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RCR Education Reconsidered

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Description

This essay provides a critique of the current RCR system and discusses how Federal mandates for RCR education seem to overlook the broad social and moral context of science. A new approach is needed that focuses more on the scientists' dual obligations to consider the role science should place in society and help shape a socially responsible research agenda.

Abstract

I argue that the dominant approach to training in the responsible conduct of research (RCR), which has been driven largely by scandals in biomedical research and shaped by mandates promulgated by the Office of Research Integrity (ORI) and the National Institutes of Health (NIH), is inadequate and probably counterproductive. The Federal mandates have inspired a system of RCR training programs usually extrinsic to the actual business of learning or doing research, marking it as an obstacle to negotiate rather than a central concern. More importantly, the Federal mandates have encouraged RCR training to overlook the broad social and moral context of science, concentrating instead almost exclusively on exhorting researchers to avoid transgressions by complying with rules and standards of behavior. This model thus fails aspiring and established researchers – and the entire research enterprise – by ignoring the scientist's dual obligations to

reflect on the proper role of science in society and take part in shaping a socially responsible research agenda. The Federal government should refrain from establishing any new RCR education mandates and the research community should live up to its moral obligation to prepare researchers to be responsible stewards of the scientific enterprise by fully integrating a full-bodied approach to research ethics into all research education.

Body

This paper is a critique of what I understand to be the standard form of training in the responsible conduct of research (RCR) in the United States today. In order to make my case clearly, I will sometimes over-generalize and express some demarcations as if they are more clear and solid than they actually are. I hope the clarity of argument thus created justifies the rhetorical excess.

In brief, I want to argue that the standard form of RCR training is inadequate and probably counter-productive, and that these unfortunate characteristics are due to the Federal mandates that have shaped RCR training. I will also offer some suggestions as to how to do it right, or at least better.

Background

Published data on offerings in research ethics are scattered and far from comprehensive (DuBois and Burkemper 2002; Mastroianni and Kahn 1998; Pimple 2001), but a review of available textbooks (Heitman 2004) and my observations over the last 15 years indicate that the dominant approach to research ethics has been driven largely by scandals in biomedical research and shaped by mandates promulgated by the National Institutes of Health (NIH) for RCR training. These mandates have steadily expanded their reach to encompass an increasing number of required topics (Pimple 2001-2002) and ever larger portions of the research community.

- In 1990, NIH established an RCR training requirement for graduate students and postdoctoral fellows funded through the National Research Award Institutional Training Grants (T32) program, referred to hereafter as the **training grant** mandate. See <http://grants1.nih.gov/grants/guide/notice-files/not92-236.html>, http://grants1.nih.gov/grants/guide/pa_files/PA-02-109.html, and <http://grants1.nih.gov/grants/guide/pa-files/PA-06-468.html>.

- In 2000, NIH issued its policy on “Required Education in the Protection of Human Research Participants,” referred to hereafter as the **human subjects** mandate. This requirement covers all NIH-funded research with human subjects. See <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.
- In 2000, the Public Health Service (PHS) issued the “PHS Policy on Instruction in the Responsible Conduct of Research (RCR),” which would have required training in 9 “core instructional areas” for all research staff receiving PHS funding, referred to hereafter as the **RCR** mandate. See http://ori.dhhs.gov/policies/RCR_Policy.shtml. This mandate would have come into effect in 2003, but it was suspended in 2001 on technical grounds; even so, many universities have prepared RCR teaching modules according to this mandate’s guidelines. The Office of Research Integrity (ORI) has expressed its intention to create an enforceable mandate along the same lines.

Although these mandates pertain only to research supported with PHS and NIH funds, most research universities receiving such funds have a Federal-wide Assurance (FWA) which requires them to apply the same regulations and policies to all research, regardless of funding source.

The training grant and RCR mandates require the institution to provide required training; the human subject mandate, however, only requires Principal Investigators applying for a grant to “provide a description of education completed in the protection of human subjects for each individual identified as ‘key personnel’ in the proposed research.”

In an effort to avoid accusations that the mandates take an inappropriate and unworkable one size-fits-all approach – or perhaps to placate segments of the research community that resisted this kind of government intrusion – all three mandates describe the topics to be covered in the training only in broad terms and specify that NIH does not endorse any particular curriculum. The RCR mandate has the most detail of the three on what is supposed to be covered in the training.

When the training grant mandate was promulgated, there were few readily-available resources on teaching research ethics. The mandate inspired many efforts to produce such resources, including two projects undertaken by the Poynter Center and several textbooks.

In contrast, the human subjects mandate points out that “a number of curricula are readily available to investigators and institutions” and gives as an example the computer-based training that “all NIH intramural investigators and research administrators who oversee clinical projects are required to complete,” which is available at <http://ohsr.od.nih.gov/> and which “can be used by other institutions seeking to meet training requirements in this area.”

NIH, ORI, and the National Science Foundation (NSF) have offered several funding opportunities for the development of teaching materials and courses in human subjects protection and RCR and made many materials freely available.

Before I turn to the shortcomings of what I will call the standard model of RCR training inspired by these mandates, I want briefly to mention some of the admirable aspects and outcomes of these mandates. The flexibility built in to the mandates and efforts by NIH and ORI to provide examples and materials are laudable. There can be no doubt that these mandates have increased the number of opportunities to learn about research ethics available to graduate students, post doctoral fellows, and established researchers, increased the number of researchers who have actually availed themselves of such opportunities, and increased the number of readily-available materials and approaches. They have also increased the number of researchers and ancillary personnel, such as myself, who take an active interest in research ethics, research on research integrity, and the teaching of research ethics. Finally, I do not doubt that the mandates were promulgated in good faith and with the best of intentions.

Shortcomings

Good intentions notwithstanding, I believe the standard model has serious flaws.

I find that the ORI Introduction to the Responsible Conduct of Research (Steneck 2004) offers a telling metaphor for the shortcomings of RCR training programs designed in the shadow of NIH mandates.

The ORI Introduction was written by Nicholas Steneck, a founding Executive Committee member of the Association for Practical and Professional Ethics and a colleague whom I hold in high esteem. On Nick’s request I read and commented on the entire manuscript in draft and made no major complaints about its structure or approach. I didn’t know better at the time.

The ORI Introduction was commissioned by the Office of Research Integrity (ORI), which asked Nick to write a book that a researcher could read in a couple of hours, that would be the RCR Education equivalent of a “driver’s manual” for responsible research. Accordingly, the book begins with a section entitled “Rules of the Road” and ends with one entitled “Safe Driving and Responsible Research.”

Like driving school, RCR training programs tend to be designed to teach researchers not to break the rules. Of course, posted speed limits and stop signs are designed to be seen, whereas research misconduct and questionable research practices are often intended to be undetectable, and whether or not they are so designed they can be hard to recognize. Thus RCR training rightly also emphasizes recognizing ethical problems so that they can be avoided. Some driving schools and RCR training programs also provide examples of good practice, such as defensive driving.

Like driving school, RCR training tends not to be part of any regular curriculum – it may be important, but it is an add-on; it stands out as something different. Teaching how to drive is not the core mission of a high school, and RCR training tends not to be integrated into research training and education. In fact, it is seldom taught by active researchers and is typically provided via static Web tutorials. Like radiation safety training, it is largely experienced by researchers as a minor and annoying adjunct to the real business of research education. It is a wart on, and decidedly not the heart of, research.

It seems obvious to me that leaving RCR training on the margins of research education sends a clear, if unintended, message: Ethical behavior per se is not part and parcel of research; it is not important; it does not really matter. If I am correct, this model of RCR training is not merely inadequate; it is actually counter-productive. Even if my assessment is exaggerated, it can hardly be productive to present RCR training in a manner that is generally considered a nuisance. How can serious discussions of research ethics take place in such an atmosphere?

Furthermore, by refusing to endorse any particular approach to or program of RCR training, and by failing to establish any standards, the Federal mandates invite research institutions to create the worst training programs they can abide rather than the best they can devise. Flexibility thus encourages a race to the bottom – or at least, no particular encouragement to rise above the bottom.

The use of static Web sites not only discourages accountability, it invites fraud.⁵ For prima facie evidence of this claim, consider the following:

The Illinois Executive Inspector General's Office has told 65 professors at Southern Illinois University at Carbondale that they could face disciplinary action for violating state ethics policy. Their offense? They breezed through a mandatory online state ethics test too quickly. (Gravois 2007a:A26)

See also Gravois 2007b. When researchers know that they have only to claim to have completed a Web tutorial to meet their obligation, some of them are bound to lie.

Most importantly, driving school and the standard model of RCR training take for granted the moral justifications of the larger enterprise they are meant to supplement, namely safe roadways and scientific research. R

As far as driving is concerned, this does not strike me as a problem. It would be absurd to expect something like 200 million Americans to critique the pros and cons of vehicular traffic and the effectiveness of the largely conventional rules governing traffic before they can be licensed to drive. The overall goal of traffic laws and the fundamental nature of traffic have not changed in at least a century and probably will not change in another century.

Science is quite different.

The role of science in society has changed dramatically since World War II and the pace of change is increasing. Not long ago we attained the capacity to destroy all life on Earth and, by most accounts, we are on the edge of not one but two scientific revolutions as applied genetic science matures and nanotechnology takes off. Both have the potential to provide great benefits to humankind and, if we wise up, the rest of our planet, but both also pose grave potential risks to human health, human liberty, and the biosphere.

Traffic laws rightly leave it up to the individual driver to decide where to go. Training in the responsible conduct of research that fails to challenge researchers to consider carefully the moral consequences of choosing one destination over another is inadequate and potentially dangerous. Scientists do not only conduct research; they also design the very landscape of science through reviewing grant proposals and manuscripts submitted for publication, by guiding public policy, even by citing previous work and thereby enhancing its status.

It would be risky for ORI or NIH or NSF overtly to promote socially responsible science; it would be uncomfortably close to taking a political stance. Individual scientists risk enough by being politically active, and administrators of Federal institutions have to walk a very fine line. Any implication of promoting a particular social or political agenda would bring a firestorm of criticism on their heads. Indeed, one searches the RCR training mandates in vain for any indication that the very goals and structure of science and science funding might be cause for moral concern; even the relatively expansive and detailed RCR mandate is silent on the matter (Pimple 2002).

Remedies

I have expressed resistance to Federal mandates on research ethics education for at least six years (Pimple 2000; Pimple 2001; Pimple 2001-2002), and my first recommendation on improving RCR education is probably predictable: The Federal government should stop issuing mandates. I fear, however, that rolling back the current mandates would be counter-productive.

It is up to a few Federal officials to refrain from imposing new mandates, and they could do so easily and silently. While this would be welcome, it would only mean that we would not suddenly be afflicted with another sudden wave of bad RCR training programs. Actually to improve research ethics education, however, will be much more difficult because it will take many more people to work on it without benefit of the governmental big stick.

To improve the situation, researchers, research administrators, research institutions, and research societies and associations should encourage in every way possible the actual integration of instruction in research ethics into every appropriate aspect of research education – and I cannot think of any where it would not be appropriate. Research ethics should not merely be an add-on and it should be taught by active researchers. The 2006 Law School Survey of Student Engagement found that “the single most influential activity” in “developing a sense of professional ethics” was “student-faculty interaction” (LSSSE 2007:11). Perhaps with the assistance of ethicists. Supplemental RCR education in the form of elective or advanced courses for students, continuing education courses for professionals, meetings at professional conferences, interdisciplinary workshops at research institutions, and so forth, would be welcome.

Furthermore, research ethics education should include a critical appraisal of the place of science in society and the social responsibilities of scientists, including the responsibility that sometimes falls upon them to buck the system.

In short, I am arguing that aspiring researchers should be trained as professionals and that they must recognize that they are members of a community from which they derive their authority and support, and to which they are accountable (Sullivan 1995). Professionals should not think of ethics as pertaining only to the relationship between means – their particular actions – and ends – the taken-for-granted goal of advancing science. Appropriate ethics education also requires scientists to understand themselves as parts of a larger whole. This perspective shifts the focus away from the image of research as isolated and disconnected from the wider fabric of institutional and civic life. By connecting their work with a larger sense of purpose, practice, and institutional arrangements, researchers can deepen their understanding of ethics as an essential ingredient in the scientific enterprise, which itself is part of a wider set of practices and institutions that depend upon the public trust.

Research ethics education should impart skills of ethical reasoning while expanding budding scientists' appreciation of their responsibilities as citizens bound by a broad range of social obligations. Such obligations should inform their actions as members of a professional guild and provide a context for understanding the ethical dimensions of their work. It should focus not only on the duties that attend to scientific research – most of which can be captured under the standard RCR training model – but also the virtues that drive good research practice and contribute to the formation of research professionals who act with integrity (May 2001).

Conclusion

My conviction that reform in RCR education is needed is not, alas, matched with optimism that it will be reformed. The research community has had several chances to clean up its own house. The 1990 training grant mandate could have served as a clarion call to action; instead, the research community treated it more-or-less as a dodged bullet; after all, only graduate students – and not all of them – were implicated.

Successful and much-needed reform in RCR education can only be effected by the research community under its own volition. History does not bode well for this to

happen. 6

Thank you for your attention.

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Notes

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This paper is based on arguments developed by Richard B. Miller, Ph.D., and myself in two grant proposals we co wrote in 2006. I wish to acknowledge Rich's substantial contributions to this paper while accepting responsibility for any flaws that remain.

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