SPONSORSHIP: BETTER THE DEVIL YOU KNOW…..

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Definition of sponsorship

The person/Organisation/Institution who takes on **ultimate** responsibility for the initiation, management, financing [*or arranging the financing*] of a clinical trial.

(GCP SA, 2006)

Aim of establishing sponsors

- Responsibility
- Liability/Indemnity
- Risk management
- Credibility
- Efficiency

SPONSORSHIP PRINCIPLES

- Who should be sponsor?
  - Commercially funded and ownership of IP = sponsor
  - Research council/med charity = may sponsor esp if IP
  - Above + does not wish to take on = Institution
  - Participants are owed a duty of care by host not investigators employer = sponsor
  - CI/PI
- Sponsor can formally delegate **BUT** remains accountable
- Frequently based on risk assessment

Trial Risk Assessment: Components

CI/Sponsor identify potential hazards for the:

1. Trial participants rights
2. Trial participants safety
3. Completion in relation to recruitment and follow-up
4. Reliability of results

Many tools available: DOH/MRC

- http://www.ct-toolkit.ac.uk/_db/_documents/MPTrials2.pdf
- http://www.ct-toolkit.ac.uk/_db/_documents/Trial_RA.pdf

Risk Assessment - process

Describe hazards

Calculate risk score

Describe control measures

Sponsor??

Sponsor: Roles & Responsibilities

Clearly defined by GCP (SA)

Can be delegated to individuals and organisations (SOP).

MUST BE AGREED IN A CONTRACT

Delegating Roles & Responsibilities

1. Chief investigator and researchers
2. Research funders
3. Universities and other organisations employing researchers
4. Organisations providing care
5. Responsibilities of care professionals
6. Sponsor

INDEMNITY – KEY POINTS

Negligent harm

Indemnity for sponsor & investigator

1. NHS liable for clinical negligence & other negligent harm to individuals covered by their duty of care

2. Researchers employer liable for negligent harm caused by design of study.

3. Producers liable for faulty medicines/devices

INDEMNITY – KEY POINTS

Non-negligent harm

- Non-negligent compensation (no legal liability) for personal injury only reqd if ethics requests.
- Universities clinical trials insurance can include no-fault cover for personal injury arising from design of study

Why does a CTU support the university as sponsor ?

- Sets the standard.
- Designed to meet responsibilities of sponsor (GCP).
- Skilled staff located within an efficient and cost effective structure.
- Builds capacity - ongoing training of CTU staff and clinicians.
- Updated database of research activities and progress.
- Structured QA processes in place.
- Quality checks in place both internally and externally.

CENTRAL ACCESS SYSTEM

THANK YOU