The History, Purpose, and Future of Instruction in the Responsible Conduct of Research

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Abstract

This article discusses the key decisions and steps that have partially formalized instruction in the responsible conduct of research (RCR) in U.S. research institutions, the different purposes for offering and/or requiring such instruction, and suggestions for what needs to be done to enhance the professional development of researchers in the future. RCR education has developed during three distinct eras: the 1980s, when policy makers were most concerned with defining and investigating research misconduct; the 1990s, when there was significant but highly decentralized growth in RCR instruction; and the years since 2000, when there have been a series of reforms and educational developments. There is still a need for scientists, universities, and professional societies to develop consensus on best ethical practices in many areas of scientific research. More also needs to be learned about assessing the quality of RCR instruction and the effects of training on researchers' behavior. To help set the course for RCR instruction in the future, more effort and funding need to be directed to studying actual research behavior and the factors that influence it; RCR educators and administrators must develop a common vocabulary and framework for developing and evaluating the impact of RCR instruction; and research institutions and funding agencies alike need to take a more active role in promoting and supporting RCR instruction.

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Professionals have long understood the importance of passing on standards and best practices from generation to generation. The Hippocratic Oath, which formed the professional basis of Western medicine for more than two millennia, opens with the promise that the physician will "impart precept, oral instruction, and all other instruction to my own sons, the sons of my teacher, and to indentured pupils who have taken the physician's oath."[1]

However, it was not until the late 1980s that biomedical scientists, then under some public scrutiny as a consequence of a decade of reports about misconduct in research, turned to formal education as one way of fostering high standards and strong public support for research.[2] In this article we discuss the key decisions and steps that have partially formalized instruction in the responsible conduct of research (RCR) in U.S. research programs.

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The Origins of RCR Education

When research misconduct surfaced as a public issue in the late 1970s and early 1980s, the way students were trained in the ethical aspects of research received little attention. Although it is difficult to explain exactly why a particular course of history was or was not taken, two reasons probably account for this historical absence of RCR training. First, research misconduct was seen as the exception to the norm, which implied that policy efforts needed to focus on consequences for the few who committed misconduct and not on preventive instruction for the presumed honest majority. Accordingly, through the 1980s, most policy making focused on defining misconduct and establishing procedures for its reporting, investigation, and adjudication. Second, researchers were confident that the standards for responsible practice are in fact passed on to new researchers through the normal research training process, and therefore they did not perceive a need for formal RCR education.

This line of thinking is evident in the 1982 report of the Committee on the Integrity of Research appointed by the Association of American Universities (published in 1983), which was established to recommend policies and procedures to ensure high ethical standards in the conduct of research.[3] Reiterating the principle of self-regulation in maintaining integrity in the academic research process, the report called for better methods for dealing with any research dishonesty that did occur. It did not have much to say about the education of the majority of researchers, young or established, and it did not mention formal education in RCR.[3]

Similar priorities are reflected in the 1982 Association of American Medical Colleges (AAMC) report entitled *The Maintenance of High Ethical Standards in the Conduct of Research*.[4] This report provided guidelines and recommendations for academic health centers (AHCs) and teaching hospitals that were designing approaches for dealing with alleged misconduct by researchers. The committee reaffirmed that academic institutions and their faculties have critical responsibilities for maintaining standards for RCR at AHCs and teaching hospitals. It also promoted the articulation and/or review of institutional policies relating to high ethical standards for research, as well as procedures to deal with allegations of misconduct or research fraud that did not require

the development of an elaborate, administrative bureaucracy. The report did not suggest that institutions undertake any type of research integrity education.[4]

In line with these and other recommendations, policy makers in the 1980s concentrated on definitions and procedures, particularly after congressional mandates were written into and passed in the 1985 Health Research Extension Act.[5] By the end of the decade, the two major U.S. research funding agencies, the National Science Foundation (NSF) and the Public Health Service (PHS), had complied with the act, establishing basic definitions and procedures that specified how the government and research institutions should respond to suspected cases of research misconduct. Through initial inquires, then investigations and adjudication, government and research institutions were thus prepared to *react* to reported cases of misconduct in research. With some important modifications, these procedures are still used today to deal with the relatively few cases of research misconduct that surface each year. Most investigations are conducted either by the Office of Research Integrity (ORI), which is part of PHS, or the Office of the Inspector General in NSF.

There were, however, some exceptions to this reactive approach to research misconduct. In 1984, the University of Michigan Joint Task Force on Integrity of Scholarship outlined seven ways in which "ethical consciousness, and perhaps responsibility as well, can be heightened [through education] during the years students prepare to become scholars."[6] Although not formally implemented at the University of Michigan, the report, *Maintaining the Integrity of Scholarship*, was widely circulated and used by other institutions to draft their own research misconduct/integrity policies. At the same time, faculty at the Graduate School of Biomedical Sciences of the University of Texas at Houston instituted a lunchtime seminar on scientific ethics for graduate students that subsequently became the country's first semester-long required course on research integrity and the ethical dimensions of the biomedical sciences for research trainees.[7]

Unfortunately, these efforts to focus more attention on education remained exceptions during the 1980s, when catching dishonest researchers, particularly high-profile ones, dominated public discussion and policy making. In the end, it took another major report to elevate the issue of RCR education to national attention, leading to a decade of pronounced but largely disorganized growth.

A Decade of Disorganized Growth

Although many influences could be cited in the gradual shift to a proactive approach to fostering RCR, major credit is usually given to the 1989 Institution of Medicine (IOM) Report *The Responsible Conduct of Research in the Health Sciences*.[8] The body of this report contained one crucial recommendation relating to education:

> Universities should provide formal instruction in good research practices. This instruction should not be limited to formal courses but should be incorporated into various places in the undergraduate and graduate curricula for all science students.[8] (p30)

This recommendation was based on the contention that the "lack of formal discussion about responsible research practice and the ethics of research is a serious flaw in the professional training of young scientists and clinicians."[8] The IOM committee understood that training should be and often was provided by mentors through existing training practices, but members felt that although the traditional approaches were "often useful, they are no longer adequate because of the size and complexity of the modern research environment."[8]

The IOM committee placed most of the responsibility for action on research institutions, but they turned to the National Institutes of Health (NIH) for leadership and direction, calling for the NIH to (1) establish an office to promote responsible research practices, (2) require grantee institutions to provide assurances of efforts to adopt responsible practices, and (3) adopt professional standards for responsible research practices by NIH intramural scientists.[8] (pp23–29) To one extent or another, the NIH adopted most of these recommendations, although not in a form that made the commitment to fostering responsible research practices a prominent feature of NIH programmatic activities. The NIH staff did, however, implement one important policy change, which in retrospect had the single biggest influence on the growth and development of RCR instruction.

After consulting with various groups and committees in 1989, the NIH and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) announced a policy change for their institutional training grants. Beginning in 1990, the NIH and the ADAMHA required "that a program in the principles of scientific integrity be an integral part of the proposed research training effort" of all National Research Service Award (NRSA T32 and T34) applications[9,10]:

> Effective July 1, 1990, all competing National Research Service Award institutional training grant applications must include a description of the formal or informal activities related to the instruction about the responsible conduct of research that will be incorporated into the proposed research training program.[9]

The policy did not set any required curriculum but allowed applicants and program directors considerable flexibility to encourage innovation in providing required RCR instruction. Suggested topics for "informal seminars and presentations" included conflicts of interest, data recording and retention, professional standards and codes of conduct, responsible authorship, institutional policies and procedures for handling allegations of misconduct, and policies regarding the use of human and animal subjects.[9] With this simple, largely unheralded half-page requirement, the era of formal RCR education was essentially born.

In 1992, the so-called RCR training grant mandate was expanded to include both pre- and postdoctoral NRSA-supported trainees. The requirement was further strengthened when the NIH added language to the mandate stating that applications without plans for RCR instruction would be considered incomplete and returned without review. The NIH also encouraged the incorporation of all graduate and postdoctoral students into the RCR education plan, and eventually specified that the plan had to address the rationale, format, frequency, and subject matter of the instruction, the degree of faculty participation, and the trainee attendance requirements, all of which were to be evaluated in the grant-review process.[11]

The NIH did not, however, set standards for reviewing applications, assess how institutions responded to the mandate, or ask whether investigators thought the investment of time and resources affected research behavior.

Instead, through the 1990s, RCR education was more or less left to grow on its own under the guidance of a small but growing corps of largely volunteer RCR instructors and meager institutional support, such as free books or meals meant to encourage attendance. These efforts were supported by a few pioneering national train-the-trainer efforts, such as the Teaching Research Ethics program organized by the Poynter Center at the University of Indiana (begun in 1993)[12] and the Trainer-of-Trainers Conferences organized by the Survival Skills and Ethics program at the University of Pittsburgh (begun in 1995).[13]

Early Assessments and Recommendations

The disorganized nature of RCR instruction in the 1990s is most evident in a formal assessment conducted by Mastroianni and Kahn.[14,15] In 1996, William F. Raub, science advisor in the Office of Science Policy, Office of the Assistant Secretary for Planning and Evaluation of the Department of Health and Human Services (HHS), decided to create a repository of course materials used to instruct T32 grantees on research integrity and misconduct. Mastroianni and Kahn's assessment of these course materials made clear that there was wide variation in the way that RCR was taught and the content that different programs covered.[14,15] Two thirds of institutions in the sample required only T32 trainees to receive RCR training, meaning that many graduate student trainees were still not receiving instruction in RCR. Coverage also varied considerably for NIH-stipulated topics, from a low of 60% (institutional misconduct policies) to a high of only 86% (authorship).[15] A more recent report by Kalichman and Plemmons[16] in this collection of articles discusses the wide variation in reported goals that still exists in teaching RCR for NIH training grants.

The demonstrated unevenness of the coverage that was provided gradually led to calls for a stronger national commitment to RCR instruction. The HHS's 1995 *Report of the Commission on Research Integrity*, although mainly concerned with the ongoing debate over the definition of research misconduct, included among its recommendations a strong endorsement of required RCR instruction. On the basis of the belief that "required [RCR] educational activity is essential and should be more broadly implemented to ensure that, through such training, *all individuals* who perform research in institutional settings are sensitized to the ethical issues inherent in research"[17] (emphasis in the original), the report recommended that the secretary of HHS

> require that each institution applying for or receiving a grant, contract, or cooperative agreement under the Public Health Service Act for research or research training add to its existing misconduct-in-science assurance a third declaration, on certifying that the institution has an educational program on the responsible conduct of research.[17]

The report also urged the secretary to encourage

> integration of the explicit teaching of the ethics of science into the classroom, laboratory, and other research sites in precollegiate education as well as in undergraduate and graduate schools; and [f]unding for scholarship, teaching, and research in science ethics.[17 (p19)]

Commission members accepted and recommended that research institutions and professional societies have important roles to play in improving RCR education.[17]

The Commission on Research Integrity's call for universal, required RCR education, at least for PHS-funded researchers, was later implicitly endorsed by the HHS Review Group on Research Misconduct and Research Integrity.[18] Like the earlier *Report of the Commission on Research Integrity* that it was asked to review, the review group focused most of its attention on the definition and policies relating to research misconduct. However, under "special considerations," it recommended that

> the principal responsibility for oversight of institutional processes, education, standards setting, and attention to HHS's interests in policing research misconduct should be vested in ORI. The role, mission, and structure of ORI should be changed to become one principally of oversight, education, and review of institutional findings and recommendations.[18]

On the basis of this and other recommendations in the report, on May 12, 2000, HHS Secretary Donna Shalala issued directives for the *Statement of Organization, Functions, and Delegations of Authority* of the ORI.[19] Under the directives, the newly created Division of Education and Integrity was authorized to

> develop and implement, in consultation with the PHS OPDIVs [Operating Divisions], activities and programs for PHS intramural and extramural research to teach the responsible conduct of research, promote research integrity, prevent research misconduct, and to enable the extramural institutions and PHS OPDIVs to respond effectively to allegations of research misconduct.[19]

On the basis of this authorization, the ORI drafted and, in December 2000, announced its intention to adopt a *Policy on Instruction in the Responsible Conduct of Research*.[20]

The PHS Policy on RCR

The 2000 PHS policy on RCR gave research institutions "flexibility to determine the exact content, length, level, and method of instruction consistent with" the policy,[20] but it set some important objectives for both government and research institutions. These objectives challenged government and research institutions to

- Increase knowledge of, and sensitivity to, issues surrounding the responsible conduct of research.
- Improve the ability of participants to make ethical and legal choices in the face of conflicts involving scientific research.
- Develop appreciation for the range of accepted scientific practices for conducting research.
- Provide information about the regulations, policies, statutes, and guidelines that govern the conduct of PHS-funded research.
- Develop positive attitudes toward lifelong learning in matters involving RCR.

The policy also set a few minimum requirements. Most important,

institutional RCR programs had to cover nine *core instructional areas*: (1) data acquisition, management, sharing, and ownership, (2) mentor/trainee responsibilities, (3) publication practices and responsible authorship, (4) peer review, (5) collaborative science, (6) human subjects, (7) research involving animals, (8) research misconduct, and (9) conflict of interest and commitment. The instructional program had to be described in writing and be applicable to all staff who had "direct and substantive involvement in proposing, performing, reviewing, or reporting research, or who receive research training supported by PHS funds."[20] Beginning October 1, 2001, compliance with this policy was to be assured on all PHS 398 grant applications, with the additional requirement that all PHS-funded staff would be trained by October 1, 2003.[20]

The announcement of the PHS RCR policy sparked an informal national debate over the need for such a policy and the role of education in fostering integrity and/or deterring misconduct in research. Particular concern was raised by university administrators and some scientific organizations, including the Federation of American Societies of Experimental Biology, which disagreed with the policy's nine core instructional areas, the large number of individuals required to be trained, and the projected costs, and questioned whether such instructional programs could be implemented in the time frame required by the policy.[21] The AAMC questioned the policy's lack of clarity, the significant time and resources needed to adhere to the policy's objectives, and its definition of a target audience.[22] These objections were brought to the attention of the House Energy and Commerce Committee, whose chair, Billy Tauzin (R–Louisiana), sent the ORI a harshly worded letter objecting to the process used to develop the policy and to the wording of its content.[23] The ORI subsequently suspended the policy, leaving institutions to decide for themselves whether instruction considered essential for graduate and postgraduate trainees should be required of all researchers.[24] A few institutions have implemented or continued to work toward a broad, comprehensive RCR instruction program, but most have not.

Recent Attempts to Foster Reform

At roughly the same time that the PHS issued its now-suspended RCR instruction policy, other efforts were under way to expand and to improve RCR education. By 1997, NSF had followed the NIH's lead and added an RCR requirement to its Integrative Graduate Education and Research Traineeship (IGERT) program.[25] In June 2000, a few months before the PHS policy on RCR instruction was published, the NIH had also issued a policy for *Required Education in the Protection of Human Research Participants*.[26] This new policy required

> education on the protection of human research participants for all investigators submitting NIH applications for grants or proposals, for contracts or receiving new or noncompeting awards for research involving human subjects.[26]

Universities accepted the new NIH requirement more readily than the PHS RCR policy, in part because many already provided instruction for institutional review board (IRB) members and clinical investigators, in accordance with earlier NIH recommendations, and in part because of a broad and long-standing understanding of the need to make researchers aware of the ethical aspects of human subjects research. Moreover, having well-educated investigators was one way to improve the quality of research protocols submitted to the IRB and, hence, decrease the effort involved in the review process. The process was also aided by freely available, Web-based, computer-graded courses on the protection of human subjects.

In issuing these and other rules relating to research behavior, the government generally understood that it had to work in partnership with research institutions. The government-wide *Federal Research Misconduct Policy*, issued in December 2000, stressed that federal agencies may "have ultimate oversight authority for federally funded research, but research institutions bear primary responsibility for *prevention* and detection of research misconduct and for the inquiry, investigation, and adjudication of research misconduct alleged to have occurred in association with their own institution."[27] In line with this thinking, governmental agencies saw RCR instruction as part of each institution's responsibility to take steps to prevent misconduct and other improper behavior in federally funded research.

By the early 2000s, some form of RCR instruction had been established at most research institutions, typically to comply with the NIH NRSA training grant or the NSF IGERT RCR requirements as well as the NIH protection of human research participants requirement. These efforts were helped along by a growing number of Web-based instruction programs, many supporting the NIH human subjects requirement. For example, as described in articles by Braunsweiger and Goodman[28] in this issue, in 2000 the University of Miami Collaborative Institutional Review Board Training Initiative released its multifaceted online course.[29] This course provided a relatively inexpensive institutional system for documenting and tracking RCR education. It and other courses were appropriate not only for research investigators but also for research coordinators, research nurses, students, and others involved with the human studies.

More broadly, since 2002, the ORI has supported over 50 RCR resource development projects and a basic textbook on RCR, most of which are freely available on the ORI Web site.[30] Additionally, the HHS Office for Human Research Protections provided initial support for a small group of researchers seeking to organize RCR instructors and professionalize their work through the formation of the RCR Education Consortium.[31] This organization subsequently became the RCR Education Committee of the Association for Practical and Professional Ethics,[32] as discussed by Kalichman[33] in this issue.

With these and other developments, a consensus has gradually emerged that research training should include some education on responsible research practices. However, beyond this general consensus, today still there is little agreement on how RCR instruction should be planned, who should provide the instruction, how it should be supported, and who should be responsible for making sure that it is delivered.[16]

Recommendations for Future Development

Given the range of opinions about teaching RCR and developing RCR programs, how should policy makers, academic administrators, and faculty proceed? We believe that the best way to plan rationally and effectively for the future requires the following steps.

1. More effort and funding needs to be directed to the study of research behavior and the factors that influence it. Not surprisingly, the few available studies strongly suggest that the research environment plays an important role in shaping research behavior.[34–37] If these conclusions are verified, then strategies for RCR instruction need to be designed to reinforce the positive and counter the negative effects of the research environment. For example, an alternative instruction plan might focus on spreading RCR experiences throughout the years of research training rather than concentrating formal instruction in the first year of a graduate program, as is now most commonly the case.
2. RCR professionals need to develop a common vocabulary and framework for discussing the development and evaluating the impact of RCR instruction. Clear definitions are needed for terms such as *research ethics* and *research integrity*, to assess their common features and real distinctions.[38] Even if there is no agreement on which goals are most important for RCR instruction, it should be possible to agree on a common list of potential goals. It should also be possible to develop strategies for collecting data and assessing the impact of different RCR programs. Not unlike the biomedical ethicists two decades ago, academics who have become experts in RCR must define their field of effort and the methods they use to achieve and assess their work, and they must establish appropriate educational programs and experiences for future RCR educators.
3. Research institutions and funding agencies need to take a more active role in promoting and supporting RCR instruction. Since initiating the RCR education requirement in 1989, the NIH has provided little guidance for institutions that have to meet the requirement or for reviewers who must assess the quality of mandated RCR instruction programs. NSF has taken a similar, hands-off approach with the IGERT requirement. With few exceptions, institutional RCR programs are underfunded and given low institutional priority compared, for example, with compliance programs and mandated human subject and animal subject reviews.

Well-Integrated RCR Instruction Can Be Achieved

Although the challenges ahead are significant, the fact that so much has been accomplished with limited resources and a few weakly enforced requirements is reassuring. Thanks to the combined efforts of some visionary policy makers and a growing core of dedicated RCR "professionals" drawn from all walks of academic life, many students and researchers today have opportunities to explore and come to understand the responsibilities they take on when they pursue careers in research. With additional support, planning, and, as needed, program requirements, the goal of well-integrated RCR instruction programs for all students, researchers, and staff can be achieved in the not-too-distant future.

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