PHS Perspectives on Misconduct in Science

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SYNOPSIS

The Public Health Service (PHS) has undertaken a major effort to develop improved policies and procedures for dealing with misconduct in its research programs. Included in the definition of "misconduct" are the violation of Federal laws, regulations, or policies governing research or research training conducted, funded, or regulated by the Department of Health and Human Services; breaches of professional ethics that raise serious questions about an investigator's or institution's scientific or fiscal integrity; and serious failures to comply with other terms or conditions of an award.

Recent incidents of falsification or misrepresentation of data and failure to comply with requirements for protection of human and animal subjects of research represent only a fraction of all research projects. However, they are troubling evidence that the traditional safeguards of science are not sufficient to prevent and detect willful wrongdoing. Research agencies, awardee institutions, and individual investigators have a collective responsibility to prevent misconduct in public research programs. The agencies and institutions, in turn, must deal promptly and equitably with allegations or evidence of misconduct.

Individual research institutions and their professional organizations have developed policy statements affirming their responsibility for the integrity of the research enterprise and proposing specific procedures for dealing with incidents of misconduct. The National Institutes of Health currently serves as lead agency for a parallel PHS effort that includes a statement of general policies and principles, to be augmented by specific procedures for awarding agencies, regulatory agencies, and PHS intramural programs, as well as procedures for information sharing and joint investigations.

DURING THE PAST 2 YEARS, participants in the biomedical research enterprise—including its public supporters—have seen dramatic and disconcerting incidents of misconduct in federally funded research programs. Recent examples include falsification, fabrication, intentional misrepresentation, and mishandling of data. There also have been reported instances of misuse of research funds and failure to comply with the terms and conditions of awards, including requirements for protection of human subjects and animal welfare.

Although some historians of science have debated whether legendary figures such as Galileo, Mendel, and others forced their observed data to conform to theoretical specifications, the recent revelations of misconduct have come as a shock to practicing scientists, research agency administrators, and the American taxpayer. For the most part, almost all of us have assumed that scientific research is immune from pressures and opportunities for fraudulent behavior.

This traditional public and professional faith in the integrity of science is, in my judgment, unquestionably well-placed. Science is, first and foremost, a quest for knowledge and truth. The rigors imposed by the scientific method are reinforced by other practices that tend to uphold the norms of the profession. Peer review of research proposed for funding, editorial practices of refereed journals, and replication of significant experimental work are designed to ensure that research findings meet the highest standards.

These practices are based on the assumption that individual investigators, while perhaps erring in methodology or hypotheses, are fundamentally honest. They are not designed, however, to detect clever,

systematic cheating. More recent requirements for protection of human and animal subjects of research similarly depend to a great extent on the cooperation and good intentions of individual researchers. Even our financial audits are designed primarily to detect inappropriate expenditures, although they can and do identify fraud as well.

Dimensions of the Problem

Although there is general agreement that the incidence of reported or suspected misconduct in science has increased, specific information has only recently become available. The National Institutes of Health (NIH) has begun compiling such information with respect to its activities. The NIH figures include data on fraudulent practices such as fabrication, falsification, and misrepresentation of data; failure to observe requirements for the protection of human subjects and welfare of laboratory animals; and other practices constituting a serious breach of professional ethics or violation of the terms and conditions of an award. Not included are strictly fiscal infractions, for which investigative techniques and sanctions have been established for some time.

The most comprehensive NIH review showed that 45 cases of alleged or suspected misconduct had come to the agency's attention between October 1, 1980, and September 30, 1982. More than half of these were shown not to be misconduct, and some could be attributed to correctable deficiencies within the awardee institution.

Viewed against a denominator of more than 20,000 NIH grants and contracts active each year, these numbers are small, almost insignificant. Viewed in the context of the ethics of science, the public's faith in research, and the unknown dimensions of possible unreported incidents, they are profoundly disquieting.

The realization that traditional safeguards of science could not entirely prevent misconduct was soon followed by the perception that awardee institutions and funding agencies were ill-prepared to deal with allegations or documentation of misconduct. We have, of course, always had audit and investigative units to pursue cases involving misuse of funds or other criminal activities. More recently, the NIH Office for Protection from Research Risks (OPRR) has played an important role in detecting and dealing with failure to comply with requirements for protecting human and animal subjects of research. Until recently, however, we have been able to treat each incident as an isolated event, employing ad hoc procedures for each case.

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But it finally became apparent that more explicit and predictable procedures were needed to enable the funding agencies to deal with the increasing number of cases of alleged or actual misconduct. It is clear in retrospect that lack of policies and procedures resulted in a number of false starts and inordinate delays. As research administrators, we were ill-equipped to deal with the conflicting demands of accountability and fiscal stewardship, on the one hand, and due process and protection of individual privacy on the other. We have benefited greatly from the public and Congressional debate engendered by some recent cases, but continue to find these conflicting considerations to be among the more troublesome issues we face.

The Public Health Service Response

The Public Health Service has responded to these developments in a number of ways. In the fall of 1981, Secretary of Health and Human Services Richard Schweiker identified as a major management initiative the development of improved policies and procedures for dealing with misconduct in science. At his request the NIH, the Alcohol, Drug Abuse, and Mental Health Administration, and the Food and Drug Administration proposed specific steps to improve the agencies' ability to prevent and deal with misconduct and to encourage the research community's support of that important effort. Among the major agency initiatives that have been carried out are the following:

- Conduct of regional seminars for investigators, academic officials, and institutional review board members regarding Department of Health and Human Services regulations for protection of human subjects and related regulations and policies.
- Presentations to members of NIH advisory coun-

cils and peer review groups concerning their responsibilities related to misconduct in science.

- Improvement of internal NIH procedures for identifying incoming grant applications and contract proposals from individuals or institutions under investigation or subject to postinvestigational sanctions.
- Modification of the coding and processing of competing grant applications to ensure that all requirements for protection of human subjects are met.
- Development of a uniform procedure for documenting the results of staff review of annual progress reports.

NIH also undertook an intensive review of its policies and procedures to determine the need for improved guidance to agency staff and awardee investigators and institutions. In August 1982, I directed NIH to take the lead in developing policies and procedures for all PHS research programs, and to include in that effort mechanisms for communication and collaboration among agencies when appropriate. An interagency committee has undertaken development of the following documents:

1. *Policy Statement.* A brief statement of policy, intended to underscore the commitment to integrity in all research funded, conducted, or regulated by the PHS. That statement accompanies this article.

2. *Policies and Procedures for Awarding Agencies.* A step-by-step guide for agency staff covering the "life cycle" of an incident. It outlines procedures for evaluating the significance of allegations, conducting an investigation, taking interim administrative actions when appropriate, and imposing postinvestigational sanctions when warranted. It emphasizes the need to protect the rights of accused individuals and "whistle blowers" and to provide an adequate public record of the agencies' actions without violating the privacy of individuals. An important section of this document is a statement of expectations for awardee institutions that underscores the institutions' responsibility for the research environment as well as their joint responsibility for the stewardship of public funds.

3. *Policies and Procedures for Intramural Research Programs.* Guidance for agency research managers who may confront allegations or evidence of misconduct in an agency's in-house research program. The document embodies many of the same principles enumerated in the extramural document, adapted to take into account the employer-employee relationship. We view it as the PHS internal counterpart of similar procedures now in place or being developed at many research institutions.

4. *Policies and Procedures for Regulatory Agencies.* A compendium of regulatory procedures, primarily those of the Food and Drug Administration. This document differs from the preceding two in that it is primarily a distillation and summary of well-established procedures used by the agencies to ensure the integrity of regulated research.

5. *Interagency Collaboration and Communication.* Establishes a forum for ongoing consultation on matters of policy and for collaboration on specific investigations of concern to more than one PHS agency. It includes two major components: a standing interagency committee to facilitate informal consultation and information-sharing and an extension of the NIH "alert" system to all PHS research programs.

The alert system deserves special mention. It was developed in response to NIH's need to be informed when an individual or institution, under investigation because of possible misconduct under one award, submits an application for funding to another awarding unit that might be unaware of the pending investigation. The alert is not intended, and is not used, to bar an award simply because an investigation is in progress. It does provide a means for appropriate sharing of information among concerned awarding units so that intelligent funding decisions can be made. More recently, its scope has been expanded so that it is also used to implement postinvestigational sanctions such as special review or terms of new awards.

The alert system is managed by the Division of Management Survey and Review (DMSR), NIH's internal investigative unit, in cooperation with the Division of Research Grants and contracting officers. The NIH Associate Director for Extramural Research and Training (ADERT) determines when an individual or institution will be placed in the alert system and must be consulted before an award is made to such an individual or institution. Individuals are frequently informed that they have been placed in the alert system, and in any case they may have access to that information under the Privacy Act. Otherwise the information is strictly limited to DMSR, the ADERT, and the director of the NIH component to which an application for funding is referred.

The interagency work group mentioned earlier is currently developing a plan to extend this alert system to all PHS research agencies. NIH will con-

PUBLIC HEALTH SERVICE POLICIES FOR HANDLING MISCONDUCT IN SCIENCE

General Policies and Principles

BACKGROUND AND PURPOSE

A. Instances of misconduct in scientific activities conducted, funded, or regulated by the Public Health Service (PHS) are infrequent. However, when such instances occur, they present a serious threat to continued public confidence in the integrity of the scientific process and the stewardship of Federal funds.

B. This policy provides the basis for uniform procedures for dealing with reports of misconduct, as the term is defined herein, and the responsibilities for such actions.

APPLICABILITY

The policies and procedures articulated in this document apply to all instances of real or apparent misconduct involving research, research training, and related activities conducted, funded or regulated by the PHS.

DEFINITION

"Misconduct" is defined as: (1) the violation by an investigator or institution of Federal laws, regulations, or policies governing research or research training conducted, funded or regulated by the Department of Health and Human Services (DHHS), e.g., mismanagement of Federal funds or material failure to comply with requirements governing the protection of human subjects or the welfare of laboratory animals; (2) breaches of professional ethics that raise serious questions about an investigator's or institution's scientific or fiscal integrity; and (3) serious failures to comply with other specific terms or conditions of an award.

POLICY

A. It is the policy of the PHS to maintain high ethical standards in research and to investigate and resolve promptly and fairly all instances of alleged or apparent misconduct.

B. The scientific community is expected to make every effort to prevent misconduct. Also, for every incident of alleged or apparent misconduct which is judged to warrant investigation by an awardee institution, that institution is expected to report on the matter to the head of the appropriate PHS agency/office or that agency's/office's designee in accordance with PHS reporting requirements.

SANCTIONS

If it is determined that misconduct has occurred, the head of the PHS agency/office has a number of options available, depending on the severity of the misconduct and the nature of the agency's mission. These could include:

1. actions with respect to present or future grant and/or contract awards (e.g., imposition of special conditions, termination, recommendation for debarment or suspension);
2. regulatory actions (e.g., disqualification);
3. in the case of intramural research programs, termination of employment or other disciplinary action.

RESPONSIBILITIES

A. The Associate Director for Extramural Research and Training (ADERT), Office of the Director, NIH, is the PHS designated official for the development and assessment of policies and procedures for preventing, detecting, reporting, and handling instances of misconduct in science and for oversight and coordination of PHS activities related to misconduct.

B. The head of each agency/office will:

1. Provide leadership to ensure appropriate agency implementation of policies and procedures for the fair and prompt handling of instances of misconduct in science.
2. Make decisions regarding sanctions that should be applied in a given case of confirmed misconduct, and
3. Designate an official for implementing PHS policies and procedures; coordinating its activities with the PHS designated official and other departmental officials, including the Inspector General and the General Counsel, as appropriate; and ensuring that each bureau, institute, and equivalent organization designate an official for handling matters related to misconduct in science.

C. Alleged violations of Federal regulations governing the protection of human subjects or PHS animal welfare policy in cases involving DHHS funded research are the responsibility of the Office for Protection from Research Risks (OPRR), NIH.

tinue to manage the system, with appropriate safeguards to ensure confidentiality.

Response of the Research Community

The biomedical research community has been quick to recognize that new Federal policies, while necessary, are not sufficient to deal with the problem of misconduct in science. Both the Association of American Medical Colleges and the Association of American Universities have developed statements of principles and model procedures for the guidance of their member institutions. Several institutions have developed their own guidelines or are in the process of doing so.

The institutions' efforts are particularly noteworthy because they do more than simply expand or elaborate existing internal procedures for investigating and adjudicating alleged misconduct. At a more fundamental level, the institutions also are concerned about whether the mores of academic science may be contributing to the problem, and for that reason they are urging less emphasis on quantity of publications and more attention to the quality of research. Although the institutions have not achieved consensus on when the funding agency should be notified about possible misconduct, they clearly recognize their obligations as recipients of public funds.

The scientific journals have similarly begun to consider whether changes in editorial policies may be needed. Many journals, for instance, do not publish retractions or do so only when all authors request it. Perhaps this policy needs to be modified in order to deal with documented but unacknowledged misconduct on the part of one of the authors of a manuscript.

Individual investigators also need to reassess their own behavior, and many are doing so. Some have learned—the hard way—that the position of coauthor or project director carries with it responsibility for the veracity of the final results. No one has any desire to police the laboratory or otherwise stifle the open atmosphere necessary to creative scientific research, but it seems clear that more caution and rigor in collaborative efforts may be warranted.

I am particularly pleased with the way in which individual scientists have contributed to our efforts to deal with the problem of misconduct. Members of NIH peer review groups and National Advisory Councils have listened to the agency's concerns and have offered helpful insights, cautions, and suggestions. Especially gratifying has been the response of those who have been asked to lend their expertise to agency investigations. Despite the arduous and often unpleasant nature of these tasks, we have been fortunate in obtaining the services of some of the most eminent scientists in the country, who clearly recognize and accept the scientific community's collective responsibility for the well-being of the research enterprise.

What Lies Ahead

As this article goes to press, the PHS policy and procedure documents will be completed, or nearly so. Presumably, the research institutions will continue to develop and refine their procedures as well. More than likely, we will see one or more new accounts of misconduct in science. I believe, however, that this unfortunate trend soon will change direction as all partners in the research enterprise learn to deal with real or apparent misconduct in a prompt and equitable manner. Thus, I would urge greater attention to preventing misconduct—through educational efforts, reexamination of our values regarding what constitutes appropriate scientific endeavor, and commitment to dealing firmly with documented instances of misconduct. Our ability to follow through on these commitments is critical if science is to enjoy the continued support of the American people and thereby give society the full measure of benefit in return.