

Guide to managing and investigating potential breaches of The Aurum Project Code for the Responsible Conduct of Research 2020

The Aurum Project
107/20 Dale St
Brookvale NSW 2100
02 99059415
info@aurumproject.org.au
www.aurumproject.org.au

The Aurum Project is a not-for-profit organisation dedicated to natural medicine research and is the peak body for homeopathy research in Australia. ABN 45162173707 Registered with the ACNC.

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Source: National Health and Medical Research Council Australia

Terms and abbreviations used in this guide

The Aurum Project (AP)

The Aurum Project Code for the Responsible Conduct of Research (AP Code)

Complementary and Alternative Medicine (CAM)

Designated Officer (DO)

The person appointed to receive complaints about conduct of research or potential breaches of AP Code and to oversee management and investigation where required.

Research Integrity Officer (RIO)

The person with knowledge of AP Code and processes, nominated by The Aurum Project to promote the responsible conduct of research and provide advice to those with concerns or complaints about potential breaches of AP Code.

Introduction

Australian and international members of the Complementary and Alternative Medicine (CAM) community have an expectation that research must be conducted responsibly, ethically and with integrity.

The Australian Code for the Responsible Conduct of Research published by the National Health and Medical Research Council has established a framework for responsible research conduct.

The Aurum Project (AP) acknowledges the *Australian Code for the Responsible Conduct of Research* and has adapted it in this document for the conduct of research into CAM. Called The Aurum Project Code for the Responsible Conduct of Research (AP Code).

The primary responsibility for ensuring the integrity of research lies with individual researchers and AP. AP Code sets out principles and responsibilities that both researchers and AP are expected to follow when conducting research.

AP Code provides the Australian CAM community, and those responsible for funding research, with confidence in the integrity of research. This AP Code does not incorporate the laws, regulations and guidelines and other codes of practice that apply to the conduct of research. Those responsible for the conduct of research are expected to be aware of and comply with them.

A breach of AP Code occurs when there is a failure to meet principles and responsibilities on a spectrum from minor breaches to those that are more serious. A serious breach of AP Code implies one that is carried out with intent, recklessness or negligence and may be referred to as research misconduct.

This *Guide to Managing and Investigating Potential Breaches of the AP Code* outlines the methods used to investigate and manage potential breaches and determine any corrective actions to ensure the integrity of the research record.

Compliance with AP Code is a requirement for inclusion in an AP Research Team, individual or collaborative research and auspiced research activity by AP or receipt of AP research funding.

AP has a responsibility for the prevention, detection, investigation and resolution of complaints about the conduct of that research.

This Guide applies to departures from the principles and responsibilities of AP Code by researchers, which are referred to as breaches.

This Guide provides examples of the range of behaviours that can constitute a breach of AP Code. The seriousness of a breach is to be determined on a case-by-case basis and requires good judgement, careful deliberation and an appreciation of the context and accepted academic disciplinary norms. This Guide describes the rigour required when investigating potential breaches of AP Code and provides a benchmark for the Australian Research Integrity Committee (ARIC) to assess AP processes used to investigate a potential breach of AP Code.

Investigations must be proportional, fair, impartial, timely, transparent and confidential. Investigations must also result in findings of fact to determine whether a breach of AP Code has occurred.

AP conducts its research activity using Teal Organisation principles and an AP structure called Research Pods (Pods). Please refer to the <u>Aurum Project Teal Organisational Theory Statement</u> for more details of Teal organisations and how this applies to AP.

To be consistent with AP Code, responsibilities of AP are to:

- promote a culture that fosters and values responsible conduct of research
- demonstrate processes that enable a complainant to lodge complaints formally in the knowledge that these will be addressed sensitively and with care, to avoid adverse consequences for the individual
- ensure those involved in the management and investigation of potential breaches of AP
 Code have the requisite expertise and are appropriately resourced
- address any systemic issues relating to matters of research integrity
- implement corrective actions
- consider advising other institutions of the outcome of a preliminary assessment or investigation where appropriate.

Breaches of AP Code

A breach is defined as a failure to meet the principles and responsibilities of AP Code, and may refer to a single breach or multiple breaches. Breaches of AP Code occur on a spectrum, from minor to major. Major breaches would typically require investigation while some minor breaches may be addressed at the preliminary assessment stage. There are also some matters that relate to research administration that can easily be rectified at the local level and resolved prior to considering a preliminary assessment. Unintentional administrative errors, clerical errors or oversights are some examples of this.

Research misconduct does not include honest differences in judgement. Unintentional errors do not usually constitute research misconduct unless they result from behaviour that is reckless or negligent.

In considering the seriousness of a breach of AP Code, the level of experience of the researcher and the extent of the departure from accepted practice must be taken into account.

Examples of breaches of AP Code include, but are not limited to, the following:

Not meeting required research standards

- Conducting research without ethics approval or failing to conduct research as approved by an appropriate ethics review body
- Conducting research without the requisite approvals, permits or licences
- Misuse of research funds
- Concealment or facilitation of breaches (or potential breaches) of AP Code by others

Fabrication, falsification, misrepresentation

- Fabrication, falsification or misrepresentation of research data or source material
- Falsification and/or misrepresentation to obtain funding

Plagiarism

- 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 acknowledgment of the source

Research data management

- Failure to appropriately maintain research records
- Inappropriate destruction of research records, research data and/or source material
- Inappropriate disclosure of, or access to, research records, research data and/or source material

Supervision

 Failure to provide adequate guidance or mentorship on responsible research conduct to researchers or research trainees under their supervision

Authorship

- Failure to acknowledge the contributions of others fairly
- Misleading ascription of authorship including failing to offer authorship to those who
 qualify or awarding authorship to those who do not meet the requirements

Conflicts of interest

• Failure to disclose and manage conflicts of interest

Peer review

• Failure to conduct peer review responsibly

Principles of procedural fairness

The principles of procedural fairness (also referred to as natural justice) apply to managing and investigating potential breaches of AP Code. These principles encapsulate the hearing rule (an opportunity to be heard), the rule against bias (decision-makers do not have a personal interest in the outcome) and the evidence rule (decisions are based on evidence).

Managing and investigating potential breaches of AP Code should be conducted in a way that is:

- Proportional to the extent of the potential breach of AP Code.
- Fair to all involved
- Impartial
- Timely to avoid undue delays and to mitigate the impact on those involved.
- Transparent, readily available and/or provided to respondents, complainants, all
 employees and students engaged in research. Accurate records should be maintained
 for all parts of the process, with records held centrally and in accordance with the
 relevant legislation.
- Confidential and not disclosed unless required.

Aurum Project roles

AP will need to identify and clearly document the roles and responsibilities of those involved in the management and investigation of potential breaches of AP Code and should indemnify individuals involved in the investigation process appropriately.

Key roles recommended for the investigation and management of potential breaches of AP Code will be adapted and delegated according to the particular circumstances at the time.

Key roles will be drawn from those filling the positions of Director, Management committee, Advisory group, Research Integrity Officer and the Research Co-ordinator.

Research Integrity Officer (RIO)

AP has an RIO to promote the responsible conduct of research and provide advice to those with concerns about potential breaches of AP Code. The role of RIO includes informing someone with concerns about research conduct about the relevant institutional processes and available

options, including how to make a complaint. Outcomes of the discussion between the RIO and the complainant may include:

- not proceeding if the complaint is clearly not related to a breach of AP Code
- proceeding under other institutional processes
- making a complaint about a potential breach of AP Code in writing to the Director.

The RIO has research experience, analytical skills, empathy, good communication skills, knowledge of AP processes and AP Code, and familiarity with accepted practices in research.

The RIO is not to advise on matters where they have a potential, perceived or actual conflict of interest.

The RIO's role does not extend to investigation or assessment of the complaint, including contacting the person who is the subject of that complaint or being involved in any subsequent investigation other than as witness or to provide testimony.

Consideration and management of complaints

Complaints may be dismissed at any stage for a variety of reasons, including if the complaint appears to have been made in bad faith or is vexatious. Alternatively, a complaint may trigger other processes or require immediate action if corrupt or criminal behaviour is potentially involved or if it relates to an activity that could harm humans, animals or the environment).

It is important to document all decisions and reasons for those decisions. These decisions include, but are not limited to, whether to proceed to a preliminary assessment, whether to investigate a complaint or whether to cease investigating a complaint.

Initial receipt of complaints

Complaints may arise from a range of sources, including from AP itself. The process for submitting, receiving and documenting a complaint about a potential breach of AP Code should address: where to lodge a complaint, how written and verbal complaints are managed and documented, the limitations of submitting anonymous complaints and/or complaints lodged by a third party and what information should be provided, and in what form, to enable a preliminary assessment.

The complainant should be encouraged to provide all information they hold pertinent to the complaint; however the process of making a complaint should not be onerous. The complainant is not required to identify parts of AP Code or relevant processes that may have been breached. AP may assist the complainant to lodge a complaint.

Where a complainant chooses not to proceed with a complaint, AP still has an obligation to assess the nature of the complaint and whether to proceed to a preliminary assessment.

After the complaint is received, it is determined whether the complaint relates to a potential breach of AP Code and, if it does, the matter proceeds to preliminary assessment.

While anonymous complaints may make subsequent processes more challenging, they may nonetheless identify potential breaches of AP Code and therefore should still be considered, based on the information provided.

To avoid compromising the assessment, anyone involved in managing a complaint should not share information unless required.

Depending on the nature of the complaint, relevant legislation may protect the complainant, for example, 'whistle-blower' or 'public interest disclosure' legislation.

Where complainants have only a general concern in the matter, it may be sufficient to provide minimal details to them to convey the outcome. These complainants will generally not have direct interests at stake and will not be directly affected by the outcome (for example, someone conducting peer review on a paper).

Preliminary assessment stage

The preliminary assessment is critical and serves as a filter to allow identification of matters that require further investigation and those that can be appropriately handled through other processes. The checklist in Appendix 1 outlines a comprehensive approach to conducting a preliminary assessment.

Expertise may be required from other sources, such as researchers from the same or aligned disciplines, especially where the complaint relates to specific disciplinary practice (for example, authorship).

A record of meetings should be prepared and the respondent provided with a copy.

On completion of the preliminary assessment, written advice should include:

- a summary of the process that was undertaken
- an inventory and evaluation of the information that was gathered and analysed
- how the potential breach relates to the principles and responsibilities of AP Code and/or institutional processes
- recommendations for further action.

Investigation stage

The purpose of the investigation is to assess whether a breach of AP Code has occurred, the extent of the breach and the recommended actions. This is done by examining the preliminary assessment, and gathering and examining further relevant evidence if required.

After it is determined that an investigation is required, the following steps should be taken:

- prepare a clear statement of allegations
- develop the terms of reference (see checklist in Appendix 2)
- nominate the investigation Panel and Chair when the Panel is more than one person
- seek legal advice on matters of process where appropriate.

A range of factors should be considered when determining the size and composition of the Panel including the potential consequences for those involved and the seniority of those involved. These factors will affect the level of independence that is required of members from both AP, the respondent and complainant. Some or all members may be external to AP.

Once potential Panel members have been selected, the respondent will be advised of the Panel's composition and provided an opportunity to raise concerns.

Once the Panel is established, it should be provided with all relevant information and documentation. A sample checklist is at Appendix 3.

It is expected that all Panel members are appointed in writing and external members are appropriately indemnified.

Members of the Panel are expected to:

- follow the procedure established for the Panel
- work within the terms of reference for the Panel
- respect any undertakings of confidentiality
- adhere to the principles of procedural fairness
- complete the investigation in a timely manner
- prepare a written report.

Appropriate resources are to be provided to the Panel including support to maintain the record of evidence.

Conduct of the investigation

Where the Panel is of the view that a party may be unable to represent themselves adequately due to the complexity of the matter, the Panel may need to take extra steps to ensure a fair investigation. This may include allowing extra time for parties to consider matters or encouraging a greater reliance on written evidence.

Where the process includes a support person, their role is to provide personal support, within reasonable limits, to the respondent and/or complainant. Their role is not to advocate, represent or speak on the other person's behalf. However, there may be times when a respondent and/or complainant requires a higher level of involvement from the support person and the Panel should consider this on a case-by-case basis.

The principles of procedural fairness do not include a right to legal representation, and the Panel should consider carefully whether to permit legal or specialist representation on request and on a case-by-case basis.

If the Panel allows a party or parties to have legal representation, the Panel should consider whether it also needs to be assisted with a similar level of representation. Legal representation may extend the timeframe of the investigation, increase the costs and overly formalise the investigation. Regardless of whether parties are legally represented, the investigation is not a court of law and cannot make legally binding findings.

As part of the investigation, the respondent should be provided with an opportunity to respond to the allegation and relevant evidence, and to provide additional evidence upon which the Panel may rely. If the respondent chooses not to respond or appear before the Panel where requested, the investigation continues in their absence. The complainant may also be given the opportunity to see relevant evidence used in the investigation (e.g., if they are directly affected by the investigation).

During its initial meeting, the Panel should:

- disclose and manage relevant interests
- be provided with all available information that will inform the investigation, which includes: the initial complaint
- the report of the preliminary assessment
- records of any communications on the matter
- develop an investigation plan (described in Appendix 3).

All those asked to give evidence are to be provided with relevant, and if necessary de-identified, information including:

- the schedule of meetings and/or hearings they are asked to attend
- the relevant parts of the terms of reference for the investigation, if appropriate
- advice as to how the Panel intends to conduct interviews
- whether they may be accompanied by a support person
- advice about whether the interviews will be recorded
- whether an opportunity will be provided to comment on matters raised in the interview
- disclosing interests
- the confidentiality requirements
- the Panel's procedures.

The Panel is to determine whether, having regard to evidence and on the balance of probabilities, the respondent has breached AP Code. To do this, the Panel:

- assesses the evidence (including its veracity) and considers if more may be required
- may request expert advice to assist the investigation
- arrives at findings of fact about the allegation
- identifies whether the principles and responsibilities of AP Code have been breached

- considers the seriousness of any breach
- provides a report into its findings of fact consistent with its terms of reference
- makes recommendations as appropriate.

If the Panel finds during the investigation that the scope and/or the terms of reference are too limiting, it should refer the matter to the Director who may decide to amend the scope of the investigation and the terms of reference. Should this occur, the respondent and relevant others are to be advised, and the respondent given the opportunity to respond to any new material arising from the increased scope.

Outcomes from the investigation

On completion of the investigation, the Panel prepares a draft written report of the investigation. Given that the report will be relied on to make a decision about whether a breach of AP Code has occurred, it is essential that the report is accurate, fully addresses the terms of reference, and includes any recommendations (see Appendix 4 for a sample checklist for the report of the investigation findings). The draft report, should be provided to the respondent with a reasonable timeframe to comment. The timeframe given should reflect the complexity of the matter. The draft report, or a summary of the information, may also need to be provided to the complainant if they will be affected by the outcome.

Finding of no breach of AP code

- If the allegation has no basis in fact then efforts must be taken to restore the reputations of those alleged to have engaged in improper conduct
- If an allegation is considered to have been frivolous or vexatious, action to address this with the complainant should be taken

Finding of a breach of AP Code

In the case of joint, adjunct and/or honorary appointments of the respondent, AP should follow processes relating to these appointments and should consider seeking legal or other expert advice in relation to the management of these appointments with other institutions.

All efforts should be taken to correct the public record of the research, including publications if a breach of AP Code has affected the accuracy or trustworthiness of research findings and their dissemination.

The Panel is encouraged to come to a consensus. If there are dissenting view(s), there should be opportunity for the Panel member to provide this view for inclusion in the draft and final report. As the dissenting view forms part of the draft report, it must be provided to the respondent and in some circumstances the complainant, if they will be affected by the outcome.

Communicating the findings

Any decisions or actions are to be communicated to the respondent and the complainant. Subsequent actions may include informing relevant parties (such as funding bodies, other relevant authorities or other institutions) of the outcome.

In cases where the respondent resigns, the institution still has an obligation to address the findings of the investigation. The matter may also need to be referred to the new employing institution. In this case, seeking legal advice should be considered to ensure that any information disclosure can be made and is done appropriately and lawfully.

Mechanisms for a review of an AP Code investigation

Only requests for a review of an AP Code investigation on the grounds of procedural fairness should be considered. The aim of a review is to affirm or not, the outcome of the investigation. AP processes for review, ideally include:

- where requests for review should be directed to and timeframes for lodgement
- how a decision to proceed with a review will be made
- ways a review may be conducted (i.e., refer to a more senior officer)
- how the outcomes of the review will be communicated.

The Australian Research Integrity Committee (ARIC) can provide an external review of any investigative processes into potential breaches of AP Code if funding from the National Health and Medical Research Council (NHMRC) or the Australian Research Council (ARC) was involved.

Additional considerations

When research is inter-disciplinary, multi-institutional and a multi-national endeavour, consideration should be given to how potential breaches of AP Code will be investigated on a case-by-case basis taking into consideration issues such as the lead institution, where the complaint was lodged, contractual arrangements or where the events occurred. Institutions should cooperate if there is a potential breach of AP Code to ensure that only one investigation is conducted. Special consideration needs to be given when research practices and guidelines about the conduct of investigations differ between countries.

Some matters may involve potentially corrupt conduct and/or criminal behaviour. These matters require referral to an appropriate agency, for example, the police. They may also trigger other institutional responsibilities and processes.

Where an external agency chooses to investigate, AP should seek advice on whether internal processing of the complaint as a potential breach of AP Code can continue and, if so, with what authority and parameters, if any.

Following completion of an external investigation, AP may need to consider if there are outstanding matters, relevant to AP Code, to be addressed internally, and may decide to initiate further internal processing.

Safety issues

If it becomes apparent that the complaint relates to an activity that could harm humans, animals or the environment, immediate action must be taken to minimise the risk of harm. This action is at AP discretion and is independent of an AP Code investigation.

These matters may require referral or notification to an appropriate agency (e.g., regulatory agencies, WorkSafe). They may also trigger other AP responsibilities and processes.

Appendix 1: Sample checklist for the preliminary assessment

- Designated Officer (DO) is assigned
- Prepare and retain records of the preliminary assessment
- Obtain information provided by the complainant, seek further information as required
- Clarify facts and/or information with the respondent if appropriate
- Obtain facts, information and/or advice from across AP if required
- Determine if and how other institutions need to be involved in the matter
- Written advice provided to DO that includes:
 - a summary of the process that was undertaken
 - an inventory of the facts and information that were gathered and analysed
 - an evaluation of facts and information
 - how the potential breach relates to the principles and responsibilities of AP Code
 - recommendations for further action
- Assess all facts and information to determine outcome, i.e., complaint is to be dismissed, resolved locally, referred for investigation or referred to other institutional processes
- Outcome of preliminary assessment advised to the complainant, respondent and other relevant parties such as funding bodies, as appropriate

Appendix 2: Sample checklist for the terms of reference for the Panel

The terms of reference for the Panel may include the following:

The date the complaint was received, the name of the complainant (where appropriate), a brief description of the matter

The name of the respondent and a list of the specific allegations

A statement that the Panel is duly constituted in accordance with the institution's processes for investigating potential breaches of AP Code

List of the Panel members

A detailed outline of the scope and purpose of the Panel, which may include the following:

- to investigate the matter
- to ensure that procedural fairness is afforded at all stages in the process to all involved
- to maintain the confidentiality of all persons involved
- to review the allegations and responses to the allegations provided by the respondent
- to review the preliminary assessment report (including any external expert advice)
- to identify and gather any other relevant evidence
- to interview the relevant parties
- to consider the evidence in the context of the principles and responsibilities of AP Code
- to make findings in accordance with this Guide
- to provide a report to the DO in a timely manner
- to provide a statement about the secretariat support given by AP (eg: RIO)
- to provide an indicative timetable for the conduct of the investigation

Appendix 3: Sample checklist for the investigation procedure

Develop terms of reference and scope for the Panel that are appropriate and proportionate to the nature of the allegation (see Appendix 2)

Determine size and composition of the Panel

Establish provision of secretariat support

Where the allegation involves outside parties determine whether the involvement of other institutions, or their staff, is necessary and, if so, whether an agreement needs to be established setting the scope of their involvement

Advise the respondent (and possibly the complainant) on the composition of the Panel and provide opportunity to raise valid concerns

Establish the Panel

Provide the Panel with an opportunity to comment on the terms of reference and scope

Provide respondent opportunity to respond to allegation and inform them about the conduct of the investigation, including the role of a support person and the circumstances under which legal representation would be allowed.

Notify those required to attend the investigation

Provide guidance on the appropriate procedures for the investigation to the Panel, such as this Guide, AP Code and any relevant government or institutional processes. This may also include definitions of a breach of AP Code and, if relevant, research misconduct (according to the institution's processes).

Provide the Panel with all available information that will inform the investigation, which may include:

- the initial complaint
- all relevant information assembled by the person appointed to conduct a preliminary assessment of a complaint about research
- records of the conduct of the preliminary assessment
- the report of the preliminary assessment
- records of any communications on the matter involving the DO, the complainant and/or the respondent

Ensure that the Panel has the authority to access all relevant information and documentation

Support the Panel to develop an investigation plan that includes the following:

- identification of the avenues of inquiry, including interviewing people who the Panel considers relevant to the matter
- the frequency of Panel meetings
- the timeline for conducting interviews
- the timeframe for submitting draft report to respondent
- the timeframe for submitting the report to the DO
- inform the Panel of the reporting requirements (Appendix 4)

Appendix 4: Sample checklist for reporting the findings of the investigation

The Panel should formulate a comprehensive report that includes the following:

The names and affiliations of the Panel members

The name of the respondent

A summary of all relevant research projects, including project summary, duration and funding

The specific allegations considered

The terms of reference of the Panel

A description of the processes that were followed

A description of the evidence considered, including the documents and other information and the names of all persons interviewed

Summaries of the interviews conducted

The findings of fact that have been reached

A conclusion as to whether or not a breach of AP Code occurred and whether or not the respondent is responsible for the breach

Identification of any systemic issues that were contributing factors

A recommendation about the seriousness of any breach

Any recommendations (for example, for corrective action), where appropriate and consistent with the terms of reference

Any recommendations about other institutions/organisations that should be advised of the outcome (for example, funders, external stakeholders)

Development of the AP Guide MB

(Review frequency - 2 yearly)

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