National Clinical Trial Governance Framework

Sample assessment questions.

Below are some sample questions that an assessor may ask during an assessment against the Framework.

We have also provided some thought starters to help you get started on formulating your answers.

Category	Question	Thought starter
Participant Information	How do you ensure that participants are provided with clear, accurate and comprehensive information?	• Describe how the Participant Information Sheets (PIS) are prepared, reviewed, updated, and process for obtaining ethics/governance approval. • Explain how participants are given adequate time to review information and ask questions before consenting.
	How do you ensure that information is accessible to diverse populations (e.g. CALD or indigenous communities)	Discuss use of translators, translation of consent materials and how they are culturally appropriate. Discuss strategies to increase inclusivity.
	Where is participant information stored and how is it confidentiality maintained?	Explain how PIS documentation is stored securely (e.g. SiteDocs, Florence, SharePoint) and access protocols Discuss separate storage of documents with identifiers from the de-identified participant data.
Consent	Describe your process for obtaining informed consent from participants	• Outline the consent process, including who obtains consent, methods of consent (in person/remote) and how it is documented. • Explain how participants are informed of their rights, including withdrawal from the study.
	How do you ensure ongoing consent throughout the trial	• Detail the process for re-consent when protocols change or for long term studies.
	What measures are taken to ensure that vulnerable populations are adequately supported in the consent process?	• Describe the use of witnesses, support for participants with cognitive impairment or use of guardians
Monitoring	How do you monitor trial progress and participant safety?	• Discuss the use of the DSMB and regular safety reviews. • Explain the process for recording and reviewing adverse events.

	What tools or platforms do you use to track recruitment and participant progress?	• Mention use of clinical trial management platforms e.g. EMR, Research Architect, REDcap)
	How are deviations from the protocol/GCP tracked and managed?	Outline the procedure for documenting, reporting and addressing protocol deviations / serious breaches.
Oversight	How do Principal Investigators/Sponsor-Investigators demonstrate oversight of the trial?	• Describe delegation responsibilities and use of delegations' logs. • Explain how regular team meetings and progress reviews are conducted
	How are training and competency of trial staff ensured and documented?	Provide examples of mandatory training and other study specific training (e.g. IATA training) and how it is recorded.
	How do you ensure the trial complies with Good Clinical Practice (GCP) and ethical standards?	Explain adherence to HREC approvals, regulatory guidelines, and governance policies, monitoring trial conduct.
	For MCRI-sponsored trials ONLY How do you report to MCRI on trial progress?	Discuss reporting to the MCRI Sponsorship Committee, including requirements (type of reports, frequency).
Reporting	How do you report a serious adverse event (SAE) and other clinical incidents?	Describe the process for reporting serious adverse events, including VHIMS where applicable
	What is the process for submitting progress reports to the ethics Committee and governance bodies	Outline timelines for regular reporting and how and where the reports are stored.
	How do you ensure timely submission of final reports when the trials is completed?	Explain the process for closing trials and submitting final reports to regulatory bodies, and closing the trial out in DERP
Additional Considerations	How do you ensure equitable access to clinical trials?	Discuss efforts to ensure diverse participant recruitment and how fairness is tracked.
	How do you manage feedback (compliments and complaints) from participants?	Describe procedures for receiving, documenting and responding to participant concerns. (reference the relevant SOP)
	What is the level of consumer involvement in the trial?	Provide examples of how consumers contributed to the development of the trial protocol and trial-related documents, and involvement in trial conduct.

We are here to help

If you have any questions about how to prepare for the SNAP, please contact the Melbourne Children's Trial Centre mctc@mcri.edu.au