



THE GEORGE INSTITUTE
for International Health



Sydney, AUSTRALIA | Beijing, CHINA | Hyderabad, INDIA | London, UK



Affiliated with the University of Sydney

Clinical Trial Case Study – Part 2

Getting ready to start the trial

Pre-recruitment Phase

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Focus

- Ethics Submissions
- Logistics
- Contracts
- Registering a clinical trial
- Investigator Meetings

Ethics Committee Submissions

- Requirement for all clinical trials to have ethical review
 - Declaration of Helsinki
 - NHMRC statement on Ethical Conduct in Human Research
 - ICH GCP
- Includes but is not limited to
 - Clinical trials
 - Clinical research
 - Data linkage
 - Epidemiological research
 - Health services research
 - Population health research
 - Qualitative research
 - Release of data
 - Tissue banking
- Pilot studies also require review and approval



Ethics Committee Submissions

- Scope of trial
 - Single centre
 - Multi- centre
 - Multiple states
 - Multiple countries
- Timelines
 - Critical pathway to ensure milestones are met

Ethics Committee Submissions

- Use of National Ethics Application Form (NEAF)
 - Web based tool
 - Provides information in a consistent way
 - Aims to increase efficiency and quality of the review process
 - NSW and QLD Health institutions have licensed copies
 - Central Multicentre HREC model

Ethics Committee Submissions

- Victoria, Dept of Health
 - Multicentre review process to be implemented Q4 2009
 - To adopt use of the NEAF
 - Victorian specific module
 - Additional information required to comply with Victorian legislation
 - Information Privacy Act 2000
 - Health Records Act 2001
 - Radiation Act 2005 and Radiation Regulations 2007
 - Guardianship and Administration Act 1986
 - Mental Health Act 1986
- Western Australia and Tasmania
 - Mutual recognition programmes in public health institutions
- South Australia
 - Site specific



Ethics Committee Submissions

- Independent HREC
 - Useful for multicentre research
 - Nominal fee for academic studies
 - Possible waiver

Useful Links

- National
 - <https://www.neaf.gov.au/>
 - <http://www.ethicsform.org/au>
- Queensland
 - http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp
- Victoria
 - <http://www.health.vic.gov.au/ethics/multi/>
- New South Wales
 - <http://www.health.nsw.gov.au/ethics/research/governance.asp>



Governance

- Specific requirements for each site
- Site Specific Assessments to be submitted simultaneously with NEAF
- Documentation
 - Informed consent forms
 - Patient information sheets
 - Budgets
 - Agreement from stakeholders
 - Labs
 - Diagnostics
 - Other

Logistics

- Factors to be considered
 - Clinical supplies
 - CRFs
 - Lab kits
 - Primary endpoint measurement e.g
 - Drugs and Devices
 - Import requirements, Labeling, Storage, Distribution, Quarantine, Destruction, Accountability and reconciliation
- Partnerships with vendors
 - IVRS
 - EDC
 - Equipment



Contracts

- Institutional specific
- Medicine's Australia CTRA
 - Collaborative or Cooperative Research Group (CRG) Studies
- Insurance and indemnity coverage for clinical trial activity
- N.B changes to standard templates may require legal review at the cost of the sponsor
 - www.medicinesaustralia.com.au

Registration

- National registry
 - www.anzctr.org.au
- Australia New Zealand Clinical Trials Registry (ANZCTR)
 - On-line register of all clinical trials conducted
 - Includes any health care interventions
 - Registration is voluntary
 - Responsibility for registration lies with the Sponsor
 - All data submitted is made publicly available
 - Meets the criteria of a WHO Primary Register

Registration

- International registry
 - www.clinicaltrials.gov
- Policy initiated by the International Committee of Medical Journal Editors (ICMJE)
- Accepts registration from WHO selected primary registers

Investigator meeting

- Forum for discussion
 - Protocol design
 - Clinical requirements
 - Investigator responsibilities
 - Consenting
 - Assessment
 - Safety reporting
 - Operational issues
 - Data collection and transfer
 - Sample collection and transfer
 - Accountability for treatment and supplies
 - Safety data management
 - Training
 - GCP requirements
 - Local regulatory requirements



Investigator Meeting

- Opportunity for interaction with all stakeholders
- Education of the study staff regarding the implementation and delivery of the protocol
- May replace the need for Site Initiation visits

Summary

- Plan your activities
 - Project management
 - Critical pathways that are milestone driven
- Strategies for management of study
 - Multi centre application versus single centre application
 - Contingency planning
- Streamline activities for efficiencies in time and cost
- Minimize deviation from standard templates