Promoting responsible research conduct in a developing world academic context

L Horn, MB ChB, DTM&H, DCH (SA), MPhil (Applied Ethics), Diploma: International Research Ethics, PhD

Centre for Applied Ethics, Department of Philosophy and Division for Research Development, Stellenbosch University, South Africa

Corresponding author: L Horn (Ihorn@sun.ac.za)

As reports of research misconduct seem to increase, research integrity and the promotion of responsible research conduct are important for academic institutions. This paper considers what research integrity means for individual researchers and institutions, and explores trends for promoting responsible research conduct. An Aristotelian concept of 'the good' is used to consider the difference between 'good' and 'successful' researchers. I argue that a balance is required between advancing an ethics of individual responsibility on the one hand, and a compliance-focused approach on the other. I discuss institutional strategies for promoting responsible research conduct, including training and mentorship, developing an appropriate institutional culture that emphasises individual responsibility and accountability, and ensuring that institutions have clear, easily accessible policies available for all aspects of research.

S Afr J BL 2013;6(1):21-24. DOI:10.7196/SAJBL.256

Science is founded on the values of integrity and trust. We must be able to trust, with certainty, that scientists present the results of their endeavours with integrity. Institutions must take seriously their responsibility for promoting scientific integrity and responsible research conduct.

Unfortunately, history reminds us that not all researchers conduct research responsibly. The Office for Research Integrity (ORI) in the USA publishes a list on their website of researchers who have been found guilty of research misconduct, [1] including plagiarism and fabrication or falsification of data. Unfortunately, the list has to be updated and added to almost monthly. An analysis of 146 ORI findings of serious research misconduct found that approximately one-third of the respondents were support staff, one-third doctoral students or postdoctoral fellows, and one-third faculty at academic institutions. [2] The circumstances surrounding each case also revealed that most respondents had participated in Responsible Conduct of Research (RCR) courses, but while such courses may increase knowledge about ethics in research, they do little to alter behaviour. It was concluded that a combination of human character and circumstance led to these

Despite many codes, guidelines, rules and regulations for research, irregularities involving research on human participants continue to emerge. One of the worst recent examples of unethical research involved a major pharmaceutical company, which tested an unregistered drug on children suffering from meningococcal meningitis in a very poor community in Nigeria.[3] This occurred even though those involved had had Good Clinical Practice (GCP) training and were operating within the highly regulated United States system for research on humans.[4]

The Singapore Statement on Research Integrity was finalised at the Second World Conference on Research Integrity, and released on 22 September 2010.^[5] Representing the joint efforts of over 350 people from 51 countries, it contains 4 principles and 14 responsibilities and

has been formally endorsed by countries, science institutions and academic institutions across the globe. The four principles are:

- honesty in all aspects of research
- accountability in the conduct of research
- professional courtesy and fairness in working with others
- good stewardship of research on behalf of others.

Note that of the 14 responsibilities, all but 2 start with the words 'Researchers should,' thus firmly placing accountability with researchers as individuals. The other 2 responsibilities start with the words 'Institutions should'. It is an important step that institutions worldwide are recognising that research integrity is a fundamental issue that requires active promotion. However, the existence of codes and guidelines cannot in itself guarantee that individuals will take notice of or internalise them.

'Successful' v. 'good' researchers

Is being a 'good' researcher the same thing as being a 'successful' researcher? The benchmarks of a successful research career would contain some of the following: the researcher's publication record, number of successful grant applications, total funding received, awards and peer recognition, number of successful master's and doctoral students supervised, etc.

However, the Greek philosopher Aristotle would probably have taken a different approach to the question of, 'What is a "good" researcher?' He may have started by contemplating what it means to have a research career in the context of the quest for optimal human flourishing (called eudaimonia by the ancient Greeks) for both researchers themselves and the world in which they live. To achieve eudaimonia, Aristotle may have argued that researchers must acquire and develop certain qualities or character traits, without which they are unlikely to become 'good' researchers even if they are considered 'successful' researchers:[6]

- Integrity. Integrity implies habitual honesty and is an essential quality of a good researcher. The 20th century philosopher Jon Rawls described truth as the first virtue of systems of thought.[7]
- Trustworthiness. Trust is the firm reliance on the integrity, ability or character of another.[8] It involves committing something into the care of another and being confident that he or she will indeed take proper care of it. To be trustworthy means that the person warrants that trust.
- Justice. It seems intuitive that a deeply ingrained sense of justice or fairness is an essential character trait of a good researcher. Justice has many manifestations within the research enterprise, from broad considerations of social justice to the just distribution of the burdens and benefits of research, and the fair allocation of credit where credit is due.
- **Courage.** Courage is one of Aristotle's cardinal virtues, midway between rashness and cowardice as 'a mean state in relation to feelings of fear and confidence'.[9] Researchers need courage to challenge assumptions and push boundaries. Without courage, stagnation is likely.
- **Discernment.** Discernment or prudence is similar to the Greek phronesis, or practical judgement. It involves the ability to reach decisions without being inappropriately influenced by non-relevant considerations or personal feelings of attachment, dislike, etc.; and being able to move to and fro between knowledge of universal moral truths and an understanding of practical considerations, in order to finally reach a judgement.[10]
- Respect or respectfulness. Plato said that 'Zeus gave to men respect and justice as the ordering principles of society.[11] To be respectful means to acknowledge human dignity in all persons no matter their standing or status, and to understand how important it is to have one's dignity acknowledged and respected.

Others could be added, but one could hypothesise that, if this range of qualities were fully developed in all scientists, we could almost do away with codes of conduct and other guidelines. Ensuring that these values or qualities become integral to the makeup of novice or upand-coming researchers is more difficult.

A contemporary approach to ethics, which has similarities to the ethics of virtue just described, is known as the 'ethics of responsibility'. First used by Max Weber, this concept has been explored and developed by other philosophers, particularly Zygmunt Bauman. Bauman suggests that a postmodern approach to ethics should consist of a 'rejection of the typically "modern" way of going about [solving] moral problems (that is, responding to moral challenges with coercive normative regulation ...)' and a return to relying on our moral conscience and individual moral responsibility to do the right thing or make the right choice. [12] Rules, codes and regulations can become structures to hide behind, and may even promote a reduction in individual ethical responsibility for the value choices we have to make and our accountability for those choices.

For example, a clinical researcher obtaining informed consent from a prospective research participant may have ethics approval for the clinical trial, use an approved informed consent form (ICF) and comply with applicable rules and regulations. However, if the participant indicates automatic trust that the clinician/researcher will act in his or her best interest (i.e. falls victim to the therapeutic misconception)

and is happy to sign the form without reading it, and the GCP-certified researcher accepts this and obtains a signature, then the researcher is making a moral choice which is in opposition to the ethical principles of clinical research. However, this is unlikely to be identified by a monitor or research ethics committee (REC): on the face of things, the research project and the researcher are compliant with ethical requirements.

Current trends

The regulation of research, particularly that involving human participants, has become highly complex, with a significant emphasis on the development of complex bureaucratic systems to promote and monitor research ethics compliance. The Office for Human Research Protections (OHRP) and the Office of Research Integrity (ORI) in the USA are examples of bureaucratic systems whose influence and control have extended globally.[1,3] All research ethics committees (RECs) or institutional review boards (IRBs) who review US Federal Governmentfunded research must be registered with the OHRP and comply with their requirements. Likewise, all institutions must have an 'assurance' registered with the ORI and ostensibly comply with their requirements, including completing an online annual statement reassuring the ORI that no incidents of research misconduct have occurred.

Many developing-world countries, including South Africa, are following the US example and developing their own legislation to regulate research and ensure the compliance of local RECs with set requirements and standards, via process auditing.

Whether these systems promote research responsibility, or prevent the regular occurrence of incidents, is difficult to determine. These activities may help promote responsible research conduct by researchers but ultimately Beecher was correct in stating that having an 'intelligent, informed, conscientious, compassionate, responsible investigator' is a more reliable safeguard.[13]

Institutional strategies for promoting research integrity

Scientific and academic integrity must be highly valued, and expected from all involved in any scholarly or scientific activity. Thoughts on how these values and behaviours can be entrenched at an institutional level in Africa and other developing world countries follow.

Training and mentorship

I have no answers to the difficult question of how to produce 'good' researchers, from Aristotle's perspective. However Aristotle made it clear that qualities of character are acquired by a process of 'moral training' that begins at home but becomes formalised at a later stage, and his Academy was the arena for such education. He also made it clear that the purpose of this education was not just to teach theory, but to teach people 'how to be good'.[8] The issue of whether or not ethical conduct can be taught is controversial. Ruth Macklin has asserted that the answer to this question is both 'yes' and 'no':

'The answer is "no" if the question means to ask whether the attitudes and behaviour of dishonest, mean, uncaring, selfish or arrogant people can be changed as a result of a course in ethics Character traits that have taken root by the time people become young adults are not likely to be changed by classroom teaching in ethics. However, the answer is "yes" if the question means to ask whether beliefs, attitudes and behaviour pertinent to the work of professionals can be instilled by teaching ethics:(14)

The characters of young adults entering into tertiary education are, hopefully, still malleable to a degree. Positively influencing the 'beliefs, attitudes and behaviour pertinent to the work of professionals' develops the qualities and values that make up character.

The CanMEDS physician competency framework^[15] is an example of a training programme that acknowledges that there is much more to producing 'good' doctors than ensuring that they are experts in their chosen field. The underlying philosophy of CanMEDS is 'Starting with the end in mind', where the 'end' is 'optimal outcomes for both patients and society'. This represents a significant shift for developers of medical education programmes. While medical expertise is the physician's 'core integrative competency,' the physician's roles as 'collaborator', 'scholar', 'manager', 'health advocate', 'professional' and 'communicator' are equally important. Similarly, while expertise as a researcher in a particular scientific field could be considered the 'core integrative competency' under this model, the other competencies (except perhaps 'health advocate', depending on the scientific field) are likely to be as essential and relevant to any researcher.[15]

Formal training programmes in the ethical and responsible conduct of research should be incorporated into degree programmes, including higher degree and 'post-doc' programmes, but the earlier this awareness can be created the better. These programmes must adopt a holistic approach, focusing on teaching an 'ethics of responsibility' together with critical thinking skills. Teaching methods, such as facilitated small group discussions of actual and constructed case studies, are often more effective in creating an awareness, understanding and engagement with the issues involved than simply teaching ethical principles and 'codes'. Martha Nussbaum comments that we must attempt to 'equip students well for the interlocking world in which they live' by cultivating their humanity and narrative imagination and teaching them to be both self-reflective and selfcritical.[16]

Mentorship of new researchers is also an important strategy in producing successful researchers. Mentors must understand that the aim is to produce both 'good' and 'successful' researchers and that these concepts are not completely interchangeable. Mentors are often chosen primarily because they are 'successful researchers', but this does not necessarily mean they are well-acquainted with or sensitised to issues surrounding responsible research conduct. They may also have their own research commitments which may interfere with their ability to be an adequate mentor, and may even express irritation to their mentees about the bureaucracy associated with ethics approval processes or other compliance issues. A study of the mentoring of 45 ORI research misconduct cases involving trainees revealed three important factors that appeared to have contributed to the incidents of research misconduct: (i) of mentors, 73% had not looked at raw data: (ii) 62% had 'little awareness' of the research they were supposedly supervising and had not set standards for their mentees, such as keeping laboratory notebooks; and (iii) mentors had not attempted to explore or intervene regarding reports of mentees' high stress levels.[17]

It therefore appears that mentors also require training to ensure that the 'responsible research' message is conveyed adequately and repeatedly to mentees. Such programmes must include the discussion of strategies for creating an institutional culture of research integrity and responsible conduct.

Developing an appropriate institutional culture

Both mentors and institutions have an obligation to create an organisational culture that encourages and demands scientific integrity and the responsible conduct of research. This expectation must be explicitly promoted, not implicitly assumed. Academic research environments are highly competitive, often characterised by significant time constraints and tight deadlines, pressure to publish and sometimes limited or strained academic collegiality in research groups or environments. These issues can hamper the creation of a culture of research integrity and responsibility.

Creative strategies must be developed and adopted, and one of the most important is obtaining leadership from the top down, i.e. from those in leadership positions such as faculty deans or a vice chancellor with a research portfolio. They need to be prepared to set aside time to speak, and/or attend meetings or symposia that address scientific and academic integrity.

A second important strategy is to minimise bureaucracy, including in the ethical approval processes, annual reporting, etc. Researchers also must be provided with adequate support systems and infrastructure to mitigate situations that may foster irresponsible research conduct.

A third important strategy is active promotion of academic collegiality. The breakdown of interpersonal relationships can often start a process leading to allegations of research misconduct. Hence actively creating opportunities to improve academic collegiality and communication is an essential institutional strategy, and can contribute to an environment that grows 'good' and 'successful' responsible researchers.

Adopting and developing research codes and policies at institutional level

Many codes of conduct or guidelines that promote responsible research conduct are recognised either internationally or nationally, e.g. the Singapore Statement on Scientific Integrity, the Declaration of Helsinki and the South African Department of Health guideline Ethics in Health Research: Principles, Structures and Processes.[5,18,19] Researchers must be aware of national or international codes of research conduct relevant to their own research, and institutions have a responsibility to promote that awareness. However, institutions also need to develop or adopt their own codes of conduct for research.

Compared with institutions in the USA, universities in Africa generally have underdeveloped institutional policies governing research conduct. If these exist they often seem hidden and are not easily accessible on institutional websites. The development and implementation of such policies is an essential component of an institutional strategy for promoting responsible research conduct. Examples of 'codes' or 'policies' that apply to a broad research context follow; others may be needed for specific research environments. Overarching policies may require modification or adaptation for faculty-specific needs (without infringing the basic principles or requirements of the 'parent' policy):

- Scientific integrity. Instead of writing their own institutions may choose to endorse an international code such as the Singapore Statement.
- The ethics of research involving humans and animals. Institutional policy codes should broadly discuss the ethics and institution-specific ethical approval requirements of all research involving humans and animals.

ARTICLE

- Plagiarism. This policy should clearly define plagiarism, discuss principles of ethical scientific writing and outline the institutional specific consequences of infringement.
- Conflict of interest. This policy will cover research, procurement and nonfinancial conflicts of interests.
- Responsible authorship. Such a policy will provide broad principles for appropriate authorship and mechanisms to resolve authorship disputes.
- Record keeping and archiving of raw data. This will provide the basic principles for the storage, protection and transfer of
- Supervisor and student mutual responsibilities. This will provide faculties with general guidelines on this topic, with the expectation that faculties would develop their own specific and more detailed guidelines.
- Appropriate use and management of research funds. Research managers and offices have a responsibility for developing these policies and for ensuring their visibility within the institution, as well as easy access for any researcher who wishes to refer to the policy (even late at night). I.e. policies must be available on websites, preferably in an easily accessible dedicated repository.

Early warning systems

If the above three strategies are well developed and function optimally, then institutions will hopefully not have to investigate or take action against researchers found guilty of research misconduct. Unfortunately, isolated incidents of allegations of research misconduct arise from time to time. Academic institutions must have 'early warning systems' [20] that can identify circumstances or situations that could lead to incidents or allegations of research misconduct, and take remedial action before they occur. Examples include a breakdown in collegial relationships between collaborators, or high levels of stress and anxiety experienced by a junior member of a research team, which, if ignored, can lead to unfortunate allegations or incidents.

Conclusion

Promoting responsible institutional research conduct will require an innovative approach that has several components. The approach should balance a focus on compliance with the need to cultivate an ethic of individual responsibility and accountability.

First, the institution must take responsibility for actively promoting an 'institutional culture' of responsible research conduct, from the undergraduate level to senior faculty. Mentorship and training are also essential elements of this strategy, as are well-constructed institutional research policies that are clearly visible, well-advertised and known, and easily accessible. Early warning systems, including

the acknowledgement of whistleblowers, must be established to detect circumstances that could lead to problems.

It is insufficient to assume that 'successful' researchers are by default also 'good' researchers. An ethic of individual responsibility must go hand-in-hand with an institutional and individual commitment to compliance with applicable rules and regulations, funder requirements and codes of ethics when and where necessary.

Acknowledgements. The author would like to thank Professor Anne Pope (Department of Private Law, University of Cape Town) for many thoughtful discussions on this topic and for introducing her to the idea of 'early warning systems'.

References

- 1. Office for Research Integrity. Misconduct Case Summaries. http:// http://ori.hhs. gov/case_summary (accessed 4 February 2013)
- 2. Kornfield DS. Perspective: Research misconduct: The search for a remedy. Acad Med 2012;87(7):877-882. [http://dx.doi.org/10.1097%2FACM.0b013e318257ee6a]
- 3. Macklin R. Bioethics, vulnerability, and protection. Bioethics 2003;7(5-6):472-486. [http://dx.doi.org/10.1111%2F1467-8519.00362]
- 4. Office for Human Research Protections, Health and Human Services, US Federal Government. http://www.hhs.gov/ohrp/policy/index.html (accessed 17 June
- 5. Second World Conference on Research Integrity 2010. Singapore Statement on Research Integrity, Singapore: Second World Conference on Research Integrity, 2010. http://www.singaporestatement.org (accessed 2 February 2013).
- 6. Horn LM. Virtue Ethics in the Development of an Ethical Framework for Public Health Policymaking. DPhil thesis. Cape Town: Stellenbosch University, 2010:167-173. https://scholar.sun.ac.za/handle/10019.1/5418 (accessed 8 March 2013).
- 7. Rawls J. A Theory of Justice. Rev ed. Boston: Harvard University Press, 1999:3.
- 8. Reader's Digest. Universal Dictionary. 1st ed. New York: Reader's Digest, 1987.
- 9. Aristotle. The Nichomachean Ethics. 4th ed. London: Penguin, 2004.
- 10. Bernstein RJ. From hermeneutics to praxis. Rev Metaphys 1982;35(4):823-845.
- 11. Jonsen AR, Butler LH. Public ethics and policy making. Hastings Cent Rep 1975;5(4):19-31. [http://dx.doi.org/10.2307/3561420]
- 12. Bauman Z. Postmodern Ethics. Oxford: Blackwell, 1993:4.
- 13. Beecher HK. Ethics and clinical research. N Engl J Med 1966;274(24):1354-1360.
- 14. Macklin R. Teaching bioethics to future health professionals: A casebased clinical model. Bioethics 1993;7(2-3):200-206. org/10.1111%2Fj.1467-8519.1993.tb00285.x]
- 15. Frank JR. The CanMEDS 2005 Physician Competency Framework. Ottawa: The Royal College of Physicians and Surgeons of Canada, 2005. http://www. royalcollege.ca/portal/page/portal/rc/common/documents/canmeds/ resources/publications/framework full e.pdf (accessed 1 March 2013).
- 16. Nussbaum MC. Cultivating humanity in legal education. U Chicago L Rev 2003;70(1):265-279. [http://dx.doi.org/10.2307%2F1600558]
- 17. Wright D, Titus L, Cornelison JB. Mentoring and research misconduct: An analysis of research mentoring in closed ORI cases. Sci Eng Eth 2008;14(3):323-336. [http://dx.doi.org/10.1007%2Fs11948-008-9074-5]
- 18. World Medical Association. Declaration of Helsinki. Ferney-Voltaire: WMA, 2011. http://www.wma.net/en/30publications/20journal/pdf/wmj31.pdf (accessed 25 February 2013).
- 19. South African Department of Health. Ethics in Health Research: Principles, Structures and Processes. 1st ed. Pretoria: Government Printer, 2004.
- 20. Pope, A. Institutionalising the Singapore Statement. Oral presentation. Cape Town: Advancing Research Ethics in Southern Africa (ARESA) conference, 2012.