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Fostering Research Integrity

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Research integrity emerged as an important matter of public concern in the U.S. in the 1980s, when Al Gore Jr., Ted Weiss, and John Dingle led Congressional hearings on fraud and conflict of interest in federally-funded biomedical research (Price 2013). After these hearing concluded, *Nature* published a short article on research integrity (Shamoo and Annau 1987), and the University of Maryland at Baltimore held a two-day conference on research integrity, which led to the launching of this journal (Shamoo 1989a). Congress also passed legislation requiring the Public Health Service (PHS), which funds National Institutes of Health (NIH) research, to develop misconduct and conflict of interest regulations (Price 2013). By the end of the decade, the PHS had decided to require graduate students and trainees supported by its funds to receive education in responsible conduct of research (RCR).

The National Academy of Sciences, Engineering, and Medicine (NAESM) has played an important role in promoting the responsible conduct of research (RCR) since the late 1980s. NASEM reports have made significant contributions to our understanding of research integrity and the strategies that scientists, academic leaders, and policymakers can use to promote ethical attitudes, decision-making, and behavior in research (NASEM 1992, 2002). NASEM reports have provided valuable insights into various RCR topics, such as: defining and investigating misconduct; protecting whistleblowers; questionable research practices; education and mentoring in RCR; RCR research; the ethics of authorship, publication, and peer review; sharing data and materials; and the role of academic leaders, journals, government agencies, and professional societies in promoting research integrity. The NAESM's guidebook, *On Being a Scientist*, which was first published in 1989 and has been revised twice since then, continues to provide useful guidance to science students and trainees concerning the ethical norms of research and how to apply them to real-world situations (NASEM 2009).

Given the NASEM's outstanding record of advancing the cause of RCR, its latest effort, *Fostering Research Integrity* (2017), comes as somewhat of a disappointment. The 274-page report covers topics already addressed by previous NASEM publications, such as RCR norms and values; important trends in the research environment; the incidence, causes, and

consequences of misconduct; detrimental vs. good research practices; and RCR education and mentoring. Most of the report's recommendations rehash familiar themes without adding much new to the discussion of research integrity. Some of these include:

To better align the realities of research with its values and ideals, all stakeholders in the research enterprise—researchers, research institutions, research sponsors, journals, and societies—should significantly improve and update their practices and policies to respond to the threats to research integrity identified in this report (NASEM 2017, p. 3).

Since research institutions play a central role in fostering research integrity and addressing current threats, they should maintain the highest standards for research conduct, going beyond simple compliance with federal regulations in undertaking research misconduct investigations and in other areas (NASEM 2017, p. 4).

Research institutions and federal agencies should work to ensure that good-faith whistleblowers are protected and that their concerns are assessed and addressed in a fair, thorough, and timely manner (NASEM 2017, p. 4).

Societies and journals should develop clear disciplinary authorship standards. Standards should be based on the principle that those who have made a significant intellectual contribution are authors (NASEM 2017, p. 5).

Through their policies and through the development of supporting infrastructure, research sponsors and science, engineering, technology, and medical journal and book publishers should ensure that information sufficient for a person knowledgeable about the field and its techniques to reproduce reported results is made available at the time of publication or as soon as possible after publication (NASEM 2017, p. 6).

Federal funding agencies and other research sponsors should allocate sufficient funds to enable the long-term storage, archiving, and access of datasets and code necessary for the replication of published findings (NASEM 2017, p. 6).

To avoid unproductive duplication of research and to permit effective judgments on the statistical significance of findings, researchers should routinely disclose all statistical tests carried out, including negative findings. Research sponsors, research institutions, and journals should support and encourage this level of transparency (NASEM 2017, p. 6).

Researchers, research sponsors, and research institutions should continue to develop and assess more effective education and other programs that support the integrity of research (NASEM 2017, p. 7).

We have no objections to these recommendations per se and find them all to be quite reasonable. We would like to observe, however, that these ideas are not new and that most of them have been discussed in previous NASEM reports or RCR textbooks or journal articles (e.g. Pimple 2002, Kalichman 2007, Titus et al. 2008, Kornfeld 2012, Macrina 2014, Shamoo and Resnik 2015).

The report devotes a great deal of attention to discussing the importance of protecting whistleblowers from retaliation and career disruption. While we agree with the report's recommendations regarding whistleblower protections wholeheartedly, we disagree with its emphasis on the role of whistleblowing in promoting research integrity. Whistleblowing is not an effective method for detecting or deterring misconduct. According to a systematic review of published survey data, about 1.7% of scientists admit to fabricating or falsifying data at least once in their careers (Fanelli 2009). The actual rate of misconduct is probably higher than 1.7%, since many scientists may not be willing to admit that they have engaged in unethical or illegal behavior (Shamoo and Resnik 2015). Even if we conservatively estimate the actual rate of misconduct to be 2.5%, evidence strongly supports the hypothesis that whistleblowing is not effective at detecting it. The Office of Research Integrity (ORI), which oversees NIH research, publishes about 10 cases of confirmed misconduct per year, which translates into a rate of one confirmed case per 100,000 NIH researchers per year (Steneck 2000). If one assumes that the average NIH-funded scientist spends at least 30 years conducting research, this would be a rate of 30 per 100,000 NIH scientists who are caught for misconduct or 0.03%. If one further assumes that the rate of misconduct among NIH scientists is the same as the rate reported by Fanelli (2009) and that most of the cases reviewed by ORI result from whistleblowing, then whistleblowing detects only about 1.2% of actual misconduct cases in NIH funded research. Obviously, a method that fails to catch cheaters 98.8% of the time cannot be a very effective deterrent. We would argue that other methods of uncovering problems with scientific research, such as data auditing and quality assurance monitoring, are far more effective at detecting and deterring misconduct than whistleblowing (Shamoo 1989b, 2013, Shamoo and Resnik 2015). However, the NASEM report barely mentions these methods.

In all fairness, the authors of the NASEM report could argue that whistleblowing is not currently an effective method of detecting or deterring misconduct because whistleblowers do not have sufficient protections. If whistleblowers had better protections, more of them would come forward and more cheaters would be caught. While we do not doubt that enhanced whistleblower protections would increase the rate of misconduct allegations, we would still maintain that auditing and quality assurance monitoring are effective methods of detecting problems in scientific research that the authors of the report have not considered in adequate depth. Many industries, such as banking, health care, insurance, and manufacturing use auditing and quality assurance monitoring to uncover fraud, error, and other problems that are not adequately detected by whistleblowing (Shamoo 2013).

The report's most innovative recommendation calls for the establishment of independent Research Integrity Advisory Board (RIAB):

To provide a continuing organizational focus for fostering research integrity that cuts across disciplines and sectors, a Research Integrity Advisory Board (RIAB) should be established as an independent nonprofit organization. The RIAB will work with all stakeholders in the research enterprise—researchers, research institutions, research sponsors and regulators, journals, and scientific societies—to share expertise and approaches for addressing and minimizing research misconduct and detrimental research practices. The RIAB will also foster research integrity by

stimulating efforts to assess research environments and improve practices and standards (NASEM 2017, p. 5).

The idea for forming an RIAB is not new, since it was included in another NASEM report twenty-five years ago (NASEM 1992). However, the 2017 NASEM report makes a novel contribution to this idea by developing the proposal in more detail than the earlier report.

On the surface, the idea of forming an RIAB sounds like a good one, but it begins to lose its luster as one examines the practical details related to its function and funding. Our biggest concern with the RIAB is that we are not sure what it would do. The NASEM report recommends that the RIAB would be a purely advisory body and would have no legal authority: “The RIAB will have no direct role in investigations, regulation, or accreditation (NASEM 2017, p. 183).” Since the RIAB would only be an advisory body that does not rule on pending cases or policies, how would it make a unique contribution to advancing the cause of research integrity? The report claims that the existing institutions are not performing the functions that would be performed by the RIAB (p. 125) but one could argue that the scientific community already has numerous bodies that provide general advice on RCR issues, such as: the NASEM, the Office of Research Integrity (ORI), the Center for Scientific Integrity (which supports Retraction Watch), the Committee on Publication Ethics, the International Committee of Medical Journal Editors, Public Responsibility in Medicine & Research, the World Conference on Research Integrity, the International Conference on Harmonization, and numerous professional societies, including the American Association for the Advancement of Science, the World Medical Association, and the American Medical Association.

The report notes that the U.K. has an advisory body like the proposed RIAB, i.e. the United Kingdom Research Integrity Office (UKRIO). However, the UKRIO, unlike the proposed RIAB, provides confidential advice pertaining to cases involving misconduct or other ethical problems for U.K. institutions, because U.K. funding agencies do not have their own offices for performing these tasks (UKRIO 2017). U.S. funding agencies, by contrast, have offices that oversee research integrity issues, such as the ORI (for NIH research) and the Office of Inspector General (for National Science Foundation (NSF) research). If the RIAB were to function like the UKRIO, it might make a unique contribution to advancing the cause of research integrity in the U.S. For example, the RIAB could provide confidential advice for misconduct cases that do not involve NIH or NSF research or it could conduct data audits for institutions (Shamoo 2013). If the RIAB provides only general advice on research integrity issues, why would academic institutions, government agencies, or other sponsors seek its advice on RCR issues? Why wouldn't they instead seek advice from their own constituencies, experts in the field, or other research organizations?

Funding is another concern we have with the RIAB. The NASEM report estimates that the RIAB would need an annual budget of \$3 million (p. 127). Since it is not likely that the RIAB could be financed solely by contributions from individuals, most of its support would need to come from large organizations, such as government agencies, academic institutions, or industry groups. We doubt that many of these organizations would allocate a substantial amount of money to a board that only provides general advice on research integrity issues.

But suppose that enough of these organizations decide that it is in their interests to fund the RIAB, then another issue arises, namely, how can the RIAB maintain actual or perceived independence? If the board receives substantial funding from private companies, critics would argue that it serves industry interests. If it obtains substantial funding from academic institutions, some would argue that it serves their interests. Funding from government agencies (and individuals) would seem to be the best way to ensure that the RIAB has independence, but government funding can still be tainted by politics.

In closing, we would like to acknowledge that the NASEM report does include insightful discussions of research best practices as well as useful references to the RCR literature. Some of the most interesting material appears in an appendix that describes five cases of alleged or actual misconduct (including discussions individual and institutional responses) and an appendix that reviews empirical research on assessing the effectiveness of RCR education, written by Michael Mumford, who has published numerous articles in this journal, e.g. Steele et al. (2016), Todd et al. (2017), and is a member of the editorial board of this journal. *Fostering Research Integrity* nevertheless makes a valuable contribution to advancing the cause of RCR even if it falls short of the standard set by earlier NASEM reports.

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