NSQHS Standards Clinical Trials Governance Framework Assessment

Final Outcome Report

Western Health

Footscray, VIC

Organisation Code: 210024
Health Service Organisation ID: F7070026
ABN:61 166 735 672
Assessment Date: 04-08 December 2023

Contents

Clinical Trials Governance Framework – Assessment Summary

An overall maturity rating of 2, Growing Systems, has been given for Clinical Trials in Western Health. This has been calculated following a review of evidence and comprehensive discussion with a range of Western Health research and support staff, clinical trial participants, and Executive and Board members. 19 clinical trials were reviewed out of 30 clinical trials currently underway.

There is a solid foundation for clinical trials, including policies, procedures, strategies, research positions, education, and a well-functioning Research Office. Ongoing work is indicated to further develop, implement, and maintain systems to partner with consumers. These partnerships relate to the planning, design, delivery, measurement, and evaluation of clinical trials and the workforce's use of these systems to partner with consumers.

The clinicians interviewed are committed to undertaking clinical trials to inform and provide evidence-based care. There is an extensive range of supporting documents for researchers. They are well-written and easily understood. There are opportunities to strengthen the Organisational and Board involvement in setting the strategic direction for Clinical Trials and Research and monitoring research KPIs.

The Research Strategic Plan sets a well-considered direction for the future expansion and development of clinical trials and other research, capitalising on strengths and opportunities. Partnering with consumers has a mix of initial and growing systems, and plans to develop these further into established systems exist. It is understood that a gap analysis of actions required within partnering with consumers will be undertaken to inform the Office for Research action plan further.

The Clinical Trials Ward is a purpose-built environment where clinical trial participants receive treatment. There is an opportunity to maximise the utilisation of this area in the future.

Considerable work has been undertaken to develop the Aboriginal and Torres Strait Peoples recruited into the Research procedure. It describes the support and consideration required to recruit Aboriginal and Torres Strait Peoples for research projects. To date, there have not been any participants who have identified as First Nations people, and this is an ongoing area for development.

Many examples of well-designed and well-managed clinical trials were seen, with two trials demonstrating consumer advisory / advocate input into the design and review of the trials.

Org Name : Western Health
Org Code : 210024

Clinical Trials Assessment Maturity Scorecard

Determine the mean maturity score:

$$\text{Mean maturity score} = \frac{\text{Total rating score for Clinical Governance Standard + Total rating score for Partnering with Consumers Standard}}{\text{Total number of actions}}$$

An example of calculations is provided at **Attachment 1**.

Maturity rating	Mean maturity score	Description
Established systems	3.0	The accreditation assessment team reviews evidence to demonstrate that all requirements of an action are in place and integrated within the operations of the health service organisation.
Growing systems	2.0–2.99	The accreditation assessment team reviews evidence to demonstrate that some of the requirements of an action are in place, with plans prepared to implement improvements to address identified gaps.
Initial systems	1.0–1.99	The evidence reviewed by the accreditation assessment team demonstrates that the requirements of the action are yet to be commenced or implemented.

Mean maturity score:

Total rating score for Clinical Governance Standard (40)	40
Total rating score for Partnering with Consumers Standard (15)	15
Total number of actions	27
Mean maturity	2.03
Overall maturity rating	**Growing systems**

Sites for Assessment

Western Health

Site	HSFID	Address	Visited	Mode
Western Health Clinical Trials Framework	O100838	176 Furlong Road ST ALBANS VIC 3021 Australia	Yes	On Site

Standard 1 - Clinical Governance

Leaders of a health service organisation have a responsibility to the community for continuous improvement of the safety and quality of their services, and ensuring that they are person centred, safe and effective.

ACTION 1.01		
The governing body: a. Provides leadership to develop a culture of safety and quality improvement, and satisfies itself that this culture exists within the organisation b. Provides leadership to ensure partnering with patients, carers and consumers c. Sets priorities and strategic directions for safe and high-quality clinical care, and ensures that these are communicated effectively to the workforce and the community d. Endorses the organisation's clinical governance framework e. Ensures that roles and responsibilities are clearly defined for the governing body, management, clinicians and the workforce f. Monitors the action taken as a result of analyses of clinical incidents g. Reviews reports and monitors the organisation's progress on safety and quality performance		
Rating	**Applicable HSF IDs**	**Recommendation(s) / Risk Rating & Comment**
Growing systems	All	**Comment:** The Board has a strong focus on research and values its inherent relationship with clinical care through the translation of evidence into practice. There is a Research Strategic Plan entitled Best Research for Best Care, which was developed by the Office for Research and compliments the Western Health Strategic Plan. An Executive Summary by the Board Chair in future Research Strategic Plans would be a way to further demonstrate the Board's influence on the strategic direction of clinical trials within Western Health. Clinical trial activities and performance measures are summarised in second monthly report to the Chief Medical Officer, and an annual presentation is given to the Board. In line with the requirements related to the quarterly reporting of performance measures outlined in Action 1.01, there is an opportunity to strengthen the reporting of more specific data related to clinical trials, including the number of clinical trials underway and Site-Specific Assessment (SSA) timelines, which would provide more visibility to the Board of clinical trial performance through quarterly reporting. The Clinical Trials Framework was presented to the October 2023 Board meeting and was approved and endorsed.

ACTION 1.01		
The governing body: a. Provides leadership to develop a culture of safety and quality improvement, and satisfies itself that this culture exists within the organisation b. Provides leadership to ensure partnering with patients, carers and consumers c. Sets priorities and strategic directions for safe and high-quality clinical care, and ensures that these are communicated effectively to the workforce and the community d. Endorses the organisation's clinical governance framework e. Ensures that roles and responsibilities are clearly defined for the governing body, management, clinicians and the workforce f. Monitors the action taken as a result of analyses of clinical incidents g. Reviews reports and monitors the organisation's progress on safety and quality performance		
		Recommendation: Develop a quarterly Board Report detailing specific performance data related to clinical trials including the number of clinical trials underway and Site-Specific Assessment (SSA). **Risk Rating:** Low

ACTION 1.03		
The health service organisation establishes and maintains a clinical governance framework, and uses the processes within the framework to drive improvements in safety and quality		
Rating	**Applicable HSF IDs**	**Recommendation(s) / Risk Rating & Comment**
Growing systems	All	**Comment:** There is a Clinical Trials Framework, approved by the Board, outlining the quality and safety mechanisms in place for Clinical Trials. There are two committees related to Clinical Trial Work: the Research Strategic Steering committee which meets annually, and the Education and Research Committee which is newly formed and reports through to the Best Practice Committee. There is an extensive work plan generated from the annual Research Strategic Steering Committee, and this plan is updated with progress reported back at the next meeting. This committee is well placed to include Board membership. It was noted that the terms of reference for the research and education Steering Committee are aligned mostly with education and there is an opportunity to have a more focused approach to research reflected in future terms of reference. There is an opportunity to clarify on the Western Health Committee chart where the Education and Research Committee sits. It was noted that there was not a consumer or a Board member on the Education and Research committee, and this could be considered in the future. **Recommendation:** Review the terms of reference for the Education and Research Steering Committee and strengthen the objectives related to Research. Consider including a consumer and Board member on this committee. **Risk Rating:** Low

ACTION 1.04		
The health service organisation implements and monitors strategies to meet the organisation's safety and quality priorities for Aboriginal and Torres Strait Islander people		
Rating	**Applicable HSF IDs**	**Recommendation(s) / Risk Rating & Comment**
Growing systems	All	**Comment:** A new process which has been put into place whereby clinical trial participants in the screening phase are asked whether they identify as First Nations Peoples. To date, there have been no trial participants who identify as Aboriginal or Torres Strait Islander people, however, there is a good process which has been established whereby any Aboriginal trial participant would have a support person from the Aboriginal Health Team allocated. There is an opportunity to be more proactive in seeking input from First Nations people when setting the strategic direction for clinical trials in Western Health. **Recommendation:** Consider progressing ongoing community engagement with Aboriginal and Torres Strait Islander people to set clinical trial strategy and monitor the protocols established to recruit and support Aboriginal and Torres Strait Islander trial participants. **Risk Rating:** Low

ACTION 1.05		
The health service organisation considers the safety and quality of health care for patients in its business decision-making		
Rating	**Applicable HSF IDs**	**Recommendation(s) / Risk Rating & Comment**
Growing systems	All	**Comment:** The Research Governance Office has a designated budget and office space allocated. There is a Clinical Trials ward at Sunshine Hospital, and some clinical departments have Research Units including Research Nurses. Additional space and resources for additional positions would be welcome in the future as Western Health increases its clinical activity. Clinical Trials have been considered in the planning of health service expansion within Western Health, including the new Footscray Hospital. It was apparent that Divisions where there were research units with allocated funding and positions for research nurses and clinicians were better placed to promote and support clinical trials and research, and to assist junior doctors, nurses, and allied health to embark on research. There was variation apparent in whether research nurses were funded to attend external education and conferences. One suggestion made to the assessors by a number of researchers was for the establishment of a central Clinical Trials Unit which could work particularly in Divisions where there were no existing stand-alone research positions. **Recommendation:** The concept of a Clinical Trials Unit could be considered in future planning processes. **Risk Rating:** Low

ACTION 1.06		
Clinical leaders support clinicians to: a. Understand and perform their delegated safety and quality roles and responsibilities b. Operate within the clinical governance framework to improve the safety and quality of health care for patients		
Rating	**Applicable HSF IDs**	**Recommendation(s) / Risk Rating & Comment**
Growing systems	All	**Comment:** It is mandatory for all staff involved in clinical trials to complete the Good Clinical Practice education, as well as the ACTEC Introduction to Clinical Trials module. Researchers are aware of their quality and safety roles in regard to clinical trials, and there is ongoing discussion at the Research Coordinators Group concerning issues such as what type of incidents should be reported through RiskMan versus through the Serious Adverse Events process. **Recommendation:** Suggestions for strengthening some components of the Clinical Trials Framework such as increasing in-house auditing of clinical trials and increasing education focusing on Partnering with Consumers have been made in other Actions. **Risk Rating:** Low

ACTION 1.07		
The health service organisation uses a risk management approach to: a. Set out, review, and maintain the currency and effectiveness of, policies, procedures and protocols b. Monitor and take action to improve adherence to policies, procedures and protocols c. Review compliance with legislation, regulation and jurisdictional requirements		
Rating	**Applicable HSF IDs**	**Recommendation(s) / Risk Rating & Comment**
Growing systems	All	**Comment:** There is a well-written and comprehensive set of Policies and Procedures in place providing clear guidance to researchers undertaking clinical trials. The policies are available on the Western Health website and are managed through the Western Health policy management system. All policies and procedures are in date. There are examples of continuing improvement, such as the move to logging all new clinical trials in the REDCap database, allowing better data capture and quality oversight. The Low-Risk Ethics committee was recently reviewed and has changed its meeting schedule to better meet the needs of clinicians. In addition to Sponsor monitoring, there is in-house auditing of selected clinical trials by the Research Governance Office. At present, this is limited by capacity and tends to be carried out where issues or concerns have been identified. It would be beneficial to be more proactive in auditing and to include a process whereby the implementation of recommendations from these audits are monitored and reported back as part of the annual project report. **Recommendation:** An audit template and calendar could be developed to carry out proactive audits which could be undertaken by researchers or peer researchers / research units particularly for studies that are not sponsored and subject to external auditing processes. These audits could include the checking of consent, clinical records management, and GCP education certificates, and the implementation of audit recommendations could be reported and monitored. **Risk Rating:** Low

ACTION 1.08		
The health service organisation uses organisation-wide quality improvement systems that: a. Identify safety and quality measures, and monitor and report performance and outcomes b. Identify areas for improvement in safety and quality c. Implement and monitor safety and quality improvement strategies d. Involve consumers and the workforce in the review of safety and quality performance and systems		
Rating	**Applicable HSF IDs**	**Recommendation(s) / Risk Rating & Comment**
Growing systems	All	**Comment:** As stated above, there is in place a safety and quality process for clinical trials with examples of improvement evident. There are opportunities for improvement in areas such as consumer and researcher feedback, trial auditing, and the reporting of KPIs to relevant stakeholders. **Recommendation:** Consideration be given to further develop the safety and quality processes for clinical trials in areas such as consumer and researcher feedback, trial auditing, and the reporting of KPIs to relevant stakeholders. **Risk Rating:** Low

ACTION 1.09		
The health service organisation ensures that timely reports on safety and quality systems and performance are provided to: a. The governing body b. The workforce c. Consumers and the local community d. Other relevant health service organisations		
Rating	**Applicable HSF IDs**	**Recommendation(s) / Risk Rating & Comment**
Growing systems	All	**Comment:** A second monthly KPI report is provided to the Chief Medical Officer, and an annual presentation of research including clinical trials is provided to the Board. An annual Research Report is produced each year and provides valuable performance information on clinical trials as well as summary information on as selection of research projects. The report is clear and in plain English, available on the Western Health website for consumers and the workforce. However, it was noted that the most recent report available on the website was the 2019 – 2020 report. Research is showcased each year during Research Week, with awards given. **Recommendation:** As mentioned previously, review the information provided to the Board regarding clinical trials performance and include more specific data. It is also suggested that the research workforce is provided with some data related to issues such as time taken to give SSA approvals and other Research Governance KPIs. **Risk Rating:** Low

ACTION 1.10		
The health service organisation: a. Identifies and documents organisational risks b. Uses clinical and other data collections to support risk assessments c. Acts to reduce risks d. Regularly reviews and acts to improve the effectiveness of the risk management system e. Reports on risks to the workforce and consumers f. Plans for, and manages, internal and external emergencies and disasters		
Rating	**Applicable HSF IDs**	**Comment**
Established systems	All	The Research Governance Office has a local risk register with 11 current risks identified. Resourcing and lack of in-house pathology are the top two rated risks. There were no risks related to research or clinical trials on the Western Health Strategic or Operational Risk Register. Clinical trial risks are carefully considered in the development and approval of study protocols and overseen during the external monitoring and auditing processes. It was noted that a new risk related to Partnering with Consumers was recently entered into the risk register, in recognition of the need to progress further work to partner consumers in clinical trial strategic planning and research co-design.

ACTION 1.11		
The health service organisation has organisation-wide incident management and investigation systems, and: a. Supports the workforce to recognise and report incidents b. Supports patients, carers and families to communicate concerns or incidents c. Involves the workforce and consumers in the review of incidents d. Provides timely feedback on the analysis of incidents to the governing body, the workforce and consumers e. Uses the information from the analysis of incidents to improve safety and quality f. Incorporates risks identified in the analysis of incidents into the risk management system g. Regularly reviews and acts to improve the effectiveness of the incident management and investigation systems		
Rating	**Applicable HSF IDs**	**Recommendation(s) / Risk Rating & Comment**
Growing systems	All	**Comment:** As with all clinical units in Western Health, the RiskMan system is utilised to record incidents. There has been recent work to clarify what should be recorded in the RiskMan system and what should be recorded as Serious Adverse Events (SAEs) and adverse events. While it is mostly clear, there are grey areas where participants may, for example, suffer from reactions to drugs taken according to trial protocol which could be regarded as hospital-acquired complications as well as adverse events. Incidents where a participant may fall and injure themselves during a clinical trial visit would be reported in RiskMan, and may or may not be related to the clinical trial drug, and could be considered adverse events. These grey areas are not specific to Western Health. During assessment, it was clear that clinical incidents were being logged in RiskMan, but there was no specific data to show aggregated data and trends for clinical trial incidents. **Recommendation:** In line with Action 1.11 (d) and 1.11 (e), consider the implementation of a system to aggregate and trend clinical incident data which could be used to inform organisational-wide improvement. **Risk Rating:** Low

ACTION 1.12		
The health service organisation: a. Uses an open disclosure program that is consistent with the Australian Open Disclosure Framework b. Monitors and acts to improve the effectiveness of open disclosure processes		
Rating	**Applicable HSF IDs**	**Comment**
Established systems	All	Open Disclosure is well practiced in clinical trials, particularly related to Serious Adverse Events (SAE). Clinicians and nurses are well aware of the requirements within the open disclosure framework and participants felt well informed of the risks of trials and supported when SAEs and adverse events occur.

ACTION 1.13		
The health service organisation: a. Has processes to seek regular feedback from patients, carers and families about their experiences and outcomes of care b. Has processes to regularly seek feedback from the workforce on their understanding and use of the safety and quality systems c. Uses this information to improve safety and quality systems		
Rating	**Applicable HSF IDs**	**Recommendation(s) / Risk Rating & Comment**
Growing systems	All	**Comment:** It has been identified on the Clinical Trials Governance Framework (CTGF) Quality Improvement Plan that more work is indicated in seeking feedback from research participants, the clinical trial workforce, and trial sponsors, and that a gap analysis will be done to better define this work. To date, feedback has been received from trial participants informally during follow up phone calls and outpatient sessions. The Maternal and Foetal Medicine Division has a good process for feeding back the outcome of clinical trials to participants who indicated they would like to be informed of the results. A short plain English synopsis is written, with references included to relevant publications. There is now an opportunity to proactively seek feedback at the conclusion of a trial and to use these trends to inform clinical trial practice across the organisation. **Recommendation:** Progress the actions in the Quality Plan to better capture and utilise feedback from trial participants to drive system-wide improvement. See Action 2.02 below.

ACTION 1.13		
The health service organisation: a. Has processes to seek regular feedback from patients, carers and families about their experiences and outcomes of care b. Has processes to regularly seek feedback from the workforce on their understanding and use of the safety and quality systems c. Uses this information to improve safety and quality systems		
		Risk Rating: Low

ACTION 1.14		
The health service organisation has an organisation-wide complaints management system, and: a. Encourages and supports patients, carers and families, and the workforce to report complaints b. Involves the workforce and consumers in the review of complaints c. Resolves complaints in a timely way d. Provides timely feedback to the governing body, the workforce and consumers on the analysis of complaints and actions taken e. Uses information from the analysis of complaints to inform improvements in safety and quality systems f. Records the risks identified from the analysis of complaints in the risk management system g. Regularly reviews and acts to improve the effectiveness of the complaints management system		
Rating	**Applicable HSF IDs**	**Recommendation(s) / Risk Rating & Comment**
Growing systems	All	**Comment:** Complaints related to clinical trials are entered into REDCap and received and investigated by the Research Program Director. The complaints are noted in the bimonthly report to the CMO. To date, there has not been any trending of complaint themes to inform organisational-wide improvements, as required under Action 1.14 (e), and it is suggested that this be implemented. It is noted that trial participants are able to use the Research page of the website to make a complaint and that this will be part of the ongoing improvement work identified in the CTGF Quality Plan. There is a process for investigation of research misconduct, and an example of the management of an actual case of research misconduct was provided. **Recommendation:** Implement a system to trend complaint themes to inform organisational-wide improvements, as required under Action 1.14 (e). **Risk Rating:** Low

ACTION 1.15		
The health service organisation: a. Identifies the diversity of the consumers using its services b. Identifies groups of patients using its services who are at higher risk of harm c. Incorporates information on the diversity of its consumers and higher risk groups into the planning and delivery of care		
Rating	**Applicable HSF IDs**	**Recommendation(s) / Risk Rating & Comment**
Growing systems	All	**Comment:** The Western Health catchment has a very diverse population and the clinical trial workforce were well aware of the needs and challenges when dealing with people who speak English as a second language, and the challenges of explaining complex science in plain English. Interpreters are used extensively, with a particular emphasis on carefully gaining formal informed and understood consent. Challenges remain in gaining access to participant information in community languages and in using standardised tests that are not validated in other languages, which can lead to the non-inclusion of participants on the basis of language. This challenge is not specific to Western Health. **Recommendation:** Continue to develop processes to support the inclusion of trial participants from diverse backgrounds, including the translation of participant information. **Risk Rating:** Low

ACTION 1.16		
The health service organisation has healthcare record systems that: a. Make the healthcare record available to clinicians at the point of care b. Support the workforce to maintain accurate and complete healthcare records c. Comply with security and privacy regulations d. Support systematic audit of clinical information e. Integrate multiple information systems, where they are used		
Rating	**Applicable HSF IDs**	**Comment**
Established systems	All	The new eMR includes tabs for Research Notes and allows research appointments to be recorded within the clinical record. Hard copies of records are kept for each trial participant, appropriately secured in locked rooms / cupboards in line with the data management requirements of the HREC and national standards. The records are included in the external auditing process undertaken by trial sponsors, and could also be included in future proactive in-house auditing. At the end of trials, the records are archived and subsequently destroyed in line with legislative timelines.

ACTION 1.20		
The health service organisation uses its training systems to: a. Assess the competency and training needs of its workforce b. Implement a mandatory training program to meet its requirements arising from these standards c. Provide access to training to meet its safety and quality training needs d. Monitor the workforce's participation in training		
Rating	**Applicable HSF IDs**	**Comment**
Established systems	All	There is a comprehensive range of training opportunities available for researchers, some of which are provided by the Office for Research. It has been identified that there is training gap related to partnering with consumers, although it is acknowledged that there is beginning to be some education related to co-design principles. It is mandatory for all researchers to undertake GCP and the Introduction to Clinical Trials module produced by the Australian Clinical Trials Education Centre. Training completion certificates are required to be submitted as part of Site-Specific Assessment (SSA) and low risk HREC applications. It would be helpful to provide aggregated data for future assessments on whether certificates have been received for all researchers on all approved trials.

ACTION 1.29		
The health service organisation maximises safety and quality of care: a. Through the design of the environment b. By maintaining buildings, plant, equipment, utilities, devices and other infrastructure that are fit for purpose		
Rating	**Applicable HSF IDs**	**Recommendation(s) / Risk Rating & Comment**
Growing systems	All	**Comment:** Clinical trials take place in wards, clinics, and outpatient areas. In addition, a clinical trials ward at Sunshine Hospital is a purpose-built environment where clinical trial participants receive treatment and follow-up. There is an opportunity to maximise the utilisation of this area in the future. The equipment tagging and checking were out of date on all the equipment seen by the assessors. **Recommendation:** Clarify the person responsible for managing the WH&S in the Sunshine Hospital Clinical Trials Ward and prioritise the checking of equipment. **Risk Rating:** Moderate

ACTION 1.33		
The health service organisation demonstrates a welcoming environment that recognises the importance of the cultural beliefs and practices of Aboriginal and Torres Strait Islander people		
Rating	**Applicable HSF IDs**	**Recommendation(s) / Risk Rating & Comment**
Growing systems	All	**Comment:** There has been consideration given to providing a welcoming environment for Aboriginal people in the Clinical Trials Unit, with a beautiful mural in place. **Recommendation:** As mentioned before, there is scope to progress additional work to partner with First Nations people related to research, cultural safety, and the welcoming environment. **Risk Rating:** Moderate

Standard 2 - Partnering with Consumers

Leaders of a health service organisation develop, implement and maintain systems to partner with consumers. These partnerships relate to the planning, design, delivery, measurement and evaluation of care. The workforce uses these systems to partner with consumers.

ACTION 2.01		
Clinicians use the safety and quality systems from the Clinical Governance Standard when: a. Implementing policies and procedures for partnering with consumers b. Managing risks associated with partnering with consumers c. Identifying training requirements for partnering with consumers		
Rating	**Applicable HSF IDs**	**Recommendation(s) / Risk Rating & Comment**
Growing systems	All	**Comment:** The Western Health (WH) Research Strategic Steering Committee oversees the implementation of the WH Clinical Trials Governance Framework. There is an Education and Research Steering Committee and a Research Co-ordinator Group which support clinical trials. It was reported that there is inadequate consumer representation on these committees. WH utilises the safety and quality systems from the Clinical Governance Standard when implementing policies and procedures for partnering with consumers. Considerable work has been undertaken to develop the Aboriginal and Torres Strait Peoples Recruited into Research procedure. It describes the support and consideration required to recruit Aboriginal and Torres Strait Peoples for research projects. It was reported there are no clinical trial participants recruited from an Aboriginal and Torres Strait population. The Office for Research (OFR) has a central clinical trials risk register although it was reported that currently they are not able to capture all risks and, therefore, manage all risks across WH associated with partnering with consumers. There is no specific training available for partnering with consumers regarding clinical trials although there is expertise that could facilitate this. There are a small number of clinical areas and staff who are partnering with consumers to develop, implement, and maintain systems to partner with consumers for clinical trials. The remaining clinical staff interviewed reported they are aware of the requirements to partner with consumers and reported being keen to develop a better understanding and skills to undertake this.

ACTION 2.01		
Clinicians use the safety and quality systems from the Clinical Governance Standard when: a. Implementing policies and procedures for partnering with consumers b. Managing risks associated with partnering with consumers c. Identifying training requirements for partnering with consumers		
		Recommendation: • Review the membership of the steering committees to include consumer representatives. • Establish processes to identify and manage risk associated with partnering with consumers. • Identify training requirements for partnering with consumers and develop training programs to support this. **Risk Rating:** Low

ACTION 2.02		
The health service organisation applies the quality improvement system from the Clinical Governance Standard when: a. Monitoring processes for partnering with consumers b. Implementing strategies to improve processes for partnering with consumers c. Reporting on partnering with consumers		
Rating	**Applicable HSF IDs**	**Recommendation(s) / Risk Rating & Comment**
Growing systems	All	**Comment:** The OFR has an established Clinical Trails Governance Framework (CTGF) Quality Improvement Plan (QIP). This was updated during the assessment period to include additional identified areas for improvement. The OFR has planned to undertake a further gap analysis against the Standard 2 Partnering with Consumers actions. The OFR has developed a clinical trials participant experience survey to capture consumer feedback. The survey is promoted on the WH website throughout the organisation on posters and clinical trials participants can complete the survey via REDCAP and log on by scanning the QR code. Data collection is in progress and is yet to be collated or analysed. The survey is only available in the English language. **Recommendation:** • Explore translating the survey into the most common language of consumers. • Develop and report strategies to improve processes for partnering with consumers from the clinical trial participants' experience survey data. • Undertake a gap analysis to further inform the quality improvement action plan. • Monitor processes for partnering with consumers and ensure improvements can be defined and demonstrated. **Risk Rating:** Low

ACTION 2.03		
The health service organisation uses a charter of rights that is: a. Consistent with the Australian Charter of Healthcare Rights b. Easily accessible for patients, carers, families and consumers		
Rating	**Applicable HSF IDs**	**Recommendation(s) / Risk Rating & Comment**
Initial systems	All	**Comment:** WH displays and promotes the use of the Charter of Healthcare Rights throughout the organisation. The clinical trial participants interviewed were not aware of the Charter of Rights and could not recall receiving this information. Discussions with staff confirmed that the Charter of Rights is not currently embedded in processes or applied to clinical trials, or provided to clinical trial participants. **Recommendation:** Embed information on healthcare rights consistent with the Australian Charter into operational processes for all clinical trial consumers and their carers. **Risk Rating:** Low

ACTION 2.04		
The health service organisation ensures that its informed consent processes comply with legislation and best practice		
Rating	**Applicable HSF IDs**	**Comment**
Established systems	All	Interviews with staff indicated that they understood their responsibilities with respect to informed consent, and the documentation reviewed confirmed that the consent policy and processes comply with legislation and reference best practices. Each clinical trial department audits compliance with the informed consent process and documentation, and this is reported to the OFR in their respective Clinical Trials Annual Progress Report.

ACTION 2.05		
The health service organisation has processes to identify: a. The capacity of a patient to make decisions about their own care b. A substitute decision-maker if a patient does not have the capacity to make decisions for themselves		
Rating	**Applicable HSF IDs**	**Comment**
Established systems	All	Interviews with staff and a review of documentation show there are processes in place to establish a patient's capacity to make decisions regarding their own care, plus the process to be followed if a substitute decision-maker is required. Staff were able to articulate this process and access the relevant policy.

ACTION 2.08		
The health service organisation uses communication mechanisms that are tailored to the diversity of the consumers who use its services and, where relevant, the diversity of the local community		
Rating	**Applicable HSF IDs**	**Recommendation(s) / Risk Rating & Comment**
Initial systems	All	**Comment:** WH provides care to a broad and diverse population. It was reported that there are over 110 different languages spoken. Interpreters are accessed to recruit clinical trial participants from culturally diverse backgrounds. Discussions with staff and a review of information provided to consumers confirmed that all information is only available in English. **Recommendation:** • Review communication mechanisms to ensure that they meet the needs and reflect the diversity of the local population. • Monitor and report the use of interpreter services for clinical trials. **Risk Rating:** Low

ACTION 2.09		
Where information for patients, carers, families and consumers about health and health services is developed internally, the organisation involves consumers in its development and review		
Rating	**Applicable HSF IDs**	**Recommendation(s) / Risk Rating & Comment**
Initial systems	All	**Comment:** Interviews with staff and the clinical trial information reviewed by the assessors found there is limited consumer participation in developing or reviewing clinical trial participant information. All consumer and carer information packages or resources regarding clinical trials are provided in English. Given the diversity of the population (greater than 110 languages of the local population), consumer information is not culturally appropriate or available in different languages / accessible formats. Two examples of how clinical teams partner with consumers include the Maternal Foetal Medicine unit, which engages a consumer advocate / advisor to review and amend clinical trial participant information prior to publication. An example of this is the PRECeDe patient booklet. The ICU Resolve Clinical Trial Project was co-designed with peer support ICU survivors. The ICU survivors assisted clinical staff in developing the ICU clinical trial protocol. The project is now in the implementation stage and a consumer panel is currently being established as part of the clinical trial management process. It was reported that no evaluation reports on existing clinical trial participant information publications had been undertaken. **Recommendation:** Seek consumer input in developing, reviewing, and evaluating the internal clinical trial participation information that is provided for their use. **Risk Rating:** Low

ACTION 2.10		
The health service organisation supports clinicians to communicate with patients, carers, families and consumers about health and health care so that: a. Information is provided in a way that meets the needs of patients, carers, families and consumers b. Information provided is easy to understand and use c. The clinical needs of patients are addressed while they are in the health service organisation d. Information needs for ongoing care are provided on discharge		
Rating	**Applicable HSF IDs**	**Recommendation(s) / Risk Rating & Comment**
Initial systems	All	**Comment:** The interview with two clinical participants confirmed the documentation they received regarding clinical trials was understandable, met their needs, and was adequate for them to make informed decisions. The OFR acknowledged that the information currently provided is only available in English. This does not support clinicians in communicating with clinical trial participants about the clinical trials in a way that meets the needs of participants, carers, and consumers. It was reported that this will be included in the gap analysis and CTGF QIP. **Recommendation:** Establish mechanisms to support clinical trial participants / consumers with information about their current care regarding clinical trials and their ongoing care that is easy to understand and use. **Risk Rating:** Low

ACTION 2.14		
The health service organisation works in partnership with consumers to incorporate their views and experiences into training and education for the workforce		
Rating	**Applicable HSF IDs**	**Recommendation(s) / Risk Rating & Comment**
Initial systems	All	**Comment:** It was reported and documented in the CTGF QIP by the OFR that there is no consumer engagement training module for clinical trials in the WH research training calendar. Clinical staff interviewed confirmed they had not undertaken any training regarding partnering with consumers regarding clinical trials. Staff expressed interest in doing so and welcomed the opportunity for consumer views and experiences to be incorporated into training and education for the workforce. **Recommendation:** Engage consumers, their views and experiences, in the clinical trials education workforce program. **Risk Rating:** Low