

The Research Governance Context

In this context the term 'research governance' comes from the Department of Health's 'Research Governance Framework for Health and Social Care', published in 2004. The Framework identified over twenty standards for the governance of health care research and defined a mechanism for assessing that standards are achieved. In 2017, the Framework was updated and a revised document produced by the Health Research Authority, the 'UK policy framework for health and social care research'.

The policy framework can be downloaded from:

<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>

Research governance:

- is a wide-ranging term that summarises how the University manages the research process from the initial inception of a health care research project through to the dissemination and exploitation of the research results;
- describes the way in which standards are set in order to achieve and improve research quality;
- involves proper planning and resourcing of activities, securing the necessary authorisations for research work, enhancing the ethical and scientific quality, maintain the safety of University researchers and third parties, ensuring high quality in research procedures and practices, identifying possible routes for the exploitation of research, reducing adverse incidents, ensuring lessons are learned and preventing poor performance and misconduct.

The general public, Government departments, research funders, publishers, professional associations, regulatory bodies, Universities and other stakeholders in the research enterprise expect research to be carried out responsibly. In 2012, a Concordat to support research integrity was published, endorsed by the government and a range of key funders and other bodies, setting out the responsibilities of those involved in the research process for setting and maintaining high standards of integrity. As the employers of researchers, many research funders (e.g. RCUK, Wellcome, European Union), publishers (e.g. NATURE) and regulatory authorities (e.g. the UK Research Integrity Office, the Human Tissue Authority, the Medicines and Healthcare products Regulatory Authority, the National Research Ethics Service) are looking to universities to ensure suitably high standards of research governance and compliance with funding rules and legislation.

The original Research Governance Framework was one of several externally-driven developments which have had an impact on how research is conducted within the UK. It directly led to universities establishing procedures for governing health care research within universities. But in recent years universities have also established Good Research Practice Policies, Procedures to Investigate Potential Research Misconduct, Ethics Review Policies and Procedures and Procedures for Clinical Trials of Investigational Medicinal Products.

The UK policy framework aims to:

'protect and promote the interests of patients, service users and the public in health and social care research, by describing ethical conduct and proportionate, assurance-based management of health and social care research, so as to support and facilitate high-quality research in the UK that has the confidence of patients, service users and the public.'

When navigating the requirements of research governance (applying for scientific review, obtaining insurance, applying for HRA approval and ethics approval, applying for a research passport etc.) one can be forgiven for forgetting the purpose of it all. It is worth then remembering that conducting research responsibly/ethically is not merely a matter of minimal compliance with codes and guidelines. Properly ethical research demands that ethical considerations should be in the forefront of our

thinking and routinely inform all that we do. A useful short guide or reference point to responsible research conduct is the University's summary leaflet on good research practice:

https://www.sheffield.ac.uk/polopoly_fs/1.223096!/file/IntegrityLeaflet.pdf

The UK policy framework sets out a number of core principles:

1. Safety (of individuals prevails over interests of science and society)
2. Competence (of individuals managing/doing research)
3. Scientific and ethical conduct
4. Patient, Service User and Public Involvement (unless otherwise justified)
5. Integrity, Quality and Transparency
6. Protocol (must be in place clearly describing the design and procedure of the research)
7. Legality (must be aware of and follow relevant legislation)
8. Benefits and risks (must be carefully considered before research starts)
9. Approval (ethics and other relevant approvals must be in place before research starts)
10. Information about the research (must be made publicly available before research starts)
11. Accessible findings (positive and negative findings should be available in a timely manner)
12. Choice (must be afforded to participants taking account of their capacity to understand)
13. Insurance and indemnity (must be in place)
14. Respect for Privacy
15. Compliance (sanctions for non-compliance with these principles)

There are also additional principles that apply to interventional research.

One particularly important requirement of research governance is that universities must have systems in place to ensure all research in the organisation has a nominated research governance sponsor. It is worth understanding this concept as it gets to the heart of what the UK policy framework is about, its origins and what it is trying to prevent.

Research Governance Sponsorship:

The catalyst for the original Research Governance Framework was the Alder Hey organs scandal which involved the unauthorized removal, retention, and disposal of human tissue at Alder Hey Children's Hospital, Liverpool from 1988 to 1995. Further information is at: http://en.wikipedia.org/wiki/Alder_Hey_organs_scandal

When news of the scandal broke neither the Hospital or the local University took responsibility for what had taken place over the years – the lines of accountability and responsibility were vague.

In introducing the concept of the research governance sponsor clarifies which organisation is ultimately responsible for a health care research project (e.g. a University?, an NHS Trust?, a Primary Care Trust?). Should anything go wrong on a health care research project (e.g. the dignity, rights, safety and well-being of human participants are put at risk and/or doubts arise over the validity of research data or findings) then the buck stops with the research governance sponsor. The term research governance sponsor should not be confused with the term sponsor (which is often used to mean research funder).

The research governance sponsor is the “organisation that takes on overall responsibility for a health care research project from conception to final completion including arrangements for the project's initiation, management and financing. The sponsor must satisfy itself that the project meets the standards prescribed by the UK policy framework and makes sure arrangements are established and kept in place for project management, monitoring, reporting and audit”.

The RGF framework applies only to health and social care research.