Australia needs an office of academic integrity

Bruce M Hall

he prevention and investigation of research misconduct, particularly in medicine, remain in the news, with reports of cases in South Korea, 1.2 Norway, the United States, India and Canada. Some countries have established procedures and designated bodies for investigating allegations of research misconduct: in the US there is the Office of Research Integrity (ORI); n Germany, the Committee of Inquiry on Allegations of Scientific Misconduct; and, in Denmark, the Committees on Scientific Dishonesty. A national office for this purpose is under consideration in the United Kingdom. In Australia, we have guidelines on research practice; the National Health and Medical Research Council (NHMRC), the Australian Vice-Chancellors' Committee (AVCC) and the Australian Research Council are currently revising the Joint NHMRC/AVCC statement and guidelines on research practice (1997). 11,12

Academic integrity requires standards of scrupulous honesty and high moral values in all academic and scientific endeavours and its maintenance is ultimately dependent on individuals. Bodies that conduct and fund research — universities, research institutes, government agencies, and private corporations (eg, the pharmaceutical industry) — all have policies and procedures to promote integrity in research. However, under current circumstances, they will never be able to ensure that every link in the chain strictly adheres to these ideals, or that any complaints related to academic research are justly and thoroughly investigated. Furthermore, institutions investigating allegations of research misconduct are vulnerable to claims they have inadequate processes or have an institutional conflict of interest. I believe that Australia needs to establish an office of academic integrity based on the ORI model in the US.

What is research misconduct and is it widespread?

"Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results." It may also include "other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research". The "other practices" rule is not universally accepted and is not in the ORI definition because it could lead to novel research methods being deemed misconduct. According to Rennie and Gunsalus,

[there] is a fear that the vague language will result in application of a vague and misty standard of misconduct that cannot be known in advance. It seems fundamentally unfair to stigmatise someone for behavior they had no way of knowing was "wrong". 8

Sabotage and interference, misrepresentation, conflicts of interest and authorship issues are also not included in the ORI definitions, but many of these issues remain in the Australian, ¹⁴ UK (Medical Research Council Policy and Procedure for Inquiring into Allegations of Scientific Misconduct), ¹⁵ and Danish policies. ¹⁶

The true extent of research misconduct is unknown and may never be determined, as most studies published in scientific journals are not cited by other authors and no one attempts to reproduce their results.³ Within the area of health and medical research, Nordic countries receive one to two complaints of

ABSTRACT

- Institutions investigating allegations of research misconduct are vulnerable to claims that their processes are inadequate or that they have an institutional conflict of interest.
- The Office of Research Integrity in the United States
 sets down standards for and reviews the adequacy of investigations of research misconduct by institutions;
 - > recognises that internal politics and the involvement of non-experts can lead to honest mistakes being regarded as serious misconduct;
 - > requires complainants and investigators to act "in good faith"; and
 - > reduces damaging publicity when complaints are misconceived or false.
- Australia needs an office of academic integrity to ensure that
 all complaints are thoroughly investigated;
 - > the investigative procedures meet international standards;
 - > fair processes are provided for complainants and respondents; and
 - > institutions are protected from claims of "cover-up" and institutional conflict of interest.

MJA 2006; 185: 619-622

See also page 623

research misconduct per million population each year; ^{9,16} the ORI received 265 allegations in 2005 but, of these, only 30 resulted in an inquiry. ¹⁷ An anonymous survey of US researchers, in which about half responded, found 0.3% admitted to falsification, 12.5% overlooked the use of flawed data or questionable interpretation of data by others, and 15.5% had changed "the design, methodology or results of a study in response to pressure from a funding source". ¹⁸

Differentiating honest mistake from intentional deceit

Rennie and Gunsalus argue that investigations into research misconduct should use a two-step process.⁸ First, establish the facts. Is there a material error? Material errors alter the meaning of a body of work and require retraction. It is self-evident that mistakes that make no difference to any conclusion are not misconduct.

The second step is to assess whether a material error was made with intent, either deliberately or recklessly, rather than being a genuine mistake or human error. This step needs to consider circumstances and track record. A material error is not misconduct if it is an honest mistake, or the best interpretation that could be made at the time. Misconduct is a knowing, deliberate or reckless action to advance a false proposition.

The need for an independent body with statutory, defined investigative procedures

The Baltimore case in the US, around the time of the establishment of the ORI, illustrates the role of an independent body in

RESEARCH ENTERPRISE

1 Selected definitions and procedures of the Office of Research Integrity (US Public Health Service Policies on Research Misconduct)¹³

Confidentiality

Disclosure of the identity of respondents and complainants in research misconduct proceedings is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceedings, and as allowed by law.

Notice to responent and custody of research records

An institution must make a good faith effort to notify in writing the presumed respondent ... [and] ... promptly take all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceedings.

Institutional inquiry

- An inquiry is warranted if the allegation . . . falls within the
 definition of research misconduct . . . [and] preliminary fact finding
 from the inquiry indicates the allegation may have substance.
- The institution must provide the respondent an opportunity to review and comment on the inquiry report . . .
- The institution must complete the inquiry within 60 calendar days of its initiation . . .

Institutional investigation

- Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practicable, including participation of persons with appropriate scientific expertise who do not have unresolved personal, professional, or financial conflicts with those involved in the . . . investigation.
- Interview each respondent, complainant and any other available person . . . including witnesses identified by the respondent.
- An institution must complete all aspects of an investigation within 120 days of beginning it . . .
- The institution must give the respondent a copy of the draft investigation report and, concurrently, a copy of, or supervised access to, the evidence on which the report is based. The comments of the respondent on the draft report, if any, must be submitted within 30 days...

Institutional policies and procedures

All reasonable and practical efforts ... [must be made] to protect or restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made.

Good and bad faith

Good faith as applied to a complainant or witness, means having a belief in the truth of one's allegation or testimony that a reasonable person in the complainant's or witness's position could have based on the information known to the complainant or witness at the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if made with knowing or reckless disregard for information that would negate the allegation or testimony.

Good faith as applied to a committee member means cooperating with the research misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping an institution meet its responsibilities under this part. A committee member does not act in good faith if his/her acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

investigating allegations of research misconduct, particularly when the process is complicated by political interference. David Baltimore, a Nobel Laureate, defended Thereza Imanishi-Kari, his coauthor on an article in the journal *Cell* in 1986, when allegations of scientific misconduct were made by a postdoctoral fellow in his laboratory. The matter went on for 10 years, kept alive by political pressure from members of the US Congress and scientific colleagues, and a persistent campaign by the whistleblower, with wide public and media debate. Baltimore later commented:

In protecting the reputation of science, we must be careful to preserve the distinction between error and misconduct. Error is unavoidable, and misconduct is intolerable. Error in science will be found out because of the self-correcting nature of the scientific process. This process can be slow and often is not transparent, but the self-correcting function of science is one of its strengths.²⁰

In the mid 1980s, the National Institutes of Health (NIH) used ad-hoc committees of scientists to investigate such allegations, one of which investigated Imanishi-Kari in 1987 and did not find misconduct. The Office of Scientific Integrity, established as part of the NIH in 1989, reopened the case that year in response to new evidence from a Congressional Inquiry. An ad-hoc scientific review committee found misconduct in 1991, the its findings were contested by Imanishi-Kari and Baltimore.

The ORI was formed in 1992 to be independent of funding agencies and to have legally based processes. Its charter was to educate as well as develop regulations and review investigations. Box 1 lists some important ORI regulations.

The ultimate inquiry that exonerated Imanishi-Kari had rules of evidence and included cross-examination in front of two judges, with advice from an independent overseas expert. The article in question was withdrawn, but the error was not misconduct.¹⁹

ORI regulations have been debated and refined over the past 14 years. Thirty-seven per cent of complaints of misconduct handled by the ORI are substantiated. There is recognition that not all complainants and investigators act in "good faith". Research practices relevant to the field of science are the benchmark.

The processes of the ORI appear to have reduced congressional and press interference in complaints about research integrity in the US.

An office of academic integrity for Australia

In Box 2, I summarise the basic requirements for improving assessment of allegations of research misconduct in Australia, the first of which is the establishment of an office of academic integrity. This would give the Australian public and the international academic community confidence that all complaints related to academic standards in Australian universities, research institutions and research organisations would be thoroughly and justly investigated. Such an office would protect individual institutions from claims of "cover-up" or institutional conflict of interest by confirming that their procedures meet international standards.

With Australia's research base being much smaller than that in the US, an office restricted to overseeing investigations of research misconduct may not be viable. Thus, I propose that this office set standards and review investigations related to other complaints about academic standards. Initially, such an office would establish procedures for investigating research misconduct — falsification, fabrication and plagiarism — in scientific and scholarly work.

RESEARCH ENTERPRISE

2 Improving assessment of allegations of research misconduct in Australia

- Establish an office of academic integrity under federal law to draw up policies and procedures for dealing with complaints and to review all investigations to ensure they comply with these policies
- Mandate that complainants (who usually should be identified) should detail allegations in writing and provide evidence
- Secure all records and evidence immediately, including those
 of the complainants, respondents and other involved parties
- Determine any underlying reasons for the complaints. Is there
 malice or poor performance by the staff/students making the
 complaints? Are there differences between the complainants
 and the respondent over a hypothesis or scientific principle?
- Investigate counter allegations by the respondent in parallel
- Establish evidence of a prima facie case through an institutional inquiry, using expert external advice if required, looking at the data and allowing the respondent to respond to a draft report
- If there is a prima facie case, make further investigations that comply with those prescribed by the office of academic integrity
- Facilitate review of the institution's investigation by the office of academic integrity and ensure its concerns are addressed, including recommendations for an external investigation

Requirements for external investigators

- Use independent experts in the appropriate field of science with no links or conflicts with the complainants or the respondent, usually an independent expert from another country
- Give investigating panels the power to cross-examine and subpoena witnesses, including the complainants, and to retrieve records and computer files during their investigation
- Use a prosecutor who is not a member of the investigating panel •

Over time, it could also provide guidelines for investigating other perennial complaints, including plagiarism by students, conflicts of interest, sabotage and interference, authorship, curriculum vitae inaccuracies, unfair academic promotions, and other matters that undermine academic integrity.

An office of academic integrity would have well developed processes for ensuring procedural fairness, similar to those of the ORI in the US (Box 1), 13 including what to do first when confronted with research misconduct. The Director of the ORI, Chris B Pascal, stated that if "you don't know what to do first ... you may end up violating legal norms ... The mistakes that often follow make it hard to reach a fair decision". 22 In the US, the ORI only covers government-funded health research, but its policies set the standards for dealing with all complaints. 7

Although investigations would be supervised by the office of academic integrity, the primary responsibility for investigation would remain with institutions, unless they were unwilling or unable to do so, or the investigations they carried out were inadequate. An office of academic integrity would establish regulations and provide advice on the processes required for institutional investigations. It would then monitor all investigations and review their final reports. If it was not satisfied, it could require further investigation.

These requirements are essential, as there are major problems with hastily convened external committees, as was the practice in the US before the ORI was set up. According to Rennie: "... ad-hoc panels, sometimes with glaring conflicts of interest ...

were frequently slow, bungled, idiosyncratic, and unfair to almost everyone". An external inquiry can make major mistakes, including making findings by omission of key evidence and data, misusing scientific facts, and rewriting sentences under investigation and in key evidence. (This happened when I was subjected to an external investigation. Subsequent internal investigations, taking advice from internationally recognised experts in my field, could not substantiate the findings of this external committee. ²⁴)

Procedures for a new system of investigation by an office of academic integrity

Improved methods of reporting complaints

All complaints received by an institution would be registered with the office of academic integrity. Institutions would be required to secure all research records. Misconduct associated with removal or destruction of records would be acted upon.

Whistleblowers would be protected from reprisal and this would be mandated by the office of academic integrity. On the other hand, they would also be required to cooperate fully with any inquiry and to undergo cross-examination. If there were counter allegations, they would be subject to investigation. Malicious or vexatious complaints, not made in "good faith", would be subject to sanctions, as recommended by UK policies. ¹⁵

Assessing the presence of a prima facie case

The institution receiving the complaint would conduct a preliminary investigation to determine whether there was a prima facie case. The respondent would be told of the allegations and given access to all records and evidence, as well as a chance to respond to any findings presented in a draft report.

If the preliminary inquiry did not find a prima facie case, the report, the evidence, and the respondent's comments on the report would be reviewed by the office of academic integrity. If the office ratified the procedures and findings, the matter would be closed. A prima facie case would lead to a more extensive investigation.

3 Key tasks of an Australian office of academic integrity

- To define scientific misconduct, as falsification, fabrication and plagiarism, with provision to alter the definition after wide consultation
- To supervise the investigation of scientific and academic misconduct in all, not just federally funded, research
- To set standards for fair investigations using those developed by the US Office of Research Integrity
- To set guidelines for investigative committees, including providing the respondent with a draft report and the evidence on which findings are based before the report is finalised
- To establish processes that will withstand legal challenge and will give investigating panels power to retrieve records and cross-examine
- To ensure a lack of conflict of interest or bias, and to separate investigators and prosecutors from judges
- To ensure timely completion of investigations
- To correct the scientific record, including examining all other publications of those found guilty of misconduct, and retracting false publications

RESEARCH ENTERPRISE

External assistance may be required, even in preliminary investigations. This would include experts in the field if complex science were involved, or an experienced patent attorney for intellectual property disputes. Misuse of research funds or criminal activity, such as sabotage, would be referred to the police.

Resignation or confession of misconduct by a researcher at this stage would be followed by an examination of published papers and appropriate retraction or correction.

Further investigation and appeals

An office of academic integrity would regulate the procedures for further investigation and appeals, and ensure the use of rules of evidence, cross-examination and the advice of independent experts. It has been suggested that such experts should mostly be from overseas. ¹² Committees established for the purpose, as in Denmark, could be considered, as it takes too long to establish adhoc committees. These investigations would have defined procedures, including supplying the respondent with a draft report.

All investigations need to ensure that investigators have no conflicts of interest related to the complainants or respondents, as defined in Box 1. The standards of independence and absence of bias of members of all investigative committees should be similar to those of jury members. Committee members would be required to serve as part of their academic appointment, much as citizens are required to do jury duty. This would be part of the unpaid peer review process.

Circumventing early disclosure in the media

The fair processes of an office of academic integrity would remove a complainant's need to seek publicity. Suppression of the name of the respondent and complainant would be the norm, as occurs in many cases before medical boards. This is essential to avoid irreparable harm from unsubstantiated, false or misconceived allegations, as over 60% of the complaints handled by the ORI do not lead to findings of misconduct.

In proven cases of misconduct, when processes are completed and there is confidence that the outcome is just, then the case can be publicised. An office of academic integrity would sanction complainants who breach confidentiality and make false claims in public before due processes were completed.

Conclusions

All countries need national bodies with statutory power to regulate investigation of complaints of scientific and scholarly misconduct. Australia and the UK are 20 years behind the US in developing national procedures. The ORI was not established without controversy and robust debate; it evolved from legislation enacted in 1985. ^{7,8} In Denmark, there are now three committees: one for health sciences, one for non-health sciences, and one for social sciences and the humanities. ¹⁵ I argue that an office of academic integrity should be established in Australia by federal government legislation and the key elements for its operation adapted from those of the ORI (Box 3). An office of academic integrity would make genuine whistleblowers confident to come forward, as their concerns would be fairly investigated. It would ensure that respondents have fair and timely investigations and that errors in published work are retracted.

Competing interests

I have been the subject of innumerable allegations resulting in over 20 investigations over 5 years. I am employed by the University of New South Wales, whose thorough internal inquiries exonerated me on several hundred false allegations including scientific misconduct and financial fraud.

Author details

Bruce M Hall, MBBS, FRACP, PhD, Professor of Medicine Australian Technology Park, University of New South Wales, Sydney, NSW. *Correspondence*: b.hall@unsw.edu.au

References

- 1 Chong S, Normile D. Stem cells. How young Korean researchers helped unearth a scandal [news]. *Science* 2006; 311: 22-25.
- 2 Couzin J. Stem cells ... and how the problems eluded peer reviewers and editors [news]. Science 2006; 311: 23-24.
- 3 Gerber P. What we can learn from the Hwang and Sudbø affairs? *Med J Aust* 2006; 184: 632-635.
- 4 Sox HC, Rennie D. Research misconduct, retraction, and cleansing the medical literature: lessons from the Poehlman case. Ann Intern Med 2006; 144: 609-613.
- 5 White C. Suspected research fraud: difficulties of getting at the truth. BMJ 2005; 331: 281-288.
- 6 Smith R. Investigating the previous studies of a fraudulent author. *BMJ* 2005; 331: 288-291.
- 7 Rennie D. Dealing with research misconduct in the United Kingdom. An American perspective on research integrity. *BMJ* 1998; 316: 1726-1728.
- Rennie D, Gunsalus CK. Scientific misconduct: new definition, procedures and office — perhaps a new leaf. JAMA 1993; 269: 915-917.
- 9 Riis P. Dealing with research misconduct in the United Kingdom. Honest advice from Denmark. *BMJ* 1998; 316: 1733.
- 10 Lock S, Wells F, Frathings MJG, editors. Fraud and misconduct in biomedical research. 3rd ed. London: BMJ Publishing Group, 2001.
- 11 Anderson WP, Cordner CD, Breen KJ. Strengthening Australia's framework for research oversight [editorial]. *Med J Aust* 2006; 184: 261-263.
- 12 Van Der Weyden MB. Preventing and processing research misconduct: a new Australian code for responsible research [editorial]. Med J Aust 2006; 184: 430-431
- 13 Public Health Service Policies on Research Misconduct; Final Rule; 42 CFR Parts 50 and 93. Part III. Federal Register 2003; 70 (94): 28369-284000. (Rules and Regulations, May 17, 2005) http://www.ori.dhhs.gov/documents/42_cfr_parts_50_and_93_2005.pdf (accessed Oct 2006).
- 14 National Health and Medical Research Council/Australian Vice Chancellors' Committee. Joint NHMRC/AVCC statement and guidelines on research practice. Canberra: NHMRC, AVCC, 1997. http://www.nhmrc.gov.au/funding/ policy/researchprac.htm (accessed Oct 2006.
- 15 Medical Research Council. Policy and Procedure for Inquiring into Allegations of Scientific Misconduct. London: Medical Research Council, 1997. http:// www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002454 (accessed Nov 2006).
- 16 Riis P. Misconduct in clinical research the Scandinavian experience and actions for prevention. *Acta Oncol* 1999; 38: 89-92.
- 17 Office of Research Integrity. Annual Report 2005. Rockville, Md: US Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science, May 2006. http://www.ori.dhhs.gov/documents/annual_reports/ori_annual_report_2005.pdf (accessed Nov 2006).
- 18 Martinson BC, Anderson MS, de Vries R. Scientists behaving badly. *Nature* 2005; 435: 737-738.
- 19 Kevles D. A beautiful paper. In: The Baltimore case. A trial of politics, science and character. Chapter 1. New York, NY: WW Norton & Co, 1998: 1-33.
- 20 Baltimore D. Baltimore's travels continued. *Issues in Science and Technology Online*. Summer 2003. http://www.issues.org/19.4/baltimore.html (accessed Nov 2006).
- 21 Baltimore D. Dr Baltimore says "sorry". Nature 1991; 351: 94-95.
- 22 Marshall E. Scientific misconduct: crime scene investigation. How to handle misconduct. *Science* 2006; 312: 1465.
- 23 Hall B. Response of Professor Bruce M Hall to Senator K Carr. Tabling of the report of the External Independent Inquiry into Scientific Misconduct, commissioned by the Council of the University of New South Wales. Australian Senate, Hansard 9 August 2004.
- 24 Hume RW. Report by the Vice-Chancellor on findings relative to allegations of misconduct against Professor Bruce Hall. University of New South Wales. December 2003. http://www.secretariat.unsw.edu.au/council/Hall_Matter_3/Hall_Docs/Report_%20by_the_Vice-Chancellor_23_Dec_03.pdf (accessed Nov 2006).

(Received 18 Jul 2006, accepted 21 Sep 2006)