NATIONAL CLINICAL TRIALS GOVERNANCE FRAMEWORK
FACT SHEET FOR CABRINI RESEARCH – BECOMING ASSESSMENT READY

WHAT IS THE NATIONAL CLINICAL TRIALS GOVERNANCE FRAMEWORK?

The National Clinical Trials Governance Framework (NCTGF) is the national safety and quality healthcare standards for the conduct and accreditation of clinical trials.

It applies to all aspects of hospital service and support of clinical trials, and describes the roles and functions for staff who are involved in clinical trial service provision.

The Commission developed an introductory video that explains what the NCTGF is.

WHY DO WE HAVE A NCTGF?

The Australian Commission on Safety and Quality in Health Care (the Commission) developed the NCTGF with a view to support:

- High quality research and better outcomes for patients and the broader community
- a nationally consistent approach to the accreditation of health services for the conduct of clinical trials
- clinical trials as a core part of routine hospital service delivery
- patient trust and participation in high quality research
- Incentive for research investment in Australia

WHAT IS A CLINICAL TRIAL?

A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

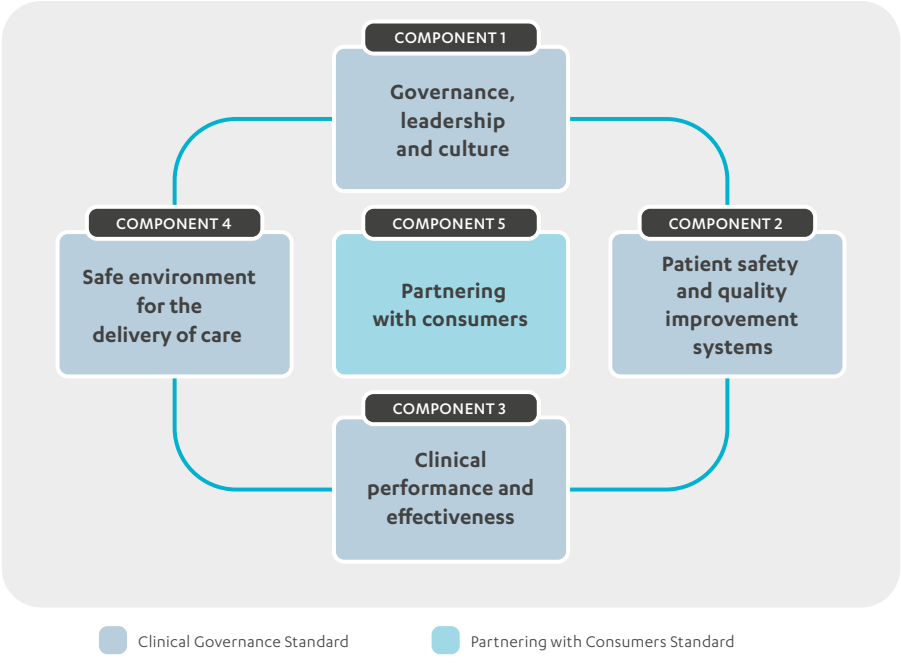
WHAT ARE THE STANDARDS?

The NCTGF incorporates the first two Safety and Quality Health Service Standards

CLINICAL GOVERNANCE STANDARD

PARTNERING WITH CONSUMERS STANDARD

Figure 1: Components of the National Clinical Trials Governance Framework



WHAT IS ASSESSMENT AND WHAT DOES IT INVOLVE?

Accreditation is an evaluation process that involves assessment of a health service organisation's compliance with the safety and quality standards by an external accrediting agency.

Cabrini's assessment agency is *The Australian Council on Healthcare Standards (ACHS)*

The agency will assess between 5 and 30 clinical trials at Cabrini, depending on the number of active clinical trials. They are selected by the accrediting agency, without taking into consideration the preference of the health service organisation or the researchers.

The assessors are trained to understand that assessment adds pressure to the clinical trials workforce, and will work in a collaborative and supportive way. They will spend the majority of their time reviewing trial service operations, including interviewing stakeholders, staff, patients and consumers.
The assessors use the PICMoRS tool for reviewing clinical trials ahead of assessment. This stands for Process, Improvement, Consumer participation, Monitoring, Reporting and Systems.

NSQHS Standards fact sheet - Using PICMoRS

The results of the first assessment will be rated in accordance with a maturity rating of **Initial systems, Growing systems or Established systems.**

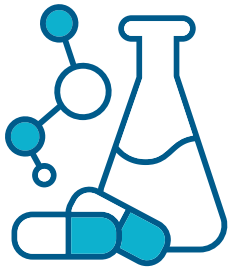
Fact Sheet - Sampling for clinical trials accreditation assessment

Fact Sheet - Maturity rating for clinical trial service assessment

IS THIS DIFFERENT TO A TGA INSPECTION?

Yes, clinical trials of medicines and biologicals regulated under the TGA's CTN or CTA schemes are subject to the TGA's Good Clinical Practice (GCP) Inspection Program. The scope of a TGA Inspection is to examine your compliance with the applicable Australian legislation and guideline(s):

- Therapeutic Goods Act 1989 (the Act)
- Therapeutic Goods Regulations 1990 (the Regulations)
- the GCP guideline(s)



Frequently Asked Questions (FAQs)

Good Clinical Practice (GCP) inspection program

WHAT SHOULD I DO PREPARE?

If you work in clinical trials, you need to become familiar with the Governance Framework and understand what is needed to meet requirements:

Fact Sheet - Roles and functions for site principal investigators

Fact Sheet - Roles and functions for the clinical trial workforce

From July 2023, short notice assessments will be mandatory for all health service organisations assessed to the NSQHS Standards. Hospitals will be given 24 hours' notice of an assessment before commencement.

Fact sheet 17: Short notice accreditation assessment

ASSUME YOUR STUDY WILL BE SAMPLED BY THE ACCREDITING AGENCY, AND BE ASSESSMENT READY AT ALL TIMES!

Please understand that the assessors are not looking for a compliance checklist, they are seeking to see clinical trials embedded within hospital service provision

1. It is essential that your study file is in impeccable condition; retaining clear, accurate, secure and complete records of all clinical trial information and approvals. See Cabrini guide on organisation of a site file (see guide)
2. Ensure your GCP certificate is current and logged with the Cabrini Research Governance Office (CRGO)
3. Are your post approval monitoring and reporting responsibilities up to date? For example, have annual progress reports been submitted to the HREC and CRGO? Are you using the correct version of the protocol and consent forms? Have all required protocol deviations been reported to the sponsor? Have all required safety events been submitted to the CRGO?
4. Refresh your awareness of all of Cabrini clinical trials SOPs and Policies
5. Please ensure all study details are current:
   - Clinical trial name
   - Clinical trial phase (I, II, III, IV)
   - Sponsor type (commercial, university, hospital) and sponsor name
   - Principal investigator (name and position)
   - Number of staff allocated to the trial — this includes the names of people from contributing departments
   - Number of patients in the trial
   - Number of Aboriginal and Torres Strait Islander and linguistically diverse patients in the trial

WHAT QUESTIONS MAY I BE ASKED BY THE ASSESSORS?

Be prepared for the following possible types of questions

1. How are potential participants of a clinical trial identified?
2. Talk us through the consent process. What is the process if a participant wants to withdraw from a study? Where is the Cabrini SOP for this?
3. Has there been any feedback or complaints from clinical trial participants, and what did you do with that feedback?
4. Where do you report your safety events to at Cabrini? What policy or procedure do you follow for this?
5. How many participants do you have in your study and how many of them are from diverse backgrounds, or are Aboriginal or Torres Strait Islander? How do you find out this information?
6. How many staff and different departments are involved in your study at Cabrini?
7. Does your department have a research strategic plan? Do the operational or business plans describe clinical trials research? Do position descriptions articulate quality and safety in research?
8. What sort of reports are you required to provide to the research governance office or HREC?
9. Have you completed any training related to quality and safety in clinical trials? Any health literacy training? Where are training records kept?
10. Where and how are all the study materials/essential documents stored?

FURTHER INFO:

National Clinical Trials Governance Framework and User Guide

Cabrini Clinical Quality Systems are outlined in The Clinical Governance Framework.

If you have any question please contact the Cabrini Research Governance Office via e: researchgovernance@cabrini.com.au

Author: Dianne Biermann, Project Lead Research Governance, NCTGF. July 2023

Cabrini RESEARCH | NSQHS STANDARDS