

STANDARD OPERATING PROCEDURE (SOP):

TITLE: RESEARCH MISCONDUCT - MANAGING AND INVESTIGATING POTENTIAL BREACHES OF THE AUSTRALIAN CODE FOR THE RESPONSIBLE CONDUCT OF RESEARCH



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1. PURPOSE:

The Research Policy requires that all research in which Epworth HealthCare (Epworth) is involved, complies with 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 (the Code), provides guidance to researchers for the responsible conduct of research for Institutions and Researchers. 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.

The purpose of this SOP is to describe the process for managing and investigating potential breaches of the Australian Code for the Responsible Conduct of Research (the Code) and, in particular, allegations of research misconduct at Epworth.

Research misconduct is defined as a serious breach of the Code which is also intentional or reckless or negligent.

2. SCOPE:

Protocol deviations and 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-QA-02 Management of Serious Breaches and CAPA).

3. APPLICABILITY:

This SOP is applicable to all researchers and collaborators at Epworth.

4. GLOSSARY OF TERMS:

Please refer to Epworth SOP Glossary of Terms (see Related Documents).

5. PROCEDURE:

The principles and processes of the NHMRC 'Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research (2018)' will be followed by Epworth. The following procedure describes the Epworth specific roles, responsibilities and processes for managing potential breaches of the Code, including research misconduct, at Epworth.

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. The Epworth process for managing and investigating potential breaches of the Code will be:

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- Proportional
- Fair
- Impartial
- Timely
- Transparent
- Confidential

The process for handling potential breaches of the Code is summarised in Appendix A.

5.1 Epworth Roles in the Management and Investigation of Potential Breaches

5.1.1 The following roles within Epworth will have the responsibilities of the corresponding roles listed in Table 1 of the NHMRC Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research ('The Guide'), 2018:

The Guide Term	Epworth Role	Definition of Responsibilities
Responsible Executive Officer (REO)	Chief Executive Officer	The CEO 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.
Designated Officer (DO)	Group Director of Research and Development (GDRD)	The GDRD will receive complaints about the conduct of research or potential breaches of the Code and will oversee their management and investigation, where required.
Assessment Officer (AO)	Senior staff member or researcher or nominated equivalent	A person or persons appointed by the GDRD to conduct a preliminary assessment of a complaint about research.
Research Integrity Advisor (RIA)	Clinical Institute appointees	RIAs will be appointed at the Clinical Institute (CI) level to provide advice to staff on issues relating to research practice and possible research misconduct or other Code breaches. They: a. must be familiar with this SOP and other relevant policies, procedures and the Code b. promote the responsible conduct of research

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		c. provide advice to those with concerns or complaints about potential breaches of the Code
Research Integrity Office (RIO)	Research and Development Governance Unit (RDGU)	<p>The RDGU is responsible for management and research integrity at Epworth. The RDGU:</p> <ul style="list-style-type: none">• Promotes the responsible conduct of research at Epworth• Educates and advises on the responsible conduct of research to staff and students• Supports a network of RIAs• Develops and manages processes related to the responsible conduct of research• Receives complaints about potential breaches of the Code• Supports the conduct of preliminary assessments and investigations• Promotes a consistent and robust approach to manage and investigate potential breaches of the Code.
Review Officer (RO)	Senior officer of Epworth not listed above	The RO is responsible for receiving requests for a procedural review of an investigation of a breach of the Code.

5.2 Receipt of Allegations of Research Misconduct or Code Breaches

5.2.1 Allegations of breaches of the Code and/or research misconduct must be handled carefully and all interested parties protected as far as possible. Interested parties may include:

- The person bringing the allegation (the complainant)
- The person against whom the allegation is made (the Researcher)
- Participants in clinical research whose interests may be affected

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- Research students and other colleagues with the person concerned
 - Journals in which allegedly fraudulent papers have been or may be about to be published
 - Funding bodies
 - In some case, the public
- 5.2.2 Allegations should be made to the GDRD, preferably in writing, and if received elsewhere must be referred to the GDRD. The GDRD may refer minor breaches of the Code to the Cls for resolution.
- 5.2.3 If a verbal complaint is received, this must be documented. The RDGU can assist the complainant to lodge a written complaint.
- 5.2.4 Anyone who forms a reasonable suspicion that a breach of the Code and/or research misconduct has occurred, must act in a timely manner.
- 5.2.5 The GDRD will review the allegation and determine whether it relates to a potential breach of the Code and, if it does, the matter should proceed to a preliminary assessment.
- 5.2.6 Allegations must be handled carefully and all interested parties protected as far as possible.

5.3 Summary Dismissal

- 5.3.1 If upon receipt of an allegation, the GDRD concludes that it lacks substance and could not, even if proved, amount to either research misconduct or a Code breach, the GDRD may summarily dismiss the allegation and take no further action.

5.4 Anonymous Complaints

- 5.4.1 An anonymous allegation of a breach will not ordinarily initiate a formal review but should still be considered, based on the information provided.
- 5.4.2 In some cases, a complainant may not wish to be identified as the source of the allegation. They may not wish the Researcher, anyone involved in the review, or other third parties, to know their identity. This may be because the complainant believes there will be recriminations if they are identified. If this is the case, everyone involved in the processing of the matter should, if possible, abide by the complainant's wishes. It should be explained to the complainant that:
- There may be practical limitations to this confidentiality (e.g. if a party seeks access to their identity through legal action)

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- Removing information that might enable the complainant to be identified by inference, might limit the effectiveness of the review of the allegations
- Issues of natural justice may necessitate revealing the identity of the complainant to the Researcher.

5.5 Preliminary Assessment of a Potential Breach of the Code and/or Research Misconduct

- 5.5.1 A formal complaint should be made by letter or email to the GDRD.
- 5.5.2 Upon receipt, the GDRD or delegate will log the complaint in [RiskMan](#).
- 5.5.3 The GDRD will assign the complaint to a suitable senior staff member or senior researcher (the Assessment Officer – the AO). The AO is responsible for the conduct of the preliminary assessment, ensures timeliness and consults with the GDRD as required. The AO should identify, collect and secure facts and information on the complaint. It may be necessary to discuss the matter with the Researcher in question during the preliminary assessment to clarify the facts and/or information. In this case the AO notifies the Researcher and provides:
- Sufficient detail for the Researcher to understand the nature of the complaint
 - An opportunity to respond in writing within a nominated timeframe
 - A record of meetings should be prepared and the Researcher provided with a copy
- 5.5.4 The AO should consider consulting others at Epworth and the involvement of those in supervisory roles in the potential breach.
- 5.5.5 The AO must provide written advice to the GDRD which should include the following:
- A summary of the preliminary investigation
 - An inventory of the facts and information gathered and analysed
 - An evaluation of the facts and information
 - How the potential breach relates to the Code and/or Epworth processes
 - Recommendations for further action
- 5.5.6 The GDRD will review the advice and documents provided by the AO and decide whether the matter should be:
- Dismissed

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- Resolved locally with or without corrective actions
 - Referred for investigation
 - Referred to other Epworth processes
- 5.5.7 If the preliminary assessment does not support a referral of an allegation of a breach of the Code for investigation, the following actions should be considered:
- If the complaint has no basis in fact, then efforts, if required, must be made to restore the reputation of affected parties
 - Frivolous, vexatious, malicious allegations of either breaches or research misconduct will not be tolerated or investigated by Epworth. Persons making such allegations may be the subject of disciplinary actions.
 - Epworth will investigate any systemic issues that have been identified
- 5.5.8 If the Researcher admits the breach of the Code, it may still be necessary to conduct a further investigation to identify appropriate corrective actions, any other parties who may be complicit or other necessary steps. The Researcher may also leave Epworth; however, it is still the responsibility of Epworth to address the complaint.
- 5.5.9 The GDRD should provide the outcomes, if appropriate, to the Researcher and the complainant at the conclusion of the preliminary assessment in a timely manner.

5.6 Investigation of a Potential Breach of the Code and/or Research Misconduct

- 5.6.1 If further investigation is needed, the GDRD will:
- Prepare a clear statement of allegations
 - Develop the terms of reference for the investigation
 - Nominate the investigation Panel and Chair in consultation with the Executive Director (ED) of Academic and Medical Services (AMS)
 - Seek legal advice on matters of process

5.6.2 Composition of the Panel

- 5.6.2.1 The GDRD will convene an expert Panel which may draw upon suitably qualified people from both within Epworth and externally. In some instances, external representation may be the most appropriate course of action to guarantee the independence of the Panel. Legal counsel will be made available to the expert Panel to guide their work.

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5.6.2.2 The Panel will be provided with all relevant information and documentation.

5.6.2.3 All Panel members will be appointed in writing and external members will be appropriately indemnified by Epworth.

5.6.2.4 The RDGU will support the Panel by:

- Notifying all those that are required to attend or participate in the investigation, in particular the Researcher
- Provide the Panel with relevant documentation
- Ensures the Panel works within Epworth processes
- Schedules meetings and records interviews
- Provides relevant written information to the Researcher and relevant others
- Assists the Panel

5.6.2.5 Once potential Panel members have been selected, the GDRD will advise the Researcher of the composition and provide an opportunity for the respondent to raise concerns.

5.7 Conduct of the Investigation

5.7.1 The investigation will be conducted according to the principles of procedural fairness and will follow the processes of the Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research (2018): Section 7.5 Conduct of the Investigation.

5.7.2 The Researcher will be provided with a written statement of the allegations of the suspected breach and the suggested action to follow. Where appropriate, the approving HREC of any trial will be notified by the GDRD or delegate that a formal investigation is underway noting that no findings have been made at this stage.

5.7.3 The Researcher will have ten (10) working days in which to respond to the allegations.

5.7.4 The expert Panel will review the allegations in the light of the Researcher's response to them. The Researcher may be asked to attend a meeting to respond to the allegations in person and to provide additional supporting information.

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5.7.5 Outcomes from the Investigation

5.7.5.1 The expert Panel will provide a draft written report to the GDRD, which contains findings of fact and recommendations regarding whether to dismiss or uphold the allegations or any part of them. The GDRD will consult with the ED of AMS and provide a final report to the CEO.

5.8 Finding of Breach of the Code

- 5.8.1 The CEO will determine whether a breach of the Code has occurred and decides on the extent of the breach. The CEO will also decide on the course of action, which may include corrective actions, referral to the Epworth disciplinary processes and/or other Epworth processes.
- 5.8.2 The GDRD will notify the Researcher and complainant and put into action the recommendation(s) of the CEO. This will involve notification of the HREC that approved the trial so that they may make a determination of any impact the findings have on the continued ethical acceptability of the trial or those involved in it. It may also involve notification of any other academic institutions, funding bodies, journals or colleges that may have an interest in knowing about the breach.
- 5.8.3 The CEO should consider whether a public statement is appropriate to communicate the outcome of the investigation.
- 5.8.4 The GDRD will table a report of the investigation, its findings and recommendations to the ERAC at its next meeting. This will also be tabled as a board report by the ERAC board member for noting.

5.9 General Conduct of an Investigation

- 5.9.1 The GDRD will ensure that the complainant and Researcher receive appropriate communication at all times during the process.
- 5.9.2 At all stages outlined in these processes, comprehensive records about all allegations, the processes followed and the outcome/resolution must be maintained by those conducting the inquiry.
- 5.9.3 Epworth will not tolerate any reprisal action against staff who accurately and honestly report possible breaches or research misconduct. In assessing and dealing with reports, Epworth will consider the possibility of reprisal action and seek to minimize its occurrence. If a staff member is concerned about the possibility of reprisal action, they should raise the matter with the GDRD.

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5.10 Appeals

- 5.10.1 When communicating the outcome of an investigation, the GDRD will inform the Researcher, and possibly the complainant if they are directly affected by the outcome, of their right to request a review and how to lodge a request for review, including timeframes and the information required for a request to be considered.
- 5.10.2 Only requests for a review of a Code investigation on the grounds of procedural fairness will be considered.
- 5.10.3 The Researcher has the right to request a review of the investigation. A formal, written request for review of the investigation from the Researcher should be sent to the ED of AMS within 30 days of the final investigation report being issued.
- 5.10.4 The ED of AMS shall appoint a Review Officer (RO). The RO shall be a senior manager from within Monash Partners with responsibility for receiving requests for procedural review of an investigation of a breach of the Code.

6. REFERENCES:

- 1. Australian Code for the Responsible Conduct of Research (2018) (the 2018 Code).
<https://nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018>
- 2. Guide to Managing and Investigating Potential Breaches of the Code
<https://nhmrc.gov.au/about-us/publications/guide-managing-and-investigating-potential-breaches-code>

7. RELATED DOCUMENTS:

7.1 Related Forms and Templates

7.2 Related SOPs

- SOP-QA-02 Management of Serious Breaches and CAPA
- SOP-Glossary-of-Terms

8. VERSION CONTROL

Document History	
Version	Summary of Changes
1.0	N/A - First issue

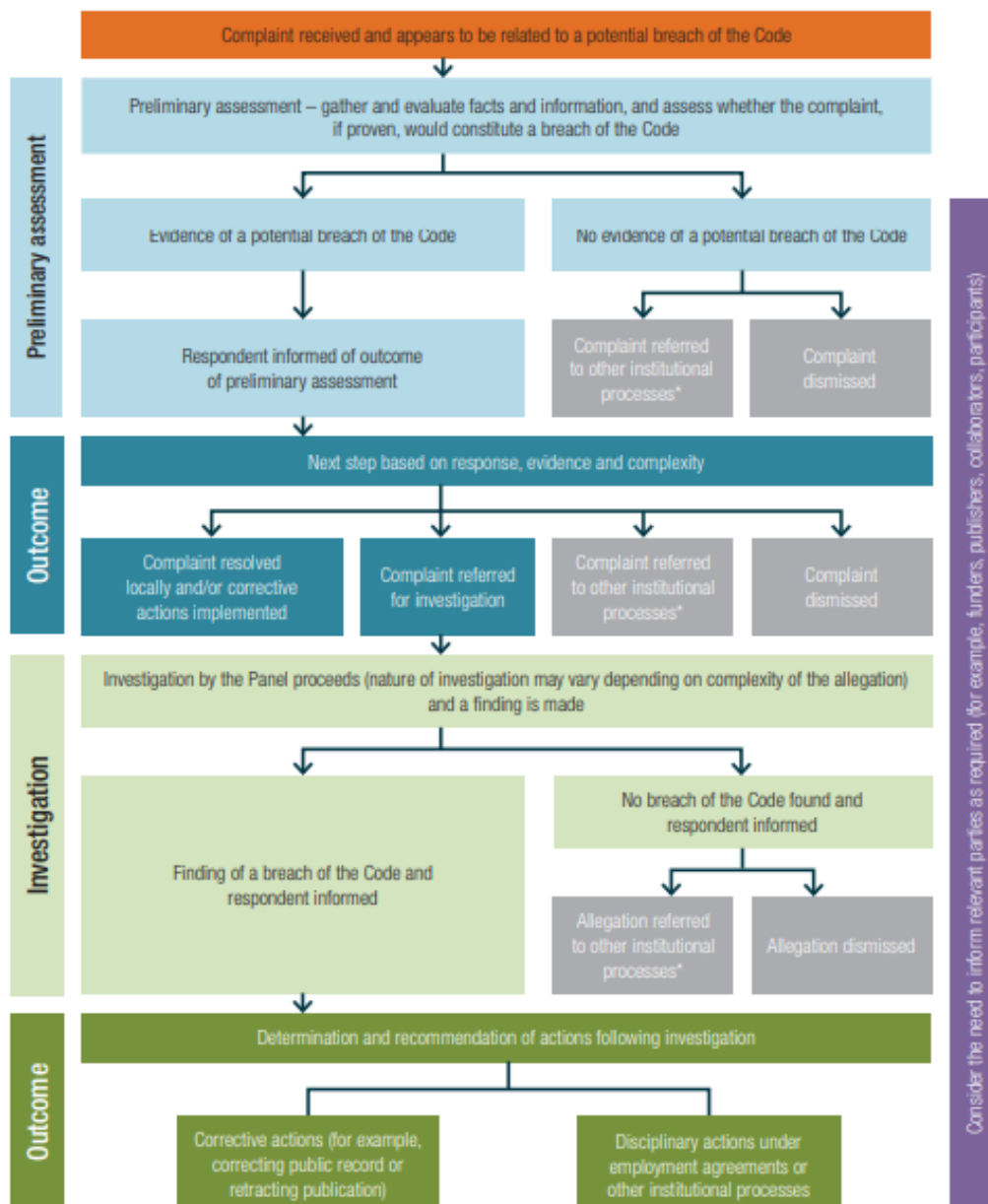
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APPENDIX A: Overview of the Epworth Approach to Dealing with a Potential Breach of the Code



Consider the need to inform relevant parties as required (for example, funders, publishers, collaborators, participants)