UK policy framework for health and social care research
Summary for funders, sponsors and employers

WHAT IS THE PROPOSAL?

- England, Wales, Scotland and Northern Ireland each have their own Research Governance Framework. These Research Governance Frameworks are policy documents that set out principles, requirements and standards for research in health and social care. All four UK countries intend to withdraw these separate policies and replace them with a single new policy framework to support good practice across the UK in the conduct and management of health and social care research.

WHAT IS THE SCOPE?

- The policy framework will apply to all health and social care research involving patients, service users or their relatives or carers. This includes research involving them indirectly, for example using information that the NHS or social care services have collected about them.
- The policy framework is a high-level document. Its implementation will be supported by more detailed guidance.

WHAT ARE THE MAIN ISSUES?

The policy framework takes account of what we and our partners have heard since the four separate Research Governance Frameworks were issued in each UK country over ten years ago. In particular, it reflects what we learned from a series of projects that looked into key known issues affecting good practice in the management and conduct of research, and from responses to the initial draft policy framework we subsequently issued for comment in spring 2015:

- Not all research is either registered or made publicly available. This means that other researchers may unnecessarily repeat research as they are unaware of previous studies. This can cause unnecessary inconvenience and possibly risk for participants and can mean that we don't have the evidence we need to know which treatments, care or services are safe and effective.
- Researchers do not always pass the research findings on to the people who take part in their studies.
- Implementation of the previous Research Governance Frameworks often treated all research as having the same level of risk when in fact different types of studies expose participants to different levels of risk. We heard that the regulation of research should be proportionate to the level of risk the participants are exposed to. So, for example, someone completing a short questionnaire about smoking behaviour is exposed to far less risk than someone testing a new medical treatment.
- Sometimes research can be slowed down by the procedures used by local research sites and as a result funding may be wasted.

WHAT ARE THE PRINCIPLES WHICH MIGHT BE OF INTEREST TO FUNDERS, SPONSORS AND EMPLOYERS?

- Patients, service users and the public should be involved, where appropriate, in the design, management and conduct of research.
- Information about research projects should normally be available on a public register before they are started.
- The findings of research should normally be made available after the study has finished.
- The findings of the research should normally be provided to those took part in it.
- Poorly designed or planned research and poor-quality research proposals, protocols or applications should be identified and addressed earlier by employers and sponsors, not left to funders and approval bodies such as research ethics committees.
- Researchers and research managers should understand that different research projects expose participants to different levels of risk. Research sites should accept assurances from others in a position to give them, such as the Health Research Authority and other regulators, in order to minimise duplication and speed up the overall research approval process. Funders, sponsors and employers can play an influential role in promoting proportionality in the conduct and management of research by challenging and resisting disproportionate practices and demands.
- Urgent research which might be needed in a public health emergency – for example, development of a vaccine for Ebola – should be facilitated by the timely co-operation of all the relevant parties.
- If the principles set out in the policy framework are not complied with, measures may be taken by research ethics committees (and/or, in England, by the Health Research Authority). These measures will be proportionate and effective.

WHEN WILL THE NEW POLICY FRAMEWORK COME INTO EFFECT?

- The policy framework will be revised in light of responses to the consultation and will then be published later in 2016.

HOW CAN I COMMENT ON THE POLICY FRAMEWORK?

You can respond in a number of different ways:

- You can reply using the response form available from the Health Research Authority web site, on behalf of the Devolved Administrations, at www.hra.nhs.uk/about-the-hra/consultations-calls/uk-policy-framework-health-social-care-research-consultation-active. Information in Welsh is also available, at www.healthandcareresearch.gov.wales/research-governance-framework.
- You can email your response to policyframework@nhs.net.
- You can reply by post. Please post your response to:

  England – Policy Framework Consultation, Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH

  Wales – Policy Framework Consultation, Division for Social Care and Health Research, Welsh Government, Cathays Park, Cardiff, CF10 3NQ

Scotland – Policy Framework Consultation, Chief Scientist Office, Scottish Government Health Directorates, St Andrew's House, Regent Road, Edinburgh, EH1 3DG

Northern Ireland – Policy Framework Consultation, HSC R&D Division, Public Health Agency, 12–22 Linenhall Street, Belfast, BT2 8BS

- You can find out more and have your say in person at one of the consultation events the Health Research Authority is holding for different audiences:

Audience	Date	Location
Patients and service users	24 Feb	Birmingham
Patients and service users	9 March	London
Researchers	1 March	Manchester
Researchers and non-commercial funders and sponsors	8 March	London
Commercial funders and sponsors	3 March	London
R&D directors and managers	23 Feb	Birmingham
Regulators	10 March	London

All events run 1.30 to 4.30 p.m. Please e-mail hilary.tulloch@nhs.net to register.

- **The deadline for responses is Thursday 24th March 2016.**