Western Health Clinical Trials Governance Framework

Staff this document applies to:

All staff members, students, volunteers and honorary appointees. This framework also applies to any contractors and research partners that are involved in aspects of clinical trial service delivery at Western Health

State any related Western Health policies, procedures or guidelines:

The following agreements, policies and procedures are endorsed by the relevant governing bodies and implemented by Western Health to meet its requirements under the Clinical Trials Governance Framework.

- Western Health Research Code of Conduct 2023
- Relevant Research Partnership Agreements (including, but not limited to University and Medical Research Institute partners)
- WH Strategic Directions 2021-2023
- WH Research Strategic Plan 2021-2026
- Aboriginal Health Cultural Safety Plan 2022-2025
- Western Health Research Policy
- Research Standard Operating Procedures
- Occupational Health & Safety Requirements
- Radiation Safety Procedure
- Research Agreements and Memorandums of Understanding
- WH Intellectual Property and Moral Rights Policy
- The following committees are integral in the management and monitoring of research at Western Health and in helping inform aspects of clinical trial service delivery
  - Right Care Committee
  - Research Strategic Steering Committee
  - Low Risk Ethics Panel
  - Research Coordinators Group

Background / Purpose:

The aim of the Clinical Trials Governance Framework is to embed clinical trials into the 'Business as Usual' practices of the organization in order to help facilitate appropriate, safe and high quality clinical research. This framework will:

- Outline how clinical trials will be administered, monitored, supported and promoted at Western Health
- Outline the set of relationships and functions established by Western Health with the various stakeholders involved in the administration, conduct and monitoring of clinical trials at Western Health sites.
- Ensure clinical trials governance oversight is an integrated component of the corporate and clinical governance at Western Health. This ensures that everyone, including frontline investigators undertaking clinical trials and members of governing bodies such as Committees and Boards, are accountable to patients and the community for assuring the delivery of appropriate and safe clinical trials which are integrated into clinical care and continuous quality improvement.

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Attestation Statement

This statement confirms that the Western Health Executive have endorsed the National Clinical Trials Governance Framework and this document outlines how it has been implemented at Western Health.

Our Vision and Values

Our vision:

Together, we deliver the healthcare of the future

Our purpose:

Providing the Best Care for the people of the West, in the right place and at the right time

Our Guiding Principles are:

Simple, Sustainable, Connected and Innovative healthcare

To establish Western Health as a leader in research innovation by creating a research platform that enables researchers to spend more time on designing and delivering safe, inclusive and high-quality research to our patients and community. This will produce high quality and real-time translational research which will give our patients and research participants access to safer and more effective clinical trials and clinical care. By doing this, Western Health researchers will be empowered to engage in higher return on investment activities. Together this brings a clear and strong direction of priorities that are aligned with the Western Health Strategic Directions 2021-2023 and Research Strategic Plan 2021-2026.

Our values: Our Research Values are in line with our corporate values, in that we demonstrate:

- **Compassion;** by adopting a research partnership model where initiatives are co-designed with our stakeholders and where possible we promote co-design methodology for our clinical trials. We ensure research design is inclusive, has integrity and is embedded within Western Health and supported by the organization to ensure a safe and high-quality research environment.
- **Accountability;** by driving excellence across Western Health precinct to deliver fast, sustainable, safer, and more efficient research practices to our patients and regional partners.
- **Respect;** by working collaboratively with our partners and consumers to better understand their needs and expectations.
- **Excellence;** by providing research infrastructure, support and guidance that fosters cutting edge research and innovation for better health outcomes.
- **Safety;** by ensuring appropriate ethics and governance review, approvals and authorizations are obtained for all research.

We try to achieve this by:

Partnering with patients and families
Our patients and families are actively involved in their care and connected to the right services.

Caring for our people
Our staff and volunteers are supported, engaged and equipped to embrace a dynamic future.

Delivering services for the future
Our services are expanding within and beyond hospital walls, advancing high-quality and connected care.

Working together
Our respectful relationships with our community, system-wide partners and each other drive collaboration and better outcomes.

Discovering and learning
Our innovation, research and education inspires and benefits our patients, staff and communities, to deliver a better future.

As a health service that aims to address current and emerging healthcare needs of our community and more broadly we will:

Try to meet Community expectations; Patients have emphasised to us that family, carers and advocates are critical to their care and that clear communication is central to making informed decisions. In addition, the development of technology has provided opportunities for patients to better access care services from home. These findings and trends motivate us to continue to work together with patients and families to empower their decision making and realize the benefits of technology to improve access to care.

Priorities our people: Western Health staff are exceptional. They are committed to their work, treat each other with respect and respond to challenges with conviction. Our culture is built on a foundation of support, trust, communication, innovation, safety and respect. The strength of our culture will continue to be key to attracting and retaining talented and compassionate people as we grow and approach a different and constantly changing future.

Build a sustainable Health Service: As we experience increasing health costs, Western Health has a responsibility to use resources wisely, provide best value for communities, ensure funds are well directed and innovate in areas that reduce the burden of disease. We continue to lead in sustainability through infrastructure design and renewal and through our strategies to reduce our carbon footprint and minimize waste.

Work across the health system: Western Health has a strong track record of working across the care continuum and beyond organizational boundaries. We will continue to work with our partners and neighboring health services to address shared challenges, spark innovation and drive system reform to improve the health of all Victorians.

Accelerate digitalization: Advances in medical and digital technology are changing healthcare. These are providing greater opportunity to gain insights in real-time, predict future events and use digital devices to complement care. This also brings greater responsibility for strong data governance and cybersecurity, while also continuing to strengthen collaboration, data analysis and access to information for patients and system partners.

Speed up innovation: At Western Health we have learned to adapt, take on new roles, and respond to our community's needs at greater speeds than ever before. We are well positioned to maintain our momentum and drive and adopt new ways of working through our open, learning culture and commitment to innovation and change.

Western Health Clinical Trials Governance Framework

The following flow diagram shows the relationship between the various elements that comprise the Clinical Trials Governance Framework:

Overview of Clinical Trials Governance Framework

The custodian of the Clinical Trials Governance Framework is the Chief Medical Officer (CMO). The Chief Medical Officer provides leadership and direction for reviewing, monitoring and evaluating matters related to the provision of t care across Western Health (WH). The CMO Office will seek to continuously improve outcomes for all patients and services within WH.

The aim of the Clinical Trials Governance Framework is to provide appropriate and safe clinical trials by:

- Integrating corporate & clinical governance systems for research via clearly articulated leadership, and policies and procedures to deliver clinical trials that are appropriate, safe and of high quality.
- Improving collaboration across health service organizations and other stakeholders.
- Strengthening governance arrangements for clinical trial services.
- Providing clarity to those responsible for administering clinical trials, including government bodies, health services, hospital administrators, clinicians, trial sponsors and patients.
- Reducing duplication and increasing efficiency, cohesion and productivity across clinical trial teams.
- Encouraging participant feedback and involvement through co-design as appropriate.
- Identifying vulnerable groups and having place in place measures to ensure appropriate and equitable participation.
- Promoting environmental and sustainable clinical trial practices.

Measures of operational efficiency and success will align with the National Aggregate Statistics (NAS).

The operational measures are:

- Facilitate rapid sponsorship of new clinical trials
- Assessment of a clinical trial site (site selection, feasibility assessment).
- Pre-recruitment activities (ethical and local site-specific assessment review and approval time frames).
- Recruitment activities and trial management.
- Workforce training and engagement.
- Clinical trial related business and financial management.

Definition of Clinical Trial Stakeholders

This framework outlines key parts of clinical trial governance, and its stakeholders that support governance for the following activities:

1. Project development, review, approval and managements;
2. Trial oversight, including legal agreement sign-off;
3. Organisational governance and overall accountability;
4. Reporting, monitoring and management of clinical trials, research misconduct and integrity.

Western Health has defined the following stakeholders in its Clinical Trials Governance Framework:

Clinical Trials Governance Roles and Approvals

Governance consists of a hierarchy of formal research approvals at Western Health that helps facilitate clinical trial authorization and accountability in accordance with the Western Health Delegation of Authority and supported by related research governance procedures. Western Health has established appropriate divisions, departments and committees such as the Office for Research, Best Care Governance & Support Unit, Research Coordinators Group, Education and Research Steering Committee and the Right Care Committee to help embed and support implementation and reporting against the Clinical Trials Governance Framework across the organization.
The Chief Medical Officer is a Member of the Western Health Right Care Committee where the application of and progress against the National Clinical Trials Framework is monitored. This Committee reports to the executive level Best Care Steering Committee. This Committee in turn submits minutes and papers on the delivery of best care to the Board Quality & Safety Committee.

Additional reporting is achieved through bimonthly reporting to the CMO against defined Clinical Trial Key performance indicators.

Western Health acting as an investigating site:

- Provides access to clinical trials and other research to its community.
- Ensures effective and efficient delivery of appropriate, high-quality and safe trials.
- Implements corporate governance controls to ensure managers, research site staff, patients, consumers and sponsors fulfil their obligations and are adequately supported to do so.

Governing Bodies

1. **State Health Department:** Provides Western Health with Clinical Trial Policies and procedures to facilitate implementation of the National Clinical Trials Governance Framework. At a project level, they provide a subscription to Ethics Review Manager (ERM) system to receive new projects for ethical review and approval and/site specific governance review and authorization.
2. **Board of Directors:** Responsible for oversight of corporate governance, in particular for ensuring the effective development, implementation and review of Western Health's strategic plan which includes research initiatives to support implementation of the framework. The Board is supported by relevant committees that report to it. And its overarching responsibility is to ensure patient safety and clinical excellence.
3. **Chief Medical Officer:** Provides oversight of Western Health's responsibilities in relation to reporting of safety and the environment of care for research and has oversight over the implementation of the Clinical Trials Governance Framework at Western Health.
4. **Executive Officers:** Support culture of responsible research practice across our health service by ensuring staff are aware of their responsibilities under the framework. Ensure implementation and oversight of the Research Governance Framework is assigned to the appropriate delegate within Western Health. The delegate can be an individual or group of people who oversees research. The Executive ensure the following functions are met via their delegate/s by:

    - Ensuring implementation of the framework (delegate Chief Medical Officer as executive sponsor)

- Monitoring of research (delegate Research Program Director)
- Site-specific assessment & authorization (delegate Manager - Office for Research)
- Allocating sufficient resources for effective and efficient processing of ethical and scientific review by the Low Risk Ethics Panel (LREP) and site-specific governance assessment and authorization (delegate Manager - Office for Research)
- Managing complaints about Clinical Trials and other research, Research misconduct, breach and fraud (delegate Research Program Director and Director of Clinical Research – Office for Research);
- Allocating resources for: education and training of staff, site-specific assessment, access to facilities for safe and secure storage and management of research data (delegate Manager - Office for Research)
- Providing an annual update on Clinical Trial Activity directly to the Board of Directors (delegate to Research Program Director and Director of Clinical Research – Office for Research).
- Reporting and collecting operational metrics and reporting thereof to the CMO (delegate Research Program Director, Manager – Office for Research), Executive level and Board via the CMO.

5. **Office for Research:** The Office for Research is responsible for administering research at Western Health and its partners by ensuring that research undertaken complies with the ethical, statutory and regulatory requirements that govern that conduct of research in Australia. The Office for Research is supported by the following roles;

   - Research Program Director
   - Director of Clinical Research
   - Manager Office for Research
   - Ethics and Governance Officers
   - Ethics and Governance Administrators
   - Research Administrative Support Officers
   - Biostatistician

6. **Ethical and Scientific Review:** WH low risk studies are reviewed by the WH Low Risk Ethics Panel (LREP). More than low risk studies are reviewed by an NHMRC certified HREC. Project approval is contingent on both ethical approval and governance authorization requirements being successfully met. It is the responsibility of the principal investigators, to ensure all elements of Research Governance including research agreements and budgets are finalized in preparation for governance authorization.
   - Determination of a study's risk profile and review pathway will be determined by the Office for Research. Studies that fall under the remit of Low Risk Research and Negligible Risk Research will be reviewed by the WH LREP.
   - Institutional Biosafety Committees are provided from the University of Melbourne and Victoria University.

7. **Aboriginal Health and Medical Research Accord & Australian Institute of Aboriginal & Torres Strait Islander Studies (AIATSIS) Ethics Committee:**
   Western Health commits to the Victorian Government Aboriginal Research Accord project and recommended framework. In compliance with their recommendations, health and medical research that directly targets Aboriginal and Torres Strait Islanders will first be reviewed by a specialized and/or accredited Aboriginal and Torres Strait Islander Committee, such as the AIATSIS Ethics Committee, or

equivalent. The recommendations from this committee will then be endorsed and reviewed in line with relevant Western Health research governance processes. Studies that involve intentional or incidental recruitment of Aboriginal and Torres Strait Islander Peoples will be conducted in compliance to the WH organizational procedure "Aboriginal and Torres Strait Peoples Recruited into Research"

8. **The Right Care Committee:** It monitors the application against the National Clinical Trial Governance Framework, with a reporting line to the executive level Best Care Steering Committee and the Board Quality & Safety Committee.

9. **Research Strategic Steering Committee (RSSC):** The RSSC comprises of a core steering group of high-profile influential leaders (approximately 12-15 members) tasked with leading and overseeing a "whole of health service" approach to ensure the effective delivery of selected specific actions outlined in the Research Strategic Plan 2021-2026. The RSSC will convene annually where strategic planning will be developed underpinned around the research strategic priorities identified.

10. **Clinical and Non-Clinical Managers:**
Clinical and non-clinical managers are responsible for ensuring the systems that support research service delivery are well designed and perform well. The functions of the clinical and non-clinical managers are:
    - Ensure effective budgeting and review of budgets as prepared by the Principal Investigator and their research teams.
    - Ensure funding source and costs of the research have been identified so that the correct trial sponsor, sponsor responsibilities and research agreements can be assigned.
    - Ensure costs can be met by the sponsor and that cost centres are created (as required) to manage clinical trial funds.
    - Ensure adequate staff and resources are available to undertake the trials.
    - Ensure uploading all Clinical Trials Agreements through Western Health's e-procurement platform (e-PACE) to coordinate approvals from the various organizational stakeholders as required per the Western Health Delegation of Authority Protocol for research governance authorization.

11. **Research Workforce**
    - **Principal and Sub-Investigators:** responsible for preparing budgets, protocols and carrying out research in accordance with relevant legislation, policies, procedures, protocols and conditions of ethics approvals and site-specific governance authorization. They are also responsible for conduct of research at site, and fostering a culture of responsible conduct of research and adherence to this framework.
    - **Study Coordinators/Supporting Departments/Research Managers/Research Pharmacists/Research Nurses/Interns and Students/Any Staff or Honorary Appointees Engaging in Research Activities:** responsible to conduct and manage the daily and overall specific research activities, in accordance with procedures outlined in the Western Health Research Standard Operating Procedures.

12. **Patients, Consumers, Research Participants, Carers and Families and Patient Advocacy Organizations:** Patients and consumers participate as partners to the extent they choose. These partnerships can be in their own care, as participants in a research study, in organizational strategic planning and for governance of research services or by providing input into the design and conduct of research via the LREP and the policies of research networks. Patients

and consumers are integral to information on quality improvement in research services.

13. **Sponsors:**
    - Responsible for the initiation, management and financing (or arranging the financing) of clinical trials and cover all liabilities of trial protocol related activities.
    - Responsible for Therapeutic Goods Administration (TGA) submission and approvals.
    - Responsible for the quality and integrity of trial data.
    - Responsible for reporting and taking action on safety events as outlined in the NHMRC monitoring and reporting in clinical trials guidelines.
    - Responsible for monitoring of research and reporting suspected breaches of research as outlined in the NHMRC monitoring and reporting in clinical trials guidelines.

Integration with Clinical Governance Framework

The purpose of this document is to outline the clinical trial specific governance controls. These controls are in additional to those already outlined in the Best Care Framework. Please refer to the Western Health Best Care Framework (https://livebestcare.wh.org.au/the-framework/) for the following principles:

1. Person Centered Care
2. Coordinated Care
3. Right care
4. Safe Care

Research Governance, leadership and culture

Aim of the National Clinical Trials Governance Standards:

a) Clinical trial services are integrated into clinical and corporate governance systems for improved safety and quality of clinical trial service provision.
b) Managers and the clinical trial workforce have the right qualifications, skills and supervision to provide safe, high-quality clinical trial services to patients.
c) The environment in which clinical trials are conducted is safe and promotes high-quality clinical trial service provision.

Implementation of the standard:

This standard is implemented via the Office for Research with reporting into the CMO's Office and monitoring of National Clinical Trial Framework application and progress through the Western Health Right Care Committee. This Committee reports to the executive level Best Care Steering Committee. This Committee in turn submits minutes and papers on the delivery of best care to the Board Quality & Safety Committee.

The Research Strategic Steering and the Education and Research Steering Committees and the Research Coordinator's Group will be integral in providing guidance and feedback on the implementation of the CTGF as their membership comprises of clinical and operational staff involved in the conduct of clinical trials.

Roles and functions of governing bodies within Western Health:

- **Executive:** Responsible for leading the strategic planning, business plans, and reporting to the Board inclusive of Research matters.
- **Office for Research:** Is responsible for allocation of appropriate personnel, safety and quality and service provisions that support organizational research activities, including clinical trials. Ensure data is available to all stakeholders. Implement and resource quality improvement activities and measures e.g., safety reporting, risk management, incident management, open disclosure, feedback and complaints.

- **People and Culture:** Provides the framework to ensure staff are adequately credentialed to perform their respective duties. Respond promptly to underperformance.
- **Right Care Committee:** Monitors National Clinical Trial Framework application and with a reporting line to the executive level Best Care Steering Committee and the Board Quality & Safety Committee.
- **Research Strategic Steering Committee:** Provides oversight of planning & development against research priorities identified in the Western Health Research Strategic Plan.
    - Engagement with clinicians toward greater engagement in research.
    - Allocation of appropriate resources for supporting safe and high- quality research.

Roles and functions of research sponsors

- Retain clear, accurate, secure and complete records of all trials including trial data and primary materials. Allow access and reference to these by the regulator and interested parties, as appropriate. **Implementation is outlined in the Western Health Research Code of Conduct (2023)**

  If the health service organizations is the sponsor of a clinical trial, they have a responsibility for monitoring the conduct of the research for compliance with relevant regulations and requirements and should ensure they have sufficient resources to meet all of their monitoring obligations. **Implementation is outlined in the Western Health Research Code of Conduct (2023)**

Roles and functions for site principal investigators

- **Research Conduct**: Ensure appropriate approvals and authorizations are in place and take primary responsibility for trial conduct.
- **Safety of research participants**: Ensure welfare during trial, ongoing consent and communication to primary health care workers.
- **Reporting**: Timely and efficient reporting per current practices from the ethical and governance bodies.

Roles and functions for the research workforces

Governance, leadership, culture: Professional conduct, establish relationships around the hospital (clinical and non-clinical), guidance, mentorship & training. Implementation is outlined in the Research Steering Committee Terms of Reference and also the Education and Research Steering Committee.

Systems/Processes to support the Western Health Clinical Trial Governance Framework

- **Patient safety and quality improvement systems:** Contribute to the design of systems for the delivery of high-quality research with good communication, reporting, feedback and complaints**.** Integration of these systems with Western Health's Best Care Framework where possible and/or beneficial.
- **Research Audits:** Audit of research to ensure compliance of research against Good Clinical Practice guidelines and in accordance with regulatory and legislative obligations. Implementation please refer to **Research Audit Schedule.**
- **Research Education and Training:** To provide training opportunities for staff across a number of research methodologies to increase research capability and capacity across the organization and improve the quality of research submissions. Implementation please refer to Research Workshops

Calendar.

- **REDCap:** Platform to administer and monitor research at WH and for the generation of reports on clinical trial metrics
- **e-PACE:** E-procurement research documentation submission platform for project endorsement across a number of WH stakeholders ensuring that agreements and financials are endorsed by Head of Department and assigned Business Analysts **Implementation please refer to procurement services contact.**
- **Research Risk Register:** register for the identification, analysis, treatment and monitoring of research related risks. **Implementation please refer to Research Risk register procedures.**

Patient safety and quality improvement systems

Safety and quality systems are established and used to manage and improve the provision of clinical and research services. These systems are integrated with Western Health's Best Care Framework where possible and/or beneficial.

Clinical Performance and Effectiveness

The workforce has the right qualifications, appropriate skills and proper supervision to provide safe, high-quality clinical and research services to patients.

Clinical credentialing is managed via the medical workforce on the CGov system, and Nursing and Midwifery and Allied Health credentialing by the Australian Health Practitioner Regulation Agency (AHPRA). WH staff interested in conducting research hold additional research related credentials of which GCP training and requisite prior research experience would be necessary for particular research roles. All mandatory training is administered through WeLearn whereby research governance authorization is conditional on completing minimum clinical trial training standards of including the ACTEC online module ***– "Introduction to Clinical Trials".***

Safe environment for the delivery of care

The environment in which research is conducted is safe for staff, students and participants, and promotes high-quality research services to patients. This is managed by the WCHRE Operations Committee in partnership with the Office for Research and our collective on campus academic partners and external trial sponsors. In partnership with WH Aboriginal Health Services, spaces are configured to meet the needs and expectations of Aboriginal and Torres Strait Islander Peoples for their participation in clinical trials.

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 research services. Consumers may also work with health service organizations and others acting as trial sponsors, in the design and evaluation of research. Elements of this component include clinical governance and quality improvement systems to support partnering with researchers.
- Establish mechanisms to form partnerships with patients, in their own care, including when participating in research
- Support patients, consumers and carers to actively participate in the organizational design and governance of research services, particularly through a co-design of research projects.

- Health service organizations ensure that patients, research participants and consumers are afforded access and provided with information about their healthcare rights
- Ensure information on research is provided to research participants, patients, carers and their families and carers, and consumers.
- Expand Western Health Chronic Disease Alliance (WHCDA) as a go to site where consumers can access relevant information on clinical trials and how they can participate.
- Utilize posters in clinical areas, foyers and other high traffic areas that provide essential information on clinical trial activity at Western Health and essential information for consumers around access and participation.
- Ensure consumers are partners in the planning, design, delivery, measurement, and evaluation of systems to deliver research services. Research participants and patients are partners in their own care.
- Provide consumers with the opportunity to provide feedback on their experience of participating in a clinical trial and utilize this feedback to improve clinical trial service delivery.

Definition of research participant, patient and consumer

- A research participant may be a patient or healthy volunteer who has been enrolled in a clinical trial.
- A patient is a person who is receiving care in a health service organization.
- A consumer is a person who has used, or may potentially use health services, or is a carer for a patient using health services.
- A healthcare consumer may also act as a consumer representative to provide consumer perspective, contribute consumer experiences, advocate for the interests of current and potential health service users, and take part in a decision-making process.

Western Health Research Committee Structures

a. **Best Care Steering Committee:** To provide leadership and direction for reviewing, monitoring and evaluating all matters related to the provision of Best Care across Western Health.

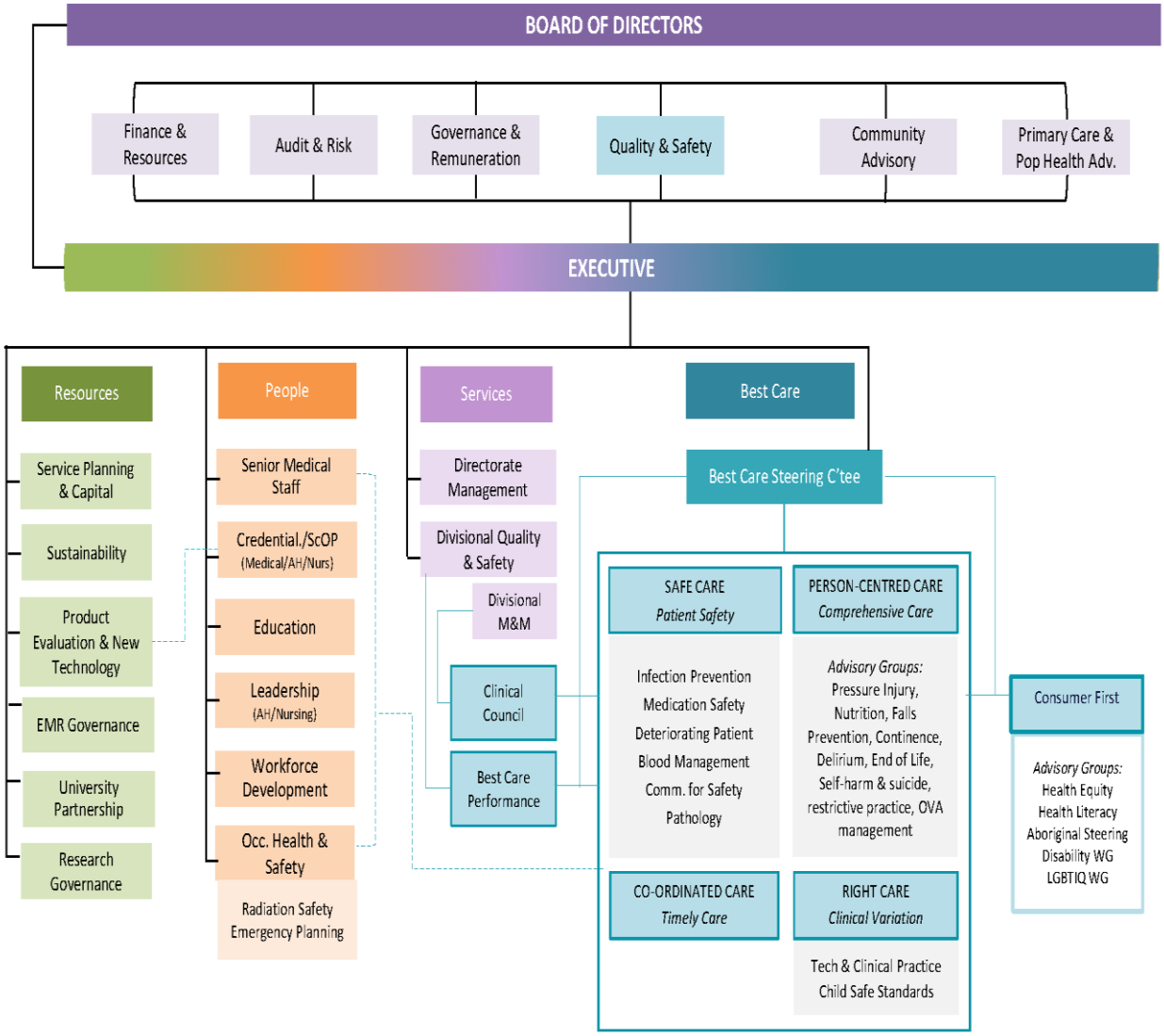
b. **Right Care Committee:** The role of the Right Care Committee is to provide leadership and direction for reviewing, monitoring and evaluating matters related to the provision of Right Care across Western Health. Right Care Committee reports into Best Care Steering Committee which has a reporting line to the Quality and Safety Board Subcommittee.

c. **Research Strategic Steering Committee:** Sets strategy and oversight of implementation and operational reporting as outlined in the framework.

d. **Research and Education Steering Committee**: Advisory committee on education and research at Western Health

e. **Low Risk Ethics Panel:** Non-HREC level of ethical review for research with no more than low risk profile with responsibilities as outlined in the National Statement on Ethical Conduct in Human Research (2018 and updates).

Western Health Organisation Committee Structure



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Version Date: October 2023
Version Number: 1

Legislation/References/Supporting Documents:

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Authorised/Endorsed by:

WH Executive with the Chief Medical Officer as the Executive sponsor

Primary Person/Department Responsible for Document:

Office for Research