

## 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 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, and also sets out a framework for responding to allegations of breaches of the Code and research misconduct.

### 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.

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

### 3. PROCEDURES

It is CERA's responsibility and aim to ensure that CERA's process for managing and investigating potential breaches of the Code and any allegations of Research Misconduct results in a proportional, fair, impartial, timely, transparent investigation and decision for all parties involved in the allegations. The principles and processes of 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". Only a full investigation can establish that an allegation has any substance.

#### 3.1. COMPLAINTS PROCESS

A CERA Staff who is considering making a disclosure of a Research Misconduct may seek advice from one of the designated roles specified in the below Table:

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| 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 nominated 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.  |

(all referred to as “**Institutional Member**”).

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

An allegation of Research Misconduct and/or 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;

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- 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 a CERA Staff.

A person seeking to make a disclosure of an alleged breach of the Code or Research Misconduct ("Complainant") can either make a disclosure directly to an Institutional Member or via email 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, allegations of breaches of the Code and Research Misconduct Disclosure Forms lodged online will be referred directly to the DO for consideration.

### 3.3 PRELIMINARY ASSESSMENT STAGE

CERA aims to follow a clear and fair investigative procedure in the assessment of all allegations as follows:

- a) The RO and DO will jointly assess the likely truth of the allegation and decide whether the allegation is likely to constitute a possible breach of the Code or a Research Misconduct.
- b) If in the RO's and DO's reasonable opinion it is determined that further investigation is warranted, a preliminary investigation will be carried out by the DO and RO. The goal of the preliminary investigation is to gather further information relating to the allegation to present to the Research Governance and Integrity Committee for a full investigation. If a full investigation is required, the procedures set out in [Section 3.4](#) will apply.
- c) If the RO and DO decide based on their reasonable opinion that an investigation is not warranted, the Complaint and the interim decision will be ratified at the next Research Governance and Integrity Committee. Further action or an investigation can be requested by the committee at the time of ratification if the committee in its sole discretion determines that this is required.

### 3.4 INVESTIGATION STAGE

If as a result of the preliminary investigation in accordance with the procedure set out in [Section 3.3](#) of this SOP, a Complaint is presented to the Research Governance and Integrity Committee for a full investigation, the Research Governance and Integrity Committee will formally review the information and evidence presented as a result of the preliminary investigation.

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.

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After consideration of all factors including requesting and obtaining any further information as may be required relating to the Complaint, the Research Governance and Integrity Committee will issue a report based on the investigation's findings. The report may determine that:

- a) 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 Research Governance and Integrity Committee 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 Research Governance and Integrity Committee, in conjunction with Human Resources 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 and misconduct that may have occurred in relation to NHMRC funding or in relation to a person who is a recipient of 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 of the particular circumstances of each case.

### 3.5 INTERNAL OR EXTERNAL RESEARCH MISCONDUCT INQUIRY

CERA can direct any Complaint to an independent external inquiry panel as CERA may determine to be necessary. Association of Australian Medical Research Institutes (AAMRI) database of external experts may be utilised for an external inquiry.

- a) CERA may draw on external expertise as required for participation in an internal investigation;
- b) The Respondent to the allegations may have a support person attend all investigations with him/her/them;
- c) Legal representation is only allowed in an independent external inquiry;
- d) Panel members who are appointed to conduct an independent external inquiry must not be employed by CERA or be connected in any way with CERA in any circumstances which may give rise to a reasonable perception of bias.

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### 3.6 RESPONDENT

The respondent is the subject of a Complaint and must comply with the following:

- a) provide all information and answer all questions asked of them honestly and truthfully by the Institutional Members and/or the independent external inquiry panel;
- b) self-disclose any conduct which may be a breach of the Code or constitute a Research Misconduct wherever possible; and
- c) comply with the findings and follow the steps outlined in the Research Governance and Integrity Committee report. Decisions by the Research Governance and Integrity Committee are final and binding unless [section 3.7](#) applies.

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.

### 3.7 DISPUTE

Respondents may only dispute the findings of the Research Governance and Integrity Committee based on errors in the report or facts or based on conflicts of interest. All disputed findings will be referred to an independent external inquiry.

A request for a review of the investigation can be submitted to [cera-rgo@cera.org.au](mailto:cera-rgo@cera.org.au). A request for appeal may be made within 20 business days of the date on which the respondent is notified of the findings.

## 4. AUTHORITY

The DO and Managing Director are ultimately accountable for managing all allegations of breach of the Code within CERA.

## 5. RELATED DOCUMENTS

| Document   | Location |
|--|----------|
| CERA Research Policy                               | On iris  |
| CERA Research Handbook                             | On iris  |
| CERA Research Misconduct Invention Disclosure Form | On iris  |

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|---|---|
| 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.   |
| 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 a 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.   |
| 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.  |

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| 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                          | The respondent is the subject of a Complaint.   |
| 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.  |
| Review Officer (RO)                 | A senior officer with responsibility for receiving requests for a procedural review of an investigation of a breach of the Code.  |

### 7. VERSION CONTROL

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|----------------------------|--|
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