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	☐
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	☐

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?

3	Responsibility	Checklist
	You are supporting the following parties in this: Manage: Clinical Trial Workforce clinical trial workforce training, Supporting Departments 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	☐

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	☐

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?

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?

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?

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?

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?

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

Reflective Questions

How do you identify and document potential risks to participants?

How do you identify and document potential risks to staff?

members?

Impact

How is the impact of these actions measured?

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

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?

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

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?

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?

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

Does your organisation support you in taking

in this work?
What systems and processes do you use for this?

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?
