Research Ethics II: Mentoring, Collaboration, Peer Review, and Data Management and Ownership

SUPPLEMENT

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Purpose: In this series of articles—*Research Ethics I, Research Ethics II,* and *Research Ethics* III—the authors provide a comprehensive review of the 9 core domains for the responsible conduct of research (RCR) as articulated by the Office of Research Integrity. In *Research Ethics II,* the authors review the RCR domains of mentoring, collaboration, peer review, and data management and ownership.
Method: They relied on authoritative documents, both historical and contemporary, insightful commentary, and empirical research in order to identify current issues and controversies of potential interest to both faculty and students.
Conclusions: The authors close by urging readers to stay abreast of the manifold ethics issues facing today's community of scientists, policymakers, and research institutions, and to adhere to best practices as they evolve.

KEY WORDS: responsible conduct of research, scientific integrity, mentoring, collaboration, peer review, data management, intellectual property

In *Research Ethics II,* we provide readers with the Office of Research Integrity (1992) definitions of each of four domains: (a) mentor and trainee responsibilities; (b) collaborative science; (c) peer review; and, finally, (d) data acquisition, management, sharing, and ownership. As in *Research Ethics I* and *Research Ethics III,* we attempt to heighten readers' appreciation for past controversies, successes, and present challenges of the responsible conduct of research (RCR) by citing the work of scientists, ethicists, and legal scholars. In the present article, we review selected empirical work to demonstrate the scope of contemporary problems and to illustrate the importance of RCR to faculty and students engaged in the biomedical and behavioral sciences. The Tudor case is presented in Horner and Minifie's (2011a; "Research and Ethics I") and in an article by Ingham and Horner (2004) in which several cases relevant to Communication Sciences and Disorders (CSD) are presented. We close by encouraging readers to be aware of these important issues and strive to adhere to best practices as they evolve.

Mentor and Trainee Responsibilities

According to the Office of Research Integrity (2000a), the scope of this topic includes the following:

> The responsibilities of mentors and trainees in predoctoral and postdoctoral research programs. Includes the role of a mentor, responsibilities of a mentor, conflicts between mentor and trainee, collaboration

and competition, selection of a mentor, and abusing the mentor/trainee relationship. (p. VIII.B.2)

In *The Responsible Researcher Paths and Pitfalls,* Sigma Xi and The Scientific Research Society (1999) underlined the need for guidance at all stages of a scientific career, and the obligations of scientists to educate and mentor other investigators. The responsibility to educate each new generation of scientists arises, in part, from the debt that scientists/researchers owe to those who have mentored them. Holton refers to mentors as "scientific parents" (1986, as cited in Sigma Xi & The Scientific Society, 1999, p. 56), echoing the Hippocratic Oath, which states "I swear … to hold him, who has taught me this art, as equal to my parents, and to live my life in partnership with him" (Chadwick & Mann, 1950).

Purposes of Mentoring and Characteristics of Mentors

"A mentor is a person who helps a more junior person develop professionally through a combination of advising on projects, skills development, creation of opportunities, and personal growth in an intensive manner over an extended period of time" (Luckhaupt et al., 2005, p. 1015). The ideal mentor teaches methodology, critiques scientific research, fosters socialization, and promotes career development (Macrina, 2005b). Many believe that mentoring is the ideal way to train scientists in the ethics of research (Faden, Klag, Kass, & Krag, 2002). Others advocate combining individual mentoring with Web-based instruction (Barnes, Hermes, & Brooks, 2006), for example, the peer-onsite-distance model of mentoring (Lewellen-Williams et al., 2006).

According to Bronze (2005), "Characteristics of a 'prized' mentoring relationship include a responsive, available, and knowledgeable mentor who recognizes potential and is supportive of the individual's career goals" (p. 211). Other attributes include personal rapport, knowledge of the field, similarity of professional interests, as well as good listening and communication skills (Barker, 2006, p. 57). Most trainees highly value career guidance, academic guidance, and personal advice (Coleman, Power, Williams, Carpentieri, & Schulkin, 2005). Of noted interest, Coleman et al. found that more minorities have mentors than nonminorities, and White women are least likely to have a mentor, for reasons not fully explained in the article. Using focus groups, Hauer, Teherani, Dechet, and Aagaard (2005) found that medical students value support and trust, personal connection, career development, and student empowerment. In another study, respondents reported that their mentors were helpful in achieving career focus, orienting to the organization, transitioning between the role of trainee to the role of faculty member, and achieving work/nonwork balance (Leslie, Lingard, & Whyte, 2005; see also Anderson & Louis, 1994).

Design of Mentoring

Although many mentoring relationships are spontaneous and informal, Macrina (2005b) recommended a systematic approach to mentor selection, including an exploration by the trainee of the potential mentor's accomplishments, the organizational structure of the learning environment, and the mentor's interpersonal interaction and mentoring style. Macrina suggested that creating an individual development plan such as that promoted by the Federation of American Societies for Experimental Biology might be useful as a mentoring tool.

Whether informally or formally structured, the goal of mentoring is to teach students about the scientific method, and to teach them how to conduct research responsibly. Heitman (2000) wrote, "In their professional customs and standard practice, biomedical researchers demonstrate a number of interrelated and mutually sustaining values: honesty and truthfulness; objectivity, disinterestedness, and skepticism; openness and trust; and intellectual freedom and tolerance" (p. S41). Ideally, mentoring should instill these values in students and young investigators, in part through role-modeling and in part by providing them the theoretical and methodological skills to do their jobs well.

Cautionary Notes About Mentoring

Despite the putative benefits of mentoring, there are cautionary notes. In a 2002 survey, Anderson, Horn, et al. (2007) compared early- and mid-career scientists, representing both biomedical and social sciences receiving National Institutes of Health postdoctoral support and independent investigator (R01) awards. The survey inquired about the method of delivery of RCR training (separate coursework, integrated with other coursework, both separate and integrated training, or neither), the types of mentoring (research, financial, survival, personal, and/or ethics), and whether respondents had engaged in any of 27 "problematic behaviors" over the previous 3 years. These problematic behaviors were analyzed according to several subcategories: data, methods, policy, use of funds, outside influence, peer review, credit, and cutting corners (see Anderson, Horn, et al., 2007, Table 2, p. 857).

The dependent variable in Anderson, Horn, et al.'s (2007) study was the odds of engaging in the problematic behavior. The final sample included 1,479 early-career and 1,768 mid-career surveys. Surprisingly, early-career scientists reported statistically increased odds of engaging in problematic behaviors, depending on the method of training and the type of mentoring, in these categories:

data, methods, use of funds, and peer review (Table 3, p. 858). Anderson, Horn, et al. concluded that future research "should focus on differences in content, pedagogy, and mode of delivery of [responsible conduct of research] instruction in relation to various categories of problematic behavior" (p. 859). In short, "efforts to promote integrity in research need to be evaluated" (Institute of Medicine & National Research Council, 2002, pp. 107–108).

In the spirit of analyzing the evidence about actual mentoring practices, Weil and Arzbaecher (1997) observed, "Personal characteristics and styles of behavior, especially of research directors, significantly affect the research atmosphere.... A research environment where relationships are distant, frayed, or fractured—an 'unhappy lab'—may well not sustain responsible research conduct" (pp. 71–72; see also Anderson, Ronning, de Vries, & Martinson, 2007). "Disparities of power" between the research director, investigators, and research technicians may leave directors "relatively free of accountability" and subordinates "particularly vulnerable" (Weil & Arzbaecher, 1997, p. 74). Shamoo and Resnik (2003) identified numerous problems that can arise in mentoring relationships (e.g., failing to give students proper credit [authorship or acknowledgment], overworking them, giving them poor advice, intimidating them, or showing favoritism).

To improve the quality and effectiveness of mentoring, Shamoo and Resnik (2003) gleaned the following recommendations from numerous sources, including the National Academy of Science's (1997) *Advisor, Teacher, Role Model, Friend: On Being a Mentor to Students in Science and Engineering* and National Institutes of Health's (2000) *Guide to Mentoring and Training*:

- rewarding mentors for effective mentoring;
- providing mentors with enough time for mentoring;
- developing clear rules concerning workloads, teaching duties, research opportunities, authorship, time commitments, and intellectual property;
- establishing procedures and channels for evaluating mentoring and for allowing students and mentors to voice their grievances;
- ensuring that students who "blow the whistle" on mentors are protected;
- promoting a psychologically safe work environment;
- promoting a nondiscriminatory work environment; and
- promoting a diverse workforce in research. (pp. 62–63)

In closing, mentoring is widely valued, but an enduring question is as follows: "Can the ethics of science be taught?" Eisen and Berry (2002) explained that because the scientific community is diverse, and the ethical norms are neither well understood nor uncontroversial, achieving comprehensive ethics education of researchers "will require a substantial investment of thought and effort in devising effective programs of formal education" (p. 41).

Collaborative Science

According to the Office of Research Integrity (2000a), this topic pertains to the following:

> Research collaborations and issues that may arise from such collaborations. Includes topics such as setting ground rules early in the collaboration, avoiding authorship disputes, and the sharing of materials and information with internal and external collaborating scientists. (p. VIII.B.5)

In Rhoten's (2007) view, the old model of "big science" is giving way to "team science," which, in turn, is giving way to an emerging model that she calls "networked science" (p. B12). In the United States, the National Institutes of Health has established the NIH RoadMap for Medical Research (n.d.), an overarching plan for research in the 21st century that embraces the concepts of team science, informatics, and innovative technologies. The NIH RoadMap refers to these concepts as "pathways to discovery," and has established a working group charged with "clinical research policy analysis and coordination" (National Institutes of Health's "Clinical Research Policy Analysis and Coordination," n.d.; see also "NIH RoadMap for Medical Research," n.d.; Zerhouni, 2005, p. 1355, 2006).

Collaborative, Translational Research

Macrina (2005d) explained that collaborative research and training programs integrate many specialized areas of science to solve complex problems "by testing the same or similar hypotheses by different means" (p. 188); for example, using imaging, genetics, engineering, informatics, mathematics, economics, neuroscience, pharmacology, and behavioral techniques. Some of these interdisciplinary, translational approaches emerged in the Decade of the Brain (the 1990s) in response to advances in neuroimaging, genetics, and pharmacology. Nanotechnology is on the horizon, as applied to disease diagnosis, noninvasive imaging, drugs and biologics, and medical devices (Food and Drug Administration, 2007; International Center for Technology Assessment, 2007; Resnik & Tinkle, 2007).

Consistent with the National Institutes of Health's 21st-century philosophy, the discipline of CSD is already involved in interdisciplinary translational work. The September 4, 2007, issue of *The ASHA Leader,* for example, featured several articles on translational neuroscience, demonstrating that interdisciplinary translational work

involving CSD is well represented in the peer review journal literature (e.g., Crosson et al., 2005; DeThorne et al., 2006; Fridriksson, Morrow, Moser, & Baylis, 2006; Ingham et al., 2004; Lewis et al., 2006; Martin-Harris, Michel, & Castell, 2005; Stager et al., 2005; Tobey et al., 2004; Wittke-Thompson et al., 2007).

In short, collaborative research integrates all basic, biomedical, as well as social and behavioral scientific disciplines, and is permeating 21st-century scientific research and training programs. See Macrina (2005d) for a discussion of underlying principles, a syllabus of collaboration principles, and collaboration models. See also Zerhouni (2005, 2006) for comprehensive analyses of the National Institutes of Health's spending portfolios and long-range strategic plan, and the Association of American Medical Colleges' (2006) report entitled *Promoting Translational and Clinical Science: The Critical Role of Medical Schools and Teaching Hospitals*.

The Office of Research Integrity's responsible conduct of research "collaboration" domain overlaps with most other responsible conduct of research domains. Readers are referred to contemporary analyses and commentaries (e.g., Avins & Goldberg, 2007; Barnes & Heffernan, 2004; Barnes et al., 2006; Bulger & Heitman, 2007; Deming et al., 2007; Heinig, Krakower, Dickler, & Korn, 2007; Jeffers, 2005; Korn & Ehringhaus, 2006; Kubetin, 2006; McMillan, Narin, & Deeds, 2000; Sung et al., 2003). See Shamoo and Resnik (2003) for further discussion of collaboration among authors, resources, and mentoring (Chapter 3, pp. 48–67) as well as academia and industry relationships (Chapter 8, pp. 163–180). A text by Macrina (2005a) and an anthology by Emanuel and colleagues are highly recommended readings (Emanuel, Crouch, Arras, Moreno, & Grady, 2003).

International Research Collaboration

Because many CSD scientists are collaborating with scientists throughout the world, it is important to mention that several international organizations have produced documents that address the importance of worldwide collaboration among scientists. The *Geneva Declaration on Science and Society* (1996) says, in part, the following:

> Mutual cooperation, reflecting the recognition that the production and utilization of scientific and technological knowledge are decisive for the future welfare of humanity and that science, with its universality, is uniquely positioned to serve as a laboratory in which mankind can work together to achieve a better future in accord with the principles of responsibility, solidarity and respect for the rights of individuals and nations. (as cited in Raza, 2005, p. 178)

The United Nations Educational, Scientific and Cultural Organization's (UNESCO) World Conference on Science published *Ethics of Science and Technology: Explorations of the Frontiers of Science and Ethics,* expressing that collaboration among nations is vital (United Nations Educational, Scientific and Cultural Organization, 2006). As in the United States, the international community is concerned with the education of scientists in research ethics. For example, UNESCO's World Commission on the Ethics of Scientific Knowledge and Technology (2003) published *The Teaching of Ethics,* which includes an agenda for ethics education and sample courses. See also *The Universal Declaration on Bioethics and Human Rights* (Gercas, 2006).

Collaboration and Responsible Science

Regulatory compliance is addressed by the RoadMap under the rubric Clinical Research Policy Analysis and Coordination, but other domains of RCR, while implicit in this enterprise, do not appear to be addressed explicitly in published materials about the NIH RoadMap (e.g., Zerhouni, 2005; see also National Institutes of Health, n.d., RoadMap Web site). Major questions for the future, during the era of collaborative science (team science and networked science), are whether collaborative research will result in more or different types of problems regarding the following areas:

- authorship and publication practices (e.g., duplicate publications, authorship disputes) and peer review (e.g., the need for interdisciplinary peer reviewers and editorial teams);
- conflicts of interest and commitment (e.g., within and among academic institutions, as well as between universities and industries);
- data acquisition, management, sharing, and ownership (e.g., the use of depositories, clinical trials registries, copyright and patent disputes);
- human participant protections (e.g., centralization of Institutional Review Boards); and
- research involving animals (e.g., global harmonization of animal care standards) and research misconduct (e.g., the ability to detect misconduct and to hold teams of individuals or institutions accountable).

A central concern is whether the complexities of collaboration will enhance or diminish the trust that the public places in individual scientists or in the scientific enterprise as a whole (see Cohen, 2001; Heitman, 2000; Kelch, 2002; Sharp & Yarborough, 2006; Steinbrook, 2004; Stossel, 2005; Vasgird, 2007; Whitbeck, 2004; Wynia & Gamble, 2006; Yarborough & Sharp, 2002).

Collaboration of Academia With Industry

In the era of collaborative science, some have asked whether scientists and academic institutions are too closely intertwined with industry. For example, Angell

(2000) asked, "Is academic medicine for sale?" Gelijns and Thier (2002) responded with a thoughtful article about medical innovation and institutional interdependence. With reference to the Bayh-Dole Act of 1980 (Pub. L. No. 96-517) and the Federal Technology Transfer Act of 1986 (Pub. L. No. 99-502)—both designed to spur the transfer of industry inventions to the marketplace—Gelijns and Thier described the remarkable innovations that have occurred in the United States in the past 50 years. Gelijns and Thier also explained how academic medical centers remain critical to the clinical research enterprise in spite of the growth of research by industry and for-profit clinical research organizations.

To support their conclusion, Gelijns and Thier (2002) offered evidence to support the idea that "medical innovation depends on extensive interactions between universities and industry, with knowledge and technology transfer flowing in both directions" (p. 75). In short, they made a persuasive case for strengthening academia–industry ties because

> both universities and industry gain from accelerated knowledge generation, new opportunities for learning, quicker development of new technologies, access to a partner's superior capacities or capabilities (e.g., new materials, research tools), and in the case of shared assets, creation of a critical mass to conduct research and development. (Gelijns & Thier, 2002, p. 76)

They concluded that "creative bridging of traditional divisions of labor is vital to medical innovation" (Gelijns & Thier, 2002, p. 77; see also Garrison, Gerbi, & Kincade, 2003; National Research Council, 2000 [workforce data]).

In closing, one critical question that should be addressed by scientific disciplines is whether education in RCR will keep pace with new approaches in the era of collaborative science. During the past two decades, great strides have been made in revising scientific and publication codes of ethics, examining the effect of mentoring and educational programs, and disseminating compliance guidelines regarding RCR. Hopefully, the achievements of science's professional leaders, policymakers, public and private institutional leaders, and individual investigators in the 20th century have prepared the community to meet the emerging challenges of collaborative science in the 21st century.

Peer Review

The Office of Research Integrity (2000a) described this core instructional area as follows:

> The purpose of peer review in determining merit for research funding and publications. Includes topics such as, the definition of peer review, impartiality, how peer review works, editorial boards and ad hoc reviewers, responsibilities of reviewers, privileged information and confidentiality. (p. VIII.B.4)

The customary practice of peer review is central to the notion of self-regulation by scientific disciplines, and historically has been considered essential to assuring the quality and integrity of the research record. According to Macrina (2005c), "The peer reviewer's job has two aims: (i) to help the editor make a good decision on the acceptability of the paper, and (ii) to help the authors communicate their work accurately and effectively" (p. 76). Some add a third role for editorial peer reviewers: to detect mistakes and misrepresentations (Fox, 1994).

To assure constructive criticism and candor during peer review, and to protect the intellectual property rights of authors, the peer review system is typically a confidential process. The confidentiality of the peer review system (or the "secrecy" of the system, depending on one's perspective) has both ethical and legal dimensions (McCutchen, 1997; Parrish & Bruns, 2002; Wagner et al., 2003). In addition to respect for confidentiality ("NIH Peer Review Policies & Practices"; National Institutes of Health, 2007a), expertise and impartiality are valued in the peer review process (Shamoo & Resnik, 2003). Documents addressing the peer review system are listed in Table 1.

Peer Review Quality and Effectiveness

Current issues being debated are not only whether the peer review system is fair (unbiased) and reliable, effective in assuring quality and integrity, but also whether it is capable of detecting misconduct. Specific questions addressed in the literature are whether reviewers are adequately prepared to conduct quality reviews, whether reviewers respect the tenets of confidentiality, and whether reviewers understand the intellectual property rights of those who created the original works under review (e.g., grant proposals, prepublication manuscripts; Cowell, 2000; Macrina, 2005c; Martinson, Anderson, Crain, & de Vries, 2006). Some commentators question whether editors and associate editors are free of conflicts of interest; that is, whether they are impartial regardless of the source of manuscripts from institutions, industries, and authors (Haivas, Schroter, Waechter, & Smith, 2004; see also DeAngelis, Fontanarosa, & Flanagin, 2001).

An additional question is whether reviewers conduct their work according to defined standards. Wagner et al. (2003) suggested that the current review system lacks both objectivity and standardization (see also Steinbrook, 2004). Jefferson, Wager, and Davidoff (2002) identified desirable outcomes of peer review, namely, that the product is "important, useful, relevant, methodologically sound, ethically sound, complete, and accurate," but noted, "surprisingly little is known about its effects on the quality

Table 1. Important publication manuals including ethics guidelines.

Publication Manual of the American Psychological Association	American Psychological Association, 2001, 2010
Guidelines on Good Publication Practice	Committee on Publication Ethics, 2000
Managing Allegations of Scientific Misconduct	Office of Research Integrity, 2000b
Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects	National Institutes of Health, 2004
Uniform Requirements for Manuscripts Submitted to Biomedical Journals	International Committee of Medical Journal Editors, 2008
AMA Manual of Style (10th ed.)	American Medical Association, 2007
White Paper on Promoting Integrity in Scientific Journal Publications	Council of Science Editors, Scott-Lichter, & Editorial Policy Committee, 2009
Guidelines for the Responsible Conduct of Research: Ethics and the Publication Process	American Speech-Language-Hearing Association, 2007

and utility of published information, much less about its beneficial or adverse social, psychological, or financial effects" (p. 2787). In a recent review of 28 studies, Jefferson, Rudin, Brodney Folse, and Davidoff (2007) found no clear benefit of reviewer and/or author concealment, referee training, or other factors on publication quality, although methods of standardizing the review process received some support in two studies.

Altman (2002) observed that the quality of published papers in medical scientific journals is poor, a factor attributable to inadequate training of investigators, lax peer review, the lack of consultation with statisticians during peer review, and other factors. Altman did not address the quality of behavioral or social science articles, nor did he address whether the scientific quality of articles is correlated with overall journal quality. Grimm (2005) found that authors who suggested or excluded reviewers were more likely to receive favorable reviews (see also Schroter, Tite, Hutchings, & Black, 2006). Studies have found that the time between submission and publication was shorter for pharmaceutical studies than for nonpharmaceutical studies (Lexchin, Beros, Djulbegovic, & Clark, 2003). In addition, although the raw number of papers with negative results represented only 4.2% (25 of 601 papers examined), the publication time was shorter for papers with negative than for positive results (Unalp, Tonascia, & Meinert, 2007). The phenomenon that so few papers with so-called "negative results" are published has been referred to by Wagner et al. (2003) as a "positive findings bias." In their view, "Positive-outcome publication bias is significant and can have serious implications for treatment practices and the accuracy of literature review" (p. 34).

Despite guidelines provided by the Council of Science Editors (Council of Science Editors & Ancker, 2004; Council of Science Editors, Scott-Lichter, & Editorial Policy Committee, 2009), the International Committee of Medical Journal Editor's (ICMJE) *Uniform Requirements* (2008), the American Psychological Association's *Publication Manual* (2001, 2010), the American Medical Association's *AMA Manual of Style* (2007), and the National Institutes of Health's (2004) final rule regarding *Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects,* reviewers ultimately set their own standards, and editors are free to set their own editorial policies and to make final editorial decisions (Johnson et al., 2007).

Detection of Research Misconduct

Despite the dissemination of RCR guidelines by governmental bodies and scientific societies over the past two decades, Claxton (2005a) concluded that "the level of fraudulent and fabricated data and plagiarized material published in peer review journals continues at approximately the same level, and co-authors, sponsoring organizations, reviewers, editors, and most readers do not routinely detect misconduct" (p. 26). Reviewers and editors focus mainly on scientific merit and innovation, and are not charged explicitly with the responsibility of detecting scientific misconduct in grants and manuscripts (see, e.g., American Speech-Language-Hearing Association, 2007). Fox (1994) suggested that when research misconduct (falsification, fabrication, or plagiarism) or publication breaches (e.g., duplicative or fragmented publications, nominal or honorary authorship) are suspected, reviewers and editors must overcome their reluctance to take action. All stakeholders have a responsibility to prevent, detect, and correct deceptive conduct (fraud), namely, any action intended "to make a thing appear to be what it is not" (LaFollette, 1992, p. 20, as cited in Fox, 1994, p. 300; see also Claxton, 2005a, 2005b).

A recent case involved a Korean scientist who fabricated data pertaining to the use of somatic cell nuclear transfer and falsely claimed that the cells had the potential to immunize organ recipients against rejection of donors' cells after transplantation. The fraudulent data were published in well-respected journals. In their analysis of this case, van der Heyden, van de Ven, and Opthof (2009) posed a provocative question:

> How can we expect reviewers to act as policemen if we have to admit that they are not even able to make

> the distinction between what is good and what is excellent? They have no training whatsoever in this, and certainly not in pursuing matters that turn out to be criminal. (p. 27)

To remedy what they perceive to be the ineffectiveness of the peer review system, van der Heyden et al. suggested (a) centralizing the peer review process, (b) increasing the number of reviewers for each submission, (c) providing open access to peer reviewers' comments, and (d) allowing editors to select from the centralized system.

In closing, lack of minimum standards in peer review and editorial policies—and lack of tools to detect falsification, fabrication, and plagiarism (and other unethical practices)—may contribute to the perception that the peer review system is unfair, unreliable, and ineffective. Authors who submit grants and manuscripts rely on reviewers to respect the confidentiality of their data and their intellectual ideas; in turn, readers rely on the peer review system to assure that scientific publications are worth reading. To maintain confidence in the peer review system, peer reviewers should engage in educational programs about RCR to assure a minimum standard of rigor in the peer review process. Central to the problem of research misconduct (discussed in Horner & Minifie, 2011b, "Research and Ethics III") is whether the lack of minimum standards and expectations during peer review undermines trust in the scientific enterprise. Central to the problem of accountability during peer review, according to Godlee (2002; Godlee, Gale, & Martyn, 1998), is whether the peer review process should be open rather than blinded as is now most often the case. Whitbeck (2004), in her article "Trust and the Future of Research," emphasized why confidence in the quality and integrity of the peer review process is important. She wrote, "Reliance without confidence leads to a downward spiral of lowered expectations, defensive behavior, and reduced cooperation" (p. 48).

Data Acquisition, Management, Sharing, and Ownership

These overlapping topics, as defined by the Office of Research Integrity (2000a), pertain to the following:

> Accepted practices for acquiring and maintaining research data. Proper methods for record keeping and electronic data collection and storage in scientific research. Includes defining what constitutes data; keeping data notebooks or electronic files; data privacy and confidentiality; data selection, retention, sharing, ownership, and analysis; data as legal documents and intellectual property, including copyright laws. (p. VIII.B.1)

Data Acquisition and Management

Good research practices outlined by Shamoo and Resnik (2003) have two cardinal rules: (a) "published data are verifiable; a paper trial exists documenting the origin of the data"; (b) "published data are reproducible: other investigators are able to reproduce the data by following the published procedures" (p. 40). Thus, the scientific process requires a sound research design, rigorous data collection, appropriate descriptive and statistical analyses, and peer review prior to publication (Shamoo & Resnik, 2003, Figure 1, p. 27). Recommended reading about best practices in scientific record keeping are Macrina (2005e) and Schreier, Wilson, and Resnik (2006).

In their article "What Makes Clinical Research Ethical?" Emanuel, Wendler, and Grady (2000) stated, "To be ethical, valuable research must be conducted in a methodologically rigorous manner" (p. 2704). Therefore, if the design, the execution, or the analysis is flawed, the ethics of the research study is open to scrutiny. For example, Ambrose and Yairi's (2002) analysis of Tudor's master's thesis at the University of Iowa "revealed fundamental flaws in its design and execution" (p. 201) and failed to support Johnson's "diagnosogenic theory" of stuttering (see also Goldfarb, 2005). Data acquisition and management are receiving a great deal of attention in the current literature. Contemporary issues include the following:

- innovative randomization schema (Gross, Krumholz, Van Wye, Emanuel, & Wendler, 2006; Palmer & Rosenberger, 1999; Rothman & Michels, 1994);
- data reporting (Jennings, 2004; Marco & Larkin, 2000);
- data retention (Johnson et al., 2007);
- control over data and the use of data repositories (Bodenheimer, 2000; Clayton, 2004; Grover, Hammermeister, & Shroyer, 1995; Motheral & Fairman, 1997);
- registration of clinical trials (Barnes et al., 2006; Byrne, Regan, & Howard, 2006; Korn & Ehringhaus, 2006; see also Food and Drug Administration, n.d.);
- the potential for misuse of data generated by new technologies (see Illes, de Vries, Cho, & Schraedley-Desmond, 2006; Kapp, 2006);
- disclosure of research records during litigation (*Chandler v. Hektoen Institute,* 2003; Parrish & Bruns, 2002; Racette, Bradley, Wrisberg, & Perlmutter, 2006);
- secondary "future uses" of data and materials collected by researchers and commercial research sponsors (Barnes & Heffernan, 2004; Law, 2005); and
- policies pertaining to intellectual property and data sharing, (e.g., Fontanarosa, Flanagin, & DeAngelis, 2005; National Institutes of Health, 2006, 2007b).

Data Analysis and Reporting

Marco and Larkin (2000) identified a host of data reporting problems in the scientific literature (see Table 2)

Table 2. Data reporting problems in the scientific literature, according to Marco and Larkin (2000).

- Failing to include the number of eligible participants
- Reporting of missing data points inaccurately
- Failing to report all pertinent data
- Failing to report negative results
- Allowing research sponsors to influence reporting of results
- Labeling graphs inappropriately
- Reporting percentages rather than actual numbers
- Reporting results of inappropriately applied statistical tests
- Reporting differences when statistical significance is not reached
- Reporting no difference, when power is inadequate
- Performing multiple comparisons without correction
- Splitting data into multiple publications
- Using terminology without precise definitions
- Reporting conclusions not supported by the data
- Ignoring citations of prior work that challenge stated conclusions
- Inflating research results for the media

Note. From "Research Ethics: Ethical Issues of Data Reporting and the Quest for Authenticity," by C. A. Marco and G. L. Larkin, 2000, *Academic Emergency Medicine, 7,* pp. 692–693.

and emphasized the importance of rigorous research designs and analytic approaches. Although no well-trained scientists would dispute the notion that both the design and the statistical methods are vitally important to the integrity of research (Altman, 1980a, 1980b, 1980c, 1980d, 1980e, 1980f, 1980g; Bailar, 1986), misunderstanding, mismanagement, and misuse of statistics are major problems in the biomedical and behavioral literature. According to the American Statistical Association's (1999) *Ethical Guidelines for Statistical Practice,* "Because society depends on sound statistical practice, *all practitioners of statistics whatever their training and occupation,* have social obligations to perform their work in a professional, competent, and ethical manner" (paragraph I.C., italics added for emphasis). The *Ethical Guidelines* also include a cautionary note to clients who employ statistical consultants. In Section H, clients are advised to

> 1. Recognize that the results of valid statistical studies cannot be guaranteed to conform to the expectations [of the client] … 2. Valid findings result from competent work in a moral environment. Pressure on a statistical practitioner to deviate from [American Statistical Association's, 1999, *Ethical Guidelines for Statistical Practice*] is likely to damage both the validity of study results and the professional credibility of the practitioner. (p. II.H.1.-2)

These words echo Marco and Larkin (2000), who remind readers that "the quest for scientific authenticity" (p. 693) depends on competent, honest, and impartial data analysis and reporting.

To highlight data analysis, interpretation, and reporting problems, Ioannidis (2005) wrote an article with the provocative title, "Why Most Published Research Findings are False." He opined that most published research findings are false, in part due to scientists' apparent lack of appreciation for the fact that "the probability that a research finding is indeed true depends on the prior probability of it being true (before doing the study), the statistical power of the study, and the level of statistical significance" (p. 0696). He argued that most studies have "very low pre- and post-study probability for true findings" (p. 0700), emphasizing that the "totality of the evidence" (not a single study) should be used to determine true findings, and that investigators should also use methods to minimize bias, to determine prestudy odds, and to correct for multiple statistics. Ioannidis also noted that the phrase "'negative' research," or "'negative' results," is a misnomer and is widely misunderstood (p. 0696). There is a dearth of "negative" reporting in the literature (Unalp et al., 2007) and a dearth of replication studies resulting from "a number of factors such as publication bias, selection bias, Type I errors, population stratification … , and lack of statistical power" (Moonesinghe, Khoury, & Janssens, 2007, p. 0218).

Citing Ioannidis, Hotz (2007) wrote, "Statistically speaking, science suffers from an excess of significance" (p. B1). To balance his rather alarming title, Hotz interviewed Yale University science historian Daniel Kevles, who opined, "Where you have new areas of knowledge developing, then the science is going to be disputed, subject to errors arising from inadequate data or the failure to recognize new matters" (as cited in Hotz, 2007, p. B1). Elaborating on this point, Hotz observed that "error is as much a part of science as discovery. It is the inevitable byproduct of a search for truth that must proceed by trial and error.… Conflicting data and differences of interpretation are common" (p. B1).

Data Sharing

A subtopic within this RCR domain is data sharing. Data sharing is particularly important for data verification and scientific replication. According to Shamoo and Resnik (2003),

> Scientists should share data and results (1) to promote the advancement of knowledge by making information publicly known; (2) to allow criticism and feedback as well as replication; (3) to build and maintain a culture of trust, cooperation, and collaboration among researchers; (4) to build support from the public by demonstrating openness and trustworthiness. (p. 36)

The National Research Council (2003) emphasized that authors should share original data to allow others to verify or replicate their work, and to allow others to advance their own work more efficiently and effectively (p. 4). Furthermore, data sharing fosters replication, to

confirm statistically the findings of earlier investigators and to allow causal inferences to be drawn (Ioannidis, 2005; Moonesinghe et al., 2007).

In *Resource Sharing in Biomedical Research,* the Institute of Medicine's Committee on Resource Sharing in Biomedical Research with Berns, Bond, and Manning (1996) used several large data resource centers as exemplars of data sharing (e.g., the American Type Culture Collection, the Genome Research Project, the Washington Regional Primate Research Center, and the Human Genome Center at Lawrence Livermore National Laboratory). The Institute of Medicine recognized numerous challenges associated with maintaining and using centralized resources (e.g., quality management, the diversity of stakeholders, and regulatory requirements), and emphasized the need for sophisticated information retrieval and transfer systems, policies for retaining and discarding data and material, and appropriate and fair incentives for data sharing.

The National Research Council (1999, 2003), respectively, wrote two important reports about sharing of research materials: *Finding the Path: Issues of Access to Research Resources* and *Sharing Publication-Related Data and Materials: Responsibilities of Authorship in the Life Sciences*. In the latter, the National Research Council explained that "sharing of scientific findings, data, and materials through publication is at the heart of scientific advancement. A robust and high-quality publication process is, therefore, in the public interest" (p. 3). In *Principles for Protecting Integrity in the Conduct and Reporting of Clinical Trials,* Ehringhaus and Korn (2006), on behalf of the Association of American Medical Colleges, articulated "consensus principles" regarding clinical trial data, dissemination of results, registration of trials, data sharing, and establishing a "publications and analysis committee" independent of the sponsor. In other words, developing databases, sharing these databases, and disseminating research findings to the larger community are aims consistent with contemporary science and evidence-based clinical practice, and with the norm of openness within the scientific community. Therefore, recognizing the logistical and ethical challenges associated with resource sharing is essential.

Data Withholding

Despite the norm of data sharing, the prevalence of data withholding among scientists is confirmed by empirical studies. For example, Campbell et al. (2002) examined geneticists' refusal to share data associated with published research. They found that commercial sponsorship and the number of requests were positively associated with refusals to grant requests for information, data, or materials (p. 478). The reasons scientists denied others' requests for information data or materials were (a) "effort required to actually produce materials or information" (80%); (b) "need to protect a graduate student's, postdoctoral fellow's or junior faculty member's ability to publish" (64%), (c) "need to protect own ability to publish" (53%), (d) "financial cost of actually providing the materials or information transfer" (45%), (e) "likelihood that the other person will never reciprocate" (28%), (f) "need to honor the requirements of an industrial sponsor" (27%), (g) "need to preserve patient confidentiality" (23%), and (h) "need to protect the commercial value of the results" (21%; Campbell et al., 2002, p. 478).

Vogeli et al. (2006) surveyed 1,077 of 1,836 (58.7%) eligible doctoral students from 115 institutions. They found that data withholding was positively associated with industry support and perceived level of competition among institutions or labs. Significantly,

> 533 respondents (50.8%) reported that withholding had had a negative effect on the progress of their own research, 508 (48.5%) on the rate of discovery in their own lab or group, 472 (45.0%) on the quality of their relationships with other academic scientists, 346 (33.0%) on the quality of the education they receive, and 299 (28.5%) on the level of communication in their lab or group. (Vogeli et al., 2006, pp. 131–132)

Data Ownership (and Copyright)

Because scientists are often motivated not only by the rewards intrinsic to fulfilling a social responsibility, but also by a desire to enhance their reputations or to improve their personal wealth (McMillan et al., 2000), sharing may not come naturally. Distributing ideas, resources, and data makes it difficult both to protect, and to profit from, one's intellectual contributions. In fact, the Council of Science Editors found that intellectual theft—taking a concept without crediting its source—was one among many types of improprieties encountered by editors (Council of Science Editors & Ancker, 2004). Unless authorship and intellectual property policies are clear to all of those with vested interests, interdisciplinary and multiinstitutional research environments might tend to exacerbate such disputes. Therefore, the Office of Research Integrity includes data ownership and copyright—a form of intellectual property—within the instructional domain of data acquisition, management, sharing, and ownership.

The backdrop of intellectual property is the U.S. Constitution (1787), which empowers Congress "to promote the progress of science and useful Arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries" (Article 1, §8). As such, the U.S. Constitution is the source of our intellectual property (ownership) rights in both inventions and creative literary works, such as scientific

manuscripts and grant proposals. To protect the ownership rights of authors and inventors, Congress enacted—and periodically amends—the U.S. Patent Act of 1952 (U.S.C. Title 35) and the U.S. Copyright Act of 1976 (U.S.C. Title 17). The U.S. Copyright Act has 13 chapters; the most important for the purposes of the present discussion are as follows:

Chapter 1. Subject Matter and Scope of Copyright

Chapter 2. Copyright Ownership and Transfer

Chapter 3. Duration of Copyright

Chapter 4. Copyright Notice, Deposit and Registration

Chapter 5. Copyright Infringement and Remedies

Creative works. The author of a scientific article who has created an "original work of authorship" (a literary work) has several exclusive rights under the U.S. Copyright Act. After the work is registered in the U.S. Copyright Office (17 U.S.C. §408(a)), the author may sue others for infringing the copyright (see 17 U.S.C. §101 for definitions; see 17 U.S.C. §501 for infringement). Regardless of whether the work is registered, however, the author (the original copyright owner) has the exclusive rights (legal rights) to reproduce the work, to distribute the work to the public, to create derivative works of the original work, and to transfer the work to others, such as journal publishers (17 U.S.C. §106).

Co-owners of creative works. Of noted importance, when two or more authors create a work, they are co-owners (17 U.S.C. §201). Each co-owner has an independent right to reproduce the work, to distribute the work to the public, and to create derivative works from the original work. However, when transferring copyright to a third party (such as a publisher), all co-authors (co-owners) must sign the written copyright transfer (17 U.S.C. §204(a)). Once the copyright transfer is properly executed, the publisher becomes the copyright owner, and assumes all of the rights of copyright ownership (to the exclusion of the original author(s)).

Fair use. The exclusive rights of the copyright owner are subject to "fair use" of the creative work by others for the purposes of criticism, education, and research. Fair use depends on the nature of the original work, how much of the work is used, the purpose of the use, and the impact on the potential market or value of the work (17 U.S.C. §107).

Term of copyright. The term of copyright for works created on or after January 1, 1978, "endures for a term consisting of the life of the author and 70 years after the author's death" (17 U.S.C. §302(a)). For works made for hire, "the copyright endures for a term of 95 years from the year of its first publication, or a term of 120 years from the year of its creation, whichever expires first" (17 U.S.C. §302(c)). (See the U.S. Copyright Office's *Copyright Office Basics,* 2008; see also Mays, 2005; McMillen, 2001.)

Ownership of ideas and data. Copyright law does not govern ownership of ideas or data:

> In no case does copyright protection for an original work of authorship extend to any idea, procedure, process, system, method of operation, concept, principle, or discovery, regardless of the form in which it is described, explained, illustrated, or embodied in such work. (17 U.S.C. §102)

To protect data or other discoveries, one must use legal protections provided by the law of trade secrets, trademarks, patents, nondisclosure agreements, and/or other contracts (see Mays, 2005; for more information, see *Information Circulars and Factsheets* provided by the U.S. Copyright Office on its Web site; see also Murashige, 2002, for a discussion of patents and research). Ownership of data, and rights of access to data, are established by the conditions of the granting agency (e.g., see National Institutes of Health's *Intellectual Property Policy,* 2006), by contract with a sponsor, by lease or lending agreements with a data repository, or by the terms of employment (see works made for hire, 17 U.S.C. §201(b)).

Some academic scholars might be surprised to learn that (a) their institutions own original data and materials funded by federal dollars (Mays, 2005, p. 213); (b) research data acquired with federal funding may be accessed by the public under the Freedom of Information Act (Mays, 2005, p. 214); (c) federal granting agencies require data to be retained for at least 3 years; (d) agencies have a right to inspect or access data "as long as the grantee is in possession of these records" (Mays, 2005, p. 214; see also National Institutes of Health's, 1998, "NIH Grants Policy Statement"); and (e) courts may order production of raw research data (*Chandler v. Hektoen,* 2003; Racette et al., 2006). Of noted importance, scientists should be aware that private contracts, as with industry sponsors, can restrict the intellectual property rights of scientific contributors, despite the efforts of editors and others to limit this practice (e.g., DeAngelis et al., 2001).

Technology transfer. The Bayh-Dole Act of 1980 (Pub. L. No. 96-517) and the Federal Technology Transfer Act of 1986 (Pub. L. No. 99-502)—both designed to speed the transfer of federally funded inventions to the public—stipulate how inventors, institutions, and commercial entities share patents and income resulting from commercially viable products (Angell, 2000; Bradley, 2005; Broccolo & Klanica, 2006; Kelch, 2002). Because commercial sponsors may desire to control data, to license patented inventions, or to preapprove presentations and publications, it is essential that legal counsel reviews all such academic–industry contracts (Mello, Clarridge, & Studdert, 2005; see also DeAngelis et al., 2001).

In short, data ownership is not governed by the law of copyright. Data ownership is a complex matter that is determined by who created the data (e.g., an individual,

an employee, a university, or a commercial entity); who subsidized the collection of data (e.g., the federal government, a state institution, or a private–commercial entity); where the data are stored (e.g., a private database or a public repository); and, most critically, what the contracts, regulations, licenses, or other legal arrangements are that govern the data.

In closing, the RCR domain known as "data acquisition, management, sharing, and ownership" encompasses a wide range of issues. As science in the 21st century moves further toward large-scale, multicenter research, and the use of cumulative databases and repositories, it is essential that scientists understand the philosophical and practical challenges, as well as the legal rules concerning intellectual property rights and data ownership. Specialized legal counsel is warranted in these matters.

Summary

The purpose of *Research Ethics II* was to review authoritative documents, insightful commentary, and empirical literature regarding the responsibilities of mentors and trainees, the purpose and challenges of collaborative science, the controversies surrounding the tradition of peer review, and the host of issues pertaining to data—acquisition, management, sharing, and ownership. All who are involved in the research enterprise, at all levels, should be aware of these issues and strive to adhere to best practices as they evolve.

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