Research Ethics III: Publication Practices and Authorship, Conflicts of Interest, and Research Misconduct

SUPPLEMENT

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Conclusions: The integrity of the scientific record—its accuracy, completeness, and value—ultimately impacts the health and well-being of society. For this reason, scientists are both entrusted and obligated to use the highest standards possible when proposing, performing, reviewing, and reporting research or when educating and mentoring new investigators.

KEY WORDS: responsible conduct of research, scientific integrity, publication practices, authorship, conflict of interest, research misconduct

n Research Ethics III, as a companion to our three-part literature review, we provide readers with the Office of Research Integrity (1992) definitions of each domain-publication practices and responsible authorship, conflicts of interest and commitment, and research misconduct. As in Research Ethics I and Research Ethics II (Horner & Minifie, 2011a, 2011b), we attempt to heighten readers' appreciation for past controversies and successes, as well as present challenges 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 the responsible conduct of research (RCR) to faculty and students engaged in the biomedical and behavioral sciences. In Ingham and Horner's (2004) article published in The ASHA Leader (http://www.asha. org/Publications/leader/2004/040316/f040316c.htm), readers can access hypothetical cases pertinent to Communication Sciences and Disorders. We close by encouraging readers to adhere to publication guidelines and conflict of interest policies and regulations, and to avoid practices that deviate from scientific norms, notably those practices that qualify as scientific misconduct under federal law-falsification, fabrication, and plagiarism.

Publication Practices and Responsible Authorship

The Office of Research Integrity (2000) defined the scope of these overlapping topics:

The purpose and importance of scientific publication, and the responsibilities of the authors. Includes topics such as collaborative work and assigning appropriate credit, acknowledgments, appropriate citations, repetitive publications, fragmentary publication, sufficient description of methods, corrections and retractions, conventions for deciding upon authors, author responsibilities, and the pressure to publish. (p. XX)

Disputes among authors "have become part of the culture of scientific publication" (Barrett, Funk, & Macrina, 2005, p. 194) and correlate with several factors: (a) the prevalence of multiauthored papers (Claxton, 2005b); (b) the number of senior authors on multiauthor papers (Drenth, 1998); (c) the number of scientists holding PhDsincreasing from 40,600 in 1975 to 93,000 in 1997 (National Research Council, 2000, p. 18; see also Garrison, Gerbi, & Kincade, 2003); and (d) the number of publicationsincreasing from 174,638 in 1966 to 529,983 in 2002 (Claxton, 2005b). Disputes about authorship and publication credit raise questions about collegiality and trust among collaborators, and about the ethical and legal norms surrounding creative works. However, the Office of Research Integrity does not consider authorship and publication credit disputes to be "plagiarism," a form of scientific misconduct under federal rules (Office of Research Integrity [ORI], 1994), because they do not constitute "the theft or misappropriation of intellectual property and/or the substantial unattributed textual copying of another's work" (Dahlberg, 2007, p. 4). In his 2007 article, Dahlberg (the director of the Division of Investigative Oversight at the Office of Research Integrity) was careful to point out that both journals and institutions are free to impose stricter standards than the Office of Research Integrity.

Publication Standards

The International Committee of Medical Journal Editors (ICMJE; 2010) revised their guidelines entitled Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication (see also Davidoff et al., 2001).

ICMJE authorship standards. The ICMJE Uniform Requirements (2010) include the central concept that "an 'author' is generally considered to be someone who has made substantive intellectual contributions to a published study" (p. 2). The ICMJE Uniform Requirements stipulate the following:

Authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3. (p. 2; see also Hoey, 2000)

Other ICMJE standards. The ICMJE Uniform Requirements stipulate the (a) responsibilities of editors and peer reviewers; (b) strategies for identifying and managing potential conflicts of interest (regarding authors' commitments, project support, editors, journal staff, and reviewers); (c) importance of privacy and confidentiality of study participants, authors, and reviewers; (d) rules regarding protection of human subjects and animals; and (e) need to publish negative studies, corrections, and retractions. The ICMJE Uniform Requirements also provide practical advice about copyright, overlapping publications (duplicate, redundant, and secondary), and other matters related to publication ethics.

Other publication ethics resources. Other valuable publication ethics guidelines can be found in the Publication Manual of the American Psychological Association (2001, 2010) and the American Medical Association Manual of Style (2007), as well as on the Web site of the Committee on Publication Ethics (Guidelines on Good Publication Practice, 2000 and The COPE Report, 2005). (See also Horner & Minifie, 2011b, "Research Ethics II: Mentoring, Collaboration, Peer Review, and Data Management and Ownership," Table 1, for a list of publication manuals with ethics guidelines.) Claxton (2005b) provided an informative review of appropriate publication practices (Table 2, p. 39) and an inventory of authorship guidelines from a sample of journals, such as The Lancet and the Journal of the American Medical Association (JAMA; Table 3, p. 40).

Publication Problems

Unfortunately, some authors either are not aware of authoritative guidelines or do not use them. For example, in their study, Barrett et al. (2005) surveyed about 400 postdoctoral fellows and found that only about half were aware of, and using, authorship and publication guidelines (p. 196).

Empirical work in the domain of "publication practices and responsible authorship" has identified several types of problems, including coercion authorship, mutual admiration authorship, gift authorship, ghost authors, and duplicate productions (Claxton, 2005b; Strange, 2008; Yank & Barnes, 2003). In pharmaceutical research, ghostwriting and guest authoring are prevalent (Blumsohn, 2006; Bodenheimer, 2000). Flanagin et al. (1998) surveyed 809 authors of three large and three small circulation peerreviewed journal articles, and found that 156/809 (19%) had evidence of honorary authors, and 93/809 (11%) ghost authors. They, like Barrett et al. (2005), concluded that authors are either unaware of or disregard publication ethics guidelines. Huth (1986a, 1986b) examined divided and repetitive publications, which he considered to be examples of irresponsible authorship. Fox (1994) suggested that Table 1. U.S. Public Health Service guidance for managing conflicts of interest.

IRBs, institutions, and investigators [should] consider whether specific financial relationships create financial interests in research studies that may adversely affect the rights and welfare of subjects.

Financial interests determined to create a conflict of interest may be managed by eliminating them or mitigating their impact. [I]nstitutions engaged in [D]HHS conducted or supported human subjects research [should] consider... Establishing the independence of institutional responsibility for research activities from the management of the institution's financial interests [or] [e]stablishing conflict of interest committees.

[1]nstitutions engaged in human subjects research and IRBs that review [D]HHS conducted or supported human subjects research or FDA regulated human subjects research [should] consider whether establishing policies and procedures addressing IRB member potential and actual conflicts of interest as part of overall IRB policies and procedures would help ensure that financial interests do not compromise the rights and welfare of human research subjects.

[IRBs should consider] the kind, amount, and level of detail of information to be provided to research subjects regarding the source of funding, funding arrangements, financial interests of parties involved in the research, and any financial interest management techniques applied.

- [Investigators should consider][i]ncluding information in the informed consent document, such as [t]he source of funding and funding arrangements for the conduct and review of research, or [i]nformation about a financial arrangement of an institution or an investigator and how it is being managed.
- [Investigators should consider][h]aving another individual who does not have a potential or actual conflict of interest involved in the consent process, especially when a potential or actual conflict of interest could influence the tone, presentation, or type of information presented during the consent process.

Note. From "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection," by the Public Health Service, *Federal Register*, 69(92), pp. 26393–26397. IRB = Institutional Review Board; DHHS = Department of Health and Human Services; FDA = Federal Drug Administration.

publication breaches may persist due to the reluctance of reviewers or editors to take action (see also Shamoo & Resnik, 2003).

Irresponsible authorship and other practices are a major problem for journal editors. For example, in the first year in his role as scientific integrity advisor for *Neurology*, Daroff (2005) found that allegations of plagiarism, theft or misappropriation of others' work, and self-plagiarism, a copyright violation (see also Bilic-Zulle, Azman, Frkovic, & Petrovecki, 2008; Bouville, 2008; Dahlberg, 2007), were the most frequent allegations. However, Daroff observed, "In no instance did we find the authors to be dishonest, but rather either sloppy, or ignorant of the 'rules"" (p. 589). In his 2007 report, Daroff found that 18 of 8,664 submissions raised concerns, but only four were judged to be examples of scientific misconduct or a breach of publication ethics. He attributed these problems to "author naivety, sloppiness, and the ambiguities involved in what may constitute self-plagiarizing" (p. 1842; see also Dahlberg, 2007; Strange, 2008).

Benos et al. (2005) examined the publications programs of the American Physiological Society. Between

Table 2. Definition of research misconduct: Fabrication, falsification, and plagiarism.

Note. From "Public Health Service Policies on Research Misconduct (Final Rule)," by the Public Health Service, Federal Register, 70(94), pp. 28370–28400.

Sec. 93.103 Research misconduct

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

⁽a) Fabrication is making up data or results and recording or reporting them.

⁽b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

⁽c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

⁽d) Research misconduct does not include honest error or differences of opinion.

Sec. 93.104 Requirements for findings of research misconduct. A finding of research misconduct made under this part requires that (a) There be a significant departure from accepted practices of the relevant research community; and

⁽b) The misconduct be committed intentionally, knowingly, or recklessly; and

⁽c) The allegation be proven by a preponderance of the evidence.

1996 and 2004, they found the following prevalence rates of publication ethics problems: redundant publications, 24%; animal welfare concerns, 16%; duplicate publications, 15%; author disputes, 14%; human welfare concerns, 8%; data fabrication, 8%; plagiarism, 7%; conflicts of interest, 5%; and other (reviewer bias, submission irregularities), 3% (see Figure 3, p. 62).

Contributorship

According to Rennie, Yank, and Emanuel (1997), published articles "establish priority, reputation and standing" (p. 579); therefore, authorship implies both "credit and accountability" (p. 580). All authors, they proposed, should be accountable for both (a) their specific contribution and (b) for the work as a whole. They also stated the following:

Contribution is the activity of science that is most relevant to publication because its disclosure can identify who is accountable for what part of the research and allows the reader to assign credit fairly. (p. 582)

Frazzetto (2004) agreed with the contributorship model proposed by Rennie et al. (1997) because the model would systematically acknowledge the type and level of contribution of each author, and help to assure accountability for specific parts of the final publication. In the *Uniform Requirements,* ICMJE (2010) wrote, "Editors are strongly encouraged to develop and implement a contributorship policy, as well as a policy on identifying who is responsible for the integrity of the work as a whole" (p. 2).

Horton's (2002) report about "The Hidden Research Paper" reinforced the need for a consensus model for defining authorship. Using a qualitative design, Horton surveyed authors of multiauthored works published in *The Lancet* during 2000 to determine whether the published manuscript reflected all of the authors' opinions about the meaning of their research results. He found that contributing authors' views about design weaknesses, the study's implications, and lines for future research were often omitted from the final publication. Horton reported a "consistent failure by scientists to provide a more rigorous overview of past evidence when considering their own findings" (p. 2777) and found a "true diversity of opinion among contributors about the meaning of their research findings" (p. 2778).

In a thorough review and analysis of authorship, Strange (2008) described both the benefits and responsibilities of authorship, and the types of authorship abuse. He also offered recommendations for "minimizing or resolving authorship disputes" (Table 4, p. C572). Germaine to the discussion about authorship criteria and the contributorship model, he proposed that—to fulfill the ICMJE requirement of "substantial contribution"—all authors should meet two requirements: namely, they should (a) "participate in the drafting or revising of the manuscript for 'important intellectual content" and (b) "be able to take public responsibility for the contributions they have made to a paper" (Strange, 2008, pp. C569–C570).

Errata and Retractions

When significant unavoidable errors or misconduct occur, published articles should be retracted, and future citation of retracted articles should be avoided. Cokol, Iossifov, Rodriguez-Estaban, and Rzhetsky (2007) surveyed 9.4 million papers in the National Library of Medicine database, published between 1950 and 2004, and found that only 596 had been formally retracted. In an earlier work about retraction presented at the Third International Congress on Peer Review in Biomedical Publication (September 1997, Prague, published in a special issue of JAMA), Budd, Sievert, and Schultz (1998) searched Medline from 1966 to August 1997, and identified 235 retracted articles. The mean time from publication to retraction was 25.8 months; the majority of articles (190 of 235) were retracted by authors. Reasons for retraction were as follows: 86, due to misconduct or presumed misconduct; 91, due to significant reporting errors; 38, due to authors' inability to replicate; and 20, for other reasons. The most striking result of this survey was the finding that "the 235 articles received a total of 2034 postretraction citations" (p. 297).

In 2007, Neale, Northrup, Dailey, Marks, and Abrams surveyed articles corrected or retracted between 1993 and 2001 after being named "in official findings of scientific misconduct" (p. 5). "As of May 2005, there were 5,393 citations to the 102 articles, with a median of 26 citations per article (range 0-592)" (Neale et al., 2007, p. 5). In 2008, Trikalinos, Evangelou, and Ioannidis analyzed 61 retracted articles in 21 top-cited journals. "In most cases (70%) the investigator implicated in the misconduct was the first author" (p. 466). They reported that among the articles that were eventually retracted, the median "survival time" was 28 months-22 months for junior researchers in contrast to 79 months for senior authors (p. 467). These data suggest that notices provided by the National Library of Medicine, as well as by the National Institutes of Health and the Office of Research Integrity, are not deterring authors from citing problematic research articles.

Sox and Rennie (2006) wrote, "Once someone identifies an article as fraudulent, the scientific community has two duties: (a) to warn scientists to ignore the article and (b) to prevent further pollution [of scientists' search for truth] by scientists who inadvertently cite the article" (p. E7). They reviewed the case of Eric T. Poehlman, PhD from the perspective of the *Annals of Internal Medicine*, in which one of Poehlman's 10 fraudulent articles had been published. (The University of Vermont's and the Office of Research Integrity's investigations, and the subsequent civil and criminal actions and penalties, are reviewed by Dahlberg and Mahler, 2006; see also Kinitisch, 2005; Sharav, 2006; *United States of America, ex rel. Walter F. DeNino v. Eric T. Poehlman, 2005; United States of America v. Eric T. Poehlman, 2005a, 2005b.*)

According to Sox and Rennie (2006), the tasks of investigating misconduct, correcting the scientific literature, and preventing or mitigating the effects of misconduct are shared responsibilities. As a result of their analysis, they called on editors to (a) call for an investigation (by the home institution) if they suspect misconduct, (b) retract tainted articles, (c) correct articles tainted by having cited the fraudulent article, and (d) publish an account of research misconduct affecting the journal. In addition, Sox and Rennie implored citing authors to check each citation, before submitting an article for peer review, to be sure it has not been retracted (see also Cowell, 2000; Strange, 2008).

Trikalinos et al. (2008) offered this insight: "A fraudulent article looks much the same as a nonfraudulent one. Thus, it would be unfair to claim that misconduct is a failure of the peer-reviewers and journal editors. Even blatant papers of falsification may require careful scrutiny to be revealed" (p. 469). In a similar vein, Marusic, Katavic, and Marusic (2007) opined, "Editors are not, could not, and should not be the policing force of science and the scientific community, but they can contribute to research integrity and ensure the trust of the public by enforcing their major responsibility—the integrity of the published record of science" (pp. 551–552).

In summary, breaches of publication ethics undermine the integrity of the research record. Preventing or remedying these types of problems requires multiple strategies. Fox (1994) emphasized that publication ethics is both an individual and institutional responsibility. Huth (1986a, 1986b) called on a more active role by scientific societies and editors, while Marusic et al. (2007), Sox and Rennie (2006), and Trikalinos et al. (2008) emphasized that the integrity of the scientific record is a responsibility shared by all stakeholders. Budd et al. (1998) and Sox and Rennie warned authors not to use retracted papers. Rennie et al. (1997) and Frazzetto (2004) recommended using the contributorship method for determining authorship, establishing an open peer review system, encouraging postpublication updating of meta-analyses, and facilitating postpublication review by readers. Cokol et al. (2007) recommended wider use of electronic and open access publishing because these methods "improve[-] the self-correction of science by making scientific publications more visible and accessible" (p. 423), and Strange (2008) recommended ways to avoid or mitigate authorship abuses.

In closing, responsible authorship is a shared responsibility among research investigators, reviewers, and editors, but authors are ultimately responsible for the integrity of their work, human subjects protections, and compliance with regulations. Individuals should be authors if, and only if, they have contributed substantially to the work. To avoid authorship disputes and other publication mishaps, authors are advised to adhere to authoritative publication guidelines, institutional policies, and editorial guidelines for specific journals. The literature suggests that journals should assess the clarity and rigor of their publication and authorship policies, should encourage readers to engage in post publication review of papers, and might want to consider appointing a "scientific integrity advisor" as Neurology has done. Many believe that education about publication practices is key to any effort to prevent breaches of publication ethics (see Ingham et al., 2011; Minifie et al., 2011).

Conflicts of Interest and Commitment

According to the Office of Research Integrity (2000), this RCR domain pertains to the following:

The definition of conflicts of interest and how to handle conflicts of interest. Types of conflicts encountered by researchers and institutions. Includes topics such as conflicts associated with collaborators, publication, financial conflicts, obligations to other constituencies, and other types of conflicts. (p. VIII.B.9)

The American Speech-Language-Hearing Association's (ASHA) *Code of Ethics* (2003) states, "Individuals shall not participate in professional activities that constitute a conflict of interest" (III.B). The American Psychological Association's *Ethical Principles of Psychologists and Code of Conduct* (2003) state the following:

Psychologists refrain from taking on a professional role when personal, scientific, professional, legal, financial, or other interests or relationships could reasonably be expected to (1) impair their objectivity, competence, or effectiveness in performing their functions as psychologists or (2) expose the person or organization with whom the professional relationship exists to harm or exploitation (Standard 3.06).

The American Medical Association (AMA) and its Council on Ethical and Judicial Affairs (CEJA) have been concerned about conflicts of interest in research for the past two decades (see American Medical Association [AMA], 1990, 2001; AMA Council on Ethical and Judicial Affairs [CEJA], 1999). Morin et al. (2002, Opinion E-8.0315), representing AMA's CEJA, emphasized that "physicians should be mindful of the conflicting roles of investigator and clinician and of the financial conflicts of interest that arise from incentives to conduct trials and to recruit subjects" (see also Brennan et al., 2006).

Types of Conflicts

Conflict of interest. What is a *conflict of interest?* A conflict of interest arises when an investigator is tempted "to compromise professional judgment for financial or personal gain" (Werhane & Doering, 1997, p. 169). "[G]ifts of even minimal value carry influence" (Brennan et al., 2006, p. 431). Conflicts are unavoidable and vary in significance (Coyne, 2005), but because they have a natural tendency to create preconceptions and biases about, or otherwise influence the thinking and behavior of investigators and authors, it is essential that the conflicts are managed appropriately and transparently. Morin et al. (2002) explained:

In law, the term *conflict of interest* is used primarily in connection with fiduciaries. A fiduciary holds some form of power that is to be used for the benefit of another, based on specialized knowledge or expertise. The fiduciary relationship involves dependence, reliance, and trust and is held to the highest legal standard of conduct. (pp. 79–80)

According to Cohen (2001),

A conflict of interest exists whenever an individual or an institution has a primary allegiance that requires certain actions and, simultaneously, has a secondary interest that (1) could abrogate that primary allegiance and (2) is sufficiently tempting to raise a reasonable possibility that it might actually do so. (p. 210)

Competing or conflicting interests may involve commercial or financial interests, reputational interests, or simply conflicting commitments of time, expertise, energy, or interest. According to Werhane and Doering (1997), a conflict of interest involves situations in which "all interests may not, or in some cases, cannot, be realized simultaneously, and where choosing a financial or personal interest over a professional one may violate a code or norm, a promise or contract, or some other specific professional responsibility" (p. 169). Perlis, Harwood, and Perlis (2005) wrote, "Although there is no general consensus on a definition for conflict of interest in clinical trials, the concept is broadly understood to arise whenever an individual or organization pursues two competing, or not necessarily compatible goals" (p. 967).

Conflict of commitment. In contrast, *conflict of commitment* "refers to any conflict between two sets of professional obligations that cannot both be adequately fulfilled without compromising one's judgment in fulfilling one or both of them" (Werhane & Doering, 1997, p. 174). The issue that is relevant to RCR is how scientists, authors, and institutions should manage conflicts to minimize their potential effects on scientists' objectivity (Shamoo & Resnik, 2003), and, most important, how scientists should respond to conflicts of interest to assure that the interests of those who place their trust in the scientific enterprise are not compromised (Bradley, 2005; Emanuel, 2005; Klanica, 2005).

Conflict of interest guidelines. In 2003, the Association of American Medical Colleges' AAMC Task Force on Financial Conflicts of Interest in Clinical Research produced two reports: Protecting Subjects, Preserving Trust, Promoting Progress. I: Policy and Guidelines for the Oversight of Individual Financial Interest in Human Subjects Research (2003a) and Protecting Subjects, Preserving Trust, Promoting Progress. II: Principles and Recommendations for Oversight of an Institution's Financial Interests in Human Subjects Research (2003b). The Association of American Medical Colleges advocated a "principled partnership between industry and academia" not only to assure integrity of data but also to protect human participants (2003a, p. 228), and implored institutions to oversee financial conflicts of interest pertaining to human subjects research (2003b, p. 239; see also Alt-White & Pranulis, 2006; Broccolo & Klanica, 2006; Weinfurt, Dinan, et al., 2006).

On January 5, 2004, the National Institutes of Health published a final notice regarding *Scientific Peer Review of Research Grant Applications and Development Contract Projects.* This final rule stipulates the terms of recusal (§52h.5), and the difference between an appearance of conflict and a real conflict (§52h.2):

52h.2(b) *Appearance of a conflict of interest* means that a reviewer or close relative or professional associate of the reviewer has a financial or other interest in an application or proposal that is known to the reviewer or the government official managing the review and would cause a reasonable person to question the reviewer's impartiality if he or she were to participate in the review.

52h.2(q) *Real conflict of interest* means a reviewer or a close relative or professional associate of the reviewer has a financial or other interest in an application or proposal that is known to the reviewer and is likely to bias the reviewer's evaluation of that application or proposal. (pp. 275–276)

Financial Disclosures

The AMA examined conflicts of interest in biomedical research (1990) and in the conduct of clinical trials (Morin et al., 2002). The AMA's VIIIth principle of medical ethics (2001) states: "A physician shall, while caring for a patient, regard responsibility to the patient as paramount." To fulfill this ethic, disclosures of conflicts of interest in the research context are considered essential. In 1999, the AMA's CEJA wrote this opinion:

Clinical investigators should disclose any material ties to companies whose products they are investigating, including financial ties, participation in educational activities supported by the companies, participation in other research projects funded by the companies, consulting arrangements, and any other ties. The disclosures should be made in writing to the medical center where the research is conducted, organizations that are funding the research, and journals that publish the results of the research. An explanatory statement that discloses conflicts of interest should accompany all published research. (Opinion E-8.031, paragraph 3; see also Morin et al., 2002)

In 2004, the Public Health Service issued a final guidance document in the Federal Register entitled *Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection* applicable to Institutional Review Boards, investigators, and research institutions. This guidance document reminded readers of existing regulations (published in the Code of Federal Regulations [C.F.R.]):

The PHS regulations require grantee institutions and contractors to designate one or more persons to review investigators' financial disclosure statement describing their significant financial interests and ensure that conflicting financial interests are managed, reduced, or eliminated before expenditure of funds. (p. 26394; 42 C.F.R. §50.604(b), 45 C.F.R. §94.4(b))

The Public Health Service (2004) "recognizes the complexity of the relationships between government, academia, industry and others, and recognizes that these relationships often legitimately include financial relationships" (p. 26395). However, in response to concerns that some investigators' financial interests may conflict with, and potentially affect, the rights and welfare of human subjects, the Public Health Service guidance document provided advice to Institutional Review Boards, institutions, and investigators. This guidance document was consistent with the National Bioethics Advisory Commission's recommendations in Ethical and Policy Issues in Research Involving Human Participants (2001). See Table 1 for excerpts from the Public Health Service guidance document that capture the essential factors that Institutional Review Boards and investigators should consider when managing conflicts of interest.

As demonstrated by the regulations reviewed here, disclosure is the primary means by which conflicts of interest and conflicts of commitment are managed. Interestingly, the goals of disclosure are not necessarily clear. Weinfurt, Friedman, et al. (2006) explored the views of Institutional Review Boards, conflict of interest committees, and investigators, and found no consensus among them about the goals of disclosure. Nevertheless, Krimsky (2007) opined that when conflicts of interest are associated with certain types of behavior that deviate from the norms of science (e.g., ghostwriting, suppressing data, and falsifying credentials), failure to adhere to disclosure requirements could be-or, perhaps, should be-considered a form of research misconduct. For example, see Singer's (2009) report in the New York Times about Senator Charles E. Grassley's hearings about research misconduct and ghostwriting.

Conflicts for Clinical Investigators

Conflicts of interest involving the solicitation of, or participation by, research volunteers in clinical studies are especially important. Morin et al. (2002) wrote:

When the scientific alliance between investigators and their subjects appears to overlap with the therapeutic alliance that bonds physicians and their patients, trial participants may become confused about the goals of treatment that is experimental but resembles the care they ordinarily received. (pp. 79–80)

This so-called "therapeutic misconception" (Appelbaum, Roth, Lidz, Benson, & Winslade, 1987; Kimmelman, 2007; Miller & Joffe, 2006; Miller & Rosenstein, 2003) may be exacerbated if the informed consent process is incomplete or tainted in some way. For example, participants' welfare might be compromised when doctors are given subject recruitment incentives, when investigators have intellectual property or equity interests (e.g., in the drug, device, or procedure being tested), when the research participant is decisionally compromised, or when the research participant is a student or employee (see Williams, 2006; see also Horner & Minifie, 2011a, "Research Ethics I: Responsible Conduct of Research (RCR)—Research Involving Human and Animal Experimentation").

When an investigator is also the health care provider (a "double agent"; Angell, 1993), the investigator and the Institutional Review Board need to be particularly vigilant about disclosing conflicts of interests or commitments (Sollitto et al., 2003; Williams, 2006). Mindful of the fiduciary responsibilities of physicians, the World Medical Association's *Declaration of Helsinki* (2008) states:

When seeking informed consent for participation in a research study the physician should be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent should be sought by an appropriately qualified individual who is completely independent of this relationship. (paragraph 26)

Impact of Conflicts

The literature provides empirical support for the influence of outside interests on investigators and authors. Several papers examined the relationship between conflicts of interest and research results; others examined conflict of interest policies; and others examined the influence of industry from the perspective of potential research participants and readers of the scientific literature.

Participants' perceptions. Kim, Millard, Nisbet, Cox, and Caine (2004) explored potential research participants'

views regarding researcher and institutional conflicts of interest. Of 5,478 individuals surveyed, 64% felt that knowing about investigators' conflict of interest was extremely or very important; 87% felt conflicts should be disclosed as part of the informed consent process. Respondents were interested in the name of the sponsor and whether the investigator received personal income, but not specific amounts; they appeared more interested in individual conflicts than institutional conflicts. Weinfurt et al. (2008) surveyed potential research participants and found, first, participants were not surprised by the financial interests of investigators, and, second, did not differ in their willingness to participate relative to the different types of conflicts (e.g., per capita compensation, equity ownership).

Readers' perceptions. Schroter, Morris, Chaudhry, Smith, and Barratt (2004) examined journal readers' perceptions of the credibility of published research relative to three types of competing interests (none declared, financial, and grants). Respondents (522 of 882, 59%) were asked to apply four ratings to two papers: importance, relevance, validity, and believability. Readers rated papers that declared a financial interest as less credible than papers that declared no conflict, and readers also rated papers that declared a financial interest less valid than papers that declared support from grants. When conflicts of interest were disclosed, readers rated a paper about herpes zoster as less credible than a paper about doctors' use of problem lists. Schroter et al. concluded, "Both the type of competing interest and the contents of a study influence readers' perceptions of the credibility of published research" (p. 743).

Alliances with the pharmaceutical industry. In a comprehensive analysis for The New England Journal of Medicine, Bodenheimer (2000) described the "uneasy alliance" between clinical investigators and the pharmaceutical industry due to the latter's influence over trial design, data analysis, decisions about what to publish and when, and the use of professional ghostwriters as authors (see also Schulman et al., 2002). In 2004, Friedman and Richter examined the relationship between conflicts of interest and research results. Combining ICMJE with their own criteria, they found that between 16.6% and 32.6% of manuscripts had one or more author with a conflict of interest, and found a strong association between positive findings and whether a study had a conflict of interest as defined by ICMJE-for both all-treatment studies and drug studies alone.

Kelly et al. (2006) found that studies sponsored by a pharmaceutical company favored the drug of interest (78%) when compared with either unsponsored studies (48%) or studies sponsored by a competitor (28%; see also Kjaergard & Als-Nielsen, 2002; Perlis et al., 2005). Buchkowsky and Jewesson (2004) examined 500 pharmaceutical trials from high-impact journals. They observed an eightfold increase over 20 years in the number of industry-sponsored trials. Although most articles reported favorable outcomes for the drug being studied, these authors found no difference between industry-funded versus publicly funded trials. Their finding contrasts with the forgoing studies that found a greater likelihood of favorable outcomes for industry-funded trials (see also Lexchin, Beros, Djulbegovic, & Clark, 2003).

Medical schools' policies. McCrary et al. (2000) conducted a national survey of the policies of 235 medical schools on disclosure of conflicts of interest in biomedical research. They found substantial variability (see Table 1, p. 1623). They also found significant differences between medical schools and other research institutions (Table 2, p. 1624). Problems included variability across institutions, vagueness of definitions, lack of procedures for managing conflicts, and lack of accountability. Fifteen institutions had no policy, despite Public Health Service and National Science Foundation requirements. Not all institutions had policies for disclosures of conflicts of interest in published works, despite ICMJE's *Uniform Requirements* (McCrary et al., 2000).

Studdert, Mello, and Brennan (2004) reviewed ethical and legal aspects of academia-industry relationships, with a cautionary note in the article's title, "Self-Regulation in the Shadow of Federal Prosecution." They provided a comprehensive review of extant conflict of interest guidelines (see Table 1, pp. 1894-1897), suggested that the law should step in only when ethical norms fail to achieve the desired standard of conduct, and concluded that "government policing in this area is likely to intensify" (p. 1891). In contrast to Studdert et al., McCrary et al. (2000) recommended a revision of federal guidelines to achieve uniformity, to require reporting of conflicts to federal agencies, and to require reporting not only to journal editors, but also to journal readers and research subjects (see also DeAngelis, Fontanarosa, & Flanagin, 2001). Stossel (2005) disagreed with a stringent regulatory approach stating, "Scandals are inevitable, and no rules will prevent them from occurring. Legislating integrity is impossible" (p. 1063). In a similar vein, Sharp and Yarborough (2006) challenged the "received view" that regulation and penalties are necessary to preserve the integrity of science. Instead, they argued that disclosuretransparency—is the key to managing conflicts.

In closing, conflicts of interest or conflicts of commitment have the potential to influence research outcomes and publication practices. Some believe that disclosure of conflicts is sufficient; others suggest that both individuals and institutions should be subject to tighter regulations to assure uniformity, to preserve research participants' trust, and to assure the integrity of the scientific record. In this era of academic–industry alliances, conflicts of interest are pervasive. As a result, both the community of scientists and federal oversight agencies need to be vigilant, but whether more regulation is required remains open to further examination.

Research Misconduct

Research misconduct, according to the Office of Research Integrity (2000), includes the following subtopics:

The meaning of research misconduct and the regulations, policies, and guidelines that govern research misconduct in PHS-funded institutions. Includes topics such as fabrication, falsification, and plagiarism; error vs. intentional misconduct; institutional misconduct policies; identifying misconduct; procedures for reporting misconduct; protection of whistleblowers; and outcomes of investigations, including institutional and Federal actions. (p. VIII.B.8)

Although research misconduct is considered to be relatively rare, the impact on science and society is significant. For cases and analyses, see Broad and Wade (1982); Claxton (2005a); Hamilton (1994, 1997); Hilts (1997); Jennings (2004); Redman, Templin, and Merz (2006); Roberts (1997); Shamoo and Resnik (2003); Sox and Rennie (2006); Steneck (1994); Wendler (2004); Wenger, Korenman, Berk, and Liu (1998); and Woolf (1986). For analyses of federal misconduct regulations and other laws, see Goldner (1998); Kalb and Koehler (2002); Redman and Caplan (2005); Sherman (1995, 1997); and Steinberg (2000). For analyses about the causes of research misconduct, see Adams and Pimple (2005); Anderson, Ronning, de Vries, and Martinson (2007); Davis (2003); Davis, Riske-Morris, and Diaz (2007); Koppelman-White (2006); and Wright, Titus, and Cornelison (2008). For discussions about the sanctions and other consequences of research misconduct, see, for example, Janssen (2003) and Keranen (2006).

The Office of Research Integrity's Web site provides institutional compliance guidelines and reports, model policies for managing misconduct allegations and protecting whistleblowers, summaries of cases, and notices of adverse findings against individual investigators. The Office of Research Integrity's Annual Reports, policies, and RCR educational materials are published on the Office of Research Integrity's Web site (http://www.ori. dhhs.gov).

Federal Definition of Research Misconduct

Over the past two decades, there has been controversy over the proper definition of research misconduct and the level of due process required for individuals against whom allegations have been made (Goldner, 1998; Mello & Brennan, 2003). High-profile cases and Congressional hearings in the 1980s brought these issues to national attention, and subsequent cases intensified the national concern about defining, reporting, and adjudicating research misconduct (see ORI's *Legal Concerns: Federal Court Decisions*, n.d.; see also ORI, 1996a [Abbs]; ORI, 1996b [Imanishi-Kari]; Steinberg, 2000; Wilson, Schreier, Griffin, & Resnik, 2007). After years of deliberation and public comment, the National Science Foundation (2002) and the Public Health Service (2005) harmonized their definitions of research misconduct. The final Public Health Service policy appeared in the Federal Register on May 17, 2005 (see Table 2).

In May 1992, the National Institutes of Health's Office of Scientific Integrity and Public Health Service's Office of Scientific Integrity Review merged to form the Office of Research (1992; Price, 1994). Since 1992, the Office of Research has overseen research misconduct by requiring institutions to have policies in place, by conducting independent investigations, and by reporting its investigative findings in annual reports (Pascal, 2006).

Prevalence of Misconduct

Between 1974 and 1981, there were 12 cases of alleged misconduct in the United States (Benos et al., 2005; see also ORI's Web site, n.d., *About ORI—History*). More recently, according to the Office of Research Integrity (2007), the numbers of new allegations were as follows: 86 (1993); 89 (1994); 104 (1995); 127 (1996); 92 (1997); 69 (1998); 89 (1999); 103 (2000); 127 (2001); 163 (2002); 136 (2003); 120 (2004); and 137 (2005a; Table 9, p. 38; see also Reynolds, 2004). Not all allegations warranted investigation under the federal rules of misconduct.

According to the Office of Research Integrity (2007), the number of actual new cases warranting at least a preinvestigatory inquiry were as follows: 77 (1993); 64 (1994); 81 (1995); 70 (1996); 64 (1997); 54 (1998); 63 (1999); 62 (2000); 72 (2001); 83 (2002); 105 (2003); 81 (2004); and 92 (2005a; Table 9, p. 38). The Office of Research Integrity (2007) reported that in 2006, it received 267 allegations, of which 22 were referred to other agencies, 174 were dismissed with no action, and 71 underwent a preassessment inquiry (p. 3). Of the 71 subject to an inquiry, 29 underwent formal investigations. During 2006, the Office of Research Integrity closed 35 cases that "resulted in sustained findings of research misconduct and PHS administrative actions against the respondent" (ORI, 2007, p. 3; case summaries are provided in the appendix to each annual report; see ORI, 2003, 2004, 2005a, 2006b, 2007). Parrish and Noonan (2009) provided a comprehensive review of the Office of Research Integrity cases in which image manipulation constituted research misconduct. In summary, the Office of Research Integrity enforces federal research misconduct regulations pertaining to intentional fabrication, falsification, and plagiarism during the proposing, performing, reviewing, or reporting of research results. The number of such cases has increased over the past several decades, but the actual prevalence of misconduct is unknown.

Penalties for Research Misconduct

Consequences for individuals found responsible for intentional misconduct can include article retraction (e.g., Daroff, 2005, citing Abbs, Hartman, & Vishwanat, 1996 [retraction]), private lawsuits (e.g., *Abbs v. Sullivan*, 1992; *Berge v. University of Alabama*, 1997; *Phinney v. Verbrugge*, 1997), adverse personnel actions by universities (Wenger et al., 1998), and administrative, civil, and criminal sanctions. Redman and Merz (2008) asked, "Do the punishments fit the crime?" and concluded, "Whether sanctions meted out across the scientific establishment are reasonable and fairly applied requires further study" (p. 775; see also Redman & Caplan, 2005).

Administrative actions. The Office of Research Integrity is empowered to take a number of administrative actions, including the following:

debarment from eligibility to receive Federal funds for grants and contracts, prohibition from service on PHS advisory committees, peer review committees, or as consultants, certification of information sources by respondent that is forwarded by institution, certification of data by institution, imposition of supervision on the respondent by the institution, submission of a correction of a published article by respondent, and submission of a retraction of a[sic] published articles by respondent. (ORI Web site, n.d., *Handling Misconduct: Administrative Actions*)

Publication of names. The names of individuals found responsible for research misconduct are published by the Office of Research Integrity on its Web site, in the Office of Research Integrity Newsletter, and in the Federal Register. The Office of Research Integrity also enters names into two of its databases. The Office of Research Integrity Annual Report 2006 (ORI, 2007) explained:

Individuals are entered into the PHS ALERT system when (a) PHS has made a finding of research misconduct concerning the individual, (b) the individual is the subject of an administrative action imposed by the federal government as a result of a determination that research misconduct has occurred, (c) the individual has agreed to voluntary corrective action as a result of an investigation of research misconduct, or (d) ORI has received a report of an investigation by an institution in which there was a finding of research misconduct concerning the individual and ORI has determined that PHS has jurisdiction. The PHS ALERT is not a public system. (p. 41) In contrast,

When individuals in the PHS ALERT system have an ORI research misconduct finding made against them and/or have PHS administrative actions imposed on them, they are also listed on the PHS Administrative Actions Bulletin Board (AABB), a public system of records that may be accessed through the ORI website. (ORI, 2007, p. 42)

Civil penalties. In addition to the Office of Research Integrity administrative actions, misuse of federal funds resulting from false or fraudulent statements can lead to civil penalties under the False Claims Act (18 U.S.C. s1001 et seq., as amended, 1986; Sherman, 1995, 1997; *Cantekin v. University of Pittsburgh*, 1999; see Dahlberg & Mahler, 2006).

Criminal penalties. Finally, egregious misconduct is susceptible to criminal sanctions (Kalb & Koehler, 2002; Redman & Caplan, 2005). For example, *United States of America v. Eric T. Poehlman* (2005b) involved a scientist at the University of Vermont. He was found liable for falsifying data records, grant proposals, and 10 published articles, as well as obstructing the investigation. The Poehlman case represented "the first occasion that a research scientist was sentenced to a term of federal imprisonment for committing fraud in PHS-supported research" (ORI, 2007, p. 70; ORI, 2005b; see also Dahlberg & Mahler, 2006).

In a case involving conduct that caused harm to a human participant, Paul H. Kornak, former research coordinator at the Stratton Veterans Administration Medical Center, was found guilty of criminally negligent homicide and other crimes after he falsely stated the patient met inclusion and exclusion criteria for a cancer treatment study (ORI, 2006a, 2007; United States of America v. Paul H. Kornak, 2005). Another disturbing case is that of Anne L. Butkovitz, a pediatric study coordinator for a safety trial of a vaccine being conducted worldwide under the auspices of the Food and Drug Administration. Trial participants were 2, 4, and 6 months of age. Butkovitz was required to contact parents at specific intervals (7, 14, and 42 days after administration of the vaccine or placebo) to inquire about intussesception (blocked bowel syndrome) and other serious adverse events. According to the legal record, she did not contact parents, yet recorded (falsely) that she had contacted them, and reported (falsely) the absence of adverse events. She received a criminal penalty under the federal False Claims Act (18 U.S.C. s1001) and was permanently debarred by the Food and Drug Administration (Food and Drug Administration, 2006; United States of America v. Butkovitz, 2005).

Improper Research Practices

Adjudicated misconduct by the Office of Research Integrity is distinguishable from the actual—or perceived-prevalence of misconduct, questionable research practices, or regulatory noncompliance. The latter data are captured in surveys of students, faculty members, and research investigators regardless of whether their research activities are federally funded. Swazey, Anderson, and Lewis (1993) surveyed faculty and students about misconduct, and found that both students and faculty had knowledge of plagiarism and data falsification by each other. They also found a high prevalence of other problems, such as misuse of institutional resources, inappropriate assignment of authorship of research papers, and reluctance to report misconduct or questionable practices due to fear of retaliation (Swazev et al., 1993). Altman (1994) explained that scientists' reluctance to report perceived misconduct has been referred to as "structured silence" (attributing this characterization to Judith P. Swazey and her colleague Renee C. Fox).

Among faculty, the "publish or perish" culture of science and academic life (Woolf, 1986) may be a contributing factor to improper research practices (actual or perceived; Braxton & Bayer, 1994); among students, the competitiveness of the research and training environment may contribute to improper practices (Anderson, Louis, & Earle, 1994; Anderson, Ronning, et al., 2007). Davis (2003) suggested that cultural differences might play a role. Research by Wright et al. (2008) suggested that trainees' levels of "stress" (p. 330) or "the absence of capable supervision and the lack of informal social interaction" among mentors and trainees (p. 334) might be causal factors. Anderson et al., in contrast, in a survey of 1,261 students across four disciplines, failed to find an association between research misconduct and "departmental structure or climate," and attributed misconduct to "individual predilections or failures of judgment" (p. 343). Davis et al. (2007) examined individual, situational, organizational, structural, and cultural factors in 92 case files in which the Office of Research Integrity had found misconduct. Their cluster analysis revealed that several factors contribute to misconduct, including stressors, personality factors, and organizational climate.

Regardless of the reasons or explanations for research misconduct, and other serious deviations from the norms of science, some notable commentators regard the situation as "scandalous." Lamenting the poor quality of medical research, Altman (1994), in *BMJ*, wrote, "We need less research, better research, and research done for the right reasons. Abandoning using the number of publications as a measure of ability would be a start" (p. 284). Wagena (2005), in the *Journal of Medical Ethics*, wrote about the unfair and unethical practice of misappropriation of authorship by senior faculty. Anderson (2007) urged scientists to adopt behavioral standards for research integrity, and Wester, Willse, and Davis (2008) developed the Responsible Conduct of Research Measure in an attempt to quantify the likelihood of engaging in research misconduct or questionable research practices. Numerous other investigators have gathered empirical data to help determine the scope of the problem.

Impact of Research Misconduct and Improper Practices

In 2002, Steneck conducted a comprehensive review of integrity of publicly funded research. He asked, "How much does a case of misconduct in research actually cost the public in terms of wasted research dollars, of deceptive findings that mislead other researchers until the misconduct is discovered, and perhaps of negative impacts on patient health?" (p. 3). Steneck's review suggested that actual misconduct as defined by federal law amounts to approximately 1 in 100,000 occurrences per year, but empirical studies suggest that intentional research misconduct rates may be much higher, and that other infractions not rising to the level of legally defined research misconduct are prevalent. Steneck also reported that (a) cheating in college may correlate with later research misconduct (see also Harding, Carpenter, Finelli, & Passow, 2004); (b) researchers are reluctant to report suspected misconduct: and (c) other "questionable research practices" (e.g., misuse of statistics, inaccurate citations, bias during in peer review, and duplicate publications) hover at prevalence rates at or above 10% (pp. 4-8).

Claxton (2005a) conducted a comprehensive review of research misconduct cases, and concluded that "fewer than 30 scientists published less than ~80 scientific papers per year out of over 400,000 (~0.02%) in the NIH funded or associated biomedical sciences containing information known to be fraudulent" (p. 23). After looking at PubMed retractions and Federal Drug Administration audits, and broadening his search to "scientifically inaccurate"—rather than scientifically fraudulent articles, Claxton (2005a) attributed published errors to "poorly conceived or executed science, investigator bias or lack of understanding, or negligence" (p. 24; see also Claxton, 2005b).

Gardner, Lidz, and Hartwig (2005) surveyed authors from the Cochrane Database of Systematic Reviews who had published results of pharmaceutical clinical trials from 1998 to 2001 and achieved a 64% (322 of 504) response rate. Their survey instrument asked whether there "was fabrication or misrepresentation in the target publication," whether "the author had participated in research involving misconduct during the past 10 years," and "whether there was fabrication in the study in the past 10 years that they personally knew about." Of the target articles, only two instances of misconduct (0.6%) occurred. However, 15 (4.7%) of the authors said they had participated in a project involving fabrication or misrepresentation as follows. Four had fabricated or falsified data; three had deleted data in an unjustified way; three had reported the design in a deceptive or misleading way; four had reported the data in a deceptive or misleading way; five had interpreted the results in a seriously misleading manner; and two reported other problems (Gardner et al., 2005, Table 2, p. 248). One in six authors (56, or 17.4%) reported at least one problem in studies they knew about (Gardner et al., 2005, Table 3, p. 249). Gardner and colleagues extrapolated from their findings, and concluded:

- less than one clinical trial report in 100 "is characterized by fraud or misrepresentation,"
- "researchers have a meaningful chance of encountering misconduct during their careers,"
- "perhaps 10–15% would be exposed to such misconduct over a 30-year career," and
- "40% or more of researchers would have personal knowledge of fraud or misrepresentation during a 30-year career." (p. 250)

In a series of papers by Martinson and colleagues (Anderson, Horn, et al., 2007; de Vries, Anderson, & Martinson, 2006; Martinson, Anderson, Crain, & de Vries, 2006; Martinson, Anderson, & de Vries, 2005), the prevalence of self-reported awareness of, or involvement in, research misconduct received further empirical support. Martinson et al. (2005) surveyed early- and mid-career extramural National Institutes of Health researchers, thus yielding 1,479 and 1,768 useable responses, respectively. Respondents admitted falsifying research data (0.3%), shirking human subject requirements (0.3%), using other's ideas without permission or attribution (1.4%), failing to present contradictory evidence (6.0%), "overlooking others' use of flawed data or questionable interpretation of data" (12.5%), and "changing the design, methodology or results of a study in response to pressure from funding source" (15.5; Martinson et al., 2005, p. 737). "Overall, 33% of the respondents said they had engaged in at least one of the top ten behaviours during the previous three years among mid-career respondents, this proportion was 38%; in the early-career group, it was 28%" (Martinson et al., 2005, p. 738). Anderson, Horn, et al. (2007) found that problematic behaviors (regarding data, methods, peer review, assignment of credit, and so on) were evident in both early- and mid-career National Institutes of Health scientists, and further, that depending on the method of ethics training and type of mentoring, the odds of occurrence of the self-reported problematic behaviors either decreased or increased, particularly in early-career respondents.

Thus, violations of the norms of the responsible conduct of research clearly go beyond the federal definition: "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results" (Public Health Service, 2005, §93.103). Approaches used to remedy this problem include (a) prevention through greater emphasis on quality over quantity of publications, as well as enhanced fairness of peer review (Martinson et al., 2006); (b) detection of fraudulent data through enhanced training and supervision, as well as through the use of statistical methods and technology (Al-Marzouki, Evans, Marshall, & Roberts, 2005; Parrish & Noonan, 2009); and (c) punishments "that fit the crime" (Redman & Caplan, 2005; Redman & Merz, 2008; Wenger et al., 1998).

In closing, research practices that represent significant departures from accepted norms are problematic for science. Different disciplines have different norms, and the publish-or-perish culture of science places enormous demands on scientists. Nevertheless, all investigators are responsible for maintaining high standards while proposing, performing, reviewing, and publishing research. All scientific professional bodies, universities, and the Office of Research Integrity are responsible for holding investigators accountable for their work. The Office of Research Integrity, policymakers, and scientists believe that prevention is the key to preserving the integrity of science, and "to have an effect on the broader research environment, education to promote research integrity must reach researchers at all levels" (Heitman, Anestidou, Olsen, & Bulger, 2005, p. 49; Vasgird, 2007; see also Minifie et al., 2011).

Summary

The purpose of this review of authoritative documents, insightful commentary, and empirical literature regarding publication practices and authorship, conflicts of interest, and research misconduct was to inform readers of the importance of RCR in all dimensions and stages of research. Regardless of one's level of experience, integrity is essential while proposing, performing, reviewing, and publishing research. All who are involved in the research enterprise-at all levels-should be aware of and adhere to publication guidelines and conflict of interest policies and regulations, and to avoid practices that falsify, fabricate, or plagiarize, or otherwise violate the expectations of the scientific community as articulated by the requirements of academic institutions, professional/ scientific societies, or journal publication boards. To act otherwise is to impair one's reputation and livelihood, to harm an enterprise that is reliant on trust, and to impair the integrity of the scientific record.

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References

Abbs, J. H., Hartman, D. E., & Vishwanat, B. (1987). Orofacial motor control impairment in Parkinson's disease. *Neurology*, 37, 394–398 [retraction in *Neurology* 1996, 47(2), 340].

Abbs v. Sullivan, 963 F.2d 918 (7th Cir. 1992).

- Adams, D., & Pimple, K. D. (2005). Research misconduct and crime lessons from criminal science on preventing misconduct and promoting integrity. *Accountability in Research, 12, 225–240.*
- Al-Marzouki, S., Evans, S., Marshall, T., & Roberts, I. (2005). Are these data real? Statistical methods for the detection of data fabrication in clinical trials. *BMJ*, 331, 267–270.
- Altman, D. G. (1994). The scandal of poor medical research: We need less research, better research, and research done for the right reasons [Editorial]. *BMJ*, 308, 283–284.
- Alt-White, A. C., & Pranulis, M. F. (2006). Addressing nurses' ethical concerns about research in critical care settings. *Nursing Administration Quarterly*, 30, 67–75.
- American Medical Association. (1990). Conflicts of interest in biomedical research. JAMA: Journal of the American Medical Association, 263, 2790–2793.
- American Medical Association. (2001). Principles of medical ethics. Retrieved from http://www.ama-assn.org/ ama/pub/physician-resources/medical-ethics/code-medicalethics/principles-medical-ethics.shtml.
- American Medical Association. (2007). AMA manual of style (10th ed.). New York, NY: Oxford University Press.
- American Medical Association, Council on Ethical and Judicial Affairs. (1999). Opinion 8.031—Conflicts of Interest: Biomedical Research. Retrieved from http://www. ama-assn.org/ama/pub/physician-resources/medical-ethics/ code-medical-ethics/opinion8031.shtml.
- American Psychological Association. (2001). Publication manual of the American Psychological Association (5th ed.). Washington, DC: Author.
- American Psychological Association. (2003). *Ethical* principles of psychologists and code of conduct. Washington, DC: Author. Retrieved from http://www.apa.org/ethics/ code2002.html.
- American Psychological Association. (2010). Publication manual of the American Psychological Association (6th ed.). Washington, DC: Author.
- American Speech-Language-Hearing Association. (2003). Code of ethics. ASHA Supplement, 23, 13–15. Rockville, MD: Author. Retrieved from http://www.asha.org/docs/ html/ET2003-00166.html.
- Anderson, L. C. (2007). Institutional and IACUC responsibilities for animal care and use education and training programs. *Institute for Laboratory Animal Research (ILAR) Journal*, 48, 90–95.
- Anderson, M. S., Horn, A. S., Risbey, K. R., Ronning, E. A., de Vries, R., & Martinson, B. C. (2007). What do mentoring and training in the responsible conduct of research have to do with scientists' misbehavior? Findings from a national survey of NIH-funded scientists. *Academic Medicine*, 82, 853–860.

- Anderson, M. S., Louis, K. S., & Earle, J. (1994). Disciplinary and departmental effects on observations of faculty and graduate student misconduct. *Journal of Higher Education*, 65, 331–350.
- Anderson, M. S., Ronning, E. A., de Vries, R., & Martinson,
 B. C. (2007). The perverse effects of competition on scientists' work and relationships. *Science and Engineering Ethics*, 13, 437–461.
- Angell, M. (1993). The doctor as double agent. *Kennedy* Institute of Ethics Journal, 3, 287–292.
- Appelbaum, P. S., Roth, L. H., Lidz, C. W., Benson, P., & Winslade, W. (1987). False hopes and best data: Consent to research and the therapeutic misconception. *Hastings Center Report*, 17, 20–24.
- Association of American Medical Colleges, AAMC Task Force on Financial Conflicts of Interest in Clinical Research. (2003a). Protecting subjects, preserving trust, promoting progress. I: Policy and guidelines for the oversight of individual financial interest in human subjects research. Academic Medicine, 78, 225–236.
- Association of American Medical Colleges, AAMC Task Force on Financial Conflicts of Interest in Clinical Research. (2003b, February). Protecting subjects, preserving trust, promoting progress. II: Principles and recommendations for oversight of an institution's financial interests in human subjects research. Academic Medicine, 78, 237–245.
- Barrett, K. A., Funk, C. L., & Macrina, F. L. (2005). Awareness of publication guidelines and the responsible conduct of research. *Accountability in Research: Policies and Quality Assurance*, *12*, 193–206.
- Benos, D. J., Fabres, J., Farmer, J., Gutierrez, J. P., Hennessy, K., Kosek, D., ... Wang, K. (2005). Ethics and scientific publication. Advances in Physiology Education, 29, 59–74.

Berge v. University of Alabama, 104 F. 3d 1453 (4th Cir. 1997).

- Bilic-Zulle, L., Azman, J., Frkovic, V., & Petrovecki, M. (2008). Is there an effective approach to deterring students from plagiarizing? *Science and Engineering Ethics*, 14, 139–147.
- Blumsohn, A. (2006, Summer). Authorship, ghost-science, access to data and control of the pharmaceutical scientific literature: Who stands behind the word? *Professional Ethics Report, 19,* 1–4.
- Bodenheimer, T. (2000). Uneasy alliance—Clinical investigators and the pharmaceutical industry. *New England Journal of Medicine*, 342, 1539–1544.
- Bouville, M. (2008). Plagiarism: Words and ideas. Science and Engineering Ethics, 14, 311–322.
- Bradley, S. G. (2005). Managing competing interests. In F. L. Macrina (Ed.), *Scientific integrity: Text and cases in responsible conduct of research* (3rd ed., pp. 159–186). Washington, DC: ASM Press.
- Braxton, J. M., & Bayer, A. E. (1994). Perceptions of research misconduct and an analysis of their correlates. *The Journal of Higher Education*, 65, 351–372.
- Brennan, T. A., Rothman, D. J., Blank, L., Blumenthal,
 D., Chimonas, S. C., Cohen, J. J., ... Smelser, N. (2006).
 Health industry practices that create conflicts of interest:
 A policy proposal for academic medical centers. *JAMA: Journal of the American Medical Association*, 295, 429–433.

- Broad, W. J., & Wade, N. (1982). Betrayers of the truth: Fraud and deceit in the halls of science. New York, NY: Oxford University Press.
- Broccolo, B. M., & Klanica, K. E. (2006). Conflicts of interest in human subject research: Adapting to evolving best practice standards. *Medical Research Law & Policy Report, 6*, 690–699.
- Buchkowsky, S. S., & Jewesson, P. J. (2004). Industry sponsorship and authorship of clinical trials over 20 years. *Annals of Pharmacotherapy, 38*, 579–585.
- Budd, J. M., Sievert, M. E., & Schultz, T. R. (1998). Phenomena of retraction: Reasons for retraction and citations to the publications. *JAMA: Journal of the American Medical Association, 280, 296–297.*
- Cantekin v. University of Pittsburgh, 192 F.3d 402 (3rd Cir. 1999).
- Claxton, L. D. (2005a). Scientific authorship Part 1. A window into scientific fraud? *Mutation Research*, 589, 17–30.
- Claxton, L. D. (2005b). Scientific authorship Part 2. History, recurring issues, practices, and guidelines. *Mutation Research*, 589, 31–45.
- **Cohen, J. J.** (2001). Trust us to make a difference: Ensuring public confidence in the integrity of clinical research. *Academic Medicine*, *76*, 209–214.
- Cokol, M., Iossifov, I., Rodriquez-Estaban, R., & Rzhetsky, A. (2007). How many papers should be retracted? *EMBO Reports (European Molecular Biology Organization), 8,* 422–423.
- **Committee on Publication Ethics.** (2000). Guidelines on good publication practice. *Journal of Urology, 163,* 249–252.
- Committee on Publication Ethics. (2005). *The COPE* report 2005. Retrieved from http://publicationethics.org/ files/u2/2005_report.pdf.
- Cowell, H. R. (2000). Ethical responsibilities of editors, reviewers, and authors. *Clinical Orthopaedics and Related Research*, 378, 83–89.
- **Coyne**, **J**. (2005). Lessons in conflict of interest: The construction of the martyrdom of David Healy and the dilemma of bioethics. *American Journal of Bioethics*, *5*, W3–W14.
- **Dahlberg, J.** (2007). ORI retains its working definition of plagiarism under new regulations. *Office of Research Integrity Newsletter, 15, 4.*
- **Dahlberg, J. E., & Mahler, C. C.** (2006). The Poehlman case: Running away from the truth. *Science and Engineering Ethics, 12,* 157–173.
- Daroff, R. B. (2005). Report from the *Neurology* scientific integrity advisor: Year 1. *Neurology*, 64, 588–589.
- **Daroff, R. B.** (2007). Report from the scientific integrity advisor: Issues arising in 2005 and 2006. *Neurology, 68,* 1841–1842.
- Davidoff, F., DeAngelis, C. D., Drazen, J. M., Hoey, J., Hojgaard, L., Horton, R., ... Wilkes, M. S. (2001). Sponsorship, authorship, and accountability. *The Lancet*, 358, 854–856.
- Davis, M. S. (2003). The role of culture in research misconduct. Accountability in Research, 10, 189–201.
- **Davis, M. S., Riske-Morris, M., & Diaz, S. R.** (2007). Causal factors implicated in research misconduct:

Evidence from ORI case files. *Science and Engineering Ethics*, *13*, 395–414.

- **DeAngelis, C. D., Fontanarosa, P. B., & Flanagin, A.** (2001). Reporting financial conflicts of interest and relationships between investigators and research sponsors. *JAMA: Journal of the American Medical Association, 286,* 89–91.
- de Vries, R., Anderson, M. S., & Martinson, B. C. (2006). Normal misbehavior: Scientists talk about the ethics of research. *Journal of Empirical Research on Human Re*search Ethics, 1, 43–50.
- Drenth, J. P. H. (1998). Multiple authorship: The contribution of senior authors. JAMA: Journal of the American Medical Association, 280, 219–221.
- **Emanuel, E. J.** (2005). Undue inducement: Nonsense on stilts? *American Journal of Bioethics*, *5*, 9–13.
- False Claims Act (1863). 18 U.S.C. §1001 et seq.
- False Claims Amendments Act of 1986. Pub. L. 99-562, 100 Stat. 3153.
- Flanagin, A., Carey, L. A., Fontanarosa, P. B., Phillips, S. G., Pace, B. P., Lundberg, G. D., & Rennie, D. (1998). Prevalence of articles with honorary authors and ghost authors in peer-reviewed medical journals. *JAMA: Journal* of the American Medical Association, 280, 222–224.
- Food and Drug Administration. (2006). Anne L. Butkovitz; Debarment order. *Federal Register*, 70, 61061.
- Fox, M. F. (1994). Scientific misconduct and editorial and peer review processes. *Journal of Higher Education*, 65, 298–309.
- Frazzetto, G. (2004). Who did what? (Uneasiness with the current authorship system is prompting the scientific community to seek alternatives). *EMBO Reports (European Molecular Biology Organization)*, 5, 446–448.
- Friedman, L. S., & Richter, E. D. (2004). Relationship between conflicts of interest and research results. *Journal* of General Internal Medicine, 19, 51–56.
- Gardner, W., Lidz, C. W., & Hartwig, K. C. (2005). Authors' reports about research integrity problems in clinical trials. *Contemporary Clinical Trials*, *26*, 244–251.
- Garrison, H. H., Gerbi, S. A., & Kincade, P. W. (2003). In an era of scientific opportunity, are there opportunities for biomedical scientists? *FASEB Journal*, 17, 2169–2173.
- Goldner, J. A. (1998). The unending saga of legal controls over scientific misconduct: A clash of cultures needing resolution. *American Journal of Law & Medicine*, 24, 293–343.
- Hamilton, D. P. (1994). In the trenches, doubts about scientific integrity: American Association for the Advancement of Science survey about scientific misconduct investigations. *Science*, 255, 1636.

Hamilton, D. P. (1997). Verdict in sight in the "Baltimore Case." In D. Elliott & J. E. Stern (Eds.), *Research ethics: A reader* (pp. 52–59). Hanover, NH: University Press of New England.

- Harding, T. S., Carpenter, D. D., Finelli, D. J., & Passow, H. J. (2004). Does academic dishonesty relate to unethical behavior in professional practice? An exploratory study. *Science and Engineering Ethics*, 10, 311–324.
- Heitman, E., Anestidou, L., Olsen, C., & Bulger, R. E. (2005). Do researchers learn to overlook misbehavior? *Hastings Center Report, 35,* 49.
- Hilts, P. J. (1997). The science mob: The David Baltimore case—And its lessons. In D. Elliott & J. E. Stern (Eds.),

Research ethics: A reader (pp. 43–51). Hanover, NH: University Press of New England.

- **Hoey, J.** (2000). Who wrote this paper anyway? The new Vancouver Group statement refines the definition of authorship. *Canadian Medical Association Journal*, *163*, 716–717.
- Horner, J., & Minifie, F. D. (2011a). Research ethics I: Responsible conduct of research (RCR)—Historical and contemporary issues pertaining to human and animal experimentation. *Journal of Speech, Language, and Hearing Research, 54*(Suppl.), S303–S329.
- Horner, J., & Minifie, F. D. (2011b). Research ethics II: Mentoring, collaboration, peer review, and data management and ownership. *Journal of Speech, Language, and Hearing Research, 54*(Suppl.), S330–S345.
- Horton, R. (2002). The hidden research paper. JAMA: Journal of the American Medical Association, 287, 2775–2778.
- Huth, E. J. (1986a). Abuses and uses of authorship. Annals of Internal Medicine, 104, 266–267.
- Huth, E. J. (1986b). Irresponsible authorship and wasteful publication. Annals of Internal Medicine, 104, 257–259.
- Ingham, J. C., & Horner, J. (2004, March). Ethics and research [Feature]. *The ASHA Leader*. Retrieved from http://www.asha.org/Publications/leader/2004/040316/ f040316c.htm.
- Ingham, J. C., Minifie, F. D., Horner, J., Robey, R. R., Lansing, C., McCartney, J. H., ... Moss, S. E. (2011). Ethical principles associated with the publication of research in ASHA's scholarly journals: Importance and adequacy of coverage. *Journal of Speech, Language, and Hearing Research, 54*(Suppl.), S394–S416.
- International Committee of Medical Journal Editors. (2010). Uniform requirements for manuscripts submitted to biomedical journals: Writing and editing for biomedical publication. Retrieved from http://www.icmje.org/urm_full.pdf.
- Janssen, R. L. (2003). Researcher liability for negligence in human subject research: Informed consent and researcher malpractice actions. Washington Law Review, 78, 229–260.
- Jennings, R. C. (2004). Data selection and responsible conduct: Was Millikan a fraud? *Science & Engineering Ethics*, 10, 639–653.
- Kalb, P. E., & Koehler, K. G. (2002). Legal issues in scientific research. JAMA: Journal of the American Medical Association, 287, 85–91.
- Kelly, R. E., Cohen, L. J., Semple, R. J., Bialer, P., Lau, A., Bodenheimer, A., ... Galynker, I. I. (2006). Relationship between drug company funding and outcomes of clinical psychiatric research. *Psychological Medicine*, 36, 1647–1656.
- Keranen, L. (2006). Assessing the seriousness of research misconduct: Considerations for sanction assignment. *Accountability in Research, 13,* 179–205.
- Kim, S. Y., Millard, R. W., Nisbet, P., Cox, C., & Caine, E. D. (2004). Potential research participants' views regarding researcher and institutional conflicts of interest. *Journal of Medical Ethics*, 30, 73–79.
- **Kimmelman, J.** (2007). The therapeutic misconception at 25: Treatment, research, and confusion. *Hastings Center Report*, *37*, 36–42.
- Kinitisch, E. (2005). Researcher faces prison for fraud in NIH grant applications and papers. *Science*, 307, 1851.

- Kjaergard, L. L., & Als-Nielsen, B. (2002). Association between competing interests and authors' conclusions: Epidemiological study of randomised clinical trials published in the BMJ. *BMJ*, 325, 249–252. Retrieved from http://www.bmj.com/cgi/reprint/325/7358/249.
- Klanica, K. (2005). Conflicts of interest in medical research: How much conflict should exceed legal boundaries? *Journal* of Biolaw & Business, 8, 37–45.
- **Koppelman-White, E.** (2006). Research misconduct and the scientific process: Continuing quality improvement. *Accountability in Research, 13,* 225–246.
- Krimsky, S. (2007). When conflict-of-interest is a factor in scientific misconduct. *Medicine and Law, 26,* 447–463.
- Lexchin, J., Beros, L. A., Djulbegovic, B., & Clark, O. (2003). Pharmaceutical industry sponsorship and research outcome and quality: Systematic review. *BMJ*, 326, 1167–1177.
- Martinson, B. C., Anderson, M. S., Crain, A. L., & de Vries, R. (2006). Scientists' perceptions of organizational justice and self-reported misbehaviors. *Journal of Empirical Research on Human Research Ethics*, 1, 51–66.
- Martinson, B. C., Anderson, M. S., & de Vries, R. (2005). Scientists behaving badly. *Nature*, 435, 737–738.
- Marusic, A., Katavic, V., & Marusic, M. (2007). Role of editors and journals in detecting and preventing scientific misconduct: Strengths, weaknesses, opportunities, and threats. *Medicine and Law*, 26, 545–566.
- McCrary, S. V., Anderson, C. B., Jakovljevic, J., Khan, T., McCullough, L. B., Wray, N. P., & Brody, B. A. (2000). A national survey of policies on disclosure of conflicts of interest in biomedical research. *New England Journal of Medicine*, 343, 1621–1626.
- Mello, M. M., & Brennan, T. A. (2003). Due process in investigations of research misconduct. New England Journal of Medicine, 349, 1280–1286.
- Miller, F. G., & Joffe, S. (2006). Evaluating the therapeutic misconception. *Kennedy Institute of Ethics Journal, 16,* 353–366.
- Miller, F. G., & Rosenstein, D. L. (2003). The therapeutic orientation to clinical trials. New England Journal of Medicine, 348, 1383–1386.
- Minifie, F. D., Robey, R. R., Horner, J., Ingham, J. C., Lansing, C., McCartney, J. H., ... Moss, S. E. (2011). Responsible conduct of research in communication sciences and disorders: Faculty and student perceptions. *Journal* of Speech, Language, and Hearing Research, 54(Suppl.), S363–S393.
- Morin, K., Rakatansjy, H., Riddick, F. A., Morse, L. J., O'Bannon, J. M., III, Goldrich, M. S., ... Spillman, M. A. (2002). Managing conflicts of interest in the conduct of clinical trials. *JAMA: Journal of the American Medical Association, 287,* 78–84.
- National Bioethics Advisory Commission. (2001). Ethical and policy issues in research involving human participants: Vol. 1. Retrieved from http://bioethics.georgetown.edu/nbac/ human/overvol1.html.
- National Institutes of Health. (2004). Scientific peer review of research grant applications and research and development contract projects (final rule). *Federal Register*, 69, 272–278.
- National Research Council, Committee on National Needs for Biomedical and Behavioral Scientists, Education and Career Studies Unit, & Office of

Scientific and Engineering Personnel. (2000). Addressing the nation's changing needs for biomedical and behavioral scientists. Washington, DC: National Academies Press. Retrieved from http://www.nap.edu/catalog.php? record id=9827.

National Science Foundation. (2002). Research misconduct (final rule). *Federal Register*, 67, 11936–11939.

Neale, A. V., Northrup, J., Dailey, R., Marks, E., & Abrams, J. (2007). Correction and use of biomedical literature affected by scientific misconduct. *Science and Engineering Ethics*, 13, 5–24.

Office of Research Integrity. (n.d.). *About ORI—History*. Rockville, MD: Author. Retrieved from http://www.ori.dhhs. gov/about/history.shtml.

Office of Research Integrity. (n.d.). *Handling misconduct: Administrative actions*. Rockville, MD: Author. Retrieved from http://ori.hhs.gov/misconduct/admin_actions.shtml.

Office of Research Integrity. (n.d.). Legal concerns: Federal court decisions. Rockville, MD: Author. Retrieved from http://ori.hhs.gov/misconduct/Legal Rulings.shtml.

Office of Research Integrity. (1992). U.S. DHHS, statement of organization, functions and delegation of authority. *Federal Register*, 57, 24262–24263.

Office of Research Integrity. (1994). ORI policy on plagiarism. Rockville, MD: Author. Retrieved from http://www.ori. dhhs.gov/policies/plagiarism.shtml.

Office of Research Integrity. (1996a). James H. Abbs, Ph.D., University of Wisconsin—Madison [Case summary]. *ORI Newsletter*, 4, 4–5. Retrieved from http://ori.hhs.gov/ documents/newsletters/vol4_no3.pdf.

Office of Research Integrity. (1996b). Thereza Imanishi-Kari. ORI Newsletter; 4, 1.Retrieved from http://ori.dhhs.gov/ documents/newsletters/vol4_no4.pdf.

Office of Research Integrity. (2000). Final PHS policy for instruction in the responsible conduct of research [Announcement]. *Federal Register*, 65(236), 76647. Retrieved from http://www.ori.dhhs.gov/policies/RCR_Policy.shtml.

Office of Research Integrity. (2003). Annual report 2002. Rockville, MD: Author. Retrieved from http://ori.dhhs.gov/ documents/annual_reports/ori_annual_report_2002.pdf.

Office of Research Integrity. (2004). Annual report 2003. Rockville, MD: Author. Retrieved from http://ori.dhhs.gov/ documents/annual_reports/ori_annual_report_2003.pdf.

Office of Research Integrity. (2005a). Annual report 2004. Rockville, MD: Author. Retrieved from http://ori.dhhs.gov/ documents/annual_reports/ori_annual_report_2004.pdf.

Office of Research Integrity. (2005b). Federal Register findings of scientific misconduct notice: Dr. Eric T. Poehlman. *Federal Register*, 70, 15092–15095.

Office of Research Integrity. (2006a). Finding of debarment notice: Paul Kornak, Stratton VA Medical Center. *Federal Register*, 71, 9555–9556.

Office of Research Integrity. (2006b). Annual report 2005. Rockville, MD: Author. Retrieved from http://ori.dhhs.gov/ documents/annual_reports/ori_annual_report_2005.pdf.

Office of Research Integrity. (2007). Annual report 2006. Rockville, MD: Author. Retrieved from http://ori.dhhs.gov/ documents/annual_reports/ori_annual_report_2006.pdf. Parrish, D., & Noonan, B. (2009). Image manipulation as research misconduct. *Science and Engineering Ethics*, 15, 161–167.

Pascal, C. B. (2006). Complainant issues in research misconduct: The Office of Research Integrity experience. *Experimental Biology and Medicine*, 231, 1264–1270.

Perlis, C. S., Harwood, M., & Perlis, R. H. (2005). Extent and impact of industry sponsorship conflicts of interest in dermatology research. *Journal of the American Academy of Dermatology*, 52, 967–971.

Phinney v. Verbrugge, 564 N.W.2d 532 (Mich. App. 1997).

Price, A. R. (1994). Definitions and boundaries of research misconduct. *Journal of Higher Education*, 65, 286–297.

Public Health Service. (2004). Financial relationships and interests in research involving human subjects: Guidance for human subject protection. *Federal Register*, 69, 26393–26397.

Public Health Service. (2005). Public Health Service policies on research misconduct (final rule). *Federal Register*, 70, 28370–28400.

Redman, B. K., & Caplan, A. L. (2005). Off with their heads: The need to criminalize some forms of scientific misconduct. *Journal of Law, Medicine & Ethics, 33,* 345–348.

Redman, B. K., & Merz, J. F. (2008). Scientific misconduct: Do the punishments fit the crime? *Science*, *321*, 775.

Redman, B. K., Templin, T. N., & Merz, J. F. (2006). Research misconduct among clinical trial staff. *Science and Engineering Ethics*, 12, 481–489.

Rennie, D., Yank, V., & Emanuel, L. (1997). When authorship fails: A proposal to make contributors accountable. JAMA: Journal of the American Medical Association, 278, 579–585.

Reynolds, S. M. (2004). ORI findings of scientific misconduct in clinical trials and publicly funded research 1992–2002. *Clinical Trials, 1,* 475–476.

Roberts, L. (1997). Misconduct: Caltech's trial by fire. In D. Elliott & J. E. Stern (Eds.), *Research ethics: A reader* (pp. 60–68). Hanover, NH: University Press of New England.

Schroter, S., Morris, J., Chaudhry, S., Smith, R., & Barratt, H. (2004). Does the type of competing interest statement affect readers' perception of the credibility of research? *BMJ*, *328*, 742–743.

Schulman, K. A., Seils, D. M., Timbie, J. W., Sugarman, J., Dame, L. A., Weinfurt, K. P., ... Califf, R. M. (2002). A national survey of provisions in clinical-trial agreements between medical schools and industry sponsors. *New England Journal of Medicine*, 347, 1335–1341.

Shamoo, A. E., & Resnik, D. B. (2003). *Responsible conduct* of research. New York, NY: Oxford University Press.

Sharav, V. H. (2006). Scientific fraud: Eric Poehlman/Richard Boris on. Retrieved from http://www.ahrp.org/cms/content/ view/370/150.

Sharp, R. R., & Yarborough, M. (2006). Currents in contemporary ethics: Informed trust and the financing of biomedical research. *Journal of Law, Medicine & Ethics*, 34, 460–463.

Sherman, S. A. (1995). The False Claims Act: Litigating scientific misconduct. *Public Health Reports*, 110, 784–789.

Sherman, S. A. (1997). The False Claims Act: Litigating scientific misconduct II. *Public Health Reports, 112,* 248.

Singer, N. (2009, August 18). Senator moves to block medical ghostwriting. *New York Times* [Business section], B1. Retrieved from http://www.nytimes.com/2009/08/19/health/ research/19ethics.html.

Sollitto, S., Hoffman, S., Mehlman, M., Lederman, R. J., Youngner, S. J., & Lederman, M. M. (2003). Intrinsic conflicts of interest in clinical research: A need for disclosure. *Kennedy Institute of Ethics Journal*, 13, 83–91.

Sox, H. C., & Rennie, D. (2006). Research misconduct, retraction, and cleansing the medical literature: Lessons from the Poehlman case. *Annals of Internal Medicine*, 144, E7–E11.

Steinberg, N. A. (2000). Regulation of scientific misconduct in federally funded research. Southern California Interdisciplinary Law Journal, 10, 39–105.

Steneck, N. H. (1994). Research universities and scientific misconduct: History, policies and the future. *Journal of Higher Education*, 65, 310–330.

Steneck, N. H. (2002). Assessing the integrity of publicly supported research. In N. H. Steneck & M. D. Scheetz (Eds.), *Investigating research integrity, proceedings of the first ORI research conference on research integrity* (pp. 1–16). Rockville, MD: Office of Research Integrity.

Stossel, T. P. (2005). Regulating academic–industrial research relationships—Solving problems or stifling progress? *New England Journal of Medicine*, 353, 1060–1065.

Strange, K. (2008). Authorship: Why not just toss a coin? American Journal of Physiology—Cell Physiology, 295, C567–C575.

Studdert, D. M., Mello, M. M., & Brennan, T. A. (2004). Financial conflicts of interest in physicians' relationships with the pharmaceutical industry—Self-regulation in the shadow of federal prosecution. New England Journal of Medicine, 351, 1891–1900.

Swazey, J. P., Anderson, M. S., & Lewis, K. S. (1993). Ethical problems in academic research. *American Scientist*, *81*, 542–553.

Trikalinos, N. A., Evangelou, E., & Ioannidis, J. P. A. (2008). Falsified papers in high-impact journals were slow to retract and indistinguishable from nonfraudulent papers. *Journal of Clinical Epidemiology, 6,* 464–470.

United States of America v. Butkovitz, Criminal No. 05-CR-10128-DPW (U.S. Dist. Ct., D. Mass., May 25, 2005).

United States of America, ex rel. Walter F. DeNino v. Eric T. Poehlman, Ph.D., No. 1:04-CV-310 (D.Vt. March 21, 2005).

United States of America v. Eric T. Poehlman, Criminal No. 2:05-cc-38-1 [Criminal information] (D.Vt. March 21, 2005a).

United States of America v. Eric T. Poehlman, No. 2:05-cv-66 [Settlement agreement and stipulation for entry of judgment] (D. Vt. March 21, 2, 2005b).

United States of America v. Paul H. Kornak, Criminal Action No. 03-CR-436 (FJS), U.S. District Court (N.D.N.Y., January 18, 2005). Retrieved from http://www.circare.org/lex/ 03cr436.pdf.

Vasgird, D. R. (2007). Prevention over cure: The administrative rationale for education in the responsible conduct of research. *Academic Medicine*, 82, 835–837.

Wagena, E. J. (2005). The scandal of unfair behaviour of senior faculty. *Journal of Medical Ethics*, 31, 308. doi: 10.1136/jme.2004.009308. Weinfurt, K. P., Dinan, M. A., Allsbrook, J. S., Friedman, J. Y., Hall, M. A., Schulman, K. A., & Sugarman, J. (2006). Policies of academic medical centers for disclosing financial conflicts of interest to potential research participants. Academic Medicine, 81, 113–118.

Weinfurt, K. P., Friedman, J. Y., Dinan, M. A., Allsbrook, J. S., Hall, M. A., Khillon, J. K., & Sugarman, J. (2006). Disclosing conflicts of interest in clinical research: Views of institutional review boards, conflict of interest committees, and investigators. *Journal of Law, Medicine & Ethics, 34*, 581–591.

Weinfurt, K. P., Hall, M. A., Dinan, M. A., DePuym, V., Friedman, J. Y., Allsbrook, J. S., & Sugarman, J. (2008). Effects of disclosing financial interests on attitudes toward clinical research. *Journal of General Internal Medicine*, 23, 860–866.

Wendler, D. (2004). Deception in the pursuit of science. Archives of Internal Medicine, 164, 597–600.

Wenger, N. S., Korenman, S. G., Berk, R., & Liu, H. (1998). Punishment for unethical behavior in the conduct of research. Academic Medicine, 73, 1187–1194.

Werhane, P., & Doering, J. (1997). Conflict of interest and conflicts of commitment. In D. Elliott & J. E. Stern (Eds.), *Research ethics: A reader* (pp. 165–189). Hanover, NH: University Press of New England.

Wester, K. L., Willse, J. T., & Davis, M. S. (2008). Responsible conduct of research measure: Initial development and pilot study. *Accountability in Research*, 15, 87–104.

Williams, J. R. (2006). The physician's role in the protection of human research subjects. *Science and Engineering Ethics*, 12, 5–12.

Wilson, K., Schreier, A., Griffin, A., & Resnik, D. (2007). Research records and the resolution of misconduct allegations at research institutions. Accountability in Research, 14(1), 57–71.

Woolf, P. K. (1986, February). Pressure to publish and fraud in science. Annals of Internal Medicine, 104, 254–256.

World Medical Association. (2008). Declaration of Helsinki: Ethical principles for medical research involving human subjects. Adopted by the 59th World Medical Association General Assembly, Seoul, Korea. Retrieved from http://www. wma.net/en/30publications/10policies/b3/index.html.

Wright, D. E., Titus, S. L., & Cornelison, J. B. (2008). Mentoring and research misconduct: An analysis of research mentoring in closed ORI cases. *Science and Engineering Ethics*, 14, 323–336.

Yank, V., & Barnes, D. (2003). Consensus and contention regarding redundant publications in clinical research: Cross-sectional survey of editors and authors. *Journal of Medical Ethics*, 29, 109–114.

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