

Sponsorship for research projects involving healthcare

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Introduction

- UK policy framework for health and social care research
- The Sponsor
- Do I need sponsorship?
- Sponsorship Review

UK policy framework for health and social care research

Applies to **health and social care research** that is within the responsibility of the HRA or the Devolved Administrations' Health Departments. This includes:

- Research concerned with the protection and promotion of public health
- Clinical and non-clinical research undertaken within the health and social care systems that might have an impact on the quality of those services

All health and social care research should have sponsorship

The Sponsor

- Organisation which takes legal responsibility for the initiation and conduct of research projects
- Confirms provision of insurance and indemnity for the research project
- Not the funder (in most cases)
- University of Edinburgh will usually take on sponsorship of a research project when a university employee has designed the study and is acting as the Chief Investigator.

Do I need sponsorship?

- Research

www.hra-decisiontools.org.uk/research/

- Healthcare and/or social care related

NHS, mental health, community, nursing homes, etc...

NOT children's social care in Scotland or research in schools

- Funded and unfunded

- Staff and student research

Example 1

- Research project looking at increasing physical activity in the elderly
- Research objective: Impact upon physical and mental health
- Recruited through nursing homes in England and Scotland
- Data to be stored at University
- **Yes** – sponsorship is required as healthcare related research (possibly NHS approvals if nursing homes are NHS facilities)

Example 2

- Research project looking at the impact of musical therapy in people with dementia
- Some participants may not have the capacity to consent
- Recruited through community centres
- Data stored at UoE
- **Yes** – sponsorship is required and NHS REC approval as involves Adults with Incapacity (AWI)

Example 3

- Research involving NHS staff investigating links between role and stress
- Recruited through NHS email address and professional bodies such as Royal College of Nursing
- Data to be stored at the University
- Yes – sponsorship is required as within healthcare (mental health). Will also require NHS R&D approval as NHS staff are to be recruited through the NHS

Not research

NHS involvement

- Service evaluation or clinical audit – requires Quality Improvement Team (QIT) approval from relevant health board(s)
- Use of identifiable NHS data – Caldicott approval
- Although sponsorship not required – happy to help/advise

No NHS involvement

- School approval and local approvals e.g. council

Why do we need Sponsorship/Research Governance?

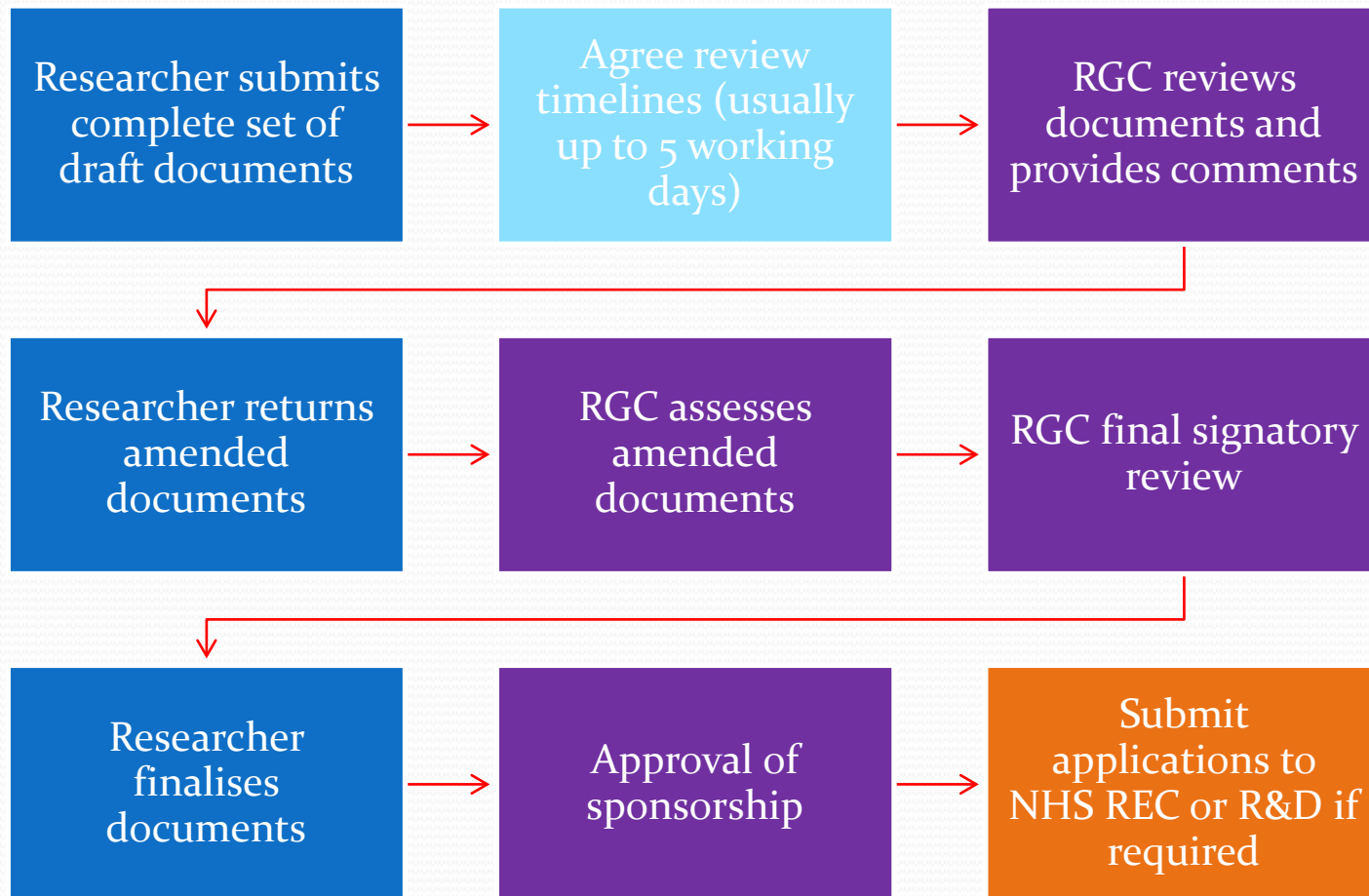
- Safeguard participants in research
- Protect investigator/researcher
- Mitigate risk
- Promote good practice
- Meet regulatory requirements
- Ensure study has adequate insurance and indemnity

Role of the RG Coordinator

Advice, support and guidance

- Advise if sponsorship is required
- Discuss any research governance issues
- Review and authorise sponsorship of healthcare research carried out by university researchers
- Ensure you have any necessary regulatory approvals in place (e.g. ethics approval)
- Ensure that adequate insurance and indemnity cover is in place
- Guide researchers in writing protocols, Patient Information Sheets and Consent Forms prior to REC and NHS approval submissions

What does a Sponsorship Review involve?



My details

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