Thinking About RCR Efficacy

Mark Holcombe

Center for Ethics and Values in the Sciences

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ABSTRACT

Are RCR training programs efficacious? What are the objectives and methods of RCR training programs? What factors contribute to misconduct? Are some researchers more likely to commit misconduct than others?

Following in the wake of high-profile cases of research misconduct, the Belmont Report, issued in 1979, established guidelines for the protection of human research subjects. So afterwards journal and organizations began formulating and implementing research guidelines. Various societies dealing with epidemiological research began formulating ethical guidelines in 1988. In the early 1990's the International Society for Environmental Epidemiology began compiling a core curriculum, ethical guidelines, and a compendium of ethical cases. Not until 1989 did any government policy mandate formal RCR training with the NIH Guide Grants Contracts; however, the policy did not set any curricular guidelines. Lack of consistency among RCR training courses remains pervasive since the early 1990s. Training in the responsible conduct of research is mandatory for anyone receiving funds supported by Public Health Services.

ORI's PHS "Policy on Instruction in the Responsible Conduct of Research" requires all researchers at extramural institutions to "complete a *basic* program of instruction in the responsible conduct of research" covering nine core areas:

- 1. Data acquisition, management, sharing, and ownership
- 2. Mentor/trainee responsibilities
- 3. Publication practices and responsible authorship
- 4. Peer review
- 5. Collaborative science
- 6. Human subjects
- 7. Research involving animals
- 8. Research misconduct
- 9. Conflict of interest and commitment

The purpose of the *basic* course is to "discourage research misconduct and questionable research practices" and "information about compliance with related PHS and institutional policies should be included in the instruction provided." Emphasis on any given core area is left to the institution's discretion; furthermore, the policy "does not establish exact content or minimum length, level, or format of instruction" as well as who qualifies as "research staff". ⁱⁱⁱ

Current enforced regulations are aimed exclusively at research misconduct—fabrication, falsification, and plagiarism—and not at "questionable research practices". Research misconduct does have serious consequences for science and the public at large. For example, Andrew Wakefield falsified data establishing a link between certain vaccines and autism. His study published in 1989 has been highly criticized over the years; nonetheless, parents continue to cite it as a reason for refusing to vaccinate their children. Actress Jenny McCarthy and actor Jim Carey continue to promote a vaccine-autism link. Since 1985, little empirical research has been conducted examining "questionable research practices". Policies aimed at research misconduct are rarely the product of practicing scientists describing the practices they deem most serious to scientific integrity.vi Greenberg and Goldberg argue that too little is known about "rank-and-file" perceptions of research misconduct in order to predict the efficacy of regulations aimed at preventing or reducing research misconduct. They identify three epistemic and empirical gaps: 1) Prevalence rates of misconduct is unknown. Research since their 1994 publication has not closed this epistemic gap. 2) Regulations may be ineffectual as the target audience has not been consulted in the writing of said regulations. The consultation problem has been reconciled since their publication but efficacy is still unknown. 3) Causes of unethical behavior are unknown.vii Their survey was aimed at identifying perceptions of causal factors of research misconduct not at identifying actual causal factors. (Greenberg and Goldberg predicted that educational programs would be more successful at reducing misconduct than regulation and audits.)

Greenberg and Goldberg hypothesized that seniority or increased years of service would be positively correlated with increased observances of unethical behavior. This does not mean that seniority or years of experience contribute to misconduct although that hypothesis seems to be supported by high profile cases such as Hwang Woo-suk, Judith Thomas and Juan Contreras, and Marc Hauser. Greenberg and Goldberg also hypothesized that scientists whose research was directly linked to financial or commercial interests would report more observances of misconduct. Again, this does not mean that financial or commercial interests contribute in some way to misconduct although that hypothesis seems to be confirmed by high profile cases such as Andrew Wakefield, Timothy Kuklo, and Scott

Reuben. Greenberg and Goldberg's study only measured scientist's intuitions or beliefs about causes and perceptions of severity regarding varying types of misconduct. Kryste suggests that the institutional/organizational culture/climate contributes to misconduct. Viii Knowing the root causes and prevalence rates is necessary for outlining a methodology for preventing or reducing misconduct. We cannot simply rest on our intuitions.

We need to look at the empirical record, where it exists, of clear cases of misconduct. Does one group (either career-level, career type, gender, etc.) engage in misconduct more than another group? Causes of misconduct probably vary between the groups. In a ten-year survey of data, 1994 – 2003, faculty accounted for 46% of closed cases where misconduct was found to have occurred. However, in the latter half of the timescale the faculty rate of misconduct findings declined by 18%. Non-faculty accounted for 49% of closed cases over the ten-year period where misconduct was found to occur with a significant increase in findings of misconduct mostly among technicians with a 14% increase. "Non-faculty" includes post-doctoral fellows, students, research assistants/associates, and technicians. Within the non-faculty rankings, research associates/assistants comprise the highest rates of misconduct findings at 77%. However Rhoades goes on to report that the majority of all misconduct findings involve technicians (31%), postdoctoral fellows (27%), and associate professors (24%) collectively accounting for 62% of all misconduct findings.ix

Martinson, et. al. relying upon self-reported behaviors analyzed organizational injustice (both procedural and distributive) along with other covariants (career-level, gender, intrinsic and extrinsic drive) as possible causal factors of misconduct and/or misbehavior (data cleaning, for example).¹ Women are less-likely to engage in misconduct even tough they are most likely to report perceived procedural injustice while comprising over half of early-career level researchers surveyed and one-third of mid-career level researchers surveyed. Mid-career level scientist are significantly more likely to engage in misconduct irrespective of their perceptions of distributive injustice. Perceptions of procedural injustice significantly predict misconduct rates and are further exacerbated by the intrinsic

¹ Martinson, et. al.'s analysis considered distant organizational injustices such as perceived injustices within the peer-review system.

drive of mid-career level researchers. (Circularly, the higher degree of self-reported intrinsic drive the more likely the perception of procedural injustice.) Mid-career level researchers significantly self-report higher rates of misconduct and misbehavior over any other group. Martinson, et. al. hypothesize that early-career level researchers with the highest rates of intrinsic drive are the ones most likely to advance to mid-career level positions. Intrinsic drive seems to be the key variable. "The critical factor is intrinsic drive. Scientists who are personally driven to achieve may be particularly sensitive to violations of procedural justice, especially if these violations are seen as hindering or thwarting their career success." Administrators, mentors, and principle investigators must be equally willing to identify and redress organizational injustices as reports of misconduct/misbehavior.*

ORI assumes and reasonably expects that RCR training, generally speaking, ought to result in reduction or prevention of serious research misconduct: falsification, fabrication, and plagiarism (FFP). However, the outcome of an individual RCR course (such as GRD 717) may be insufficient for achieving this goal. Individual RCR courses are unlikely to meet the long-term goals valued by ORI:

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

ORI suspended this policy following a flurry of protests grounded in pragmatic concerns such as funding and other monetary issues, to more logical concerns such as a perceived lack of a clear identifiable target audience. The policy defined "research staff" as "staff at the institution who have direct and substantive involvement in proposing, performing, reviewing, or reporting research, or who receive research training supported by PHS funds or who otherwise work on the PHS-supported research project even if the individual does

not receive PHS support. The institution may make reasonable determinations regarding which research staff fall within this definition."xiii

Given ORI's deferment to institutional autonomy and their lose requirements, how efficacious are RCR courses and training programs in meeting either the short, basic requirements of a basic RCR course or, inclusively, the long-term comprehensive goals? A survey of NIH grant recipients conducted by Kalichman and Plemmons illuminated a great divide between recipients of NIH grants and the instructors of the required RCR training courses. Many NIH *training grant directors* do not actually know who is providing RCR training and 25% of NIH training grant directors are not providing RCR training themselves. Furthermore, only 40% of RCR instructors (not training grant directors) stated their course met both the NIH requirements and university requirements of RCR training. The Kalichman and Plemmons survey failed to find statistically significant uniformity among the RCR instructors regarding RCR course goals and objectives. Furthermore, Kalichman and Plemmons found that RCR training is often not a part of basic research training. Their survey suggests a dire need to incorporate RCR training across the curriculum. ORI recognizes that meeting the long-term goals requires RCR training at multiple levels and stages of research.

The scientific community agrees that pressures contributing to research misconduct vary according to vocational stage. Some have suggested tailoring RCR courses or training programs such as continuing education courses to match the career stage of the researcher.xvi Once again, the expected goals of these courses need to be clearly outlined and measurable. The goal of a course aimed at graduate or medical students (in which is included dental students) may be simply to provide information regarding best research practices and/or to improve attitudes regarding the importance of responsible conduct of research. Emphasis on topical discussion may change according to career stage; courses aimed at senior faculty may concentrate on developing mentoring *skills* and less on *providing information* defining fraud, for example.xvii

Rates of ORI defined misconduct (falsification, fabrication, and plagiarism committed knowingly, willingly, or recklessly) have been estimated to range from 1/100,000 scientists to as high as 1/100.xviii Zuckerman pointed out "the irony of a profession that relies on systematic and accurate record-keeping, yet does not collect data on the incidence of [misconduct] by members".xix However, ORI sanctions an average of 13 researchers annually on these grounds.xx Some evidence suggests that misconduct is more prevalent among researchers with higher status or more years of experience; xxi although aforementioned results by Rhoades suggest otherwise. ORI's regulations may reflect the needs of research institutes more so than the scientific community writ large as they do not reflect the professional expectations of scientists more broadly.xxii A paper employing poor statistical methodologies or other dubious designs or procedures is equally worthy of retraction as one utilizing sound methodology but based upon falsified or fabricated data. Both, sloppy science and FFP, result in the same consequent—a contaminated body of knowledge. Only the latter falls under ORI regulations as the former does not carry an intent to deceive whereas the latter does so. The former is often left to peer review or critical analysis after publication but often does not result in retraction of the original paper.xxiii In 2008, *The Journal of Clinical Endocrinology and Metabolism* revised their publication standards in attempts to control quality in publication.xxiv However, poor reporting does not mean poor experimental design or conduct;xxv the peer review process itself should, at minimum, control for poor reporting.

Some suggest other practices, such as data trimming and objectionable conflicts of interest, to be more pervasive than FFP.xxvi A survey of 697 scientists and institutional representatives who receive funds from the National Science Foundation were asked to rate their normative attitudes on issues ranging from FFP to collegiality. Little difference in attitudes was observed between FFP and "misleading behaviors" ("Providing a misleading explanation of how the study was done to make it look sounder than it really is" and "Reporting the research incompletely, making it impossible to replicate in other laboratories").xxvii De Vries and his colleagues surveyed 51 scientists (associate professors, assistant professors and postdoctoral fellows) at three geographically diverse major research universities. The most important concerns for these scientists were not FFP; their

main concerns fell into four areas: "(1) the meaning of data, (2) the rules of science, (3) life with colleagues, (4) the pressures of production in science".xxviii

Issues identified within the Meaning of Data included cleaning verses cooking data, rejecting outliers, failure to replicate one's own work, and cleaning data based upon one's own past experiences. In Greenberg's and Goldberg's 1994 study, one-third of respondents reported observing biased research design whereas only one-fifth reported observing plagiarism and one-tenth reported observing data fabrication or falsification. They recognize that their study is not representative of the broader scientific community.^{xxix}

Issues within Rules of Science focused more on IRB protocols or administrative grant rules. An example offered of the latter related to buying chemicals; if you have more than one grant but need chemical *X* for each grant, then you must purchase as many bottles of chemical *X*. Subjects reported that these grant rules often create "misconduct" in terms of technical violations of misuse of grant funds. Subjects also complained about overly stringent IRB protocols. One subject reported that IRB Protocols in a clinical setting may actually hinder good science. In her clinic two patients may receive two different FDA approved drugs for treating a headache. She wants to compare the two drugs. Since the research would then involve human research subjects, the study must gain IRB approval and subjects sign a consent form thereby implying, in the minds of the subjects, potential risks. If the already FDA approved drugs weren't being compared in a formal manner, no IRB approval would be necessary and the subjects would be receiving the drugs anyway.**xxx

Issues identified within Life with Colleagues ranged from training young scientists how to design experiments and keeping notebooks to issues related to letters of recommendation (such as writing negative letters to keep a colleague from leaving) and how to deal with competition within the lab. Issues identified within Pressures of Production included "manipulation of the review system, (improper) control of research by funders, difficulties in assigning authorship, exploitation of junior colleagues, unreported conflicts of interest, the theft of ideas from conference papers and grant proposals, publishing the same thing twice (or more), withholding of data, and ignoring teaching responsibilities."xxxii Given De

Vries' results it should be clear that RCR course goals and methods need to be clearly outlined. Focus group subjects frequently cited the daily demands of doing research as an underlying driving force for "normal misbehavior". De Vries' results further suggest a need to implement integrated RCR training comprehensively throughout the curriculum.

Recent high profile cases of misconduct (FFP) prima facie suggest that misconduct is habitual and most often occurs at larger research universities with increased competition for and dominance in receiving PHS funds. Dr. Scott Reuben is accused, investigation pending, of fabricating data in 21 publications. Judith Thomas and Juan Contreras fabricated or otherwise falsified data in 16 publications over an eight-year period. However, an alternative interpretation is plausible. The nature of research entails that once an initial instance of fabrication or falsification occurs leading to publication of a paper continued misconduct is necessary otherwise the researcher runs the risk of exposing herself. Habitual misconduct supports a need for on-going RCR training aimed at improving best practices skills, a fully integrated ethics across the curriculum, expect moral development in recognizing, responding to, and thinking about responsible conduct. Individual courses aimed at graduate students may more reasonably have as primary goals: providing information defining best practices, improving attitudes regarding the need for RCR training, and demonstrating the complexities of moral issues within research best practices. Improving moral reasoning skills and best practices skills may more effectively be developed in the lab while doing research reinforced and developed by a mentor.xxxii

Little is known regarding the efficacy of RCR training programs; little comprehensive empirical research has been conducted in this area and what has been conducted has yielded conflicting results.xxxiii ORI contracted the Institute of Medicine (IOM) to assess research integrity defined as "(1) adherence to... normative practices... (2) the knowledge and awareness of the practices of responsible research, and (3) the attitudes and orientation towards the practices of responsible research...."xxxiv IOM failed in their endeavor due to a lack of methodological procedures capable of assessing and measuring disposition to research integrity contrasted against adherence to research integrity.xxxv

Whistleblowing may indirectly inform us as to the efficacy of RCR programs. Faculty ranking (dean, associate professor, assistant professor, etc.) accounts for 57% of whistleblowing although 25% of all whistleblowing is anonymous, confidential, or unknown. The majority of misconduct findings are against non-faculty rankings (postdoctoral fellows, research associates/assistants, and technicians). Are those in a mentoring position the one's whistleblowing? If so, why was the misconduct not prevented by mentoring? However, non-faculty rankings, irrespective of degree held, were the most accurate (allegations that later resulted in a positive finding) in reporting misconduct; research associates/assistants and students (graduate or undergraduate but below postdoctoral status) more accurately reported misconduct than any other group (where the whistleblower's ranking is known). Post-doctoral fellows were the least accurate at reporting misconduct. As Rhoades states, "The most successful whistleblowers seem to be the least qualified persons to make allegations..."xxxvi This finding does not bode well for the efficacy of RCR training programs as those who are least likely to be subject to RCR training or comprehensive RCR training are the most accurate at identifying and reporting misconduct. Furthermore the least accurate group, post-doctoral fellows, may also have the highest rates of misconduct. Increased focus on RCR training needs to be given to postdoctoral fellows, assuming RCR training is in any way effective.

One feature of RCR training is clear; the educational criteria demanded in other subjects—clear target audience, clear course goals and objectives (rubrics), clear methods for meeting those goals and objectives, and clearly differentiating methods from goals—is often lacking in RCR training programs.xxxviii ORI held the first biennial conference in April of 2008 to address and discuss these deficiencies, among other primary objectives.xxxviii Of course any attempt to measure the efficacy of RCR training courses must outline some methodology for assessing efficacy, which is in turn dependent upon course goals. Rest's Defining Issues Test-2 (DIT-2) based in Kholbergian psychology of moral development is the most widely used assessment for measuring both short-term and longitudinal growth in moral and critical thinking skills. Rest and his critics agree that moral reasoning and consequentially moral development is dependent upon multiple skills: 1. Ability to assess factual information, 2. Logical reasoning skills, 3. Problem-solving skills, and 4. Habituated

behavior. Rest and his colleagues suggest that advancements in moral reasoning skills may be accomplished by improving problem-solving skills generally. Improved moral reasoning skills does not necessarily translate into improved moral behavior. Indirect evidence weakly supports the conclusion that the more hours spent in formal medical best practices instruction results in habituated behavior. Chen reports a positive correlation between assessments (such as the DIT/DIT-2) aimed at measuring ethical reasoning skills and lower rates of malpractice. Furthermore, she found a positive correlation between hours spent in discussion-based formal ethics training emphasizing best practices and case studies with higher scores measuring ethical reasoning skills. However, she also reported a strong positive correlation between clinical reasoning skills and ethical reasoning skills suggesting that medical students (doctors, nurses, residents, post-doctoral fellows, etc.) may simply be better at problem-solving skills generally.**

Anderson, et. al. claim to directly asses the efficacy of responsible conduct of research courses on moral behavior. They rely upon correlations between early and mid-career researcher's self-reported behaviors and type of training received. Respondents reported receiving either (inclusively) separate RCR training—a course such as GRD 717: The Responsible Conduct of Research—or integrated training—ethics of research training integrated into other course. Integrated training includes mentoring practices aimed at developing responsible conduct of research. They assessed both misconduct (FFP) and questionable/problematic behaviors. Granting their claim to have directly assessed moral behavior, they're results are rather surprising. Three-quarters of early-career researchers and half of mid-career researchers reported receiving separate RCR coursework despite differences in federal regulations under which the careers of the two groups develop. (Mid-career researchers obtained their doctoral degrees before the NIH training grant requirement established in 1989.) Anderson, et. al. divided mentoring into five categories:

Research mentoring related to good research practice and writing. Financial mentoring had to do with grant and contract proposals and obtaining other financial support. Survival mentoring involved guidance on how to build relationships and survive in the profession, and personal mentoring was reflected in ongoing interest and emotional support. The fifth mentoring variable, ethics mentoring, was constructed in the same way from two items in the training battery that measured informal mentoring on ethical issues apart from coursework.xl

For both career groups, those in medicine and the social sciences reported receiving the most training by a significant margin over researchers in other fields such as physics, math, and engineering. Both career groups reported receiving inadequate training within survival and emotional mentoring. This finding reinforces findings by Martinson on the effects of intrinsic drive and perceptions of injustice as causal factors leading to misconduct or misbehavior.xl

Anderson, et. al. found little to no significance between ethics training (not mentoring) and problematic behavior for both career groups. In short, ethics training seems to entail no efficacy on moral behavior. However, ethics mentoring among early-career researchers seems to be efficacious but with mixed effects. In some categories, mentoring *increased* problematic behavior in some categories while reducing problematic behavior in other categories. Ethics mentoring significantly decreased problematic behavior in the areas of methods and cutting corners but lacked significance in any other area.^{xl}

A majority of respondents reported having received (or possibly just forgot having received) formal RCR training; a disturbing finding given federal regulations. Anderson, et. al. surmise that RCR training courses may be aimed at parsing moral ambiguities under specialized circumstances rather than teaching best practices or avoidance of misconduct; consequently, researchers do not view RCR training as relevant to daily operations or some categories (such as use of funds) may not be viewed as problematic.xl Anderson and Martinson's dual surveys of self-reported behavior indicate that FFP misconduct is relatively rare while other types of problematic behavior that undermines the integrity of science are commonplace. Both acknowledge the possibility of under-reporting; FFP misconduct carries clear and somewhat severe consequences whereas other types of misbehavior do not.

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