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)	☐

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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?

CLINICIAN INVESTIGATOR

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

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

CLINICIAN INVESTIGATOR

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?

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?

CLINICIAN INVESTIGATOR

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

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

CLINICIAN INVESTIGATOR

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?

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?

CLINICIAN INVESTIGATOR

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	☐

CLINICIAN INVESTIGATOR

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

CLINICIAN INVESTIGATOR

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?

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?

CLINICIAN INVESTIGATOR

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?

CLINICIAN INVESTIGATOR

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?

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?

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

CLINICIAN INVESTIGATOR

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	☐

CLINICIAN INVESTIGATOR

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?

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