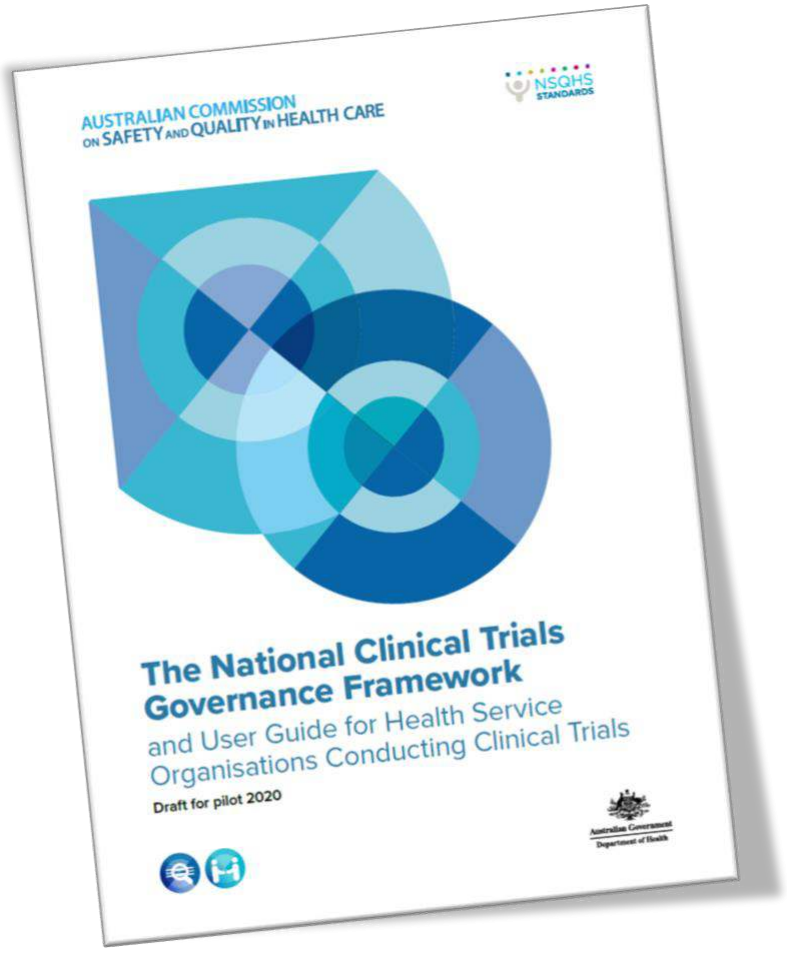
MACH
Melbourne Academic Centre for Health

PART ONE: THE NATIONAL CLINICAL TRIALS GOVERNANCE FRAMEWORK AND YOU



THE NATIONAL CLINICAL TRIALS GOVERNANCE FRAMEWORK AND YOU

Developed by the MACH group in partnership with:

Introduction

- This document is **Part One**.
  - It is background/additional information, instructions for use, relevant definitions.

- **Part Two** is the Standard 1 - Clinical Governance workbook
- **Part Three** is the Standard 2 – Partnering with Consumers workbook
  - The instructions for use are repeated in parts 2 and 3.

Background: What is accreditation?

Accreditation is the process through which your HSOs accrediting agency assesses whether your organisation meets the standards that apply to them (in this case, the framework). They do this by assessing the evidence your organisation provides to demonstrate that they meet each of the actions in the relevant standards. Accreditation assessments are pass/fail. If your organisation can demonstrate that they do meet all of the actions, they will pass, become an accredited organisation, and continue as normal. If they cannot demonstrate that they meet all of the actions in the standards, or if the assessors are unhappy with some of their evidence, they will fail, could have their accreditation withdrawn, and could have their normal business practise significantly affected[5].

Accreditation is a two-stage process.

Stage 1: Assessors look at your organisations evidence showing they comply with the standards.

Stage 2: Assessors come to site, look at the areas where care is being delivered, and ask staff accreditation-related questions (eg their awareness of and compliance with policies, their use of institutional systems, their last performance appraisal and what it involved, what support they are being given, their involvement in institutional committees, etc)[5].

Accreditation vs Audit

Both Accreditation and Audits are both about compliance. Compliance can be tested in different ways, by a federal government regulatory authority as an Inspection, by a Sponsor or third-party provider, as a Good Clinical Practice audit, or by a notified body. However, it is important to note that accreditation is not the same as an Inspection or an Audit.

Accreditation considers overall compliance with Government-set standards that are applicable to the organisations. It is not project-specific, and uses a wide scope, whole of organisation, approach to determine if your organisation complies with the applicable standards. The accrediting organisation is looking to be provided with evidence of compliance, and nothing more - they are unlikely to go through all the documents generated by a trial or a trial unit. Therefore, accreditations have a yes/no outcome - an organization is either accredited or it is not.[5]

Inspections and audits generally have a much tighter, narrower scope. They are generally project or unit specific, and more commonly involve in depth reviews of quality systems, are part of vendor assurance, involve assessments or evaluations of a project throughout its life cycle, are required due to corrective action, or are 'For Cause'. Inspections and audits are more likely to go through all the documents generated by the trial and assess them against the purpose of the inspection/audit. Therefore, an audit results in "findings" that must be remedied, rather than a yes/no outcome.

The National Clinical Governance Framework

The National Clinical Trials Governance Framework ("the framework") is being put in place as an extension to the current hospital accreditation scheme (the National Safety and Quality Health Service Standards, "the NSQHSS"), managed by the Australian Commission for Safety and Quality in Healthcare ("the Commission"). For the first time, the clinical trials service will be included in a Health Service Organisation's (HSO, hereafter "organisation") accreditation.

There are three functions that a HSO provides:

- Clinical services
- Education and training for health care professionals, and
- Conduct research

Up until now, it has been up to the Sponsor, the Investigator, and the HREC/Governance Office to ensure clinical trials were performed in a safe environment by properly qualified staff, and that the trials an organisation undertakes are of high quality and meet the needs of their community[1]. However, conducting research is a core function of public hospitals. And if research is a core function, and the Commission accredits clinical services and education and training (which are also core functions), they should also be accrediting the conduct of research.

The framework is aiming to achieve the following:

- Nationally consistent approach to clinical trial governance (i.e., because HSOs are accredited under the framework, they have a consistent approach to governance under the framework)
- Integration of the clinical trial service into routine clinical services
- Embedding the clinical trial service into clinical and corporate governance systems, and strategic and operational planning for service provision at an organisational level
- Increased visibility, awareness, and transparency of the clinical trials service to the rest of the organisation, including the governing body and the service users
- Increased awareness of, and opportunities to participate in, clinical trials and research[1].

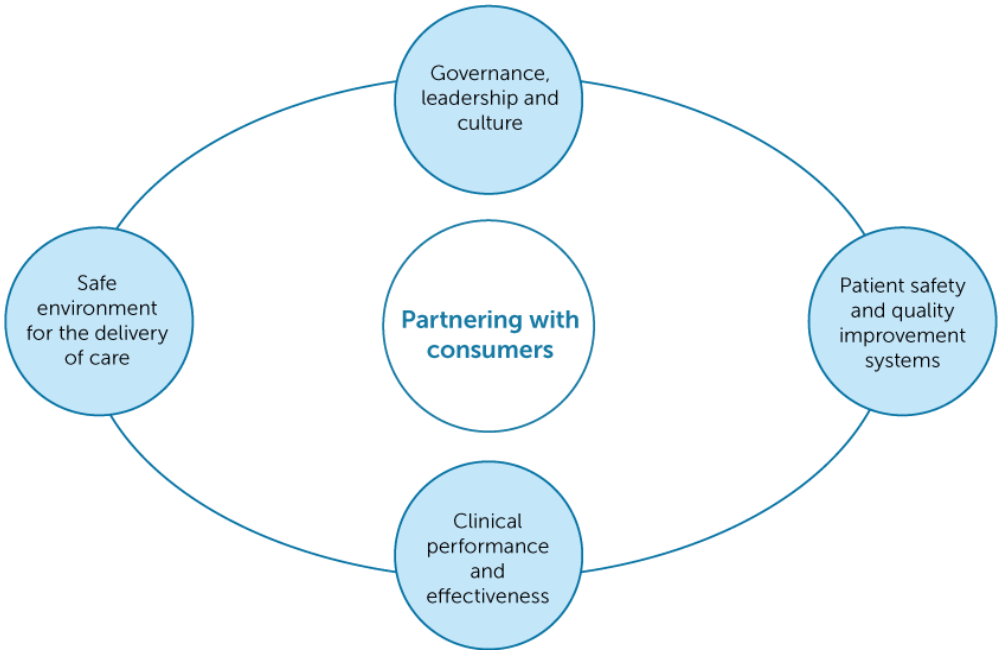


Figure 1 - The Five Components of the National Clinical Trials Governance Framework[2]

The Commission wants the clinical trials service to be "embedded" into the normal functioning of the organisation. This means organisations are expected to treat the clinical trials service the same way that they treat their other departments, and that clinical trial participants are (where possible and practical) treated the same as the other patients of the organisation.

The framework is made up of Standard 1: Clinical Governance and Standard 2: Partnering with Consumers. Each standard is made up of a set of actions, and evidence must be provided to show that the organisation meets that action. To support them in this, each action is also accompanied by lists of key tasks and suggested evidence.

The actions within the two standards of the framework align with the matching actions in the two standards of the NSQHSS, so that everyone in the organisation is working towards the same goals and meeting the same actions. This also means every action in the framework will be assessable under the current hospital accreditation scheme (the NSQHSS).

Standard 1 - Clinical Governance

To start, a definition:
Clinical 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[3]. 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. 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 health services that are safe, effective, integrated, high quality and continuously improving[1,2,3].

The overarching point here is that the governing body of an organisation needs to be aware of, and accountable for, all of the clinical trial activity that goes on in their organisation. While it is the responsibility of the governing body to set up clinical governance systems, monitor their effectiveness, and be held accountable for the outcomes of this system, it is also the responsibility of everyone in the organisation to participate in these systems[1].

The components of this Standard are:

- *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[1]

Standard 2 - Partnering with Consumers

To start, a definition
Organisational systems are designed and used to support patients, carers, families and consumers to partner in planning, design, measurement & evaluation of clinical trials and clinical trial services[4].

Partnering with consumers exists at three key levels:

- *At the level of the individual* - providing care that is respectful; sharing information in an ongoing way; working with patients, carers and families to make decisions and plan care; and supporting and encouraging patients in their own care and self-management.
- *At the level of a unit, department or program of care* - Patients, carers, families and consumers participate in the overall design and organisation of a service, department or program, and the way it delivers care.
- *At the level of the health service organisation* - Consumers and consumer representatives are full members of key organisational governance committees in areas such as patient safety, facility design, quality improvement, patient or family education, ethics and research; they are involved in policy development and planning[4].

The components of this standard are:

- *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.
- *Partnering with patients in their own care* - Systems that are based on partnering with patients in their own care are used to support the delivery of care. Patients are partners in their own care to the extent that they choose.
- *Health literacy* - Health service organisations communicate with consumers in a way that supports effective partnerships.
- *Partnering with consumers in organisational design and governance* - Consumers are partners in the design and governance of the organisation[4]

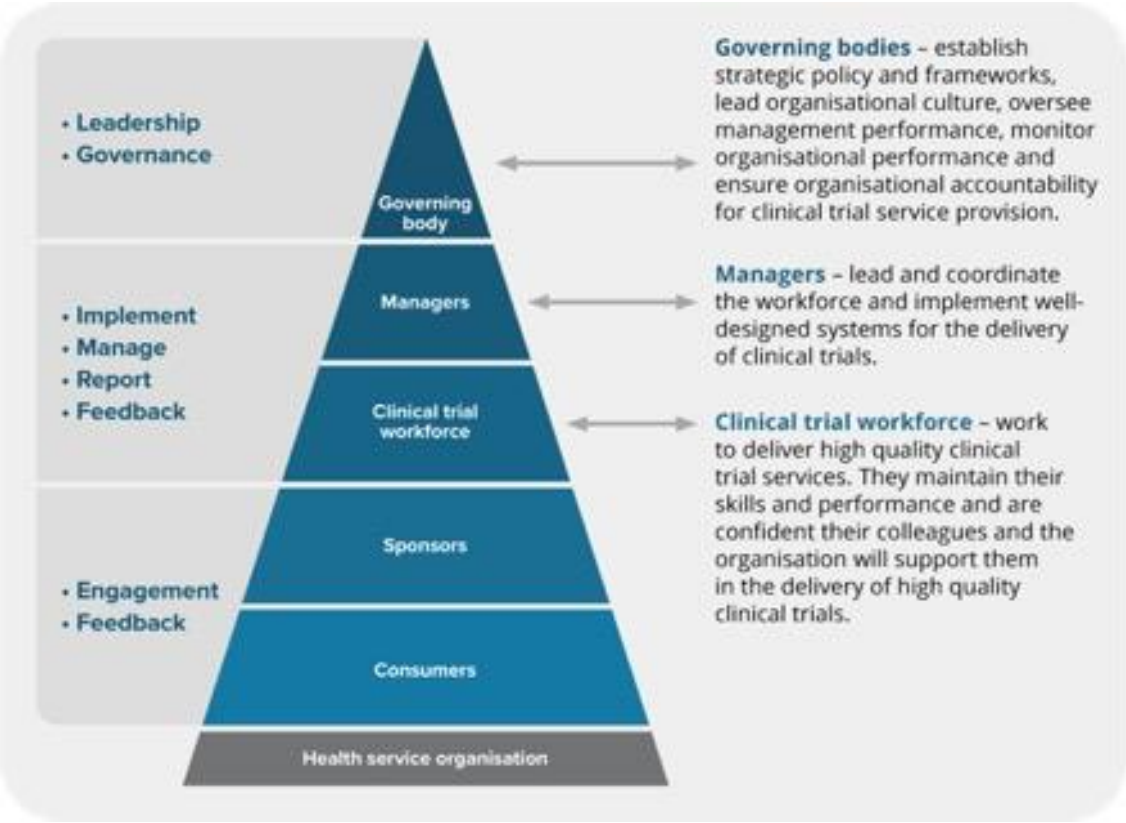


Figure 2 - Roles and Functions of identified positions relating to governance of clinical trial services[1]

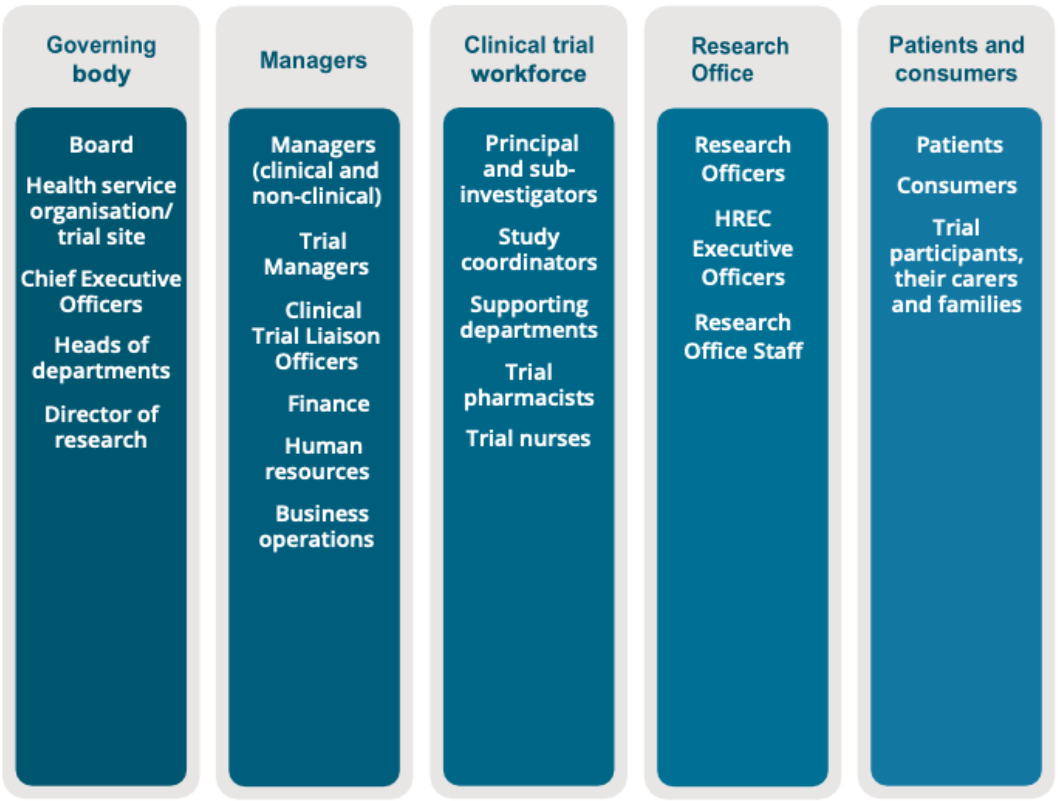


Figure 3 - Roles for identified positions and organisational relationships within a health service organisation or trial site[1]

The purpose of this workbook

This resource is designed to help members of the clinical trial workforce understand their responsibilities under the National Clinical Governance Framework ("the framework"). It should help clinical trials workforce members be able to demonstrate this understanding to assessors during accreditation.

This resource:

- Defines the different parts of the workforce
- Defines the various functions of each of these parts through the lens of the National Clinical Trials Governance Framework
- Breaks the National Clinical Trials Governance Framework down into the specific responsibilities relevant to each part of the workforce, and
- Helps you understand the framework enough to apply it at your organisation

The layout of this workbook is designed to be similar to other tools health service organisations ("HSOs", hereafter "organisations") use to track the progress of implementing each standard (NSQHS Standards monitoring tool for hospitals: find those here).

This booklet does NOT give any specific/direct guidance on how to implement the framework at your HSO. This is because every organisation has a different organisational structure and context, and therefore will need to implement the framework in a way that suits their specific organisational structure and context. Rather, it goes through "here is your responsibility about x under the framework" and "here are some things to think about if you want to demonstrate how you meet this responsibility".

How to use this workbook

This workbook is separated into sections according to the different parts of the workforce. The different sections are:

- Clinical and Non-Clinical Managers
- Research Office
- Clinical Trial Workforce
- Clinician Investigators
- Supporting Departments
- Partnering with Consumers Department
- Governing Body
- Service User/Consumer

Identify the part of the workforce you belong to, and turn to that section to receive targeted information about your responsibilities under the National Clinical Trials Governance Framework.

You only need to work through the sections of Parts 2 and 3 workbook that applies to your part of the workforce.

This workbook is written using a medium-sized tertiary HSO as the model, and the workforce parts and division of framework responsibilities are based off of this. Depending on the structure of your HSO, there may be some responsibilities in your section of the workbook that are not part of your role (for example, if you work in a supporting department, you may not be responsible for resourcing your department - that may be the responsibility of your manager), and therefore are not your responsibility.

Structure

At the front of each section is a checklist which can be used as a stand-alone tool. However, it does not provide any guidance.

Responsibility/Function	*Checklist*
Monitor and report on consumer involvement in the areas of the clinical trial service that you are responsible for, by collecting and reporting on data as per your institution's standard practices	

The content following the checklist provides more in-depth guidance on the list of responsibilities relevant to your part of the workforce. Each responsibility is listed out individually, with some additional information on who else has that responsibility, a set of reflective questions to help you understand and be able to demonstrate your responsibilities to assessors, and space for you to type notes and list evidence.

Responsibility/Function	*Checklist*
Monitor and report on consumer involvement in the areas of the clinical trial service that you are responsible for, by collecting and reporting on data as per your institution's standard practices	

You share this responsibility with:

- *Clinical and Non-Clinical Managers*
- *The Partnering with Consumers Department*

Since many of the different parts in the clinical trials workforce share responsibilities, or parts of responsibilities, we have indicated where responsibilities are shared with other parts of the workforce. This should help clarify how embedding the clinical trial service may look on a whole-of-organisation scale. It is also likely that at least some, and potentially the majority, of the responsibilities listed in your section are things you are already doing. This is intentional, if the clinical trials service is properly embedded into the HSO, then your responsibilities under the framework should already be things you do (see the introduction for more on "embedding").

Reflective Questions
What defines consumer involvement for you?

Reporting
What data do you collect and report?
How do you collect and report this data?
Who do you report to (eg. your governing body)?
How often do you have to report (eg. quarterly)?

How is this data used to inform ongoing process improvement in the areas you are responsible for?

The Reflective Questions are designed to help you determine what evidence you can show accreditors, and you should answer them with reference to organisational or departmental polices/procedures/processes/systems or communications/meeting minutes/etc where possible. If you cannot show any evidence, because there is none or because this does not exist at your organisation, then that is evidence (in itself) of a gap where your organisation does not meet the actions of the framework, and one that needs to be filled before accreditation.

So, for a question like "How do you partner with service users and consumers in ways that respect their cultural and community identity, and their identity as a patient?" you might reference your training records, which prove that you have done training to show you how to do this, or you might reference a standard field in your electronic medical record system where you can record details of cultural and community identity. Or for a question like "Do you know if your suggestions were used to support continuous improvement in safety and quality, e.g. implementing practise changes" you might be able to show a whole-of-organisation email communication discussing changes being adopted as a result of suggestions.

What evidence can you show accreditors to prove you meet this responsibility?

This box is the space provided to type notes, thoughts, and list or gather evidence. If you're completing this workbook on a computer, this space will automatically grow as you add to it.

If you need additional guidance, or if you think you found a gap, the best places to start are:

- Your Research Office
- Your Risk, Safety, and/or Quality departments

Help! What types of evidence can I use during accreditation!

As previously discussed, your organisation needs to be able to show evidence for each action under the framework. Going through the process of gathering evidence for yourself will help you to understand implementing the framework, and the accreditation process itself, at your organisation. All of your evidence should include/mention research and the clinical trials service where appropriate. Below is a list of example evidence taken from the framework itself, for your reference.

Some of these examples of evidence may not be relevant to your position, but everything in this list is relevant to at least one part of the workforce. Equally, because there is a lot of crossover in the framework, you can also expect there to be a lot of crossover in the evidence as well.

Examples of evidence

- Documents (policy, procedure, etc) describing the organisations approach to, and handling of, framework topics (risk management, partnering with consumers, information/data, etc)
- Information, tools, guidance and resources, forms, systems, templates for use in organisational processes (eg EMR + forms for EMR access, standardised patient-facing templates and wording inc. PICFs, risk and quality management systems + guidance on how and when to use, pre-filled templates or forms for reporting/providing feedback, etc)
- Strategic, business, operational, communication plans
- Departmental processes for dealing with research-specific requests and services
- Knowing who to contact about research-related incidents or questions
- Committee/meeting membership lists, terms of reference, minutes/meeting records showing framework discussions, proof of actioning/following up recommendations stemming from these
- Surveys/other mechanisms collecting feedback from consumers, service users, language groups, etc, the results of these, proof of actioning/following up recommendations stemming from these
- Communications from the governing body to the whole of the organisation, to the community, and to external parties, on organisational performance, metrics, actions taken as a result of incidents or feedback, partnering with consumers, etc
- Findings from audits, safety/risk/clinical incidents, quality improvement activities, etc, proof of actioning and following up recommendations stemming from these, and proof of whole-of-organisation visibility of these findings and processes
- Risk, complaints & feedback registers, proof of actioning/following up recommendations stemming from these, proof of whole-of-organisation visibility of these findings and processes
- Employment documents: contracts, position descriptions, performance appraisals, HR records
- Training completion records (eg GCP, partnering with consumers, open disclosure, working with participants from different language or cultural backgrounds)
- Being able to explain your framework responsibilities when asked and/or being able to identify and find organisational policies/processes/procedures when asked
- Being able to demonstrate your knowledge of, compliance with, and use of organisational policies/processes/procedures, use of organisational systems, etc in your everyday work
- Reports on metric, performance, and efficacy assessments and evaluations (eg timelines to ethics and governance approval, trial recruitment planned vs actual)
- Service user and participant documents in languages other than English (including first languages) including availability of support services for these groups, and knowing how to access and use these[1]

Definitions

Clinical Leader

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[1].

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.

Clinical trials include but are not limited to:

- Surgical and medical treatments and procedures
- Experimental drugs and diagnostics
- Biological products
- Medical devices
- Health-related service changes
- Health-related preventative strategies
- Health-related educational interventions[1]

Clinical Trial Participant

Any individual, including healthy volunteers, service users, families, and decision makers, who has consented to and been enrolled in a specific clinical trial[1].

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 and may have various roles in the clinical trial including:

- Participant recruitment and enrolment
- 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 Unit

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[1].

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, research officers, research office staff[1].

Consumer

A person who has used, may potentially use, or has interacted with health service organisations, and who is willing to provide their perspective and experiences to the organisation[1].

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[1].

For the purposes of these workbooks, an organisations quality department is considered part of the governing body.

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[1].

Managers (clinical and non-clinical)

Clinical and non-clinical managers including heads of clinical departments, supporting departments, business, finance, research offices, and human resources. They are primarily responsible for ensuring the systems that support clinical trial service delivery are well designed and perform well[1].

Managers advise and inform the governing body, and operate clinical trial services within the strategic and policy parameters endorsed by the governing body.

Managers have two different levels of responsibility:
At the individual level, to their individual team members
At the unit level, to ensure their unit functions appropriately and is resourced appropriately

Partnering with Consumers Department

The part of the organisation that has primary responsibility for, and coordination/management of, the organisations partnering with consumers responsibilities. This part of the organisation goes by a lot of different names, so you will need to find out what it is called at your organisation.

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[1].

Procedure

Procedure is the set of instructions to make policies and protocols operational, which are specific to an organisation[1].

Process

A process is a series of actions or steps taken to achieve a particular goal[1].

Quality Department

The part of the organisation that has primary responsibility for, and coordination/management of, the organisations risk, quality and safety activities. They are also the part of the organisation with the primary responsibility for accreditation. This part of the organisation goes by a lot of different names, so you will need to find out what it is called at your organisation.

For the purposes of these workbooks, an organisations quality department is considered part of the governing body.

Research Office

The part of the organisation that has primary responsibility for, and coordination/management of, the organisations research responsibilities. This part of the organisation goes by a lot of different names, so you will need to find out what it is called at your organisation.

Service User

Any person interacting with a health service organisation. including, but not limited to,

- Members of culturally diverse communities, and those whose preferred language is not English
- People whose interactions with the health service is complicated because of social, cultural, economic, or geographic circumstances
- First Peoples and Elders
- Older adults, and those from different generations,
- Children and young people,
- People with specific religious, cultural, and/or dietary requirements,
- Disabled people and those with special needs, and
- People who identify as members of the LGBTQIA+ community and/or as gender diverse

Supporting Department

If you perform any service as part of a clinical trial, you provide any care to a clinical trials participant, or you perform any trial-related administrative tasks, you are a part of the clinical trials service. This includes supporting departments (e.g. radiology and cardiology).

System

The resources, policies, processes and procedures that are organised, integrated, regulated and administered to accomplish a stated goal[1].

References

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