Office of Research Integrity

N E W S L E T T E R

IN THIS ISSUE

Research Foci

ORI invited several researchers to provide their commentaries on the future directions for developing relevant research on the responsible conduct of research. They each describe their perspectives on future research questions, and collectively they have provided a wealth of ideas that we hope will guide future research efforts. We appreciate their efforts and willingness to share their thoughts with us. Specifically, we thank the following:

- Michael Kalichman, Ph.D.
- Brian Martinson, Ph.D.
- Michael D. Mumford, Ph.D.
- David B. Resnik, J.D., Ph.D.
- Nicholas H. Steneck, Ph.D.
- Paul Root Wolpe, Ph.D.

Scientific Work in a Changing Environment
Paul Root Wolpe, Ph.D., Director, Center for Ethics, Emory University

Science is a professional activity. Although we often ascribe lofty motives to the scientific enterprise—fostering the human pursuit of knowledge, relieving suffering, unlocking the secrets of nature—in the end, the work is done by real people in institutional settings. The people who do the work of science are concerned with their careers, their income, their families, and their standing in their professional community. And, like all other people in work settings, they are profoundly influenced by the incentives, cultural and institutional, that frame their work and their professional lives.

What sociological research has shown us for almost a century is that well-meaning people, when placed in an environment that puts pressure on them to behave in certain ways, will tend to do so. If the environment encourages integrity, transparency, and fidelity to the work, people will tend to behave that way. If the environment encourages results at any cost, a me-first attitude, or cutthroat competition, people will generally conform their behavior to that mode of thinking as well.

Of course, there is variation; some will maintain integrity in the most hostile environments, and some will misbehave in supportive environments. Sociology measures group behavior, not individual behavior. The mistake, however, is to focus on the misbehaving individual and to think by sanctioning or eliminating him or her you have solved the problem of the institutional culture.

Science is a competitive and pressure-driven field, both in funding and in reputational capital. Workers quickly learn what their institutions

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value and what strategies they should pursue to be successful and to advance. The main product of academic science is the scientific article (science in industrial settings is different). Publications form the main calculus by which we evaluate scientific success. In addition, the publication has a clear hierarchy; authorship is listed right on the academic product in a well-understood matrix of credit. The main vehicle to achieve the desired product is the grant award; that is, money is required to generate articles, and the grant award is the primary means to fund the product. Therefore, the two most important achievements for scientific career advancement are scientific publications and grant awards.

In today's academic scientific environment, achieving those goals requires complex teams; the age of the individual researcher is all but over. To do modern science, therefore, the senior scientist must not only master the skills of scientific methodology, but also organizational and management skills. We do not teach those skills in graduate school or probe deeply into the nature of that aspect of science in courses on the responsible conduct of research (RCR).

Junior workers (in any occupation) understand that their professional success is highly dependent on senior workers. In academia, graduate students understand that the path to a professional life leads through their mentors and advisors. In addition—and often unlike what occurs in other work settings—these senior scientists hold the key not just to advancement but to entry into the profession itself. Without a Ph.D., a career as a lead scientific researcher is extremely difficult. In that sense, advisors hold almost unique power over their students' professional careers.

It is important to note here that the issue is not pressure alone. High-pressured work environments can also be highly ethically engaged; for example, think of emergency rooms. Modern science can be high pressure and have great integrity. It is the impact of the pressure on workers, not the pressure itself, that needs to be addressed and mitigated. Pressure affects workplace performance and morale, so it should be addressed in an atmosphere of openness, transparency, and sensitivity to worker needs for career advancement.

Finally, to understand emerging challenges, it is important to note that scientific work itself is in a state of flux. Journals are declining in their power, and new forms of communication, such as blogs and open-access platforms, are increasing their role in the scientific enterprise. Sophisticated computing, new forms of digital media, crowdsourcing science, and other changes in information technologies are transforming science in ways that are hard to predict from today's vantage point.

The potential for abuse, given these factors, is high. We have strong institutional pressures to create a particular kind of product, a product that lists on its face who should be credited with it and in what order of responsibility. The individuals who create the product are also responsible for funding it, through grant acquisition. (Imagine if the manager who designs a new car at the Ford plant was also solely responsible for funding its **(See Changing Environment, page 3)**

ORI Funding Opportunity Announcement (FOA)

On December 2, 2013, the FOA for the research on research integrity (RRI) was released. *http://www.grants.gov/view-opportunity.html?oppId=248593*

A webinar to review FOA issues will occur soon. Details on the webinar can be found at *http://ori.hhs.gov*

Changing Environment *(from page 2)*

production.) The institution evaluates career advancement, salary, and other rewards based on the success of acquiring grants and producing articles. Power relations still give the mentor and advisor authority over the trainee. Yet new forms of scientific presentation and processing are emerging rapidly, which may give graduate students, who often have more experience and skill in these new forms of scientific communication, new leverage. The confluence of these factors will, I believe, lead to new forms of misconduct or at least to novel presentation of old forms.

Because of the close relationship between the nature of professional scientific work and the reward incentives of modern scientific and academic institutions, the questions that are most pressing to the understanding of misconduct lie not in the behavior of individuals, but in the dynamic interchange between institutions and their workers in a changing scientific environment.

Therefore, I believe that the most important and productive lines of inquiry into scientific misconduct lie not in trying to understand the psychology of individual workers (though I am not discounting that line of research at all), but in understanding how specific academic scientific environments lead to patterns of misconduct. In an era of decreased funding and changing scientific work, the institutional culture around science will also change. How it changes is a fertile subject for social scientific inquiry.

What then might be some fruitful areas of inquiry that are relatively neglected? One is comparative studies of institutional environments. The business literature is full of books that look at different business and corporate environments in an attempt to determine what makes a business successful. More recently, perhaps in the wake of so many high-profile business scandals, the shelves of the business sections of bookstores have become filled with books about developing ethical leadership and building integrity, also through comparative examination of corporations. What is it that characterizes scientific enterprises where integrity is a prominent component of the team's identity and thinking versus those where it is not? We think we know the answer (e.g., leadership modeling and transparency), but there is important ethnographic and empirical work to be done here to determine whether our instincts are right or whether there are many roads to integrity in scientific work.

Second, as noted, the rise of digital media is transforming how scientific information is managed and communicated. While such developments may ultimately prove beneficial for science by leveling the playing field, breaking monopolies, and bringing more amateurs into the process (as in science crowdsourcing for things like protein-folding problems), it also poses some challenges. Without the gatekeeping of professional scientists, however flawed and sometimes prejudicial it can be, the opportunities for misbehavior increase. And what do we mean by "scientific misconduct" when the offender is an amateur or layperson? Who can sanction that individual? As new forms of scientific production develop, it is important that we use our best social scientific tools to understand the dynamics of misconduct in the emerging digital scientific environment.

The history of the sociology of science—the study of science as a social activity—has taught us that scientific knowledge is acquired in an organizational system that has all the needs, flaws, and advantages of any social collective. Academic science work definitely has special qualities. It may be true that the nature of scientific work, and the commitments of most people who choose it for a career, make it easier to develop an ethic of integrity in research. Such an ethic may be possible if we find the best strategies for developing it. What is very clear, however, is that those strategies are not exemplified in the periodic RCR course. What is needed is sophisticated inquiry into existing and emerging organizational forms of science to ensure that its changing forms continue to pursue the highest aspirations of scientific integrity.

> *"You are only afraid if you are not in harmony with yourself."*
> **Hermann Hesse**
> (1877-1962)

Essential Questions for Research on Research Integrity

Nicholas H. Steneck, Ph.D., University of Michigan

The following suggestions are based on the assumption that ORI funding for research on research integrity (RRI) should address questions that will help it carry out its two primary missions: responding to misconduct and promoting integrity in research funded by the Public Health Service (PHS).

Responding to misconduct

Researchers have previously studied ORI findings of misconduct in an effort to learn more about trends over time, reasons why researchers engage in misconduct, and the outcome of investigations. The usefulness of this research is unfortunately limited because we do not know whether the cases ORI closes are broadly representative of misconduct in PHS-funded research. There is reason to believe that they are not, because ORI's closed cases probably represent 1 percent or less of the total misconduct estimated to take place in research today.

One important question to address, therefore, is why so few cases of misconduct in research are ultimately reported to and investigated by ORI. Prior research has suggested that many researchers who suspect colleagues of misconduct do not report their suspicions. However, these suspicions may be inaccurate because they may be based on a small number of cases about which everyone is aware. We know very little about the attrition that takes place through the reporting process. And finally, we do not know whether the purposefully narrow and demanding definition of research misconduct adopted in the United States discourages researchers from reporting misconduct and other misbehaviors that undermine the reliability and usefulness of research.

Accordingly, the current system for responding to misconduct, and ORI's role in that system, need to be subject to careful investigation. Why are researchers reluctant to report misconduct? What happens when they do report it? How do research integrity officers and ORI staff triage the complaints they receive? What prompts a journal editor to pursue or ignore complaints? Why aren't more problems picked up during peer review?

RRI has already provided evidence for identifying potential target areas for studying the response to misconduct, such as the many cases of suspected duplicate publication/plagiarism identified by the eT-BLAST search engine and listed on the Deja vu web site.[1] Has anything been done by institutions and editors to follow up on what amounts to nearly 80,000 possible duplicate publications? If not, why not? There may be valid reasons why so much suspected misconduct is not addressed, but there could also be significant need to reform the current system to make it more responsible. More research is needed to clarify this issue.

Promoting integrity

Promoting integrity is a vague and potentially endless task. If the goal is to assure that every researcher meets every standard for responsible conduct all of the time, it is probably unachievable. If something less than perfection is acceptable, then where should ORI concentrate its effort? To answer this question, more information is needed about the reliability of the research record **(See Essential Questions, page 5)**

ORI Seeks Interested Reviewers

ORI is continuing to collect names of potential reviewers of grant applications. Persons with a strong interest in responsible conduct of research (RCR), and experience in teaching RCR and conducting research on research integrity, are invited to identify themselves. The review process for the 2014 granting round will be held in April or May 2014.

At the two-day review meeting, each panel of four reviewers and a chair are responsible for reviewing about 8 to 10 proposals. After an evaluation of any potential or real conflicts of interest with the submissions, each reviewer is trained on the specifics of the review process and then reviews each proposal that their committee is assigned. At the two-day webinar meeting, the reviewers discuss each submission in detail and then individually decide whether they want to change their evaluation scores. Please contact Sandra.titus@hhs.gov if you are interested in being considered.

Essential Questions *(from page 4)*

and the relative impact of different misbehaviors on society.

Reliability. The question of reliability of research has previously been approached from the perspective of specific misbehaviors, for example, plagiarism, improper authorship or image manipulation, failure to report conflicts of interest or contradictory data, improper record keeping, and the like. This research now needs to be taken one step further to assess the overall impact of the full range of misbehaviors on the reliability or quality of different areas or fields of research. In other words, RRI needs to move in the direction of and embrace some of the methods used in quality assessment (QA).

QA studies are common in business and some professional areas. With careful planning and validation, methods can be developed to assess and compare the quality of research in different research areas. To do so requires estimates of the sample sizes needed to draw generalizations, agreement on essential areas to evaluate, and approaches that focus assessment efforts on improving quality and integrity rather than on detecting misbehavior.

Impact. To focus efforts to promote integrity, we also need more information on the relative impact of different misbehaviors in research on society. When research misconduct became a public issue in the 1980s, policymakers *assumed* that three obviously wrong behaviors—fabrication, falsifica-

tion, and plagiarism—posed the greatest threat to the integrity of research. Later, when it became clear that researchers misbehaved in others ways, other misbehaviors were classed as "questionable" and *assumed* to be of less importance to society, that is, to government policy making and intervention. Neither assumption was based on empirical evidence.

Misconduct and other misbehaviors impact society in two ways: (1) deliberate or careless misbehavior wastes funds and (2) unreliable or deceptive information can lead to decisions that cause harm to individuals and to society as a whole. There is a need for research that explores ways to quantify these impacts to allow comparisons and decisions on where to focus efforts to promote integrity.

A full understanding of impacts requires the development of economic models specifically designed to study the role of integrity in research. For example, there is currently concern that the rate of retraction may be increasing.[2] Is this good, bad, or irrelevant? What does a retraction cost, measured in terms of wasted publication expenses (review, publish, and index), researcher time (review, read, and use as a basis for other research), and possible societal harm? What would measures to reduce retractions (e.g., better training and paid reviewers) cost? And, most important, how do the costs associated with retractions compare with

those associated with the three areas of defined misconduct and the broader range of other questionable research misbehaviors?

There are reasons to believe that some questionable practices, such as overestimating the effectiveness of new cancer treatments,[3] the duplicate publication of clinical trials,[4] or failing to report conflicts of interest in studies of the effectiveness of drug awareness training,[5] waste significant amounts of funding and harm society. Would society be better off if more effort were put into reducing such practices rather than focusing so much attention on research misconduct? Would society be better off if more effort were put into training new researchers in the responsible conduct of research, as suggested by others in this issue? Until there is a solution to the central question of importance based on the careful study of quality and cost, it will be difficult to plan a rational and effective RRI program.

Endnote and References

[1] Deja vu: A database of highly similar citations. (n.d.), at *http://dejavu.vbi.vt.edu/dejavu/*

[2] Steen, R. G. (2011, April). Retractions in the scientific literature: Is the incidence of research fraud increasing? *Journal of Medical Ethics, 37*(4), 249–253.

[3] Djulbegovic, B., Kumar, A., Magazin, A., Schroen, A. T., Soares, H., Hozo, I., et al. (2011, June). Optimism bias leads to inconclusive results—an empirical study. *Journal of Clinical Epidemiology, 64*(6), 583–593.

What Research Should Be Addressed? or
Moving Research Forward in RCR: Do We Dare to Study Ourselves?

Brian Martinson, Ph.D., HealthPartners

In his 1998 article on the prevention of scientific misconduct, Douglas Weed made some astute observations that are worth revisiting:

Are we as scientists willing to study our conduct as scientists? If so, then one day we may discover why we suffer from an important and sometimes disabling professional affliction and what works to prevent it. I am not suggesting, however, that we should postpone interventions until we fully understand the etiology, including the underlying biological, behavioral, and social mechanisms involved in the range of activities we call scientific misconduct. (Weed, 1998, p. 128)

Weed speaks to two points of tension in the study and application of responsible conduct of research (RCR) and other efforts to understand and promote integrity in research. Are we, as a community, really prepared to treat the topic as an area worthy of serious scholarship? And even if we are, what do we do about this "professional affliction" today? Many

Essential Questions
(from page 5)

[4] Cochrane Collaboration, Cochrane Bias Methods Group. (n.d.). Addressing reporting biases, at *http://bmg.cochrane.org/addressing-reporting-biases*

[5] Gorman, D. M., & Conde, E. (2007, November). Conflict of interest in the evaluation and dissemination of "model" school-based drug and violence prevention. *Evaluation Program Planning, 30*(4), 422–429.

involved with RCR are understandably eager to have practical tools and processes—interventions—that can be applied to foster RCR and to dissuade researchers from engaging in misconduct. Yet the apparent need to "do something" needs to be tempered with the recognition that the study of RCR and research integrity in general is still very much in its infancy. Our understanding of the etiology of misconduct in science and other undesirable research-related behaviors is woefully incomplete. Despite this fact, there is no shortage of theoretical work in a broad range of disciplines that is likely germane to understanding these phenomena! Moreover, it remains to be seen what appetite the science community as a whole has for studying its own conduct using appropriate tools of science and applying appropriate theoretical insights.

There is a need for more "basic research" at the same time there is a need for more "translational research" into the etiology of undesirable research-related behavior. The miniscule direct public funding of what are arguably quality assurance efforts in science adds further difficulty to the task. My guess is that the sum total of what ORI has invested in research on research integrity over the past 10 years comes to something less than 0.0005 percent of the National Institute of Health's (NIH's) *annual* budget. This lack of investment, particularly on the part of NIH, is both troubling and telling. We fund what we value.

My sense is that leaders in the RCR community want to move the science on research integrity away from merely descriptive analyses toward more experimental models. Such models, in particular, might be used to test the efficacy of specific types of interventions and might lead to translation of those findings into tools and practice. There are two immediate challenges: first, the very limited financial resources available to support this research agenda, and second, the need to have such research well informed by appropriate theories of the causal relationships that should be studied and intervened upon. I suggest that we attempt to address both of these challenges simultaneously. We should do so by bringing to bear the tools and concepts from the rapidly evolving areas of study sometimes referred to globally as "complexity science" or "systems science."

I am not aware of any research on research integrity that has applied tools such as simulation modeling to study any aspect of research integrity or the potential value of hypothetical interventions. Yet such models are increasingly being developed and used very effectively to understand a number of real-world complex systems; evaluate, using computer simulation, the impacts of various types of interventions on behaviors of interest within those systems; and bring about change in behavior within those systems.

(See Study Ourselves, page 7)

What Don't We Know about RCR Education

Michael Kalichman, Ph.D., Director, Research Ethics Program, University of California, San Diego

Clear goals and a reliance on evidence are hallmarks of scientific inquiry. Remarkably, the national approach to educating scientists in responsible conduct of research (RCR) is characterized by neither goals nor reliance on evidence (De-Bruin et al., 2007; Kalichman, 2009, 2013a, 2013b). In fairness, this is not surprising. RCR education is a relatively new component of the re-

search enterprise, driven largely by requirements over just the past 25 years (National Institutes of Health [NIH], 1989). As a result, research on education is increasing, but still in its infancy. Assuming RCR education should be based on evidence, the following is a personal perspective on gaps in our knowledge and recommendations researchers and policymakers might consider for

a research agenda. The domains addressed are: Goals and Topics, Approach, Culture, Institution, Teachers, Audience, Outcomes, Perceptions, and Community.

GOALS AND TOPICS

Designing an effective program begins with a clear articulation of the purpose of that program.

Study Ourselves *(from page 6)*

These models are being built to study phenomena that cannot easily or affordably be studied in their naturally occurring real-world settings but which can be modeled via computers in a much more timely and cost-efficient manner. Such models are yielding new hypotheses to be as well as informing real-world interventions. One recent example of a systems science approach that may, in fact, be relevant to understanding research integrity can be seen in a 2012 paper by Larson, Ghaffarzadegan, and Diaz, asking: "What happens within the university-based research enterprise when a federal funding agency abruptly changes research grant funding levels?" This work explores the operation of nonlinear feedback loops and emergent behavior of science as a system, in response to a perturbation. The work is illuminating in its own right, but also hypothesis generating.

Given the limited time and financial constraints of an R21 grant (the funding mechanism currently employed by ORI to disburse funds for the study of RCR and research

integrity), it is simply not possible to very effectively study many interesting and important questions. Some questions include what the optimal targets or time points are in the life course for providing RCR education, or what behavior change interventions might be effective. On the other hand, these questions could be addressed more readily within a simulation modeling framework within the time and budgetary constraints of the kind of grants that can be offered.

We also need to acknowledge that the study of research integrity does not really have its own set of theories to apply, but that there is a wealth of theories available across a broad range of disciplines that may be useful to us. For example, evolutionary game theory has recently been used to understand the evolution of cooperative behavior in small groups by implementing a concept called "coordinated punishment." Adaptations of this line of thinking might well be applied to understand small-group dynamics within research labs or academic departments

that might help us to understand the conditions under which we could expect effective whistleblowing to evolve or not (Boyd, Gintis, & Bowles, 2010). To see the applicability, consider the number of high-profile misconduct cases that have come to light in recent years because of a group of usually junior or student researchers collectively, or coordinately, blowing the whistle on a usually more senior colleague or lab leader. And then ask yourself why we insist on RCR training for our graduate students and postdocs but somehow assume that our lab leaders are saintlike in aspect…

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RCR Education *(from page 7)*

Unfortunately, the evidence is compelling that, if anything, the only common goal for RCR education is to meet federal requirements (Kalichman & Plemmons, 2007; personal observations). Further, although the scope of RCR topics is typically defined by federal requirements (NIH, 1989, 1992, 2009; Public Health Service, 2000), such lists are insufficient: (1) merely listing a topic does not define *what* should be taught about that topic; (2) topics important for one group of trainees may have little or no relevance to another group; and (3) variations in research practice are defined by far more topics and content than could possibly be taught in any one course. Conversation about why RCR should be taught (goals) and what should be taught (topics) should necessarily begin with the scientists' perspectives.

Recommendation 1 (Goals):
Conduct focus groups, interviews, and/or surveys with the scientific community to:

A. Determine whether specific and meaningful, common goals can be defined for RCR education.

B. Define general features to characterize goals for teaching any particular RCR course or program if specific goals cannot be defined.

Recommendation 2 (Topics):
Conduct focus groups, interviews, and/or surveys with the scientific community to define, if possible:

A. A minimal curriculum, both necessary and sufficient, for all scientists.

B. Optimal goals of RCR education to be met independently of the covered topics.

APPROACH
Learning theory and research strongly support the value of active engagement for adult learning (e.g., Knowles, 1980; Knowles, Holton, & Swanson, 2011; Nebeker, 2013), and case discussions have been highlighted as the way to achieve this goal in RCR education (Macrina & Munro, 1993; Stern & Elliott, 1997; Pimple, 2007). However, given that different people learn in different ways (Bransford, Brown, & Cocking, 2000; Ambrose, Bridges, DiPietro, Lovett, & Norman, 2010), and that variety of experience is more likely to be engaging than repeated experience (McLoughlin, 1999), it is worth asking whether case studies are the only way to achieve this goal. In fact, many other approaches to promote active learning have been proposed and used for RCR education (e.g., Berry, Borenstein, & Butera, 2013; Brummel, Gunsalus, Anderson, & Loui, 2010; Jones et al., 2010), and there is some evidence that while there is no clear benefit on average of one approach over another, students prefer variety (Kalichman & Plemmons, unpublished data).

Recommendation 3 (Approach): *Assess student preferences and outcomes to determine:*

A. Which teaching methods best meet the goals of RCR education.

B. Whether there is a benefit to varying the methods used.

CULTURE
It is likely unrealistic that a single RCR course will change attitudes or perceptions reinforced by the daily experience of a multiyear graduate experience or postdoctoral position. Because this "informal" or "hidden" curriculum constitutes the bulk of training time for emerging researchers, it may simply be wishful thinking to expect any form of formal course training to counter perceptions of the institutional culture or what is seen and done on a daily basis. This intuition is consistent with the evidence and commentary on the relative importance of the "hidden curriculum" (Snyder, 1971; Fryer-Edwards, 2002; Peiffer, Laurenti, & Hugenschmidt, 2008).

Recommendation 4 (Culture):
Correlate student perceptions pre- and post-course to determine whether a short-term RCR course can:

A. Outweigh a perceived ambivalence of institutional leadership to RCR.

B. Outweigh ongoing perceptions of poor standards of conduct in the research environment.

C. Provide additional value when institutional leadership and the research groups are supportive of RCR.

INSTITUTION
The RCR requirement is often described as an unfunded mandate and a burden to institutions. Despite the perception that many institutions

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have taken a limited view of RCR education as a mandate to be met solely to continue receiving federal funding, the actual cost of this mandate has not been assessed. In practice, it may be that only sufficient resources are allocated to provide RCR education for those populations for whom it is required (e.g., Pimple, 2013). If so, the risk of this approach is that trainees and other researchers will not see RCR education as an end in itself, but only as a means to continue receiving federal funds.

Recommendation 5 (Institution): *Survey student, teacher, and institutional perspectives to determine:*

A. What is being done to meet the mandate (e.g., standalone courses, institution-wide efforts, and department-specific efforts).

B. What resources, perhaps as a percentage of direct research costs, are allocated to support RCR education.

C. To what extent student attitudes about RCR reflect the perspectives of their teachers and institution.

D. How perceptions about RCR for those who do and do not take RCR courses are affected if institutional support is perceived to be narrow.

In the next *ORI Newsletter*, Part 2 of this commentary will address research questions relevant to a better understanding of the teachers and audience for RCR courses as well as assess the outcomes of the courses.

TEACHERS

It is noteworthy that the responsibility for teaching RCR courses does not reside in a particular department or in a particularly trained group of individuals. There is no "RCR Department," and there are few programs that might be considered to provide certification for RCR teachers. While it would be expected that a teacher of biology should be trained in biology or have demonstrable experience in biology, it isn't clear that this minimal standard is met for RCR education.

Recommendation 6 (Teachers): *Survey or interview teachers of RCR to determine:*

A. Who is teaching the courses (e.g., social scientists, philosophers, or practitioners from the same field as the students).

B. What is the teachers' understanding or conception of RCR and what sort of training or preparation do they have to equip them for their role.

AUDIENCE

RCR education variably comprises elements likely already part of what is known and learned. Adult students do not need to be taught that research misconduct (or, more generally, lying, cheating, and stealing) is wrong (Kalichman, 2011). And beginning researchers, in conducting mentored research, will almost unavoidably be exposed to many research-specific rules, regulations, and standards of conduct. Further, if the goal is the development of ethical decision-making skills,

there is no reason to believe that people in academia are any worse than the general public. This isn't to say that all emerging researchers know everything (Heitman, Olsen, Anestidou, & Bulger, 2007), but should required training programs for everyone be justified by a possibly small subset for whom training may be of value?

Recommendation 7 (Audience): *Conduct focus groups, interviews, and/or surveys with incoming and continuing graduate students, and postdoctoral trainees, to assess their knowledge, skills, and perceptions without having taken an RCR course.*

OUTCOMES

Nearly all attempts to measure the impact of RCR education have focused on an averaging of individual outcomes (e.g., performance on a test of knowledge or development of ethical decision-making skills). This model is attractive and fits well with one of teaching other traditional classroom topics, such as biology, physics, and engineering. However, it misses the focus of much of RCR training: (1) to discourage research misconduct (i.e., lying, cheating, and stealing), something most, if not all, adult scientists and engineers already know and (2) to emphasize specifics of conducting science that typically become apparent when actually conducting research. In short, it is not unreasonable to expect that for any given issue, many, if not most, of the students will already have learned what is to be taught **(See RCR Education, page 10)**

RCR Education *(from page 9)*

(e.g., Heitman et al., 2007; Powell, Allison, & Kalichman, 2007). This finding has an important implication for measuring the impact of RCR education.

Recommendation 8 (Outcomes): *Rather than average classroom performance, assess **individual** student changes to determine whether:*

A. Those who started with a deficit for a particular outcome improved substantially or remained the same.

B. Those who started by performing well for a particular outcome measure retained that performance or developed a deficit.

PERCEPTIONS

A degree of assurance goes with having quantitative measurements as outcomes, but numbers are not a guarantee that what is being measured reflects what is intended to be measured. Because the quality of positive outcomes can vary as a result of RCR education, one valuable measure may be *student perceptions* of how, if at all, they had been changed by participating in the course. Two qualitative studies showing the most robust changes as a result of RCR education reported highly positive findings for an overwhelming number of students (Plemmons, Brody, & Kalichman, 2006; McGee, Almquist, Keller, & Jacobsen, 2008).

Recommendation 9 (Perceptions): *Use pre- and post-course qualitative assessments of students to*

measure changes in student perceptions of RCR.

COMMUNITY

A case can be made that the purpose of RCR education is not to train the individual, but to foster an environment conducive to RCR. The endpoint is not the ability of an individual to pass a test, but to create a setting in which diverse researchers talk about RCR. Doing so would broaden the view of what RCR means, provide experience in articulating personal perspectives, and promote a culture in which conversation rather than silence is the expected response to questionable behavior or uncertainty about how best to act. Developing assessment tools for individuals that reflect these community goals would be a valuable new perspective on the goals and outcomes for RCR education.

Recommendation 10 (Community): *Develop, validate, and implement tools to assess individual students in order to identify changes in community approach to RCR.*

The recommendations provided here for a research agenda are not intended to be comprehensive, nor is there a presumption that these issues have not been addressed at all. However, it seems reasonable to assert that the quality of RCR education could be markedly improved by a better understanding of the issues proposed above.

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RCR Education *(from page 10)*

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> *"I have found that great people do have in common an immense belief in themselves and in their mission. They also have great determination as well as an ability to work hard. At the crucial moment of decision, they draw on their accumulated wisdom. Above all, they have integrity."*
>
> **Yousuf Karsh**
> (1908-2002)

Some Thoughts about Directions for Research on Research Integrity

Michael D. Mumford, The University of Oklahom

Economic pressures, competitive pressures, and the increased visibility of the sciences have put scientists at risk for ethical misconduct. Recognition of these risks led the Office of Research Integrity to initiate a research program more than a decade ago. Over the intervening period, real progress has been made in understanding the sources of misconduct and development of procedures for managing misconduct. New research, and new management procedures, raise as many questions as they answer, as is always the case in any viable scientific enterprise. In this article, I will try to sketch out some critical research issues bearing on both the responsible conduct of research and research on research integrity.

Education

In recent years, it has become apparent that while some ethics educational programs do work, many programs do not (Antes et al., 2009). This key finding suggests a need for research on both educational models and the standards to be employed in evaluating educational programs. Some critical issues include the following:

- Is ethics education more effective in team-based instruction or in-struction in which the individual is asked to work alone?

- What is the core content that should be provided in ethics education? Should we teach principles, cases, or a mix of principles and cases?

- What content will prove most useful in ethics education? Should we teach strategies for thinking about ethical problems, strategies for identifying ethical issues, procedures for managing ethical issues, or perhaps strategies for managing competing professional demands?

- When should ethics education begin, and how should it be delivered at different points in a person's career?

Evaluation

If ethics educational programs sometimes work but sometimes do not work, we must evaluate the effectiveness of these educational programs (Mumford et al., 2008). Evaluation, moreover, allows for progressive refinement of instruction and effective day-to-day program management. Evaluation, however, is a complex process broaching a number of issues:

- What are the "best" available measures for evaluating different types of educational programs?

- What measures have proven viable in other fields that should also be used to evaluate ethics educational programs in the sciences: knowledge? ethical decision making? moral sensitivity? institutional outcomes?

- How should evaluation of ethics educational programs be conducted—by using standard evaluations or improvements documented in multiple alternative measures?

- What is the most appropriate format for developing viable evaluation measures: student self-appraisals? low-fidelity exercises? role-play performance?

Work Practices

Ethical breaches, of course, occur as scientists conduct their day-to-day work. Moreover, the available evidence indicates the work practices to which students are exposed have a powerful impact on their subsequent ethical conduct (Mumford et al., 2009). This area needs more attention in studies of scientists' ethical conduct than it has received, including studies examining questions such as:

- What work experiences (i.e., behaviors of a major professor) influence students' subsequent ethical conduct?

- What laboratory practices (e.g., requiring teamwork and peer interactions on project work) serve to minimize misconduct?

- What normative work practices lead a field to be especially sensitive to ethical breeches?

- What interventions (e.g., principal investigator leadership training) might result in better work practices in laboratories?

Scientific Thinking

Scientists, by nature and training, think about issues in a distinctive way (Mumford et al., 2005). More centrally, the "typical" scientists'

Some Thoughts *(from page 12)*

understanding of issues and problems is often not consistent with ethical considerations such as forecasting social impacts (Mumford et al., 2010). These inconsistent demands raise a number of research questions:

- Under what conditions do scientists forecast the impact of their work on others?

- Who are the key stakeholders that scientists view as central to their work and the ethical implications of their work?

- How do scientists work through, or think about, ethical issues, and when and how do they trade off ethical and technical concerns?

- What is the impact of ethical guidelines and ethics education on scientists' ethical thinking?

- What are the critical skills scientists must acquire to promote day-to-day ethical decision making?

Work Context

The context in which scientists conduct their work is intensely competitive and personally demanding with respect to time, stress, and resource requirements (Barrett, Vessey, Griffith, Mracek, & Mumford, in press). This general pressure may be a critical cause of ethical breeches. This observation, in turn, brings up a number of research questions bearing on career management processes worthy of investigation:

- How do policies and practices in the management of scientific

careers (e.g., tenure) influence ethical conduct?

- How are scientists prepared to cope with job stress and career pressures, and what forms of preparation work best with respect to subsequent ethical behavior?

- Do we adequately prepare scientists to monitor and manage ethical breeches personally or with staff?

- What social and economic conditions operating in different fields influence the propensity for misconduct?

Conclusions

Each of these research questions is, in my view, of some interest to those of us concerned with research ethics. Implicit in this list of concerns, however, is a broader set of conclusions. Scientists work in a distinctive, demanding context, and approach the problems arising in their fields, including ethical problems, in a distinct way. We must understand how scientists think about their work and the ethical problems it broaches to provide a basis for developing viable interventions. The understanding of the work pressures and thought processes provided by such basic research, in turn, provides a basis for the development of new, more effective educational interventions and behavioral practices in our laboratories. I hope that my observations in this article will provide an impetus for future research on those ethical problems. A viable

solution may be one that does not look for a "magic bullet." Rather, the solution may be an integrated, sustained system of interventions that will help scientists cope with the ethical issues which arise in their work.

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Future Directions in Research on Research Integrity

David B. Resnik, J.D., Ph.D., NIEHS/NIH

Research on research integrity (RRI) began to emerge as a distinct interdisciplinary field in November 2000, when ORI held its first RRI conference in Bethesda, Maryland. In the years since then, numerous articles, books, grants, and conferences have focused on research integrity, addressing such topics as misconduct, conflict of interest, bias, authorship, collaboration, data management, peer review, intellectual property, and mentoring and education in responsible conduct of research (RCR) (Shamoo & Resnik, 2009). Though much has been accomplished, much remains to be done. We in the RRI community need to investigate the following key questions in greater depth (in no particular order of importance):

What is research misconduct? After nearly a decade of debate, in December 2000, the U.S. federal government agreed upon a definition of research misconduct as fabrication, falsification, or plagiarism (FFP) (Office of Science and Technology Policy, 2000). A fourth category, other serious deviations, was eliminated from the definition because it was regarded as too vague to be enforceable. However, universities, private funding organizations, and other countries have definitions of misconduct that are broader than FFP. Some of these definitions include behavioral violations of rules on research with human subjects or animals, lying on a curriculum vitae, interfering with a misconduct investigation, inappropriate authorship, and misuse of confidential information (Steneck, 1999; Resnik, 2003; Lind, 2005).

The diversity of misconduct definitions suggests that there is not widespread agreement about what counts as misconduct and that additional discussion and analysis are warranted. The discussion and analysis of misconduct should explore the difference between behavior defined as misconduct and other questionable research practices (QRPs). It is important to have a common definition of misconduct for two reasons: First, research often involves collaborations among investigators working in different institutions and in different countries. Second, investigators need to know which definition to use when reporting suspected misconduct.

What is the relationship between misconduct and QRPs? Surveys have estimated the prevalence of misconduct and QRPs, but they have not examined the relationship between these categories of behavior (Martinson, Anderson, & De Vries, 2005; Titus, Wells, & Rhoades, 2008; Fanelli, 2009). Additional research is needed to understand whether some types of behavior, such as inappropriate authorship, poor record keeping, secrecy, exploitation of subordinates, and violations of research regulations, are risk factors for misconduct. Empirical research on the relationship between misconduct and QRPs should be informed by analyses of these concepts and studies of misconduct definitions adopted by institutions and organizations (Resnik, Neal, Raymond, & Kissling, 2013). Improvements in our understanding of the relationship between misconduct and QRPs may help efforts to promote integrity in research.

What role do cultural factors play in misconduct and QRPs in research? The literature on the causes of misconduct and QRPs tends to focus on the role of individual psychology and the research environment and has little to say about cultural norms and traditions (Institute of Medicine [IOM], 2002; Anderson et al., 2007; Martinson, Crain, De Vries, & Anderson, 2010). However, culture has a tremendous influence over human behavior. Different conceptions of individual rights and responsibilities, respect for authority, fairness, and other cultural values may lead to ethical misunderstandings or transgressions in research (Davis, 2003; Bosch & Titus, 2009). It is especially important to enhance our understanding of the role of culture in research integrity, given the increasingly international and multicultural nature of science.

What is the relationship between research integrity and public trust? RRI researchers have written a great deal about how ethics affects trust among scientists, but very little about how ethics impacts the public's trust in science (Whitbeck, 1995; IOM, 2002). More research is needed on the public's expectations concerning ethical behavior in science, and the public's reaction to misbehavior. It is important to better **(See Future Directions, page 15)**

Future Directions *(from page 14)*

understand the relationship between research integrity, and the public's acceptance of scientific ideas (such as global warming) and support for science (such as funding), because this information may be useful in guiding policy development (Resnik, 2011).

What is the status of research integrity in the private sector and how does it differ from the public sector? Studies of misconduct, QRPs, conflict of interest, and other ethical problems and concerns in science have focused on scientists working at publicly funded, academic institutions. We know relatively little about the integrity of research conducted in private laboratories or for private companies. Of course, it may not be easy to obtain data about research integrity in the private sector, because companies may not want to expose themselves to legal liability, public embarrassment, or threats from competitors. They may treat everything that goes on inside the company as confidential, proprietary information and not allow employees to answer survey questions or participate in interviews. Despite these potential problems, it is important to get a better understanding of research integrity in the private sector, since a substantial percentage of research takes place in this realm.

What are some effective strategies for preventing misconduct and QRPs other than education and mentoring? Since the 1990s, most of the efforts by federal agencies, universities, and professional associations to promote research integrity have focused on education and mentoring in RCR (IOM, 2002; Shamoo & Resnik, 2009). While education and mentoring are clearly very important in promoting integrity, other prevention strategies need to be investigated in more depth, such as auditing data and research records, accreditation, and enhanced protections for whistleblowers (Titus et al., 2008; Shamoo & Resnik, 2009). Institutions could pilot these and other prevention strategies to obtain data on costs, effectiveness, etc.

What is the impact of mentoring and education on research integrity? Although many articles in the RRI literature deal with this question, it still has not been answered fully, and more research is needed (Powell, Allison, & Kalichman, 2007; Antes et al., 2009, 2010; May & Luth, 2013). Future research efforts should focus on understanding the relationship between education and mentoring and different outcomes, such as ethical behavior, knowledge of ethical concepts and rules, moral reasoning, and attitudes. The impact of different instructional designs (such as formal courses, workshops, and online modules) and mentoring styles also should be assessed.

Acknowledgments

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Case Summaries

Nitin Aggarwal, Ph.D.
Medical College of Wisconsin
and University of Wisconsin-
Madison

Based on the reports of the investigations conducted by the Medical College of Wisconsin (MCW) and the University of Wisconsin-Madison (UW) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Nitin Aggarwal, former Graduate Student, MCW, and former Assistant Scientist, UW, engaged in research misconduct in research supported by National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grants R01 HL37981, R01 HL54075, and R01 HL57414.

ORI found that that the Respondent engaged in research misconduct by falsifying and/or fabricating PHS-supported data in six (6) figures that were included in the following two (2) publications, one (1) grant application to the American Heart Association (AHA), one (1) grant application to NIH, and the Respondent's Ph.D. thesis:

- Aggarwal, N.T., Pfister, S.L., & Campbell, W.B. "Hypercholesterolemia Enhances 15-Lipoxygenase Mediated Vasorelaxation and Acetylcholine-Induced Hypoten-

sion." Arteriosclerosis, Thrombosis, and Vascular Biology 28:2209-2215, 2008 (hereafter the "ATVB paper").

- Aggarwal, N.T., Pfister, S.L., Gauthier, K.M., Chawengsub, Y., Baker, J.E., & Campbell, W.B. "Chronic hypoxia enhances 15-lipoxygenase-mediated vasorelaxation in rabbit arteries." *American Journal of Physiology - Heart Circulation Physiology* 296:H678-H688, 2008 (hereafter the "AJP paper").

- Aggarwal, N.T., Principal Investigator (P.I.), National Scientist Development grant application to the American Heart Association No. 11SDG7650072, "Sulfonylurea rReceptor-2 splice variant and mitochondrial mechanisms for cardioprotection and arrhythmia" (hereafter the "AHA grant application").

- K99 HL113518-01, "Mitochondrial ATP-sensitive K-channels and pharmacological approaches for cardioprotection," Aggarwal, Nitin, Ph.D., P.I.

- Aggarwal, N.T. "Endothelial 15-lipoxygenase regulates vasorelaxation and blood pressure in rabbits in normal and pathological condictions." A Dissertation Submitted to the Faculty of the Graduate School of Biomedical Science of the Medical College of Wisconsin in Partial Fulfillment of the Requirements for the Degree of Doctor of Philosophy, Milwaukee, Wisconsin, 2008 (hereafter the "thesis").

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Martinson, B. C., Anderson, M. S., & De Vries, R. (2005). Scientists behaving badly. *Nature, 435*(7043), 737–738.

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Case Summaries *(continued)*

Specifically, ORI found that Respondent engaged in research misconduct by falsifying Western blot loading control data by inverting, duplicating, and cropping source blot films and/or using films from unrelated experiments to construct five (5) false Western blot figures. In the absence of valid blot images, Respondent falsified and/or fabricated the corresponding quantitative data for summary bar graphs and the data statistics in related text. Respondent admitted to falsely reporting the number of mice reported for an experiment reported in Figure 4 in grant application HL113518-01 to support the hypothesis of the research. The falsified and/or fabricated data are:

- false ß-actin data and statistics in Figures 1A and 1B in the *AJP* paper and Figures 41A and 41B in the thesis (p. 131) that purport to represent a time-course of 15-LO-1 protein expression in rabbit aortic endothelial cells (RAECs) following hypoxia

- false ß-actin and 15-LO-1 data and statistics in Figures 2A and

2B in the *AJP* paper and Figures 45A and 45B in the thesis (p. 135) that purport to represent 15-LO-1 expression in aortic rings of normoxic and hypoxic rabbits

- false ß-actin data and statistics in Figures 3A and 3B in the *AJP* paper and Figures 46A and 46B in the Respondent's Ph.D. thesis (p. 137) that purport to represent 15-LO-1 expression in different arteries after hypoxia

- false ß-actin data and statistics in Figures 1A and 1B in the *ATVB* paper and Figures 26A and 26B in the thesis (p. 105) that purport to demonstrate changes in 15-LO-1 expression in different arteries of cholesterol-animals; the false ß-actin data in Figure 1A, *ATVB* was the same image as that used for Figure 1A, *AJP* but flipped vertically

- false GAPDH data and statistics in Figure 7 in the AHA grant application that purport to represent SUR2A-55 expression in murine heart following left ventricular hypertrophy (LVH)

- false reporting in Figure 4A of grant application HL113518-01 for the number of mice used for the physiological data for ATP-induced potassium influx in murine mitochondria as three to four, when only a single mouse was studied.

Dr. Aggarwal has entered into a Voluntary Settlement Agreement and has voluntarily agreed for a period of three (3) years, beginning on September 17, 2013:

(1) to have his research supervised; Respondent agreed that prior to the submission of an application for U.S. Public Health Service (PHS) support for a research project on which his participation is proposed and prior to his participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of his duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of his research contribution; he agreed that he shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed-upon supervision plan;

(2) that any institution employing him shall submit in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived, and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract; and

(3) to exclude himself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

> *"Confidence in others' honesty is no light testimony of one's own integrity."*
>
> **Michel de Montaigne**
> (1533-1592)

Case Summaries *(continued)*

Hao Wang, M.D., Ph.D.
Western University–Canada
(formerly University of Western
Ontario)

Based on the report of an investigation conducted by Western University–Canada (WU) and ORI's subsequent oversight analysis, ORI found that Dr. Hao Wang, former Associate Professor of Surgery and Pathology, Schulich School of Medicine and Dentistry, WU, engaged in research misconduct in research supported by National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), subaward 0016244 from Prime Award U01 AI074676 to the University of Pittsburgh.

ORI found that Respondent engaged in research misconduct by falsifying data that were included in:

• An abstract and poster presentation for the 2011 American Transplant Congress – Abstract [1537.5]: Wang, H., Baroja, M., Lan, Z., Arp, J., Lin, W., Rellmann, K., Garcia, B., Jevnikar, A., & Rothstein, D. "Combination of Novel Anti-CD45RB and Anti-CD40 Chimeric Antibodies Proglons Renal Allograft Survival in Cynomolgus Monkeys."

Specifically, ORI found that the Respondent falsified the status of two animals as successfully treated renal allograft recipients in a 2011 American Transplant Congress abstract and meeting presentation and in false representations to the project principal investigators and colleagues. Respondent falsely claimed long-term survival, normal serum creatinine concentrations, and lack of adverse effects in two Cynomolgus monkeys treated with chimeric antibodies following bilateral nephrectomies and receipt of renal allografts, when in fact the transplant surgery had failed and the animals' survival was due to a native kidney that was left in place in each animal. Respondent also falsified or failed to correct known falsifications (identifying the two monkeys as transplant recipients) in numerous clinical records, including anesthesia records, progress notes, treatment records, and clinical laboratory reports.

It is expressly agreed that while Respondent asserts that there are extenuating factors for his actions, Respondent agrees to enter into the Agreement because contesting the findings would cause him undue financial hardship and stress, and Respondent wishes to seek finality. Respondent also claims that based on the data obtained from the same experimental group, the removal of these two monkeys from the data would not alter the scientific conclusion.

Dr. Wang has entered into a Voluntary Settlement Agreement and has voluntarily agreed for a period of three (3) years, beginning on October 22, 2013:

(1) To have his research supervised; Respondent agreed that prior to the submission of an application for U.S. Public Health Service (PHS) support for a research project on which the Respondent's participation is proposed and prior

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Disclaimer

Case Summaries *(continued)*

to Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of his duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agreed that he shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed-upon supervision plan;

(2) that any institution employing him shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived, that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract, and that the text in such submission is his own or properly cites the source of copied language and ideas; and

(3) to exclude himself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

ORI thanks the following people for contributing articles to the newsletter:

Michael Kalichman

Brian Martinson

Michael D. Mumford

David B. Resnik

Nicholas H. Steneck

Paul Root Wolpe