



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



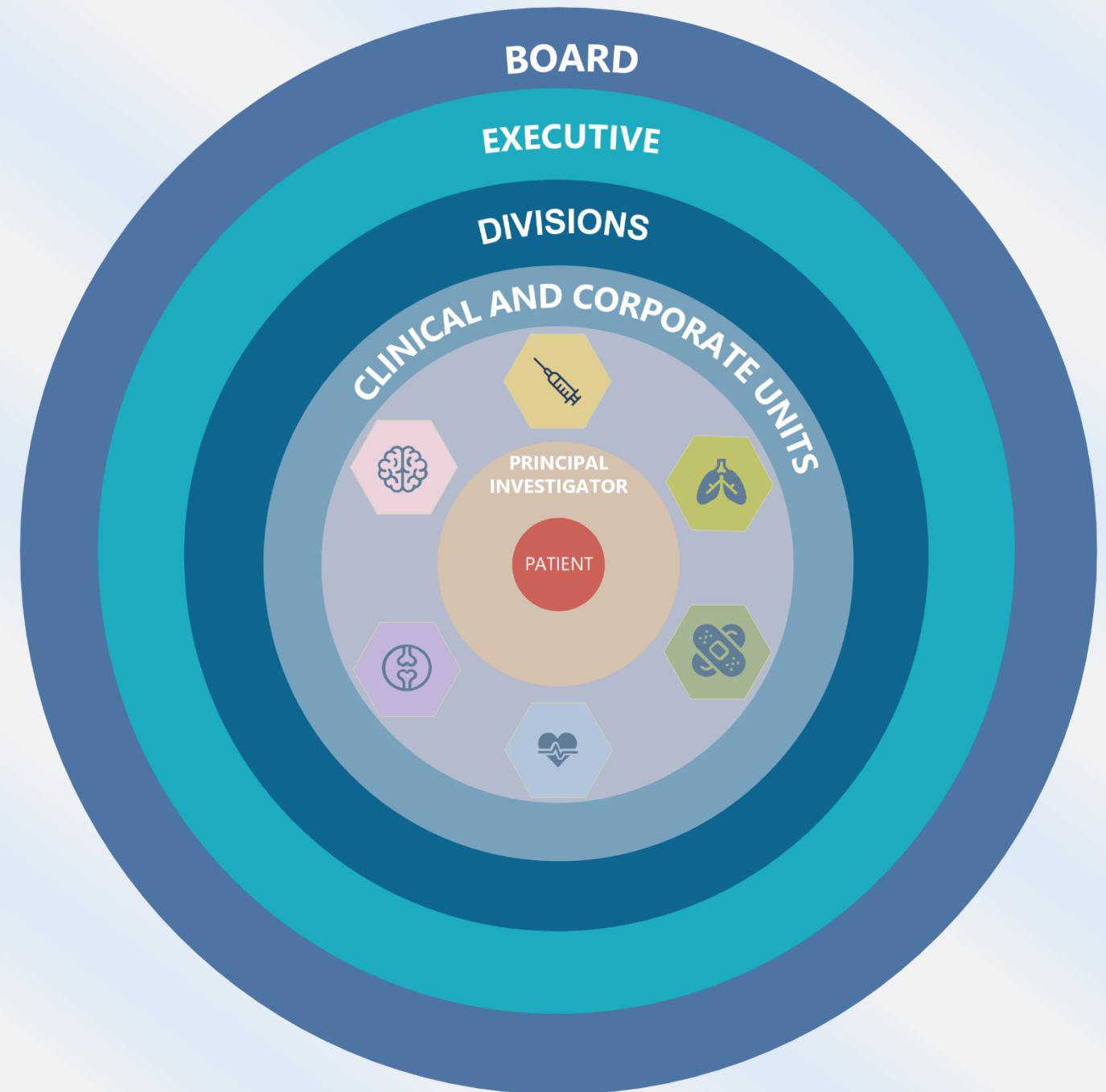
Clinical Governance



Consumer Partnership

**Partnering Departments, Clinicians/
Investigators & Non-Clinical Staff**

Partnering Departments, Clinical and Corporate Units &
Principal Investigator



The **Austin Health Partnering Departmtnes, Clinicians, Non-Clinical Staff & Principal Investigators** are responsible for providing safe & high quality care and services. They actively monitor and improve their skills & knowledge to support and provide best care in accordance with health standards and protocols.

Governance Framework Accreditation Preparedness Activities – Clinicians & Non-Clinical Staff

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

| # | Responsibility | Reflective questions | Who shares responsibility | Evidence checklist | Notes |
|----|---|---|--|---|-------|
| 1. | Use and working familiarity of your Organisational Clinical Governance framework policies, procedures, and the relevant processes and systems including those surrounding capacity, informed consent and decision-making/ decision-maker status. | <p>Identify</p> <ul style="list-style-type: none"> Identify and location your Organisational Charter, Australia Charter of Healthcare Rights. Identify your organisation's clinical governance frameworks, policies, and procedures. Identify your organisations capacity, informed consent and decision-making/decision maker status policies and procedures. Identify the related processes and systems. <p>Use</p> <ul style="list-style-type: none"> How do you use these principles guide you in your everyday work and interactions with service users? Are these ever discussed in staff meetings? Where and how do patients and consumers find copies of these? How is your use of these assessed? <p>Find</p> <ul style="list-style-type: none"> Who in your organisation can help you with this? | <p>Clinical Trials Workforce Clinical/Non-Clinical Managers Supporting departments Discovery & Innovation Unit</p> <p>Supported by: Partnering with Consumers Department</p> | <p>Austin Health National Standard Accreditation page for:</p> <ul style="list-style-type: none"> Patient Safety and Clinical Excellence Framework, this incorporates the National Clinical Trials Governance Framework. Organisational Charter – Austin Health Board Committee Charter Manual. This outlines the roles and responsibilities of the Board's subcommittees. Austin Health Organisational Chart Austin Health Governance Structure <p>OPPIC for:</p> <ul style="list-style-type: none"> Organisational policies and procedures Related processes and systems. Research Policy Research Data Management Procedure Research Authorship and Outputs Procedure Privacy Policy Patient Information Privacy Policy Protecting Your Privacy - brochure for patients Consent Policy Incident Management Policy Incident Management Procedure <p>Communications:</p> <ul style="list-style-type: none"> Department staff meetings All staff organisation forums & meetings Organisation Newsletter Continuous education – Direct, Departmental, Organisational & External Organisation, Department and Individual training Research Architect – Austin Health clinical research management platform <p>Leadership and Reporting:</p> <ul style="list-style-type: none"> Organisation Structure and Reporting line | |
| 2. | Understand the complexity of service user interactions with the clinical trial service, the complexity of the context in which they reside, and their needs as a clinical trial participant. | <p>Identify</p> <ul style="list-style-type: none"> Identify other organisational Partnering with consumers policies and procedures relevant to your work. Identify related processes and systems. <p>Process</p> <ul style="list-style-type: none"> How do you partner with service users and consumers in ways that respect their cultural and community identity, and their identity as a patient? What additional supports do your clinical trial participants need to effectively participate? How do you find these supports? <p>Support</p> <ul style="list-style-type: none"> How does your organisation support you in finding these supports? Who in your organisation can help you with this? <p>Use</p> <ul style="list-style-type: none"> How do you use these in your everyday work and interactions with service users? How is your use of these assessed? Are they ever discussed in staff meetings? | <p>Clinical Trials Workforce Clinical/Non-Clinical Managers Discovery & Innovation Unit</p> <p>Supported by: Partnering with Consumers Department</p> | <p>Training:</p> <ul style="list-style-type: none"> ATLAS: Organisation training for all personnel in accordance with role and responsibility Continuous education and training per respective role aligning with current and valid practice. Good Clinical Practice (GCP) Austin Health Research Competency Framework outlines the mandatory training requirements at Austin Health. <p>Support:</p> <ul style="list-style-type: none"> Australian Clinical Trial Education Centre (A-CTEC, including Good Clinical Practice) | |
| 3. | Undertake regular education and training to maintain credentialling and keep skills and competencies up to date, and expand your scope of practise, as per your organisation's standard schedule. | <p>Identify</p> <ul style="list-style-type: none"> What training do you need to complete? Are you clear on when and how you need to complete this training? <p>Process</p> <ul style="list-style-type: none"> How does your organisation support you in completing this training? How do you identify opportunities to expand your scope of practise? How does your organisation support you in taking advantage of these opportunities? <p>Support</p> <ul style="list-style-type: none"> Who can help you with these things? | <p>Discovery & Innovation Unit Credentialling Committee Patient Safety & Clinical Excellence</p> | <p>Credentialling</p> <ul style="list-style-type: none"> Position Description - Including description of job role, responsibilities and targets Austin Health competency framework Human Resources documentation as evidence of and terms of employment Clinical Training & Credentialling via the Austin Health Clinical Education Unit. <p>Training:</p> <ul style="list-style-type: none"> Austin Health Competency framework Training certificates Training & Education Action Plan including mandatory organisation training Loggin in ATLAS & Research IT platform | |

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| 4. | <p>Work within your defined scope of practise and in line with your skills and experiences. Work with your clinical lead to assess your scope of practise, performance, and professional competencies at regularly scheduled intervals, as per your organisational standard practise.</p> | <p>Identify</p> <ul style="list-style-type: none"> How do you know what credentials and professional competencies you need to meet? How familiar are you with the tasks and responsibilities in your position description? <p>Assessment</p> <ul style="list-style-type: none"> How often do you meet with your clinical lead to assess your scope of practise, performance, and professional competencies? What systems and processes do you use for this? <p>Support</p> <ul style="list-style-type: none"> How does your organisation support you in this? Who in your organisation can help you with this? | <p>Discovery & Innovation Unit</p> <p>Your professional craft group for clinical practice.</p> | <p>Credentialling</p> <ul style="list-style-type: none"> Position Description – Including description of job role, responsibilities and targets Austin Health competency framework Human Resources documentation as evidence of and terms of employment Clinical Training & Credentialing via the Austin Health Clinical Education Unit. <p>Training:</p> <ul style="list-style-type: none"> Austin Health competency framework ATLAS Training certificates Departmental/ Unit Training & Education Action Plan including mandatory organisation training <p>Assessment</p> <ul style="list-style-type: none"> Austin Health Competency Framework Professional Review and Development <p>Support</p> <ul style="list-style-type: none"> Staff team meetings Department and Organisation-wide meetings, seminars, newsletters, training, education and library resources Research Architect – Austin Health clinical research management platform | |
| 5. | <p>Conduct clinical trials in line with relevant national requirements and in a way that is responsive to change. Including: the National Statement and the Code, the National Clinical Trials Governance Framework, the Australian Open Disclosure Framework, National regulations, standards, codes of conduct, and legislation.</p> | <p>Process</p> <ul style="list-style-type: none"> What are the relevant national requirements you must operate in line with? How do you ensure your continued compliance? How do you change your practise if you learn about changes in requirements? What systems and processes do you use for this? <p>Support</p> <ul style="list-style-type: none"> How does your organisation support you in this? Who in your organisation can help you with this? | <p>Discovery & Innovation Unit</p> <p>Patient Safety & Clinical Excellence</p> <p>Partnering Departments</p> | <p>Process</p> <ul style="list-style-type: none"> Patient Safety and Clinical Excellence Framework, this incorporates the National Clinical Trials Governance Framework. Organisational Charter – Austin Health Board Committee Charter Manual. This outlines the roles and responsibilities of the Board’s subcommittees. Austin Health Organisational Chart Austin Health Governance Structure Austin Health site governance & ethics processes as outlined on website. <p>Support & Training</p> <ul style="list-style-type: none"> Staff team meetings Department and Organisation-wide meetings, seminars, newsletters, training, education and library resources Research Architect – Austin Health clinical research management platform | |

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| 6. | Conduct clinical trials in line with relevant local requirements. Including the trial protocol, Conditions of HREC and Governance approvals, Your organisational charter and clinical governance framework, Local policies and procedures, Contractual and sponsor requirements | <p>Process</p> <ul style="list-style-type: none"> What are the relevant local requirements you must operate in line with? How do you ensure your continued compliance? How do you change your practise if you learn about changes in requirements? What systems and processes do you use for this? <p>Support</p> <ul style="list-style-type: none"> How does your organisation support you in this? Who in your organisation can help you with this? | Discovery & Innovation Unit Partnering Departments Principal Investigators Research Teams | <p>Process</p> <p>Austin Health National Standard Accreditation page for:</p> <ul style="list-style-type: none"> Patient Safety and Clinical Excellence Framework, this incorporates the National Clinical Trials Governance Framework. Organisational Charter – Austin Health Board Committee Charter Manual. This outlines the roles and responsibilities of the Board’s subcommittees. Austin Health Organisational Chart Austin Health Governance Structure Austin Health site governance & ethics processes as outlined on website. Austin Health Research Competency Framework Austin Health Risk Based Monitoring Program <p>OPPIC for:</p> <ul style="list-style-type: none"> Organisational policies and procedures Related processes and systems. Research Policy Research Data Management Procedure Research Authorship and Outputs Procedure Privacy Policy Patient Information Privacy Policy Protecting Your Privacy - brochure for patients Consent Policy Incident Management Policy Incident Management Procedure <p>Communications:</p> <ul style="list-style-type: none"> Department staff meetings All staff organisation forums & meetings Organisation Newsletter Continuous education – Direct, Departmental, Organisational & External Organisation, Department and Individual training <p>Leadership and Reporting:</p> <ul style="list-style-type: none"> Organisation Structure and Reporting line | |
| 7. | Lead by example in: modelling responsible clinical trial conduct, focussing on safety and quality, and acting with integrity. Cultivate a culture of this amongst your clinical trial team members | <p>Process</p> <ul style="list-style-type: none"> How do you model responsible clinical trial practise? How do you model acting with safety, quality, and integrity as a focus? How do you know if your team members are conducting the trials you are responsible for as delegated, responsibly, and with integrity? Do you ever discuss examples of responsible clinical trial practise and/or acting with integrity with your clinical trials team? <p>Support</p> <ul style="list-style-type: none"> How does your organisation support you in learning about and modelling responsible clinical trial practise, safety, quality and integrity? Who in your organisation can help you with this? | Discovery & Innovation Unit Partnering Departments Principal Investigators Research Teams | <p>Support & Training</p> <ul style="list-style-type: none"> Scheduled frequent team meetings Planned continuous education and training Australian Clinical Trial Education Centre (A-CTEC, including Good Clinical Practice) (mandatory) Organisational Charter – Austin Health Board Committee Charter Manual. This outlines the roles and responsibilities of the Board’s subcommittees. Patient Safety and Clinical Excellence Framework, this incorporates the National Clinical Trials Governance Framework Organisational Charter – Austin Health Board Committee Charter Manual. This outlines the roles and responsibilities of the Board’s subcommittees. Austin Health site governance & ethics processes as outlined on website. Austin Health Research Competency Framework Austin Health Risk Based Monitoring Program | |
| 8. | Develop relationships with key stakeholders (clinicians, colleagues at other sites, consumers, supporting departments, etc) to support clinical trial operations, service improvement, and best clinical outcomes for participants | <p>Identify</p> <ul style="list-style-type: none"> How do you define an “effective relationship”? Who are the key stakeholders (both internal and external) that you need to work with for the clinical trials service to operate effectively? <p>Improvement</p> <ul style="list-style-type: none"> How do you assess whether these relationships are effective? How do you use this assessment to inform ongoing process improvement in the areas of the clinical trial service you are responsible for? <p>Support</p> <ul style="list-style-type: none"> How does your organisation support you in this? Who in your organisation can help you with this? | Discovery & Innovation Unit Partnering Departments Principal Investigators Research Teams Patient Safety & Clinical Excellence | <ul style="list-style-type: none"> Austin Health Organisational Chart Austin Health Governance Structure Internal and external training Professional development Evidence of review of Research Projects by Discovery & Innovation Unit e.g. emails Evidence of review of Research Projects by Human Research Ethics Committee e.g. emails Austin Health Community of Practice Terms of Reference Austin Health Community of Practice communications and meetings | |

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| 9. | <p>Develop strategies to engage and communicate with service users (particularly First Peoples, members of culturally diverse peoples, and those whose preferred language is not English) about participating in clinical trials.</p> <p>Tailor your approaches to meet the differing communication needs. Provide participants access to high-quality easy-to-understand information in varied languages, formats and ways that reflect their needs (e.g. Telehealth, translations, interpreter services etc).</p> | <p>Process</p> <ul style="list-style-type: none"> How do you identify the communication needs of service users, families and the wider community? How do you develop strategies to engage and communicate with these groups? Have you had any direct interactions with consumers or service users as part of this? <p>Support</p> <ul style="list-style-type: none"> How are you supported to meet the needs of participants for ongoing care, especially past the end of the trial? How does your organisation support you in this? Who in your organisation can help you with this? | <p>Nagra Jarra Aboriginal Liaison Office Discovery & Innovation Unit Partnering Departments Principal Investigators Research Teams Patient Safety & Clinical Excellence</p> | <p>Process, Support & Training</p> <ul style="list-style-type: none"> Patient Safety and Clinical Excellence Framework, this incorporates the National Clinical Trials Governance Framework. Austin Health Community of Practice Human Research Ethics Committee review of Research Projects Austin Health Reconciliation Plan 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 & Innovation Unit will provide support to VACCHO's Aboriginal Ethics Committee. Austin Health is a signatory to the marra nqarraqoo, marra goorri: The Victorian Aboriginal Health, Medical and Wellbeing Research Accord | |
| 10. | <p>Hold overall responsibility for the individual trials and research projects you conduct, by supervising the conduct and performance of your research/clinical trial team(s) and working with clinical and non-clinical managers to resolve performance concerns</p> | <p>Responsibility</p> <ul style="list-style-type: none"> Do you know what it means to "hold overall responsibility" for a clinical trial? Have you undergone appropriate training and education for you to feel confident taking overall responsibility for these? How do you know your team members are appropriately trained, working in line with relevant requirements and the protocol, and as delegated? <p>Performance</p> <ul style="list-style-type: none"> What makes a "performance concern"? What is your process for working with managers if you identify a performance concern? How is the information incorporated into your organisation's systems? <p>Support</p> <ul style="list-style-type: none"> How does your organisation support you in this? Who in your organisation can help you with this? | <p>Principal Investigator Discovery & Innovation Unit HR Performance Review Framework</p> | <p>Performance Reviews against</p> <ul style="list-style-type: none"> Position Description – Including description of job role, responsibilities and targets Austin Health competency framework Human Resources documentation as evidence of and terms of employment Clinical Training & Credentialing via the Austin Health Clinical Education Unit. <p>Training:</p> <ul style="list-style-type: none"> Austin Health competency framework ATLAS Training certificates Departmental/ Unit Training & Education Action Plan including mandatory organisation training <p>Assessment</p> <ul style="list-style-type: none"> Austin Health Competency Framework Professional Review and Development <p>Support</p> <ul style="list-style-type: none"> Staff team meetings Department and Organisation-wide meetings, seminars, newsletters, training, education and library resources | |
| 11. | <p>Delegate clinical governance and/or clinical trial responsibilities to team members (where relevant)</p> | <ul style="list-style-type: none"> How do you delegate tasks? How do you ensure tasks are delegated to team members who are qualified to perform them? How is this information incorporated into your organisation's systems? | <p>Principal Investigators Research Teams</p> | <ul style="list-style-type: none"> Human Research Ethics Committee approval obligations Austin Health Research Competency Framework Austin Health Organisational Structure Delegations logs | |
| 12. | <p>Educate yourself on the value of participant and decision maker engagement and how it contributes to the safety and quality of healthcare. Encourage active participation and sharing in decision making and care planning (to the extent that they choose). Undertake regular Partnering with Consumers training and education as per Organisation schedule.</p> | <p>Education</p> <ul style="list-style-type: none"> What resources have you used/training have you undertaken, to educate yourself about participant and decision-maker engagement? Have you had any direct interactions with participants/decision makers as part of this? Are you clear on when and how you need to complete this training? <p>Process</p> <ul style="list-style-type: none"> What is your organisational process for documenting and prioritising patient welfare and desires? What systems and processes are available for you to partner with participants/decisionmakers to plan, communicate, set goals, and be actively involved in their current and future care? How is this information incorporated into your organisational systems? <p>Support</p> <ul style="list-style-type: none"> How does your organisation support you in safely involving participants/decisionmakers? Who in your organisation can help you with this? | <p>Discovery & Innovation Unit Patient Safety & Clinical Excellence</p> | <ul style="list-style-type: none"> Patient Safety & Clinical Excellence Framework, Policies & Training ATLAS training – standard 2 Professional development External training Austin Health Shared decision making Austin Health Standard 2 Committees | |
| 13. | <p>Involve participants, families, and decision makers in the decision-making process about their participation in a clinical trial and their overall care, to the extent that they choose, ensuring patient welfare and desires are prioritised and they receive concomitant care during and after the trial.</p> | <p>Process</p> <ul style="list-style-type: none"> What is your process for documenting and prioritising patient welfare and desires? How is this information incorporated into your organisational systems? <p>Support</p> <ul style="list-style-type: none"> Does your organisation support educating yourself on safely involving participants, family, and decision-makers? Who in your organisation can help you with this? | <p>Clinician Investigators Patient Safety & Clinical Excellence</p> | <ul style="list-style-type: none"> Patient Safety & Clinical Excellence Framework and Policies Clinical review notes Other communication and documentation e.g. emails to participants and/or family members Feasibility Process, including documentation | |
| 14. | <p>Assess the feasibility of new trials in partnership with clinical and non-clinical managers, and make your current trial portfolio and service user population primary considerations here</p> | <p>Process</p> <ul style="list-style-type: none"> How do you take in account your current trial portfolio when selecting new trials? How do you take in account your current service user population when selecting new trials? How do you engage with groups of service users to determine their needs? <p>Support</p> <ul style="list-style-type: none"> Does your organisation support you bringing in new trials by offering a strategic plan for the clinical trials service? Who in your organisation can help you with this? | <p>Clinical/Non-Clinical managers Partnering Departments Discovery & Innovation Unit</p> | <ul style="list-style-type: none"> In-house department feasibility process with partnering departments Austin Health Community of Practice Human Research Ethics Committee review, outcomes and amendments | |

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| 15. | Perform HREC and SSA submissions of new trials (including budget and contract negotiations), in partnership, and ensure trials have received all relevant approvals before starting | <p>Approvals</p> <ul style="list-style-type: none"> What processes and systems do you use to ensure trials do not start before they have received all relevant approvals? How does your organisation support you in being ready to start your trial as soon as you receive all the relevant approvals? <p>Submissions</p> <ul style="list-style-type: none"> What is your standard submissions procedure for submissions? Does it define standard timelines and systems? <p>Support</p> <ul style="list-style-type: none"> Who in your organisation can help with this? | <p>Trusted Clinical Trials Managers and Principal Investigators</p> <p>Supported by Discovery & Innovation Unit & Partnering Departments</p> | <ul style="list-style-type: none"> Austin Health Community of Practice Terms of Reference Human Research Ethics Committee Terms of Reference Research Policy | |
| 16. | Identify and report risks, issues, or anything that could compromise your ability to deliver care in a safe environment. Report using both clinical trial and research-specific systems and organisation processes and systems. Work with clinical leaders to resolve issues and implement preventative and corrective actions if incidents occur | <ul style="list-style-type: none"> Identify the relevant systems & processes used for risk, safety, and incident reporting. <p>Process</p> <ul style="list-style-type: none"> What has to be reported where, to whom, and in what timeframe? What policies and procedures dictate your organisational reporting responsibilities? What are the relevant requirements that dictate your clinical trial/research-specific reporting responsibilities? How was the need for preventative and corrective actions communicated to you? Did these help mitigate the issues? Are examples of this ever discussed in staff meetings? <p>Support</p> <ul style="list-style-type: none"> How does your organisation support you in fulfilling your reporting responsibilities? Who in your organisation can help you with this? | <p>Discovery & Innovation Unit Patient Safety & Clinical Excellence Existing Clinical Governance reporting and oversight.</p> | <ul style="list-style-type: none"> Austin Health Research Strategy Austin Health Risk Statement & Appetite Riskman Austin Health Safety Reporting Austin Health Annual Progress Reports Patient Information Privacy Policy Protecting Your Privacy - brochure for patients Consent Policy Incident Management Policy Incident Management Procedure | |
| 17. | Use the relevant processes and systems to receive and respond to consumer and service user feedback and complaint. Work with clinical leads to resolve issues and implement preventative and corrective actions if feedback and/or complaints are received. | <ul style="list-style-type: none"> Identify the organisational systems used for complaints and feedback What are your associated reporting requirements? <p>Complaints</p> <ul style="list-style-type: none"> If complaints were received, how was the need for preventative and corrective actions communicated to you? Did these help mitigate the issues that caused the situation? <p>Feedback</p> <ul style="list-style-type: none"> What feedback have you received? What improvements have you made in response to feedback? <p>Support</p> <ul style="list-style-type: none"> Are these ever discussed in staff meetings? How does your organisation support you in this? Who in your organisation can help with this? | <p>Discovery & Innovation Unit Patient Safety & Clinical Excellence Use existing clinical governance feedback mechanism</p> | <ul style="list-style-type: none"> Austin Health Feedback Policy via Patient Safety & Clinical Excellence Framework and Policies Austin Health Feedback survey Austin Health Research Safety and Incident Reporting Human Research Ethics Committee Terms of Reference Patient Information Privacy Policy Protecting Your Privacy - brochure for patients Consent Policy Incident Management Policy Incident Management Procedure | |

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| 18. | Contribute to the development, management, and review of clinical trials service governance (including the National Clinical Trials Governance Framework), where opportunities present themselves. | <p>Process</p> <ul style="list-style-type: none"> How do you identify opportunities to involve yourself in this work? What systems and processes do you use for this? <p>Support</p> <ul style="list-style-type: none"> How does your organisation support you in taking advantage of these opportunities? Who in your organisation can help you with this? | Discovery & Innovation Unit Partnering Departments Patient Safety & Clinical Excellence | <p>Process</p> <p>Austin Health National Standard Accreditation page for:</p> <ul style="list-style-type: none"> Patient Safety and Clinical Excellence Framework, this incorporates the National Clinical Trials Governance Framework. Organisational Charter – Austin Health Board Committee Charter Manual. This Austin Health site governance & ethics processes as outlined on website. Austin Health Research Competency Framework Austin Health Risk Based Monitoring Program Log improvement projects on ORACLE <p>OPPIC for:</p> <ul style="list-style-type: none"> Organisational policies and procedures Related processes and systems. Research Policy Research Data Management Procedure Research Authorship and Outputs Procedure Privacy Policy Patient information Privacy Policy Protecting Your Privacy - brochure for patients Consent Policy Incident Management Policy Incident Management Procedure <p>Communications:</p> <ul style="list-style-type: none"> Department staff meetings All staff organisation forums & meetings Organisation Newsletter Continuous education – Direct, Departmental, Organisational & External Organisation, Department and Individual training <p>Leadership and Reporting:</p> <ul style="list-style-type: none"> Organisation Structure and Reporting line | |
| 19. | Provide feedback on the functioning of the clinical trials service by using your organisational standard processes and channels | <ul style="list-style-type: none"> Are you clear on when and how to provide feedback to your organisation? Do you know if your suggestions were used to support continuous improvement in safety and quality, e.g. implementing practise changes? | Discovery & Innovation Unit Divisional Directors | <ul style="list-style-type: none"> Divisional reports to Executive Safety, Quality & Risk Committee Reporting processes as set out by the Discovery & Innovation Unit | |
| 20. | Look for opportunities to improve the areas of the clinical trials service that you are responsible for, and the care given to participants | <ul style="list-style-type: none"> How do you identify and report opportunities for improvement? What systems and processes do you use for this? Do you know if your suggestions were used to support continuous improvement in safety and quality? <p>Support</p> <ul style="list-style-type: none"> How does your organisation support you in taking advantage of these opportunities? Who in your organisation can help you with this? | Divisional Directors Discovery & Innovation Unit Parenting Departments | <ul style="list-style-type: none"> Divisional meetings Team meetings Reports to Executive (Research Steering Committee) and Board Patient Safety & Clinical Excellence Framework Research Steering Committee Organisation Structure and Reporting line | |