AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

NSQHS STANDARDS

The National Clinical Trials Governance Framework

and User Guide for Health Service Organisations Conducting Clinical Trials

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Contents

Summary 3

Introduction 5

Definitions of clinical trials, governance, patients and consumers 6

Purpose of the National Clinical Trials Governance Framework 7

Application and use of the National Clinical Trials Governance Framework 8

Health service organisational governance 9

Key concepts 9

Clinical trials governance as an integrated component of organisational governance 11

Importance of organisational culture in clinical trial governance 11

Components of the National Clinical Trials Governance Framework 13

Accreditation to the NSQHS Standards 15

Core principles of governance for clinical trial services 16

Roles and functions of identified positions 18

1. Clinical Governance Standard 19

1. Clinical Trial Governance Standard 20

Governance, leadership and culture 20

Organisational leadership 24

Clinical leadership 28

Patient safety and quality improvement systems 31

Policies and procedures 31

Measurement and quality improvement 33

Risk Management 37

Incident management systems and open disclosure 39

Feedback and complaints management 43

Diversity and high-risk groups 45

Healthcare records 46

Clinical performance and effectiveness 50

Safe environment for the delivery of care 54

2. Partnering with Consumers Standard 58

2. Partnering with Consumers 60

Clinical governance and quality improvement systems to support partnering with consumers 60

Applying quality improvement systems 62

Partnering with patients in their own care 64

Health literacy 68

Partnering with consumers in organisational design and governance 72

Appendix 1 74

Roles and functions of identified positions 74

Glossary of terms and definitions 83

Acknowledgements 90

References 92

Summary

A thriving clinical trials environment is essential for a robust healthcare system. Clinical trials provide early access to innovative treatments and interventions for patients, and improve the overall standard of medical care provided in Australian hospitals through the uptake of evidence into practice.[1] Data suggest that improved outcomes for patients participating in clinical trials are due in part to the increased clinical surveillance a trial provides and greater clinician adherence with evidence-based care.[2] The National Clinical Trials Governance Framework supports the integration of clinical trial service provision into routine hospital care for improved patient outcomes.

The National Clinical Trials Governance Framework is underpinned by best practice principles which are consistent with existing regulations for the conduct of clinical trials in Australia. The National Clinical Trials Governance Framework strengthens governance arrangements for clinical trial services and provides clarity to governments, health service organisations, hospital administrators, clinicians, and others responsible for delivering clinical trials.

Governance is the set of relationships and functions established by a health service organisation or trial service between its state or territory department of health, governing body, executive, workforce, patients, consumers, and other stakeholders to ensure good clinical trial service provision.

Clinical trial governance is an integrated component of the corporate and clinical governance of health service organisations and trial sites. It ensures that everyone, including frontline trial investigators undertaking clinical trials and members of governing bodies such as boards, is accountable to patients and the community for assuring the delivery of clinical trials is of high quality, integrated into clinical care and continuously improving.

To support the delivery of high-quality clinical trial services the Australian Commission on Safety and Quality in Health Care (the Commission) has developed the National Clinical Trials Governance Framework on behalf of all jurisdictions in collaboration with the Australian Government Department of Health. The National Clinical Trials Governance Framework is a key initiative of the Council of Australian Government Health Council's revitalised clinical trials agenda. An expert advisory group and state and territory representatives have also contributed to the development of the National Clinical Trials Governance Framework and this document reflects the feedback received from national sector wide consultation.

The National Clinical Trials Governance Framework builds on the National Model Clinical Governance Framework and the National Safety and Quality Health Service (NSQHS) Standards, providing:

- Roles and functions for identified positions relating to clinical trial service provision within a health service organisation
- Actions against which health service organisations with a clinical trial service will be assessed for accreditation
- Suggested strategies health services may implement to meet the actions within the NSQHS Standards
- Examples of evidence a health service organisation may provide that demonstrate they have met the actions within the NSQHS Standards for clinical trial service provision.

The National Clinical Trials Governance Framework is aligned with the NSQHS Standards, in particular, the Clinical Governance Standard and the Partnering with Consumers Standard.

There are five components within these two Standards:

- Governance, leadership and culture
- Patient safety and quality improvement systems
- Clinical performance and effectiveness
- Safe environment for the delivery of care
- Partnering with consumers.

Just as health service organisations need to meet requirements of the NSQHS Standards when they are accredited, the actions in the National Clinical Trials Governance Framework are also mandatory for health service organisations and trial sites providing clinical trial services. The National Clinical Trials Governance Framework does not specify how a health service organisation should develop or implement its clinical trials governance systems. Each health service organisation should consider its local circumstances when developing strategies to meet the requirements of the NSQHS Standards for clinical trials.

Once accreditation for clinical trial service provision is embedded into routine practices of health service organisations under the NSQHS Standards, measureable operational efficiencies across multiple therapeutic areas delivering clinical trial services will be realised to inform process improvement. These include optimising organisational strategic planning to deliver clinical trial services and more efficient trial operations. Notably, more than half the actions within the NSQHS Standards 1 and 2 apply to clinical trial services.

The National Clinical Trials Governance Framework provides information about each component and action within the NSQHS Standards and the roles and functions of identified positions relating to clinical trial service provision. This document also provides suggested strategies to support health service organisations meet the actions within the Standards. As such, this document comprises a complete and robust National Clinical Trials Governance Framework and User Guide.

Introduction

In Australia, clinical trials are delivered by teams of clinical trial investigators and clinical and non-clinical staff working in partnership with trial sponsors, regulators, trial participants, consumers, patients their families and carers. Clinical trials are delivered in public and private health service organisations and trial sites ranging from sole proprietorships to large statutory corporations and public companies.

Patients, consumers and the community trust clinicians and health service organisations to undertake high-quality clinical trial services in a safe environment, and believe Australians should have equitable access to relevant clinical trials as part of routine care or as an additional treatment option. Australia generally performs well in international comparisons in the quality of trial conduct. Australia's clinical trial investigators are highly regarded as skilled clinical trial researchers and clinicians who are committed to meeting the healthcare needs of their patients. An active clinical trials environment supports the retention of clinicians and medical researchers in our healthcare system through the provision of technical skills and global recognition of their contribution to international research.

Clinical trials in Australia are conducted within a strong regulatory framework underpinned by the principles of Good Clinical Practice (GCP). Clinical trials are undertaken to determine the safety and effectiveness of therapies, devices and techniques or where there is uncertainty about absolute or comparative effectiveness of healthcare interventions.

The International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)[3], European Committee for Standardisation and the International Organisation for Standardisation (ISO) provide standards of conduct for clinical trials (and clinical investigations) which are the basis for regulation across most regions under the remit of the major regulatory agencies world-wide. These regulations also take into account the principles of GCP.[4]

Although the methods for implementing and enforcing the principles of GCP vary, the main objective is a global environment in which trials collect high quality, credible data that contribute to the answering of specific scientific and clinical questions, while most importantly protecting the rights, safety and well-being of clinical trial participants.[5]

In Australia, the Therapeutic Goods Administration (TGA) requires to be notified of clinical trials involving unregistered therapeutic goods of the intention to start a new trial under the Clinical Trial Notification (CTN) scheme or the Clinical Trial Exemption (CTX) Scheme. The TGA also ensure compliance with International Organisation for Standardisation Guidelines for Therapeutics and Medical Devices.[6]

Clinical trials that do not make use of unapproved goods are not required to undergo either the CTN or CTX process, and trials that use Australian registered products within their marketing approval do not require an exemption from the notification scheme.[7] The TGA provides guidance materials including the Australian Clinical Trial Handbook (2018)[8] and the annotated Guidance for Good Clinical Practice (2016) (ICH-GCP).[9]

Clinical trials are required to be registered on a publically available platform.[10] The preferred national platform is the Australian and New Zealand Clinical Trials Registry (ANZCTR).

In Australia, clinical trial protocols need to be reviewed by a Human Research Ethics Committee (HREC) which is constituted according to guidelines issued by the National Health and Medical Research Council (NHMRC) in *the National Statement on Ethical Conduct in Human Research* (the National Statement).[11] The National Statement is incorporated by reference in the Therapeutic Goods Regulations (1990) and compliance with the National Statement is a condition of approval for the conduct of a clinical trial.

A HREC is required to have notified its existence to the Australian Health Ethics Committee (AHEC) of the NHMRC to provide assurance that it is operating within NHMRC guidelines. HRECs in Australia (sometimes with the assistance of sub-committees) generally provide both an ethical and scientific review, which may be supplemented on an as-needed basis by external expert advice as the committee(s) concerned sees fit. Applications to a HREC for approval of a clinical trial are usually made using a standardised form that includes a number of essential elements.[12]

In addition to the National Statement the HREC considers other guidance material including: Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018),[13] Keeping research on track: a guide for Aboriginal and Torres Strait Islander peoples about health research ethics,[14] and the Australian Code for the Responsible Conduct of Research[15] (the Code). Other guidance material may also be referred to including, but not limited to: Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) and the Consolidated Standards of Reporting Trials (CONSORT).

The delivery of clinical trials is a complex endeavour with multi-level reputational, financial, ethical, clinical and administrative implications for health services that conduct clinical trials. Clinical trial sponsors can be commercial companies, collaborative research groups, government entities including health service organisations, individual investigators, or universities. All sponsors have a responsibility to ensure the integrity and ethical appropriateness of each trial that they sponsor, including protecting the safety and welfare of participants in their clinical trials.

Traditionally, ensuring an acceptable standard for the conduct of high-quality clinical trials in a safe environment was viewed predominantly as the responsibility of the trial sponsor and the individual trial investigator, in conjunction with HREC review. Now, the importance of the individual and collective roles and functions of patients, consumers, clinicians, clinical trial teams, clinical and non-clinical managers, directors, governing bodies and departments of health, is well recognised.

A strong system-wide commitment to continuous improvement to minimise pre-approval delays and problems with conducting a clinical trial is required to guard against failures in efficient and effective clinical trial service delivery.

Just as the safety and quality of health care provided to each trial participant is highly dependent on the trial protocol and the skills and performance of study teams, safety and quality are also a professional and organisational responsibility. They rely on effective governance and management processes, and the establishment of systems involving a large number of contributors to clinical trial services across the health system.

To support the delivery of high-quality clinical trials that promote the best possible outcomes for patients in the clinical trials environment, the Commission on behalf of all jurisdictions, and in consultation with clinical trial experts and representatives from all Australian states and territories have developed the National Clinical Trials Governance Framework for public and private healthcare organisations and trial sites.

The National Clinical Trials Governance Framework is based on the Clinical Governance Standard and the Partnering with Consumers Standard within the NSQHS Standards. As part of the complete set of NSQHS Standards, these two standards constitute a complete and robust National Clinical Trial Governance Framework.

Definitions of clinical trials, governance, patients and consumers

Definitions of key terms are provided in the Glossary and the definition of clinical trials, governance, patients and consumers are also provided below:

Clinical trial: A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.[16]

Clinical trials include but are not limited to:

- Surgical and medical treatments and procedures
- Experimental drugs and diagnostics[17]
- Biological products
- Medical devices
- Health-related service changes
- Health-related preventative strategies
- Health-related educational interventions.

Governance: The definition of governance that underpins the National Clinical Trials Governance Framework is as follows:

> *Governance is the set of relationships and responsibilities established by a health service organisation between its state or territory department of health (for the public sector), governing body, executive, clinicians, patients, consumers and other stakeholders to ensure good clinical outcomes.*[18] *It ensures that the community and health service organisations can be confident that systems are in place to deliver safe and high-quality health care, and continuously improve services.*

Governance of clinical trial services should be an integrated component of corporate and clinical governance of health service organisations. It ensures that everyone – from frontline clinical trial teams including trial investigators, study coordinators, clinicians, researchers, sponsors, HRECs and those undertaking site-specific assessment to clinical and non-clinical managers and members of governing bodies, such as boards – is accountable to patients and the community for assuring that the delivery of clinical trial services are effective, integrated, high quality and continuously improving.

Trial participant, patient and consumer: In the context of the National Clinical Trials Governance Framework a trial participant maybe a patient or a healthy volunteer who has been enrolled in a clinical trial. A patient is a person who is receiving care in a health service organisation and a consumer is a person who has used, or may potentially use, health services, or is a carer for a patient using health services. A healthcare consumer may also act as a consumer representative, to provide a consumer perspective, contribute consumer experiences, advocate for the interests of current and potential health service users, and take part in decision-making processes.[19]

Purpose of the National Clinical Trials Governance Framework

The purpose of the National Clinical Trials Governance Framework is 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 National Clinical Trials Governance Framework describes the actions that are essential for health service organisations to achieve integrated corporate and clinical governance systems for clinical trial service delivery. Through these systems, organisations and individuals are accountable to patients and the community for continuously improving the safety and quality of their clinical trial services.

The National Clinical Trials Governance Framework:

- Defines clinical trial governance
- Places clinical trial governance as an integrated component of corporate governance for the delivery of organisational systems and processes
- Places clinical trial governance as an integrated component of clinical governance and clinical service provision
- Describes the key components of a clinical trial governance framework, based on the NSQHS Standards
- Discusses the role of organisational culture in supporting good clinical trial governance
- Outlines the roles and functions of, and essential partnerships between, patients and consumers, clinicians, managers, and governing bodies (such as boards) and trial sponsors for implementing effective governance systems in health service organisations.

Application and use of the National Clinical Trials Governance Framework

It is mandatory for all public and private Australian hospitals and day procedure services to be assessed through an independent accreditation process to determine whether they have implemented the NSQHS Standards. Therefore, the actions in the National Clinical Trials Governance Framework are also mandatory for health service organisations that provide a clinical trials service.

Consistent with the NSQHS Standards, the National Clinical Trials Governance Framework does not specify how a health service organisation or trial site should develop or implement its governance systems. Rather, it describes the systems and processes that should be in place to implement an effective Clinical Trials Governance Framework considering local needs, values and the context in which services are provided.

The National Clinical Trials Governance Framework builds on the NSQHS Standards, describes roles and functions of those people involved in clinical trial service provision within a health service organisation or trial site; the actions and suggested strategies a health service organisation or trial sites may implement to meet the actions and examples of evidence a health service may provide to demonstrate they have met the actions as required under the scheme.

The National Clinical Trials Governance Framework can be used by clinicians, managers, executives, governing bodies, state and territory departments of health and consumer organisations to support effective clinical trial governance for improved efficiency, safety and quality of clinical trial services.

The National Clinical Trials Governance Framework applies to public and private health services and day procedure facilities. However, the delivery of clinical trials in Australia is complex, and patients move between different clinical services across the public and private acute and primary care sectors.

Health service organisational governance

Clinical trial governance is an integrated component of corporate and clinical governance. This section provides an overview of key concepts and elements of corporate governance, particularly regarding the responsibilities of governing bodies (such as boards).

Key concepts

In Australia, a large proportion of clinical trials are delivered in public sector and private sector organisations governed by bodies such as Boards of Directors. Boards are generally well versed in the concepts and practices of corporate governance, which is recognised as a responsibility of governing bodies. This responsibility is distinguished from the responsibility for management and service delivery. The concept of clinical trial governance is best understood as founded in, and consistent with, broader concepts of corporate or organisational governance.[20] Robert Tricker is credited with creating the term 'corporate governance'. According to Tricker[21]

> *The governance role is not concerned with the running of the company, per se, but with giving overall direction to the enterprise, with overseeing and controlling the executive actions of management and with satisfying legitimate expectations of accountability and regulation by interests beyond the corporate boundaries.*

Corporate governance encompasses the establishment of systems and processes that shape, enable and oversee management of an organisation. It is the activity, undertaken by governing bodies such as boards, of formulating strategy, setting policy, delegating responsibility, overseeing management, and ensuring that appropriate risk management and accountability arrangements are in place throughout the organisation. Management, on the other hand, is concerned with doing – with coordinating and managing the day-to-day operations of the business.[22]

Good governance is clearly recognised as a responsibility of governing bodies. It is the governing bodies responsibility to ensure good governance and to account to [shareholders] for their record in this regard.[23] Management has an operational focus, whereas governance has a strategic focus. The executive and managers run organisations, whereas their governing bodies ensure that organisations are run well and in the right direction.

The governing body derives its authority to conduct the business of the organisation from the enabling legislation and the organisation's constitutional documents, where applicable. The governing body 'governs' the organisation by establishing a 'governance system', elements of which are implemented by the governing body itself, managers and the workforce at all levels of the organisation. As part of its governance system, the governing body:

- Endorses a strategic and policy framework
- Ensures a system of delegated responsibility for the operation of the organisation
- Monitors the performance of the chief executive officer
- Monitors the performance of the organisation and ensures that there is a focus on continuous quality improvement.

The model described by Tricker for the role and functions of governance highlights both the forward-looking (leadership and performance) and retrospective (accountability and conformance) elements of good governance.[24]

The generally accepted governance duties and responsibilities of a governing body such as a board include: appointing a chief executive officer, supporting them to lead the organisation and evaluating their performance in consultation with management, setting and reviewing organisational plans and strategies.

The governing body also endorses and approves budgets, and major financial and organisational decisions, and:

- Ensures that the organisation is being properly managed, including that
  - systems of production or service delivery are well designed and fit for purpose
  - services meet desired standards
  - the organisation meets its compliance obligations
- Challenges the assumptions of management
- Reviews and monitoring performance of the control framework to ensure that major risks are identified and managed
- Ensures that there is an ongoing focus on quality improvement
- Evaluates reports, and reviewing feedback, suggestions and complaints
- Ensures the continuing development of the executive management team
- Plans for succession
- Communicates with, and is accountable to, patients and consumers and, internal and external stakeholders.

Ultimately it is the governing body's responsibility to ensure good corporate governance. That is, organisational systems and processes. Many governance responsibilities are delegated to individuals or groups throughout the organisation. For example, people at all levels of a health service organisation may be involved in the design and implementation of risk management, performance monitoring and audit programs, which are key elements of good governance systems.

Clinical trials governance as an integrated component of organisational governance

This section describes how clinical trial governance is an integrated component of organisational governance and sets out the key components of the National Clinical Trials Governance Framework.

Clinical trials governance is a fundamental part of the governing body's responsibilities and accountabilities. Clinical trials governance involves a complex set of leadership behaviours, policies, procedures, monitoring and improvement mechanisms that ensure good clinical outcomes.

The clinical trials governance system of a health service organisation therefore needs to be conceptualised as a system within a system – a clinical trials governance system within a corporate and clinical governance system.

Under this model, it is important to recognise the following:

- Governance of clinical trial services is of equivalent value to financial, risk and other business governance
- Decisions about other aspects of corporate governance can have a direct affect on the quality of care provided through a clinical trial, and decisions about clinical trial service delivery can have a direct effect on other aspects of corporate governance, such as financial performance and risk management
- Governing bodies are ultimately responsible for effective clinical trials governance
- Governing bodies cannot govern clinical services relating to clinical trials well without the deep engagement of individuals working at all levels of the organisation
- Clinicians, managers and members of the governing bodies have individual and collective responsibilities for ensuring the safety and quality of clinical care and clinical trial service provision, as reflected in the NSQHS Standards.

Implementation of the National Clinical Trials Governance Framework involves individuals and teams at all levels of the organisation as well as well-designed systems to deliver, monitor and account for the quality of clinical trial service provision.

Good clinical trial operational outcomes rely on both effective organisational systems and the integration and linkages of the health service organisation within a network of other groups including trial sponsors, trial regulators, trial networks and individuals within health service organisations or trial sites in the acute and primary care sectors. These networks may include general practitioners, other specialists or allied health providers, or aged care homes.

Importance of organisational culture in clinical trial governance

The NSQHS Standards (2nd ed) specify the actions that a health service organisation needs to meet to develop systems for good clinical trial governance. Culture, however, is just as important in governance in ensuring that patients and consumers receive high-quality care in a safe environment when they are participating in a clinical trial. Culture is a complex and contested concept that has many different definitions.

Central to most of these definitions is that culture consists of:

> *… the values, beliefs and assumptions shared by occupational groups. These shared ways of thinking are then translated into common and repeated patterns of behaviour: patterns of behaviour that are in turn maintained and reinforced by the rituals, ceremonies and rewards of everyday organisational life.*[25]

Factors that have been identified as being important for sustaining cultures that ensure clinical trials are delivered in a high-quality manner and promote safety standards include:[26,27]

- Leaders articulating a vision for high-quality, compassionate and safe care, and acting on this vision throughout the organisation
- Translating the vision into clear objectives for safety and quality at all levels of the organisation, and establishing measures to assess progress
- Providing a supportive and positive working environment for the workforce
- Ensuring that members of the workforce are engaged in their work
- Having an organisation that is transparent about performance, open to learning and continuously improving
- Supporting multidisciplinary teams to work together effectively.

To put in place the requirements of the NSQHS Standards that are the basis of the National Clinical Trials Governance Framework, health service organisations and trial sites need to have a culture that provides:[28]

- Strong strategic and cultural leadership of clinical trial services, that prioritises:
  - effective planning to enable development and improvement opportunities to be captured
  - selecting high quality clinical trials that will provide value to patients and consumers, improves the clinical evidence-base and supports continuous improvement in clinical trial service provision
  - allocating resources to support the delivery of high-quality clinical trial services
- Clear responsibilities for managing high quality clinical trials services and appropriate delegation of the necessary management authority for this purpose
- Reliable processes for ensuring that systems for delivering clinical trials perform well, and clinicians are fully engaged in the design, monitoring and development of these systems
- Effective use of data and information to monitor and report on operational performance, through the health service organisation to the governing body to support ongoing quality improvement
- Well-designed systems for identifying, quantifying, and managing risk
- Opportunities for consumer engagement in the design of clinical trial services and processes that supports consumer engagement as a part of the health service organisation strategic plan.

Components of the National Clinical Trials Governance Framework

The National Clinical Trials Governance Framework is based on the NSQHS Standards in particular, the Clinical Governance Standard and the Partnering with Consumers Standard.

The NSQHS Standards were developed by the Commission in collaboration with the Australian Government Department of Health, states and territories, the private sector, executives and managers, clinical experts, patients, and carers. Since 2013, it has been mandatory for all Australian hospitals and day procedure services to be assessed through an independent accreditation process to determine whether they have implemented the NSQHS Standards.

Strategies to meet the Clinical Governance Standard and the Partnering with Consumers Standard as part of the National Clinical Trials Governance Framework has been further refined in consultation with the Australian Government Department of Health, the Clinical Trials Governance Framework Steering Committee, the Clinical Trials Project Reference Group (CTPRG) and the Clinical Trials Collaborative Forum comprising government, public and private health care sector, health administrators university, industry and consumer representatives across the clinical trials sector.

To fully apply the NSQHS Standards in a health service organisation or trial site, governing bodies, clinicians, clinical and non-clinical managers, patients, consumers researchers, clinical trial coordinators and sponsors need to be engaged in the implementation of actions set out in the NSQHS Standards.

The Clinical Governance Standard and the Partnering with Consumers Standard together ensure the creation of governance systems within healthcare organisations that:

- Generate evidence that can be used to improve health outcomes for patients and the community
- Are fully integrated within overall corporate and clinical governance systems
- Are underpinned by robust safety and quality management systems
- Maintain and improve the reliability, safety and quality of health care.

Reflecting the NSQHS Standards, the National Clinical Trials Governance Framework has five components (Figure 2).[29] The central component relates to patients and consumers, who are at the centre of the National Clinical Trials Governance Framework. The five components of the Clinical Trials Governance Standard are as follows:

Governance, leadership and culture – integrated corporate and clinical trials governance systems are established, and used to improve the safety and quality of clinical trial service provision for patients, their carers and consumers.

Patient safety and quality improvement systems – safety and quality systems are established and used to manage and improve the provision of clinical trial services.

Clinical performance and effectiveness – the workforce has the right qualifications, skills and supervision to provide safe, high-quality clinical trial services to patients.

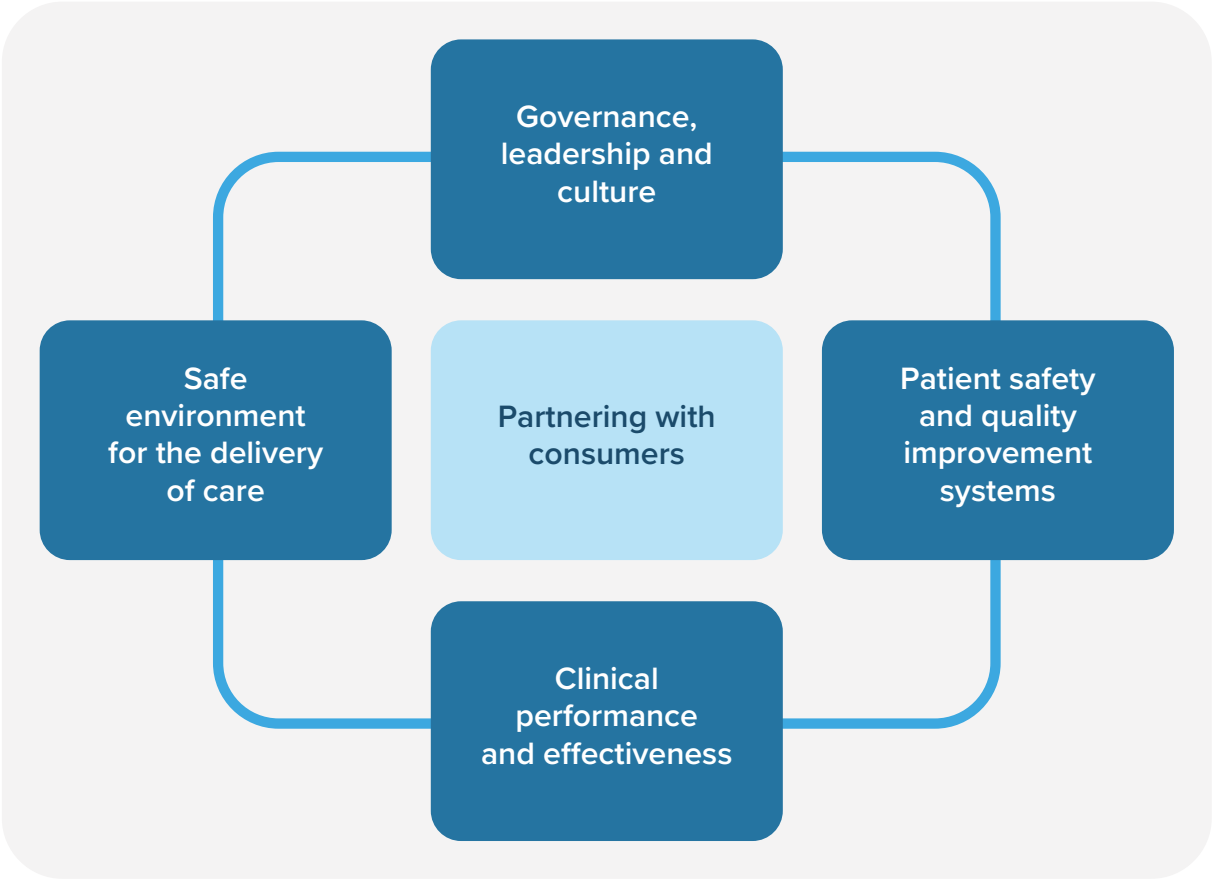
Safe environment for the delivery of care – the environment in which clinical trials are conducted is safe and promotes high-quality clinical trials to patients.

Partnering with consumers – systems are designed and used to support patients, carers, families and consumers to be partners in planning, design, measurement and evaluation of clinical trial services. Consumers may also work with health service organisations and

others acting as trial sponsors, in the design, and evaluation of clinical trials. Elements of this component include clinical governance and quality improvement systems to support partnering with consumers:

- Partnering with patients in their own care, and in trial participation
- Health literacy
- Partnering with consumers in organisational design and governance of clinical trial services.

Figure 1 *Components of the National Clinical Trials Governance Framework*



Accreditation to the NSQHS Standards

It is mandatory for all public and private Australian hospitals and day procedure services to be assessed through an independent accreditation process to determine whether they have implemented the NSQHS Standards for clinical service provision. Therefore, actions within the NSQHS Standards are also mandatory for health service organisations that provide a clinical trials service.

As with the NSQHS Standards, the National Clinical Trials Governance Framework and User Guide does not specify how a health service organisation or trial site should develop or implement its governance systems. Rather, it describes the systems and processes that should be in place to implement effective clinical trials governance considering local needs, values and the context in which services are provided.

The National Clinical Trials Governance Framework and guide for implementation applies to public and private health services and day procedure facilities. The suggested strategies to meet the actions within the NSQHS Standards is supported by national regulation, policies and guidance material with which clinical trials must comply; jurisdictional policies; work flow systems and standard operating procedures. Jurisdictions, health services and individuals are expected to adopt this approach to governance of clinical trial services and the operational actions outlined in this document should be reflected in their policies and processes in relevant operational documents.

Core principles of governance for clinical trial services

The National Clinical Trials Governance Framework and Guide for Implementation reflect national regulation and national and jurisdictional legislation, policies and guidance materials and meets the core principles of the Council of Australian Government Health Council revitalised clinical trials agenda:

- The patient is at the centre of clinical trials
- Clinical trials are a core activity to delivery of health services
- Navigating clinical trial services and accessing clinical trials is made easier for patients and consumers
- Partnerships and collaboration are at the core of a successful clinical trials sector
- Clinical trials are undertaken in a safe environment and foster a culture of quality and innovation
- Workforce support retains skills and knowledge to build capacity, capability, predictability and career pathways for trial site staff
- Transparency is measurable using key performance indicators to increase accountability and promote the value Australia offers as a destination for clinical trials.

The core principles of the National Clinical Trials Governance Framework provide clear guidance for governments, health service organisations, trial sites, clinical trial investigators and clinical trial site staff, trial sponsors and consumers on what is expected of them directly. To ensure efficient and equitable provision of clinical trials services, the following core principles of the National Clinical Trials Governance Framework underpin clinical trial service delivery.

Patient centred and meets the needs of the community

Clinical trial services are patient-centred and are prioritised to meet community needs. Respect for research participants and the wider community is demonstrated at all levels of the health service organisation or trial site. Clinical trials integrate existing evidence and the outcomes of clinical trials conducted by the health service organisation or trial site are reviewed and contribute to the translation of evidence into clinical practice.

Safe environment

Clinical trial services are provided in an environment that supports safety and a commitment to safety permeates at all levels of an organisation or trial site and there is a willingness of the organisation or trial site to direct resources to deal with safety concerns.

Quality

Clinical trials are designed, reviewed, managed and undertaken in a way that ensures integrity, quality and transparency in trial conduct and the provision of clinical care. The health service organisation or trial site is committed to undertaking quality improvement activities in sequence, intermittently or on a continual basis, and the quality of the service is measured against specific actions to support the accreditation process.

The health service organisation or trial site uses data sources to undertake a trial feasibility assessment to determine the availability of potential clinical trial participants, the likelihood of meeting recruitment targets and implements a process for closing a trial that fails to recruit participants.

The combined efforts of the workforce and others – including consumers, patients and their families, clinical trial investigators and their teams, managers and sponsors – make operational changes using data from the National Aggregate Statistics[30] to improve clinical trial service provision and support staff professional development.

Risk and proportionality

Health service organisations are accountable to the community for the use of funding, skills and resources required to provide clinical trial services. The assessment of risk for a health service organisation to undertake a clinical trial should be balanced in proportion to the resources required to undertake the trial, the capacity of the trial to have impact on the wider community and the potential risk to trial participants.

Accountability and transparency

Clinical trials comply with the relevant legislation and meet national and international standards and, in doing so ensure good stewardship of clinical trial service provision. Clinical trials are reviewed and conducted by an expert workforce with the appropriate training, skills, professional development, clinical competencies and organisational delegations. This includes members of HRECs, local site-specific assessment officers, clinical trial investigators, research mangers, clinicians and study coordinators.

It is incumbent upon the health service organisation or trial site to ensure all people involved in clinical trial service provision are qualified by education, training and experience, or otherwise competent under the supervision of a suitably qualified person, to perform their tasks.

Organisational culture, partnerships and collaboration

Organisational culture, partnerships and collaboration are at the core of successful clinical trial service provision. The governing body and health administrators are the champions of clinical trial services and clinical trials align with the organisational mission. Clinical trials are considered in health system planning for service provision and the delivery of clinical care.

The duty of care owed by health service providers continues to apply when their patients and service users take part in a clinical trial. A relevant health care professional[31] retains responsibility for the treatment, care or other services given to patients and trial participants and for decisions about their treatment, care or other services. If an unmanageable conflict arises between the trial and patient interests, the duty to the participant as a patient prevails.

Partnering with consumers increases consumer awareness of the benefits of clinical trials, promotes access for patients to clinical trials and improves navigation of the trial process by patients and consumers.

Collaboration between trial sponsors, trial investigators and their trial teams within and between health service organisations, clinical trial networks and universities build capacity and support health services to deliver high quality clinical trials in a safe environment.

Equity

Clinical trials are provided as part of routine health service provision and health services provide equitable access to both commercially sponsored trials and investigator-initiated trials in a timely manner. Health service organisations observe cultural safety, competence and respect in providing clinical trial services to meet the needs and priorities of Aboriginal and Torres Strait Islander people in delivering clinical trial services and, Clinical trials are provided as part of routine health service provision and health services provide equitable access to both commercially sponsored trials and investigator-initiated trials in a timely manner. Health service organisations observe cultural safety, competence and respect in providing clinical trial services to meet the needs and priorities of Aboriginal and Torres Strait Islander people in delivering clinical trial services and, provide appropriate resourcing to allow patients and consumers from different demographic locations and culturally diverse backgrounds to participate in all available trials within and across health service organisations.

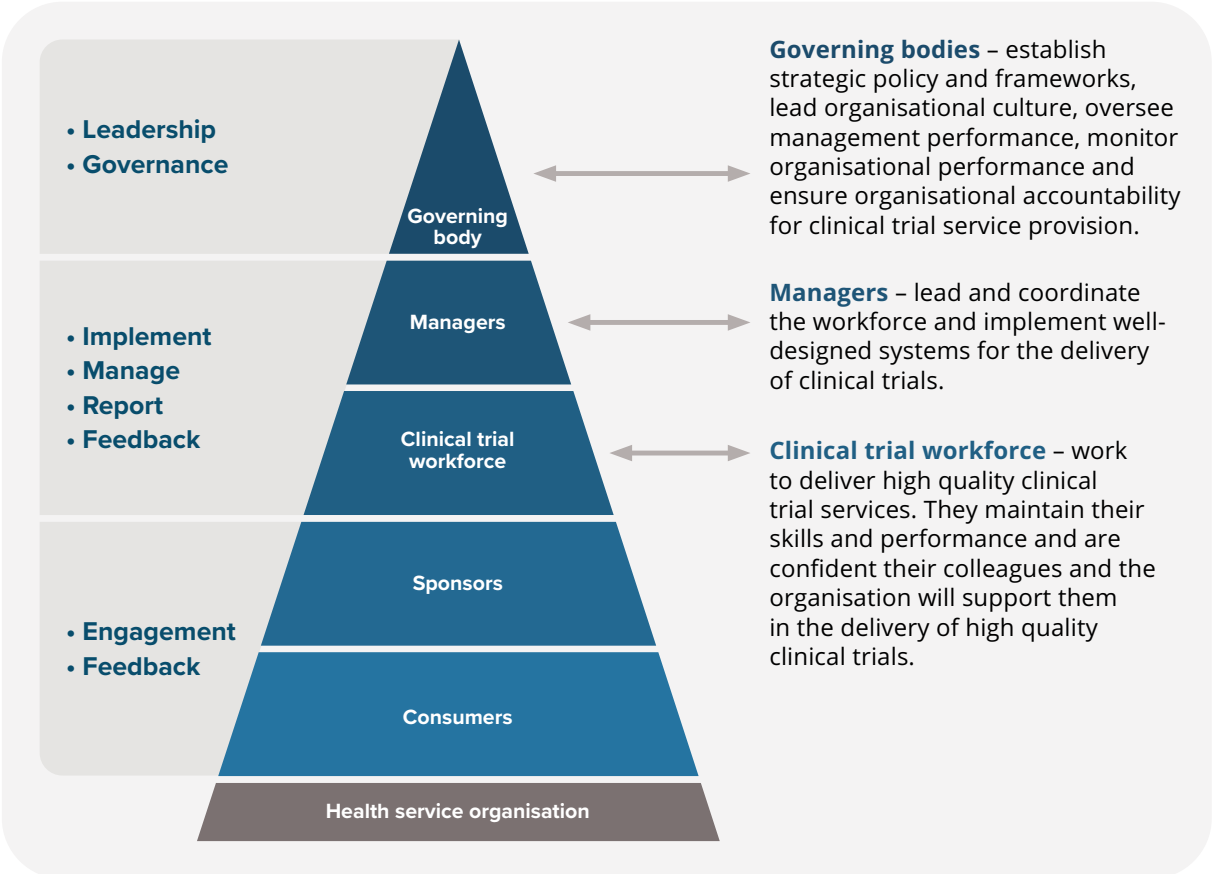
Roles and functions of identified positions

The roles and functions relating to identified positions are consistent with the roles and functions of individuals in health service organisations undertaking clinical trials as outlined the Australian clinical trials handbook V2.1 2018;[32] the National Statement; Statement on Consumer and Community Participation in Health and Medical Research[33] and state and territory policies.[34,35,36,37,38,39,40,41,42,43,44,45,46]

The roles and functions of the positions and relationship groups are provided as *guidance* for health service organisations to establish or continue to deliver clinical trial services are provided in **Appendix 1**. The roles and functions of the positions and relationship groups are provided as guidance for health service organisations to establish or continue to deliver clinical trial services. Many of these functions currently exist in health service organisations and are provided here as *suggested* roles with functions to support small and large health service organisations to implement the NSQHS Standards 1 and 2 for clinical trial services. For example, a health service organisation may allocate one or several functions relating to clinical trial service provision to an identified position.

Health service organisations and trials sites may also benefit from ensuring appropriate linkages to the Central Points of Contact being established in each jurisdiction to improve overall system navigation for sponsors and participants, to streamline trial processes and time to trial start-up; and improve workforce capacity under the Council of Australian Government Health Council revitalised clinical trials agenda and as part of national initiatives.

Figure 2 *Roles and functions of identified positions relating to governance of clinical trial services*



1. Clinical Governance Standard

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.

Intention of this standard for clinical trial services

To implement governance for clinical trial services that ensure patients and consumers receive safe and high-quality clinical trial services.

Criteria

- Governance, leadership and culture
- Patient safety and quality systems
- Clinical performance and effectiveness
- Safe environment for the delivery of care

Key resources

- National Model Clinical Governance Framework
- NSQHS Standards Guide for Governing Bodies
- NSQHS Standards User Guide for Aboriginal and Torres Strait Islander Health
- Australian Open Disclosure Framework

1. Clinical Trial Governance Standard

Governance, leadership and culture

Leaders at all levels in the organisation set up and use governance systems to improve safety and quality of clinical trial service provision for patients, trial participants, consumers and their families.

Action 1.1

The governing body:

a. **Provides leadership to develop a culture of safety and quality improvement, and satisfies itself that this culture exists within the organisation**
b. **Provides leadership to ensure partnering with patients, carers and consumers**
c. **Sets priorities and strategic directions for the conduct of safe and high-quality clinical care, and ensures that these are communicated effectively to the workforce and the community**
d. **Endorses the National Clinical Trials Governance Framework within the health service**
e. **Ensures that roles and responsibilities are clearly defined for the governing body, management, clinicians and the workforce**
f. **Monitors the action taken as a result of analyses of incidents**
g. **Reviews reports and monitors the organisation's progress on safety and quality performance.**

How does this action apply to a health service organisation with a clinical trial service?

For health service organisations with a clinical trial service, the governing body must assure itself that a culture of ongoing quality improvement operates in the organisation delivering clinical trial services. The governing body sets priorities and strategic directions for the conduct of high-quality clinical trial service provision and ensures that these are communicated effectively to the workforce and the community. The strategic importance of quality should be visible throughout the organisation and in health service planning to deliver a clinical trial service.

The governing body endorses the organisation's National Clinical Trials Governance Framework and ensures that roles and functions are clearly defined for the governing body, management, clinical and non-clinical managers and the clinical trial workforce. The governing body communicates across the organisation on quality issues and measures performance and progress benchmarked against self and peers and the actions taken as a result of underperformance or safety concerns.

Suggested strategies to meet this action

Set strategic direction for the delivery of clinical trial services across the organisation

The NSQHS Standards require the governing body to provide leadership to develop a culture of safety and quality improvement in their organisation. For this to occur, the governing body needs to have a good understanding of the organisation's existing values, behaviours and attitudes, and prioritise clinical trial service provision.

The governing body ensures that effective partnerships are developed, and promotes the organisation's engagement with clinical and non-clinical managers and the clinical trial workforce including trial investigators and their clinical trial teams, sponsors, HRECs and those undertaking site-specific assessment.

Strategies may involve:

- Developing an organisational strategic plan to deliver clinical trial services across multiple therapeutic departments
- Establishing and supporting a multidisciplinary team of experienced staff including heads of clinical departments, finance, human resources, clinical and non-clinical managers, trial investigators and their clinical trial teams including trial managers, IT staff, the HRECs office, research office and/or site-specific assessment office
- Establishing and maintaining governance and management practices for the responsible conduct of clinical trials across the health service organisation
- Ensuring clinical trial services are run well and deliver high-quality clinical trials in a safe environment
- Establishing a strong safety culture through an effective clinical trial governance system that operates effectively
- Ensuring there is an ongoing focus on quality improvement.

The governing body should define the expected quality of trial service provision and consider the core principles of governance for clinical trial services in their decision making. Setting priorities and targets enables the organisation to define the roles and functions of the workforce to achieve these goals, and systems that support quality service provision.

Define safety culture

An organisation's culture is important. Based on values, beliefs and assumptions, culture is a way of describing the repeated patterns of behaviours that are reinforced in the organisation by its rituals, ceremonies and reward structures. There are many definitions of a safety culture. It involves the interaction of attitudes, beliefs and behaviours of members of the workforce that influence their commitment to the organisation's safety management.[47]

Positive cultures in health care have strong leadership to drive and prioritise safety and quality in service provision of all. Commitment from leadership and management in this context is important because their actions and attitudes influence the perceptions, attitudes and behaviours of members of the workforce throughout the organisation.

Organisations with positive cultures have:

- Strong leadership to drive the safety, quality culture and continuous improvement
- Strong management commitment, with culture as a key organisation priority
- A workforce that is engaged and always aware that things can go wrong
- Acknowledgement at all levels that mistakes can and do occur
- Ability to recognise, respond to and give feedback about underperformance and learn from adverse events in clinical trial operations.

Define governance processes

The governing body should define its expectations about the quality of operational performance of the organisation, and the behaviours expected from its workforce. It should also be clear about how and when the quality culture of the organisation will be measured and monitored. The governing body and management need to regularly assess the systems in place to help them perform their clinical governance roles, such as:

- Identifying the appropriate structures and processes to manage and monitor clinical trial operational performance
- Describing the expected outcomes in clinical trial operations through the organisation's vision, mission and goals
- Setting the requirements for time frames, targets, and reporting on clinical trial service provision performance

- Monitoring implementation and compliance with strategic, business, or safety and quality improvement plans
- Involve consumers and define patient experience.

The governance system should provide:

- A clear definition of operational quality that articulates reporting lines
- Position descriptions for all members of the workforce that clearly document roles and functions for quality clinical trial service provision
- Policies, procedures or protocols that describe how quality is in embedded in the operation of the organisation including clinical trial services
- A structured performance development system for managers, trial investigators and their clinical trial teams that incorporates a regular review of their engagement in organisational goal setting and in the monitoring and review of operational and professional performance.

The governing body is responsible for reviewing reports and monitoring the quality of the organisation's operational performance. The governing body should regularly review a selection of the organisation's most important quality metrics, which may include:

- Key national priority indicators and regulatory requirements
- A selection of measures covering service provision effectiveness, patient experience, access, and efficiency and appropriateness of care
- Trends in complaints from patients and the workforce, and action taken to resolve complaints
- Trends in reported incidents relating to clinical trial service provision and near misses, and actions taken
- Findings from sponsor and regulatory audits
- Workforce surveys to monitor the organisational culture
- Risk ratings
- Compliance with GCP training
- Comparisons with peer organisations, and state and territory or national performance data.

In addition to monitoring indicators and trends, governing bodies should review relevant organisational systems to ensure that they are fit for purpose and being used to deliver clinical trial services.

Key tasks

- Identify the governing body – this is the group of people or individuals with ultimate responsibility and accountability for decision-making about safety and quality
- Ensure that the roles, functions and accountabilities for governance within the organisation are clearly articulated
- Review the organisational structure, and the position descriptions and contracts for managers, and ensure that roles, functions and accountabilities for quality service provision are clearly defined and articulated at all levels in the organisation
- Endorse the organisation's governance framework and strategic plans, such as the operational plan for clinical trial service provision, safety and quality improvement plan, and the plan for partnering with consumers
- Review the template or calendar for reporting to the governing body on safety and quality indicators and data, and ensure that it covers all services, locations, major risks, dimensions of quality and key elements of the quality improvement system
- Regularly review quality indicators to ensure that they are relevant and comprehensive
- Review relevant data from clinical incidents, and reports of complaints and other incidents
- Review the processes for providing feedback to the workforce, patients, consumers and the community about the organisation's safety and quality performance
- Identify risks and ensure that mitigation strategies are in place to manage all major risks
- Ensure that systems are in place to regularly survey and report on organisational culture. Heads of clinical departments, finance, human resources, clinical and non-clinical managers, trial investigators, study coordinators, including trial managers, IT staff, the HRECs office, governance office

and/or site-specific assessment office have an important role in influencing quality of clinical trial service provision by shaping culture within the organisation, setting direction, providing support to the workforce, and monitoring progress and improvement in clinical trial service provision.

Examples of supporting evidence

Examples of evidence a health service organisation may provide to demonstrate implementation of governance systems for clinical trial services may include:

- Policy documents that describe:
  - the roles and functions of the governing body
  - the health service organisation's strategic plan for clinical trial services
  - processes for partnering with consumers
- Strategic, business or risk management plans that describe the priorities and strategic directions for high quality clinical trial services that are endorsed by the governing body
- Committee and meeting records in which clinical trial governance, leadership, patient safety and quality culture, or partnering with consumers are discussed
- Attestation Statement which documents that the clinical trial governance framework is endorsed by the governing body and implemented in the health service organisation
- Quality performance data including, but not limited to the National Aggregate Statistics (NAS)[48]:
  1. Number of new trials and breakdown by trial phase, and by sponsor type
  2. Overall study start-up timeline (regulatory timeline)
  3. Ethics and governance approval timeline
  4. Human Research Ethics Committee (HREC) approval timeline
  5. SSA/site assessment timeline
  6. Trial recruitment: actual and planned number of participants recruited
  7. Site recruitment: actual and planned number of participants recruited
  8. Total inbound (internal and external) investment annually.

Additional metrics may also be collected for local quality improvement purposes such as[49]:

- Number of new enrolments to clinical trials by clinical trial and trial unit for the reporting period and year to date
- Number and median calendar days from HREC approval to RGO submission year to date, (include trial type ie: multi-centre clinical trials approved via the NMA scheme)
- Median calendar days from local Site-Specific Assessment submission to authorisation by clinical trial
- Number of trials pending RGO authorisation by reporting period and /or year to date
- Median calendar days from recruitment open date to first participant on trial by clinical trial and trial unit for the reporting period and/or year to date
- Median calendar days from recruitment open date to first participant on trial by clinical trial and trial unit for the reporting period and/or year to date
- Proportion of enrolments to total Full Time Equivalent (FTE) trial coordinator or staff member with functions undertaking trial recruitment for the reporting period and/or year to date
- Recruiting to site target by recruiting clinical trial and trial unit for the reporting period and/or year to date
- Clinical trials financial reconciliation by clinical trial and trial unit for the reporting period and/or year to date
- A summary of data collated from clinical trial annual reports; sponsor and regulatory audit reports and reports of clinical incidents that are monitored by managers and the governing body
- Terms of reference or letters of appointment to the governing body that describes members' clinical trial roles and functions
- Workforce survey
- Cultural assessment tool used by the organisation and reports of assessment conducted
- Communication with the clinical trial workforce and consumers on the health service organisation's clinical governance framework for safety and quality performance.

Organisational leadership

Management and executive leadership

Action 1.3

The health service organisation establishes and maintains a clinical governance framework, and uses the processes within the framework to drive improvements in safety and quality.

How does this action apply to a health service organisation with a clinical trial service?

Health service organisations are responsible for designing and implementing the systems to operationalise an effective clinical trial governance system as directed by the governing body. The health service organisation establishes and maintains the National Clinical Trials Governance Framework and establishes an operational plan that is comprehensive and includes measures of operational effectiveness.

Managers (clinical and non-clinical) should ensure that well-designed and integrated systems are in place to provide high-quality clinical trial service provision. This may include systems and processes to:

- Advise and inform the governing body on matters related to clinical trial services
- Operate clinical trial services within the strategic and policy parameters endorsed by the governing body
- Ensure the systems that support clinical trial service delivery are well designed and perform well
- Lead the development of business plans, strategic plans, and organisational policies and procedures relevant to clinical trial service provision
- Integrate quality clinical trial service provision into organisational plans, policies and procedures
- Set up effective relationships with relevant individuals across the health service organisation to support quality clinical trial operations
- Support clinicians who embrace clinical trial leadership roles
- Ensure the workforce has opportunities to receive education in Good Clinical Practice in the conduct of clinical trials and education relating to engaging with consumers
- Identify and manage risk relating to clinical trial service provision
- Test and influence organisational culture to ensure attitudes and behaviours support an active clinical trial environment
- Manage clinical trial service provision
- Manage workforce performance and skills
- Manage incidents and complaints relating to clinical trial service provision
- Ensure patients' and consumer rights are reflected in all aspects of clinical trial service provision.

Suggested strategies to meet this action

Strategies health service organisations may implement to meet this action include:

- Establishing a committee that is responsible for overseeing the implementation of the National Clinical Trials Governance Framework
- Implementing policies, procedures and protocols that describe and bring effect to the National Clinical Trials Governance Framework
- Clearly defining and articulating the roles and functions of clinical leaders and members of the clinical trial workforce at all levels of the health service organisation

- Monitoring the implementation of the National Clinical Trials Governance Framework
- Monitoring and reviewing findings of compliance with policies, procedures and protocols.

Key tasks

To ensure the effectiveness of systems and processes to implement the National Clinical Trials Governance Framework, the managers should:

- Develop an operational plan to implement the National Clinical Trials Governance Framework
- Educate the workforce about the key aspects of the National Clinical Trials Governance Framework, and their roles and functions
- Review policies, procedures and protocols to ensure that they align with the National Clinical Trials Governance Framework
- Review results of trial sponsor or regulatory audits and system evaluation reports for compliance with the National Clinical Trials Governance Framework
- Monitor, analyse and report on clinical trial service provision performance
- Collect, analyse and report on workforce, patient and consumer feedback
- Recommend actions to improve the quality of clinical trial service provision and provide advice to the governing body about the issues identified and actions taken.

Examples of supporting evidence

- Documented operational plan that supports the implementation of the National Clinical Trials Governance Framework
- Documented goals and performance indicators of clinical trial service provision
- Documented organisational clinical trial governance committee structure
- Findings from trial sponsor or regulatory audit reports
- Reviews or evaluation reports on the effectiveness of the health service organisation's clinical trial systems.

Action 1.4

The health service organisation implements and monitors strategies to meet the organisation's safety and quality priorities for Aboriginal and Torres Strait Islander people.

How does this action apply to a health service organisation with a clinical trial service?

Health service organisations should consider how clinical trial services will be designed, implemented and evaluated to meet the priorities for Aboriginal and Torres Strait Islander people. This may be achieved by forming sustainable partnerships with local Aboriginal and Torres Strait Islander people and working with local communities to understand and acknowledge their healthcare needs, the risks and barriers to accessing treatment through a clinical trial and developing strategies and priorities for improved clinical trial service delivery.

Suggested strategies to meet this action

Although the governing body is responsible for ensuring that the organisation's priorities consider the specific health needs of Aboriginal and Torres Strait Islander people, management, is responsible for actively engaging with Aboriginal and Torres Strait Islander people to identify and implement priorities for clinical trial service provision including:

- The health service organisation plans to undertake clinical trials that meet the priorities of Aboriginal and Torres Strait Islander people

- The health service organisation engages Aboriginal and Torres Strait Islander liaison officers to work with clinicians and interpreters to improve access to clinical trials and opportunities for Aboriginal and Torres Strait Islander to participate in a clinical trial
- Developing a workforce and employment strategy that sets targets and identifies how to increase or maintain the participation of Aboriginal and Torres Strait Islander people in the clinical trial workforce across clinical, managerial, support and advocacy roles
- Provide cultural mentors for non-Indigenous members of the clinical trial workforce
- The health service organisation promotes collaboration with Aboriginal and Torres Strait Islander community-controlled health services and adopts a holistic model of health and wellbeing in planning, designing and implementing clinical trial services
- Establishing mechanisms to review the appropriateness and effectiveness of clinical trial services for Aboriginal and Torres Strait Islander people, including options to improve access to a clinical trial using tele-health strategies[50]
- Actively engage with the Aboriginal and Torres Strait Islander community to improve health literacy and encourage engagement with research
- Coordinating communication about clinical trials between the Aboriginal and Torres Strait Islander community and the health service organisation
- Evaluate and routinely report on clinical trial service provision improvement initiatives to the governing body, clinicians and the local Aboriginal and Torres Strait Islander communities
- Providing clinical trial related information materials in Aboriginal and Torres Strait Islander languages, as appropriate.

Key tasks

- Engage with Aboriginal and Torres Strait Islander patients and communities to set priorities and plan clinical trial services that meet the priorities of Aboriginal and Torres Strait Islander people, and develop mechanisms to continuously review the appropriateness and effectiveness of clinical trial services for Aboriginal and Torres Strait including data relating to patient experience and engagement and complaints
- Implement, monitor and report on strategies for workforce development and communication between Aboriginal and Torres Strait Islander community-controlled organisations and the health service organisation regarding clinical trial services.

Examples of supporting evidence

- Documents that incorporate the priorities and strategies to deliver clinical trial services to meet the priorities of Aboriginal and Torres Strait Islander people
- Documented goals and performance indicators of clinical trial services for Aboriginal and Torres Strait Islander health outcomes and targets that are regularly monitored and reported to the governing body
- Documented workforce training to deliver clinical trial services for Aboriginal and Torres Strait Islander people
- Committee and meeting records that describe priorities and strategies to deliver clinical trial services for Aboriginal and Torres Strait Islander people
- Examples of specific strategies that have been implemented and, community engagement that has been undertaken to meet the needs of Aboriginal and Torres Strait Islander people to access and/or participate in a clinical trial.

Action 1.5

The health service organisation or trial site considers the safety and quality of health care for patients in its business decision-making.

How does this action apply to a health service organisation with a clinical trial service?

Clinical trial services are provided in an environment that supports a commitment to quality clinical trial service provision in its business decision making and the health service organisation considers the safety and quality implications for patients, trial participants, consumers and the workforce when determining a suitable workspace. That is, the health service organisation or trial site is willing to direct resources relating to equipment, buildings and physical work space, consumables, staffing and staff training to clinical trial services.

Suggested strategies to meet this action

- Include safety and quality goals, objectives and strategies to deliver clinical trial services prominently in business and operational strategic plans. This ensures that all strategic and decision-making processes consider the quality of clinical trial service provision across multiple therapeutic areas within the organisation
- If a proposal for service development or a change in scope of clinical trial services explicitly identifies implications for the quality of clinical trial service provision, the health service organisation adopts policies, procedures or protocols to explain how risks associated with the change will be managed
- Train the workforce to consider quality issues when developing business cases or influencing business decisions.

Other strategies may include ensuring that:

- The terms of reference for committees (for example, finance and audit committees, strategic planning committees) consider quality clinical trial service provision when making business decisions
- Decisions about the procurement of building, plant, consumables and equipment are informed, and that products and services are fit for purpose, comply with relevant standards, and take into consideration the needs of the clinical trial service.

Key tasks

- Review the organisation's strategic planning and business planning processes to ensure that they explicitly capture strategies and initiatives to deliver clinical trial services across multiple therapeutic areas
- Review templates for submitting business proposals to the governing body and management, and ensure that they take account of the impacts on quality of clinical trial service delivery.

Examples of supporting evidence

- Strategic plans, operational plans or business plans that outline the potential impact of decisions to deliver clinical trial services
- Committee and meeting records for strategic planning committees, finance and planning committees, that show the quality of clinical trial service provision is considered in business decision-making
- Business proposal templates that include consideration for developing and delivering quality clinical trial services at the clinical department levels and across the health service organisation
- A register of safety and quality risks relating to clinical trial service provision that includes actions to manage the identified risks.

Clinical leadership

Action 1.6

Clinical leaders support clinicians to:

a. **Understand and perform their delegated safety and quality roles and responsibilities**
b. **Operate within the clinical governance system to improve the safety and quality of health care for patients.**

How does this action apply to a health service organisation with a clinical trial service?

Clinical leaders and leaders of clinical trial services work to support a culture of responsible research conduct in the health service organisation, and actively take part in the development of an organisational culture that enables and gives priority to highly quality clinical trial service provision.

The clinical trial workforce actively communicates their commitment to the delivery of high-quality clinical trial services and operates within the National Clinical Trials Governance Framework to improve the quality of a clinical trial service provision and patient and consumer access to this service.

Clinical trial investigators understand and perform their delegated safety and quality roles and functions in their field of practice and are responsible for supervising his or her clinical trial team.

Suggested strategies to meet this action

The health service organisation can ensure that the clinical trial workforce operates within the National Clinical Trials Governance Framework through strong leadership. Commitment from leaders is important, because their actions and attitudes influence the perceptions, attitudes and behaviours of the workforce.[51]

Clinical leaders engage with managers (clinical and non-clinical) regarding the quality of clinical trial service provision by defining the delegated roles and functions of the clinical trial workforce. These may include implementing strategic direction, managing the operation of the clinical trials governance system, reporting on quality and effectiveness of the system, and implementing the organisation's quality clinical trial service provision culture.

Strategies to support health service organisations meet this action include:

- Ensure clinical trial investigators and their clinical trial teams safety have access to and undertake training in the principles of GCP as a minimum requirement
- Ensure all members of the workforce have access to information about their expected roles and functions in the operation of the National Clinical Trials Governance Framework
- Clearly documenting the reporting lines and relationships for performance in clinical trial service delivery
- Conducting performance appraisals and auditing clinical trial service delivery to ensure workforce operate within the National Clinical Trials Governance Framework
- Reviewing regulatory and sponsor audit results and take action to deal with any issues identified.

Clinical leaders support their clinical trial workforce and other clinicians by:

- Supervising clinical trial site staff in the delivery of safe, high-quality clinical trials
- Conducting performance appraisals or peer reviews
- Reviewing safety and quality performance data, such as clinical trial operational metrics, clinical trial annual reports within their unit and comparing these data with units across the health service organisation

- Ensuring that the workforce understands the clinical trials governance system and receives mentoring to develop this understanding.

Key tasks

- Define and allocate the delegated roles and functions of the clinical trial workforce
- Conduct clinical audits to ensure that clinicians operate within the National Clinical Trials Governance Framework
- Report audit findings to the governing body.

Examples of supporting evidence

- Policy documents that outline the delegated roles and functions of clinical leaders for delivery and supporting clinical trial services
- Employment documents that describe the roles and functions of clinical leaders who undertake roles and functions such as: trial investigators, trial coordinators, trial managers and/or clinical trial pharmacists
- Documented workforce performance appraisals that include feedback to clinical leaders on the performance of their roles and functions as they relate to clinical trial service delivery
- Work force training documents
- Reviews of workforce performance (individually and collectively) under the National Clinical Trials Governance Framework
- Documented results of audits and actions taken to deal with any identified issues.

Governance, leadership and culture

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

- Establish and supports 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 HRECs office, research office and/or site-specific assessment office
- Establish and maintains the National Clinical Trials Governance Framework and management practices for the responsible conduct of clinical trials across their health service organisation and delegates 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
- Takes the lead on setting the organisation's expectations for partnering with consumers
- Review reports on the health service organisation's 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.

Roles and functions of managers (clinical and non-clinical)

- Advise and inform the governing body on matters related to clinical trials
- Operate clinical trial services within the strategic and policy parameters endorsed by the governing body
- Ensure the systems that support clinical trial service delivery are well designed and perform well
- Lead the development of business plans, strategic plans, and organisational policies and procedures relevant to safety and quality
- Integrate safety and quality processes into organisational plans, policies and procedures
- Set up effective relationships with relevant individuals across the health service organisation to support good clinical trial operational outcomes

- Model the safety and quality values of the health service organisation in all aspects of management
- Support clinicians who embrace clinical trial leadership roles
- Create opportunities for the workforce to receive education in Good Clinical Practice in the conduct of clinical trials.

Roles and functions of the clinical trial workforce

- 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 National Clinical Trials Governance Framework.

Patient safety and quality improvement systems

Policies and procedures

Action 1.7

The health service organisation uses a risk management approach to:

a. **Set out, review, and maintain the currency and effectiveness of, clinical trial policies, procedures and protocols**
b. **Monitor and take action to improve adherence to clinical trial policies, procedures and protocols**
c. **Review compliance with legislation, regulation and jurisdictional requirements.**

How does this action apply to a health service organisation with a clinical trial service?

Safety and quality systems are integrated with governance processes to enable health service organisations and trial sites to actively manage and improve the quality and efficiency of clinical trials for patients, trial participants and consumers.

In order to meet this action the health service organisation ensures that its clinical trials policies comply with legislation, regulation, and state or territory requirements. The health service organisation also ensures documents are current, comprehensive and effective.

Effective clinical trial governance creates a learning environment and a comprehensive program of continuous quality improvement. The organisation's quality systems should ensure that incidents are recognised, reported and analysed, and used to improve the clinical trial service. It is important that these systems are integrated with governance processes to enable the health service organisation to actively manage risk, and to improve quality of clinical trial services.

Suggested strategies to meet this action

The governing body should ensure the development, review and maintenance of a comprehensive set of organisational policies, procedures and protocols. These documents should cover clinical trial service provision and be consistent with the organisation's regulatory obligations.

The organisation's approach to delivering and supporting clinical trials should be described and endorsed by the governing body, and include the following topics:

- Process for developing policies, procedures and protocols
- Process for monitoring and reporting on the quality of clinical trial service provision and also trial conduct (that is, trial operations and trial conduct)
- Managing risk relating to clinical trial service provision
- Managing complaints and compliments
- Managing open disclosure
- Engaging the clinical trial workforce in planned, systematic audits of clinical trial services following agreed protocols and schedules.

Develop policies, procedures and protocols

The governing body must clearly delegate responsibility for developing and maintaining policies, procedures and protocols. This includes identifying a custodian to ensure that the processes for developing, reviewing and monitoring compliance with policies, procedures and protocols are documented. Roles and functions of identified positions and committees with the authority to amend or endorse each policy, procedure or protocol should be documented.

Policies relating to clinical trial service provision may be developed or adapted at different levels within the organisation. However, all policy, procedure and policy documents should be incorporated into a single coherent suite to maximise the effectiveness of the policy development process.

Support effective implementation of a policy system by ensuring that the clinical trial workforce has:

- Ready access to relevant policies, procedures and protocols
- Position descriptions, contracts, by-laws or other mechanisms that require the workforce to comply with their roles, functions and accountabilities, and with organisational policies, procedures and protocols.

Monitor compliance with legislation, regulation and state or territory requirements

Keep information about instances of noncompliance with the organisation's policies, procedures and protocols. Where appropriate, incorporate the information into the organisation's risk register and quality improvement planning processes.

Maintain well-designed legislative compliance processes. Incorporate a compliance register to ensure that the organisation's policies are regularly updated, enabling the organisation to respond to regulatory changes, compliance issues and case law.

Identify relevant industry standards, and develop processes to implement and monitor compliance with these standards, which may include legislative and guidance material such as:

- The Australian Code for the Responsible Conduct of Research (2018) (the Code)
- The National Statement on Ethical Conduct in Human Research (2007) - Updated 2018
- The Clinical Trial Handbook, September 2018
- Guidance for Good Clinical Practice 2016 (ICH-GCP)
- Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018)
- Keeping research on track: a guide for Aboriginal and Torres Strait Islander peoples about health research ethics (2018)
- Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)
- Consolidated Standards of Reporting Trials (CONSORT).

Key tasks

- Set up a comprehensive suite of policies, procedures and protocols that emphasise quality in clinical trial service provision
- Set up mechanisms to maintain currency of policies, procedures and protocols, and to communicate changes in them to the workforce
- Review the use and effectiveness of organisational policies, procedures and protocols through audits or performance reviews
- Periodically review policies, procedures and protocols to align them to state or territory requirements, and ensure that they reflect best practice and current evidence
- Develop or adapt a legislative compliance system that incorporates a compliance register to ensure that policies, procedures and protocols are regularly and reliably updated, and respond to relevant regulatory changes, compliance issues and case law.

Examples of supporting evidence

- Documented processes for developing, authorising, and monitoring the implementation of the health service organisation's policy documents relating to clinical trial service provision
- Register of policy document reviews, including the date of effect, dates that policy documents were amended and a prioritised schedule for review
- Examples of policy documents that have been reviewed in response to identified risks, or changes in legislation, regulation or best practice
- Committee and meeting records that describe the clinical trial service governance structure, including delegations and roles and functions for overseeing the development of policy documents
- Results from workforce surveys and feedback on policy documents
- Communication with the workforce on new or updated policy documents
- Training documents on new or amended policy documents, or use of policy documents.

Measurement and quality improvement

Action 1.8

The health service organisation uses organisation-wide quality improvement systems that:

a. **Identify safety and quality measures, and monitor and report performance and outcomes**
b. **Identify areas for improvement in clinical trials safety and quality**
c. **Implement and monitor safety and quality improvement strategies**
d. **Involve consumers and the workforce in the review of safety and quality performance and systems.**

How does this action apply to a health service organisation with a clinical trial service?

An effective quality improvement system reflects the health service organisation's priorities and strategic direction for clinical trial service provision. Through this system, the health service organisation identifies and documents risks, and actions taken to manage identified risks.

Suggested strategies to meet this action

Develop a quality improvement system

The elements of a successful quality improvement system include:

- A description of 'high quality' that is reflected through the organisation's vision, mission and values for the delivery of clinical trial services
- A definition of the organisation's clinical trials stakeholders
- Clearly defined and aligned organisational objectives and clinical trial service objectives
- Clearly defined processes and functions that are required to meet objectives for clinical trial service provision
- Evidence of training for the organisation's trial investigators, their clinical trial teams and other members of the workforce in Good Clinical Practice for conducting clinical trials
- Processes to verify that the quality improvement system is operating effectively
- Mechanisms for monitoring trial participant and consumer satisfaction on the quality of clinical trial service provision.

Define quality and how it will be measured

Provide a common language and understanding for the design, implementation and monitoring of clinical trial service provision performance throughout the organisation and define the elements of quality to be used by the organisation, for example:

- Timeliness of HREC and local Site-Specific Assessment review and approval decision
- Process for selecting clinical trials to maximise the most effective use of resources, taking into account other current or potential trials and available resources & patient populations to maximise likely success
- Effectiveness of trial sites to determine the available trial population and meet recruitment targets
- Process to monitor the conduct of the trial in adherence to the approved clinical trial protocol to minimise the number of trial protocol deviations and violations
- Process for referring patients to clinical trials
- Process for reviewing inactive trials or trials that fail to recruit participants to maximise the most effective use of resources
- Patient, trial participant and consumer experience.

Key tasks

- Define quality for clinical trial service provision and share this information with the workforce (for example, effectiveness, safety, consumer experience)
- Review the quality improvement system, including the vision, mission, values and objectives, to ensure that they reflect the organisation's clinical trial service provision priorities, and strategic direction
- Decide how feedback will be collected from the workforce, patients and consumers
- Consider whether there is a coherent, planned and systematic schedule of review of clinical trial organisational systems, and reliable processes to capture findings and implement necessary improvements
- Develop a schedule for reporting to the governing body and managing the design and performance of key clinical trial systems
- Monitor and review progress on actions taken to improve quality, and provide feedback to the workforce, patients, trial participants and consumers
- Provide information and training, where necessary, to the workforce, patients and consumers to encourage their involvement in the analysis of performance data.

Examples of supporting evidence

- Policy documents that describe the process for monitoring the quality of clinical trial service provision
- Feedback from the workforce about the use of clinical trial operational performance data
- Feedback from consumers about their involvement in the review of safety and quality performance data
- Quality improvement plan that includes actions to deal with identified risks and issues as they arise
- Examples of specific improvement activities that have been implemented and evaluated
- Committee and meeting records in which reports, presentations, and performance data are regularly reviewed and reported to the governing body or relevant committees
- Audit report from regulatory agencies and trial sponsor organisations, presentations and analysis of quality performance data
- Documented national quality performance measures such as:
  1. Number of new trials and breakdown by trial phase, and by sponsor type
  2. Overall study start-up timeline (regulatory timeline)
  3. Ethics and governance approval timeline
  4. Human Research Ethics Committee (HREC) decision approval timeline
  5. SSA/site assessment timeline
  6. Trial recruitment: actual and planned number of participants recruited
  7. Site recruitment: actual and planned number of participants recruited
  8. Total inbound (internal and external) investment annually.

Additional metrics may also be collected for local quality improvement purposes such as:[52]

- Number of new enrolments to clinical trials by clinical trial and trial unit for the reporting period and year to date
- Number and median calendar days from HREC approval to RGO submission year to date (report by trial type ie: multi-centre trials approved via the NMA scheme)
- Median calendar days from local Site-Specific Assessment submission to authorisation by clinical trial

- Number of trials pending RGO authorisation by reporting period and /or year to date
- Median calendar days from recruitment open date to first participant on trial by clinical trial and trial unit for the reporting period and/or year to date
- Median calendar days from recruitment open date to first participant on trial by clinical trial and trial unit for the reporting period and/or year to date
- Proportion of enrolments to total Full Time Equivalent (FTE) trial coordinator or staff member with functions undertaking trial recruitment for the reporting period and/or year to date
- Recruiting to site target by recruiting clinical trial and trial unit for the reporting period and/or year to date
- Clinical trials financial reconciliation by clinical trial and trial unit for the reporting period and/or year to date.

Action 1.9

The health service organisation ensures that timely reports on safety and quality systems and performance are provided to:

a. **The governing body**
b. **The workforce**
c. **Consumers and the local community**
d. **Other relevant health service organisations.**

How does this action apply to a health service organisation with a clinical trial service?

Health service organisations develop processes to provide accurate and timely performance information on clinical trial operations to key stakeholders. Key stakeholders include but are not limited to: the governing body, state or territory health department, clinical trial workforce, consumers and the local community, other relevant health service organisations and trial sponsors.

Suggested strategies to meet this action

Routinely collecting clinical trial process (operational) data and outcome (operational outcomes and trial findings) data and monitoring data for trends enables organisations to understand outcomes from service delivery, and to respond to deviations from the expected outcomes promptly.

Reporting the outcomes of trials the health service organisations conducts and sharing these findings with clinical staff and the community supports the translation of evidence into clinical practice.

Monitoring clinical trial service delivery performance data should include all therapeutic areas and cover all locations where clinical trials are being conducted across the organisation to ensure a comprehensive picture of performance.

Providing the governing body and the clinical trial workforce with access to the organisation's most important clinical trial operational metrics (indicators) will enable regular review and facilitates the health service organisation to respond to issues as they arise. Suitable metrics should include key relevant national priority indicators and regulatory requirements such as those provided at Action 1.8 and in addition, those covering workforce and trial participant experience.

Provide the governing body and management with regular, comprehensive safety and quality presentations and reports from managers (clinical and non-clinical) and the clinical trial workforce. Schedule data presentations following agreed criteria (for example; HREC and site-specific assessment review and approval time lines, participant recruitment, organisational priority or focus for clinical trial service delivery).

Effective data presentations should cover:

- The design of the systems and processes being used to support and enhance clinical trial service delivery
- Evaluation on the effectiveness of organisational systems to support clinical trial service delivery
- Comparisons with clinical trial operational practice benchmarks from health networks, jurisdictional and national data sets
- Safety and quality outcomes, including consumer and workforce experience and patient-reported outcomes
- Plans to improve the quality of clinical trial service provision.

Key tasks

- Endorse a schedule of reporting that outlines the topic areas, format and frequency of reporting on clinical trial service delivery performance, and the effectiveness of the clinical trial service delivery systems
- Collaborate with the clinical trial workforce, consumers, clinical trial networks and other health service organisations to identify the topic areas, format and frequency of reporting to these groups on clinical trial service provision performance, and the effectiveness of systems to support this service.

Examples of supporting evidence

- Reports on clinical trial service provision performance data that are provided to all stakeholders including: the governing body, clinical and non-clinical managers, national, state and territory governments, trial sponsors, health service organisation committees, the clinical trial workforce and/or consumers
- Committee and meeting records in which clinical trial service operational indicators, data or recommendations by the governing body are discussed
- Committee and meeting records in which the appropriateness and accessibility of the health service organisation's clinical trial service provision performance information are discussed
- Communication strategy that describes processes for disseminating information on clinical trial service provision performance to the community
- Communication with the clinical trial workforce and consumers on the health service organisation's clinical trial operational performance
- Clinical trial service provision operational performance information published in annual reports, newsletters or other local media
- Reporting templates and calendars
- Clinical trial service provision operational performance provided to external organisations such as clinical trial networks and universities.

Risk Management

Action 1.10

The health service organisation:

a. **Identifies and documents organisational risks**
b. **Uses clinical and other data collections to support risk assessments**
c. **Acts to reduce risks**
d. **Regularly reviews and acts to improve the effectiveness of the risk management system**
e. **Reports on risks to the workforce and consumers**
f. **Plans for, and manages, internal and external emergencies and disasters.**

How does this action apply to a health service organisation with a clinical trial service?

This action relates to, and relies on Actions 1.11; 1.12 and 1.13. Risk management and incident management relies on strong governance arrangements, a culture of quality improvement as well as support from research information management and work flow systems and other data collections (such as clinical trial annual reports) that provide good quality reliable data about risks and also issues as they occur.[53]

A risk is a factor or hazard that has the potential to cause harm in clinical trial service provision. An issue is a factor that has occurred. The health service organisation identifies risks, develops mitigating strategies, analyses and evaluates the risk associated with that potential hazard (risk analysis, and risk evaluation) and uses risk assessments to set priorities for, and improve the quality of clinical trial service provision.

Suggested strategies to meet this action

Define the governing body's responsibility

The governing body is responsible for ensuring the integrity of the risk management system, the organisational research information management and work flow systems and other data collections.

The governing body should:

- Determine the organisation's risk appetite and tolerance – that is, the amount and type of risk that an organisation is willing to take to meet its strategic objectives for delivery clinical trial services
- Ensure that the organisation's risk management system is clearly documented in policies, procedures and protocols that define a vision, principles, objectives, practices, roles and functions, resources, service outcomes and how outcomes will be measured
- Ensure that enough resources are allocated to the organisation's risk management system
- Foster an organisational culture that focuses on quality clinical trial service provision and continuous improvement in identifying and managing risk
- Incorporate systematic audits of safety and quality systems relating to clinical trial service provision in the whole-of-organisation audit program
- Ensure availability of data and information to support quality assurance and review of clinical trial services across the health service organisation or trial site
- Monitor clinical trial service provision performance, and consider implications for system design and opportunities for improvement.

Embed a systems approach to risk management in the provision of clinical trial services

Embed a systems approach to risk management by:

- Establishing a reliable and systematic process for identifying risks relating to clinical trial service provision across all therapeutic areas
- Ensuring that the risk management system adopted by the health service organisation is fit for purpose for clinical trials services
- Maintaining risk management policies, procedures and protocols for quality service provision and ensuring that all trial investigator and their clinical trial teams, clinical and non-clinical managers and other members of the workforce are familiar with them
- Maintaining a comprehensive, accurate and current risk register, which can be used as a practical tool for risk management
- Actively encouraging and supporting the clinical trial workforce, patients and other stakeholders, such as clinical trial sponsors to report risks and issues as they arise
- Describing and establishing a mechanism for capturing risks in the risk management system
- Assigning all risks to a 'risk owner', who is responsible for managing and monitoring risks, and ensuring that appropriate accountability arrangements are in place
- Making use of clinical registers, if possible
- Systematically providing appropriate information, orientation, education and training to employees and students on using the risk management system, at induction and at regular intervals
- Systematically monitoring and assessing performance regarding risk, within a defined performance monitoring framework, at all levels of the organisation, including the governing body and management.

Engage the clinical trial workforce

Trial investigators, clinical trial site staff, clinical and non-clinical managers and the clinical trial workforce has the best knowledge of, and ability to identify, risks relating to clinical trial service provision. Foster engagement and participation of the workforce by:

- Regularly providing information about the organisation's risk management system at orientation, and through ongoing education and training
- Reinforcing information about roles, responsibilities and accountabilities for reporting and managing risk to managers, clinicians and other members of the workforce (for example, by using screensavers, the intranet, newsletters and standing items on meeting agendas)
- Establishing within the committee structure responsibility for systematic risk identification, assessment, review and management
- Using routine meetings as an opportunity to identify and discuss clinical and other safety concerns
- Including patient safety as a standing item on meeting agendas of the governing body and management
- Including questions about patient safety risks in employee culture surveys
- Providing feedback to the workforce and consumers on actions taken to mitigate risks
- Regularly assessing the organisational climate in areas of risk, safety and quality using validated survey tools
- Codify the retention of organisational knowledge and intellectual property.

Key tasks

- Review the organisation's risk management system, and ensure that it is appropriately designed, resourced, maintained and monitored
- Consider existing sources of information such as research information management and work flow systems and other data collections (such as clinical trial annual reports) clinical trial service provision
- Ensure clear allocation of roles, functions and accountabilities for maintaining the risk management systems and for performing the actions required
- Regularly review risks and report on risk to the governing body, the clinical trial workforce and consumers
- Periodically review the effectiveness of the risk management system
- Implement and monitor a risk register and review it regularly to ensure that it is kept up to date it includes all relevant information relating to clinical trial service provision.

Examples of supporting evidence

- Policy documents that describe the processes for implementing and monitoring the risk management system
- Risk register that includes actions to manage identified risks relating to clinical trial service provision
- Reports on safety and quality data that are analysed to identify and monitor clinical trial service operational risks
- Feedback from the workforce on safety and quality risks relating to clinical trial service provision, and the effectiveness of the risk management system
- Committee and meeting records regarding oversight of the risk management system, or the review of other data collections relating to clinical trial services
- Committee and meeting records in which risk, and the appropriateness and accessibility of safety and quality performance information have been discussed
- Communication with the workforce and consumers on risks and risk management
- Records of safety and quality performance information published in annual reports, newsletters, newspaper articles, radio items, websites or other local media
- Business continuity plan, or emergency and disaster management plan
- Training documents relating to risk management, and the management of emergencies and disasters, including evacuation and emergency drills.

Incident management systems and open disclosure

Action 1.11

The health service organisation or trial site has organisation-wide incident management information management and investigation systems, and:

a. **Supports the workforce to recognise and report incidents**
b. **Supports patients, carers and families to communicate concerns or incidents**
c. **Involves the workforce and consumers in the review of incidents**
d. **Provides timely feedback on the analysis of incidents to the governing body, the workforce and consumers**
e. **Uses the information from the analysis of incidents to improve safety and quality**
f. **Incorporates risks identified in the analysis of incidents into the risk management system**
g. **Regularly reviews and acts to improve the effectiveness the incident management system and investigation systems.**

How does this action apply to a health service organisation with a clinical trial service?

There are requirements and clear guidelines for safety reporting during the conduct of a clinical trial. Reference material including the NHMRC National Statement[54] and in other guides such as Safety monitoring and reporting in clinical trials involving therapeutic goods[55] provide guidance on clinical trial safety monitoring and reporting requirements and the responsibilities of those involved in clinical trials to monitor and report adverse events and other safety issues as they occur.

This action relates to the health service organisation having a system for appropriately identifying and managing incidents relating to

clinical trial service provision. Just as the health service organisation has systems for identifying and managing clinical incidents, the incident management and investigation system may also be used by trial investigators, their clinical trial teams, clinical and non-clinical managers and the clinical trial workforce to improve the quality of clinical trial service provision.

Suggested strategies to meet this action

Incident reporting can improve clinical trial service provision through process improvement and can change the way the trial investigators and clinical and non-clinical managers and the clinical trial workforce think about risk, and incidents and raise awareness of risks and issues as they occur. The nature of the risks identified and the occurrence of incidents faced by organisations may vary according to the type of organisation and the context of the clinical trial service.[10]

Support the workforce

Trial investigators, clinical and non-clinical managers, should encourage the clinical trial workforce to use the incident management system to report clinical incidents, near misses and adverse events relating to clinical trial service provision.[56] When an incident or near miss occurs the clinical trial workforce with clinical and non-clinical managers, work to find solutions for improving safety,[57] especially when the improvement actions require coordination across teams or departments. The requirement to report and manage incidents as they arise should not be considered as a punitive exercise, but should be considered though an educative and systems improvement approach.

Support trial participants, patients, carers and their families

Support trial participants, patients, carers and their families to communicate their concerns by:

- Training the clinical trial workforce on how to respond to sponsors, trial participants and their families who raise concerns or report an incident
- Providing, when possible, appropriately skilled members of the workforce to liaise with trial sponsors, trial participants, carers and their families who report concerns or incidents
- Conducting patient experience surveys or seeking feedback on incidents
- Providing information about improvement activities that have been implemented based on trial sponsor and trial participant feedback, patient and consumer feedback.

Report on, and review, incidents

Include information such as the actions taken as a result of a specific incident or category of incidents, and indicators such as time to complete actions stemming from incident reports. This will enable governing bodies and management to fulfil their governance responsibilities.

Define a reporting framework that clearly identifies the data that will be available and reported at each level in the organisation. This will enable members of the clinical trial workforce and the governing body to monitor and respond to system performance.

The clinical trial workforce, trial participants, patients and consumers can be involved in the review of incidents through:

- Regular review of reports or data analysis on incidents relating to clinical trial service delivery
- Periodic review of incident management and investigation systems to ensure that they are effective in improving safety.

Key tasks

An incident management and investigation system may already be in place in the health service organisation. Ensure the incident management system is resourced, maintained and monitored to report incidents relating to clinical trial service provision. Train the clinical trial workforce about the risk management and incident management systems and:

- Inform trial participants, their families and carers and trial sponsors about how they can report risks or concerns and, make this process easy to navigate
- Implement a reporting and management framework to ensure that incident data are used to inform the governing body, the clinical trial workforce and consumers, to drive improvements in safety and quality
- Periodically audit the incident management and investigation system to improve its design and performance, and assess whether it is adequately resourced.

Examples of supporting evidence

- An accessible incident reporting system
- Safety and quality performance data that includes the actions taken following review of incidents that occur
- Policy documents for reporting, investigating and managing clinical incidents
- Information on clinical incidents and near misses, and the actions taken to manage identified risks that are incorporated into the health service organisation's risk management system or quality improvement plan
- Committee and meeting records that describe the incident management and investigation system, and the strategies and actions to reduce risk
- Information and resources that support the workforce and consumers to report clinical incidents
- Clinical incident reporting forms and tools that are accessible to the workforce and consumers
- Feedback from the workforce and consumers regarding their involvement in the review and analysis of organisational safety and quality performance data
- Results of completed clinical incident investigations and examples of specific improvement activities that have been implemented and evaluated to reduce the risk of incidents identified through the incident management and investigation system.

Action 1.12

The health service organisation:

a. **Uses an open disclosure program that is consistent with the Australian Open Disclosure Framework**[58]
b. **Monitors and acts to improve the effectiveness of open disclosure processes.**

How does this action apply to a health service organisation with a clinical trial service?

The successful implementation of incident reporting is underpinned by an open disclosure process. An open disclosure process enables the health service, trial investigators, clinical trial workforce, trial sponsors, trial participants their carers and their families to communicate openly about an incident that resulted in harm to a trial participant.[59] Open disclosure is:

- A patient and consumer right
- An essential professional requirement and institutional obligation
- A normal part of an episode of care should the unexpected occur
- An attribute of a high-quality service organisation and an important part of healthcare quality improvement.

The health service ensures that the clinical trial investigators and the clinical trial workforce are trained and supported to discuss incidents that occur with trial participants, and that there is a process for trial participants to escalate their concerns and should include:

- The elements of an apology or expression of regret (including the word 'sorry')
- A factual explanation of what happened
- An opportunity for the patient to relate their experience
- An explanation of the steps being taken to manage the event and prevent a recurrence.

Suggested strategies to meet this action

Health service organisations implementing an open disclosure program for a clinical trial service should:

- Develop or adapt policies, procedures or protocols that are consistent with the Australian Open Disclosure Framework[62]
- Implement a monitoring and reporting process for open disclosure events to ensure that they are followed up and improvements are actioned
- Review open disclosure events to find out how the open disclosure program could be improved
- Provide access to training and support for relevant members of the workforce who have responsibility for managing issues involving open disclosure within the organisation.

Key tasks

- Adopt and implement the Australian Open Disclosure Framework in a way that reflects the context of clinical trial service provision
- Ensure that trial investigators and members of the clinical trial workforce who will be involved in open disclosure are trained so that focus on the management of incidents is consistent with the Australian Open Disclosure Framework.

Examples of supporting evidence

- Policy documents that are consistent with the principles and processes outlined in the Australian Open Disclosure Framework[58]
- Reports on open disclosure that are produced by the health service organisation
- Information and data on open disclosure presented to the governing body and relevant committees
- Committee and meeting records about issues and outcomes relating to open disclosure.

Feedback and complaints management

Action 1.13

The health service organisation:

a. **Has processes to seek regular feedback from patients, carers and families about their experiences and outcomes of care**
b. **Has processes to regularly seek feedback from the workforce on their understanding and use of safety and quality systems**
c. **Uses this information to improve safety and quality systems.**

How does this action apply to a health service organisation with a clinical trial service?

Feedback from trial investigators, the clinical trial workforce, trial sponsors, trial participants, their families and carers is used to improve safety and quality. The health service organisation collects feedback from the workforce and uses patient experience data to improve the quality of clinical trial service provision.

Suggested strategies to meet this action

Develop mechanisms to gather feedback, and report outcomes

The health service organisation adopts a validated and reliable method to systematically seek feedback from the clinical trial workforce, trial sponsors and trial participants their carers and families. Feedback may be sought on a general (that is, organisation-wide) or specific (that is, individual service or unit basis) and ideally, should be gathered using well-designed (and, validated) data collection tools and should be used to improve the quality of care. The feedback system should be readily accessible easy to use and facilitate the inclusion of this feedback into the health service organisations feedback and reporting systems.

The health service organisation may consider using existing tools such as The Australian Hospitals Patient Experience Question Set (AHPEQS).[60] The Commission has developed a set of 12 questions, which hospitals and day procedures services use to understand what patients and observed and experienced about their care. The Commission developed AHPEQS may be used to assess trial participant experience and facilitates comparisons internally and with health services elsewhere for effective benchmarking of improvements in service provision over time.

Ensure trial participants and the clinical trial workforce are aware of how to provide feedback

The health service organisation ensures that the clinical trial workforce, trial sponsors, trial participants their carers and families receive information about what has been learned from the feedback system, and how it has been used to generate improvements in clinical trial service provision.

Key tasks

Implement approaches and systems that are appropriately designed, resourced and maintained to collect trial participant experience data to collect data from the clinical trial workforce and trial sponsors on their understanding of quality clinical trial service provision, and periodically review the effectiveness of the organisation's feedback system.

Examples of supporting evidence

- Data collection tools for collecting clinical trial workforce, trial sponsor, trial participants their carers, and family feedback
- Committee or meeting records about the selection of patient experience questions, and review of clinical trial workforce, trial sponsor and trial participant and their carer and family feedback.

Action 1.14

The health service organisation or trial site has a complaints management system, and:

a. **Encourages and supports patients, carers and families, and the workforce to report complaints**
b. **Involves the workforce and consumers in the review of complaints**
c. **Resolves complaints in a timely way**
d. **Provides timely feedback to the governing body, the workforce and consumers on the analysis of complaints and actions taken**
e. **Uses information from the analysis of complaints to inform improvements in safety and quality systems**
f. **Records the risks identified from the analysis of complaints in the risk management system**
g. **Regularly reviews and acts to improve the effectiveness of the complaints management system.**

How does this action apply to a health service organisation with a clinical trial service?

The health service organisation has an effective complaints management system which is used to improve the quality of clinical trial service provision. That is, complaints from patients, trial sponsors trial participants, their carers and families are received, reviewed and resolved in a timely manner and, there are mechanisms in place to review the effectiveness of the complaints management system. The effective implementation of this action is supported by or relies on Action 1.11 incident management system and open disclosure.

Suggested strategy to meet this action

The policy framework underpinning the complaints management system, includes the roles, and functions of individuals and committees relevant to clinical trials.

Key tasks

- Implement and maintain capacity for reporting complaints regarding clinical trial service provision into the organisation's complaints management and investigation system for quality improvement
- Implement processes to involve the trial investigators and the clinical trial workforce in the review of organisational safety and quality performance information including reports on the analysis of complaints data and the actions to deal with identified issues.

Examples of supporting evidence

- Policy documents that describe the processes for recording, managing and reporting complaints
- Complaints register that includes responses and actions to deal with identified issues, and its schedule for review
- Training documents about the complaints management system
- Consumer and patient information and resources about the health service organisation's complaints mechanisms
- Feedback from the workforce on the effectiveness of the complaints management system
- Feedback from consumers and carers on the analysis of complaints data
- Audit results of compliance with complaints management policies
- Evaluation reports that note the effectiveness of responses and improvements in clinical service delivery

- Committee and meeting records in which trends in complaints and complaints management are discussed
- Reports or briefings on complaints provided to the governing body, the workforce or consumers
- Quality improvement plan that includes actions to deal with issues identified
- Examples of improvement activities that have been implemented and evaluated.

Diversity and high-risk groups

Action 1.15

The health service organisation or trial site:

a. **Identifies the diversity of the consumers using its services**
b. **Identifies groups of patients using its services who are at higher risk of harm**
c. **Incorporates information on the diversity of its consumers and higher-risk groups into the planning and delivery of care.**

How does this action apply to a health service organisation with a clinical trial service?

The health service organisation considers the diversity of consumers and high-risk groups in their planning and delivery of clinical trial services. For example, the health service organisation considers the cultural safety needs of people who identify as Aboriginal and Torres Strait Islander and, also consider the needs of culturally and linguistically diverse populations, those individuals with a disability, the elderly, children and those who may be socially disadvantaged.

Suggested strategies to meet this action

Understanding the characteristics of the patient population allows health services to identify groups of people who, because of their condition, either age or gender; social, economic or geographic circumstances; cultural background, religion or preferred language or sexuality may have increased needs when considering or participating in a clinical trial.

Information about the population who access the health service may be gathered from demographic data (such as age, gender, postcode or ethnicity) to understand the diversity of the patient population. Additionally, including risk assessment for groups of patients, procedures or locations of treatments that are known to be high risk into the organisation's quality improvement system and, discussing the strategies to overcome these risks with trial investigators, trial sponsors, the clinical trial workforce and representatives of the different risk groups.

Patient information sheets and consent forms (PICF), including the consent procedure are consistent with national and state and territory legislation and are developed by trial sponsors with health service organisation and approved by the HREC. Trial sponsors are encouraged to use standardised templates, such as those hosted by the NHMRC.[61]

Key tasks

- Identify clinical and administrative data systems that indicate the diversity of the patients using the organisation's health services and the formats, languages and tools to be used to communicate and recruit patient to clinical trials
- Develop strategies to identify high risk patients who maybe potential trial participants and implement mechanisms to provide safety and quality protections for these patients participating in a clinical trial.

Examples of supporting evidence

- Demographic data for the health service organisation and community that are used for strategic planning purposes
- Sample health service user demographic report
- Organisational risk profile that details patient safety and quality risks, and their potential impact clinical trial participants
- Results of an assessment or survey of local needs for clinical trial services
- Consumer and trial participant information that is available in different formats and languages that reflect the diversity of the patient population
- List of local interpreters or consumer advocacy services, and reports on interpreter use and access
- Health service organisation representation at local clinical trial network meetings that reflect the local diversity of the patient population
- Membership of committees with consumer representation that reflect the diversity of the patient population.

Healthcare records

Action 1.16

The health service organisation or trial site has healthcare records systems that:

a. Make the healthcare record available to clinicians at the point of care
b. Support the workforce to maintain accurate and complete healthcare records
c. Comply with security and privacy regulations
d. Support systematic audit of clinical information
e. Integrate multiple information systems, where they are used.

How does this action apply to a health service organisation with a clinical trial service?

The health service organisation ensures that trial investigators and the clinical trial workforce have access to comprehensive, accurate and integrated healthcare records (including clinical and administrative data bases) across multiple therapeutic areas to determine the availability of patient populations suitable for participation in a clinical trial. Health care records maybe used to complete the site feasibility assessment for a clinical trial by a trial site, and to screen and recruit trial participants.

- Periodically review the performance of the healthcare records systems, and improve them as necessary.

Suggested strategies to meet this action

Health service organisations should facilitate access to the healthcare record by trial investigators, clinical trial site staff for trial site feasibility assessments. Access to the healthcare record at the point of care should also be provided to facilitate trial participant screening and recruitment and for recording the patient's status and/or changes to treatment according to the clinical trial protocol. Additionally, there should be processes in place to facilitate access to trial sponsors and contracted research organisations for the purpose of monitoring a clinical trial.

Data storage and retention of trial participant's clinical information should be undertaken in compliance with national, state and territory legislation and guidelines.

Access the healthcare records for trial monitoring purposes

Information about an individual's physical or mental health and wellbeing is both personal and sensitive, and there are many ethical, professional and legal restrictions on the way this information can be used. A number of standards, guidelines and policies currently apply to healthcare record documentation. These standards and processes include facilitating access to data for the appropriate people for quality and research purposes, such as trial sponsors or their delegates. The health service ensures there are systems in place to record and store information regarding details and qualifications of the all personnel accessing the healthcare record for purpose of monitoring or recruiting patients to a clinical trial, and ensures that access to the healthcare record for trial related purposes are provided in a timely manner. Facilitation of remote monitoring by trial sponsors should also be considered.

Additionally, health services should facilitate the exchange of information within and between health service organisations for the purpose of recording, managing and accessing safety information relating to hospital readmissions and adverse events of trial participants to ensure complete and accurate data reporting of the trial.

Key tasks

- Review the availability of healthcare records and clinical and administrative data bases across multiple therapeutic areas to clinical trials staff
- Review the design of the healthcare record to ensure that it facilitates documentation of the relevant clinical trials
- If multiple information systems are used to capture patient clinical information, periodically review the data systems to ensure that the processes for information capture are well designed, well-resourced and working effectively.

Examples of supporting evidence

- Policy documents on access to the healthcare record for, storage, security, consent and sharing of patient information
- Audit results of healthcare records for compliance with policies, procedures or protocols on healthcare records management, including access to healthcare records and sharing of information
- Audit results of the accuracy, integration and currency of healthcare records
- Observation that healthcare records are accessible at the point of patient care
- Observation that computer access to electronic records is available to the clinical trial workforce in clinical areas
- Committee and meeting records in which the governance of the health service organisation's data and information technology (IT) systems is monitored or discussed
- Code of conduct that includes privacy and confidentiality of consumer information
- Signed trial sponsor and clinical trial workforce confidentiality agreements
- Secure archival storage and disposal systems
- Observation of secure storage systems in the clinical trial work space
- Observation that computers are password protected
- Records of ethics approval for research activities that involve sharing patient information
- Templates for issuing login and password details for electronic healthcare records systems
- Audit results of the use of a unique identifier in the healthcare records management system
- Systems in place that enable combining of multiple information systems.

Patient Safety and Quality Improvement Systems

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

- Ensure that all systems for the delivery of clinical trial services are regularly reviewed for their ability to support safe, high-quality care
- Incorporate systematic audits of safety and quality systems relating to clinical trial service provision in the whole-of-organisation audit program
- Ensure availability of data and information to support quality assurance and review of clinical trial services across the health service organisation or trial site
- Monitor system performance, and consider implications for system design and opportunities for improvement
- Ensure that the safety and quality systems in place involve all members of the clinical trial workforce and are subject to periodic review of performance quality improvement and measurement including: effectiveness of clinical trial systems; safety reporting; risk management; incident management; open disclosure; feedback and complaints management.

Roles and functions of managers (clinical and non-clinical)

- Coordinate and oversee the design of systems for the delivery of clinical trial services
- Engage with clinicians and study teams on all clinical trial system design issues
- Allocate appropriate resources to implement well-designed clinical trial systems of care
- Respond to identified concerns about the design of systems
- Periodically and systematically review the design of systems for high quality clinical trial services that promote and maximise safety
- Ensure availability of data and information to clinical trial teams to support quality assurance and improvement
- Ensure that safety and quality systems for undertaking clinical trials reflect the role of the health service organisation within a wider network of other health services and providers
- Implement and resource effective systems for management of quality improvement and measurement: safety reporting; risk management; incident management; open disclosure; feedback and complaints
- Systematically monitor performance across all safety and quality systems relating to the conduct of clinical trials.

Roles and functions of the clinical trial work force

- 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.

Roles and functions of clinical trial sponsors

- Ensure open and transparent communication with the trial site personnel including the principal investigator, clinical trial teams, site coordinating and authorising offices
- Conduct the trial according to the trial protocol and the conditions of the HREC approval
- Provide required documents in a timely manner and support trial sites with document submission to the relevant office (HREC and SSA Office) for adverse event and annual reporting
- Support quality processes and reporting as required on the conduct of clinical trials within the health service organisation or trial site.

Roles and functions of consumers, patients trial participants, their carers and families

- Use opportunities to take an active role in providing feedback, complaints and compliments about experiences in clinical trial participation and, communicate with the organisation about any opportunities for improving clinical trial services
- Participate in the review of safety and quality incidents or other serious adverse events relating to clinical trials
- Reviews and commenting on reports on safety and quality in clinical trial operations
- Communicates with the organisation about potential safety and quality risks in clinical trial service provision
- Becomes involved in quality improvement projects within the health service organisation
- Advocates for, or represents other patients in focus groups and meetings to improve clinical trial participation.

Clinical performance and effectiveness

Safety and quality training

The workforce has the right qualifications, skills and supervision to provide safe, high-quality clinical trials to patients, trial participants and consumers.

Action 1.20

The health service organisation uses its training systems to:

a. **Assess the competency and training needs of its workforce**
b. **Implement a mandatory training program to meet its requirements arising from these standards**
c. **Provide access to training to meet its safety and quality training needs**
d. **Monitor the workforce's participation in training.**

How does this action apply to a health service organisation with a clinical trial service?

Training in Good Clinical Practice

The health service organisation ensures that trial investigators and their clinical trial teams have access to, and undertake training in Good Clinical Practice (GCP) for the conduct of all clinical trials. This is because both industry sponsored clinical trials, and non-industry sponsored clinical trials (investigator-initiated, cooperative group or academic) rely heavily on a skilled and reputable clinical trials workforce.[62]

GCP is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. The standard provides public assurance that the rights, safety, and wellbeing of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki.[63]

Health service organisations have a responsibility to ensure the integrity and ethical appropriateness of each clinical trial they undertake, including protecting the safety and welfare of participants in their clinical trials. The **Australian Code for the Responsible Conduct of Research 2018**[64] and the National Statement[65] promotes integrity in research. In line with best practice it is recommended that all trial investigators and their clinical trial site staff have an understanding of, and receive training in the Principles of GCP for the conduct of clinical trials.[66]

Suggested strategies to meet this action

GCP training may be achieved through a class or course, academic training program, or certification from a recognised clinical research professional organisation.[67] In Australia, low cost and no cost GCP training programs are being promoted, developed and provided by some state health departments;[68] research institute member organisations[69] and by health service organisations.[70]

GCP training should be refreshed at least every three years in order remain current with regulations, and guidelines and both the individual and the health service organisation are expected to retain GCP training documentation.

GCP training for trial investigators and their clinical trial teams

The clinical trial investigator is the individual responsible for the conduct of the clinical trial at a trial site. If a clinical trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and is usually referred to as the principal investigator.[71] The principal investigator is responsible for supervising his or her research team and they have a responsibility to ensure the integrity and ethical appropriateness of the individual

trials they conduct. The principal investigator responsibilities cover all aspects of a clinical trial and is an ongoing responsibility, sometimes extending beyond the time a research project has formally closed.

The clinical trial team includes individuals, identified by the investigator on the site staff personal log, and may be called the research coordinator, study coordinator, research nurse, study nurse or sub-investigator, and /or clinical trial pharmacist.[72] The clinical trial team may have various roles relating to the conduct of a clinical trial including, but not limited to the following:

- Study coordination and data collection
- Participant recruitment and enrollment
- Obtaining consent from prospective participants
- Undertaking study visits with research participants, and collect and record information from research participants
- Maintain consistent trial conduct
- Handling specimens
- Data management
- Dispensing and administering the investigational product
- Compliance with regulatory and reporting requirements.

Minimum criteria are described by international organisations[73] and national organisations. Health service organisations and trial sponsors consider how best to ensure trial investigators meet minimum GCP training criteria. For trial investigators GCP training may include but is not limited to ensuring an understanding of:

- Definition of ICH GCP
- Definition of Investigator
- Definition of sub investigator
- The principles of GCP

And compliance with the following:

- Investigator responsibilities relating to:
  - investigator qualifications and agreements
  - adequate resources to undertake the trial
  - medical care of trial participants
  - communication with HREC
  - compliance with the Protocol
  - investigational products
  - randomisation procedures and unblinding
  - informed consent of trial subjects
  - records and reports
  - progress reporting and Final reports
  - safety reporting
  - premature termination or suspension of a trial.

Clinical staff providing usual care, are not required to have undertaken GCP training for the conduct of clinical trials.

Key task

Health service organisations ensure that trial investigators and their clinical trial teams have access to, and undertake GCP training for the conduct of all clinical trials.

Examples of supporting evidence

- Policy documents relating training requirements within the health service organisation
- GCP training records of health service organisation delegates, trial investigators and the clinical trial workforce
- Employment records that detail the skills and competencies required of the individuals undertaking clinical trials
- Evidence of the assessment of trial investigators and their trial teams' needs for education and competency-based training
- Schedule of clinical trial workforce education and competency-based training
- Education resources or records of attendance at clinical trial training
- Audit results of clinical trial inspections relating to GCP training
- Feedback from the clinical trial workforce about their training needs
- Reviews and evaluation reports of education and training programs
- Communication to the workforce about training requirements
- Training documents about new clinical trials in emerging procedures and technologies
- Communication to the workforce that defines the scope of clinical practice in clinical trials of emerging procedures and /or technologies.

Clinical performance and effectiveness

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

The health service organisation ensures that trial investigators and their clinical teams have access to, and undertake GCP training for the conduct of all clinical trials.

Health service organisation as a clinical trial sponsor

If the health service organisation is the sponsor of a clinical trial they have a responsibility for monitoring the conduct of a research project for compliance with relevant regulations and requirements and should ensure they have sufficient resources to meet all of their monitoring obligations. In this case, the health service organisation should:

- Ensure that it exercises appropriate quality control over a clinical trial such that researchers or other staff over whom it has authority conform to any contracts and agreements and comply with any relevant internal or applicable external policies
- Ensure that it has an opportunity to consider any changes to a research project that have implications for its capacity to support the conduct of the trial in accordance with any ethical and administrative requirements
- Have some role in protecting the safety and welfare of participants in the trial via notification of relevant information from appropriate parties
- Ensure that data collected and used are properly secured and that project records are properly kept
- Ensure that financial matters related to a research project are being properly managed
- Oversee the conduct of the project via receipt of progress reports on at least an annual basis (at a minimum) during the active phases of the research project
- Oversee the conduct of the project via receipt of final reports on the clinical trial
- Ensure that project closure proceeds in accordance with any contractual or internal site requirements
- Ensure that research outcomes that are published are notified to the institution
- Ensure that any complaints raised by participants in the trial, allegations of research misconduct or potential post-project authorisation conflicts of interest are properly investigated and that any resulting recommendations are implemented and, if appropriate, notified to the reviewing HREC and/or the NHMRC as appropriate and,
- Ensure that any special conditions that it has imposed at the time of project authorisation are met.

Roles and functions of the trial investigator

The clinical trial investigator is the individual responsible for the conduct of the clinical trial at a trial site. If a clinical trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team responsible for:

- Supervising his or her research team
- Conducting the clinical trial in accordance with the clinical trial protocol including the review of protocols for feasibility and delivering care as specified in the approved protocol
- Ensure the integrity and ethical appropriateness of the individual trials that they conduct
- Maintain personal professional skills, competence and performance
- Contribute to relevant organisational policies and procedures relating to the conduct of clinical trials
- Comply with professional regulatory requirements and codes of conduct
- Supervise and manage the performance of junior clinical trial investigators
- Ensure that specific performance concerns are reported appropriately
- Work constructively in clinical trial teams

- Take part in the design and implementation of the organisation's systems for defining scope of clinical trial practice, clinical trial education and training, performance monitoring and management of clinical trial education and training.

Roles and functions of the clinical trial workforce

- Study coordination, data collection and data management
- Participant recruitment and enrolment
- Obtaining consent from prospective participants
- Undertaking study visits with trial participants, and collect and record information from research participants
- Maintain consistent study implementation
- Handling specimens
- Data management
- Dispensing and administering 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.

Roles and functions of managers (clinical and non-clinical), finance, human resources, business, research officers (HREC and SSA)

- Set up an operational policy and procedure framework for delivering clinical trial services, including training requirements
- Maintain records of professional skills, competence and performance in the conduct of clinical trials
- Implement and resource effective systems for management of credentialing and defining scope of clinical trial practice including: education and training and performance monitoring
- Respond in a prompt and effective way to indications of clinical trial operations underperformance
- Systematically monitor safety and quality performance across all clinical trial services.

Safe environment for the delivery of care

Safe environment

The environment promotes safe and high-quality health care for patients.

Action 1.29

The health service organisation maximises safety and quality of care:

a. **Through the design of the environment**
b. **By maintaining buildings, plant, equipment, utilities, devices and other infrastructure that are fit for purpose.**

How does this action apply to a health service organisation with a clinical trial service?

All clinical and non-clinical departments within health service organisations require a safe environment (including buildings and work space) with the appropriate and well maintained equipment. Similarly, clinical trial services should be located in buildings and areas of the health service that supports clinical trial activity and provides ease of access to recruit potential trial participants and conduct trial related visits.

Health service organisations should ensure the workspace, equipment including computers, software technology, communication equipment, utilities, devices and other infrastructure such as shelves and storage space are fit for purpose for clinical trial services. This could be achieved by:

- Conducting an environmental or workplace health and safety risk assessment and ensure the work space and equipment supports a secure and safe environment for study files and trial related data
- Developing a strategic plan and process for capital and equipment maintenance and replacement and ensure the technology supports clinical trial data capture and reporting
- Establish a system for maintaining the work space equipment and devices.

Suggested strategies to meet this action

Australian standards are available for devices and equipment, and these should be reflected in the organisation's policies and procedures for clinical trial services so that purchases, repairs and replacements are carried out and follow a specified standard. Also, the equipment is fit for purpose for undertaking clinical trials. Additionally, manufacturers also set guidelines for the use and tolerance of equipment and devices.

Develop and resource a comprehensive maintenance plan that includes:

- Clear and easy-to-use documentation of maintenance and repairs
- Records of all plant and equipment, including (as a minimum) the date of purchase, preventive maintenance schedule, location and serial number
- Details of routine and preventive maintenance performed for each item of equipment and plant, including electro-medical equipment
- Records of dates when equipment is regularly tested to ensure its readiness, including information relating to generators and battery backup
- Where equipment is regularly tested to ensure its readiness, record these dates, including information relating to generators and battery backup.

Clinical trial work space

The physical environment can have a major impact on the delivery and performance of the clinical trial service. Good design promotes safe practices and removing potential hazards improves safety and quality, reduces risks and medical errors,[74] improves patient and workforce satisfaction, and increases organisational performance.[75]

Key tasks

Review the clinical trial work spaces within the health service organisation:

- Ensure work spaces are scalable, adaptable and flexible to support the administrative functions of clinical trial services
- Ensure the work space is appropriate for conducting trial related study visits
- Ensure the layout and placement of supplies and equipment in rooms improve efficiency and reduce errors
- Provide information on clinical trials that is visible and easily accessible to patients, trial participants, consumers and the clinical trial workforce
- Provide clearly marked signs, maps and instructions to help patients and visitors navigate the clinical trial service within the health service organisation.

Examples of supporting evidence

- Policy documents that describe the health service organisation's requirements for maintaining buildings, plant, equipment, utilities and devices required to deliver clinical trial services
- Strategic plan for facilities and capital works
- Maintenance schedule for buildings, equipment, utilities and devices
- Audit results of compliance with maintenance schedules and inspections of equipment
- Register of equipment that is assigned to meet individual trial participants needs
- Risk assessment to identify suitability of all new equipment
- Observation of design and use of the environment to reduce risks relating to self-harm (for example, removal of ligature points, collapsible curtain rails)
- Observation that the physical environment includes consideration of safety and quality (for example, interview rooms in high-risk areas that have double doors, use of CCTV surveillance, duress alarms, access to security services, a secure environment after hours)
- Business continuity plan
- Analysis of incident reports and action taken to deal with issues identified
- Risk register and quality improvement plan that includes information from an analysis of incidents.

Action 1.33

The health service organisation demonstrates a welcoming environment that recognises the importance of the cultural beliefs and practices of Aboriginal and Torres Strait Islander people.

How does this action apply to a health service organisation with a clinical trial service?

Health service organisations ensure Aboriginal and Torres Strait Islander patient's carers and families feel welcome and safe to participate in a clinical trial and that information is provided to them in a way that supports their understanding of, and potential participation in a clinical trial.

Key tasks

Just as health service organisations establish relationships with local Aboriginal and Torres Strait Islander communities, and seek feedback on current practices in the organisation and areas for improvement, the health service organisation also reviews factors that create a welcoming environment for Aboriginal and Torres Strait Islander people to participate in a clinical trial.

Suggested strategies to meet this action

Engaging the community in the development of messages to explain clinical trials and create a welcoming, culturally sensitive and safe environment for Aboriginal and Torres Strait Islander people to participate in a clinical trial:[76]

- Collaborating with local Aboriginal and Torres Strait Islander people and communities to review the design, use of information and availability of information in Aboriginal and Torres Strait Islander languages as appropriate
- Seeking feedback on the signs, symbols and displays that could be used to promote clinical trials in a culturally safe manner
- Supporting Aboriginal and Torres Strait Islander consumers to have access to culturally appropriate services.

Examples of evidence

- Policy documents about cultural diversity that deal with the needs of Aboriginal and Torres Strait Islander patients, their carers and families relating to clinical trial services
- Committee and meeting records that show that the local community provided input about the cultural beliefs and practices of Aboriginal and Torres Strait Islander people
- Availability of an Aboriginal support officer to support Aboriginal and Torres Strait Islander patients participation in clinical trial
- Information brochures that outline the role of the Aboriginal support officer, and the services available to support Aboriginal and Torres Strait Islander patients
- Results of consumer satisfaction surveys that provide feedback on actions to meet the needs of Aboriginal and Torres Strait Islander patients.

Safe environment for the delivery of care

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

- Ensure that the environment of the health service organisation promotes safe and high-quality clinical trial service provision, and that the clinical trial workforce and consumers participate in operational decisions regarding the clinical trial operational environment.

Roles and functions of managers (clinical and non-clinical)

- Coordinate and oversee planning and development of the clinical trial service to support safety and quality within the health service organisation
- Engage with clinicians in clinical trial services within the health service organisation
- Allocate appropriate resources to ensure that the environment supports safety and quality in the conduct of clinical trials
- Respond to identified concerns about the clinical trial environment within the health service organisation.

Roles and functions of the clinical trial workforce

- 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.

Roles and functions of patients and consumers

- Communicate with the organisation about potential safety and quality risks
- Share experiences through patient stories, information sessions, letters, pictures, patient journeys, or presentations at meetings or training sessions for the workforce
- Participate in recruitment processes for the workforce, when opportunities exist
- Provide feedback, complaints and compliments about experiences in the health service, including participating in patient experience surveys.

2. Partnering with Consumers Standard

Leaders of a health service organisation develop, implement and maintain systems to partner with consumers. These partnerships relate to the planning, design, delivery, measurement and evaluation of care. The workforce uses these systems to partner with consumers.

Intention of this standard for clinical trial services

To create an organisation in which there are mutually beneficial outcomes by having:

- Consumers as partners in planning, design, delivery, measurement and evaluation of systems to deliver clinical trial services
- Trial participants and patients as partners in their own care, to the extent that they choose.

Criteria

- Clinical governance and quality improvement systems to support partnering with consumers
- Partnering with patients in their own care
- Health literacy
- Partnering with consumers in organisational design and governance

Partnering with Consumers Standard

Effective partnerships exist when people are treated with dignity and respect, information is shared with them, and participation and collaboration in healthcare processes are encouraged and supported to the extent that people choose.[77] The health system includes different types of partnerships, which are not mutually exclusive. Partnerships are necessary at all levels to ensure that a health service organisation achieves the best possible outcomes for all parties.[78]

At the level of the individual, partnerships relate to the interaction between clinical trial site staff, patients, and their carers and families when a patient is participating in a clinical trial. Partnership involves engaging consumers and patients in a clinical trial in a way that that is respectful, sharing information in an ongoing fashion, working with trial participants, carers and families to make decisions and plan treatment associated with participating in a clinical trial and supporting and encouraging patients in their own care.

At the level of a service, department or program of care, partnerships relate to the organisation and delivery of clinical trials within specific clinical areas. Partnership involves the participation of consumers, patients and their carers and families in planning clinical trial services within particular health service departments. That is, as members of quality improvement and redesign teams, and participating in planning, implementing and evaluating change.

At the level of the health service, partnerships relate to the involvement of consumers in overall governance, policy and planning. This level overlaps with the previous level, since clinical trials are provided in a number of departments within a health service organisation. At the level of the health service, partnerships relate to the involvement of consumers and consumer representatives as full members of key organisational governance committees in areas such as patient safety, facility design, quality improvement, patient and family education, ethics and research. This level can also involve partnerships with local community organisations and members of local communities.

Delivering clinical trials that is based on partnerships provides many benefits for patients, consumers, clinicians, health service organisations and the health system. There is evidence for links between the existence of effective partnerships, a positive experience for patients, and high-quality health care, and improved safety.[79,80] Also, the involvement of patients and consumers in planning, delivery, monitoring and evaluation of clinical services can have a positive impact on service planning and development, information development and dissemination, and the attitudes of healthcare providers.[81,82,83]

2. Partnering with Consumers

Clinical governance and quality improvement systems to support partnering with consumers

Systems are designed and used to support patients, carers, families and consumers to be partners in healthcare planning, design, measurement and evaluation.

Integrating governance systems into clinical trial service provision

Action 2.1

Clinicians use the safety and quality systems from the Clinical Governance Standard when:

a. Implementing policies and procedures for partnering with consumers
b. Managing risks associated with partnering with consumers
c. Identifying training requirements for partnering with patients and consumers.

How does this action apply to a health service organisation with a clinical trial service?

This action is aligned with a core principle of the National Clinical Trials Governance Framework that is: *organisational culture, partnerships and collaboration* are at the core of successful clinical trial service provision. This principle also recognises that *partnering with consumers increases consumer awareness of the benefits of clinical trials, promotes access for patients to clinical trials and improves navigation of the trial process by patients and consumers.*

To meet this action health service organisation implements policies and procedures for partnering with consumers to determine the local community priority areas for the clinical trial services that the health service organisation provides. The health service organisation also manages the relationship with consumers, potential risks and ensures their training needs regarding clinical trials are met.

Suggested strategies to meet this action

All policy documents should be incorporated into a single, coherent set to maximise the effectiveness of the policy development process.

There are specific actions that relating to health service organisations' support policies and procedures, risk management and training for partnering with consumers including Action 1.7 – policies and procedures; Action 1.10 – risk management systems and Action 1.20 – education and training.

Establish governance for partnering with consumers

For Action 2.1, the health service organisation should ensure that actions in the Partnering with Consumers Standard that relate to clinical trial services have appropriate governance structures and support from the governing body and management. Action 2.14 outlines strategies for partnering with consumers in discussions and decisions regarding the design, implementation and evaluation of clinical trial services.

Implement policies and procedures

Ensure that the health service organisation has policies and procedures in place that cover:

- Healthcare rights
- Process for obtaining informed consent or opt out consent to participate in a clinical trial
- Shared decision making and planning care relating to participation in a clinical trial
- Health literacy and effective communication with patients, carers, families and consumers
- Partnering with consumers in governance.

Manage risks

- Use the organisation's risk management systems (see Action 1.10) to identify, monitor, manage and review risks associated with partnering with consumers. Develop processes to manage clinical risks for different populations served within the organisation, clinical and workplace risks for the workforce, and organisational risks
- Use information from measurement and quality improvement systems, adverse events, outcomes of clinical trials and patient experiences to inform and update risk assessments and the risk management system.

Identify training requirements

- Assess the competency and training needs of the workforce in line with the requirements of Actions 1.20. Perform a risk assessment to inform the training schedule and to set priorities for the members of the workforce who require training. Develop, or provide access to, training and education resources to meet the needs of the workforce with regard to partnering with consumers
- Education and training to support understanding and awareness of the value of partnerships with consumers can include training on person-centred care, shared decision making, communication techniques and health literacy. It may also involve consumer input through stories, presentations or advice on the development of training materials
- Consider the training the workforce may need to effectively use the incident management and investigation system to inform risk management, and to plan and implement quality improvement processes to mitigate risks.

Key tasks

- Align existing governance structures for partnering with consumers with governance structures for clinical trial services
- Develop and implement policies and procedures for partnering with consumers across clinical trial services
- Use organisation-wide risk management systems to identify, monitor, manage and review risks associated with partnering with consumers
- Deliver or provide access to training on partnering with consumers based on the specific needs of the clinical trial service and workforce.

Examples of supporting evidence

Examples of evidence demonstrating governance structures, policies and processes for engaging with consumers to inform clinical services can also be applied to clinical trial service delivery:

- Policy documents that describe the health service organisation's processes for partnering with consumers, including the mechanisms available to engage with consumers
- Financial and physical resources that are available to support consumer participation and input at the governance level
- Observation of clinicians' practice that demonstrates use of the health service organisation's processes for partnering with consumers

- Records of interviews with clinicians that show that they understand the health service organisation's processes for partnering with consumers
- Organisational structure that identifies where and how consumers are engaged
- Committee and meeting records that show clinician and consumer involvement in the discussion of consumer engagement strategies, including implementing policy, managing risk, and building skills and capacity for partnering with consumers
- Data from the health service organisation's risk management and reporting systems on risks associated with partnering with consumers and risk mitigation strategies
- Training documents that include information on the value of consumer engagement, and the potential roles for consumer partners in clinical governance and strategic leadership
- Documented examples of consumer engagement in workforce recruitment or review of recruitment processes
- Feedback from consumers, consumer representatives, consumer organisations and carers on their experience of engagement with the health service organisation in clinical governance.

Applying quality improvement systems

Action 2.2

The health service organisation applies the quality improvement system in the Clinical Governance Standard when:

a. Monitoring processes for partnering with consumers
b. Implementing strategies to improve processes for partnering with consumers
c. Reporting on partnering with consumers.

How does this action apply to a health service organisation with a clinical trial service?

The quality systems in place in the organisation to support processes for partnering with consumers are used to support partnering with consumers for quality improvement systems in clinical trial service delivery.

Suggested strategies to meet this action

Use the organisation's quality improvement systems to identify and set priorities for the organisational and clinical trial strategies for partnering with consumers. The following actions rely on, and relate to this action include: Action 1.8 – quality improvement systems; Action 1.9 – reporting and Action 1.11 – incident management and investigation systems.

Health service organisations should use currently available systems and other established safety and quality systems to support monitoring, reporting and implementation of quality improvement strategies for partnering with consumers such as:

- Develop or adopt indicators that are relevant to the organisation and can be used to measure improvements in consumer partnerships
- Conducting an internal evaluation of consumer partnerships across governance, strategic leadership, safety and quality, and performance management systems[84] use the *Organisational Self-Assessment Survey for Consumer Engagement*[85] to assist with an internal evaluation
- Conducting a gap analysis to identify areas that need improving by comparing current systems for partnering with consumers with an ideal future state[86]

- Engaging independent evaluators or state or territory based consumer peak organisations to provide an external perspective on the organisation's consumer partnership systems[87]
- Integrating consumer partnership into the overall goals of the organisation, so that it is assessed alongside other business goals and includes clinical trial services
- Routinely collecting data about the experience of consumers, including feedback and complaints through surveys or suggestion forms:
  - trial participant stories
  - feedback from consumers who are currently using the service, through informal discussions, interviews, and the use of handheld devices or computers for capturing survey responses.

Implement quality improvement strategies

Strategies to improve systems and performance for partnering with consumers may include:

- Problem-solving methods such as hosting a brainstorm involving consumers, the workforce and governance members to generate improvement ideas
- Engaging managers to act as champions of consumer partnership
- Providing education to the workforce to reinforce the roles of consumers
- Review the strategies for partnering with consumers presented in Action 2.11 to identify opportunities for improving systems of partnership.

Report outcomes

Strategies for reporting on the effectiveness and outcomes of partnering with consumers may include:

- Developing formal progress and evaluation reports for members of the organisation's leadership and governing body, the clinical trial workforce, consumers and consumer organisations, and the wider community
- Using internal newsletters or memos to report on the effectiveness and outcomes of the organisation's consumer partnership
- Using local community media to disseminate stories about the effectiveness and outcomes of the organisation's consumer partnership to the wider community
- Publishing profiles or stories of consumers involved in consumer partnerships with the organisation, and the contributions they have made
- Hosting events to present the outcomes of systems for partnering with consumers, inviting members of the organisation's leadership and governing body, the clinical trial workforce, consumers and consumer organisations, and the wider community.

Key tasks

- Review, measure and assess the effectiveness and performance of organisational and clinical strategies for partnering with consumers
- Implement quality improvement strategies for partnering with consumers based on the outcomes of monitoring activities
- Provide information on the outcomes of quality improvement activities to the governing body, the workforce, consumers and other organisations.

Examples of supporting evidence

- Organisation-wide quality improvement system that includes performance measures for partnering with consumers
- Audit of health service organisation performance against identified measures for partnering with consumers
- Results of consumer and carer experience surveys reviewed by the governing body or relevant committees
- Committee and meeting records in which feedback from consumers and the workforce on the health service organisation's safety and quality systems are reported
- Review of the incident monitoring system to identify areas of concern in consumer partnerships
- Quality improvement plan that includes actions to deal with issues identified
- Consumer and carer information packages or resources about the health service organisation's processes for partnering with consumers
- Examples of improvement activities that have been implemented and evaluated to maximise the engagement of patients and consumers

- Reports on safety and quality performance that are published in annual reports, newsletters, newspaper articles, radio items, websites or other local media
- Records of focus groups or meetings involving consumers in which the appropriateness and accessibility of safety and quality performance information were discussed
- Communication with the workforce and consumers about the effectiveness and outcomes of the health service organisation's consumer partnerships
- Formal progress reports or evaluation reports provided to members of the health service organisation's governance committees, leadership team and workforce; consumers; and the wider community
- Feedback of clinical trial data to consumers
- Feedback from consumers, carers and the workforce on the involvement of consumers in quality improvement systems.

Partnering with patients in their own care

Healthcare rights and informed consent

Action 2.3

The health service organisation uses a charter of rights that is:

a. Consistent with the Australian Charter of Healthcare Rights[88]
b. Easily accessible for patients, carers, families and consumers.

How does this action apply to a health service organisation with a clinical trial service?

Health service organisations ensure patients, trial participants and consumers are provided with information about their healthcare rights and implement strategies for engaging with and providing information to, trial participants, patients' carers and families, and consumers. Carers and families can often provide insights into a trial participant's health history, and provide reassurance to the trial participant during their trial treatment.

In this way the health service organisation adopts a person-centred care focus on the relationship with a trial participant, and recognises that trust, mutual respect and sharing of knowledge are needed for the best outcomes.[89]

Key strategies have included:

- Providing trial related information in engaging and accessible formats, such as print, mobile apps and online channels and story boards
- Eliciting and documenting individual needs, preferences and goals
- Using patient and trial participant decision aids
- Encouraging and prompting patient questioning during clinical trial visits
- Providing education to support self-management
- Establishing self-help and support groups
- Developing tools to encourage adherence to the trial treatment.

Suggested strategies to meet this action

The Australian Charter of Healthcare Rights[90] was developed by the Australian Commission on Safety and Quality in Health Care (the Commission) and adopted by all health ministers in 2008. It describes the rights of patients and other people using the Australian healthcare system. These rights are essential to ensure that safe and high-quality care is provided to all people, in all health settings in Australia (including public and private hospitals).

Adopt the charter of rights

Support the effective adoption of the charter in the organisation, and ensure the Charter is available to clinical trial participants. Strategies may include:

- Allocating responsibility for implementing and reviewing the charter to a manager with decision-making authority
- Including information about the charter during orientation for new members of the workforce
- Running regular education and training sessions for the workforce on their responsibilities for implementing the charter; this includes clinical and non-clinical members of the workforce, and, if relevant, volunteers
- Building the charter into organisational processes, policies and codes of conduct
- Developing policies and procedures that outline how the rights in the charter will be achieved at the organisation
- Inform patients, carers and families about the charter, and make sure that they can find it easily. Strategies may include:
  - discussing the charter with patients
  - displaying brochures or posters advertising the charter at reception desks, and in waiting areas, wards, corridors, consulting rooms and other strategic locations
  - incorporating information about the charter into communication with patients, such as on the organisation's website or in information brochures
  - incorporating the charter into information packs sent to elective patients before admission
  - making information about the charter available to patients at their bedside
  - ensuring that copies of the charter are available in community languages, and providing copies of the charter to any nominated interpreters
  - providing information in a format that is suitable for patients who are visually impaired, such as audio, in braille or on fully accessible websites.

Key tasks

The health service organisation adopts the Australian Charter of Healthcare Rights (with or without amendments) and provides ready access to copies of the charter, in appropriate languages or formats, to all trial participants, patients, their carers and families.

Examples of supporting evidence

- Policy documents that describe the use of a charter of rights in clinical trial services
- Charter of rights that is consistent with the Australian Charter of Healthcare Rights in different languages and formats, consistent with the patient profile
- Observation that a charter of rights is displayed in areas that are accessible to trial participants and the public
- Consumer and carer information packages or resources that explain consumer healthcare rights
- Evidence that patients and carers received information about their healthcare rights and responsibilities, such as audits of patients, interviews or surveys
- Admission checklist that includes provision and explanation of a charter of rights
- Feedback from patients and consumers about awareness of the charter of rights.

Action 2.4

The health service organisation ensures that its informed consent processes comply with legislation and best practice.

How does this action apply to a health service organisation with a clinical trial service?

This action relates to the health service organisation ensuring that trial investigators and their clinical trial teams have sufficient knowledge and skill to provide information to a potential trial participant and undertake the consent process, as outlined in the approved clinical trial protocol.

Suggested strategies to meet this action

Approaches to obtaining informed consent or the opt out process are provided in the National Statement, documented in the clinical trial protocol and approved by a HREC that considers specific consent requirements established by state or territory legislation – such as mental health Acts, guardianship and administration Acts, and human tissue Acts – are complied with. The health service organisation ensures compliance with the protocol when obtaining consent including to:

- Inform trial participants (and, if applicable, their carers and substitute decision-makers) about the risks and benefits of participating in a clinical trial, including the time taken, any fees and charges associated with treatment and referrals
- Determine patient preferences for standard of care and/or trial treatment
- Follow documentation procedures relating to the participant consent process.

Effective processes may include policies and procedures to guide and support the clinical trial workforce towards good standards of practice that meet legal and ethical requirements for obtaining participant consent (or, if applicable, that of their substitute decision-maker).

Key tasks

The health service organisation ensure trial investigators and their clinical trial teams adopt approaches to obtaining consent that are consistent with the approved trial protocol. A comprehensive policy and associated procedures on obtaining informed consent and opt-out consent supports this action.

Examples of supporting evidence

- Policy documents relating to obtaining informed consent that reference relevant legislation or best practice
- Training documents on informed consent processes
- Standardised consent form that is adopted by the trial sponsor for the clinical trial. The NHMRC recommends using standard consent forms[91]
- Audit or sponsor monitoring reports of healthcare records for compliance with informed consent policies, procedures or protocols
- Audit or sponsor monitoring reports and of healthcare records confirming a record of the consent form is retained in the health service organisation
- Results of trial participant and carer experience surveys, and actions taken to deal with issues identified about informed consent
- Trial participant information packages or resources about treatment and consent processes that are available for consumers in different formats and languages, consistent with the patient profile
- Feedback about the consent process from trial participants and carers after treatment.

Action 2.5

The health service organisation has processes to identify:

a. **The capacity of a patient to make decisions about their own care**
b. **A substitute decision-maker if a patient does not have the capacity to make decisions for themselves.**

How does this action apply to a health service organisation with a clinical trial service?

This action is related to Action 2.4. Patients who do not have the capacity to make decisions about their care are identified, and systems are put in place so that if appropriate they, or agreed substitute decision-makers, are involved in obtaining informed consent to participate in a clinical trial.

Suggested strategies to meet this action

Under Australian legislation, all adults are presumed to have the capacity to decide whether they wish to receive health care, except when it can be shown that they lack the capacity to do so. The National Statement provides guidance on consent procedures to participate in a clinical trial and these are documented in the clinical trial protocol and approved by the HREC. A person has the capacity to make a decision about their care if they can[57]:

- Understand and retain the information needed to make a decision
- Use the information to make a judgement about the decision
- Communicate the decision in some way, including by speech, gestures or other means.

Decision-making capacity can be decision- and situation-specific. This means that a person's capacity can vary at different times, in different circumstances and between different types of decisions.

Review processes for determining patients' capacity to make decisions

Ensure that effective and HREC approved processes are in place to identify:

- Patients who do not have the capacity to make decisions about their own health care
- Appropriate substitute decision-makers who can make decisions on behalf of the patient as relevant to the jurisdiction.

Implement strategies to:

- Develop an organisational policy that outlines the requirements of clinicians to assess patients for their capacity to make health decisions regarding participation in a clinical trial
- Document the requirements for recording and documenting decisions
- Educate the workforce about assessing a person's capacity to make decisions about their care; consider training from a third party with expertise in this area, such as **Capacity Australia**
- Develop or provide resources and tools to reinforce training and assist the workforce to assess a person's capacity to make decisions such as SA Health's *Impaired Decision-Making Factsheet*.[92]

Key tasks

The health service organisation complies with policies and associated procedures to identify patients who do not have the capacity to make decisions about their own care and ensures that mechanisms to recruit trial participants is consistent with the consent procedures in the approved clinical trial protocol.

Examples of supporting evidence

- Policy documents that reference relevant legislation or best practice relating to the process for obtaining consent in patients with reduced capacity to provide consent
- Training documents relating to the informed consent processes
- Standardised consent form that is adopted by the trial sponsor for use in clinical trials. The NHMRC recommends using standard consent forms[93]
- Audit or sponsor monitoring reports of healthcare records for compliance with informed consent policies, procedures or protocols
- Audit or sponsor monitoring reports and of healthcare records confirming a record of the consent form is retained in the health service organisation.

Health literacy

Health service organisations communicate with consumers in a way that supports effective partnerships.

Communication that supports effective partnerships

Action 2.8

The health service organisation uses communication mechanisms that are tailored to the diversity of the consumers who use its services and, where relevant, the diversity of the local community.

How does this action apply to a health service organisation with a clinical trial service?

Patients, consumers and trial participants receive information relating to clinical trials they need in a way that is appropriate for them.

Suggested strategies to meet this action

There is no 'one size fits all' solution to meeting the communication requirements of a diverse consumer population. However, health service organisations can work to develop a framework that integrates cultural competency into its communication mechanisms.[94]

Determine the diversity of consumers and the local community

Patient and community data are essential to understanding consumer communication needs, and developing or improving communication mechanisms to meet these needs.

Administering surveys to help identify diversity among consumers

Using demographic data from the Australian Bureau of Statistics, or local, or state and territory government sources to understand the background of the organisation's consumers.

Networking with other organisations or individuals in the community – such as culturally and linguistically diverse community groups; community participation managers; Primary Health Networks; Local Hospital Networks; local, state and territory government organisations; and professional associations – to share knowledge about communication preferences and needs.

Review current communication mechanisms

Determine whether the organisation's current communication mechanisms meet the needs of diverse patient populations by reviewing:

- Consumer information developed by the organisation, such as patient brochures, posters and consent forms, to see whether they are culturally appropriate or available in culturally appropriate formats
- The availability of interpreting services, and methods of access to these services for patients and members of the workforce
- The cultural competency and confidence of the workforce in communicating with diverse patient populations
- Educating the workforce about the diversity of the consumers who use the organisation's services; consider accessing cultural competency training if people from culturally and linguistically diverse communities, or Aboriginal and Torres Strait Islander communities regularly use the service[80]
- Engaging consumers in developing and reviewing health communications
- Facilitating easy access to interpreting services by identifying and promoting appropriate interpreting services that are competent at working in a health setting (for example, discussing health and medical issues); the Australian Government's Translating and Interpreting Service can supply phone and on-site services.

Key tasks

- The health service organisation provides communication material in general and specifically in relation to clinical trials that meets the needs of their diverse consumer and community population, and ensure that accredited interpreter services are available to consumers who require them
- A variety of mechanisms to meet the communication needs of the diverse consumer and community population are also used to improve participant recruitment and to support the retention of participants on a clinical trial.

Examples of supporting evidence

- Policy documents about communication, including the use of plain language, and addressing the cultural and linguistic diversity of the community that the health service organisation serves
- Demographic profile or demographic survey for the health service organisation that identifies the diversity of the community it serves
- Results of a needs assessment project that identifies local health needs
- Demographic data from external sources that are used for strategic and communication planning to identify the cultural diversity and needs of patients and carers
- Training documents about cultural awareness and diversity
- Consumer and carer information packages or resources that are culturally appropriate, and are available in different languages and accessible formats
- Feedback from consumers from culturally or linguistically diverse backgrounds during the development or review of information packages or resources
- Committee and meeting records that show that the health service organisation is represented at local network meetings that reflect the local diversity of the patient population
- Reports on interpreter use and access
- Feedback from patients and carers about whether communication processes meet their needs
- Observation that clinicians have access to communication resources that provide contact details for support services such as local consumer health advocates, interpreters, or cultural support and liaison services.

Action 2.9

Where information for patients, carers, families and consumers about health and health services is developed internally, the organisation involves consumers in its development and review.

How does this action apply to a health service organisation with a clinical trial service?

Consumers, patients, trial participants, their carers and families are involved in the development of information about clinical trial services within the health service organisation.

Suggested strategies to meet this action

Involving consumers in the development of consumer information on clinical trials

- Establishing a consumer-based patient information working group to lead and advise on developing consumer information[95]
- Attending community meetings to discuss the information needs of consumers, and the barriers and facilitators to understanding health information regarding clinical trials in the community
- Collaborating with local health consumer organisations to develop information.

Incorporate feedback from consumers on the information provided to improve the development of patient information publications (for example, feedback might indicate that language needs to be modified so that the information is understandable for consumers with low levels of literacy) or, if the organisation does not develop its own information publications, source and use publications that have been developed in partnership with consumers, such as those developed by state and territory health or other government departments, professional associations or external providers.

Key tasks

- Develop and implement a process for engaging consumers during the development of consumer information about clinical trials and clinical trial services within the health service organisation
- Develop and implement a process for sourcing consumer feedback on internally developed consumer information and incorporating this feedback to inform future improvements in clinical trial services.

Examples of supporting evidence

- Committee and meeting records that show consumer involvement in the development and review of clinical trials information in general and clinical trial service information resources
- Feedback from consumers who have used the health service organisation's clinical trial information publications
- Communication with consumers who provided input into the development or review of resources about the types of changes made in response to their feedback.

Action 2.10

The health service organisation supports clinicians to communicate with patients, carers, families and consumers about health and health care so that:

a. **Information is provided in a way that meets the needs of patients, carers, families and consumers**
b. **Information provided is easy to understand and use**
c. **The clinical needs of patients are addressed while they are in the health service organisation**
d. **Information needs regarding their ongoing care are provided on discharge.**

How does this action apply to a health service organisation with a clinical trial service?

Patients and consumers receive the information they need to understand clinical trials including the benefits and risks of trial participation and this information is easy to understand and act on.

Key tasks

Trial investigators and the clinical trial workforce receive training and support to communicate effectively with patients and consumers about clinical trial services and clinical trial participation.

Suggested strategies to meet this action

Processes to support clinicians to communicate effectively with patients and their carers about clinical trials involve obtaining informed consent, and determining a patient's goals of care requires an environment that supports open, clear and effective communication between clinicians, patients and consumers. To achieve this health services may need to:

- Provide clinicians with training that highlights the importance of health literacy
- Implement a plain-language policy that makes written information easier to understand
- Ensure the patient information sheets and consent forms provided to potential trial participants are in plain language and all information regarding trial participation are easy to navigate and interpret by clinicians, consumers, patients, their carers and families
- Provide a single page summary for complex trials.

Information resources and tools that clinicians can use to support their communications may include:

- Written information (for example, brochures, fact sheets, posters, online material); if developed locally, consumers should be involved in developing these resources (Action 2.9)
- Visual diagrams and decision aids (for example, the Commission's **patient decision aids**)
- Cue cards or symbols to support communication with people who do not understand English (for example, Eastern Health's *Cue Cards in community languages*[96]).

Monitor and assess communication

Strategies may include:

- Auditing healthcare records to assess the information provided to patients and carers
- Providing a mechanism for patients to give feedback about the communication and information they receive during a clinical trial
- Seeking feedback on communication and information resources from trial participants who use the services (for example, including questions about medicines information in patient experience surveys).

Examples of supporting evidence

- A register of interpreter and other advocacy and support services available to the clinical trial work force trial participants, their carers and families
- Examples of information materials provided to trial participants and their carers and families that are in plain language, and available in different languages and formats
- Results of patient and carer experience surveys regarding the information provided
- Feedback from trial participants and carers about the information communicated to them about the clinical trial.

Partnering with consumers in organisational design and governance

Action 2.14

The health service organisation works in partnership with patients and consumers to incorporate their views and experiences into training and education for the workforce.

How does this action apply to a health service organisation with a clinical trial service?

The clinical trial workforce has an understanding of clinical trials from the consumer's perspective, and the value that consumers can bring to organisational design and governance of clinical trial services. The health service organisation adopts policies that involve consumers in the design and delivery of workforce training and consult with consumers to seek their views and input for the development and delivery of workforce training.

Suggested strategies to meet this action

Develop or adapt policies or processes on clinical trial workforce training to include consumer involvement

Consider the current processes for training and identify whether they can be used or modified to address this action. Strategies to involve consumers in the development of training could include:[97,98]

- Involving consumers in committees or advisory groups tasked with developing or reviewing training materials and resources
- Informally talking with consumers and carers in waiting areas about what they would include in person-centred care and partnership training for the clinical workforce
- Convening focus groups or workshops to seek consumers' advice on critical information, resources and strategies for training the clinical trial workforce
- Inviting trial participants, their carers and families to present on their experiences.

Examples of supporting evidence

- Project plans, communication strategies or consultation plans that describe the involvement of consumers in the development of training curriculums and materials
- Committee and meeting records in which training curriculums for the workforce were discussed and feedback was provided by consumers
- Training documents that incorporate trial participants consumers' views and experiences
- Records of training or presentations provided to the workforce by consumers
- Feedback from consumers involved in developing training and education resources for the workforce.

Partnering with consumers

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

- Show leadership and commitment to partnerships with consumers regarding clinical trial services
- Set up 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.

Roles and functions of managers (clinical and non-clinical)

- Understand the barriers for patients and consumers to understand and use health services, and develop strategies to improve the health literacy environment of the health service organisation
- Ensure that patients and consumers have access to high-quality, easy-to-understand information about health care and clinical trials
- Set up organisational systems to enable consumers to fully engage in planning and sharing decisions about their own health care planning and participation in clinical trials
- Collect and review patient experience information as part of quality improvement processes
- Create opportunities for consumer involvement in relevant operational committees and, planning, designing, and evaluating clinical trial services
- When appropriate, set up specific consumer advisory committees.

Roles and functions of the clinical trial workforce

- 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.

Roles and functions of consumers, patients, trial participants their carers and families

- Are involved in planning and sharing decisions about participation in clinical trials
- Have opportunity to ask for more information about clinical trials information, in different formats or a translator, if required
- Let the clinical trial workforce know who should be involved in sharing decisions about their participation in a clinical trial
- Provide feedback to the health service organisation or clinician about experiences of trial participation
- Consider being involved in the governance of clinical trials within the health service organisation, when opportunities exist
- Consider being involved in the development and review of health information for consumers about clinical trials.

Appendix 1

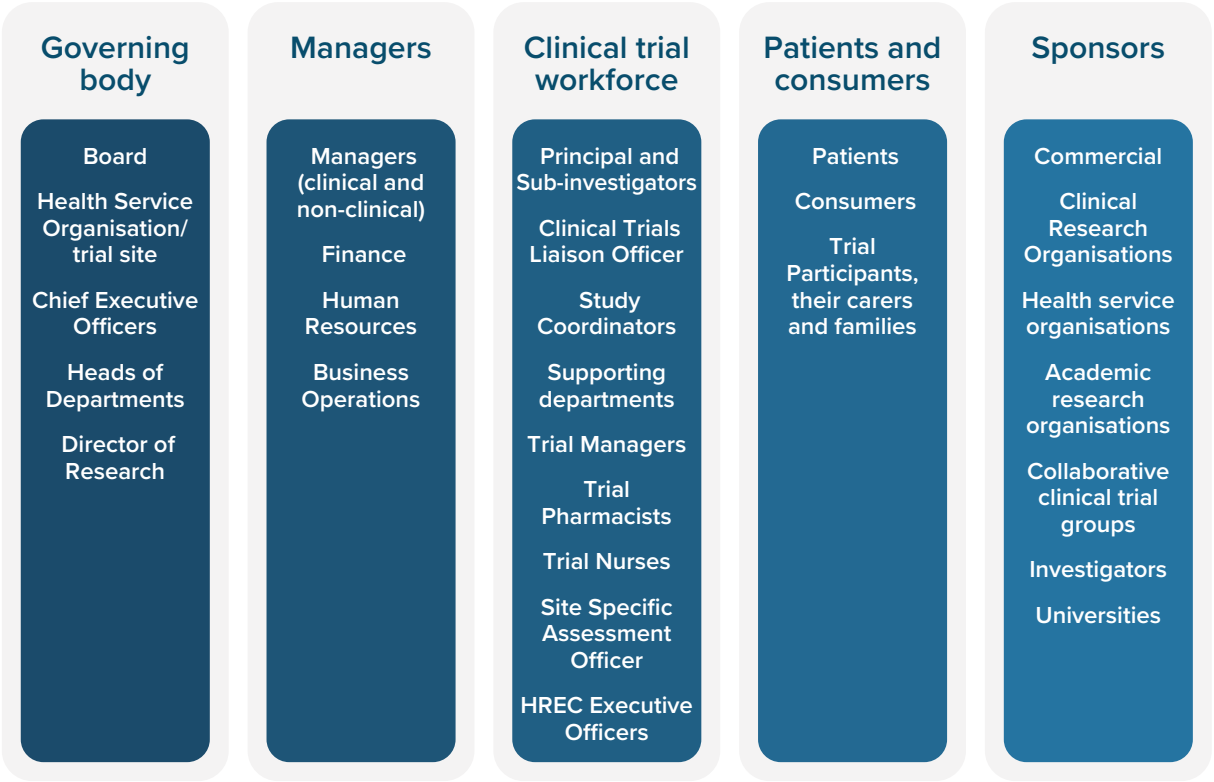
Roles and functions of identified positions

The roles and functions of the positions and relationship groups are provided as guidance for health service organisations to establish or continue to deliver clinical trial services. Figure 3 provides an example of the set of relationships, roles and functions that may be established by a health service organisation or trial site between its governing body, workforce (including managers and clinical trial site staff), patients and consumers and clinical trial sponsors.

Health service organisations or trial sites may also consider these roles and functions to increase the speed and efficiency of trial processes.[99]

The health service organisation may implement roles, systems and processes to ensure effective clinical trials governance in consideration of their local needs, values and the context in which services are provided. Consideration should be given for cultural safety, competence and respect in providing clinical trial services that meet the needs and priorities for Aboriginal and Torres Strait Islander people.

Figure 3 *Roles for identified positions and organisational relationships within a health service organisation or trial site*



State and Territory Departments of Health

State and territory health departments are responsible for ensuring that clinical trial policies and procedures applicable to public health organisations, are in place, reviewed regularly, and communicated to facilitate implementation. This includes the implementation of the National Clinical Trials Governance Framework. State and territory departments of health provide centralised and coordinated oversight of the performance of clinical trial services within health service organisations and trial sites and, contribute to a common set of metrics that report meaningful clinical trial operational outcomes.

Health service organisation

Good clinical trial governance provides confidence to the community and everyone who works in a health service organisation or trial site that systems are in place to support the efficient delivery of high-quality clinical trial services. A well-governed healthcare organisation ensures managers and clinical trial site staff, patients, consumers, clinical trial sponsors and the health service organisation is accountable to governing body for their contribution to the delivery of clinical trial services.

Health service organisations as sponsors of a clinical trial

Sponsors of clinical trials can be commercial companies, collaborative research groups, government entities including health service organisations, individual investigators, or universities.

There are differences between industry-sponsored and non-industry sponsored clinical trials in how the responsibilities and obligations of a clinical trial sponsor are met. Industry sponsors of clinical trials typically commit significant resources to meeting their responsibilities including costly[100] on-site monitoring of investigative sites.

It is clear that larger-sized industry sponsors, are aware of the various codes, regulations and guidelines, in a manner consistent with their international peers.[101] Smaller and less-experienced industry sponsors are unlikely to have access to the same level of resources in this area.[102] This is demonstrated by the findings of GCP inspections of non-industry sponsors reported by international regulators.[103,104]

However, health service organisations have a responsibility to protect the safety and welfare of participants who may also be cared for within their health service organisation and as such, should ensure training in GCP for the integrity of their research programs and their researchers and the individual projects that those researchers conduct.

If a health service organisation is the sponsor of a clinical trial, the responsibilities attributable to the sponsors of clinical trials involving unapproved therapeutic goods, as mentioned above, are articulated in ISO 14155 and the ICH Guideline for Good Clinical Practice E6 (and revisions). For clinical trials conducted under the CTN or CTX scheme in Australia, the TGA also provide the annotated Guidance for Good Clinical Practice (2016) and guidance materials including the Australian Clinical Trial Handbook (2018).[105]

Patients and consumers and trial participants

Patients and consumers participate as partners to the extent that they choose. These partnerships can be in their own care, as participants in a clinical trial, in organisational strategic planning for and governance of, clinical trial services or by providing input into the design and conduct of clinical trials and the policies and priorities of clinical trial networks. Patients and consumers are integral to informing on going quality improvement in clinical trial services.

Governing body

While there may be differences in the composition of the governing body within and between states and territories, broadly speaking the governing body is the board, or the individuals with overall responsibility for the local health district/local health network/health service organisation(s) or trial site. The governing body is also the approving authority (*see also, approving authority*).

The governing body endorses and monitors multidisciplinary teams of experienced staff managers including finance, human resources personnel, clinical and non-clinical managers, clinicians, site-level trial investigators, trial managers, study coordinators, informational technology (IT) staff, the HREC office, governance office and/or site-specific assessment office.

The governing body is ultimately responsible for ensuring an appropriate institutional response to the National Clinical Trials Governance Framework and establishing management practices for the responsible conduct of clinical trials across their health service organisation or trial site. The governing body ensure clinical trial services, and all services, operate well and deliver high-quality clinical trials in a safe environment. It does this by establishing a strong safety and risk management culture through an effective clinical trials governance system, satisfying itself that this system operates effectively and efficiently, and ensures there is an ongoing focus on quality improvement.

The governing body identifies and complies with laws, regulation, 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 clinical trials. Communication pathways should be clear in terms of what is communicated, how, to whom, when and why, with documented roles and functions that are agreed by all parties.

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 and trial information systems. The governing body ensures quality systems and processes to ensure that staff work to appropriate guidelines and standards and that processes are in place for continuing professional development including but not limited to, Good Clinical Practice (GCP) training for staff in order to retain a competent and appropriately skilled clinical trials workforce.

Chief Executive Officers of local health district/local health network/health service organisation or trial site

The governing body may also include Chief Executive Officers (CEOs)/ Chief Executives/ Executive Directors / General Managers (or equivalent) of health service organisations/ local health districts/local health networks. Health service organisations are responsible for reporting to the board on the implementation of the National Clinical Trials Governance Framework. CEOs are required to support a culture of responsible clinical trial practice across hospitals within their sphere of responsibility and for ensuring staff are aware of their responsibilities as outlined in the National Clinical Trials Governance Framework. CEOs (or equivalent) are responsible for ensuring all clinical trials undertaken within their organisation complies with the requirements of national and local legislation and ensures appropriate research governance personnel, systems and structures are in place, and attests to this in the health service organisation's Attestation Statement. The CEO (or equivalent) is also responsible for:

- Ensuring the implementation and oversight of the National Clinical Trials Governance Framework is assigned to the appropriate delegate within the health service organisation. The delegated individual or group oversees clinical trials operations including compliance with the actions against which health service organisations will be assessed for accreditation
- Ensuring effective communication across the organisation with key individuals responsible for clinical trials
- Monitoring clinical trials conducted within the health service organisation for compliance with policy and procedures
- Delegating a person responsible for site-specific assessment and authorisation and, an escalation process for disputed local site-specific authorisation of clinical trials if required
- Allocating sufficient resources for effective and efficient processing of ethical and scientific review by the HREC and, site-specific assessment and authorisation
- Establishing systems for the management of complaints about clinical trials, including clinical trial research misconduct and fraud. This may include identifying and training research integrity advisors who assist in the promotion and fostering of responsible clinical trial conduct
- Allocating resources for education and training of HREC members and site-specific assessment personnel
    - providing access to ongoing training and education that promotes and supports responsible clinical trial conduct for all members of clinical trial teams, researchers and those in other relevant roles such as staff in supporting departments

- ensuring supervisors of clinical trial research trainees have the appropriate skills, qualifications and resources
- providing access to facilities for the safe and secure storage and management of clinical trial data, records and primary materials and, where possible and appropriate, facilitate access for study personnel

- Ensuring mechanisms are in place to collect and report on operational metrics, such as the National Aggregate Statistics and other agreed measures of operational performance to the governing body as required.

Approving authorities

Approving authorities are public or private legal entities (institutions or organisations) where trials are conducted. Approving authorities conducting trials under the CTX and CTN schemes have specific responsibilities as outlined in the National Statement, Guideline for Good Clinical Practice and the *Therapeutic Goods Act 1989*.

For investigator initiated trials the health service organisation or trial site that is the approving authority may also be the trial sponsor. In such cases the governing body ensures that its overarching governance and quality management systems delineate its responsibilities as a trial sponsor from its responsibilities as a trial site and ensures that the requirements of sponsorship are able to be met.

Managers (clinical and non-clinical)

Clinical and non-clinical managers including heads of clinical departments, business, finance and human resource managers advise and inform the governing body, and operate clinical trial services within the strategic and policy parameters endorsed by the governing body. They are primarily responsible for ensuring the systems that support clinical trial service delivery are well designed and perform well. The functions of the business manager include:

- Ensuring effective budgeting and the review of budgets prepared by the Principal Investigator and their clinical trial teams for the conduct of the both single-centre and multi-centre clinical trials
- Ensuring funding sources and costs of the trial have been identified
- Ensuring costs can be met by the sponsor or the health service organisation or that there is an adequate plan to ensure costs can be met and that cost centres are created (as required) to manage clinical trial funds
- Ensuring adequate staff and resources are available to undertake the trial.

Human Research Ethics Committee (HREC)

The HREC is responsible for assessing the ethical acceptability of a proposal to conduct a clinical trial within the requirements of the National Statement and supporting guides such as: Keeping research on track: a guide for Aboriginal and Torres Strait Islander peoples about health research ethics (2018); Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018); and relevant national and jurisdictional legislation including guardianship legislation and the roles of civil and administrative tribunals for participation of people without the capacity to provide consent. HRECs also monitor compliance, during ongoing trial conduct for the ethical conduct of the trial, in accordance with the National Statement and provide advice on strategies to promote awareness of the ethical conduct of clinical trials and research more broadly.

HRECs that review and approve clinical trials are registered with NHMRC and may or may not be co-located with public and private health service organisations. HRECs that review and approve clinical trials must have access to the expertise necessary to enable it to address the ethical issues arising from the categories of research it is likely to consider. This may necessitate going outside the HREC membership.

HREC Executive Officer

This position may provide expert advice to investigators seeking to undertake clinical trials within health service organisations in accordance with the National Statement and the Code, national regulation and legislation, and jurisdictional policies. The HREC Executive Officer provides secretariat support for a HREC (and sub-committees as applicable) and may undertake functions including:

- Documenting HREC decisions and maintain a current record in the designated IT system
- Managing approved clinical trial amendments

- Managing annual progress/final reports
- Assisting in the preparation on the annual reporting of HREC activity to the governing body and NHMRC as required
- Managing the process to undertake appeals and notification of complaints, misconduct and conflicts of interest
- Providing advice on strategies to promote awareness of the ethical conduct of clinical trials and clinical trials.

Research Governance Officer or compliance officer

The purpose of this role is to provide support and advice to the relevant CEO or their delegate, Director of Research, HREC, site-specific assessment office, trial investigators and their teams and trial sponsors in accordance with the National Statement, national regulation and legislation and jurisdictional policies. The Research Governance Officer (or similar) provides oversight of the implementation of the National Clinical Trials Governance Framework and facilitates a culture of high quality clinical trials that promotes awareness of the organisation wide approach to providing clinical trial services and ensures administrative systems are in place to review, monitor and evaluate clinical trials being conducted within a health service organisation. The Research Governance Officer or their delegate may also be responsible for:

- Ensuring awareness of the importance of the National Statement and the Code across the organisation
- Monitoring relevant regulatory and policy developments to ensure changes are incorporated into local policies and procedures in a timely manner
- Leading the development and implementation of systems and implementation of best practice policy, procedures, and standardised systems within the relevant health system to improve the conduct and governance of clinical trials in collaboration with the governing body, managers, clinicians, patients, consumers and trial sponsors
- Providing information, education and advice on research governance matters to a range of parties including trial investigators and trial study coordinators seeking to undertake a clinical trial within a health service organisation, ethics officers, clinical trial sponsors and other parties involved in the conduct and management of clinical trials in accordance with national and local policies, guidelines and other reference material adopted by the jurisdiction
- Monitoring clinical trial activity within the relevant health service organisation or trial site, and facilitating or coordinating the preparation of the annual clinical trial report
- Undertaking risk management assessments regarding clinical trial services and procedures to promote responsible clinical trial conduct
- Implementing systems for the management of complaints about clinical trials including clinical trial misconduct and fraud and manage clinical trial complaints, misconduct or conflicts of interest related to the conduct of authorised clinical trial projects
- Conducting or co-ordinating audits of clinical trial projects, where required
- Preparing reports to regulatory bodies as required
- Maintaining records, including databases and filing systems
- Determining compliance with relevant legislative and policies.

Site-Specific Assessment Officer

The site-specific assessment officer responsibilities are distinct from those of the HREC and the Research Governance Officer. The granting of ethical approval by a HREC does not oblige an approving authority to grant authorisation at their site as the site may not have the capacity or capability to undertake the trial based on the protocol requirements. As part of the process to confirm whether authorisation should be granted, the site-specific assessment officer confirms the clinical trial has undergone HREC review and received approval prior to commencement. Specifically, this position is responsible for undertaking authorisation activities in a timely manner.

The SSA process considers the following:

- The capacity for the site to support the project, including the availability of potential trial participants at the site
- Financial arrangements for the project
- Insurance arrangements
- The availability of appropriately certified and trained staff to meet the requirements of the trial
- Data access
- Local approvals relevant to the conduct of the trial.

Preauthorisation activities including:

- Pre-authorisation must occur in a timely manner and may be undertaken in parallel with HREC review
- Liaising with the trial investigators and their teams and sponsors regarding the preparation of applications for site authorisation
- Managing the process of site authorisation, reviewing the SSA form and recommending authorisation of the trial to the Chief Executive or delegate
- Ensuring a copy of the HREC approval, agreements applicable to the clinical trial, indemnity and insurance documents have been received and signed
- Ensuring collection of appropriate fees for site authorisation
- Documenting all site specific clinical trial assessment decisions and maintaining a current record on the appropriate database
- Reviewing and managing amendment documentation related to authorised clinical trials
- Collecting and providing data on operational metrics to the governing body.

Post-authorisation activities including:

- Managing and reviewing amendments to authorised clinical trial projects
- Having an oversight of authorised clinical trial projects through review of annual
- and final site progress reports submitted by the Principal Investigator
- Receiving complaints related to the conduct of a clinical trial and escalating these to the appropriate officer within the health service organisation.

Clinical trial site staff

Clinical trial site 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 National Clinical Trials Governance Framework. Clinical trial site staff includes, but are not limited to the following:

- Site Principal and co-investigators
- Study coordinators/clinical trial coordinators/ trial nurse/ clinical trial pharmacists.

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 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 principal investigator must conduct the clinical trial in accordance with the approved clinical trial protocol. The 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 to adhere with the regulatory requirements associated with both the management and conduct of the trial. Principal investigators are 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 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 principal investigator include:

- 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
- Take 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
- 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
- Providing reports to the HREC and site on:
  - adverse events
  - proposed amendments to the protocol
  - 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
- 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 principal investigator should make a reasonable effort to ascertain the reason(s), whilst fully respecting the participant's rights
- Retaining clear, accurate, secure and complete records of all clinical trial 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
- 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*.

**Principally relates to investigator initiated clinical trials*

Site Clinical Trial Coordinator

The clinical trials coordinator position liaises between the principal investigator, HREC and Site-Specific Assessment Office and works collaboratively with the governing body, clinical and non-clinical managers, clinicians, patients, trial participants, consumers and sponsors. The clinical trials coordinator works with the principal investigator to:

- Undertake site feasibility assessments as required
- Facilitate arrangements for the clinical trial team to access resources and support provided by the health service organisation, as agreed in the clinical trial contract and identified on the SSA form

- Disclose actual or potential conflicts of interest
- Liaise with the Principal Investigator and Sponsor regarding the management, monitoring and financial requirements of the clinical trial
- Submit the ethics application(s), with input from the principal investigator, for ethical and scientific approval of the clinical trial or providing approval documents where ethical approval is obtained at a lead-site
- Ensure that, the clinical trial project satisfies relevant review requirements
- Relay information between the HREC and the principal investigator
- Communicate the outcome of the ethical review to the principal investigator
- Prepare a budget for the conduct of the project in association with the business manager or similar individual within the health service organisation or trial site
- Submit the SSA form for institutional approval
- Submit an Access Request Form for clinical trial that requires support from a health service organisation in the form of access to participants, tissue or data but does not involve the conduct of clinical trial at that health service organisation
- Ensure the clinical trial is registered on a publicly accessible clinical trial registry, prior to the commencement of the clinical trial if required
- Undertake participant screening and recruitment activities
- Maintain trial participants on a clinical trial and, where specified in the protocol, deliver or facilitate the delivery of the trial intervention
- Conduct clinical trials in accordance with credentialing privileges, skills and experience relating to the conduct of clinical trials
- Ensure clinical trial practices reflect current professional (ethical and legal) standards for clinical trial , including reporting conflicts of interest
- Ensure compliance with the trial approved protocol which will result in compliance with National Statement, legislative and policy requirements for patient contact, consent, and confidentiality of patient information
- Conduct clinical trial in accordance with national guidelines and jurisdictional health clinical trial policy and procedures
- Ensure that the clinical trial is carried out in accordance with the conditions of the HREC approval
- Maintain good clinical trial records and making records available for review
- Respond promptly to reporting and monitoring standards, including adverse events, complaints and clinical incidents
- Submit annual and final reports to the HREC and institution in a timely fashion
- Submit notification of early project termination
- Retain and storing clinical trial data securely and for a period of time as required by national and jurisdictional legislation.

Sponsors and contract research organisations

All clinical trials conducted in Australia must have a trial sponsor that is an Australian entity (an overseas company cannot be the sponsor of a trial in Australia). Sponsors of trials under the TGA CTN or CTX schemes may include individuals, companies, institutions, or organisations.[106]

The trial sponsor is responsible for the initiation, management and financing (or arranging the financing) of the trial and carries the medico-legal responsibility associated with its conduct. The Australian trial sponsor is also the entity that is responsible for submitting a CTN or CTX to the TGA if required.

The ultimate responsibility for the quality and integrity of the clinical trial data resides with the trial sponsor. The trial sponsor retains overall responsibility for all delegated functions in accordance with the Guideline for Good Clinical Practice and the International Organisation for Standardisation for trials under the CTN or CTX schemes.[107] This also applies when a non-commercial trial sponsor delegates duties to a coordinating Principal Investigator, trial coordinating centre or clinical research organisation.

The sponsor is also responsible for ensuring that appropriate approvals are obtained prior to the commencement of the clinical trial, that conditions of any approvals are adhered to during the course of the clinical trial and, ensures that the ethics principles of research merit and integrity, justice, beneficence and respect are applied to the conduct of clinical trials.

Trial sponsors ensure that a trial is appropriately monitored for compliance with the protocol. The quality of information generated when clinical trials are conducted impacts on the future care of the Australian population. Before initiating a trial, the trial sponsor should ensure that quality management systems are in place and that these systems are robust enough to fulfil all the requirements of the protocol and relevant regulatory requirements, including relevant state and territory legislation. For example, when designing a trial, the principles of Good Clinical Practice requires trial sponsors to use a multi-disciplinary team of qualified individuals (for example, biostatisticians, clinical pharmacologists, and physicians) as appropriate, throughout all stages of the trial process, from designing the protocol and case report forms to analysing and preparing interim and final clinical trial reports.

For investigator initiated trials the health service organisation or trial site that is the approving authority may also be the trial sponsor. In such cases the governing body ensures that its overarching governance and quality management systems delineate its responsibilities as a trial sponsor from its responsibilities as a trial site and ensures that the requirements of sponsorship are able to be met.

When planning a clinical trial, trial sponsors should have processes in place to ensure the risks associated with its conduct are identified and assessed so that adequate trial monitoring and management plans can be developed to mitigate risk that may adversely impact on trial quality or participant safety. Trial sponsors, or their delegate, are also required to:

- Retain clear, accurate, secure and complete records of all clinical trial including clinical trial data and primary materials. As appropriate, allow access and reference to these by the regulator and interested parties
- Disseminate clinical trial findings responsibly, accurately and broadly. Where necessary, take action to correct the record in a timely manner
- Disclose and manage actual, potential or perceived conflicts of interest
- Ensure 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
- Acknowledge those who have contributed to the clinical trial, and cite and acknowledge other relevant work appropriately and accurately
- Report suspected breaches of the Code to the relevant institution and/or authority.

Glossary of terms and definitions

TERM	DEFINITION
Adverse event	An adverse event (AE) is any unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.[108] An adverse event is an incident that results, or could have resulted, in harm to a patient or consumer. An unintended near miss is a type of adverse event. *See also near miss*.
Attestation Statement	Statement signed by the governing body of the Health Service Organisation that attests to the implementation of the National Clinical Trials Governance Framework across all clinical trial services within the health service organisation.
Australian Charter of Healthcare Rights	Australian Charter of Healthcare Rights specifies the key rights of patients when seeking or receiving healthcare services. It was endorsed by health ministers in 2008.[109]
Australian Open Disclosure Framework	The Australian Open Disclosure Framework was endorsed by Health Ministers in 2013. It provides a framework for health service organisations and clinicians to communicate openly with patients when health care does not go to plan.[110]
Clinical governance	Clinical governance is an integrated component of corporate governance of health service organisations. It ensures that everyone – from frontline clinicians to managers and members of governing bodies, such as boards – is accountable to patients and the community for assuring the delivery of safe, effective and high-quality services. Clinical governance systems provide confidence to the community and the healthcare organisation that systems are in place to deliver safe high-quality health care.
Clinical leaders	Clinical leaders are clinicians with management or leadership roles in a health service organisation who can use their position or influence to change behaviour, practice or performance. Examples are directors of clinical services, heads of units, clinical supervisors and clinical trial principal investigators.
Clinician	A clinician is a healthcare provider, trained as a health professional, including registered and non-registered practitioners. Clinicians may provide care within a health service organisation as an employee, a contractor or a credentialed healthcare provider, or under other working arrangements. They include nurses, midwives, medical practitioners, allied health practitioners, technicians, scientists and other clinicians who provide health care and students who provide health care under supervision.

TERM	DEFINITION
Clinical trial	A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.[111] Clinical trials include but are not limited to: ▪ Surgical and medical treatments and procedures ▪ Experimental drugs ▪ Biological products ▪ Medical devices ▪ Health-related service changes ▪ Health-related preventative strategies ▪ Health-related educational interventions.
Clinical trial governance office review	Clinical trial 'governance' is the term used for institutional review or site-specific assessment (SSA). From a broader perspective, ethics-approval forms part of the overall governance framework that ensures the compliance, accountability and transparency of research activity at a site.[112]
Clinical Trial Notification Scheme	The Clinical Trial Notification Scheme (CTN) is established under the *Therapeutic Goods Act 1989 (Cth)* and is administered by the TGA. Under the CTN scheme, therapeutic goods are permitted to be used for experimental purposes if the relevant clinical trial is notified to the TGA.
Clinical Trial Exemption Scheme	The Clinical Trial Exemption Scheme (CTX) is established under the *Therapeutic Goods Act 1989 (Cth)* and is administered by the TGA. Under the CTX scheme, therapeutic goods are permitted to be used for experimental purposes if the relevant clinical trial is approved by the TGA.
Clinical trial team	The clinical trial team includes individuals, identified by the investigator, who are responsible for study coordination, data collection and data management. Members of the clinical trial team may also be called the research coordinator, study coordinator, research nurse, study nurse or sub-investigator, clinical trial pharmacist[113] and may have various roles in the clinical trial including: ▪ Participant recruitment and enrollment ▪ Obtaining consent from prospective participants, meet with research participants, and collect and record information from research participants ▪ Maintain consistent study implementation ▪ Data management, and to ensure integrity ▪ Dispensing and administering the investigational product ▪ Compliance with regulatory and reporting requirements.
Clinical trial workforce	The clinical workforce includes, but is not limited to: trial investigators, trial sub-investigators, clinical trial pharmacists, trial managers, trial coordinators HREC Executive Officers, Site Specific Assessment Officers, research office staff.
Choice	Research participants are afforded respect and autonomy, taking account of their capacity to understand. Where there is a difference between the research and the standard practice that they might otherwise experience, research participants are given information to understand the distinction and make a choice, unless a research ethics committee agrees otherwise. Where participants' explicit consent is sought, it is voluntary and informed Where consent is refused or withdrawn, this is done without reprisal.[114]

TERM	DEFINITION
Consumer	A person who has used, or may potentially use, health services, or is a carer for a patient using health services. A healthcare consumer may also act as a consumer representative, to provide a consumer perspective, contribute consumer experiences, advocate for the interests of current and potential health service users, and take part in decision-making processes.[115]
Contract research organisation	A person or an organisation (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.[116]
Coordinating Committee	A committee that a sponsor may organise to coordinate the conduct of a multicentre trial.[117]
Credentialing	Credentialing is the formal process used by a health service organisation to verify the qualifications, experience, professional standing, competencies and other relevant professional attributes of clinicians, so that the organisation can form a view about the clinician's competence, performance and professional suitability to provide safe, high-quality healthcare services within specific organisational environments.[118]
Environment	Environment is the physical surroundings in which health care is delivered, including the building, fixtures, fittings, and services such as air and water supply. Environment can also include other patients, consumers, visitors and the workforce.
Good Clinical Practice	A standard for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of trial subjects are protected.[119]
Governance	Governance is a set of relationships and responsibilities established by a health service organisation between its executive, workforce and stakeholders (including patients and consumers). Governance incorporates the processes, customs, policy directives, laws and conventions affecting the way an organisation is directed, administered or controlled. Governance arrangements provide the structure for setting the corporate objectives (social, fiscal, legal and HR) of the organisation and the means to achieve the objectives. They also specify the mechanisms for monitoring performance. Effective governance provides a clear statement of individual accountabilities within the organisation to help align the roles, interests and actions of the different participants in the organisation to achieve the organisation's objectives. In the National Safety and Quality Health Service (NSQHS) Standards (second edition) governance includes both corporate and clinical governance.[120]
Governing body	The governing body is a board, chief executive officer, organisation owner, partnership or other highest level of governance (individual or group of individuals) that has ultimate responsibility for strategic and operational decisions affecting safety and quality in a health service organisation.
Health care	Health care is the prevention, treatment and management of illness and injury, and the preservation of mental and physical wellbeing through the services offered by clinicians, such as medical, nursing and allied health[121] professionals.[122]
Healthcare record	Healthcare record includes a record of the patient's medical history, treatment notes, observations, correspondence, investigations, test results, photographs, prescription records and medication charts for an episode of care.

TERM	DEFINITION
Health literacy	The Australian Commission on Safety and Quality in Health Care separates health literacy into two components – individual health literacy and the health literacy environment. The health literacy environment is the infrastructure, policies, processes, materials, people and relationships that make up the health system, which affect the ways in which consumers access, understand, appraise and apply health-related information and services.[123]
Human research ethics review	A process to explore the ethical issues presented by, and implications of, a research project. Human Research Ethics Committees (HREC) play a central role in the Australian system of ethical oversight of research involving humans. HRECs review research proposals involving human participants to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines, including the National Statement on Ethical Conduct in Human Research (the National Statement 2007, updated, 2018).[124]
Health service organisation	A separately constituted health service that is responsible for implementing clinical governance, administration and financial management of a service unit or service units providing health care at the direction of the governing body. A service unit involves a group of clinicians and others working in a systematic way to deliver health care to patients. It can be in any location or setting, including pharmacies, clinics, outpatient facilities, hospitals, patients' homes, community settings, practices and clinicians' rooms.
Incident	An incident (clinical) is an event or circumstance that resulted, or could have resulted, in unintended or unnecessary harm to a patient or consumer; or a complaint, loss or damage. An incident may also be a near miss. *See also near miss*.
Informed consent	Informed consent is a process of communication between a patient and a clinician about options for treatment, care processes or potential outcomes. This communication results in the patient's authorisation or agreement to undergo a specific intervention or participate in planned care. The communication should ensure that the patient has an understanding of the care they will receive, all the available options and the expected outcomes, including success rates and side effects for each option.[125]
Investigational Brochure	Compilation of the clinical and non-clinical data available on the experimental products intended for use in the clinical trial in question. It provides trial organisers and staff with an understanding of the rationale of the trial, in order to inform their compliance with the protocol requirements. The information enables a risk/benefit assessment of the appropriateness of the proposed trial, of vital importance to HREC considerations.
Investigational product	The Investigational Product (IP) includes any product, or intervention being investigated, tested or used as a placebo or reference point in a clinical trial. This includes a pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use. The sponsor or their delegate, is responsible for the provision and maintenance of the IP.[126]
Individual Health literacy	Individual health literacy is the skills, knowledge, motivation and capacity of a consumer to access, understand, appraise and apply information to make effective decisions about health and health care, and take appropriate action.

TERM	DEFINITION
Jurisdictional requirements	Jurisdictional requirements are those systematically developed statements from state and territory governments about appropriate healthcare or service delivery for specific circumstances. Jurisdictional requirements encompass a number of types of documents from state and territory governments, including legislation, regulations, guidelines, policies, directives and circulars. Terms used for each document may vary by state and territory.[127]
Leadership	Leadership is having a vision of what can be achieved, and then communicating this to others and evolving strategies for realising the vision. Leaders motivate people, and can negotiate for resources and other support to achieve goals.[128]
Local community	The local community are those people living in a defined geographic region or from a specific group who receive services from a health service organisation.
Near miss	Near miss is an incident or potential incident that was averted and did not cause harm, but had the potential to do so.[129]
Open disclosure	Open disclosure is an open discussion with a patient and carer about an incident that resulted in harm to the patient while receiving health care. The criteria of open disclosure are an expression of regret, and a factual explanation of what happened, the potential consequences, and the steps taken to manage the event and prevent recurrence.[130]
Organisation-wide	Organisation-wide is intended for use throughout the health service organisation.
Outcome	Outcome is the status of an individual, group of people or population that is wholly or partially attributable to an action, agent or circumstance.[131]
Partnership	Partnership is a situation that develops when patients and consumers are treated with dignity and respect, when information is shared with them, and when participation and collaboration in healthcare processes are encouraged and supported to the extent that patients and consumers choose. Partnerships can exist in different ways in a health service organisation, including at the level of individual interactions; at the level of a service, department or program; and at the level of the organisation. They can also exist with consumers and groups in the community. Generally, partnerships at all levels are necessary to ensure that the health service organisation is responsive to patient and consumer input and needs, although the nature of the activities for these different types of partnership will vary depending on the context of the health service organisation.
Participant	A participant is a clinical trial subject (*see trial subject*) patient or consumer who is enrolled to participate in a clinical trial.[132]
Patient	A patient is a person who is receiving care in a health service organisation.
Patient safety	Patient safety is the prevention of errors and adverse effects on patients associated with health care.
Phase I	Phase I clinical trials involve the first administration of the medicine to humans, usually to small numbers of healthy volunteers. Phase I trials determine the safety of the medicine, how it works and how well it is tolerated and are usually undertaken in specially equipped centres.
Phase II	Phase II clinical trials are normally the first trials of the medicine in patients suffering the condition for which the medicine is intended. The principal aim of Phase II clinical trials is to determine effectiveness and safety.

TERM	DEFINITION
Phase III	Phase III clinical trials involve greater numbers of patients and are undertaken for the purpose of determining whether the medicine confers clinical benefit in the disease/s for which effectiveness was demonstrated in Phase II clinical trials. They also determine the nature and likelihood of any side effects.
Phase IV	Phase IV clinical trials are those clinical trials undertaken after the medicine has been approved for the treatment of a particular disease. Phase IV clinical trials are undertaken to compare a new medicine to a wider range of existing therapies and interventions, as well as to further investigate the use of medicines in the normal clinical setting of the disease as opposed to the conditions under which the trial was conducted.
Principal Investigator	The Principal Investigator (PI) is the investigator responsible for the conduct of a trial at a particular trial site.
Policy	Policy is a set of principles that reflect the organisation's mission and direction. All procedures and protocols are linked to a policy statement.
Procedure	Procedure is the set of instructions to make policies and protocols operational, which are specific to an organisation.
Process	A process is a series of actions or steps taken to achieve a particular goal. [133]
Program	A Program is an initiative, or series of initiatives, designed to deal with a particular issue, with resources, a time frame, objectives and deliverables allocated to it.
Protocol	A detailed clinical trial plan that includes the purpose and procedures of the research and who can be part of the trial. The protocol provides the rationale, design, methodology for the trial conduct, who may participate in a trial, the length of a trial and the schedule of tests, procedures, medications and dosages, method of analysis, monitoring of data safety and quality. The sponsor of the trial is responsible for the protocol.[134]
Quality improvement	Quality improvement is the the combined efforts of the workforce and others – including consumers, patients and their families, researchers, planners and educators – to make changes that will lead to better patient outcomes (health), better system performance (care) and better professional development. Quality improvement activities may be undertaken in sequence, intermittently or on a continual basis.[135]
Research	Research includes investigation undertaken to gain knowledge and understanding or to train researchers.[136]
Risk	Risk is the chance of something happening that will have a negative or positive impact. Risk is measured by the consequences of an event and its likelihood.
Risk assessment	Risk assessment is the assessment, analysis and management of risks. It involves recognising which events may lead to harm in the future, and minimising their likelihood and consequence.[137]
Risk management	Risk management is the design and implementation of a program to identify and avoid or minimise risks to patients, employees, volunteers, visitors and the organisation.

TERM	DEFINITION
Safety culture	Safety culture is a commitment to safety that permeates all levels of an organisation, from the clinical workforce to executive management. Features commonly include acknowledgement of the high-risk, error-prone nature of an organisation's activities; a blame-free environment in which individuals are able to report errors or near misses without fear of reprimand or punishment; an expectation of collaboration across all areas and levels of an organisation to seek solutions to vulnerabilities; and a willingness of the organisation to direct resources to deal with safety concerns.[138]
Scope of clinical practice	Scope of clinical practice the extent of an individual clinician's approved clinical practice within a particular organisation, based on the clinician's skills, knowledge, performance and professional suitability, and the needs and service capability of the organisation.[139]
Safety Events	A serious adverse event (experience) or reaction is any untoward medical occurrence that at any dose results in death or is life threatening.[140]
Site	A facility, location or institution (or group of institutions) that resource, conduct and manage clinical trials that come under one of the final research authorisation sign off.[141]
Sponsor	An individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study.[142]
Standard	A standard agreed attributes and processes designed to ensure that a product, service or method will perform consistently at a designated level.[143]
System	The System is the resources, policies, processes and procedures that are organised, integrated, regulated and administered to accomplish a stated goal. A system: ▪ Brings together risk management, governance and operational processes and procedures, including education, training and orientation ▪ Deploys an active implementation plan; feedback mechanisms include agreed protocols and guidelines, decision support tools and other resource materials ▪ Uses several incentives and sanctions to influence behaviours and encourage compliance with policy, protocol, regulation and procedures. The workforce is both a resource in the system and involved in all elements of systems development, implementation, monitoring, improvement and evaluation.
Therapeutic Goods Administration	The Therapeutic Goods Administration (TGA) is the Australian Government Department of Health agency responsible for the regulation of, supply, import, export, manufacturing and advertising of therapeutic goods in Australia.
Training	Training is the development of knowledge and skills.
Trial investigator	The individual responsible for the conduct of the clinical trial at a trial site. If a clinical trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.
Trial subject	An individual who participates in a clinical trial, either as a recipient of the investigational product(s) or as a control.[144]
Workforce	Workforce includes all people working in a health service organisation, including clinicians, and any other employed or contracted, locum, agency, student, volunteer or peer workers. The workforce can be members of the health service organisation or medical company representatives providing technical support who have assigned roles and responsibilities for care of, administration of, support of, or involvement with, patients in the health service organisation or trial site.

Acknowledgements

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Dr Robert Herkes	Chief Medical Officer	Australian Commission on Safety and Quality in Health Care	National
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COMMITTEE MEMBER NAME	COMMITTEE CONTRIBUTION	ROLE TITLE AND ORGANISATION	STATE
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