The Responsible Conduct of Research in the Health Sciences

Committee on the Responsible Conduct of Research, National Research Council

ISBN: 0-309-56462-X, 106 pages, 8.5 x 11, (1989)

THE RESPONSIBLE CONDUCT OF RESEARCH IN THE HEALTH SCIENCES

Report of a Study by a
Committee on the Responsible Conduct of Research
INSTITUTE OF MEDICINE
Division of Health Sciences Policy

National Academy Press
Washington, D.C. 1989

NOTICE: The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competencies and with regard for appropriate balance.

This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

The Institute of Medicine was chartered in 1970 by the National Academy of Sciences to enlist distinguished members of the appropriate professions in the examination of policy matters pertaining to the health of the public. In this, the Institute acts under both the Academy's 1863 congressional charter responsibility to be an advisor to the federal government and its own initiative in identifying issues of medical care, research, and education.

Support for this project was provided by the National Institutes of Health, Department of Health and Human Services pursuant to Contract No. NO1-OD-7-2111.

2101 Constitution Avenue, N.W.

Washington, D.C. 20418

(202) 334-2352

Publication IOM-89-01

INSTITUTE OF MEDICINE

COMMITTEE FOR THE STUDY ON THE RESPONSIBLE CONDUCT OF RESEARCH

ARTHUR H. RUBENSTEIN, * (Chairman), Chairman of Medicine, University of Chicago, Chicago, Illinois.
WILLIAM G. ANLYAN, * Chancellor for Health Affairs, Duke University Medical Center, Durham, North Carolina.
MARCIA E. ANGELL, Executive Editor, The New England Journal of Medicine, Boston, Massachusetts.
BERNARD BARBER, Chairman of Sociology, Barnard College, Columbia University, New York, New York.
EMILIO. Q. DADDARIO, * Attorney, Washington, D.C.
JOSEPH M. DAVIE, * President, Searle Research and Development, Skokie, Illinois.
CARL DJERASSI, * Professor of Chemistry, Stanford University, Stanford California.
PAUL J. FRIEDMAN, Associate Dean of Academic Affairs, School of Medicine, University of California at San Diego, LaJolla, California.
JULES HALLUM, Chairman of Microbiology and Immunology, The Oregon Health Sciences University, Portland, Oregon.
FRED JEROME, Director, Media Resource Service, Scientists' Institute for Public Information, New York, New York.
LINDA K. LORIMER, President, Randolph Macon Woman's College, Lynchburg, Virginia.
WILLIAM F. MAY, Cary M. McGuire Professor of Ethics, Southern Methodist University, Dallas, Texas.
CURTIS L. MEINERT, Professor of Epidemiology, School of Hygiene and Public Health, Johns Hopkins University, Baltimore, Maryland.
CHARLES G. MOERTEL, Director of Comprehensive Cancer Center, Mayo Clinic, Rochester, Minnesota.

*Member, Institute of Medicine

HOWARD E. MORGAN, * Senior Vice President for Research, Geisinger Clinic, Danville, Pennsylvania.
MARTIN F. SHAPIRO, Associate Professor of Medicine, University of California, Los Angeles, California.
ROBERT A. WEINBERG, Associate Professor of Biology, The Whitehead Institute for Biomedical Research, Cambridge, Massachusetts.

PREFACE

In 1985, the President of the Institute of Medicine (IOM) requested its Board on Health Sciences Policy to advise him on a program that would respond to the occurrence of misconduct in biomedical research. The board discussed this topic and concluded that the IOM should examine the subject in a context larger than the conduct of investigations into allegations of scientific fraud. Those matters already were receiving widespread attention as a result of the development of federal regulations concerning research misconduct. The board saw a need to identify the positive steps that could be taken to improve the conduct of research and to address types of scientific misconduct other than fraud.

Subsequently, discussions were held with the National Institutes of Health (NIH) about areas of mutual concern in reference to possible misconduct that might not constitute fraud but would still represent potentially serious violations of professional norms in areas of publication practice, recordkeeping, release of data, and other activities of health sciences research.

In September 1987, the Institute of Medicine initiated the project for which this is the report. IOM appointed a 17-member committee to conduct a workshop and to develop recommendations that would assist NIH, other government agencies, professional societies and journals, and universities in formulating policies and procedures to improve the integrity and quality of biomedical research.

The committee was not asked to develop specific guidelines for the technical issues related to the conduct of research (such as the length of time that research data should be stored or retained) or to carry out a comprehensive study. Our study sought neither to improve research methodology nor to evaluate the technical quality of current individual research practices.

The primary task of the committee was the development of principles and proposals to guide both national and local institutions in strengthening the professional standards of academic research. Our concern was the moral and professional climate of the research environment, which influences everyday practice and sets the tone for future generations of researchers. By improving the integrity and quality of the institutional environment of research, we sought to foster professional research standards of individual researchers and to discourage future incidents of scientific misconduct.

Quality in this sense 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.

Error is accepted as part of the price of doing experimental research, but responsible investigators assume that when errors are detected they will be corrected by the publication of new findings.

Throughout this report we refer to terms such as "good research practices," "standards of research," "guidelines for the conduct of research," and so forth. These terms were used interchangeably in both the committee discussions and in the workshop. They are synonymous, and the committee did not attempt to define them in detail. At some later point, we believe it will be important to clarify the meaning of concepts that are just beginning to emerge in the consideration of policies and procedures to encourage responsible research practices.

This report summarizes the findings and recommendations of the committee following a year of discussion and analysis. The recommendations are based in part on ideas and proposals presented at a workshop on September 6-8, 1988, in Washington, D.C. The workshop was cosponsored by the Institute of Medicine and the Academy's Committee on Science, Engineering, and Public Policy.

The committee also commissioned two background papers and conducted, as part of the project, a limited review of selected government reports and research literature on scientific misconduct, research quality, professional ethics, and deviance in science. The background papers included a review of the federal regulations establishing good laboratory practices, prepared by Sheila Jasanoff at Cornell University, and an analysis of scientific authorship and publication practices, prepared by Edward Huth, editor of the Annals of Internal Medicine. These papers are not included in the final report but are available from the National Academy Press upon request.

The committee's findings and recommendations address the initial steps that should be taken to improve the responsible conduct of health sciences research in the American university system. The committee believes, however, that these insights and proposals also will have value for other fields of research and other institutional settings.

Arthur H. Rubenstein
Chairman
Committee on the Responsible Conduct of Research

CONTENTS

CHAPTER 1

SUMMARY

Several strong themes have emerged in policy discussions about the appropriate nature of public and private institutional responses to incidents of scientific fraud and research misconduct. First, government agencies, professional organizations, and research institutions have consistently affirmed that the primary responsibility for handling these cases should rest with awardee institutions, the ones doing the research. Second, recent federal regulations have generated new requirements for research institutions to adopt explicit, written guidelines for handling allegations of scientific misconduct. Third, these misconduct guidelines and policy directives reveal a need for additional mechanisms to encourage high ethical standards for research.

There is wide variation among universities in their efforts to define appropriate standards for research, and professional standards that govern various research practices have remained ambiguous in some instances. The absence of formal standards or written guidelines for the ethical performance of research has generated uncertainty about the criteria for distinguishing practices that violate professional norms from activities that are simply part of the variation around these norms.

Investigations of cases of scientific fraud suggest that various factors in the research environment may contribute to the occurrence of scientific misconduct even though they are not the direct causes of these occurrences. Examples include pressures to "publish or perish," an emphasis on competition and secrecy in research performance, and inadequate interaction of young researchers with their peers and mentors. There is concern that not only ethics but also the quality of scientific research in general may suffer in this environment.

These concerns have prompted research institutions, professional organizations, government agencies, and congressional oversight committees to search for policies that will strengthen the integrity and quality of the research environment. As in the case of public concern over the research use of human and animal subjects, these policy discussions raise fundamental questions about the adequacy and effectiveness of the current self-regulatory system in assuring responsible research practices and preventing scientific misconduct.

PURPOSE OF THE STUDY AND APPROACH

The purpose of this study was to examine these questions and to propose ways to encourage high ethical standards in the conduct of research without damaging the freedom and creativity that have traditionally characterized American research institutions. A workshop

was a productive means for the IOM study committee to gather information and perspectives about standards and practices that affect the conduct of research in the health sciences. More than 100 clinical and basic research scientists, government and university officials, professional society officers, journal editors, and members of the press attended the workshop, held in September 1988 in Washington, D.C. An agenda and list of participants are included as appendixes to this report.

ASSUMPTIONS AND FINDINGS

In meetings before and after the workshop, the committee arrived at assumptions and findings that formed the basis for their policy proposals and final recommendations contained in this report. In the absence of definitive data documenting the integrity of existing research practices and the level of misconduct in health sciences research, the committee relied upon expert opinion. These assumptions and findings may not be shared by all members of the research community--indeed, they were not shared by all workshop participants--but they quickly emerged as a consensus of the committee. These assumptions and findings deserve explanation and clarification because they form the foundation for this report.

- Scientists develop and maintain quality and accuracy in research practice by self-regulation, extensive reliance on each investigator's professional standards, and the traditions and collegiality that characterize research institutions.
- A variety of informal and formal practices and procedures exist in the academic research environment to assure and maintain the high integrity of research conduct.
- 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 committee believes that 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.
- There are very few courses of instruction dedicated to communicating professional standards and the ethics of research practice to young scientists.
- The culture of the American university is distinguished by traditions and styles of governance that assume professional integrity and that place great value on the independence and collegiality of individual faculty.

— Investigations of a small number of publicly reported cases of scientific fraud and other research misconduct suggest that a mix of factors contributed to this deviant behavior. One of these was an unhealthy research environment that failed to discourage (or even tolerated) sloppy or careless research standards. Although the committee believes that serious misconduct in science is rare and is ultimately a manifestation of individual deviance, it concludes that institutions fail to detect and correct early deviant behavior primarily because of an excessively permissive research environment that tolerates careless practices. The committee also believes that substandard practices are encouraged by funding pressures and an overemphasis on publication as the main means of achieving status and recognition for scientific advancement and research support.

— Increasing budgetary and competitive pressures in science demand that local research institutions and government research funders develop standards to ensure responsible research practices to ensure the integrity of the academic research enterprise.

— Effective institutional reforms to improve integrity and responsible research practices require better understanding of the key factors that influence professional development and performance in science.

RECOMMENDATIONS

In developing recommendations, the committee sought to define appropriate roles for government, universities, research institutions, professional organizations, and scientific journals that would stimulate local institutional and professional efforts without creating an unjustifiable regulatory burden on the research community. These recommendations represent the steps that the committee believes are most appropriate for action at this time in seeking to promote integrity in health sciences research.

Recommendations for the National Institutes of Health

1. The National Institutes of Health should establish an office to promote responsible research practices. This office should be coordinated with an expanded NIH effort to evaluate institutional investigations of misconduct in scientific research. The primary function of the office should be to foster and monitor the development of high professional standards of research practice by all grantee and applicant institutions.
2. By 1992, NIH should require all grantee and applicant institutions to provide assurances that they have adopted policies and procedures to encourage responsible research practices. Research applicants should affirm their familiarity with these policies and

procedures and should also propose how they plan to store research data in the course of their study.

3. NIH should not implement random data audits as a mechanism for ensuring the responsible conduct of investigator-initiated research.
4. NIH should adopt professional standards to ensure responsible research practices by its intramural scientists.
5. NIH should adopt policies to limit the number of publications that can be considered as part of any grant application, in order to emphasize quality over quantity.

Recommendations for Universities and Other Research Centers

6. Universities, medical schools, and other research organizations should adopt guidelines to clarify the expectations of each institution about the professional standards to be observed by investigators in the conduct of research.
7. Universities should provide formal instruction in good research practices. This instruction should not be limited to formal courses, but it should be incorporated into various places in the undergraduate and graduate curricula for all science students.
8. Universities should designate one or more administrative officers or faculty members to promote responsible research practices within the institution. The institution should also provide mediation and counseling services for faculty, staff, and students who wish to express concerns about professionally questionable training or research practices.
9. Universities and other research institutions should strengthen the integrity and quality of research by modifying incentives and academic guidelines in order to reduce the pressure for excessive publication.
10. Academic departments and research units should monitor the supervisory and training practices of their faculty and research staff to ensure that adequate oversight is provided for young scientists.
11. Academic departments and research units should adopt authorship policies to improve the publication practices of their faculty, staff, and students.

Recommendations for Professional and Scientific Organizations and Journals

12. Professional and scientific organizations representing the research community should develop educational and training activities

and materials to improve the integrity of research. These organizations should assist universities in identifying substandard research and training practices that compromise the integrity or quality of research.

13. Scientific journals should develop policies to promote responsible authorship practices, including procedures for responding to allegations or indications of misconduct in published research or reports submitted for publication.
14. The National Academy of Sciences should pursue the issues and findings developed by the Institute of Medicine in this report and examine their relevance and application to other fields of scientific research.
15. An interdisciplinary committee should be convened to study the issue of rights and responsibilities of all relevant parties to research data and to prepare model guidelines for data sharing and data access.
16. There are many issues that deserve further analysis to enhance institutional and policy efforts to discourage scientific misconduct and to improve the integrity and quality of research. The committee recommends that professional and scientific organizations initiate studies to understand and encourage responsible research practices.

CHAPTER 2

HISTORY

Many agencies and organizations have recently discussed the policies and procedures that government, universities, and other research organizations should develop to deal with complaints of scientific misconduct. However, insufficient attention has been given to identifying and encouraging practices that will promote responsible and honest science. The purpose of this report is to foster these practices and to identify next steps that can be taken by various components of the research system to improve the quality and integrity of research in the health sciences.

Quality in this sense 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. Error is accepted as part of the price of doing experimental research, but responsible investigators assume that when errors are detected they will be corrected by the publication of new findings.

Discussions of integrity and quality in research have led the research community and others to examine more closely the reliability and effectiveness of the current mix of formal and informal practices and procedures in promoting a healthy research environment. Many organizations are now seeking to define appropriate guidelines that should govern scientific research and the principles that should be observed by individual investigators and trainees in day-to-day practice.

Over the past decade misconduct in research has attracted increasing attention from the press, the public, the Congress, and the academic and research communities. This attention was initially drawn by a few highly publicized instances of data fabrication, plagiarism, and misrepresentation, such as the incidents involving John Long at Massachusetts General Hospital, Vijay Soman at Yale University, and Mark Spector at Cornell University (Broad and Wade, 1982). Because many of these cases involved federal research funds and prestigious institutions, congressional hearings were convened in 1981 to review the policy implications of scientific fraud (U.S. Congress, 1981). During these hearings, representatives of the scientific community claimed that incidents of scientific fraud were rare, that existing mechanisms were adequate to deal with these events, and that there was no need for additional policies or procedures to ensure the integrity of federally funded biomedical research.

Shortly after these hearings, new cases of serious scientific misconduct came to light. The handling of these cases, involving John

Darsee at Harvard Medical School, Marc Strauss at Boston University, and others, raised new questions about the ability of academic institutions to conduct objective investigations of misconduct by their own faculty members or research staff.

PROFESSIONAL AND UNIVERSITY EFFORTS

In October 1981, the Association of American Universities (AAU) established a Committee on the Integrity of Research, chaired by William H. Danforth, chancellor of Washington University. The charge to the committee stated:

> Incidents of misconduct which raise concern about integrity in scientific research have come to our attention. Although we believe research, even rare occurances are unacceptable. such instances to be rare for such a large enterprise as university
>
> The AAU therefore recognizes a need for universities to collaborate with professional societies and related organizations in the examination of the sources of such problems and remedies available to them (AAU, 1983).

The report of the AAU Committee on the Integrity of Research was published in 1982. It affirmed the principle of self-regulation in maintaining the integrity of the academic research process. The committ concluded, however, that informal and quiet efforts to deal with intellectual dishonesty were no longer acceptable: “Although these methods may have generally worked well in the past, experience suggests that it is now appropriate to give serious thought to better methods for preventing and detecting irregularities and to the manner in which universities deal with them” (AAU, 1983).

The AAU committee recommended that all academic research institutions develop policies and procedures to ensure a high standard of ethical behavior for researchers, to define mechanisms for dealing with suspected deviations from intellectual honesty, and to warn of available sanctions. The report was approved by the AAU, the American Council on Education, and the National Association of State Universities and Land Grant Colleges. The report was disseminated to a broad audience of university administrators, professional society and government officials, and others, but the society did not conduct a systematic inquiry to evaluate the response of the university community to its recommendations.

In January 1982, the Association of American Medical Colleges (AAMC) appointed an ad hoc Committee on the Maintenance of High Ethical Standards in the Conduct of Research. Chaired by Julius R. Krevans, then dean of the Medical School of the University of California at San Francisco, the AAMC committee reaffirmed the responsibility of research faculties and their institutions to maintain research standards and to

investigate allegations of scientific misconduct. The guidelines and recommendations set forth in the committee report were adopted by AAMC in June 1982 as a guide for the faculties of medical schools and teaching hospitals to assist them in promoting the integrity of the biomedical research enterprise (AAMC, 1982).

The AAMC report recommended nine elements, including an explicit mechanism for dealing with allegations of misconduct; policies on openness of research; policies to assure that quality rather than quantity of publications be emphasized in promotion decisions; and policies to ensure appropriate supervision of research teams.

Despite these initiatives by professional organizations, only a small number of research institutions made a systematic effort in the early 1980s to develop written policies or procedures to handle cases of scientific misconduct. A survey conducted from 1982-1984 by Penelope Greene and her colleagues at Harvard University reviewed the policies and procedures adopted by universities following the AAMC report (Greene et al., 1985). Almost 500 institutions responded to the Greene survey. Of this number, about 25 percent (116) had adopted rules for dealing with allegations of misconduct; another 25 percent (124) had no such rules. More than half of the respondents indicated that they were formulating procedures at the time of the survey. About half of the institutions that had adopted policies at the time of the Greene survey indicated that they had used the AAMC recommendations in developing their misconduct rules.

Most academic institutions appeared to believe that the problem of scientific misconduct did not deserve policy or procedural guidelines and that existing faculty disciplinary mechanisms were adequate to handle the problem if it should arise on their campus.

Other national organizations have since prepared materials to educate young scientists on the responsible conduct of research. The best known among these efforts is the report Honor in Science, published by the research honorary society Sigma Xi (Sigma Xi, 1986). This 42-page booklet offers “practical advice to those entering careers in scientific research” and sets forth clearly and informally the basic principles of intellectual honesty in science.

At the local level, a few universities formed faculty committees in the mid-1980s to promote research integrity and to discourage scientific misconduct. The University of Michigan, for example, published a report of the Joint Task Force on the Integrity of Scholarship in June 1984. Entitled Maintaining the Integrity of Scholarship, the report defined the ethical obligations of scholarship, pressures that can discourage integrity in scholarship, and steps to be taken to encourage integrity in scholarship and offered recommendations, guiding principles, and procedures for the university community.

In September 1985, Donald Kennedy (1985), president of Stanford University, published a report titled On Academic Authorship, which discussed the need to clarify the allocation of responsibility and credit for scholarly work and the factors that complicate determinations of appropriate authorship.

Harvard Medical School released a set of guidelines in February 1988 for the performance of scientific research by all faculty, trainees, and research staff at that institution (Tosteson, 1988). The Harvard guidelines have attracted national attention because they codify generally accepted research practices and set forth recommendations for supervision of research trainees, data recording and retention, responsible authorship, avoidance of excessive publication practices, and individual laboratory written procedures. These recommendations are not promulgated as rules, but are intended to guide the development of written procedures for each research group affiliated with the Harvard Medical School, according to its dean, Daniel C. Tosteson.

During the past year, this IOM committee has learned of other professional efforts to encourage research integrity and to improve the ability of academic institutions to handle incidents of scientific fraud and research misconduct. The National Conference of Lawyers and Scientists, a joint project of the American Association for the Advancement of Science and the American Bar Association, is sponsoring a series of workshops to evaluate the features of effective misconduct policies and procedures for universities. Background papers commissioned for the NCLS workshops provide additional analysis of the significance of the publicly reported cases of scientific misconduct and institutional efforts to handle these cases (AAAS, 1988).

A consortium of educational organizations under the leadership of AAU is also developing a framework, or model guidelines, for institutional policies and procedures to deal with research fraud (AAU, 1988).

GOVERNMENT EFFORTS

One of the first efforts by a government agency to address the issue of scientific misconduct was a workshop convened in 1981 by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (U.S. President's Commission, 1982). In response to reports of harassment of persons who raised concerns about scientific misconduct (these individuals are often called “whistle-blowers”), the commission cosponsored the workshop with AAAS and the organization Medicine in the Public Interest to review institutional experiences in handling reports of research fraud. The workshop report, Whistleblowing in Biomedical Research, provides a study of the initial policies and procedures used by universities to investigate charges of scientific misconduct.

The oversight subcommittee of the House Science and Technology Committee held hearings on March 31-April 1, 1981, to review institutional experiences in handling cases of scientific fraud in biomedical research (U.S. Congress, 1981). Chaired by Representative (now Senator) Albert Gore, the subcommittee received testimony various institutional representatives, including Philip Handler, then president of the National Academy of Sciences. The witnesses suggested that the problem of scientific fraud had been greatly exaggerated and that the cases that had surfaced were adequately addressed by existing self-regulatory mechanisms.

Following continued press reports of cases of serious scientific misconduct, Congress enacted legislation in 1985 that required the U.S. Public Health Service (USPHS) to develop procedures for investigating charges of scientific misconduct involving federally funded research activities (P.L. 99-158). USPHS subsequently adopted interim guidelines (USDHHS, 1986) in July 1986 that required local research institutions to adopt misconduct guidelines as a condition of funding for grants and contracts awarded by the National Institutes of Health and other USPHS-funded research programs.

In September 1988, USPHS proposed draft regulations in the Federal Register further defining the responsibilities of USPHS awardee and applicant institutions for dealing with and reporting possible misconduct (USDHHS, 1988a). The notice of proposed rulemaking (NPRM) states:

> Before 1980, instances of reported misconduct in PHS-funded research programs were infrequent. In recent years, however, there has been a small number of highly publicized instances of scientific misconduct....From what little we do know, it would appear that reported instances of scientific misconduct represent only a small fraction of the total number of research and research training awards funded by PHS. Nevertheless, even a small number of instances of scientific misconduct is considered a threat to the continued public confidence in the integrity of the scientific process and in the stewardship of Federal funds. The traditional safeguards such as peer review and guidance from professional organizations must be supplemented by explicit institutional commitment to high ethical standards in research.

The proposed rule sets forth the following definition for "misconduct in science": "(1) fabrication, falsification, plagiarism, deception or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research; or (2) material failure to comply with federal requirements that [are] uniquely related to the conduct of research." The latter portion of this definition covers areas such as the federal regulations governing the handling of hazardous research materials, the use of animals or human subjects in research, and the use of recombinant-DNA materials.

The proposed rule again affirms that the primary responsibility for detecting, investigating, reporting, and resolving allegations of scientific misconduct rests with awardee institutions. These institutions will now be required to provide assurances that they have established appropriate procedures to review reports of misconduct in biomedical or behavioral research at their institution. The proposed rule establishes minimum standards for these procedures and requires the institutions to notify the funding agency when misconduct investigations are initiated.

In the same issue of the Federal Register announcing the proposed rule discussed above, the U.S. Public Health Service also published an advanced notice of proposed rulemaking (ANPRM in the development of future regulations protecting against scientific fraud or misconduct (USDHHS, 1988).

The ANPRM invited public comment on several complex and controversial aspects of scientific misconduct that might be considered by the government in formulating new regulations. In particular, comments were solicited on the following topics:

- definition of scientific misconduct;
- responsibilities of awardee institutions;
- responsibilities of the Department of Health and Human Services;
- joint responsibilities of the department and awardee institutions; and
- governmentwide policy on scientific misconduct.

A 60-day comment period was provided for the NPRM, and 90 days were provided for comment on the ANPRM.

The pace of governmental interest in scientific misconduct picked up in 1988. In addition to the regulatory proposals discussed above, three congressional hearings and an investigative study by the Office of the Inspector General in the Department of Health and Human Services focused on this topic.

In April 1988, two separate House subcommittees held hearings to review recent allegations of scientific misconduct and the experience of NIH in investigating these cases. Representative John Dingell, chairman of the House Energy and Commerce Committee, strongly criticized government agency performance, contending that the agencies inadequately addressed key issues regarding disclosure, notification, and protection of whistle-blowers in these cases (U.S. Congress, 1988a). Representative Ted Weiss, chairman of the Human Resources and Intergovernmental Relations Subcommittee of the House Government Operations Committee, also held hearings to review similar charges and to explore the public health and safety questions that might arise as a result of fraudulent research (U.S. Congress, 1988b).

Congressman Weiss convened a second day of hearings in September 1988 to pursue these issues and to examine conflict of interest charges in academic research (U.S. Congress, 1988c). The congressional hearings attracted national media attention and highlighted congressional concerns about the appropriateness of the governmental policy of relying upon local institutions to investigate charges of scientific misconduct.

In late September 1988, the Office of the Inspector General (OIG) of the Department of Health and Human Services released a draft report on misconduct in scientific research (USDHHS, 1988c). The report included the results of a recent study of the extent to which NIH and its grantees have developed policies and procedures to prevent, detect, and handle scientific misconduct and a description of what selected grantee institutions have learned as a result of experiences with research fraud.

The draft OIG report recommended that the Secretary of HHS establish investigatory and oversight functions independent of the research funding agencies and develop a more formal process to deal with scientific misconduct. The recommendations included additional notification requirements for the awardee institutions and the development of alternative methods of detecting possible misconduct, including spot audits of scientific data and specific reviews by editors of scientific journals.

The OIG staff surveyed a random sample of FY 1986 NIH grantee institutions by telephone and also conducted site visits to nine such institutions that had experience with scientific misconduct cases. The draft report concluded that although only 22 percent of NIH grantee institutions overall have policies and procedures to deal with scientific misconduct, 93 percent of such grantees with 100 or more awards have such policies and procedures in place. The scientific misconduct procedures that are in place are generally not comprehensive, often failing to require notification to NIH. The report noted that 36 percent (17 of 47) of the grantee institutions with established procedures reported cases of misconduct that required their use. Sixteen of the 34 cases (47 percent) investigated by these 17 institutions were substantiated. Extrapolating from these figures, the OIG estimated that 95 scientific misconduct cases (47 substantiated and 48 unsubstantiated) have been addressed by NIH grantee institutions.

This estimate, as noted in the OIG report, is consistent with records maintained by NIH since 1982, which show that 102 cases have been investigated by its grantees and reported to the agency in that time period.

The OIG report (USDHHS, 1988c) emphasizes that, “The estimate of 95 cases does not represent an estimate of the actual prevalence of scientific misconduct. In fact, our grantees were about evenly split on whether or not more misconduct occurs than is reported.”

OBSERVATIONS

Several strong themes have emerged in policy discussions about the appropriate nature of public and private institutional response to incidents of scientific fraud and research misconduct. First, government agencies, professional organizations, and research institutions have consistently affirmed that the primary responsibility for handling these cases should rest with awardee institutions, the ones doing the research. Second, recent federal regulations have generated new requirements for research institutions to adopt explicit, written guidelines for handling allegations of scientific misconduct. Third, these misconduct guidelines and policy directives reveal a need for additional mechanisms to encourage high ethical standards for research.

There is wide variation among universities in their efforts to define appropriate standards for research, and professional standards have remained ambiguous in some instances. The absence of formal standards or written guidelines for the ethical performance of research has generated uncertainty about the criteria for distinguishing practices that violate professional norms from activities that are simply part of the variation around these norms.

Investigations of cases of scientific fraud suggest that various factors in the research environment may contribute to the occurrence of scientific misconduct even though they are not the direct causes of these occurrences. Examples include pressures to "publish or perish," an emphasis on competition and secrecy in research performance, and inadequate interaction of young researchers with their peers and mentors. There is concern that not only ethics, but also the quality of scientific research in general may suffer in this environment.

These concerns have prompted research institutions, professional organizations, government agencies, and congressional oversight committees to search for policies that will strengthen the integrity and quality of the research environment. As in the case of public concern over the research use of human and animal subjects, these policy discussions raise fundamental questions about the adequacy and effectiveness of the current self-regulatory system in assuring responsible research practices and preventing scientific misconduct.

The purpose of this study was to examine these questions and to propose ways to encourage high ethical standards in the conduct of research without damaging the freedom and creativity that have traditionally characterized American research.

CHAPTER 3

THE WORKSHOP

An invitational workshop was convened to develop principles and procedures for promoting scientific responsibility and ensuring quality in health sciences research. Held in Washington D.C., in September 1988, the workshop was organized by the IOM Committee on the Responsible Conduct of Research and cosponsored by the Committee on Science, Engineering, and Public Policy (COSEPUP), an entity jointly administered by the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

The workshop was a productive means for the IOM study committee to gather information and perspectives about standards and practices that affect the conduct of research in the health sciences. More than 100 clinical and academic research scientists, government and university officials, professional society officers, journal editors, and members of the press attended the workshop. An agenda and list of participants are included as appendixes to this report.

After an opening plenary session, the participants met in six panels. Each panel explored a different set of discussion topics designed to elicit perspectives and experiences about (1) laboratory practices and standards, (2) clinical research practices and standards, (3) institutional oversight, (4) education and training for research, (5) academic and career advancement, and (6) authorship, referee, and publication standards. Summaries of the panel discussions were prepared by panel rapporteurs following the workshop and are included in the appendixes to this report.

Before the workshop, the participants had received discussion papers prepared for each panel. They also received two background papers commissioned by the committee, addressing concerns about authorship practices and the relevance of Good laboratory Practices (GLPs) regulations to academic research.

The panels formulated more than 60 proposals suggesting various means to improve the quality of academic health sciences research. The workshop panels also identified several key issues for further attention in the final plenary session. These issues are described briefly below.

KEY ISSUES

The Organization of the Research Unit

There was general agreement among the workshop participants that current practices and policies of individual research centers need

special attention. The sharing and division of investigator and institutional responsibilities for the integrity and quality of research conducted in these centers was identified as an issue requiring review and analysis. For example, should the research centers formulate their own professional guidelines or should these be developed by the university or medical center on a broader institutional level? Would stronger internal or external oversight of laboratory researchers improve quality? What processes would improve peer review of senior and junior faculty members' work? Who is responsible for the work conducted in a laboratory or clinical research center?

Data Retention and Sharing

Many participants affirmed the importance of ensuring access by institutional officers to research data as the primary means of verifying the validity of questioned research results. Several panels made proposals in this area, focusing on the need for institutional policies and procedures regarding access to investigator data and minimal time limits for the retention of data.

The participants suggested that research institutions need policies to address the interests of different parties--the institution, principal investigator, postdoctoral fellows, students, and collaborators--with respect to the sharing of research data, materials, and methods. Although there was extensive agreement around the principle that institutions had a right to require data retention for certain periods of time--three years was commonly suggested as a traditional minimum that is consistent with NIH guidelines--there was much less agreement about the rules under which an institution could require its investigators to share research data with others.

Education, Training, and Mentorship

Much attention was focused on mechanisms that would improve the training of young scientists and students. Some workshop participants made proposals to clarify the roles of laboratory chiefs and department chairmen in developing the careers of young faculty members. Others proposed curriculum reforms to require formal training in research standards and practices for all science students.

Authorship Practices

The participants expressed great interest in recent guidelines announced by Harvard Medical School suggesting limits on the number of publications to be considered in appointment and promotion decisions. Many participants suggested that this principle should be incorporated into funding and tenure decisions at other institutions. Others cautioned that setting limits on publications in research evaluation

decisions might have little effect on authorship practices. There was consensus that journals as well as research institutions need to define more clearly the criteria governing allocation of authorship and the responsibilities for publishing retractions of faulty research.

Institutional Oversight

The workshop panel proposals supported the need for formal institutional policies and procedures to handle cases of alleged misconduct in science. They noted the particular difficulties in carrying out responsible notification and disclosure if investigations are prematurely terminated with the resignation of an accused researcher or if a private settlement is negotiated.

A few participants suggested that institutional data audits could improve the quality of academic research, but most agreed that this approach could be very costly, could lead to an undesirable degree of standardization of research, and could damage the collegiality of the university. Several participants requested greater institutional review of manuscripts submitted for publication to verify the authenticity of the reported results and the contributions of the designated authors. These suggestions were challenged by others who believed that such institutional review would impose unnecessary restrictions on investigator autonomy and threaten academic freedom.

The Effects of Commercialism on the Integrity of Academic Research

Several panels voiced concern that open communication of research results and sharing of materials were increasingly inhibited by commercial and competitive interests of academic researchers. These concerns were discussed in a preliminary manner, but the schedule of the workshop did not allow time for the development of specific proposals in this area.

CHAPTER 4

ANALYSIS

In meetings before and after the September workshop, the committee arrived at assumptions and findings that would form the basis for the evaluation of policy proposals and final recommendations contained in this report. In the absence of data documenting the integrity of existing research practices and the level of misconduct in health sciences research, the committee relied on expert opinion. These assumptions and findings may not be shared by all members of the research community--indeed, they were not shared by all workshop participants--but they quickly emerged as a consensus of the committee. These assumptions and findings deserve explanation and clarification because they form the foundation for this report.

ASSUMPTIONS AND FINDINGS

— Scientists should develop and maintain quality and accuracy in research practice by self-regulation, extensive reliance on each investigator's professional standards, and the traditions and collegiality that characterize research institutions.

The balance between emphasizing individual and emphasizing collegial responsibility for the integrity of research may vary by discipline, research field, or institution, but self-regulation is the principal system used by the government and the research community to provide integrity and quality in research. The nature of the scientific enterprise is such that only those persons familiar with the methods and analytical basis of science are capable of understanding and evaluating the research results of others. Scientists are not separate from society, however, and they are subject to the same laws and standards that govern responsible social behavior.

The norms of responsible research practice are usually communicated through oral tradition and personal example. These norms have exercised a significant but poorly understood role in regulating the conduct of individual investigators and in encouraging honesty in academic research.

Self-regulation includes peer review and replication of reported research findings. Peer review evaluates the adequacy of scientific methods, the significance of the research, and the consistency of the reported findings. Replication involves repeating the work of others. It may confirm or contradict earlier work, a situation that requires explanation.

The argument that replication and peer review will guarantee the integrity of all research is incorrect. Many studies are not replicated in detail (it would be highly inefficient if they were). Trust in researchers' descriptions of their methods and findings has been fundamental to scientific communication. In the past, scientific skepticism has not extended to the honesty of an investigator's factual statements, but has been directed toward interpretation of reported results.

Throughout the discussions, the committee agreed that the primary responsibility for the oversight of quality and responsible research practices in the health sciences should continue to rest with the research community itself. At the same time, the committee recognized limitations of the existing self-regulatory system in encouraging responsible research conduct and detecting scientific misconduct.

— A variety of informal and formal practices and procedures currently exist in the academic research environment to assure and maintain the high quality of research conduct.

Until very recently, governmental and private institutions assumed that the principle of self-regulation was sufficient to promote and maintain the integrity and quality of federally funded research. Recent cases of scientific fraud, however, have challenged the wisdom of relying entirely upon investigator honesty and unwritten collegial standards as the sole means of assuring integrity and quality in research. These cases have fostered a perception that existing institutional and professional controls have been inadequate to assure integrity in federally funded research.

The effectiveness of self-regulation depends upon those practices and procedures that have evolved over time as part of the scientific method. Such practices are intrinsic to the conduct of science and they are expected to be a fundamental part of the professional training of each scientific investigator. Informal practices include collegial interaction, skepticism, and criticism; sharing of research data, methods, and materials; serving as mentors and role models; consensual assignment of authorship credit; and post-publication review by colleagues.

Formal mechanisms that promote responsible research conduct include the peer review systems administered by scientific journals and funding agencies; departmental research seminars; the criteria, policies, and procedures that govern appointment and promotion decisions; the use of “visiting committees” and interdepartmental reviews in evaluating the quality of graduate research and training programs; and the coordinating committees and data-collection audits used in multicenter clinical research programs. However, the use of these mechanisms varies widely among different academic institutions.

The committee believes that existing internal systems of peer review and university oversight in academic research are fundamentally sound, but it recognizes that many of these procedures are not uniformly followed and investigator practices vary. Most of the existing institutional controls rely upon the effectiveness of social and professional sanctions. It appears that these controls may have limited impact on some investigators.

— 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.

As a first step in promoting scientific responsibility and providing quality assurance, some research institutions and scientific organizations are trying to enhance the visibility and effectiveness of generally accepted research practices already in place.

In addition to institutional guidelines, the conduct of research is governed in some matters by various professional and regulatory standards. For example, federal and state laws govern the use of animals and human subjects in research; the use of hazardous research equipment and materials; the use of recombinant-DNA material; and general laboratory safety. Professional codes of ethics developed by individual scientific societies also establish certain standards for the conduct of rest. For the most part, however, professional and regulatory standards are not integrated in an explicit manner into the social setting and training of scientific investigators.

The committee has received reports that some institutional investigations of allegations of scientific misconduct are hampered by the absence of written standards against which to measure charges of improper practice. For example, some investigators fail to keep research data and are unable to document or verify their results when questioned. Others may seriously neglect their supervision and training responsibilities or may request “honorary authorship” on publications for which they made no significant contribution.

The committee believes that 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 these standards leads to a perception that the institution or the profession is unwilling or unable to correct abusive practices.

— There are very few courses of instruction dedicated to communicating professional standards and the ethics of research practice to young scientists.

Although some university courses and publications offer instruction in the standards and ethics of research practice, most science students do not receive formal exposure to this topic. The absence of these

courses limits the opportunity for discussion of the norms and ideals that should guide research practice and for identifying aberrant or deviant practices. The lack of instruction in this area also creates a perception that the faculty places more emphasis on the results than the methods of scientific research.

The communication of the ideals of science, its values and methods, traditionally occurred through individual discussions between senior investigators and students. Given the increased size, complexity, and heterogeneity of the research training process, the committee believes that reliance on these discussions alone is not sufficient to provide effective instruments of professionalization and education.

— The culture of the American university is distinguished by traditions and styles of governance that assume professional integrity and that place great value on the independence and collegiality of individual faculty.

In contrast to some other academic systems, American universities are not hierarchical structures. Their demonstrated effectiveness in generating new knowledge and training young scientists depends greatly upon investigator autonomy and the collegial good will, trust, and academic freedom that are the foundations of academic governance in our society.

Although the committee agrees that American biomedical research and training can benefit from improvements in policies and practices, it believes that some administrative changes could create more serious problems than those they are designed to alleviate. Strict or intrusive regulations governing the details of research conduct may damage the creativity and quality of the research environment, especially if those regulations are unsupported by documented evidence of widespread dishonesty or ethical misconduct by investigators.

The collegiality of the faculty also discourages individuals from revealing negative information about a colleague or student. If faculty are to be encouraged to take a more active role in exposing the deficiencies and weaknesses of their peers, they must be assured that their institutions are prepared to act on their information and that whistle-blowers will not be punished for exposing substandard or deviant practices.

The committee believes that better education of academic officials, faculty, and students and, where appropriate, legislative protection could help reduce the barriers that discourage the reporting of scientific misconduct when it occurs.

— Investigations of a small number of publicly reported cases of scientific fraud and other research misconduct suggest that a mix of factors contributed to this deviant behavior. One of these was an

unhealthy research environment that failed to discourage (or even tolerated) sloppy or careless research standards.

Cases of serious misconduct in science are rare events and there are only a handful of studies of their origins and causes. Some factors that have been identified in these preliminary analyses include denial, self-deception, and unwillingness to believe that such actions could be detected and punished. Some of those found guilty of fabricating or distorting research results denied that their practices were wrong or substandard, often using the expression that "everyone does it" to justify their behavior.

The committee believes that, in the long run, 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. The committee did not have the resources to try to conduct a systematic study of the integrity and quality of current research practices or incidence of scientific fraud in the health sciences. But 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.

There are several kinds of contemporary research activities that lie on the edges of acceptable professional practice; many researchers would regard them as irresponsible practices. Examples include abuses of multiple authorship, such as the practice of "gift authorship"; repetitive publication of short-term research results; the neglect of young researchers by their peers and mentors; inadequate training and supervisory practices; and sequestering or withholding of research data from peers and colleagues.

Although the committee believes that serious misconduct in science is rare and is ultimately a manifestation of individual deviance, it concludes that institutions fail to detect and correct early deviant behavior, primarily because of an excessively permissive research environment that tolerates sloppy and careless practices. The committee also believes that substandard practices are encouraged by funding pressures and an overemphasis on publication as the main means of achieving status and recognition for scientific advancement and research support.

— Increasing budgetary and competitive pressures in science demand that local research institutions and government research funders develop standards to ensure responsible research practices to ensure the integrity of the academic research enterprise.

The committee identified a need for higher professional standards at all levels in the research system. There was consensus that, although the fundamental values and standards of the research community are appropriate, the expression and implementation of these standards

are insufficient to promote responsible research practices in an increasingly large, heterogeneous, and competitive research environment. New and comprehensive guidelines should be developed by the research community to clarify traditional practices, to strengthen the mix of formal policies and informal practices currently in place, and to correct actions that seriously deviate from these standards.

The committee believes that the most effective sites for the development of these guidelines are the immediate social setting of the investigators, represented by the laboratory and clinical research centers, universities, professional societies, and scientific journals. The adoption of such standards will require leadership from government and other funding sources.

In developing final recommendations, the committee sought to define appropriate roles for government agencies and the Congress that would stimulate local institutional and professional efforts without creating an unjustifiable regulatory burden on the research community.

— Effective institutional reforms to improve integrity and responsible research practices require better understanding of the key factors that influence professional development and performance in science.

During the workshop, many participants identified a need for additional research to clarify the basic factors that influence professional conduct in the contemporary research environment. In particular, they cited the need to evaluate the experiences of different kinds of research institutions in training investigators and monitoring, rewarding, or correcting research practices. Other participants urged that extensive studies of the incidence and prevalence of scientific misconduct should be undertaken before the development of substantive changes in research oversight.

Institutional policy reforms ideally should be based on a deeper understanding of professional behavior and the effects of training, role models, peer pressure, and the structure of the research system on professional development and behavior. However, the limitations of current understanding of these processes should not delay the development of explicit guidelines when there is clear consensus about what represents responsible research and training practices.

CHAPTER 5

RECOMMENDATIONS

In preparing recommendations, the committee considered more than 60 proposals developed in the six panels and plenary discussions of the September 6-8 workshop, regulatory proposals published by the National Institutes of Health and the Department of Health and Human Services (DHHS) in the September 19 Federal Register (USDHHS, 1988a, 1988b), a draft report on scientific misconduct released by the HHS Office of the Inspector General in late September (USDHHS, 1988c), and legislative proposals developed by members of Congress (Culliton, 1988a). The committee also reviewed two background papers commissioned for the workshop (Huth, 1988; Jasanoff, 1988) and selected literature from the project bibliography, including reports on integrity of research and scientific misconduct published by the American Association for the Advancement of Science, the Association of American Universities, the Association of American Medical Colleges, and Sigma Xi discussed in Chapter 2.

After reviewing this material, the committee formulated the following recommendations. They describe the actions that the committee believes are most appropriate to be taken at this time by government agencies, universities, professional organizations, and journals in seeking to promote integrity and quality in health sciences research.

RECOMMENDATIONS FOR THE NATIONAL INSTITUTES OF HEALTH

1. The National Institutes of Health should establish an office to promote responsible research practices. This office should be coordinated with an expanded NIH effort to evaluate institutional investigations of misconduct in scientific research. The primary function of the office should be to foster and monitor the development of high professional standards of research practice by all grantee and applicant institutions.

   The National Institutes of Health needs to respond vigorously to the perception that science has not maintained high standards of integrity. Although the committee believes that the primary responsibility for developing and implementing professional research standards rests with principal research investigators, medical schools, universities, and other research institutions and professional organizations, the members conclude that NIH must provide leadership and motivation to induce the research community to define professional standards for research practice, monitor levels of supervision, and provide education in professional standards and the ethics of research. Taking steps to promote the development of these standards at the local level is one of the most important actions that NIH can take to improve the integrity of research.

Many academic institutions and medical schools have recently developed policies and procedures for responding to allegations of scientific misconduct. Some institutions did so in response to cases of misconduct. Others are doing so now in response to regulatory requirements. These policies and procedures are important, but they are insufficient to promote integrity and quality in the research environment. The committee believes that additional standards are necessary to define the means by which the institution will promote the responsible conduct of research.

As with the requirements for safeguarding human and animal research subjects, the proposed office will provide institutions an opportunity to involve their faculties and administrations in developing policies and procedures that are consistent with traditional practices and that also meet federal standards. It is the perception of the committee that institutional self-regulation will be strengthened as a result of this approach.

The committee recommends that the proposed office be established as an administrative unit within the Office of the Director of NIH and have oversight responsibility for all NIH grant and contract awards. The office should assist local research institutions in developing professional standards of research practice and define those areas that must be addressed by local policies and procedures, including the way the institution monitors the research environment, and how it proposes to respond to charges of misconduct in research. The areas to be addressed by local institutions should include:

- policies for recording and retention of research data;
- professional standards for training and supervision;
- education in professional standards and the responsible conduct of research;
- policies and procedures for responding to allegations of misconduct;
- designation of an institutional official to address concerns related to the conduct of research; and
- description of the process by which the university--faculty, staff, and students--are kept informed of institutional and professional research standards and policies.

There are some potential disadvantages with the establishment of an office to promote responsible research practices as proposed. For example, the additional amount of paperwork required would involve time of scientists and university officials, as well as the efforts of some administrators at the NIH and comparable agencies, and for these reasons could add some additional expense to research. In addition, the mission of this office might be inappropriately broadened.

The proposed NIH office should disseminate information about institutional policies and procedures governing professional standards and assist in their development; receive regular reports, possibly on a biannual basis from institutional officials charged with addressing

research concerns, describing developments that affect the integrity of health sciences research; convene occasional forums for these officers and the general research community to promote broad awareness of important trends or new issues that influence the conduct of research; interact with other NIH offices that monitor compliance with regulations on research involving human subjects and animals, the use of hazardous substances, or recombinant-DNA materials; and work closely with, but be distinct from, the NIH office charged with evaluating the adequacy of institutional misconduct investigations.

The proposal to locate the office for the promotion of responsible research in NIH is based on the relationship of the scientifically trained administrators at NIH with the research community, whose activities they understand and whose expertise they often solicit in evaluating specific problems.

NIH and other research funders can exercise an influential role by organizing conferences and workshops in which their grantees and professional organizations exchange information about and experience with the development of standards to promote responsible research practices. These meetings could highlight useful models, identify problems and barriers to the development of effective research guidelines, and suggest collaborative solutions to problems that may appear intractable to individual institutions.

2. By 1992, NIH should require all grantee and applicant institutions to provide assurances that they have adopted policies and procedures to encourage responsible research practices. Research applicants should affirm their familiarity with these policies and procedures and should also propose how they plan to store research data in the course of their study.

The proposed NIH office should require assurances that applicant institutions have adopted guidelines and oversight mechanisms for the responsible conduct of research analogous to those required for research involving human subjects or animals. To enable the proposed office to carry out its functions, NIH should require applicant institutions to forward a copy of their research standards when developed. NIH should also announce a specific date after which grant applications that do not include the required assurances will not qualify for funding. The areas to be addressed by local institutions are listed under Recommendation 1.

The subjects of the proposed standards for the responsible conduct of research involve difficult and controversial matters. Development of policies and procedures for satisfying these requirements will take time, because they require debate and education within the local institutions. At the same time, it is important that these institutions initiate a process to develop formal guidelines in order to comply with

funding requirerements. Thus, the committee suggests a three-year time period, at the most, for the implementation of the institutional assurances requirement.

When the assurances are received, the NIH office for the promotion of responsible research should monitor the adequacy of local institutional guidelines and statements of compliance by investigators with these standards. The office should notify applicants and grantees from institutions that have not developed appropriate guidelines that they will no longer qualify for NIH-funded research support. The office should provide educational support and guidance for institutions that have difficulties in developing appropriate standards.

The committee also encourages NIH to require their research grantees and applicants to describe within each proposed study the mechanisms for data retention and consider the issue of data access in the course of their research. While institutions are being charged to develop overall policies to deal with these issues, the individual grant will serve as the best location for detailed specifications of the data access and storage procedures to be followed. The appropriateness of these procedures can then be evaluated as part of the study section review of the research proposal.

This approach provides for the increasingly common and difficult circumstances of multi-institutional or other collaborative studies, in which concerns about intellectual ownership may not become serious problems if they are resolved before the research is performed. In such circumstances, no single institution can provide oversight based on its own policies.

3. NIH should not implement random data audits as a mechanism for ensuring the responsible conduct of investigator-initiated research.

Data audits are occasionally used by government research agencies when there is reason to question an investigator's reported research results. These “for-cause” audits are often useful in identifying incidents of fabrication, falsification, or serious distortion of research data. For-cause audits may result in punitive actions, such as criminal prosecution, disqualification of an investigator or, in the case of the Food and Drug Administration (FDA), restriction of his or her access to new drugs (Shapiro and Charrow, 1985).

In recent regulatory proposals the HHS Inspector General and the Department of Health and Human Services have suggested various means to enhance the detection of research fraud, such as the use of random or systematic data audits by government investigatory bodies. These random audits differ from the for-cause audits because they are conducted without reason to suspect or question the reported research results.

It has been argued that data audits are useful and accepted by investigators conducting studies subject to FDA oversight and by

investigators conducting multicenter collaborative studies funded by the National Cancer Institute (NCI) (Shapiro and Charrow, 1985; Lisook, 1986).

In the case of FDA-regulated studies, systematic review of data is performed in the final stage of new drug applications to ensure compliance with formal, mutually agreed-upon, predefined protocols and to determine that all data have been correctly collected and recorded. This form of data audit can be carried out by individuals with minimal scientific training.

Similarly, contract work and multi-institutional studies for NCI or NIH require precise adherence to protocols accepted by all investigators at the initiation of the study. Spot-check audits of the data reported in these studies allow for a technical review similar to that used in the FDA audits. In these studies, the investigators know about and agree to the use of data audits as a form of quality control in the development of the study contract and the research protocol. Uniform practices and prearranged agreements characterize these studies. Thus, this research activity lends itself to auditing and is enhanced by the systematic audit requirement.

Some investigator-initiated, grant-supported research involves therapeutic trials, other interventions, or measurements on human subjects following clearly specified protocols that have been filed with Institutional Review Boards. Data audits of these studies could be conducted by auditors without extensive scientific expertise.

On the other hand, much of the investigator-initiated research that NIH supports is basic or discovery research. The nature of the research and its susceptibility to scrutiny by nonscientists are dramatically different from clinical trials. Protocols submitted in the research application are often changed as preliminary results reveal unexpected findings. The research is more exploratory and less repetitive. The technical difficulty of comparing raw data with reported results is far greater, because the data are not the end result of the investigation. The task of auditing and interpreting data in basic research would require scientists with considerable expertise in the subject matter to interpret most laboratory records.

There are other potential problems and limitations to the extension of random or systematic data audits to investigator-initiated research. It is possible that the introduction of auditors into the scientific laboratory would diminish spontaneity and creativity in research. The anticipation of visits from auditors charged with the task of identifying inconsistencies between recorded data and reported results might preoccupy researchers and administrators with defensive recordkeeping, perhaps at the expense of the substance of the research.

Furthermore, the introduction of data audits will not identify all dishonest researchers. As the program became known, unscrupulous investigators in some fields might become adept at fabricating their raw data as well as their reported results. Thus, there might still be fraud, but it would be occurring earlier in the process of reporting.

Finally, the costs of an audit program for basic and discovery research are unknown and might be prohibitive if the program is other than very limited in scope, considering the extensive data that would have to be reviewed by skilled scientists. Government policies currently encourage regulatory approaches that provide the least net cost to society (U.S. Office of the President, 1981).

To date, the number of cases of scientific fraud that have been publicly reported is small relative to the amount of research that is conducted. Given that an audit program could have deleterious effects on the research environment, would not detect all cases of fraud, and would be associated with unknown and possibly large costs, the committee does not favor its current introduction into basic or discovery research.

4. NIH should adopt professional standards to ensure responsible research practices by its intramural scientists.

NIH is in a key position to develop and implement responsible research practices in its intramural research program. NIH should adopt professional standards that clarify the basic guidelines to be observed by intramural investigators in the conduct of research.

The intramural research standards should address, but not be limited to, the recording and retention of research data, the training and supervision of young scientists, and authorship and other publication practices. NIH should take the lead in studying the issue of rights and responsibilities of all relevant parties to research data within the intramural program and prepare model guidelines for data sharing and access. NIH should promote the quality and integrity of research conducted within the intramural program by adopting incentives and guidelines that reduce the pressure to publish.

NIH should designate administrative officers or scientific staff members to promote responsible research practices within the intramural program. These individuals should be available to provide mediation and counseling services for staff who wish to express concerns about questionable training and research practices. They should also work with the office for the promotion of responsible research to disseminate guidelines developed by the intramural research program to other public and private research institutions.

5. NIH should adopt policies to limit the number of publications that can be considered as part of any grant application, in order to emphasize quality over quantity.

NIH is in a key position to demonstrate that quality rather than quantity of publications is the proper measure of scientific achievement in the extramural research program. Through the Division of Research Grants, study sections, and councils, for example, NIH should adopt policies that limit the number of publications considered by initial review groups as part of a grant application. This action, along with the development of a model system for promotion of responsible research conduct, will demonstrate that NIH is firmly behind efforts to promote research quality in the health sciences.

Among the factors that predispose to sloppy or dishonest science is the emphasis on quantity of publications that pervades the research community. Although it is clearly not the only such factor in the research environment, it is one that is exacerbated by the competition for research support. NIH, which has been in a pivotal position in the creation of the competitive research environment, can alleviate this problem by developing procedures that reduce the incentive for large bibliographies.

RECOMMENDATION FOR UNIVERSITIES AND OTHER RESEARCH CENTERS

6. Universities, medical schools, and other research organizations should adopt guidelines to clarify the expectations of each institution about the professional standards to be observed by investigators in the conduct of research.

Recognizing that many medical schools and universities have begun to develop policies and procedures to handle allegations of scientific misconduct, the committee recommends that all academic institutions, medical schools, and research institutes develop guidelines for the responsible conduct of research. These should be developed in consultation with the faculty, research staff, and students and should reflect the standards of accepted practice of the research community. The guidelines should specify desirable behaviors and also provide a basis for identifying unacceptaable research practices. At a minimum, these guidelines should be in accord with the requirements discussed in Recommendation 1.

In addition to these requirements, the committee encourages institutions to address other areas in developing their research conduct guidelines. The committee recognizes the difficulties in reaching a consensus or standard that can be applied by NIH within the next few years to such matters as the appropriate conditions for sharing research data, authorship and publication criteria, regulations governing financial conflict of interest concerns, and efforts to reduce excessive publication pressures, particularly in appointment and promotion decisions.

However, Harvard Medical School has recently adopted a set of research guidelines that address many of these issues. A faculty committee at the University of Michigan has also recommended

development of a code for ethical conduct in scholarship. Other institutions, such as the university of Texas at Houston, have adopted policies on authorship and plagiarism that address selected aspects of these issues.

The requirement that all research institutions develop professional research sta ndards as a condition of NIH funding will stimulate much debate and reflection among scientists. The committee believes this discussion itself will improve the conditions under which science is conducted and the environment that shapes the training of young scientists.

7. Universities should provide formal instruction in good research practices. This instruction should not be limited to formal courses but should be incorporated into various places in the undergraduate and graduate curricula for all science students.

The lack of formal discussion about responsible research practice and the ethics of research is a serious flaw in the professional training of young scientists and clinicians. Many medical schools and universities have traditionally avoided this topic and have relied instead upon the faculty to communicate the standards and traditions of research practice through personal example and mentoring. Others have suggested that this information can best be communicated through guest presentations or occasional lectures in traditional science courses. Although these approaches are often useful, they are no longer adequate because of the size and complexity of the modern research environment.

The committee believes that instruction in the standards and ethics of research is essential to the proper education of scientists. Some organizations, including Sigma Xi and the American Association for the Advancement of Science, have published materials appropriate for this instruction (Sigma Xi, 1986; Chalk, 1988).

The committee urges professional organizations to expand their training activities to help and encourage faculty to offer seminars or courses on the standards and ethics of research. Private and public research funding agencies are encouraged to support projects that will create and disseminate model curricula and supporting materials related to the responsible conduct of research.

The committee emphasizes that the value of mentoring should not be overlooked in institutional efforts to communicate responsible research practices. The challenge to the universities is to identify ways to support and reward professional mentoring, to ensure that investigators communicate responsible research standards in their interaction with trainees and students, and to supplement this informal communication with instruction designed to expand the student awareness of the ethical and professional dimensions of research work throughout the training experience.

8. Universities should designate one or more administrative officers or faculty members to promote responsible research practices within the institution. The institution should also provide mediation and counseling services for faculty, staff, and students who wish to express concerns about professionally questionable training or research practices.

Universities should not rely upon formal complaints of scientific misconduct as the sole means of monitoring the integrity and quality of the research conducted under their auspices. They need continuing mechanisms to review and evaluate the research and training environment of their institution. They also need personnel who think critically about the integrity and quality of the research environment and ways in which it could be improved. These or other selected individuals should be available to discuss, on a confidential basis, incidents that raise questions of judgment or professional behavior or the appropriate standards that should guide research conduct. Because even serious misconduct may be recognized only by pursuing minimal evidence or suspicion, it is important to be open to questions of all levels of apparent seriousness. Large institutions may wish to designate such an individual for each college or major research unit.

The current use of ombudspersons by some universities and medical schools deserves consideration as one means of providing mediation and counseling services to those who raise concerns about questionable practices. The organizational factors that promote or inhibit the effectiveness of ombudspersons in changing substandard practices deserve further analysis.

Some universities may wish to form faculty committees to monitor the conduct of research within their institution. These committees my develop other mechanisms both to identify and correct substandard practices within the university and to promote standards of excellence in the performance of research.

9. Universities and other research institutions should strengthen the integrity and quality of research by modifying incentives and academic guidelines in order to reduce the pressure for excessive publication.

Publication is the end result of nearly all scientific research, and researchers are too often evaluated for academic appointments, promotion, and funding primarily by their number of publications. A prolific researcher may have several hundred publications, and evaluating committees cannot possibly read them all. Although some members of evaluating committees may read some of the papers and know the reputations of the researcher and of the journals in which the papers are published, the increasing tendency over the past 30 years or more is to allow the number of publications to serve as an index of quality.

Quantity of publications as an index of quality may be reasonable, insofar as the number of publications suggests industry and productivity, and may be a valid indicator of future research performance. However, as large bibliographies become the norm, it has become necessary to undertake smaller and easier projects to attain the highest possible rate of publication. Researchers tend to divide a large or complicated study into many parts so that each can be published separately, resulting in multiple, overlapping, and trivial papers. This is also a feature of collaborative studies, which are increasingly common in today's science.

The committee believes that the pressure to attain a long bibliography leads to poorer rather than higher quality work. It also leads to the widespread practice of including as authors those who did not contribute substantially to the work. This is sometimes done out of generosity towards a younger colleague, sometimes at the insistence of the laboratory chief, and sometimes because it is thought that including the name of a well-known senior researcher will enhance the chances of publication in a particular journal.

Not only does the pressure to publish lead to the practices of repetitive publication, trivial work, and loose authorship, but it may also tempt researchers to engage in more serious misconduct to achieve a publishable result. This misconduct may range from sloppiness, to trimming and selecting data for more compelling results, to major fraud. How far a researcher is willing to move along this spectrum of misconduct is, of course, a function of personal character as well as of the external pressures. Obviously, many are willing to engage in forms of repetitive publication, although it is likely that only a few are willing to commit fraud. It is of interest, however, that several recent highly publicized instances of fraud in biomedical research occurred in very productive laboratoriess where the head of the laboratory had a long bibliography and there was great emphasis on frequent publication (Woolf, 1986).

One way of dealing with the deleterious effects of excessive publication pressure is to allow only a limited number of publications to be considered for academic appointment, promotion, or funding. Harvard Medical School, which at one time required a researcher to have a minimum number of publications to be considered for appointment as assistant professor on the basic science faculty, now has guidelines suggesting maximum numbers of publications to be considered for promotion or appointment to each faculty level: 5 for assistant professor, 7 for associate professor, and ten for full professor (Tosteson, 1988).

For such a scheme to have the desired effect of reversing the trend toward greater numbers of publications, it will be essential that the candidate submit a list of only the maximum number of publications allowed (presumably those considered the best) without mentioning others. Only in this way can the emphasis on numbers be changed.

It is sometimes objected that this will deprive those evaluating a researcher from learning of the individual's worst work. But perhaps the most important factor should be the best the researcher can do and not the worst. The hope is that each study would become commensurately more substantial and that evaluators would find it not only possible, but also necessary, to read the limited number of publications.

It is difficult to say what the effect of such a system would be on the incidence of misconduct in scientific research. Almost certainly, the practices of repetitive publication and honorary authorship would be sharply curtailed, as would sloppiness and more benign forms of cutting corners. Although major fraud might not necessarily be much affected, it is likely that in a less cluttered system, misconduct would be easier to detect.

10. Academic departments and research units should monitor the supervisory and training practices of their faculty and research staff to ensure that adequate oversight is provided for young scientists.

Several sociological analyses of selected professions, such as medicine and law, have concluded that the most significant determinant of compliance with professional norms is the social setting of professional practice (Bayles, 1981; Carlin, 1966; Freidson, 1970). In keeping with this finding, there is a real need for scientific institutions to address the social environment of their faculty, staff, and students and to identify organizational elements, incentives, and barriers that shape their understanding of, and adherence to, responsible research standards.

As a first step in implementing this approach, the committee recommends that universities and research centers develop new policies to guide the training and supervisory practices of their research personnel. These policies should require that a primary supervisor be designated for each trainee and that the supervisor provide adequate review of the trainee's research performance.

The committee considered, but did not endorse, a proposal that institutions limit the number of trainees assigned to a senior investigator. Although this approach may be desirable, there is insufficient information at this time to suggest that numbers alone significantly affect the quality of research supervision. There is a critical need for more analysis of the organizational and social components of research settings that influence the quality of research performance.

There are many different steps that should be considered by department chairs and laboratory chiefs in strengthening the research environment. The most intense surveillance of research practice should occur on an ongoing basis within the confines of the research unit. Research personnel should be explicitly instructed in the

proper means of designing experiments and collecting experimental data. Laboratory chiefs should insist that raw data be preserved within notebooks and other repositories in a way that is readily interpretable by qualified researchers beyond those directly responsible for conducting the research.

In addition, there should be frequent interaction between the principal investigator of the research unit and the individuals conducting the research. Effective interactions require frequent review and interpretation of raw data. There should also be regular meetings in which the individuals within a research unit are able to scrutinize and critique each other's work.

Conversely, laboratory or clinical research practices that encourage compartmentalization, secrecy, or isolation within the research unit should be viewed as incompatible with the conduct of good research. Departmental officers and laboratory chiefs should discourage practices in which experimentalists routinely describe their work only to their supervisor and not to their peers.

The committee also recommends that universities, especially the medical schools, expand their use of interdepartmental reviews and visiting committees as mechanisms to promote the integrity and quality of research training programs. These evaluation procedures are traditionally used in graduate research programs throughout the universities, but they have not been commonly applied to other research settings, such as medical schools and hospitals that conduct clinical research.

11. Academic departments and research units should adopt authorship policies to improve the publication practices of their faculty, staff, and students.

Authorship of a scientific report is a responsibility as well as a privilege. It implies that a person has contributed essentially and substantially to the study and is able and willing to defend the work publicly. This does not mean that each author participated in all parts of the study, but it does mean that all authors have familiarized themselves with the general principles of all aspects of the study.

Authors who have not substantially contributed to the study are often added to papers, a situation that reflects the importance to each researcher of lengthening a personal bibliography (Huth, 1988). Sometimes the head of the laboratory, who may have obtained the funding for the study, requires recognition as an author. Sometimes authorship is added willingly, because it is thought that the name of a well-known, senior researcher as author will increase the report's chances of being published. In general there is a tendency to add names as a form of collegiality.

There are different opinions as to the minimum level of participation necessary to qualify for authorship. For example, one proposal has been suggested by the International Committee of Medical Journal Editors (ICMJE, 1988): "Authorship credit should be based only on substantial contributions to (a) conception and design, or analysis and interpretation of data; (b) drafting the article or revising it critically for important intellectual content; and (c) final approval of the version published. Conditions (a), (b), and (c) must all be met."

Although these criteria have been accepted by many medical journal editors, they have not been accepted by the research community as a whole and have been questioned by those who think they are too restrictive. According to the ICMJE criteria, the contribution must be substantial, but it need not be to all parts of the study. Thus, someone who conceives of and designs a lengthy study would be included as an author even if the individual did not participate in the analysis and interpretation. However, merely generating the data, no matter how laborious a task, without involvement in design or analysis does not qualify a person for authorship. Nor does simply acquiring the funding or supervising the laboratory where the work is done, if the investigator is not involved in the substance of the research.

The committee did not endorse these particular criteria, but believes that they represent a useful starting point for the development of institutional guidelines. It is important to limit authorship to those who make substantial contributions. First, it is confusing and deceptive to include supernumerary authors. More important, gift co-authorship diminishes the concept of responsibility and makes it easier for the writer to publish fraudulent data. When criteria for authorship are loose, co-authors may evade all questions about the integrity of the work. If stringent criteria for authorship were widely accepted, this is less likely to happen.

Senior researchers can provide important encouragement to junior researchers by designating them as co-authors. However, unjustifiable authorship should not be used as encouragement, no matter how generous the impulse, because it erodes the concept of responsibility. Preferably, a junior researcher should be involved in a study early enough and broadly enough to satisfy the criteria for authorship.

The committee considered, but opposes, a proposal that universities review research manuscripts prior to their submission to journals or professional meetings. This review is unnecessary and intrudes upon traditions of academic freedom by suggesting that some form of administrative or departmental clearance is required prior to the commununication of research findings.

The committee believes that scientific journals and research institutions can address the problem of supernumerary authors by

establishing criteria for authorship and requiring each author of a report to specify a contribution that satisfies the criteria.

In addition, the committee recommends that each academic department and research center maintain an up-to-date record of the publications of its faculty, staff, and students. The departmental record will help facilitate collegial review of published research and will also highlight excessive publication practices. If questions are raised about inappropriate assignment of authorship credit, the department and its institution should take appropriate steps to investigate the allegation.

RECOMMENDATIONS FOR PROFESSIONAL AND SCIENTIFIC ORGANIZATIONS AND JOURNALS

12. Professional and scientific organizations representing the research community should develop educational and training activities and materials to improve the integrity of research. These organizations should assist universities in identifying substandard research and training practices that compromise the integrity or quality of research.

Professional organizations, including the various disciplinary societies, play an important role in developing consensus about the goals and values that should shape research practice. Scientific meetings and journals often provide young scientists with a first glimpse of the issues of importance to the research community as a whole and allow greater insight into the social context of individual or institutional research projects.

The committee has taken note (Chapter 2) of several current projects conducted by scientific and educational organizations that address issues of research misconduct. These include a series of workshops conducted by the National Conference of Lawyers and Scientists and the "framework" project currently sponsored by the Association of American Universities and the Association of American Medical Colleges.

The committee believes that much more can be done by these and other organizations to promote the responsible conduct of research. Some topics that are suitable for development include the issue of rights and responsibilities with respect to sharing research data and unique biological materials; the professional duties and expectations that shape the career development of young scientists; and the appropriate means of acknowledging scientific achievement and contributions in collaborative efforts.

There are many practices that most researchers would recognize as distasteful although they may not be viewed as serious scientific

misconduct. Several panels convened at the workshop suggested examples of such practices, including: misuse of statistics, selective interpretation of research findings, unjustified secrecy and compartmentalization of research projects, incomplete acknowledgment of contributions from colleagues or trainees, and inappropropriate publication practices, such as divided publication, repetitive publication, or incomplete or inaccurate publication.

Most of these practices, although deplorable, do not fit the proposed federal definitions of scientific misconduct and they are not suitable for investigation and punitive action by research institutions. In the long run, however, substandard practices may damage or seriously compromise the integrity of scientific research and the quality of the research environment. Furthermore, these practices, if left uncorrected, may evolve into research fraud or other serious deviations from professional standards (Bosk, 1981).

The committee recommends that professional organizations develop forums and publications to identify substandard practices that compromise the integrity or accuracy of scientific research. Once consensus about these practices has been achieved, they should be addressed by NIH and the university research guidelines and oversight mechanisms.

13. Scientific journals should develop policies to promote responsible authorship practices, including procedures for responding to allegations or indications of misconduct in published research or reports submitted for publication.

The committee commissioned one background paper on issues of scientific misconduct in connection with authorship and publication practices (Huth, 1988). These issues were also addressed by a workshop panel whose members included both research scientists and editors of various research journals.

There are a host of topics related to the responsible conduct of research that need to be addressed by scientific journal editors and publishers. Several organizations, including the Council on Biology Editors, the International Committee of Medical Journal Editors, and the American Medical Association, are developing programs and policies that address many of these concerns (Culliton, 1988; AMA, 1988).

The topics that require immediate attention by scientific journals include repetitive publication, supernumerary authorship, institutional responsibilities for disclosure and notification of research misconduct in publication, the use and misuse of peer review, and the appropriate response to suspicions or confirmations of misconduct in published work or work submitted for publication.

The committee endorses proposals made at the workshop that encourage journals to reqrequire all authors submitting a manuscript to

the journal to sign a statement that defines their individual contributions to the manuscript. Co-authors of research reports might be asked explicitly to assume responsibility for the integrity of the data.

Although the committee believes it is unwise to require institutional review and approval of manuscript submissions as a means of assuring integrity in published work, the members conclude that journals can do much more to ensure that authorship criteria are taken seriously. In developing their policies, journals need to work closely with research institutions to encourage good publication practices that will protect the variation that is important for discipline-specific journals.

The committee also believes that journals should disclose to appropriate persons at the research institutions substantial allegations or indications of research misconduct that are detected in the course of peer review. Many journals are presently in the position in which research institutions found themselves before federal regulations required the development of misconduct policies and procedures. The editors are often ill-prepared to deal with cases that are brought to their attention, and they are reluctant to call attention to complaints of unprofessional behavior that have not been formally substantiated.

Journals have an obligation to publish retractions of published reports that have been found erroneous by the original authors or that have been declared fraudulent by appropriate authorities at the research institutions. The committee recommends that science journal editors develop a uniform system for reporting serious violations of professional standards to research institutions so that institutional officers can be informed in a timely manner of the nature of these complaints.

The committee does not encourage editors of journals to conduct random data audits to ensure the responsible conduct of research (see Recommendation 3). Editors seldom have the resources or the expertise to carry out such audits.

14. The National Academy of Sciences should pursue the issues and findings developed by the Institute of Medicine in this report and examine their relevance and application to other fields of scientific research.

The committee has examined the issue of the responsible conduct of research with particular emphasis on the health sciences, as requested by the National Institutes of Health. Throughout this study, however, questions have been raised about the significance and applicability of this issue to other fields of scientific inquiry.

Scientific misconduct is not limited to biomedical and behavioral research (Kohn, 1986). Although serious cases of scientific fraud have appeared most commonly in health sciences research, there are also examples of data falsification, fabrication, and plagiarism in chemistry, geology, physics, and other fields of scientific and scholarly inquiry (Kohn, 1986; Broad and Wade, 1982).

The committee urges the Academy to develop additional activities to pursue the issues and findings discussed in this report. Topics that seem to warrant immediate attention by the Academy include the following:

— Concerns about scientific misconduct and responsible research practices are currently very visible in the health sciences. Although the committee believes that the issues addressed in this study are relevant to other fields of research, it has not attempted to judge the value of its recommendations for all of science. The Academy could play an important role by examining the need for policies and procedures to assure responsible research practices throughout the scientific community and by highlighting factors that differentiate the quality assurance programs of different disciplinary fields.
— The traditional procedures used by various research institutes and fields of study to detect and correct errors and to encourage quality in research and scientific training are not well defined or well understood. In particular, training evaluation systems (such as “visiting committees”) deserve further characterization and analysis to determine their strengths and limitations. There is a need to highlight effective methods of professionalization that should be more broadly disseminated throughout the research community.
— The rights and responsibilities surrounding access to research data, methods, and materials, deserve analysis to assist in the development of policies and procedures that affirm the traditional openness of the scientific process while also protecting important intellectual property interests.

Although the issues of data access and data sharing have been discussed in many settings, there does not yet appear to be real consensus over the basic standards that should govern individual practice (see Recommendation 15). Sound policies require thoughtful analysis by experts in many disciplines. This area provides an opportunity for the Academy to build upon its earlier work in analyzing data sharing practices in the social sciences and to recommend practices that are consistent with the norms of good science (Fienberg et al., 1985).

— With the requirement that there be exposure to professional standards and ethical issues in the training of scientists will come the practical need to develop ways to achieve this instruction. The committee seeks to maintain creativity and flexibility in

institutional approaches fulfilling this requirement. There is a need for an assessment of existing instructional materials. There is also a need for national forums to disseminate effective educational materials, including texts, case studies, video tapes, or booklets, since few institutions can claim to have the practical expertise that will be required for sound teaching materials.

— Although it is clear that poorly supervised scientists are more likely to develop unacceptable research practices, it is not known with any precision what constitutes adequate supervision. The perception needs to be addressed that there are large laboratories with absentee chiefs, who are training a correspondingly large number of young scientists and failing to indoctrinate them adequately into the professional as well as the techical standards of science.

15. An interdisciplinary committee should be convened to study the issue of rights and responsibilities of all relevant parties to research data and to prepare model guidelines for data sharing and data access.

The integrity of science is directly influenced by the verifiability and reproducibility of research data. The committee believes that the issues surrounding access to and sharing of research data are especially complex, and the members wish to highlight this topic as one that clearly deserves further consideration. This topic is appropriate for individual or collaborative studies by organizations such as the National Academy of Sciences, the American Association for the Advancement of Science, and the Association of American Universities.

As mentioned previously, the National Research Council has conducted a study on data-sharing practices in the social sciences. Sharing Research Data provides a useful reference and good beginning for a broader examination by professional and scientific organizations of the principles that should guide research practice in all fields of science. AAAS has also published an important report on this topic (Science as Intellectual Property) and has hosted several symposia to identify and evaluate current data sharing practices (Nelkin, 1983).

The committee believes a study of the rights and responsibilities of all parties to research data is especially important, given the perceptions expressed by many workshop participants that commercial and entrepreneurial interests as well as competitive academic pressures are affecting traditional data sharing practices.

The committtee suggests that this study not be limited to the sharing of research data, but include related issues such as the appropriate conditions for sharing research methods and materials.

16. There are many issues that deserve further analysis to enhance institutional and policy efforts to discourage scientific misconduct and to improve the integrity and quality of research. The committee recommends that professional and scientific organizations initiate studies to understand and encourage responsible research practices.

In its review of the topic of fraud and quality assurance in health sciences research, the committee identified a number of areas in which information is insufficient to warrant specific policy recommendations. The committee urges professional and scientific organizations, as well as individual investigators, to undertake studies in these areas to assist in the development of informed policies and procedures to promote the responsible conduct of research.

The following topics seem most appropriate for further analysis at this time:

— The effectiveness of mechanisms currently used to monitor quality in graduate research programs. The proposed study should explore (1) how mechanisms such as visiting committees and research ranking systems actually work, (2) the experience of selected institutions in using these systems to determine research quality, and (3) the means by which they could be introduced into other research settings.

— The existence of ethical concerns among research scientists and trainees and the ways in which these concerns are addressed. A few surveys have been conducted to determine professional awareness of incidents of misconduct (Sigma Xi, 1988; Tangney, 1987, 1988). Much greater understanding is needed of the types and prevalence of ethical concerns--including, but not limited to, concerns about misconduct-among scientists and trainees. It would be useful, for example, to study the opinions of individual scientists about the manner in which institutions develop and monitor responsible research practices.

— The roles and responsibilities of research staff in the laboratory or clinical research center. The rapid growth and complexity of health sciences research in recent decades has spawned tremendous diversification and variation within the research environment. There is some confusion over the roles--and responsibilities--of junior and senior personnel. Studies designed to analyze the expectations of the performance of different personnel in the laboratory and clinical research centers will identify other factors that affect the integrity of research.

— The detection and correction of error in science and scholarship. Various disciplines rely on systematic mechanisms, such as the replication studies required by some chemistry journals, to

identify research errors. The quality of research would be improved by characterization and analysis of the procedures used by research institutions, journals, professional groups, and individual investigators in various disciplines to detect and correct error.

REFERENCES

AAAS (American Association for the Advancement of Science) . 1988 . Project on Scientific Fraud and Misconduct . Report of a workshop sponsored by the National Conference of Lawyers and Scientists . Washington, D.C. : author

AAMC (Association of American Medical Colleges) . 1982 . AAMC Ad Hoc Committee on the Maintenance of High Ethical Standards in the Conduct of Research . Journal of Medical Education 57 : 895-902 .

AAU (Association of American Universities) . 1983 . Report of the AAU Committee on the Integrity of Research . Washington D.C. : author .

AAU (Association of American Universities) . 1988 . Framework for Institutional Policies and Procedures to Deal with Fraud in Research . Washington, D.C. : author . November .

AMA (American Medical Association) . Announcement of First International Congress on Peer Review in Biomedical Publication, to be held May 10-12, 1989 .

Bayles , Michael D. 1981 . Professional Ethics . Belmont, Calif. : Wadsworth Publishing Company .

Bosk , Charles . 1981 . Forgive and Remember , Chicago : University of Chicago Press .

Broad, W. J. and N. Wade . 1982 . Betrayers of the Truth: Fraud and Deceit in the Halls of Science . New York : Simon and Schuster .

Carlin, J. E. 1966 . Lawyers' Ethics: A Survey of the New York City Bar . New York : Russell Sage Foundation .

Chalk, R. 1988 . Science, Technology and Society: Emerging Relationships . Washington, D.C. : American Association for the Advancement of Science .

Culliton, B. J. 1988a . Scientists confront misconduct . Science 241 : 1748-1749 .

Culliton, B. J. 1988b . Bill would set fraud guidelines for scientific publications . Science 242 : 187 .

Fienberg, S. , M. Martin , and M.L. Straf. 1985 . Sharing research data . Washington, D.C. : National Academy Press .

Freidson, E. 1970 . Profession of Medicine: A Study of the Sociology of Applied Knowledge . New York : Dodd, Mead & Company .

Gould, S. J. 1972 . Zealous advocates (book review) . Science 176 : 623-625 .
Greene, P. J. , J. S. Durch , W. Horwitz et al. 1985 . Policies for responding to allegations of fraud in research . Minerva 23 : 203-215 .
Huth, E. J. 1988 . Scientific Authorship and Publication; Process, Standards, Problems, Suggestions . Background paper prepared for the Institute of Medicine/National Academy of Sciences. December .
ICMJE (International Committee of Medical Journal Editors) . 1988 . Uniform requirements for manuscripts submitted to biomedical journals . Annals of Internal Medicine 108 : 258-265 .
Jasanoff, S. 1988 . Good Laboratory Practices: Regulating Responsibility in Science . Background paper prepared for the Institute of Medicine/National Academy of Sciences. August .
Kennedy, D. 1985 . Academic authorship . Stanford University .
Kohn, A. 1986 . False Prophets: Fraud and Error in Science . New York : Basil Blackwell .
Lisook, A. B. 1986 . FDA Inspection of U.S. and Foreign Clinical Studies . Unpublished remarks to the Regulatory Affairs Professionals Society. Munich, FRG. May 5 .
Nelkin, D. 1983 . Science as intellectual property . Washington, D.C. : American Association for the Advancement of Science .
Shapiro, M. F. , and R. P. Charrow . 1985 . Scientific misconduct in investigational drug trials . New England Journal of Medicine 312 : 731-736 .
Sigma Xi . 1986 . Honor in Science . New Haven, Conn.
Sigma Xi . 1988 . Sketches of the American Scientist . New Haven, Conn.
Tangney, J. P. 1988 . Testimony before the United States House of Representatives Committee on Government Operations Subcommittee on Human Resources and Intergovernmental Relations . April 11 .
Tangney, J. P. 1987 . Fraud will out--or will it? New Scientist (August 6) .
Tosteson, D. C. 1988 . Harvard Medical School Memorandum . March 7 .

U.S. Congress . 1981 . House Committee on Science and Technology . Fraud in Biomedical Research. Hearings. March 31-April 1 .

U.S. Congress . 1988a . House Committee on Energy and Commerce . Scientific Fraud and Misconduct in the National Institutes of Health Biomedical Grant Programs. Hearings. April 12 .

U.S. Congress . 1988b . House Committee on Government Operations . Scientific Fraud and Misconduct and the Federal Response. Hearings. April 11 .

U.S. Congress . 1988c . House Committee on Government Operations . .

USDHHS (U.S. Department of Health and Human Services) . 1986 . National Institutes of Health . Guide for Grants and Contracts: Policies and Procedures for Dealing with Possible Misconduct in Science . Vol. 15, No. 11. July 18 .

USDHHS (U.S. Department of Health and Human Services) . 1988a . Public Health Service . Responsibilities of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science . 42 CFR Part 50. Federal Register. Vol. 53, No. 181. September 19 .

USDHHS (U.S. Department of Health and Human Services) . 1988b . Public Health Service . Announcement of Development of Regulations Protecting Against Scientific Fraud or Misconduct; Request for Comments . 42 CFR Part 50. Federal Register. Vol. 53, No. 181. September 19 .

USDHHS (U.S. Department of Health and Human Services) . 1988c . Office of the Inspector General. Misconduct in Scientific Research (Draft). September.

U.S. Office of the President . 1981 . Executive Order 12291 .

U.S. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research . 1982 . Whistleblowing in Biomedical Research: Policies and Procedures for Responding to Reports of Misconduct . Edited by Judith P. Swazey and Stephen R. Scher . Proceedings of a workshop sponsored by the Commission, the AAAS Committee, on Scientific Freedom and Responsibility and Medicine in the Public Interest. Washington, D.C. September 21-22 .

University of Michigan . 1984 . Maintaining the Integrity of Scholarship . A joint task force report for the Senate Advisory Committee on University Affairs .

Woolf, P. K. 1986 . Pressure to publish and fraud in science . Annals of Internal Medicine 104(2) : 254-256 .

BIBLIOGRAPHY

Altman, L. K. 1986 . Medical journals' muzzling policies threaten quality . Sciencewriters 34(3) : 1-4 .
Altman, L. K. and L. Melcher . 1983 . Fraud in science . British Medical Journal 286 : 2003-2006 .
AAAS (American Association for the Advancement of Science) . 1988 . Project on Scientific Fraud and Misconduct . Report of a workshop sponsored by the National Conference of Lawyers and Scientists . Washington, D.C. : author
Angell, M. 1983 . Editors and fraud . Council of Biology Editors Views 6(2) : 3-8 .
Angell, M. 1986 . Publish or perish: A proposal . Annals of Internal Medicine 104(2) : 261-262 .
Angell, M. and A. S. Relman . 1988 . Fraud in biomedical research . New England Journal of Medicine 318(22) : 1462-1463 .
Appelbaum, P. S. , L. H. Roth , C. W. Lidz , et al. 1987 . False hopes and best data: Consent to research and the therapeutic misconception . Hastings Center Report. April .
Aronson, L. R. 1975 . The case of The Case of the Midwife Toad . Behavior Genetics 5(2) : 115-125 .
AAMC (Association of American Medical Colleges) . 1982 . AAMC Ad Hoc Committee on the Maintenance of High Ethical Standards in the Conduct of Research . Journal of Medical Education 57 : 895-902 .
AAMC (Association of American Medical Colleges) . 1982 . The Maintenance of High Ethical Standards in the Conduct of Research . Washington D.C. : author .
AAU (Association of American Universities) . 1983 . Report of the AAU Committee on the Integrity of Research . Washington D. C. : author .
AAU (Association of American Universities) . 1988 . Framework for Institutional Policies and Procedures to Deal with Fraud in Research . Washington, D.C. : author . November .
AAU (Association of American Universities) . 1988 . Framework for Institutional Policies and Procedures to Deal with Fraud in Research . Washington, D.C. : author . November .

Bailar, J. C. 1985 . When research results are in conflict . New England Journal of Medicine 313(17) : 1080-1081 .
Bailar, J. C. 1986 . Science, statistics, and deception . Annals of Internal Medicine 104(2) : 259-260 .
Batshaw, M. L. , L. P. Plotnick , B. G. Petty , et al. 1988 . Academic promotion at a medical school: Experience at Johns Hopkins University School of Medicine . New England Journal of Medicine 318(12) : 741-747 .
Bayles, Michael D. 1981 . Professional Ethics . Belmont, Calif. : Wadsworth Publishing Company .
Beardsley, T. 1986 . Do libel risks prevent publication? Nature 320(6) : 6 .
Beaty, H. N. , D. Babbott , E. J. Higgins , et al. 1986 . Research activities of faculty in academic departments of medicine . Annals of Internal Medicine 104 : 90-97 .
Bick, K. L. 1988 . Statement before the House Government Operation Subcommittee on Human Resources and Intergovemental Relations . U.S. Congress. April 11 .
Blumberg, B. S. and R.C. Fox . 1985 . The Daedalus effect: Changes in ethical questions relating tohepatitis B virus . Annals of Internal Medicine 102 : 390-394 .
Blumberg, P. I. 1978 . Commentary on ‘professional freedom and responsibility.' Science, Technology and Human Values (22) : 43-46 .
Bok, Derek . 1988 . Ethics, the university, and society . Harvard Magazine (May-June) : 39-50 .
Bosk, Charles . 1981 . Forgive and Remember . Chicago : University of Chicago Press .
Braunwald, E. 1987 . On analyzing scientific fraud . Nature 325 : 215-216 .
Broad, W. J. 1981 . Fraud and the structure of science . Science 212 : 137-141 .
Broad, W. J. and N. Wade . 1982 . Betrayers of theTruth: Fraud and Deceit in the Halls of science . New York : Simon and Schuster .
Bulger, R. E. 1988 . The need for anethical code for teachers of the basic biomedical sciences . Journal of Medical Education 63 : 131-133 .

Burman, K. D. 1982 . “Hanging from the masthead”: Reflections on authorship . Annals of Internal Medicine 97 : 602-605 .
Byrne, G. 1988 . Breuning sentenced . Science 242 : 1004 .
California Caucus of College and University Ombudsmen . 1986 . Directory of College and University Ombudsmen for the United States and Canada 1986-1987 .
Carlin, J. E. 1966 . Lawyers' Ethics: A Survey of the New York City Bar . New York : Russell Sage Foundation .
Carney, M. J. 1986 . A difficult balance: Editorial peer review in medicine (book review) . Journal of the American Medical Association 256 (2) : 255 .
Chalk, R. 1978 . Scientific society involvement in whistleblowing . Science, Technology and Human Values (22) : 47-51 .
Chalk, R. 1988 . Science, Technology and Society: Emerging Relationships . Washington, D.C. : American Association for the Advancement of Science .
Cohen, S. N. , R. A. Goldstone , S. D. Nightingale , et al. 1984 . Dealing with conflicts of interest (letters) . New England Journal of Medicine 311 : 404-405 .
Cordes, C. 1988 . College officials wary of expansion of audits of how federal research money is spent . Chronicle of Higher Education (May 25) .
Culliton, B. J. 1987 . Integrity of research papers questioned . Science 235 : 422-423 .
Culliton, B. J. 1988 . A bitter battle over error . Science 240 : 1720-1723 .
Culliton, B. J. 1988 . A bitter battle over error (II) . Science 241 : 18-21 .
Culliton, B. J. 1988 . Harvard tackles the rush to publication . Science 241 : 525 .
Culliton, B. J. 1988 . Panel completes interviews in “Baltimore Case.” Science 241 : 286 .
Culliton, B. J. 1988 . Scientists confront misconduct . Science 241 : 1748-1749 .
Culliton, B. J. 1988 . Bill would set fraud guidelines for scientific publications . Science 242 : 187 .

Cupples, B. , and G. Myron . 1985 . The investigator's duty not to deceive . IRB: A Review of Human Subjects Research 7(5) : 1-6 .
Dawson, N. J. ; and A. Shamoo and Z. Annau . 1987 . Ensuring scientific integrity (letters) . Nature 327 .
Djerassi, C. 1986 . Castor's dil-emma . Hudson Review 39(3) : 405-418 .
Donaldson, V. H. 1984 . When things are not as they seem . Journal of Laboratory and Clinical Medicine 103(4) : 491-496 .
Dworkin, G. 1983 . Fraud and science . Progress in Clinical Biology Research 128 : 65-74 .
Edsall, J. T. 1985 . Two aspects of scientific responsibility . Science 212 : 11-14 .
Edsall, J. T. 1988 . The nature of whistle-blowing (letter) . Science 241 : 11-12 .
Edsall, J. T. 1988 . Science papers need new publishing guidelines (letter) . Boston Globe (June 20) .
Edsall, J. T. 1988 . Some thoughts on scientific fraud and misconduct . cgs Communicator 21(5) : 1-2 .
Engler, R. L. , J. W. Covell , P. J. Friedman , et al. 1987 . Misrepresentation and responsibility in medical research . New England Journal of Medicine 317 : 1383-1389 .
Epstein, R. 1986 . On drafting rules and procedures for academic fraud . Minerva 24(2-3) : 344-347 .
Ewing, T. 1988 . Australian scientists differ on how to attack fraud . Nature 332 : 671 .
Federation of American Societies for Experimental Biology . 1988 . Multiple authorship on scientific papers should be discouraged, panel advises . Public Affairs Newsletter 21(6) : 5 .
Ferguson, D. G. , N. A. Davidson , and A. Poling . 1988 . Request for retraction (letters) . Archives of General Psychiatry 45 : 685-686 .
Fienberg, S. , M. Martin , and M. L. Straf . 1985 . Sharing research data . Washington, D.C. : National Academy Press .
Fox, R. C. 1985 . Reflections and opportunities in the sociology of medicine . Journal of Health and Social Behavior 26 : 6-14 .
Fox, R. C. In press . Medical science and medical research . Chapter 6 in The Sociology of Medicine . New York : Prentice-Hall .

Fred, H. L. 1984 . Dishonesty in medicine . Southern Medical Journal 77(10) : 1221-1222 .
Freedman, D. X. 1988 . The meaning of full disclosure (editorial) . Archives of General Psychiatry 45 : 689-691 .
Freeman, G. H. , A. M. W. Porter , and J. R. Sabine . 1987 . Accuracy, statistics and fraud (letters) . Nature 325 : 656 .
Freidson, E. 1970 . Profession of Medicine: A Study of the Sociology of Applied Knowledge . New York : Dodd, Mead & Company .
Friedman, P. J. 1988 . Research ethics, due process, and common sense . Journal of the American Medical Association 260(13) : 1937-1938 .
Galtung, J. 1983 . Researchers, elites, and people in a rapidly changing world . Progress in Clinical Biology Research 128 : 95-108 .
Garfield, E. 1987 . Current comments: Some deviant behavior in science has nothing at all to do with fraud . ISI Press Digest 49 : 3-4 .
Gjerde, C. L. and S. E. Colombo . 1982 . Promotion criteria: Perceptions of faculty members and departmental chairmen . Journal of Medical Education 57 : 157-162 .
Golberg, L. 1982 . A code of ethics for scientists reporting and reviewing information on chemicals . Fundamental and Applied Toxicology 2 : 289-292 .
Gould, S. J. 1972 . Zealous advocates (book review) . Science 176 : 623-625 .
Greene, P. J. , J. S. Durch , W. Horwitz et al. 1985 . Policies for responding to allegations of fraud in research . Minerva 23 : 203-215 .
Hall, E. C. , C. M. Huguley, Jr. , and P. N. Panagiotis . 1985 . Report of ad hoc committee to evaluate research of Dr. John R. Darsee at Emory Universiy . Miverva 23(2) : 277-305 .
Hamblin, T. 1983 . Fraud in science (letter) . British Medical Journal 287 : 355 .
Holden, C. 1987 . Fraud reimbursement . Science 237 : 1563 .
Holden, C. 1988 . Whistle-blowers air cases at House hearings . Science 240 : 386-387 .

Hollis, B. W. 1987 . I turned in my mentor . Scientist 1(27) : 2-4 .
Horne, R. A. 1983 . Science fraud (book review) . Physics Chem. and Physics and Med. NMR . 15 : 365-367 .
Howard, R. B. 1983 . 'Betrayers of the truth' (editorial) . Postgrad. Med. 74(6) : 13, 16, 19, 22 .
Hunter, H. O. 1985 . Academic self-government in the United States . Minerva 23(1) : 1-28 .
Huth, E. J. 1988 . Scientific Authorship and Publication; Process, Standards, Problems, Suggestions . Background paper prepared for the Institute of Medicine/National Academy of Sciences . December .
Huth, E. J. 1986 . Irresponsible authorship and wasteful publication . Annals of Internal Medicine 104(2) : 257-258 .
Huth, E. J. 1986 . Abuses and uses of authorship . Annals of Internal Medicine 104(2) : 266-267 .
Huth, E. J. 1986 . Guidelines on authorship of medical papers . Annals of Internal Medicine 104 : (2)269-274 .
ICMJE (International Committee of Medical Journal Editors) . 1982 . Uniform requirements for manuscripts submitted to biomedical journals . British Medical Journal 284 : 1766-1770 .
ICMJE (International Committee of Medical Journal Editors) . 1985 . Guidelines on authorship . British Medical Journal 291(14) : 722 .
ICMJE (International Committee of Medical Journal Editors) . 1988 . Uniform requirements for manuscripts submitted to biomedical journals . Annals of Internal Medicine 108 : 258-265 .
Jackson, C. I. , and J. W. Prados . 1983 . Honor in science . American Scientist 71(5) : 462-464 .
Jacobstein, J. G. 1988 . Testimony before the House Committee on Government Operations . April 11 .
Jacobstein, J. 1987 . I am not optimistic . Scientist 1(27) : 2-4 .
Jasanoff, S. 1988 . Good Laboratory Practices: Regulating Responsibility in Science . Background paper prepared for the Institute of Medicine/National Academy of Sciences. August .
Kass, L. R. 1983 . Professing ethically: On the place of ethics in defining medicine . Journal of the American Medical Association 249(10) : 1305-1310 .

Kennedy, D. 1985 . Academic authorship . Stanford University .
Knight, J. A. 1984 . Exploring the compromise of ethical principles in science . Perspectives in Biology and Medicine 27(3) : 432-442 .
Knox, R. 1983 . The Harvard fraud case: where does the problem lie? Medical News 249(14) : 1797-1799, 1802-1807 .
Kohn, A. 1986 . False Prophets: Fraud and Error in Science . New York : Basil Blackwell .
Koshland, D. E., Jr. 1987 . Fraud in science (editorial) . Science 235 : 141 .
Koshland, D. E., Jr. 1988 . Science, journalism, and whistle-blowing (editorial) . Science 240 : 585 .
Koshland, D. E., Jr. 1988 . The price of progress (editorial) . Science 241 : 637 .
Lafollette, M.C. 1988 . Ethical Misconduct in Research Communication: An Annotated Bibliography . Boston, Mass. : author . August .
Laor, N. 1985 . Prometheus the impostor . British Medical Journal 290 : 681-684 .
Last, J. M. 1986 . Disclosure of journal referees' reports (letter) . Lancet (March 15) .
Lewin, B. 1987 . Fraud in science: The burden of proof (editorial) . Cell . 48 : 1-2 .
Lind, S. E. 1986 . Fee-for-service research . New England Journal of Medicine 314(5) : 312-15 .
Lisook, A. B. 1986 . FDA Inspection of U.S. and Foreign Clinical Studies . Unpublished remarks to the Regulatory Affairs Professionals Society. Munich, FRG. May 5 .
List, C. J. 1985 . Scientific fraud: Social deviance or the failure of virtue . Science, Technology, and Human Values 10(4) : 27-36 .
Lo, B. 1987 . Behind closed doors: Promises and pitfalls of ethics committees . New England Journal of Medicine 317(1) : 46-50 .
Lock, S. 1985 . A Difficult Balance: Editorial Peer Review in Medicine . London : Nuffield Provincial Hospitals Trust .

Lock, S. 1988 . Scientific misconduct . British Medical Journal 296 (September 24) .
Lock, S. 1988 . Fraud in medicine . British Medical Journal 296 .
Macdonald, D. I. 1987 . Scientific misconduct is revealed . Journal of the American Medical Association 258(11) : 1440 .
Maddox, J. 1985 . Fraud prevention: Only colleagues can judge the value and authenticity of a person's work (editorial) . Nature 315(6) : 444 .
Maddox, J. 1987 . Fraud, libel and the literature (editorial) . Nature 325 : 181-182 ;
Maddox, J. 1987 . Getting to grips with fraud (editorial) . Nature 329 : 377 .
Maddox, J. 1987 . Whose misconduct? The delay in performing an investigation of an allegation of misconduct may itself be improper (editorial) . Nature 326 .
Maddox, J. 1988 . Can a Greek tragedy be avoided? Nature 333 : 795-797 .
Maddox, J. 1988 . Why the pressure to publish? Nature 333 : 493 .
Mahoney, M.J. 1976 . Scientist as Subject . Cambridge, Mass. : Ballinger .
Majerus, P. W. 1982 . Fraud in medical research . Journal of Clinical Investigation 70 : 213-217 .
May, W. F. 1980 . Professional ethics: Setting, terrain, and teacher . Pp. 205-241 in D. Callahan and S. Bok , eds. Ethics in Higher Education . New York : Plenum .
Mazlish, B. 1982 . The quality of ‘the quality of science': An evaluation . Pp. 48-67 in M. Chotkowski , ed. Quality in Science . Cambridge, Mass. : MIT Press .
Miers, M. L. 1985 . Current perspectives in misconduct in science . American Psychologist 40 : 831-835 .
Mishkin, B. 1988 . Responding to scientific misconduct . Journal of the American Medical Association 260(13) : 1932-1936 .
Moore, F. D. 1987 . False prophets: Fraud and error in science and medicine (book review) . New England Journal of Medicine 316(21) : 1349-1350 .

Nelkin, D. 1983 . Science as intellectual property . Washington, D.C. : American Association for the Advancement of Science .
Nelkin, D. 1983 . Whistle blowing and social responsibility in science . Progress in Clinical Biology Research 128 : 351-357 .
Norman. C. 1988 . Stanford inquiry casts doubt on 11 papers . Science 242 : 659 .
Osmond, D. H. 1983 . Malice's wonderland: Research funding and peer review . Journal of Neurobiology 14(2) : 95-112 .
Petersdorf, R. G. 1982 . Preventing and investigating fraud in research (editorial) . Journal of Medical Education 57 : 880-881 .
Petersdorf, R. G. 1984 . The case against tenure in medical schools . Journal of the American Medical Association 251(7) : 920-924 .
Petersdorf, R. G. 1986 . The pathogenesis of fraud in medical science . Annals of Internal Medicine 104(2) : 252-254 .
Phelps, J. R. 1982 . Disqualification of investigators . Remarks before the Food and Drug Law Institute Symposium on Disqualification of Investigators. March 6, 1980. RS 8249. The Center for the Study of Drug Development, Univ. Rochester Med. Ctr., February.
Price. D. K. 1979 . The ethical principles of scientific institutions . Science, Technology and Human Values (26) : 46-60 .
Rangachari, P. K. , and H. Hillman . (letters) 1987 . Fraud versus carelessness . Nature 326 : 736 .
Relman, A. S. 1983 . Lessons from the Darsee affair . New England Journal of Medicine 308(23) : 1415-1417 .
Relman, A. S. 1984 . Dealing with conflicts of interest (editorial) . New England Journal of Medicine 310 : 1182-1183 .
Relman, A. S. 1984 . Responsibilities of authorship: Where does the buck stop? (editorial) . New England Journal of Medicine 310(16) : 1048-1049 .
Rennie, D. 1986 . (Guarding the guardians: a conference on editorial peer review (editorial) . Journal of the American Medical Association 256(17) : 2391-2392 .

Schmaus, W. 1983 . Fraud and negligence in science . Connecticut Medicine 27(3) : 155-158 .
Shader, R. I. , and D. J. Greenblatt . 1988 . Authorship and coauthorship--working out the meaning (editorial) . Journal of Clinical Psychopharmacology 7(5) : 293 .
Shapiro, M. F. , and R. P. Charrow . 1985 . Scientific misconduct in investigational drug trials . New England Journal of Medicine 312 : 731-736 .
Sigma Xi . 1986 . Honor in Science . New Haven, Conn.
Sigma Xi . 1988 . Sketches of the American Scientist . New Haven, Conn.
Southgate, M. T. 1987 . Conflict of interest and the peer review process (editorial) . Journal of the American Medical Association 258(10) : 1375 .
Sprague, R. L. 1987 . I trusted the research system . The Scientist 1(27) : 2-4 .
Sprague, R. L. 1988 . Testimony before the House Committee on Goverment Operations . April 11 .
Stetten, D., Jr. 1984 . Reported laboratory frauds in biomedical sciences (letter) . Science 226 : 1374-1375 .
Stetten, D., Jr. 1988 . Publication: Numbers and quality (letter) . Science 232 : 11 .
Stewart, W. W. , and N. Feder . 1986 . Why research fraud thrives . Boston Sunday Globe 230(153) . November 30 .
Stewart, W. W. , and N. Feder . 1987 . The integrity of the scientific literature . Nature 325 : 207-214 .
Stewart, W. W. , and N. Feder . 1987 . Research practices (letter) . Science 235 : 146 .
Stewart, W. W. , and N. Feder . 1987 . We must deal realistically with fraud and error (editorial) . The Scientist (December 14) .
Stewart, W. W. , and N. Feder . 1988 . Statement before the Subcommittee on Human Resources and Intergovernmental Relations of the House Committee on Government Operations . April 11 .
Stolinsky, D. C. , J. D. Howell , J. A. Witkowski , et al. 1988 . Misrepresentation and responsibility in medical research (letters) . New England Journal of Medicine 318(21) : .

Stossel, T. P. 1985 . Reviewer status and review quality . New England Journal of Medicine 312 : 658-659 .
Strassburger, V. C. 1986 . (letter). Journal of the American Medical Association 255(15) : 2024 .
Tangney, J. P. 1988 . Testimony before the United States House of Representatives Committee on Government Operations Subcommittee on Human Resources and Intergovernmental Relations . April 11 .
Tangney, J. P. 1987 . Fraud will out--or will it? New Scientist (August 6) .
Tosteson, D. C. 1988 . Harvard Medical School Memorandum . March 7 .
Tranoy, K. E. 1983 . Is there a universal research ethics? Progress in Clinical Biology Research 128 : 3-12 .
U.S. Congress . 1981 . House Committee on Science and Technology . Fraud in Biomedical Research . Hearings . March 31-April 1 .
U.S. Congress . 1988 . House Committee on Energy and Commerce . Scientific Fraud and Misconduct in the National Institutes of Health Biomedical Grant Programs . Hearings . April 12 .
U.S. Congress . 1988 . House Committee on Government Operations . Scientific Fraud and Misconduct and the Federal Response . Hearings . April 11 .
U.S. Congress . 1988 . House Committee on Government Operations . Federal Response to Scientific Fraud and Misconduct . Hearings . September 29 .
USDHHS (U.S. Department of Health and Human Services) . 1986 . National Institutes of Health . Guide for Grants and Contracts: Policies and Procedures for Dealing with Possible Misconduct in Science . Vol. 15, No. 11. July 18 .
USDHHS (U.S. Department of Health and Human Services) . 1988 . Public Health Service . Responsibilities of PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science . 42 CFR Part 50. Federal Register. Vol. 53, No. 181. September 19 .
USDHHS (U.S. Department of Health and Human Services) . 1988 . Public Health Service . Announcement of Development of Regulations Protecting Against Scientific Fraud or Misconduct; Request for Comments . 42 CFR Part 50. Federal Register. Vol. 53, No. 181. September 19 .

USDHHS (U.S. Department of Health and Human Services) . 1988 . Office of the Inspector General . Misconduct in Scientific Research (Draft) . September .

U.S. Office of the President . 1981 . Executive Order 12291 .

U.S. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research . 1982 . Whistleblowing in Biomedical Research: Policies and Procedures for Responding to Reports of Misconduct . Edited by Judith P. Swazey and Stephen R. Scher . Proceedings of a workshop sponsored by the Commission, the AAAS Committee on Scientific Freedom and Responsibility and Medicine in the Public Interest . .

University of Michigan . 1984 . Maintaining the integrity of scholarship . A joint task force report for the Senate Advisory Committee on University Affairs .

van de Kamp, J. , and M. M. Cummings . 1987 . Misconduct and fraud in the life sciences: A selected bibliography of 450 Citations . Washington, D.C. : National Library of Medicine .

Vanderpool, H. Y. , and G. B. Weiss . 1987 . False data and last hopes: Enrolling ineligible patients in clinical trials . Hastings Center Report. April .

Verma, S. , R. A. Rosenblatt , and W. J. Holloway , et al. 1988 . (letters) . New England Journal of Medicine 318(1) : 52-54 .

Walsh, J. 1979 . ‘Unfaculty' a growing factor in research . Science 204 : 286 .

Weinstein, D. 1981 . Scientific fraud and scientific ethics . Connecticut Medicine 45(10) : 655-658 .

Woolf, P. K. 1981 . Fraud in science: How much, how serious? The Hastings Center Report 11(5) : 9-14 .

Woolf, P. K. 1986 . Pressure to publish and fraud in science . Annals of Internal Medicine 104(2) : 254-256 .

Woolf, P. K. 1987 . ‘Pressure to publish' is a lame excuse for scientific fraud . Chronicle of Higher Education (September 9) .

Woolf, P. K. 1988 . Science needs vigilance not vigilantes . Journal of the American Medical Association 260(13) : 1939-1940 .

Woolf, P. K. 1988 . Deception in Scientific Research . In Project on Scientific Fraud and Misconduct: Report on Workshop Number One . Washington, D.C. : American Association for the Advancement of Science .

Yankauer, A. 1987 . Editor's report--on decisions and authorships . American Journal of Public Health 77(3) : 271-273 .

Yolles, B. J. , J. C. Connors , and S. Grufferman . 1986 . Obtaining access to data from governmental-sponsored medical research 315(26) : 1669-1672 .

Zuckerman, H. 1977 . Deviant behavior and social control in science . Pp. 87-138 in E. Sagarin , ed. Deviance and Social Change . Beverly Hills : Sage .

Zurer, P. S. 1987 . Misconduct in research . Chemical & Engineering News . April 13 .

Zurer, P. S. 1987 . Workshop airs research ethics and monitoring of scientific misconduct . Chemical & Engineering News . October 5 .

(unsigned) . 1985 . Standards on author's responsibilities . Annals of Internal Medicine 103 : 797-798 .

(unsigned) . 1983 . Responsibilities of coauthorship . Annals of Internal Medicine 99(2) : 266-267 .

APPENDIXES

APPENDIX A

NATIONAL ACADEMY OF SCIENCES/NATIONAL RESEARCH COUNCIL INSTITUTE OF MEDICINE

and the

COMMITTEE ON SCIENCE, ENGINEERING AND PUBLIC POLICY

WORKSHOP ON THE RESPONSIBLE CONDUCT OF RESEARCH IN THE HEALTH SCIENCES

Ramada Renaissance Hotel

Washington, D.C.

Agenda

Tuesday, September 6

7:30 p.m.	OPENING SESSION Welcoming Remarks Arthur H. Rubenstein, University of Chicago Dr. Rubenstein is the chairman of the IOM Committee on the Responsible Conduct of Research. Alfred P. Fishman, University of Pennsylvania Dr. Fishman is the chairman of the IOM Board on Health Sciences Policy and is a member of COSEPUP.
8:00 p.m.	Setting Standards for Research in the Health Sciences: Whose Responsibility? Samuel O. Thier, President, Institute of Medicine William Raub, Deputy Director National Institutes of Health Robert P. Charrow, Deputy General Counsel U.S. Department of Health and Human Services
9:00 p.m.	Review of Panel Structure and Format Rosemary Chalk, Study Director IOM Committee on the Responsible Conduct of Research Dr. Rubenstein will introduce the panel chairs and will review the purpose and objectives of the panel sessions. General Discussion
10:00 p.m.	ADJOURNMENT

Wednesday, September 7

8:30 a.m. - Noon	PANEL SESSIONS Panels 1-6 will meet in separate rooms.
12:15 p.m.	LUNCHEON
1:00 p.m.	Luncheon Address by William May, Southern Methodist University "The Role of Individuals in Transmitting Professional Standards"
1:30 p.m.	PANEL SESSIONS (Panel members will return to their meeting rooms.)
3:30 p.m.	PLENARY SESSION The rapporteurs will give preliminary reports from the panel discussions.
5:30 p.m.	ADJOURNMENT

Thursday, September 8

8:30 - 10:15 a.m.	PANEL SESSIONS The panels will each prepare proposals and recommendations for discussion in the plenary session.
10:30 - 12:15 p.m.	PLENARY SESSION The rapporteurs will present the panel proposals for discussion by the workshop participants
12:30 p.m. LUNCHEON	
2:00 p.m.	PLENARY SESSION Continued discussion of the panel reports
4:00 - 4:30 p.m.	Closing Remarks Arthur Rubenstein
4:30 p.m.	ADJOURNMENT

APPENDIX B

IOM/COSEPUP WORKSHOP on the RESPONSIBLE CONDUCT OF RESEARCH IN THE HEALTH SCIENCES

PARTICIPANTS

Richard Adelman, Ph.D.
Director, Institute of Gerontology
University of Michigan
Phyllis Albritton
Office of Representative Ron Wyden
U.S. House of Representatives
Robert M. Andersen, J.D.
National Science Foundation
Marcia E. Angell, M.D.
Deputy Editor
The New England Journal of Medicine
William G. Anlyan, M.D.
Chancellor for Health Affairs
Duke University Medical Center
Michele Applegate
Associate Administrator for Extramural Programs
Alcohol, Drug Abuse, and Mental Health Administration
John Bailar, M.D., Ph.D.
Science Advisor, Office of Disease Prevention and Health Promotion
Department of Health of Human Services
Albert A. Barber, Ph.D.
Vice Chancellor - Research Programs
University of California of Los Angeles
Bernard Barber, Ph.D.
Chairman, Department of Sociology
Barnard College
Columbia University
Katherine Bick, Ph.D.
Deputy Director for Extramural Research
National Institutes of Health
Steven J. Bongard, Ph.D.
Staff Director, Forum on Drug Development and Regulation
Institute of Medicine
Samuel Broder, M.D.
Deputy Clinical Director
National Cancer Institute
Kathleen Bruvold, J.D.
Legal Adivsory Services
University of Cincinnati
Roger J. Bulger, M.D.
President
Association of Academic Health Centers
Ruth Ellen Bulger, Ph.D.
Director
Division of Health Sciences Policy
Institute of Medicine
Robert E. Burke, M.D.
Chief, Laboratory of Neural Control
National Institute of Neurologic, Communicative Diseases, and Stroke
John Burris, Ph.D.
Executive Director
Commission on Life Sciences
National Academy of Sciences

R. William Butcher, Ph.D.
Vice President for Scientific Affairs
Dean of the Graduate School of Biomedical Sciences
University of Texas Health Science Center
Rosemary Chalk
Study Director
Institute of Medicine
David R. Challoner, M.D.
Vice President for Health Affairs
University of Florida
Robert Charrow, J.D.
Deputy General Counsel
Office of the General Counsel
Department of Health and Human Services
W. Maxwell Cowan, M.D., Ph.D.
Vice President and Chief Scientific Officer
Howard Hughes Medical Institute
Joseph Craft, M.D.
Assistant Professor of Medicine
Yale University School of Medicine
Robert Cutler, M.D.
Senior Associate Dean for Faculty Affairs
Stanford University Medical Center
Carl Djerassi, Ph.D., D.Sc.
Professor, Department of Chemistry
Stanford University
John T. Edsall, M.D.
Professor Emeritus
Department of Biochemistry and Molecular Biology
Harvard University
Ronald Evans, Ph.D.
Salk Institute
Ned Feder, M.D.
Chief, Biophysical Histology
National Institute of Diabetes and Digestive and Kidney Diseases
Stephen E. Fienberg, Ph.D.
Dean, College of Humanities and Social Science
Carnegie Mellon University
Barbara Filner, Ph.D.
Program Officer
Howard Hughes Medical Institute
Alfred P. Fishman, M.D.
Director, Cardiovascular-Pulmonary Division
Hospital of the University of Pennsylvania
Mark S. Frankel, Ph.D.
Head, Office of Scientific Freedom and Responsibility
American Association for the Advancement of Science
Arnold J. Friedhoff, M.D.
Professor and Director,
Millhauser Labs
New York University Medical Center
Paul J. Friedman, M.D.
Associate Dean of Academic Affairs
School of Medicine
University of California at San Diego
Donald Ganem, M.D.
Department of Microbiology
University of California at San Francisco
Bradford H. Gray, Ph.D.
Study Director
Institute of Medicine

Suzanne Hadley, Ph.D.
Acting Deputy Director
Division of Extramural Activities
National Institute of Mental Health
Laura L. Hall, Ph.D.
Department of Anatomy
Uniformed Services University of the Health Sciences
Jules Hallum, Ph.D.
Chairman, Department of Microbiology and Immunology
School of Medicine
Oregon Health Sciences University
Barbara C. Hansen, Ph.D.
Vice Chancellor for Graduate Research and Studies
University of Maryland Graduate School, Baltimore
Wayne Hendrickson, Ph.D.
Department of Biochemistry and Molecular Biophysics
Columbia University
Patricia Hoben, Ph.D.
Office of the Assistant Secretary for Health
Department of Health and Human Services
Allan R. Hoffman, Ph.D.
Executive Director
Office of Government and External Affairs
National Academy of Sciences
Rachelle Hollander, Ph.D.
Ethics and Values Studies
Division of Science, Technology and Society Studies
National Science Foundation
Edward Huth, M.D.
Editor
Annals of Internal Medicine
Sheila Jasanoff, Ph.D., J.D.
Director
Program on Science, Technology & Society
Cornell University
Thomas J. Kennedy Jr., M.D.
Associate Vice President
Association of American Medical Colleges
Michael Konstan, M.D.
Assistant Professor of Pediatrics
University Hospitals of Cleveland
Robert J. Levine, M.D.
Professor
School of Medicine
Yale University
Benjamin Lewin, Ph.D.
Editor
Cell
Stuart Linn, Ph.D.
Professor of Biochemistry
University of California at Berkeley
Stephen Lock
Editor
British Medical Journal
Linda K. Lorimer, J.D.
President
Randolph-Macon Woman's College
William F. May, Ph.D.
Cary M. Maguire Professor of Ethics
Southern Methodist University
Lawrence E. McCray, Ph.D.
Executive Director
Committee on Science, Engineeringand Public Policy
National Academy of Sciences

Curtis L. Meinert, Ph.D.
Professor
Department of Epidemiology
School of Hygiene and Public Health
Johns Hopkins University
Mary Miers
Institutional Liaison Officer
Office of Extramural Research
National Institutes of Health
Howard E. Morgan, M.D.
Senior Vice President for Research
Weis Center for Research
Geisinger Clinic
Patricia A. Morgan
Managing Editor
Science
Lynn Morrison
Director for Public Policy
American Federation for Clinical Research
Dennis O'Connor, Ph.D.
Vice Chancellor for Research and Dean of Graduate Studies
University of North Carolina
Marian Osterweis, Ph.D.
Associate Executive Officer for Program
Institute of Medicine
Constance M. Pechura, Ph.D.
Study Director
Institute of Medicine
Oscar D. Ratnoff, M.D.
Professor Emeritus of Medicine
Case Western Reserve University
University Hospitals of Cleveland
William Raub, Ph.D.
Deputy Director
National Institutes of Health
Martha Reitman, M.D.
Associate Medical Director
Cardiovascular Research
Syntex Research
Arnold S. Relman, M.D.
Editor
The New England Journal of Medicine
Drummond Rennie, M.D.
Deputy Editor (West)
Journal of the American Medical Association
Richard Riseberg, LL.B.
Chief Counsel
Public Health Service
R. Paul Robertson, M.D.
Professor of Medicine and Cell Biology
Director Diabetes Center
University of Minnesota Hospital and Clinic
Robert Rosenzweig, Ph.D.
President
Association of American Universities
Aldo A. Rossini, M.D.
Director
Division of Diabetes
University of Massachusetts Medical Center
Arthur H. Rubenstein, M.D.
Chairman, Department of Medicine
Division of the Biological Sciences
The University of Chicago

Lesley Russell, Ph.D.
Professional Staff
Energy and Commerce Committee
U.S. House of Representatives
Mona Sarfaty, M.D.
Health Policy Advisor
Labor and Human Resources Committee
U.S. Senate
Frederick Savage, J.D.
Associate General Counsel
Office of the General Counsel
Johns Hopkins University
Carol R. Scheman
Director of Federal Relations
Association of American Universities
Gilbert Schiff, M.D.
President of the James N. Gamble Research Institute
Richard Shader, M.D.
Professor and Chairman of Psychiatry
Tufts University Medical School
Adil E. Shamoo, Ph.D.
Department of Biological Chemistry
School of Medicine
University of Maryland
Martin F. Shapiro, M.D., Ph.D.
Department of General Internal Medicine
University of California at Los Angeles
Eleanor G. Shore, M.D.
Associate Dean for Faculty Affairs
Harvard Medical School
Nancy L. Silva, Ph.D.
NRC Fellow, Lab of Neurophysiology
National Institute of Neurological and Communicative Diseases and Stroke
Lana Skirboll, Ph.D.
Deputy Science Advisor
Alcohol, Drug Abuse, and Mental Health Administration
Kent Smith
Deputy Director
National Library of Medicine
Jay Sternberg
Research Assistant
Institute of Medicine
Walter Stewart
Research Physicist
National Institute of Diabetes Digestive and Kidney Diseases
Michael Stoto, Ph.D.
Study Director
Institute of Medicine
Albert Teich, Ph.D.
Head, Office of Public Sector Programs
American Association for the Advancement of Science
Samuel O. Thier, M.D.
President
Institute of Medicine
Neal A. Vanselow, M.D.
Vice President of Health Sciences
University of Minnesota
Robert A. Weinberg, Ph.D.
Member of the Whitehead Institute for Biomedical Research
Professor of Biology, MIT
Jonathan Weissler, M.D.
Assistant Professor of Medicine
Southwestern Medical Center
University of Texas

George Whitesides, Ph.D.
Professor of Chemistry
Department of Chemistry
Harvard University
Kern Wildenthal, M.D., Ph.D.
President
Southwestern Medical Center
University of Texas
Robert E. Wittes, M.D.
Associate Director
Cancer Therapy Evaluation
Division of Cancer Treatment
National Cancer Institute
Patricia Woolf, Ph.D.
Department of Sociology
Princeton University
Tadataka Yamada, M.D.
Department of Internal Medicine
Division of G.I.
University of Michigan Medical Center
Rosemary Yancik, Ph.D.
Office of Extramural Research
National Institutes of Health
Diana Zuckerman, Ph.D.
Professional Staff Member
Human Resources and Intergovernmental Relations Subcommittee
Government Operations Committee
U.S. House of Representatives
Harriet Zuckerman, Ph.D.
Department of Sociology
Columbia University

APPENDIX C

PANEL 1 REPORT OF THE PANEL ON LABORATORY STANDARDS AND PRACTICES

The panel was convened to discuss ways to improve current laboratory research practices in the academic environment. The members indicated that two goals were thought desirable: improving the overall quality of research as currently practiced by university investigators and also remedying conditions that may fail to discourage misconduct in the research process.

Sixteen members participated in the panel discussions, most of whom were practicing scientists (primarily Ph.Ds) covering a wide range of fields, including molecular biology, biophysics, biochemistry, and science and law. The group also included several senior research administrators, including two academic research center directors, two vice-president/vice-chancellors for research and graduate deans, a chief scientific officer of a major private research funding agency, a laboratory chief from the National Institutes of Health, and staff members from the Academy.

The panel addressed a broad set of topics during its discussion. These topics included the handling, storage, and archiving of research data; existing models for quality control in science, including regulations governing the use of animals, the handling of hazardous materials, and experiments with recombinant DNA technologies; the applicability of the Good Laboratory Practices (GLPs) guidelines used by the Food and Drug Administration and the Environmental Protection Agency; the value of external audits in basic research; training and supervisory practices; the relevance of lab size and structure to research integrity; authorship practices; the significance of formal and informal rules in achieving good laboratory practice; the communication of high standards of research practice; and the relevance of good laboratory practices to fields of research beyond the biomedical sciences.

In these discussions, the panel members identified problems in evaluating the effectiveness of current mechanisms designed to promote integrity and quality in academic research. A majority of the participants thought that instances of fraud in science are rare but that sloppy research practices are more common than would be desired. The panel members expressed concern that the relatively rare instances of scientific fraud might provoke regulatory reforms that would be inappropriate for improving the conduct of responsible research practices and that would also threaten the vitality of creative research.

Most of the panel members agreed that substantial improvement in laboratory practices could be achieved most readily through mechanisms that improve oversight of the work of those directly involved in experimentation. An appreciable number of the participants thought that certain reforms should be initiated by the universities and professional

organizations to improve the effectiveness of existing oversight mechanisms. A minority expressed doubts that these reforms were necessary, indicating that the monitoring system worked well, that peer review was highly successful, and that evidence of serious problems in the conduct of research was insufficient to justify changes. A smaller minority supported more extensive reforms, including the use of external auditing as a means of assuring quality in academic research.

GOOD LABORATORY PRACTICE GUIDELINES AND THE USE OF AUDITS

Most of the panel participants expressed serious reservations about the need for and impact of legislative or regulatory actions in improving the quality of basic research practices. For example, the panel considered the rules associated with the FDA and EPA GLP guidelines that regulate chemical and drug testing. These GLPs describe in detail the procedures to be followed during the tests and include periodic audits by a regulatory agency to ensure adherence to the guidelines and the study protocol agreed upon at the inception of an experimental study. Federal regulations governing the handling of radioactivity and other hazardous materials, the manipulation of recombinant DNA, and the use of animal and human research subjects also rely extensively upon oversight of research protocols.

The panel believed this regulatory approach was impractical and injurious to the conduct of good science in fields involving basic or discovery research and noted that the agencies that use GLPs had rejected their application to basic research. A regulatory approach based on oversight of the research protocols requires that a detailed canon of research practices be established, that detailed research plans be drawn up at the initiation of the study, that deviations from the study protocol be justified in advance, and that adherence to these practices and protocols be monitored through periodic audits by responsible parties outside the research unit. The audits might be conducted by granting agencies, by governmental auditing agents, or by institutional officials empowered to conduct such procedures.

These plans were viewed as unworkable by the panel. Much of the research in question concerns basic discovery research, and it necessarily involves constantly changing protocols and research procedures. Adherence to a preplanned search trajectory would hamper basic science and foreclose the pursuit of unexpected but promising findings. The auditing bodies will be unlikely to acquire the necessary expertise to monitor effectively the activities of a large and diverse array of specialized research enterprises. Perhaps most important, the concept of routinized institutional auditing of the details of basic research procedures undermines the principles of trust and personal integrity that currently govern the conduct of academic research and the professional status of its practitioners.

PEER REVIEW

The panel explored a second regulatory strategy involving a strengthening of existing peer review processes. The process of peer review occurs at several distinct levels, and a majority of the panel agreed that each of these could benefit from substantial improvement.

Peer Review Within the Research Unit

The most intense surveillance of research practices occurs on a frequent and ongoing basis within the confines of the research unit. The review of this work depends on a number of practices, many of which are implicit or intrinsic in the conduct of scientific investigation and experimentation. These include:

- instruction of research personnel in how to properly design experiments and collect experimental data;
- insistence that raw data be preserved within notebooks and other repositories so that they are clear and readily interpreted by qualified researchers beyond those directly responsible for conducting the research in question;
- frequent interaction between the principal investigator of the research unit and the individuals conducting the research. Effective interactions require frequent review of raw data and interpretation of their implications; and
- frequent interactions between the experimentalists within a research unit involving those not directly concerned with the research in question. The panel thought it desirable that research units conduct frequent, periodic seminars in which investigators and trainees are able to scrutinize and critique each others' work. Conversely, laboratory practices that encourage compartmentalization, secrecy, or isolation within the research unit were viewed as incompatible with the conduct of good research. Moreover, the panel sought to discourage practices in which experimentalists would describe their work only to a supervisor and not routinely discuss findings with their peers within the laboratory.

Peer Review Within the Department

Most research units are affiliated with a larger administrative unit, usually termed a “department.” The panel thought it important to recognize that departments have an essential role in monitoring the integrity and quality of the science within their constituent research units. Intradepartmental review my not be invested with the same degree of specialized expertise that resides within the research unit itself, but it should play a useful and essential part in assuring quality. The panel members indicated that departmental affiliation implies interest and

willingness to subject one's research to the scrutiny of other departmental members, including those outside one's own research group.

A variety of mechanisms can be used to achieve this end, including:

- departmental research seminars,
- joint research meetings involving multiple research units,
- annual or semi-annual reports of investigators' work, and
- other means of engaging contact between members of different research units, including participation in joint training programs.

This approach assumes that such review and scrutiny should be undertaken as a matter of common practice and not only on rare occasions and in response to suspicion of implications of poor quality or misconduct. Mutual review performed in a constructive and collegial manner was viewed by the panel as a normal, routine element of good science and a characteristic of an active and productive research departmental.

Review of the Department by Outside Peers

Because the departments exercise a central role in the existing peer review process, the panel considered mechanisms to ensure that departments and their component research units function in an appropriate manner. One useful mechanism is the use of periodic review, often performed every several years, by peers outside a department. These peers may come from related departments within a university or from other universities in the form of “visiting committees.” These departmental reviews often include:

- surveys of representative research projects,
- surveys of the entire output of the department,
- interviews with trainees, supervisors, and principal investigators, and
- preparation of candid reports for department heads and higher administrative personnel, including deans, provosts, and the president of the university.

Review of Published Work by Peers

The three levels of peer review discussed above monitor the everyday process of science within the laboratory. These activities include data acquisition and interpretation. The panel felt that the end point of this work--the formalization of results in a published report--also requires an increased level of peer monitoring.

This monitoring of published work begins at the stage of drafting reports for eventual publication. The panel thought it essential that all parties contributing to the report and appearing as authors be involved in its creation. In certain cases, this might involve only a detailed reading of the report prior to submission. In others, co-authors might redraft portions of the text. In all cases, the panel stated that participation as author implies a detailed understanding and agreement with the report and a certification that the results contributed by an author are properly represented by the finished text.

A subsequent level of manuscript review occurs by qualified peers following submission for publication. The panel did not discuss changes in this process as presently constructed. They did focus attention on the post-publication process--the scrutiny of a published report by peers throughout the world. The central effectiveness of this scrutiny relies on the ability of peers to reproduce or replicate published results. In the end, the panel believed that independent reproduction represents the ultimate and most credible measure of scientific veracity.

SHARING DATA, METHODS, AND REAGENTS

The panel indicated that authors of published work have a traditional obligation to aid scientists interested in independent replication. This obligation includes the duty to assist in providing raw data, if requested, and access to the methods and reagents necessary for reproduction. The panel further noted that this obligation is usually an unstated assumption in academic research and that there may be a need to develop written policies to clarify and strengthen traditional practices. The panel observed that whether or not written guidelines were developed, certain practices needed to be addressed to improve the fulfillment of data retention and sharing duties.

Raw Data

In certain cases, questions from peers may arise that can only be adequately addressed by examining the raw data that underlie a published report. These data should be written in a form that is subject to independent reexamination, readily interpretable by qualified practitioners in the field. Moreover, the data need to be preserved for reexamination for a period of time after publication. Several panel members suggested that five years seemed to be an appropriate period for data retention.

Equally important is the implied readiness to supply these data to a qualified peer. The panel indicated that customary practice attaches two conditions to this access:

— The party requesting access to raw data should have a well-articulated justification for reexamination of the raw data and a history of experience in the scientific speciality in question or in the

examination of closely related problems in the field. This experience ensures qualification to interpret critically the data requested.

— The data requested should directly underlie a scientific conclusion that has been questioned. Requests for data not associated with published reports are seen as improper and may intrude on the rights of an investigator to maintain individual control of preliminary results. Moreover, requests for raw data not directly related to the narrow issue in question are seen as inappropriate. The panel recognized the need for safeguards to prevent requests for wide-ranging, blanket surveys of data records stored in a laboratory's archives. These surveys are seen as an unreasonable imposition on an investigator's time and resources and represent unjustifiable and arbitrary intrusions into the workings of a scientist's activities.

Access to Methods and Reagents

Publication of methods in a fashion enabling independent replication is a well-established procedure and requires little elaboration. A more difficult problem is the customs that govern access to reagents necessary for reproduction of the work. In most instances these are readily available commercially or through wide distribution among laboratories; in some instances they are not. The panel suggested that investigators have a responsibility to share with qualified peers attempting reproduction of published work the reagents that are essential to the independent reproduction of the work when these reagents are not generally available. It is believed that many biomedical research journals, such as Cell, have formal guidelines requiring this practice as a condition of publication.

Panel members identified several considerations that may govern the sharing of reagents.

— The reagents should be made available within a reasonably short time after publication, such as several months.
— The reagents may be distributed to academic researchers for their own use, but investigators should not be expected to share them with industrial concerns.
— The amount requested should be minimally essential for reproduction of published results.
— The request should not impose an unreasonable supply burden on the original laboratory.
— Certain requests for distribution may be unreasonable. These would include reagents available only in small amounts, such as unique antiserum or animal strains bred in small number, or otherwise unique and not susceptible to distribution. Certain animal populations, as well as human clinical study populations, for example, cannot be expected to be shared.

Training and Supervisory Practices

The panel participants discussed training and supervisory practices and noted that many principal investigators my be inadequately trained to manage a research group. This was thought to be more common in the case of investigators who receive research training in a medical school rather than a graduate school program.

There was also significant discussion about the effect of size of research groups on the quality of academic research. Recognizing that individual investigators are competent to direct the activities of a limited number of people, the panel hesitated to suggest an effective limit because of the wide variance of managerial competence among investigators. The panel noted with concern, however, that when an investigator heads a group that exceeds his or her competence, these circumstances heighten the possibility for inadequate control, sloppy research, and fraud.

The panel suggested that each laboratory employing trainees and students have a set of generally accepted good laboratory practices defined for the members of the research staff. There was consensus that it would be important and useful for a national research organization to describe the essential elements of these practices in a document that could be provided to all investigators and trainees involved in discovery research.

INSTITUTIONAL OVERSIGHT

The panel observed that various institutions place significant pressures on invesigators which, if carried to the extreme, threaten the responsible conduct of research. These pressures include the perception that administrative officers value numbers of publications and the accumulation of research dollars from external funding agencies as the most important indicators of research quality.

The panel also noted that sponsoring institutions and universities have a right to expect mechanisms to be in place to ensure and improve the reproducibility of published work. In particular, panel members suggested that the institution needs to recognize the crucial role and influence of the laboratory director. Academic officers need to provide guidance to their lab chiefs about the problems of overcommitment, distraction by other activities, and how to resolve individual variations in the quantitative aspects of laboratory direction.

Finally, the panel stated that universities, medical shools, hospitals, and other research centers have a fundamental responsibility for the research environment of their faculty and staff. There was general agreement that the officers of these institutions need to assure themselves and others, when questioned, that the environment for their research faculty, staff, and students is intellectually, structurally, and administratively supportive of the conduct of good science.

Chair: Robert Weinberg Rapporteur: R. William Butcher

PANEL 2 REPORT OF THE PANEL ON CLINICAL RESEARCH PRACTICES AND STANDARDS

The panel examined issues regarding research practice and training, with specific relevance to clinical research. Three main topics emerged during its discussions: the diverse nature of clinical research, the adequacy of training, and the efficacy of existing monitoring mechanisms.

The panel included research directors and scientists from academic, industrial, and government research centers; the chairman of medicine and faculty members from major medical schools; the director and staff members from professional associations representing academic health centers and clinical investigators; and the editor of a journal on institutional review boards. In addition to medical specialties, the participants included two sociologists and a biostatistician.

THE DIVERSE NATURE OF CLINICAL RESEARCH

The panel examined the diverse nature of clinical research, which may include both physicians conducting original research and those conducting therapeutic drug trials. The former group represents the focus of the discussion; the latter often have technical rather than scientific responsibilities. The panel indicated that scientists who conduct research in a clinical setting should be guided by the same principles in research as their colleagues in the university. The research of the clinical scientist, however, may be subject to additional regulations associated with human subjects research.

Given this distinction, clinical research on human subjects is still complicated by diversity. For example, clinical trials sometimes involve multiple institutions and large numbers of subjects. These studies are quite different in scope and execution from more conventional studies within a single institution on a limited number of individuals.

Behavioral research on humans is inherently different from trials of therapeutic agents in a specialized medical unit. The principles and practice of obtaining “informed consent” are more straightforward in some experimental circumstances than in others.

In the conduct of research on humans, conflicting pressures can arise if the established experimental design entails a risk to the welfare of the patient. This prospect is minimized by the careful design of experimental protocols so that guidelines for behavior of the investigator will prevent loss of scientific objectivity. Nonetheless, despite the best experimental design, research on humans often has to strike a balance between patients' rights and welfare on the one hand and the scientific endeavor on the other.

The panel discussed a third feature of research on humans: it is often conducted in a “fishbowl,” in full view of many parties with diverse

interests. This is entirely appropriate. However, it is sometimes difficult to transmit to all interested parties, professional and lay, the nature of the research and the balance between risk and benefit.

THE ADEQUACY OF RESEARCH TRAINING

Not infrequently, those conducting research on humans are physicians trained in a postdoctoral program within a medical school. As a rule, this training is supervised by an experienced individual, often termed a "mentor," rather than a department. As a result, the nature of training for research within a specialty can vary widely. Panel members suggested that the sponsoring institution often plays only a minor role in the training of a physician-scientist.

The background of the physician-scientist before undertaking research training also bears upon the behavior of the clinical investigator. Premedical education is a highly competitive undertaking. Inevitably, the habits and attitudes acquired before entry into medical school and hospital staff overflow into the research experience. Collaborative efforts are uncommon. The combination of competitiveness and lack of opportunity for collaborative undertakings is an obstacle to the team research requirements that are often mandated by clinical investigation studies. Scientists trained in a medical school setting often do not receive the same exposure to courses in statistics and research techniques as their colleagues trained in a graduate school curriculum.

The panel members suggested that the role of the mentor is central to responsible research training for human research, as may also be the case in other fields of basic research. In recent years, mentors have become increaingly remote from junior personnel, depriving emerging investigators of necessary moral and professional as well as scientific guidance. Responsibilities for training have become diffused, while the number of fellows has increased. As a result, communications between the scientific head of the laboratory and those in the initial phases of training have become increasingly casual and sporadic.

The physician-scientist also operates under different conditions than the basic scientist. The physician-scientist is often required to commit extensive time to activities that are peripheral to research. For example, patient care is a demanding pursuit that can disrupt research schedules. Committee assignments and administrative responsibilities in the clinical departments are time consuming. These distractions from research generate stresses and may impede proper professional development in research. Rarely is the developing independent investigator protected from the pressure to achieve independent funding and to participate in teaching and administration during the formative period of a physician-scientist.

Some panel members observed that the absence of a written set of research guidelines exacerbates the dependence of the young physician-scientist. Consequently, much of the professional training of the

clinical scientist is influnced by the manner in which the research environment to which the trainee is exposed interprets standards and handling and sharing of research data; the exchange of experimental results; and the general sense of how science is properly conducted.

The panel believed that, as a rule, there is little explicit attention to the ethics of good scientific research on humans or to the responsibility of the individual scientist to the scientific community at large.

MONITORING

Clinical research is often more intensely monitored than other types of research. Institutional review boards are central to the review process. Moreover, collaborative trials generally have built-in review mechanisms.

In research universities, institutional review boards are quite busy when working at full capacity. The panel believed that, in considering strategies for improving research monitoring, new oversight responsibilities should not be imposed on these boards.

The panel suggested that effective in developing proper research attitudes and practices are the mechanisms used to train young scientists. Of particular concern is the training of the physician-scientist as a responsible independent investigator. Panel members expressed concern about the lack of attention by the teaching institutions to mentors and their research conduct. This deficiency affects both the training of physician-scientists and also influences their subsequent behavior as independent investigators.

Chair: Alfred P. Fishman Rapporteur: Bernard Barber

PANEL 3 REPORT OF THE PANEL ON INSTITUTIONAL OVERSIGHT

The panel focused on the role of the university or academic research center, as an institution, in ensuring and promoting scientific responsibility. Recognizing that governmental institutions, including the National Institutes of Health and the Congress, have emphasized the role of the universities in detecting and preventing scientific misconduct, the panel sought to discern institutional practices that would support and promote good science.

The 17-member panel included government and university attorneys, academic administrators, government officials, and professional society officers. Many of the members had direct experience in handling or investigating allegations of scientific misconduct.

The panel accepted the premise that peer review at the institutional level is the cornerstone of good science. They explored whether a system of incentives and structures can be devised to enhance responsible science and to discourage the impulses and practices that contribute to scientific misconduct. In discussing actions to enhance good science, the panel sought to identify areas where initiative by university officers, rather than action at the level of the laboratory or professional association or journal, would have a comparative advantage.

The panel identified five areas where institutions could profit increased attention:

— training and mentoring;
— handling, storage and maintenance of research data;
— the meaning and responsibilities of authorship;
— definition and assessment of scientific accomplishment; and
— processes to assure full and fair review of allegations of impropriety.

A common theme for all five areas was the need for each institution to clarify and communicate its expectations for individual investigators about the environment in which scientific inquiry is to be conducted. A striking example of one institution's efforts to articulate these expectations is the set of guidelines recently adopted by the Harvard Medical School, which address many of these five areas.

TRAINING AND MENTORING

Effective training of young scientists is an essential duty for the perpetuation of good science. Training is teaching, and the primary responsibility for carrying out this duty necessarily rests with individual faculty members and research supervisors. The academic institution's role is secondary and largely supportive.

The panel agreed that an institution has the obligation to assure itself and others that its laboratories and departments function in ways that ensure adequate supervision for each student and trainee. Effective supervision requires adequate identification of mentors and assurance that roles and regulations regarding research methods and practices are conveyed to the student or trainee.

Neither institutions nor individual faculty members should assume that trainees and students are aware of relevant protocols, ground rules for data retention, and regulations applicable to human or animal subjects research or hazardous waste-handling methods. The panel identified a need to inform students and trainees of the institutional officers, in addition to the mentor, who are available to address concerns about inadequate supervision. These officers may include departmental chairs, section chiefs, and ombudspersons. The panel also suggested that guidelines for good mentoring, tailored as necessary for a particular discipline or specialty, would promote good training.

There was general agreement that each institution should ensure that its students and trainees are acquainted with the expectations of the scientific community research practices and the ethical foundations of science. Recognizing that this exposure could be accomplished through a general or discipline-based program of instruction, the panel endorsed the need to include the subject of teaching research practices as a formal part of the training process.

The experience of the panel members suggested that departmental chairs or section chiefs are the appropriate university officials responsible for good mentoring, since these individuals are aware of the quality of supervision within their units. The departmental chairs and section chiefs are responsible for assuring that each trainee knows his or her mentors, the other channels for communication, and the ground rules for scientific inquiry in their research unit.

The panel believed that an institutional reporting requirement documenting this assurance was unlikely to contribute to better science and that so-called “quality assurance forms,” in which trainees would indicate their knowledge of supervisory and training procedures, seemed unnecessarily bureaucratic.

THE HANDLING, STORAGE, AND MAINTENANCE OF DATA

The panel discussed how complex this set of issues has become. The complexity is derived in part from the various forms in which research information is now generated (e.g., computer tapes, multilaboratory settings) and the matrix of players who have rights and responsibilities for the data. The panel concluded that there was no generally shared set of norms about the respective rights of principal investigators, academic institutions, trainees, other related investigators or sponsoring agencies to inspect and use the data and even less agreement about who should be responsible for retention of the data.

Given the lack of common norms for data handling in the scientific community, the panel members generally agreed that each institution should have a policy that informs its faculty, scientists, and students of the institutional expectations concerning data retention, storage and transfer. This policy should address several issues:

- the need for retention of research data;
- the minimum number of years for which data should be retained (the policy might also suggest that a longer period of time would be desirable in most cases);
- the rights and responsibilities of the principal investigator, trainee, institution, and the funding sponsor to the data; and
- the process for reviewing the transfer of data when a principal investigator relocates to another research center.

The panel suggested that a national blue ribbon commission might study the issues affecting the use and sharing of research data. This study could lead to the development of a set of model guidelines for local institutional policies. The commission could evaluate the feasibility of greater use of data documentation services and consider the applicability of current protocols from the transfer of equipment when a principal investigator relocates to the physical movement of research data.

The panel expressed interest in a suggestion that journals could contribute to good data-handling processes by requiring that each published article indicate the length of time for which relevant data would be retained.

THE MEANING AND RESPONSIBILITY OF AUTHORSHIP

The panelists strongly agreed that academic institutions should not preempt the peer review process sponsored by the journals and research funders. There was an equal consensus that institutions not intervene in a way that stifles scientific creativity or that undermines collegiality among scientists within an institution or between scientists and the officers of the institution.

At the same time the panel recognized the need for minimum standards of institutional review and oversight to assure integrity of the research reported by members of the academic institution. The panel sought to define some appropriate middle ground for institutional supervision of faculty and research staff publications. The panel considered a suggestion that academic institutions require an expanded annual report in which each faculty member lists the publications he or she has authored and explains his or her contribution to each paper. Another suggestion was that each head of a department or research unit should be expected to have a continuous familiarity with the scholarly works submitted for publication by the members of that unit.

One member of the panel described the salutary effects of an institutional policy that requires each author to send a letter to a department chair describing his or her role in a publication. This policy also requires that one author involved in a study should confirm to the supervisory head that the reported work was completed.

The panel did not achieve consensus on general norms governing authorship, but there was agreement that each institution should develop and circulate a policy on authorship. This policy should include a statement of expectations about authorship, clarify the roles of contributors, and establish principles concerning multiple submission of research manuscripts. The policy could establish guidelines for the institution as a whole or require that they be developed by separate departmental or research units.

The panel recognized the important role of professional journals in addressing the difficult issues of authorship. The panel suggested that journals require authors to explain their contributions to the paper and to confirm that each author has reviewed the entire paper and has approved the description of his or her contribution.

SCIENTIFIC ACCOMPLISHMENT AND THE INSTITUTIONAL REWARD SYSTEM

The panel discussed at length the institutional reward system for advancing good science. The members affirmed that academic advancement should be based on the entire record of scientific accomplishment rather than numbers of published articles. The panel explored how to encourage quality contributions to science and how to diminish the perception by some that accomplishment is measured primarily in terms of quantity of publications. Members of the panel cited with approval efforts by the National Institutes of Health to limit a grant applicant's bibliography to two pages. Although the panel expressed concern that an emphasis on the number of publications could detract from other measures of quality, there was also concern that a large number of publications should not be suspected of other than quality research.

There was much discussion of the new guidelines adopted by the Harvard Medical School and their effect on appointment and promotion decisions. Several panel members expressed interest in monitoring those procedures to see if they discourage practices that lead to miniaturizing research or otherwise improve the environment for conducting and publishing research. The panel commended Harvard for adopting these initiatives but agreed that other strategies may be equally or more useful for other institutions. For example, tenure decisions may come too soon and place undue pressure on young scientists. It was suggested that some institutions may wish to adopt a longer probationary period for junior faculty; it was noted that the American Association of University Professors has accepted probationary periods longer than seven years.

The panel suggested that many different institutions in the research reward system--universities, granting agencies, journals, and professional

associations--should consider further incentives for promoting a standard based on research quality rather than simple quantity. Professional associations may promote this standard by evaluating their current guidelines for awarding honorific membership.

PROCEDURAL REVIEW OF ALLEGED IMPROPRIETIES

The panel members were aware that new federal regulations establishing guidelines for the handling of cases of scientific fraud and misconduct were under consideration by the government. (Note: These regulations were published in the Federal Register on September 19, following the conclusion of the workshop.)

The panel primarily focused on efforts that might prevent scientific misconduct, but the members also discussed the need for institutional procedures to address issues of scientific impropriety when they arise. The panel agreed that ad hoc institutional responses to complaints of misconduct were inadequate and that a full and fair review process would improve the integrity of the institution and of science in general.

The panel proposed that each institution develop a written misconduct policy that informs its community of the procedures for handling allegations of scientific impropriety. This policy should address the following issues:

- definition of improprieties that warrant investigation;
- procedural protections for all parties;
- description of the reviewing authority, right to appeal, and review process; and
- process of notification and disclosure of institutional investigations and the timing of these communications.

The panel suggested that institutions regularly review the adequacies of their procedures in this area and revise them as necessary.

Chair: Howard E. Morgan Rapporteur: Linda K. Lorimer

PANEL 4 REPORT OF THE PANEL ON EDUCATION AND TRAINING FOR RESEARCH

The panel examined issues pertaining to the education and training of young scientists and explored areas that may need improvement in the curriculum; the effect of role models and mentoring relationships in research education; and the role of professional societies in promoting the responsible conduct of research.

Panel members included faculty members representing specialities in medicine, chemistry, microbiology, ethics, and sociology; professional society and Academy staff officers; and a representative from a research funding institute. Two of the members were postdoctoral fellows who had just recently completed doctoral training in biomedical research.

The panel addressed several key questions:

- Should ethics courses be made part of the formal training of young scientists?
- Is there a need for guidelines for those persons responsible for supervising student research efforts?
- Would students and research trainees benefit from a statement clarifying their responsibilities and institutional expectations of their performance?
- What steps should be taken to improve the manner in which research misconduct is detected and corrected?
- What is the role of professional societies in developing educational and training activities in this area?
- What research analysis would improve understanding of the educational and training components of science?

The initial premise of the panel was that the ethical conduct of science requires an understanding of the ends of science, which was defined as the acquisition of knowledge. This activity requires certain moral responsibilities, including accuracy, honesty, and the acquisition of significant knowledge. The panel identified a set of problems that impede the exercise of these responsibilities and suggested several methods to address them, as outlined in the following discussion. The issues are listed here in the priority order assigned by the panel members.

THE NEED FOR EXPOSURE TO THE ETHICS OF SCIENCE

The panel members believed that formal exposure of students to the ethical conduct of science should be required as part of the professional

training of young scientists. This exposure should include instruction in good research practices. Research laboratories might be encouraged to develop research guidelines clarifying practices affecting data collection, notebook keeping, safety, etc. More general guidelines could be developed for selected disciplines that are affected by regulatory standards governing professional practice with respect to animal care, human subjects research, and the handling of toxic or hazardous materials.

GUIDELINES FOR TRAINEES AND MENTORS

The panel proposed that those persons responsible for conducting research training (mentors) as well as students and trainees would benefit from the development of guidelines that clarify institutional expectations of their performance and their professional responsibilities. Several key principles were discussed that might serve as the basis for the development of model guidelines in this area.

The Responsibilities of Mentors

- Those responsible for research training should create an atmosphere of openness in their group. Competition between trainees should be discouraged because it often results in secrecy and isolation in the group. Students and trainees should participate as colleagues in frequent review of data by the research group. The mentor should be easily accessible to the trainees and should introduce students to the cultural and substantive aspects of their discipline.
- A successful mentor will openly deal with data that may contradict a current hypothesis being pursued in the laboratory. Rather than discarding the data, the mentor should seriously examine them as representing possible flaws in the hypothesis under study. Research mistakes should be considered in a similar analytic manner.
- Error or misdirection can result from trainees or students being given too little supervision in the early stages of a research career. A conscientious mentor will limit the initial freedom of a student or trainee in designing experiments, gradually increasing the student's autonomy as the trainee demonstrates competence. Begining research students will require greater supervision than those more advanced.
- A conscientious mentor will accept full responsibility for all published work resulting from research conducted under the mentor's supervision. Faulty data in research publications cannot be excused as errors made by a poorly trained student or technician.
- If a mentor does not have time to review daily progress of the group's research because of other duties, the mentor should disassociate from either research supervision or the conflicting duties. The mentor should be an active, participating scientist in the research project, not simply someone who has obtained funding for the research.

— The size of a research group must be kept within the limits of a mentor's ability to supervise it. While not recommending limits on the number of trainees that may be assigned to a single mentor, the panel indicated that the university has a responsibility to ensure that the size of a research unit does not outstrip the mentor's ability to maintain adequate supervision.
— If the institution has not adopted a policy governing authorship practices, it is the responsibility of the research mentor to prepare guidelines promoting responsible and equitable publishing practices within the research group.

Expectations and Responsibilities of Students and Trainees

— Students/trainees have a right to expect professional supervision and training from the mentor and to expect that they are not merely assistants to the mentor. Students/trainees should recognize the many responsibilities of their mentors and should not make unreasonable demands of them.
— Students/trainees have a right to expect to be considered junior colleagues of their mentors. They can advance from this junior status by their learning and demonstrated competence.
— Students/trainees have a right to receive professional scrutiny and review of their work from their mentors, similar to the peer review provided senior faculty by journal editors and referees. Written reports should be timely and treated fairly and promptly. Substandard work may be rejected but students/trainees should be given a reasonable opportunity to improve it.
— Students/trainees have the right to know the publication policies and practices of their research unit, including the criteria for authorship and the publication standards of their mentor. This right includes the right of students/trainees to have their work considered for publication in a timely and proper manner.
— Students/trainees deserve an opportunity to discuss research findings and data in an open and candid manner. Their frequent participation in laboratory meetings will contribute to the esprit de corps of the laboratory.
— Students/trainees should have appropriate and consistent access to research data and materials developed through their research efforts.

A RESEARCH AGENDA FOR INSTRUCTION IN THE ETHICS AND STANDARDS OF RESEARCH

The panel indicated that a research agenda should be formulated to improve the education and training of young scientists. In particular,

more understanding of the role and place of ethics and professional practice in scientific instruction needs to be acquired. Items that should be considered in fostering this research effort include:

- the nature of supervision in group settings;
- the effect of the structure of the research group and peer influences on the training experience;
- factors influencing satisfaction of students/trainees with their research experience;
- areas of convergence or divergence in comparing the expectations and attitudes of students/trainees and their research mentors;
- patterns of conflict resolution in the educational environment; and
- the emergence of ethical concerns among students/trainees and their supervisors and the characterization and frequency of these concerns.

DETECTING AND REPORTING ERRORS AND MISCONDUCT

The panel recognized that errors, misconduct, and other problems of professional practice are often first detected by students or trainees in the research unit. They suggested that academic administrators have a responsibility to ensure that young scientists are aware of the proper mechanisms to use in reporting practices that appear to be irregular or substandard. These mechanisms might include the traditional processes of collegial review of research data, the right of a student/trainee to change supervisors, and the availability of an ombudsperson or other institutional representative to review in a confidential manner the concerns expressed by students and trainees.

THE ROLE OF PROFESSIONAL SOCIETIES

Panel members indicated that professional societies have an important role in the development of educational and training materials fostering the responsible conduct of research. Several examples of ways in which the societies might exercise this role include:

- collaborative efforts with academic institutions in the development of guidelines and curricular materials on research ethics;
- education and training efforts for the society members on the responsible conduct of research; and
- incentives that acknowledge exemplary behavior, such as recognition of outstanding role models in the society meetings and publications.

Chair: Carl Djerassi Rapporteur: Jules Hallum

PANEL 5 REPORT OF THE PANEL ON ACADEMIC AND CAREER ADVANCEMENT

The panel considered aspects of the academic environment that promote or detract from good quality and responsible research practices. The members focused their attention on incentives that are inherent in academic personnel practices and customs and the interactions of the individual with the institution.

Members of the panel possessed a wide range of experience. They included an administrative leader of two large university medical centers; three medical school associate deans for faculty affairs; three academic internists, one of whom edits a major journal; a sociologist of science; senior officers of two national academic organizations and the Academy; government agency counsel; and laboratory administrators. The group brought academic, legal, and government backgrounds to the discussion. Several panel members had ongoing experience in dealing with issues of research misconduct in their own institutions.

The panel concluded that institutions have important responsibilities that cannot be left to individual investigators, shunted to journal editors or the professional societies, or allowed to pass to government and research funders by default. Institutions do not need to develop new codes of behavior, but they need to demonstrate more active interest in assuring faithfulness to the ethics and ideals that already form the foundation of the ethos of science in the academic sector.

The panel indicated that institutional responsibility may be broadly divided into two categories. First, the university must be able to assure others--whether journals, research funders, or the government--that academic research work is properly supervised by responsible individuals. This responsibility includes an obligation to provide assurances that the research reported by members of the institution to the outside world, including the manuscripts and abstracts submitted for publication as well as oral presentations at professional meetings, reasonably represent both the work itself and the contributions of those designated as authors. The university traditionally delegates this responsibility to its constituent faculty and investigators, with oversight provided by department chairs and laboratory chiefs. When individual research findings or authorship are questioned, there is usually a formal or informal mechanism in place by which the institution can verify the integrity (or lack of it) of the questioned work.

Second, the institution has a responsibility to promote an atmosphere that encourages the performance of good quality work, with adequate supervision of young investigators and opportunities for their interaction and socialization into the moral principles as well as the methods of science, Similarly, there should be a mechanism for the institution to assure itself and others that this atmosphere exists and that the interactions among senior and junior faculty and trainees promote the responsible conduct of research.

Who or what is this institution? Individual and collective faculty and administrative officers comprise the university. The collective faculty, overseeing the individual faculty member, is the core of a modern academic institution. The collective faculty holds the primary responsibility for the integrity and quality of the institution, although the degree of care with which they exercise this responsibility is often influenced by the administration. The administration communicates with the outside world and sends internal messages as well, supervises the expenditure of grants and contracts, and prods the faculty to provide the oversight and verification duties described above.

In exploring the often-discussed issues of academic advancement and the reward structure of science, the panel identified some unexpected problems on first taking up the initial step of an academic career: appointment. The panel considered whether individuals were adequately reviewed with regard to their ethical as well as their scientific qualifications.

APPOINTMENT

Personality defects of varying seriousness usually play a significant and perhaps dominant role in cases of scientific misconduct. However, it is difficult to screen for deviant personalities at the stage of faculty or staff appointments because the interview process is unreliable and is usually not aimed toward this particular goal. The communication of relevant information from previous employers and associates is restricted by federal state and privacy laws. Frank and candid answers may often be obtained only by asking specific questions directed toward the detection of improper behavior, and it is rare that this behavior would be suspected at the time of recruitment. The panel suggested that a formal waiver of privacy by academic applicants could help overcome the legal barriers to sharing information about prior forms of misconduct. They proposed that this waiver could be modeled on the statement used as a standard for obtaining clinical privileges to avoid deleterious efforts.

The panel also suggested that it would be useful have models for responsible reference letters, highlighting the questions that should be routinely asked in the course of recruitment and evaluation of applicants. They proposed that state privacy laws could be surveyed to determine the legal standards governing communication of misconduct or deviant behavior. Panel members suggested that there may be a need for legal protection for institutions who wish to request or report confidential information relevant to academic performance in cases involving scientific misconduct or when resignation has occurred during the course of an investigation. Several panel members questioned the legality as well as the desirability of incorporating gag orders into private agreements or settlements between academic institutions and faculty or research staff members accused of misconduct.

ADVANCEMENT

Panel members observed that many people perceive an overemphasis on publication as a source of advancement both by institutions and research funders. This “publish or perish” perception has been suggested as a source of excessive pressure on faculty and the cause of major and minor abuses of research standards.

Better authorship practices might encourage the faculty to take more individual and collective responsibility for the integrity of published material. These practices could be achieved by steps designed to reduce gift co-authorship and the fragmentation of data. However, the panel was not certain that reducing the number of publications by each author will significantly relieve the “publish or perish” pressure. A more important consideration, in seeking to reduce the reality of this pressure as well as the perception of its importance by the faculty and young scientists, may be the need for institutions to structure their performance evaluations to reflect the value of quality over quantity.

The criteria for advancement outlined in recent guidelines issued by the Harvard Medical School were considered by the panel, particulary the criteria in the guidelines that limit the number of publications used to support a promotion decision. The panel thought that these criteria the papers to be considered? Should the candidate justify the value of the selected papers? Should the entire bibliography be available to the selection committee, automatically or on request? What are effective methods of distinguishing competent individuals of differing productivity?

The panel suggested that the faculty of a selected institution should develop the criteria that affect their appointment and advancement decisions. If different institutions adopt significantly different guidelines, a broader consensus will need to be achieved to change the existing criteria used by funding agencies to predict productivity and quality.

The issue of size of bibliography stimulated debate within the panel, partly because of a paucity of information about the significance of either unusually long or short bibliographies of research scientists. The identification of correlative factors and other assessments of creativity were thought to be desirable, and the panel suggested that this area be designated for further study.

The panel also considered problems in obtaining genuinely critical peer reviews of performance or even quality of publications by colleagues or referees. Some obvious reasons for these difficulties include the time-consuming and analytical nature of careful reviews and the lack of incentive to devote significant time to this area. Many faculty do not wish to risk faulty judgment that may hurt someone else's chances, and they are less likely to write negative than positive comments when there

is uncertainty. Collegial relationships are essential to the smooth functioning of the academic unit and these may be threatened by too frank criticism. In small specialities or groups, there may be too few individuals willing to provide the necessary reviews. Faculty engaged in clinical work and teaching may have limited evidence of creative scholarship and may receive harsh criticism at the time of academic advancement reviews by peers who are often tenured faculty, primarily engaged in research.

The panel suggested that the area of group pressures and psychosocial limitations on peer review needed further study. Research in this area could lead to significant improvements in the quality of journal or personal referee systems. There is also a need to define and popularize alternatives to counting papers in evaluating faculty performance.

Many young faculty develop unrealistic expectations based on lack of knowledge of and experience with actual performance evaluations. The panel members thought this was a problem of uncertain dimensions, but it may reflect an underlying disorder and it can be aggravated by the competitive, overproductive atmosphere of some disciplines. Many young faculty are uncomfortable about their perceptions of what is expected of them, although even accurate perceptions may not diminish pressures to cut corners in order to advance quickly. The panel suggested that closer supervision and mentoring of junior faculty would help them to understand professional standards and would provide an early opportunity to detect aberrant ideas or behavior.

The panel also considered the special problems of M.D. rather than Ph.D. investigators. These often include little or no formal research training before faculty appointment and inadquate research time following appointment. The panel believed these problems promote sloppy or inaccurate reearch, bad authorship practices, and even misconduct. One approach that may alleviate these problems is extending the probationary period, with subsidized research experience, for M.D. investigators. Another may be stricter requirements for appointment of medical school graduates to research investigator positions. Neither approach may be realistic in many specialities. A more feasible approach may be the promotion of support for part-time clinical investigators by experienced researchers through special grant mechanisms.

The periodic peer review of Ph.D. programs in many graduate schools (often through the use of “visiting committees”) is a common mechanism for assuring the quality of graduate school training and research programs. A common feature of this review is the use of outside expert scholars to evaluate the strengths and weaknesses of an individual graduate program. It is not certain whether these reviews also examine the experience of postdoctoral fellows or the mentoring of junior faculty. The panel observed that research and training programs conducted in the medical schools usually do not receive comparable external peer reviews. They suggested that a study of the methods used to evaluate academic research and training practices, and their applicability to the medical school environment, deserved consideration.

ASSURANCES

The panel spent substantial time discussing the need for mechanisms to demonstrate the performance and integrity of academic research. The panel did not support the need for broader institutional involvement in providing assurances about research performance and authorship contributions. They did perceive a need for more extensive counseling and mediation services within academic institutions, with easy and confidential access to designated institutional officers.

The panel considered one suggestion that an individual outside of a research group be designated to sign off on manuscripts but concluded that this approach was excessively intrusive and overly bureaucratic for the academic environment. A similar institutional sign-off mechanism was explored in the context of confirming attribution of authorship. The consensus of the panel was that this confirmation should be made by the research group itself, not a supervisor or administrator.

The panel considered with favor a proposal that each co-author should sign a statement confirming approval of a final manuscript and concurring in the designation of authors as part of the submission of the manuscript to scientific journals. The value of an additional confirmation statement by a university official seemed superfluous.

These proposals are directly aimed at remedying the problem of co-authors failing to take collective responsibility for the integrity and quality of a research project or publication. Panel members observed that some faculty seeking to build their bibliographies would not be inhibited by these procedures. Faculty willing to put their name on anything may also be willing to sign anything. In the final analysis, the criteria proposed by many organizations and journals for entitlement to authorship are no more useful than the scrupulousness of those who use the criteria. Some persons who have not taken any responsible action may claim to have performed several functions, including the planning and the writing or revision of a paper, without objections by co-authors.

Panel members expressed concern that co-authors who are not satisfied with the assignment of credit have limited resources to assist them in settling disputes. Department chairs should assist in mediating these conflicts in theory, but in an era of mega-departments and multicenter collaboration, they may not be able to play an effective role. Junior co-authors may be unwilling to approach senior faculty to avoid being characterized as troublemakers. The panel perceived a need for improved consultation and mediation services within the academic institution and expressed particular interest in the ombudsperson positions used by several universities and medical schools (including MIT and Stanford). In many cases, the ombudsperson provides a confidential advisory service and has the resources to assemble a panel of experts to mediate disputes on an ad hoc basic.

The panel suggested that authorship guidelines may be helpful in resolving disputes by clarifying in advance of the submission of a manuscript the criteria to be observed in recognizing individual contributions. Professional societies and journals play an important role in defining these criteria, since authorship is often influenced more by disciplinary customs than institutional traditions.

AREAS FOR FURTHER STUDY

The panel emphasized the increasingly important influence of commercial or industrial ties by university research laboratories and academic scientists. There has been concern about the effects of these affiliations on graduate education and the open exchange of ideas and research materials, but there has been less discussion of their impact on research quality.

Though research fraud cases have been extensively discussed, there is still much to learn about patterns of misconduct, their precipitating factors, and ultimate outcomes of the corrective process. Some studies of deviance have indicated that these incidents have a significant impact on the "victims" or colleagues of the perpetrator. The panel thought it would be useful to study research centers where fraud has occurred to explore how this incident has affected the structures, practices, and relationships of the research environment. For example, what happens to the whistle-blowers and to those guilty of misconduct? The panel identified a need for a comprehensive review and follow-up on recently documented cases.

The panel also reviewed the subject of data ownership, custody, and access. Panel members recognized this as a complex area and expressed a lack of knowledge about the status of intellectual property law and government regulations and their impact on research data-handling practices. The panel suggested that this important area deserved careful analysis, separate from the study of other research practices, and that this analysis should precede the development of institutional guidelines and standards.

Finally, the panel considered the importance of collaborative efforts in modern research. Multiple authorship practices suggest that collaborative efforts have been increasing for years. The problems discussed above take on a new complexity when considered in the context of interdepartmental or multicenter research efforts. There may be unique problems in assigning credit when first authorship must be limited, although these problems may be alleviated when multiple papers are produced. Data access and storage issues acquire greater significance when the research data result from a unique, time-consuming, and valuable collaborative effort. Institutional assurances of validity and integrity require new forms of interinstitutional cooperation. The panel suggested that the particular influences of interdisciplinary and multicenter collaboration deserve priority in further investigations of this topic.

Chair: William Anlyan Rapporteur: Paul Friedman

PANEL 6 REPORT OF THE PANEL ON AUTHORSHIP, REFEREE, AND PUBLICATION STANDARDS

The panel addressed current authorship practices, publication procedures in institutions and journals, and post-publication procedures that may affect the integrity and reliability of published results, with particular attention to medical science and clinical research in the United States.

The 14 panel members included editors from basic science and clinical journals (including one British journal), faculty from basic research departments, and government agency officials (including the National Library of Medicine).

The panel discussed an array of topics concerning authorship and publication standards. These topics included repetitive publication, supernumerary authorship, institutional responsibilities, peer review, documentation of reported research results, errors and corrections, frequency of fraud and other misconduct, the role of government, and pressures to publish.

REPETITIVE PUBLICATION

The panel members recognized that publication of more than one report of the same research material (repetitive publication) may be advantageous to authors for their personal interests and to readers who use the journal literature for "awareness needs." Members indicated that these interests needed to be weighed against the economic costs and intellectual confusions caused by this practice.

The panel attempted to define repetitive publication. This practice includes identical republication; rereporting observations in one or more additional papers with different emphasis and detail; and reporting a small portion of data from a single study, often referred to as "salami science" or the "least publishable unit." Authors may justify the practice of repetitive publication to address different audiences or to meet requirements for participation in a symposium or congress. Editors view repetitive publication as causing excessive costs in manuscript handling, peer reviewing, and journal space and distribution. Readers may have difficulty deciding on the uniqueness of the content of a particular paper.

The panel considered several possible solutions to this practice, including the need for editors to define repetitive publication explicitly, to state penalties for violations, to find means of informing readers of occurrences, and to consider other possible means of prevention such as maintenance of a "blacklist" for a journal's own use.

SUPERNUMERARY AUTHORSHIP

Are new criteria for authorship needed? Panel members indicated that the criteria adopted by some journals may not be wellknown to the community of authors. Should a category “contributing author” be established and added to present definitions of true authorship? Should readers assume that all listed authors can take responsibility for a paper?

The panel agreed that proper authorship practices protect the scientific community against misconduct in research and its reporting. The trend of an increasing number of authors per paper may be explained by the increasingly complex nature of research, but there is also evidence of not infrequent gratuitous or “gift” authorship.

Authorship assignments tend to be based on traditional practices. Professional societies, editors' associations, and a few institutions have published detailed criteria for authorship, but panel members believed these criteria are often violated. It is difficult for the editors to obtain proof of violation of authorship guidelines. They could ask for more detailed and explicit justifications of authorship, but these requests would not necessarily be more reliable than present authorship statements or copyright agreements.

The panel indicated that editors would prefer to trust authorship assignments. The members believed that the proper locus of authorship control is institutions. They proposed alternate means for institutions to screen papers prior to their submission so that authorship criteria could be properly applied. The panel indicated that existing authorship criteria should be disseminated more widely. There may also be a need for new collective efforts to develop a national standard of authorship criteria for academic institutions. New categories of authorship, such as a secondary level like “contributing author,” or wider use of collective or corporate authorship may be needed, and a few individual editors have established criteria for these categories.

INSTITUTIONAL RESPONSIBILITIES

Should universities screen papers prior to their submission for publication? Should this screening seek to prevent repetitive publication? What disadvantages might result from institutional screening?

Panel members indicated that a few academic departments and research units do screen manuscripts of their faculty and staff. They suggested that institutional screening could reduce undesirable publication practices. The members recognized that screening could add a new administrative burden in academic departments and might pose risks of censorship. Although screening manuscripts may not be the best solution, the editors on the panel thought that academic institutions need to establish some means of controlling irresponsible publication practices.

PEER REVIEW

The panel also examined aspects of the peer review process including: Can peer review detect fraud? How might adequate peer review be facilitated? How desirable is anonymity of reviewers and/or authors in peer review?

The panel concluded that research fraud is unlikely to be detected by peer review. Data that are "too good," logically impossible, or from unspecified locations can be clues to fraud in a particular paper, but well-constructed fraud may readily escape detection. Large numbers of papers attributed to a particular author could be a signal to an institution of possible fraud, if it maintains manuscript records.

Peer review is expensive. It might be improved if journals conduct more vigorous screening and reject submitted papers immediately. The process might also be improved by providing reviewers with more explicit criteria for making critical judgments. At present, the panel concluded that the advantages of using anonymity for reviewers outweighs the disadvantages. It is more difficult to ensure the anonymity of authors, and the editors believe they can easily detect the biases often attributed to author non-anonymity. The panel indicated that there is a need for more research on the peer review process to develop firmer answers to these questions.

DOCUMENTATION OF REPORTED RESEARCH RESULTS

The panel examined the question of whether authors should be expected to supply data to editors and peer reviewers beyond those presented in the paper itself. A paper should carry all the data needed to support its analyses and conclusions. Authors should be expected, however, to submit additional data for an editor or peer reviewer if needed for critical judgments. The panel believed that routine requirements for submission of supplementary data with papers would put unnecessary administrative burdens on the journal editors.

RESPONSES TO FRAUD, RETRACTIONS, AND CORRECTIONS

How should editors respond to charges or suspicions of fraud? How should journals publish retractions or other statements concerning fraud? How should they handle errors and corrections?

Some differences of opinion emerged in the panel regarding the appropriate procedures for editors in addressing the first issue. Most panel members believed that editors have a limited ability to resolve questions of fraud and that allegations of wrongdoing are more properly addressed at the institutional level. Others suggested that editors should respond to these incidents by initially approaching the authors and then approaching their institutions to investigate the claims if the initial approaches have failed. A differing view is that the problem should be taken to the institution immediately.

The panel noted that The International Committee of Medical Journal Editors has issued a policy statement on editors' responsibilities for responding to charges of scientific misconduct, which requires the appropriate publication of relevant notices. The National Library of Medicine has developed a system for tagging references in MEDLINE to alert bibliographic searchers to notices of fraud or scientific error. With this system in place, the panel believed that editors have a responsibility to publish notices of retraction, investigatory conclusions of fraud, and errors and corrections. This responsibility includes a duty to publish these notices in a standard format and location. The panel agreed that there is a need to publicize, this responsibility to editors and editors' associations.

FREQUENCY OF FRAUD AND OTHER MISCONDUCT

How frequent are fraud and other kinds of substantial misconduct? How does this question affect editorial and institutional responses to scientific misconduct?

The panel had no evidence of an increase in the frequency of fraud and other kinds of misconduct in publication, but members indicated an impression that there is an increase in the number of incidents. This perception may simply be the result of wider awareness of the problem. Two members of the panel favored the use of research audits as a means of determining the extent of the misconduct in science. Other members felt that the lack of evidence of incidence should not preclude the development of measures to control or reduce the problem. While serious research misconduct must be controlled, most panel members felt that other publication abuses, such as irresponsible authorship and repetitive publication, are probably far more frequent and present a greater threat to the efficiency of research and the integrity of the publication process.

THE ROLE OF GOVERNMENT

What should be the role of government in supporting the responsible conduct of research? Should federal agencies require institutional controls as part of grant-supported or contract research? Should government exert more direct controls, such as audits?

The panel members believed that government's interest in reliable authorship stems from a need to verify reported research results, especially when the products of research have economic and regulatory importance (e.g., patents and copyrights). In addition, government agencies are publicly accountable for proper use of tax funds, and maintaining the integrity of authorship is one avenue of demonstrating accountability. Misconduct in research can suggest evidence of governmental mismanagement of public funds.

The panel suggested that government can provide incentives and apply pressure for the responsible conduct of research. At a minimum, government research funders need assurances that the research is conducted

in a responsible manner. These assurances could come from institutional and journal processes related to authorship and publication practices.

PRESSURES TO PUBLISH

The panel discussed the various pressures to publish and ways to reduce these pressures. The economic rewards from publication are seen as driving both supernumerary authorship and repetitive publication. These rewards include not only direct monetary gains but also the professional prestige derived from appointment, promotion, and tenure decisions. One attractive control on pressures to publish might be the creation of institutional limits on the number and frequency of publications to be considered for decisions on faculty status.

One panel member questioned whether these controls would reduce unjustified authorship, as there are substantial personal gains other than academic status associated with the high visibility resulting from frequent and widespread publication. Some control might come from editors limiting the numbers of authors and more frequently requiring collective authorship, but these controls may require wide adoption to be effective.

As noted above, the panel came to general agreement on a number of steps that academic institutions, individuals, and government might take to reduce the severity, number, and frequency of abuses of scientific publication. These actions could demonstrate the research community's commitment to assuring the integrity of scientific research. The panel's proposals were formulated with the following criteria in mind:

- In order to remain highly productive, the research community must take responsibility for the conduct of its work and its relations with the public and government.
- Appropriate conduct in research should be developed and supported as far as possible by the institutions of science itself.
- Recommendation should identify measures that avoid excessive control, address present concerns, and not expect a utopian state of science.
- Recommendations should not suggest measures likely to increase the burdens of documentation.
- Clear distinctions should be drawn between misrepresentation, such as fraud and data-trimming, and errors of fact and interpretation.

Chair: Marcia E. Angell Rapporteur: Edward Huth