

Human Research: We're alert, but should we be alarmed?

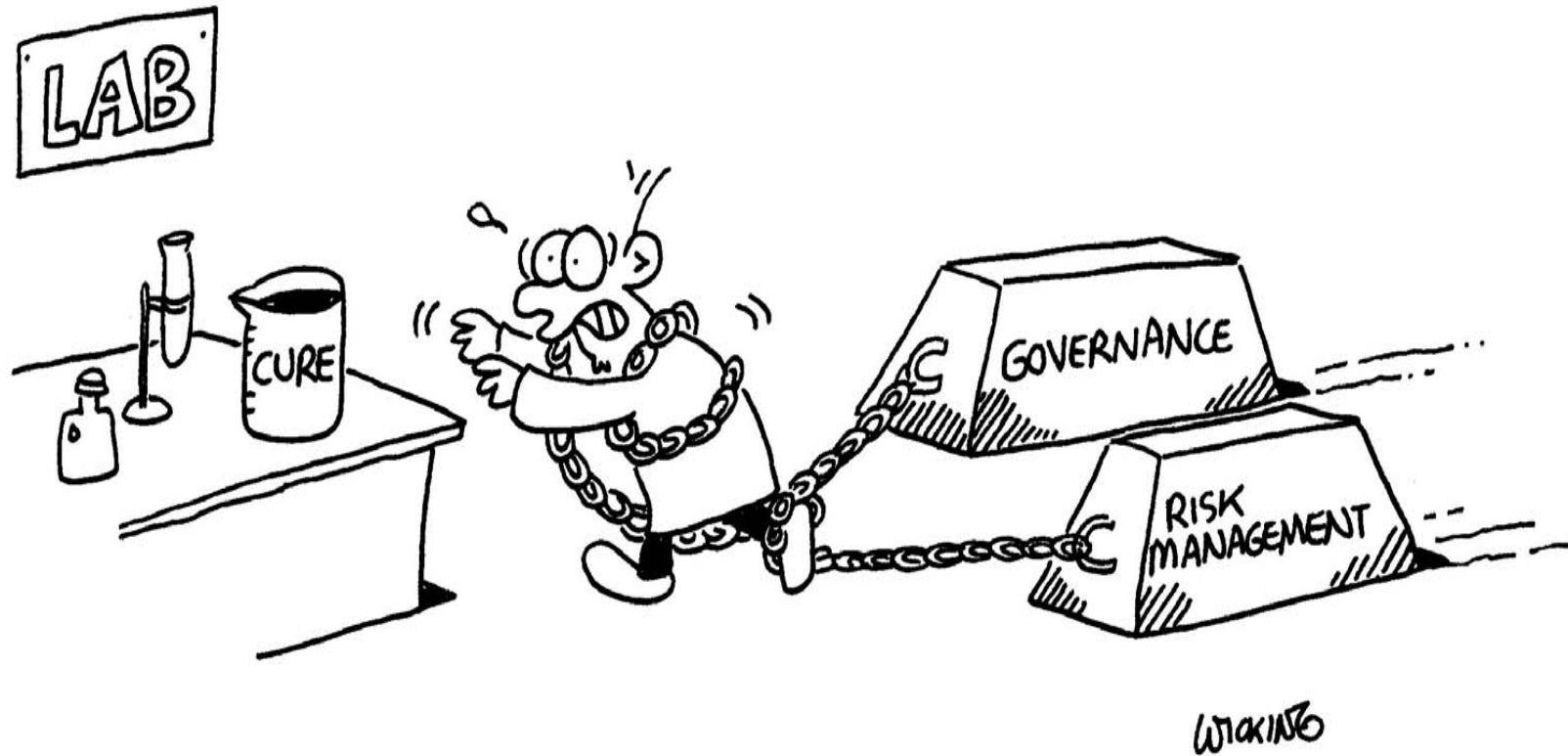
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Some initial food for thought



Introduction

- A brief introduction to the governance of ethical conduct in research
- The scope of human research
- Ethical review
- Institutional responsibility

Risks in human research

- What are the risks?
 - Risks to participants
 - Risks to the research team
- Institutional risks
 - Funding (Johns Hopkins)
 - Reputation (2006 Health Report case)
 - Legal or civil exposure
 - Participant and gate keeper perceptions

The Typical **Institutional Response** to these **Risks**

- How are the risks understood?
- Typical institutional responses to risks
- HRECs and risk management
- Published commentary on ethics committees
 - Workload
 - Membership and expertise
 - Risk aversion and role creep
 - Conservatism, arbitrary one size-fits-all rules, and inflexibility
 - Distortion, frustration and non-compliance
- The risks of blind 'rule following' and non-compliance
- The risks of misapplied governance

Features of a targetted *Smarter* approach

- Transparent, verifiable and endorsed systems
- Risk-based review
- Online, timely and quality review
- Policy-based decision making
- Resourcing reflective practice
- Dispersed knowledge and ownership
- Centralised oversight and decision making
- Cultural change

The Griffith University Model

- Griffith University – baseline information
- Research Ethics review 2003
- Risk-based ethical review
- Replacement of department-level review
- Online tools
- Research Ethics Advisors
- Griffith University Research Ethics Manual
- Training resources
- Audits
- Embedding within other University systems

The Griffith Experience

- Transparency, quality and timeliness
- Increased participation
- Client satisfaction
- Committee meetings
- Committee activities
- Administrative efficiencies
- Ethics as a conduct and quality issue
- Dispersed knowledge base

Initiating **change**

- Adopting a system and policy based approach
- A focus on resourcing conduct, not policing
- Executive support
- Resourcing and profile
- Striving for transparent expert systems
- A culture of continual improvement
- Separating governance from ethics review
- Material available on CD

Thank you for your attention

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