National Clinical Trials Governance Framework

Sample assessment questions

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Purpose

This document presents sample assessment questions aligned with the National Clinical Trials Governance Framework (NCTGF). Questions are organised by NCTGF topic, with relevant NCTGF actions referenced, and are intended to support health services in preparing for accreditation assessments. The questions are drawn from actual assessments, and not all questions will apply to all health services.

Topic	Sample Questions	Relevant NCTGF actions
Patient identification, recruitment and consent	• What is your role in the recruitment and consenting patients for clinical trials?	**Standard 1**
	• How do you identify if a patient is suitable for a trial?	1.15
	• Walk me through your patient recruitment process.	1.16
	• Outline the screening process, including the number of patients screened to meet recruitment targets.	1.20
	• How do you confirm eligibility?	**Standard 2**
	• How are patients consented?	2.1
	• Can you show me the completed consent forms for this study?	2.2
	• Can you show me the consent forms for this study? Have you reconsented any patients for this study?	2.4
	• What are the organisational processes for informed consent?	2.5
	• Can you describe how you obtain consent for a patient for a clinical trial? If not you, who is responsible for consenting patients to trials?	2.10
	• How do you ensure a patient, family or carer understands the information they have been given?	
	• What is the expectation of clinical trial staff to ensure patients fully understand the information provided prior to consenting?	
	• How do you confirm informed consent is in place for each participant before proceeding with the trial?	
	• How do you consent a non-English speaking patient for a clinical trial?	
	• How do you manage the consent process for patients who do not speak English?	
	• Was there provision in this trial for people who cannot give consent?	
	• How does the opt-out consent procedure work?	
	• If a participant decides to withdraw consent from a clinical trial, what is the process you would follow? Where would you find information on this process? How is this documented?	
	• Tell me about what would happen if recruitment for a clinical trial had to close early.	
	• How do you identify a patient is on a clinical trial?	

Topic	Sample Questions	Relevant NCTGF actions
Consumer and community engagement	• How do you ensure your health services' partnering consumer policies are extended to clinical trials? • Do you have a consumer engagement program at your health service/as part of your clinical trials unit? • How do you involve consumer advisors in clinical trials? • Do you have a quality improvement process for your engagement with consumer advisors? • Have consumers contributed to your trials designs or had input for the Participant Information and Consent Form (PICF) wording? • Did you have any consumer involvement in the design of your study and brochures/PICFs? • Do you have any processes to ensure PICFs are appropriate for their target population in terms of length and readability? • Did you have participant information reviewed by a health literacy group? • How do you assist participants and/or their families/carers to provide feedback about the care they received while on a clinical trial? • What are the different ways a participant can provide feedback? Are there different formats? • How do you provide opportunities for participants to present at meetings about their trial experience? • Highlight how participants have been included in education sessions to share their stories/experience. • Do you have a policy for ensuring consumers are involved in education and training of the clinical trial workforce? • How do you ensure consumer input is included into training of the clinical trial workforce? • Describe how have you engaged with consumers throughout their clinical trial journey. • How do you engage consumers in making trials accessible to patients closer to home? • How do you inform the community about trial activity at your health service? • How do you inform the community about trial results? • If any trials conducted at your health service are published, are participants and/or consumers acknowledged in publication?	**Standard 1** 1.1 1.13 **Standard 2** 2.1 2.2 2.4 2.8 2.9 2.14

Topic	Sample Questions	Relevant NCTGF actions
Cultural safety and diversity	• Have you included Aboriginal and Torres Strait Islander patients in clinical trials at your health service? • How do you ensure Aboriginal and Torres Strait Islander people are included in clinical trials at your health service? • How do you incorporate Aboriginal and Torres Strait Islander peoples in your clinical trials? • How do you identify Aboriginal and Torres Strait Islander clinical trial participants? • How are Aboriginal and Torres Strait Islander people proactively included and provisioned for in clinical trials? • Do you have an Aboriginal and Torres Strait Islander liaison officer role? • How do you facilitate interaction with the Aboriginal and Torres Strait Islander liaison officer (or similar role) at your health service? • How do you document Aboriginal and Torres Strait Islander liaison officer involvement? • How do you ensure clinical trial services provide a culturally welcoming and safe space for Aboriginal and Torres Strait Islander participants? • Have you included recruited any patients who speak a language other than English or whose primary language is not English in clinical trials at your health service? • Do you have patient information about clinical trials available in languages other than English? • How do you ensure information is provided in plain language? • What is the process for engaging interpreter services if required? • How do you document translation or use of interpreters in clinical trials? • How do you ensure culturally diverse patients are not disadvantaged due to their race or cultural background when participating in a clinical trial? • Do you have data on the cultural diversity of the hospital population? • What kind of cultural safety training do you undertake at your health service? Who is offered/required to do this training?	**Standard 1** 1.4 1.15 1.33 **Standard 2** 2.8 2.10

Topic	Sample Questions	Relevant NCTGF actions
Safety, incidents and risk management	• How is information on clinical trial risk and safety reported to the executive and/or Board? • How do you report clinical trial incidents within your organisation? • What is your incident reporting system? Who are incidents reported to? • What is your process for reporting incidents for clinical trials within the organisation (e.g. Victorian Health Incident Management System (VHIMS)? • Describe the process for reporting adverse events (AEs) and safety incidents. • How do you inform/update the principal investigator (PI) and the trial team about a safety event? • How do you report any adverse drug reactions for a participant on a clinical trial? • Can you show me how you manage adverse events? Do you have a log of them? • What's your process for reporting serious adverse events (SAEs)? • You have received notification that a clinical trial participant has been admitted to hospital, what do you do? • How do you inform the study team if a participant involved in a clinical trial is admitted to hospital? • Explain the use of open disclosure in how information is communicated to participants and/or carers and families for incidents/adverse events. • How do you ensure trial staff have completed open disclosure training? • What do you do if you find a piece of faulty equipment? • Do you audit the types of equipment and whether they have had an annual quality check? • How do you report a risk or hazard you have identified in your clinical trial work area? • How would you handle a serious data breach? • Do you have a risk register dedicated to research/clinical trials? • Do individual trial units have their own risk registers? • What made you identify this item as a risk for the risk register?	**Standard 1** 1.9 1.10 1.11 1.12

Topic	Sample Questions	Relevant NCTGF actions
Training and workforce	• How did you get to be in this position/in this role in clinical trials? What training and experience do you have? • How are you trained on a new clinical trial? How are new staff members trained on the trials they will be managing/involved in? • How are clinical trial coordinators trained for their roles? • What is included in your mandatory training at your health service? • How are clinical trials staff supported if they encounter a difficult situation with a clinical trial participant or their family/carers? • Can I see evidence of training for your clinical trials team? For example, records of Good Clinical Practiced (GCP) certification and protocol training records. GCP • Do your investigator site files (SFs) have copies of staff GCP certificates? • Do you have a preferred training program for GCP? • How do you ensure trial staff have done GCP training? • What training systems do you use? • Can I see your site files to check GCP training certificates are on file? • Where are GCP certificates stored and how is compliance monitored? • How is GCP is managed within the team?	**Standard 1** 1.3 1.6 1.20

Topic	Sample Questions	Relevant NCTGF actions
Trial operations	• What is your process to assess whether your site should participate in a specific trial? • How do you select trials that are fit for your community's needs? • How did you become involved in this trial? • Tell me about your team involved in this clinical trial. • Can I see the latest version of your protocol for this clinical trial? • How do you run a clinical trial? • What are some of the mechanisms you or your team have in place to ensure everyone is consistent in their approach and practice? • How many guidelines are there to guide your practice? • How do you find a policy or guideline if you need to refer to it? • Do you have any local guidelines, if so, where are they kept? How are they updated? When are they updated and by whom are they updated? • What are barriers to participant recruitment you have experienced in your trials? • What are some of the challenges you have experienced in your trials? • How do you escalate issues with clinical trial specific interventions? • How do you maintain oversight of your trials? What happens if you are not available or away? (directed to the PI) • Demonstrate the trial process from start-up to close-out, including related documentation. • Describe how clinical trial practices integrate with clinical departments. • How do participants complete questionnaires? By post? Electronically via a QR code? Online into REDCap? • How do you maintain good quality data collection? • Why is data quality important in trials? • Can you show me your participant data? (REDCap, electronic medical record) • Can I see the participants in the electronic medical record associated with the study?	**Standard 1** 1.5 1.6 1.7 1.8 1.16 1.20 **Standard 2** 2.3 2.4

Topic	Sample Questions	Relevant NCTGF actions
Trial operations (continued)	• Can you show me the approval letters for this study? • How do you store trial-related documents? What are your procedures for storing paper documents? • Where are your clinical trial staff site files kept, including delegation logs and screening logs? Is this a secure location? • How and where are trial specific assessments documented for participants in a clinical trial? • How do you store data - paper or electronically? • Where are files stored? How do you ensure security of paper and electronic files? • How do patients access the Charter of Healthcare Rights?	
Pharmacy & investigational product (IP)	• What is the training program in place for pharmacists involved in clinical trials? • Explain how you dispense and deliver drug for a clinical trial participant. • An investigational medical product (IMP) shortage has occurred. There is no drug available for a participant who has arrived onsite for planned clinical trial treatment. What happens in this situation? Is the event reported, to who, in what time frame? • A pharmacy temperature excursion has occurred. Describe the process that you would follow.	**Standard 1** 1.6 1.7 1.10 1.11
Research governance	• What is the National Clinical Trials Governance Framework? • How do you monitor quality and safety in clinical trials? • Do you know where to find information about the NCTGF? • Do you understand why this framework is important and what it means? • Do you have a governance structure? • How is research embedded in the culture of the organisation? • Do you have a research strategy? Is this new? • Can you provide your schedule of reporting to the hospital board?	**Standard 1** All actions

Topic	Sample Questions	Relevant NCTGF actions
Research governance (continued)	• What reports do you provide to board? How often? Do you have examples of these? • Provide examples of subcommittee reports to the Clinical Trials Governance Committee. • Can you provide me your operational plan for clinical trials? • Can you provide me with your Gap Analysis? • Can you show me the KPIs / measures included in the hospital Quality Scorecard. • How do you capture the metrics required for the NCTGF? If you do not, what are your plans? • Who is the metric data reported to? • Can you provide data on the current compliance rate of GCP completion by the clinical trials workforce? • How are reports about research activity provided downwards and to consumers? • As the research governance office (RGO), you have received a complaint from a clinical trial participant? What is your process for capturing this information? Who is this reported to? • How are ethics/site specific assessment (SSA) applications processed? By whom? • How many ethics/SSA applications do you receive per year? • How do you manage creation and updates of policies and procedures? Do you have any outstanding reviews or updates? • How does information about audits flow from the clinical trial units to the RGO?	
Funding and resources	• What's the cost for your research? How is this funded? • How is the clinical trial centre funded? • How are clinical trial coordinators funded? • Can you provide examples of business templates and how clinical trials are included in hospital business plans? • Does the health service make decisions with consideration towards clinical trial service facilities? • Can you show me where clinical trials are specifically referred to in the hospital strategic plan and its priorities?	**Standard 1** 1.29