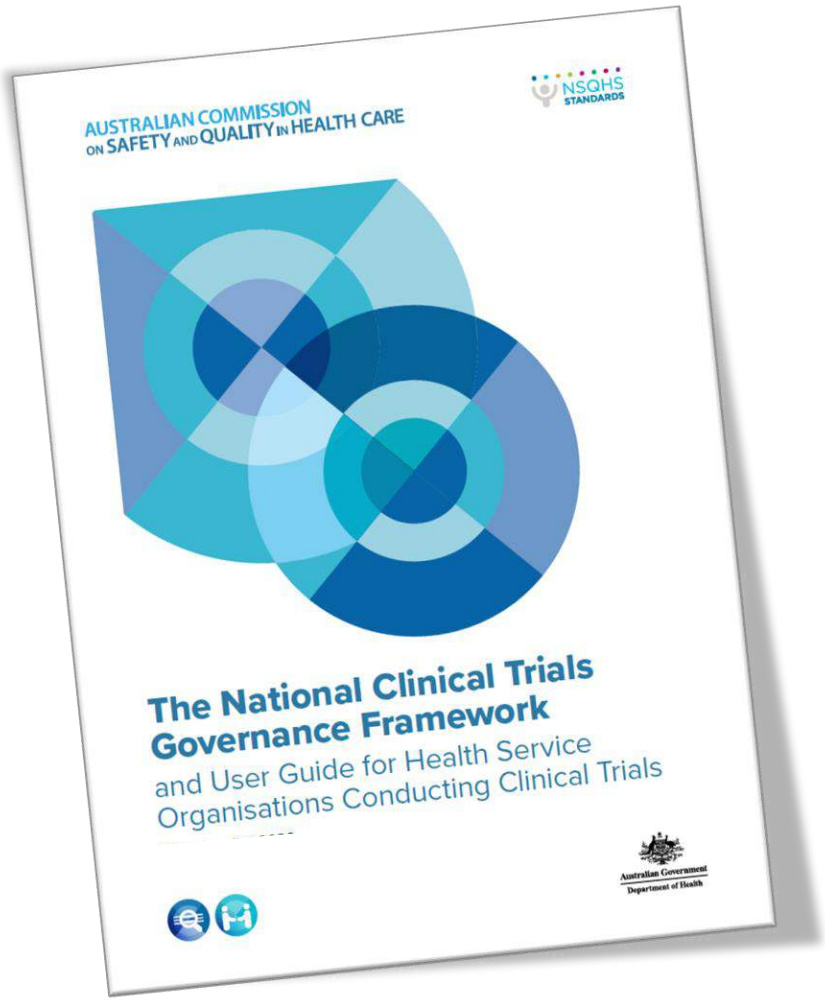
MACH
Melbourne Academic Centre for Health

PART TWO:
CLINICAL GOVERNANCE AND YOU



Developed by the MACH group in partnership with:

Disclaimer:

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. If necessary, you may need to make some changes to the content below to better reflect your specific organisational structure. This is why this document has been provided in an editable format.

The MACH group takes no responsibility or liability for any inaccuracies in the content of this workbook caused by any changes made to the content of this workbook.

References

Australian Commission on Safety and Quality in Health Care. The National Clinical Trials Governance Framework and user guide for health service organisations conducting clinical trials. Sydney: ACSQHC; 2022.

With thanks to:

The MACH NCTGF Clinical Governance and Partnering with Consumers Working Groups
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- This document is **Part Two.**
    - It is the Standard 1 - Clinical Governance workbook

- **Part Three** is the Standard 2 – Partnering with Consumers workbook
- **Part One** contains background/additional information, instructions for use, relevant definitions.

The purpose of this workbook

This resource is designed to help health service organisation employees involved in research and clinical trials understand their responsibilities under the National Clinical Governance Framework ("the framework"). It should also help them 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 framework
- Breaks the framework down into 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 organisation. 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 them. 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

These resources are designed to be completed on computers, so any given space to write will automatically expand as you type.

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

- 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 section of this 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 organisation, 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	*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	*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 of the clinical trials service 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

RESEARCH OFFICE

	Responsibility	Checklist
1	Working familiarity of your Organisational Clinical Governance framework, policies, procedures, and related processes and systems	☐
2	Undertake all of your required training and education, as per your organisation's schedule	☐
3	Work within your defined role. Work with your manager to assess your performance and responsibilities at regularly scheduled intervals, as per your organisational standard practise	☐
4	Understand the complexity of service user interactions with the clinical trial service, the complexity of the context in which they reside, and their needs as a clinical trial participant	☐
5	Advise and assist in the development, periodic review, and update of policies and procedures for the clinical trial service to ensure they stay up to date on relevant requirements. Including the National Statement and the Code, the National Clinical Trials Governance Framework, the Australian Open Disclosure Framework, your organisational charter and clinical governance framework, national and local guidelines, standards, regulations, and legislation	☐
6	Develop relationships with key stakeholders (clinicians, colleagues at other sites, consumers, supporting departments, etc) to support clinical trial operations and service improvement	☐
7	Facilitate the provision and delivery of clinical trials, and clinical trial information, in languages, formats, and ways that reflect the needs of the service users, by making consideration of this part of the ethics and governance review process	☐
8	Provide information and education to researchers on GCP, how to responsibly conduct clinical trials, and research integrity, by working with and supporting researchers throughout the lifecycle of their research project, and implementing and managing systems for this	☐
9	Ensure the clinical trial workforce is appropriately credentialled and trained before conducting any research or clinical trial work (including GCP training) by making this part of the SSA review process	☐
10	Maintain records of work done and decisions made by entering and updating records in real time	☐

11	Manage conflicts of interest, complaints, risks, and incidents resulting from the functioning of the clinical trials service by implementing, resourcing, and managing systems and processes for this purpose	☐
12	Monitor and assess potential risks by using clinical trial risk assessments specific to clinical governance and, if relevant, use organisational systems and processes (including the organisational risk register) to record them	☐
13	Use the relevant processes and systems to receive and respond to consumer, service user, and workforce feedback and complaints (including the Australian Open Disclosure Framework). Work with management to resolve issues and implement preventative and corrective actions if feedback and/or complaints are received.	☐
14	Conduct audits to check clinical trials and research are operating in line with relevant requirements. Including clinical governance requirements, the National Statement, the Code, national and local guidelines, standards, regulations, and legislation, etc	☐
15	Monitor for, and report on, clinical trial activity and performance in the areas of the clinical trials service you are responsible for, by reporting on relevant metrics, using data collected at the trial unit level as per your organisation's standard practises	☐
16	Monitor for, and respond to, changes in the areas of the clinical trials service you are responsible for, by collecting and reporting on data collected at the trial unit level as per your organisation's standard practices.	☐
17	Provide feedback on the functioning of the clinical trials service by using your organisational standard processes and channels	☐
18	Contribute to the development, management, and review of clinical trials service governance (including the National Clinical Trials Governance Framework), where opportunities present themselves	☐
19	Look for opportunities to improve the areas of the clinical trials service that you are responsible for, and the care given to participants	☐

1	Responsibility	Checklist
	Working familiarity of your Organisational Clinical Governance framework, policies, procedures, and related processes and systems	☐

You share this responsibility with:
- Supporting departments
- Clinician Investigators
- Clinical Trial Workforce

You are supported by:
- Clinical/Non-Clinical Managers

Reflective Questions

Identify your organisation's clinical governance frameworks, policies, procedures

Identify the related processes and systems
Who in your organisation can help you with this?

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

2	Responsibility	Checklist
	Undertake all of your required training and education, as per your organisation's schedule	☐

You share this responsibility with:
- Clinical Trial Workforce
- Supporting Departments
- Clinician Investigators

You are supported by:
- Clinical/Non-Clinical Managers

Reflective Questions

Are you clear on what training you are required to complete to perform your role?
When and how do you need to complete this training?

Support
How does your organisation support you in completing this training?
Who in your organisation can help you with this?

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

3	Responsibility	Checklist
	Work within your defined role. Work with your manager to assess your performance and responsibilities at regularly scheduled intervals, as per your organisational standard practise	☐

You share this responsibility with:
- Clinician Investigators
- Clinical Trial Workforce
- Supporting Departments

You are supported by:
- Clinical/Non-Clinical Managers

Reflective Questions

How familiar are you with the tasks and responsibilities in your position description?

Assessment

How often do you meet with your manager to assess the definition of your role, your performance, and your professional competencies? What systems and processes do you use for this?

Support

How does your organisation support you in this? Who in your organisation can help you with this?

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

4	Responsibility	Checklist
	Understand: - the complexity of service user interactions with the clinical trial service - the complexity of the context in which they reside - their needs as a clinical trial participant	☐

You share this responsibility with:
- Clinical Trials Workforce
- Clinician Investigators

You are supported in this by:
- Clinical/Non-Clinical Managers
- Partnering with Consumers Department

Reflective Questions

Process

How do you partner with service users and in ways that respect their cultural and community identity, and their identity as a patient?

How do you identify the communication needs of service users and the community?

Support

Who in your organisation can help you with this?

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

5	Responsibility	Checklist
	Advise and assist in the development, periodic review, and update of policies and procedures for the clinical trial service to ensure they stay up to date on relevant requirements. Including ○ the National Statement and the Code ○ the National Clinical Trials Governance Framework ○ the Australian Open Disclosure Framework ○ your organisational charter and clinical governance framework ○ national and local guidelines, standards, regulations, and legislation	☐

You are supporting the following parties:
- Clinical Trials workforce
- Supporting departments
- Clinical/Non-Clinical Managers
- Clinician Investigators

Reflective Questions

How familiar are you with the tasks and responsibilities in your position description?

Assessment
How often do you meet with your manager to assess the definition of your role, your performance, and your professional competencies? What systems and processes do you use for this?

Support
How does your organisation support you in this? Who in your organisation can help you with this?

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

6	Responsibility	Checklist
	Develop relationships with key stakeholders ○ clinicians, colleagues at other sites, consumers, supporting departments, etc to support clinical trial operations and service improvement	☐

You share this responsibility with:

- Clinician Investigators
- Clinical Trial Workforce
- Supporting Departments

You are supported by:

- Clinical/Non-Clinical Managers

Reflective Questions

Who are the key stakeholders (both internal and external) that you need to work with for the clinical trials service to operate?
How do you define an "effective relationship"?

Improvement
How do you assess whether these relationships are effective?

How do you use this assessment to inform ongoing improvement in the areas of the clinical trials service you're responsible for?

Support
How does your organisation support you in this?
Who in your organisation can help you with this?

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

7	**Responsibility**	**Checklist**
	Facilitate the provision and delivery of clinical trials, and clinical trial information, in languages, formats, and ways that reflect the needs of the service users, by making consideration of this part of the ethics and governance review process	☐

You are supporting the following parties in this:

- Clinical Trial Workforce
- Clinician Investigators

Reflective Questions

Ethics
How do you check that researchers have a plan to accommodate participants from diverse populations in their research?
How do you check whether participant-facing documents reflect the inclusion of diverse populations in the research project?
How do you partner with service users in this?

Governance
How do you assess whether governance applications have evidence of appropriate resourcing for plans to include diverse populations?

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

8	Responsibility	Checklist
	Provide information and education to researchers on: ○ GCP, ○ how to responsibly conduct clinical trials, ○ research integrity. Work with and support researchers throughout the lifecycle of their research project Implement and manage systems for this	☐

You are supporting the following parties in this:

- Clinician Investigators
- Clinical Trial Workforce

Reflective Questions

What information and education resources do you provide to the clinical trials workforce?
How do you ensure regulatory compliance with ICH-GCP and research integrity for the clinical trials workforce?

Tracking
How do you track what education new researchers need to do, and how do you follow up with them to ensure it is done?
How do you track when education expires for existing researchers?
How do you track who has completed, and passed, what education?
How do you escalate education non-compliance by the clinical trials workforce and how is this followed-up?
How is the information incorporated into your organisation's training systems?
How do you measure the impact of this preparation in submissions to the office?

Support
How does your organisation support you in this?
Who in your organisation can help you with this?

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

9	Responsibility	Checklist
	Ensure the clinical trial workforce is appropriately credentialled and trained before conducting any research or clinical trial work (including GCP training) by making this part of the SSA review process	☐

Reflective Questions

How do you determine the credentials the clinical trial workforce need to meet?
How do you check whether the nominated clinical trials team are appropriately credentialled and trained?
What do you do if they aren't, and how is this followed up?

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

10	Responsibility	Checklist
	Maintain records of work done and decisions made by entering and updating records in real time	☐

Reflective Questions

What is your standard procedure for recording your work?
Does it define standard timelines and systems for this work

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

11	Responsibility	Checklist
	Manage: ○ conflicts of interest ○ complaints ○ risks ○ incidents resulting from the functioning of the clinical trials service by implementing, resourcing, and managing systems and processes for this purpose	☐

Reflective Questions

Process

What organisational systems and processes must be used to report on, and manage, these situations when they occur?

Who else in your organisation is involved in the management and review of these situations?

Do you know if consumers and service users are involved where appropriate?

How do you assess the effectiveness of these systems and processes?

Support

If your systems and processes involve service users, consumers, and researchers, how do you support them in fulfilling their responsibilities in these areas?

How does your organisation support you in this?

Who in your organisation can help you with this?

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

12	Responsibility	Checklist
	Monitor and assess potential risks by using clinical trial risk assessments specific to clinical governance. If relevant, use organisational systems and processes (including the organisational risk register) to record them	☐

You share this responsibility with:

- Clinical/Non-Clinical Managers

Reflective Questions

How do you identify, document, and manage risks?

How do you communicate the need for preventative and corrective actions to the clinical trials workforce?

Assessment

How is the impact of these actions measured?

How do you assess whether risk management systems and processes are effective?

How do these processes support continuous improvement in safety and quality?

Support

How does your organisation support you in managing this?

Who in your organisation can help you with this?

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

13	Responsibility	Checklist
	Use the relevant processes and systems to receive and respond to consumer, service user, and workforce feedback and complaints (including the Australian Open Disclosure Framework). Work with management to resolve issues and implement preventative and corrective actions if feedback and/or complaints are received.	☐

You share this responsibility with:

- Clinician Investigators
- Clinical Trial Workforce
- Supporting departments

You are supported by:

- Clinical/Non-Clinical Managers
- Partnering with Consumers Department

Reflective Questions

Identify your organisations complaint and feedback systems and processes

Process

How do you receive service user feedback and complaints, if there are any?

If feedback or complaints are received, what are your associated reporting requirements?

If complaints were received, how was the need for preventative and corrective actions communicated to you?

Support

Are these ever discussed in staff meetings?

How does your organisation support you in this?

Who in your organisation can help you with this?

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

14	Responsibility	Checklist
	Conduct audits to check clinical trials and research are operating in line with relevant requirements. Including: - clinical governance requirements - the National Statement - the Code - national and local guidelines, standards, regulations, and legislation, etc	☐

You share this responsibility with:

- Clinical/Non-Clinical Managers

Reflective Questions

Process

What is your process for determining when and where audits need to be conducted?
What is your process to see if all audit findings have been addressed?
Who else in your organisation is involved in the management and review of these situations?
Do you know if consumers and service users are involved where appropriate?
How do you communicate the need for preventative and corrective actions to the clinical trials workforce?

Assessment

How is the impact of these actions measured?
How do these processes support continuous improvement in safety and quality?

Support

How does your organisation support you in this?
Who in your organisation can help you with this?

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

15	Responsibility	Checklist
	Monitor for, and report on, clinical trial activity and performance in the areas of the clinical trials service you are responsible for, by reporting on relevant metrics, using data collected at the trial unit level as per your organisation's standard practises	☐

You share this responsibility with:

- Clinical/Non-Clinical Managers

Reflective Questions

Reporting

What data do you collect, and why?
What metrics do you report on, and why?
What is your process for collecting data and reporting on metrics?
Who do you report to (eg. your governing body)?
How often do you have to report (eg. quarterly)?
How is this information used to inform ongoing process improvement in the areas of the clinical trial service you are responsible for?

Support

How does your organisation support you in this?
Who in your organisation can help you with this?

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

16	Responsibility	Checklist
	Monitor for, and respond to, changes in the areas of the clinical trials service you are responsible for, by collecting and reporting on data collected at the trial unit level as per your organisation's standard practices.	☐

You share this responsibility with:

- Clinical/Non-Clinical Managers

Reflective Questions

What defines a change in clinical trial service safety, quality, and/or compliance for you?

Process

What data points do you monitor to look for changes?

What is your process for monitoring and identifying changes?

How do you communicate the need for preventative and corrective actions to the clinical trials workforce?

Impact

How do you measure the impact of these changes?

How is this information used to inform ongoing process improvement in the areas of the clinical trial service you are responsible for?

Support

How does your organisation support you in this?

Who in your organisation can help you with this?

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

17	Responsibility	Checklist
	Provide feedback on the functioning of the clinical trials service by using your organisational standard processes and channels	☐

You share this responsibility with:

- Supporting Departments
- Clinician Investigators
- Clinical Trial Workforce

You are supported by:

- Clinical/Non-Clinical Managers

Reflective Questions

Are you clear on when and how to provide feedback to your organisation?

Do you know if your suggestions were used to support continuous improvement in safety and

Support

How does your organisation support you in this?

Who in your organisation can help you with this?

quality, e.g. implementing practise changes?

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

18	Responsibility	Checklist
	Contribute to the development, management, and review of clinical trials service governance (including the National Clinical Trials Governance Framework), where opportunities present themselves	☐

You share this responsibility with:
- Clinician Investigators
- Clinical Trial Workforce
- Supporting departments

You are supported in this by:
- Clinical/Non-Clinical Managers

Reflective Questions

How do you identify opportunities to involve yourself in this work?
Do you know if your suggestions were used to support continuous improvement in safety and quality, e.g., implementing practise changes?
What systems and processes do you use for this?

Support
Does your organisation support you in taking advantage of these opportunities?
Who in your organisation can help you with this?

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

19	Responsibility	Checklist
	Look for opportunities to improve the areas of the clinical trials service that you are responsible for, and the care given to participants	☐

You share this responsibility with:
- Clinician Investigators
- Clinical Trial Workforce
- Supporting departments

You are supported in this by:
- Clinical/Non-Clinical Managers

Reflective Questions

How do you identify opportunities to involve yourself in this work?
Do you know if your suggestions were used to support continuous improvement in safety and quality, e.g., implementing practise changes?
What systems and processes do you use for this?

Support
Does your organisation support you in taking advantage of these opportunities?
Who in your organisation can help you with this?

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