TITLE	Research Integrity and Misconduct Policy
SETTING	All staff, honorary appointments, VMOs, and students engaged in research (or research support) at Cabrini Health - All sites engaged in research, or research support

Contents

PURPOSE

- Cabrini Health is committed to a research culture that encourages responsible conduct of research.
- The purpose of this policy is to ensure that all members of the Cabrini research community conduct their research with honesty, integrity, scientific rigour, and transparency.
- The policy is based on the *Australian Code for the Responsible Conduct of Research*, 2018 (the Code) and its related guides. It includes guidelines for managing and investigating potential breaches of the Code, and research misconduct.

ROLES AND RESPONSIBILITIES

The following roles are nominated for the management of research integrity at Cabrini, and managing breaches of the Code:

Role	Responsibility
Promotion of responsible research conduct and provide advice in regard to potential breaches of the Code	Research Integrity Advisors
Record keeping of research integrity inquiries, complaints, investigations and outcomes	Research Governance Office
Monitoring of GCP certification and other mandatory research training	Research Governance Office
Receives Complaints/breach related to the Code	Research Governance Officer
Arrange investigation of a suspected breach	Assessment Officer/Director of Research Operations
Impose corrective actions or other Cabrini disciplinary processes.	Designated Officer/Group Director, Cabrini Research
Declaration of Interests register	Research Governance Office

DEFINITIONS

The Code: *Australian Code for the Responsible Conduct of Research*, 2018

Breach: a breach is defined as a failure to meet the principles and responsibilities of the Code. It may refer to a single breach or multiple breaches.

Conflict of interest is a situation where an independent observer might reasonably conclude that the professional actions of a person are or may be unduly influenced by other interests. Conflict of interest may be actual, potential or perceived.

Assessment Officer (AO) A person or persons appointed by an institution to conduct a preliminary assessment of a complaint about research.

Designated Officer (**DO):** Designated Officer is a senior professional appointed to receive complaints about the conduct of research or potential breaches of the Code and to oversee their management and investigation where required.

GCP: Good Clinical Practice, including training that is internationally mutually recognised standards for conducting clinical trials.

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

Peer Review: The impartial and independent assessment of research by others working in the same or a related field.

Research misconduct is a serious breach of the Code which is intentional, reckless or negligent.

Research outputs includes all products of research

RIA Research Integrity Advisor

VMO Visiting Medical Officer

POLICY

1.0 Principles of research integrity and responsible conduct of research

The principles of research integrity, and the responsible conduct of research, are specified in the Code. Cabrini adopts the following principles of the Code in the Research Integrity Policy.

1.	**Honesty** in the development, undertaking and reporting of research. Information is to be presented truthfully and accurately in proposing, conducting and reporting research.
2.	**Rigour** in the development, undertaking and reporting of research. Research requires attention to detail and robust methodology, avoiding or acknowledging biases.
3.	**Transparency** in declaring interests and reporting research methodology, data and findings. The research methodology, data and findings are to be shared openly, responsibly and accurately. Any conflicts of interest must be disclosed.
4.	**Fairness** in the treatment of others. Researchers and others involved in the research are to be treated fairly and with respect. This includes referencing and citing the work of others, and properly attributing authorship to those who have contributed.
5.	**Respect** for research participants, the wider community, animals and the environment. Participants and communities that are affected by the research are to be treated with care and respect. Appropriate consideration to the needs of minority groups or vulnerable people is required and ensure that respect underpins all decisions and actions related to research.
6.	**Recognition** of the right of Aboriginal and Torres Strait Islander peoples to be engaged in research that affects or is of particular significance to them. Recognise, value and respect the diversity, heritage, knowledge, cultural property and connection to land of Aboriginal and Torres Strait Islander peoples. Engage with Aboriginal and Torres Strait Islander peoples prior to research being undertaken, so that they freely make decisions about their involvement. Report to Aboriginal and Torres Strait Islander peoples the outcomes of research in which they have engaged.

7.	**Accountability** for the development, undertaking and reporting of research. Comply with relevant legislation, policies and guidelines. Ensure good stewardship of resources used to conduct research. Consider the consequences and outcomes of research prior to its communication
8.	**Promotion** of responsible research practices by fostering a research culture and environment that supports the responsible conduct of research.

1.1 Responsibility of Cabrini:

- Establish and maintain good governance and management practices for responsible research conduct.
- Develop and promote policies, including compliance with relevant laws, regulations and guidelines.
- Provide training and continuing education in order to enhance research quality and safety.
- Support the welfare of researchers through providing mechanisms for reporting research concerns, and promoting a culture of research integrity.
- Embed clinical trials into routine health service provision as per the National Clinical Trials Governance Framework.
- Create a culture of trust, accountability, and diffusing power imbalance to allow people to feel safe and empowered to "speak up".

1.2 Responsibility of researchers:

Researchers at Cabrini must foster quality research and abide by the following additional regulatory requirements:

- The National Clinical Trials Governance Framework
- NHMRC the National Statement on Ethical Conduct in Human Research
- NHMRC Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders
- World Medical Association (WMA) Declaration of Helsinki.
- International Conference on Harmonisation (ICH) Guideline for Good Clinical Practice, and Guidance for Good Clinical Practice (ICH-GCP) (Annotated by the TGA)
- Catholic Health Australia Code of Ethical Standards

1.3 Research integrity

Research integrity is fostered through the following actions:

- Provide guidance and mentorship on responsible research conduct to other researchers or research trainees
- Undertake and promote education and training in research integrity. This includes completing and maintaining mandatory Good Clinical Practice (GCP) training every three years (or other training as stipulated by the Research Governance Office)
- Ensure that ethical approval *and* site governance approval are both obtained prior to the commencement of research, and that conditions of any approvals are adhered to during the course of research.
- Retain clear, accurate, secure and complete records of all research including research data and primary materials.
- Disseminate research findings responsibly, accurately and broadly. Where necessary, take action to correct the record in a timely manner.
- Disclose and manage actual, potential or perceived conflicts of interest.

- Ensure that authors of research outputs are all those, and only those, who have made a significant intellectual or scholarly contribution to the research and its output, and that they agree to be listed as an author.
- Acknowledge those who have contributed to the research. Cite and acknowledge other relevant work appropriately and accurately.
- Participate in peer review in a way that is fair, rigorous and timely and maintains the confidentiality of the content.
- Report suspected breaches of the Code to an RIA (as specified below)
- Make themselves familiar and act consistently with the NHMRC guides accompanying the codes including areas of **authorship**, **peer review, supervision, collaborative research, publication** and **dissemination of research, management of data, and disclosure of interests**.

The Code includes guides for supporting research integrity under the following criteria:

1.4 Authorship

- An author is an individual who has made a significant intellectual or scholarly contribution to research and its output, and agrees to be listed as an author.
- Authorship at Cabrini will be attributed as per Cabrini Authorship and Publications Policy and underpinned by the NHMRC Authorship: A guide supporting the Australian Code for the Responsible Conduct of Research

1.5 Collaborative research

- Collaborative multi-site research is encouraged but must be managed consistent with the principles of the Code. A research agreement in writing is required as part of the research governance submission to Cabrini Research Governance Office.
- Agreements should be reviewed periodically to ensure that provisions remain current.
- The NHMRC Collaborative research A guide supporting the Australian Code for the Responsible Conduct of Research articulates expectations when developing collaborative research and should include:
  - the expectations of each party in terms of definitions of roles and responsibilities, including reporting, management and oversight of the study (the sponsor)
  - the use, management, sharing, and ownership of research data, materials, and intellectual property
- Cabrini is committed to cooperating with partner institutions to ensuring that only one investigation is conducted in the event of a possible breach of the Code in a multi-site study, where possible and appropriate. The process of that investigation should be arranged by the Assessment Officer, and agreed to in writing with the collaborating institution(s). Where an agreement cannot be reached Cabrini may conduct its own investigation.

1.6 Disclosure of interests

- The Code requires researchers to disclose all perceived or actual interests related to research. Interests may also need to be disclosed to funding bodies, research participants, publishers and journal editors, collaborators and the public.
- The Disclosure of interests and management of conflicts of interest: A guide supporting the Australian Code for the Responsible Conduct of Research specifies the disclosure of both financial and non-financial interests (See addendum for prescribed list of interests):
- A conflict of interest in research is to be documented in the initial ethics and governance applications, or during the study, via Cabrini Conflict of Interest Declaration Form and/or the Declaration of Interest Form.

- The completed Conflict of Interest Declaration Form is to be submitted to the Cabrini Research Governance Office.
- After an individual discloses their interests, the Assessment Officer will determine what measure may be required as per Cabrini Conflicts of interest Policy.
- These measures will be tailored to the individual circumstances and may include one or more of the following:
  - requiring the public disclosure of the interests, for example when presenting or publishing the research
  - involving an appropriate individual to oversee some or all of the research activity
  - requiring the researcher to absent themselves from any deliberative decision making regarding the research
  - requiring the researcher to play a different or reduced role in some or all of the research
  - requiring the researcher to relinquish financial or other interests
  - disclosure to the research participant

- When assessing a financial interest disclosure the Cabrini assessing officer will consider the significance of the financial interest, including:
  - the monetary value of the payment, gift, or interest
  - the significance that a reasonable, independent observer would attach to the payment, gift or interest
  - the circumstances under which a gift or payment is made, for example, if the gift or payment is a regular payment or a single instance

1.7 Management of data and information in research

- The responsible conduct of research includes within its scope the appropriate generation, collection, access, use, analysis, disclosure, storage, retention, disposal, sharing and re-use of data and information. Cabrini researchers must abide by the *NHMRC Management of Data and Information in Research-A guide supporting the Australian Code for the Responsible Conduct of Research, The Health Records Act 2001(VIC)* and the *Cabrini Research Data Management, Sharing & Access policy.*
- The materials and data retained at the end of a project are the property of the institution that hosted the project or a central repository. They are not the property of the Investigator, and must be retained by the institution if an Investigator leaves
- Research data, whether held in a Cabrini repository or externally, requires a data management plan.

1.8 Peer review

- Peer review enhances research integrity by providing expert scrutiny, accurate and credible reporting, detection of errors, and reduce departures from the Code.
- Guidance for peer review may be found at Peer review: A guide supporting the Australian Code for the Responsible Conduct of Research.

1.9 Publication and dissemination of research

- In order to maximise the benefits of research Cabrini supports transparency, dissemination, and communication of the findings and results of research as per Cabrini Authorship & Publication policy, consistent with *Publication and dissemination of research: a guide to supporting the Australian Code for the Responsible Conduct of Research.*

1.10 Supervision

- Supervision plays a critical role in the responsible conduct of research and is supported by *Supervision A guide supporting the Australian Code for the Responsible Conduct of Research*
- Supervisory roles require the following actions and responsibilities:
  - Serve as role models to less experienced researchers and maintain a high degree of professionalism and current knowledge of their field
  - Supervisors and those whom they supervise should agree on expectations related to progress and deliverables, level of oversight, authorship arrangements, training, frequency of meetings and contact, the nature and format of feedback, how disagreements will be resolved
  - Ensure that the more junior researchers receive appropriate credit for their work (see authorship)
  - Be satisfied that the research methods and outcomes of researchers under their supervision are appropriate and valid
  - Incorporate oversight of all relevant stages of the research process from conceptualisation and planning through to dissemination of outcomes, publication and follow-up activities.
  - Maintain objectivity in their relationships with those whom they supervise.
  - Planned mechanism for raising or responding to concerns around supervision and resolving in a fair and timely manner.

1.11 Research Fraud and Corruption

- Suspected research fraud or corruption may be reported and managed in accordance with the Cabrini Fraud and Corruption Control Plan. The Plan outlines Cabrini's commitment to prevention, detection and response.
- Reports of suspected fraud or corruption can alternatively be made in accordance with the Cabrini Whistleblowing / Whistleblower Policy

2.0 Research Integrity Advice Research Complaints

- RIAs promote the responsible conduct of research by providing advice on research practices and researcher responsibilities. RIAs have knowledge of the Code (and associated Guides) and other Cabrini research policy and procedures. Anyone with concerns about research integrity, research misconduct, a possible breach of the Code is encouraged to discuss the matter with an RIA before submitting a formal complaint via researchgovernance@cabrini.com.au
- The role of RIAs is advisory only; they have no involvement in the assessment or investigation of a complaint, or in contacting the people who are the subject of a complaint. RIAs keep a record of all formal discussions and advice given
- RIAs keep confidential all matters concerning complaints and grievances except to the extent that the disclosure is necessary for the purpose of addressing the complaint or grievance.
- Where the relevant experience and expertise within Cabrini is limited, or where there is conflict of interest, it may choose to come to an arrangement to utilise external independent RIAs.
- RIAs may be contacted at Cabrini via researchgovernance@cabrini.com.au

3.0 Mandatory Training

- Cabrini seeks to promote research integrity through mandatory Good Clinical Practice (GCP) training for clinical trial investigators and their clinical trial teams every three years.

- Good Clinical Practice (GCP) training is also mandated for Investigators of all other studies approved by the Cabrini Research Governance Office. An exception to this requirement is for quality assurance or evaluation activities.
- From 2024, evidence of Research Integrity training is mandated for all Principal Investigators of clinical trials and other clinical research.
- Adherence to mandatory training (and refresher training) will be monitored by the Cabrini Research Governance Office and reported quarterly to the Cabrini Research Committee.

4.0 Breaches of this policy

- Failure to comply with the obligations and procedure set out in this policy, and the Code, may be a breach of this policy.
- The process for managing breaches under this policy will depend on the nature of the breach, and will be assessed on a case by case basis.
- Breach of this policy may result in disciplinary or remedial action.
- Where a Role described by this policy has a perceived or potential conflict, an alternative person will be nominated to fulfil the role responsibility required under the policy. The Cabrini Legal Counsel can provide guidance on the selection of an alternative person(s) for the role, ensuring transparency and impartiality.

- Cabrini will manage and investigate concerns or complaints about potential breaches of the Code, and this policy, in accordance with the Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research (*See Addendum 3 below*) and in abidance with other relevant Cabrini policies, which may include:
  - Values and Behaviours Policy
  - Managing Issues in Employment Policy
  - Managing Conduct Issues procedure
  - Managing Performance Issues procedure
  - Complaints and Grievances procedure
  - Conducting disciplinary meetings
  - Conducting meetings with staff in conflict
  - Conflicts of interest Policy
  - Respect in the workplace guidance note
  - Whistleblowing / Whistleblower Policy
  - Fraud and Corruption Control Plan

- Anonymous complaints are permitted but may make subsequent processes more challenging.
- A complainant is provided protections as per Cabrini Whistleblowing / Whistleblower Policy.
- The principles of procedural fairness apply to managing and investigating potential breaches of the Code, and this policy. This means that the process for managing and investigating potential breaches are Proportional, Fair, Impartial, Timely, Transparent and Confidential (not disclosed unless required). Throughout the investigation or management of a complaint, the welfare of the complainant and respondent is a key concern for Cabrini.

- In the event of a possible breach of the Code in a multi-site study, the process for investigation should be arranged by the Assessment Officer, and agreed to in writing with the collaborating institution(s).
- The Cabrini Health Bylaws Appointment of Medical Practitioners - Medical Staff Bylaws specifies that VMO's must practise in accord with the policies, procedures and protocols of Cabrini Health. Where a possible breach of this policy occurs at Cabrini, by a VMO or honorary appointee, the Assessment Officer, in consultation with the Group Director Medical Services and Clinical Governance, will notify and liaise with the employing institution to initiate a single investigation.

Addendum 1: Items for disclosure of interest

Financial interests

- direct payments to the researcher, such as salary, consultancy payments, speaking fees, panel memberships
- indirect payments to the researcher, for example funding of travel, accommodation, professional development, hospitality
- payments to support research, such as funding from an industry or interest group
- company shares or options
- royalties
- directorships
- some scholarships
- operational or infrastructure support
- future expectation of a benefit, for example, proceeds from the sale of intellectual property arising from a project or the promise of shares in a spin-off company

Non-Financial interests

- board membership (even if unpaid), consultancies, advisory groups, committees or other affiliation with an organisation that could stand to benefit from or be affected by the research
- personal or social relationships and current and past professional relationships, where relevant
- recent employment with, or role in, organisations with financial links or affiliations with industry groups that could stand to benefit from or be affected by the research

Addendum 2: Examples of possible breaches

Authorship Breach

- For a person to claim, demand, or accept authorship without having made a significant intellectual or scholarly contribution is a breach of the Code

- Examples of Breaches of the Code are:
  - crediting authorship to or accepting authorship from individuals who do not meet the criteria for authorship (for example, honorary, gift or guest authorship)
  - failing to ascribe authorship to individuals where those individuals meet the requirements of authorship (for example, ghost authorship)
  - attributing authorship to individuals without their consent
  - publishing research without the final approval of the attributed authors
  - failure to comply with a written authorship agreement
  - making false claims about the authorship in a grant application.

Data Breach

- Breaches of the Code that are related to management of data and information in research include, but are not limited to:
  - falsification of research data or primary materials
  - fabrication of research data or primary materials
  - failure to notify the institution and relevant authorities in a timely manner of a data breach or instance of inappropriate access to data held by the researcher
  - failure to retain clear, accurate, secure and complete records of all research including research data and primary materials
  - failure to adhere to the conditions of any institutional policy or ethical or governance approvals that relate to the retention, sharing or destruction of research data or primary materials
  - selective retention of research data or primary materials so as to hinder the verifiability of a
  - research output or access request
  - failure to apply appropriate security controls to research data or primary materials
  - failure to obtain ethics or governance approvals or acting inconsistently with a condition of any
  - approval granted in relation to the management of research data or primary materials.

Disclosure and Management of Conflicts of Interest

- Having a conflict of interest does not, in itself, imply improper motivation or individual wrongdoing
- Examples of breaches of the Code that are related to the disclosure of interests may include:
  - failing to disclose a relevant interest in a timely manner
  - failing to abide by any decisions as to the management of a conflict of interest

Publication and dissemination of research breach

- Examples of breaches of the Code that are related to the dissemination of research may include (see also Authorship):
  - fabrication, falsification or misrepresentation of research data or source material in a research output or any communication, including social media and grant applications
  - plagiarism of someone else's work, including theories, concepts, research data and source material
  - duplicate publication (also known as redundant or multiple publication, or self-plagiarism) without acknowledgement of the source or original publication
  - failure to maintain records required by an export control body as a condition of publication and dissemination
  - failure to take active, reasonable and timely steps to correct the public record upon becoming aware of errors or misleading information in their published research outputs
  - public dissemination of research (e.g. via social media) that is yet to be tested in peer review without providing an appropriate caveat
  - failure to honour a restriction on publication or dissemination imposed by Cabrini, a sponsor, ethics or other approval body

Peer Review

- Examples of breaches of the Code that are related to peer review may include:
  - failing to conduct peer review responsibly and fairly
  - taking advantage of knowledge obtained through peer review processes
  - disclosing the content or outcome of peer review processes

Supervision

- Examples of breaches of the Code related to research supervision may include:
  - Failure by a supervisor to provide adequate guidance or mentorship on the responsible conduct of research to researchers or research trainees under their supervision.
  - Demanding or accepting authorship of a research output on the basis of supervision, where the individual does not satisfy authorship criteria.

Addendum 3: Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research

Inquiry Stage

- Seek advice from an RIA who can advise on breaches of the Code, Cabrini policies, and available options, including how to make a complaint. RIA's role does not extend to investigation or assessment of the complaint, nor do they contact the person who is the subject of the complaint
- Upon receipt of a complaint by the Research Governance Office, the DO decides how to proceed as per *Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research*. If the complaint represents a potential breach of the Code, then the process continues to preliminary assessment. If the complaint does not represent a potential breach of the Code, then it may be dismissed or referred to other institutional processes.

Preliminary assessment

- At preliminary assessment the assessing officer identifies, collects, and records facts and information.
- The officer considers whether an expert needs to be engaged to provide specific and/or independent advice

- The preliminary assessment will include the following:
  - a summary of the process that was undertaken
  - an inventory of the facts and information that was gathered and analysed
  - an evaluation of facts and information
  - how the potential breach relates to the principles and responsibilities of the Code and/or institutional processes
  - recommendations for further action, including whether the matter should be: dismissed, resolved locally with or without corrective actions, referred for investigation or referred to other institutional processes
  - assessment of conflict of interest, and requirement for referral to an external independent agency/RIA
  - notification of the relevant Group Director for whom the breach relates to (eg Group Director, Medical Services and Clinical Governance, in the event a breach relates to a VMO;
    notification of Group Director, Nursing and Clinical Education in the event a breach relates to an a nursing team member)

Investigation Stage (if required)

- prepare a clear statement of allegations
- develop the terms of reference for the investigation
- nominate the investigation Panel/Independent Agency (and Chair when the Panel is more than one person)

- seek legal advice on matters of process where appropriate
  - Panel Completes an investigation into a potential breach of the Code
  - Panel Produces a report on the findings of facts (whether a breach of the Code has occurred and extent of a breach) and may make recommendations to Group Director Cabrini Research
  - Group Director Cabrini Research (or independent delegate where there is conflict of interest) to decide on course of action, which may include corrective actions or other Cabrini disciplinary processes.

EVALUATION

De-identified summary reports will be reported to the Governing Body on a quarterly basis.

REVIEW

This policy will be reviewed every two years and presented to the appropriate Board sub-committee for approval. Non-material amendments may be proposed at any time and approved by the Director Research Operations.

REFERENCES and ASSOCIATED DOCUMENTS

Cabrini Policies Procedures and Protocols

Declaration of Interest Policy
Conflict of Interest Declaration Form
Conflict of interest guidance note
Values and Behaviours Policy
Managing Conduct Issues procedure
Managing Performance Issues procedure
Complaints and Grievances procedure
Conducting disciplinary meetings
Conducting meetings with staff in conflict
Fraud and Corruption Control Plan
Whistleblowing / Whistleblower Policy

Key Legislation and Standards

- Australian Code for the Responsible Conduct of Research
- National Clinical Trials Governance Framework https://www.safetyandquality.gov.au/standards/national-clinical-trials-governance-framework#the-national-clinical-trials-governance-framework
- National Statement on Ethical Conduct in Human Research
- Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders
- Catholic Health Australia Code of Ethical Standards
- International Conference on Harmonisation (ICH) Guideline for Good Clinical Practice, and Guidance for Good Clinical Practice (ICH-GCP) (Annotated by the TGA)

REVISION HISTORY

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