

“A Suggestion”

The Hon. Bruce Lander KC

30 September 2022

**A Suggestion for a Statutory Body
to Deal with Allegations of Research Misconduct**

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1. During the course of conducting a recent review into questions of scientific medical research misconduct, I have had occasion to consider, when a person suspects another of engaging in research misconduct, the best practice for:
 - a) receiving reports of that kind; and
 - b) dealing with those reports by way of investigation.
2. Medical research is carried out for the greater good.¹ Scientists who engage in medical research are dedicated to finding better ways to treat and prevent disease. The purpose of medical research is to improve or gain knowledge to that end.
3. Scientific research in Australia is a large industry. Medical research is a significant part of the research industry. Almost \$2bn each year is provided for medical research by the Australian Government. The Australian Government and the Australian people are entitled to expect that those moneys will be used for the purpose they are provided and not wasted. The research industry's reputation needs to be protected from persons or institutions that engage in research misconduct.
4. It is critical that medical research, as any other scientific research, is conducted transparently and honestly.
5. The *National Health and Medical Research Council Act 1992* (Cth) ("the NHMRC Act") has established the National Health Medical Research Council ("NHMRC")² to pursue activities including:

“ ...

 - (c) *to foster medical research and training and public health research and training throughout Australia; and*
 - (d) *to foster consideration of ethical issues relating to health.*”³
6. The functions of the Chief Executive Officer (“CEO”) of the NHMRC include issuing guidelines on public health research and medical research.⁴ The NHMRC has issued

¹ The Preamble to the *Queensland Institute of Medical Research Act 1945* (Qld) (“the QIMR Act”) which creates the Queensland Institute of Medical Research (“QIMR”) says: “...it is considered that a system of research in medical science, particularly in relation to diseases of particular significance to Queensland is an essential factor in and towards the betterment of the health and general wellbeing of the people of the State.”

² Section 5B of the NHMRC Act.

³ Section 3 of the NHMRC Act.

⁴ Section 7 of the NHMRC Act.

a number of documents that impact upon the conduct of medical research and other research in Australia.⁵

7. Medical research must proceed in the principled way identified in those publications. Those publications and in particular, the Guide, accept that from time to time those engaged in scientific research will breach the Code. The types of breaches are identified in Section 2.1 of the Guide; not meeting required research standards; fabrication, falsification, misrepresentation of data or science material or of findings; plagiarism; management of research data; supervision; authorship; conflicts of interest; and peer review.
8. The institutions which employ those people have the ultimate responsibility for ensuring that the research conduct within the institution itself complies in all respects with the Code and the Animal Code and the Guide.
9. The Guide Provides:

“Breaches of the Code occur on a spectrum, from minor (less serious) to major (more serious). Major breaches would typically require investigation, while some minor breaches may be addressed at the preliminary assessment stage.”
10. The Guide identifies the factors to consider when determining the seriousness of the breach:

“In considering the seriousness of a breach of the Code, the factors to be considered (without excluding other factors) are:

 - *the extent of the departure from accepted practice*
 - *the extent to which research participants, the wider community, animals and the environment are, or may have been, affected by the breach*
 - *the extent to which it affects the trustworthiness of research*
 - *the level of experiment of the researcher*
 - *whether there are repeated breaches by the researcher*
 - *whether institutional failures have contributed to the breach*
 - *any other mitigating or aggravating circumstances.”*
11. The objects of the *Australian Research Council Act 2001* (Cth) (“ARC Act”) include establishing a body for making “*high quality*” recommendations to the Minister in relation to which research programs should receive financial assistance, administering

⁵ The Australian Code for the Responsible Conduct of Research (“the Code”); The Australian Code for the Care and Use of Animals for Scientific Research (“the Animal Code”); The Guide to Managing and Investigating Potential Breaches for the Australian Code for the Responsible Conduct of Research (“the Guide”). The Animal Code has the force of law in Queensland because of Section 49 of the *Animal Care and Protection Act 2001* (Qld).

regimes of financial assistance, providing “*high quality*” advice to the Minister about matters related to research, and to provide funding for research.⁶

12. The Australian Research Council (“ARC”) is established by s5 of the ARC Act and it comprises the CEO, the designated committees⁷ and the staff of the ARC.⁸ There is a Chief Executive Officer (“ARC CEO”) of the ARC,⁹ whose functions include:

“...

(c) *to provide advice to the Minister on research matters;*

(d) *any other functions conferred on the CEO by this or any other Act.”*

13. The ARC Act empowers the Minister to establish committees to assist or carry out the ARC CEO’s functions.¹⁰

14. Pursuant to that section, the Minister has established the Australian Research Integrity Committee (“ARIC”). In its introduction the ARIC Framework mentions the Background to the establishment of the Committee:

“The Australian and international community expects institutions and individuals in respect of public funds to apply the highest ethical and professional standards to their work and workplace relations. The Australian Code for the Responsible Conduct of Research, 2018 (the Code), jointly authorised by the Australian Research Council (ARC), National Health and Medical Research Council (NHMRC) and the Universities Australia, clearly articulates the broad principles that underpin an ‘honest, ethical and conscientious research culture’.¹ It is a condition of NHMRC and ARC funding that institutions ensure research is conducted according to the Code. This also requires institutions to facilitate the prevention and detection of potential breaches of the Code, to provide mechanisms to receive concerns or complaints about potential breaches of the Code and to investigate and resolve potential breaches of the Code.²

The Code requires that institutions have processes for managing and investigating concerns or complaints about potential breaches of the Code in a timely and effective way and in accordance with procedure fairness.³ In managing and investigating potential breaches of the Code, institutional processes must support the welfare of all parties (including complainants), result in findings based on the balance of probabilities and lead to actions (including corrective actions) that are commensurate with the seriousness of the breach.⁴ Further guidance for institutions on the management of potential

⁶ s3 ARC Act.

⁷ A designated committee is defined in s30(1) of the ARC Act and is a committee established by the ARC CEO to assist in carrying out the functions of the ARC CEO. A designated committee has the functions determined in writing by the Minister: s31(1). A designated committee must comply with any directions given to the committee by the Minister: s31(2).

⁸ The Minister may establish a designated committee to assist in carrying out the functions of the ARC CEO; Section 30(1).

⁹ s33A ARC Act.

¹⁰ Section 30 of the ARC Act.

breaches of the Code is set out in the Guide to Managing and Investigating Potential Breaches of the Code (the Investigation Guide).

This Framework sets out the background to the Australian Research Integrity Committee (ARIC), its scope and purpose, the process for seeking an ARIC review and an overview of how the committee operates. This Framework was updated in 2019 to align with the Code and Investigation Guide.

¹ *Preamble, Australian Code for the Responsible Conduct of Research, 2018.*

² *R9, R10, Australian Code for the Responsible Conduct of Research, 2018.*

³ *R11, Australian Code for the Responsible Conduct of Research, 2018.*

⁴ *R12, R13, Australian Code for the Responsible Conduct of Research, 2018.”*

15. The ARIC Framework identifies ARIC’s responsibilities:

“ARC and NHMRC jointly administer ARIC to:

- review, on receipt of a valid request, the processes by which an institution that is eligible to receive funding from the ARC and/or NHMRC has managed and/or investigated a potential breach of the Code*
- provide findings and, where relevant, recommendations to the CEO of the ARC and/or the CEO of NHMRC*
- provide reports or verbal advice to the Council of NHMRC of other Principal Committees, as requested, on the activities of ARIC-NHMRC, and*
- publish de-identified information on its activities at least annually.*

In all matters, ARIC considers whether the institution’s response to a potential breach of the Code was consistent with the principles and responsibilities in the Code, the guidance in the Investigation Guide, and the institution’s policies and procedures for investigating potential breaches of the Code.

It is not the role of ARIC to determine whether a breach of the Code occurred.”¹¹

16. An institution or a person can request ARIC to conduct an independent review of the processes followed by an institution in investigating alleged breaches of the Code and to determine whether the investigation has been conducted in accordance with the Code and the Guide and/or in accordance with the institution’s own policies and procedures.¹²
17. ARIC can also be asked to provide advice to the institution on the outcome of the review and to make recommendations for any further action by the institution.
18. An application for an ARIC review “*may be made only in relation to the processes used by institutions*” when investigating potential breaches of the Code involving

¹¹ Page 3 of the ARIC Framework.

¹² Page 3 of the ARIC Framework.

research that has been funded under the NHMRC Act or the ARC Act or the *Higher Education Support Act 2003*.¹³

19. The grounds for review include a failure by the institution to provide procedural fairness, delay that compromised procedural fairness or caused detriment to either the complainant or the respondent, or a failure to follow the prescribed processes in the Code or Guide or the institution's own processes.¹⁴
20. There are time limits that apply to requests for an ARIC review.¹⁵
21. The ARIC Secretariat will decide whether a matter should be referred to ARIC "*depending on the nature of the research, the institute at which the research occurred and whether the research in question was funded by the one of the Funding Agencies.*"¹⁶
22. If the Secretariat or the ARIC Chair accept a request, the Chair will convene a panel of usually three or more members of ARIC to conduct an investigation or develop advice on the outcome of the review.¹⁷
23. Section 3 of the ARIC Framework addresses ARIC's responsibility to provide parties subject to ARIC review, with procedural fairness. It also addresses "*Privacy*". Section 3 warns individuals and organisations that ARIC is unable to provide protection to whistleblowers and Commonwealth employees and of their obligations under Commonwealth legislation not to disclose Commonwealth information without authorisation.
24. ARIC will determine whether the institution's response to a potential breach of the Code was consistent with the principles and responsibilities of the Code, the guidance in the Investigation Guide, and the institution's own policies and procedures for investigating potential breaches of the Code.
25. The ARIC Framework also indicates what ARIC will not enquire into:¹⁸

"ARIC will not enquire into:

- 1) *The conduct, act or omission that is alleged to be a potential breach of the Code (as distinct from complaints about institutions' processes in response to potential breaches of the Code).*
- 2) *The merits of any findings made by the institution in a preliminary assessment or by an investigation panel (whether internal or external) at the institutional level, except to the extent that finding of an error or flaw in the institution's processes necessarily reflects on the merits of the preliminary assessment or findings of the investigation panel conducted under those processes.*

¹³ Section 2 of the ARIC Framework.

¹⁴ Section 2 of the ARIC Framework.

¹⁵ Section 2 of the ARIC Framework.

¹⁶ Section 2 of the ARIC Framework.

¹⁷ Section 1 of the ARIC Framework.

¹⁸ Section 1 of the ARIC Framework.

- 3) *Institutional processes involving allegations of misconduct on the part of any employee other than potential breaches of the Code, and any sanctions applied to such a matter.*
 - 4) *Institutional decisions regarding sanctions consequent upon a finding of a breach of the Code.*
 - 5) *Funding agency decisions about actions consequent upon a finding of a breach of the Code.*
 - 6) *Institutional processes still underway (but see Grounds for Review below).*
 - 7) *Any other matter that the CEO directs ARIC in writing to disregard.”¹⁹*
26. Research misconduct, at its highest, might involve “*corrupt conduct*” as that term is defined in the *Crime and Corruption Act 2001 (Qld)* (“CCA”). Section 32 of the CCA requires a public official who reasonably suspects that a complaint or information or matter involves corrupt conduct to notify the commission.²⁰
27. One of the main functions of the *Public Interest Disclosure Act 2010 (Qld)* (“the PID Act”) is to promote the public interest by facilitating public interest disclosures of wrongdoing in the public sector.²¹
28. Section 13 of the PID Act applies to public officers, which includes an employee, member or officer of a public sector entity.²² Section 13 of the PID Act provides that a public officer who has information of the kind mentioned in s13(1) may make a disclosure under s17 in relation to the information to a proper authority.²³
29. Where the proper authority is a public sector entity, the public officer may make the disclosure to its chief executive officer, a member of its governing body or an officer of the entity who has the function of receiving or taking action on the type of information being disclosed.²⁴
30. The PID Act imposes obligations on the public sector entity to ensure that:
- (a) *public officers of the entity who make public interest disclosures are given appropriate support; and*
 - (b) *public interest disclosures made to the entity are properly assessed and when appropriate, properly investigated and dealt with; and*
 - (c) *appropriate action is taken in relation to any wrongdoing that is the subject of a public interest disclosure made to the entity; and*

¹⁹ Page 4 of the ARIC Framework.

²⁰ A public official includes the Chief Executive Office of a unit of public administration.

²¹ Section 3(a) of the PID Act.

²² A public sector entity includes an entity established under an Act: s6(1)(j).

²³ A proper authority is a public sector entity.

²⁴ Section 17(3) of the PID Act.

- (d) *a management program for public interest disclosures made to the entity, consistent with any standard made under section 60, is developed and implemented; and*
- (e) *public officers of the entity are offered protection from reprisals by the entity or other public officers of the entity.*²⁵

31. The PID Act provides protections to persons who make public interest disclosures in accordance with the PID Act.²⁶
32. There are different levels of persons engaged in scientific medical research. At the apex of any team is the Principal Investigator (“PI”). The PI may be supported by research assistants; postdocs; students and support staff. In the case of research that uses animals for scientific research, Animal Ethics Committees and those engaged in the breeding and care of animals for use in scientific research will also be involved.
33. At present, if a person employed in a medical research institute suspects that another person has engaged in research misconduct, and who wishes to report that misconduct, and must make a report to the institution in which they are both employed.²⁷ That person will enjoy some level of protection if the State in which he or she works, has Whistleblower legislation, like the PID Act, which applies to the type of allegations made.
34. Because of the absence of any statutory framework and regulatory authority, at present, allegations of research misconduct can only be investigated by the institution in which the conduct occurred.²⁸
35. The persons employed in a medical research institute, who are most likely to be aware of research misconduct in a medical research institute, are the researchers and those employees within the institute who are working with the person who is suspected to have engaged in research misconduct, or those employees who are providing support to that research. In a medical research institute, such as QIMRB, that would include those working in the lab in which the impugned conduct is said to have occurred, or if the research involves animals, the Animal Facility, or persons who have access to the Animal Facility where the experiments take place. It is possible that a person engaged in peer review could acquire that knowledge or suspicion.
36. There are barriers to reporting that conduct internally, especially when the suspected researcher is the PI. If the suspect is the PI there is an obvious power imbalance between the suspect and the potential reporter.
37. If the potential reporter is employed in the lab, the potential reporter has to report the person, to whom he or she answers, to another internal authority which has employed the PI. That potential reporter might also be concerned that making a report could adversely affect his or her career, especially if the suspicion is later deemed to be unproved or ill founded. If the potential reporter is a student, he or she may be

²⁵ Section 28(1) of the PID Act.

²⁶ Chapter 4 of the PID Act.

²⁷ The reporter could, but is not obliged, to report the conduct to the CCC, but only if the conduct was corrupt conduct. The obligations to report to the CCC is on the public official not the reporter.

²⁸ If the research misconduct also can be categorised as corrupt conduct, the CCC could investigate.

- concerned that if the suspicion were substantiated that the students own work might become contaminated.
38. Because of those concerns, which are real, there are good arguments from the reporter's point of view for there to be an outside agency which is empowered to receive complaints and reports of research misconduct.
 39. An internal report about the conduct of someone engaged in research also raises a potential conflict of interest. It is, of course, in the institution's best interests that all of its research is carried out strictly in accordance with the Code and the Animal Code. Any kind of research misconduct within the institution has the potential to impact adversely on the institution's reputation and therefore the reputation of its other researchers. If, as a consequence of an investigation, research misconduct is established, the institution might suffer reputational harm. It follows that while it is in the institution's best interests to prevent, or if not able to prevent, uncover research misconduct, it is not necessarily in the institution's best interests for it to become known that someone within the institution has engaged in research misconduct. There is a real disincentive for an institution to investigate its own researchers. Because of that disincentive, there is a risk that it might be perceived, if the institution carries out an investigation, but does not establish that the complaint or report has been made out, the institution's investigation lacked rigour. An institution which receives a complaint or report of research misconduct by one of its researchers also might have a perceived conflict of interest in that an investigation into the conduct might, if the conduct is established, cause financial loss to the institution and reputational harm.
 40. If an institution is itself the subject of the complaint or report for a breach of the Code or Animal Code, the institution has an obvious conflict of interest. It could not investigate its own conduct. It could commission a person or person outside the institution to carry out the investigation but even that appointment might raise a perceived conflict of interest.
 41. There are persuasive arguments for asking the Commonwealth to create a statutory body ("the Regulator") which has the powers to receive complaints and reports about breaches of the codes; to require institutions to investigate those allegations, subject to the oversight of the Regulator; or where appropriate and having regard to the seriousness of the allegations or the target of the allegations, conduct the investigation itself.
 42. Creating an outside statutory body to receive complaints and reports about research misconduct would encourage persons within institutions that making such a complaint or report would not adversely affect their employment or their career. As it stands, being required to report to the institutions in which the reporter is employed must be a disincentive. It would also assist to reduce the power imbalance that might exist between the complainant/reporter and the person about whom the complaint or report has been made.
 43. If a person wished to make a complaint or report about a breach of the Code or the Animal Code that person would make that complaint or report to the Regulator.

44. The Regulator would be empowered to seek further information from the complainant before making a decision as to whether the complaint or report was made bona fide and was not frivolous or vexatious.
45. The Regulator, if satisfied that the complaint or report was bona fide and not frivolous or vexatious, would next consider whether the allegations required investigation. This would be a triaging process. The Regulator could be empowered to deal with some reports without the need for an investigation where the cost of the investigation, for example, would not be justified for the likely outcome or where the allegations could be dealt with by an instruction to an institution or its researcher.
46. If the Regulator determined that there was a need for an investigation, it would next decide whether the investigation should be carried out by the institution, by investigators commissioned by the institution, or by the Regulator itself. In determining which was the appropriate course of action, it would have regard to the target of the allegations, i.e. whether it is the institute itself or a researcher and, if it is a researcher, the seniority or reputation of the researcher; the capacity of the institution to carry out an investigation; and of course, and importantly, the seriousness of the allegations.
47. In most cases the Regulator would conclude that the investigation should be carried out by the institution itself or by investigators commissioned by the institution.
48. It would only reserve investigations for itself when it was of the opinion that the circumstances demanded that course be adopted.
49. If it directed the institution to either carry out the investigation, or commission investigators to do so, the Regulator would have the oversight of the investigation as it proceeds. It would have the power to give directions as to who should be the designated officer within the institution; the terms of reference of the investigation; and the manner in which the investigation should proceed. The directions could include the persons who should be interviewed or the evidence that should be collected. The oversight would not require the Regulator to be an interventionist. It might take a benign position and simply watch the investigation unfold and take its course.
50. An institution, of course, as is presently the case, would not have the power to compel persons to give evidence on oath or at all. Nor would it have the power to compel the production of documents, except insofar as they are the institution's own documents. The powers of compulsion should not be given to institutions.
51. To assist an investigation carried out by the institution or its investigators, the Regulator would be empowered to issue notices directed to persons or institutions to provide evidence, documentary or oral, to the institution's investigators. It would only do so where satisfied that there was a need for such a notice and when the recipient of the notice can be properly protected against the risk of self incrimination.
52. A person who has engaged in research misconduct may have also committed a criminal offence. If that person can be directed to provide evidence to the investigation, he or she should be protected from the later use of that evidence in any criminal procedure. Where a person is required to give oral or documentary evidence

to a body that is not a Court, that person's rights in relation to any subsequent criminal process are usually protected. That is most commonly done by requiring the person to whom the notice is given to comply with the notice, but at the same time, allowing that person to claim the privilege against self incrimination, so that any evidence obtained by the compulsory process is not admissible in any future criminal prosecution.

53. The Regulator would be empowered to carry out an investigation itself but only when the Regulator deemed an institutional investigation to be inappropriate.
54. The Regulator would have the power to compel the production of evidence by way of notice. It could require a person or an institution to provide documents. The Regulator could require a person to give evidence, under oath, but with the same protections for witnesses mentioned above.
55. The person or persons conducting the investigation would have to provide the person under investigation with procedural fairness. The need for procedural fairness arises because the investigator, whether it is the institution or the Regulator has the responsibility of making a decision and is therefore liable to make decisions which might adversely affect the rights, interests or legitimate expectations of the person under investigation. A person's reputation is a right or interest that must be protected. The remedy for the failure to provide procedural fairness would depend upon whether the failure to do so was the institution, the institution's investigators or the Regulator's.
56. One of the advantages of such a proposed scheme is that the Regulator could require the person under investigation to cooperate in the investigation. A Researcher, who has engaged in serious research misconduct, is unlikely to cooperate in an investigation under the current regime.
57. That is especially so if the Researcher's conduct is criminal. The proposed scheme would not allow the Researcher to refuse to cooperate in the investigation and the best evidence would be capable of being obtained. At present, because there is no compulsion to cooperate and produce evidence, there is a real risk that relevant evidence will not be detected or discovered. Moreover because Researchers do not presently have to cooperate in the investigation the opportunity to obtain evidence of that misconduct on any other persons who might have assisted in the research misconduct or been aware of that misconduct is significantly reduced.
58. The present ARIC process would not be needed because the process that has been suggested has been oversighted from start to finish. If a person or institution wished to challenge the Regulator's conduct they could apply to the Court for a Judicial Review.
59. At the completion of the investigation, if the misconduct of a Researcher were proved, the Regulator could impose whatever sanction was considered appropriate without, of course, purporting to exercise judicial power. That would allow a sanction to be imposed on a Researcher who could not be subject to a NHMRC or ARC sanction.
60. The Regulator would have two other basic functions. It would provide an educative function for institutions on how to guard against, prevent and detect research

misconduct. It would also provide training for institutions in the manner in which investigations should be conducted.

61. The proposed scheme would need to be costed, because it would have a cost. How that cost would be met would be a matter of policy for government.
62. The actual cost would be outweighed by the enhancement of the reputation for integrity in the Australian scientific research industry.



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