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Site readiness for anaesthesia research departments

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Purpose of document:

This guidance outlines essential domains and practical considerations for determining whether an anaesthesia department or site is prepared to participate in ANZCA Clinical Trials Network (CTN) endorsed clinical trials. It is designed to support Principal Investigators (PI), department heads, and research teams in evaluating readiness and enabling high-quality participation in CTN studies and research.

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Version	Contributors	Reviewed/Approved	Date Approved by ARCN Sub-Committee & CTN Executive	Changes
1.0	Karen Goulding Gillian Ormond	Allison Kearney Kaitlin Kramer Prof Victoria Eley	1/8/2025	Creation

Table of contents

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1. Organisational and governance capacity

a. Ethics and research governance

- Confirm Research Governance Office (RGO) and Human Research Ethics Committee (HREC) (Australia) or Health and Disability Ethics Committee (HDEC) (New Zealand) structures are in place.
- Assess experience with single and multi-site ethics submissions.
- Understand Site Specific Application (Australia) or Locality Application (New Zealand) processes and governance timelines.

b. Leadership, governance and succession planning

- Identify a committed PI and support team.
- Establish departmental governance processes (e.g. regular research meetings).
- Ensure processes / policies / Standard Operating Procedures (SOPs) are documented and saved in an accessible spot for all to access.
- Plan for continuity via mentoring, deputy roles or associate investigators.

c. Executive and departmental support

- Confirm endorsement from the Director of anaesthesia and/or Director of anaesthesia research and other leaders.
- Confirm endorsement with supporting departments e.g. Intensive Care Unit (ICU), surgical department.
- Align with the department's and institute/hospital research strategy or goals.
- Identify champions or collaborators interested in research in internal and external departments.

2. Operational infrastructure

a. Staffing and capability

- Confirm presence of Good Clinical Practice (GCP) trained research staff (research co-ordinators, research assistants, medical/nursing students).
- Identify administrative and clinical support for recruitment/follow-up.
- Explore part-time/shared staffing and onboarding support.
- Explore engaging with motivated junior doctors/medical students to assist with research activities.

b. Training and professional development

- Ensure staff have access to trial-specific training and software.
- Promote shadowing or mentoring via the Anaesthesia Research Co-ordinator Network (ARCN).
- Encourage attendance at CTN workshops and investigator meetings.
- Ensure access to CTN resources.

c. Financial and cost centre readiness

- Confirm existence or feasibility of a research cost centre.
- Identify staff for financial oversight and trial related invoicing.
- Ensure readiness to manage multi-source funding streams.

d. Data and consent systems

- Use secure platforms for data collection and storage e.g. REDCap, Electronic Medical Records (EMRs).
- Maintain version control for trial documents e.g. study protocols and Patient Information and Consent Forms (PICFs).
- Support both digital and paper consent pathways.

3. Site-Level Logistics

a. Access to clinical pathways

- Verify access to theatre, theatre lists and pre-admission clinics for screening.
- Ensure researchers can attend or view assessments.
- Delegate roles to research staff based on time/availability and workflow.
- Establish relationships with perioperative or bookings teams.

b. Patient follow-up and retention

- Assess capability of research team to do weekend/holiday follow-up.
- Confirm phone/email access to conduct follow up data collection.
- Secure permissions for outcome data and discharge summaries from EMR's or other medical appointments.

c. Site logistics and accessibility

- Identify access to theatres, wards, secure offices, and secure storage of trial documents.
- Confirm secure handling of consent forms, Case Record Forms (CRFs), and Investigational Product (IP).
- Ensure there are appropriate workspaces for the research team.
- Ensure access to hospital programs e.g. EMR, theatre lists.

d. Research Governance Office (RGO) engagement

- Engage early with your RGO for trial feasibility and correct documents to submit for governance approval.
- Understand local insurance, indemnity, and contract approval processes.

4. Culture, collaboration and communication

a. Research culture and collaboration

- Promote research visibility in departmental meetings.
- Document past and ongoing studies.
- Connect with ICU, surgical, Emergency Department (ED), pain and perioperative departments.
- Maintain collaborative research efforts through education, meetings and networking opportunities.
- Consider regular emails/newsletters/meetings and presentations to keep departments motivated and involved in research.

b. Consumer and multidisciplinary engagement

- Involve clinicians, nurses, and allied health in trial awareness.
- Ensure consumer involvement where required (especially paediatric/pain trials).
- Document consumer engagement in the study protocol.

c. Departmental communication and networking

- Connect site to CTN/ARCN mailing lists.
- Share updates and learnings across trial sites.
- Hold trial briefings or info sessions.

5. CTN-informed site feasibility factors (Based on Sanders *et al.* 2023)

These cross-cutting factors should guide a holistic assessment of your site's trial readiness:

1. Shared vision and motivation: Is there cultural and clinical buy-in for research?
2. Leadership and governance: Are roles, plans, and succession clear?
3. Staffing and GCP-training: Are there capable and credentialed staff available?
4. Trial pipeline and prioritisation: Has the site contributed to or reviewed CTN studies?
5. Embedded practice: Can trials integrate with routine care?
6. Infrastructure and tools: Are Information Technology (IT), space, and documentation systems ready?
7. Patient follow-up systems: Can longitudinal follow-up be supported?
8. Financial readiness: Can costs and invoicing be managed?
9. Colleague and consumer involvement: Is the wider department engaged?
10. Communication pathways: Are research updates part of the local culture?

This framework is a starting point. For support or to be connected with experienced investigators or the ARCN, contact:

ANZCA Clinical Trials Network: ctn@anzca.edu.au

6. Reference

1. Sanders M, Goulding K, Oakley E, Reidlinger D, Groom KM. Activities critical to success and growth of clinical trials networks. What is needed and how are we doing? An Australian and New Zealand perspective. *Trials*. 2023 Nov 4;24(1):707. doi: 10.1186/s13063-023-07709-y. PMID: 37925441; PMCID: PMC10625692.