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.	

1 Responsibility		Checklist
Working familiarity of your Organisational C Healthcare Rights	Charter, and the Australian Charter of	
You share this responsibility with:	ou are supported in this by:	rtment
Reflective Questions Finding Identify and locate at your organisation: o your Organisational Charter o 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 as Who in your organisation can help yo this?	
What evidence can you show accreditors to pr	rove you meet this responsibility?	
2 Responsibility Working familiarity of the policies, procedur systems surrounding capacity and decision response.	-	Checklist
	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?	interactions with service users? How is your use of these assessed? Are they ever discussed in staff me	
What evidence can you show accreditors to pr	rove you meet this responsibility?	

3 Responsibility		Checklist
Working familiarity of your organisational in	•	
procedures, and the related processes and sy	ystems	
You share this responsibility with: O Clinician Investigators	D : : : : : : : : : : : : : : : : : : :	artment
Reflective Questions		
Finding	Use	
Identify your organisation's informed consent	How do you use these in your ever	
policies and procedures	and interactions with service user	·s?
Identify the related processes and systems	How is your use of these assessed	
Who in your organisation can help you with this?	Are these ever discussed in staff n	neetings?
What evidence can you show accreditors to pr	ove you meet this responsibility?	,
4 Responsibility		
		Checklist
Working familiarity of other relevant Partne	ring with Consumers policies,	Checklist
·	_	Checklist
Working familiarity of other relevant Partne	_	Checklist
Working familiarity of other relevant Partne procedures, and related processes and syste	ms	Checklist
Working familiarity of other relevant Partne procedures, and related processes and syste You share this responsibility with:	You are supported in this by:	
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Working familiarity of other relevant Partne procedures, and related processes and syste You share this responsibility with: Clinician Investigators	You are supported in this by: Clinical/Non-Clinical Manag	ers
Working familiarity of other relevant Partne procedures, and related processes and syste You share this responsibility with: Clinician Investigators	You are supported in this by: • Clinical/Non-Clinical Manag	ers
Working familiarity of other relevant Partne procedures, and related processes and syste You share this responsibility with: Clinician Investigators Research Office	You are supported in this by: • Clinical/Non-Clinical Manag	ers
Working familiarity of other relevant Partne procedures, and related processes and syste You share this responsibility with: Clinician Investigators Research Office Reflective Questions	You are supported in this by:	ers Department
Working familiarity of other relevant Partne procedures, and related processes and syste You share this responsibility with: Clinician Investigators Research Office Reflective Questions Finding	You are supported in this by:	ers Department
Working familiarity of other relevant Partne procedures, and related processes and syste You share this responsibility with: Clinician Investigators Research Office Reflective Questions Finding Identify other organisational Partnering with	You are supported in this by:	ers Department ryday work a
Working familiarity of other relevant Partne procedures, and related processes and syste You share this responsibility with: Clinician Investigators Research Office Reflective Questions Finding Identify other organisational Partnering with consumers policies and procedures relevant to your work	You are supported in this by:	ers Department ryday work ar
Working familiarity of other relevant Partne procedures, and related processes and syste You share this responsibility with: Clinician Investigators Research Office Reflective Questions Finding Identify other organisational Partnering with consumers policies and procedures relevant to your work	You are supported in this by:	ers Department ryday work a
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Working familiarity of other relevant Partne procedures, and related processes and syste You share this responsibility with: Clinician Investigators Research Office 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?	You are supported in this by: Clinical/Non-Clinical Manag Partnering with Consumers Use How do you use these in your ever interactions with service users? How is your use of these assessed? Are they ever discussed in staff me	ers Department ryday work and eetings?
Working familiarity of other relevant Partne procedures, and related processes and syste You share this responsibility with: Clinician Investigators Research Office Reflective Questions Finding Identify other organisational Partnering with consumers policies and procedures relevant to your work Identify the related processes and systems	You are supported in this by: Clinical/Non-Clinical Manag Partnering with Consumers Use How do you use these in your ever interactions with service users? How is your use of these assessed? Are they ever discussed in staff me	ers Department ryday work and eetings?
Working familiarity of other relevant Partne procedures, and related processes and syste You share this responsibility with: Clinician Investigators Research Office 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?	You are supported in this by: Clinical/Non-Clinical Manag Partnering with Consumers Use How do you use these in your ever interactions with service users? How is your use of these assessed? Are they ever discussed in staff me	ers Department ryday work a: ? eetings?

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: O Clinician Investigators You are supported in this by: Partnering with Consumers			

Research Office

- 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	<i>i</i> ?

6	Responsibility	Checklist
	Educate yourself on the value of	
	o 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 yourself on safely involving consumer Who in your organisation can help yo this?	rs?
What evidence can you show accreditors t	o prove you meet this responsibility	?
7 Responsibility		Checklist
Undertake regular Partnering with Consyour organisation's schedule	umers training and education, as per	
You share this responsibility with:	You are supported in this by: Partnering with ConsumersClinical/Non-Clinical Manag	•
Reflective Questions Are you clear on when and how you need to deliber the downward of the dow		
What evidence can you show accreditors t	o prove you meet this responsibility	?

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

Checklist

Responsibility

You share this responsibility with: Research OfficeClinician Investigator	You are supported by:	_
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 finding these supports? Who in your organisation can help y this?	ou with
What evidence can you show accreditors	to prove you meet this responsibili	ity?
9 Responsibility		Checklist
Tailor your approaches to meet the diff Provide them with access to, and use of high-quality, easy-to-understand in languages, formats, and ways that retelehealth, translations, interpreters	eflect their needs	
You share this responsibility with: Clinician Investigators	You are supported in this by: Partnering with ConsumersDepartmentClinical/Non-Clinical ManagerResearch Office	'S
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 this? Who in your organisation can help your?	
What evidence can you show accreditors	to prove you meet this responsibili	ity?

10 Responsibility		Checklist
Look for opportunities to improve the ary you are responsible for, and the care give		
You share this responsibility with:	You are supported by: • Clinical/Non-Clinical Mana	igers
Reflective Questions Process Support How do you identify and report opportunities for improvement? identifying and reporting opportunities for improvement? What systems and processes do you use for this? Who in your organisation can help you with this? Who in your organisation can help you with this? this? who in your organisation can help you with this?		
What evidence can you show accreditors to	prove you meet this responsibility	?
11 Responsibility		Checklist
Identify and report risks, issues, or anyth ability to safely partner with service user Report using both clinical trial/research	rs and consumers. and organisational systems and	
processes. Work with management to re	solve issues and implement	

You share this responsibility with:

preventative and corrective actions.

You are supported in this by:

Clinician Investigators

- 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	Checkli st
	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

Reflective Questions

Identify the organisational systems used for complaints and feedback

What are your associated reporting

requirements?

Feedback

What feedback have you received? What improvements have you made in

response to feedback?

Complaints

If complaints were received, how was the need for preventative and corrective actions

communicated to you?

Did these help mitigate the issues that caused

this situation?

Support

Are these ever discussed in staff meetings? How does your organisation support you in

this?

Who in your organisation can help with this?

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