Beyond Conflict of Interest: The Responsible Conduct of Research*

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ABSTRACT: *This paper reports data and scholarly opinion that support the perception of systemic flaws in the management of scientific professions and the research enterprise; explores the responsibility that professional status places on the scientific professions, and elaborates the concept of the responsible conduct of research (RCR). Data are presented on research misconduct, availability of research guidelines, and perceived research quality.*

Abuses of the research process have been filing into the public policy arena in the United States for at least five decades in an uninterrupted parade. The welfare of laboratory animals initiated the march in the 1960s; the protection of human research subjects followed in the 1970s; research misconduct fell into step in the 1980s; and conflict of interest moved front and center in the 1990s. Each abuse has been addressed, in turn, as an isolated problem and piecemeal solutions were applied. The endurance of multiple abuses, however, suggests that the abuses may be symptomatic of systemic flaws in the management of scientific professions and the research enterprise. Although data on deviant behavior in the scientific professions and the research enterprise are limited, scholarly opinion published in documents produced by elite organizations within the research community and in scientific journals support the perception that such systemic flaws may exist.

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SYSTEMIC FLAWS

The data and scholarly opinion on the perception of systemic flaws in management of scientific professions and the research enterprise fall into the following categories: (1) research misconduct, (2) questionable research practices, (3) careless and sloppy research, and (4) research quality.

Research Misconduct

The incidence of research misconduct is unknown. The data presented here are limited to findings of misconduct made from 1993-2001 in research funded only by the U. S. Public Health Service (PHS). In that nine year period, the Office of Research Integrity (ORI) received 1,752 allegations that resulted in 310 formal cases and 124 misconduct findings.

Only a small fraction (17.7%) of the allegations have resulted in formal PHS cases because (1) the alleged behavior did not fall under the PHS definition of research misconduct;[a] (2) the research involved was not funded by the PHS, or (3) sufficient information about the misconduct could not be obtained to permit the allegation to be pursued. Although research misconduct may be under-reported because of the limited opportunity for detection. the constraints against reporting, and the reluctance to investigate allegations, research misconduct is viewed as a low probability event with high impact potential. High frequency, however, is not a necessary condition for research misconduct to have a high impact on the management of the research enterprise; the entire regulatory apparatus created to ensure that allegations of research misconduct would be properly investigated began with congressional hearings investigating research misconduct at four major research institutions.[1]

Current data suggest that any member of the research team may engage in research misconduct; respondents who have had research misconduct findings made against them and/or PHS administrative actions imposed on them cover the range of academic ranks. The rank of associate professor appears most frequently, followed by postdoctoral fellows, technicians, professors, and graduate and undergraduate students. Because senior researchers (full and associate professors) account for 29.9% of these respondents (or 33.9% if nonacademic scientists are included) the practice of limiting RCR training to graduate students appears shortsighted. See Table 1.

a. Misconduct or misconduct in science means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research. It does not include honest error or hoest differences in interpretations or judgments of data. 42 C.F.R. Part 50, Subpart A.

Table 1: Academic rank of respondents who had research misconduct findings made against them and/or had PHS administrative actions imposed on them: 1993-2001

Rank	Frequency	Percent
Professor	15	12.1%
Associate professor	22	17.8
Assistant professor	10	8.1
Scientist: non-academic	5	4.0
Postdoctoral fellows	21	16.9
Clinical Coordinator	3	2.4
Nurse	3	2.4
Research Assistant/Associate	11	8.9
Technician	18	14.5
Student: graduate/undergraduate	13	10.5
Other	3	2.4
Total	**124**	**100.0**

The highest academic degree held by respondents who had a finding of research misconduct made against them and/or PHS administrative actions imposed on them raises concerns about the socialization of new members by the profession, the self-regulation of the professions, and the management of the research enterprise. At least three-fifths of the respondents (61.3%) hold doctorates and nearly 70% have graduate degrees and almost all were employed by medical schools, colleges or universities. Of the respondents who hold doctorates, at least 64.5% hold Ph.Ds. and 32.9% have M.Ds. See Table 2.

Table 2: Highest academic degree held by respondents who had research misconduct findings made against them and/or had PHS administrative actions imposed on them: 1993-2001.

Degree	Frequency	Percentage
Ph.D.	49	39.5
M.D.	25	20.2
D.V.M.	1	0.8
Ed.D.	1	0.8
Masters	10	8.1
Bachelors	20	16.1
RN	2	1.6
Unknown	16	12.9
Total	**124**	**100.0**

Because the PHS definition of research misconduct focuses on fabrication, falsification and plagiarism, the deviance underlying the misconduct findings represent felonious assaults on the integrity of PHS supported research rather than slight transgressions.

(See Table 3.) Falsification is the most frequent offense followed by fabrication and plagiarism. Falsification and fabrication either alone or in combination with each other account for 86% of the misconduct findings. Plagiarism is involved in only 14% of the misconduct findings. Some critics contend that the plagiarism cases are artificially low because ORI labels many plagiarism allegations as "authorship disputes" and refers them to institutions for settlement. At the National Science Foundation (NSF), nearly 60% of the cases involve plagiarism.[b]

Table 3: Types of misconduct in cases involving respondents who had research misconduct findings made against them and/or had PHS administrative actions imposed on them: 1993-2001.

Type	Frequency	Percent
Fabrication	27	21.8%
Falsification	46	37.1
Plagiarism	10	8.1
Fabrication/falsification	34	27.4
Fabrication/falsification/plagiarism	3	2.4
Fabrication/plagiarism	1	.8
Falsification/plagiarism	3	2.4
Total	**124**	**100.0**

Questionable Research Practices

Although research misconduct may be the most visible and sensational indicator of management problems in the research professions and the research enterprise, a report issued by the U.S. National Academy of Sciences (NAS) in 1992 stated that a category of behavior called "questionable research practices"[c] requires the attention of the research community because these behaviors "can erode confidence in the integrity of the research process, violate traditions associated with science, affect scientific conclusions, waste time and resources, and weaken the education of new scientists."[2]

Questionable research practices concern such matters as the recording and retention of research data, access to data or research materials supporting published papers, honorary authorship, inadequately supervising subordinates, and enhancing the significance of research findings through inappropriate statistical or other methods of measurement. The NAS report also indicated that attention need to be given to other behaviors that directly affect the detection, reporting, and investigation of research misconduct: cover-ups of misconduct in science, reprisals against whistleblowers, and violations of due process protections in handling misconduct complaints.

b. Personal communication from the Associate Inspector General for Investigations, U.S. National Science Foundation.

c. Questionable research practices are actions that violate traditional values of the research enterprise and that may be detrimental to the research process.

The NAS report noted that there is "at present neither broad agreement as to the seriousness of these actions nor any consensus on standards for behavior in such matters."[3] This situation creates serious problems for any education, prevention or enforcement efforts as recognized in an Institute of Medicine (IOM) report issued in 1989:

> Few academic institutions have established explicit standards for responsible research practices, such as guidelines for the recording and retention of research data or for inclusion as an author...the absence of explicit institutional standards allows the research system to tolerate substandard activities by a small number of individual investigators who fail to observe generally accepted practices. Furthermore, the absence of a mechanism to enforce standards leads to a perception that the institution or the profession is unwilling or unable to correct abusive practices.[4]

A recent study conducted for ORI shows the situation had not changed much by 2000.[5] Although considerably more medical schools do offer some research guidance to their faculty than in 1990 (78 vs. 13%), the guidelines demonstrate limited scope, a narrow focus, and lack of agreement on what topics guidelines should address.

In the study, each of the 125 accredited U. S. medical schools was asked to submit its guidelines on nine topics, eight of which are listed in Table 4, and on any other topic for which guidelines were available. Guidelines were provided on one additional area—intellectual property rights. No specific guidelines were submitted on two requested topics: collaborative research between scientists and laboratory management. When addressed, these topics were included under responsibilities of principal investigators, authorship, and data management. Guidelines were not requested on animal care, human protection, or research misconduct.

Conflicts of interest and intellectual property rights were the only topics for which the majority of medical schools had guidelines. Almost one-third of the institutions submitted guidelines that only covered these two topics. Each of the remaining six topics were in less than half of the guidelines.

Table 4: Medical School Research Guidelines. N=98

	N	**%**
Conflicts of interest	86	87.8
Intellectual property rights	65	66.3
Responsibilities of PIs	48	49.0
Data management	45	45.9
Authorship	34	34.7
Mentoring	23	23.5
Publication practices	16	16.3
Peer review	8	8.2

The number of topic areas covered by guidelines in each school was relatively small. Over 42 percent of the guidelines only covered two of the eight topic areas; 61.2 percent of the guidelines addressed no more than three topics, and 74.5 percent were limited to no more than four topics. Only six institutions covered seven or more areas.

Table 5: Number of topics per guideline

Number of topics	N	%
One	16	16.3
Two	26	26.5
Three	18	18.4
Four	13	13.3
Five	9	9.2
Six	10	10.2
Seven	4	4.1
Eight	2	2.0
Totals	**98**	**100.0**

The elaboration of each topic area was also somewhat limited. A content analysis examining behavioral recommendations made under the eight topics found that the 98 guidelines produced 48 content areas. The number of content areas under each topic ranged from 3-12. On average, guidelines included about half of the available content areas under each topic.

Table 6: Number of content areas covered under each topic

Topic	Total Content Areas	Average Number Included
Data management	5	2.0
Publication practices	4	2.0
Authorship	5	2.2
Peer review	3	1.8
Principal investigator	4	1.6
Mentoring	5	2.2
Conflict of interest	12	5.2
Intellectual Property	10	4.0

Sloppy/Careless Research Practices

Besides research misconduct and questionable research practices, concerns have been expressed about sloppy and careless research practices. Sloppy and careless research practices are worrisome, especially if widespread, because they directly threaten the reproducibility of research by introducing undisclosed, and perhaps unknown, variation in the conduct of experiments and studies. Unfortunately, data are not available on sloppy and careless research practices. Nevertheless, the IOM report contains this warning:

> ...the quality of the research environment may be more damaged by sloppy or careless research practices and apathy than by incidents of research fraud or other serious scientific misconduct...preliminary studies and workshop discussions suggest that the research community tolerates too many substandard practices. These abuses must be corrected to restore a sense of moral integrity and professionalism in research.[6]

Research Quality

Concerns about research misconduct, questionable research practices, and sloppy and careless research are raising questions about research quality. A study of the perceived quality of basic and clinical research conducted in U.S. academic health centers suggested ample room for improvement.[7] The study subjects were research administrators and department heads in the centers. In the article, the authors collapsed the two positive categories—very high and high. Employing this procedure, 79 percent of the subjects gave very high/high ratings to nonclinical research while 57 percent awarded comparable ratings to health services research. Nonclinical research was rated as highest quality and health services as the lowest. The three types of clinical research evaluated rated from 65 to 70 percent.

Table 7: Percentage of respondents perceiving high or very high research quality in academic health centers.

Type of Research	Very High	High	Total	N
Phase 1 and 2 trials	21	44	65	345
Phase 3 trials	28	42	70	413
Translational	29	38	67	347
Health services	24	34	57	381
Nonclinical	39	40	79	414

When the data are reported separately for the two categories, however, concern about research quality rises even further because the totals are primarily based on the "high" rating rather than the "very high" rating.[d] In no instance does the percent of high ratings exceed the percent of very high ratings. Only in nonclinical research is equality nearly achieved between the very high and high ratings.

The study director for the IOM and NAS studies has suggested that concerns about research integrity may be more effectively addressed by a "quality" approach:

> Integrity in science is perhaps better seen today as an extension of current concerns with *quality*—and the concept of quality represents a potent framework for fostering moral behavior as well as professional practices. If shoddy research means sloppy science as well as dishonest exchanges, then a concern for quality in research may create incentives to address the type of wrongdoing that falls short of serious misconduct but still disturbs and creates a sense of unease and dissatisfaction with the practice of science.[8]

PROFESSIONAL STATUS

Like doctors, lawyers, accountants, and engineers, scientists think of themselves as members of professions. And as members of a profession scientists claim special status in the world of work, especially autonomy from the larger society; they want to run their own affairs without interference from the external community. Although the

d. Personal communication with corresponding author.

definition of profession remains problematic, several criteria have been traditionally applied to the term:[9]

- grounded in systematic theory based on research, and unintelligible to lay persons;
- an extended socialization period required to learn the knowledge base and professional culture;
- a grant of autonomy from the community to exclusively deal with a set of problems that includes a fiduciary responsibility to those outside the profession;
- a normative structure that regulates relationships with clients and among colleagues;
- a commitment to a calling and service orientation; and
- a degree of self-regulation of the profession to ensure that certain standards of behavior are met by its members and that violations of those standards will be addressed appropriately.

The claim of professional status generates a professional responsibility to maintain oversight of the profession and its members. When a profession claims that the action of its members can only be understood and evaluated by other members of the profession, it obligates itself to conduct those evaluations. When a profession claims control over admission to its profession, it obligates itself to adequately train novices in the knowledge and techniques of the profession and socialize them into its values, norms and beliefs. When a profession finds deviant behavior among its members, it is obligated to take corrective actions to ensure protection of the public trust.

With professional status and the desired autonomy comes the responsibility for self-regulation; with the failure of self-regulation comes external control and reduced autonomy. The regulatory apparatus that has been developed over the last five decades is directly related to the failure of the research community to self-regulate in a manner that met its fiduciary responsibility to the larger community.

RESPONSIBLE CONDUCT OF RESEARCH

The concept of the responsible conduct of research (RCR) is being promoted as a comprehensive approach to the abuses of the research process.[10] As such, the RCR concept joins an array of terms—scientific misconduct, research integrity, research ethics, questionable research practices, sloppy or careless research, research quality, conflict of interest, animal welfare, human research protections - that are used to address abuses of the research process. Unfortunately, RCR like some of the other terms has not been explicitly defined. Neither the IOM nor the NAS report contain a definition of RCR. Instead, the IOM report defines "responsible and honest science" in terms of quality and integrity:

> Quality...refers to the rigor with which experiments are designed and carried out; statistical analyses performed, and results accurately recorded and reported, with credit given where it is due. Integrity in research means that the reported results are honest and accurate and are in keeping with generally accepted research practices.[11]

The NAS report defines the integrity of the research process and stipulates the components of the research process:

> By *integrity of the research process*, the panel means the adherence by scientists and their institutions to honest and verifiable methods in proposing, performing, evaluating, and reporting research activities.[12]
>
> The research process includes the construction of hypotheses; the development of experimental and theoretical paradigms; the collection, analysis, and handling of data; the generation of new ideas, findings, and theories through experimentation and analysis; timely communication and publication; refinement of results through replication and extension of the original work; peer review; and the training and supervision of associates and students.[13]

These definitions focus on proposing, performing and reporting research activities, but they are not limited to those activities. The IOM definition includes "with credit given where it is due." The NAS definition of the research process includes "peer review; and the training and supervision of associates and students." This elaboration suggests that RCR is not limited to proposing, performing, and reporting research activities, but encompasses other activities that protect the professional status of science and contribute to its maintenance as a social institution held in high repute in perpetuity. If so, the RCR concept may need to include the following:

Proposing, conducting and reporting research – These are the core elements in the responsible conduct of research. The components of the research process enumerated in the NAS report need to be characterized by honesty, accuracy, and verifiability. Also included are the acquisition, management, access. sharing, ownership, and retention of data, publication and reporting practices, and the integrity of proposals.

Socializing new members of the research community – Perpetuation of science as a social institution requires intergenerational transmission of the values, norms, and beliefs of science. The internalization of the culture of the profession provides the foundation for self-regulation. The socialization process and the role of mentor and supervisor are critically important.

Evaluating the work of other researchers – If members of the profession can only be evaluated by other members of the profession, then all members of the profession are obligated to provide competent and fair reviews of the work and conduct of their peers. This obligation includes the maintenance of confidentiality, the protection of intellectual property rights, prompt review, the elimination of conflicts of interest, and participation in misconduct proceedings.

Collaborating with other researchers – Research is a group activity that requires voluntary contributions to a coordinated endeavor. To be successful, these endeavors must establish explicit responsibility, authority, and reward structures.

Maintaining the commitment and morale of the scientific labor force – Commitment and morale depends on an equitable division of labor, the opportunity for professional growth, promotion and tenure policies, a fair distribution of credit for achievements, procedures for conflict resolution, effective communication, and pleasant working conditions.

Fostering research integrity – Research integrity is promoted by establishing expectations for behavior and employing mechanisms to control deviance. Expectations for behavior are communicated through policies, guidelines, codes, supervision, performance evaluations, and education programs. Deviance is controlled by employing mechanisms to detect, report, investigate, and sanction it.

Promoting public trust – Public trust is promoted by creating effective clinical treatments, producing dependable basic research findings, complying with the regulations developed to control the abuses of the research process, demonstrating accountability for public funds, and fulfilling the fiduciary responsibility the research professions have to the larger society.

The institutionalization of the RCR concept cannot be achieved by education programs alone because its impact goes beyond individual scientists to the functioning of research institutions, scientific societies, professional and institutional associations, journal publishers, and funding sources. Consequently, implementing the RCR concept will require a major and ongoing collaboration among these stakeholders in the research community. ORI is ready to facilitate and participate in that collaboration because it is the "right thing" to do for science.

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