National Clinical Trial Governance Framework

Operational Plan

Discovery & Innovation Unit April 2024 Version 1.0

Version Control

Version	Updated	Amendments	Author
Draft 0.1	10 April 2024	First draft	Heidi Gaulke

Acknowledgement

Austin Health is extremely grateful to the Royal Children's Hospital for providing their operational plan for implementation of the National Clinical Trial Governance Framework (NCTGF). This plan has been modified to meet Austin Health's requirements but has not been substantially changed from the RCH's version.

Introduction to the Framework

Why is the Framework important?

The National Clinical Trials Governance Framework supports the integration of clinical trial service provision into routine hospital care for improved patient outcomes. Clinical trials are one of the highest risks for healthcare services. Embedding clinical trials into clinical governance systems requires collaboration across the health service from ward to Board.

The National Clinical Trials Governance Framework strengthens governance arrangements for clinical trial services and provides clarity of responsibilities and outcomes to governments, health service organisations, hospital administrators, clinicians, and others responsible for delivering clinical trials.

What is clinical research governance?

The set of relationships and functions for the conduct and oversight of clinical research established by Austin-Mercy Health & Education Precinct, which contains:

- Two Health Services
- Five Medical Research Institutes
- Two Academic Partners

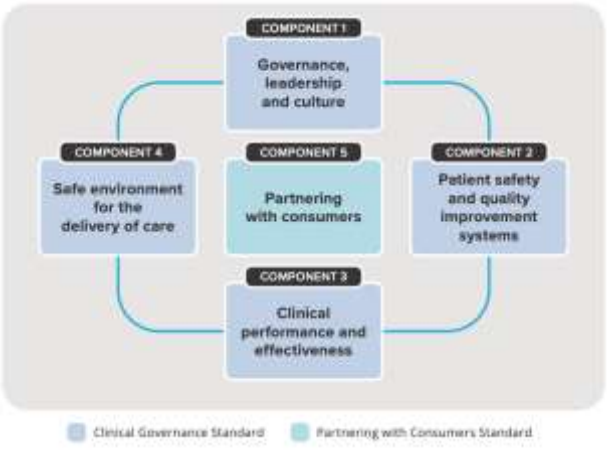
Clinical research also involves relationships with Victorian Government, executives, workforce, patients, consumers, and any others who contribute to clinical research.

Appropriate governance ensures that everyone, including frontline clinical investigators undertaking the clinical trials and members of the governing bodies (respective Boards of Austin-Mercy Health & Education Precinct Partners), is accountable to patients and the broader community for assuring the delivery of high-quality clinical trials, integrated into clinical care, and continuously improving.

The Standards

The National Clinical Trials Governance Framework is aligned with the National Health Safety and Quality Healthcare Standards (NHSQHS), in particular,
the Clinical Governance Standard and Partnering with Consumers Standard. These two Standards are assessed as part of the organisation wide survey against the National Standards.

There are five main components within these two Standards.



Component 1
Governance, leadership, and culture

Our board, executive and senior leadership team establish and use clinical governance systems to lead and set a clear vision and culture for improving the safety and quality of care.

At the Austin Health, we put into place appropriate governance structures to effectively review, report and monitor progress on clinical research with a focus on safety and quality performance.

Visible, accountable, and purposeful leadership ensures our people are clear about the strategic priorities for safe and high-quality care, and that the clinical trial workforce understand their delegated roles and responsibilities.

What will we do?

- **Activity 1.1 Define and strengthen the Clinical Trial Governance Framework**

Review the Clinical Research Governance committee structure to enhance effectiveness and efficiency in monitoring clinical trial operational performance, quality and safety, and compliance with strategic business plans. Provide regular reports from ward to board.

- **Activity 1.2 Clearly define and articulate the roles and responsibilities of the clinical trials workforce**

Write the Research Operational Excellence document. As part of this task, articulate and communicate with the clinical trials workforce, their defined roles, responsibilities and required actions for good clinical governance and patient safety.

- **Activity 1.3 Develop processes for identifying honorary and affiliate staff undertaking clinical trials**

Implement a robust system to ensure that all Austin Health honorary and affiliate staff involved in clinical research are identified and have appropriate credentials and education/ training.

- **Activity 1.4 Structure a performance development system for managers, trials investigators and their clinical trial teams**

Embed a Research Competency Framework into the education and professional development system, that incorporates regular review of engagement in goal setting, monitoring, and operational and professional performance.

- **Activity 1.5 Report audits, metrics and outcome measures**

On a quarterly basis, review the current suites of mandatory performance KPIs, measures and audits, and implement a regular report inclusive of all the measures required by the NCTGF, Activity Item 1.1 and health service requirements. Share findings with staff and consumers.

What will this mean?

- A clear and effective clinical governance structure for clinical trials (inclusive of honorary and affiliate staff)Defined and articulated roles and responsibilities for the clinical trials workforce
- Effective systems for monitoring audits, mandatory performance KPIs and documents (policies / procedures), reported to the highest level of governance in the organisation

Component 2
Patient safety and quality improvement systems

At Austin Health, we integrate safety and quality systems with governance processes to manage and improve health outcomes for our patients and their families/carers.

Safety and quality systems (such as policies, procedures, clinical practice guidelines, incident management systems, risk management, and quality improvement processes) involve all members of the clinical research workforce with clearly defined roles and responsibilities and require regular review of performance.

We embed clinical research safety and quality systems within a system of measurement and continuous improvement and innovation, so we know how we are performing and can track our improvement progress.

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What will we do?

- **Activity 2.1 Clinical trial policies and procedures**

Review the current suite of research related policies and procedures in accordance with the NCTGF.
Review existing organisational policies and procedures to ensure that there is adequate reference to research.

- **Activity 2.2 Incident reporting, investigation, and monitoring implementation of recommended actions.**

Integrate incident reporting and monitoring with the organisation's incident reporting systems (VHIMS2).

Develop an education and training suite to support the clinical trials workforce in navigating a) SAPSE reviews b) SDC processes c) local level clinical incident system review, including investigation, formulation of recommendations, monitoring improvement work.

- **Activity 2.3 Complaint management**

Integrate research related complaints with the Austin Health organisational complaint management system and develop a training package for the research workforce to utilise the system.

- **Activity 2.4 Risk monitoring**

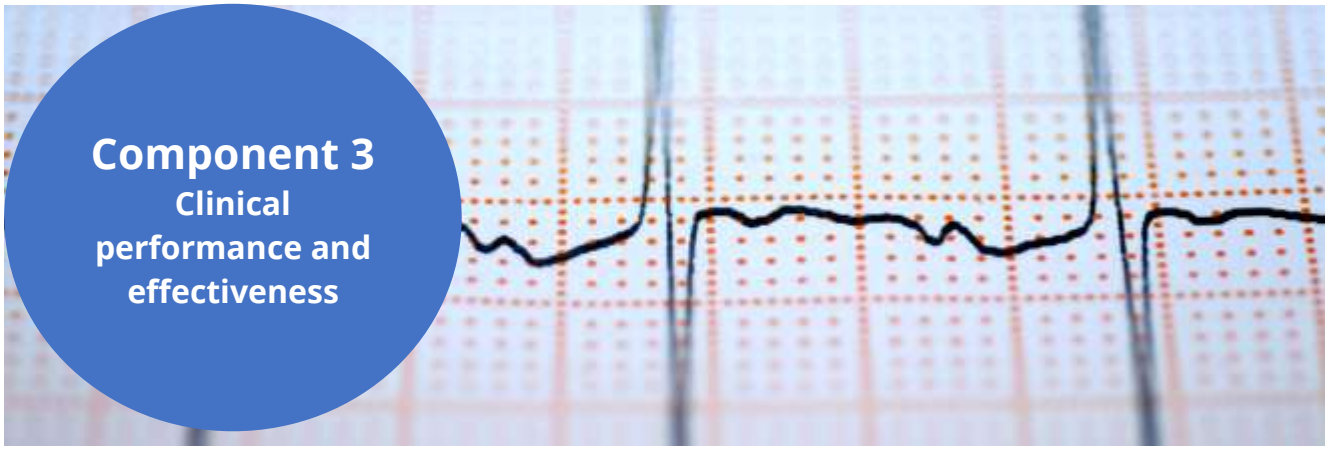
Enhance the process of thematic analysis of clinical incidents, compliance with legislative requirements and organisational policies and procedures and report any lapses through the governance committees. This approach will inform ongoing opportunities for improvement and innovation in research systems and processes.

- **Activity 2.5 Legislative compliance**

Review the current suite of research related compliance register requirements and assess in accordance with the NCTGF.
Undertake an annual audit for ongoing compliance.

What will this mean?

- Enhanced processes and reporting and sharing learnings from clinical incident reviews and other non-compliances.
- Compliance with the Health Act legislation (Quality and Safety)
- Enhance the suite of Research related policies and procedures and legislative requirements.



Component 3
Clinical performance and effectiveness

An effective quality improvement system reflects the health service organisation's priorities and strategic direction for clinical trial service provision.

We achieve high level clinical trial performance by ensuring that the research workforce has the right qualifications, skills, and supervision to provide safe and high-quality clinical trials to participants.

Austin Health ensures that all researchers and their team have access to and undertake training in Good Clinical Practice (GCP) for the conduct of all clinical trials.

Develop a KPI to report on compliance with training to the highest level of governance in the organisation.

What will we do?

- **Activity 3.1 Develop a clinical trials competency framework**
  Implement a formal research competency program for the research workforce, which complements existing training and scope of practice training. Include the mandatory requirement for research staff to undertake the training programme.

- **Activity 3.2 Monitor Good Clinical Practice (GCP) training.**
  Provide a report on training compliance to the peak governance committee through the quarterly report.

- **Activity 3.3 Review position descriptions to encompass requirements for training in clinical trials**
  Undertake a review of position description templates for the research workforce to include the requirements for training to align with the National Clinical Trial Governance Standards.

- **Activity 3.4 Review the Performance Development and Appraisal Program (PDAP) to include provision for staff involved in clinical trials**
  Undertake a review of the PDAP to include requirements for professional development related to clinical trials.

- **Activity 3.5 Good datagGovernance**
  Review current systems and processes for safe data collection, storage and transfer of health service performance metrics.

What will this mean?

- Visibility of the education and training required for the clinical trial workforce
- Compliance with the required training and competency packages
- Enhanced oversight of compliance with education and training

Component 4
Safe environment for the delivery of care

We achieve the provision of high-quality care for our patients through coordination and planning of clinical research, along with appropriate allocation of resources, to ensure the safety and security of our patients, families/carers, and our Austin Health team.

We provide a safe environment for clinical research (including building and facilities), with appropriate and well-maintained equipment.

Designated research spaces are provided where possible and are integrated into the broader hospital environment to ensure safe delivery of care.

We engage the community in the development of messaging to explain clinical trials and create a welcoming, culturally sensitive environment for Aboriginal and Torres Strait Islander people to participate in clinical trials.

What will we do?

- **Activity 4.1 Designated clinical trial facilities**
  Enhance the provision of designated clinical trial facilities to allow for the growth of the clinical trial capability.

- **Activity 4.2 Analysis of incident reports to identify risks**
  Enhance the current VHIMS2 system to capture patients on clinical trials and analyse the incident reports on a regular basis to identify immediate and emerging issues for clinical trial participants.

- **Activity 4.3 Integrate risk identified in clinical trials into the Austin Health Enterprise Risk Register and the Quality Improvement Plan**
  Regular review (e.g. 6 monthly) of incidents related to clinical trials to be discussed with the Director Quality and Improvement to incorporate into the organisation's clinical risk register and Quality Improvement Plan.

- **Activity 4.4 Enhance accessibility and appeal of research to Aboriginal and Torres Strait Islander people**
  Engage with Aboriginal advisers to incorporate culturally sensitive and welcoming language and physical cues to enhance Aboriginal and Torres Strait Islander people recruitment into clinical trials.

- **Activity 4.5 Aboriginal support officer to support Aboriginal and Torres Strait Islander participation in clinical trials**
  Use existing processes to ensure that Aboriginal and Torres Strait Islander participants are supported and provided interpreters as required.

What will this mean?

- Austin Health provides a safe environment for the delivery of research
- Incidents and clinical risk are identified and acted upon in the organisation's Quality Improvement Plan
- Austin Health provides the Aboriginal and Torries Strait Islander population with a welcoming and culturally sensitive environment for inclusion in research

Component 5

Partnering with consumers in Governance and applying quality improvement svstems

Partnering with consumers in Governance and Applying Quality Improvement Systems

Partnering with consumers is a cornerstone of service delivery at Austin Health and is key to achieving the organisation's strategic goals. Consumers of Austin Health, their families, and carers are people who receive care for their health and wellbeing or who play a vital role in supporting patients in their time of need.

Consumer experience through participation in clinical trials are crucial indicators of quality. Effective consumer partnerships, representative of the diverse community we care for, are essential for improving healthcare outcomes and driving continuous improvement.

What will we do?

- **Activity 5.1 Align the existing clinical governance structures for partnering with consumers with governance structures for research services**
  Review the current Austin Health partnering with consumers operational plan to incorporate research.

- **Activity 5.2 Review existing procedures to ensure inclusion and alignment of research**
  Review the Healthcare Rights, consent procedures, care planning and Partnering with Consumers Operational Excellence documents for alignment with the requirements of the National Clinical Trial Governance Standards.

- **Activity 5.3 Education and training for the research workforce on partnering with consumers**
  Ensure researchers use existing training packages to ensure appropriate training requirements for partnering with consumers.

- **Activity 5.4 Develop a system for measuring and reporting of indicators of consumer partnership**
  Create measures relevant to research on consumer partnership and report as part of the measures for 'Partnering with Consumers'.

- **Activity 5.5 Enhance current systems to improve the process for consumers to provide feedback about research.**
  Review current systems for consumers to provide feedback about clinical trials through consumer surveys, feedback forums, providing information to investigators, and establish a complaint management system.

What will this mean?

- Consumer partnership for research aligned with Austin Health Strategy and Enabling Research Strategy and consumer partnerships workplan
- Regular feedback from consumers on research experience
- Enhanced reporting on quality improvement in research

Component 5
Partnering with consumers in their own care

Partnering with consumers in their own care

We ensure that patients, as trial participants and consumers, are included as part of the care team when engaged in research. Austin Health recognises the voice of the consumer, including the family/carer, in knowing the patient best and therefore as an active and crucial member of the care team.

We adopt a person-centred care focus on the relationship with a research participant and recognise that trust, mutual respect and sharing of knowledge are needed for the best clinical outcomes.

What will we do?

- **Activity 5.6 Provide information to clinical trial participants in accessible formats**
  Review and develop materials for the wider community to know about clinical trials at Austin Health, and review formats for information e.g. videos, podcasts etc.

- **Activity 5.7 Review existing processes to ensure that consumers are provided with relevant information and opportunity to ask questions when involved in a clinical trial**
  Review the requirements of clinical research applications to ensure that consumer engagement / participation questions are incorporated into research design as a co-design piece before approving the trial.

- **Activity 5.8 Establish a self-help / town hall forum for participants in clinical trials**
  Establish an annual (or bi-annual) forum for clinical trial participants to be informed of quality improvements in clinical trials and provide two-way communication, including the chance to ask questions of the clinical trials process.

- **Activity 5.9 Review existing consent information for consumers**
  Review and enhance the current information for consumers on the consent processes for Clinical Trials and ensure that it is appropriate for all levels of health literacy.

- **Activity 5.10 Create a consumer group to review consumer facing document**
  Create a group of consumers who can review documents and provide advice on the content and wording of the document, designated a 'Consumer Approved Document'.

What will this mean?

- Research participants are well informed and have sufficient information regarding clinical trial processes at Austin Health
- Consumers are engaged in the clinical trial process and have the opportunity to provide feedback to Austin Health
- Information about the consent process is readily available and accessible to consumers

Component 5
Health literacy & partnering with consumers

Health Literacy and partnering with consumers in organisational design and governance.

We ensure that patients, as trial participants and consumers, receive the information relating to clinical trials that they need, in a way that is appropriate for them.

We adopt a person-centred care focus on the relationship with a trial participant and recognise that trust, mutual respect and sharing of knowledge are needed for the best clinical outcomes.

We recognise and embrace the diversity of our patient population and community and aim to improve communication mechanisms to meet the needs of our diverse population.

What will we do?

- **Activity 5.11 Interpreter services and translation**

Review the interpreter services for the research programs and ensure that the research workforce is educated on the need for and how to access interpreter services. Review accessibility to translation services for clinical trial information.

- **Activity 5.12 Provide education to the clinical trial workforce on the diversity of our consumers**

Include diversity and culturally sensitive care as part of the clinical trial education program, with input from consumer groups.

- **Activity 5.13 Participant information packs**

Develop a process for the required documentation to be provided to consumers when registering for a clinical trial, inclusive of healthcare rights, contact persons and information about the research.

- **Activity 5.14 Consumer engagement in training curriculums**

Include consumer input and 'voice' in education and training for the research workforce, Including presentations from consumers about their experience.

What will this mean?

- Research participants are well informed and have sufficient information regarding clinical trial processes at Austin Health
- Consumers are engaged in the clinical trial process and have opportunity to provide feedback to Austin Health
- Consumers are part of the education process for the research workforce and their 'voice' is included in the training program

References:

1. Austin Health Patient Safety & Clinical Excellence Framework
2. Australian Commission on Safety and Quality in Health Care: National Model Clinical Governance Framework.
3. Safer Care Victoria, Clinical Governance Framework

Attachment

- Standard 1: Quality Improvement Plan – Activity plan tracker
- Standard 2: Quality Improvement Plan – Activity plan tracker
- Work Streams
- Project Plan