

CLINICAL / NON-CLINICAL MANAGER

	Responsibility	Checklist
1	Identify and communicate to your team, your Organisational Charter, and the Australian Charter of Healthcare Rights	<input type="checkbox"/>
2	Identify, communicate to your team, and periodically review, the policies, procedures and related processes and systems surrounding capacity and decision-making/decision maker status. If relevant to your role, be able to use them	<input type="checkbox"/>
3	Identify, communicate to your team, and periodically review, your organisational informed consent policies, procedures, and the related processes and systems If relevant to your role, be able to use them	<input type="checkbox"/>
4	Identify, communicate to your team, and periodically review, other relevant Partnering with Consumers policies, procedures, and related processes and systems. If relevant to your role, be able to use them	<input type="checkbox"/>
5	Lead by example by participating in education and training on the value of service user engagement, the barriers to service user engagement, and how to encourage active participation and sharing in decision making and care planning (to the extent that they choose)	<input type="checkbox"/>
6	Lead by example by participating in education and training on the value of consumer engagement, how it contributes to the safety and quality of health care, and how it supports clinical trial participation)	<input type="checkbox"/>
7	Oversee your team members keeping up to date with their Partnering with Consumers training and education requirements	<input type="checkbox"/>
8	Undertake regular Partnering with Consumers training and education, as per your organisation's schedule	<input type="checkbox"/>
9	Support team members to develop meaningful relationships with participants by understanding 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	<input type="checkbox"/>
10	Support team members to involve service users, decision makers, and families to participate in making decisions about their own care and their participation in clinical trials, while prioritising their welfare and desires	<input type="checkbox"/>
11	Support team members to tailor their approaches and provide consumers and service users access to high-quality, easy-to-understand information about clinical trials in languages, formats, and ways that reflect their needs	<input type="checkbox"/>

12	Cultivate a team culture where participants feel safe and confident with your team members, who are competent and available to participants when they need them	<input type="checkbox"/>
13	<p>Identify and report risks, issues, or anything that could compromise you or your team members ability to safely partner with service users and consumers.</p> <p>Report using both clinical trial/research-specific and organisational systems and processes.</p> <p>Work with team members to resolve issues and implement preventative and corrective actions</p>	<input type="checkbox"/>
14	<p>Use the relevant processes and systems to receive and respond to consumer, service user, and team member feedback and complaints (including the Australian Open Disclosure Framework), oversee your team members being trained in, aware of, and actively carrying out their responsibilities in this area.</p> <p>Work with team members to resolve issues and implement preventative and corrective actions if feedback and/or complaints are received.</p>	<input type="checkbox"/>
15	Monitor and report on consumer involvement in the areas of the clinical trial service you are responsible for, by collecting and reporting on data as per your organisation's standard practices	<input type="checkbox"/>
16	Look for opportunities to improve the areas of the clinical trials service that you are responsible for, and the care given to participants	<input type="checkbox"/>

1	Responsibility	Checklist
	Identify and communicate to your team, your Organisational Charter, and the Australian Charter of Healthcare Rights	<input type="checkbox"/>

You share this responsibility with:

- Research Office
- Clinician Investigators
- Partnering with Consumers Department

You support the following groups in this:

- Clinical Trials Workforce

Reflective Questions

Finding

Identify and locate at your organisation

- your Organisational Charter
- the Australian Charter of Healthcare Rights

Where and how do your team members find copies of these?

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

Use

How do you communicate these to your team members?

How do you assess team members use of these principles 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
	Identify, communicate to your team, and periodically review, the policies, procedures and related processes and systems surrounding capacity and decision-making/decision maker status. If relevant to your role, be able to use them	<input type="checkbox"/>

You share this responsibility with:

- Research Office
- Clinician Investigators
- Partnering with Consumers Department

You support the following groups in this:

- Clinical Trials Workforce

Reflective Questions

Finding

Identify your organisational policies and procedures around capacity and decision-making/decision maker status
Identify the related processes and systems
Where and how do your team members find copies of these?

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?

Review

What is the review process for these?

Who in your organisation can help you get involved in this review process?

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

3	Responsibility	Checklist
	Identify, communicate to your team, and periodically review, your organisational informed consent policies, procedures, and the related processes and systems If relevant to your role, be able to use them	<input type="checkbox"/>

You share this responsibility with:

- Research Office
- Clinician Investigators
- Partnering with Consumers Department

You support the following groups in this:

- Clinical Trials Workforce

Reflective Questions

Finding

Identify your organisation's informed consent policies and procedures
Identify the related processes and systems
Where and how do your team members find copies of these?

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?

Review

What is the review process for these?

Who in your organisation can help you be involved in this review?

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

4	Responsibility	Checklist
	Identify, communicate to your team, and periodically review, other relevant Partnering with Consumers policies, procedures, and related processes and systems. If relevant to your role, be able to use them	<input type="checkbox"/>

You share this responsibility with:

- Research Office
- Clinician Investigators
- Partnering with Consumers Department

You support the following groups in this:

- Clinical Trials Workforce

Reflective Questions

Finding

Identify other Partnering with consumers policies and procedures relevant to your work, and the work of your team members
 Identify the related processes and systems

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?

Use

How do you communicate these to your team members?

Review

What is the review process for these?
 Who in your organisation can help you be involved in this review?

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

5	Responsibility	Checklist
	Lead by example by participating in education and training on: <ul style="list-style-type: none"> ○ the value of service user engagement ○ the barriers to service user engagement ○ how to encourage active participation and sharing in decision making and care planning (to the extent that they choose) 	<input type="checkbox"/>

You share this responsibility with:

- Research Office
- Clinician Investigator
- Partnering with Consumers Department

You are supporting the following groups in this:

- Clinical Trials Workforce

Reflective Questions

Process

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

Are examples of good practise, resources, or education and training outcomes ever discussed in staff meetings?
 How does your organisation support educating yourself on safely involving participants and decision-makers?
 Who in your organisation can help you with this?

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

6	Responsibility	Checklist
	Lead by example by participating in education and training on <ul style="list-style-type: none"> ○ the value of consumer engagement ○ how it contributes to the safety and quality of health care ○ how it supports clinical trial participation 	<input type="checkbox"/>

You share this responsibility with:

- Research Office
- Clinician Investigator
- Partnering with Consumers Department

You are supporting the following groups in this:

- Clinical Trials Workforce

Reflective Questions

Process

What resources have you used, and/or training have you undertaken, to educate yourself about consumer engagement?
 Have you had any direct interactions with consumers as part of this?

Support

Are examples of good practise, resources, or education and training outcomes ever discussed in staff meetings?
 How does your organisation support educating yourself on safely involving consumers?
 Who in your organisation can help you with this?

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

7	Responsibility	Checklist
	Oversee your team members keeping up to date with their Partnering with Consumers training and education requirements	<input type="checkbox"/>

Reflective Questions

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 follow up with them to ensure it is done?
- How do you track who has completed, and passed, what training?
- How do you escalate non-compliance, and how is this followed-up?
- How is the information incorporated into your organisations training systems?

Assessment

- How do you monitor performance, and when?
- How is this information incorporated into your organisation’s training systems?
- 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?

8	Responsibility	Checklist
	Undertake regular Partnering with Consumers training and education, as per your organisation’s schedule	<input type="checkbox"/>

You share this responsibility with:

- Partnering with Consumers Department
- Research Office
- Clinician Investigators

You are supporting the following groups in this:

- Clinical Trials Workforce

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?

9	Responsibility	Checklist
	Support team members to develop meaningful relationships with participants by understanding 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	<input type="checkbox"/>

You share this responsibility with:

- Research Office
- Clinician Investigators
- Partnering with Consumers Department

You are supporting the following groups in this:

- Clinical Trials Workforce

Reflective Questions

Process

How do you support your team members in partnering with consumers and service users in ways that respect their cultural and community identity, and their identity as a patient?

How do you support your team members in learning what additional supports they can provide to their participants?

Support

Do you ever discuss this in staff meetings. How has your organisation supported you, and them, in this?

How is the impact of this support measured?

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

10	Responsibility	Checklist
	Support team members to involve service users, decision makers, and families to participate in making decisions about their own care and their participation in clinical trials, while prioritising their welfare and desires	<input type="checkbox"/>

You share this responsibility with:

- Research Office
- Clinician Investigators
- Partnering with Consumers Department

You are supporting the following groups in this:

- Clinical Trials Workforce

Reflective Questions

Process

How do you support your team members in developing meaningful partnerships with participants so they can be actively involved in their own care?

Support

Do you ever discuss this in staff meetings?
How has your organisation supported you, and them, in this?
How is the impact of this support measured?

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

11	Responsibility	Checklist
	Support team members to tailor their approaches and provide consumers and service users access to high-quality, easy-to-understand information about clinical trials in languages, formats, and ways that reflect their needs	<input type="checkbox"/>

You share this responsibility with:

- Clinician Investigators
- Research Office
- Partnering with Consumers Department

You are supporting: the following groups in this.

- Clinical Trials Workforce

Reflective Questions

Process

How do you support your team members in partnering with consumers and service users in ways that respect their cultural and community identity, and their identity as a patient?

How do you support your team members in learning what additional supports they can

provide to their participants.

Support

Do you ever discuss this in staff meetings?
How has your organisation supported you, and them, in this?
How is the impact of this support measured?

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

12	Responsibility	Checklist
	Cultivate a team culture where participants feel safe and confident with your team members, who are competent and available to participants when they need them	<input type="checkbox"/>

Reflective Questions

What resources have you used, or training have you undertaken to develop and maintain this?

partnerships with your team members, and providing feedback on their interactions?

Process

How do your systems and processes support you in ensuring staff are competent in caring for, and available to, participants?

How can you tell participants feel safe and confident to develop meaningful and open

Support

How has your organisation supported you, and your team members, in this?

Do you ever discuss this in staff meetings?

How is the impact of this support measured?

Who in your organisation can help you with this?

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

13	Responsibility	Checklist
	Identify and report risks, issues, or anything that could compromise you or your team members ability to safely partner with service users and consumers. Report using both clinical trial/research-specific and organisational systems and processes. Work with team members to resolve issues and implement preventative and corrective actions	<input type="checkbox"/>

You share this responsibility with:

- Research Office
- Clinician Investigators
- Partnering with Consumers Department

You are supporting the following groups in this:

- Clinical Trials Workforce

Reflective Questions

Identify the relevant systems & processes used for risk, safety, and incident reporting
How do you know if your team members carry out these responsibilities in their everyday work?

Process

What organisational policies and procedures dictate your reporting responsibilities?
What are the relevant requirements that dictate your clinical trial/research-specific reporting responsibilities?
How do you communicate the need for

preventative and corrective actions?
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?

14	Responsibility	Checklist
	Use the relevant processes and systems to: <ul style="list-style-type: none"> ○ receive and respond to consumer, service user, and team member feedback and complaints (including the Australian Open Disclosure Framework) ○ 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. 	<input type="checkbox"/>

You share this responsibility with:

- Research Office
- Clinician Investigators
- Partnering with Consumers Department

You are supporting the following groups in this:

- Clinical Trials Workforce

Reflective Questions

Identify the relevant systems & processes used for this.

How do you know if your team members carry out these responsibilities in their everyday work?

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?

Who is involved in the review of these, and are consumers and service users involved where appropriate?

How do you communicate the need for preventative and corrective actions to your

team members?

Feedback

What feedback have you received?

What improvements have you made in response to feedback?

How is the impact of these changes measured?

Support

How do you support your team members in fulfilling these responsibilities in this area?

How does your organisation support you in fulfilling your responsibilities in this area?

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?

15	Responsibility	Checklist
	Monitor and report on consumer involvement in the areas of the clinical trial service you are responsible for, by collecting and reporting on data as per your organisation's standard practices	<input type="checkbox"/>

You share this responsibility with:

- Research Office

Reflective Questions

What defines consumer involvement for you?

Reporting

What data do you collect and report?

What is your process for this?

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?

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
	Look for opportunities to improve the areas of the clinical trials service that you are responsible for, and the care given to participants	<input type="checkbox"/>

You share this responsibility with:

- Research Office
- Clinical/Non-Clinical Managers

You are supporting the following groups in this:

- Clinical Trials Workforce

Reflective Questions

What defines consumer involvement for you?

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

Reporting

What data do you collect and report?
 What is your process for collecting and reporting on this data?
 Who do you report to (eg. your governing body)?
 How often do you have to report (eg. quarterly)?

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?

