RESEARCHER TIPSHEET – WHAT TO KNOW & HOW TO PREPARE FOR ASSESSMENT!

National Clinical Trials Governance Framework (NCTGF)

Is your study a clinical trial that includes an intervention? → Your study is included on a list produced by CRGO that will be provided to the accrediting agency for the ACSQHC SNAP 24-hour notice hospital NCTGF accreditation assessment. See Fact Sheet 12: Assessment framework for safety and quality systems and Fact sheet 17: Short notice accreditation assessment. Assessors will conduct the review using PICMoRS evaluation.
Is your study under the TGA CTN or CTA Scheme? You may be subjected to a TGA Good Clinical Practice Inspection (approx. 4 weeks' notice given) see TGA guidance on the Good Clinical Practice (GCP) Inspection program

NCTGF Component	Advice & Tips	Compliance Source	Your Checklist
Governance & Leadership: Performance	➢ You contribute to quarterly reports to CRGO on operational performance: number of trials, number of staff working on trials, and if you are meeting the forecast number of trial participants. ➢ You are aware of your patient safety and quality care responsibilities. Tip: check the Role and Function fact sheet from the Commission →PI → Clinical Trial Workforce ➢ Your Position Description articulates commitment to quality and safety in delivery of clinical trials as per Roles and Functions Fact Sheet ➢ You understand your reporting responsibilities, and how CRGO monitors active research as per Cabrini Monitoring of Research Policy	NCTGF Action 1.1 Fact Sheet - Roles and functions for the clinical trial workforce Fact Sheet - Roles and functions for site principal investigators	○ Complete ○ Gaps/Action Needed Comment:
Clinical Leadership	➢ Your study site file is always audit ready ➢ Contact details for *all* study staff are accurate and current ➢ You are prepared for a SNAP assessment notification (usually notified Thursday for the following Monday) ➢ You are ready to be observed and/or interviewed by assessors/auditors ➢ You understand the process of ethics and governance approval ➢ You comply with *Cabrini* Research Integrity and Misconduct policy ➢ You report any quality & safety risks to your manager. You follow the Monitoring of Research Policy to notify CRGO (for inclusion into the Research Risk Register)	NCTGF Action 1.6 CABRINI RESEARCH GOVERNANCE HANDBOOK Cabrini Monitoring of Research Policy	○ Complete ○ Gaps/Action Needed
Informed Consent (PICF) & Eligibility	➢ During screening, eligibility criteria for the participant is documented as being confirmed (and no exclusion criteria are met) ➢ The consent form for each participant is signed and dated correctly by both the Investigator (PI or delegated AI) and the participant ➢ Correct HREC/governance approved PICF version and date is in use ➢ The participant had sufficient time and opportunity to ask questions prior to consent, and this process is documented ➢ The participant had an adequate understanding of the purpose, methods, demands, risks, and potential benefits of the research	ICH GCP E6 R3 *The National Statement on Ethical Conduct in Human Research (2023)* NCTGF Action 2.4	○ Complete ○ Gaps/Action Needed

Informed Consent (PICF) *continued*	➢ Record that a copy of the consent form was given to the participant ➢ Documentation if an interpreter is required ➢ Participants are aware of the study complaints process, withdrawal process, and emergency or after hours contact. ➢ You are familiar with research consent SOPs for your department		
Diversity and Inclusion	➢ As part of onboarding a new trial participant you ask questions about Aboriginal or Torres Strait Islander identity as per Aboriginal and Torres Strait Islander Health - asking for Aboriginal and Torres Strait Islander identity ➢ Where relevant, you apply principles of Indigenous data sovereignty ➢ You recruit for equity and access in clinical trials – you know who to contact for a participant consent form in another language and/or access to an interpreter. ➢ You have participated in cultural awareness and/or cultural safety training. ➢ Any participant materials you design for Investigator led research have been reviewed by consumers (e.g. Cabrini Research Community and Community Involvement Committee) ➢ You are aware the Cabrini PICF must include a QR code to access information on Healthcare Rights, and Open Disclosure (which links to other languages)	NCTGF Action 1.15	○ Complete ○ Gaps/Action Needed Comment:
Feedback and Complaints	➢ You know what to do with patient/participant feedback. ➢ Complaints and compliments related to research are to be logged with Customer Relations (they will include the complaint in the Riskman feedback module). ➢ Liaise with CRGO and Customer Relations in management of complaints as per *Cabrini* Research Participant Complaints and Compliments Procedure ➢ Be aware that CRGO is implementing an automated short feedback survey for clinical trials *participants* via eCaptis, utilising WebPAS ➢ Be aware WebPAS now has an alert flag for a clinical trial participant	NCTGF Action 1.13-1.14	○ Complete ○ Gaps/Action Needed Comment:
Safety Reporting	➢ Evidence of Principal Investigator oversight of reportable safety events ➢ SAEs reported to sponsor as per protocol ➢ SSIs and SUSARS reported to HREC and/or CRGO in a timely manner as per Cabrini Safety Monitoring and Reporting in Research policy	NCTGF Action 1.7 *NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods*	○ Complete ○ Gaps/Action Needed
Incident Reporting	➢ Incidents related to a clinical trial participant are reported into Riskman if a *Cabrini system or process has led to harm or a near miss* (see Cabrini Monitoring of Research Policy) ➢ Understand how and when to complete a Riskman report	NCTGF Action 1.11	○ Complete ○ Gaps/Action Needed
Policy & Procedures	➢ You access and follow your department SOPs ➢ You know how to access Research Policies (Tip: Employees via Prompt; VMOs via Doctor's Portal, Cabrini website or Site Docs) ➢ You know how to contact the CRGO with any research or research policy questions ➢ Policy List: Monitoring of Research Policy, Research Participant Complaints and Compliments Procedure, Safety Monitoring and Reporting in Research,	NCTGF Action 1.7 *National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia 2023*	○ Complete ○ Gaps/Action Needed Comment:

Training	➢ Your Good Clinical Practice Certification is renewed every 3 years and submitted to CRGO ➢ Principal Investigators complete A-CTEC Research Integrity training from Q3 2024 ➢ Complete other training/education such as cultural awareness, health literacy, assessing competency, healthcare rights, open disclosure ➢ Training logs and delegation logs are complete, accurate and current ➢ Cabrini Research Sessions recordings: https://www.cabrini.com.au/news/videos/		○ Complete ○ Gaps/Action Needed
Open Disclosure/Healthcare Rights	➢ You are aware of, understand, and practice the principles of open disclosure and healthcare rights. (These are now included as links/QR codes in Cabrini consent forms). Please also display pamphlets/posters at point of care of research participants	NCTGF Actions 1.12 and 2.3	○ Complete ○ Gaps/Action Needed Comment:
Data Handling & Record Keeping	➢ The responsible conduct of research includes appropriate generation, collection, access, analysis, disclosure, storage, retention, disposal, sharing and re-use of data and information. Ensure study files are secure/locked! ➢ Review section 1.7 of Cabrini Research Integrity and Misconduct policy ➢ Refer Chapter 3.1 The *National Statement on Ethical Conduct in Human Research (2023)*	NCTGF Action 1.16 NHMRC Management of Data and Information in Research-A guide supporting the Australian Code for the Responsible Conduct of Research	○ Complete ○ Gaps/Action Needed
Partnering with consumers	➢ Share and promote stories of research participation at Cabrini ➢ Promote Cabrini Clinical Trials virtual tour and CRCCIC (consumer committee) ➢ Involve consumers: from setting research priorities to co-design of protocols, through to seeking feedback, and communication of findings ➢ Refer Consumer engagement in research Top 10 tips for researchers and Consumer Engagement Toolkit	NCTGF Action 2.14	○ Complete ○ Gaps/Action Needed Comment:
ETIQUETTE FOR INSPECTION DAY	**Do's** ☑ Make yourself available if requested for an interview ☑ Be calm, positive, and respectful ☑ Seek clarity if unsure of a question ☑ Refer to relevant policy/SOP, and colleagues by role/ title ☑ Say if you do not know the answer but explain how you will find out (need to check with a colleague/other subject matter expert). Respond within given time. ☑ Participate in any internal briefing and debriefing	**Don'ts** ☒ Don't fabricate answers or bluff your way through ☒ Don't be afraid to ask if you can check with a colleague or policy and get back to them ☒ Don't talk too much or be afraid of silence ☒ Don't show annoyance or provide unsolicited opinions. ☒ Don't forget to wear name badges and practice hand hygiene	
Support and Mentoring Contact Info	Cabrini's Research Quality Manager may contact you for a pre-assessment meeting. Contact, Dianne Biermann: dbierman@cabrini.com.au https://cabinet.cabrini.com.au/departments-services/cabrini-research/national-clinical-trials-governance-framework Cabrini Research Governance Office: ResearchGovernance@cabrini.com.au https://www.cabrini.com.au/research/research-with-us/ethics-and-governance/		