Integrity and misconduct in research : report of the Commission on Research Integrity to the Secretary of Health and Human Services, the House Committee on Commerce, the Senate Committee on Labor and Human Resources.

Integrity and Misconduct in Research

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To the Secretary of Health and Human Services
The House Committee on Commerce
The Senate Committee on Labor and Human Resources

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

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To the Secretary of Health and Human Services
The House Committee on Commerce
The Senate Committee on Labor and Human Resources

1995

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Commission on Research Integrity

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Letters of Transmittal

On November 3, 1995, Dr. Kenneth J. Ryan, Chair of the Commission on Research Integrity, sent the following message to the Secretary of Health and Human Services and to the Chairs of the House Committee on Commerce and the Senate Committee on Labor and Human Resources:

> On behalf of the Commission on Research Integrity, I am pleased to transmit our final report and recommendations: *Integrity and Misconduct in Research*. The Commission's mandate was established in Section 162 of Public Law 103-43, the NIH Revitalization Act of 1993, in reaction to continuing misconduct in research and retaliation against whistleblowers in spite of federal regulations existing since 1989 and more than a dozen congressional hearings. According to the Commission charter, we were asked to consider: a new definition of research misconduct; an assurance process for institutional compliance with HHS regulation; mechanisms by which to respond to and oversee related administrative functions and investigations; and development of a regulation to protect whistleblowers.
>
> In fulfilling its mandate, the Commission held a total of 11 meetings open to the public in the Washington area and 4 regional hearings on university campuses in California, Illinois, Massachusetts, and Alabama. The Commission proved to be an effective forum for soliciting testimony on research integrity from all affected constituencies, including scientists, whistleblowers, attorneys, institutions, scientific organizations, the press, interested citizens, and federal officials. We have listened and deliberated carefully based on the extraordinary outpouring of commentary on the issues. We believe the recommendations unanimously supported by the Commission are realistic and balance the interests of the Federal Government, research institutions, scientists, and the public. We believe that the individual scientists and their research institutions and societies bear the primary responsibility for preserving integrity and dealing with misconduct when it occurs. We are not recommending a bigger federal role, only a more effective one.
>
> The creation and functioning of the Commission gave fresh expression and hope to many disillusioned scientists and whistleblowers that their voices could be heard and might make a difference in advancing the cause of scientific integrity and public trust. It is for this reason that the Commission urges that an independent oversight review body with a membership like the Commission's be created to periodically conduct hearings and review regulations and policies that affect federally funded biomedical and behavioral research. The Commission also hopes that the resources needed for effective oversight and timely disposition of investigations be carefully considered.
>
> We appreciate the opportunity to have served on this task, which is so important to the public and the scientific community.

Acknowledgments

The Commission on Research Integrity is indebted to the many individuals and institutions who have helped it fulfill its mission. We are grateful to the following consultants for the knowledge and expertise they shared with the Commission: Stephanie J. Bird, Ph.D., Cambridge, MA; Louis M. Guenin, J.D., Boston, MA; David H. Guston, Ph.D., New Brunswick, NJ; and Stephen E. Toulmin, Ph.D., Los Angeles, CA.

We give special thanks to Dr. Lyle Bivens, DHHS, and Dr. Donald Buzzelli, NSF, for their dedication and untiring support of the Commission.

We are also indebted to the following DHHS employees for sharing professional skills that have immeasurably enhanced the effectiveness and efficiency of our work: Ms. Elaine Alvarez de Benavides, Ms. Doris Campos-Infantino, Ms. Hilda Goldstein, Mr. Chris McNickle, Ms. Maria Mone, Ms. Karen Patrias, Ms. Catherine West, and Andrea Selzer, Esq., as well as Mr. George Getsinger of CASET Associates.

Our thanks are extended as well to the four universities that graciously offered to host the Commission's regional meetings: De Paul University, Chicago, IL; Harvard University, Boston, MA; University of Alabama, Birmingham, AL; and University of California, San Francisco, CA.

We also deeply appreciate the contributions of all witnesses who generously shared experience, expertise, and advice with the Commission, often at considerable personal expense.

The Commission would especially like to acknowledge the extraordinary contributions of its Executive Secretary Henrietta Hyatt-Knorr and science writer Anne Rosenfeld in the organization and conduct of our meetings and the development of this report.

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Executive Summary

Commission on Research Integrity: Origins and Charge

Congress created the Commission on Research Integrity in 1993 in response to continuing controversy concerning the apparent inability of the scientific community and the Federal Government to deal adequately with misconduct in scientific research. The Commission's task was to advise the Secretary of Health and Human Services and Congress about ways to improve the Public Health Service (PHS) response to misconduct in biomedical and behavioral research receiving PHS funding. Issues to be addressed included: 1) the definition of research misconduct; 2) the assurance process for research institutions' compliance with DHHS regulations; 3) the administrative processes of institutions and the PHS for dealing with allegations of misconduct; 4) and the development of a regulation to protect whistleblowers.

The Commission's 12 members, chaired by Dr. Kenneth Ryan of Harvard University Medical School, were selected to include scientists, research misconduct investigators, administrators of research institutions, attorneys, and ethicists. The Commission held public meetings monthly from June 1994 through October 1995, primarily in the Washington, D.C., metropolitan area; regional public hearings were held in San Francisco, Chicago, Boston, and Birmingham. These meetings and hearings elicited a range of opinion and experience regarding weaknesses in current institutional and federal policies and practices related to research misconduct, as well as suggestions for improvement. The Commission also consulted informally with relevant non-PHS federal agencies, and with professional and scientific organizations.

Guiding Considerations and Principles

In its deliberations, the Commission sought to develop a fair, balanced, and realistic response to its charge, while taking into account the many parties potentially affected by the implementation of its recommendations. Certain principles emerged as fundamental to this effort:

Balancing responsibilities: Individual scientists, research institutions and professional societies have primary responsibility for preserving research integrity and pursuing research misconduct; the role of the Federal Government should complement and enhance that of institutions and societies, and federal intervention should occur only when institutional processes fail.

Clarifying the federal interest in research misconduct: A federal definition of research misconduct should bridge legal and scientific perspectives to state clearly for all

potential users: (a) the principles on which it is based; (b) the federal interest in research misconduct; and (c) the specific behaviors to be prohibited and their boundaries.

Reducing unnecessary complexity and conflicting requirements in federal regulations related to research misconduct: Consistency is needed among all federal definitions of research misconduct and among the administrative mechanisms related to them.

Promoting research integrity and attempting to prevent research misconduct: Research integrity is best fostered by developing and disseminating clear standards of behavior in science (whether by professional organizations or by research institutions or both), and by reinforcing those standards through education and example at all stages of scientific development, and at all levels of research administration.

Creating an institutional climate in which concerns about unethical research conduct can be voiced without fear: Good-faith whistleblowers are important to the identification and ultimate punishment of those who violate research ethics. Both whistleblowers and those they accuse of research misconduct must be treated with respect, fairness, and openness. In addition, whistleblowers need to be protected from retaliation, and their concerns should be resolved by decision makers whose judgment is not tainted by bias.

Assuring fairness in misconduct proceedings: In pursuing allegations of research misconduct at both the federal and institutional levels, a separation must be maintained between investigation and adjudication.

Mitigating inherent conflicts of interest and promoting impartiality in institutional inquiries and investigations of alleged research misconduct: Whatever processes individual institutions develop or adopt, they must achieve a fair balance of impartiality and advocacy in all proceedings. Allegations must be addressed through procedures that are impartial, fair, fact-based, accessible, and open.

Summary of Commission Recommendations

The Commission on Research Integrity recommends to the Secretary of Health and Human Services (HHS) and to Congress a plan to improve the administration of the Federal Government's research integrity and research misconduct activities and to encourage an appropriate assumption of self-regulatory responsibility by the scientific community. (The Commission's major recommendations are briefly summarized here, with a full summary presented in Section IIF.)

The Commission recommends that the Secretary of HHS:

- Adopt a new federal definition of research misconduct and other professional misconduct related to research. The proposed definition specifies offenses that by themselves constitute research misconduct: misappropriation, interference, and misrepresentation (MIM). Each is a form of dishonesty or unfairness that, if sufficiently serious, violates the principles on which the definition is based. The definition clarifies the role of intent in research misconduct, and distinguishes such behavior from other defined forms of research-related professional misconduct, including obstruction of investigations of research misconduct and noncompliance with research regulations.

- Form an interagency task force to develop a common federal definition of research misconduct and other forms of professional misconduct related to research.

- Expand existing institutional assurances to require that research institutions provide research integrity education for all individuals supported by PHS research funds.

- Develop a regulation guaranteeing appropriate standards for protection of whistleblowers, based on "Responsible Whistleblowing: A Whistleblower's Bill of Rights." (See Section IID.)

- Require that intramural research programs of the PHS be subject to requirements concerning assurances, annual reports, and monitoring that parallel requirements for research institutions.

- Streamline DHHS administrative requirements and mechanisms concerning investigation and adjudication of research misconduct allegations, federal intervention in institutional misconduct proceedings, and the imposition of federal sanctions.

- Focus federal oversight of institutional research integrity and research misconduct activities.

In other recommendations, the Commission encourages:

- Scientific and professional societies to adopt and apply codes of ethics in research to educate their membership and to help ensure that all scientists follow professional ethical standards for their particular disciplines; and

- Research institutions to develop and disseminate specific guidelines for good scientific practices.

The Commission believes that, if implemented with sensitivity to the individual characteristics of research institutions and disciplines, these recommendations can contribute to a scientific environment that nurtures research integrity.

Introduction

The Commission on Research Integrity was created by Congress in 1993 to address an apparent failure to solve the important ethical, scientific, social, and legal problems posed by allegations against scientists of misconduct in research (see Charter, Appendix A).

In 1989, Federal regulations governing scientific misconduct in research funded by the Public Health Service (PHS) were put in place in response to reports of fraudulent behavior by scientists, the evident plight of mistreated whistleblowers, more than a dozen congressional hearings, and widespread media coverage. The public, the Congress, and the media perceived that the scientific community was not taking allegations of misconduct in publicly funded research seriously enough. At the same time, scientists and institutional administrators tended to regard the publicity as an overreaction to the malfeasance of a very few of their number, and to worry that any attempts to regulate the investigation of such cases would harm science as a whole.

In that same year, the Department of Health and Human Services (DHHS) set up the investigatory Office of Scientific Integrity (OSI) within the National Institutes of Health (NIH), and a second, review, Office of Scientific Integrity Review (OSIR), within the Office of the Assistant Secretary for Health. Misconduct in science was defined as:

> "...Fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data."[1]

A procedure was established whereby institutions receiving PHS funds were required to respond to allegations of misconduct and report their findings to OSI for review and final disposition. Institutions receiving funds from the PHS were required to adopt the PHS definition as well as policies and procedures acceptable to the Secretary of HHS. At about the same time, the National Science Foundation (NSF) promulgated a similar definition for its grantees; it was augmented in 1991 to include retaliation against good-faith whistleblowers.[2]

Since 1989, as numerous cases worked their way through the process, research institutions as well as the federal offices gained experience and expertise in working within the federal framework. At the same time, dissatisfaction was expressed with the handling of two prominent cases (those associated with the names of Robert Gallo at NIH and Thereza Imanishi-Kari in David Baltimore's laboratory).

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[1] 42 *C.F.R.* Part 50, subpart A; August 8, 1989. This definition is still in use in the Public Health Service, and is referred to in this document as "the current PHS definition" or "the current DHHS definition."

[2] National Science Foundation (1991): Misconduct in science and engineering: Final rule. *Federal Register* 56 (May 14): 22286-90.

OSI and OSIR were accused of having inconsistent policies, vague rules, and procedures that were either biased against defendants or illegal. OSI was said to be at once too aggressive and not aggressive enough; too quick and too slow to close cases.[3] It was also said to be easily influenced, incompetent, and both secretive and leaky.[4 5 6 7] Furthermore, OSI's basic approach, "the scientific dialogue model," devised to keep the process in the hands of scientists rather than lawyers, was widely criticized as unfair and procedurally flawed.

To answer these criticisms, DHHS made structural changes in 1992. OSI and OSIR were merged into the Office of Research Integrity (ORI), outside the NIH but within the DHHS Office of the Assistant Secretary for Health.[8] In the same year, procedures were altered to allow those found guilty to contest the finding with a *de novo,* trial-like hearing before the Research Integrity Adjudication Panels (RIAPs) appointed by the Departmental Appeals Board (DAB). Although the option to include a scientist on these hearing panels was welcomed by the research community, no one was satisfied with how long the process took.

Since 1992, there has been continuing controversy over definitions, procedures, and outcomes. For example, sanctions against institutions have been nonexistent or ineffective. In addition, accused scientists have not hesitated to fight their cases in court. Further, whistleblowers, who are essential to bringing many cases of misconduct to light, have continued to report retaliation from their institutions and those they accuse. Some whistleblowers have begun to use the False Claims Act, through which they can win a portion of grant monies they may recover for the Federal Government in the courts. In this way, they by-pass the designated institutional routes, while institutions object that the very evidence they have gathered in properly conducted investigations is used against them in lawsuits.

In short, events since 1989 have revealed widespread dissatisfaction with federal definitions of misconduct, with the offices and procedures established to deal with allegations against scientists, and with the migration to the courts of what researchers feel should be a matter of professional discipline. Dissatisfaction has been voiced alike--although for different reasons--by accused scientists, their accusers, research institutions, members of the scientific community, professional societies, the public, the media, and the Federal Government, including the Congress.

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3 Aldhous, P. (1991): Trouble for Healy over misconduct office. *Science* 252: 361.

4 Greenberg, D.S. (1991): NIH's bungling goes on in the Baltimore case. *Science & Government Report* 21: 1-4.

5 Greenberg, D.S. (1992): At NIH, a new maelstrom over misconduct. *Lancet* 338: 301-302.

6 Greenberg, D.S. (1991): Leaks in the house of science. *Lancet* 338: 1195-1196.

7 Hamilton, D.P. (1992): FBI investigates leaks at OSI. *Science.* 255: 1503.

8 In 1995 ORI was relocated to the Office of the Secretary, DHHS. For a brief description of the structure and function of ORI, see Appendix C.

The principal issues emerging from the debate and addressed by the Commission are the following:

- The definition of research misconduct: How narrow or broad should the federal definition be? Specifically, should it include other misconduct beyond fabrication, falsification, and plagiarism? How should questions about intent and honest differences in interpretation of data be addressed? How should the line be drawn between serious and less-serious offenses?

- Process: What process is owed to an accused scientist? At what point should a scientist be able to confront his or her accuser in a trial-type setting? How can inherent institutional conflicts of interests and individual biases be mitigated? What form should an appeals process take, and should the evidence at that point be limited to that disclosed by review of the record? What sanctions are necessary to protect the integrity of science, the federal interest in funded research, and the interests of institutions in which research is conducted?

- Federal oversight: What assurances regarding the active presence of fair procedures should the Federal Government require of research institutions to protect the federal investment in research? What office should review institutional assurances and findings, having what powers of investigation? What powers should such an office have to overturn the findings of an institution? What is rightfully in the interest of the Federal Government?

- Protection of whistleblowers: What rights do whistleblowers have? Should retaliation against witnesses be punished, and if so, how? How much federal oversight should there be?

- Prevention: What role should the Federal Government have in evaluating educational programs and providing outreach and technical assistance to institutions in efforts to prevent misconduct? How can the scientific community be encouraged toward greater self-assessment and self-governance?

Members of the Commission have attempted to formulate answers to the preceding questions in the context of the Commission's driving concern: "What is in the best interest of the public and science?" The Commission reached its unanimous conclusions (presented in Section II) after considering extensive testimony by scores of witnesses representing the spectrum of interested parties, as well as review of a broad sample of the relevant literature. Despite differences in goals and methods, there is considerable consistency between the Commission's recommendations and those reached in the 1992 National Academy of Sciences (NAS) report, *Responsible Science*.[9]

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[9] National Academy of Sciences, Panel on Scientific Responsibility and the Conduct of Research (1992): *Responsible Science: Ensuring the Integrity of the Research Process*. Washington, D.C.: National Academy Press, pp. 13-16.
NOTE: This report will be cited as "NAS report" in subsequent references.

Commission Deliberations and Recommendations

Promoting and Maintaining Research Integrity: A Shared Responsibility

Who is responsible for promoting and maintaining research integrity? The Commission on Research Integrity endorses the concept that individual scientists, research institutions, and professional societies bear primary responsibility for the integrity of science, the legitimacy of scientific practices, and the investigation and response to cases of alleged research misconduct. Institutions and units within them that train and hire investigators are responsible for selecting, socializing, educating, supervising, and disciplining research scientists. This responsibility must be shared, however, by professional societies and the journals that review and publish results of research. Any activity of the Federal Government in this domain should support and complement the institutional role, and federal intervention should occur only when institutions fail to fulfill their responsibilities.

With this perspective in mind, the Commission, in keeping with its charge, focused primarily on the Federal Government's role in ensuring the integrity of PHS-funded research. The Commission believes that a federal presence is and will continue to be needed to protect the federal interest in funded research and in public health. Furthermore, federal intervention is specifically required when misconduct allegations concern research studies that span multiple institutions. The Federal Government's role should also include stimulating the best efforts of all members of the scientific community to create an environment conducive to research integrity and, in its own intramural laboratories, serving as an exemplar of research integrity. Finally, a federal presence can protect the rights of whistleblowers and respondents who, for a variety of reasons, believe that their local institution cannot or did not provide a fair forum for examining misconduct allegations.

After assessing current federal oversight activities, the Commission proposed changes intended to focus and strengthen the contributions of DHHS to research integrity--without imposing undue burden on institutions, individual scientists or, for that matter, on federal oversight mechanisms. The Commission devoted particular attention to ways to enhance nonfederal responsibility for promoting and maintaining research integrity. As noted above, it attaches great importance to the educational responsibilities of research institutions and of professional and scientific associations in creating and preserving research environments that foster the ethical conduct of science.

In making its recommendations, the Commission made a concerted effort to minimize the need for additional regulatory activities. However, implementing some of its recommendations will, of necessity, require new federal regulations. Recommendations that address issues involving

compliance with or changes to current federal regulations related to research misconduct and professional misconduct include:

- A new definition of research misconduct (see IIB);
- A change in the existing institutional misconduct assurance to require educational programs on the responsible conduct of research for recipients of PHS research grants and all researchers, students, fellows, research technicians, and others supported by these grants (see IIC);
- An approach for identifying obstruction of research misconduct investigations--including retaliation against whistleblowers--as an actionable offense (see IIB and IID);
- A foundation for dealing more effectively with individuals who fail to comply with research regulations regarding matters such as human subjects, the humane treatment of animals, and safe handling of biohazardous materials. The Commission expects that implementation of this recommendation will make noncompliance an actionable offense within research institutions, and it expects improved coordination among agencies and offices in achieving compliance (see IIB).

The Commission hopes that the Secretary of HHS, in implementing these recommendations, will keep the regulations simple and will delegate as much responsibility to individual institutions as is reasonably possible.

Definition of Research Misconduct and Other Professional Misconduct

Introduction: Considerations in Reaching a Definition of Research Misconduct and Other Professional Misconduct

Defining the Federal Interest

The Federal Government's interest in research misconduct stems from its funding of research and, in the biomedical sphere, its interest in the collective health of the citizenry. To protect the quality of our Nation's scientific enterprise, some research agencies of the Federal Government have developed definitions and procedures for addressing misconduct in research. A definition of research misconduct provides vital guidance for personal and ethical judgments and decisions concerning the professional behavior of scientists. It also provides a legal framework for formal proceedings. Any such definition to be used in the context of federal research funding must rest upon a clear statement of the federal interest.

A federal research agency must refuse to fund researchers who have engaged in certain actions, or deny them participation as reviewers, or place conditions on their applying for or using its funds. A research misconduct regulation enables the Federal Government to take such actions

when research-related misconduct occurs in connection with proposals and awards. Given these considerations, the Commission sought to write a definition that would include all research-related behaviors that are serious enough to require a federal agency to take action.

The Current PHS Definition

The current definition of "misconduct in science" used by the Public Health Service has elicited extensive criticism from many sides and on many grounds since its adoption in 1989. The PHS definition has been criticized for being at once too narrow and too broad, as well as for being too vague. Some of the perceived deficiencies stem from the wording of the definition, and others from the interpretations and implementation by ORI and its predecessor agencies. A vocal segment of the scientific community favors a definition based on, or even limited to, falsification and fabrication of data and plagiarism. Still others argue for a broader view of misconduct, pointing to various types of misconduct that they believe significantly affect the integrity of research but fall outside an overly narrow definition.

To address these issues, the Commission on Research Integrity was charged with developing a new DHHS definition. Commission members recognized from the outset that because of the Federal Government's extensive role in funding research, any definition it adopts to protect federal interests in research is likely to have far-reaching consequences for the scientific community.[10] Thus, changes in such definitions should not be adopted lightly.

Responding to its definitional challenge was a major focus of the Commission's work. Commission members assessed extensive testimony and written commentary related to the strengths and weaknesses of the current PHS definition and ways to improve it, including alternatives proposed by other deliberative bodies.[11] They also examined definitions currently in use by other federal agencies outside the PHS.[12] At its hearings, the Commission discussed all these alternatives with their proponents and with members of the research community.

Commission Deliberations

This section discusses the many considerations weighed by the Commission in fulfilling that part of its charge requiring it to recommend a new definition of research misconduct.

"Research misconduct" vs. "research fraud": An early issue addressed by the Commission was whether to use the term "research misconduct" or "research fraud" in its recommendation. In common law, "fraud" typically encompasses elements that are often not

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[10] One unintended consequence is confusion because federal agencies differently enforce and interpret their respective definitions. This issue is addressed in recommendation #2 (see Section F, Summary of Recommendations).

[11] NAS report, p. 5.; PHS Advisory Committee on Research Integrity, Transcripts of March 7, 1992 and June 11-12, 1992 meetings.

[12] National Science Foundation (1991): Misconduct in science and engineering: Final rule. *Federal Register* 56 (May 14): 22286-90.

present in the acts the definition would deter and punish.[13] The Commission was assured by legal experts that the term "fraud" could be used without invoking those legal provisions. Nonetheless, to avoid the potential confusion the term "research fraud" might elicit[14], the Commission chose to use the term "research misconduct." That choice was made knowing that some may believe the term does not sufficiently indicate the seriousness of the offenses it defines.

After choosing the term to be encompassed by its recommended definition, the Commission examined deficiencies in the current PHS definition.

Fabrication, falsification, and plagiarism: Despite the preference of the National Academy of Sciences panel for a narrow and precise definition centered upon "fabrication, falsification, and plagiarism (FFP),"[15] the Commission learned in its work that "FFP" is neither narrow nor precise. The current FFP definition covers a wide range of intellectual property and data-handling offenses, as well as misrepresentations of all sorts, without providing standards that indicate which of these actions warrant federal action. The constituent elements of FFP are variously interpreted because they are not defined within the current PHS definition. The breadth and vagueness of the definition are not widely understood in the scientific community, which takes false comfort from the presumed precision and narrowness of the terms.

At the same time, the current PHS definition does not encompass conduct outside the scope of FFP that can significantly impair the integrity of research supported by federal funds. Thus, unethical actions directly related to the conduct of federally funded research that are not covered by other regulations or laws are effectively outside the reach of federal sanctions. Furthermore, in the many situations in which research institutions adopt the federal definition without modification, it leaves those actions outside the scope of institutional reach as well.

The NAS panel "...did not reach final consensus on whether additional flexibility was needed to address as misconduct in science other practices of an egregious character similar to fabrication, falsification, and plagiarism." The panel noted, "These issues deserve further consideration by the scientific research community to determine whether the panel's definition of misconduct in science is flexible enough to include all or most actions that directly damage the integrity of the research process and that were undertaken with the intent to deceive."[16]

Building on the work of the NAS panel, and in light of its own examination of FFP, the Commission concluded that some additional elements were required; they are incorporated into the Commission's proposed definition. One example is sabotage of research. The

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[13] For further discussion, see Appendix D.

[14] For example, "fraud" indicates some kind of deception, while not all kinds of research misconduct--such as tampering with experiments--are deceptions.

[15] NAS report, pp 27-28.

[16] NAS report, pp. 27-8.

Commission examined the factual basis for assertions that laws against vandalism are adequate to cover such situations. It learned that they are not adequate if tangible property is not damaged or if other procedural and technical legal requirements--which vary by jurisdiction--are not met. Thus, the Commission concluded that such laws are inadequate to protect the integrity of research, and that such cases should be specifically addressed in a recommended federal definition.

The "other practices that seriously deviate" clause: In the current PHS definition, the clause "or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, and reporting research" is intended to address serious misconduct that violates the ethical standards of the research community but is not encompassed by FFP. This "other practices" clause has been heavily criticized by some members of the scientific community on the grounds that it might be used to punish creative or novel science. However, no case has occurred in which an agency has attempted to treat novel research as misconduct, and definitions of this type, which appeal to standards accepted in certain professional groups without stating them, are, in fact, frequently used in federal regulations.

A second objection concerns the vagueness of the "other practices" clause, which does not indicate the specific actions that might elicit sanctions. This concern, coupled with the first, convinced the Commission that it should not include the clause in its proposed definition. The Commission did, however, examine carefully cases that might fall under the clause to determine if specific offenses should be itemized in a federal definition. As a result of this examination, "interference" is included within the proposed definition of research misconduct, and a distinction is made between "research misconduct" and "other forms of professional misconduct related to research" (i.e., obstruction of investigations and noncompliance with research regulations). The Commission views the "other forms of professional misconduct" as types of professional misconduct that may require federal action because of their damaging effects, although they lack sufficient involvement with the performance of research to be called "research misconduct."

Type of definition: The Commission chose to cast its proposed definition in the form of "leading principles with examples" after considering carefully other possibilities, particularly a "list of offenses" approach. It rejected the latter approach on the grounds that it is neither possible nor desirable to make an exhaustive list of all conduct that could pose a serious threat to the integrity of federally funded research. Such a list is likely to omit some significant type of misconduct that should be covered. It also can become legalistic and unwieldy, and it may appear to be arbitrary unless some guiding concept is given to explain what is and is not included in the definition.

The Commission based its definition on the fundamental principle that scientists be truthful and fair in the conduct of research and the dissemination of research results. It then listed outstanding examples of this central idea, leaving it to the evolution of ethical standards and "case law" to discover whether actions not on that list meet the requirement for consideration as "misbehavior" that seriously undermines the integrity of science. The examples it selected are significant misbehavior that improperly appropriates intellectual property or contributions of others, that intentionally impedes the progress of research, or that risks corrupting the

scientific record[17] or compromising the integrity of scientific practices. The misrepresentation, interference, and misappropriation (MIM) categories of research misconduct are intended to encompass these items.

Supporting the federal role: The Commission recognized that although the primary responsibility for dealing with research misconduct rests with research institutions, its task was to propose a definition that could be used by a federal agency that supports research. Thus, the definition must distinguish misconduct in research from those undesirable actions that would concern any federal agency that distributes federal funds, and those undesirable actions by a scientist that do not affect his or her work as a scientist. It must also distinguish the Federal Government's interest in research misconduct and other forms of professional misconduct from the concerns of institutions and professional societies.

Communicating clearly and effectively to intended users: An effective system for responding to allegations of misconduct in research requires a clear understanding of the interests and roles of all participants in the scientific enterprise. They include the public, the Federal Government, other funding agencies, institutions where research is conducted, individual researchers, their professional societies and organizations, and the journals in which the results of research are published. The Commission has tried to address the concerns of these constituencies.

In meeting the needs of the scientific community, a definition concerning unacceptable conduct in research must be clearly stated, and framed so that individual scientists can understand and accept it as it applies to them, and can take part in resolving alleged cases of misconduct in their institutions.

A new definition also must be understandable and usable by grantee institutions, some of which copy the federal definition directly into their own policies. All institutions that accept PHS funds must administer the federal definition when misconduct allegations arise among individuals receiving such support.

Meeting both scientific and legal requirements: The Commission's definition attempts to bridge the awkward intersection of two professional perspectives--the scientific and the legal--each with its own language, values, and requirements. The first is predominant in the beginning of research misconduct procedures, and the second becomes increasingly prominent when cases progress through more formal procedures and eventually involve federal adjudication proceedings (such as those of the Research Integrity Adjudication Panels appointed by the DHHS Departmental Appeals Board) or the court system. Thus, in framing its definition, the Commission chose to describe specific kinds of misconduct in legally enforceable language.

Both lawyers and scientists recognize that the Federal Government should respond to allegations of research misconduct only in sufficiently serious cases (e.g., those that involve allegations of serious infractions that undermine the integrity of research). The Commission's

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[17] The record encompasses any documentation or presentation of research, oral or written, published or unpublished.

proposed definition addresses this issue in several ways. First, it explicitly incorporates the seriousness requirement, rather than invoking it indirectly, as does the present definition through the phrase "or other practices that **seriously** deviate" (emphasis added). Second, the fundamental principle defining research misconduct is explained in terms of serious violations of the obligations of researchers to be truthful and fair. Third, research misconduct is defined as "significant misbehavior" with four specific effects upon research. Fourth, explicit standards for the level of intent are provided for each included violation.

In sum, the proposed definition continues the seriousness requirement, but makes it explicit. Assessments of seriousness--that is, whether any given case meets the requirements of the definition--must continue to be made on a case-by-case basis.

Scientists and lawyers also recognize that a scientist should not be penalized for unintended and unforeseeable outcomes if that person acted as an ordinarily prudent person would, and with an acceptable level of care; this issue is also addressed in the "intent" part of the definition. Both lawyers and scientists recognize, further, that the scientific process inherently involves making mistakes. Errors are not research misconduct and should not be punished as such; the Commission's research misconduct definition makes that clear.

Misappropriation: The Commission's proposed definition replaces the undefined word "plagiarism" in the current federal definition with the defined term "misappropriation." In choosing the scope of its definition of misappropriation, the Commission was guided by the NAS report, *Responsible Science*, which states that plagiarism is:

> ". . . using the ideas or words or another without giving appropriate credit. Plagiarism includes the unacknowledged use of text and ideas from published work, as well as the misuse of privileged information obtained through confidential review of research proposals and manuscripts."[18]

The Commission's two-part definition of misappropriation tracks the NAS panel's recommendations directly, but uses the term "misappropriation" to emphasize that the proscribed misconduct is broader than most of the commonly used definitions of plagiarism. In its work, the Commission identified instances in which alleged cases of plagiarism among and between collaborators that would be deemed "significant misappropriation" in the proposed definition --and would fall within the jurisdiction of the Office of Research Integrity-- were previously dismissed by ORI as mere "authorship disputes" or "collaborative disputes."

Interference: As described above, the Commission adopted "interference" as an element of research misconduct to address situations in which a person's research is seriously compromised by the intentional and unauthorized taking, sequestering, or damaging of property he or she is using in the conduct of research. The Commission believes such interfering acts are antithetical to integrity in research and should be placed within the definition of research misconduct rather than be left for litigation under State tort laws dealing with acts of vandalism. It is important to emphasize that misconduct allegations in this area

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[18] NAS report, p. 54.

require proof that a person has acted without authority and in violation of another person's ownership or possessory interests in the property.

Misrepresentation: The Commission's proposed definition replaces the undefined words "falsification" and "fabrication" with the defined term "misrepresentation." The definition has two essential parts: first, a material or significant false statement or an omission that significantly distorts the truth; and second, a culpable mental state. The definition consciously excludes the common law fraud elements of reliance, causation, and damages, which are unnecessary--indeed inappropriate--in the context of research misconduct. Consistent with interpretations of current law, the Commission believes that, to qualify as research misconduct, an erroneous statement must be made with an intent to deceive. This element is more explicit and more helpful analytically than the statement in the current definition that says, "It does not include honest error or honest differences in interpretations or judgments of data." The current phrase fails to identify or define what is dishonest and fails to tell the decision maker what is required to reach a finding of misconduct.

An intent to deceive is often difficult to prove; proof almost always relies on circumstantial evidence, which can, however, include an analysis of the behavior of the person accused of misconduct. One commonly accepted principle, adopted by the Commission, is that an intent to deceive may be inferred from a person's acting in reckless disregard for the truth. Conduct that is merely careless or inadvertent is not included in the Commission's proposed definition of research misconduct. However, the Commission intends that such careless conduct continue to be addressed in the high standards of grant application review and in institutional and professional standards for appointment, promotion, publication, and other incentives.

The Commission does not suggest any modification in the Federal Government's use of the preponderance of the evidence standard in research misconduct cases.

Finally, the Commission's definition sets the standard for federal agency enforcement. The Commission hopes that the definition will not only be adopted by DHHS, but will serve as the basis for interagency discussion leading to consistent misconduct policies and procedures among all federal agencies that support science. The sanctionable behaviors defined and elaborated here are not intended to limit or define comprehensively the oversight role of academic and research institutions, which are free to adopt more demanding standards.

In sum, the new definition introduces an ethical approach to behavior rather than serving as vehicle for containing or expanding the basis for blame or legal action. It specifies offenses that by themselves constitute research misconduct. These are identified as misappropriation, interference, and misrepresentation, each a form of dishonesty or unfairness that, if sufficiently serious, violates the ethical principles on which the definition is based. Appendix D further explains these offenses, their significance in comparison with alternative approaches, and how and why they differ from offenses in the current definition.

Recommendation:

The Commission recommends that the Secretary replace the existing definition of misconduct in science[19] with the definition of research misconduct and definitions of other forms of professional misconduct related to research, to follow. The definition of research misconduct is based on the premise that research misconduct is serious violation of the fundamental principle that scientists be truthful and fair in the conduct of research and the dissemination of its results.

The Federal Government has an interest in professional misconduct involving the use of federal funds in research, as covered by the following definitions:

1. Research Misconduct

Research misconduct is significant misbehavior that improperly appropriates the intellectual property or contributions of others, that intentionally impedes the progress of research, or that risks corrupting the scientific record[20] or compromising the integrity of scientific practices. Such behaviors are unethical and unacceptable in proposing, conducting, or reporting research, or in reviewing the proposals or research reports of others.

Examples of research misconduct include but are not limited to the following:

Misappropriation: **An investigator or reviewer shall not intentionally or recklessly**

a. plagiarize, which shall be understood to mean the presentation of the documented words or ideas of another as his or her own, without attribution appropriate for the medium of presentation; or
b. make use of any information in breach of any duty of confidentiality associated with the review of any manuscript or grant application.

Interference: **An investigator or reviewer shall not intentionally and without authorization take or sequester or materially damage any research-related property of another, including without limitation the apparatus, reagents, biological materials, writings, data, hardware, software, or any other substance or device used or produced in the conduct of research.**

Misrepresentation: **An investigator or reviewer shall not with intent to deceive, or in reckless disregard for the truth,**

a. state or present a material or significant falsehood; or

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[19] The Commission does not suggest that other forms of misconduct, such as financial improprieties, are not of serious concern. It has limited its definitional recommendations, however, to areas that are specifically related to the **conduct** of research.

[20] The record encompasses any documentation or presentation of research, oral or written, published or unpublished.

b. omit a fact so that what is stated or presented as a whole states or presents a material or significant falsehood.

Free scientific inquiry naturally includes proposing hypotheses that may ultimately prove to be false, offering interpretations of data that conflict with other interpretations, and making scientific observations and analyses that may prove to be in error. The Commission's recommendations pose no threat to such inquiry, which is essential to the advancement of science.

The sanctionable behaviors defined and elaborated here are not intended to limit or define comprehensively the oversight role of academic and research institutions, which are free to adopt more demanding standards.

2. Other Forms of Professional Misconduct

a. Obstruction of Investigations of Research Misconduct

The Federal Government has an important interest in protecting the integrity of investigations into reported incidents of research misconduct. Accordingly, obstruction of investigations of research misconduct related to federal funding constitutes a form of professional misconduct in that it undermines the interests of the public, the scientific community, and the Federal Government.

Obstruction of investigations of research misconduct consists of intentionally withholding or destroying evidence in violation of a duty to disclose or preserve; falsifying evidence; encouraging, soliciting or giving false testimony; and attempting to intimidate or retaliate against witnesses, potential witnesses, or potential leads to witnesses or evidence before, during, or after the commencement of any formal or informal proceeding.

b. Noncompliance with Research Regulations

Responsible conduct in research includes compliance with applicable federal research regulations. Such regulations include (but are not limited to) those governing the use of biohazardous materials and human and animal subjects in research.

Serious noncompliance with such regulations after notice of their existence undermines the interests of the public, the scientific community, and the Federal Government and constitutes another form of professional misconduct.

The Commission's proposed definition of research misconduct and definitions of other forms of professional misconduct related to research will reach their full meaning when tested with real-world experience, cases, and commentaries. The Commission is relying on professional societies, research institutions, science ethics scholars, and case law to develop the interpretive context.

Uniform Federal Definition

In common with other observers, most particularly the NAS report, *"Responsible Science,"*[21] the Commission is aware of the intense need to coordinate and unify the efforts and activities of federal agencies related to research integrity and research misconduct. It is wasteful and confusing to subject individual investigators and their research institutions to inconsistent federal definitions and policies issued by different federal research sponsors.

Recommendation:

The Commission recommends that:

- **The Secretary encourage an interagency task force to develop a common federal definition of research misconduct and other forms of professional misconduct related to research.**

Education and Standards for Research Integrity

Research institutions, professional societies, and the Federal Government share with individual scientists in the task of ensuring integrity in research funded by the Public Health Service. The Commission examined critical aspects of their individual roles, and, as presented below, developed specific recommendations intended to strengthen the unique contributions of each to research integrity.

Role of Research Institutions and the Federal Government

Introduction

A deep commitment to scientific integrity is best achieved by providing sound training in scientific practices and the ethical conduct of science, and by creating institutional and professional environments that reinforce the high standards addressed in that training. Ideally, this educational process should begin early in the training of future scientists and continue through the most senior career stages.

In scientific research, no formal process exists for reviewing questions about the scientific integrity of individuals and assessing and periodically renewing their professional membership and privileges in the scientific community. Thus, academic institutions bear particular responsibility for maintaining high professional standards.

The Commission believes that a positive ethical example set by a research supervisor or mentor in a laboratory or other research setting provides a powerful learning experience. However,

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[21] NAS report, Recommendation #5, p.14.

given the size, complexity, and at times impersonality of many training environments, other mechanisms are also needed to ensure that high ethical standards and exemplary scientific practices are clearly and credibly communicated and fostered. Institutions, professional societies, and the Federal Government all have important roles to play in creating and reinforcing these mechanisms.

Research institutions with good standards of conduct are the backbone of research integrity.[22] At their best, they provide an educational environment that, both in form and in content, fosters the highest standards of research and ethical behavior. Essential elements of this role include:

- Developing and disseminating specific guidelines for good scientific practices; and
- Providing formal and informal educational opportunities to sensitize both junior and senior scientists to critical issues in research ethics and their institution's guidelines.

Commission members heard testimony and read reports suggesting that there is considerable variation in how extensively and how well institutions now fulfill these roles. The Commission has sought to encourage institutions to strengthen their efforts without federal intervention or requirements. It has attempted to minimize administrative burdens while encouraging both federal research sponsors and grantee institutions to fulfill their responsibility for maintaining the public's trust in research and for assuring that such research conforms to the highest scientific and ethical standards.

Developing and Disseminating Guidelines for Good Scientific Practices: The Commission believes that institutional guidelines on data management and retention, authorship, and on supervision of students, fellows, and technicians are of paramount importance because they clarify for every member of the research environment the professional practices expected of them. Some research institutions have already developed such guidelines.[23]

The Commission initially considered recommending that institutions be required to submit to the PHS an assurance that they have developed specific practice guidelines (standards) pertaining to these issues. After further deliberation, the Commission decided that ongoing educational programs offer the best way to stimulate institutional awareness of research integrity issues.[24] Consequently, as described below, it recommends that the existing PHS research integrity assurance requirement be expanded, but only to require of institutions an educational program on the responsible conduct of research. Institutions are, however, strongly encouraged to develop practice guidelines, as some have already done.

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[22] The Commission is not alone in recognizing this primacy. See NAS report, pp. 13-15.

[23] See, for example, guidelines developed by the NIH intramural research program, Harvard Medical School, the University of Illinois, Urbana-Champaign, and the University of California, San Francisco.

[24] See also NAS report Recommendation #2, p.13.

The Commission did not recommend specific standards to be adopted by institutions because it recognizes that each institution must tailor programs to its particular needs. An additional consideration was to limit the burden on institutions of compliance and the potential for inappropriate expansion of federal oversight.

Providing Education in the Responsible Conduct of Research: Since late 1992, the National Institutes of Health (NIH) have required that all institutions receiving NIH training grants offer programs in research integrity for trainees funded by institutional training grants. Anecdotal reports suggest that this policy has met with a positive response from many students and faculty. A notable recent increase in the professional literature related to research integrity may reflect growing awareness of and interest in ethical issues in research stimulated in part by the NIH training requirement.[25]

The Commission believes that, on balance, this required educational activity is essential and should be more broadly implemented to ensure that, through such training, **all individuals** who perform research in institutional settings are sensitized to the ethical issues inherent in research. At present, the training is required only of recipients of institutional training grants, and does not reach all graduate, professional, and postdoctoral students or more senior researchers and other members of research groups, such as technicians. The Commission strongly believes that all of these individuals would benefit from participation. Providing such training is an important step toward creating a positive research environment that stresses the achievement of research integrity more than the avoidance of research misconduct.

Current policy governing PHS research funding requires each institution to submit an assurance to the Office of Research Integrity (ORI)[26] declaring that: (a) the institution has an administrative process for handling allegations of research misconduct and that it complies with the Public Health Service regulation;[27] and (b) the institution will follow its own policy and applicable regulatory requirements when responding to allegations of research misconduct.

The same regulation requires institutions to "foster a research environment that discourages misconduct in all research..."[28] However, institutions are not required by regulation to provide assurances regarding their efforts to promote research integrity, nor are there formal requirements of individual scientists.

In the Commission's view, expanding the existing PHS assurance is the most reliable and institutionally effective--yet least burdensome and intrusive--way to broaden the scope of research integrity training and to buttress research integrity. Although this assurance program

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[25] Examples include: AAMC Subcommittee on Teaching Research Ethics of the AAMC Ad Hoc Committee on Misconduct and Conflict of Interest in Research (1994): *Teaching the Responsible Conduct of Research through a Case Study Approach: A Handbook for Instructors*. Washington, D.C.: Association of American Medical Colleges; Friedman, P.J. (Ed.) (1993): Integrity in Biomedical Research. *Academic Medicine* 68(9) Supplement; Benditt, J. (Ed.) (1995): "Conduct in Science: A Special News Report"*Science* 268: 1705-1718.

[26] For a brief discussion of the structure and function of ORI, see Appendix C.

[27] 42 *C.F.R.* Part 50, Subpart A.

[28] *Ibid.*, p.162.

will carry additional costs for institutions, the Commission believes they will be offset by the benefits to education, training, and research practices. The Commission specifically seeks to encourage self-regulation by institutions and individual scientists; if self-regulation succeeds, expansion of the federal role would be minimized.

Recommendations:

The Commission recommends that the Secretary:

- **Require that each institution applying for or receiving a grant, contract, or cooperative agreement under the Public Health Service Act for research or research training add to its existing misconduct-in-science assurance a third declaration, one certifying that the institution has an educational program on the responsible conduct of research. Through this mechanism, the current NIH research integrity education requirement,[29] now limited to recipients of institutional training grants at NIH-funded institutions, would be augmented by an assurance applied to all individuals supported by PHS research funds.**

- **The proposed research integrity education assurance should be implemented in the following manner: The assurance should be included in the checklist that accompanies every PHS research or training grant application. The institutional official's signature would signify the institution's compliance with the assurance. In addition, the application would state clearly that the signature of the scientist submitting the application signifies that he/she is familiar with (a) the institution's policies and procedures regarding scientific misconduct; and (b) the institution's educational program on the responsible conduct of research.**

The specific content of educational programs on the responsible conduct of research should be at the discretion of each institution, and tailored to that institution's configuration and culture. However, programs should include discussion of areas in which problems are known to arise, such as supervision of trainees; data management; publication practices; authorship; peer review of privileged information[30]; conflicts of interest or commitment; integrity issues in clinical and epidemiological research; whistleblower rights and responsibilities, including their right to be protected from retaliation; and responsibilities and procedures for reporting suspected misconduct.[31]

Institutions that have not already done so should develop educational programs related to research integrity that range from laboratory meetings to institution-wide events. All individuals engaged in research or research supervision should participate regularly in these programs.

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[29] Reminder and Update: Requirement for Instruction in the Responsible Conduct of Research in National Research Service Award Institutional Training Grants. *NIH Guide* 21 (43), November 27, 1992.

[30] See, for example,"Guidelines for the Conduct of Research within the Public Health Service," a 1992 publication of the DHHS Office of the Assistant Secretary of Health.

[31] See NAS report, pp. 128-144.

The Secretary should also encourage:

- **Integration of the explicit teaching of the ethics of science into the classroom, laboratory, and other research sites in precollegiate education as well as in undergraduate and graduate schools; and**

- **Funding for scholarship, teaching, and research in science ethics. Such funded research should include an experimental audit of the prevalence of data misrepresentation.**[32] [33] [34] [35]

Role of Professional Societies and Codes of Ethics

Because of their obligation to their membership and the scientific community at large to protect scientific integrity, professional societies are responsible for articulating, fostering, and maintaining standards of responsible conduct in scientific research. The Commission commends professional societies' existing activities that foster these ends, and recommends that they continue and strengthen their efforts.

Testimony to the Commission by members of professional organizations, including both single-discipline and multidisciplinary groups, has underscored both the diversity of these societies and their potential importance in encouraging research integrity and preventing research misconduct.[36] The Commission is particularly concerned with three aspects of their role: (a) setting explicit standards for professional research practices; (b) enforcing those standards among society members; and (c) actively advocating for and educating members and potential members through preparation and dissemination of educational materials related to ethical behavior.

Codes of ethics should provide clear statements of norms of practice. When matters are ambiguous or appear to go awry, codes can offer a standard by which people can check their practices or help to resolve ambiguities and proceed in the pursuit of scientific integrity. As societies move to adopt or develop codes of ethics in research, they could choose to address the following areas: conflict of interest; responsibility to society; authorship; responsibility to expose misconduct; peer review; mentoring or supervision; management of data; discrimination and harassment; humane treatment of animals; responsibilities to patients;

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[32] Rennie, D. (1989) Editors and auditors. *JAMA* 261: 2543-2545; Rennie, D. (1989): Let's do an experimental audit. *AAAS Observer*, 6 January 1989.

[33] Shamoo, A.E. (1988): We need data audit. *AAAS Observer*, 4 November, 1988.

[34] Glick, J.L. (1976): Reflections and speculations on the regulation of molecular genetic research. *Annals of the New York Academy of Sciences* 265: 178-192.

[35] Because this audit would be undertaken solely to establish the prevalence of research misconduct and not to detect dishonest scientists, it should be confidential and its results reported in the aggregate. The results would be used to inform institutions' decisions about monitoring and enhancing the quality of research.

[36] S. Bird, testimony to Commission on Research Integrity, January 5, 1995.

competence in research methods; knowledge of the definition of misconduct; transmission of values--including fostering collegial trust and sharing--to scientists in training; and nonretaliation against witnesses.[37]

Recommendation:

The Commission recommends that:

- **Professional societies each adopt a code of ethics in research and encourage their members to use these codes as a framework for considering emerging ethical issues in science. In addition, professional societies should consider initiating activities that will further promote the ethical conduct of research and professionalism in science.**

To promote professionalism in science, it is suggested that societies adopt a statement about integrity and misconduct in research, and teach scientific integrity through conferences, seminars, workshops, and classes at all educational levels. Societies might further develop educational and programmatic materials, such as cases, scenarios, and interpretive commentary, and more generally foster scholarship and empirical research in research ethics. Some societies may elect to develop model standards for their particular disciplines, to share with other disciplines regarding, for example, supervisory responsibilities, authorship, data management, peer review, and conflict of interest.

To promote self-regulation in science, it is suggested that professional societies develop rosters of professionals from which institutions can draw unbiased members for investigatory and adjudicatory bodies that consider allegations of misconduct. Societies might also consider making their membership term-limited and conditionally renewable, with membership explicitly stated to be incompatible with participation in actions that have elicited or would elicit federal sanctions for research misconduct. Finally, societies that have journals might encourage the publication of articles on research ethics and criteria for responsible authorship and publication practices.

Editors of scientific journals have a duty to report allegations of misconduct to the relevant institutions; to assist in the resolution of allegations of misconduct; and, where appropriate, to correct the literature by publishing retractions that are clearly linked to the original fraudulent publications and that state the reasons for retraction.

Authorship

The Commission heard many examples of the conflicts that can and do arise as a result of disputes over authorship. Such conflicts can generally be avoided if researchers have early and frequent discussions on the allocation of authorship and intellectual property. Those conflicts that do arise can be handled more effectively if institutions have a mechanism in place for

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[37] The first 10 items were found in one study to appear frequently in the codes of 36 scientific societies (S. Bird, presentation to Commission on Research Integrity, January 5, 1995); the remaining items were added by the Commission.

responding to them. The Commission encourages institutions, professional societies, and journals to develop, disseminate, and discuss policies governing authorship.

Responsible Whistleblowing

Introduction

The scientific endeavor requires creating and maintaining an environment in which good-faith questions about the integrity of scientific information or methods can be raised without penalty, and in which such issues are reviewed objectively and impartially. The scientific community's response to questions about the validity of research should be consonant with these goals and processes. Neither the scientific community nor the public can afford to let secrecy in misconduct cases shield scientists from accountability.

Whistleblowers in research--those who raise questions that lead to concerns about the integrity of research--have at times found themselves penalized and retaliated against by the individuals they question, by their colleagues, and by their institutions, rather than being recognized for their effort. The Commission heard testimony and reviewed documentation confirming that good-faith whistleblowers are not always as protected as they should be.

Whistleblowers provided extensive testimony to the Commission alleging destructive and painful retaliation they had experienced in response to their allegations of research misconduct. The public record demonstrates that good-faith whistleblowers, some publicly vindicated, have experienced harm or ruin to their professional careers through threats, censorship, physical isolation, retaliatory investigations, accusations of racial bias or of the very misconduct they challenged, academic expulsion, denial of access to their data and laboratories, and even threatened deportation or physical injury.[38] [39] [40] [41] The research community must squarely address this issue.[42]

Members of the scientific community with knowledge of research misconduct have an ethical responsibility to come forward. But few are likely to fulfill this responsibility in the absence of a system that provides a fair review of concerns and effective protection from retaliation.

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[38] U.S. Merit Systems Protection Board (1981): *Whistleblowing and the Federal Employee: Blowing the Whistle on Fraud, Waste, and Mismanagement--Who Does It and What Happens?* Washington, D.C.: U.S. Government Printing Office.

[39] U.S. Merit Systems Protection Board (1984): *Blowing the Whistle in the Federal Government: A Comparative Analysis of 1980 and 1983 Survey Findings.* Washington, D.C.: U.S. Government Printing Office.

[40] U.S. Merit Systems Protection Board (1993): *Whistleblowing in the Federal Government: An Update.* Washington, D.C.: U.S. Government Printing Office.

[41] Lubalin, J.S., Ardini, M.E., and Matheson, J.L. "Consequences of Whistleblowing for the Whistleblower in Misconduct in Science Cases: Final Report." Unpublished. Submitted to ORI by Research Triangle Institute, Contract No. 282-92-0045, October 2, 1995.

[42] This concern was shared by the NAS panel; see NAS report Recommendation #11, pp 15-16.

To strengthen whistleblower protection, the Commission has taken several steps:

a. It has developed a Whistleblower's Bill of Rights (see Section 2 below), which is intended to encourage institutions to treat good-faith whistleblowers fairly, shield them from retaliation, and articulate the responsibilities of any individual who accuses another of research misconduct.

b. During the Commission's tenure, the Office of Research Integrity, in consultation with the Commission, developed institutional guidelines to protect whistleblowers against retaliation. The draft guidelines proposed by ORI (Appendix E) support the principles articulated in the Whistleblower's Bill of Rights, below. The final regulation that is required by law should ensure these principles.

c. In its proposed definition of research misconduct and other forms of professional misconduct, the Commission has stated clearly that obstruction of investigations of research misconduct is a major concern of the Federal Government--a step that provides an explicit foundation for the protection of whistleblowers. The Commission also recommends strengthening the capacity of ORI/DHHS to respond to instances of alleged retaliation against whistleblowers and institutional complicity in or indifference to such retaliation.

An issue repeatedly raised by whistleblowers who risked retaliation is the absence of an independent, credible forum free from inherent institutional conflicts of interest, providing them with a right to develop the record and seek corrective action on their concerns. During its deliberations, the Commission considered the potential roles of an independent advocate or ombudsperson for whistleblowers at the institutional level. Members failed to agree, however, that individuals with such a narrow focus of concern would improve matters sufficiently, either for whistleblowers or for scientific research in general, to warrant recommendation. The Commission nonetheless endorses the broad role of ombudspersons as a source of improved communication, useful information, and reduced interpersonal strife.

The Commission believes that the best protection for whistleblowers and witnesses lies not in federal regulation, but in an institutional culture that is committed to integrity in research. To establish such a culture, committed institutional leadership is an essential component. Institutional commitment expedites good-faith resolution of disputes over alleged research misconduct and helps to prevent prolonged adversarial proceedings.

Each institution must accept responsibility for adopting a structure and procedures that protect the rights summarized below. This responsibility includes implementing the Commission's recommended assurance on research integrity education.[43]

Recommendation:

The Commission recommends that the Secretary develop regulations guaranteeing the standards expressed in the following statement of principles:

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[43] See Recommendations #3 and 4, Section F.

Responsible Whistleblowing: A Whistleblower's Bill of Rights

a. *Communication:* **Whistleblowers are free to disclose lawfully whatever information supports a reasonable belief of research misconduct as it is defined by PHS policy. An individual or institution that retaliates against any person making protected disclosures engages in prohibited obstruction of investigations of research misconduct as defined by the Commission on Research Integrity. Whistleblowers must respect the confidentiality of sensitive information and give legitimate institutional structures an opportunity to function. Should a whistleblower elect to make a lawful disclosure that violates institutional rules of confidentiality, the institution may thereafter legitimately limit the whistleblower's access to further information about the case.**

b. *Protection from retaliation*[44]**: Institutions have a duty not to tolerate or engage in retaliation against good-faith whistleblowers. This duty includes providing appropriate and timely relief to ameliorate the consequences of actual or threatened reprisals, and holding accountable those who retaliate. Whistleblowers and other witnesses to possible research misconduct have a responsibility to raise their concerns honorably and with foundation.**

c. *Fair procedures:* **Institutions have a duty to provide fair and objective procedures for examining and resolving complaints, disputes, and allegations of research misconduct. In cases of alleged retaliation that are not resolved through institutional intervention, whistleblowers should have an opportunity to defend themselves in a proceeding where they can present witnesses and confront those they charge with retaliation against them, except when they violate rules of confidentiality.**

Whistleblowers have a responsibility to participate honorably in such procedures by respecting the serious consequences for those they accuse of misconduct, and by using the same standards to correct their own errors that they apply to others.

d. *Procedures free from partiality:* **Institutions have a duty to follow procedures that are not tainted by partiality arising from personal or institutional conflict of interest or other sources of bias. Whistleblowers have a responsibility to act within legitimate institutional channels when raising concerns about the integrity of research. They have the right to raise objections concerning the possible partiality of those selected to review their concerns without incurring retaliation.**

e. *Information:* **Institutions have a duty to elicit and evaluate fully and objectively information about concerns raised by whistleblowers. Whistleblowers may have unique knowledge needed to evaluate thoroughly responses from those whose**

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[44] The Commission on Research Integrity supports the Institute of Medicine recommendation that universities should "provide mediation and counseling services for faculty, staff, and students who wish to express concerns about professionally questionable training or research practices." Institute of Medicine (1989): *The Responsible Conduct of Research in the Health Sciences.* Washington, D.C.: National Academy Press, p. 4.

actions are questioned. Consequently, a competent investigation may involve giving whistleblowers one or more opportunities to comment on the accuracy and completeness of information relevant to their concerns, except when they violate rules of confidentiality.

f. *Timely processes:* **Institutions have a duty to handle cases involving alleged research misconduct as expeditiously as is possible without compromising responsible resolutions. When cases drag on for years, the issue becomes the dispute rather than its resolution. Whistleblowers have a responsibility to facilitate expeditious resolution of cases by good-faith participation in misconduct procedures.**

g. *Vindication:* **At the conclusion of proceedings, institutions have a responsibility to credit promptly--in public and/or in private as appropriate--those whose allegations are substantiated.**

Every right carries with it a corresponding responsibility. In this context, the Whistleblower Bill of Rights carries the obligation to avoid false statements and unlawful behavior.

Administrative Processes and Investigations in Research Misconduct

Structures and Procedures of Research Institutions[45]

An environment that protects and nurtures research integrity is one in which questions can be freely raised. All individuals actually or potentially involved in maintaining scientific integrity need the security of knowing that open-mindedness and fair procedures are ensured. Rigorous adherence to fair procedures must occur from the very first exploration by an individual who questions the behavior of another, to the final disposition of formal inquiries and hearings.

Institutions must guard against all factors that may undermine impartiality and fairness in such proceedings, including those that place narrow views of institutional self-interest above all others. When conduct is questioned in research institutions, even the earliest and least formal phases of proceedings are vulnerable to mishandling, and power inequalities can contribute to unfair treatment of both whistleblowers (who may be of junior status) and the accused. Testimony to the Commission underscored the potential dangers of partiality in the institutional handling of misconduct allegations from the inception to the completion of investigations.

Mediation by an ombudsperson or mediator from inside or outside the institution should be possible if agreeable to all parties. When academic institutions offer mediation or conciliation, it should be provided by an individual who is independent of the dispute. (See Whistleblower's Bill of Rights, section (d).)

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[45] This section draws on concepts developed by C.K. Gunsalus and others within and outside of the Commission.

Whatever processes individual institutions develop or adopt, they must achieve a fair balance of impartiality and advocacy in all proceedings. Guidelines for adequate process are required to ensure that allegations are addressed through procedures that are impartial, fair, fact-based, accessible, and open.

The Commission examined diverse model assurances and guidelines developed by institutions, professional organizations, and the Federal Government, and considered suggestions for their implementation.[46,47,48,49] No single specific set of guidelines can ensure satisfactory procedures in all settings because institutions vary considerably in style, size, and structure. Nonetheless, existing policies and guidelines offer important principles and procedures that must be borne in mind. Based on these, the Commission believes institutional procedures must be:

Accessible from multiple entry points, such as through the mentor, lab supervisor, department head or other scientific colleagues, and the research integrity officer or ombudsperson. The existence of multiple entry points requires consistent mechanisms for assessing allegations as well as adequate communications among these components.

Overseen by individuals or by committees whose members are free from bias and conflict of interest. At every stage of the process, institutions must demonstrate that none of those assessing the allegations have substantial personal or professional involvement with the facts at issue or the individual(s) whose conduct is in question. In whatever manner institutional committee membership is determined, those making the determination must not be directly involved with the unit in which the allegation is made. At least one person who is not from the institution in which the allegation arose should be included in the investigation phase. It is also good practice to include one or more experts in the scientific field, also from outside the institution. The rosters of professionals that the Commission has suggested be developed by professional societies could provide one useful source of such "outside" professional expertise. Whenever possible, the whistleblower and the accused should have equal input in assembling the committee.

Based on independent investigation. The factual basis for allegations of misconduct must be established without regard to the personality and motivations of

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46 Gunsalus CK. (1993): Institutional structure to ensure research integrity. *Academic Medicine* 68 S33-S38 (Supplement 3).

47 *Framework for Institutional Policies and Procedures to Deal with Fraud in Research.* Washington, D.C.: Association of American Universities, National Association of State University and Land-Grant Colleges, Council of Graduate Schools, Nov. 4, 1988; reissued Nov. 10, 1989; developed by an interassociation working group.

48 AAMC Ad Hoc Committee on Misconduct and Conflict of Interest in Research: *Beyond the "Framework": Institutional Considerations in Managing Allegations of Misconduct in Research.* Washington, D.C.: Association of American Medical Colleges, Sept. 1992.

49 Office of Research Integrity advisory document: "Model Policy and Procedures for Responding to Allegations of Scientific Misconduct," April 1995.

whistleblowers or the reputations of those whose behavior they question. The only relevant issue is the facts.

Overseen by bodies that are separated in their investigatory and adjudicatory functions. It is well established that justice is not usually served by having a single individual or group function as investigator, prosecutor, judge, and jury. The checks and balances provided by separating investigatory and adjudicatory functions are essential to fair process.[50]

Balanced in advocacy. Testimony to the institutional committee from both sides of the dispute must be reasonably balanced. Institutions must recognize and adjust for differences in power and resources among participants.

Capable of preventing retaliation against participants. To protect the integrity of the investigative process, the accuser and the accused should receive protection from being silenced, or punished, whether by retaliation or by damage to reputation or resources. Methods for achieving this protection include notifying all faculty members of acceptable and unacceptable procedures; making available an independent ombudsperson; and appointing a senior advisor to both accuser and accused.

Open. While confidentiality is necessary to protect reputations from inappropriate damage, excessive secrecy undermines justice. Proceedings, or at a minimum their results, should be open whenever possible. Anyone whose conduct is questioned should have an opportunity to respond.

Federal Structures and Procedures

Institutions and the Federal Government are partners in the effort to foster research integrity and minimize research misconduct. In fulfilling its responsibility for overseeing the appropriate use of public funds in research, DHHS oversight of research misconduct (as defined in this report) encompasses several distinct but broadly interrelated administrative functions, which include:

- Proposing and implementing regulations;
- Ensuring that institutions and scientists comply with regulations;
- Monitoring and reviewing compliance with institutional assurances and misconduct investigations;
- Conducting DHHS misconduct investigations under specified circumstances;
- Reviewing and adjudicating misconduct cases based on institutional or agency investigations; and
- Imposing remedies and administrative actions.

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[50] This principle applies equally to federal proceedings.

Most of these functions are now the responsibility of the DHHS Office of Research Integrity.[51] The discussion and recommendations to follow focus particularly on the role of DHHS in investigation and adjudication of alleged cases of misconduct. Both the testimony and the literature analyzed by the Commission offered mixed praise and criticism of the work of ORI and its predecessors, OSI and OSIR. Testimony by whistleblowers, respondents, and institutional officials included critiques of ORI's criteria for selecting cases for review, the duration of its inquiries and investigations, and the use of unwarranted secrecy in dealing with whistleblowers. In addition, ORI has been compared unfavorably with the Office of the Inspector General at the National Science Foundation, which has similar responsibilities.

The Commission also received testimony from representatives of the Departmental Appeals Board as well as attorneys for respondents, and reviewed the rulings of cases that were brought to the DAB. Commission deliberations have been aided by testimony and background material from ORI and by recent federal assessments of ORI functions.[52]

Investigating Allegations

Based on its analysis of the sources mentioned above, the Commission believes that the federal investigatory role should be improved, based on the following principles:

- The Department must rely upon institutions as the primary site of investigations.

- Effective and timely federal investigation and oversight require appropriate resources, including the power to subpoena persons and documents; a mix of expertise in investigative staffing; and administrative mechanisms that assure adequate speed in the investigatory process.

- A functional separation is necessary between investigation and adjudication; this principle applies in both institutional and federal proceedings. In the latter case, it applies equally to federal oversight of institutional investigations and to investigations conducted by the Federal Government. The success of these functions requires having people with research expertise and investigative skills be involved with the investigation, and having the adjudication involve both scientific and legal competence.

The Commission believes that it would help ORI's procedures to have subpoena power, which it currently lacks. This change was recommended in the DHHS Office of the Inspector General's report,[53] and would follow, in part, the model of NSF, which has the power to subpoena documents, but not witnesses.

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[51] For a brief description of ORI structure and functions, see Appendix C.

[52] Office of Inspector General, DHHS: "Study of the Staffing and Management of the Office of Research Integrity," November 1994; United States General Accounting Office: "Health Research Misconduct: HHS' Handling of Cases is Appropriate, but Timeliness Remains a Concern." United States General Accounting Office Report to Congressional Requesters, August 1995.

[53] Office of Inspector General, DHHS: "Study of the Staffing and Management of the Office of Research Integrity," November 1994.

Over the years, a number of commentators have stated that the processes of investigation and adjudication are not sufficiently separated in the DHHS process. For example, the in-house committee that advises the Director of ORI on the disposition of individual cases includes a representative from the ORI Division of Research Investigations (the investigative arm of ORI). Furthermore, the Director of ORI, who cannot be considered a disinterested party to the success of the investigative effort, makes the final determination in ORI cases.

A clear separation would occur if, for example, following the National Science Foundation model, investigatory functions were assisted or directed by the Office of the DHHS Inspector General. Such an approach might also remedy the limited supply of skilled investigators in ORI. ORI conceivably could then spend more of its efforts in policy development, education, monitoring institutional assurances, compliance reviews, and investigating retaliation against witnesses.

Recommendations:

Regarding the federal investigation of allegations, the Commission recommends that:

- **The Secretary ensure that the investigation of misconduct and subsequent adjudication are organizationally separated in DHHS, as they are, for example, at the National Science Foundation.**

- **DHHS ensure that legal, law-enforcement, and scientist-investigator staff participate in each federally conducted investigation and ensure that scientists participate in hearings and appeal procedures.**

- **Those conducting investigations have subpoena power over persons and documents, subject to specific case-by-case authorization by the Office of the General Counsel.**

- **The Secretary establish a specific mechanism for reviewing and auditing the record of DHHS in enforcing the laws that prohibit research misconduct and other professional misconduct.**

- **ORI address as research misconduct those cases that it previously would have dismissed as mere "authorship disputes" or "collaborative disputes," namely, serious cases of alleged plagiarism (which under the proposed definition would be considered "significant misappropriation") among and between collaborators.**

- **DHHS and institutions deal with retaliation against whistleblowers as rigorously at the inquiry, investigation, and adjudication stages as they do with cases of research and other professional misconduct.**

- **The Secretary review the current assignment of responsibility for responding to allegations of retaliation against whistleblowers to the ORI Division of Policy and Education and consider placing it in a unit capable of carrying out investigations.**

- **The Secretary seek, through appropriate channels and procedures, to have the False Claims Act amended because it serves as a disincentive for thorough institutional**

investigations. The principle should be established that institutions may expeditiously investigate scientific misconduct allegations, protected from adverse use of their findings in litigation, if thorough, competent investigations have been conducted.

Federal Adjudication

To dispel any perception of partiality by the Federal Government, a public (open), trial-like proceeding must be available, upon request, in cases adjudicated at the federal level. However, such proceedings should not be required when the DHHS role is limited to reviewing the record of a case based on an adequate institutional investigation.

It is important to note that the federal standard, as expressed in its regulation, is only a minimum standard; institutions have the prerogative of establishing their own standards at or above that level and are encouraged to do so. This prerogative must not be undermined by the federal role. Occasionally, in cases in which an institution had previously found no misconduct, ORI subsequently made a finding of no misconduct without clearly delineating to the institution the basis for such rulings. At the very least, there should be a more careful framing of ORI judgments, since the institution's findings often do and should go beyond the more limited federal interest. Moreover, where an ORI decision would tend to undermine the efficacy of the prior institutional decision, the institution should be granted a right to appeal such ORI decision.

To adjudicate research misconduct cases in which an ORI decision is contested, DHHS now relies upon Research Integrity Adjudication Panels (RIAPs) appointed by the Departmental Appeals Board.[54] The Commission endorses this approach.

For the Federal Government and the scientific community, allegations of retaliation against witnesses are as serious as allegations of research misconduct. Thus, it is essential for DHHS to develop a more systematic, thorough, and effective process for monitoring institutional investigations of such allegations, as well as a way to call institutions to task when they fail to fulfill their obligations.

Recommendations:

The Commission recommends that DHHS:

- **Use institutional findings related to misconduct as final and binding if they are supported by the evidence and were obtained through a process that afforded due process and complied with federal regulations and the institution's own policies.**

- **Limit any subsequent federal review of a decision reached after ORI has reviewed and accepted an institutional finding of misconduct. That subsequent review should be confined to the existing record rather than a *de novo* proceeding, except when**

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[54] In this role, the RIAP is carrying out a trial function, not an appellate function.

DHHS proposes to impose a separate federal sanction. In such instances, if the institutional record is not adequate, further fact-finding by ORI may be required, and, upon request, the respondent should receive a trial-like adjudicatory process to review any such further fact-finding.

- **Permit an institution to contest the decision of the Department's reviewing office if that office has reviewed and disapproved an institutional finding of misconduct or nonmisconduct. In addition, the original respondent should be given an opportunity to make a submission to that office in this review process.**

The Commission also recommends that the Secretary:

- **Continue to permit a respondent to request a trial-type, de novo hearing when proposed findings of misconduct are based on an ORI investigation. Such hearings should continue to be held before a Research Integrity Adjudication Panel appointed by the Departmental Appeals Board. However, the Secretary should consider steps to strengthen and streamline the process to expedite the proceedings.**

- **Require widespread, systematic public disclosure of all outcomes of federal research and research-related professional misconduct cases, with detailed, specific statements of their rationale, in view of the strong public interest in the disclosure of information underlying such cases. In addition, the Secretary should require public disclosure of all factual information developed in misconduct cases that affects the public welfare, unless disclosure is expressly prohibited by law.**

Effective Oversight of Assurances and Misconduct Investigations

The Commission's hearings underscored major differences among research institutions in their awareness of research integrity issues and their administrative capacity to deal appropriately with them. The Commission believes that all available educational avenues should be used to strengthen the scientific community's overall capacity to encourage research integrity and cope fairly and effectively with allegations of research misconduct. Thus, in addition to strongly encouraging the efforts of professional societies and professional training programs and requiring expanded training in research integrity, the Federal Government, in partnership with the scientific community, should develop information that can assist institutions in dealing more effectively with specific federal requirements regarding research integrity and professional misconduct issues.

ORI has developed a model policy and instructions that institutions may use, if they desire, when developing policies that satisfy regulatory requirements. However, instead of being geared exclusively to the current PHS regulation, the model needs to be revised and tailored more toward the broader needs of institutions. Such a revision should involve institutions to the greatest extent possible and should be coordinated with other funding agencies.

The Inspector General of DHHS has suggested that ORI initiate a systematic monitoring program for compliance with assurances, train and use special staff, and make on-site visits for

cause.[55] The Commission concurs that these measures would enhance considerably the effectiveness of the DHHS oversight role in this area.

The large number of institutions required to provide assurances and annual reports presents ORI with a daunting oversight task. The annual reports, which it now receives only from extramural institutions, provide a basis for assessing compliance with institutional assurances. Although the NIH Intramural Research Program also falls within the monitoring jurisdiction of ORI, it is not required to file an assurance or annual report similar to that required of extramural programs receiving PHS funding. The Commission believes this inequality should be remedied.

Recommendations:

The Commission recommends that DHHS:

- **Use procedures that incorporate the experience and knowledge within the institutions it oversees in developing guidance intended for their use.[56]**

- **Oversee institutions more systematically for compliance with federal assurances, using an appropriate array of mechanisms, including on-site visits by specially trained staff.[57] During site visits, investigator-reviewers should be available for public or confidential interviews with members of the institution's community regarding compliance with federal assurances.**

- **Require from the intramural NIH programs the same assurances and annual reports that are required from other institutions, and monitor NIH accordingly. NIH should have exemplary procedures in place to establish and maintain integrity in intramural research programs, including responses to cases of alleged misconduct and retaliation against whistleblowers.**

- **Avoid, whenever possible, a separate federal investigation as an acknowledgment of the primary responsibility of institutions. DHHS should not reinvestigate or relitigate factual matters if an institution has substantially complied with its procedures and reached findings of misconduct supported by the evidence, unless required to do so as a prerequisite for imposing a federal sanction.**

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55 Office of the Inspector General, DHHS: "Study of the Staffing and Management of the Office of Research Integrity," November 1994.

56 Examples of successful, widely adopted guidance documents using such procedures include the following: *Framework for Institutional Policies and Procedures to Deal with Fraud in Research.* Washington, D.C.: Association of American Universities, National Association of State University and Land-Grant Colleges, Council of Graduate Schools, Nov. 4, 1988 (developed by an interassociation working group); and AAMC Ad Hoc Committee on Misconduct and Conflict of Interest in Research: *Beyond the "Framework": Institutional Considerations in Managing Allegations of Misconduct in Research.* Washington, D.C.: Association of American Medical Colleges, Sept. 1992.

57 ORI now does this only on a selective basis. It has stated that systematic monitoring would exceed its current resources.

- **Publish criteria, under the Secretary's direction, to be used for rejecting institutional findings and for intervening in ongoing institutional procedures that respond to allegations of research misconduct and other professional misconduct.**

- **Develop a specific mechanism for determining: (a) whether, when whistleblowers contact the federal agency directly because they lack faith in the fairness of the institutional process, a fair process can and will take place at an institution; and (b) when and how to intervene when such intervention is deemed appropriate.**

- **Adopt a procedure (analogous to that provided by the Whistleblower Protection Act of 1989 for Civil Service disclosures) in which, once the federal agency receives an institution's investigative report concerning allegations of research misconduct or other forms of professional misconduct, it makes available to the whistleblower relevant portions of the institution's response (except where prohibited by law, and with due concern for confidentiality). The federal agency should allow the whistleblower to comment on the adequacy of that response prior to the Federal Government's decision to accept or reject the report as a resolution of the whistleblower's charges. The final judgment is reserved to the Federal Government.**

Imposing Federal Sanctions

Introduction

Many research institutions are exemplary in fulfilling their responsibilities to preserve scientific integrity and honor their assurances to federal research funders. However, some have been shown to tolerate repeated and fundamental violations of research integrity. Such chronic patterns of unethical behavior by scientists and their institutions can endanger the integrity of federally funded biomedical research and the public health the research is intended to serve.

In the Commission's view, the sanctions imposed by DHHS and ORI for individual and institutional violations related to research misconduct have not always been well matched to the seriousness of specific offenses. These discrepancies appear to stem, in part, from the lack of clear DHHS policy statements regarding both incentives for appropriate behavior and a spectrum of sanctions for levels and types of inappropriate behavior.

The application of sanctions to PHS-funded research institutions should be guided by the following general principles: When institutions follow in good faith their own research integrity assurances, DHHS should not penalize them for acts of their staff. However, when they do not follow their own policies, when they tolerate or ignore retaliation against whistleblowers, allow obstruction of investigations, or tolerate noncompliance with research regulations, institutions should be held accountable. The range of potential sanctions against institutions should include censure, the return of research funds, additional fines, and institutional debarment from DHHS funding.

Recommendations:

The Commission recommends that DHHS:

- **Publicly disclose any instance in which, because an institution did not process a case in good faith, ORI replaced the institution as fact finder in resolving allegations of research misconduct and other forms of professional misconduct.**

- **Require the federal office responsible for adjudication to formulate criteria for the severity of sanctions, and in each case articulate the specific reasons for the choice of sanction.**

- **Use a range of potential sanctions against institutions, including censure, the return of research funds, fines, suspension, and institutional debarment from DHHS funding.**

- **Take enforcement action--after notice and an opportunity for institutional corrective action--to discontinue PHS funding to institutions that lack a system of rules and procedures for complying with the regulations prohibiting research misconduct and other forms of professional misconduct, or that willfully do not follow their own rules and procedures.**

- **Broaden the range of administrative actions applied as sanctions to individuals found guilty of professional misconduct (including research misconduct and obstruction of investigations of such misconduct). The type of sanction used should depend on the seriousness and consequences of the misdeed and any mitigating circumstances. These actions should include reprimands, mandatory supervision of future work, and debarment for varying periods of time. Research misconduct that places human subjects at risk, including data fabrication affecting treatment, should elicit particularly severe sanctions.**

Summary of Recommendations

In keeping with its charge, the Commission on Research Integrity makes the following recommendations to Congress and the Secretary of Health and Human Services:

Definition

•1•

The Commission recommends that the Secretary replace the existing definition of misconduct in science[58] with the definition of research misconduct and definitions of other forms of professional misconduct related to research, to follow. The definition of research misconduct is based on the premise that research misconduct is serious violation of the fundamental principle that scientists be truthful and fair in the conduct of research and the dissemination of its results.

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[58] The Commission does not suggest that other forms of misconduct, such as financial improprieties, are not of serious concern. It has limited its definitional recommendations, however, to areas that are specifically related to the **conduct** of research.

The Federal Government has an interest in professional misconduct involving the use of federal funds in research, as covered by the following definitions:

1. Research Misconduct

Research misconduct is significant misbehavior that improperly appropriates the intellectual property or contributions of others, that intentionally impedes the progress of research, or that risks corrupting the scientific record[59] or compromising the integrity of scientific practices. Such behaviors are unethical and unacceptable in proposing, conducting, or reporting research or in reviewing the proposals or research reports of others.

Examples of research misconduct include but are not limited to the following:

Misappropriation: **An investigator or reviewer shall not intentionally or recklessly**
a. plagiarize, which shall be understood to mean the presentation of the documented words or ideas of another as his or her own, without attribution appropriate for the medium of presentation; or
b. make use of any information in breach of any duty of confidentiality associated with the review of any manuscript or grant application.

Interference: **An investigator or reviewer shall not intentionally and without authorization take or sequester or materially damage any research-related property of another, including without limitation the apparatus, reagents, biological materials, writings, data, hardware, software, or any other substance or device used or produced in the conduct of research.**

Misrepresentation: **An investigator or reviewer shall not with intent to deceive, or in reckless disregard for the truth,**
a. state or present a material or significant falsehood; or
b. omit a fact so that what is stated or presented as a whole states or presents a material or significant falsehood.

2. Other Forms of Professional Misconduct

a. Obstruction of Investigations of Research Misconduct

The Federal Government has an important interest in protecting the integrity of investigations into reported incidents of research misconduct. Accordingly, obstruction of investigations of research misconduct related to federal funding constitutes a form of professional misconduct in that it undermines the interests of the public, the scientific community, and the Federal Government.

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[59] The record encompasses any documentation or presentation of research, oral or written, published or unpublished.

Obstruction of investigations of research misconduct consists of intentionally withholding or destroying evidence in violation of a duty to disclose or preserve; falsifying evidence; encouraging, soliciting or giving false testimony; and attempting to intimidate or retaliate against witnesses, potential witnesses, or potential leads to witnesses or evidence before, during, or after the commencement of any formal or informal proceeding.

b. Noncompliance with Research Regulations

Responsible conduct in research includes compliance with applicable federal research regulations. Such regulations include (but are not limited to) those governing the use of biohazardous materials and human and animal subjects in research.

Serious noncompliance with such regulations after notice of their existence undermines the interests of the public, the scientific community, and the Federal Government and constitutes another form of professional misconduct.

Uniform Federal Definition

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The Commission recommends that the Secretary encourage an interagency task force to develop a common federal definition of research misconduct and other forms of professional misconduct related to research.

Role of Research Institutions and the Federal Government

•3•

The Commission recommends that the Secretary require that each institution applying for or receiving a grant, contract, or cooperative agreement under the Public Health Service Act for research or research training add to its existing misconduct-in-science assurance a third declaration, one certifying that the institution has an educational program on the responsible conduct of research. Through this mechanism, the current NIH research integrity education requirement, now limited to recipients of institutional training grants at NIH-funded institutions, would be augmented by an assurance applied to all individuals supported by PHS research funds.

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The proposed research integrity education assurance should be implemented in the following manner: The assurance should be included in the checklist that accompanies every PHS research or training grant application. The institutional official's signature would signify the institution's compliance with the assurance. In addition, the application would state clearly that the signature of the scientist submitting the application signifies that he/she is familiar with (a) the institution's policies and procedures regarding scientific misconduct; and (b) the institution's educational program on the responsible conduct of research.

•5•

The Secretary should also encourage:

a. **Integration of the explicit teaching of the ethics of science into the classroom, laboratory, and other research sites in precollegiate education as well as in undergraduate and graduate schools; and**

b. **Funding for scholarship, teaching, and research in science ethics. Such funded research should include an experimental audit of the prevalence of data misrepresentation.**[60]

Role of Professional Societies and Codes of Ethics

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The Commission recommends that professional societies each adopt a code of ethics in research and encourage their members to use these codes as a framework for considering emerging ethical issues in science. In addition, professional societies should consider initiating activities that will further promote the ethical conduct of research and professionalism in science.

Responsible Whistleblowing

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The Commission recommends that the Secretary develop regulations guaranteeing the standards expressed in the following statement of principles:

Responsible Whistleblowing: A Whistleblower's Bill of Rights

a. Communication: **Whistleblowers are free to disclose lawfully whatever information supports a reasonable belief of research misconduct as it is defined by PHS policy. An individual or institution that retaliates against any person making protected disclosures engages in prohibited obstruction of investigations of research misconduct as defined by the Commission on Research Integrity. Whistleblowers must respect the confidentiality of sensitive information and give legitimate institutional structures an opportunity to function. Should a whistleblower elect to make a lawful disclosure that violates institutional rules of confidentiality, the institution may thereafter legitimately limit the whistleblower's access to further information about the case.**

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[60] Because this audit would be undertaken solely to establish the prevalence of research misconduct and not to detect dishonest scientists, it should be confidential and its results reported in the aggregate. The results would be used to inform institutions' decisions about monitoring and enhancing the quality of research.

b. Protection from retaliation:[61] **Institutions have a duty not to tolerate or engage in retaliation against good-faith whistleblowers. This duty includes providing appropriate and timely relief to ameliorate the consequences of actual or threatened reprisals, and holding accountable those who retaliate. Whistleblowers and other witnesses to possible research misconduct have a responsibility to raise their concerns honorably and with foundation.**

c. Fair procedures: **Institutions have a duty to provide fair and objective procedures for examining and resolving complaints, disputes, and allegations of research misconduct. In cases of alleged retaliation that are not resolved through institutional intervention, whistleblowers should have an opportunity to defend themselves in a proceeding where they can present witnesses and confront those they charge with retaliation against them, except when they violate rules of confidentiality.**

Whistleblowers have a responsibility to participate honorably in such procedures by respecting the serious consequences for those they accuse of misconduct, and by using the same standards to correct their own errors that they apply to others.

d. Procedures free from partiality: **Institutions have a duty to follow procedures that are not tainted by partiality arising from personal or institutional conflict of interest or other sources of bias. Whistleblowers have a responsibility to act within legitimate institutional channels when raising concerns about the integrity of research. They have the right to raise objections concerning the possible partiality of those selected to review their concerns without incurring retaliation.**

e. Information: **Institutions have a duty to elicit and evaluate fully and objectively information about concerns raised by whistleblowers. Whistleblowers may have unique knowledge needed to evaluate thoroughly responses from those whose actions are questioned. Consequently, a competent investigation may involve giving whistleblowers one or more opportunities to comment on the accuracy and completeness of information relevant to their concerns, except when they violate rules of confidentiality.**

f. Timely processes: **Institutions have a duty to handle cases involving alleged research misconduct as expeditiously as is possible without compromising responsible resolutions. When cases drag on for years, the issue becomes the dispute rather than its resolution. Whistleblowers have a responsibility to facilitate expeditious resolution of cases by good faith participation in misconduct procedures.**

g. Vindication: **At the conclusion of proceedings, institutions have a responsibility to credit promptly--in public and/or in private as appropriate--those whose allegations are substantiated.**

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[61] The Commission on Research Integrity supports the 1989 recommendation by the Institute of Medicine of the National Academy of Sciences stating that universities should "provide mediation and counseling services for faculty, staff and students who wish to express concerns about professionally questionable training or research practices." Institute of Medicine (1989): *The Responsible Conduct of Research in the Health Sciences*, Washington, D.C.: National Academy Press, p. 4.

Every right carries with it a corresponding responsibility. In this context, the Whistleblower Bill of Rights carries the obligation to avoid false statements and unlawful behavior.

Administrative Processes and Investigations

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Regarding the federal investigation of allegations, the Commission recommends that:

a. **The Secretary ensure that the investigation of misconduct and subsequent adjudication are organizationally separated in DHHS, as they are, for example, at the National Science Foundation.**

b. **DHHS ensure that legal, law-enforcement, and scientist-investigator staff participate in each federally conducted investigation and ensure that scientists participate in hearings and appeal procedures.**

c. **Those conducting investigations have subpoena power over persons and documents, subject to specific case-by-case authorization by the Office of the General Counsel.**

d. **The Secretary establish a specific mechanism for reviewing and auditing the record of DHHS in enforcing the laws that prohibit research misconduct and other professional misconduct.**

e. **ORI address as research misconduct those cases that it previously would have dismissed as mere "authorship disputes" or "collaborative disputes," namely, serious cases of alleged plagiarism (which under the proposed definition would be considered "significant misappropriation") among and between collaborators.**

f. **DHHS and institutions deal with retaliation against whistleblowers as rigorously at the inquiry, investigation, and adjudication stages as they do in cases with research and other professional misconduct.**

g. **The Secretary review the current assignment of responsibility for responding to allegations of retaliation against whistleblowers to the ORI Division of Policy and Education and consider placing it in a unit capable of carrying out investigations.**

h. **The Secretary seek, through appropriate channels and procedures, to have the False Claims Act amended because it serves as a disincentive for thorough institutional investigations. The principle should be established that institutions may expeditiously investigate scientific misconduct allegations, protected from adverse use of their findings in litigation, if thorough, competent investigations have been conducted.**

Federal Adjudication

•9•

The Commission recommends that DHHS:

a. Use institutional findings related to misconduct as final and binding if they are supported by the evidence and were obtained through a process that afforded due process and complied with federal regulations and the institution's own policies.

b. Limit any subsequent federal review of a decision reached after ORI has reviewed and accepted an institutional finding of misconduct. That subsequent review should be confined to the existing record rather than a de novo proceeding, except when DHHS proposes to impose a separate federal sanction. In such instances, if the institutional record is not adequate, further fact-finding by ORI may be required, and, upon request, the respondent should receive a trial-like adjudicatory process to review any such further fact-finding.

c. Permit an institution to contest the decision of the Department's reviewing office if that office has reviewed and disapproved an institutional finding of misconduct or nonmisconduct. In addition, the original respondent should be given an opportunity to make a submission to that office in this review process.

The Commission also recommends that the Secretary:

d. Continue to permit a respondent to request a trial-type, de novo hearing when proposed findings of misconduct are based on an ORI investigation. Such hearings should continue to be held before a Research Integrity Adjudication Panel appointed by the Departmental Appeals Board. However, the Secretary should consider steps to strengthen and streamline the process to expedite the proceedings.

e. Require widespread, systematic public disclosure of all outcomes of federal research and research-related professional misconduct cases, with detailed, specific statements of their rationale, in view of the strong public interest in the disclosure of information underlying such cases. In addition, the Secretary should require public disclosure of all factual information developed in misconduct cases that affects the public welfare, unless disclosure is expressly prohibited by law.

Effective Oversight of Assurances and Misconduct Investigations

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The Commission recommends that DHHS:

a. Use procedures that incorporate the experience and knowledge within the institutions it oversees in developing guidance intended for their use.

b. Oversee institutions more systematically for compliance with federal assurances, using an appropriate array of mechanisms including on-site visits by specially

trained staff. During site visits, investigators/reviewers should be available for public or confidential interviews with members of the institution's community regarding compliance with federal assurances.

c. Require from the intramural NIH programs the same assurances and annual reports that are required from other institutions, and monitor NIH accordingly. NIH should have exemplary procedures in place to establish and maintain integrity in intramural research programs, including responses to cases of alleged misconduct and retaliation against whistleblowers.

d. Avoid, whenever possible, a separate federal investigation as an acknowledgment of the primary responsibility of institutions. DHHS should not reinvestigate or relitigate factual matters if an institution has substantially complied with its procedures and reached findings of misconduct supported by the evidence, unless required to do so as a prerequisite for imposing a federal sanction.

e. Publish criteria, under the Secretary's direction, to be used for rejecting institutional findings and for intervening in ongoing institutional procedures that respond to allegations of research misconduct and other professional misconduct.

f. Develop a specific mechanism for determining: (a) whether, when whistleblowers contact the federal agency directly because they lack faith in the fairness of the institutional process, a fair process can and will take place at an institution; and (b) when and how to intervene when such intervention is deemed appropriate.

g. Adopt a procedure (analogous to that provided by the Whistleblower Protection Act of 1989 for Civil Service disclosures) in which, once the federal agency receives an institution's investigative report concerning allegations of research or other forms of professional misconduct, it makes available to the whistleblower relevant portions of the institution's response (except where prohibited by law, and with due concern for confidentiality). The federal agency should allow the whistleblower to comment on the adequacy of that response prior to the Federal Government's decision to accept or reject the report as a resolution of the whistleblower's charges. The final judgment is reserved to the Federal Government.

Imposing Federal Sanctions

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The Commission recommends that DHHS:

a. Publicly disclose any instance in which, because an institution did not process a case in good faith, ORI replaced the institution as fact finder in resolving allegations of research misconduct and other forms of professional misconduct.

b. Require the federal office responsible for adjudication to formulate criteria for the severity of sanctions, and in each case articulate the specific reasons for the choice of sanction.

c. **Use a range of potential sanctions against institutions, including censure, the return of research funds, fines, suspension, and institutional debarment from DHHS funding.**

d. **Take enforcement action--after notice and an opportunity for institutional corrective action--to discontinue PHS funding to institutions that lack a system of rules and procedures for complying with the regulations prohibiting research misconduct and other forms of professional misconduct, or that willfully do not follow their own rules and procedures.**

e. **Broaden the range of administrative actions applied as sanctions to individuals found guilty of professional misconduct (including research misconduct and obstruction of investigations of such misconduct). The type of sanction used should depend on the seriousness and consequences of the misdeed and any mitigating circumstances. These actions should include reprimands, mandatory supervision of future work, and debarment for varying periods of time. Research misconduct that places human subjects at risk, including data fabrication affecting treatment, should elicit particularly severe sanctions.**

Appendix A

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

Charter

Commission on Research Integrity

Purpose

The Commission on Research Integrity shall develop recommendations for the Secretary of Health and Human Services on the administration of Section 493 of the Public Health Service Act as amended by and added to by Section 161 of the NIH Revitalization Act of 1993.

Authority

Section 162 of Public Law 103-43, the NIH Revitalization Act of 1993. The Commission is also governed by the provisions of Public Law 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formulation and use of advisory committees.

Function

The Commission shall advise the Secretary on issues of research misconduct and integrity such as a new definition of research misconduct, an assurance process for institutional compliance with DHHS regulations, processes by which to respond to and monitor related administrative processes and investigations, and development of a regulation to protect whistleblowers.

Structure

The Commission shall be composed of 12 members, including the Chair. Members shall be appointed by the Secretary. Not more than three members of the Commission may be officers or employees of the United States Government.

Of the members of the Commission

- three shall be scientists with substantial accomplishments in biomedical or behavioral research;
- three shall be individuals with experience in investigating allegations of misconduct with respect to research;
- three shall be representatives of institutions of higher education at which biomedical or behavioral research is conducted; and
- three shall be individuals who are not described above. Of these at least one shall be an attorney and one shall be an ethicist.

Members shall be invited to serve for the duration of the Commission; terms of more than two years are contingent upon the renewal of the Commission by appropriate action prior to its termination.

Subcommittees composed solely of members of the parent commission may be established as necessary. Where appropriate, advice might be sought by the Commission or subcommittee(s) from special consultants. The Department Committee Management Officer shall be notified upon establishment of each subcommittee, and shall be provided information on its name, membership, function, and estimated frequency of meetings.

Management and support services shall be provided by the Division of Policy and Education, Office of Research Integrity.

Meetings

Meetings shall be held approximately six times a year at the call of the Chair with the advance approval of a Government official who shall approve the agenda. A Government official shall be present at all meetings.

Meetings shall be open to the public except as determined otherwise by the Secretary; notice of all meetings shall be given to the public.

Meetings shall be conducted, and records of proceedings kept, as required by applicable laws and Departmental regulations.

Compensation

Members of the Commission may not receive compensation for services on the Commission. Members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Commission in accordance with Standard Government Travel Regulations.

Annual Cost Estimate

The estimated annual cost for operating the Commission, including travel and reimbursement for other allowable expenses but excluding staff support, is $206,168. The estimated annual person years of staff support required are .6, at an estimated annual cost of $43,403.

Reports

Not later than 120 days after the date on which the Commission is established, the Commission shall prepare and submit to the Secretary of Health and Human Services, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate, a report containing recommendations as required by Section 162 (e) of the NIH Revitalization Act of 1993.

In addition, an annual report shall be submitted to the Secretary no later than December 31 of each year, which shall contain, at a minimum, the Commission's function, a list of members and their business addresses, the dates and places of meetings, and a summary of the Commission's activities and recommendations made during the fiscal year. A copy of all reports shall be provided to the Department Committee Management officer.

Termination Date

Unless renewed by appropriate action prior to its expiration, the charter of the Commission on Research Integrity will terminate two years from the date of approval.

Approved:

November 4, 1993

Donna E. Shalala
Secretary

Appendix B
Commission Meetings/Hearings

Meeting 1:	Hubert Humphrey Bldg., Washington, DC June 20, 1994
Meeting 2:	Crystal Gateway Marriott, Arlington, VA July 25, 1994
Meeting 3:	Crystal Gateway Marriott, Arlington, VA August 31, 1994
Meeting 4:	Stouffer Renaissance Hotel, Arlington, VA October 19, 1994
Meeting 5:	National Institutes of Health, Bethesda, MD November 7, 1994
Meeting 6:	Washington Dulles Airport Marriott, Chantilly, VA December 1-2, 1994
Meeting 7:	Crystal Gateway Marriott, Arlington, VA January 5, 1995
Meeting 8:	University of California at San Francisco, CA February 9-10, 1995
Meeting 9:	De Paul University, Chicago, IL March 9-10, 1995
Meeting 10:	Harvard Medical School, Boston, MA April 10-11, 1995
Meeting 11:	University of Alabama at Birmingham, ALA May 4-5, 1995
Meeting 12:	Washington Dulles Airport Marriott, Chantilly, VA June 26-27, 1995
Meeting 13:	Belmont Conference Center, Elkridge, MD July 30-August 1, 1995

Meeting 14:	Washington Dulles Airport Marriott, Chantilly, VA September 18-19, 1995
Meeting 15:	National Institutes of Health, Rockville, MD October 24-25, 1995

Appendix C
Structure and Function of the DHHS Office of Research Integrity (ORI)[1]

ORI is an independent group within DHHS; its Director reports to the Secretary. Created from a merger of two offices within DHHS,[2] ORI's mission is to oversee and direct PHS research integrity activities, which it does primarily through its handling of scientific misconduct investigations. In fiscal year 1994, ORI had a total operating budget of $4 million and maintained a staff of about 50 employees; currently [August 1995] it has 43 employees.[3]

Although ORI investigates misconduct related to intramural research programs, about three-fourths of its caseload in 1994 related to oversight of extramural integrity reviews conducted by grantee institutions. ORI generally monitors progress of an extramural investigation and reviews the institution's final report.[4] ORI also presents the results of misconduct investigations in administrative hearings before the DHHS Departmental Appeals Board[5] if ORI's decisions are challenged.

Besides its investigative function, ORI performs other research integrity activities. These efforts include developing model policies and procedures for handling allegations of scientific misconduct; evaluating institutional policies and processes for conducting investigations; investigating whistleblower retaliation complaints; and promoting scientific integrity through educational initiatives and other collaborations with universities, medical schools, and professional societies.

Most allegations of scientific misconduct are made directly to the institutions conducting the research. Responding to an allegation involves a two-step process: an inquiry and, if necessary, an investigation. Institutions have the primary responsibility for responding to allegations involving extramural research; ORI's role in these instances is usually that of reviewing the

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[1] Excerpted from "Health Research Misconduct: HHS' Handling of Cases is Appropriate, but Timeliness Remains a Concern," United States General Accounting Office Report to Congressional Requesters, August 1995, pp. 3-5.

[2] ORI replaced the Office of Scientific Integrity, within the NIH Office of the Director, and the Office of Scientific Integrity Review, within the Office of the Assistant Secretary for Health. The NIH Revitalization Act of 1993 designated ORI as an independent entity within HHS.

[3] The ORI budget is $3.86 million for FY 95 and potentially $3.83 million for FY 96. It had 39 employees at the end of FY 95.

[4] ORI may conduct extramural investigations in cases where the institution is unwilling or unable to do so or if the case involves special circumstances such as multisite clinical trials.

[5] Persons found by ORI to have engaged in scientific misconduct can appeal such decisions to this unit within HHS.

institution's investigation report. ORI generally does not review institutional inquiries because an institution is not required to inform ORI that an inquiry is under way nor to submit a report at its conclusion.

ORI does, however, review all investigations. Institutions must inform ORI when they begin an investigation and submit a report at its conclusion. ORI reviews the final report, the supporting materials, and the determinations to decide whether the investigation has been performed with sufficient objectivity, thoroughness, and competence.[6]

ORI plays a more direct role in responding to scientific misconduct allegations in PHS intramural research programs. It reviews all misconduct inquiries conducted by PHS agencies and conducts all investigations when they are needed. ORI's handling of intramural scientific misconduct cases can be a complex undertaking that may involve collaborations among ORI staff, other agencies, and institutions performing research.

In general, for intramural allegations, the review process begins when an individual making an allegation (referred to as a complainant) alleges to either ORI or a PHS agency that another researcher (a respondent) committed scientific misconduct.[7] If a misconduct allegation is made to ORI, an investigator within ORI's Division of Research Investigations (DRI) conducts an initial screening primarily to determine if PHS funding is involved and whether the allegation falls within the PHS definition of scientific misconduct. Allegations that do not meet these criteria result in no action or are referred outside of ORI for consideration.[8]

When allegations do fall within PHS' definition of misconduct, ORI forwards them to the PHS agency that funded the research and directs that agency to conduct a formal inquiry. This involves gathering information--including interviewing the subjects involved--to determine the nature of evidence available to support the allegation. ORI investigators may monitor inquiries and advise PHS agencies on matters such as procedures for sequestering laboratory research notebooks. They often directly assist the agency in sequestering the research data and other evidence.

If the results of an inquiry suggest that misconduct may have occurred, ORI then opens a full investigation to determine the existence and magnitude of misconduct. An investigation could involve an extensive review of experiments and other scientific data as well as interviews with all parties involved with the research. The ORI investigator assigned to the case may seek assistance from a staff bio-statistician and other in-house experts. Also, ORI may elicit assistance from outside scientists who have expertise in subject areas that ORI staff lack.

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[6] ORI may accept or reject the findings, ask for additional information, request further investigation, or begin its own investigation.

[7] The PHS definition of misconduct in science is fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. The definition does not include honest error or honest differences in interpretation or judgment of data. Moreover, according to ORI documents and officials, disputes over credit or authorship generally do not fall under the definition of scientific misconduct.

[8] After initial review and screening, only about 18 percent of the allegations received in 1994 led to a formal inquiry or investigation. About 30 percent resulted in a detailed allegation assessment or formal referral to other HHS offices, including the Food and Drug Administration, the Office for Protection from Research Risks, and the Inspector General.

Investigators produce a written report with findings. The report is reviewed by ORI management, its legal staff, and the respondent before being issued by the ORI Director. For investigations that result in a finding of misconduct, the ORI Director, in combination with the DHHS debarring official, determines possible sanctions against the respondent, which may include debarment from receiving federal grant or contract funds for a specified period.[9]

[9] A respondent charged with misconduct may be required to correct the relevant research literature, withdraw from participating in PHS-funded research and PHS advisory committees, or a combination of these and other actions.

Appendix D
Commentary on Offenses Described in the Definition of "Research Misconduct"

Introduction

For purposes of research funded by the Public Health Service, the current definition of "misconduct" survives in a 1989 regulation describing the Office of Scientific Integrity. Such definition reads as follows:

> Misconduct or Misconduct in Science means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.[1]

This regulation requires amendment to reflect the replacement in 1992 of the Office of Scientific Integrity by a differently structured Office of Research Integrity. Even more urgent is the question of the adequacy of the foregoing definition. Among criticisms of it has been the conclusion of a panel of the National Academy of Sciences that the lack of a clear definition of "actions highly detrimental to the integrity of the research process" has "impeded development of effective institutional oversight and government policies and procedures . . ."[2]

The National Institutes of Health Revitalization Act of 1993, which provided for creation of the Commission on Research Integrity, directed the Secretary of Health and Human Services to promulgate a definition of "research misconduct" within 90 days after submission of the Commission's report.[3] The definition of "research misconduct" proposed by the Commission prohibits overt forms of intellectual dishonesty that are inconsistent with the ethical principles with which the definition begins. In light of the significant number of issues posed by any formulation of misconduct offenses, the substantial history of discussion to date, and the

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[1] 42 *C.F.R.* § 50.102. Interim procedures that have not been codified appear at 56 *F.R.* 27384 (June 13, 1991) and 57 *F.R.* 53125 (November 6, 1992).

[2] National Academy of Sciences, Panel on Scientific Responsibility and the Conduct of Research: *Responsible Science: Ensuring the Integrity of the Research Process.* Washington, D. C.: National Academy Press, 1992, p. 25.

[3] P.L. 103-43 § 165 [a][2].

importance of a clear rationale for regulatory change in any notice of proposed rulemaking, the following further explains the offenses set forth in the definition proposed by the Commission. It discusses the legal context of concepts incorporated in the definition and contrasts them with alternatives, especially the provisions of the current PHS definition.[4]

Scope and Jurisdiction: The definition applies to acts and omissions that occur in "proposing, conducting or reporting research or in reviewing the proposals or research reports of others." The investigators and reviewers may include students and technicians as well as senior investigators, as the facts of any case may reveal. The actual conduct of persons and, where the definition so provides, their mental state, control the extent of persons' responsibility. The definition does not imply attribution of the acts or omissions of one person to another.

The scope of activities as well as the persons responsible are subject to the limits of applicable jurisdiction. Assurances of misconduct procedures are expected of institutional applicants for grants. The statutory authority applicable to ORI, Section 493 of the Public Health Service Act[5], both before and after amendment[6], provides for enforcement action by the Secretary against misconduct only "in connection with projects for which funds have been made available under this Act." Accordingly, federal jurisdiction to enforce the definition of "research misconduct" is predicated on receipt of grant funds, with the exception that the reference to "proposing" research reaffirms present ORI policy to recognize the entire contents of any application or report to the PHS as within the scope of sanctionable conduct. For example, a misrepresentation in the bibliography of a research paper where neither that research nor preparation of the paper has received PHS funding would not fall within the reach of "research misconduct"; the same misrepresentation of previous work accompanying an application for a PHS grant would fall within the jurisdictional reach.

The current regulation requires that grantees "foster a research environment that discourages misconduct in all research and that deals forthrightly with possible misconduct . . . ," and that records must be retained.[7] The Commission's recommendations concerning an expanded program of assurances reflect the primacy of institutional activity in preventing and adjudicating misconduct. It thus may be expected that institutions will investigate charges of misconduct unrelated to PHS-funded research. The definition of "research misconduct" does not incorporate institutional rules, whose content will rest with the respective institutions and vary among them, as defining or interpreting offenses. The self-contained offenses described in the Commission's definition constitute that subset of conduct that is subject to federal sanctions.

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[4] The following discussion anticipates but does not presume that the proposed definition will in due course appear within a comprehensive regulation, incorporating all regulations and procedures of ORI, that will replace the regulation of 1989.

[5] 42 U.S.C. § 289b.

[6] By the NIH Revitalization Act of 1993, P. L. 103-43 §161.

[7] 42 *C.F.R.* § 50.105; 45 *C.F.R.* Part 74, Subpart D.

While the jurisdictional reach is clearly limited to matters involving PHS funds, the language of the definition, containing no reference to the PHS, is intended to be suitable for all federal agencies that support research. In contrast with an array of conflicting definitions across agencies, uniformity in the definition of "research misconduct" is seen by the Commission as an aid to clarity and education within institutions.

Elements of Offenses

Misappropriation

The proposed definition replaces "plagiarism" with the following:

> *Misappropriation.* An investigator or reviewer shall not intentionally or recklessly
> (a) plagiarize, which shall be understood to mean the presentation of the documented words or ideas of another as his or her own, without attribution appropriate for the medium of presentation, or
> (b) make use of any information in breach of any duty of confidentiality associated with the review of any manuscript or grant application.

Since it is not the responsibility of the Secretary to press private grievances on behalf of those who report alleged misconduct, copyright infringement per se is not appropriately investigated by ORI. The scholarly concept of integrity about the work of others is, in any event, broader than copyright infringement. The offenses of plagiarism and misuse of the work of another, embodied in the definition's reference to "the documented words or ideas of another," follow the distinction between the two offenses developed by the American Historical Association (AHA), which has had occasion to study such questions in recent years. In its words,

> The *misuse* of the writings of another author, even when one does not borrow the exact wording, can be as unfair, as unethical, and as unprofessional as plagiarism. . . .
> . . . . The clearest abuse is the use of another's language without quotation marks and citation. More subtle abuses include the appropriation of concepts, data, or notes all disguised in newly crafted sentences, or reference to a borrowed work in an early note and then extensive further use without attribution. All such tactics reflect an unworthy disregard for the contributions of others.[8]

The reference to "attribution appropriate to the medium" reflects the circumstance that the expectation of originality may be less, for example, for an introductory textbook, in which style may result in less attribution, than in a research paper. This contrast has been noted by both the AHA and the American Association of University Professors.[9] The requirement of intent to

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[8] "Statement on Standards of Professional Conduct," pp. 13-14 (1993).

[9] *Ibid.*; American Association of University Professors, "Statement on Plagiarism" (1989).

deceive or recklessness is discussed below with respect to misrepresentation; the same rationale applies to its inclusion here. The definition thus follows the current regulation in prohibiting plagiarism, but (1) it provides a definition of the concept, and (2) it also embraces, by the reference to "ideas," the offense of misuse.

The prohibition on breach of any duty of confidentiality is not intended to permit misconduct investigations to be vehicles for the enforcement of contract claims, particularly with respect to confidentiality and trade secret agreements between scientists and commercial parties. It does recognize that one who undertakes to keep a confidence and breaks it may evince lack of trustworthiness that is relevant to eligibility for future PHS grants.

Interference

The definition also prohibits the following:

> *Interference:* An investigator or reviewer shall not intentionally and without authorization take or sequester or materially damage any research-related property of another, including without limitation the apparatus, reagents, biological materials, writings, data, hardware, software, or any other substance or device used or produced in the conduct of research.

The defined offense of "interference" embraces the taking or damaging of items used in the research of another. A recent case of NIH intramural misconduct consisting of property damage was litigated under Maryland law[10] because, for such conduct, the only successful remedies to date are the tort laws of various States. These vary. Such acts are so clearly antithetical to integrity in research as to be an appropriate basis for the sanctions imposed for research misconduct.

Misrepresentation

The definition replaces "fabrication" and "falsification" with the following:

> *Misrepresentation.* An investigator or reviewer shall not with intent to deceive, or in reckless disregard for the truth,
> (a) state or present a material or significant falsehood, or
> (b) omit a fact so that what is stated or presented as a whole states or presents a material or significant falsehood.

Precedents and Nature of Conduct

This definition of "misrepresentation" consciously excludes the common law elements of reliance, causation, or damages, which are unnecessary--indeed inappropriate--in the context of research misconduct.

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[10] *United States* v. *Arora*, 860 F. Supp. 1091 (D. Md. 1994).

The definition subsumes the terms "falsification and fabrication" in the current regulation and includes an investigator's statement or presentation of a material or significant falsehood, by act or omission. Omission of relevant data that materially affects an inference from the data presented can be as culpable as an explicit misstatement. The facts of each case must be scrutinized to ascertain whether, taken as a whole, a statement or presentation contains a material falsehood as a result of any challenged omission.

The verb "present" makes clear that the concept extends to nonprose communications, as in tables and graphs of data, and to noncommunicative acts, as, for example, in adding a dye to a solution, or assembling a residue, with the intent falsely to suggest some process or result that is not occurring.

Mental State

The definition follows the interpretation of the current definition by the Departmental Appeals Board to the effect that intent to deceive is an element of "research misconduct" because the current definition excludes "honest error."[11] The exclusions in the present definition of "honest error" and "honest differences in interpretations or judgments of data" are superseded and rendered unnecessary in the proposed definition by the explicitly stated elements of intent to deceive and recklessness and by the explicit reference to "fact" in the definition of "misrepresentation."

Conduct that is merely careless or inadvertent is not proscribed as "research misconduct." It is intended that such conduct continue to be addressed by the high standards of grant application review, institutional and professional standards for appointment, promotion, publication, and other incentives.

One whose acts or omissions go beyond carelessness to recklessness may reasonably be said to display insufficient trustworthiness for purposes of being eligible for PHS grant support.

Materiality and Significance

The extent of harm is an element of torts and crimes. Without condoning the undesirability of immaterial wrongs, it is appropriate that a system of sanctions be invoked only for material wrongs. Quality in research, on the other hand, depends in many instances on meticulous attention to fine detail. The concept of "material or significant" must be refined for the scientific context from case to case. "Material" and "significant," one a familiar legal standard, the other a more common term in scientific discourse, are here intended to be synonymous. One indicator of whether an item is material or significant may be whether it or its absence would be reasonably likely to affect the plausibility, reproducibility, or eligibility for funding of data, procedures, or conclusions.

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[11] *In re Popovic*, Research Integrity Adjudications Panel, Departmental Appeals Board (No. A-93-100), Decision No. 1446, November 3, 1993.

Matters Not Included in the Definition

1. In general, crimes reflecting moral turpitude and other torts are not included in "research misconduct," which is confined to matters peculiar to research. Nor is there included misuse of grant funds or other financial wrongdoing. Such matters may be pursued by other agencies to the extent that they constitute violations of applicable law and regulations.

2. The offenses defined are not graduated. It remains properly a matter of enforcement policy that, to the extent practicable, sanctions be applied evenly from respondent to respondent based on the extent of misconduct established.

3. No change is indicated in the standard for burden of proof applied by the Departmental Appeals Board, which is that of "a preponderance of the evidence."

4. The "deviation" phrase in the present definition has been or could be criticized on several grounds. These include: (1) it is vague because it refers to norms of conduct that are not in fact established;[12] (2) it effects an invalid delegation of executive authority to private parties;[13] and (3) as a matter of policy, it does not give scientists notice of the conduct proscribed. The Federation of American Societies for Experimental Biology (FASEB) also argued before the Commission that such phrase violates Executive Order No. 12866 (September 30, 1993), which requires an agency, as a precondition of any regulation, to "identify the problem" that the regulation would purport to redress; the Director of ORI testified that the "deviation" phrase has not proven necessary to the prosecution of any case. The definition of "research misconduct" has not been reviewed by any federal court, and hence the validity of the foregoing legal objections has not been resolved.

With respect to the breadth for which the "deviation" phrase was designed, the proposed definition is considerably more inclusive than the current. The former includes omissions within misrepresentation, introduces misuse alongside the literal transcription that is plagiarism, adds a new offense of interference, and penalizes recklessness as well as intentional conduct. This breadth and the specificity of the proposed definition obviate need for the "deviation" phrase. The ability to amend ORI's regulations protects against the possibility that the proposed definition might later appear to omit mention of some wrongful conduct. The phrase "include but are not limited to" that precedes the definitions of misappropriation, interference, and misrepresentation invites the Secretary by future regulation to close any gap that may emerge between such offenses and later discerned wrongs.

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12 *Carter* v. *Carter Coal Co.*, 298 U. S. 238 (1936), and *Schechter Poultry Corp. v. U. S.*, 295 U. S. 495 (1935). See also *Lime & Avocado Growers, Inc. v. Paul*, 373 U. S. 132, 150-1 (1963).

13 See *Connally* v. *General Construction Co.*, 269 U.S. 385, 391 (1926), *Lanzetta v. New Jersey*, 306 U.S. 451 (1939), and *Kolender v. Lawson*, 461 U.S. 352 (1983).

Appendix E
Draft Whistleblower Protection Guidelines

October 30, 1995

ORI GUIDELINES FOR INSTITUTIONS AND WHISTLEBLOWERS: RESPONDING TO POSSIBLE RETALIATION AGAINST WHISTLEBLOWERS IN EXTRAMURAL RESEARCH

Introduction

The Office of Research Integrity (ORI), Department of Health and Human Services (DHHS), strongly believes in the importance of protecting whistleblowers who make good-faith allegations of scientific misconduct to ORI or appropriate institutional authorities. In particular, ORI is committed to protecting good- faith whistleblowers from retaliation by covered institutions and their members.

By regulation, each extramural entity that applies for a biomedical or behavioral research, research-training, or research-related grant or cooperative agreement under the Public Health Service (PHS) Act must establish policies and procedures that provide for "undertaking diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations." 42 C.F.R. § 50.103(d)(13).

Although the regulation does not provide specific direction on how to protect whistleblowers, ORI has determined that adherence to the policies and procedures set forth in these Guidelines is one method of satisfying the requirements of the regulation. ORI will recognize an institution's substantial conformity with these Guidelines as meeting the whistleblower protection requirement of 42 C.F.R. § 50.103(d)(13). Specifically, each institution which substantially adheres to Sections IV and V of these Guidelines in responding to whistleblower retaliation complaints will be considered in technical compliance with the regulatory whistleblower protection requirement.

However, institutions are free to disregard these Guidelines and adopt other procedures that conform to the regulatory requirement.

If an institution elects to adopt these Guidelines, it must abide by each provision that uses the operative word "shall." On the other hand, provisions which employ the words "should" or "may" are merely practical suggestions. An institution will not be out of conformity with the Guidelines if it fails to carry out these recommendations. Rather, an institution may substitute

for these suggested provisions alternative procedures that are consistent with the mandatory provisions of these Guidelines and the regulatory whistleblower protection provisions.

In addition to the requirements of 42 C.F.R. § 50.103(d)(13), ORI encourages covered institutions to adopt policies and procedures that conform to PHS Act § 493(e), a whistleblower protection statute enacted by § 163 of the National Institutes of Health Revitalization Act of 1993, although § 493 has not been implemented by regulation at the time of this publication. Besides protecting good-faith allegations of scientific misconduct, PHS Act § 493(e) mandates the protection of whistleblowers for (1) good-faith allegations of an inadequate institutional response to scientific misconduct allegations and (2) good-faith cooperation with investigations of such allegations. The statute covers allegations of misconduct which involve research or research-related grants, contracts or cooperative agreements under the PHS Act.

ORI also encourages institutions to adopt principles consistent with the Whistleblower's Bill of Rights recommended by the Commission on Research Integrity and to foster institutional commitment to those principles. The specific principles of the Whistleblower's Bill of Rights are as follows:

(1) Whistleblowers have the freedom to disclose lawfully information that evidences a reasonable belief of research misconduct,

(2) Institutions have a duty not to tolerate or engage in retaliation against good-faith whistleblowers,

(3) Institutions have a duty to provide fair and objective procedures for the examination and resolution of complaints, disputes and allegations of research misconduct,

(4) Institutions have a duty to implement procedures that are not tainted by partiality arising from personal or institutional conflict of interest or other sources of bias,

(5) Institutions have a duty to elicit and evaluate fully and objectively information about concerns raised by the whistleblower,

(6) Institutions have a duty to handle cases involving alleged research misconduct as expeditiously as possible without compromising responsible resolutions, and

(7) At the conclusion of proceedings, institutions have a responsibility to credit promptly, in public and/or in private as appropriate, those whose allegations are substantiated.

These Guidelines are consistent with the rights and responsibilities enumerated in the Whistleblower's Bill of Rights.

While compliance with these Guidelines will satisfy the existing regulatory requirements at 42 C.F.R. § 50.103 (d)(13). This publication does not bind the Department in any way as to the substantive provisions of the forthcoming new regulation implementing the whistleblower protection statute, PHS Act § 493(e).

Purpose

The purpose of these Guidelines is to set forth ORI's suggested approach for handling whistleblower retaliation cases which arise at covered institutions. Substantial adherence to the Guidelines in each whistleblower case affords a "safe harbor" in which conforming institutions will be deemed in compliance with § 50.103(d)(13) of the scientific misconduct regulation. Although nonconformity with the specific procedures of these Guidelines does not by itself indicate a regulatory infraction, ORI may review those cases which do not abide by these Guidelines to determine whether an institution has taken diligent efforts to protect the positions and reputations of good faith whistleblowers in compliance with the existing regulatory requirement.

These Guidelines also provide information to whistleblowers on an appropriate method of submitting retaliation complaints and subsequent procedures for resolving the complaints. ORI encourages whistleblowers to refer institutions to these Guidelines when making specific complaints of retaliation.

These Guidelines apply to all instances of possible retaliation against whistleblowers whose allegation of scientific misconduct is covered by 42 C.F.R. Part 50, Subpart A.

Definitions

"Adverse action" means any action taken by a covered institution or its members which negatively affects the terms or conditions of the whistleblower's status at the institution, including but not limited to his or her employment, academic matriculation, awarding of degree, or institutional relationship established by grant, contract or cooperative agreement.

"Allegation" means any disclosure, whether by written or oral statement, or any other communication, to an institutional, a Department of Justice (DOJ), or a DHHS official, that a covered institution or member thereof has engaged in scientific misconduct. Allegations made to any of the above officials may include communications to Congress.

"Arbitration" means the process described in this Part through which an unresolved dispute regarding whistleblower retaliation is submitted to an arbitrator for a final and binding decision.

"Arbitrator" means one or more impartial persons selected according to the rules of a designated arbitration association who shall hear and decide whistleblower retaliation complaints under this Part.

"Covered institution" means any entity, whether individual or corporate, which applies for or receives funds under a research, research-training, or research-related grant or cooperative agreement under the PHS Act.

"Deciding official" means the official designated by the administrative head of a covered institution to make a final institutional determination as to whether retaliation occurred.

"Good faith allegation" means an allegation of scientific misconduct made with a belief in the truth of the allegation which a reasonable person in the whistleblower's position could hold based upon the facts. An allegation is not in good faith if made with reckless disregard for or willful ignorance of facts that would disprove the allegation.

"Institutional member, or member" means a person who is employed by, affiliated with under a contract or agreement, or under the control of a covered institution. Institutional members include but are not limited to administrative, teaching and support staff, researchers, clinicians, technicians, fellows, students, and contractors and their employees.

"Office of Research Integrity (ORI)" means the office to which the Secretary has delegated responsibility for addressing scientific misconduct issues related to PHS activities, including the protection of good-faith whistleblowers.

"Responsible official" means the official designated by and reporting to the administrative head of a covered institution to establish and implement the institution's whistleblower policies.

"Retaliation" means any adverse action or credible threat of an adverse action taken by a covered institution, or member thereof, in response to a whistleblower's good-faith allegation of scientific misconduct.

"Scientific misconduct" means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

"Whistleblower" means an individual who makes an allegation or indicates an intent to make an allegation or what is perceived to be an allegation while a member of the institution at which the alleged scientific misconduct occurred.

Processing Whistleblower Retaliation Complaints

Responsible Official

1. Covered institutions shall designate a "responsible official" to establish and implement the institution's whistleblower policies according to 42 C.F.R. §50.103(d)(13) and these Guidelines. The responsible official also serves as a liaison between the institution and ORI for transmitting such information as ORI may require.

2. The responsible official shall be free of any real or apparent conflicts of interest in any particular case.

3. If involvement of the responsible official in a particular case creates a real or apparent conflict of interest with the institution's obligation to protect good faith whistleblowers, and the conflict cannot be satisfactorily resolved for that case, the administrative head shall appoint a substitute responsible official who has no conflict of interest.

Notice of Institutional Policy

The institution shall provide to all its members notice of its whistleblower policies and these Guidelines with Appendices (Whistleblower's Bill of Rights and Attachment to this guideline). The notice shall include the requirement set forth below regarding a whistleblower's deadline for filing a retaliation complaint. The institution's policies and these Guidelines shall be either disseminated or be publicized and made readily available to all institutional members.

Filing Complaints

1. A whistleblower who wishes to receive the procedural protections described by these Guidelines shall file his or her retaliation complaint with the responsible official at the appropriate institution within 180 days[1] from the date the whistleblower became aware or should have become aware of the alleged adverse action. Covered institutions shall review and resolve all whistleblower retaliation complaints and should do so within 180 days after receipt of the complaint. If the whistleblower fails to receive an institutional response to the complaint in accordance with these Guidelines within ten (10) working days[2], the whistleblower may file the retaliation complaint directly with ORI at the following address:

Office of Research Integrity
Division of Policy and Education
5515 Security Lane, Suite 700
Rockville, MD 20852

Telephone: (301) 443-5300
Fax: (301) 594-0042

ORI will forward such complaints to the institution's responsible official for appropriate action.

2. In addition to prospective complaints, institutions may apply these Guidelines to complaints of retaliation made prior to the effective date of the institution's adoption of these Guidelines.

3. The retaliation complaint must include a description of the whistleblower's scientific misconduct allegation and the asserted adverse action, or threat thereof, against the whistleblower, by the institution or its members in response to the allegation. If the retaliation complaint is incomplete, the responsible official shall describe to the whistleblower what additional information is needed in order to meet the minimum requirements of a complaint under this Part.

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1 The institution may establish a longer period of time.

2 The institution may establish a shorter period of time.

Responding to Complaints

1. Upon receipt of a whistleblower retaliation complaint, the responsible official shall notify the whistleblower of receipt within ten (10) working days[3] after receipt. The notice shall also inform the whistleblower of which process under Section V of the Guidelines the institution proposes to follow in resolving the retaliation complaint and the necessary actions by the whistleblower required under that process. The notice shall also notify the whistleblower of his/her choice of responses listed below.

2. The whistleblower may raise any concerns about the proposed process and the institution may modify the process in response the whistleblower's concerns.

3. The whistleblower has five working days from the date of the initial notification in Part 1 above to

a. accept the proposed process, although the whistleblower may also submit documentation for the official record about any concerns he/she may have about the proposed process; or

b. not accept the proposed process and may seek other remedies.

4. If the whistleblower does not accept the proposed process, the institution may, but is not required to, propose the alternative option under Section V of the Guidelines.

5. The institution shall notify ORI of any whistleblower retaliation complaint it receives within ten (10) working days[4] after receipt of the complaint.

Interim Protections

1. At any time before the merits of a whistleblower retaliation complaint have been fully resolved, the whistleblower may submit a written request to the responsible official to take interim actions to protect the whistleblower against an existing adverse action or credible threat of an adverse action by the institution or member.

2. Based on the available evidence, the responsible official shall make a determination of whether to provide interim protections and shall advise the whistleblower of its decision in writing. Documentation underlying the decision whether to provide interim protections shall become part of the record of the complaint. When the whistleblower retaliation complaint is fully resolved, any temporary measure taken to protect the whistleblower shall be discontinued or replaced with permanent remedies.

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[3] The institution may establish a shorter period of time consistent with footnote 2.

[4] The institution may establish a shorter period of time.

Resolving Complaints

1. For each whistleblower retaliation complaint received, a covered institution shall adhere to one of the two alternative processes for resolving the whistleblower retaliation complaint, or settle the complaint, as described below.

2. Whichever process is elected shall be implemented in a timely fashion. The process should be completed within 180 days of the date the complaint is filed, unless the whistleblower agrees to an extension of time. The institution shall promptly report the final outcome of either process or any settlement to ORI.

3. If the whistleblower declines the institution's proposed process according to these Guidelines, he/she may pursue any other legal rights available to the whistleblower for resolution of the retaliation complaint. However, ORI will deem the institution to have met its obligation under 42 C.F.R. § 50.103(d)(13) and will not pursue the whistleblower complaint further.

Option A: Institutional Investigation

1. If the institution elects Option A, the institution shall conduct an investigation of the whistleblower retaliation complaint according to these Guidelines and implement appropriate administrative remedies consistent with the investigation's finding and institutional decision thereon.

2. An investigation of whistleblower retaliation shall be timely, objective, thorough, and competent. The investigation should be conducted by a panel of at least three (3) individuals appointed by the responsible official. The members of the investigation panel, who may be from outside the institution, shall have no personal or professional relationship or other conflict of interest with the whistleblower or the alleged individual retaliator(s), and shall be qualified to conduct a thorough and competent investigation.

3. The investigation shall include the collection and examination of all relevant evidence, including interviews with the whistleblower, the alleged retaliator(s), and any other individual who can provide relevant and material information regarding the claimed retaliation.

4. The institution shall fully cooperate with the investigation and use all available administrative means to secure testimony, documents, and other materials relevant to the investigation.

5. The confidentiality of all participants in the investigation shall be maintained to the maximum extent possible throughout the investigation.

6. The Panel members shall evaluate objectively and respond accordingly to any concerns raised by the whistleblower, including the identity of the deciding official, responsible official and specific panel members prior to resolution of the complaint.

7. The conclusions of the investigation shall be documented in a written report and made available to the parties. The report should include findings of fact, a list of witnesses interviewed, an analysis of the evidence, and a detailed description of the investigative process.

8. The deciding official shall make a final institutional determination as to whether retaliation occurred. This decision shall be based on the report, the record of the investigation, and a preponderance of evidence standard.

9. If there is a determination that retaliation has occurred, the deciding official shall determine what remedies are appropriate to satisfy the institution's regulatory obligation to protect whistleblowers. The deciding official shall, in consultation with the whistleblower, take measures to protect and/or restore the whistleblower's position and reputation, including making any public or private statements, as appropriate. In addition the deciding official may impose any protections against further retaliation by establishing a system to monitor or discipline the retaliator.

10. The institution shall promptly notify ORI of its conclusions and remedies, if any, and forward the underlying investigation report to ORI.

11. The ORI will review the institutional report to determine whether the institution has substantially followed the process described herein. If the institution has substantially conformed to the process, ORI will not review the merits of the institutional determination under Paragraph 8.

12. Institutional compliance with Section V does not bar the whistleblower from challenging the process or the objectivity, thoroughness, competence, or results of the process, under State law, institutional procedure, policy or agreement, or as otherwise provided by law.

Option B: Arbitration

1. If the institution elects Option B, the institution shall offer the whistleblower the opportunity to submit the retaliation dispute to binding arbitration. The parties shall sign a written agreement that the retaliation dispute will be decided by final and binding arbitration, identifying by whom the arbitration will be conducted.

2. The arbitration agreement shall specify that the institution and the whistleblower abrogate all other rights under Federal, State and local law, and other institutional policies or employment agreements pertinent to the resolution of the whistleblower retaliation complaint, other than enforcement of the arbitration award. However, the parties may enter into any legally enforceable settlement agreement before a final arbitration award is made. A sample arbitration agreement is attached.

3. Any retaliation complaint submitted to arbitration shall be arbitrated according to the rules and procedures of the presiding arbitrator and designated arbitration association.

4. An arbitration under these Guidelines shall be conducted by an arbitrator who has no personal or professional relationship or conflict of interest with the whistleblower, the

institution, the alleged retaliator(s), or any person who is the subject of the underlying scientific misconduct allegation. The institution and the whistleblower shall agree on the choice of arbitrator. The arbitration should be facilitated by the American Arbitration Association or any other recognized non-profit arbitration association.

5. The institution and the whistleblower shall share equally the administrative costs of the arbitration. Each party is responsible for the cost of presenting its own case.

6. The arbitration agreement shall specify that the arbitrator shall require the institution to compensate the whistleblower for part or all of his or her arbitration costs, including attorney fees, if the arbitrator finds that the institution, or its members, retaliated against the whistleblower.

7. The arbitration agreement shall also specify that the arbitrator shall require the whistleblower to compensate the institution for part or all of any filing fees and arbitrator's costs if the arbitrator finds that the whistleblower's allegation of scientific misconduct was not made in good faith. If an institution seeks compensation on this basis, it shall make a preliminary motion to dismiss the retaliation complaint prior to commencement of a hearing. The arbitrator shall, if possible, make a threshold decision on the question of good faith based on written submissions prior to commencement of a hearing on the merits of the retaliation dispute. The institution has the burden of proving by a preponderance of the evidence that the allegation of scientific misconduct was not made in good faith.

8. The arbitration agreement shall specify a preponderance of the evidence standard in determining whether retaliation occurred or any other standard mutually agreed to by the parties.

9. The arbitration agreement shall state that the arbitrator's award is final and binding on all parties, and enforceable as provided by law.

10. If the arbitrator finds that the institution, or its members, retaliated against the whistleblower, the arbitrator may order any relief necessary to make the whistleblower whole for the direct or indirect consequences of retaliation, including protection against further retaliation through imposing a system to monitor or discipline the retaliator. The institution shall abide by the arbitrator's final award and shall implement any additional administrative actions it determines is necessary to correct the retaliation.

11. The institution shall promptly forward a copy of the final arbitration award to ORI.

Settlement

In lieu of the two options described above, an institution and whistleblower may, at any time after the retaliation complaint is made, enter into any binding settlement agreement which finally resolves the retaliation complaint. If both parties agree, the responsible official shall facilitate such settlements. If such an agreement is reached, the institution and the whistleblower shall sign a statement indicating that the retaliation complaint has been resolved. The institution shall within 30 days send a copy of the signed statement to ORI. ORI

does not require a copy of the actual terms of the settlement. The settlement may not restrict the whistleblower from cooperating with any investigation of an allegation protected by 42 C.F.R. Part 50, Subpart A. ORI shall consider a settlement meeting these requirements as fulfilling the institution's regulatory obligation under 42 C.F.R. § 50.103(d)(13).

Institutional Compliance

At any time ORI may review a covered institution's compliance with 42 C.F.R. § 50.103(d)(13) and these Guidelines to the extent that the institution relies on these Guidelines for regulatory compliance. Covered institutions and their members shall cooperate with any such review and provide ORI access to all relevant records. If a covered institution's procedures and implementation thereof substantially conforms to Sections IV and V above, it shall be deemed to have met its whistleblower protection obligation under 42 C.F.R. § 50.103(d)(13).

ATTACHMENT

Sample Arbitration Agreement to Resolve Whistleblower Retaliation Complaint

1. Name of whistleblower ("Complainant") and institution agree that Complainant's whistleblower retaliation complaint against institution and/or members will be submitted to an arbitration proceeding for final resolution of that complaint. Specifically, the parties agree to abide by all of the provisions of this Agreement. Moreover, the parties agree to abrogate all other rights under Federal, State, or local law, and other institutional policies or employment agreements pertinent to the resolution of the whistleblower retaliation complaint, other than enforcement of the arbitration award. This Agreement may not be modified in any manner absent the consent of both parties.

2. Complainant and institution agree that the arbitration shall be conducted by name of arbitrator according to the rules of arbitration association. The parties agree that arbitrator has no professional or personal relationship or conflict of interest with any of the parties.

3. Institution and Complainant agree to share equally the administrative costs of the arbitration proceeding subject to modification by the arbitrator as part of his/her final award. Each party shall be responsible for the costs of presenting its own case subject to modification by the arbitrator as part of his/her final award. The arbitrator shall modify the allocation of costs in favor of the whistleblower including the award of attorney's fees if the arbitrator finds that institution and/or members retaliated against the whistleblower.

The arbitrator shall modify the allocation of costs and dismiss the retaliation dispute in favor of institution if the arbitrator finds that Complainant's allegation of scientific misconduct was not made in good faith. The institution, however, shall be compensated only if it has timely made a preliminary motion to dismiss the retaliation claim on the basis that the allegation of scientific misconduct was not made in good faith, and proves its contention by a preponderance of the evidence.

4. The arbitrator's award shall be limited to Complainant's whistleblower retaliation claim. By submitting this dispute to arbitration under this Agreement, the parties agree that the retaliation claim will be fully settled under this Agreement, shall be dropped from all pending suits, and shall not be part of any future suits in any court of law other than suits to enforce the arbitration award.

5. The arbitrator shall apply a preponderance of the evidence standard in determining whether retaliation occurred [or any other standard mutually agreed to by the parties].

6. Upon completion of the parties' presentations, the arbitrator shall render an award which is final and binding upon both parties. The arbitrator shall grant any remedy or relief that the arbitrator deems just and equitable and is consistent with 42 C.F.R. § 50.103(d)(13) and Sections

IV and V of the ORI Guidelines. The arbitrator's award is not appealable before any court of law and may be enforced by the prevailing party in court or otherwise.

_____ _____

(whistleblower) Date

_____ _____

(institution) Date

Appendix F

Abbreviations

AAMC	Association of American Medical Colleges
DAB	Departmental Appeals Board at DHHS
DHHS	Department of Health and Human Services
FFP	Fabrication, falsification, and plagiarism
HHS	Health and Human Services (as in "Secretary of...")
MIM	Misappropriation, interference, and misrepresentation
NIH	National Institutes of Health
NSF	National Science Foundation
ORI	Office of Research Integrity
OSI	Office of Scientific Integrity
OSIR	Office of Scientific Integrity Review
PHS	Public Health Service
RIAP	Research Integrity Adjudications Panel at the DAB

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HEALTH & HUMAN SERVICES**

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