

# National Safety & Quality Health Service Standards

## Sample assessment questions

Please find below some sample questions that are typical of what you'll be asked in an assessment, as well as thought starters to help get you started on your answers.

These questions will typically fall within the PICMOR framework.

Category	Question	Thought starters
<b>Participant information (PI)</b>	How do you ensure participants are provided with clear, accurate, and comprehensive trial information?	<ul style="list-style-type: none"><li>• Describe how Participant Information Sheets (PIS) are prepared, reviewed, and updated.</li><li>• Explain how participants are given adequate time to review information before consenting.</li></ul>
	How do you ensure information is accessible to diverse populations (e.g., CALD or Indigenous communities)?	<ul style="list-style-type: none"><li>• Discuss use of translators, culturally appropriate materials, and strategies to ensure inclusivity.</li></ul>
	Where is the Participant Information stored, and how is its confidentiality maintained?	<ul style="list-style-type: none"><li>• Explain how PIS documentation is stored securely (e.g., SiteDocs, SharePoint) and access protocols.</li></ul>
<b>Consent (C)</b>	Describe your process for obtaining informed consent from participants.	<ul style="list-style-type: none"><li>• Outline the consent process, including who obtains consent and how it is documented.</li><li>• Explain how participants are informed of their rights, including withdrawal from the study.</li></ul>
	How do you ensure ongoing consent throughout the trial?	<ul style="list-style-type: none"><li>• Detail the process for re-consent when protocols change or for long-term studies.</li></ul>
	What measures are taken to ensure vulnerable populations are adequately supported in the consent process?	<ul style="list-style-type: none"><li>• Describe the use of witnesses, support for participants with cognitive impairments, or use of guardians.</li></ul>
<b>Monitoring (M)</b>	How do you monitor trial progress and participant safety?	<ul style="list-style-type: none"><li>• Discuss the use of Data Safety Monitoring Boards (DSMBs) and regular safety reviews.</li></ul>



Category	Question	Thought starters
		<ul style="list-style-type: none"> <li>• Explain the process for recording and reviewing adverse events.</li> </ul>
	What tools or platforms do you use to track recruitment and participant progress?	<ul style="list-style-type: none"> <li>• Mention use of clinical trial management platforms (e.g., Research Architect, CERNER).</li> </ul>
	How are deviations from the protocol tracked and managed?	<ul style="list-style-type: none"> <li>• Outline procedures for documenting, reporting, and addressing protocol deviations.</li> </ul>
<b>Oversight (O)</b>	How do Principal Investigators demonstrate oversight of the trial?	<ul style="list-style-type: none"> <li>• Describe delegation of responsibilities and use of delegation logs.</li> <li>• Explain how regular team meetings and progress reviews are conducted.</li> </ul>
	Q: How are training and competency of trial staff ensured and documented?	<ul style="list-style-type: none"> <li>• Provide examples of mandatory training (e.g., GCP, Open Disclosure) and how it is recorded.</li> </ul>
	How do you ensure the trial complies with Good Clinical Practice (GCP) and ethical standards?	<ul style="list-style-type: none"> <li>• Explain adherence to HREC approvals, regulatory guidelines, and governance policies.</li> </ul>
<b>Reporting (R)</b>	How do you report serious adverse events (SAEs) and other incidents?	<ul style="list-style-type: none"> <li>• Describe the use of RiskMan or equivalent systems for reporting and documenting SAEs.</li> </ul>
	What is the process for submitting progress reports to Ethics Committees and governance bodies?	<ul style="list-style-type: none"> <li>• Outline timelines for regular reporting and how reports are stored.</li> </ul>
	How do you ensure timely submission of final reports when a trial is completed?	<ul style="list-style-type: none"> <li>• Explain the process for closing trials and submitting final reports to regulatory bodies.</li> </ul>
<b>Additional considerations</b>	How do you ensure equitable access to clinical trials?	<ul style="list-style-type: none"> <li>• Discuss efforts to ensure diverse participant recruitment and how fairness is tracked.</li> </ul>
	How do you manage feedback or complaints from participants?	<ul style="list-style-type: none"> <li>• Describe procedures for receiving, documenting, and responding to participant concerns.</li> </ul>
	What consumer involvement was included in the trial design?	<ul style="list-style-type: none"> <li>• Provide examples of how consumers contributed to the development of the trial protocol.</li> </ul>

### We're here to help

If you have any questions about how to prepare for the SNAP, please contact the Discovery & Innovation Unit on +61 (3) 9496 4090 or email [research@victri.org.au](mailto:research@victri.org.au) for some more tips and guidance.

