

Accreditation Ready

The National Clinical Trials Governance Framework

Practice questions for Researchers

Remember: the assessor wants to hear about the great work you do everyday

The work you do and the processes you follow

Your approach to specific scenarios

How you document and report in different scenarios

The entire process using the PICMoRS approach

Education and training that helps you do your role



Explain this clinical trials and its aims.

How many participants have been enrolled? Is this on target?

What recruitment challenges have you faced?

What is your consenting process? Has this changed over time?

Where does your study coordinator fit into the consenting process?

How does care of a clinical trial participant differ from routine clinical care?

What avenues of feedback do your participants have?

Have you received any participant feedback for this clinical trial? Have you had any learning from this?

How do you ensure oversight as a PI when associate investigators are enrolling participants?



When a participant withdraws from a trial, is there continuity of care?

Are there ways you could use patient trial stories for educating nursing, allied health or medical students?

How are clinical trials integrated with clinical care?

Do you have membership with aligned (disease) groups?

How do you manage health literacy?

What has the National Clinical Trials Governance Framework meant for you?

What has improved as a result of the National Clinical Trials Governance Framework?

What has the National Clinical Trials Governance Framework meant for your practice?

How do you work as a team to comply with SOPs?



How can you support partnering with consumers? Do you ask consumers to share their experiences?

Trials are a collaborative process – how do you receive feedback and what feedback have you received?

Are consumer stories used in the on-boarding/induction of staff?

What have you learnt about the complexity of multi-centre clinical trials?

Is the Research Support Services office supportive?

How do you collaborate with other researchers at Monash Health?

In terms of rights of trial participants, what are the processes around patient rights at Monash Health?

What resources do you have for participants if they are not proficient in English?

Have there been any critical incidents in this clinical trial? Was Open Disclosure a part of it?





Need help with accreditation?



Visit the [ACSQHC website](#)



Find resources on [The National Clinical Trials Governance Framework](#) intranet page



Email Research@monashhealth.org to ask questions or arrange and education session

