Research Governance in a public health service

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Research Governance

"For the remainder of this patient safety discussion, I shall refrain from leaning back too far on my chair."

HEALTHCARE GOVERNANCE REVIEW
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Research Governance – What & Why?

• A framework through which institutions are accountable for the research they allow to be conducted under their auspices – *rules of engagement*.
• Research must be conducted according to ethical principles, guidelines for responsible research conduct, legislation and regulations – this includes ICH-GCP and safety monitoring.
• Emphasis on continuous monitoring and quality improvement.
• **ALL** research projects need governance.
Good research governance is essential for the responsible conduct of research:

- Enhances ethical and scientific quality.
- Promotes good research practice and accountability.
- Reduces adverse incidents and ensures lessons are learned – reduces likelihood of poor performance and research misconduct.
- Is a way of thinking about and managing research.
- Applies to everyone involved.
- Is about how research is conducted and facilitating good (ethical and worthwhile) research.
- Is about responsibility and managing risk.
**Ethics**

Ethics Submission - the scientific and ethical review of a research project by an HREC.

Any accredited HREC can review – National Mutual Acceptance

DO ethics and RG in parallel

**Governance**

Governance Submission - to facilitate assessment of overall feasibility and compliance with institutional requirements and responsibilities in relation to a research project by the governance office(r): Institution specific

**Respect and trust – research is a privilege**
Elements of RG

- Compliance with legislation, regulations, guidelines and codes of practice, incl. GCP.
- Ethics review and approval.
- Legal and Insurance – consent, indemnity, liability, agreements.
- Credentialing, induction, training, accreditation.
- Intellectual property and managing collaborative research, incl. publication.
- Financial management – hospital and research group budgets.
- Performance measurement, reporting and planning – time frames, recruitment, partnerships.
- Risk management – safety (patients and staff), data quality and integrity, reputational.
RG needed to open a trial

- HREC approval (scientific merit, safety and ethics)
- SSA form
- Insurance and indemnity
- e-CTN
- CTRA - agreement
- Budget
- Service department approvals

- Credentialing/mentoring/GCP training
- Risk Assessment – esp. for IITs
- Ionising Radiation
- Site-specific PICF
- Compliance with guidelines and legislation
Steps for RG (SSA) approval

• Obtain a HREC Project Number
• Confirm date of site selection
• Complete the RG Checklist
• Complete the Governance Cover Letter
• Submit a SSA form
• Complete fee payment form
• Provide a copy of all HREC documentation where ethics review was not undertaken by Melbourne Health
• Submit a project budget for review
• Complete statement of approval and departmental forms
• Complete documentation required for Clinical Trials (if applicable)
• Complete an agreement where MH and at least one other institution is involved in the study
• Submit your application
RG Roadblocks

• Insufficient time and resources – on all our parts.
• Lack of attention to details – documents are incomplete, incorrect or missing altogether.
• Required templates (e.g., PICF, agreements) are not used – *why not?*
• “Non-standard” agreements.
• People get it wrong – over and over again.
• Getting final budget, lab and imaging manuals, etc. from sponsor is difficult.
• Different perspectives, different expectations – investigators, sponsors, hospital management…
Initiatives to help

• Commitment to streamlined processes for all research – NMA, NHMRC GPP, MACH, REx…
• Your Research Office.
• Ongoing education – GCP, ethics, biostatistics, protocol design.
• Clinical Research Manager.
• Management Accountant Research.
• Focus on progress – shared goals, tracking metrics, investigating delays, constructive and pragmatic approach.
Please call or drop in to see us:
Talk to us...ALL welcome
Our door is open ...

- START EARLY.
- Phone or visit the Office for Research
- Do it right the first time.
- Read the instructions.
- Attend a HREC meeting.
- Ask, over and over again (don’t guess) – all squeaky wheels will be oiled.
- We want the same thing as you - we want to help.
- Don’t be afraid and don’t wait.
- 835 unread emails…
A win-win for everyone

Australian patients get access to the best new treatments sooner and Australia as a nation benefits from the investment in clinical research and the results that research…