



National Clinical Trials Governance Framework

Accreditation

Preparedness Activities



Clinical Governance



Consumer Partnership

Consumer or Service User





The **Austin Health acknowledges Consumers and Service Users** as experts working in active partnership with health professionals to have greater control over their lives and healthcare they receive. This involves sharing of knowledge, skills and expertise between staff, service users and people who support consumers to improve health conditions and outcomes.

Governance Framework Accreditation Preparedness Activities – Consumer or Service User

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

#	Responsibility	Evidence checklist	Notes
1.	<p>Speak up about potential/actual safety and quality issues, risks, or incidents that you encounter while participating in the clinical trials service. Communicate about individual needs, preferences and goals.</p>	<p>Tier 1-3 Committee level:</p> <ul style="list-style-type: none"> · Austin Health Consumer Advisory Committee · Partnering with Consumers Committee · Clinical Governance Committee · Research Steering Committee · Human Research Ethics Committee · <p>Org-wide approach to Risk Management, Complaints and Compliments</p> <ul style="list-style-type: none"> · Partnering with Consumers Policy · Consumer Partnership Procedure · Austin Health Patient Feedback Survey (QR code to survey is provided with each Participant Information Statement & Consent Form (PICF) per approved projects · Raise a complaint with Patient Feedback Unit via feedback@austin.org.au. · RiskMan Reporting by Austin Health staff · RiskMan training, Policies and Procedures <p>Project level</p> <ul style="list-style-type: none"> · Research Teams should follow best practice consumer guidelines https://machaustralia.org/themes/consumer-and-community-involvement/ · Research study design inclusive of consumer consultation. · Research feasibility at a clinical unit level (often disease specific) · Research Project amendments based on evidence and/or feedback · Research Annual Reports which ask for commentary from consumers pertaining to specific projects 	

2.	Speak up about potential opportunities you see for improving the clinical trials service	<p>Tier 1-3 Committee level:</p> <ul style="list-style-type: none"> · Austin Health Consumer Advisory Committee · Partnering with Consumers Committee · Clinical Governance Committee · Research Steering Committee · Human Research Ethics Committee · <p>Org-wide approach to Risk Management, Complaints and Compliments</p> <ul style="list-style-type: none"> · Partnering with Consumers Policy · Consumer Partnership Procedure · Austin Health Patient Feedback Survey (QR code to survey is provided with each Participant Information Statement & Consent Form (PICF) per approved projects · Raise a complaint with Patient Feedback Unit via feedback@austin.org.au. · RiskMan Reporting by Austin Health staff · RiskMan training, Policies and Procedures <p>Project level</p> <ul style="list-style-type: none"> · Research Teams should follow best practice consumer guidelines https://machaustralia.org/themes/consumer-and-community-involvement/ · Research study design inclusive of consumer consultation. · Research feasibility at a clinical unit level (often disease specific) · Research Project amendments based on evidence and/or feedback · Research Annual Reports which ask for commentary from consumers pertaining to specific projects 	
3.	Give feedback and compliments and/or raise concerns and make complaints about your experience with the clinical trials service, including participating in organisational feedback surveys	<p>Org-wide approach to Risk Management, Complaints and Compliments</p> <ul style="list-style-type: none"> · Partnering with Consumers Policy · Consumer Partnership Procedure · Austin Health Patient Feedback Survey (QR code to survey is provided with each Participant Information Statement & Consent Form (PICF) per approved projects · Raise a complaint with Patient Feedback Unit via feedback@austin.org.au. · RiskMan Reporting by Austin Health staff · RiskMan training, Policies and Procedures 	
4.	Consider getting involved in the review of safety and quality incidents, clinical trial performance reports, risks, and other related events, where such opportunities exist	<p>Tier 1-3 Committee level:</p> <ul style="list-style-type: none"> · Austin Health Consumer Advisory Committee · Partnering with Consumers Committee · Clinical Governance Committee · Research Steering Committee · Human Research Ethics Committee 	

5.	Consider getting involved in the strategic and operational decision making about the conduct, direction, and priorities of the clinical trials service, where such opportunities exist	<p>Tier 1-3 Committee level:</p> <ul style="list-style-type: none"> · Austin Health Consumer Advisory Committee · Partnering with Consumers Committee · Clinical Governance Committee · Research Steering Committee · Human Research Ethics Committee <p>Affiliated Committee, managed by Process</p> <ul style="list-style-type: none"> · Victorian Translational Research Institute Community Priorities Committee (TBC) 	
6.	Consider getting involved in the development and review of information about clinical trials, either at a trial level or at a service level, where such opportunities exist	<p>Tier 1-3 Committee level:</p> <ul style="list-style-type: none"> · Austin Health Consumer Advisory Committee · Partnering with Consumers Committee · Clinical Governance Committee · Research Steering Committee · Human Research Ethics Committee <p>Affiliated Committee, managed by Process</p> <ul style="list-style-type: none"> · Victorian Translational Research Institute Community Priorities Committee (TBC) <p>Project level</p> <ul style="list-style-type: none"> • Consumers involved in unit level service improvement committees/processes. Consumers should have lived experience for the area they are providing expertise in. Documentation of their participation should be in line with org-wide processes for consumer involved e.g., agenda, minutes, consultation, feedback documents and other correspondence. 	
7.	Consider getting involved in quality improvement projects at the health service organisation, where such opportunities exist	<p>Tier 1-3 Committee level:</p> <ul style="list-style-type: none"> · Austin Health Consumer Advisory Committee · Partnering with Consumers Committee · Clinical Governance Committee · Research Steering Committee · Human Research Ethics Committee <p>Affiliated Committee, managed by Process</p> <ul style="list-style-type: none"> · Victorian Translational Research Institute Community Priorities Committee (TBC) <p>At a project level</p> <ul style="list-style-type: none"> · Embed feedback and consumer check-in points in your protocol · Volunteer for opportunities to help design, plan and implement quality improvement projects 	

8.	Actively involve yourself and your friends, family, and carers, in the decision-making process about your participation in a clinical trial, to the extent that you choose	<ul style="list-style-type: none"> · Patient Safety & Clinical Excellence Framework · Austin Health Shared Decision Making Framework · Participant Information Statement & Consent Form, including appendix with charter of HealthCare Rights and QR code for patient feedback survey · Partnering with Consumers Policy · Consumer Partnership Procedure 	
9.	Share your experiences, to the extent you feel comfortable, at meetings, focus groups, training sessions, or the like as a form of advocacy for clinical trial participants and to improve the clinical trials service	<p>Org-wide & service level</p> <ul style="list-style-type: none"> · Austin Health Consumer Advisory Committee · Partnering with Consumers Committee · Clinical Governance Committee · Research Steering Committee · Human Research Ethics Committee <p>Affiliated Committee, managed by Process</p> <ul style="list-style-type: none"> · Victorian Translational Research Institute Community Priorities Committee (TBC) <p>Project level:</p> <ul style="list-style-type: none"> • Any focus groups, meetings, training sessions • Any alliances, networks or consumer advocacy groups relating to a particular health priority. • Involvement in the design and planning of grants 	
10.	Involve yourself in training where appropriate, to inform and support your engagement in the conduct, direction, and priorities of the clinical trials.	<p>Consumer Training – there are many bodies that provide consumer training. Some of the bodies are listed below, however this list is not exhaustive.</p> <ul style="list-style-type: none"> · Research Teams should follow best practice consumer guidelines https://machaustralia.org/themes/consumer-and-community-involvement/ · Austin Health Mandatory Training for Consumers per: <ul style="list-style-type: none"> ○ Partnering with Consumers Policy ○ Consumer Partnership Procedure 	