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Unintended Consequences of RCR EIT Mandates

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Description

This essay discusses some of the problems that exist with current Federal mandates that currently govern responsible conduct of research education. Instead of mandating this training, the research community should live up to its own publication to prepare researchers to be responsible stewards of the research enterprise.

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. I urge the Federal government to refrain from establishing any new RCR education mandates and the research community to 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

Introduction

I presented an [earlier version](#) of this paper at the annual meeting of the Association for Practical and Professional Ethics in February of 2007.

I apologize to anyone present who has heard this before. I also want to make clear from the beginning that neither this paper nor the one I am scheduled to present tomorrow is intended as an attack on the Office of Research Integrity. Both papers are meant to express serious concerns about Federal mandates related to RCR EIT, which is a very small part of ORI’s portfolio. Its oversight of misconduct investigations, its support of research on research integrity, and its efforts to improve RCR EIT are all laudable.

This paper is a critique of what I believe 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.

Background

For the sake of time, I will name, but not review, the three most influential mandates – the 1990 NIH training grant mandate, the 2000 NIH human subjects mandate, and

the suspended 2000 PHS RCR mandate.

In an effort to avoid accusations that the mandates take an inappropriate and unworkable one size-fits-all approach, 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. Of the three, the RCR mandate is the most detailed.

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 research staff, 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

There is not much known about the impact of these mandates, but two recently published and nicely complementary studies(Anderson et al. 2007; Funk, Barrett, and Macrina 2007) on the effects of the training grant mandate come to the same conclusion: Federally mandated instruction in RCR appears to have no positive effect on research behavior, and may have a negative impact. The authors of these studies offer several plausible explanations for these findings, but not, as I will argue here, that the nature of the mandates is a significant part of the problem.

I believe the standard model of RCR EIT 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, an organizer of this conference, a colleague whom I hold in high esteem, and an untiring promoter of research integrity and RCR EIT. In using the ORI Introduction as an example, I do not

intend to be handing out blame. In fact, if any blame is warranted, I deserve some share of it, because, on Nick's request, I read and commented on the entire manuscript in draft, and I did not express any serious concerns about its structure or approach.

ORI asked Nick to write a book that a researcher could read in a couple of hours and would be the 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. Posted traffic signs are designed to be seen, but the "signs" of research misconduct can be hard to spot; 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 is an add on. 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.

Furthermore, by refusing to endorse any particular approach to 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 fails to entice us to rise above the bottom.

The use of static Web sites not only discourages accountability, it invites fraud. 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. As far as I'm concerned, this is acceptable for driving school, but not for research education.

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 play a key role in designing 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.

Remedies

I have expressed resistance to Federal mandates on research ethics education since before the turn of the century, (Pimple 2000; Pimple 2001-2002). and my first recommendation on improving RCR education is simple: The Federal government should stop issuing mandates.

That said, rolling back the current mandates would probably be counter-productive, sending the message, "Oh, it really doesn't matter after all."

As long as the status quo holds – that is, as long as we work under the current mandates and no new ones – we are unlikely to be afflicted with another sudden wave of bad RCR training programs. Actually to improve research ethics education, however, will be much more difficult, in part because it will have to be done 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, 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. Naturally efforts to improve the moral climate of research should reach beyond education, instruction, and training, but I limit the scope of my discussion to the topic at hand.

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.

RCR training as I believe it is typically provided today has many of the same problems and shortcomings of ethics education in the professions.(Sullivan 1995). Both mirror the pervasive postmodern view that society is nothing but a more-or-less chance coming-together of individuals, each with his or her own distinct needs and goals; that any overlap in goals is a happy coincidence; that the overriding – perhaps only – moral authority is the individual conscience; and that the only moral questions concern how I should behave rather than how I should live. My thoughts on this matter have been influenced by two books by Alasdair MacIntyre (MacIntyre 1981; MacIntyre 1998).

I contrast the questions, “How should I behave?” and “How should I live?” to re-state the point I made earlier about learning how to drive versus designing the highway system, or my doing research as an individual versus doing my part to shape the entire research agenda and the moral climate of research.

It is right for RCR EIT to provide guidance in research behavior, but it must also emphasize the social nature of research, it must make clear that individual researchers make up the research community, but that the research community is not a chance conglomeration of atomistic individuals. Rather it is a community of purpose and value, of intent and meaning, of responsibility not just to rules and to accepted procedures but also to each other, to the world, to the future.

Emphasizing the social nature of research requires attention to the connections not just between my individual actions and a set of ethical standards, but also between my self and my colleagues, my university, my discipline, my country, and the research enterprise as a whole. I cannot be responsible, in either the moral or causal sense, for how my colleagues behave in the same way that I can be responsible for my own behavior, but I also cannot shirk my real, if limited, responsibilities to my

colleagues.

Conclusion

My conviction that reform in RCR education is needed is not, alas, matched with optimism that it will be reformed in the way I advocate. The research community has had many 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 bullet successfully dodged. Successful and much-needed reform in RCR education can only be effected by the research community under its own volition, not under duress. History does not bode well for this to happen.

Thank you for your attention.

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Notes

resented at the first biennial conference on "Responsible Conduct of Research (RCR) Education, Instruction, and Training" (<http://epi.wustl.edu/epi/rcr2008.htm>) St. Louis, Missouri, April 17, 2008, sponsored by the Office of Research Integrity and the Washington University School of Medicine.

An earlier version of this paper, entitled "RCR education reconsidered," was presented at the annual meeting of the Association for Practical and Professional Ethics, February 2007. It 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 Dr. Miller's substantial contributions to this paper while accepting responsibility for any flaws that remain.

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