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Establishing a research
department: Guidance for
anaesthesia investigators

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Purpose of document:

This document integrates guidance for setting up a research department and implementing a clinical trials governance framework within the ANZCA Clinical Trials Network (CTN). It outlines the foundational elements for infrastructure, staffing, funding, operations, and governance required to run clinical trials responsibly and efficiently.

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Establishing a research department: Guidance for anaesthesia investigators

Introduction

This document integrates guidance for setting up a research department and implementing a clinical trials governance framework within the ANZCA Clinical Trials Network (CTN). It outlines the foundational elements for infrastructure, staffing, funding, operations, and governance required to run clinical trials responsibly and efficiently.

1. Define scope and structure

- Determine if the unit will support CTN-only, broader anaesthesia/Intensive Care Unit (ICU) studies or any other collaborative trials, or quality improvement projects.
- Develop a clear mission statement to align with institutional research and clinical goals.

2. Leadership and oversight

- Hospital/site management would be required to appoint a research governance lead
- Appoint a lead for the research department (e.g., Director of research, Principal Investigator (PI)).
- Appoint a manager if possible, for the clinical trials unit.
- Establish oversight from a research committee or hospital executive sponsor.
- Ensure all governance processes align with [National Health and Medical Research Council \(NHMRC\) National Statement on Ethical Conduct in Human Research](#) and [International Council of Harmonisation Good Clinical Practice \(ICH GCP\)](#).
- Get the medical director on board as eventually they will sign the agreements.
- Get help, it is useful to have a mentor and advice. Reach out to the CTN office about the [mentorship program](#).

3. Staffing and roles

- Appoint a Site PI with GCP certification for each trial.
- Recruit a research co-ordinator (minimum 0.5 Full Time Equivalent (FTE) recommended).
- Assign governance support for ethics submissions and legal support for contracts.
- Consider additional roles: associate-investigators, data managers, research administrators.
- Reach out to collaborating departments and establish connections e.g. surgical/Intensive Care Unit (ICU) teams, pharmacy, pathology.
- Reach out to collaborative departments to determine if any resources such as administrative staff can be shared.

4. Funding and sustainability

- Use hybrid models: Per Patient Payments (PPPs) from clinical trials, hospital contributions, grants, departmental funds.
- Apply for [CTN Pilot Grants](#), [ANZCA Foundation Grants](#), [NHMRC/MRFF](#), [HRC](#) or institutional seed funding.
- Explore co-funding models with other departments i.e. ICU, surgical, infectious diseases, or neurosurgery.
- Diversification of income streams and staffing models builds strength and avoids funding gaps.

5. Ethics and governance submissions

- Define a clear internal pathway for Human Research Ethics Committee (HREC) (Australia) and [Health and Disability Ethics Committees \(HDEC\) \(New Zealand\)](#) and Site Specific Application (SSA) (Australia) or Locality Application in New Zealand.
- Create templates for low and high risk study approvals if these are not already in existence.
- Track timelines using a Gantt chart and ensure all submissions meet local governance standards.
- Consider application fees for HREC and governance review/approval for different types of trials/studies.

6. Site readiness and trial start-up

- Conduct trial feasibility (contact the CTN office for an example of a trial feasibility document or use trial specific feasibility assessment form).
- Hold a Site Initiation Visit (SIV) for all new studies.
- Ensure ethics, governance and legal approvals are in place before recruitment commences and the site is activated.
- Confirm trial budgets, investigator agreements, and indemnity/insurance and any other trial specific training required for the staff.

7. Policies and Standard Operating Procedures (SOPs)

- Implement SOPs for key areas: consent, Adverse Events (AE), Serious Adverse Event (SAEs), safety reporting, recruitment tracking, database management, delegation logs etc. Some may be trial specific.
- Store SOPs where all team members have access and review and update annually.

8. Data and document management

- Use standardised tools: screening logs, delegation logs, investigator site file (ISF) templates. Some trials may have specific requirements for these.
- Ensure compliance with document retention and data security policies both locally and trial specific.
- Maintain a trial master file (TMF)/ ISF or equivalent site file.

9. Monitoring and quality assurance

- Schedule regular self-monitoring (e.g. quarterly site file reviews) preferably by team members who are not the primary co-ordinator for the trial
- Host monitoring visits from sponsors or CTN when applicable.
- Track recruitment, follow-ups, and protocol deviations with audit-ready logs.

10. Training and culture

- Maintain GCP certification and CV's for all key team members.
- Provide onboarding, mentoring, and annual SOP reviews.
- Embed a research culture through team engagement, recognition, and education sessions.

11. Stakeholder engagement and communication

- Establish contact with ANZCA CTN, [Anaesthesia Research Coordinator Network \(ARCN\)](#) and trial managers early and research managers of other departments in your hospital to seek support
- Attend multidisciplinary team and interdepartmental meetings to raise visibility.
- Maintain regular reporting to the hospital Research Governance Office (RGO), CTN office, and sponsor teams.
- Make sure to disseminate the results of the studies to other departments that supported the trial such as surgical and nursing teams.

12. Sample start-up timeline (first 6–12 months)

- Month 1: Appoint research team members e.g. Head of Department (HOD) and unit manager and/or PI and co-ordinator for specific trials or, define scope, confirm hospital support.
- Month 2–3: Submit ethics/governance, prepare SOPs, complete feasibility.
- Month 4–6: Launch first trial, begin recruitment, initiate monitoring.
- Month 6–12: Review metrics, join a second trial, expand infrastructure.