Nicholas H. Steneck, "Assessing the Integrity of Publicly Supported Research." In *Investigating Research Integrity: Proceedings of the First ORI Research Conference on Research Integrity,* edited by Nicholas H. Steneck and Mary D. Scheetz, Washington, DC: Office of Research Integrity, 2002, pp. 1-16.

Assessing the Integrity of Publicly Funded Research

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***Keywords** Accuracy, Authorship, Bias, Conflict of interest, Duplicate publication, Misconduct, Other research practices, Peer review, Research on research integrity, Self correction*

Since the early 1980s, when research integrity became a major national concern as a consequence of reports of misconduct in research, several thousand publications have in one way or another reported on, analyzed, and/or expressed opinions about the integrity of publicly funded research. Despite widespread interest in research integrity, however, the integrity of researchers has not been subject to the same critical study as other professionals. The research articles listed at the end of this paper account for no more than 3-4% of the total literature on research integrity.

The lack of research on research integrity presents a significant problem for government, research institutions, and professional societies. If integrity is defined as being honest in your dealings with others, there is ample evidence to suggest that from time to time publicly funded research falls short of this mark. As the articles summarized in this Paper confirm, researchers do commit misconduct; research results are inappropriately influenced by bias, conflicts of interest, and just plain carelessness; and researchers allow personal ambitions and biases to get in the way of the supposed objectivity of the research process. Publicly funded research does not always achieve the high standards that researchers, research institutions, and professional societies commonly set for themselves. This much is known.

In contrast, too little is known about the causes and significance of, or remedies for, research practices that fall short of the ideals set for the responsible practice of research.

- Is research misconduct rare or are the cases reported simply the tip of some unmeasured iceberg?
- Are there accepted norms or standards for research and, if so, how are they set, learned, and monitored?
- Are the regulations that currently govern publicly supported research sufficient and well enough enforced?
- Which practices that seem to fall short of accepted standards matter most from the standpoint of protecting the public's investment in research?
- Are there ways to foster integrity and thereby to prevent misconduct?
- Do research ethics courses make any difference?
- What influence does the research climate have on research integrity?

Each of these questions has at one time or another been raised and answered in the literature on research integrity. Few of the answers given have been based on critical understandings of research

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as a profession, largely, as noted, because research as a profession has not be the subject of careful observation and controlled study.

The remainder of this Paper presents a brief analysis and summary of the research literature on research integrity.

- Section one presents an overview of what is known about the frequency of research misconduct (FFP).
- Section two discusses the complex and growing literature on research practices that seemingly compromise professional standards but may not constitute outright misconduct.
- Section three surveys the research that has been done on approaches to providing instruction on the responsible conduct of research (RCR).
- Section four explains how the literature cited in this Paper was selected, some of its characteristics, and the limitations of this analysis.

The bibliography at the end provides a complete list of references cited in the Paper, a summary of the RRI literature sorted by topics, and a comprehensive listing, sorted by first author, of the RRI literature with abstracts.

Throughout this Paper, I have used the terms "research misconduct," "scientific misconduct," or simply "misconduct" to refer to the three behaviors outlined in the common government definition of research misconduct, namely fabrication, falsification,and plagiarism (FFP) in proposing, conducting or reporting the results of research. While none of these behaviors is self-explanatory, the crucial element in each is a deliberate intent to deceive or mislead. Deliberate deception is clearly not consistent with good research practice and is generally agreed to constitute misconduct.

A second term used throughout this report, "integrity," is more difficult to define. Integrity is a measure of wholeness or completeness. When applied to professional behavior, it is essentially a measure of the degree to which someone's (or some institution's) actions accord with ideal or expected behavior. However, the ideals or expected behaviors for professional conduct are complex, not always well defined, and subject to change or reinterpretation. I have, therefore, adopted a fairly inclusive definition of integrity and assumed that it can be thought of as a measure of the degree to which researchers adhere to the rules or laws, regulations, guidelines, and commonly accepted professional codes and norms of their respective research areas.

Finally, a note of caution needs to be added. This survey of the RRI literature is of necessity selective and evolving. It places more emphasis on the biomedical sciences than the physical or social sciences. It does not do justice to the rich literature on peer review. It almost certainly has missed important articles that need to be included in the RRI literature. As a result, it will almost certainly be updated, and therefore comments and additions are welcomed.

Misconduct

Opinion about the extent of misconduct (FFP) in publicly funded research is sharply divided. In public testimony and editorials, researchers have commonly argued that research misconduct is rare. Support for this position is based on the fact that the documented cases of misconduct are few in number in comparison with the total number of individuals engaged in research. Approximately 200 cases of misconduct have been confirmed by the federal government over the last decade. Dividing cases by total researchers, this works out to a rate of about 1 in 10,000 over 20 years, assuming approximately 2,000,000 active researchers, or 1 in 100,000 per year. Critics of the way publicly funded research is conducted and administered counter that the reported cases represent the tip of a larger but uncharted iceberg. Support for this view is based in part on documented and presumed examples of the reluctance of researchers and research institutions to pursue cases of misconduct (for early warnings about possible larger numbers, see: 1, 2). Which, if either, opinion is correct remains to be determined.

Direct evidence

Research undertaken to clarify the extent of scientific misconduct suggests that it may be more common than the 1 in 10,000 or lower estimates. Evidence for this position comes from three direct approaches to measurement:

- It is reasonable to presume, based on research in other fields, that confirmed cases underestimate actual cases (3). Further research is needed to determine whether under-reporting in research is trivial or significant.

Year Author	Population Place	Sample Size	Responses (%)	Mis-conduct	FFP
1976 St. James-Roberts	Readers, *New Scientist* England	??	199 (?)	92%	?
1987 Tagney	Phys, biol, behav, & soc. scientists Major research university, US	1100	245 (22%)	–	32%
1992 Kalichman	Biomedical trainees UC San Diego, US	2010	549 (27%)	36%	–
1993 Swazey	Chem., civil eng., microbiol., sociol. US survey, faculty/graduate	4000	--/-- (72/59%)	44/50%	6/9%
1993 Hals	PIs, biomedical sciences Health Region IV, Norway	159	119 (70%)	27%	–
1995 Bekkelund	Biomedical researchers Norway, random survey	274	215 (80%)	22%	3%
1996 Eastwood	Post-doctoral training fellows US, random national survey	1005	324 (33%)	58%	3-12%

Table 1. Surveys of the Level of Misconduct in Research

- Surveys of knowledge of misconduct consistently report knowledge rates above 1% (Table 1). Reported knowledge of misconduct remains above 1% (1 in 100, or 100 times higher than the 1 in 10,000 estimate) even when researchers are asked about their own research group and when misconduct is specifically limited to FFP. One survey specifically asked researchers whether the misconduct they were aware of was public knowledge. Of the roughly one-in-four researchers who were aware of misconduct (27%), 47% said that the cases were not public knowledge (4).
- Audits of research procedures and results have turned up "significant problems" or "major deviations" a levels that range at and above the 10% level (5-8). These results do not correlate directly with FFP, since they do not take into account whether discrepancies result from deliberate actions.

The results of surveys, audits, and estimates of the rate of under-reporting raise two important issues for further consideration. First, however the results of surveys and audits are ultimately interpreted or clarified, there remains the troubling discrepancy between public statements about how "rare" misconduct in research supposedly is and the more private belief on the part of many researchers that it is in fact fairly common. How can these two views be reconciled?

Second, whatever the actual rate of misconduct, it is not so much the rate as the significance of the misconduct that matters most. Summarizing the results of scientific data audits of the Cancer and Leukemia Group B's clinical trials, Weiss et al. conclude that "scientific improprieties have occurred very rarely..." (8, p. 459). "Very rarely, in this case, is based on a quantitative estimate of 0.28% (p. 462)–28 cases of misconduct for every 10,000 clinical researchers or one case for every 357 clinical researchers. On what basis can this rate be judged as either "rare" or "significant"? Clearly, understanding the importance of misconduct in research requires not only better estimates of numbers but also of significance. 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?

Indirect evidence

Gathering information on the likely prevalence of misconduct in research can be approached indirectly. For example, many studies have documented that cheating is common in the educational system at all levels and in all programs. The rates vary from well above 50% for high school and college undergraduates (9-12) to levels between 10% and 30% for professional students (13-20). One survey specifically asked whether misconduct at this level was indicative of future performance. Of 246 faculty and administrators responding, 216 (86%) felt that it was so indicative (14, p. 34). If this estimate of the relationship between student conduct and later professional conduct is true, it would support the contention that the prevalence of misconduct in research may be higher than the small number of confirmed cases suggest.

The prevalence of a willingness to engage in misconduct has been documented into graduate and post-doctoral research education. Kalichman's and Eastwood's surveys report that significant numbers of students (above 10%, except for fabricating data) will omit or change evidence and add honorary authors if it will help get papers published or grants funded (Table 2) (21, 22). Students who are in the beginning stages of becoming researchers clearly feel that career pressures may make it necessary to engage in practices that they also know are wrong.

That significant numbers of beginning researchers may in fact do what they say they will do has been confirmed in a series of audits of the research publications listed on residency fellowship applications. These audits report significant numbers (15% and higher) of misrepresentations, from seemingly trivial offenses such as inflating author rank to listing articles "in press" when they were not, listing papers in journals that do not exist, and listing bogus articles in real publications (Table 3) (23-27). Similar practices are generally counted as FFP when they occur in research grant applications or resumes submitted for promotion.

One final piece of indirect evidence that should be noted is the confirmed reluctance of researchers to report suspected misconduct.

- As noted above, Hals reported that roughly one-in-four researchers (27%) who knew of misconduct, said that the cases they knew of were not public knowledge, which could mean they were not reported (4).
- In Tagney's survey conducted at one research institution, roughly half of those who reported suspecting misconduct took no action (28).
- Korenman's study of the attitudes of researchers and institutional representatives toward misconduct found that researchers were more likely to favor informing

Action	**1992 Kalichman**	**1996 Eastwood**
Past misconduct (yes/no?)	15.1%	12%
Future misconduct (yes/no?)	14.8%	
...modify data for paper	7.3%	15%
...modify data for a grant application	13.5%	--
...fabricate date for a paper or grant application	1.3%	< 2%
...select or omit data for paper or grant application	14.2%	27%
...list an undeserving author	--	41%

Table 2. Self-reported attitudes toward misconduct

Author	**1995 Sekas**	**1996 Gurudevan**	**1997 Panicek**	**1998 Bilge**	**1999 Dale**
Specialty	***Gastro-enterology***	***Emergency Medicine***	***Radiology***	***Pediatrics***	***Orthopaedic Medicine***
Total applications	236	350	201	404	213
...with citations	53 (22%)	113 (32%)	87 (43%)	147 (36%)	64 (30%)
...misrepresented	16 (30%)	23 (20%)	14 (16%)	29 (20%)	11 (17%)
Total citations	--	276	261	410	76
...misrepresented	--	44 (16%)	39 (15%)	41 (10%)	14 (18%)
Research experience	138 (59%)	--	--	--	--
...not confirmed	47 (34%)	--	--	--	--

Table 3. Misrepresentation in medical resident training program applications

colleagues whereas institutional representatives favored reporting to supervisors and deans (29).

These findings confirm the suspicions of the "tip-of-the iceberg" school, which argues that reported cases are not an accurate measure of actual levels of misconduct. No controlled studies of under-reporting have been undertaken to assess the rate of under-reporting, making it difficult to conclude whether it is significant.

Cheating or misconduct on the path toward becoming a researcher does not, of course, demonstrate that misconduct continues once students become researchers. Under-reporting may not seriously compromise estimates of the amount of misconduct. Reasons can be given to suggest that some of the estimates of misconduct given in the various surveys reported above may be too high as well as reasons to suggest that they may be too low. The differences between the "rare" and "tip-of-the-iceberg" schools can therefore not be resolved easily. What is important to note, however, is that in seeking to refine understandings and resolve the differences between the two schools, the range of uncertainty that exists is significant. In terms of decimal points, the range is not a matter of one or two orders of magnitude but closer to four or five orders of magnitude, varying from 1 in 100,000 or less to 1 in 100 or more. And this, in turn, makes it difficult, if not impossible, to estimate the public costs of misconduct when determining what policies are needed to protect the public's investment in research.

Other Research Practices

Over the past twenty years or longer, the discussion of "research integrity" has focused primarily on "research misconduct," based on widespread agreement that misconduct (FFP) is wrong or fraudulent. While it is true that research misconduct clearly can undermine the integrity of publicly supported research and therefore needs to be taken seriously, so can other research practices, such as sloppy research, inappropriate bias, conflict of interest, or poor mentoring.

The existence of other research practices that can compromise integrity has been recognized by the research community, but there has been no agreement on how to respond to them or how seriously they should be taken. In its 1992 report, Responsible Science, the NAS/NAE/IOM Panel on *Scientific Responsibility and the Conduct of Research* specifically set out a separate category of research behavior called "Questionable Research Practices." The Panel recognized that such practices "...violate traditional values of the research enterprise and ... may be detrimental to the research process," but it was not willing to include them under "misconduct." It did concede, however, that since "...the relationship between these two categories is not well understood ... [i]t may be difficult to tell, initially, whether alleged misconduct constitutes misconduct in science or a questionable research practice" (30, pp. 5-6, 29).

Whether or not "other questionable practices" constitute misconduct is irrelevant for the purposes of this Report. What is relevant is the fact that any practice that deviates significantly from the "rules, regulations, guidelines, and commonly accepted professional codes or norms for the responsible conduct of research" (the definition for integrity given in the Introduction) can compromise and currently are compromising the integrity of publicly funded research. However, until more is known about these practices, it will be difficult to suggest how seriously they need to be taken.

The remainder of this section summarizes some of the research on other practices that can compromise the integrity of research. The summary is intended to be more illustrative than exhaustive. Some aspects of research practice, such as authorship and peer review, have been the subject of intense study and hundreds of publications, thanks in large part to the Congresses on Biomedical Peer Review organized by JAMA editor, Drummond Rennie (31). Exhaustive coverage is therefore not possible. Rather, the goal of this section is to focus on some areas of potential concern and illustrate some of the findings that have emerged.

Accuracy

Accurate information is vital to research. Research is a cooperative and cumulative enterprise. Researchers build on the work of others, which means the information they have about other work and the way research is conveyed must be accurate; however, a number of studies suggest that research results are not always conveyed accurately.

- Information presented in abstracts does not always accurately reflect the information given in the article itself. One study reported major discrepancies in abstracts (inconsistencies or information that was not contained in the body of the article) in 55 of 203 randomly selected articles (32).

- Studies have reported that significant numbers (above 10%) of published articles misuse statistics or contain statistical errors (33).
- Random checks on citations and quotations in published articles have reported error rates well above 10%. Errors were counted as "citation errors" when the names, pages, or other information needed for locating an article was inaccurate (minor) or when the referenced article could not be located based on the information given (major). Errors were counted as "quotation errors" when the reference oversimplified or exaggerated information given in the referenced article (minor) or when the information given in the original article did not support or contradicted claims made in the reference (major) (34, 35).

Inaccuracies in abstracts, the use of statistics, and references do not necessarily invalidate research results. Conclusions or pieces of evidence presented only in an abstract but not in the body of an article could be true. Research results bolstered by inflated or deceptive statistics or inaccurate references to other studies might still be true. At issue, however, is not whether the results are ultimately true or accurate but whether the word (or words in this case) of researchers can always be trusted. The clear answer to this question, unfortunately, is that it (they) cannot.

Peer Review

Inaccuracy and other problems in publication are purportedly reduced, if not eliminated, through peer review. In general, the peer review system enjoys considerable support within the research community and is seen by most as the foundation on which professional self-regulation rests. This does not mean, however, that peer review is above criticism or not in need of further improvement.

- That peer reviewers miss problems in publications has been documented by the fact that different reviewers detect different problems in manuscripts, even when they are in substantial agreement about whether to publish (36) and by studies of how fraudulent publications have made it to press (37). How much effort should be made to improve peer review requires more information about how well it is working and the price of its shortcomings.
- Peer review has been shown to have institutional (38), national (39, 40), methodological (39, 41), gender (42) and outcome biases (43-45). Bias, obviously, runs counter to the value-neutral goal of research.
- Considerable uncertainty exists about the best ways to improve peer review. Traditional approaches, such as blinding, issuing clear instructions, or relying on experienced researchers, have had different measures of success (46-53).
- Studies of peer review have raised questions about whether it helps or hinders innovation (54, 55).

One review of the rich literature on peer review concludes: "Because of the central place of peer review in the scientific community and the resources it requires, more studies are needed to define what it does and does not accomplish" (56). This work will fortunately be fostered by the future Congresses on Biomedical Peer Review and similar efforts.

Self-Correction

Researchers constantly read and check each other's work. The routine process of using the work of others in the day-to-day practice of research provides an additional mechanism for detecting and correcting errors and other problems in research, such as research misconduct. Research is, in other words, self-correcting, which further ensures its integrity. However, research on the effectiveness of self-correction in research has shown that this mechanism is not as vigilant as one might expect.

- Studies of some of the first publicly documented cases of misconduct found that publication of a retraction reduced the citation of fraudulent articles but did not eliminate it (57-59).
- One recent study of articles retracted for a broad range of reasons, from outright fraud to acknowledged experimental errors or later failure to replicate, concluded that retracted

articles continue to be cited and used as a significant rate. Of 299 post-retraction citations listed in the Abridged Index Medicus, only 19 (6%) mentioned the retraction; 17 (6%) explicitly and 263 (88%) implicitly reported the retracted work as "valid" (60).

- Research on the process by which articles are retracted and erroneous information withdrawn has show that it is slow (60, 61) and in some key ways ineffective (60-63).

Findings such as these have important policy implications. In his study of retraction notices, Budd agrees that research is self-correcting, but then he adds: "...there may be a great deal of time, effort, and money spent in discovering that some research is not useful. If erroneous or fraudulent work lives on in the literature, the amount of time, effort, and money to correct work may be even greater" (60, p. 297). At issue, in other words, is not whether research errors are corrected, but when. Failure to correct the literature in a timely and responsible manner is as much a matter of integrity, viewed from the public's investment in research, as a failure to correct at all.

Authorship

In principle, research results are more important than researchers. Who publishes an article should not matter. What matters most are the results. In practice, however, authorship is vitally important to, and significantly influences, the research process. Most research funding today is dependent on productivity. Review panels want to know not only what a researcher is planning to do but what she or he has done. Advancement in academic research is not possible without publication. Getting one's name on research papers is important–so important that as many as one in five aspiring researchers misrepresents publications on résumés in an attempt to improve his or her standings as a researcher (see Table 4).

As with the other research practices discussed in this section, there is considerable evidence to suggest that the ideal standard for determining authorship is not followed in practice and that expected authorship practices in general are sometimes not clearly defined or conveyed.

- Two studies that used the ICMJE criteria (64) for judging authorship found that 19% (65) and 36.4% (66) of papers did not meet these criteria.
- Evidence suggests that the rules for authorship are poorly understood, interpreted differently by different researchers, and not well communicated from senior to junior researchers (22, 67, 68).
- Patterns of authorship and the increase in disputes over authorship suggest that decisions about authorship are significantly influenced by the research environment (69, 70).

The importance of the truthful reporting of research contributions through authorship is widely recognized. The NIH Guidelines for the Conduct of Research note in particular that:

> For each individual the privilege of authorship should be based on significant contribution to the conceptualization, design, execution, and/or interpretations of the research study, as well as a willingness to assume responsibility for the study. Individuals who do not meet these criteria but who have assisted the research by their encouragement and advice or by providing space, financial support, reagents, occasional analyses or patient material should be acknowledged in the text but not be authors. (71, p. 10)

Authors who ask or agree to be listed on papers to which they have not made substantial contribution compromise the integrity of the research environment. The same is true of the 41% of graduate students who report a willingness to list undeserving authors on their papers (see Table 3, above).

Duplicate Publication

In its advice to intramural researchers, NIH research Guidelines caution researchers about duplicate publication:

> Timely publication of new and significant results is important for the progress of science, but fragmentary publication of the results of a scientific investigation or multiple publications of the same or similar data are inappropriate. (71, p. 8)

Despite widespread agreement that duplicate publication is inappropriate, the rate of duplicate publication (publishing the same article twice without reference) seems to hover at about 10% (Table 4) (72-76). Based on his study of publication trends in the *British Medical Journal*, Waldron suggested that duplicate publication was

Study	*Journal*	*Articles*	*Duplicate %*
Waldron (1992)	BMJ	354 published	6-12%
Bernard (1993)	NTvG	172 published	11%
Koen (1994)	NTvG	108 rejected	4%
Blancett (1995)	INJS	642 published	9%
Bloemenkamp (1999)	NTvG	148 published	7%

Table 4. Percent duplicate publication

increasing (72). Bleomenkamp more recently reported that the duplicate publication rate for articles in *Nederlands Tijdschrift voor Geneeskunde* has remained constant over the last 10 years and the number of authors referencing the second publication has increased significantly, from 22% to 73%.(76).

Duplicate publication adversely effects research in a number of ways. It can waste time (editors and reviewers) and resources (library funds and reprint costs). It also makes it difficult to evaluate the productivity of researchers. But perhaps most importantly, in clinical research it has the potential to inappropriately distort or bias findings if the duplicate publications are more prevalent in one treatment regimen.

- In a meta-analysis of post-operative effects of ondansetron, Tramer and Reynolds reported that "17% of published studies and 28% of the patient data were duplicated. Moreover, duplication was more common in studies that reported greater treatment effect. This bias, according to Tramer and Reynolds, "led to a 23% overestimation of ondansetron's antiemetic efficacy" (77).
- Jefferson reports that in a Cochrane review of the effects of Plasma Derived Vaccines, he and his colleagues suspected that 25% (15 of 60) of the trials identified during the first phase of review were duplicate publications. This percentage increased to 43% (3 of 7) when they progressed to the second phase of review. Being aware of the problem of duplicate publication, his group excluded the duplicate studies, but doing so is not common practice (78).

In the final analysis, Jefferson considers only "publishing redundant material with the intention of misleading the public, editors and readers, in order to make them believe the study is different from the original" as a "breach of current ethical tenets" (p. 138). From the public's perspective, however, it makes no difference whether the duplication is intended or not. If researchers do not take steps to ensure that a second or third publication of a body of data is recognized as such, the public could be harmed and the integrity of the research process undermined.

Bias and Conflict of Interest

There has been considerable debate about the role of values and personal interest in research ever since Merton proposed "disinterestedness" as one of four key values on which science rests (79, p. 116). It is now widely recognized that values influence research (80), but there is also a common understanding that the influence of values should be minimized and made public, particularly when financial interests are involved.

Considerable evidence exists to support the contention that personal interest does influence research behavior. Positive-outcomes bias (favoring publications that report positive results over those that report negative results or that do not find results) has been demonstrated in a number of studies (44, 81, 82). The reverse effect has also been reported, that is, slower publication rates for studies that fail to find a particular result (45). Studies are just beginning to assess how these interests affect research and whether they are being properly managed (83-85).

In calling controversial publication, reporting, and other research practices "questionable," the NAS report, *Responsible Science*, highlights an important problem. (30) "Integrity" is not an all-or-nothing proposition. There is a difference between a failure to check the spelling of every author's name or to catch every typo and using improper statistics or delaying the publication of a manuscript to please a sponsor. It is not easy to pinpoint where or when high standards for integrity in research give way to careless research practices, to irresponsible research practices or to misconduct. The extremes (high standards for integrity and misconduct) can be defined, but behaviors that fall between, to one extent or another, are all subject to interpretation. This, in turn, makes it imperative that these behaviors are well understood and their consequences evaluated, both as part of the process of reassuring the public that its research funds are being spent responsibility and as needed background information for developing responsible conduct of research training programs.

Education

It is commonplace for reports on research misconduct/integrity to emphasize the importance of education. Professions have an obligation to society to educate future generations of professionals, which includes making future professionals aware of the standards for responsible practice. Moreover, if professional ethics education prevents misconduct, it is in a profession's best interest to encourage this education, which most in fact do.

Through the 1980s, research ethics training was commonly relegated to the laboratory and to mentoring. This changed in 1989 when NIH and ADAMHA instituted required "instruction in the responsible conduct of research" (RCR) for all training grants (86). The requirement stipulated that training programs had to have instruction in RCR, which in turn had to be described in the training grant application. Although the requirement technically had no "regulatory teeth," coming as it did in the highly competitive environment of grant-getting, researchers and research institutions quickly complied and instituted a wide variety of research ethics or RCR training programs (87).

The increase in formal RCR training raises an obvious and researchable question: has it or will it make any difference? At the present time, there is no convincing evidence that it does, but this does not necessarily lead to the conclusion that RCR training is ineffective, unnecessary, or unwise. The newness of most programs means that their impact may not yet be apparent. RCR training is delivered in different ways and different settings, making it difficult to isolate the influence this one factor has on the complex process of becoming a responsible researcher. And perhaps most importantly, there is no agreement on the goals of RCR education, making it difficult to judge whether it is succeeding.

RCR training

Straightforward efforts to evaluate the impact RCR training has on attitudes or anticipated behaviors have not reported any clear positive results. Studies by Kalichman et al. and Eastwood et al. compared receiving or not receiving RCR training with anticipated research behaviors. A study by Brown compared receiving or not receiving RCR training with self-reported perceptions of different ethical standards. None of the studies found any significant correlations between attitudes or anticipated behaviors and RCR training (21, 22, 88). Brown's study did report that RCR training increased awareness of options in ambiguous situations (p. 490). However, Eastwood's study reported that fellows who received RCR training were more willing to grant honorary authorship than fellows who did not (p. 95). Overall, direct measures of attitudes and anticipated behavior have pointed to some possible benefits, perhaps one puzzling negative, and a great deal of similarity between those receiving and not receiving RCR training.

Efforts to refine the study of the impact of RCR training have led to a difference of views on appropriate outcome measures. Based on a three-year effort to develop and assess an RCR course at Dartmouth College, Elliot and Stern argue that "if 'ethical behavior' is removed as a basis for the evaluation of teaching ethics," effective assessment tools can be developed. In the place of ethical behavior, they propose using two familiar measures of success in academic courses in general: "the skills and content taught in the course and the learning environment in which the teaching takes place" (89, p. 348). The project allowed them to develop and test various tools for evaluating these ends, which they argue can be accomplished, "but only if [teaching of academic research ethics] is treated as an academic discipline by both faculty and students" (p. 355).

Others believe that striving for some type of behavioral or moral reasoning change is appropriate for professional ethics instruction, including RCR training, and that such change can be measured. In a series of studies of medical, veterinary, and dental education, Self, Baldwin, Bebeau and colleagues have reported that: a) traditional professional education programs may erode and b) the addition of ethics instruction to traditional programs improves the ability of students to engage in moral reasoning (90-97). Whether changes in the ability to engage in moral reasoning measured in professional education settings generally can be applied to RCR training in particular and whether changes in moral reason have any lasting professional consequences remains to be determined.

The research needed to plan effective RCR programs will clearly need to take into account more than what goes on in the RCR classroom. Studies have shown that environment is closely linked to what students feel they must do as opposed to what they should do (17, 18, 20, 22). Although the 1995 survey of the attitudes and experiences of 2,000 graduate students with misconduct (Table 2, above) indicates "that fraud, plagiarism, and related forms of misconduct are the results of individual predilections or failures of judgement..." (98, p. 225), Anderson et al. in commenting on these results still point to important influences exerted by environment and mentoring relations (p. 226). Without attention to the full context within which integrity is learned and decisions made about right and wrong actions, the goal of ensuring the responsible conduct of research through RCR training could well be negated by influences in the research environment.

Other efforts to educate

In discussions of ways to improve the integrity of research, surprisingly little attention has been given to the role of clear rules and routine monitoring or data audits. If the ultimate goal of research ethics/integrity policy is simply to ensure high standards for publicly supported research, the simplest way to achieve this goal may be to make the rules as explicit and clear as possible and then to check to make sure they are being followed. For each of these approaches to "educating" researchers, there is interesting research that suggests what may or may not work.

Over the last decade, new rules have been formulated for reporting research. Particular attention has been paid to two key areas–journal publication in general and clinical trial reporting. Studies of the effect of new rules suggested that they have had mixed results.

- Two studies that looked at the adoption of specific standards for reporting clinical trials by several medical journals concluded that there was room for improvement (99, 100). Junker suggest that more journals should require authors to follow the Consolidated Standards of Reporting Trials (CONSORT) (101). Clarke and Chalmers conclud that "there is little evidence that journals have adequately implemented the CONSORT recommendation that results of an RCT [randomized controlled trial] be discussed in light of the totality of the available evidence" (p. 280).
- In studies of measures to improve the quality of abstracts, Pitkin found that instructions to the authors had little impact (32, 102, 103).
- In a study of the impact of guidelines published in the *British Medical Journal* for manuscripts on the economics of health care, no difference was found in the quality of manuscripts, although the guidelines were judged to be useful for editorial purposes (104).
- In a comparison of systematic reviews and meta-analyses published following the procedures of the Cochrane Collaboration versus the more open-ended general reviews published in journals, Jadad reported more methodological rigor in the Cochrane reviews (41).
- In a study of the impact of professional codes in physics, Tarnow reported that postdoctoral students were generally not aware of publication rules and spent little time with advisors discussing publication practices (68).

As a group, this research seems to support the perhaps not unexpected conclusion that rules alone will not change behavior and must be accompanied by efforts to both make them known and take them seriously. Simply making information about rules for responsible behavior available is not an effective way to foster responsible behavior.

In contrast, data audits seem to have a significant effect on research behavior. Two studies of major government data audit programs both report that serious misconduct declined over the course of the studies.

- Shapiro and Charrow's study of FDA audits conducted between 1977 and 1988 reported that the rates of specific deficiencies remained about the same throughout but "the overall level of seriousness of the problems ... declined" (7, p. 130).

- Weiss et al. in their detailed look at the results of audits conducted by the Cancer and Leukemia Group B (CALGB) conclude that: "The CALGB data audit process has been successful in uncovering the very rare instances of scientific misconduct and pressuring group members to improve adherence to administrative requirements, protocol compliance, and data submission. It has also served to weed out poorly performing institutions" (8, p. 464).

If results matter, then one of the most effective ways to educate researchers about their responsibilities may be to check more carefully the work they produce.

Data audits have been resisted because they are allegedly expensive, time-consuming, and perhaps even counter-productive; e.g. too much concern about the bookkeeping required to pass audits might slow the progress of science. There currently are no data to support these concerns. There is evidence, reviewed by Armstrong, that peer review can slow innovation in research (54, pp. 70-71), but no evidence that data audits have a similar effects. Moreover, Glick's rough estimates of the cost of data audits, based on conservative estimates of the amount of careless work and misconduct that may be affecting research results, suggests that over the long term, they will save public dollars. "Data auditing would increase research productivity by 2.5-6% (...), so that each dollar spent on such audits might eventually benefit the public, 20 years later, by an amount equivalent to $25-60" (3, p. 81). These results and estimations will no doubt be challenged, but for now the evidence seems to suggest that research audits might be an effective and efficient way to detect misconduct and reduce the rate of other questionable practices.

Research Literature Overview

As noted in the Introduction, over the last 20 years or longer, several thousand publications have in one way or another addressed the issue of integrity and/or misconduct in research. Most of these publications are based on some research. Reporters do research for news stories. Journal editors investigate problems before writing editorials. Taken to mean simply investigation or study, most if not all that has been written about research integrity is based on some research.

For the purposes of this Report, "research" has been defined as studies that have some element of controlled investigation, which means primarily but not exclusively surveys and quantitative assessments. Limiting the definition of research in this way obviously eliminates many thoughtful articles and books from the literature review, such as editorials, analytical writings, historical and cases studies, and philosophical analyses. The fact that works such as these are not included in this Report should not be taken as suggesting they are not important. They clearly are crucial and in other contexts certainly need to be considered. However, for the purposes of the ORI RRI program, the immediate goal is to gather hard evidence relating to actual research practices, so that policy-making can be based on the way research is conducted as opposed to the way we may think it is conducted.

Controlled quantitative research plays an important role in scholarly investigation. Most significantly, it helps establish reference points for organizing and evaluating other information. For example, historians, journalists, and others have amply documented that misconduct takes place in research. However, without some quantitative assessments, it is difficult to know what to make of individual cases of misconduct or even of the entire body of confirmed cases. Are they typical or atypical? Is misconduct common or rare? Without some controlled counting or surveys, it is difficult to place individual events and behaviors into context.

Locating research on research integrity is not a simple task. Keyword searching for the most part does not separate scholarly analyses from empirical studies. References located through searches for "scientific misconduct," "research ethics" and other keywords need to be evaluated for both relevance and method. The articles summarized in this Report have been located through standard keyword searches in several different databases, checking references listed in bibliographies, and in some cases by searching for publications by scholars with known RRI interests. Major emphasis has been placed on work relating to the biomedical sciences in particular and the hard sciences more generally. Less attention has been paid to research on integrity in the social sciences. The final RRI bibliography contains 136 entries, most of which, but not all, have some empirical or controlled research component.

That RRI has not yet developed into an organized research field is more than evident from the fact that the 136 articles summarized in this Report appeared in 45 different journals (Table 5) and two books (105, 106). Most journals published only one or two articles. There are, however, three important exceptions.

- Fifty-one of the 136 (37.5%) articles appeared in JAMA. Most of these articles are on integrity in publication and are the product of the three peer review conferences organized by Drummond Rennie.
- Fourteen of the 136 articles (10%) appeared in Academic Medicine. These articles are mostly concerned with student conduct, not research integrity specifically, but have been included because they provide important background on the values researchers may have had as students.
- Eleven of the 136 articles (8%) appeared in *Science and Engineering Ethics*. This group of publications is split nearly evenly between research ethics training and publication practices. SEE is unfortunately not indexed in MedLine®, which limits the knowledge of this important group of publications.

Together, these three journals account for 76 of the 136 articles. Three journals had three research articles; five journals had two, and the remainder published a single research article on research integrity.

The fact that research on research integrity is distributed so broadly through the scholarly literature almost certainly slows research progress. At the present time, the standard search tools simply do not cut across the different disciplines that contribute to RRI. What is "discovered" in one field is thus not easily known in other fields. More importantly, however, is the fact that the absence of a well defined literature and corresponding research community makes interdisciplinary research on research integrity more difficult. This second shortcoming is particularly important for the development of research on research integrity, which of necessity must be interdisciplinary and

Journal of the American Medical Association (51)	Cancer Investigation (1)
Academic Medicine (14)	Cognitive Therapy and Research (1)
Science and Engineering Ethics (11)	Controlled Clinical Trials (1)
British Medical Journal (3)	Image: The Journal of Nursing Scholarship (1)
Journal of Professional Nursing (3)	Journal of Allied Health (1)
Nederlands Tijdschrift voor Geneeskunde (3)	Journal of Bone and Joint Surgery (1)
Accountability in Research (2)	Journal of Clinical Epidemiology (1)
Bulletin of the Medical Libraries Association (2)	Journal of General Internal Medicine (1)
Journal of Dental Education (2)	Journal of Higher Education (1)
Lancet (2)	Journal of Information Ethics (1)
Medical Education (2)	Journal of Investigative Medicine (1)
Medical Reference Services Quarterly (2)	Journal of Medical Education (1)
New Scientist (2)	Journal of Medical Ethics (1)
Tidsskrift for den Norske lægeforening (2)	Journal of the Am. Veterinary Medical Association (1)
AIDS Education and Prevention (1)	Journal of the Royal College of Physicians, London (1)
American Journal of Medicine (1)1	Minerva (1)
American Journal of Public Health (1)	Nature (1)
American Journal of Roentgenology (1)	New England Journal of Medicine (1)
American Scientist (1)	Nordisk Medicin (1)
Annals of Emergency Medicine (1)	Nurse Educator (1)
Annals of Internal Medicine (1)	Research in Higher Education (1)
Cambridge Quarterly of Healthcare Ethics (1)	The Psychological Report (1)
Canadian Medical Association Journal (1)	

Table 5. Journals with RRI articles, listed by number of articles.

broadly inclusive.

The need for interdisciplinary research raises one last observation about the RRI literature and by implication the RRI community. Most of the literature cited in this Report appears in biomedical journals. The only major exception are the eleven articles in Science and Engineering Ethics, which, it should be noted, are not indexed in MedLine® but are in BioEthicsLine, without abstracts. That research on the integrity of biomedical research (the primary focus of this report) appears in biomedical journals is certainly understandable, but the existence of this publication pattern raises serious questions for interdisciplinary research.

To be taken seriously in most academic settings today, researchers must first succeed in their primary research field. This means that sociologists must publish in sociology journals, psychologists in psychology journals, and so on. In addition, they must pursue research that is important to their primary fields of research. Institutional factors such as this unquestionably make the development of interdisciplinary research on research integrity more difficult. When added to the fact that there are few incentives for researchers who are the subject of RRI investigations to study their own integrity, rather than pursuing research in their primary fields of interest, establishing an interdisciplinary RRI initiative and RRI community poses a significant challenge.

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