

## MANAGING POTENTIAL BREACHES OF THE AUSTRALIAN CODE (2018) AND RESEARCH MISCONDUCT

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### 1. BACKGROUND

All research that the Centre for Eye Research Australia (CERA) is involved in must comply with the CERA Research Policy, all relevant local, state, national and international codes of research conduct and ethical and regulatory requirements.

The [Australian Code for the Responsible Conduct of Research \(2018\)](#) (the Code), provides guidance to Institutions and Researchers for the responsible conduct of research. It encompasses principles and practices to maintain a responsible and respectful research environment. A failure to meet the principles and responsibilities set out in the Code is a breach of the Code. A breach of the Code occurs on a spectrum from minor breaches to those that are more serious. The Code sets out a framework for responding to allegations of breaches of the Code.

### 2. PURPOSE & SCOPE

The purpose of this SOP is to describe the process for managing and investigating potential breaches of the Code and, in particular, allegations of research misconduct at CERA. Serious and non-serious breaches of GCP or a clinical trial protocol that do not fulfil the criteria for serious breach of the Code (i.e., involve intentional, reckless or negligent intent) are outside the scope of this SOP (refer to *SOP Management of breaches of GCP and CAPA process*).

This SOP applies to all Staff engaged in research activities at CERA.

### 3. PROCEDURES

It is CERA's responsibility and aim to ensure that CERA's process for managing and investigating any allegation of a potential breach of the Code is proportional, fair, impartial, timely and transparent. The principles of procedural fairness and the recommended approach described in the NHMRC Guide to Managing and Investigating Potential Breaches of the Code will be followed by CERA.

All investigations will be kept confidential and all interested parties protected as far as possible. Only people directly involved in dealing with the complaint or making decisions after an investigation, will have access to information about the complaint.

A report of a potential breach of the Code is only an allegation and does not imply that there has been any actual breach of the Code or research misconduct. These will be termed "potential breaches".

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### 3.1. COMPLAINTS PROCESS

CERA Staff who are considering making a disclosure of a potential breach of the Code may seek advice from a Research Integrity Advisor (RIA) in the first instance.

Guide Term	CERA Role	Definition of Responsibilities
Responsible Executive Officer (REO)	Managing Director	A senior officer in an institution who has final responsibility for receiving reports of the outcomes of processes of assessment or investigation of potential or found breaches of the Code and deciding on the course of action to be taken.
Designated Officer (DO)	Research Governance Manager	A senior professional or academic institutional officer or officers appointed to receive complaints about the conduct of research or potential breaches of the Code and to oversee their management and investigation where required.
Assessment Officer (AO)	Research Governance Officer	A person or persons appointed by an institution to conduct a Preliminary Assessment of a complaint about research.
Research Integrity Advisor (RIA)	As recorded on <a href="#">iris</a>	A person or persons with knowledge of the Code and institutional processes nominated by an institution to promote the responsible conduct of research and provide advice to those with concerns or complaints about potential breaches of the Code. The RIA's role does not extend to investigation or assessment of the complaint.
Review Officer (RO)	Head of Commercialisation and Legal	A senior officer with responsibility for receiving requests for a procedural review of an investigation of a breach of the Code.

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Contact details of the relevant individuals can be found online on CERA's [intranet](#).

An allegation of a potential breach of the Code may arise from the following:

- a) Self-disclosure – An individual CERA Staff member may disclose information about their own research conduct that may be considered a potential breach to the Code and/or Research Misconduct;
- b) Internal complaint - A CERA Staff discloses information about another CERA Staff's research conduct that may be considered a potential breach to the Code and/or Research Misconduct;
- c) Audit- Internal or external audit activities may reveal a potential breach to the Code and/or Research Misconduct; and/or
- d) External complaint - A person external to CERA discloses information about a research conduct that may be considered a potential breach to the Code and/or Research misconduct by CERA Staff.

A person seeking to make a disclosure of an alleged breach of the Code or Research Misconduct (“Complainant”) can make a disclosure directly to the Research Governance Manager [cera-rgo@cera.org.au](mailto:cera-rgo@cera.org.au).

It is preferable that complaints are made in writing.

All Research Misconduct allegations and allegations of breaches of the Code will be referred to the DO for consideration.

### 3.2 INITIAL RECEIPT OF A COMPLAINT

After a complaint is received and acknowledged, the DO determines whether the complaint relates to a potential breach of the Code and, if it does, the matter proceeds to a 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.

### 3.3 PRELIMINARY ASSESSMENT STAGE

CERA aims to follow a clear, fair and robust process to conducting a Preliminary Assessment of a potential breach of the Code:

- a) The DO will assign the complaint to the AO. The AO is responsible for the conduct of the Preliminary Assessment (PA) and ensures timelines and consults with the DO as required. The AO collects, inventories and secures facts and information.
- b) The AO provides advice to the DO.
- c) The Preliminary Assessment advice will be considered by the DO who determines, based on facts and information presented whether the matter should be;
  - dismissed
  - resolved locally with or without corrective actions
  - referred for investigation

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- referred to other institutional processes.
- d) If a full investigation is required, the procedures set out in [Section 3.4](#) will apply.

### 3.4 INVESTIGATION STAGE

In accordance with the procedure set out in [Section 3.3](#) of this SOP, if the DO determines an investigation is required, the following steps should be taken;

- prepare a clear statement of allegations;
- develop the terms of reference for the investigation; and
- nominate an Investigator, or Investigation Panel and chair.

CERA may consider taking Precautionary Action once an allegation has been referred for investigation following a Preliminary Assessment. Precautionary Action is not a sanction against a CERA Staff or decision which is pre-emptive of the findings of an investigation. It is a decision to mitigate the risks to CERA.

The Investigation Panel should follow section 7.5 of the [NHMRC Guide to Managing and Investigating Potential Breaches of the Code](#).

Once the report is finalised, the DO will consider the findings of fact, evidence presented and any recommendations made by the Investigator or Investigation Panel. The DO will consider the extent of the breach, the appropriate corrective actions and if referral to disciplinary procedures is required. The DO will provide the final report to the REO (or appropriately delegated decision-making committee) with recommendations.

### 3.5 OUTCOMES OF THE INVESTIGATION

- a) After consideration of all factors including requesting and obtaining any further information as may be required relating to the Complaint, the REO will determine whether: No breach of the Code (including Research Misconduct) has occurred and the allegation(s) should be dismissed; or
- b) The allegation involves a breach of the Code however does not constitute Research Misconduct due to lack of intent or seriousness of the breach. In this case, the DO will provide recommendations to ensure the breach is corrected and to reduce the likelihood of any recurrence; or
- c) A case of Research Misconduct is evident. The DO, in conjunction with Human Resources, the Chief Operating Officer and the Managing Director, may determine appropriate sanctions, including disciplinary and legal action, for anyone found to have committed Research Misconduct, report investigation findings to those parties who need to know and correct the research record as may be required.

The NHMRC Research Integrity and Misconduct Policy will be followed for breaches of the Code and Research Misconduct that may have occurred in relation to NHMRC funding or in relation to a person who is a recipient of

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NHMRC funding even if the breach or Research Misconduct does not arise in relation to a project which is funded by NHMRC funding.

CERA's decision about which consequential actions may be taken will be made on a case-by-case basis depending on the scope of the findings and the level of risk involved. A principle of proportionality will be applied in all cases, and CERA aims to implement actions that are appropriate and effective in the context and circumstances of each case.

### 3.6 INTERNAL OR EXTERNAL INVESTIGATION

CERA can direct any Complaint to an independent external inquiry panel as CERA may determine to be necessary. In addition;

- a) CERA may draw on external expertise as required for participation in an internal investigation;
- b) All parties to the allegations may have a Support Person attend any interviews with him/her/them;

### 3.7 RESPONDENT

As part of an investigation, the respondent(s) is (are) provided with an opportunity to respond to the allegation(s) and relevant evidence, and to provide additional evidence upon which the Panel may rely. If the respondent(s) chooses not to respond or appear before the Panel where requested, the investigation continues in their absence. CERA's decision regarding when to notify a respondent of an investigation will be made on a case-by-case basis depending on the type of breach and investigation required.

### 3.8 DISPUTE

A request for a review of the investigation on the grounds of procedural fairness can be submitted to [cerarg@cera.org.au](mailto:cerarg@cera.org.au). The aim of the review is to affirm or deny the outcome of the investigation. A request for review must be made within 20 business days of the date on which any decisions or actions are communicated to the respondent and the complainant. Upon receipt of a request for a review, the RO will decide whether to proceed with a review, whether the review will be referred back to the Panel or to REO, and how the outcome of the review will be communicated.

Additional complaint or review mechanisms are available including an external review by the [Australian Research Integrity Committee \(ARIC\)](#) of any investigative processes used by CERA.

## 4. AUTHORITY

The Managing Director is ultimately accountable for managing all allegations of breaches of the Code within CERA.

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### 5. RELATED DOCUMENTS

Document	Location
CERA Research Policy	On iris
CERA Research Handbook	On iris
CERA Research Misconduct Invention Disclosure Form	On iris
National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)	<a href="https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018">https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018</a>
Australian Code for the Responsible Conduct of Research Conduct (2018)	<a href="https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018">https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018</a>
NHMRC Research Integrity and Misconduct Policy→	<a href="https://www.nhmrc.gov.au/research-policy/research-integrity/our-policy-misconduct">https://www.nhmrc.gov.au/research-policy/research-integrity/our-policy-misconduct</a>

### 6. DEFINITIONS

Term	Definition
Assessment Officer (AO)	A person or persons appointed by an institution to conduct a Preliminary Assessment of a complaint about research.
the Code	Refers to the National Health and Medical Research Council Australian Code for the Responsible Conduct of Research, 2018.
Breach	A failure to meet the principles and responsibilities of the Code. May refer to a single breach or multiple breaches.

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CERA Staff	Includes an employee, honorary, visiting researcher, student, volunteer or any person who has been granted any other type of appointments by CERA.
Complaint	Refers to an allegation of a breach of the Code or Research Misconduct.
Complainant	Refers to the person seeking to disclose or lodge a Complaint as defined in <a href="#">Section 3.1</a> of this SOP.
Designated Officer (DO)	A senior professional or academic institutional officer or officers appointed to receive complaints about the conduct of research or potential breaches of the Code and to oversee their management and investigation where required.
Institutional Member	Refers to a person who holds the positions as set out and defined in <a href="#">Section 3.1</a> of this SOP.
Investigator	Refers to a person who is appointed by CERA to investigate a potential breach of the Code.
Investigation Panel	Refers to the persons appointed by CERA to investigate a potential breach of the Code.
Chair	The person appointed by CERA to be a chairman of the Investigation Panel.
Precautionary Action	Precautionary action refers to any temporary action initiated by CERA to manage any risks, at any time prior to the conclusion of a research integrity matter.
Preliminary Assessment	In this SOP, the term 'Preliminary Assessment' is used to describe the gathering and evaluating of evidence to establish whether a potential breach of the Code warrants further investigation.
Research Integrity Advisor (RIA)	A person or persons with knowledge of the Code and institutional processes nominated by an institution to promote the responsible conduct of research and provide advice to those with concerns or complaints about potential breaches of the Code. The RIA's role does not extend to investigation or assessment of the complaint.
Respondent	Person or persons subject to a complaint or allegation about a potential breach of the Code.
Responsible Executive Officer (REO)	A senior officer in an institution who has final responsibility for receiving reports of the outcomes of processes of assessment or investigation of potential or found breaches of the Code and deciding on the course of action to be taken.
Research Misconduct	Means an act which is a serious breach of the Code which is also intentional, reckless or negligent.

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Review Officer (RO)	A senior officer with responsibility for receiving requests for a procedural review of an investigation of a breach of the Code.
Support Person	A person who accompanies a party to an interview.

### 7. VERSION CONTROL

Date Authorised	13 <sup>th</sup> February 2023
Review Date	13 <sup>th</sup> February 2025
Author	Research Governance Manager
Approved by	PPWG, Research Governance & Integrity Committee
Document History	
Date	Summary of Changes
20 <sup>th</sup> June 2022	N/A First issue- adapted from CERA Research Misconduct Policy dated Jul-2019 (replaced by this SOP).
7th December 2022	Revision of the SOP
13 <sup>th</sup> February 2023	Revision and updates conducted by Chrysalis