



# National Clinical Trials Governance Framework **Accreditation** Preparedness Activities

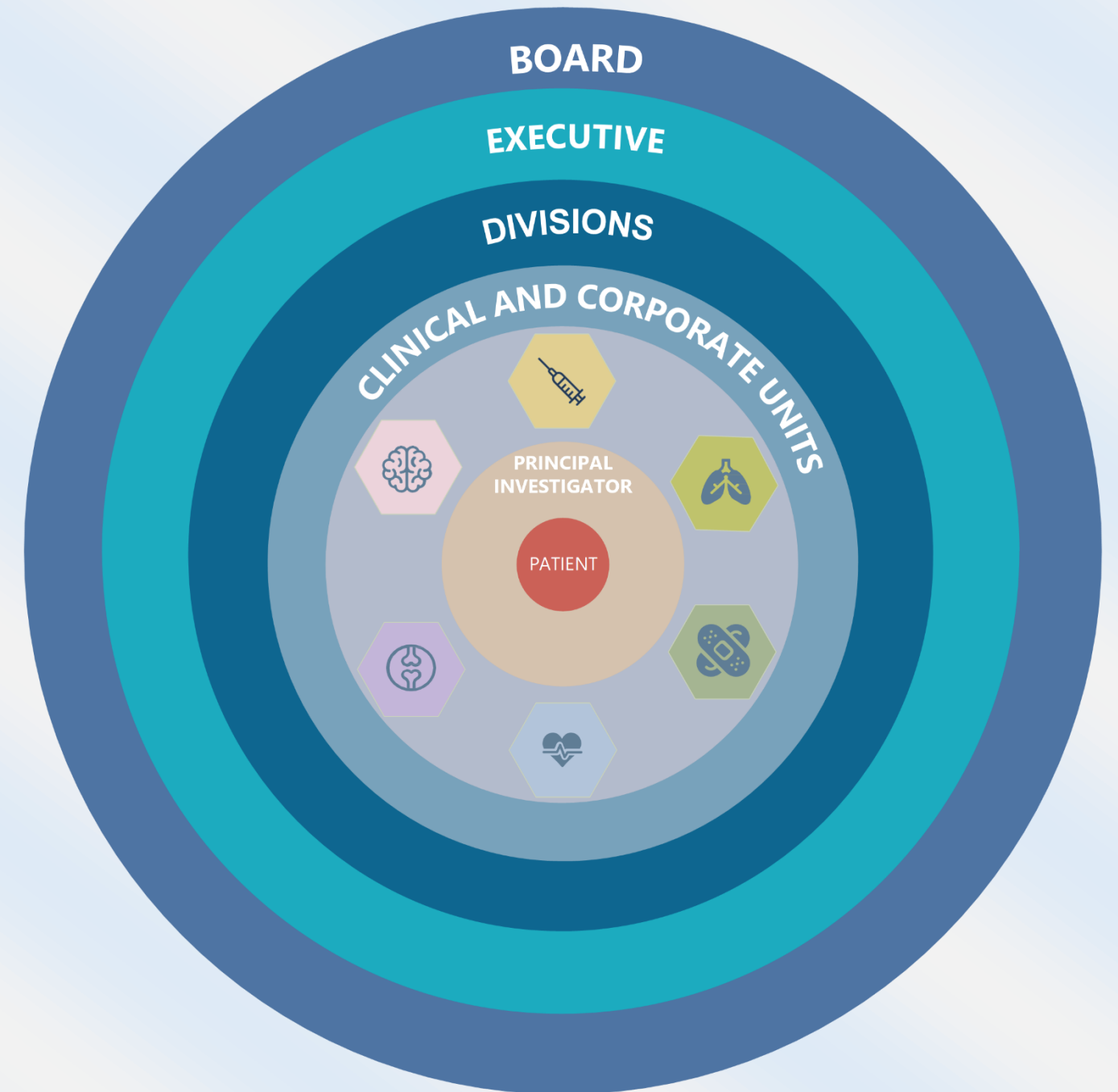


Clinical Governance



Consumer Partnership

**Governing Body**  
Board & Executive





The **Austin Health Board with the Chief Executive Officer and Executives** are responsible for setting strategic priorities, visible leadership and commitment in delivering the vision for safe and quality care within the organisation, ensuring the voice of the patient is at the centre of decision-making.

## Governance Framework Accreditation Preparedness Activities – Governing Body (Board and Executive)

### STANDARD 1: Clinical Governance | STANDARD 2: Partnering with Consumers

| # | Description                     | Responsibility  | Who shares responsibility   | Evidence checklist   |
|---|---------------------------------|---|---|--|
| 1 | <b>Responsibility</b>           | <ul style="list-style-type: none"> <li>Hold overall responsibility for the conduct, direction, and priorities of the clinical trials service at their Health Service Organisation, and delegate management of the service as and where appropriate.</li> <li>Dedicate time to review and report on clinical trial service systems, performance, and metrics (including the National Aggregate Statistics), and to resolve or delegate issues.</li> <li>Establish and maintain appropriate healthcare record systems, including electronic medical record systems, for use by the clinical trial workforce.</li> <li>Ensure clinical trials are delivered in a safe environment.</li> </ul>  | Discovery & Innovation Unit<br><br>Patient Safety & Clinical Excellence<br><br>Clinical Units<br><br>Divisional Managers & Directors<br><br>Executive   | <ul style="list-style-type: none"> <li><a href="#">Patient Safety &amp; Clinical Excellence Framework</a></li> <li><a href="#">Austin Health Research Strategy</a></li> <li>TBC - Board Research Report</li> <li>Reports and meeting minutes from Clinical Governance, Partnering with Consumers and Executive Safety, Quality and Risk Committees.</li> </ul>   |
| 2 | <b>Regulatory</b>               | <ul style="list-style-type: none"> <li>Ensure clinical trial conduct meets legislative, regulatory, and compliance requirements, including the National Clinical Trials Governance Framework and the organisation's Clinical Governance Framework and endorse/authorise organisational policies for the same.</li> <li>Establish and monitor an organisational culture that values safety, compliance, risk management and quality, and continuously look for opportunities for improvement.</li> </ul>   | Patient Safety & Clinical Excellence<br><br>Discovery & Innovation Unit<br><br>Human Research Ethics Committee<br><br>Research Steering Committee<br><br>General Counsel  | <ul style="list-style-type: none"> <li><a href="#">Patient Safety &amp; Clinical Excellence Framework</a></li> <li>Research Risk Registry</li> <li><a href="#">Research Policy</a></li> <li><a href="#">Research Misconduct Procedure</a></li> <li><a href="#">Research Authorship &amp; Outputs Procedure</a></li> <li><a href="#">Research Data Management Procedure</a></li> <li><a href="#">Research Steering Terms of Reference</a></li> <li><a href="#">Austin Health HREC Committee Terms of Reference</a></li> <li><a href="#">Animal Ethics Committee Terms of Reference</a></li> <li>Institutional Biosafety Committee Terms of Reference</li> <li><a href="#">Incident Management Policy</a></li> <li><a href="#">Incident Management Procedure</a></li> <li><a href="#">Consent Policy</a></li> <li><a href="#">Informed Consent</a></li> <li><a href="#">Shared Decision Making and Informed Consent Committee</a></li> <li><a href="#">Medical Treatment Decision Maker (MTMD) identification Procedure</a></li> </ul> |
| 3 | <b>Business</b>                 | <ul style="list-style-type: none"> <li>Include consideration of the clinical trial service in all business decision-making. Ensure the clinical trial service delivers high-quality clinical trials, responsibly and in a safe environment, to all service users.</li> <li>Resource and monitor systems and processes used to deliver the clinical trial service, and continuously look for opportunities for system improvement.</li> <li>Include resources for clinical trials in organisational identification, reporting, and management systems (including risk, incident and complaint systems) and continuously look for opportunities for system improvement.</li> <li>Acquire, resource, and routinely engage with a multi-disciplinary workforce and network of consumers (that represent the service users) who participate in strategic and operational decision making.</li> </ul> | Patient Safety & Clinical Excellence<br><br>Divisional Safety, Quality & Risk Committees<br><br>Clinical Units<br><br>Divisional Managers & Directors<br><br>Executive  | <ul style="list-style-type: none"> <li><a href="#">ORACLE quality improvement</a></li> <li>RiskMan <a href="#">Incident Management Policy</a></li> <li>RiskMan <a href="#">Incident Management Procedure</a></li> <li><a href="#">Executive Safety, Quality and Risk Committee</a></li> <li>Divisional Safety, Quality and Risk Committee</li> <li><a href="#">Risk Enterprise Management Framework</a>, org-wide Research Summary and Research Risk Profile available from Director Enterprise Risk Management</li> <li><a href="#">Divisional Risk Profiles (which will have research embedded into their risk specific to that area).</a></li> </ul>  |
| 4 | <b>Education &amp; training</b> | <ul style="list-style-type: none"> <li>Resource education, training and other requirements for staff, including Good Clinical Practice, research integrity, and cultural sensitivity training.</li> <li>Ensure skills and qualifications match responsibilities, functions, and accountabilities.</li> </ul>  | Discovery & Innovation Unit<br><br>People & Culture<br><br>Patient Safety & Clinical Excellence Unit<br><br>Clinical Units<br><br>Divisional Managers & Directors   | <ul style="list-style-type: none"> <li><a href="#">Austin Health's Core Education Training and Development Policy</a></li> <li>TBC - Research credentialling and training framework (Feb 2024)</li> <li>TBC - Position Descriptions for each role in Clinical Trials Workforce</li> </ul>  |
| 5 | <b>Inclusivity</b>              | <ul style="list-style-type: none"> <li>Develop dedicated plans to meet the specific needs of First Peoples as part of the clinical trials service.</li> <li>Involve First Peoples in the workforce to improve access to, knowledge of, and trust in, clinical trials involving these communities, and to mentor and support non-Indigenous members of the workforce.</li> </ul>   | Chief Allied Health Officer<br><br>Discovery & Innovation Unit<br><br>Victorian Translational Research Institute (VicTRI) through its affiliation agreement with Austin Health and MoU with VACCHO<br><br>Austin Health is a signatory to the <a href="#">marra ngarragoo, marra goorri: The Victorian Aboriginal Health, Medical and Wellbeing Research Accord</a> | <ul style="list-style-type: none"> <li><a href="#">Austin Health Reconciliation Plan</a></li> <li>Victorian Translational Research Institute (Austin Health Research Partner) MoU with Victorian Aboriginal Centre for Controlled Health Organisation (VACHHO). Through this relationship, Austin Health's Research Director will build capability and capacity in Indigenous workforce. The Discovery &amp; Innovation Unit will provide support to VACCHO's Aboriginal Ethics Committee.</li> </ul>  |