

PROCEDURE

Managing Potential Breaches – Research Conduct

Scope (Staff):	All CAHS and Telethon Kids Institute (TKI) employees who seek to conduct research at CAHS.
Scope (Area):	All CAHS sites, and TKI for collaborative research

Child Safe Organisation Statement of Commitment

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

This document should be read in conjunction with DOHWA Research Policy Framework

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Compassion

Aim

This procedure is designed to ensure that all complaints related to the conduct of research are considered with procedural fairness, to adopt a consistent approach across both organisations, and to minimise duplication in managing potential breaches of <u>The Australian Code for the Responsible Conduct of Research</u> (The Code).

Risk

The risk of not complying with this procedure, include:

- Increased risk of client / patient / participant harm.
- Non-compliance with legislation and WA Health Department policy.
- Risk of legal claims including trespass to the person (assault and battery) and/or negligence.
- Damage to CAHS' reputation.

Definitions

Definitions		
Allegation	A claim or assertion arising from a preliminary assessment that there is a prima facie case to believe a breach of <u>the Code</u> has occurred. May refer to a single allegation or multiple allegations	
Balance of probabilities	The civil standard of proof, which requires that, on the weight o evidence, it is more probable than not that a breach has occurred	
Breach	A failure to meet the principles and responsibilities of <u>the Code</u> . May refer to a single breach or multiple breaches.	
CAHS	Child and Adolescent Health Service, which includes the Perth Children's Hospital and all CAHS community and remote sites.	
Complaint	A concern, grievance or complaint about the conduct of research.	
Complainant	A person or persons who has made a complaint about the conduct of research.	
NHMRC	National Health and Medical Research Council is a national organisation who provides a framework for research integrity and development.	
Panel	Refers to the person or persons appointed by an institution to investigate a potential breach of <u>the Code</u> .	

Definitions				
Procedural fairness	That a fair and proper procedure is used when making a decision.			
Research	The concept of research is broad and includes the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies, inventions and understandings. This could include synthesis and analysis of previous research to the extent that it is new and creative.			
Respondent	Person or persons subject to a complaint or allegation about a potential breach of <u>the Code</u> .			
ткі	Telethon Kids Institute			

Principles

Child and Adolescent Health Service (CAHS) and Telethon Kids Institute, as campus and research partners, endorse <u>the Code</u>.

These procedures are based on and will be read in conjunction with <u>the Code</u>, <u>the</u> <u>Guide to Managing and Investigating Potential Breaches of the Australian Code for the</u> <u>Responsible Conduct of Research</u> (the Investigation Guide) and relevant institutional policies, including the current relevant employment contracts and Awards.

1. Scope

- 1.1. This procedure applies to all CAHS and Telethon Kids Institute staff, past and present (paid or unpaid, voluntary or honorary appointments) who are engaged in research in any location or site or facility, whether in or outside of Australia.
- 1.2. Complaints regarding the conduct of students in research will be referred to their enrolling institution.
- 1.3. An investigation under this procedure constitutes an investigation under:
 - 1.3.1. The Code and Investigation Guide,
 - 1.3.2. CAHS Formal Grievance Resolution Process outlined in the <u>Employee</u> <u>Grievance Resolution</u>,
 - 1.3.3. <u>Telethon Kids Institute Grievance Handling Policy.</u> (Link accessible to Telethon Kids Institute staff only)

2. Responsibilities

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. 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. Assessment Officer (AO) A person or persons appointed by an institution

to complaint about research.

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.

3. Procedure

3.1 Concerns about research conduct

- 3.1.1. Anyone who has a concern about the conduct of research will seek to resolve their complaint directly with the responsible party, if they believe it is appropriate to do so.
- 3.1.2. Where 3.1.1 is not appropriate, anyone who has a concern about the conduct of research will, within a timely manner, discuss their concern with their line manager.

3.1.3. If the line manager has a conflict of interest the concern will be discussed with a Research Integrity Advisor.

3.2. Lodging a complaint

- 3.2.1. Anyone may lodge a complaint about matters concerning the conduct of research.
- 3.2.2. Complaints about the conduct of research will be lodged either verbally or in writing to CAHS Director of Research Operations via the Research Department (<u>cahs.rgo@health.wa.gov.au</u>),, Telethon Kids Institute Research Integrity (<u>researchintegrity@telethonkids.org.au</u>), or online via the <u>Telethon Kids Institute Feedback or Complaints Form</u> (Link accessible to Telethon Kids Institute staff only).
 - 3.2.2.1. Complaints received via the Telethon Kids Institute Feedback or Complaints Form will be managed in accordance with the Feedback and complaints handling procedure.
- 3.2.3. A complainant may consider making a public interest disclosure to a Proper Authority, in accordance with the <u>Public Interest Disclosure Act</u> (WA) 2003 and/or through Telethon Kids Institute <u>Whistleblower Policy</u>.

3.3. Managing a complaint

- 3.3.1. Complaints about the conduct of research will be processed and investigated in accordance with the process described in <u>The Code</u> and <u>Investigation Guide</u>, <u>Telethon Kids Institute Grievance Handling</u> <u>Policy</u> (TKI staff only),CAHS <u>Employee Grievance Resolution</u> procedure and where relevant employment contract or Award.
- 3.3.2. After the complaint is received, the DO will determine whether the complaint relates to a potential breach of <u>The Code</u> and, if it does, the matter proceeds to preliminary assessment.
- 3.3.3. If the matter proceeds to preliminary investigation, the DO will assign the complaint to a suitable AO, either internal or external to the institutions, to conduct the preliminary assessment in a timely manner.
 3.3.3.1. The DO may also function as the AO.

- 3.3.4. On completion of the preliminary assessment, and on the recommendation of the DO, the REO will determine, on the balance of probabilities, whether the matter should be:
 - 3.3.4.1. dismissed,
 - 3.3.4.2. resolved locally with or without corrective actions,
 - 3.3.4.3. referred for investigation, or
 - 3.3.4.4. referred to other institutional processes e.g.
 - Line Manager or Executive Director
 - Open Disclosure policy (if patient/participant impact)
 - Human Resources
 - Integrity & Ethics
- 3.3.5. If the matter is referred for investigation, the REO will authorise a suitable panel, either internal or external to the institutions, to undertake the investigation.
- 3.3.6. On completion of the investigation, on the recommendation of the DO, the REO will determine, on the balance of probabilities:
 - 3.3.6.1. finding of no breach of <u>The Code</u>, and/or
 - 3.3.6.2. finding of a breach of <u>The Code</u>.
- 3.3.7. Actions may be undertaken to correct the research record and inform relevant parties of any outcomes pertaining to the complaint.
- 3.3.8. If at any time it becomes apparent that the complaint relates to an activity that could harm humans, animals or the environment, immediate action will be taken to minimise the risk of harm which may include, but is not limited to, suspension of the research associated with the complaint.

3.4. Multi-institutional

- 3.4.1. Where the complaint extends across both CAHS and Telethon Kids Institute jurisdictions, the matter will be investigated jointly.
 - 3.4.1.1. Decisions related to this procedure will be made jointly by the appropriate decision maker/s.
 - 3.4.1.2. Decisions related to institutional procedures, including the CAHS <u>Employee Grievance Resolution</u> procedure and Telethon Kids Institute <u>Grievance Handling Policy</u> (link

accessible to Telethon Kids Institute staff only), will be made by the appropriate decision maker at the relevant institution.

- 3.4.2. Where the complaint is limited to a single institution, that institution will take responsibility for the investigation of the complaint in accordance with this procedure and relevant institutional policies.
- 3.4.3. Where the complaint does not relate to CAHS or Telethon Kids Institute, the matter will be referred to the relevant institution as appropriate.

3.5. Reporting requirements

- 3.5.1. Where applicable, the DO will report or refer the complaint to regulatory bodies and other agencies, including but not limited to the <u>Western Australian Public Sector Commission</u>, the <u>WA Crime and</u> <u>Corruption Commission</u>, <u>National Health and Medical Research</u> <u>Council</u>, <u>Australian Research Council</u>, <u>National Institutes of Health</u>, regulators and/or funding bodies in accordance with their policies.
- 3.5.2. Details of complaints, decisions, reports and other information or evidence may be shared between CAHS and Telethon Kids Institute for the purposes of cross-institutional honesty, rigour, transparency, fairness, respect, recognition, accountability and promotion.

3.6. Appeals

- 3.6.1. Appeals, or requests for review of an investigation, can only be considered on the grounds of procedural fairness.
- 3.6.2. Appeals can be made through the following mechanisms:
 - 3.6.2.1. Request a review through the <u>Australian Research Integrity</u> <u>Committee</u>.
 - 3.6.2.2. Make a complaint to the Ombudsman WA.

References and related external legislation, policies, and guidelines

ARC Research Integrity Policy

Australian Research Council

Australian Research Integrity Committee

DOH WA Research Policy Framework

Guide to Managing Potential Breaches of the Code

National Health and Medical Research Council

National Institutes of Health

NHMRC Research Integrity and Misconduct Policy

Ombudsman WA

Public Interest Disclosure Act (WA) 2003

<u>Telethon Kids Institute Feedback and complaints handling procedure</u> (link accessible to Telethon Kids Institute staff only)

<u>Telethon Kids Institute Grievance Handling Policy</u> (link accessible to Telethon Kids Institute staff only)

Telethon Kids Institute Whistleblower Policy

WA Crime and Corruption Commission

WA Health Grievance Resolution Policy

Western Australian Public Sector Commission

Related CAHS internal policies, procedures and guidelines

Employee Grievance Resolution (CAHS Policy Manual)

Investigator Responsibilities – Research (CAHS Policy Manual)

Research Policy (CAHS Policy Manual)

This document can be made available in alternative formats on request.

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