This must be done before the research commences by an appropriate NHS Research Ethics Committee.

- NHS R&D Approval – This considers issues such as sponsorship and the scientific rigour of the project. It is performed by Trust Research and Development Departments and approval must be given before research commences.

- Monitoring and Auditing – all projects must comply with monitoring and auditing arrangements set down by the sponsor and the host Trust.

Further resources

Research Governance Framework in Health and Social Care (2005 and 2008)

https://www.gov.uk/government/publications/research-governance-framework-for-health-and-social-care-second-edition

For Research Ethics Committee details see http://www.nres.nhs.uk/

For audit details see the Healthcare Quality Improvement Partnership website http://www.hqip.org.uk/

For more information including copies of this leaflet please contact the Research & Development Department or visit the website

http://www.leedsandyorkpft.nhs.uk/professionals/RD

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R & D

Research Governance explained

Information leaflet 2

About us

This leaflet explains the requirements and implications of the Research Governance Framework for Health and Social Care (RGF) in relation to those who host, conduct, participate in and manage health and social care research. The RGF was established by the Department of Health in 2001 (with revisions in 2005 and 2008) and seeks to promote improvements in research quality across the board. It also aims to provide a context in which to encourage creative and innovative research to allow the effective transfer of learning, technology and best practice to improve care.

Research is essential to the successful promotion and protection of health and wellbeing and to modern and effective health and social care services. Research involves benefits and also risks, both in terms of return on investment and potentially for the safety and wellbeing of the participants.

Proper governance is therefore essential to ensure the public benefit from and have confidence in quality research in health and social care. The public has a right to expect high scientific, ethical and financial standards, transparent decision-making processes, clear allocation of responsibilities and robust monitoring arrangements.

Who does the Research Governance Framework (RGF) apply to?

The RGF is not restricted to Principal Investigators, managers or any one professional group. All clinical and academic staff (including student researchers) at all levels have a role to play in the proper conduct of research. Service Users and Carers conducting research themselves are also bound by the RGF.

What type of research does the RGF cover?

It covers all health and social care environments and applies to clinical and nonclinical research. It covers research involving NHS patients, staff and premises and research undertaken by others (industry, charities, universities) within the health and social care systems.

The RGF aims to improve research quality and safeguard the public. It does this by:

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

Responsibilities of the researchers' employing organisation

The organisation employing the researcher(s) should promote excellence in research and create a quality research culture; ensuring that researchers understand and work to the required standards. The employing organisation also takes responsibility for ensuring research is conducted, managed and monitored in line with the protocol. Arrangements should also be in place to deal with the exploitation of any intellectual property associated with a project (more details on this in leaflet 7).

Organisations are mandated to undertake regular monitoring and audits of projects to ensure the above.

Responsibilities of sponsors

Sponsors may be NHS trusts, universities, research councils / Department of Health or commercial partners. They take on the responsibility of securing the arrangements to initiate, manage and finance a study. They must ensure the Research Ethics Committee approval has been obtained (applied for by the Chief Investigator) and ensure that arrangements for the management and monitoring are in place; confirming that researchers have the appropriate training, experience and resources to deliver the research and reviewing the progress of the research.

Responsibilities of research funders

The organisation providing the funding for a study has the responsibility to ensure the scientific quality of the research. They also need to ensure that any research undertaken is an appropriate use of funds and that it provides value for money.

Responsibilities of researchers

Researchers and their teams must be aware of and adhere to the following:

- Informed Consent – All studies must have appropriate arrangements for obtaining and recording fully informed consent from all research participants.
- Data Protection Act – Confidentiality and security of personal information must be ensured.
- Health and Safety Act – The safety of participants and other staff must be given priority at all times.

Responsibilities of the Chief / Principal Investigator

The CI / PI must ensure the dignity, rights, safety and wellbeing of the participants in the research. They must also ensure that the research is carried out in accordance with the RGF and that it is subject to the following approvals:

- Research Ethics Committee Approval – All research involving patients and users of the NHS (including volunteers and staff), data, organs (or other bodily material), NHS premises or facilities must be reviewed independently to ensure it meets ethical standards.

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