CRGO Pathways

Clinical Governance QA & QI Pathway QA & QI Pathway

Lower Risk Research Non-HREC Pathway

HREC / Site Specific Assessment (SSA) Pathway

Clinical Quality Registries & Databases Pathway

Use this pathway if your project:

- is a 'business-as-usual' quality activity (e.g. aims to confirm or improve a practice or process within Cabrini), and is measuring against a NSQHS standard or an industry preset benchmark
- is only being undertaken at Cabrini
- is evaluating data that have been collected as part of routine clinical care or service delivery at Cabrini
- involves the aggregation of nonidentifiable data about patients or staff
- only involves team members who have usual access to the type of patient data being accessed
- only engages patients or staff with prospective anonymous simple questionnaires or surveys (e.g. Likert, yes/no responses) to collect new data, and includes the provision of an explanatory statement

Use this pathway if your project:

- follows the criteria outlined for projects in the Clinical Governance QA & QI Pathway
- ✓ And, includes at least one of these additional criteria specific to the CRGO QA & QI pathway:
- will be disseminated to external audiences, including publishing in a journal, presenting at a conference or symposium, presented on a public facing website (including Cabrini Health website), and meetings with people from external organisations
- forms part of a professional qualification or degree
- will involve collaborators external to Cabrini (e.g. university academics)

Use this pathway if your project:

- will generate findings that contribute to generalisable knowledge outside of Cabrini
- involves data that patients or staff have consented to be used in research
- is only being undertaken at Cabrini
- involves focus groups
- involves a dataset from an approved Cabrini database/registry and only includes Cabrini patients (dependent on the data access requirements of the approved database/registry protocol, and approval by the Cabrini Data Governance Committee)

Use this pathway if your project:

has received NHMRC
 certified HREC approval
 (Cabrini must be listed as a site) and your project now requires governance approval at Cabrini

Regardless of ethics approval being granted by a HREC, all research projects must receive CRGO governance approval before commencing.

Use this pathway if your project:

- is developing /setting up a new CQR or database
- will contribute data to a national or international CQR or database
- requires the extraction of a subset of data from a CQR or database (some exemptions will apply)

Seek HREC approval and use SSA

involves data linkage from multiple sources

CQR and Database projects require the review and approval of the Cabrini Data Governance Committee or a representative prior to HREC and CRGO SSA approvals.

Do not use this pathway if your project:

- will be disseminated to external audiences, including publishing in a journal, presenting at a conference or symposium, presented on a public facing website (including Cabrini Health website), and meetings with people from external organisations
- will involve collaborators external to Cabrini (e.g. university academics)
- forms part of a professional qualification or degree
- poses risk to patients or staff participating (e.g. psychological harm)
- is targeting groups of individuals who are vulnerable or identify as Aboriginal or Torres Straight Islander people
- Will involve focus groups

Do not use this pathway if your project:

- will generate findings that contribute to generalisable knowledge outside of Cabrini
- will take longer than two years to complete
- will use a waiver of the requirement for consent or opt-out approach
- involves the randomisation of staff or patients to an intervention

Seek a CRGO pathway

- will require patients to undergo procedures that are outside of the normal standard of care delivered at Cabrini
- is targeting groups of individuals who are vulnerable or identify as Aboriginal or Torres Straight Islander people
- Will involve focus groups

Do not use this pathway if your project:

- is developing a CQR, Database or Biobank
- involves personal or health data that is being used for a purpose other than the purpose for which it was collected
- will use a waiver of the requirement for consent or optout approach

pathway

CRGO Lower Risk Research pathway or HREC/SSA

Seek th

- involves the randomisation of staff or patients to an intervention
- is a prospective investigation of non-standard of care interventions including products not registered with the TGA, or used in an unapproved manner
- will use a product in a trial to gain further information about an approved use
- will pose potential risk of physical or psychological harm beyond that of standard of care
- is targeting groups of individuals who are vulnerable or identify as Aboriginal or Torres Straight Islander people
- will require patients to undergo procedures that are outside of the normal standard of care delivered at Cabrini
- involves the use of genetic testing
- will be examining potentially sensitive or contentious issues, involve the deception of participants, or involve concealment or covert observations
- involves xenotransplantation or GMOs
- may show unknown disabilities; disease status or risk; or have the potential for discovery of nonpaternity
- involves exposure to ionizing radiation above standard of care

HREC/SSA approval and then use the SSA pathway

Seek the

GLOSSARY OF TERMS

CQR Clinical Quality RegistryCRGO Cabrini Research Governance Office

GMO Genetically Modified Organism

HREC Human Research Ethics Committee

NHMRC National Health and Medical Research C

NHMRC National Health and Medical Research Council
QA Quality Assurance
QI Quality Improvement

Therapeutic Goods Administration

Site Specific Assessment

DEFINITIONS

SSA

TGA

GENERALISABLE KNOWLEDGE – the extent to which the findings from a study can be applicable to other settings

QUALITY ASSURANCE (QA) – the use of quality control tools to certify that performance remains at the level of identified industry quality standards or benchmarks

QUALITY IMPROVEMENT (QI) – a systematic approach to improving processes and outcomes using methods such as Plan-Do-Study-Act (PDSA)

STANDARD OF CARE (SOC) – normally expected as routine clinical practice

Projects submitted through the Clinical Governance QA & QI pathway cannot be given retrospective approval to publish or disseminate to external audiences by the CRGO.

For some projects, the opportunities to present may not always be evident at the beginning.

To protect future opportunities to present your work, you may want to consider submitting an application through a CRGO pathway.

Information, contacts and pathway submission forms

CRGO Pathways

Clinical Governance
QA & QI Pathway

QA & QI Pathway

Lower Risk Research Non-HREC Pathway HREC / Site Specific Assessment (SSA) Pathway

Clinical Quality Registries & Databases Pathway

Who can I contact?

Clinical Governance Office

qualityandsafety@cabrini.com.au

Where can I find more information?

More information to come

What information and forms will I need to submit to make an application?

More information to come

Who can I contact?

Cabrini Research Governance Office (CRGO)

researchgovernance@cabrini.com.au

Where can I find more information?

CRGO website

https://www.cabrini.com.au/res earch/research-with-us/ethicsand-governance/

What information and forms will I need to submit to make an application?

Required Forms

- Quality Initiative Application
 Form
- Quality Initiative Protocol Template (or equivalent document)
- Department Resourcing and Costing Approval Form

Who can I contact?

Cabrini Research Governance Office (CRGO)

researchgovernance@cabrini.com.au

Where can I find more information?

CRGO webpage

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What information and forms will I need to submit to make an application?

Required Forms

- Risk Assessment Checklist
- Lower Risk Non-HREC Review Application Form
- Department Resourcing and Costing Approval Form

Project Dependent Forms

 Artificial Intelligence (AI) Usage Checklist

Who can I contact?

Cabrini Research Governance Office (CRGO)

researchgovernance@cabrini.com.au

Where can I find more information?

CRGO website

https://www.cabrini.com.au/ research/research-withus/ethics-and-governance/

What information and forms will I need to submit to make an application?

Required Forms

- Letter of HREC approval and documents approved
- HREA and VSM
- Site Specific Assessment (SSA) Application form
- Department Resourcing and Costing Approval Form
- Data Governance Checklist

Project Dependent Forms

- Artificial Intelligence (AI)
 Usage Checklist
- Victorian Research
 Translation Centres
 Research Collaboration
 Agreement
- Medicines Australia CTRA

Who can I contact?

Cabrini Research Governance Office (CRGO)

researchgovernance@cabrini.com.au

Data Governance & Registries Manager, Chair of the Data Governance Committee

Dr Stefanie Elbracht-Leong

email-datagovernance@cabrini.com.au

Where can I find more information?

CRGO website

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- Data Governance Checklist
- Department Resourcing and Costing Approval Form

Project Dependent Forms

 Victorian Research Translation Centres Research Collaboration Agreement

Your feedback is important to us.

Feedback will help us to continually evolve processes that best suit Cabrini. Please reach out to us through qualitygovernance@cabrini.com.au