FACT SHEET
for health service organisations

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 a nationally consistent approach to the accreditation of health services for the conduct of clinical trials.

The aims of the Governance Framework are to support the delivery of high-quality clinical trial services and to ensure that clinical trials are conducted in a safe environment. The Governance Framework is based on the National Safety and Quality Health Services (NSQHS) Clinical Governance Standard and Partnering with Consumers Standard.

In February 2022, all jurisdictions agreed to implement the Governance Framework in health service organisations as an embedded under the Australian Health Service Safety and Quality Accreditation (AHSSQA) Scheme. That is, health service organisations will be assessed concurrently for clinical and corporate services and clinical trial service provision.

To give health services time to implement the Governance Framework, for the first three-year accreditation cycle, they will be assessed against a maturity scale. That is, health service organisations will be assessed as either having 'Established systems', 'Growing systems', or 'Initial systems' in place to meet the NSQHS Standards (as provided in the Governance Framework) for clinical trial service provision.

Beyond the first three-year accreditation cycle, health services will transition fully to the assessment of their clinical trial services under the AHSSQA Scheme and be assessed as either having met or not met the actions within the Governance Framework and receive 60 business days to remediate.

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.

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.

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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.

Relevant resources

- National Clinical Trials Governance Framework resources
  - **user guide for HSOs conducting clinical trials**
  - **introductory video**
  - **fact sheets**
  - **case studies**
- ***NSQHS Standards (second edition)***
- ***National Model Clinical Governance Framework***
- ***NSQHS Standards User Guide for Governing Bodies***

Questions?

For more information, please visit the **Commission's website**. You can also email the **Advice Centre** or call 1800 304 056.