CLINICIAN INVESTIGATOR

	Responsibility	Checklist
1	Working familiarity of your Organisational Charter, and the Australian Charter of Healthcare Rights	☐
2	Use of the policies and procedures, and the related processes and systems surrounding capacity and decision making/ decision maker status	☐
3	Use of your organisational informed consent policies, procedures, and the related processes and systems	☐
4	Use of other relevant Partnering with Consumers policies and procedures, and the related processes and systems	☐
5	Educate yourself on the value of participant and decision maker engagement. Encourage active participation and sharing in decision making and care planning (to the extent that they choose)	☐
6	Educate yourself on the value of consumer engagement, how it contributes to the safety and quality of health care, and how it supports clinical trial participation	☐
7	Undertake regular Partnering with Consumers training and education, as per your organisation's schedule	☐
8	When developing meaningful relationships with participants, understand the complexity of the 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	Tailor your approaches to meet the differing communication needs of your service user population and provide participants access to, and use of, high-quality, easy-to-understand information in languages, formats and ways that reflect their needs (including telehealth, translations, the interpreter service, etc)	☐
10	Delegate partnering with consumers responsibilities to clinical team members (where relevant)	☐
11	Identify and report risks, issues, or anything that could compromise your ability to safely partner with service users and consumers. Report using both clinical trial/research-specific and organisational systems and processes, using the relevant processes and systems. Work with clinical leads to resolve issues and implement preventative and corrective actions	☐

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12	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.	☐
13	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
	Working familiarity of your Organisational Charter, and the Australian Charter of Healthcare Rights	☐

You share this responsibility with:

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

You are supported in this by:

- Partnering with Consumers Department

Reflective Questions

Finding

Identify and locate at your organisation

- your Organisational Charter
- the Australian Charter of Healthcare Rights

Where and how do patients and consumers find copies of these?

Use

How do these principles guide your interactions with service users?
How is your use of these principles 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
	Use of the policies, procedures, and related processes and systems surrounding capacity and decision making/ decision maker status	☐

You share this responsibility with:

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

You are supported in this by:

- Partnering with Consumers Department

Reflective Questions

Finding

Identify your organisations capacity and decision-making/decision maker status 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 they ever discussed in staff meetings?

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

3	Responsibility	Checklist
	Use of your organisational informed consent policies, procedures, and related processes and systems	☐

You share this responsibility with:

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

You are supported in this by:

- Partnering with Consumers Department

Reflective Questions

Finding

Identify your organisation's informed consent 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?

4	Responsibility	Checklist
	Use of other relevant Partnering with Consumers policies, procedures, and related processes and systems	☐

You share this responsibility with:

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

You are supported in this by:

- Partnering with Consumers Department

CLINICIAN INVESTIGATOR

Reflective Questions

Finding

Identify other organisational Partnering with consumers policies and procedures relevant to your work

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 they ever discussed in staff meetings?

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

5	Responsibility	Checklist
	Educate yourself on the value of participant and decision maker engagement. Encourage active participation and sharing in decision making and care planning (to the extent that they choose)	☐

You share this responsibility with:

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

You are supported in this by:

- Partnering with Consumers Department

Reflective Questions

Education

What resources have you used/training have you undertaken, to educate yourself about participant and decision-maker engagement?

Have you had any direct interactions with participants/decision makers as part of this?

Process

What is your organisational process for documenting and prioritising patient welfare and desires?

What systems and processes are available for you to partner with participants/decision-makers to plan, communicate, set goals, and be actively involved in their current and future care?

How is this information incorporated into your organisational systems?

Support

How does your organisation support you in safely involving participants/decision-makers?

Who in your organisation can help you with this?

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

6	Responsibility	Checklist
	Educate yourself on the value of: • consumer engagement • how it contributes to the safety and quality of health care • how it supports clinical trial participation	☐

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

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

Reflective Questions

Education

What resources have you used/training have you undertaken, to educate yourself about participant and decision-maker engagement?
Have you had any direct interactions with participants/decision makers as part of this?

Support

How does your organisation support you in safely involving participants/decision-makers?
Who in your organisation can help you with this?

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

7	Responsibility	Checklist
	Undertake regular Partnering with Consumers training and education, as per your organisations schedule	☐

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

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

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Reflective Questions

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

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

8	**Responsibility**	**Checklist**
	When developing meaningful relationships with participants, understand: • the complexity of the 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:

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

You are supported by:

- Partnering with Consumers Department

Reflective Questions

Process

How do you partner with service users 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?

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9	Responsibility	Checklist
	Tailor your approaches to meet the differing communication needs of your service user population. Provide participants access to, and use of: • high-quality, easy-to-understand information • languages, formats and ways that reflect their needs • telehealth, translations, the interpreter service, etc	☐

You share this responsibility with:
- Clinical Trials Workforce

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

Reflective Questions

Process

How do you identify the communication needs of service users, families, and the community?
How do you do to tailor communication to meet their needs?

Support

How are you supported to meet the needs of participants for ongoing care, especially past the end of the trial?
Who in your organisation can help you with this?

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

10	Responsibility	Checklist
	Delegate partnering with consumers responsibilities to clinical 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

11	Responsibility	Checklist
	Identify and report risks, issues, or anything that could compromise your ability to safely partner with service users and consumers. Report using both clinical trial/research and organisational systems and processes. Work with clinical leads to resolve issues and implement preventative and corrective actions	☐

You share this responsibility with:

- Clinical Trial Workforce
- Clinical/Non-Clinical Managers

You are supported in this by:

- Research Office

Reflective Questions

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

Process

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 measures 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 with this?

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

CLINICIAN INVESTIGATOR

12	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:

- Clinical Trial Workforce
- Clinical/Non-Clinical Managers

You are supported in this 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?

13	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:

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

CLINICIAN INVESTIGATOR

Reflective Questions

Process

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 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?
