TITLE	Research Governance
TARGET AUDIENCE	Staff Involved in Research
SCOPE	Cabrini Research – all sites

INTRODUCTION

The National Clinical Trials Governance Framework and User Guide for Health Service Organisations Conducting Clinical Trials was introduced and piloted in 2020 by the Australian Commission on Safety and Quality in Health Care. The National Clinical Trials Governance Framework is underpinned by best practice principles which are consistent with existing regulations for the conduct of clinical trials in Australia. The National Clinical Trials Governance Framework strengthens governance arrangements for clinical trial services and provides clarity to governments, health service organisations, hospital administrators, clinicians, and others responsible for delivering clinical trials.

The National Clinical Trials Governance Framework builds on the National Model Clinical Governance Framework and the National Safety and Quality Health Service (NSQHS) Standards, providing:

1. Roles and functions for identified positions relating to clinical trial service provision within a health service organisation
2. Actions against which health service organisations with a clinical trial service will be assessed for accreditation
3. Suggested strategies health services may implement to meet the actions within the NSQHS Standards
4. Examples of evidence a health service organisation may provide that demonstrate they have met the actions within the NSQHS Standards for clinical trial service provision.

The National Clinical Trials Governance Framework is aligned with the NSQHS Standards, in particular, the Clinical Governance Standard and the Partnering with Consumers Standard. There are five components within these two Standards:

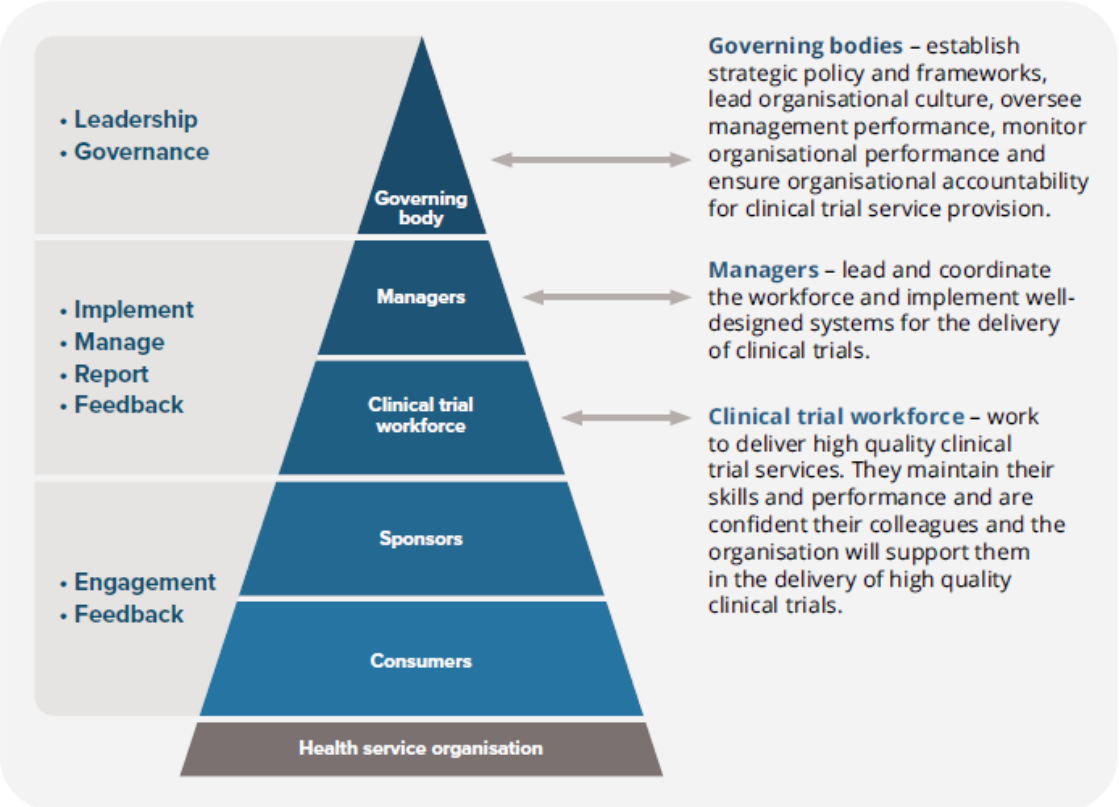
1. Governance, leadership and culture –integrated corporate and clinical trials governance systems are established, and used to improve the safety and quality of clinical trial service provision for patients, their carers and consumers.
2. Patient safety and quality improvement systems – safety and quality systems are established and used to manage and improve the provision of clinical trial services.
3. Clinical performance and effectiveness –the workforce has the right qualifications, skills and supervision to provide safe, high-quality clinical trial services to patients.
4. Safe environment for the delivery of care –the environment in which clinical trials are conducted is safe and promotes high-quality clinical trials to patients.
5. Partnering with consumers – systems are designed and used to support patients, carers, families and consumers to be partners in planning, design, measurement and evaluation of clinical trial services. Consumers may also work with health service organisations and others acting as trial sponsors, in the design, and evaluation of clinical trials. Elements of this component include clinical governance and quality improvement systems to support partnering with consumers:
    - Partnering with patients in their own care, and in trial participation
    - Health literacy
    - Partnering with consumers in organisational design and governance of clinical trial services.

It is mandatory for all public and private Australian hospitals and day procedure services to be assessed through an independent accreditation process to determine whether they have implemented the NSQHS Standards. Therefore, the actions in the National Clinical Trials Governance Framework are also mandatory for health service organisations that provide a clinical trials service.

To put in place the requirements of the NSQHS Standards that are the basis of the National Clinical Trials Governance Framework, health service organisations and trial sites need to have a culture that provides:

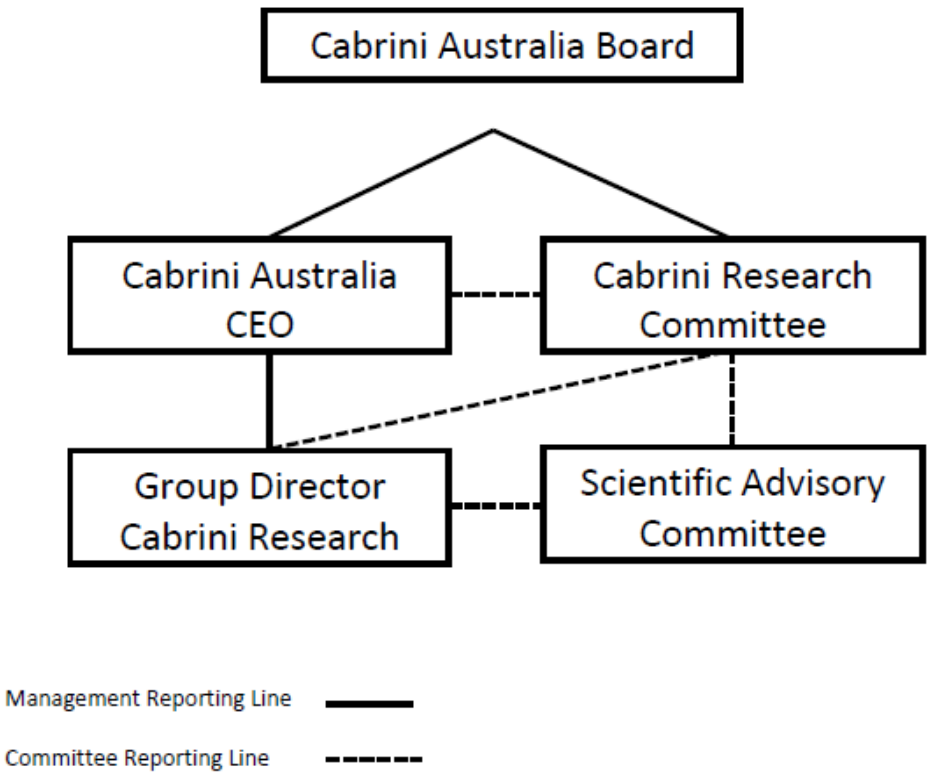
1. Strong strategic and cultural leadership of clinical trial services, that prioritises:
   - effective planning to enable development and improvement opportunities to be captured
   - selecting high quality clinical trials that will provide value to patients and consumers, improves the clinical evidence-base and supports continuous improvement in clinical trial service provision
   - allocating resources to support the delivery of high-quality clinical trial services
2. Clear responsibilities for managing high quality clinical trials services and appropriate delegation of the necessary management authority for this purpose
3. Reliable processes for ensuring that systems for delivering clinical trials perform well, and clinicians are fully engaged in the design, monitoring and development of these systems
4. Effective use of data and information to monitor and report on operational performance, through the health service organisation to the governing body to support ongoing quality improvement
5. Well-designed systems for identifying, quantifying, and managing risk
6. Opportunities for consumer engagement in the design of clinical trial services and processes that supports consumer engagement as a part of the health service organisation strategic plan

Roles and functions of identified positions relating to governance of clinical trial services



Cabrini Research Governance Structure

Cabrini Research Organisational Structure



The Governing Body

The Board of Cabrini is responsible for the conduct of research at Cabrini Health Limited (herein referred to as Cabrini). The Cabrini Research Committee (CRC), a committee of the Board, supervises the conduct of research. The conduct of the CRC is governed by its Terms of Reference, which is approved by the Board (refer to the Cabrini Research Committee Terms of Reference)**.**

The CRC, as outlined in the National Clinical Trials Governance Framework, is responsible in conjunction with the CEO and Group Director, Cabrini Research, for the following actions:

1. Provide leadership to develop a culture of safety and quality improvement, and satisfy itself that this culture exists within the organisation
2. Provide leadership to ensure partnering with patients, carers and consumers
3. Set priorities and strategic directions for the conduct of safe and high-quality clinical care, and ensures that these are communicated effectively to the workforce and the community
4. Endorse the National Clinical Trials Governance Framework within the health service
5. Ensure that roles and responsibilities are clearly defined for the governing body, management, clinicians and the workforce
6. Monitor the action taken as a result of analyses of incidents
7. Review reports and monitor the organisation's progress on safety and quality performance
8. Identify risks and ensure that mitigation strategies are in place to manage all major risks

An external review of this committee will be conducted every five years.

The Scientific Advisory Committee

Reporting to the Cabrini Research Committee is the Scientific Advisory Committee (SAC), whose specific role is to ensure the highest quality of the results of the research activities. In particular, it will have the following functions:

1. Advise strategic direction of research at Cabrini
2. Identify opportunities and facilitate collaborations with other institutions
3. Provide peer review for research programs and projects (validate the process and results of the research activities)
4. Assess and evaluate quality of research at Cabrini
5. Report and make recommendations to the Cabrini Research Committee regarding research at Cabrini
6. Identify areas of unmet need
7. Endorse the organisation's governance framework and strategic plans, such as the operational plan for clinical trial service provision, safety and quality improvement plan, and the plan for partnering with consumers
8. Review the template or calendar for reporting to the governing body on safety and quality indicators and data, and ensure that it covers all services, locations, major risks, dimensions of quality and key elements of the quality improvement system
9. Regularly review quality indicators to ensure that they are relevant and comprehensive

An external review of this committee will be conducted every five years.

The Group Director, Cabrini Research

The Group Director, Cabrini Research reports directly to the CEO and the CRC, and is an employee of Cabrini, and has day to day responsibility for ensuring that Cabrini Research's responsibilities for the supervision of research at Cabrini are fulfilled. These include:

1. Oversight of strategic, business and risk management plans
2. Oversight of clinical trial governance, leadership, patient safety and quality culture
3. Chair the Research Governance Committee
4. Foster a culture and environment of innovative clinical research excellence through the development of research teams and translational research projects
5. Provide academic and administrative leadership within Cabrini Research by participating in the development and delivery of policy and strategy
6. Provides administrative leadership, management and direction
7. Represent the Institute as delegated in appropriate research and other committees
8. Work with the Director of Infrastructure to create an optimal working culture
9. Maintain an effective and collaborative relationship with the Director of Infrastructure and the Director of Research, providing leadership and support
10. Collation of data to meet the National Clinical Trials Governance Framework
11. Facilitate an external review of the Committee every five years, which will be provided to the Committee and the findings reported to the Board

The Research Governance Committee

The Research Governance Committee (RGC) oversees the activities of the Cabrini Research Governance Office (CRGO). Members include the Group Director Cabrini Research, the Director of Research Infrastructure, the Director of Research, a representative of Cabrini Medical Administration, and the staff of the CRGO.

The CRGO is operationally responsible for ensuring that:

1. Ethically sound research is promoted, conducted and monitored at Cabrini
2. The research affirms the mission and values of Cabrini and the teachings of the Catholic Church
3. Ethical standards are maintained in research to protect the interests of the research participants, the investigator and the institution.
4. Relevant data from clinical incidents (adverse events), and reports of complaints and other incidents are reviewed
5. Identify relevant industry standards, and develop processes to implement and monitor compliance with these standards, which may include legislative and guidance material such as:
    - The Australian Code for the Responsible Conduct of Research, 2018 (the Code)
    - The National Statement on Ethical Conduct in Human Research (2007) - Updated 2018
    - The Clinical Trials Governance Framework, September 2018
    - Guidance for Good Clinical Practice 2016 (ICH-GCP)
    - Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018)
    - Keeping research on track: a guide for Aboriginal and Torres Strait Islander peoples about health research ethics (2018)
    - Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)
    - Consolidated Standards of Reporting Trials (CONSORT).
    - The Australian Code for the Responsible Conduct of Research, 2018;
    - Chapter 6: Catholic Health Australia's Code of Ethical Standards for Catholic Health and Aged Care Services in Australia (2001);
    - International Conference on Harmonisation (ICH) Guideline for Good Clinical Practice;
    - The Privacy Act 1988 (Commonwealth) and the Health Records Act 2001 (Victorian);
    - Cabrini's Research Strategy and the Cabrini Research Governance Handbook;
    - Clinical Trials Research Governance Framework;
    - Therapeutic Goods Administration (TGA) Australian Clinical Trial Handbook; and
    - Other relevant Commonwealth and State legislation; and NHMRC guidelines.

Research ethics submission at Cabrini can involve:

- CRGO review and approval (where applicable) of low and negligible risk studies.
- CRGO site governance review and approval of studies pre-approved by an external Human Research Ethics Committee.

The RGC convenes monthly to review and approve studies of all risk levels, although studies may be approved out of session depending on their level of urgency. This committee also reviews clinical trial serious adverse events (SAE's) and study progress reports.

All pharmaceutical company sponsored clinical trials at Cabrini must be indemnified and insured, in accordance with Medicines Australia Guidelines. All other studies are reviewed by the CRGO, or in consultation with the RGC.

Clinical Trial Workforce

Research projects at Cabrini are conducted either by researchers located within the Cabrini Research academic departments, health professionals or other employees of Cabrini, or by Cabrini accredited medical practitioners within their private practices. Students are encouraged to undertake research at Cabrini campuses if they are supervised by an authorised Cabrini employee or visiting medical officer. These students must secure honorary appointments before commencing research at Cabrini. Research projects may be investigator-initiated or sponsored trials.

Roles and functions of the clinical trial workforce:

1. Model professional conduct that is consistent with a commitment to safety and quality at all times
2. Embrace opportunities to take part in the management of clinical trial service provision across the health service organisation
3. Actively take part in the development of an organisational culture that enables clinical trial service provision
4. Establish contacts and relationships with all key stakeholders, including governing bodies, clinical and non-clinical managers, trial site staff, patients and consumers and sponsors
5. Collaborate with clinical and non-clinical managers to ensure the systems to support clinical trial service delivery are well designed and perform well
6. Ensure compliance with legislative and policy requirements and conduct clinical trials as specified by the trial protocol and in accordance with the conditions of the HREC approval
7. Provide guidance and mentorship on responsible research conduct to other researchers or research trainees under their supervision, and where appropriate monitor their conduct
8. Undertake and promote education and training in responsible research conduct
9. Comply with the relevant laws, regulations, disciplinary standards, ethics guidelines and institutional policies related to responsible research conduct
10. Encourage, mentor and guide clinical trial site staff in the delivery of safe, high-quality clinical trials
11. Take part in all aspects of the development, implementation, evaluation and monitoring of clinical trial governance processes
12. Collaborate with the key individuals and groups within the trial site and/or health service organisation to deliver the National Clinical Trials Governance Framework.

Executive Sponsor	**Group Director, Cabrini Research**	
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