AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

NSQHS STANDARDS

KEY ACTIONS
for health service organisations

Fact sheet 8:
National Clinical Trials Governance Framework –
Roles and functions for site principal investigators

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.

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.

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. The workforce uses these systems to partner with consumers.

What is the role of the site principal investigator?

The site principal investigator is the person responsible, individually or as a leader of the clinical trial team at a site, for the conduct of a clinical trial at that site. As such, the site principal investigator supports a culture of responsible clinical trial conduct in their health service organisation, in their field of practice and, is responsible for adequately supervising his or her clinical trial team.

The site principal investigator must conduct the clinical trial in accordance with the approved clinical trial protocol. The site principal investigator must ensure adequate clinical cover is provided for the trial and ensure compliance with the trial protocol. Where an investigator initiates and organises a trial, he or she must act within their scope of practice and adhere to the regulatory requirements associated with both the management and conduct of the trial. The site principal investigator is accountable to their employer who may or may not be the health service organisation hosting the clinical trial research and, the clinical trial sponsor.

The site principal investigator provides guidance and mentorship on responsible clinical trial conduct to other researchers or research trainees under their supervision, promotes education and training in responsible clinical trial conduct and complies with the relevant laws, regulations, disciplinary standards, ethics guidelines and institutional policies related to responsible clinical trial conduct.

Additionally, the functions of the site principal investigator include:

Trial conduct

- Ensuring that appropriate approvals are obtained prior to the commencement of the trial, and that conditions of any approvals are adhered to during the course of trial
- Taking primary responsibility for implementation of the approved trial protocol
- Ensuring any contractual requirements such as those under a clinical trial agreement are met
- Engaging with Aboriginal and Torres Strait Islander peoples and respecting their legal rights and local laws, customs and protocols as they relate to clinical trials
- Complying with the requirements for consent as approved in the trial protocol.

Safety of trial participants

- Ensuring participants' welfare during the clinical trial
- Ensuring the necessary clinical care is provided to study participants for care required as a result of any adverse events experienced during or following the study, that are related to the study
- Informing the participant's primary physician about the participant's involvement in the project. That is, if the participant has a primary physician and if the participant agrees to the primary physician being informed
- Responsible for ongoing consent
- Retaining the participant on a clinical trial. Although a participant is not obliged to give his/her reason(s) for withdrawing prematurely from a study, the site principal investigator should make a reasonable effort to ascertain the reason(s), whilst fully respecting the participant's rights.

Reporting

- Providing reports to the Human research Ethics Committee (HREC) and site on:
  - adverse events
  - proposed amendments to the protocol and,
  - information that might affect the continued ethical and scientific acceptability of the project
- Providing, at a minimum, annual progress reports and a final report to the HREC and the site
- Disclosing and managing actual, potential or perceived conflicts of interest
- Retaining clear, accurate, secure and complete records of all clinical trials including clinical trial data and primary materials. Where possible and appropriate, allow access and reference to these by interested parties

- Complying with the applicable regulatory requirement(s) related to the reporting of unexpected serious adverse drug reactions to the regulatory authority and the HREC as required by the approved clinical trial protocol
- Reporting suspected breaches of the Code to the relevant institution and/or authority.

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

NSQHS Standards User Guide for Governing Bodies

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