Health & Safety**

Research may involve potentially harmful procedures, equipment, substances or organisms. Safety of participants, researchers and other staff must be given priority at all times. It is a legal requirement under the **Health and Safety at Work Act (1974)** that health and safety guidelines must be strictly observed.
Finance

Financial probity

Public funds used for research must comply with the requirements of the funding body and the policies of the organisation administering the grant.

Compensation & indemnity

Organisations employing researchers must be in a position to compensate anyone harmed as a result of their negligence. NHS organisations cannot offer compensation for non-negligent harm; any organisation offering participants compensation in the event of non-negligent harm must be in a position to do so.

The University of Manchester is able to offer participants compensation in the event of non-negligent harm where research is registered with the University Research Ethics Office.

The “quality research culture”

The standards of Research Governance enable a quality research culture to thrive. A quality research culture is essential for proper governance of research; it promotes:

• Respect for participants’ dignity, rights, safety and well being
• Valuing the diversity within society
• Personal and scientific integrity
• Leadership
• Honesty
• Accountability
• Openness
• Clear and supportive management
Responsibilities and accountability

Key responsibilities of the principal investigator and research team

• Developing proposals that are ethically sound and seeking the favourable opinion of an appropriate research ethics committee

• Notifying the host organisation of the research to be/being conducted

• Conducting research to the agreed protocol and in accordance with legal requirements and guidance, e.g. on informed, written consent

• Ensuring participant welfare while in the study

• Feedback of results of research to participants (sponsors, funders, host organisations)

Key responsibilities of the host organisation

• Providing a suitable environment for research

• Recording of research activity

• Ensuring researchers understand and discharge their responsibilities—issuing honorary research contracts

• Taking responsibility for ensuring the research is monitored effectively

Key responsibilities of research sponsors

All research must have a sponsor, responsible for:

• Arrangements for initiation, management and funding of research

• Ensuring the research protocol, research team and environment have passed necessary quality assurance measures

• Ensuring research has a favourable ethical opinion

• Ensuring clinical trials have competent authority (MHRA in UK) authorisation

• Ensuring arrangements for good practice, and for monitoring and reporting (including prompt reporting of suspected unexpected adverse reactions
Monitoring & inspections

Monitoring and inspection measures are required to ensure that individuals and organisations involved in health or social care research adhere to the standards and principles set out in the Research Governance Framework. This is essential for the reassurance of patients, service users and care professionals.

Methods (such as audit, risk management and staff appraisal) used in monitoring clinical governance are also useful in the monitoring of research governance.

Systems are also necessary for monitoring research practice. These can help to:

- Identify best practice and shortfalls
- Educate researchers
- Help prevent adverse incidents and their effects
- Enhance research quality
- Enhance public confidence

Agreed procedures for research governance promotion and monitoring arrangements have been established by:

- Sponsors of research
- Organisations hosting and participating in research
- Universities/organisations employing researchers
- Other organisations

Monitoring methods should check that systems are in place for the detection and investigation of research fraud, and that appropriate actions will be taken if found.

Sanctions may apply where the acceptable standards are not met.
Implementation and delivery

Organisations have implemented systems to ensure that they and their staff understand and follow the standards and good practice set out in the Research Governance Framework.

Health and Social care providers must have delivery systems to ensure:

• They are aware of all research being conducted within or through their organization

• Anybody conducting research within or through the organisation holds a substantive or honorary research contract

• Research is sponsored

• All research conducted within or through the organisation conforms to appropriate scientific and ethical standards and value for public money

• Failures to adhere to requirements can be detected

• Routine and random monitoring and audit of research

• Facilitated and supported reporting of critical incidents, near-misses, systems failures and misconduct, either by self-reporting or whistle-blowing
Research Governance and The University of Manchester

This University has a number of systems in place to support compliance with Research Governance and to help its staff conduct research to the highest possible standards. Your Faculty or School research support staff will collaborate with the University of Manchester Research Office to manage a number of systems:

Project notification & approval

All research must be approved before it can commence. The Care organisation R&D and Faculty Research Offices should be notified of projects using the relevant research notification form. Approval ensures that all research has received a favourable ethical opinion and appropriate authorisations are in place. This process also involves setting up of commercial contracts and other agreements with collaborating research organizations as well as issuing honorary research contracts to researchers.

Research monitoring

To fulfil its obligations for monitoring research the University must have a full oversight of the research activity that is conducted by its staff and students. Monitoring for compliance with relevant management procedure and regulations may either be conducted remotely with reference to electronic research records or using document inspection visits.

Our objectives:

• To identify and promote good research practice.

• To identify shortfalls in research practice in order to

• Provide assistance for research teams to achieve the required standards.

• To provide a forum for researchers to learn from their own and other research teams’ experiences during the monitoring process as a method of developing research practice

Monitoring, audit or even inspection of your research may also be performed by the host organisation(s), the funders of the research or by regulatory bodies.
**Research Training Programme**

The University provides a rolling programme of half and one day courses that cover topics related to Research Governance. Details of future training events will be disseminated via your research business or development manager.

University of Manchester staff also have access to courses run by partner NHS Trusts, details of which are disseminated via Faculty Research Offices and Training Teams.

**Support for researchers**

The University, Faculty and School Research Offices offer support for people who wish to undertake research. Your first point of contact should be your School Research Development Manager/ Division Research Business Manager. She/ he will either be able to respond to your query or seek guidance from an appropriate source.

The Research Office in the host organisation (NHS Trust, Social Care) must also be contacted as early as possible in the research planning process.
Checklist

I have read and understood the Research Governance Framework and am aware of the appropriate sections of the Annexe that I need to be familiar with.

I am conducting my research within all relevant laws, regulations and guidelines.

I have notified my employer and the host organisation. They have both given approval for my research. All other necessary approvals have been obtained (e.g. Clinical Trials Authorisation).

The research I am involved with is ethically sound and respects the rights, dignity and well being of the participants, their families or carers. All information about participants will be kept confidential and within the rulings of the Data Protection Act 1998. The research proposal has received a favourable opinion from an appropriate Research Ethics Committee.

The research is novel and of sufficient quality to contribute something useful to the existing knowledge base. The research question and proposal have been validated by independent review.

Information about the research will be freely available. The findings will be made available to the public following peer review. However the potential need for protecting intellectual property will be taken into account.

The health and safety of all participants, researchers and other staff are a priority. All research will be conducted within the rules of the Health and Safety at Work Act.

Public funds relating to the research will be used carefully and within the rules and the Law. My organisation must be in the position to offer compensation to participants should they come to harm as a result of negligence during the research.

I am aware of my responsibilities and those of other individuals and organizations involved in the research. If I am not happy with any of the aspects of the research, I know who to talk to about it.

The organisation I work for, and others involved in the research are actively involved in making sure that expected standards and good practice are followed.

The research I am involved in and the organisations and individuals involved in it may be monitored to ensure that the standards and principles of the Research Governance Framework are adhered to. If there are shortfalls in the research I expect them to be addressed.
Useful contacts & other sources of information

Department of Health Research Governance website
www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/

UNIVERSITY OF MANCHESTER

The Faculty of Medical & Human Sciences
The Research Practice Coordinator
0161 275 5436
Richard.sherburn@manchester.ac.uk

Research Ethics Queries
The University of Manchester Research Ethics Committee
0161 275 2046
Timothy.stibbs@manchester.ac.uk

University Research Governance Policy Queries
The University Research Governance Coordinator
0161 275 7583
Research-governance@manchester.ac.uk

NHS

CMMC NHS Trust R&D Office
0161 276 3565
South Manchester University Hospital NHS Trust R&D Office
0161 291 5775
Christie Hospital NHS Trust R&D Office
0161 446 8286
Salford Royal Hospitals NHS Trust
0161 206 5583
Manchester Mental Health and Social Care Trust
0161 291 4301
ReGroup (Greater Manchester Primary Care Trusts)
0161 212 4929
PReview NoW Coordinator, (Independent Expert Review)
0161 276 8016

Greater Manchester NHS Research Ethics Committees

Central: 0161 237 2153
NW MREC: 0161 237 2394
Salford & Trafford: 0161 237 2438