

Developing Caldicott Guardians

Research Governance

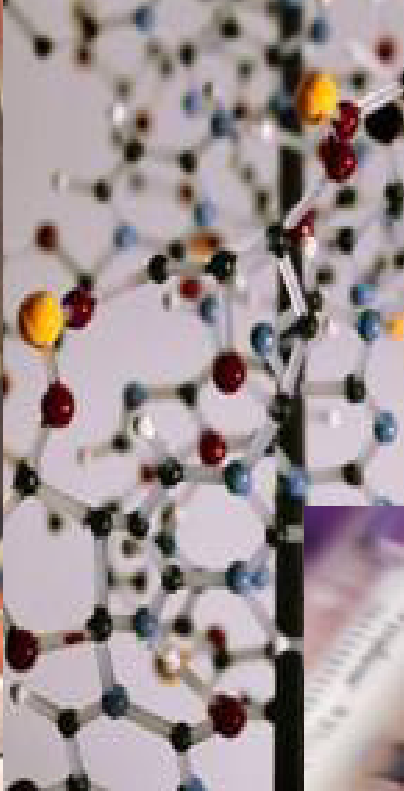
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Timetable and Objectives

- Introduction
- Research Governance Framework
 - Purpose
 - Scope
 - Standards
 - Responsibilities and accountability
 - Delivery Systems
 - Monitoring, Inspection and Sanctions
- Patient Information Advisory Group and Health & Social Care Act Section 60
- Questions

Purpose

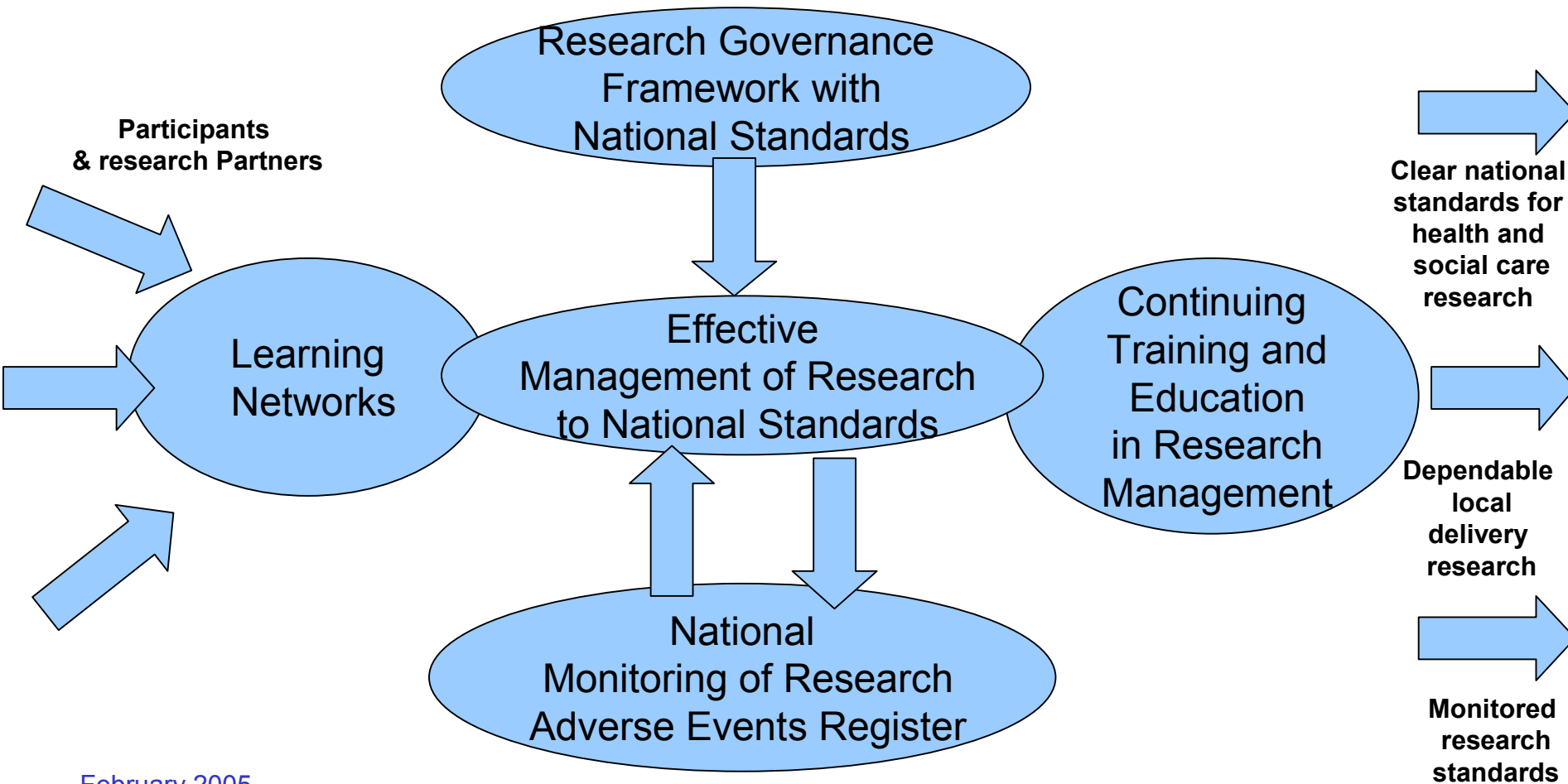
- Government commitment
- Partnership between services and science
- Promotion and protection of health and well-being
- Development of modern and effective health and social care services
- Not without risk
- Public expectations

Scope

- Framework as a model
- Relevant to all
- Promote improvements in research quality
- Encourages creative and innovative research
- Transfer of learning technology and best practice to improve care
- Prevent poor performance, adverse incidents
- Clarifying responsibilities

What Research Governance means for Participants

Extract from Research Governance framework for Health and Social Care – Department of Health



Standards

- Ethics
- Science
- Information
- Health, Safety and Employment
- Finance and Intellectual Property

Responsibilities & Accountability

- Principal Investigator
- Research Ethics Committee
- Sponsor
- Employing organisation
- Care organisation

Delivery systems

- Local Research & Development Consortium
- Research Ethics Committee
- Central Office for Research Ethics Committees
- Training
- Advice and guidance
- NHS Research & Development Management Forum

Monitoring, Inspection & Sanctions

- Demonstration of adherence to framework
 - Controls Assurance
 - Performance monitoring
 - Department of Health Standards for Better Health – Core standard 12
 - Publication of data – National Research Register
 - Surveys of staff
 - Medicines and Healthcare Products Regulatory Agency inspections

Recruitment

- Must be entirely voluntary
- Only member of clinical team to access notes to check suitability (without consent)
- If using someone outside clinical team as first contact – justify and explain
- Inclusion/exclusion stated and justified

Informing the Participant

- Informed Consent
 - Ideally consent should be in writing
 - Non-written consent must be justified, documented and witnessed
 - Consent should be recorded in patient's notes and research documents
 - Patient Information Sheet to be given to each patient
 - children

Patient Information Sheet & Consent Form

- Information should clearly reflect protocol
- Language used should be suitable for a lay person
- All technical words explained
- Tone should be invitational and not coercive!

The Use & Storage of Samples

- Collection and storage of samples
- Information relating to specimens
- Use of genetic material
- Additional information available from other organisations

Audio/Video recording

- Specific consent is required for this
- Specify uses, how material will be stored and how and when it will be destroyed.
- Note that videos will not be used for commercial purposes
- Use General Medical Council guidance

Confidentiality

- **Data Protection Act 1998**
 - The safe acquisition, storage and transmission of personal data are legal requirements
 - Investigator's responsibility to be aware of and comply with data protection legislation
 - Discuss data protection aspects of protocol before submission to the REC
- **NHS Code of Practice – Confidentiality**
 - Use of patient information for Medical purposes other than healthcare
 - Examination of records by those outside the NHS e.g. sponsored drug trials
- **Consult Medical Research Council Guidelines**

Encryption or Anonymisation

- What is in place
- At what stage is information encrypted or anonymised
- Is any data “pseudonymised”
- Definitions supplied

ANONYMISATION – the permanent removal of personal identifiers from personal data. This occurs when data are aggregated with a view to the production of statistics (for instance the proportion of the population that has contracted a particular disease). Anonymisation only occurs if there is NO reasonable possibility that the data will not in the future be linked again with the data subject.

PSEUDONYMISATION – this occurs when a true identity e.g. name, address, national health number etc is replaced by a pseudonym – an identifier by which the patient is known within a system but which does not readily identify them. It is typically reversible in that information linking the pseudonym to the real identity is held in a secure part of a computer system or away from the system as a whole. The information can therefore be linked back to the individual and retrieved for legitimate purposes if necessary.

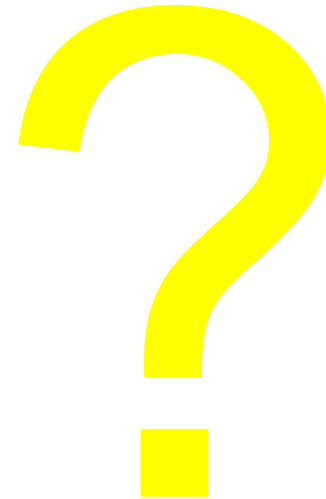
PIAG & Section 60

“The traditional paternalistic attitude of the NHS, that the benefits of science and research are somehow self-evident, was no longer acceptable”

Royal Liverpool Children's' Inquiry

- Patient Information Advisory Group
- Section 60 Health & Social Care Act 2001

ANY QUESTIONS?



References 1

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- www.advisorybodies.doh.gov.uk/PIAG/Index.htm - Patient Information Advisory Group