

# Responding to Challenges in Educating for the Responsible Conduct of Research

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## Abstract

The importance of responsible conduct of research (RCR) is widely recognized, but the necessary role for RCR education is limited by three significant challenges. First, the stated goals and purpose of RCR education are diverse, inconsistent, and sometimes not feasible. RCR is variably defined as knowing and following the rules, being a moral person, having good character, exhibiting good ethical judgment, and acting with integrity and responsibility. However, a case can be made that the long-term goals of RCR education can be reduced simply to decreasing research

misconduct and increasing responsible conduct. A second challenge is that the methods for fostering RCR are unclear because the relationship between the goals and role of education has been unclear. To reconcile goals with feasible objectives, it is proposed that the focus of RCR education can be limited to three specific purposes: empowering trainees to respond to the ethical challenges raised in the conduct of research, increasing awareness of the purpose and value of ethical decision making as well as the roles and responsibilities of whistleblowers, and fostering a positive

attitude about promoting an environment that values RCR. The third and final challenge is that a lack of dedicated financial support has decreased the likelihood that thoughtful, successful RCR programs can be developed. One means proposed to address the challenges of goals, methods, and strategies is a recently created national partnership, the RCR Education Committee (RCREC), a special interest group of the Association for Practical and Professional Ethics.

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It would be hard to find anyone in academia opposed to the responsible conduct of research (RCR). Virtually everyone agrees that ethics and responsibility are essential to the integrity of science.<sup>1–5</sup> However, consensus and commitment disappear when it comes to promoting instruction in responsible conduct. It seems that we are unclear about our goals, the methods for achieving those goals, and our willingness to pay for programs.

Experimental science arguably has a history of over 300 years. If in that time we have been unable to answer basic questions about goals, methods, and funding for education in research ethics, then perhaps these are simply unanswerable challenges. However, in this article I examine the fact that in recent years we have begun to see ways in which each of these questions can and should be addressed. I explore underlying assumptions for each of these topics in the following three sections. A fourth, concluding section summarizes the

role of a new national partnership, the Responsible Conduct of Research Education Committee (RCREC), in helping to overcome each of these three hurdles. The premise of the RCREC is not that these problems can be eliminated, but that we can effectively and economically do better than we have done to date in addressing them.

## What Are the Goals of RCR Education?

The term *responsible conduct of research* has been in wide use since the inception of the National Institutes of Health (NIH) requirement for RCR training for National Research Service Award training grants more than 15 years ago,<sup>6,7</sup> but it continues to defy definition. It is worth remembering that the training requirement was partly a response to increasing concerns about highly publicized allegations of research misconduct.<sup>8–10</sup> Correspondingly, the requirement called for training to include “policies for handling misconduct.” However, RCR education was meant to cover much more than the rules about research misconduct. Other topic areas to be covered included both research regulations (“conflict of interest . . . policies regarding the use of human and animal subjects”) and areas in which there are few regulations (“responsible authorship

. . . and data management”).<sup>6,7</sup> The extent to which RCR was expected to mean still more is exemplified by the fact that the keywords for the 1992 announcement of this program included *ethics* and *values*.<sup>6,7</sup> Further, courses that address RCR typically have titles that include words like *ethics*, *integrity*, and *responsibility*. Finally, in describing their experience in these courses, students sometimes use words that suggest *morality* and *character*.<sup>11</sup> Taken together, we expect a great deal of RCR education.

The problem with defining the scope of RCR education is that it is not one thing. RCR has come to include a wide-ranging mix of knowing and following the rules, being a moral person, having good character, exhibiting good ethical judgment, and acting with integrity and responsibility. The breadth of possible purposes for RCR education is further emphasized by a survey of RCR instructors, who report a diverse and sometimes conflicting array of goals that could be classified into the domains of knowledge, skills, attitudes, and behavior.<sup>12,13</sup> All of these goals are to be valued, but that does not mean that they need to be, and realistically can be, the purpose of RCR education.

At first glance, it appears hopeless to reconcile the diverse goals for RCR education, but it is worth taking a closer

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look to see whether there is common ground for a clear and manageable purpose. To begin, rather than focusing on specific objectives for an RCR education program, it is worth asking what we hope for in the long term. The two most obvious goals are: (1) less research misconduct, and (2) more RCR, that is, promoting a common understanding and practice of accepted standards of scientific conduct. These goals are desirable not only as ends, but as the means to optimize a research environment that is well supported and effective. A proposed scheme for the desired outcomes and factors that have an impact on those outcomes is illustrated in Figure 1.

Decreasing the risk of research misconduct and increasing the likelihood of responsible conduct presumably depends on much more than RCR education.<sup>4</sup> A variety of factors external to RCR education are equally or more important. First and foremost, the individual researcher brings her or his background to the research enterprise. Individuals vary in a lifetime of experience that has helped to shape their moral disposition and character. Further, an individual's conduct depends on the strength of her or his moral reasoning, or ethical-decision-making skills. The

development of these skills is frequently seen as a purpose of RCR education,<sup>4,14</sup> but a case can be made that moral reasoning is largely just an extension of the critical-thinking skills that are typically the focus of much of research training. The problem is not that researchers lack the necessary reasoning skills, but perhaps that they lack either access to the necessary information or they lack recognition of the need to apply their skills to the ethical dimensions of the practice of research.

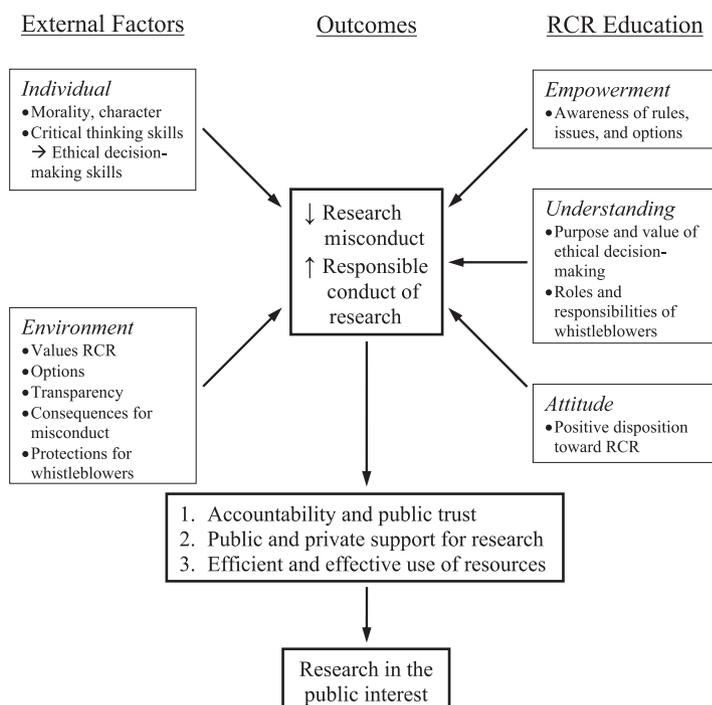
The conduct of individuals depends not only on their character and training but also on the environment in which they work. Many environmental factors have potential for an impact on the conduct of research, but some are likely to be particularly important. Some basic questions for any institution or organization should be:

1. Does the research environment place a demonstrated *value* on RCR?
2. Are *options* available to address concerns about research conduct when they occur?
3. Is communication sufficiently open to foster *transparency* for standards of conduct and expectations?

4. Are the *consequences* of deviations from RCR clear and appropriate?
5. Are *protections* in place to encourage open discussion of possible problems and responsible whistleblowing?

Assuming that these questions can be answered in the affirmative, the purpose of RCR education can have more focus and clarity than the wide range of goals described above. In brief, the focus of RCR education can be limited to just three specific purposes: *empowerment*, *understanding*, and *attitude*. The corresponding objectives are:

1. *Empowerment*: Trainees should have information about the relevant rules and issues related to RCR, as well as the options available to them, so that they are equipped to respond to the ethical challenges raised in the conduct of research.
2. *Understanding*: Trainees should be aware of the purpose and value of ethical decision making as well as the roles and responsibilities of whistleblowers.
3. *Attitude*: Trainees should be positively disposed to promoting an environment that values RCR.



**Figure 1** Proposed framework for the relationship between external factors (i.e., factors external to responsible conduct of research [RCR] education programs), RCR education, and outcomes of RCR education.

### What Is the Role of Education in Promoting RCR, and How Should RCR Be Taught?

As illustrated in Figure 1, RCR education is only part of the equation in promoting and achieving RCR. If the factors external to RCR courses are not aligned in favor of RCR, the lessons of RCR education will be greatly devalued and the outcomes will be diminished. However, assuming that external factors provide the necessary base for RCR education programs, then the challenge is to consider what approaches might best achieve the three defined goals of RCR education. Each of these goals is distinctive, but it is first worth considering *common approaches* relevant to all three before examining the unique features of *empowerment*, *understanding*, and *attitude*.

#### Common approaches

It is reasonable to assume that education for all of the selected areas of RCR is accomplished best by approaches that engage trainees in an active learning experience. It is widely known from

individual experience and research studies that active learning modalities are more effective than passive learning.<sup>15</sup> We are more likely to internalize and understand new information when challenged to do something with it than when someone simply tells us what we “should” know. Remarkably, this simple observation about education is often missed in RCR education. Frequently, institutions hope to meet NIH requirements for providing RCR education solely by giving lectures, playing videotapes of previous lectures, or requiring trainees to complete a Web-based, multiple-choice exam. Although it is true that some information can be conveyed with all of these approaches, they are unlikely to foster memory, understanding, or positive changes in attitude. Instead, it is clearly desirable that trainees should be exposed to RCR through participating in discussion, raising questions, and solving problems. These activities typically occur around case studies, but can equally well occur as adjuncts to role-playing exercises, watching appropriate movies, responding to thought-provoking questions, or completing a survey.

RCR education does not occur only in a formal setting. In nearly all cases, researchers learn about their profession as apprentices to other, more established researchers. This can reasonably be assumed to be the ideal setting in which to teach RCR. Unfortunately, this approach to RCR instruction occurs infrequently and minimally.<sup>16,17</sup> Even when RCR is covered in this informal setting, it is still likely to be less than optimal. Mentors may be insufficiently knowledgeable, too overworked to focus on such training, or unwilling to do so. Finally, even if such training occurs and is appropriate, it will still risk being isolated, lacking connection to other research groups or disciplines. Training in the individual research environment can be an important component of a complete RCR program, but it is distinct from and external to formal institutional RCR training.

The three proposed goals of empowerment, understanding, and attitude also have in common the fact that what is appropriate in one institutional setting is not necessarily appropriate somewhere else. The generic goals may be similar in all settings, but the specifics of different research projects,

different research disciplines, and different research experiences ensure that no one curriculum will suit everyone. This is why it is difficult, and probably inappropriate, to impose a single educational regulation or curriculum on all researchers. It is clear that there would be value in widespread sharing of useful tools and resources, but each research setting will ideally need to generate a curriculum that is matched to its audience and its institutional culture.

### Empowerment

The integrity of science depends not only on the ability of researchers to identify what is right, but also on their confidence to act on that knowledge. Unfortunately, research can be quite hierarchical, leaving students, staff, postdoctoral researchers, and other more junior researchers in a position of clearly diminished power. This power differential can inhibit the questioning of research practices that seem inappropriate, the reporting of possible research misconduct, and the active promotion of practices that maximize research integrity. However, when people fail to speak out about misconduct, it is often because they lack a basic awareness of the rules that govern research conduct, the ethical dimensions of research practice, and options for addressing concerns (e.g., peers, respected mentors, ombuds programs, or anonymous hotlines to report concerns). These gaps in knowledge are readily addressed through lectures, Web sites, or even brief assigned readings or handouts. This material may be enough if individuals are positively disposed to this information and the environment is highly supportive. In cases where the external factors are not so potent, more active learning strategies are needed. However, in all cases, it is important to recognize the extent to which the relevant rules, issues, and options vary among research environments. For this reason alone, it is necessary that RCR programs be custom designed for each specific audience.

### Understanding

In Figure 1, it is proposed that researchers need understanding in two specific domains: ethical decision making and whistleblowing. In the case of ethical decision making, the focus is not on morality or character. The starting presumption is that trainees in RCR courses are good people who may lack information, tools, or resources. For

those cases in which this is not true, it is too much to expect that one or two “ethics” classes will change the character of adult students. And, although ethical decision making is important, the focus in RCR education need not be on the skill of making ethical decisions; the requisite critical-thinking skills represent an “external factor” that is already embedded in the curriculum for research training. Instead the focus should be on the purpose and value of ethical decision making in research. The purpose is to address true ethical dilemmas, hard cases in which two or more vital principles (e.g., truth, do no harm, justice, open communication, loyalty, or individual rights) are in conflict. It is not an ethical dilemma when the decision to protect a research subject from harm is in competition with personal greed. Such a choice is unambiguous and only difficult for those not inclined to moral behavior. However, when ethical principles are in conflict, the challenge to the researcher is to make use of his or her critical-thinking skills and intellect to recognize the moral dilemma and to find the best possible solution.<sup>18</sup> In this view of ethical decision making, ethics is not about a particular outcome; it is a process, not unlike the scientific method. In short, the problem for RCR education is not to convince researchers of the correctness of basic ethical principles, it is to convince them that their challenge (responsibility) is to reconcile those principles when they come into conflict. The value of doing so is clearly to the benefit of the integrity of the scientific enterprise.

Whistleblowing is essential to protect against the risk of false research reports. The vast majority of researchers are presumably honest and unlikely to commit research misconduct; however, it is important that mechanisms are in place to identify and respond to those rare cases of fabrication, falsification, or plagiarism in research. That said, despite the importance of whistleblowing, it is a double-edged sword. On the one side, it is important that false research reports are identified early, even if their occurrence is embarrassing to the institution or science. On the other side, whistleblowers often suffer even if their allegations or concerns are true, whistleblowers can sometimes be malicious, and it may be that whistleblowing is not even the appropriate action. Whistleblowers may

be mistaken about the seriousness or even the reality of the misconduct that they believe they have witnessed. However, even if whistleblowing is inappropriate, the integrity of science still depends on addressing concerns or questions that arise in the conduct of research.

An essential part of the understanding of responsible whistleblowing is recognizing both that we can be mistaken about what we believe we have seen and that responsibility in science requires us to address all questions or concerns, not just those that involve serious wrongdoing. A part of being a responsible researcher is to ensure that all researchers, even those who are most junior, are given the tools and empowerment to raise questions. Integrity of research is more likely to derive from an environment that values openness and transparency about the conduct of research than one in which it is mistakenly assumed that everyone understands what is and is not acceptable practice. Taken together, a well-trained researcher will understand that her or his responsibilities include the need to initiate conversations about the responsible dimensions of the practice of research, to seek perspective from others when something doesn't seem right or doesn't make sense, to nurture good conflict resolution skills to minimize the risk of misunderstandings and disputes, and to seek out help with mediation or arbitration of disputes that cannot be otherwise resolved.

In this complex environment, the interests of the whistleblower, the interests of the accused, and the integrity of science all need to be protected. Therefore, a central part of RCR education must be an understanding by all researchers of their roles and responsibilities with respect to whistleblowing.<sup>19</sup>

The methods for teaching about ethical decision making and whistleblowing depend much more on case-based discussion than on simply relaying information. Although there is a pure informational component to these topics, the relevant concepts and processes cannot be reduced to a formula or list. For these areas, it is particularly important that trainees be challenged to struggle with resolving tough cases. This means participating in discussions with other researchers, or role-playing.

### Attitude

Although *attitudes* of researchers might seem less concrete conceptually than ethical decision making or whistleblowing, this domain may be the most important endpoint for RCR education. Trainees can be provided with extensive information and develop outstanding skills for dealing with the ethical dimensions of the practice of research, but knowledge and skills will mean little if they perceive that RCR is not valued or, even worse, seen as counterproductive. It is hoped that RCR education will promote the attitude that RCR is in the best interest of individual researchers, science, and society. In practice, the individual researcher should be positively inclined to avoid violating regulations or accepted standards of conduct, to take the extra effort needed to enhance the integrity of her or his conduct in research, to speak out against actual or potential deviations from high standards of conduct, and to favor both informal and formal education to promote RCR in the scientific community. Such attitudes are not taught by simply telling someone this is the way to behave. It is reasonable to assume that formation of these attitudes will depend on the ways in which RCR is addressed in the training environment and, perhaps more importantly, on the ways in which the research environment demonstrates a commitment to RCR. In short, it is not enough merely to teach information and skills. Promoting positive attitudes depends on evidence that responsible conduct is highly valued both by those teaching RCR and by the institution in which research is being conducted.

### Who is Going to Pay for These Programs?

RCR education is needed, but it cannot be provided without cost. If the task of RCR education is important, and if producing effective programs requires effort, then it is necessary that someone is given the time and resources to create such programs. Time for instructors to prepare and present a course comes with a cost. Unfortunately, for most institutions it is not clear how that cost is to be covered. RCR instruction is not provided by a research ethics department, because few, if any, such departments exist. Instead, it might be provided by individuals who are researchers in any of a wide variety of disciplines, teachers

from departments of philosophy, history, or sociology, or administrators responsible for research compliance. Teaching RCR is not a primary mission in any of these cases. Instead, to the extent that a teaching mission exists, it is for courses in particular departmental disciplines (e.g., biochemistry, neurosciences, pharmacology, or psychology). Appropriately, faculty, researchers, and departments will argue that such a course is a responsibility of the institution, not the individual department.

Institutions are also in a bind because resources are limited. Indirect costs from research grants or other external sources of funding are typically committed and simply not available unless the institution perceives that an expense is essential. Although a case can be made that commitment of at least minimal resources for research ethics is essential,<sup>20</sup> few institutions take this approach.

The result is that, in practice, RCR courses are the products of the initiatives of individual faculty or researchers. The courses are taught by individuals who have been assigned—or have volunteered to be assigned—to the responsibility of creation and presentation of RCR instruction. Unfortunately, with minimal resources to carry out this task, the risk is that instruction will be minimally effective or, worse, counterproductive. No systematic survey is yet available for either the quality or effectiveness of RCR education programs, but it is clear that even among well-established programs, the variability is high for course goals,<sup>12,13</sup> course approaches and content,<sup>21,22</sup> and perceptions of course purpose.<sup>11</sup> Although diversity in programs can be valuable, it is clear that there is room for improving consistency in the delivery of RCR education.

### The RCR Education Committee Solution

All too often, and despite the 1992 NIH policy<sup>6</sup> that “[p]lans that incorporate instruction in the responsible conduct of research for all graduate students and postdoctorates in a training program or department, regardless of the source of support, are particularly encouraged,” RCR education continues to be limited to those trainees for whom it is required as a condition of federal funding. It seems that after more than 15 years, it is still the

exception that institutions require RCR instruction for everyone, not just those for whom such instruction is a condition for funding of training grants.<sup>13</sup> Thus, the dilemma is that although we know that RCR is an important part of the training of the next generation of scientists, the resources are not available to develop independent and robust programs in the absence of federal mandates to create such programs. However, the history of such mandates is that they are either too vague to encourage action or too prescriptive to accommodate the variation in research environments.

In February 2001, a summit meeting was convened by several federal agencies, including the Office of Research Integrity and the Office for Human Research Protections, to consider how best to resolve this dilemma. A variety of proposals were presented at that meeting, but one that was actively pursued by the participants was the creation of a national, nongovernmental partnership involving those individuals, institutions, and organizations with a central interest in promoting RCR. Such an organization would provide a compromise between an absence of programs and an imposition of a single federal model on all research institutions. The intention was to ensure that the best available resources could be shared and that collaborative efforts could develop new materials and programs with relatively low cost to the individual institutions.

The path for the creation of this national organization has been anything but linear. However, in early 2004, the RCREC was inaugurated with a provisional home at the University of California, San Diego. One of the goals during this early stage of development was to establish a sustainable, long-term basis for the RCREC. That solution was developed in 2005 and formalized with an agreement, effective May 1, 2006, for the RCREC to be hosted by the Association for Practical and Professional Ethics (APPE). The RCR Education *Consortium* has now been renamed the RCR Education *Committee*, a standing committee of APPE and a focus for members of APPE who have a special interest in meeting the RCREC mission (<http://rcrec.org>):

The mission of the RCREC is to provide leadership to the research community in identifying, developing, and promoting

programs of education in the responsible conduct of research. This is accomplished by collaborations among institutions, organizations, and federal agencies that have roles and interests in the responsible conduct of research.

The RCREC has begun the process of carrying out its mission in several ways. The RCREC Web site (<http://rcrec.org>) hosts a section of online resources, freely available to new and continuing instructors of RCR courses. Organizational members are provided with an Internet-based course to be used as a framework for a classroom or instructor-moderated online course. The RCREC continues to convene annual and informational meetings in conjunction with several organizations, particularly the annual meetings of the APPE and the Society of Research Administrators International (SRA). In addition to keeping participants apprised of new developments in RCR education, these meetings help to promote collaborations among institutions and individuals in the sharing and creation of new resources for RCR education. The RCREC and its members are collaborating in the planning of APPE and SRA meetings to include significant content in RCR education. As the field of RCR education evolves, it will be the continuing goal of the RCREC to play a lead role in promoting the development of effective programs and resources for RCR education.

### Challenges and Opportunities

RCR should be not just a high priority, but the highest priority, for any research institution. For this reason, nearly everyone speaks in favor of RCR even as RCR education remains ad hoc and variable in quality. The barriers are clear. Without definitive goals for RCR education, all of those involved are uncertain about the purpose of the enterprise. Without clarity about the methods that are most appropriate for promoting RCR, there is no guidance about what is and is not useful to do. Without adequate support for the mission of RCR education, it is unrealistic to expect that RCR education will be effective. These problems may never be completely resolved, but there is room to do better than we are now doing. One option for improvement is to share resources and costs through joint efforts. This is the goal of the RCREC, which, through the partnership of its member institutions, is

working to establish RCR as our first priority in conducting research.

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### Disclaimer

The views expressed in this article are those of the author and are not necessarily shared by the acknowledged individuals, the RCR Education Committee, or the Association for Practical and Professional Ethics.

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## Teaching and Learning Moments

### On Becoming a Doctor: A Patient Teaches

I was the preceptor for several second-year medical students, who were interviewing and performing physical examinations on volunteer simulated patients for an advanced physical diagnosis class. After the examinations, we gathered in each patient's room for the student to present the history, review the physical findings, if any, and critique the encounter, including receiving feedback from the patient about the exercise. After several weeks of the course, I knew a little about the students' medical career goals and their personalities. Two were hoping to become procedural specialists and had the expected confidence to go with that training. One was unsure of what he planned to practice, but he wanted to know his patients as people and to help manage their long-term health care. He thought that family medicine or general internal medicine might be the path for him. He seemed more reserved and guarded during his encounters with standardized patients, although he always related well to them and evinced empathy for the possible impact the illness might have on their families.

One afternoon, a female patient gave a history indicating the recent onset of

diabetes mellitus, and the "generalist" oriented student connected all of the thirst and urinary symptoms into a nice working diagnosis. He presented her physical findings in order and gave a detailed, ophthalmologic examination, explaining what findings in the eyegrounds might denote diabetes. He came to the chest and the cardiac findings and began to present the findings. "I think," he hesitated, "I know I heard a soft heart murmur in the aortic area that did not radiate into her neck and might be a functional flow murmur." He finished the rest of the examination and summarized the case.

In wrapping up the discussion, I asked the patient for feedback about the interview and presentation. Where upon, she turned quickly and looked directly at her student examiner, and said, "Doctor." She called him doctor. "I have known since I was a teenager about that heart murmur which has been confirmed with an echocardiogram; it is what you said. Many doctors I have seen in the past have not heard that murmur. I am used frequently as a practice patient, I am an actress, but no other medical students have said they heard that

murmur. Congratulations." I was watching the student. He did not suppress a smile, nor puff up. But he bit down on his lower lip, he breathed in and his nostrils flared, and I saw his eyes squint and congest. A doctor was born that moment, and he truly entered our profession.

Preparing for a career in medicine is arduous and students and trainees need to receive periodically personal reinforcement to keep spirits and learning momentum positive. Often this arrives from good test performance and in comments from teachers and mentors. Unexpectedly witnessing medical confidence being built is spellbinding, if not magical. Here it was given by a patient. As we often experience, the joy from medicine and helping others frequently comes from what our patients teach us.

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