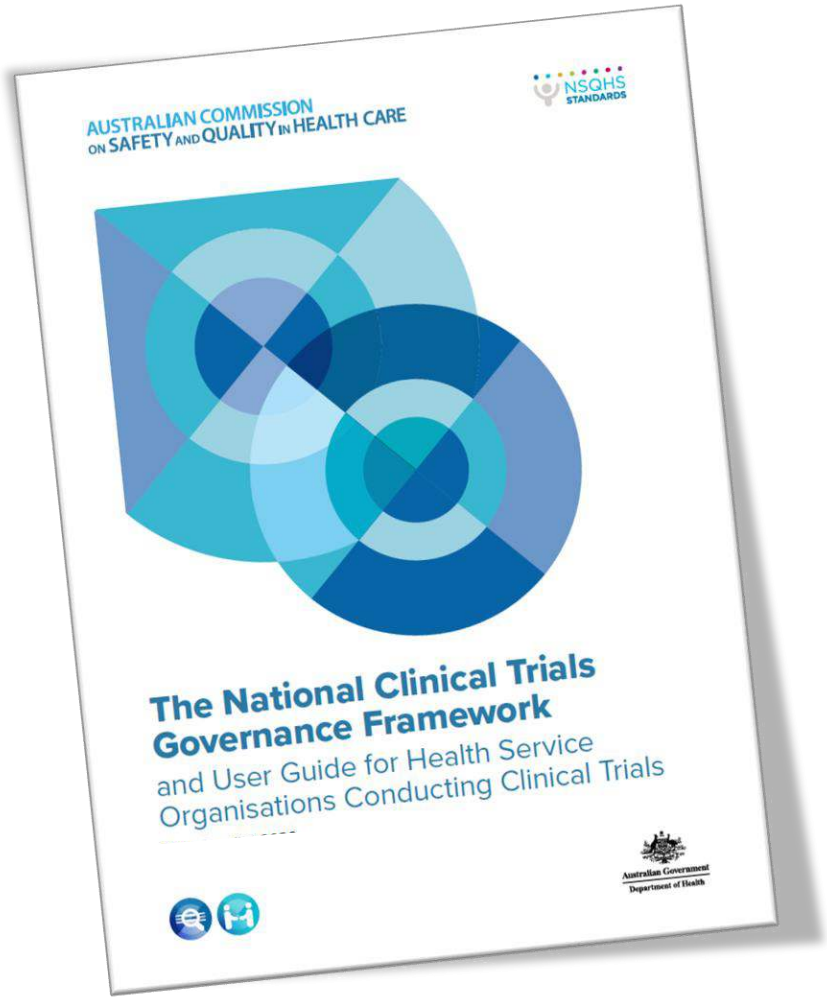
MACH
Melbourne Academic
Centre for Health

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.

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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

SUPPORTING DEPARTMENTS

	Responsibility	Checklist
1	Working familiarity of your Organisational Clinical Governance framework policies, procedures, and the related processes and systems	☐
2	Undertake regular education and training to maintain credentialling and keep skills and competencies up to date, and expand your scope of practise, as per your organisation's standard schedule	☐
3	Work within your defined scope of practise and in line with your skills and experiences. Work with your manager to assess your scope of practise, performance, and professional competencies at regularly scheduled intervals, as per your organisations standard practise	☐
4	Perform delegated clinical trial tasks in line with relevant national requirements and in a way that is responsive to change. Including the National Statement and the Code, the National Clinical Trials Governance Framework, the Australian Open Disclosure Framework, National regulations, standards, codes of conduct, and legislation	☐
5	Perform delegated clinical trial tasks in line with relevant local requirements: Including the trial protocol, Conditions of HREC and Governance approval, your organisational charter and clinical governance framework, Local policies and procedures, Contractual and sponsor requirements	☐
6	Develop relationships with key contacts (clinicians, colleagues at other sites, consumers, supporting departments, etc) to support clinical trial operations, service improvement, and best clinical outcomes for participants	☐
7	Manage departmental resourcing and budgeting, identifying funding sources and whether the organisation can provide appropriate space, capacity and resourcing	☐
8	Appropriately resource your team members in delivering your departmental services. Including: adequate staff numbers and appropriate workloads, working space, equipment, supplies (clinical and office), storage/secure storage, access to computers and EMR systems, etc	☐
9	Assess the feasibility of providing services to new trials, in partnership with clinical and non-clinical managers and researchers, making your overall workload a primary consideration	☐

10	In partnership with researchers and the clinical trial workforce, identify and report risks, issues, or anything that could compromise your ability to deliver care in a safe environment. Report using both clinical trial/research-specific and organisational systems and processes. Work with management to resolve issues, implement preventative and corrective actions, and improve practise if incidents occur	☐
11	Use the relevant processes and systems to receive and respond to consumer and service user feedback and complaints. Work with management to resolve issues, implement preventative and corrective actions, and improve practise if feedback and/or complaints are received.	☐
12	Provide feedback on the functioning of the clinical trials service by using organisational processes and channels	☐
13	Contribute to the development, management, and review of clinical trials service governance (including the National Clinical Trials Governance Framework), where opportunities present themselves	☐
14	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 the related processes and systems	☐

You share this responsibility with:
- Research Office
- Clinician Investigators
- Clinical Trial Workforce

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

Reflective Questions

Finding

Identify your organisation's clinical governance frameworks, policies, and procedures
Identify the related processes and systems are
Who in your organisation can help you with this?

Use

How do you use these in your everyday work and interactions with service users?
How is your use of these assessed?
Are these ever discussed in staff meetings?

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

2	Responsibility	Checklist
	Undertake regular education and training to maintain credentialling and keep skills and competencies up to date, and expand your scope of practise, as per your organisation's standard schedule	☐

You share this responsibility with:
- Research Office
- Clinician Investigators
- Clinical Trial Workforce

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

Reflective Questions

Process

What training do you need to complete?
Are you clear on when and how you need to complete this training?
What systems and processes do you use for this?
How do you identify opportunities to expand your scope of practise?

Support

How does your organisation support you in completing this training?
How 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?

3	Responsibility	Checklist
	Work within your defined scope of practise and in line with your skills and experiences. Work with your manager to assess your scope of practise, performance, and professional competencies at regularly scheduled intervals, as per your organisations standard practise	☐

You share this responsibility with:

- Clinician Investigators
- Clinical Trial Workforce
- Research Office

You are supported by:

- Clinical/Non-Clinical Managers

Reflective Questions

How do you know what credentials and professional competencies you need to meet?
How familiar are you with the tasks and responsibilities in your position description?

Assessment
How often do you meet with your manager to assess your scope of practise, performance, and 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
	Perform delegated clinical trial tasks in line with relevant national requirements and in a way that is responsive to change. Including: - the National Statement and the Code - the National Clinical Trials Governance Framework - the Australian Open Disclosure Framework - National regulations, standards, codes of conduct, and legislation	☐

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

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

Reflective Questions

Process

What are the relevant national requirements you must operate in line with?
How do you ensure your continued compliance?
Are they ever discussed in staff meetings?
How do you change your practise if you learn. about changes in requirements?
What systems and processes do you use for this?

Support

How does your organisation support you working within these requirements, and with practise changes where necessary?
Who in your organisation can help you with this?

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

5	Responsibility	Checklist
	Perform delegated clinical trial tasks in line with relevant local requirements: - Trial protocol - Conditions of HREC and Governance approvals - Your organisational charter and clinical governance framework - Local policies and procedures - Contractual and sponsor requirements	☐

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

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

Reflective Questions

Process

What are the relevant national requirements you must operate in line with?
How do you ensure your continued compliance?
Are they ever discussed in staff meetings?
How do you change your practise if you learn. about changes in requirements?
What systems and processes do you use for this?

Training

Have you had training in completing these tasks and activities?
Do you feel confident in completing them?
How do you change your practise if you learn about changes in requirements?

Support

How does your organisation support you working within these requirements, and with practise changes where necessary?

Do you have a clear understanding of what tasks and activities you are delegated to do?

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 contacts ○ Clinicians, colleagues at other sites, consumers, supporting departments, etc. to support clinical trial operations, service improvement, and best clinical outcomes for participants	☐

You share this responsibility with:

- Clinician Investigators
- Clinical Trial Workforce
- Research Office

You are supported by:

- Clinical/Non-Clinical Managers

Reflective Questions

How do you define an "effective relationship"?
Who are the key contacts (both internal and external) that you need to work with for the clinical trials service to operate effectively?
Do you know who to contact about the different aspects of the clinical trial service?

Improvement
How do you assess whether these relationships are effective?
How do you use this assessment 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?

7	Responsibility	Checklist
	Manage departmental resourcing and budgeting, identifying funding sources and whether the organisation can provide appropriate space, capacity, and resourcing	☐

You share this responsibility with:

- Clinical/Non-Clinical Managers

Reflective Questions

Is resourcing and costing a part of your role?

Trial Level

How do you assess what resources each trial will need?

How do you assess what each trial will cost?

How do you work with clinical and non-clinical managers and researchers to ensure you are reimbursed for your costs and resources?

Unit Level

How do you balance the available resources across your department?

How do you know you are recovering your costs?

Service Level

How do you partner with stakeholders across your organisation to communicate your capacity and resources to support additional trials?

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

8	Responsibility	Checklist
	Appropriately resource your team members in delivering your departmental services. Including: - adequate staff numbers and appropriate workloads - working space, equipment, supplies (clinical and office) - storage/secure storage - access to computers and EMR systems, etc	☐

You share this responsibility with:

- Clinical/Non-Clinical Managers

Reflective Questions

Is departmental resourcing a part of your role?

Resourcing

How do you determine the level of resourcing your

How often do you check if you are meeting this level?

What do you do if you do not meet this level?

department requires to effectively deliver its services?
How do you assess whether or not you are meeting this level?

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

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

9	Responsibility	Checklist
	Assess the feasibility of providing services to new trials, in partnership with clinical and non-clinical managers and researchers, making your overall workload a primary consideration	☐

You share this responsibility with:

- Clinician Investigators
- Clinical/Non-clinical managers

Reflective Questions

Are new trial assessments a part of your role?

Assessment
What is your process for assessing the feasibility of adding a new trial to your departmental workload?
Does this process take in account your current workload, available resources, and departmental skills and expertise?
What processes and systems do you use for this?

Support
Does your organisation support you taking on new trials by offering a strategic plan for the clinical trials service, and your involvement in it?

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

10	Responsibility	Checklist
	In partnership with researchers and the clinical trial workforce, identify and report risks, issues, or anything that could compromise your ability to deliver care in a safe environment. Report using both clinical trial/research-specific and organisational systems and processes. Work with management to resolve issues, and implement preventative and corrective actions if incidents occur	☐

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

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

Reflective Questions

Identify the relevant systems & processes used for risk, safety, and incident reporting

Process

What has to be reported where, to whom, and in what timeframe?
What policies and procedures dictate your reporting responsibilities?
How was the need for preventative and corrective actions communicated to you?

Did these help mitigate the issues that caused the situation?
Are examples of this ever discussed in staff meetings?

Support

How does your organisation support you in understanding and fulfilling your reporting responsibilities?
Who in your organisation can help you with this?

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

11	Responsibility	Checklist
	Use the relevant processes and systems to receive and respond to consumer and service user feedback and complaints. 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

You are supported by:
- Clinical/Non-Clinical Managers
- Research Office
- Partnering with Consumers Department

Reflective Questions

Identify the organisational systems used for complaints and feedback
What are your associated reporting requirements?

Complaints

Feedback

What feedback have you received?
What improvements have you made in response to feedback?

Support

If complaints were received, how was the need for preventative and corrective actions communicated to you?
Did these help mitigate the issues that caused the situation?

Are these ever discussed in staff meetings?
How does your organisation support you in this?
Who in your organisation can help with this?

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

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

You share this responsibility with:
- Research Office
- 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 quality, e.g., implementing practise changes?

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?

13	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
- Research Office

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

- Clinical trials workforce

Reflective Questions

Process
How do you identify opportunities to involve yourself in this work?
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?

14	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
- Research Office
- Clinical Trials Workforce

You are supported in this by:
- Clinical/Non-clinical managers

Reflective Questions

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

Support
Does your organisation support you in identifying and reporting opportunities for improvement?
Who in your organisation can help you with this?

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