Expanding Responsible Conduct of Research Instruction across the University

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Abstract

During the past two decades, serious intellectual effort by governmental agencies, research institutions, professional societies, and educators has promoted education in the responsible conduct of research (RCR), defined present standards of RCR, and shaped the debate on how best to promote research integrity in the biomedical sciences. However, revisions to the Federal Policy on Research Misconduct in 2000 specifically expanded the policy's scope to include disciplines outside the biomedical and behavioral sciences, thus creating a need for RCR education in such fields as economics, education, mathematics, and linguistics. Even as some institutions have applied the Office of Research Integrity's (ORI) framework for RCR instruction university-wide, academic administrators and faculty from fields beyond the biomedical sciences have rightly noted that several of ORI's nine core instructional areas are tangential or irrelevant to the many disciplines whose research practices differ substantially from those of the biomedical sciences. These disciplines can benefit from the rich history of discourse, policy making, and education in RCR in the biomedical sciences, but they must not simply apply the standards of biomedical and behavioral science to their own, quite different research. Creative leadership from these newly included disciplines is needed to define standards of ethical research in their areas, prepare relevant educational materials, and promote a multidisciplinary perspective on research integrity across the university. The authors suggest that the scope of RCR education for federally funded research in other areas be addressed on two levels: (1) the content of generally applicable RCR education, and (2) the special, discipline-specific content.

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The article in this issue's collection on the responsible conduct of research (RCR) entitled, "The History and Purpose of Instruction in the Responsible Conduct of Research," describes the many efforts of governmental agencies, research institutions, professional societies, and biomedical educators to encourage RCR in the biomedical and behavioral sciences.[1] As detailed in that essay, these efforts began in the 1980s, largely in response to reports of misconduct in biomedical research. Early work stressed the importance of establishing institutional policies and procedures for RCR, defining what constituted misconduct, developing ways to investigate suspected misconduct, and promoting discussion among university faculties about responsible research practices. These policies and definitions created the foundation for understanding what constituted responsible biomedical research conduct in academic institutions.

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The 1989 and 2002 reports *The Responsible Conduct of Research in the Health Sciences*[2] and *Integrity in Research*[3] from the Institute of Medicine, together with the 1989 National Research Service Award training grant mandate from the National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (then constituting ADAMHA),[4] introduced and reinforced a concept of RCR education that would serve as the framework for ensuring that academic institutions encouraged RCR and taught its principles and practice. In December 2000, the Office of Research Integrity (ORI) published its now-suspended *Policy on Instruction in the Responsible Conduct of Research*,[5] defining instruction in nine core areas determined by the Public Health Service (PHS) to be significant in conducting responsible research and ensuring integrity of the research record. This proposed instruction was specifically tailored to research in the biomedical and behavioral sciences.

Defining Misconduct and RCR beyond the Biomedical and Behavioral Sciences

On December 6, 2000, the White House Office of Science and Technology Policy published a revised version of the *Federal Research Misconduct Policy*, developed by the National Science and Technology Council.[6] Its primary objective was to provide a new, comprehensive definition of research misconduct and basic guidelines for all federal agencies and research institutions to use in responding to allegations of wrongdoing.[6] This policy applied to all federal agencies and departments that supported either intramural or extramural research—to *all* federally funded research, regardless of discipline.

Under this policy, federal concern for research misconduct was defined to include "all basic, applied, and demonstration research in all fields of science, engineering, and mathematics . . . includ(ing), but . . . not limited to, research in *economics, education, linguistics, medicine, psychology, social sciences, statistics*" (emphasis added).[6] As of April 2007, nine federal agencies or departments that fund research have implemented this policy, including the Department of Transportation, the Department of Labor, and the National Endowment for the Humanities, and five additional departments report that they have draft statements under review. ORI provides links to these new policies on its Web page.[7] Because *all federally funded*

research is governed by this policy, universities with broad, multidisciplinary research agendas that extend beyond the NIH's purview face the task of addressing RCR education in these areas, where practices may differ substantially from those of research in the biomedical sciences.

The 2000 Federal Research Misconduct Policy[6] creates significant informational and educational challenges for the disciplines that are now included in its definitions but that have little or none of biomedical science's history of discourse, policy making, or education in the ethics of research. Although it is tempting to try to place these additional disciplines under the umbrella of established RCR education, it would be a poor fit. The nine core instructional areas that are the focus of the ORI's attention to RCR education were developed out of and for the biomedical sciences,[5] tailored to the needs of research funded by the PHS.[8] Some of the ORI's core instructional areas are simply not applicable to these additional nonbiomedical disciplines, whereas other areas of instruction specifically relevant to them—and yet undescribed—may be needed.

Academic officials' quandaries about the scope of RCR instruction have been evident in recent activities sponsored by the ORI, including the 2004 Summit on the Responsible Conduct of Research at Michigan State University[9] and the Council of Graduate Schools (CGS) RCR education initiative completed in late 2006.[10] The RCR Summit was described by its organizers as "a national dialogue on future directions of RCR," which Lawrence Rhoades, director of the ORI's division of Education and Integrity, described as "a social movement within the scientific community."[11] Publicity for the conference was aimed at faculty and administrators in graduate programs in the biomedical and social sciences, but ultimately many participants were institutional officials representing a much wider academic community. Although most of the issues discussed by the presenters at the summit were relevant to the broader audience, several participants repeatedly expressed concern and frustration that some of the ORI's core instructional areas were either tangential or completely irrelevant to many research disciplines at their institutions. Their questions focused on how to provide meaningful RCR resources and education for nonscientists, which of the RCR core areas they should include or require in instruction across their systems, and how best to address a multidisciplinary research community that typically includes scholars in the humanities as well as the sciences.

Similarly, although the RCR Initiatives project, cosponsored by the CGS and the ORI, funded institutions to generate and test innovations, interventions, and assessment strategies for improving RCR education in the behavioral and biomedical sciences,[10] many of the deans participating in the CGS/ORI program also have been interested in university-wide education in integrity in research.[10,12] Some of the schools that participated in the CGS/ORI program developed teaching materials and evaluation instruments that used examples of questionable research practices in history, French, business, and other nonbiomedical disciplines, and a recurring, unstated theme in the CGS/ORI program was the challenge of moving from the existing biomedical framework for RCR instruction to teaching and evaluation strategies for research integrity education in the social sciences, humanities, and even the fine arts.[10] A subsequent project sponsored by the CGS and the National Science Foundation (NSF)[10] has funded efforts to promote implementation of RCR education, as required by the NSF Integrative Graduate Education and Research Traineeship Program,[13] in science and engineering. This project ultimately faces the same issues that the CGS/ORI program faced.

It is not necessary for individuals to gain expertise in the ethics of research in areas in which they are not engaged, but *all* academics should have a basic understanding of the principles of academic integrity and expertise in the ethical standards of their own fields. We would suggest that the scope of RCR education for federally funded research disciplines be addressed on two levels: (1) the content of generally applicable RCR education, and (2) special, discipline-specific content. In addition, concerted attention must be given to developing materials and teaching methods that can provide appropriate discipline-specific education effectively.

Level 1: The content of generally applicable core instructional RCR material. On the first issue, we believe that ORI's core instructional areas of data management, conflicts of interest and commitment, responsible authorship and publication, and research misconduct are generalizable to all kinds of academic research and could be considered basic to RCR education across numerous research disciplines university-wide. The discipline-specific standards of responsible scholarship may vary across these fields, but many common questions and issues are evident.

Level II: Discipline-specific content. Other topics included in ORI's nine instructional areas of RCR, such as human-participant research and research involving animals, have limited or no applicability to disciplines outside the biomedical and social sciences and, therefore, would not necessarily belong in RCR instruction for these disciplines. Similarly, research and scholarly activity in mathematics, engineering, economics, and the humanities raise special discipline-specific issues that should be included in discipline-specific RCR education for these disciplines, as related to the focus of the researchers and trainees involved. These issues must be identified by experts within the fields themselves, and they cannot be easily or comprehensively delineated by others.

Instructional Methods

Methods that might be used to present the instructional content of RCR effectively in the newly included nonbiomedical research-related disciplines could be similar to those presently used in biomedical and behavioral RCR education. In response to the NIH training grant mandate, many institutions offer formal courses that provide didactic presentations and small-group case discussions to explore and analyze the principles of research integrity and related regulations, as well as to give trainees the opportunity to develop skills in moral reasoning and practical problem solving. Other institutions rely on interactive Web-based courses, with or without supplemental discussion or didactic sessions, which engage the learner as an individual rather than as part of a group.[14–17] Although we strongly endorse group discussion and analysis of ethical

issues and standards of practice aimed at developing trainees' ethical skills and moral imaginations, Web-based courses are a cost-effective and efficient means of providing instruction on rule-based knowledge.

Using a modular, Web-based format, such as the one used in the Collaborative IRB Training Initiative course described by Braunschweiger and Goodman earlier in this issue,[16,17] RCR educators can develop an institutional or even national curriculum that includes general principles of academic research integrity relevant to all scholars and specific modules directed toward individual disciplines identified in federal policies. Institutions could then tailor required instruction to their learners' specific needs by assigning different components to trainees in different disciplines. These components could include modules on university policies or areas of special institutional concern.

The expansion of the federal definition of misconduct to all federally funded research, regardless of discipline, raises pressing issues for all faculty in research disciplines for which RCR educators in the biomedical sciences can only begin to offer guidance. Just as ORI prepared standards, policies, and developed a funding mechanism for the preparation of didactic materials for the PHS, each funding agency that implements the federal policy on research misconduct might become involved in defining the essential knowledge for disciplines under their purview and provide funding for the preparation of appropriate educational materials. Following the models of Sigma Xi, The American Society of Microbiology, the Association of American Medical Colleges, and the National Academies of Science, the academic and professional organizations in disciplines outside of the biomedical and behavioral sciences might also contribute to determining what constitutes important topics in RCR for their members and promote instruction in these areas.

Just as RCR education in the biomedical sciences has developed incrementally, often in fits and starts, RCR education in other research disciplines is likely to grow in uneven stages, propelled by external events as well as internal forces. What remains as crucial, however, is leadership in defining RCR in these fields, promoting RCR education for investigators and trainees, and developing relevant educational materials. We hope that a comprehensive look at RCR education in the biomedical and behavioral sciences, with its challenges and partial solutions, will help to stimulate creative leadership from these newly included research disciplines to define their own standards of ethical behavior, prepare relevant educational materials on the ethical standards in research and, thereby, promote integrity in research across the university.

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