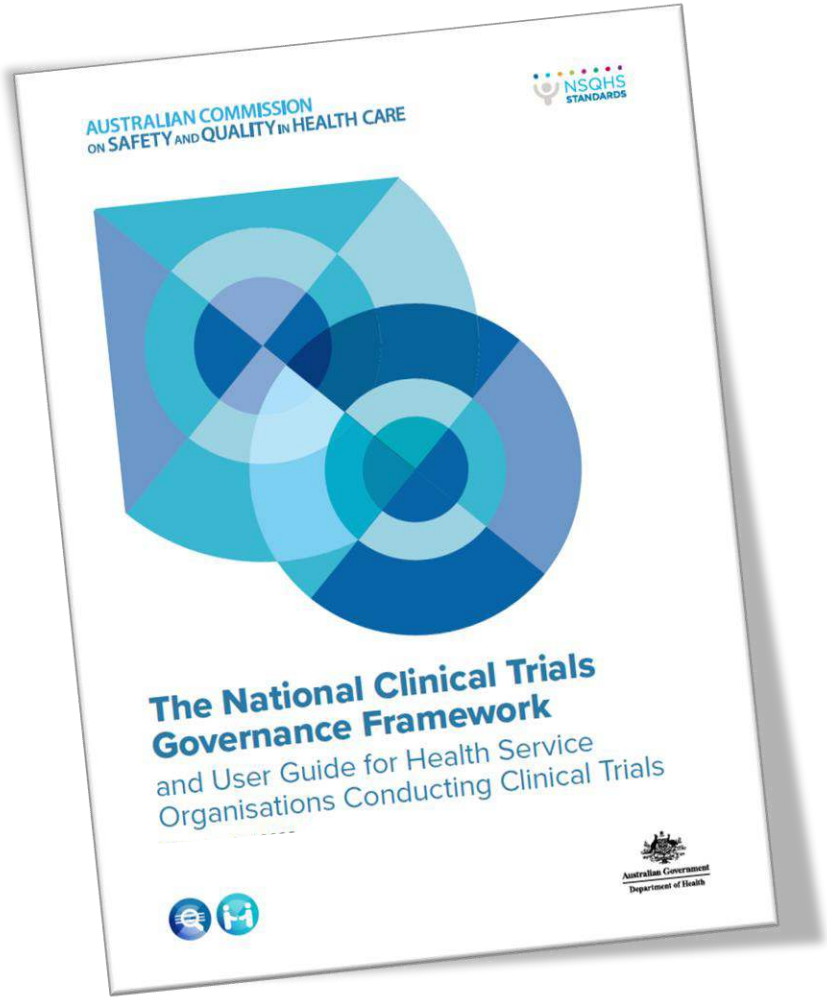
MACH
Melbourne Academic Centre for Health

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
The VCCC Alliance Strategic Planning/Enhance Business Capabilities Working Group: Program 4, Projects 3 and 4
Kate Scarff
Michelle Iddles
Di Tucker
Each and every single reviewer

CLINICAL GOVERNANCE AND YOU

You only need to work through the section of this workbook that applies to your part of the workforce.

Click on your section of the workforce above to go straight to that section.

- 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

CLINICAL TRIAL WORKFORCE

	Responsibility	Checklist
1	Working familiarity of your Organisational Clinical Governance framework policies, procedures, and the related processes and systems	☐
2	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 Learn to tailor your approaches to meet the differing needs of service users.	☐
3	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	☐
4	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	☐
5	Conduct clinical trials in line with relevant national requirements and in a way that is responsive to change. Including: he National Statement and the Code, the National Clinical Trials Governance Framework, the Australian Open Disclosure Framework, National regulations, standards, codes of conduct, and legislation	☐
6	Conduct clinical trials in line with relevant local requirements. Including the trial protocol, Conditions of HREC and Governance approvals, Your organisational charter and clinical governance framework, Local policies and procedures, Contractual and sponsor requirements	☐
7	Conduct clinical trials responsibly, focussing on integrity, safety, and quality, and within the bounds of organisational systems Support other team members to do the same	☐
8	Develop relationships with key stakeholders (clinicians, colleagues at other sites, consumers, supporting departments, etc.) to support clinical trial operations, service improvement, and best clinical outcomes for participants	☐
9	Perform study, data management, and participant-related tasks, as delegated by the trial investigator and indicated by your skills, experience, and scope of practise	☐
10	Encourage participants, families, and decision makers to actively involve themselves in the decision-making process about their participation in a clinical trial, and their overall care (to the extent that they choose). Ensure participants welfare and desires are prioritised.	☐
11	Perform HREC and SSA submissions of new trials (including budget and contract negotiations), in partnership with the Investigator, and ensure trials have received all relevant approvals before starting	☐

CLINICAL TRIAL WORKFORCE

12	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	☐
13	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.	☐
14	Provide feedback on the functioning of the clinical trials service by using organisational processes and channels	☐
15	Contribute to the development, management, and review of clinical trials service governance (including the National Clinical Trials Governance Framework), where opportunities present themselves	☐
16	Look for opportunities to improve the areas of the clinical trials service that you are responsible for, and the care given to participants	☐

CLINICAL TRIAL WORKFORCE

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

You share this responsibility with:
- Clinician Investigators
- Research Office
- Supporting departments

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

Reflective Questions

Finding

Identify your organisation's clinical governance frameworks, policies, and procedures
Identify the related processes and systems
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
	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 Learn to tailor your approaches to meet the differing needs of service users.	☐

You share this responsibility with:
- Clinician Investigators
- Research Office

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 consumers in ways that respect their cultural and community identity, and their identity as a patient?
What additional supports do your clinical trial participants need to effectively participate?
How do you find these supports?
How do you identify the communication needs of consumers and the community?
How do you tailor your communication to meet these needs?

Support

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

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

CLINICAL TRIAL WORKFORCE

3	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:
- Clinician Investigators
- Research Office
- Supporting Departments

You are supported in this 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?

4	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
- Research Office
- Supporting Departments

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?

CLINICAL TRIAL WORKFORCE

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

5	Responsibility	Checklist
	Conduct clinical trials 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:
- Supporting Departments
- Clinician Investigators

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

<u>Reflective Questions</u>

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 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
	Conduct clinical trials 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:
- Supporting Departments
- Clinician Investigators

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

CLINICAL TRIAL WORKFORCE

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 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
	Conduct clinical trials ○ Responsibly ○ Focussing on integrity, safety, and quality ○ Within the bounds of organisational systems Support other team members to do the same	☐

You share this responsibility with:

- Clinician Investigators

You are supported in this by:

- Research Office
- Clinical/Non-Clinical Managers

Reflective Questions

How do you model these values?

How do you support team members in modelling these values?

Are examples of these ever discussed in staff meetings?

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?

CLINICAL TRIAL WORKFORCE

8	Responsibility	Checklist
	Develop relationships with key stakeholders • 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
- Research Office
- Supporting Departments

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

Reflective Questions

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

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 trials 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?

9	Responsibility	Checklist
	Perform study, data management, and participant-related tasks, as delegated by the trial investigator and indicated by your skills, experience, and scope of practise	☐

You are supported by:
- Clinician Investigators

Reflective Questions

Do you have a clear understanding of what tasks you are delegated to do for each trial?
Have you had training in completing these tasks, and do you feel confident in them?
If your skills or scope of practise change, do the tasks you are delegated to do change as well?

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?

CLINICAL TRIAL WORKFORCE

10	Responsibility	Checklist
	Encourage participants, families, and decision makers to actively involve themselves in the decision-making process about their participation in a clinical trial, and their overall care (to the extent that they choose). Ensure participants welfare and desires are prioritised.	☐

You share this responsibility with:

- Clinician Investigators

Reflective Questions

Process

What is your process for documenting and prioritising patient welfare and desires?
How is this information incorporated into your organisational systems?

Support

How does your organisation support educating yourself on safely involving participants, family, and decision-makers?
Who in your organisation can help you with this?

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

11	Responsibility	Checklist
	Perform HREC and SSA submissions of new trials (including budget and contract negotiations), in partnership with the Investigator, and ensure trials have received all relevant approvals before starting	☐

You share this responsibility with:

- Clinician Investigators

Reflective Questions

Approvals

What processes and systems do you use to ensure trials do not start before they have received all relevant approvals?
How does your organisation support you in being ready to start your trial as soon as you receive all the relevant approvals?

Submissions

Are submissions a part of your role?
What is your standard procedure for submissions?
Does it define standard timelines and systems for this work?

Who in your organisation can help you with this?

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

CLINICAL TRIAL WORKFORCE

12	Responsibility	Checklist
	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
- Supporting Departments

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 organisational reporting responsibilities?

What are the relevant requirements that dictate your clinical trial/research-specific 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 these 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 with this?

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

CLINICAL TRIAL WORKFORCE

13	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
- Supporting departments

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

Reflective Questions

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

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

Complaints
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?

Support
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?

14	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
- Supporting Departments

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?

CLINICAL TRIAL WORKFORCE

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

15	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
- Supporting departments

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

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?

16	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
- Supporting departments

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?

CLINICAL TRIAL WORKFORCE

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

CLINICIAN INVESTIGATOR

	Responsibility	Checklist
1	Use of your Organisational Clinical Governance framework policies, procedures, and the relevant processes and systems	☐
2	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	☐
3	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	☐
4	Work within your defined scope of practise and in line with your skills and experiences Work with your clinical lead to assess your scope of practise, performance, and professional competencies at regularly scheduled intervals, as per your organisational standard practise	☐
5	Conduct clinical trials 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	☐
6	Conduct clinical trials in line with relevant local requirements. Including the trial protocol, Conditions of HREC and Governance approvals, Your organisational charter and clinical governance framework, Local policies and procedures, Contractual and sponsor requirements	☐
7	Lead by example in: modelling responsible clinical trial conduct, focussing on safety and quality, and acting with integrity. Cultivate a culture of this amongst your clinical trial team members	☐
8	Develop relationships with key stakeholders (clinicians, colleagues at other sites, consumers, supporting departments, etc) to support clinical trial operations, service improvement, and best clinical outcomes for participants	☐
9	Develop strategies to engage and communicate with service users (particularly First Peoples, members of culturally diverse peoples, and those whose preferred language is not English) about participating in clinical trials	☐
10	Hold overall responsibility for the individual trials and research projects you conduct, by supervising the conduct and performance of your research/clinical trial team(s) and working with clinical and non-clinical managers to resolve performance concerns	☐
11	Delegate clinical governance and/or clinical trial responsibilities to team members (where relevant)	☐

CLINICIAN INVESTIGATOR

12	Involve participants, families, and decision makers in the decision-making process about their participation in a clinical trial and their overall care, to the extent that they choose, ensuring patient welfare and desires are prioritised and they receive concomitant care during and after the trial	☐
13	Assess the feasibility of new trials in partnership with clinical and non-clinical managers, and make your current trial portfolio and service user population primary considerations here	☐
14	Perform HREC and SSA submissions of new trials (including budget and contract negotiations), in partnership, and ensure trials have received all relevant approvals before starting	☐
15	Identify and report risks, issues, or anything that could compromise your ability to deliver care in a safe environment. Report using both clinical trial and research-specific systems and organisation processes and systems. Work with clinical leaders to resolve issues and implement preventative and corrective actions if incidents occur	☐
16	Use the relevant processes and systems to receive and respond to consumer and service user feedback and complaint. Work with clinical leads to resolve issues and implement preventative and corrective actions if feedback and/or complaints are received.	☐
17	Contribute to the development, management, and review of clinical trials service governance (including the National Clinical Trials Governance Framework), where opportunities present themselves	☐
18	Provide feedback on the functioning of the clinical trials service by using your organisational standard processes and channels	☐
19	Look for opportunities to improve the areas of the clinical trials service that you are responsible for, and the care given to participants	☐

CLINICIAN INVESTIGATOR

1	Responsibility	Checklist
	Use of your Organisational Clinical Governance framework policies, procedures, and the relevant processes and systems	☐

You share this responsibility with:

- Clinical Trials Workforce
- Research Office
- Supporting departments
- Clinical/Non-Clinical Managers

Reflective Questions

Identify your organisation's clinical governance frameworks, policies, and procedures
Identify the related processes and systems
Are these ever discussed in staff meetings?
How do you use these in your everyday work and interactions with service users?
How is your use of these assessed?
Who in your organisation can help you with this?

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

2	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
- Research Office
- Clinical/Non-Clinical Managers

You are supported in this by:

- Partnering with Consumers Department

Reflective Questions

Process
How do you partner with service users and consumers in ways that respect their cultural and community identity, and their identity as a patient?
What additional supports do your clinical trial participants need to effectively participate?
How do you find these supports?

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

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

CLINICIAN INVESTIGATOR

3	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
- Supporting Departments
- Clinical Trial Workforce
- Clinical/Non-Clinical Managers

Reflective Questions

What training do you need to complete?
Are you clear on when and how you need to complete this training?
How does your organisation support you in completing this training?

How do you identify opportunities to expand your scope of practise?
How does your organisation support you in taking advantage of these opportunities?
Who can help you with these things?

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

4	Responsibility	Checklist
	Work within your defined scope of practise and in line with your skills and experiences Work with your clinical lead to assess your scope of practise, performance, and professional competencies at regularly scheduled intervals, as per your organisational standard practise	☐

You share this responsibility with:

- Clinical Trial Workforce
- Supporting Departments
- Clinical/Non-Clinical Managers
- Research Office

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 clinical lead 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?

CLINICIAN INVESTIGATOR

5	Responsibility	Checklist
	Conduct clinical trials 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 Trials workforce
- Supporting departments
- Clinical/Non-Clinical Managers

You are supported in this by:
- Research Office

Reflective Questions

Process

What are the relevant national requirements you must operate in line with?
How do you ensure your continued compliance?
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 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
	Conduct clinical trials 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 Trials workforce
- Supporting departments
- Clinical/Non-Clinical Managers

You are supported in this by:
- Research Office

CLINICIAN INVESTIGATOR

Reflective Questions

Process

What are the relevant local requirements you must operate in line with?

How do you ensure your continued compliance?

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 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
	Lead by example in: • Modelling responsible clinical trial conduct • Focussing on safety and quality • Acting with integrity. Cultivate a culture of this amongst your clinical trial team members	☐

You share this responsibility with:

- Clinical Trial Workforce
- Clinical/Non-Clinical Managers

You are supported in this by:

- Research Office

Reflective Questions

How do you model responsible clinical trial practise?

How do you model acting with safety, quality, and integrity as a focus?

How do you know if your team members are conducting the trials you are responsible for as delegated, responsibly, and with integrity?

Do you ever discuss examples of responsible clinical trial practise and/or acting with integrity with your clinical trials team?

Support

How does your organisation support you in learning about and modelling responsible clinical trial practise, safety, quality and integrity?

Who in your organisation can help you with this?

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

CLINICIAN INVESTIGATOR

8	Responsibility	Checklist
	Develop relationships with key stakeholders • 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:

- Clinical Trial Workforce
- Supporting Departments
- Clinical/Non-Clinical Managers
- Research Office

Reflective Questions

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

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?

9	Responsibility	Checklist
	Develop strategies to engage and communicate with service users • particularly First Peoples, members of culturally diverse communities, and those whose preferred language is not English) about participating in clinical trials	☐

You share this responsibility with:

- Clinical/Non-Clinical Managers

You are supported in this by:

- Partnering with Consumers Department

Reflective Questions

Process
How do you identify the communication needs of service users, and the wider community?
How do you develop strategies to engage and communicate with these groups?
Have you had any direct interactions with consumers or service users as part of 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?

10	Responsibility	Checklist
	Hold overall responsibility for the individual trials you conduct, by supervising the conduct and performance of your clinical trial team(s) Work with clinical and non-clinical managers to resolve performance concerns	☐

Reflective Questions

Responsibility

Do you know what it means to "hold overall responsibility" for a clinical trial?

Have you undergone appropriate training and education for you to feel confident taking overall responsibility for these?

How do you know your team members are appropriately trained, working in line with relevant requirements and the protocol, and as delegated?

Performance

What makes a "performance concern"?

What is your process for working with managers if you identify a performance concern?

How is the information incorporated into your organisation's systems?

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?

11	Responsibility	Checklist
	Delegate clinical governance and/or clinical trial responsibilities to team members (where relevant)	☐

Reflective Questions

How do you delegate tasks?

How do you ensure tasks are delegated to team members who are qualified to perform them?

How is this information incorporated into your organisation's systems?

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

CLINICIAN INVESTIGATOR

12	Responsibility	Checklist
	Involve participants, families, and decision makers in the decision-making process about their participation in a clinical trial and their overall care, to the extent that they choose Ensure patient welfare and desires are prioritised and they receive concomitant care during and after the trial	☐

You share this responsibility with:

- Clinician Investigators

Reflective Questions

Process

What is your process for documenting and prioritising patient welfare and desires?
How is this information incorporated into your organisational systems?

Support

Does your organisation support educating yourself on safely involving participants, family, and decision-makers?
Who in your organisation can help you with this?

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

13	Responsibility	Checklist
	Assess the feasibility of new trials in partnership with clinical and non-clinical managers Make your current trial portfolio and service user population primary considerations here	☐

You share this responsibility with:

- Clinical/Non-Clinical managers
- Supporting Departments

Reflective Questions

Process

How do you take in account your current trial portfolio when selecting new trials?
How do you take in account your current service user population when selecting new trials?
How do you engage with groups of service users to determine their needs?

Support

Does your organisation support you bringing in new trials by offering a strategic plan for the clinical trials service?
Who in your organisation can help you with this?

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

CLINICIAN INVESTIGATOR

14	Responsibility	Checklist
	Perform HREC and SSA submissions of new trials (including budget and contract negotiations), in partnership with clinical/non-clinical managers, and ensure trials have received all relevant approvals before starting	☐

You share this responsibility with:

- Clinical Trial Workforce

Reflective Questions

Approvals

What processes and systems do you use to ensure trials do not start before they have received all relevant approvals?

How does your organisation support you in being ready to start your trial as soon as you receive all the relevant approvals?

Submissions

What is your standard submissions procedure for submissions?

Does it define standard timelines and systems?

Support

Who in your organisation can help with this?

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

15	Responsibility	Checklist
	Identify and report risks, issues, or anything that could compromise your ability to deliver care in a safe environment. Report using both clinical trial and research-specific systems and organisation processes and systems. Work with clinical leaders to resolve issues, and implement preventative and corrective actions if incidents occur	☐

You share this responsibility with:

- Supporting Departments
- Clinical Trial Workforce
- Clinical/Non-Clinical Managers

You are supported by:

- 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 organisational reporting responsibilities?

What are the relevant requirements that dictate your clinical trial/research-specific reporting responsibilities?

How was the need for preventative and corrective actions communicated to you?

Did these help mitigate the issues?

Are examples of this ever discussed in staff meetings?

Support
How does your organisation support you in 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?

16	Responsibility	Checklist
	Use the relevant processes and systems to receive and respond to consumer and service user feedback and complaint. Work with clinical leads 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
- Clinical/Non-Clinical Managers

You are supported by:
- Research Office
- Partnering with Consumers department

Reflective Questions

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

Complaints
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?

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

Support
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?

17	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
- Supporting departments
- Clinical/Non-Clinical Managers
- Research Office

Reflective Questions

Process

How do you identify opportunities to involve yourself in this work?
What systems and processes do you use for this?

Support

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?

18	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:

- Clinical/Non-Clinical Managers
- Clinical Trial Workforce
- Research Office
- Supporting Departments

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?

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	☐

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?

Support

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

CLINICIAN INVESTIGATOR

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

CLINICAL/NON-CLINICAL MANAGER

	Responsibility	Checklist
1	Identify, communicate to your team and, if relevant, be able to use 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	Manage clinical trial workforce training, credentialling and professional competencies, scope of practise and performance by overseeing your team members keeping up to date on all their regular education and training, and assessing their performance at regularly scheduled intervals, as per your standard organisational schedule	☐
4	Conduct the clinical trials service in line with relevant 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, your organisational charter and clinical governance framework, national and local guidelines, standards, regulations, and legislation	☐
5	Develop relationships with key stakeholders (team leaders, consumers, supporting departments, colleagues at other sites, etc) to support clinical trial operations, service improvement, and best clinical outcomes for service users	☐
6	Develop strategies to engage & communicate with service users about clinical trials (particularly First Peoples, members of culturally diverse peoples, and those whose preferred language is not English) Support team members to tailor their approaches to meet the differing needs of service users	☐
7	Cultivate a team culture where team members conduct clinical trials responsibly, focus on integrity, safety and quality, and work within the bounds of organisational systems	
8	Support team members to 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	☐
9	Support your team members to expand their scope of practise (eg by taking on leadership opportunities)	☐
10	Support team members and service users in identifying opportunities to be involved in the development and review of clinical trials service governance	☐
11	Manage clinical trial resourcing and budgeting, identify funding sources, assess whether your organisation has appropriate capacity and resources to support your clinical trials portfolio	☐

CLINICAL/NON-CLINICAL MANAGER

12	Appropriately resource your team members to deliver the clinical trials service. Including adequate staff numbers and appropriate workloads, working space, equipment, supplies (clinical and office), access to computers, EMR systems, etc	☐
13	Make your current trial portfolio and service user population primary considerations when assessing the feasibility of new trials. Periodically review trial recruitment to ensure your current trial portfolio is the best use of your resources	☐
14	Monitor and assess potential risk by undertaking clinical trial risk assessments, covering both staff and participants If relevant, use organisational systems and processes (including the organisational risk register) to identify and report risks as they occur	☐
15	Use the relevant processes and systems to manage safety and incident reporting responsibilities. Oversee your team members being trained in, aware of, and actively carrying out their responsibilities in this area. Work with team members to resolve issues and implement preventative and corrective actions if incidents occur	☐
16	Use the relevant processes and systems to receive and respond to consumer, service user, and team member feedback and complaints. Oversee your team members being trained in, aware of, and actively carrying out their responsibilities in this area. Work with team members to resolve issues and implement preventative and corrective actions if feedback and/or complaints are received.	☐
17	Receive and respond to audit findings to monitor clinical governance compliance, clinical trial conduct, and take action to deal with any findings	☐
18	Monitor and report on clinical trial activity and performance, in the areas of the clinical trials service that you are responsible for, by reporting on relevant metrics, using data collected at the trial unit level as per your organisation's standard practises	☐
19	Monitor for, and respond to, changes in the areas of the clinical trial service you are responsible for by collecting and reporting on data collected at the trial unit level as per your organisation's standard practise	☐
20	Provide feedback on the functioning of the clinical trials service by using organisational processes and channels	☐
21	Contribute to the development, management, and review of clinical trials service governance (including the National Clinical Trials Governance Framework), where opportunities present themselves	☐
22	Look for opportunities to improve the areas of the clinical trials service that you are responsible for	☐

CLINICAL/NON-CLINICAL MANAGER

1	Responsibility	Checklist
	Identify, communicate to your team and, if relevant, be able to use your Organisational Clinical Governance framework, policies, procedures and related processes and systems	☐

You share this responsibility with:
- Clinician Investigators
- Research Office

You support the following groups in this:
- Supporting departments
- Clinical Trials Workforce

Reflective Questions

Identify your Clinical Governance framework, policies and procedures
Identify the related processes and systems
Where and how do your team members find copies of these?
Who in your organisation can help you with this?

Use
How do you communicate these to your team members?
How do you assess whether team members are aware of, and use these in their everyday work and interactions with service users?
Are they ever discussed in staff meetings?

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:
- Research Office
- Clinician Investigators
- Clinical Trial Workforce
- Supporting Departments

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?

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?

CLINICAL/NON-CLINICAL MANAGER

3	Responsibility	Checklist
	Manage: ○ clinical trial workforce training, ○ credentialling and professional competencies, ○ scope of practise ○ performance by overseeing your team members keeping up to date on all their regular education and training, and assessing their performance at regularly scheduled intervals, as per your standard organisational schedule	☐

You are supporting the following parties in this:

- Clinical Trial Workforce
- Supporting Departments

Reflective Questions

How do you determine the credentials and professional competencies your team members need to meet?
How do you determine the scope of practise of your team members?

Tracking
How do you track who needs to do what training, and when?
How do you communicate to your team members about when and how to complete their training?
How do you track who has completed, and passed, what training?
How do you escalate non-compliance, and how is this followed-up?

Assessment
How do you ensure they meet the relevant credentials and professional competencies?
How do you ensure they work within their scope of practise?
How do you monitor performance, and when?
How is this information incorporated into your organisation's training systems?

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
	Conduct the clinical trials service in line with relevant 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, ○ Your organisational charter and clinical governance framework, ○ National and local guidelines, standards, regulations, and legislation	☐

CLINICAL/NON-CLINICAL MANAGER

You share this responsibility with:
- Research Office
- Clinical/Non-Clinical Managers

You are supporting the following parties in this:
- Clinical Trial Workforce
- Supporting Departments

Reflective Questions

Process

What are the relevant requirements you, and your team members, must operate in line with?

How do you ensure your, and your team members, continued compliance with these?

How do you communicate new or updated requirements to your team members?

Are they ever discussed in staff meetings?

Support

How has your organisation supported you in this?

Who in your organisation can help you with this?

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

5	Responsibility	Checklist
	Develop relationships with key stakeholders ○ team leaders, consumers, supporting departments, colleagues at other sites, etc to support clinical trial operations, service improvement, and best clinical outcomes for service users	☐

You share this responsibility with:
- Research Office
- Clinician Investigators

You are supporting the following parties in this:
- Clinical Trial Workforce
- Supporting Departments

Reflective Questions

How do you define an "effective relationship"?

Who are the key stakeholders (both internal and external) that you need to work with for the clinical trials service to operate effectively?

Improvement

How do you assess whether these relationships are effective?

How do you use this assessment to inform ongoing process improvement in the areas 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?

CLINICAL/NON-CLINICAL MANAGER

6	Responsibility	Checklist
	Develop strategies to engage & communicate with service users about clinical trials ○ particularly First Peoples, members of culturally diverse peoples, and those whose preferred language is not English Support team members to tailor their approaches to meet the differing needs of service users	☐

You share this responsibility with:
- Clinician Investigators

You are supported in this by:
- Partnering with Consumers Department

Reflective Questions

How do you develop strategies to engage and communicate with these groups?
Have you had any direct interactions with consumers and service users as part of this development?

Support
How do you support your team members in identifying, and tailoring their approaches to service user needs?
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
	Cultivate a team culture where team members ○ conduct clinical trials responsibly ○ focus on integrity, safety and quality ○ work within the bounds of organisational systems	☐

You share this responsibility with:
- Clinician Investigators
- Research Office

You are supporting the following parties in this:
- Clinical Trial Workforce

Reflective Questions

Process
What resources have you used or training have you undertaken to develop and maintain your team culture?
How do you know if your team members are using your organisational values in their everyday work and interactions with service users?
Are examples of these ever discussed in staff meetings?

Support
How has your organisation supported you, and your team members, in this?
Who in your organisation can help you with this?

CLINICAL/NON-CLINICAL MANAGER

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

8	Responsibility	Checklist
	Support team members to 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	☐

You share this responsibility with:
- Clinician Investigators
- Research Office

You are supporting the following parties in this:
- Clinical Trial Workforce

Reflective Questions

How do you support your team members in partnering with service users in ways that respect their cultural and community identity, and their identity as a patient?
Do you ever discuss this in staff meetings?
How is the impact of this support measured?

Support
How has your organisation supported you, and them, 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
	Support your team members to expand their scope of practise (eg by taking on leadership opportunities)	☐

You are supporting the following parties in this:
- Clinical Trial Workforce

Reflective Questions

Process
How do you, or your team members, identify opportunities to expand their scope of practise?
What systems and processes do you use for this?

Support
How do you support them in taking advantage of these opportunities?
How does your organisation support you, and them, in this?

CLINICAL/NON-CLINICAL MANAGER

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

10	Responsibility	Checklist
	Support team members and service users in identifying opportunities to be involved in the development and review of clinical trials service governance	☐

You are supporting the following groups in this:

- Clinical Trial workforce
- Supporting departments

Reflective Questions

Process

How do you, or your team members, identify opportunities for them to be involved in this?
What systems and processes do you use for this?

Support

How do you support them in taking advantage of these opportunities?
How does your organisation support you, and them, in this?

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

11	Responsibility	Checklist
	Manage: - clinical trial resourcing and budgeting - identify funding sources - assess whether your organisation has appropriate capacity and resources to support your clinical trials portfolio	☐

You share this responsibility with:

- Supporting departments

Reflective Questions

Trial Level

How do you assess what resources each trial will need?
How do you assess what each trial will cost?

Unit Level

How do you balance the available resources across the trials portfolio?
How do you know you are recovering the costs to deliver your trials portfolio?

Service Level

How do you partner with stakeholders across your organisation to assess whether they have the capacity and resources to support additional trials?

CLINICAL/NON-CLINICAL MANAGER

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

12	Responsibility	Checklist
	Appropriately resource your team members to deliver the clinical trials service: ○ adequate staff numbers and appropriate workloads, ○ working space, ○ equipment, supplies (clinical and office), ○ access to computers, EMR systems, etc	☐

You share this responsibility with:

- Supporting departments

Reflective Questions

Trial Level

How do you assess what resources each trial will need?

How do you assess what each trial will cost?

Unit Level

How do you balance the available resources across the trials portfolio?

How do you know you are recovering the costs to deliver your trials portfolio?

Service Level

How do you partner with stakeholders across your organisation to assess whether they have the capacity and resources to support additional trials?

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

CLINICAL/NON-CLINICAL MANAGER

13	Responsibility	Checklist
	Make your current trial portfolio and service user population primary considerations when assessing the feasibility of new trials. Periodically review trial recruitment to ensure your current trial portfolio is the best use of your resources	☐

You share this responsibility with:

- Clinician Investigators
- Supporting Departments

Reflective Questions

How do you define "success" for a clinical trial?

New Trials

What is your process for selecting new trials?
How do you take in account your current trial portfolio and available resources when selecting new trials?
How do you take in account your current service user population when selecting new trials?
How do you engage with service users to determine their needs?

Current Trials

What is your process for reviewing inactive trials, or trials that fail to recruit participants?

Support

Does your organisation support you bringing in new trials by offering a strategic plan for the clinical trials service?

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

14	Responsibility	Checklist
	Monitor and assess potential risk by undertaking clinical trial risk assessments, covering both staff and participants If relevant, use organisational systems and processes (including the organisational risk register) to identify and report risks as they occur	☐

You share this responsibility with:

- Research Office

CLINICAL/NON-CLINICAL MANAGER

Reflective Questions

How do you identify and document potential risks to participants?
How do you identify and document potential risks to staff?

Process
How do you develop and assess your risk mitigation systems and processes, and are service users and consumers involved where relevant?
How do you communicate the need for preventative and corrective actions to your team members?

Impact
How is the impact of these actions measured?
How do these processes support continuous improvement in safety and quality?
Are these ever discussed in staff meetings?

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
	Use the relevant processes and systems to manage safety and incident reporting responsibilities. Oversee your team members being trained in, aware of, and actively carrying out their responsibilities in this area. Work with team members to resolve issues and implement preventative and corrective actions if incidents occur	☐

You share this responsibility with:
- Clinician Investigators
- Research Office

You support the following parties in this:
- Clinical Trial Workforce
- Supporting Departments

Reflective Questions

Identify the relevant processes and systems used for safety and incident reporting

Process
How do you know if your team members carry out these responsibilities in their interactions with service users?
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

Impact
How is the impact of these actions measured?
How do these processes support continuous improvement in safety and quality?
Are these ever discussed in staff meetings?

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

CLINICAL/NON-CLINICAL MANAGER

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

16	Responsibility	Checklist
	Use the relevant processes and systems to receive and respond to consumer, service user, and team member feedback and complaints. Oversee your team members being trained in, aware of, and actively carrying out their responsibilities in this area. Work with team members to resolve issues and implement preventative and corrective actions if feedback and/or complaints are received.	☐

You share this responsibility with:

- Clinician Investigators
- Research Office
- Partnering with Consumers Department

You support the following parties in this:

- Clinical Trial Workforce
- Supporting departments

Reflective Questions

Identify the relevant processes and systems to manage service user feedback and complaints
How do you know if your team members carry out these responsibilities in their interactions with service users?

Complaints
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?

Feedback
What feedback have you received?
What improvements have you made in response?
How is the impact of these actions measured?

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

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

17	Responsibility	Checklist
	Receive and respond to audit findings to monitor clinical governance compliance, clinical trial conduct, and take action to deal with any findings	☐

You share this responsibility with:

- Research Office

CLINICAL/NON-CLINICAL MANAGER

Reflective Questions

Identify what audit processes there are within your organisation

Process

Do you involve service users, consumers, and team members in the audit process/review of audit findings, or is this done by those conducting the audit?

What is your process for ensuring all of your findings have been addressed?

How do you communicate the need for preventative and corrective actions ?

Impact

How is the impact of these actions measured?

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

How are audit findings (or themes from audit findings) shared with the wider organisation for oversight and quality improvement measures?

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?

18	Responsibility	Checklist
	Monitor and report on clinical trial activity and performance, in the areas of the clinical trials service that 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:

- Research Office

Reflective Questions

Reporting

What data do you collect and report, 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 (e.g., your governing body)?

How often do you have to report (e.g., quarterly)?

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

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?

CLINICAL/NON-CLINICAL MANAGER

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

You share this responsibility with:

- Research Office

Reflective Questions

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

Process

What data points do you monitor for changes?
What is your process for monitoring and identifying changes?
How do you communicate the need for preventative and corrective actions?

Impact

What is your process for identifying and measuring the impact of these changes?
How is this data used to inform ongoing process improvement in the areas of the clinical trials service you are responsible for?

Support

How does your organisation support you, and your team members, in implementing changes?
Who in your organisation can help with this?

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

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

You share this responsibility with:

- Clinical/Non-Clinical Managers
- Research Office
- Supporting Departments

You support the following parties in this

- Clinical Trial Workforce

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?

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

CLINICAL/NON-CLINICAL MANAGER

21	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
- Supporting departments
- Clinical Trials Workforce

Reflective Questions

How do you identify opportunities to involve yourself in this work?
What systems and processes do you use for this?

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?

22	Responsibility	Checklist
	Look for opportunities to improve the areas of the clinical trials service that you are responsible for	☐

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
How 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?

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	☐

SUPPORTING DEPARTMENT

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	☐

SUPPORTING DEPARTMENT

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?

SUPPORTING DEPARTMENT

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

SUPPORTING DEPARTMENT

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

Do you have a clear understanding of what tasks and activities you are delegated to do?
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?
Who in your organisation can help you with this?

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

SUPPORTING DEPARTMENT

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?

SUPPORTING DEPARTMENT

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 department requires to effectively deliver its services?

How do you assess whether or not you are meeting this level?

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

What do you do if you do not meet 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

SUPPORTING DEPARTMENT

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?

SUPPORTING DEPARTMENT

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
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?

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

Support
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?

SUPPORTING DEPARTMENT

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
- Clinical trials workforce

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

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?

SUPPORTING DEPARTMENT

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

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	☐

RESEARCH OFFICE

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	☐

RESEARCH OFFICE

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	☐

RESEARCH OFFICE

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?

RESEARCH OFFICE

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?

RESEARCH OFFICE

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?

RESEARCH OFFICE

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?

RESEARCH OFFICE

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 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?

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?

SERVICE USER/CONSUMER

	Responsibility
1	Speak up about potential/actual safety and quality issues, risks, or incidents that you encounter while participating in the clinical trials service
2	Speak up about potential opportunities you see for improving the clinical trials service
3	Give feedback and compliments and/or raise concerns and make complaints about your experience with the clinical trials service, including participating in organisational feedback surveys
4	Consider getting involved in the review of safety and quality incidents, clinical trial performance reports, risks, and other related events, where such opportunities exist
5	Consider getting involved in the strategic and operational decision making about the conduct, direction, and priorities of the clinical trials service, where such opportunities exist
6	Consider getting involved in the development and review of information about clinical trials, either at a trial level or at a service level, where such opportunities exist
7	Consider getting involved in quality improvement projects at the health service organisation, where such opportunities exist
8	Actively involve yourself and your friends, family, and carers, in the decision-making process about your participation in a clinical trial, to the extent that you choose
9	Share your experiences, to the extent you feel comfortable, at meetings, focus groups, training sessions, or the like as a form of advocacy for clinical trial participants and to improve the clinical trials service

GOVERNING BODY

	Responsibility
1	Hold overall responsibility for the conduct, direction, and priorities of the clinical trials service at their Health Service Organisation, and delegate management of the service as and where appropriate
2	Ensure clinical trial conduct meets legislative, regulatory, and compliance requirements, including the National Clinical Trials Governance Framework and the organisation's Clinical Governance Framework and endorse/authorise organisational policies for the same
3	Include consideration of the clinical trial service in all business decision-making Ensure the clinical trial service delivers high-quality clinical trials, responsibly and in a safe environment, to all service users
4	Dedicate time to review and report on clinical trial service systems, performance, and metrics (including the National Aggregate Statistics), and to resolve to or delegate issues
5	Resource and monitor systems and processes used to deliver the clinical trial service, and continuously look for opportunities for system improvement
6	Resource for clinical trials to be included in organisational identification, reporting, and management systems (including risk, incident and complaint systems) and continuously look for opportunities for system improvement
7	Establish and monitor an organisational culture that values safety, compliance, risk management, and quality, and continuously look for opportunities for improvement
8	Acquire, resource, and routinely engage with a multi-disciplinary workforce and network of consumers (that represent the service users) who participate in strategic and operational decision making
9	Resource education, training and other resources for staff, including GCP, research integrity, and cultural sensitivity training
10	Ensure skills and qualifications match responsibilities, functions, and accountabilities
11	Establish and maintain and work with appropriate healthcare record systems, including electronic medical record systems, for use by the clinical trial workforce
12	Develop dedicated plans to meet the specific needs of First Peoples as part of the clinical trials service
13	Involve First Peoples in the workforce to both improve access to, knowledge of, and trust in, clinical trials involving these communities, and mentor and support non-Indigenous members of the workforce
14	Ensure clinical trials and study visits are delivered in a safe environment