**National Clinical Trials Governance Framework Checklist questionnaire for Managers and Heads of Departments at Cabrini**

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

The NCTGF specifies the [roles and functions of managers (clinical and non-clinical)](https://www.safetyandquality.gov.au/publications-and-resources/resource-library/fact-sheet-roles-and-functions-managers-clinical-and-non-clinical) for ensuring systems for clinical trials service delivery perform well.

The checklist questions are based on the Commission’s expectations, and may be asked as part of the short notice accreditation assessment. The checklist ensures systems are in place at Cabrini to maintain and improve quality and safety in clinical trials

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| **Department Details** |
| Name of Department |  |
| Head of Department/Manager Name |  |
| Head of Department/Manager Email |  |

\* A clinical trial is defined as 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.

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| There are active clinical trials in my department at Cabrini (or will open new clinical trials in the next 3 months at Cabrini)  | yes/no  |

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| **Business operations & Finance** |
| There is a process in place for review of budgets prepared by the principal investigator/clinical trial team for the conduct of clinical trials | yes/no | Comment/Evidence |
| There is a process for identifying funding sources and ensuring costs of the trial are met | yes/no | Comment/Evidence |
| Cost centres are created (as required) to manage clinical trial funds and invoice for expenses are generated as per contractual arrangements | yes/no | Comment/Evidence |
| There are adequate staff and resources available to undertake the trials in your department | yes/no | Comment/Evidence |

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| **Standard 1.1 Governance, leadership, culture**  |
| Safety and quality in clinical trials is included in departmental business plans, strategic plans, policies and procedures. | yes/no | Comment/Evidence |
| The department keeps a central record of all active clinical trials by title, phase, Investigator name, sponsor type, and number of staff allocated to each trial (EFT) | yes/no | Comment/Evidence |
| If I was asked by an assessor how research is approved at Cabrini I am able to describe (or refer to) the Cabrini Research Governance Office process | yes/no | Comment/Evidence |
| **Standard 1.8 Quality Improvement systems** |
| My department has systems/procedures for management of clinical trials risks such as safety reporting, incidents (including data), protocol deviations, and complaints | yes/no | Comment/Evidence |
| My department monitors and reports on safety and quality performance relating to the conduct of clinical trials and takes actions to reduce risk  | yes/no | Comment/Evidence |
| Is there a process in place for more active monitoring of trials that have issues (e.g. poor recruitment, data handling, staff turnover, low funding) | yes/no | Comment/Evidence |
| Clinical trial performance data and information is disseminated/discussed within the department on a routine scheduled basis (e.g. departmental clinical trials meetings) | yes/no | Comment/Evidence |
| I am confident my department conducts clinical trials research consistent with the conditions of the research contracts, protocol, ethics and governance approvals, and post approval monitoring responsibilities. | yes/no | Comment/Evidence |
| I am confident that if an Investigator left Cabrini the project could continue because the department ensures study master files are stored on a secure network drive and are current, accurate, complete and legible at all times.  | yes/no | Comment/Evidence |
| **Standard 1.20 Safety and Quality Training** |
| I am aware of Cabrini policies for delivering clinical trial services, including training requirements | yes/no | Comment/Evidence |
| My department maintains records of professional skills, training and performance in the conduct of clinical trials | yes/no | Comment/Evidence |
| In addition to GCP, does your department implement training for clinicians/staff involved in research? | yes/no | Comment/Evidence |
| Clinical trials workforce staff have position descriptions which documents research safety and quality responsibilities | yes/no | Comment/Evidence |
| **Standards 1.29 & 1.33 Safe environment for the delivery of care** |
| My department allocates appropriate resources to ensure the environment supports safety and quality in the conduct of clinical trials (eg maintains equipment, secure data, devices and other infrastructure) | yes/no | Comment/Evidence |
| My department responds to identified concerns about the clinical trial environment at Cabrini | yes/no | Comment/Evidence |
| My department demonstrates a welcoming environment that recognises the importance of cultural beliefs and practices of diverse groups | yes/no | Comment/Evidence |
| My department follows policy to ask if a clinical trial participants identifies as Aboriginal or Torres Strait Islander? | yes/no | Comment/Evidence |
| **Standard S2: Partnering with Consumers**  |
| My department has adequate access to interpreters and information in different languages for clinical trials participants and their carers | yes/no | Comment/Evidence |
| There is a culture in the department which enables patients to engage in decisions about their own health care planning and participation in clinical trials | yes/no | Comment/Evidence |
| My department collects and reviews patient feedback on their clinical trials experience | yes/no | Comment/Evidence |
| My department seeks or requires evidence of consumer input when developing investigator led clinical trials projects | yes/no/na | Comment/Evidence |

Current number of clinical trials\* active (including those open in follow up/no longer recruiting) in your department: \_\_\_\_\_\_\_\_\_\_

Declaration

I have familiarised myself with the requirements of the National Clinical Trials Governance Framework roles and responsibilities

My department will commit to a review of gaps relating to the framework

Any updated policies, procedures and training will be communicated to the Cabrini Research Governance Office and updated in the next checklist questionnaire

Name

Title

Date