UK policy framework for health and social care research[1]

Information Sheet for GPs

Key Points

- The UK Policy Framework, published October 2017 is a new UK wide framework for health and social care research, which sets out principles of good practice in the management and conduct of health and social care research, and the responsibilities of the parties involved - - it replaces the Research Governance Framework (RGF) for Health and Social Care in England and corresponding documents in devolved nations
- The responsibilities have not changed – there is an expectation that the good practice described in the Framework already is or should be happening.
- Practices need to be aware of their responsibilities predominantly as **Research Sites**, Members of **Research Teams** and **Employers** of Research Teams, although some practices may act in other capacities.
- Practices who are not research active still have responsibilities as Health and Social Care Providers and are expected to *"recognise the importance of research in improving treatments, care and other services and their outcomes"*[2].
- It is important to note that whilst the role of support organisations such as CRN / Primary and Community Care Research Offices is to **support** General Practices and organisations undertaking research to fulfil their responsibilities, they do not take these responsibilities away.

Scope

- Applies to Health and Social Care Research within the responsibility of HRA (or Devolved Administrations):
    - Research concerned with protection & promotion of Public Health
    - Research undertaken in or by a UK Health Dept; its non-Departmental Public Bodies or NHS or social care providers
        - Incl. contractors providing NHS or social care services (e.g. care homes, private treatment services, services bought via Personal Health Budgets)
    - Both Clinical and non-clinical research undertaken by NHS or social care staff using resources of Health and Social Care providers, and any research undertaken within health and social care systems that might have impact on the quality of those services

Glossary

- **CRN – Clinical Research Network -** The NIHR CRN is a national network across England that provides the infrastructure for delivering nationally important research in the NHS. It is made up of 15 local CRNs.
- **HRA** – The Health Research Authority was established in December 2011 to protect and promote the interests of patients and the public in health research, and to streamline the regulation of research. In 2015/16 HRA Approval was introduced to centralize the process of approval of research in the NHS.
- **Sponsor –** The Sponsor is the organisation that takes on responsibility for initiation, management and financing (or arranging the financing) of the research.
- **Chief Investigator (CI)** - An individual who is responsible for the conduct of the whole project in the UK.
- **Principal Investigator (PI)** - An individual responsible for the conduct of the research at a research site.
- **Research Site** - the single organisation responsible for hosting the research at a particular locality.

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

[2] UK Policy Framework for Health and Social Care, October 2017, Section 9.23

Responsibilities

- Practices are likely to have responsibilities as Research Sites; where they undertaking procedures in line with the research protocol, also act as members of a Research Team, and as Employers of research teams. In some circumstances GPs / Practices may also act as Chief Investigator (CI) or Sponsor, or have delegated responsibilities from the CI.

Party	Responsibilities
Research Sites	• Demonstrating location is suitable for undertaking the research • Being aware of all research being undertaken at your site • Ensuring roles and responsibilities of parties are agreed and documented, this includes where CRN nurses are acting on your behalf to see patients for a research project • Satisfying yourself that all necessary approvals are in place. Research sites are expected to accept reliable assurances from appropriate others and not duplicate checks already done (e.g. acceptance of HRA Approval, checks on suitability of researchers etc) • To make available information about your capability and capacity to undertake research – e.g via the RCGP Research Ready Accreditation Scheme
Research Teams	• Demonstrating suitability of staff • Conducting Research in accordance with the approved protocol and supporting documentation • Ensuring participants' safety and wellbeing • Ensuring appropriate provision of information to participants in order for them to decide whether to take part, and that consent (where required) is documented and available for inspection
Employers (of CI / Research Team)	• Encourage a high-quality research culture • Ensuring research team members understand and discharge their responsibilities, and ensure individual learning and competence • Have systems for identification of and learning from errors and breaches
Health & Social Care Providers	• Promotion of Research; • Care of participants; • Have regard to the Framework
Chief Investigator	• Additional guidance on Students; • Clarity of protocol avoiding amendments
Funders	• Using contracts to promote compliance with Framework
Sponsors	• Has overall responsibility for the research, all research much have a Sponsor • Usually expected to be Employer of CI; Universities/Colleges for student research
Regulators	• E.g. General Medical Council (GMC); Nursing and Midwifery Council (NMC); Health Research Authority (HRA)

Principles

- The Policy Framework sets out 19 Principles of Good Practice in Health and Social Care research. Different parties have responsibilities against the different principles.

Principle	Responsibilities							
	Chief Investigator	Research Teams	Funders	Sponsors	Research Sites	Regulators	Employers	Providers
1. Safety Safety & wellbeing prevail over interests of science & society	■	■		■			■	
2. Competence People involved in research are qualified by education, training and experience	■	■		■	■		■	
3. Scientific & Ethical Conduct Projects are scientifically sound and guided by ethical principles	■		■	■	■	■	■	
4. Patient, Service User and Public Involvement In design, conduct and dissemination unless otherwise justified	■		■	■				
5. Integrity, Quality & Transparency Ensured through design, review and management of research	■	■	■	■	■		■	
6. Protocol To provide a clear description and justification of the research	■	■		■		■		
7. Legality Researchers and Sponsor are familiar with relevant legislation / guidance	■	■		■	■	■		■
8. Benefits & Risks Anticipated benefits is weighed against foreseeable risks / inconvenience	■	■		■	■	■		■
9. Approval By appropriate approval bodies	■		■	■	■	■		
10. Information about the research Is made publically available before they start	■		■	■				
11. Accessible Findings Findings whether positive or negative made available in a timely manner	■		■	■				
12. Choice Participants given information sufficient to make an informed, voluntary choice with no reprisals	■	■						
13. Insurance and Indemnity[3] Adequate provision is made to cover liabilities that may arise				■				
14. Respect for Privacy Information collected is recorded, handled and stored appropriately	■		■	■	■	■		
15. Compliance Sanctions for non-compliance by funders, employers, regulators or other bodies	■	■	■	■	■	■	■	
Interventional Research Only								
16. Justified Intervention Adequate information to support intended deviation from normal care	■	■		■				
17. Ongoing Provision of Treatment Protocol / Info sheet includes arrangements (if any) for continuation of care (in whatever form)			■	■	■			■
18. Integrity of the Care Record Information about care recorded so it can be understood by others involved in the participants' care	■			■				
19. Duty of Care Duty of care by providers remains. This prevails over research interests.		■						■

[3] Whilst the Sponsor has overall responsibility to ensure indemnity provision is adequate, it is expected that GPs check their professional and practice indemnity covers any research activities they will be undertaking.

Useful Links - National

UK Policy Framework for Health and Social Care

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

Health Research Authority

Research Approvals - https://www.hra.nhs.uk/approvals-amendments/

Research Best Practice - https://www.hra.nhs.uk/planning-and-improving-research/best-practice/

Research Roles and Responsibilities - https://www.hra.nhs.uk/planning-and-improving-research/research-planning/roles-and-responsibilities/

National Institute for Health Research (NIHR)

https://www.nihr.ac.uk/

Useful Links - Local

Norfolk & Suffolk Primary and Community Care Research Office

http://nspccro.nihr.ac.uk/

National Institute for Health Research Clinical Research Network (CRN) – Eastern

https://www.nihr.ac.uk/nihr-in-your-area/eastern/