

**KEY ACTIONS**  
for health service  
organisations

**Fact sheet 4:**  
**National Clinical Trials Governance Framework –**  
**Roles and functions of the**  
**governing body/health service**  
**organisation boards/CEOs**

**Background**

The Australian Commission on Safety and Quality in Health Care (the Commission) has developed the National Clinical Trials Governance Framework (Governance Framework) as a first step towards implementing the National Safety and Quality Health Service (NSQHS) and achieving accreditation of health services for the conduct of clinical trials.

The Governance Framework aims to ensure that clinical trials are conducted in a safe environment and in a high-quality manner for improved health outcomes for patients and the community. The Governance Framework is based on the NSQHS Standard 1: Clinical Governance Standard and Standard 2: Partnering with Consumers.

Since 2013, it has been mandatory for all public and private hospitals and day procedure services to be assessed through an independent accreditation process to determine whether they have implemented the NSQHS Standards.

Following the pilot, it is anticipated that clinical trial services will be assessed using a maturity scale for each action within the Governance Framework to provide a description of success. That is, the Commission recognises that health services will be at different stages of maturity in their ability to implement the actions provided in the Governance Framework. It is expected that improvements should be achievable over a planning cycle of three years, although this will depend on the health service organisation.

The maturity scale is a guide for progressive improvements in each of the criteria within the Governance Framework including: demonstration that initial systems are in place; the health service organisation is growing systems and the health service organisation has established systems.

It is anticipated that, accreditation to the NSQHS Standards will optimise organisational strategic planning to deliver clinical trial services, and assess that efficient processes have been implemented to undertake:

- Trial site feasibility assessment
- Pre-recruitment activities (timely ethics and local site review and approval)
- Participant recruitment
- Trial management
- Workforce management
- Trial related financial management.

Health service organisations will be required to attest that Actions 1.1 and 1.2 of the NSQHS Standards, which explicitly set out key responsibilities for governing bodies, have been met.



## What is the role of the governing body?

A governing body is an individual or group that has ultimate responsibility for strategic decisions affecting safety and quality in a health service organisation. It may be a board, chief executive officer, organisation owner partnership. It is the highest level of governance.

The governing body ensures, endorses and monitors multidisciplinary teams of experienced staff managers including, finance, human resources personnel, clinical and non-clinical managers, clinical trial workforce, informational technology (IT) staff, the Human Research Ethics Committee (HREC) office, research and site-specific assessment office. The governing body is ultimately responsible for ensuring an appropriate institutional response to the Governance Framework and establishing management practices for the responsible conduct of clinical trials across their health service organisation or trial site. The governing body establishes a strong safety and risk management culture through an effective clinical trials governance system to ensure clinical trial services operate well and deliver high-quality clinical trials in a safe environment.

The governing body identifies and complies with laws, regulations, national and jurisdictional guidelines and policies relating to the conduct of clinical trials. The governing body ensures there is appropriate designation of responsibility and accountability with clear lines of communication between all those involved in delivering clinical trial services.

The governing body demonstrates robust leadership and strategic planning for clinical trial service provision and provides adequate resources and stable infrastructure to support clinical trials with adequate staff and the required resources to support relevant clinical trial information systems.

## Clinical Governance Standard

The Clinical Governance Standard aims to ensure leaders of a health service organisation have a responsibility to the community for continuous improvement of the safety and quality of their organisation, including clinical trial services, and ensuring that they are patient centred, safe and effective.

## Roles and functions of the governing body/ health service organisation boards/CEOs

- Establish and support a multidisciplinary team of experienced staff including heads of clinical departments, finance, human resources, clinical and non-clinical managers, trial investigator and their clinical trial teams - including trial managers, IT staff, the human research ethics office, research office and/or site-specific assessment office
- Establish and maintain the Governance Framework and management practices for the responsible conduct of clinical trials across their health service organisation and delegate authority to manage clinical trial service provision
- Ensure clinical trial services and all services are run well and deliver high-quality clinical trials in a safe environment
- Establish a strong quality culture through a clinical trial governance system that operates effectively
- Ensure there is an ongoing focus on quality improvement
- Take the lead on setting the organisations expectations for partnering with consumers
- Review reports on the health service organisations clinical trial service performance
- Allocate time at governing body meetings to review clinical trial service governance issues and ensures the effectiveness of systems to address issues.

## Partnering with Consumers Standard

The Partnering with Consumers Standard aims to ensure leaders of a health service organisation develop, implement and maintain systems to partner with consumers. These partnerships relate to the planning, design, measurement and evaluation of care.

## Roles and functions of the governing body/ health service organisation board/CEOs

- Show leadership and commitment to partnerships with consumers regarding clinical trial services
- Ensure high-level policies and procedures that support partnerships with consumers



- Ensure that the organisation has effective systems for consumer complaints and open disclosure about the care provided through a clinical trial, and monitor performance of these systems
- Ensure consumer input into decisions of the governing body regarding clinical trial service provision
- Create opportunities for consumer involvement in clinical trial subcommittees of the governing body
- Ensure that organisational systems support consumer engagement in decision-making about clinical trial services and clinical trial participation
- When appropriate, set up a specific consumer advisory committee to the board on clinical trial related matters.

## Next Steps

1. In early 2020, the Commission will pilot the Governance Framework in hospitals and day procedure units. Insights gained from the pilot will inform the approach to implementing the Governance Framework and the refinement of supporting resources.
2. Following the pilot, it is anticipated that when your organisation accreditation next occurs, your clinical trials service will also be assessed to the actions identified in the Governance Framework using a maturity scale.

## Find out more

Information on the Governance Framework is available on the Commission website at [safetyandquality.gov.au/clinical-trials](https://safetyandquality.gov.au/clinical-trials)

### Relevant information and documents:

[National Clinical Trials Governance Framework and User Guide for Health Service Organisations Conducting Clinical Trials](#)

[National Clinical Trials Governance Framework introductory video](#)

[National Clinical Trials Governance Framework fact sheets](#)

[NSQHS Standards \(second edition\)](#)

[National Model Clinical Governance Framework](#)

[NSQHS Standards User Guide for Governing Bodies](#)

[NSQHS Standards Fact Sheet 7: Governing body attestation statement](#)

You can also email the clinical trials project team at: [CTgovernance@safetyandquality.gov.au](mailto:CTgovernance@safetyandquality.gov.au) or call 02 9123 3600

