National Clinical Trials Governance Framework Accreditation Preparedness Activities

Clinical Governance

Consumer Partnership

Research Office

The Austin Health Discovery & Innovation Unit are responsible for the strategic and operational management of clinical and non-clinical research, education, training and mentorship of clinical professionals conducting research at Austin Health.

Governance Framework Accreditation Preparedness Activities – Research Office

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

Theme	Description	Reflective questions	Who is involved	Who shares responsibility	• Evidence checklist
Researcher Support, Advice and Collaboration	Develop and maintain clear, open communication channels with key stakeholders.	**Who are the key stakeholders (both internal and external) that you need to work with for the clinical trials service to operate?** • Principal Investigators • Research Teams • Sponsors/Universities/Medical Research Institutes • Funders (e.g., NHMRC, MRFF) • Department of Health • Commission on Health, Quality & Safety • Executive, Senior Management, Partnering Departments **How do you define an "effective relationship"?** • Frequency of communication by keeping stakeholders up to date, responding within a week, and responding via their preferred method e.g., phone, in person, email etc.. • Quality of communication by being clear about the information we need, clear on advice given, and clear on next steps. • Meeting Key Performance Indicators by responding to emails within 5 business days, providing complete answers, and updates so that stakeholders know where their requests are up to. **How do you assess whether these relationships are effective?** • Number of complaints • Number of compliments • Formal and informal feedback from stakeholders **How does your organisation support you in this?** • Weekly all staff emails with updates • Patient Safety and Clinical Excellence Newsletters • Standard of the month • Targeted research webinars and consultations run from the Office.	**Manager, Discovery & Innovation Unit** – Outward facing stakeholders, Senior Management & Executive Level stakeholders **Team Leaders** – Principal Investigators, Sponsors, Partnering Departments, Funders & supports Ethics, Integrity & Governance Advisors **Ethics, Integrity & Governance Advisors** – Provides the support, advice, collaboration and escalates to line manager when they have reached their technical capacity.	1. Partnering departments 2. Clinical & Non-Clinical Managers (including Divisional Managers and Divisional Directors) 3. Patient Safety and Clinical Excellence Unit Executives 1. Our People & Culture Committee 2. Diversity & Inclusion Committee 3. Research Steering Committee 4. Austin-Mercy Precinct Research Collaborative Committee	• **Organisation wide** • ATLAS training – living the Austin Values • Code of Conduct Policy • Patient Safety and Clinical Excellence Framework • Consumer Partnership Procedure • **Research Specific** • Research Policy 2023, • Part A, C, M, O, P • OfR Onboarding & Training • Human Research Ethics Committee Terms of Reference • Huddle Check, Emails, Meetings, Minutes • [Meetings include Research Steering Committee, Austin-Mercy Collaborative Committee. Clinical Governance, Board etc] • SMART Governance Committee • Research Architect – Austin Health clinical research management platform
Researcher Support, Advice and Collaboration	Provide information, education and resources on partnering with consumers.	**What resources have you used, and/or training have you undertaken, to educate yourself about consumer engagement?** Austin Health ATLAS Health Literacy Training - Communicating in Plain Language - Victorian PCP Health Literacy Online learning course Manager, Discovery & Innovation Unit sits on Standards 2 Committee. **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**? Austin Health ATLAS Health Literacy Training - Cultural Awareness Training - Aboriginal Cultural Awareness Actively recruiting culturally and linguistically diverse Human Research Ethics Committee members **How do you support your team members in becoming culturally aware?** • Mandate cultural awareness training • Awareness of impact of student design on cultures • Awareness of the value-add co-designing with target cultures/populations on study design and success of study.	Patient Experience Office provides education and resources on partnering with consumers. The Discovery & Innovation Unit ensures mandatory training, and initiatives are inline with Patient Experience Office. For research specific toolkits, researchers can access Melbourne Academic Centre for Health (MACH) toolkits for free. External funding bodies provide guidance to researchers and Discovery & Innovation Unit on specific requirements for partnering with Consumers.	**Patient Safety and Clinical Excellence** • Clinical Excellence Lead, Standard 2 • Partnering with Consumers Committee	• Partnering with Consumers Policy • Consumer Partnership Procedure • Patient Safety and Clinical Excellence Framework • Language Services Policy • Health Literacy Guideline • Health Literacy Training – ATLAS • Communicating in Plain Language • Victorian PCP Health Literacy Online learning course • **Cultural Awareness Training** • Cultural Awareness Training • Aboriginal Cultural Awareness • Research Policy 2023 • Austin Health HREC Committee Terms of Reference

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Researcher Support, Advice and Collaboration	Advise and assist researchers to develop clinical trial information appropriate to their patients and service users	**How do you check that researchers have a plan to accommodate participants from diverse populations in their research?** • Consumer section of investigator initiated protocols • Inclusion/exclusion criteria • Human Research Ethics Committee review & answers to questions around diversity & inclusion. • Ensuring all Aboriginal and Torres Strait Islander research is compliant with Victorian Aboriginal Health, Medical and Wellbeing Research Accord **How do you check whether participant-facing documents reflect the inclusion of diverse populations in the research project?** • The Discovery & Innovation Unit creates the patient facing documents on behalf of most Investigator Initiated trials to ensure inclusivity. • When the Discovery & Innovation Unit doesn't create the materials, evidence from the research team outlining the process to include diverse populations is required. **How do you partner with service users in this?** • It is expected clinical areas seeing patients will work with their consumers to create a culturally appropriate area, and approaches. **How do you assess whether governance applications have evidence of appropriate resourcing for plans to include diverse populations?** • Ask for evidence in the protocol or ethically approved documents.	Patient Experience Unit Consumer Bodies Principal Investigators Human Research Ethics Committee/Discovery & Innovation Unit	Partnering with Consumers Committee Patient Safety & Clinical Excellence	• Diversity and Inclusion Plan 2020-2023 • Recruitment and orientation for consumer partners • Consumer Partnership Procedure • Partnering with Consumers Standard 2 Pulse Page • Participant Information Statement & Consent Addendum (Charter of HealthCare Rights in top 10 languages & feedback)
Researcher Support, Advice and Collaboration	Enable consumer involvement in the development and review of consent forms and other participant-facing information.	**Can you identify your organisation's informed consent policies and procedures?** • All policies and procedures are on OPPIC **Where and how do your team members find copies of these?** • All policies and procedures are on OPPIC **Where and how do patients and consumers find copies of these?** • Austin Health Patient Resources **How do you communicate these to your team members?** • Through Discovery & Innovation Unit Onboarding Processes.	Patient Safety & Clinical Excellence Unit Principal Investigators/Sponsors Human Research Ethics Committee	Partnering with Consumers Committee Clinical Excellence Lead, Standard 2	• Consent Policy • Informed Consent • Shared Decision Making and Informed Consent Committee • Medical Treatment Decision Maker (MTMD) identification Procedure • Research Policy 2023
Researcher Support, Advice and Collaboration	Develop research-specific informed consent policies and procedures to assist in maintaining an effective informed consent process.	**Identify your organisation's informed consent policies and procedures** • All policies and procedures are on OPPIC **Where and how do your team members find copies of these?** • All policies and procedures are on OPPIC **How do you communicate these to your team members?** • Through Discovery & Innovation Unit Onboarding Processes. **How do you assess whether team members are aware of, and use these in their everyday work and interactions with service users?** • Huddle checks • Human Research Ethics Committee Minutes • Creation of patient facing models • One on one discussions with line manager abour consent strategies **What is the review process for these?** • Policies and procedures are reviewed in line with our corporate governance requirements https://austinhealth.sharepoint.com/sites/CorporateServices/SitePages/Documents-Policy-and-OPPIC-Support.aspx#key-organisational-policies.	Patient Safety & Clinical Excellence Unit Principal Investigators/Sponsors Human Research Ethics Committee	Clinical Excellence Lead, Standard 2 Clinical Ethics Lead Chief Medical Officer General legal council Executive Safety Quality and Risk Committee Partnering with Consumers Committee External Funding Bodies External Consumer Bodies/Advocacy Bodies	• Code of Conduct Policy • Health Literacy Guideline • Consent Policy • Austin Health HREC Committee Terms of Reference • Research Policy 2023 • Daily huddles

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Research Integrity, Compliance, and Institutional Risk Assessment	Ensure the submission of clinical research governance documents required by organisational and legislative requirements	How do you assess whether governance applications have evidence of appropriate resourcing and planning? • Read the protocol • Create governance framework using Huddle checks • Ensure internal sign-offs include current information & advice • All internal sign-offs must be obtained prior to giving final approval	Discovery & Innovation Unit	Executive Safety Quality and Risk Committee Research Steering Committee Partnering Departments Sponsors Principal Investigators Department of Health	• Human Research Ethics Committee Terms of Reference • Research Policy 2023 • Work Instructions for the Office • Clinical Governance Committee Terms of Reference • Huddle Checks
Research Integrity, Compliance and Institutional Risk Assessment **Research Integrity, Compliance and Institutional Risk Assessment**	Conduct audits of research projects and clinical trials to ensure compliance with codes and frameworks. Monitor potential research related risks and record as required by organisational processes.	**What is your process for determining when and where audits need to be conducted?** • Discovery & Innovation Unit is building Risk Based Audit Tool to go on org-wide Pulse Page https://austinhealth.sharepoint.com/sites/CorporateServices/SitePages/Clinical-Audit-Portal.aspx. **What is your process to see if all audit findings have been addressed?** Audit findings are reviewed in the following order: • Executive Sponsor • Research Steering Committee • Board Audit & Risk Committee (if part of internal audit) • For Clinical Areas, they report their risks through their divisional risk registries, this is then managed by their Divisional Managers and Directors. **Who else in your organisation is involved in the management and review of these situations?** • Research Steering Committee • Advice from Director Risk • For Clinical Areas, they report their risks through their divisional risk registries, this is then managed by their Divisional Managers and Directors. **Do you know if consumers and service users are involved where appropriate?** The process that is yet to be developed will include consumers and service users where appropriate. For Clinical areas, they may already involve consumers. **How do you communicate the need for preventative and corrective actions to the clinical trials workforce?** • Research Risk Registry • Research Steering Committee • For clinical areas, preventative and corrective actions are managed via their normal Safety & Quality processes. **How is the impact of these actions measured?** • In accordance with our Enterprise Risk Appetite Statement. **How do these processes support continuous improvement in safety and quality?** • For clinical areas, preventative and corrective actions are managed via their normal Safety & Quality processes. • For Discovery & Innovation Unit continuous improvement is managed via CMO reporting line and Research Steering Committee **How does your organisation support you in this?** • Enterprise Risk Management Framework	Discovery & Innovation Unit Manager, Discovery & Innovation Unit is responsible for org-wide Research Risk Profile. Clinical Research Risks are managed via Divisional Processes through their Divisional Managers and Directors, and relevant Divisional Safety & Quality Committees	Austin Health Research Steering Committee Director Enterprise Risk Management Board Audit & Risk Committee Divisional Safety & Quality Committees	• Research Policy 2023 • Enterprise Risk Management Framework • Summary Research Risk Profile from Director Enterprise Risk & Research Risk Profile • Minutes Research Steering Committee • Minutes of Divisional Safety & Quality Committees • Divisional Risk Profiles (which will have research embedded into their risk specific to that area).

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Research Integrity, Compliance and Institutional Risk Assessment		• Director Enterprise Risk presents on Research Risk Registry to the Research Steering Committee in May and September of each year.			
	Contribute to the development, management and review of clinical trials service governance	**How do you identify opportunities to involve yourself in this work?** • Through membership on the Standards 1 & 2 Committee • Through sector wide changes • Through governance issues raised at Research Steering Committee, or other sources that require an org-wide approach and expertise. **Do you know if your suggestions were used to support continuous improvement in safety and quality, e.g., implementing practise changes?** • For org-wide approaches, the Discovery & Innovation Unit is responsible for evaluating change management and implementation strategies. • For division wide approaches, this information does not need to go to Discovery & Innovation Unit, instead it should be reported up through Divisions reporting lines	Manager, Discovery & Innovation Unit Divisional Managers and Directors in consultation with Research managers within their divisions	Standard 1 & Standard 2 Committee Research Steering Committee Partnering Departments Divisions	• Clinical Governance Committee Terms of Reference • Patient Safety and Clinical Excellence Framework • Research Steering Committee Terms of Reference • Divisional Safety, Quality and Risk Committee Terms of Reference (search "Safety, Quality & Risk Terms of Reference) in OPPIC.
	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	**How do you partner with service users and in ways that respect their cultural and community identity, and their identity as a patient?** • Service providers must follow the organisation's approach to cultural and community identity. **How do you identify the communication needs of service users and the community?** • This is managed within the Division's own processes, and should follow the org-wide process outlined by the Patient Safety and Clinical Excellence Unit. **Who in your organisation can help you with this?** • Patient Safety and Clinical Excellence Unit	Divisions, and each clinical unit within the divisions	Patient Safety and Clinical Excellence Unit Executive Sponsor, Divisional Directors and Managers of each division.	• Patient Safety and Clinical Excellence Framework
Research Integrity, Compliance and Institutional Risk Assessment	Monitor and report on consumer involvement in research projects as required by organisation policies and processes.	**What defines consumer involvement for you?** Consumer involved happens are different levels. They are: • Sponsor defines it, usually in the protocol • External funding agency sets rules around consumer involvement • Human Research Ethics Committee advises on relevance • Abide by an industry standards for specific cultural communities e.g., First Nations research should abide by VACCHO research accord. **What data do you collect and report?** Research Architect – Austin Health clinical research management platform captures which projects involve consumers and the number. **What is your process for this?** • Researchers self declare when they submit • Encourage researchers to include consumer involvement in protocol • Commercial Sponsors are harder to capture the information, and no formal process has been established. **How is this data used to inform ongoing process improvement in the areas of the clinical trials service you are responsible for?** • Discovery & Innovation Unit checks and reports via Huddle checks and HREC agendas on a per project basis if consumers are involved, and what level of involvement. **How does your organisation support you in this?** Partnering with Consumers Committee & Unit. HREC provides support	Discovery & Innovation Unit to set expected standard for consumer involvement in line with External funding bodies, regulatory requirements and Human Research Ethics Committee	Patient Safety and Clinical Excellence Unit Partnering with Consumers Committee	• Patient Safety and Clinical Excellence Framework • Consumer Partnership Procedure • Quality Management Policy

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		External bodies, funders and translational research centres also help to set out expectations and standards.			
Research Integrity, Compliance and Institutional Risk Assessment	Receive and respond to consumer, service user, and workforce feedback and complaints. Work with management to resolve issues and implement preventive and corrective actions if feedback and/or complaints are received.	**Identify your organisations complaint and feedback systems and processes?** • RiskMan • Patient feedback survey • Via research@austin.org.au **How do you receive service user feedback and complaints if there are any**? The Discovery & Innovation Unit can receive user feedback in the following ways: • Via research@austin.org.au • Patient feedback survey • RiskMan **If feedback or complaints are received, what are your associated reporting requirements**? • Report to the area the feedback or complaint is for. If this involves a patient, work with Principal Investigator, Divisional Manager/Directors and Executive as well as OfR Research Director and CMO. • If complaint is about Ethics Committee decision, work with HREC chair to resolve. **Are these ever discussed in staff meetings?** • Yes internally with OFR staff. • At Research Steering Committee **How does your organisation support you in this?** • Patient Experience Team passes on any feedbacks or complaints to research@austin.org.au. • Access to RiskMan and enhancements to RiskMan to include research in reporting.	Manager, Discovery & Innovation Unit	Austin Health Research Steering Committee Chief Medical Officer Chair, Human Research Ethics Committee Associate Director Patient Experience Unit Divisional Directors/Managers Principal Investigators	• Managing Consumer Feedback Policy • Consumer Feedback Management Procedure • Research Policy • Research Misconduct Procedure • Patient Safety and Clinical Excellence Framework • Research Steering Committee Terms of Reference • Human Research Ethics Committee Terms of Reference
Research Integrity, Compliance and Institutional Risk Assessment	Manage conflicts of interest, complaints, risks and incidents resulting from the conduct of the clinical trials.	**What organisational systems and processes must be used to report on, and manage, these situations when they occur?** • **Incidents:** RiskMan (yet to be implemented for research. Due in 2024) • **Conflicts of Interest:** Per Conflicts of Interest Policy + upon submission of research to Discovery & Innovation Unit. It is then documented against the project file and documented in HREC agenda and minutes. • Declared conflicts of interest are also registered in the Participant Information Statement & Consent Form and any published journals. **Who else in your organisation is involved in the management and review of these situations?** • Line Managers, Divisional Managers, Divisional Directors & Executive per Conflicts of Interest Policy. **How do you assess the effectiveness of these systems and processes?** • If researchers self-declare conflicts of interest without being prompted & if the mitigation strategies to manage the conflict show depth of understanding. • Logging and documenting conflicts of interest in Huddle checks and HREC meeting minutes. • Incident management via formal correspondence and RiskMan, and meeting NHMRC and clinical governance reporting timelines. **If your systems and processes involve service users, consumers, and researchers, how do you support them in fulfilling their responsibilities in these areas?** • Work with them to appropriately document and manage their conflict of interests.	General Legal Counsel	Divisional Managers People and Culture Committee Discovery & Innovation Unit Austin Health Research Steering Committee Chief Medical Officer Human Research Ethics Committee Divisional Directors/Managers Principal Investigators/Research Team	• Conflict of Interest Policy • Incident Management Policy • Incident Management Procedure • Research Policy 2023 • Human Research Ethics Committee Terms of Reference

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		How does your organisation support you in this? • RiskMan • Incident policy and procedure • Conflict of interest policy			
Research Integrity, Compliance and Institutional Risk Assessment	Monitor and report on clinical trial activity and performance and changes.	**What data do you collect, and why?** Reporting will commence in 2024. Baseline reporting will be National Aggregate Statistics **What metrics do you report on, and why?** • Time to approval HREC and SSA • Actual and expected number of participants • Calendar days from site activation to first patient on trial • Total inbound expected investment • Calendar days from site selection to trial open for recruitment **What is your process for collecting data and reporting on metrics?** Currently, metrics are collected from ERM, there will be a new IT system in 2024, which will report all metrics end to end. **Who do you report to (eg. your governing body)?** • Research Steering Committee which reports into Board. **How often do you have to report (eg. quarterly)?** • End of Calendar year reporting to commence in 2024. **How is this information used to inform ongoing process improvement in the areas of the clinical trial service you are responsible for?** • Shows research activities & areas of the Health Service which have efficient processes and can mentor less efficient and effective areas **How does your organisation support you in this?** • Implementing IT system and Board reporting. **Who in your organisation can help you with this?** • Clinical Units, as the metrics are shared and not mutually exclusive **What defines a change in clinical trial service safety, quality, and/or compliance for you?** • Low numbers of breaches, deviations and Serious Safety Inssues. • Low number of non-compliances with protocols • High number of culturally diverse patients • On/ahead of target recruitment. **What data points do you monitor to look for changes?** See points above. **What is your process for monitoring and identifying changes?** • Sponsor audit reports & root cause analysis. • RiskMan reports • Processes per Standard 1 and 2 in divisional reporting lines **How do you communicate the need for preventative and corrective actions to the clinical trials workforce?** • Communicated on a per project basis & org-wide training, policies and procedures. **How do you measure the impact of these changes?** • Changes to National aggregated statistics	Discovery & Innovation Unit	Clinical Units, including Principal Investigators and Research Managers.	• Research Policy (Part N and P) • Annual and Final Reporting Requirements • Safety Reporting Requirements • Human Research Ethics Committee Terms of Reference • Quality Management Policy • Clinical Governance Committee Terms of Reference • Research Steering Committee • Austin Health Board Meetings • Discovery & Innovation Unit continuous and relevant seminars, training and education

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Research Integrity, Compliance and Institutional Risk Assessment	Conduct clinical trial risk assessments specific to consumers and partnering with consumers and record as required by organisational processes.	**How do you identify, document and manage risks?** Risks are managed via risk mitigation strategies outline in the protocol or a separate document reviewed and approved by the Human Research Ethics Committee **How do you communicate the need for preventive and corrective actions to the clinical trials workforce?** Training on the protocol and risk mitigation strategies **How is the impact of these actions measured?** The number, type and root cause of preventable incidents. **How do you assess whether risk management systems and processes are effective?** The number, type and root cause of preventable incidents. **How do these processes support continuous improvement in safety and quality?** Root cause analysis and corrective actions inform continuous improvement strategies. **How does your organisation support you in managing this?** • ORACLE, continuous improvement database • Quality Improvement Framework.	Principal Investigator & Clinical Manager	Audit & Risk Committee Safety Quality & Risk Committee Director, Enterprise Risk Management Human Research Ethics Committee Discovery & Innovation Unit	• Risk Management Policy • Safety, Quality and Risk Management Committee Terms of Reference • Patient Safety Pulse Page • Patient Safety and Clinical Excellence Framework, Seminars, Webinars, Training • OPPIC, Pulse, ATLAS
Research Integrity, Compliance and Institutional Risk Assessment	Contribute to the development, management, and review of clinical trials service governance	**How do you identify opportunities to involve yourself in this work?** • If there is a need for org-wide governance & oversight. **Do you know if your suggestions were used to support continuous improvement in safety and quality, e.g., implementing practise changes?** • If we are involved, we would be running the project, and therefore evaluating effectiveness and compliance. **What systems and processes do you use for this?** • Divisional Strategy, Risk and Safety, Quality and Risk meeting minutes and reports **Does your organisation support you in taking advantage of these opportunities?** • Support from Divisional Managers and Directors **Who in your organisation can help you with this?** • Patient safety and clinical excellence unit • Divisional Managers and Directors	Clinical Units	Partnering Departments Patient Safety & Clinical Excellence	• Clinical Governance Committee Terms of Reference
	Continuously record decisions and work completed.	**What is your standard procedure for recording your work?** • Project specific correspondence on access restricted H-Drive • Meeting minutes on access restricted H-Drive **Does it define standard timelines and systems for this work?** • Our key performance indicators are outlined in the Discovery & Innovation Unit Onboarding Documents, and spoken about in office-wide daily huddles.	Discovery & Innovation Unit – corporate recording keeping for decision making, reviews, responses and approvals	Executive Safety, Quality and Risk Committee Research Steering Committee Human Research Ethics Committee	• Research Policy 2023 • Work Instructions for the Office • Human Research Ethics Committee Terms of Reference
	Ensure the clinical trial workforce is appropriately credentialled and trained before conducting any research or clinical trial work.	**How does your organisation support you in this?** • To be implemented in 2024, Research Credentialling and training framework. **Who in your organisation can help you with this?** • This is the responsibility of the Discovery & Innovation Unit, and if possible the ATLAS team.	Discovery & Innovation Unit	Principal Investigators /Research Teams Human Research Ethics Committee Research Steering Committee	• Human Research Ethics Committee Terms of Reference • Research Policy 2023 • TBC – Research credentialling and training framework
Research Integrity, Compliance and Institutional Risk Assessment	Advise and assist in the development, periodic review, and updating of research related policies and procedures.	**How familiar are you with the tasks and responsibilities in your position description?** • OfR members have an onboarding process which outlines their roles and responsibilities, including training. **How do these processes support continuous improvement in safety and quality?**	Manager, Discovery & Innovation Unit	Austin Health Research Steering Committee Chief Medical Officer OfR Research Director Executive Policy and Procedure Committee	• OPPIC policy and procedure manual

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		• Research Office has office wide project work that is co-designed with the whole office to ensure relevance knowledge, skills and expertise in policies and procedures. **What systems and processes do you use for this?** • OPPIC **How does your organisation support you in this?** • Provide frameworkto develop policies and procedures. **Who in your organisation can help you with this?** • Manager, Discovery & Innovation Unit and Corporate Policy Officer			
	Maintain a working knowledge of the Organisational Charter, and the Australian Charter of Healthcare Rights	**Identify and locate your Organisational Charter & the Australian Charter of Healthcare Rights?** • See evidence **Where and how do your team members find copies of these?** • OPPIC **Where and how do patients and consumers find copies of these?** • https://www.austin.org.au/your-rights-responsibilities/ **How do you communicate these to your team members?** • OFR team member include these in PICF addendum. • Organsiational Charter is part of onboarding process. **How do you assess team members use of these principles in their everyday work and interactions with service users?** • Huddle check • Quality of minutes • Emails • Daily office wide meetings to discuss roadblocks and seek answers to questions.	Patient Safety and Clinical Excellence Unit	Standard 1 and 2 committees	• OPPIC • Patient Safety and Clinical Excellence • National Standards Page • Austin Health Board Charter • Austin Health Board Committee Charter Manual • Australian Charter of Healthcare Rights • Austin Health – Your Healthcare, Safety and Rights • Organisational Charter Internal Document
Training and Education of both Research Advisors and Stakeholders	Provide feedback on research-related functions to enable continuous improvement.	**What feedback have you received?** • Continuous improvement comes from indirect feedback/problem solving from stakeholders/Research Office • Direct feedback from annual committee surveys. **What improvements have you made in response to feedback?** • Training for HREC members and format of onboarding. • SMART Governance Committee to bring decision makers together, designed with Partnering Departments. Aim to increase efficient and effective governance of research. • Research Architect – Austin Health clinical research management platform	Manager, Discovery & Innovation Unit	Patient Safety and Clinical Excellence Committee Partnering Departments Principal Investigators/Research Team Clinical Units	• Research Steering Committee Terms of Reference • Human Research Ethics Committee Terms of Reference • Research Policy • Quality Management Policy
Training and Education of both Research	Complete regular meetings with Team Leader/Manager to discuss responsibilities and performance.	**How familiar are you with the tasks and responsibilities in your position description?** **How often do you meet with your manager to assess the definition of your role, your performance, and your professional competencies?** • Weekly in One-on-Ones with line manager (O3's) • Weekly in team meetings • Quarterly in performance review. • Daily in Huddles **What systems and processes do you use for this?** • See above **Do you know if your suggestions were used to support continuous improvement in safety and quality, e.g., implementing practise changes?** • Yes because we are used as part of the team to design solution.	Manager, Discovery & Innovation Unit	Chief Medical Officer	• Weekly One-On-One's (O3's) with the Manager **(5.1)** • Probation goals and tools • Daily huddles • Professional Competencies

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Advisors and Stakeholders **Training and Education of both Research Advisors and Stakeholders**		**What systems and processes do you use for this?** • Weekly team meetings, daily huddles and one-on-ones **Does your organisation support you in taking advantage of these opportunities?** • Yes			
	Maintain a working knowledge of organisational informed consent policies, procedures, and related processes and systems	Identify your organisation's informed consent policies and procedures Identify the related processes and systems • See evidence **How do you assess whether team members are aware of and use this knowledge in their everyday work.** • Quality of pre-review of new projects, including issues relating to consent. • Quality of HREC meeting minutes. • Ability to respond to researcher queries around troubleshooting consent issues.	Patient Safety and Clinical Excellence	Human Research Ethics Committee Partnering Departments Principal Investigators National Statement on Ethical Conduct in Research	• OPPIC • OfR Onboarding, Training & Education • Consent Policy • Informed Consent • Shared Decision Making and Informed Consent Committee • Medical Treatment Decision Maker (MTMD) identification Procedure • Research Policy 2023 • Determining Decision Making Capacity • Improving the consumer experience • https://www.informedpicf.com.au/ • https://hemingwayapp.com/ • https://apps.lib.umich.edu/medical-dictionary/ • https://online.stanford.edu/courses/som-y0010-writing-sciences • http://www.vicpcphealthliteracycourse.com.au/
Training and Education of both Research Advisors and Stakeholders	Contribute to the development of organisation-wide informed consent policies and procedures	Identify your organisation's informed consent policies and procedures? • Consent policies and procedures are updated with stakeholder engagement. The Manager, Discovery & Innovation Unit sits on Standard 1 and 2 Committees, which must review the policies and procedures prior to submission to Executive Policy and Procedure Commtitee.	Manager, Discovery & Innovation Unit	Clinical Excellence Lead, St 2 Executive Safety Quality and Risk Committee Chief Medical Officer	• Shared Decision Making and Informed Consent Committee Terms of Reference • Consent Policy • Informed Consent • Shared Decision Making and Informed Consent Committee • Medical Treatment Decision Maker (MTMD) identification Procedure • Research Policy 2023
Training and Education of both Research Advisors and Stakeholders	Provide information and education to researchers on appropriate clinical research practice and research integrity and ways manage this.	**What information and education resources do you provide to the clinical trials workforce?** • TBC - Research credentialling and training framework **How do you ensure regulatory compliance with ICH-GCP and research integrity for the clinical trials workforce?** • GCP certificates are submitted for each project and reviewed by EIG adivsors for currency. **How do you track what education new researchers need to do, and how do you follow up with them to ensure it is done?** • Research Architect – Austin Health clinical research management platform tracks training, and send automatic reminders for training that is expiring. **How do you track when education expires for existing researchers?** • See above. **How do you track who has completed, and passed, what education?** • Research Architect – Austin Health clinical research management platform tracks education. **How do you escalate education non-compliance by the clinical trials workforce and how is this followed-up?**	Discovery & Innovation Unit	Patient Safety and Clinical Excellence Committee Divisional Managers/Director Executive Board	• Research Policy (Part E) • Research Misconduct Procedure • Patient Safety and Clinical Excellence Framework • HREC Committee Terms of Reference • TBC – Research credentialling and training framework

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Training and Education of both Research Advisors and Stakeholders		• Researchers won't receive approvals for their work until they have been adequately trained. **How is the information incorporated into your organisation's training systems?** • In 2025, the Discovery & Innovation Unit will work with ATLAS team to work out integration. **How do you measure the impact of this preparation in submissions to the office?** • If training is successful, submissions should be higher quality in terms of content and completeness. **How does your organisation support you in this?** • Provides training and education framework and already has an org-wide expectation around mandatory training.			
Committee Management	Understand the value of consumer engagement, how it contributes to the safety and quality of health care, and how it supports clinical trial participation	**What resources have you used, and/or training have you undertaken, to educate yourself about consumer engagement?** • In 2024, resources will be available to HREC members, including training. **Have you had any direct interactions with consumers as part of this?** • Process currently not in place **Are examples of good practise, resources, or education and training outcomes ever discussed in staff meetings?** • Process currently not in place **How does your organisation support educating yourself on safely involving consumers?** • ATLAS training modules & Partnering with consumers policies and procedures.	Discovery & Innovation Unit	Clinical Excellence Lead, Standard 2 Executive Safety Quality and Risk Committee Partnering with Consumers Committee Chair, Human Research Ethics Committee	• NSQHSS (2nd Ed) – Standard 2 • Patient Safety and Clinical Excellence Framework • Partnering with Consumer Policy • Recruitment and Orientation for Consumer Partners • Plain Language Coaching - Quality & Safety 07.03.2023
	Manage recruitment, on-boarding, professional development and performance of Committee members.	**What information and education resources do you provide to the clinical trials workforce?** • HREC Member onboarding document/process • Professional Development throughout year • Performance indicators to be implemented in 2024.	Discovery & Innovation Unit, predominantly responsibility of Ethics, Integrity & Governance Advisors	Chief Officer, People and Culture Director, Talent Acquisition and Workforce Planning	• National Statement s5.1, 5.2 • Recruitment and Selection Policy • Human Research Ethics Committee Terms of Reference • Discovery & Innovation Unit Committee Membership Records • Human Research Ethics Committee Minutes
	Ensure compliance with any conflicts of interest and relevant confidentiality requirements.	**What organisational systems and processes must be used to report on, and manage, these situations when they occur?** • Conflicts of Interest are registered at time of project submission. **Who else in your organisation is involved in the management and review of these situations?** • Line Manager, Divisional Manager, Divisional Director, Executive, HREC	Discovery & Innovation Unit through Ethics, Integrity and Governance Advisors read and document Conflicts of Interest. They manage this via Huddle checks, agendas and meeting minutes.	Executive Policy Review Committee General Legal Counsel Chief People and Culture Officer Human Research Ethics Committee.	• The National Statement on Ethical Conduct in Human Research s5.1, 5.2, 5.4, 5.6 • The Australian Code for the Responsible Conduct of Research • Conflicts of Interest Policy • Confidentiality Policy • Human Research Ethics Committee Terms of Reference • Human Research Ethics Committee Minutes
	Ensure Committee members compliance with relevant legislation and guidelines.	**How do you ensure regulatory compliance with ICH-GCP and research integrity for the Human Research Ethics Committee?** • Discovery & Innovation Unit provides mandatory onboarding and continuous training. • Discovery & Innovation Unit (via Ethics, Integrity & Governance Advisors) conducts detailed analysis and checks for compliance with legalisation and guidelines, this is documented in the agenda. Before placing projects on the agenda, the EIG advisors work with the researchers to ensure compliance prior to review.	Discovery & Innovation Unit provides advice to the Human Research Ethics Committee.	Chief People & Culture Officer Executive Policy Review Committee Austin Health Board	• The National Statement on Ethical Conduct in Human Research s5.1.1, 5.1.26 • The Australian Code for the Responsible Conduct of Research • Code of Conduct Policy • Human Research Ethics Committee Terms of Reference • Human Research Ethics Committee Minutes

	The Austin Health Discovery & Innovation Unit are responsible for the strategic and operational management of clinical and non-clinical research, education, training and mentorship of clinical professionals conducting research at Austin Health.

Governance Framework Accreditation Preparedness Activities – Research Office

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

Theme	Description	Reflective questions	Who is involved	Who shares responsibility	• Evidence checklist
Committee Management	Prepare and coordinate meeting agendas, papers, dates and venues relevant to committees and committee members.	**What is your standard procedure for recording your work?** • Access restricted H-Drive for agendas and minutes • Website for dates • Email for Committee members	Discovery & Innovation Unit (Ethics, Integrity & Governance Advisors key responsibilities under the guidance of Team Leaders).	Research Steering Committee Human Research Ethics Committee	• The National Statement on Ethical Conduct in Human Research s5.1.37, 5.2 • Human Research Ethics Committee Terms of Reference • Human Research Ethics Committee Minutes • Ethics, Integrity and Governance Advisor Position Description
	Assist in the preparation of annual reports of HREC activity to internal and external parties/bodies.	**Who do you report to (eg. your governing body)?** • NHMRC • Austin Health Board **How often do you have to report (eg. quarterly)?** • End of calendar year	Manager, Discovery & Innovation Unit	Research Steering Committee	• Human Research Ethics Committee Terms of Reference - Section 15 • Research Policy - Part B, M and P • The National Statement on Ethical Conduct in Human Research - Chapter 5