

MELBOURNE HEALTH

Research Governance in a public health service

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AHRDMA Annual Scientific Meeting
16 June 2017

Research Governance



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

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.

Research 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 (eg 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...



