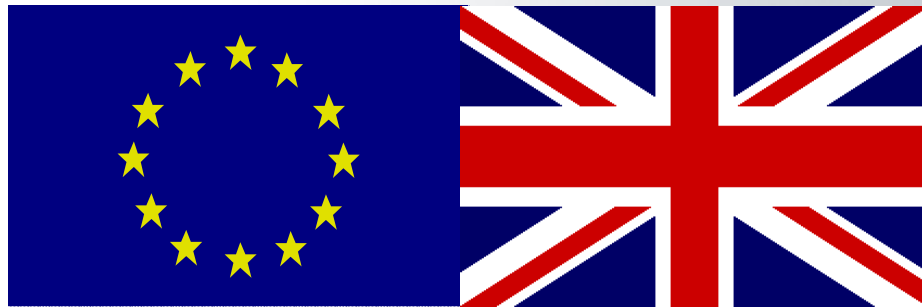


Research Regulation and Guidance

By Gill Sims



Structure of Presentation



- Applicable Regulations
- Research Governance
- Investigational Drug Specific Legislation
- Implications

Relevant legislation



- ❑ Research Governance Framework (2001/2005)
- ❑ E U Clinical Trials Directive (2001/20/EC)
- ❑ Medicines for Human use (Clinical Trials) Regulations (2004)
- ❑ GCP Directive (2005/28/EC)
- ❑ (Clinical Trials) Amendment Regulations (2005 / 2006 / 2008)
- ❑ 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?

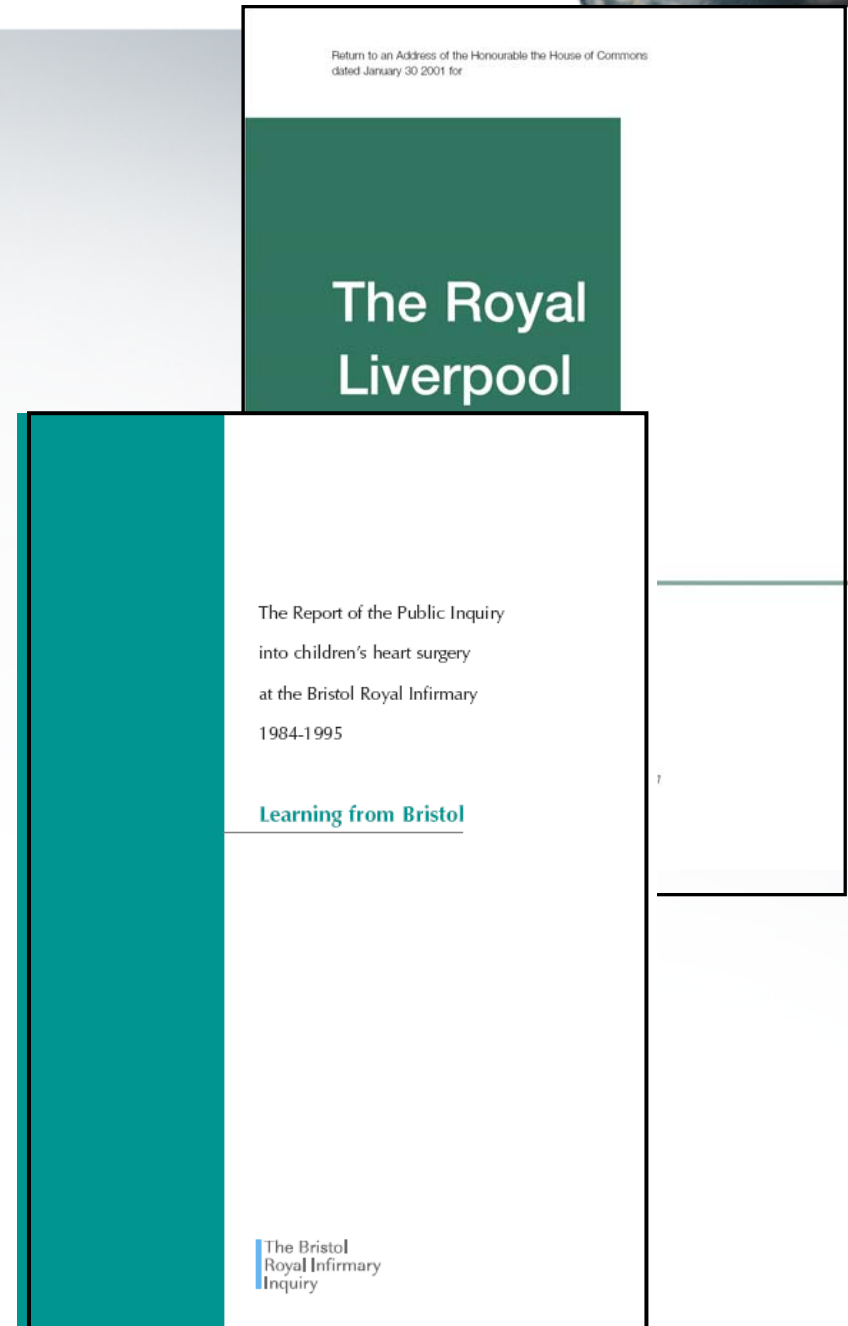


Inquiry:

- ❑ Griffiths Report (2000)
- ❑ Kennedy Report (Bristol Inquiry) 2001
- ❑ Redfern Report (Alder Hey Inquiry) 2001

Publications:

- ❑ Retained Organ Census (2001)
- ❑ Removal, Retention and Use of Human Organs and Tissue from Post Mortem examination (CMO 2001)




Implications



UK Clinical Trials
Regulations 2004

Research Governance
Framework 2001/2005

Human Tissue Act 2004



Human Tissue Act 2004

CHAPTER 30

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PART 1

REMOVAL, STORAGE AND USE OF HUMAN ORGANS AND OTHER TISSUE FOR SCHEDULED PURPOSES

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- 2 "Appropriate consent": children
- 3 "Appropriate consent": adults
- 4 Nominal/d representatives
- 5 Prohibition of activities without consent etc.
- 6 Activities involving material from adults who lack capacity to consent
- 7 Powers to dispense with need for consent
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REGULATION OF ACTIVITIES INVOLVING HUMAN TISSUE

The Human Tissue Authority

- 13 The Human Tissue Authority
- 14 Remit
- 15 General functions

Licensing

- 16 Licence requirement
- 17 Persons to whom licence applies
- 18 Duty of the designated individual

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

Investigational Drugs Specific Legislation



- Pre May 2004
 - CTX / DDX exemptions

- Post May 2004
 - EU Clinical Trials Directive 2001/20/EC
 - UK Statutory Instrument 2004/1031

Clinical Trial Legislation



- 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 Implications



- ❑ Ethics approval is a Statutory Requirement
 - ❑ ...What type of research requires ethics approval?
 - ❑ **Answer: effectively all research.**
 - ❑ introduction of time frames for ethics approval

- ❑ Requires the manufacture of IMP's to be undertaken in accordance with GMP.

- ❑ Requires that all Clinical Trials (IMP) are registered with and authorised by the Competent Authority (CA)

- ❑ Provides a statutory basis for GCP
 - ❑ What is the standard for CTIMP's?
 - ...**UK Regulations (which includes ICH GCP).**

- ❑ Clearly defined responsibilities for Investigators and **sponsors** (including responsibilities in respect of reporting adverse events)

Definition of Sponsor



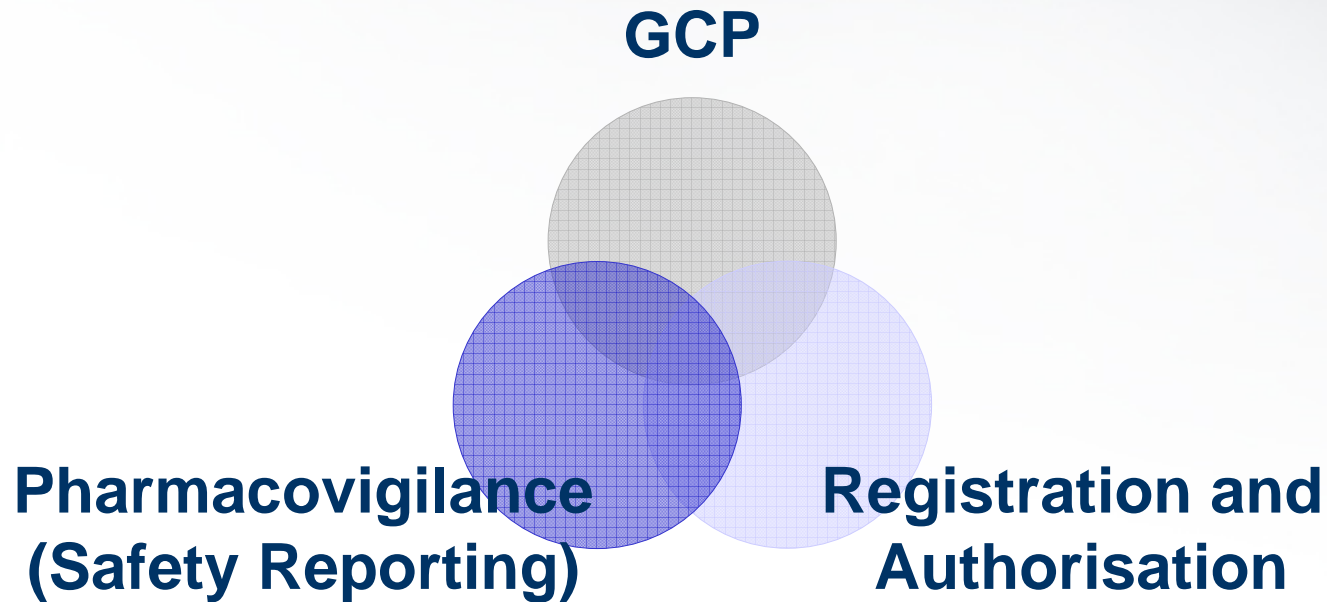
“The person who takes responsibility for the initiation, management and financing (or arranging the financing) of that trial”

(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
- Ensures that all Non NHS staff have Honorary Research Contracts (as applicable)
- Ensure Clinical Trials are conducted to the standards of GMP and all research to the standards of ICH GCP and applicable regulations

Investigator Responsibilities



Pharmacovigilance (safety reporting):

SAE's and other Safety issues are recorded appropriately and reported according to the applicable regulations and the Protocol

Authorisation and Registration:

Delegated responsibility to obtain Ethics, Research Governance and MHRA approval (the latter applies to Drug Trials and some Medical Device Research only)

- ❑ Overall supervision of a study
- ❑ That the study is undertaken in accordance with the approved Protocol

GCP:

Ensuring the applicable regulations are being adhered to and that the principles of ICH GCP are being applied effectively