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Implementing the National Clinical Trials Governance Framework: Guidance for anaesthesia research departments

August 2025

Purpose of document:

This guidance document is designed to support anaesthesia and perioperative research teams, research co-ordinators, and hospital governance personnel in Australia and New Zealand. It provides detailed guidance on how to implement the National Clinical Trials Governance Framework (NCTGF), based on the experiences of ANZCA CTN sites that have undertaken or are preparing for accreditation.

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Version	Contributors	Reviewed/Approved	Date Approved by ARCN Sub-Committee & CTN Executive	Changes
1.0	Kush Katairi Louise de Prinse Dr Sophie Wallace Jonathan Termaat Gillian Ormond Karen Goulding Paige Druce	Natalie Hird Louise de Prinse A/Prof Stefan Dielemanl	1/8/25	Creation

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Introduction

This guidance document is designed to support anaesthesia and perioperative research teams, research co-ordinators, and hospital governance personnel in Australia and New Zealand. It provides guidance on how to implement the National Clinical Trials Governance Framework (NCTGF), based on the experiences of ANZCA CTN sites that have undertaken or are preparing for accreditation.

The content is based on real-world case studies and firsthand accounts presented during the ANZCA CTN educational session titled "Unlocking Success: Case Studies on Implementing the National Clinical Trials Governance Framework, March 2024 ." The aim is to provide structured, practical advice that reflects a diversity of institutional settings, staffing levels, and levels of preparedness.

Session objectives

- Provide practical insight into how hospitals are implementing the NCTGF in Australia.
- Highlight the current state of clinical trial credentialing in New Zealand.
- Share tools, templates, and strategies to enhance preparedness and compliance.
- Foster collaboration between research units, governance offices, and clinical departments.
- Promote research integration into routine clinical care and hospital systems.

1. Understanding the NCTGF (Australia)

Presented by: Kush Katairi (Monash Health Research Governance Office).

Background

The NCTGF was developed by the Australian Commission on Safety and Quality in Healthcare to embed clinical trials into routine hospital operations. It aligns clinical trials with the National Safety and Quality Health Service (NSQHS) Standards, particularly:

- Standard 1: Clinical Governance.
- Standard 2: Partnering with Consumers.

This framework is designed to ensure clinical trial participants receive care of the same standard and safety as other patients and that clinical research is properly supported by robust, transparent systems.

Purpose of the framework

- Integrate research into hospital-wide governance and service delivery.
- Improve visibility, accountability, and resource allocation for clinical trials.
- Enhance patient safety and consumer involvement.
- Ensure workforce qualifications and training are aligned with best practices.

Key components of the framework

1. Governance, leadership and culture:
    - Recognise research as a core hospital function.
    - Ensure clear organisational charts and reporting lines.
    - Incorporate research performance into corporate governance.
2. Patient safety and quality improvement systems:
    - Embed safety incident reporting mechanisms for trials.
    - Monitor adverse events and protocol deviations.
    - Develop corrective action plans and foster continuous improvement.
3. Safe environment for care delivery:
    - Maintain clinical trial infrastructure in line with hospital safety standards.
    - Ensure trial facilities are adequately equipped and maintained.
4. Clinical performance and effectiveness:
    - Credential all clinical trial staff appropriately.
    - Verify up-to-date CVs, Good Clinical Practice (GCP) certification, and mandatory training.
5. Partnering with consumers:
    - Engage patients and families from trial design through dissemination.
    - Incorporate feedback mechanisms to improve health literacy
    - Ensure compliance with healthcare rights and informed consent principles.

Accreditation process

- Short-notice assessments started in May 2023.
- Hospitals are initially rated on a maturity scale:
    - Initial System: Requirements not yet in place.
    - Growing System: Some requirements met with plans for improvement.
    - Established System: Fully compliant, embedded research governance.
- Future assessments will involve pass/fail evaluations and require rectification within 60 days if gaps are found.

Tools from Monash Health

- Created a detailed accreditation readiness checklist for all research teams.
- Conducted training sessions ("roadshows") for co-ordinators and investigators.
- Encouraged interdepartmental collaboration and integration into hospital-wide policies.

2. Case Study – Flinders Medical Centre, South Australia

Presented by: Louise de Prinse (Research Co-ordinator).

Accreditation journey

Flinders Medical Centre became the first Australian hospital to undergo formal accreditation under the new NCTGF. The team had limited resources, operating with only 1.2 Full Time Equivalent (FTE) dedicated research staff.

Preparation steps

- Built a comprehensive master site file for all CTN and investigator-initiated trials.
- Developed critical templates from scratch:
    - Standard Operating Procedures (SOPs) for data management, consenting, adverse events, monitoring.
    - Protocol and delegation logs.
    - Training records.

- Created a document tracking system for 30+ clinicians.
- Established central digital filing systems to ensure document accessibility.

Challenges encountered

- Received only two week's notice to draft 13 SOPs based on the framework.
- Minimal guidance from the hospital research governance office.
- Required to retrieve archived documents (e.g., Clinical Trial Research Agreements (CTRAs) for past studies) with very little notice.
- Underwent spot audits and had to demonstrate compliance with safety procedures and Adverse Event (AE) reporting.

Lessons learned

- Accreditation reveals gaps in organisational and governance readiness.
- Research units must maintain a "clean and audit-ready" environment at all times.
- SOP development is crucial to demonstrating compliance.
- Co-ordinators must advocate for infrastructure and funding to support accreditation-related workload.

3. Case study – Alfred Hospital, Victoria

Presented by: Sophie Wallace (Research Manager).

Institutional approach

The Alfred Hospital used an institution-wide approach to prepare for accreditation, investing significant resources over several years.

System enhancements

- Developed hospital-wide SOPs through working groups across departments.
- Integrated electronic clinical trial systems that:
    - Track trial participation in patient Electronic Medical Records (EMRs).
    - Record trial status and documentation (Patient Information Statement Consent Form (PISCF), CVs, ethics approvals).
- Enabled ethics department to manage credentialing and training notifications.

Accreditation experience

- Received short-notice audit request on a Thursday for Monday visit.
- Highlighted consumer engagement that was already occurring on the date of audit and governance response to a trial safety issue (TRIGS trial).
- Successfully demonstrated cross-functional collaboration and patient-centred processes.

Advantages

- Institutional support streamlined accreditation.
- Digital tools enhanced documentation and transparency.
- Multi-year investment in SOP development paid off.

4. Clinical Trial Credentialing in New Zealand

Presented by: Jonathan Termaat (Waikato Hospital, Clinical Trials Co-ordinator).

National context

New Zealand does not currently operate under a national clinical trials governance framework. Instead:

- Hospitals undergo general quality reviews every 3 years.
- Trial-specific review and credentialing vary widely by institution.

Challenges

- Fragmentation due to legacy district health board system (23 boards).
- Unequal distribution of governance resources.
- No consistent SOPs or digital infrastructure across hospitals.

Recent reforms

- Creation of Health New Zealand, a centralised public health agency.
- Plans to develop:
    - A national ethics and governance portal for clinical trial approvals.
    - A national registry of active trials using REDCap.
    - Greater focus on equity, especially for Māori and Pacific Islander patients.

Current efforts

- Internal governance boards maintain local SOPs.
- Emphasis on streamlining approval processes and avoiding duplication.
- Hope for eventual adoption of national standards.

5. Accreditation readiness tools

Monash Health Readiness Checklist Includes:

- Confirming current Human Research Ethics Committee (HREC) and Site Specific Assessment (SSA) approvals for all studies.
- Ensuring up-to-date GCP, mandatory training, and CVs for all staff.
- Accessibility of participant documentation and consent processes.
- Evidence of safety event reporting and incident follow-up.
- Records of consumer engagement and feedback mechanisms.
- Create archiving systems and SOPs for data management

Recommended steps for CTN sites:

1. Conduct internal gap analyses: Assess existing resources and documentation.
2. Establish SOPs: Align with NCTGF components and local hospital policy.
3. Create shared templates: Logs, training trackers, safety forms.
4. Train staff regularly: Encourage active participation in hospital-wide accreditation planning.
5. Document everything: Keep complete, auditable records for all trials.

6. Reflections and forward planning

What accreditation offers:

- Legitimacy and institutional recognition for research activities.
- Justification for increased funding, staff, and protected time.
- Improved consumer trust and patient engagement.
- A more sustainable, audit-ready research ecosystem.

Supporting a research-ready culture:

- Include research in hospital Key Performance Indicators (KPIs) and strategic plans.
- Encourage collaboration between governance teams and researchers.
- Invest in centralised tools and training resources.
- Celebrate success and share lessons across the network.

Supporting resources:

- Short Notice Assessment Checklist February 2024 (available on request from the CTN office).
- The National Clinical Trials Governance Framework (NCTGF).
- National Safety and Quality Health Service (NSQHS) Standards.