

COMMENTS

Ethics in Research² (44535B)

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The well-being of our modern society depends on data obtained through research. Our daily lives are intertwined with decisions and acts that are based directly or indirectly on information compiled from research data. In the United States alone, there are 1 million scientists with 1.5 million support staff (1). Scientific research has become big business.

The American research enterprise grew rapidly after World War II. The increased government and private funding of scientific research led to increased numbers of scientists. Unfortunately, the postwar era of the scientific enterprise also brought with it complexities and dimensions not confronted before within the scientific milieu. Issues such as quality and integrity of data, conflict of interest, university-industry relationships, and misconduct behavior including fabrication, falsification, and plagiarism of data became part of the scientific community. In the past 10 years, increased attention has been focused on these issues. The critical issue for those of us engaged in the research enterprise is how to deal with and solve these problems. These problems need to be resolved, ideally by practicing scientists, because they conflict with our society's moral values and ethics.

What is Ethics? Ethics is a branch of philosophy that deals with morals (2, 3). By another definition, it is the philosophy of what is right and wrong. Our society has accumulated a set of values throughout its history that are recognized as intrinsically right or wrong. This set of values is an outgrowth of Greco-Roman and Judeo-Christian-

Islamic ethical codes. The basic principles of ethics are derived from the concept that we as individuals should treat others as we wish them to treat us. In other words, we would like to live in a society that protects individual liberties and that is eminently fair and just (2, 3). Ethics is an abstract concept until and when it becomes a reality to us. Then it becomes an action concept of what ought to be done—a code. This happens when we have to decide our actions in a context that affects us and our families. Whether a loved one should have an organ transplant, a decision concerning abortion, or what to do when someone takes away your hard-earned product, be it an intellectual or physical property. These are stark examples; however, there are thousands of other cases of lesser import that have a great impact on the quality of our lives as individuals or as a society.

Ethics as a discipline deals with the broader value system of our society that encompasses the consensual agreement on what is right and wrong. This set of values is much broader than that which is legislatively defined as legal and illegal. These values are the basic underpinning that helps to maintain civil and tranquil acceptance and agreement within society. The scientific community needs to address and resolve ethical problems not only because of their inherent unacceptableness to scientific research, but also to avoid the corrosive effect these problems eventually will have, if not resolved, on our society's mores. We need to be deeply involved in the ethical dialogue to at least maintain, and if possible, raise the barrier of unethical behavior in science. A climate of silence with regard to these problems will undoubtedly result in lowering the ethical barriers, to the detriment of our society.

Two key areas that need to be changed to insure the integrity of research are (i) institutional policies; and (ii) the attitudes and behaviors of individual investigators. Both areas are important; however, institutional policy changes can have quicker and farther reaching consequences. Therefore, we need to address policy makers and emphasize to them that certain policies can either foster integrity in research or breed fraud, misconduct, and sloppy work. To influence individual investigators without changes in institutional

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policies is nearly impossible. However, even if institutional policies are appropriate, then modifications in the behavior of individual investigators will be slow.

Are the current concerns regarding the integrity of research data an indication of (i) the decline in the ethical values and conduct of research by investigators and perhaps other segments of society; (ii) a new awareness of an old problem that is produced by a small and negligible number of sociopaths and deviants in our society; or (iii) an old problem that reflects an increasingly larger enterprise? Furthermore, what are we talking about—fraud, misconduct, careless practice, or errors?

Research is the attainment of new knowledge. This new knowledge is supposed to represent the current truth of our state of knowledge. Therefore, truthfulness is one of the pillars of conduct in research.

Ethical responsibility lies in defining clear boundaries concerning generally accepted norms of behavior for the public or private good. Philosophers throughout history have emphasized the importance of ethical and virtuous behavior by the individual. Ethical behavior within a society usually follows from the characteristics of individuals that form the institutions and society. This is a correct formulation. However, in a modern society, with its complex modern institutions, we need institutional policies that promote ethical behaviors. Therefore, as stated earlier, the ethical responsibilities within society should be divided between institutions and individuals.

The institutional ethos can have a profound effect on the prevalence of ethical behavior. It cannot eliminate unethical behavior but it can either minimize or foster unethical behavior. Individual ethical responsibility was emphasized by Thomas Jefferson who, in 1785, wrote: "An honest heart being the first blessing, a knowing head is the second" (4).

There is no doubt that Jefferson put an honest person and his or her integrity ahead of intelligence. Pellegrino, a well-known biomedical ethicist, further modernized Jefferson's statement to accommodate the current research environment when he stated: ". . .when no one is watching it is the character of the investigator that determines the moral quality of research. If research integrity is problematic, we must start, and end, with the investigator" (4).

Science in general and research in particular are strongly intertwined with social well-being. In modern times, practically all of the public policy decisions are, at least in part, based on research information. Our environmental laws are dependent on toxicological data. Our national security decisions are based on intelligence data-gathering. Our rockets, buildings, and biotechnology are all based on research data. The integrity and the quality of research data are intricately related to public policy, as emphasized by David Hamburg, President of the Carnegie Corporation, who, in his preface to the 1993 report to the Carnegie Commission on Science, Technology, and Government, said: "Science is not a separate entity, remote from

the lives of people. Indeed, science provides the basis for most of the requirements of modern living: the world has been transformed by science and technology in this century and this transformation is continuing, even accelerating, as the century comes to a close" (5).

Hamburg's statement emphasizes the enormous importance placed on the integrity and quality of data, as research data produced in the lab are intimately linked with the well-being of both our present and future society. Many scientists of great stature have long recognized the absolute need for maintaining data integrity. The late Richard P. Feynman, a Nobel Laureate in theoretical physics, and also a member of the investigative commission on the Challenger disaster, summarized his thoughts on the fundamental need for data integrity when he said:

"It's a kind of scientific integrity, a principle of scientific thought that corresponds to a kind of utter honesty—a kind of leaning over backwards. For example, if you're doing an experiment, you should report everything that you think might make it invalid, not only what you think is right about it: other causes that could possibly explain your results; and things you thought of that you've eliminated by some other experiment, and how they worked, to make sure the other fellow can tell they have been eliminated" (6).

To answer some of the questions raised herein, a historical perspective of the problem is needed. A biography of Abraham Lincoln written by Stephen B. Oates clearly defines what Lincoln thought of unethical behavior (7). Abraham Lincoln was known to tell humorous stories; eventually, the newspapers of the day started to refer to them as Lincoln's stories. Lincoln did not like that at all and made it known by stating, "I am a retail dealer" (7). He was clearly saying that he was not the author of these stories. Even in Lincoln's era, honest individuals would not take credit for things that were not theirs.

Researchers at the turn of the 20th century were no longer monks on top of a mountain. After the industrial revolution, and specifically, after World Wars I and II, the research enterprise grew very rapidly. As mentioned earlier, today in the United States alone, there are 1 million research scientists with a total of 2.5 million participants and a budget exceeding \$160 billion dollars annually (1).

Irregularities in research in the early 20th century include the famous story of the "Piltdown Man." Piltdown is a city near London where, in 1908, skull bones were found that seemed to prove that man was descended directly from apes. It is interesting how the original "finding" was well accepted by the scientific community without any intellectual appraisal simply because it fit the existing biases about evolution at the time. This "amazing" discovery was unfortunately subsequently discovered to be fraudulent, as the bones had been made to appear thousands of years old, and arranged in such a way as to imply that the single skull was a mixture of monkey and man. As Charles Blinderman stated when discussing the case: "Anyone conversant with the Piltdown history will rapidly, if not eagerly, agree that

many of the researchers shaped reality to their heart's desire, protecting their theories, their careers, their reputations, all of which they lugged into the pit with them" (8).

Table I depicts the number of scientific misconduct allegations received by the Office of Research Integrity (ORI) from 1992 to 1995. These data were received primarily from NIH funded research. Table II depicts the disposition of cases by ORI. As you can see, there are about 15–20 misconduct determinations per year, a very small number. This represents a percentage of about 0.035% of scientists who committed misconduct, as shown next:

Average rate of allegations and misconducts for NIH funded scientists, 1994–1995 (assuming NIH has 50,000 scientists)

Allegations = 0.047%

Misconduct = 0.035%

Source: ORI Annual Reports

It is important to remember that these numbers are the result of discovery of misconduct by accident (i.e., whistle blowers and self-confessors). There has never been a scientific way of random sampling or any other way to determine the true problems in research data. As you can see, total reliance of a system based on personal motivation is troubling. More importantly, this is not a scientific way of addressing the problem.

The initial institutional response to the problems in data integrity is similar to a very sick patient being told for the first time of his/her illness—denial, defensiveness, combativeness, reluctance, and acceptance. However, due to public pressure, research operations now have new regulations.

L.B. Lave, in his book "The Strategy of Social Regulation: Decision Frameworks for Policy" (9) summarized our society's dilemma with regulations in this way:

"Americans can't live with social regulation because of its cost and disruption and can't live without it because of the strong public desire to curb the worst abuses of an industrial economy. Neither of the extreme choices, putting more resources into the regulatory agencies or increasing promulgation rules versus eliminating the laws and agencies, is viable. Americans have no choice but to learn to accomplish these social goals with less controversy and greater efficiency."

Sociologists such as Emile Durkheim of the late 18th and early 19th centuries and those, such as Robert K. Merton and Harriet Zuckerman, who applied Durkheim's theories to the sociology of science in the past 50 years tell us

Table I. ORI Allegations

Year	Number of misconduct allegations by NIH
1992	56
1993	118
1994	100
1995	69

Note. Office of Research Integrity, U.S. Public Health. ORI Newsletter, 1, December 4, 1995.

Table II. ORI Misconduct Statistics

Year	Total	No misconduct	Misconduct	Adm. closure
1992	20	10	10	—
1993	16	6	10	—
1994	26	14	11	1
1995	41	14	24	3
Total	103	44	55	4

Note. Office of Research Integrity, U.S. Public Health Services. Annual Reports, 1992–1995.

that deviant behavior is due to a "breakdown in values," whether in the community at large or a subgroup such as the scientific community. Furthermore, sociologists deduced that "social control" was the guardian of norms and values in science. In 1977 Zuckerman stated: "Social control in science depends partly on scientists' internalizing moral and cognitive norms in the course of their professional socialization and partly on social mechanisms for the detection of deviant behavior and the exercise of sanction when it is detected" (10).

Also, she says: "[Society] must also provide for the detection of deviant behavior and for the exercise of sanctions when it occurs. In science, the institutionalized requirement that new contributions be reproducible is the cornerstone of the system of social control. It has two functions: deterrence and detection" (10).

Zuckerman then realized the potential weakness in her argument when she stated:

"Critics of the social organization of science contend that in all fields, insufficient incentives are provided for replication. And, of course, as long as reproducibility of scientific results remains an ideal not often realized in practice, it cannot serve as a deterrent to the 'cooking' of data" (10).

This is exactly one of the reasons why dependence on social control alone to deter the "cooking" of data, as she stated, does not work. More importantly, the cost of reproducing large and complex research projects is financially prohibitive. It is also undesirable for society to wait for a very long time (such a 5–10 years) to repeat a study when the research results address an important public health or security goal. As a matter of fact, by its very nature, the majority of research is not contestable and so won't be reproduced. Social controls also fall apart when research scientists promote a product or a drug in which they themselves have a large financial interest.

The three generic pillars of the problem of unethical behavior are: (i) conflict of interest; (ii) complexity; and (iii) remoteness (11).

Research is no longer conducted by one individual in a small laboratory, but rather by large and complex groups with differing expertise. Thus, laboratory directors rely on numerous portions of research data from different areas. Furthermore, the project leader may physically be at a remote location from the research laboratory as well as disconnected from the daily bench research.

The conflict of interest issue is even more important and critical in research than in any other system. In the financial world, one can compartmentalize and isolate several functions that have inherent conflict of interest. For example, those who send products to customers are separated from those who receive the payments. In research, those who collect, analyze, and manipulate the data are one and the same. Furthermore, in research it is not only undesirable to compartmentalize, but rather nearly impossible. In a fertile research environment you want all those involved to know and have access to the research data. Accessible research data are crucial for each subsequent step in research. Judge Learned Hand described conflict of interest well when he stated in 1939:

“Our convictions, our outlook, the whole make-up of our thinking, which we cannot help bringing to the decision of every question, is the creature of our past; and into our past have been woven all sorts of frustrated ambitions with their envies and of hopes of preferment with their corruption, which long since forgotten, still determine our conclusion. A wise man is one exempt from the handicap of such a past; he is a runner stripped for the race; he can weigh the conflicting factors of his problems without always finding himself in one scale or the other” (12).

An example of how research processes are affected by the investigator’s bias and motivation was found by Chalmers who, in 1983, evaluated 145 clinical trials of therapeutic drugs used in treating myocardial infarction (13). Chalmers categorized the studies in terms of three levels of bias control. For example, a good bias control is the double-blind experiment where neither the patient nor the physician knows who is receiving the new drug or placebo control. He found that the new drugs were effective: only 9% of the time when bias control was maximum; 24% of the time when bias control was moderate; and 58% of the time when no bias control procedures were in place.

Another example of how conflict of interest can raise serious issues involves the process of grant application by members of scientific advisory groups. In the United States, a large number of “Advisory Groups” in both science and related areas render “objective” and “unbiased” opinions on numerous public-health policy issues. The primary reason for the presumed objectivity of members of these advisory groups is their “expertise” in the subject matter. One should not underestimate the importance of these groups because they determine the expenditure of hundreds of millions of dollars. What is more important, these groups influence the direction of science and research in the country. In 1993 we conducted an analysis encompassing 10 years (1979–89) of advisory council members’ own research grant applications (14). This analysis examined the advisory council members’ merit rating and funding decision as compared with the rest of the scientific community. All research grant applications are first rated for merit (i.e., overall quality) by an expert scientific panel serving below the advisory council. The merit ratings of the grant proposals submitted by members

of the advisory council were found to be basically similar to the merit rating for the rest of the scientific community, indicating a fair and functional peer review. However, the percentage of applications from members of the advisory groups that were funded were almost twice as much as those grants submitted by the rest of the scientific community. This suggests that members of the advisory council may have inside information as to which programs are the least competitive; therefore, they gear their research project titles and abstracts toward those programs. This reflects a biased funding mechanism favoring those who sit in judgment of others.

Conflict of interest and objectivity in science can also interfere with giving proper recognition and credit to others. An example of this involves the Nobel prize-winning work of Brown and Goldstein. Their work involved discoveries related to the elucidation of the mechanism of familial hypercholesterolemia (FH) which explains in part the bigger issue of atherosclerosis. In 1964, Khachadurian was the first to show that FH was due to a single Mendelian gene disorder (15). There were three key discoveries: (i) the genetic pattern; (ii) the discovery that the disorder must be between the blood and the inside of the cell; and (iii) the discovery that the disorder involves a receptor on the cell membrane. Khachadurian made two of these three discoveries 4–7 years earlier than Brown and Goldstein. Brown and Goldstein discovered the receptor, and were awarded the Nobel prize. In our work, we demonstrated that there was a consistent pattern by Brown and Goldstein in not quoting Khachadurian’s work in the 70s and early 80s. However, after the award of the Nobel prize in 1985, Brown and Goldstein, as well as others, gave clear recognition of Khachadurian’s discoveries. Phillip Siekivitz, a leading U.S. scientist at Rockefeller University, addressed the intense competition faced by many scientists:

“The intense competition for recognition by peers and by the general public, for prizes, for commercial gain, is slowly eroding the scientific ethic, this is the ethic that depends on cooperation among scientists, on a morality that drives out selfishness, one’s acknowledgments of and by others. And if this ethos is disappearing, then the citation indices no longer reflect worth but a lack of the scientific *communitas*. The future of the scientific endeavor depends on regaining the scientific soul” (15).

A final example of unethical behavior in research can be found in studies conducted in the past 30 years that involve the mentally disabled. We surveyed published reports of research conducted using schizophrenic patients from 1966 to 1989 (16). It was found that a group of human subjects, many of whom were cognitively impaired, signed informed consent forms to participate in high-risk research experiments that would not benefit them. These kinds of experiments consisted of a sudden withdrawal of medications from medicated patients, who were stable and functional, to study relapses for days, weeks, months and, at times, up to a year. The methodology section claimed to

have recruited schizophrenic patients who were psychotic and delusional, but they were reported to have all voluntarily signed informed consent documents. However, Table III shows that in some studies the next of kin signed the informed consent document, and in a large number of cases the study does not even mention informed consent. Moreover, in 30 years of reported research in the United States, there was not a single case of reported suicides despite the fact that, in general, about 1% of schizophrenic patients commit suicide each year (17). The lack of reported suicides is also in direct contrast to both the recent testimonies of families and patients to the National Bioethics Advisory Commission (18), and the reported suicide rates in non-U.S. studies (Table IV) (17).

Peer Review/Data Audit

Issues that are critical to data integrity include: (i) falsification of data; (ii) fabrication of data; (iii) plagiarism; (iv) suppression and selection of data; (v) misuse of privileged information; (vi) poor data quality; (vii) abuse of human subjects; and (viii) abusive animal use.

In the search for a solution to ensure the integrity of research data, we found no reason to reinvent the wheel, but rather to adapt a formula used in the financial community and in its transactions, namely, auditing (19). Despite major differences in the implications of research data developed for our society and financial procedures within our society, common characteristics are shared by both. Therefore, it is proposed that peer review/auditing research data can become an essential tool in ensuring the integrity of research data. What is meant by peer review/data audit? Peer review/data audit is defined as a data review, conducted every 3–5 years if necessary, by one of the following: the research chief, an outside researcher within the university, and an outside researcher not affiliated with the university. These reviewers would determine the degree of correspondence between published reports and the original data, as well as identify any conflict of interest, financial or otherwise. As can be seen, peer review/data audit is an extension of peer review. The peer review/data audit should be flexible to accommodate the whole spectrum from pure peer review to pure audit depending on the case and subject.

There is a serious concern that peer review/data audit may be expensive and have a chilling effect on freedom of inquiry. To address this concern, let us share with you what

Table III. Comparison of U.S. and Non-U.S. Studies

Consent form signed by:	U.S. % (n = 2309)	Non-U.S. % (n = 1259)	British only % (n = 718)
	Pooled rates		
Patient	32	61	36
Next of kin	12	7	27
None ^a	56	32	37

^a Indicates that the study did not mention or specify anything about signatures on informed consent.

was suggested in an article in the AAA Observer, November 4, 1988:

“[I suggest the] establishment of an independent unit devoted solely to studies of research policies and quality assurance. The unit will fund badly needed training, education, and research. The unit will function by funding outside research activities. The unit will not monitor or enforce quality assurance. . . [but will oversee these areas:]

- the development of a code of ethics for research investigators (e.g., the Hippocratic Oath for physicians)
- the development of standards of research
- [the creation of] independent data auditors who will monitor the quality and integrity of research data. [These independent auditors] should function independently of academic institutions and government agencies” (20).

As can be seen from this earlier writing, training, education, research on the subject, and the protection of the creative process are emphasized. Moreover, to protect the creative process it was previously argued that:

“Often scientists test market several approaches to a research question without the need for well kept records. These are considered pilot experiments to test the feasibility, conditions, and potential worthiness of the project. Scientists legitimately fear that data audit will curtail and hamper this initial process. Common sense tell[s] us that data audit need not interfere with their initial process since science derives a great benefit from it. However, later and certainly before publishing or communicating these observations to the public, they should be subjected to vigorous scientific testing. It is in this second stage of development that the data should be susceptible to audit” (21).

Peer involvement is suggested, not government intervention. Admittedly, these suggestions could still be intrusive and detract from the autonomy currently practiced. However, a lack of action by our profession after we have been confronted with serious problems will result in greater intrusions into our autonomy if we do not act proactively to resolve them.

As an example of a situation where peer review/data audit could have been employed to great advantage, let us take the case of Imanishi-Kari versus Baltimore (22, 23). It took nearly nine years, and consisted of congressional hearings, media coverage, overzealous self-appointed fraud busters, and ego clashes between a Nobel laureate and a powerful congressman. This congressman headed the government operation oversight subcommittee and a data audit performed by lawyers, not scientists. This is a case where, if reason had prevailed, we could have had a peer review/data audit by scientists (peers) working independently of both the government and the university involved. The data auditors would have examined the degree of correspondence between the published results and the original data. If errors, sloppiness, or intentional alterations had occurred, they could have determined it without the intrusion of publicity, fame, egos, or lawyers. The matter could probably have been resolved in less than 1 year. Congress, whether

Table IV. Comparison of U.S. and Non-U.S. Studies

Country	Pooled rates					"Person years"
	No. of studies	No. of patients	No. of relapses (%)	No. of dropouts (%)	No. of suicides (%)	
U.S.	41	2309	900 (39%)	243 (10.5%)	0 (0%)	1798
Non-U.S.	25	1259	583 (46%)	95 (7.6%)	7 (0.6%)	1727
<i>p</i> value ^a			0.001	0.004	0.001	

^a U.S. versus Non-U.S. (Pearson χ^2) Fisher's Exact Test.

the executive or legislative branch, should not micromanage science but should stick to broad policy issues and true oversight. The university that is involved should not be investigating itself because of the inherent conflict of interest. We should have an independent group of scientists who, on a case-by-case basis, perform a scientific data audit based on valid statistical sampling techniques and render judgment.

In this century, errors, deceptions, and fraud have lasted too long (as in the case of the Piltdown man), have had tragic consequences (e.g., the Challenger disaster), or have resulted in protracted misconduct investigations as discussed above in the David Baltimore case. Justice delayed is justice denied. It is apparent that society cannot fully depend on the current system that exhibits a lack of concern over the issue of unethical conduct in research. Our proposals are straightforward and simple and provide for an increase in education, training, and research, as well as the introduction of peer review/data audit by organizations run independently from the government. These are reasonable avenues with very modest costs that would result in reducing (and the emphasis is on the goal of reduction, not elimination of) fraud, misconduct, and shoddy work. More important, a system of self-monitoring by practicing scientists will restore public confidence in one of our most vital institutions. Ironically, it was Nicolo Machiavelli who said:

"There is nothing more difficult to carry out, nor more doubtful of success, nor more dangerous to handle, than to initiate a new order of things. For the reformer has enemies in all who profit by the older, and only lukewarm defenders in all those who would profit by the new order" (24).

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