AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

NSQHS STANDARDS

FACT SHEET
for health service organisations

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 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.

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.

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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

Clinical leadership

- Taking responsibility for site co-investigators
- Supervising and working with site clinical trial coordinators
- Acknowledging those who have contributed to the clinical trial, and cite and acknowledge other relevant work appropriately and accurately*
- Participating in peer review in a way that is fair, rigorous and timely and maintains the confidentiality of the content*
- Adopting methods appropriate to the aims of the clinical trial and ensure that conclusions are justified by the results*
- Disseminating clinical trial findings responsibly, accurately and broadly. Where necessary, take action to correct the record in a timely manner*
- Ensuring that authors of clinical trial outputs are all those, and only those, who have made a significant intellectual or scholarly contribution to the clinical trial and its output, and that they agree to be listed as an author

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.

* Principally relates to investigator initiated clinical trials.