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Association of Australian  
Medical Research Institutes

## SUBMISSION

# PUBLIC CONSULTATION ON THE REVIEW OF THE AUSTRALIAN CODE FOR THE RESPONSIBLE CONDUCT OF RESEARCH (THE CODE)

February 2017

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## ABOUT AAMRI

**The Association of Australian Medical Research Institutes (AAMRI) is the peak body representing medical research institutes (MRIs) across Australia.** Our 47 member institutes are leaders in health and medical research, working on an extensive range of human health issues, from preventative health and chronic disease, to mental health, Indigenous health and improved health services. Collectively AAMRI's members employ over 15,000 staff and students and have an annual turnover of more than \$1.3 billion. MRIs are engaged at all stages of the research commercialisation pipeline. In 2014-2015 MRIs recorded 150 invention disclosures, were awarded 207 new patents, were active in 1,220 clinical trials, undertook nearly 1,200 contracts, consultancies and collaborations, and generated nearly \$90 million in commercial income from research IP.

## RESPONSE TO CONSULTATION QUESTIONS

### **Q.1 Do you like the new approach to the Code, namely the principles-based document being supported by several guides that provide advice on implementation?**

The new approach to the Code is a great improvement and provides greater clarity and guidance to institutions, researchers and members of the community on how to ensure the good conduct of research.

There are some outstanding areas that would benefit from further attention, and these are outlined in further details in response to consultation questions 2-6. To summarise these areas are as follows:

1. Defining and using the term research misconduct with the Code
2. Ensuring adequate external oversight of investigations into breaches of the Code
3. Providing guidance on how any complaints of research misconduct against an institution might be handled
4. Providing guidance on how multi-institution research misconduct complaints are best handled
5. Clarifying and better describing the nature of the preliminary assessment stage and the investigation stage
6. Developing an appeals process that can take into account substantial and compelling new evidence
7. Providing detailed case study examples through a dedicated website for the Code
8. Developing a database or list of suitably qualified expert panel members
9. Creating training resources for Research Integrity Advisors

### **Q.2 The draft code is intended to be used by all research disciplines. Do the principles adequately capture the expectations for responsible research across all research disciplines?**

The principles adequately capture the expectations for responsible research. The following comments are offered to assist in further improving certain aspects of the principles and responsibilities outlined in the draft Code.

#### **P8 Promotion of responsible conduct in the research community**

Principle number P8, the *promotion of responsible conduct in the research community* might need some further revision. It states that:

“Researchers and institutions will promote responsible research conduct principles and mentor and supervise research trainees and early career researchers”

This principle should make it clear that there are different expectations of researchers with regards to the promotion of the principles and the mentoring or research trainees and early career researchers, depending on their relative level of seniority and experience. Students and post-doctoral researchers should not necessarily be expected to uphold this principle to the same extent as senior researchers, as they might not yet have gained the expertise necessary to supervise other researchers in this area.

### **R-23 Authorship of research outputs**

The expectations and norms surrounding authorship are different in (and even within) medical science disciplines, compared to social science and humanities disciplines. The amount of work and involvement required by a researcher to be listed as an author does differ significantly between disciplines. For the Code to be applicable across disciplines these differences need to be acknowledged, and how the Code applies to researchers in this regard will need to be managed sensitively. Further guidance on adhering to this responsibility should feature in the proposed guide on authorship which the consultation documents state is in line for development.

In developing the guide on the authorship of research outputs it will be important to take into account authorship guidelines produced by international scientific community, such as by the International Committee of Medical Journal Editors (ICMJE). Researchers in Australia will expect to have similar authorship expectation practices compared to their peers in the international community.

### **Q.3 The draft Guide refers to breaches of the Code rather than providing a definition of research misconduct, and states that institutions can decide whether or not to use the term research misconduct in their own processes. Is this guidance clear and implementable? What issues do you foresee with that approach?**

**The term 'research misconduct' should continue to be used, and should be defined as a major breach of the Code.**

### **Addressing the three stated reasons in the consultation documents for dropping the use of the term research misconduct within the draft Code**

The three reasons outlined in the consultation documents for dropping the use of the term research misconduct within the Code are not compelling, and do not outweigh the value of continuing of its continued use.

1. That the term is not used within the Canadian model

While it is appreciated there are models overseas that do not use the term 'research misconduct', many overseas models do employ the term research misconduct. The absence of the term within the Canadian model is not a compelling reason in itself for to discontinue its use within the Code. A definition can be incorporated into the new approach using the proposed definition put forward by AAMRI.

2. That there is no internationally agreed definition of research misconduct

The absence of an internationally agreed definition should not preclude Australia from adopting a suitable definition, as is the case in most leading research systems. While there might not be an internationally agreed definition as to what constitutes research misconduct, the term is universally understood by researchers and the community more broadly. Researchers throughout the world are familiar with the term research misconduct and have a relatively common understanding as to what is meant by it, and the serious nature of what it implies. A finding of research misconduct in any leading research system would be understood elsewhere.

3. The current definition of research misconduct has been problematic in its application, particularly relating to enterprise agreements and current approaches to the management of behaviours that may require corrective action.

There have been cases where an institution's enterprise agreement and its definition of misconduct have not aligned with the definition in the Code. This has the potential for a conflict in terms of the process or outcome from an investigation into research misconduct. Rather than removing the definition from the Code it would be preferable for institutions to align their future enterprise agreements with the expectations set out in the Code, including any definition of research misconduct. Furthermore, the definition offered by AAMRI should make it easier to do this.

The serious nature of having been found to have engaged in research misconduct could potentially make some institutions more hesitant to come to an adverse finding against an individual, particularly where the intent behind actions is disputed. The solution would not be to drop the use of the term research misconduct entirely, but rather define it as "major breaches of the Code". The major breaches listed in Figure 1 of the *Guide to investigating and managing potential breaches of the Australian Code for the Responsible Conduct of Research* provides guidance as to what would constitute a major breach, and therefore an example of what constitutes research misconduct.

### **Ensuring public confidence in the good conduct of research**

The Code should be used to ensure continued public trust in the good conduct of research. The Australian community expects that researchers conduct their work responsibly, ethically and for the benefit of the community. Where this is not taking place the community would rightly have an expectation that adequate processes are in place to investigate, and where necessary sanction those that are found to have not met these standards.

The positive intent behind the broader changes to the Code is greatly appreciated, but there is a risk that in no longer using the term research misconduct public confidence in Australian research could be undermined. There is a risk that this change could be viewed by some as a watering down of the existing Code, reducing the seriousness to which behaviour that includes fabrication, falsification, and plagiarism is managed by the sector. While AAMRI does not take this view, it is important to understand and respond to such perceptions to ensure continued confidence in the Code.

### **Application by different institutions**

Allowing institutions to determine whether they decide to use the term research misconduct within their own framework is problematic. This will lead to some institutions using the term, while others might drop it entirely. The result of this will be that similar types of breaches of the Code will be defined as research misconduct by some institutions, whereas other institutions will make no such finding and instead just refer to a breach of the Code. It would be better for the application of the Code to be universal, and in the interests of fairness and transparency it would not be reasonable to put in place a Code that can lead to different outcomes at different institutions.

### **Q.4 Do you think the process described for investigating and managing potential breaches of the Code is clearly described and practical?**

The process outlined in the draft Guide for investigating and managing potential breaches of the Code is clear and will be of great assistance to institutions and those charged with undertaking investigations. The following comments are made to help clarify particular aspects of the Guide and to help make the process clearer.

### **Section 3.2, Box 1 Extent: breaches occur on a spectrum (mitigating circumstances)**

Within Box 1 factors are listed to guide the consideration of degree of departure from the Code, along with examples of mitigating or extenuating circumstances. In addition to the first mitigating point relating to institutions that do not provide appropriate resources or facilities to researchers, the failure

of institutions to provide appropriate training, particularly for early career researchers, should also be listed as a mitigating factor.

### **Section 3.2, Box 1 Extent: breaches occur on a spectrum (pattern of breaches)**

A pattern of breaches by the researcher is listed in Box 1 as an example of mitigating or extenuating circumstances. This should be removed as an example of mitigating or extenuating circumstances, and instead be relied upon to determine the severity of a breach.

### **Section 4.2, Figure 2 - Overview of the process for investigating and managing potential breaches of the code**

Figure 2 provides a helpful overview of the process for investigating and managing potential breaches of the Code.

The flowchart along with the list of roles outlined in table 1 could clearly be applied to large organisations with the capacity to employ separate people in the various roles at all stages of the investigation. Many research organisations, including hospitals and MRIs, would not maintain a distinct Research Integrity Office. It must be made clear in the Code that organisations without a Research Integrity Office are not automatically considered as unable to conduct a fair investigation. It would be helpful to indicate which roles could be combined and undertaken by one person without compromising the process and procedural fairness. The Code could also be specific and state that smaller organisations could outsource some of the roles to another research organisation during an investigation.

The Figure could be further improved by including the different individuals and their responsible roles at the different points of the flowchart. This would help to provide an ongoing overview as to who was responsible for the different actions without having to refer separately to Tables 2 and 3.

### **Section 4, absence of guidance on potential breaches by research organisations**

The Guide assumes that the breaches of the Code being investigated are breaches by a researcher or multiple researchers. Given the Code ascribes responsibilities to institutions it is possible that complaints regarding breaches of the Code could relate to institutions as a whole, rather than individual researchers. As such a process for investigating such breaches might also be needed, and would presumably need to involve external investigators. It might be that such guidance would form part of a separate future guide.

### **Section 4.3, Institutional roles (indemnifying individuals involved in the investigation process)**

Those involved in the investigation process should have complete confidence that in acting in their role they are indemnified from the threat of civil legal action from either the complainant or the respondent. Providing such indemnity will be particularly important for external panel members who are not in an employment relationship with the institution where the investigation is taking place. Advice on the level of protection that is required would be useful.

### **Section 4.3, Table 1**

The title of the table begins with “Table 1: Terms used in this BPG”, but there is no explanation as to what BPG stands for or refers to. Presumably BPG stands for best practice guide.

## **Section 5 and 6, Preliminary assessment stage and investigation stage – purpose and name for each stage**

It is sensible to have two different stages in the process whereby an inquiry into whether a breach of the Code might have taken place is first undertaken, before a separate process of determining whether a breach has actually occurred takes place. These two stages are described in section 6 and 7 of the Guide. However, the functions undertaken during these stages are not adequately reflected in how stages are named.

It is during the preliminary assessment stage (section 6) where the investigative work is undertaken. It is here where the AO identifies, collects, inventories and secures evidence. In contrast the ‘investigation’ stage as described in the Guide (section 7) offers little in terms of new investigative work to be undertaken. Evidence beyond that collected in section 6 appears to be limited to either evidence in reply, or from testing the veracity of evidence already collected through interviews with the respondent, complainant or others. That is to say section 6 appears to be more of a presentation and questioning of evidence, rather than an investigation itself. In this regard the preliminary assessment stage shows greater resemblance to an investigation stage, and the investigation stage shows greater resemblance to a tribunal stage, given that the Panel is being asked to make findings.

Consideration needs to be given as to the appropriate names of these stages, and in particular, whether the role and function of the Panel is to investigate and make findings, or make findings based on the investigative work already undertaken. At present it appears to be the latter, and the Guide should make this clear so that roles and responsibilities are fully understood.

### **Section 5.2, Initial receipt of complaints**

In addition to providing details on where to make a complaint it should be made clear to the respondent that the complaint will be sent to the Designated Officer (DO) for action.

### **Section 5.4, Communicating with the complainant**

The Guide could be improved by stating who is responsible for communicating with the complainant throughout the process as this is currently unspecified. It might be that different people are responsible for different aspects of communication. Furthermore, as the welfare of the complainant could change over the course of the investigation it is important to state that ongoing communication with regards to welfare and support needs.

### **Section 6.2 Conduct of the preliminary assessment**

It would be useful if the Guide stated that the Designated Officer should provide the Assessment officer (AO) with all necessary authority to access the data and information required to conduct their assessment.

### **Section 6.3 Outcomes from the preliminary assessment**

The Guide could state that whether on receipt of the preliminary assessment report from the AO whether the DO is permitted to seek advice from any other parties. This advice could be both in terms of the substance of the case and also procedural matters surrounding how it is being investigated.

### **Section 6.5 Summary, Table 2 Roles and functions of Officers (Role of the research integrity officer (RIO) within section 6 Preliminary assessment stage)**

Within the summary of section 6, table 2, an outline of the different roles and their functions during the preliminary assessment is provided. The role of the research integrity officer (RIO) is listed within the table but this is not discussed within section 6. Given the way the RIO is listed within the table it

appears that the role has the same functions as that of the Assessment Officer (AO), but whether this is the case or not is unclear.

It is suggested that mention of the RIO within table 2 is removed so that it is clear that only the AO is responsible for the tasks associated with conducting a preliminary assessment. If the role of the AO can be fulfilled by RIO staff then this should be made clear. Should this be the case then it should also be made clear that the RIO staff member fulfilling the role of AO should not be involved in any of the RIO functions following the preliminary assessment during the investigation stage.

### **Section 6.5 Summary, Table 2 Roles and functions of Officers (Role of the DO)**

In addition to the functions for the role of the DO in Table 2 the need to advise the respondent that a complaint has been made should also be listed, along with notifying the AO of the need for a preliminary assessment.

### **Section 7.2, Preparing for the investigation (use of external panel members)**

Consideration by the Designated Officer (DO) for the use of external panel members is suggested in the Guide. There are no suggested criteria on which to base the decision on whether or not external panel members are required.

All contested allegations that have the potential to result in a finding more serious than that of a minor breach of the code should be investigated by a wholly external panel. The use of external panel members will help reduce conflicts of interest (real and perceived), and help give greater confidence in the process to the complainant, respondent, and the broader community.

### **Section 7.3, Conduct of investigation (terms of reference)**

The Guide states that if the Panel finds during the investigation that the scope and/or terms of reference are too limiting then it should refer the matter back to the Designated Officer (DO) who then may decide to amend the scope of the investigation. The Guide should make it clear that at this point the DO can refer the matter back to the AO for further investigation. The AO should then be authorised to undertake additional evidence collecting.

### **Section 7.4.3 Evidence to support a breach of the code (institutions response)**

In formulating a response to where a breach of the Code has been found, in addition to taking into account the severity of the breach, the REO should also consider the institutions own policies with dealing with misconduct.

### **Section 7.5, Communicating the findings**

With respect to communicating findings, in section 7.5 it states that:

“The REO should consider whether a de-identified public statement should be made to communicate the outcomes of an investigation”

It is unclear whether the recommendation to consider communicating a de-identified public statement relates solely to the cases where a respondent resigns (as outlined in the previous paragraph), or whether it applies to all cases where there has been an adverse finding against a respondent. The intent of this statement should be clarified in the final Guide.

The expectation should be that for major breaches of the Code a public statement is usually issued. The broader research community has a need to know when, where and who has committed breaches

of the Code, and the public have an expectation that the outcomes of due process are fair and transparent. The communication of findings of major breaches of the Code is essential in this regard.

### **Section 8, Multi-institutional collaborations and breaches of the Code**

The draft Code states that where there have been potential breaches of the Code during multi-institution collaborations it would be preferable for only one investigation to take place. Guidance is needed on how to determine which institution should lead any investigation, or whether an investigation would fall under the joint-auspices of multiple institutions. Furthermore, guidance is needed on whether each of the roles described in the process would need to be fulfilled by each of the institutions or just one institution.

### **Q5 The Code Review Committee and working group are considering what additional resources should be developed to support implementation of the Code and Guide. Do you think that case studies would assist you to investigate and manage potential breaches of the Code in accordance with the Guide?**

The development of case studies to assist institutions in investigating and managing potential breaches of the Code is strongly supported. The case studies should provide step-by-step guidance of different types of breaches, including providing details on how assessments were made at the different stages, how to determine the severity of the breach, and how final outcomes were arrived at.

It would assist institutions, research integrity advisers, and researchers if these guides were made available through a website that supported all aspects of the Code. This website could include providing the Code, the guides, case studies, and training material. The US Office of Research Integrity provides a similar website and Australia would benefit from something similar.

### **Q6 Are the mechanisms for review of an investigation clearly and correctly described in Section 7.6 of the Guide? If not, where are the inaccuracies?**

The Guide states that institutions should have processes for considering appeals about the way an investigation into a breach of the Code was conducted. The Guide would be improved by providing further information about what those processes should be, and which responsible officers should manage the process. For example, it might be better for an appeal process to be overseen by persons who were not party to original investigation.

The Guide states that requests to review the conduct of an investigation should only be made on the grounds of procedural fairness. The Guide should be amended to allow appeals, and potentially new investigations, on the grounds of substantial and compelling new evidence. There might be occasions where new evidence comes to light, such as missing records being found, and there needs to be a mechanism in place to correct the record.

### **Q7 NHMRC, ARC and UA are considering the development of additional guides to support implementation of the Code. The next two guides will likely focus on authorship and data management. The possible topics for additional guidance are supervision, conflicts of interest, peer review, collaborative research, intellectual property and copyright, the role of research integrity advisers, the role of research integrity officers, strategies to encourage compliance or clinical trials. All of these are currently covered in varying amounts of detail in the current Part A of the Code and in other material. Please comment on which three topics you would nominate as being the highest priority and why.**

AAMRI supports both authorship and data management as being the next two guides for development. The authorship guide will need to be sensitive to different disciplinary practices and norms. It would be helpful for the data management guide to include details on the responsibilities of institutions and research for managing data once researchers move institutions.

The next guides should cover supervision and investigating breaches of the Code that take place across multiple institutions. Supervision is a critical part of ensuring ongoing adherence to the Code, and underpins all the other areas. Ensuring responsible conduct of research requires adequate training, and in large part this comes from research supervisors.

## **Other comments**

### **Expert panel members**

The use of expert panel members is essential to investigating and managing breaches of the Code. In many cases it will be necessary to call on the use of external expert panel members. The Guide does not provide advice on how to identify relevant and suitably qualified expert panel members. A single up to date database or list of suitably qualified expert panel members who would be willing to assist should be compiled and made available to institutions undertaking investigations into breaches of the Code.

### **Training of Research Integrity Advisors**

Critical to the implementation of the Code will be for adequate numbers of RIAs to be in place at research institutions. This will require ongoing training for those that fulfil this role. The Code does make it clear that institutions have a responsibility to provide such training (R10). However, there might be a role for the NHMRC or other organisations to fulfil in establishing a high quality training program for RIAs.

## AAMRI MEMBERS

