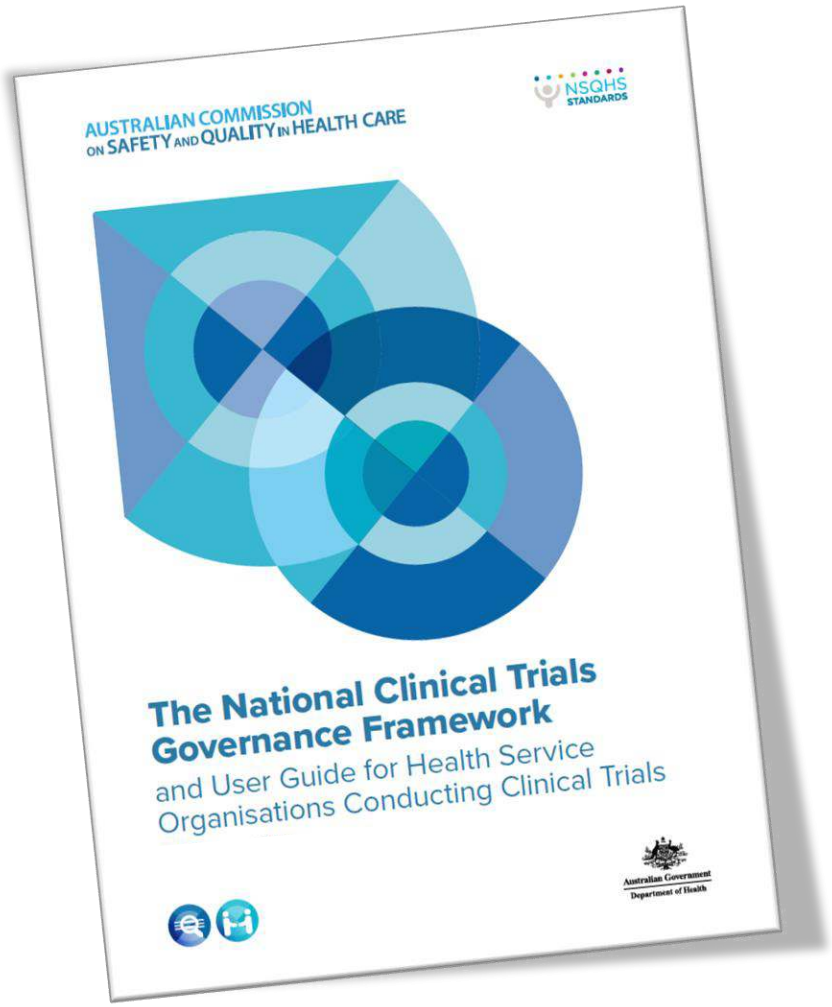
MACH
Melbourne Academic
Centre for Health

PART THREE: PARTNERING WITH CONSUMERS 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
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PARTNERING WITH CONSUMERS 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 Three**.
    - It is the Standard 2 – Partnering with Consumers workbook

- **Part Two** is the Standard 1 - Clinical Governance workbook
- **Part One** contains background/additional information, instructions for use, relevant definitions.

The purpose of this workbook

This resource is designed to help members of the clinical trial workforce understand their responsibilities under the National Clinical Governance Framework ("the framework"). It should help clinical trials workforce members 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 HSO. 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 their specific organisational structure and context. 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 HSO, 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/Function	*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 organisation'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/Function	*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 organisation'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 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 gather evidence. If you're doing 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 Charter, and the Australian Charter of Healthcare Rights	☐
2	Working familiarity of the policies and procedures, and the related processes and systems surrounding capacity and decision making/ decision maker status	☐
3	Working familiarity of other relevant Partnering with Consumers policies and procedures, and the related processes and systems	☐
4	Working familiarity of your organisational informed consent policies, procedures, and the related processes and systems	☐
5	Educate yourself on the value of participant and decision maker engagement, and 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 service users, understand the complexity of their 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 service users and provide them with access to, and use of, high-quality, easy-to-understand information in languages, formats, and ways that reflect their needs (including telehealth, translations, interpreter service, etc)	☐
10	Look for opportunities to improve the areas of the clinical trials service that you are responsible for, and the care given to participants	☐
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. Work with management to resolve issues and implement preventative and corrective actions.	☐
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.	☐

CLINICAL TRIAL WORKFORCE

1	Responsibility	Checklist
	Working familiarity of your Organisational Charter, and the Australian Charter of Healthcare Rights	☐

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

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
	Working familiarity of the policies, procedures, and related processes and systems surrounding capacity and decision making/decision maker status	☐

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

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?

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

CLINICAL TRIAL WORKFORCE

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

You share this responsibility with:
- Clinician Investigators

You are supported in this by:
- Clinical/Non-Clinical Managers
- Partnering with Consumers Department
- Research Office

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
	Working familiarity of other relevant Partnering with Consumers policies, procedures, and related processes and systems	☐

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

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?

CLINICAL TRIAL WORKFORCE

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:
- Clinician Investigators
- Research Office

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

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?
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?

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:
- Clinician Investigators
- Research Office

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

Reflective Questions

Process

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

Support

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
	Undertake regular Partnering with Consumers training and education, as per your organisation's schedule	☐

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

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

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 service users, understand: - the complexity of their 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
- Clinician Investigator

You are supported 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?

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

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

You share this responsibility with:
- Clinician Investigators

You are supported in this by:
- Partnering with Consumers Department
- Clinical/Non-Clinical Managers
- Research Office

Reflective Questions

Process

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

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
	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

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

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, 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?

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

CLINICAL TRIAL WORKFORCE

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 management to resolve issues and implement preventative and corrective actions	☐

You share this responsibility with:
- Clinician Investigators

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

Reflective Questions

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

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 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?

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:
- Clinician Investigators

You are supported in this by:
- Research Office
- Clinical/Non-Clinical Managers
- Partnering with Consumers Department

CLINICAL TRIAL WORKFORCE

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 this 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?

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	☐
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?

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

CLINICIAN INVESTIGATOR

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

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

CLINICIAN INVESTIGATOR

	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?

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

CLINICIAN INVESTIGATOR

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

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?

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?

CLINICIAN INVESTIGATOR

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?

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?

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?

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

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?

CLINICIAN INVESTIGATOR

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

CLINICAL / NON-CLINICAL MANAGER

	Responsibility	Checklist
1	Identify and communicate to your team, your Organisational Charter, and the Australian Charter of Healthcare Rights	☐
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	☐
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	☐
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	☐
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)	☐
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)	☐
7	Oversee your team members keeping up to date with their Partnering with Consumers training and education requirements	☐
8	Undertake regular Partnering with Consumers training and education, as per your organisation's schedule	☐
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	☐
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	☐
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	☐

CLINICAL / NON-CLINICAL MANAGER

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	☐
13	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	☐
14	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. Work with team members to resolve issues and implement preventative and corrective actions if feedback and/or complaints are received.	☐
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	☐
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 / NON-CLINICAL MANAGER

1	Responsibility	Checklist
	Identify and communicate to your team, your Organisational Charter, and the Australian Charter of Healthcare Rights	☐

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	☐

You share this responsibility with:
- Research Office
- Clinician Investigators
- Partnering with Consumers Department

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

CLINICAL / NON-CLINICAL MANAGER

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	☐

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?

CLINICAL / NON-CLINICAL MANAGER

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	☐

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

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?

5	Responsibility	Checklist
	Lead by example by participating in education and training on: • 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)	☐

You share this responsibility with:
- Research Office
- Clinician Investigator
- Partnering with Consumers Department

You are supporting the following groups in this:
- Clinical Trials Workforce

CLINICAL / NON-CLINICAL MANAGER

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 • 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:

- 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?

CLINICAL / NON-CLINICAL MANAGER

7	Responsibility	Checklist
	Oversee your team members keeping up to date with their Partnering with Consumers training and education requirements	☐

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	☐

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?

CLINICAL / NON-CLINICAL MANAGER

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	☐

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	☐

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	☐

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	☐

Reflective Questions

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

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

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?

CLINICAL / NON-CLINICAL MANAGER

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	☐

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?

CLINICAL / NON-CLINICAL MANAGER

14	Responsibility	Checklist
	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. • 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:

- 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	☐

CLINICAL / NON-CLINICAL MANAGER

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	☐

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?

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)?

How is this data used 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?

RESEARCH OFFICE

	Responsibility	Checklist
1	Working familiarity of your Organisational Charter, and the Australian Charter of Healthcare Rights	☐
2	Working familiarity of the policies and procedures, and the related processes and systems surrounding capacity and decision making/ decision maker status	☐
3	Working familiarity of your organisational informed consent policies, procedures, and the related processes and systems	☐
4	Working familiarity 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, your organisational policies and procedures, and the related processes and systems	☐
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	Educate yourself on 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	☐
8	Undertake regular Partnering with Consumers training and education, as per your organisation's schedule	☐
9	Facilitate researchers in partnering with consumers in their research by providing information & education resources, supporting them throughout the lifecycle of their projects, and making consumer involvement a part of Ethics and Governance review	☐
10	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	☐
11	Involve consumers in the development of information about clinical trials by involving them in the review of ethics and governance submissions, consent forms, and other participant-facing information	☐
12	Assist in maintaining an effective informed consent process by developing research-specific informed consent policies and procedures, and participating in the development of organisational-wide informed consent policies and procedures	☐
13	Monitor and assess potential risks by undertaking clinical trial risk assessments specific to consumers and partnering with consumers and, if relevant, use organisational systems and processes (including risk registers) to record them	☐
14	Conduct audits to check informed consent compliance	☐

15	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.	☐
16	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	☐
17	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 Charter, and the Australian Charter of Healthcare Rights	☐

You share this responsibility with:
- Clinician Investigators
- Clinical/Non-Clinical Managers
- Clinical Trials Workforce

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

Reflective Questions

Identify and locate at your organisation
- your Organisational Charter
- a copy of the Australian Charter of Healthcare Rights

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

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

2	Responsibility	Checklist
	Working familiarity of the policies and procedures, and the related processes and systems surrounding capacity and decision making/ decision maker status	☐

You share this responsibility with:
- Clinician Investigators
- Clinical/Non-Clinical Managers
- Clinical Trials Workforce

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

Reflective Questions

Identify your organisational capacity and decision-making/decision maker status policies and procedures

Identify the related processes and systems

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

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

You share this responsibility with:
- Clinician Investigators
- Clinical/Non-Clinical Managers
- Clinical Trials Workforce

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

Reflective Questions

Identify your organisational informed consent policies and procedures
Identify the related processes and systems

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**
	Working familiarity of other relevant Partnering with Consumers policies and procedures, and the related processes and systems	☐

You share this responsibility with:
- Clinician Investigators
- Clinical/Non-Clinical Managers
- Clinical Trials Workforce

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

Reflective Questions

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

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

RESEARCH OFFICE

5	Responsibility	Checklist
	Educate yourself on • the value of participant and decision maker engagement • your organisational policies and procedures • related processes and systems	☐

You share this responsibility with:
- Clinician Investigators
- Clinical Trials Workforce
- Clinical/Non-Clinical Managers

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

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 education?

Support

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
	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:
- Clinician Investigators
- Clinical Trials Workforce
- Clinical/Non-Clinical Managers

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

Reflective Questions

Process

What resources have you used/training have you undertaken, to educate yourself about consumer engagement?

Have you had any direct interactions with consumers as part of this education?

Support

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
	Educate yourself on: • 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:
- Clinical/Non-Clinical Managers
- Clinician Investigator
- Clinical Trials Workforce

You are supported 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?

Support

How does your organisation support you in this?

Who in your organisation can help you with this?

What additional supports do clinical trial participants need to effectively participate in clinical trials?

Do you help researchers identify and find these supports?

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	☐

You share this responsibility with:
- Clinician Investigators
- Clinical Trials Workforce

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

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?

RESEARCH OFFICE

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

9	Responsibility	Checklist
	Facilitate researchers in partnering with consumers in their research by providing information & education resources, supporting them throughout the lifecycle of their projects, and making consumer involvement a part of Ethics and Governance review	☐

You share this responsibility with:

- Clinical/Non-Clinical Managers

You are supported by:

- Partnering with Consumers Department

Reflective Questions

Process

What information and education resources do you provide to the clinical trials workforce?

How does your office prepare researchers to partner with consumers in their research?

How do you track who has completed, and passed, what education?

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

How do you measure the impact of this 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?

10	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 share this responsibility with:

- Clinical/Non-Clinical Managers

You are supported by:

- Partnering with Consumers Department

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 the review of this material?

Governance

How do you identify the communication needs of consumers and the community in your service area?

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?

11	Responsibility	Checklist
	Involve consumers in the development of information about clinical trials by involving them in the review of ethics and governance submissions, consent forms, and other participant-facing information	☐

Reflective Questions

What is the process for new consumer and lay members to be added to the HREC?

Training

What training is given to consumer and lay members of the HREC?

How are consumers involved?

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?

12	Responsibility	Checklist
	Assist in maintaining an effective informed consent process by developing research-specific informed consent policies and procedures, and participating in the development of organisational-wide informed consent policies and procedures	☐

You share this responsibility with:

- Partnering with Consumers Department

Reflective Questions

Identify your informed consent process

Development

How was your informed consent process developed, and how often is it reviewed?
What are the relevant requirements it must conform to?
How do you assess whether your informed consent process is equitable for all participants?
Did you have any direct interactions with consumers and/or service users as part of developing this process?

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?

13	Responsibility	Checklist
	Monitor and assess potential risks by undertaking clinical trial risk assessments specific to consumers and partnering with consumers and, if relevant, use organisational systems and processes (including risk registers) to record them	☐

You share this responsibility with:

- Clinical Trials Workforce
- Clinician Investigators
- Clinician/Managers

Reflective Questions

How do you identify and document risks?
How do you communicate the need for preventative and corrective actions to the clinical trials workforce?

Assessment

How do you assess the effectiveness of risk management systems and processes?
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?

RESEARCH OFFICE

14	Responsibility	Checklist
	Conduct audits to check informed consent compliance	☐

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 of your audit findings have been addressed?

Who else in your organisation is involved in the management and review of these situations?

Assessment

How is the impact of these changes actions measured?

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

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?

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?

15	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:

- Clinical Trials Workforce
- Clinician Investigators

You are supported by:

- 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?

Are these ever discussed in staff meetings?

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?

16	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	☐

You share this responsibility with:

- Clinical/Non-Clinical Managers

Reflective Questions

What defines consumer involvement for you?

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)?

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

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?

17	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 Trials Workforce

You are supported by:

- Clinical/Non-Clinical Managers

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

Does your organisation support you in identifying and reporting opportunities for improvement?
Who in your organisation can help you with this?

RESEARCH OFFICE

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

PARTNERING WITH CONSUMERS DEPARTMENT

	Responsibility
1	Work with and support the clinical trials service to meet the standards for consumer engagement in clinical trials
2	Manage onboarding and ongoing training requirements for consumers.
3	Develop a process for recruitment of consumers for engagement in clinical trials and monitor a register of consumers interested in being involved in this.
4	Manage Partnering with Consumers training and education for the clinical trial workforce, and involve consumers themselves in the design, development, and delivery.
5	Develop and communicate processes and systems for partnering with consumers, for use by the clinical trial service, that are responsive to change and have been developed in collaboration with consumers
6	Monitor and assess risks by undertaking risk assessments specific to consumers and partnering with consumers
7	Advise and assist in the development of processes and systems that manage consumer complaints and open disclosure
8	Monitor and report on consumer involvement in the clinical trial service, and continuously look for opportunities for improvement
9	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
10	Involve consumers in the development of information about clinical trials
11	Develop systems to support consumers and service users in engaging with their care and the clinical trials service
12	Support the clinical trial workforce in providing consumers and service users access to high-quality, easy-to-understand information about clinical trials in languages, formats and ways that reflect their needs
13	Support the clinical trial workforce to empower consumers and service users in making decisions about their own care and their participation in clinical trials
14	Support the clinical trial workforce in tailoring their approaches to meet the differing communication needs of the 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 translations, the interpreter service, etc)
15	Publish information and stories from service users, on service users, and about their engagement with the service to increase the profile of consumer awareness

SERVICE USER/CONSUMER

	Responsibility
1	Communicate with clinicians about your individual treatment, needs, preferences, and goals
2	Actively involve yourself in the decision-making process about your participation in a clinical trial, to the extent that you choose
3	Get the information you need in the formats that you need it, including asking questions of your clinician or asking for an interpreter (if necessary), to the extent that you choose
4	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
5	Consider getting involved in the development and review of information about clinical trials, either at a trial level or at a service level
6	Provide feedback to clinicians and health service organisations you attend about your experiences of being a clinical trial participant and/or being involved in the conduct, direction, and priorities of the clinical trials service
7	Involve yourself in training where appropriate, to inform and support your engagement in the conduct, direction, and priorities of the clinical trials

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 as and where appropriate
2	Ensure the clinical trial service delivers high-quality clinical trials, responsibly and in a safe environment, to all of the service users
3	Commit to reviewing and reporting on clinical trial service systems, performance, and consumer involvement, involving consumers in these reviews (eg through a Consumer Advisory Committee or the like), and to resolve or delegate management of consumer complaints and open disclosure
4	Lead and commit to partnering with consumers in the ongoing management of the clinical trial service
5	Resource and monitor systems used to deliver the clinical trial service, and continuously look for opportunities for system improvement
6	Establish and monitor an organisational culture that values safety, partnering with consumers, risk management, and quality, and continuously look for opportunities for improvement – do this also with partnering with consumers
7	Acquire, resource, and routinely engage with a multi-disciplinary workforce and network of consumers, that reflect the diversity of service users, who participate in strategic and operational decision making
8	Resource education and training for staff, including GCP, effective Partnering with Consumers, and Cultural Sensitivity training, ensuring skills and qualifications match positions, functions, and accountabilities
9	Adoption of the Australian Charter of Healthcare Rights