Walter+Eliza Hall Institute of Medical Research

DISCOVERIES FOR HUMANITY

Policy

Policy and procedures for good scientific practice

Document control

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Background

This statement on research practice has been developed by the Walter and Eliza Hall Institute of Medical Research (The Institute) to foster integrity in scientific research, and is based on the Singapore Statement on Research Integrity, and the Australian Code for the Responsible Conduct of Research.

The value and benefits that can flow from research depend on adhering to these principles and responsibilities with integrity.

Objectives

The goals of this policy are 1) to promote the integrity of the scientific literature by minimizing errors that enter it, and correcting errors when they are detected, and 2) to promote integrity in research practice.

The key principles of research are honesty in all aspects of research, accountability in the conduct of research, professional courtesy and fairness in working with others, and good stewardship of research on behalf of others.

Scope

All Walter and Eliza Hall Institute staff, students and visiting scientists are required to adhere to this policy and the Australian Code for the Responsible Conduct of Research (or its successor document, as it is currently under review).

Staff, students and visiting scientists must also maintain awareness of and adhere to current laws, regulations, policies, and guidelines relevant to their work, including those from:

- The Institute
- Regulatory authorities
- Funding Bodies
- The University of Melbourne
- Government

Policy statement(s)

1. Responsibility

1.1 The Director is responsible for the research policy and direction of the Institute.

1.2 All research staff, scientific visitors, and students ("Researchers") are expected to maintain the highest standards of professional conduct in scientific research including:

- when planning and conducting experiments
- by recording and documenting observations with honesty, diligence and objectivity
- by interpreting results fully and objectively
- by disseminating the results accurately and responsibly.

1.3 All research conducted in the Institute must comply with current regulations governing occupational health and safety, conditions of use of hazardous materials including ionising substances, toxic chemicals, recombinant DNA technology and waste disposal. Prior approval must be sought from appropriate ethics committees for all experimentation involving human subjects or human material, and for experiments involving animals.

It is the responsibility of each Laboratory Head to ensure that all members of their group are aware of and adhere to these requirements and that appropriate approvals have been obtained before the research program commences.

1.4 All researchers are accountable for meeting responsibilities for maintaining a healthy and safe working environment, as required of them by policy and legislation. **(See the Institute's Health and Safety Manual)**

1.5 In general, research results and methods should be open to scrutiny by colleagues within the Institute and, through appropriate publications, patents, presentations and interviews, to the wider scientific profession and community. However, discussion of research findings in the public arena should not occur until the findings have been tested by peer review. Public release should also be preceded by assessment of which parties should first be informed, such as those directly impacted, or a stock exchange in the case of research with a strong commercial impact.

1.6 Researchers must, where feasible, provide research participants with an appropriate summary of the research results.

1.7 Researchers must register clinical trials with a recognised register such as the Australian New Zealand Clinical Trials register (www.anzctr.org.au).

1.8 Confidentiality must be observed for data of a confidential or private nature, for example from individual patient or population records. The Institute is required to maintain a register for research that falls under the Privacy Legislation (**See NHMRC National Statement on Ethical Conduct in Research involving Humans, 2007)**.

1.9 Confidentiality must be maintained for information received under a third-party confidentiality agreement, and may also be necessary, for a limited period, in the case of research with commercial interest or research performed under a commercial agreement. **(See the Institute's Intellectual Property and Commercial Relations Policy).**

1.10 Researchers intending to commence a research project in collaboration with another organization should ensure timely action to enable prior agreement to be reached between institutions on the management of the research. INSTITUTE researchers are required to comply with the terms of such agreements.

1.11 Researchers who consider that research misconduct has or is likely to have occurred have a responsibility to report it, either by using (when it is available) the “Speak Up” link on Catalyst, through discussion with an Advisor on Integrity in Research **(See Section 8.3)**, or directly with the Designated Person. **(See Section 8.4)**.

1.12 Researchers must cooperate with the assessment and review of any allegation of research misconduct or breaches of this policy.

2. Data access, gathering, storage and retention

2.1 Data must be accurately recorded in a durable, safe, secure, and appropriately accessible form. This original data must be able to be distinguished from subsequent analyses and the preparation of material for publication. Where particular confidentiality or privacy considerations apply, the materials and data must be kept secure, safe, and access to it recorded.

2.2 Original data from research carried out at the Institute is the Institute's property and will be retained by the Institute for at least five years from publication or conclusion of the research, whichever is later. An investigator may make copies of original data, within the constraints of confidentiality as set out in Sections 1.9 and 1.10. Data from on-going studies, e.g. Registers of human populations or clinical trials, should be maintained securely for at least 15 years. Data from gene therapy studies (e.g. patient records) must be kept permanently. Materials and data from research that is subject to patent protection must be held until the last expiry date of the patent. Materials and data relating to investigations of research misconduct will be retained indefinitely. At the end of the required retention period, research data and materials must be disposed of safely and securely.

2.3 For inter-institutional collaborative research programs each institution is responsible for retaining data conducted at its facilities and for documenting the location of relevant materials and data held at other institutions.

2.4 Wherever possible, original data should be retained in the research Division/Laboratory in which they were generated. In some cases, such as when data are obtained from limited access databases, or in a contracted project, it may not be possible to hold them in this way. In such cases, a written indication of the location of the original data, or key information regarding the limited-access database from which it is extracted, must be kept in the research division. Individual researchers should be able to hold copies of the data for their own use.

2.5 Confidential databases, e.g. Genetic registers or patient files, must be maintained in a manner that prevents unauthorised access and records any approved access.

2.6 Access to the full set of data must be granted to all those in the research team that participated in generating it.

2.7 Electronic data should be backed up regularly and copies kept at secure separate sites, e.g. through use of the Institute’s IT servers.

2.8 Responsibility for recording data and maintaining laboratory notebooks rests with the individual researcher. If researchers leave The Institute, laboratory heads will be responsible for retention and management of stored data.

3. Authorship

Authorship establishes responsibilities, as well as accountability and credit. Where a work has several authors, one should be appointed corresponding author to record authorship and to manage communication about the work with the publisher.

3.1 Authorship must be based on substantial intellectual or practical contributions in:

- conception, design, or planning of the project, **or**
- generating, analysing or interpreting research data, **or**
- drafting significant parts of the work or critically revising it so as to contribute to the interpretation.

3.2 Agree on authorship
Collaborating researchers should agree on authorship of a publication at an early stage in the research project and should review their decisions periodically.

3.3 Inclusion of authors
All those who meet the criteria for authorship must be offered to be listed as an author, and all authors must consent to being listed. A person who qualifies as an author according to the criteria above must not be excluded as an author without their written permission, and if not listed as an author, must be named in the acknowledgements.

3.4 Ghost authorship – when an individual makes a substantial contribution, but is not listed as an author – is not permissible.

3.5 Plagiarism - using another's words, results, or ideas without attribution - is not permissible.

3.6 Honorary authorship
Authorship must not be given to those who do not meet the requirements above, because it attributes credit falsely. For example, none of the following contributions, in and of themselves, justifies inclusion as an author:

- being head of laboratory or division, or having a personal relationship with the authors
- supervising a student, post-doc, or research team, or holding other positions of authority
- providing routine technical assistance or routine gathering of data
- providing editing or minor corrections to a manuscript
- acquiring or providing funding
- providing data or materials that have already been published, or materials obtained from third parties

3.7 Acknowledge other contributions fairly
Researchers must ensure that all those who have contributed to the research but are not listed as authors are properly acknowledged, as are those who provided key research materials.

3.8 Acknowledge funding sources and affiliations
Unless prevented by a journal's guidelines, all publications from the Institute should list affiliation with the Department of Medical Biology, the University of Melbourne, and acknowledge Victorian State Government Operational Infrastructure Support and funding from the Australian Government NHMRC IRIISS. All sources of direct funding for the project and salaries/fellowships should also be acknowledged.

3.9 Web-based publications
Authors of web-based publications must be able to take responsibility for the publication's content and must be clearly identified in the publication.

3.10 Corresponding author
One author should be appointed corresponding author to record authorship decisions and to manage communication about the work with the publisher.
Corresponding authors must notify all co-authors each time they submit a manuscript or a substantially revised manuscript.
One of the authors, often the corresponding author, must be responsible for ensuring all primary data associated

with the publication are stored safely, robustly, in accordance with regulations, and can be readily retrieved.

3.11 Circulation of manuscripts
Manuscripts and substantially revised manuscripts should be sent to co-authors allowing sufficient time for them to read and approve it before it is submitted.

3.12 All authors individually must:
- have read and approved the manuscript before submission; **and**
- agree to the composition and order of the author list; **and**
- take responsibility for at minimum their contribution if questions are raised; and
- co-operate with any investigation; **and**
- register for ORCID iD digital identifiers

3.13 Collectively, all authors must:
- provide materials and protocols so that others can repeat the experiments; **and**
- correct the publication if they become aware of errors

3.14 Authorship disputes
Researchers should try to prevent misunderstandings and authorship disputes by discussing authorship and author order at the outset of projects, as they proceed, and as manuscripts are drafted. Disputes that could, if substantiated, amount to scientific misconduct (e.g. plagiarism, honorary authorship, ghost authorship), can be reported to the Designated Person, to be handled as allegations of research misconduct. Where disputes of a lesser nature (e.g. authorship order, whether to include someone as an author or cite in the Acknowledgements) cannot be resolved by laboratory and division heads, they can be referred to the Designated Person (or if there is a conflict of interest, one of the alternatives) who will make a final decision in consultation with one or more of the Advisors in Scientific Integrity.

4. Collaborative Research (inter-institutional)

For collaborative research projects that involve sharing of grant funding with other institutions there must be formal written agreement between the institutions prior to transfer of funds, initiation of the research program or publication of results.

The agreement must address the following issues:
- which institution will act as the administering institution to manage the grant
- how grant funds (including indirect cost funding associated with the grant) will be distributed between the institutions
- how and by whom intellectual property will be managed
- who will be the owner of the intellectual property and how any commercial proceeds will be distributed
- a common understanding that authorship of any research outputs will be determined according to the Australian code
- a process to ensure there is regulatory compliance, including ethics approvals, for all the research activities and personnel involved
- a common understanding about ownership of and responsibilities for research equipment and research data (including its retention)
- any restrictions imposed on the research or its dissemination, such as by confidentiality agreements, commercial contracts, or privacy legislation
- agreements will contain a clause on conflicts of interest
- all conflicts of interest that are related to the research involved in the collaboration must be disclosed to the COO who will decide whether disclosure to the collaborating institute is required.

5. Supervision of Students/Research Trainees

5.1 Responsibility for supervision of each research student/trainee investigator (including honours, masters, doctoral and junior postdoctoral research workers) will be assigned to one or more specific senior research workers.

5.2 The ratio of students/trainees to supervisors must be small enough to ensure effective guidance and interaction, as well as effective supervision of the research at all stages.

5.3 For doctoral students a PhD Committee will be constituted to monitor progress, provide advice and provide a forum for both student and supervisor to raise any issues that could affect progress of the research project.

5.4 Research supervisors must advise each trainee of applicable guidelines for the conduct of research, as well as guidelines, regulations and restrictions that apply as a result of commercial, confidentiality or privacy issues.

5.5 Supervisors and students have joint responsibility for accurate and timely reporting (both oral and written) on progress of the research.

6. Disclosure of potential conflicts of interest

6.1 Potential conflicts of interest, such as holding shares, or having an affiliation with, or financial involvement in, any organization with a direct commercial interest in the research of any staff, must be forwarded in writing to the Director, and updated on an annual basis. **(See the Institute's Policy and Guidelines on Conflict of Interest in Research)**

Researchers must also disclose such interests to the editors of journals to which papers are submitted, and to external organisations from which other funds are sought.

6.2 Where the circumstances constitute an actual conflict of interest, or may lead people to perceive a conflict of interest, whether personal or financial, the person concerned must declare that they have a possible conflict of interest and not take part in decision-making processes that relate to the conflicted interest.

While it may be sometimes appropriate for the person to be in the room to answer questions, it is preferable that the person concerned does not remain in the room while the matter is debated and decided.

7. Peer Review

The Institute recognizes the importance of the peer review process of impartial and independent assessment of research by others working in the same or similar field. Peer review has a role in publication, grant applications, performance review and staff selection. Researchers whose work is undergoing peer review must not seek to influence the process or outcomes.

7. 1 It is important that participants in peer review:

- are fair and timely in their review
- act in confidence and do not disclose the content or outcome of any process in which they are involved
- declare all conflicts of interest, do not permit personal prejudice to influence the peer review process, and do not introduce considerations that are not relevant to the review criteria
- do not take undue or calculated advantage of knowledge obtained during the peer review process
- ensure that they are informed about, and comply with, the criteria to be applied
- do not agree to participate in peer review outside their area of expertise

7.2 Destruction of confidential peer review material
Peer reviewer comments and copies of grant and fellowship applications should be destroyed in accordance with the instructions of the funding body. If there are no explicit instructions, applications should be destroyed after the peer review comments have been submitted

8. Inappropriate Research Behavior

Breaches of the Australian Code for the Responsible Conduct of Research (The Code) that both lack serious consequences and are not deliberate, are considered to be poor research practice that should be corrected, but are not research misconduct.

Research misconduct is defined as a deliberate breach, or persistent breaches, of the Code.

If proven, research misconduct would lead to disciplinary action by the Institute.

Research misconduct includes, but is not limited to, fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting the results of research, and failure to declare or manage a serious conflict of interest. It includes misleading ascription of authorship. It includes conducting research that has not been approved by a research ethics committee, particularly where this may result in risk or harm to humans, animals or the environment. It includes willful concealment or facilitation of research misconduct by others.

8.1 Complaints or Allegations of Research Misconduct or Suspected Research Misconduct

If an individual has concerns, but is uncertain whether the issue amounts to research misconduct, they should approach their Laboratory or Division Head, or one of the Research Integrity Advisors.

Suspected research misconduct by INSTITUTE personnel must be reported to the Designated Person, and this can be anonymously, by written, oral, or other communication, either directly to the Designated Person, or indirectly, via one of the Research Integrity Advisors, or via the “Speak Up” link on Catalyst.

8.2 Responsibility to speak up

INSTITUTE staff and students are expected to speak up if they believe, in good faith, that someone has done, is doing, or may be about to do something that violates our standards of scientific integrity or policy on Good Scientific Practice.

8.3 Procedures for reporting and handling research misconduct or suspected research misconduct

Allegations of misconduct or possible misconduct can be received from within the Institute or from outside.

Those from within the Institute can obtain advice from Advisors on Integrity in Research, or directly approach the Designated Person.

Allegations from outside the Institute will be forwarded on to the Designated Person.
All allegations of misconduct or suspected misconduct will be investigated

8.4 Advisors on Integrity in Research

Advisors on integrity in research are familiar with the literature and guidelines on scientific misconduct, and can give confidential advice about what constitutes misconduct in research and options open to a potential complainant. If they are advising the complainant, they do not communicate with the subject of an accusation. If they are advising the accused person, they do not communicate with the complainant.

As at June 2017, the Institute's Advisors are:

- Phil Hodgkin
- Joan Heath
- Nicos Nicola
- Andreas Strasser
- Gabrielle Belz
- Ashley Ng
- Len Harrison

8.5 Designated Person

If an allegation of scientific misconduct is received by the Designated Person, their task is to obtain sufficient information to decide either a), that further inquiry is required, or b), that the allegation can be dismissed. Allegations will only be dismissed if the Designated Person has a high degree of confidence that research misconduct has not occurred.

In order to reach this decision, the Designated Person may need to obtain information from the complainant, the person accused, or others (such as managers of data storages and archives.) At the point at which the accused person is informed that allegations have been made, the Designated Person will ask one of the Research Integrity Advisors to explain, advise and offer support to the person who has been accused.

When the Designated Person has reached a decision, he/she will then advise the Director either that the case should be dismissed, that it should be referred to another process, or that further investigation should be carried out through a research misconduct inquiry.

If in the opinion of the Designated Person the Director would have a real or potential conflict of interest in the case, the Designated Person will advise the Chairman of the Board, who will then find a Board Member to act in place of the Director for the purposes of this allegation.

When the Director receives advice from the Designated Person, the Director will inform relevant funding bodies about the case, whether it is to be dismissed or further action is required.

The Designated Person will retain records of all communications related to the allegation, and when he/she advises the Director, these records will be transferred to the Directorate where they will be archived.

If the allegation is dismissed, the person making the allegation or raising the concern will be notified in writing and be given reasons for the decision.

If the allegation cannot be dismissed, the Designated Person will recommend that further investigations are carried out, which may or may not include establishing a formal panel of inquiry, and this panel might have one or more members from outside the Institute (an "internal inquiry"), or might be entirely comprised of members external to the Institute (an "independent external inquiry").

The Designated Person will retain all records related to allegations of possible misconduct, and after the Director has been advised, these records will be deposited with the Directorate, to be stored indefinitely.

As at June 2017, the Institute's designated person and alternatives are:

- David Vaux (Designated Person)
- Peter Colman (Alternative)
- Jane Visvader (Alternative)

Alternatives will be used by the complainant if the Designated Person is unavailable or has a conflict of interest. If, in the opinion of the Designated Person or the Director there is a real or potential conflict of interest, or if the Designated Person is not available, or if one of the Alternative Designated Persons has a more relevant skill set, one of the alternatives will be appointed to act as the Designated Person.

9 Investigations of Research Misconduct.

The purpose of the investigation is to substantiate or refute the allegation

9.1 Composition of internal research misconduct inquiry panels

An internal institutional research misconduct inquiry will include at least one member with knowledge and experience in the relevant field of research and at least one member who is familiar with the responsible conduct of research. At least one member will have experience on similar panels or have relevant experience or expertise. One or more members of the panel may be external to the Institute.

All members of the panel must be free from bias or conflicts of interest.

9.2 Role of the internal inquiry panel

Each allegation will be considered separately from the character, position or reputation of the person who made the allegation, and if the allegations are true, the motive of the accuser is irrelevant.

The inquiry panel will be authorized to obtain, copy, and/or secure, relevant evidence including laboratory books, biological specimens, experimental data, electronic files, financial records, manuscript drafts, and emails.

A person appearing before the research misconduct inquiry may be accompanied by a support person.

The inquiry panel will consider:

- the seriousness of the alleged breach
- the intent or willfulness of the breach
- the severity of the consequences
- the strength of the evidence
- whether the breach is admitted
- relevant employment law

If the allegation is substantiated, the inquiry panel may extend its investigation to determine whether other related breaches have occurred.

The inquiry panel will make findings:

- whether the Code has been breached and whether misconduct has occurred

- the nature, extent and severity of the breach
- who is responsible for the breach
- whether the research literature needs to be corrected

The panel will report findings to the Director of what, if any, research misconduct has occurred.

Records of communications, evidence and findings of the investigatory committee will be transferred to the Directorate where they will be secured and archived indefinitely.

Where adverse findings have been made, the Director will decide what disciplinary actions are required within the agreed disciplinary processes of the Institute.

The Director will decide what remedial action should be taken to correct the scientific literature, and will inform funding bodies.

9.3 Appeals

Both the accused person and the person making the accusation may appeal decisions of an internal research misconduct inquiry by requesting an independent external misconduct inquiry.

If an appeal is received, or if requested by the Director, an independent external misconduct inquiry will be established. The only role of the earlier internal inquiry will be to provide evidence and records to the independent inquiry.

10 Independent external research misconduct inquiry

10.1 Composition of independent external inquiry panel

If an independent external inquiry is to be conducted, panel members will not be INSTITUTE employees or have other current or recent dealings with the Institute, or otherwise be subject to a reasonable perception of bias.

The panel will have a minimum membership of three people. At least one member will have extensive experience as a member of a tribunal or similar body. At least one member should have knowledge and research experience in a relevant field of research.

10.2 The Institute will legally indemnify those serving on an independent research misconduct inquiry panel

10.3 Preventing retaliation against the person making the allegation

The name of the person who raised the concern will not ordinarily be disclosed to the subject of the inquiry. During the inquiry, their role will be limited to provision of evidence and/or acting as a witness.

When a complaint has been brought in good faith, even if mistakenly, the Institute will provide appropriate support to the reporting person. Individuals who provide information to assist in resolving of a complaint will also be protected.

The Institute's *Complaints and Internal Reporting* policy and procedure applies, and in particular, victimisation of a complainant, or anyone assisting someone make a complaint, will not be tolerated, and is in many cases prohibited by legislation with applicable penalties.

No one will retaliate against individuals who acted in good faith in reporting or providing information about suspected or alleged misconduct. Individuals engaging in acts of retaliation will be disciplined according to the appropriate institute policies on workplace bullying and harassment.

10.3 Legal representation

The person subject to the inquiry will be given an opportunity to hear and respond to any and all material to be used by the panel in its decision-making process. The person is entitled to legal representation.

The panel must be assisted by a legally qualified person acting as 'counsel assisting'. This person is not a member of the inquiry panel but may provide the panel with legal advice during the hearing.

10.4 Standards of evidence

The inquiry is not bound by the rules of evidence but its procedures must be consistent with the principles of natural justice and due process.

In making findings related to errors that have entered the scientific literature, the standard of proof needs only be balance of probabilities, and the relevant publications should be corrected or retracted.

In making findings of scientific misconduct, a higher standard of proof is required.

10.5 Open or closed hearings

Whether an external research misconduct inquiry by people external to the institution is open to the public or conducted in private should be determined by the panel itself on the basis of public interest. The panel has the responsibility to hear the views of all parties on this matter before such a decision is made.

10.6 Findings by an independent external research misconduct inquiry

Upon completion of its tasks, the independent external research misconduct inquiry must advise the Director of its findings; whether the scientific record needs to be corrected; and what, if any, research misconduct has occurred. The Director must, in due course, inform the Board and the relevant funding body(s) of the outcome of the inquiry. The research misconduct inquiry findings must be considered by the Director and appropriate actions taken in accordance with institutional instruments regarding employment conditions. Appropriate actions must also be taken when the allegations of misconduct are shown to be unfounded. The findings of an independent, external research misconduct inquiry may be made available to the public. When conducting an independent external research misconduct inquiry, the person subject to the inquiry may have an entitlement to appeal to a higher authority, such as the courts, and/or the Australian Research Integrity Committee (ARIC).

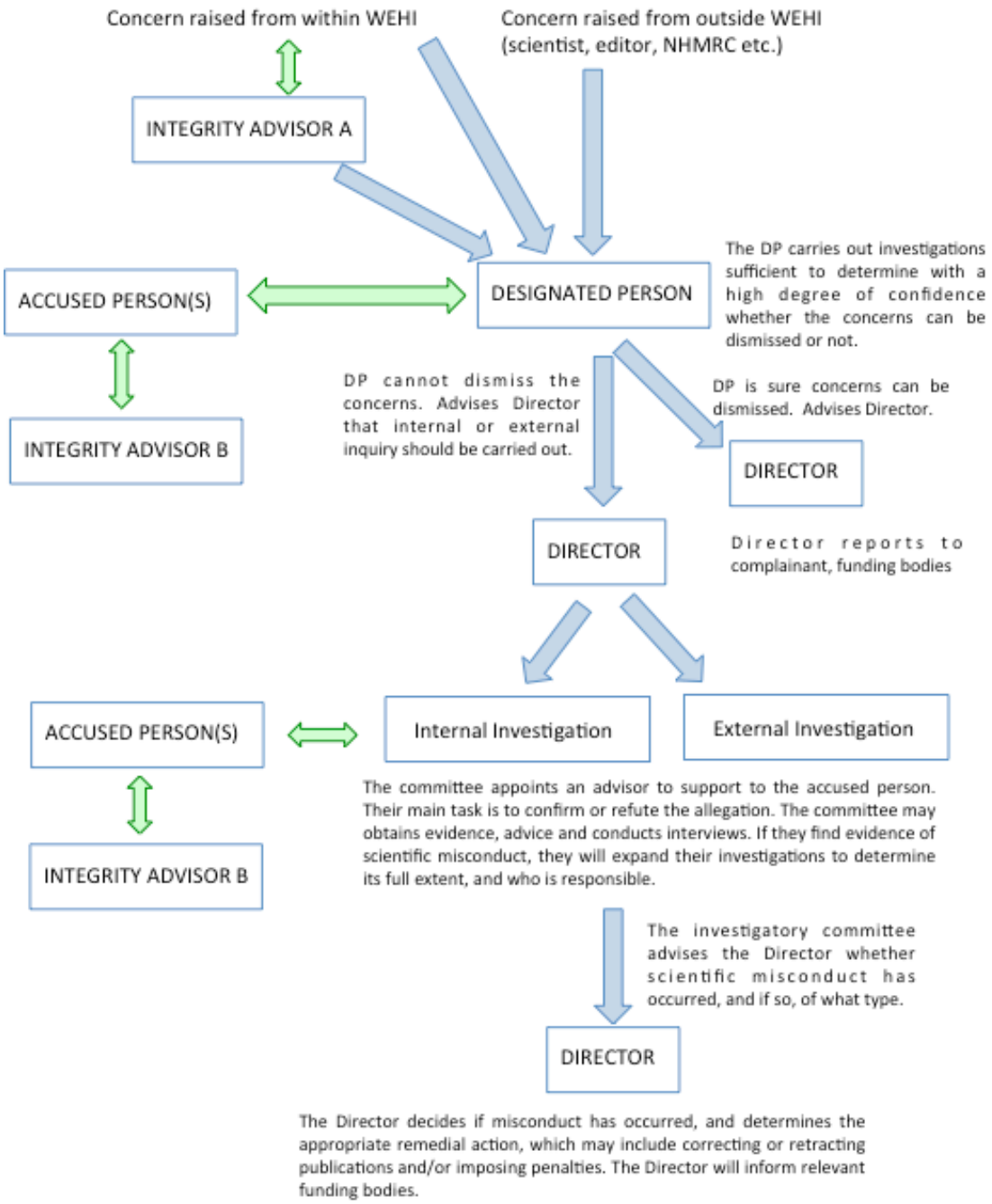
The Director will take action that may include any or a combination of:

- dismissing the case
- retraction or correction of publications
- notification of person who raised the allegation
- counseling/supervision/dismissal
- return of funds to funding bodies
- making the findings of the inquiry public

Associated documents

APPENDIX 1

Flow chart outlining the process for handling allegations of possible research misconduct



APPENDIX 2

Australian Code for the Responsible Conduct of Research
(http://www.nhmrc.gov.au/publications/synopses/r39syn.htm)

Singapore Statement on Research Integrity
(http:// http://www.singaporestatement.org/statement.html)

Australian Code of Practice for the Care and Use of Animals for Scientific Purposes
(http://www.nhmrc.gov.au/publications/synopses/ea16syn.htm)

National Statement on Ethical Conduct in Human Research
(http://www.nhmrc.gov.au/publications/synopses/e72syn.htm)

Statement on Consumer and Community Participation in Health and Medical Research
(http://www.nhmrc.gov.au/publications/synopses/r22syn.htm)

Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research
(http://www.nhmrc.gov.au/publications/synopses/e52syn.htm)

Ethical guidelines on the use of assisted reproductive technology in clinical practice and research
(http://www.nhmrc.gov.au/publications/synopses/e78syn.htm)

Handbook on the Regulation of Gene Technology in Australia (http://www.ogtr.gov.au/pubform/handbook.htm)

ORI Model Policy for Responding to Allegations of Scientific Misconduct
(http://www.ori.dhhs.gov/publications/handbooks.shtml)

ORI Introduction to the Responsible Conduct of research (http://www.ori.dhhs.gov/publications/ori_intro_text.shtml)
• Guidelines for the conduct of research in the intramural research program at NIH
(http://www.nih.gov/science/irnews.htm)

Standards for Clinical Research within the NIH Intramural Research program
(http://www.cc.nih.gov/ccc/clinicalresearch/index.html)

Australian New Zealand Clinical Trials register (www.anzctr.org.au)

Australian Research Integrity Committee (ARIC)
(http://www.arc.gov.au/pdf/aric_request_for_review.pdf)