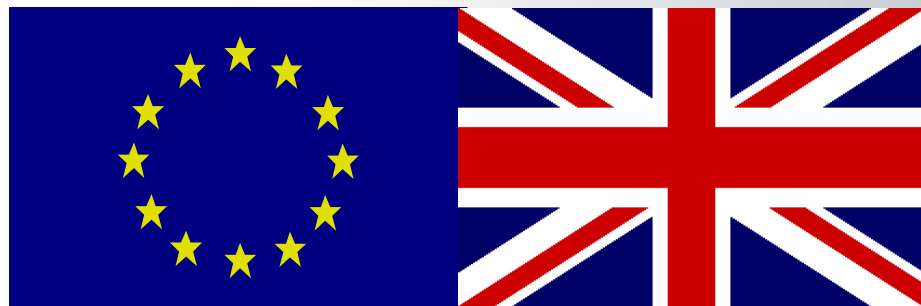


Research Governance and the EU Clinical Trials Directive

By Gill Sims



Structure of Presentation



- What is Research Governance
- Why do we have Research Governance
- Implications of the EU Clinical Trials Directive (and subsequent UK Clinical Trials Regulations)

Relevant legislation



- Research Governance Framework (2001/2005)
- E U Clinical Trials Directive (2001/20/EC)
- Medicines for Human use (Clinical Trials) Regulations (2004)
and:
(Clinical Trials) Amendment Regulations (2005/ 2006)
- The Mental Capacity Act (2005)
- Human Tissue Act (2004)
- Data Protection Act (1998)

What is Research Governance?

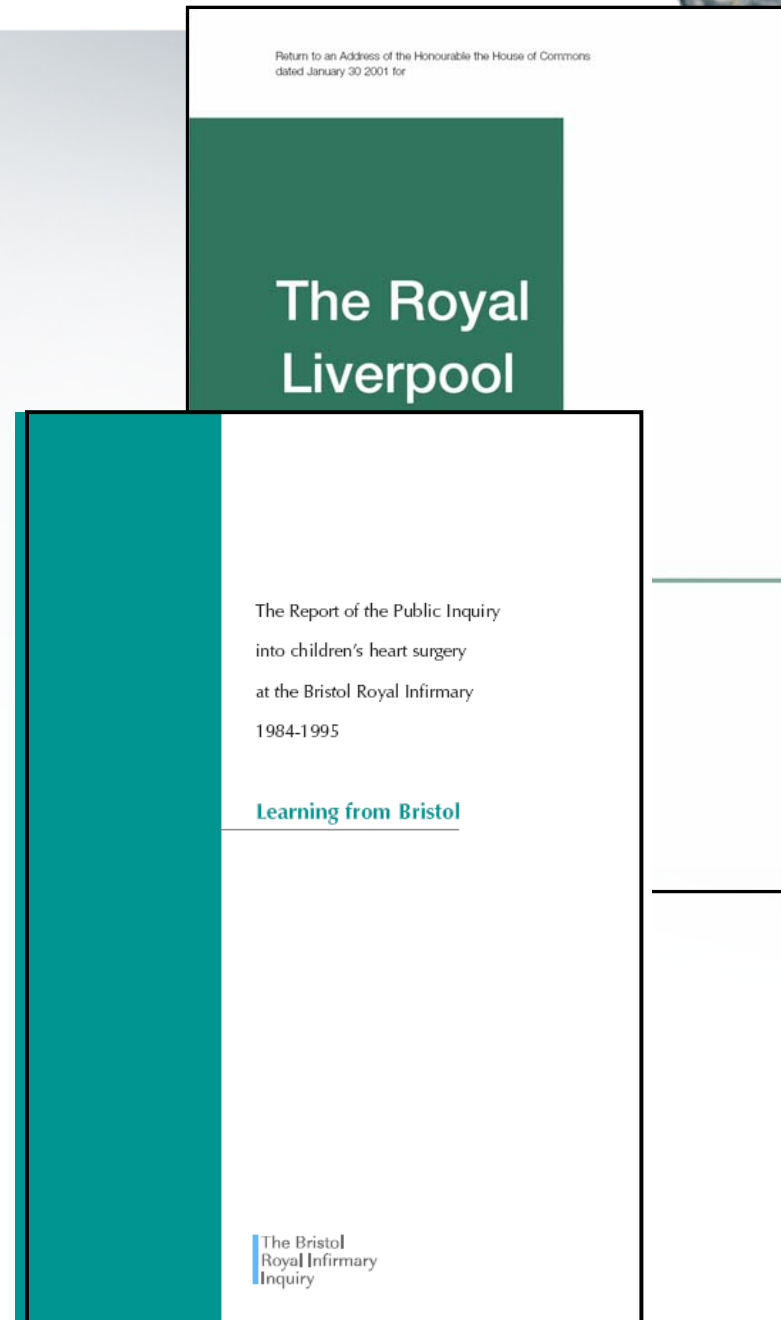
A framework to ensure standards of quality are developed, continuously improved upon & monitored in all research activity that the minister for Health & Social Care has responsibility for.



Why do we need Research Governance?



- ❑ Griffiths Report (2000)
- ❑ Kennedy Report (2001)
- ❑ Redfern Report (2001)



Why do we need Research Governance?

Professor Van Velzen:

- Unethically and illegally retained the organs of every child who had had a post mortem
- Falsifying post mortem reports
- Ignoring written consents
- Encouraging staff to falsify records
- Lying to parents



Report findings (corporate)



- Failings in the supervision and performance management of a new unit
- Failure to follow up complaints
- Failure to apply or follow up proper audit procedures and management systems
- Failure to investigate PM practice

Why do we need Research Governance?



- ❑ Kennedy Report (Bristol Inquiry) 2001
- ❑ Redfern Report (Alder Hey Inquiry) 2001
- ❑ Retained Organ Census (2001)
- ❑ Removal, Retention and Use of Human Organs and Tissue from Post Mortem examination (CMO 2001)
- ❑ Isaacs Report (2003)

Poor Practice ?

The human Tissue Act 1961

- ❑ No requirement for consent to be given for the removal or use of tissue and organs.
- ❑ No legal penalties for breaches of the Act

Anatomy Act (1998)

- ❑ needed up dating



Changes in the Law



The Human Tissue Act (1961) and
The Anatomy Act (1998)

Have been repealed and replaced by the:

Human Tissue Act (2004)

The Act came into full effect April 2007

Other Recommendations



“...formal guidance on research governance within the NHS be developed and issued to the NHS and to partners whose research it hosts”

....The Research Governance Framework



*Research Governance
Framework
For
Health and Social Care*

What does the Framework do?



- Sets national standards
- Defines the mechanisms to deliver standards
- Defines responsibilities of all those involved in **research** (including responsibilities of the research sponsor and the Principal / Chief Investigator)
- Ensures research is monitored
- Aims to improve research quality & safeguard the public

The Clinical Trials Directive



Transposed into UK law by:

The Medicines for Human Use (Clinical Trials)
Regulations (2004)

Followed by:

2ND Edition of the Research Governance
Framework (2005)

Purpose of Regulations



- Harmonise and simplify the conduct of research within the EU community
- To protect human subjects who take part in Clinical Trials
- To ensure that the results of research are credible

The Regulations



- Provide a statutory basis for ethics committees and introduce time frame for ethics approval
- Requires the manufacture of IMP's to be undertaken in accordance with GMP.
- Requires that all Clinical Trials are registered with and authorised by the Competent Authority (CA)
- Provides a statutory basis for GCP
- Lays down responsibilities for Investigators and sponsors (including their responsibilities in respect Of reporting adverse events)

Definition of Sponsor



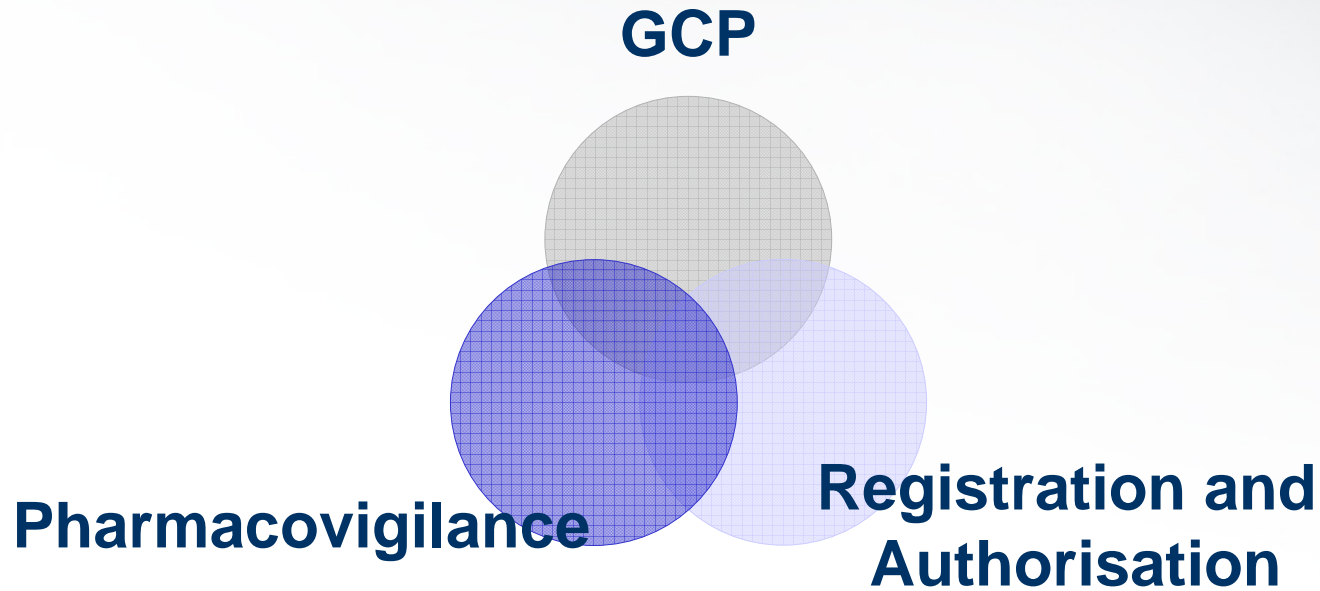
“The person who takes responsibility for the initiation, management and financing (or arranging the financing) of that trial”

(HMSO, SI:1031 2004)

Responsible for ensuring that arrangements are in place for the management, monitoring and financing of research

(DH 2001)

Sponsor Responsibilities



Sponsor Responsibilities



- Ensure systems for reporting SAE (CTIMP: The Sponsor is legally responsible for accurate and timely reporting)
- Assures the scientific quality of a research study
- Ensures all regulatory approvals have been obtained
- Ensures arrangements have been made for the management and monitoring of research
- Continue to have a duty of care to all patients (Not just patients on studies for which they sponsor)
- Ensures that all Non NHS staff have Honorary Research Contracts
- Ensure Clinical Trials are conducted to the standards of GMP and all research to the standards of ICH GCP