



National Clinical Trials Governance Framework

Accreditation

Preparedness Activities



Clinical Governance



Consumer Partnership

Clinical and Non-clinical Managers



The **Austin Health Divisional Directors, Medical Directors and Departmental Directors** are responsible for developing and supporting leadership regarding patient safety and clinical excellence across their respective services. They develop and communicate policies and procedures that govern patient and staff support, safety and care.

Governance Framework Accreditation Preparedness Activities – Clinical and Non-Clinical Managers

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

#	Responsibility	Reflective questions	Who you share this responsibility with	Evidence checklist	Notes
1.	Identify and communicate to your team and, if relevant, be able to use your Organisational Clinical Governance framework, policies, procedures and related processes and systems.	<p>Identify:</p> <ul style="list-style-type: none"> Australian Charter of HealthCare rights Clinical Governance framework Organisational Charter Organisational policies and procedures around capacity and decision making/ decision maker status such as organisational Informed consent and Partnering with Consumers policy. Related processes and systems. <p>Find</p> <ul style="list-style-type: none"> Where and how do your team members find copies of these? Where and how do patients and consumers find copies of these? Who in your organisation can help you with this? <p>Use</p> <ul style="list-style-type: none"> How do you communicate these to your team? How do you assess whether team members are aware of, and use these in their everyday work and interactions with service users? Are they discussed in staff meetings? <p>Review</p> <ul style="list-style-type: none"> What is the review process for these? <ul style="list-style-type: none"> The Clinical Governance Committee, and its sub-committees adopts the Australian Charter of HealthCare rights and reviews the Patient Safety and Clinical Excellence framework which is then endorsed/approved by Executive Safety and Quality Committee. Policies and procedures are to be created and reviewed in accordance with Austin Health's Documents Manual as outlined on the OPPIC Pulse Page. Research specific policies and procedures are reviewed by the Research Steering Committee and approved by Executive Policy Review Committee Who in the organisation can help you get involved in the review process? <ul style="list-style-type: none"> Each policy and procedure published on OPPIIC has a document Author, Authorised Committee and Primary Person/Department Responsible. Please contact one of those people if updates are needed. 	<p>Discovery & Innovation Unit</p> <p>Clinician investigators</p> <p>Partnering departments</p>	<p>Links:</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 <p>Leadership and Reporting:</p> <ul style="list-style-type: none"> Organisation Structure and Reporting line 	
2.	Undertake all your required training and education, as per your organisation's schedule.	<ul style="list-style-type: none"> Are you clear on what training you are required to complete to perform your role? When and how do you need to complete this training? How does your organisation support you in completing this training? Who in your organisation can help you with this? 	<p>Discovery & Innovation Unit</p> <p>Clinician investigators</p> <p>Partnering departments</p> <p>Clinical Trials Workforce</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) TBC (launch date Feb 2024): 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) (mandatory) 	
3.	Manage clinical trial workforce training, credentialling and professional competencies, scope of practice and performance by overseeing your team members keeping up to date on all their regular education and training, and assessing their performance at regularly scheduled intervals, as per your standard organisational schedule. This includes regular Partnering with Consumers training and other education requirements.	<p>Process</p> <ul style="list-style-type: none"> How do you determine the credentials and professional competencies you and your team members need to meet? How do you determine the scope of practice of your team members? 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? <p>Tracking</p> <ul style="list-style-type: none"> How do you track who needs to do what training, when and how? How do you communicate to your team members about when and how to complete their training? How do you track who has completed, and passed, what training? How do you escalate non-compliance, and how is this followed-up? <p>Assessment</p> <ul style="list-style-type: none"> How do you ensure they meet the relevant credentials and professional competencies? How do you ensure they work within their scope of practice? How do you monitor performance, and when? How is this information incorporated into your organisation's training systems? <p>Support</p> <ul style="list-style-type: none"> Are examples of good practise, resources, or education and training outcomes ever discussed in staff meetings? How does your organisation support educating yourself on safely involving participants and decision-makers? How does your organisation support you in this? Who in your organisation can help you with this? 	<p>Discovery & Innovation Unit</p> <p>Clinical Education Unit & Credentialling Committees</p>	<p>Credentialling</p> <ul style="list-style-type: none"> Position Description – Including description of job role, responsibilities and targets TBC (launch date Feb 2024): Austin Health Research 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 Research 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 Research 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 Continuous education – Direct, Departmental, Organisational & External Organisation, Department and Individual training 	

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4.	<p>Conduct the clinical trials service in line with relevant 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, your organisational charter and clinical governance framework, national and local guidelines, standards, regulations, and legislation.</p>	<p>Process</p> <ul style="list-style-type: none"> What are the relevant requirements you, and your team members, must operate in line with? How do you ensure your, and your team members, continued compliance with these? How do you communicate new or updated requirements to your team members? <p>Support</p> <ul style="list-style-type: none"> How has your organisation supported you in this? Who in your organisation can help you with this? 	<p>Discovery & Innovation Unit</p> <p>Quality & Safety</p> <p>Partnering departments</p> <p>Clinical/ Non-Clinical Managers</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 	
5.	<p>Develop relationships with key stakeholders (team leaders, consumers, supporting departments, colleagues at other sites, etc) to support clinical trial operations, service improvement, and best clinical outcomes for service users.</p> <p>Understand the complexity of the consumer 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>	<p>Process</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? How do you support your team members in partnering with consumers and service users in ways that respect their cultural and community identity, and their identity as a patient? How do you support your team members in learning what additional supports they can provide to their participants? <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 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? 	<p>Discovery & Innovation Unit</p> <p>Clinician investigators</p> <p>Partnering departments</p>	<p>Process</p> <ul style="list-style-type: none"> Austin Health Organisational Chart Austin Health Governance Structure Patient Safety and Clinical Excellence Framework, this incorporates the National Clinical Trials Governance Framework. <p>Support & Training</p> <ul style="list-style-type: none"> Austin Health Research Competency Framework 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 SMART Governance Committee Austin Health SMART Governance Committee communications and meetings 	
6.	<p>Support team members to involve service users, decision makers, and families to participate in making decisions about their own care and their participation in clinical trials, while prioritising their welfare and desires.</p>	<p>Process</p> <ul style="list-style-type: none"> How do you support your team members in developing meaningful partnerships with participants so they can be actively involved in their own care? <p>Support</p> <ul style="list-style-type: none"> Do you ever discuss this in staff meetings? How has your organisation supported you, and them, in this? How is the impact of this support measured? 		<p>Support</p> <ul style="list-style-type: none"> Austin Health Shared Decision Making Framework Austin Health Board Consumer Advisory Committee Feedback from consumers with lived experience Including consumers in the design of trials, including approach and consent 	
7.	<p>Develop strategies to engage & communicate with consumers/ service users about clinical trials (particularly First Peoples, members of culturally diverse peoples, and those whose preferred language is not English). Support team members to tailor their approaches to meet the differing needs of service users.</p>	<p>Process</p> <ul style="list-style-type: none"> How do you develop strategies to engage and communicate with these groups? Have you had any direct interactions with consumers and service users as part of this development? <p>Support</p> <ul style="list-style-type: none"> How do you support your team members in identifying, and tailoring their approaches to service user needs? How does your organisation support you in this? Who in your organisation can help you with this? 	<p>Research Office</p> <p>Partnering departments</p> <p>Ngarra Jarra Aboriginal Health Unit</p>	<ul style="list-style-type: none"> marra ngarrqoo, marra goorri Aboriginal Research Accord Austin Health Reconciliation Plan Patient Safety and Clinical Excellence Framework, this incorporates the National Clinical Trials Governance Framework. Ngarra Jarra Aboriginal Health Unit Mandatory cultural training Team meetings Writing procedures in protocols, or referring to organisational policies and procedures. 	
8.	<p>Cultivate a team culture where team members conduct clinical trials responsibly, focus on integrity, safety and quality, and work within the bounds of organisational systems</p>	<p>Process</p> <ul style="list-style-type: none"> What resources have you used or training have you undertaken to develop and maintain your team culture? How do you know if your team members are using your organisational values in their everyday work and interactions with service users? Are examples of these ever discussed in staff meetings? <p>Support</p> <ul style="list-style-type: none"> How has your organisation supported you, and your team members, in this? Who in your organisation can help you with this? 	<p>Research Office</p> <p>Principal Investigators</p> <p>Research workforce & managers</p>	<ul style="list-style-type: none"> Scheduled frequent team meetings Planned continuous education and training Divisional/Unit safety, quality & risk committees RiskMan reporting <p>Support & Training</p> <ul style="list-style-type: none"> Austin Health Research Competency Framework 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 SMART Governance Committee Austin Health SMART Governance Committee & Human Research Ethics Committee formal letters and feedback. Research Architect – Austin Health clinical research management platform 	

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9.	<p>Support team members to 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> <p>Support team members to tailor their approaches and provide consumers and service users access to high-quality, easy-to-understand information about clinical trials in languages, formats, and ways that reflect their needs.</p>	<p>Process</p> <ul style="list-style-type: none"> How do you support your team members in partnering with service users in ways that respect their cultural and community identity, and their identity as a patient? How do you support your team members in learning what additional supports they can provide to their participants? <p>Support</p> <ul style="list-style-type: none"> Do you ever discuss this in staff meetings? How is the impact of this support measured? How has your organisation supported you, and them, in this? Who in your organisation can help you with this? 	Discovery & Innovation Unit	<ul style="list-style-type: none"> Austin Health SMART Governance Committee Austin Health Consumer Engagement Committee Research Architect – Austin Health clinical research management platform Consumer Engagement toolkits Patient Safety and Clinical Excellence Framework, this incorporates the National Clinical Trials Governance Framework. Austin Health Research Competency Framework Scheduled team meetings Austin Health Patient Feedback survey Austin Health literacy training 	
10.	<p>Support your team members to expand their scope of practice (e.g., by taking on leadership opportunities)</p>	<p>Process</p> <ul style="list-style-type: none"> How do you, or your team members, identify opportunities to expand their scope of practice? What systems and processes do you use for this? <p>Support</p> <ul style="list-style-type: none"> How do you support them in taking advantage of these opportunities? How does your organisation support you, and them, in this? 	Human Resources Discovery & Innovation Unit Academic partners	<ul style="list-style-type: none"> Planned Professional Development Scheduled team meetings One on one meetings with manager Austin Health Research Competency Framework 	
11.	<p>Support team members and service users in identifying opportunities to be involved in the development and review of clinical trials service governance</p>	<p>Process</p> <ul style="list-style-type: none"> How do you, or your team members, identify opportunities for them to be involved in this? What systems and processes do you use for this? <p>Support</p> <ul style="list-style-type: none"> How do you support them in taking advantage of these opportunities? How does your organisation support you, and them, in this? 	Partnering departments Research Office	<ul style="list-style-type: none"> Austin Health SMART Governance Committee Research Architect – Austin Health clinical research management platform Team meetings discussing feasibility Austin Health Risk Appetite Statement Austin Health strategy 	
12.	<p>Manage clinical trial resourcing and budgeting, identify funding sources, assess whether your organisation has appropriate capacity and resources to support your clinical trials portfolio</p>	<p>Trial Level</p> <ul style="list-style-type: none"> How do you assess what resources each trial will need? How do you assess what each trial will cost? <p>Unit Level</p> <ul style="list-style-type: none"> How do you balance the available resources across the trials portfolio? How do you know you are recovering the costs to deliver your trials portfolio? <p>Service Level</p> <ul style="list-style-type: none"> How do you partner with stakeholders across your organisation to assess whether they have the capacity and resources to support additional trials? 	Partnering departments	<ul style="list-style-type: none"> Austin Health SMART Governance Committee Research Architect – Austin Health clinical research management platform Finance Business Partner Austin Health Foundation 	
13.	<p>Appropriately resource your team members to deliver the clinical trials service. Including adequate staff numbers and appropriate workloads, working space, equipment, supplies (clinical and office), access to computers, EMR systems, etc</p>	<p>Trial Level</p> <ul style="list-style-type: none"> How do you assess what resources each trial will need? How do you assess what each trial will cost? <p>Unit Level</p> <ul style="list-style-type: none"> How do you balance the available resources across the trials portfolio? How do you know you are recovering the costs to deliver your trials portfolio? <p>Service Level</p> <ul style="list-style-type: none"> How do you partner with stakeholders across your organisation to assess whether they have the capacity and resources to support additional trials? 	Partnering departments Research Office Legal	<ul style="list-style-type: none"> Austin Health SMART Governance Committee Research Architect – Austin Health clinical research management platform Finance Business Partner Austin Health Foundation Diversifying the workforce and funding streams 	
14.	<p>Make your current trial portfolio and service user population primary considerations when assessing the feasibility of new trials. Periodically review trial recruitment to ensure your current trial portfolio is the best use of your resources</p>	<p>How do you define “success” for a clinical trial?</p> <p>New Trials</p> <ul style="list-style-type: none"> What is your process for selecting new trials? How do you take in account your current trial portfolio and available resources when selecting new trials? How do you take in account your current service user population when selecting new trials? How do you engage with service users to determine their needs? <p>Current Trials</p> <ul style="list-style-type: none"> What is your process for reviewing inactive trials, or trials that fail to recruit participants? <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? 	Clinician investigators Partnering departments	<ul style="list-style-type: none"> Austin Health SMART Governance Committee Research Architect – Austin Health clinical research management platform Austin Health Patient Safety & Clinical Excellence Framework Austin Health Research Strategy 2023 – 2027 Involve consumers with lived experience Team meetings discussing trials, metrics and opportunities for improvement Divisional Safety, Quality and Risk meetings 	

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15.	<p>Monitor and assess potential risk by undertaking clinical trial risk assessments, covering both staff and participants. If relevant, use organisational systems and processes (including the organisational risk register) to identify and report risks, issues or anything that could compromise you or your team members ability to safely partner with consumers/ service users as they occur.</p>	<ul style="list-style-type: none"> How do you identify and document potential risks to participants? How do you identify and document potential risks to staff members? Identify relevant systems & processes used for risk, safety and incident reporting. <p>Process</p> <ul style="list-style-type: none"> How do you develop and assess your risk mitigation systems and processes, and are service users and consumers involved where relevant? What organisational policies and procedures that dictate your organisation, clinical trial and research specific reporting responsibilities? How do you communicate the need for preventative and corrective actions to your team? Did these help mitigate the issues that caused the situation? <p>Impact</p> <ul style="list-style-type: none"> How is the impact of these actions measured? How do you know your team members carry out these responsibilities in their everyday work? How do these processes support continuous improvement in safety and quality? Are these ever discussed in staff meetings? <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 Divisional Safety & Quality meetings	<ul style="list-style-type: none"> Riskman Divisional Safety, Quality & Risk Meetings Austin Health SMART Governance Committee Research Architect – Austin Health clinical research management platform Human Research Ethics Committee Austin Health Risk Appetite Statement Austin Health Risk Management Framework Patient Safety & Clinical Excellence Clinical Audit Policy Integrity 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 	
16.	<p>Use the relevant processes and systems to manage safety and incident reporting responsibilities. Oversee your team members being trained in, aware of, and actively carrying out their responsibilities in this area. Work with team members to resolve issues and implement preventative and corrective actions if incidents occur.</p>	<ul style="list-style-type: none"> Identify the relevant processes and systems used for safety and incident reporting. <p>Process</p> <ul style="list-style-type: none"> How do you know if your team members carry out these responsibilities in their interactions with service users? Who else in your organisation is involved in the management and review of these situations? Do you know if consumers and service users are involved where appropriate? How do you communicate the need for preventative and corrective actions <p>Impact</p> <ul style="list-style-type: none"> How is the impact of these actions measured? How do these processes support continuous improvement in safety and quality? Are these 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? 	Discovery & Innovation Unit Clinician investigators Partnering departments Clinical Trials Workforce	<ul style="list-style-type: none"> Riskman Divisional Safety, Quality & Risk Meetings Austin Health SMART Governance Committee Research Architect – Austin Health clinical research management platform 	
17.	<p>Use the relevant processes and systems to receive and respond to consumer, service user, and team member feedback and complaints. Oversee your team members being trained in, aware of, and actively carrying out their responsibilities in this area. Work with team members to resolve issues and implement preventative and corrective actions if feedback and/or complaints are received.</p>	<ul style="list-style-type: none"> Identify the relevant processes and systems to manage service user feedback and complaints. How do you know if your team members carry out these responsibilities in their interactions with service users? <p>Complaints</p> <ul style="list-style-type: none"> Who else in your organisation is involved in the management and review of these situations? Do you know if consumers and service users are involved where appropriate? How do you communicate the need for preventative and corrective actions? <p>Feedback</p> <ul style="list-style-type: none"> What feedback have you received? What improvements have you made in response? How is the impact of these actions measured? <p>Support</p> <ul style="list-style-type: none"> How do you support your team members in this? How does your organisation support you in this? Who in your organisation can help you with this? Are these ever discussed in staff meetings? 	Discovery & Innovation Unit Clinician investigators Partnering departments Partnering with consumers department Clinical Trials Workforce	<ul style="list-style-type: none"> Human Research Ethics Committee review with lay members and consumers Research study design inclusive of consumer consultation Austin Health SMART Governance Committee Research Architect – Austin Health clinical research management platform Research Project amendments based on evidence and/or feedback Team meetings discussing feedback Austin health Patient Feedback Survey 	
18.	<p>Receive and respond to audit findings to monitor clinical governance compliance, clinical trial conduct, and take action to deal with any findings</p>	<ul style="list-style-type: none"> Identify what audit processes there are within your organisation <p>Process</p> <ul style="list-style-type: none"> Do you involve service users, consumers, and team members in the audit process/review of audit findings, or is this done by those conducting the audit? What is your process for ensuring all of your findings have been addressed? How do you communicate the need for preventative and corrective actions? <p>Impact</p> <ul style="list-style-type: none"> How is the impact of these actions measured? How do these processes support continuous improvement in safety and quality? How are audit findings (or themes from audit findings) shared with the wider organisation for oversight and quality improvement measures? <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	<ul style="list-style-type: none"> Annual Progress Report Reporting to Research Steering Committee via Discovery & Innovation Unit Austin Health Reporting to Executive and Board Research Audit for sponsored clinical research Team meetings Divisional safety, quality and risk meetings 	

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19.	Monitor and report on consumer involvement, clinical trial activity and performance, in the areas of the clinical trials service that you are responsible for, by reporting on relevant metrics, using data collected at the trial unit level as per your organisation's standard practices.	<p>Reporting</p> <ul style="list-style-type: none"> What data do you collect and report, and why? What metrics do you report on, and why? What is your process for collecting data and reporting on metrics? Who do you report to (e.g., your governing body)? How often do you have to report (e.g., quarterly)? How is this data used to inform ongoing process improvement in the areas you are responsible for? <p>Support</p> <ul style="list-style-type: none"> How does your organisation support you through this process? Who in your organisation can help you with this? 	Discovery & Innovation Unit	<ul style="list-style-type: none"> Involve consumers in aspects of planning and delivery Embed consumer engagement and check-in points within protocol, or as an appendix to the protocol Track consumer feedback and progress throughout trial Annual Progress Reports documentation e.g, submission and acknowledgement/ approval emails Safety Reporting documentation e.g. e submission and acknowledgement/ approval emails Organisation Structure and Reporting line Patient Safety and Clinical Excellence Framework, this incorporates the National Clinical Trials Governance Framework. 	
20.	Monitor for, and respond to, changes in the areas of the clinical trial service you are responsible for by collecting and reporting on data collected at the trial unit level as per your organisation's standard practice	<p>Reporting</p> <ul style="list-style-type: none"> What data do you collect and report, and why? What metrics do you report on, and why? What is your process for collecting data and reporting on metrics? Who do you report to (e.g., your governing body)? How often do you have to report (e.g., quarterly)? How is this data used to inform ongoing process improvement in the areas you are responsible for? <p>Support</p> <ul style="list-style-type: none"> How does your organisation support you through this process? Who in your organisation can help you with this? 	Discovery & Innovation Unit	<ul style="list-style-type: none"> Mandatory reporting via Organisational wide IT platform & visible dashboards 	
21.	Provide feedback on the functioning of the clinical trials service by using organisational 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 practice changes? 	Discovery & Innovation Unit Partnering departments Clinical/Non-Clinical Managers Clinical Trials Workforce	<ul style="list-style-type: none"> Mandatory reporting via Organisational wide IT platform & visible dashboards Research Steering Committee Divisional & Executive Safety, Quality and Risk Committee Log quality improvement activities on ORACLE improvement database 	
22.	Contribute to the development, management, and review of clinical trials service governance (including the National Clinical Trials Governance Framework), where opportunities present themselves.	<ul style="list-style-type: none"> How do you identify opportunities to involve yourself. Does your organisation support you in taking in this work? What systems and processes do you use for this? advantage of these opportunities? Who in your organisation can help you with this? 	Discovery & Innovation Unit Clinician investigators Partnering departments Clinicals Trials Workforce	<ul style="list-style-type: none"> Expert advisor for initiatives and working groups Clinical level expert advisor Member of Divisional Safety, Quality and Risk Committees 	
23.	Look for opportunities to improve the areas of the clinical trials service that you are responsible for.	<ul style="list-style-type: none"> What defines consumer involvement for you? <p>Reporting</p> <ul style="list-style-type: none"> How do you identify and report data and opportunities for improvement? Who do you report to (e.g., your governing body)? What is the process for collecting and reporting this data? What systems and processes do you use for this? How is the data used to inform ongoing process improvement in the areas you are responsible for? Do you know if your suggestions were used to support continuous improvement in safety and quality, e.g., implementing practice changes? <p>Support</p> <ul style="list-style-type: none"> How does your organisation support you in identifying and reporting opportunities for improvement? Who in your organisation can help you with this? 	Discovery & Innovation Unit Clinician investigators Clinical/Non-Clinical Managers Clinicals Trials Workforce	<ul style="list-style-type: none"> Use publicly available consumer engagement toolkits Ask consumers with lived experience to provide feedback Embed feedback and consumer check-in points in your protocol Reporting on improvement via ORACLE improvement database and Divisional Safety, Quality and Risk Committee Look for opportunities to support/become a sponsor/leader in key strategic areas for Research Strategy 	