AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

NSQHS STANDARDS

KEY ACTIONS
for health service organisations

Fact sheet 9:
National Clinical Trials Governance Framework –

Roles and functions for the clinical trial workforce

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.

Services not required to be assessed to the NSQHS Standards can voluntarily opt to apply the Governance Framework, for best practice and quality improvement purposes.

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.

Roles and functions of the clinical trial workforce

Clinical trial staff work within, and are supported by health service organisations and trial sites to deliver high-quality clinical trials in a safe environment. Clinicians working on clinical trials are responsible for their own professional practice as required by their professional codes of conduct. Clinical trial site staff

communicate and work with their governing body, clinical and non-clinical managers, clinicians, patients, consumers and sponsors to implement the Governance Framework. Clinical trial staff includes, but are not limited to the following:

- Principal and sub-investigators
- Trials managers, study coordinators, trials liaison officers, trial nurses, trial pharmacists, site specific assessment officers, Human Research Ethics Committee (HREC) executive officers.

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 clinical trial services, and ensuring that they are patient centred, safe and effective. There are four criteria within this Standard. The functions of the clinical trial workforce that apply to each criteria for the conduct of clinical trials are listed below.

Governance, leadership, culture

- Model professional conduct that is consistent with a commitment to safety and quality at all times
- Embrace opportunities to take part in the management of clinical trial service provision across the health service organisation
- Actively take part in the development of an organisational culture that enables clinical trial service provision
- Establish contacts and relationships with all key stakeholders, including governing bodies, clinical and non-clinical managers, trial site staff, patients and consumers and sponsors
- Collaborate with clinical and non-clinical managers to ensure the systems to support clinical trial service delivery are well designed and perform well
- Ensure compliance with legislative and policy requirements and conduct clinical trials as specified by the trial protocol and in accordance with the conditions of the HREC approval
- Provide guidance and mentorship on responsible research conduct to other researchers or research trainees under their supervision, and where appropriate monitor their conduct
- Undertake and promote education and training in responsible research conduct
- Comply with the relevant laws, regulations, disciplinary standards, ethics guidelines and institutional policies related to responsible research conduct
- Encourage, mentor and guide clinical trial site staff in the delivery of safe, high-quality clinical trials
- Take part in all aspects of the development, implementation, evaluation and monitoring of clinical trial governance processes
- Collaborate with the key individuals and groups within the trial site and/or health service organisation to deliver the Governance Framework.

Patient safety and quality improvement systems

- Contribute to the design of systems for the delivery of safe, high-quality clinical trial service provision
- Provide clinical trial services within the parameters of these systems
- Communicate with clinicians in other health service organisations to support good clinical outcomes, for trial participants
- Ensure contemporary knowledge about safe system design
- Maintain vigilance for opportunities to improve systems
- Ensure that identified opportunities for improvement are raised and reported appropriately
- Educate junior clinicians in the importance of working within the organisational systems for the delivery of clinical trial services
- Take part in the design and implementation of systems within the health service organisation for quality improvement and measurement, risk management, incident management, open disclosure, feedback and complaints management
- Comply with professional regulatory requirements and codes of conduct.

Clinical performance and effectiveness

- Study coordination, data collection and data management
- Participant recruitment and enrolment
- Obtaining consent from prospective participants
- Undertake study visits with trial participants, and collect and record information from research participants
- Maintain consistent study implementation
- Handle specimens

- Data management
- Dispense and administer the investigational product
- Compliance with regulatory and reporting requirements
- Screen and recruit trial participants
- Deliver concomitant care (with responsibility aligned to clinical governance)
- Contribute to organisational data collection on clinical trial operations as required by the health service organisation.

Safe environment for the delivery of care

- Site principal investigators and sub-investigators, clinical trial coordinators/study coordinators/ research nurses contribute to planning and development activities regarding the environment for clinical trial service provision within the health service organisation and provide clinical trials and clinical care within the parameters of this environment including:
  - screen and recruit trial participants
  - deliver the treatments and interventions as required by the trial protocol
  - deliver concomitant care (with responsibility aligned to clinical governance)
  - contribute to organisational data collection on clinical trial operations as required by the health service organisation.

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.

- Understand the evidence on consumer engagement, and its contribution to the safety and quality of health care and clinical trial participation
- Understand how health literacy might affect the way a consumer gains access to, understands and uses health information relating to clinical trials
- Support patients to have access to and use, high-quality, easy-to-understand information about clinical trials
- Support patients to share decision-making about their own health care, and the benefits of clinical trial participation to the extent that they choose
- Work with consumer representative groups to ensure that systems of care are designed to encourage consumer engagement in decision-making about clinical trial participation.

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**

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

You can also email the clinical trials project team at: **CTgovernance@safetyandquality.gov.au** or call 02 9123 3600