OFFICE OF RESEARCH INTEGRITY

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(HHS Emblem)

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ORI Annual Report 1994

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PART I: INTRODUCTION

The Office of Research Integrity (ORI) publishes an annual report[1] to assist research institutions, Public Health Service (PHS) agencies, and the scientific community to pursue their common interest in protecting the integrity of PHS-supported research. This report supports that end in three ways. First, the report describes the actions taken by ORI to protect the integrity of research supported by PHS extramural and intramural programs. Second, the report contains information that will assist institutional officials to comply with the PHS regulation[2] on scientific misconduct. Third, the report presents data on scientific misconduct in PHS-supported research to stimulate discussion, action, and research on the problem.

ORI MISSION

ORI[3] was established in May 1992 by the Assistant Secretary for Health to oversee and direct the PHS research integrity effort.[4]

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[1]This is the second ORI annual report. Information on the PHS effort to handle scientific misconduct is also presented in *ORI Biennial Report: 1991-92* and *Scientific Misconduct Investigations: 1989-90*.

[2]Henceforth, the term "PHS regulation" refers to 42 C.F.R. Part 50, Subpart A - Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science.

[3]The Office of Research Integrity replaced the Office of Scientific Integrity (OSI) in the Office of the Director, National Institutes of Health (NIH), and the Office of Scientific Integrity Review (OSIR) in the Office of the Assistant Secretary for health (OASH). These offices were organized in 1989 to implement Section 493 of the Public Health Service Act which was established by the Health Research Extension Act of 1985. Prior to 1989, scientific misconduct allegations were handled by the Institutional Liaison Office, NIH, and other PHS research agencies.

[4]The PHS is composed of the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Health Resources and Services Administration (HRSA), the Agency for Health Care Policy and Research (AHCPR), the Agency for Toxic Substances and Disease

(continued...)

In June 1993, ORI became an independent entity within the Department of Health and Human Services (DHHS) with the Director, ORI, reporting directly to the Secretary of Health and Human Services when President Clinton signed the National Institutes of Health (NIH) Revitalization Act of 1993.

The mission of ORI includes the following responsibilities:

- Assure that all institutions applying for or receiving PHS funds have appropriate mechanisms for dealing with allegations of scientific misconduct and the protection of whistleblowers; conduct reviews of institutional programs to determine whether they comply with Federal requirements; and investigate and resolve problems of institutional compliance.

- Oversee the conduct of institutional investigations of scientific misconduct allegations through the review of the reports of these investigations and the imposition of PHS administrative actions when misconduct is found.

- Conduct inquiries and investigations of scientific misconduct allegations at institutions when necessary; conduct all investigations of such allegations in PHS intramural programs.

- Develop, present, and defend findings of scientific misconduct before the Departmental Appeals Board (DAB) for those cases where a hearing has been requested.

- Develop regulations and policies to assure full and fair investigations of scientific misconduct allegations; establish appropriate due process protections for those accused of misconduct; and protect against institutional cover-up of misconduct or retaliation against whistleblowers.

- Promote research integrity through collaborative efforts with colleges and universities, scientific and professional organizations, and other Federal agencies.

ORI STRUCTURE

ORI is composed of an Office of the Director (OD), the Division of

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Registry (ATSDR), and the Indian Health Service (IHS). The mission of ORI does not include the regulatory research activities of the FDA.

Policy and Education (DPE), and the Division of Research Investigations (DRI). In addition, ORI receives legal services from the Research Integrity Branch, Office of the General Counsel (OGC), DHHS.

The OD provides overall management and administrative support for the office. DPE develops regulations, policies and procedures, manages the assurance program, conducts institutional compliance reviews, oversees institutional responses to allegations of retaliation against whistleblowers, monitors the implementation of administrative actions, responds to Freedom of Information Act (FOIA) and Privacy Act requests, produces publications, and organizes conferences and workshops. DRI assesses queries, monitors and reviews institutional inquiries and investigations, conducts inquiries and investigations at extramural institutions, and conducts investigations in PHS intramural programs. The OGC branch provides legal advice on all ORI activities and represents ORI before the DAB.

PART II: SIGNIFICANT ACCOMPLISHMENTS

In 1994, ORI recorded significant accomplishments in the pursuit of the three major long-term goals it enunciated in 1993: (1) Improve Internal Operations, (2) Improve Institutional Capabilities, and (3) Foster Research Integrity.

IMPROVE INTERNAL OPERATIONS

Strategic Planning Process

ORI initiated a strategic planning process in 1994 to guide the development of the office. The planning process serves as a mechanism for monitoring current performance and formulating annual and longer term objectives. The planning process is expected to improve the operation of the office through a more effective and efficient allocation of resources.

Case Management

The case management review and tracking system implemented within the DRI in 1993 resulted in 50 closed cases in 1994, the highest number of cases ever closed in a single year.[5] The backlog, cases opened from 1989 to 1992, was reduced from 54 to 17 cases or 69

[5]ORI closed 28 cases in 1993; OSI/ORI closed 55 cases in the biennial period, 1991-92; OSI/OSIR closed 21 investigations from March 1989 to December 1990; data are not available on the number of inquiries closed during this period.

percent. This high level of productivity enabled ORI to reduce the number of cases it carried into 1995 to the lowest level achieved to date (67) even though the number of new cases opened in 1994 was a record high (38).[6]

Recovery of Funds

ORI began notifying PHS agencies in 1993 about scientific misconduct cases which provide a basis for seeking a recovery of funds. In 1994, two scientific misconduct cases resulted in the recovery of $1.228 million from three institutions by the NIH.

In the first case, the Department of Justice settled a False Claims Act action against Dr. John L. Ninnemann, the University of Utah and the University of California, San Diego, for $1,575,000. *U.S. ex. rel. Condie* v. *Regents of the University of California, et al.*, No. 89-3550 (N.D. CA., July 22, 1994). The suit was originally filed by J. Thomas Condie, Dr. Ninnemann's former laboratory assistant, under the *qui tam* provisions of the False Claims Act which permits citizens to initiate a suit on behalf of the government. The suit was based on numerous alleged false statements in several NIH grant applications and progress reports submitted during the 1980's. As part of the settlement agreements, the University of California and the University of Utah agreed to establish programs to prevent future scientific misconduct and to correct deficiencies identified in their institutional policies and procedures for addressing scientific misconduct. Of the $1.575 million award, NIH received $1.009 million and Mr. Condie received $311,100 plus $255,000 for legal expenses.

ORI believes that the *Condie* case strongly supports the applicability of the False Claims Act to incidents of scientific misconduct in PHS-funded research and places institutions and individual investigators on notice of the potential implications of false claims in obtaining PHS funds.

The second case involved an investigation by ORI into false credentials claimed by two researchers in grant applications submitted by a university over a 13-year period. The university repaid $219,686 to NIH to cover the excess compensation paid to the researchers through PHS grants.

IMPROVE INSTITUTIONAL CAPABILITIES

Regulation on the Protection of Whistleblowers

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[6]The previous low was 71 cases forwarded into 1993; the previous high was 35 cases opened in 1993.

ORI developed a draft proposed regulation on the protection of whistleblowers in 1994. The development of the regulation is mandated by the NIH Revitalization Act of 1993. In January 1995, the draft regulation was submitted to the PHS and the Commission on Research Integrity for review. The draft regulation will be revised appropriately upon receipt of PHS and Commission comments. Following review and clearance by the Department and the Office of Management and Budget, the ORI plans to seek public comment on the regulation by publishing a Notice of Proposed Rulemaking in the *Federal Register*.

Model Policy and Procedures

ORI developed two draft documents in 1994 designed to facilitate institutional compliance with the PHS regulation. The "Draft ORI Model Policy for Responding to Allegations of Scientific Misconduct" provides guidance to institutions in establishing an administrative policy and process for responding to allegations of scientific misconduct. The PHS regulation requires institutions to develop such an administrative policy and process to be eligible for PHS funding. The "Draft Model Procedures for Conducting Scientific Inquiries and Investigations" provides detailed guidance for conducting inquiries and investigations into allegations of scientific misconduct. ORI decided to develop these documents because of the numerous requests for assistance it has received from institutions. The draft documents were sent to the PHS agencies, the Commission on Research Integrity, and 40 institutions for review and comment.

FOSTER RESEARCH INTEGRITY

Notification to Journal Editors

To further protect the integrity of the scientific literature, ORI began notifying the editors of scientific journals containing the publications that might require correction or retraction as a result of confirmed scientific misconduct. Such notification is made at the time of publication of the *Federal Register* notice announcing the ORI findings and administrative actions. The notice and a copy of the ORI report on the case is provided to the editor(s).

PART III: RESOLUTION OF MAJOR LEGAL ISSUES

Several significant legal decisions were rendered in civil litigation involving ORI in 1994 in addition to the suit filed under the *qui tam* provision of the False Claims Act discussed on page 7. Taken together, these cases continue to support strongly ORI procedures and authorities in protecting research integrity in

PHS funded programs.

Hiserodt v. Shalala

On July 20, 1994, the U.S. District Court for the Western District of Pennsylvania granted the Government's motion for summary judgement in *Hiserodt* v. *Shalala*, C.A. No. 91-0224, thereby dismissing the remaining three counts of Dr. John C. Hiserodt's complaint seeking declaratory and injunctive relief from the ORI's investigation and finding that Dr. Hiserodt engaged in scientific misconduct. In upholding ORI's position, the court rejected Dr. Hiserodt's contention that the three-year ORI investigation and appeal process constituted an "inordinate delay" in violation of due process of law. The court further held that the ORI investigation was not barred under the doctrine of administrative *res judicata* because the scientific misconduct regulations provided that the ORI reserves the right to perform its own investigation at any time prior to, during, or following an institution's investigation. The court also rejected Dr. Hiserodt's claims that ORI denied him equal protection of the laws and violated his First Amendment rights to "research, publish on research, and to hold an academic position and enjoy academic freedom." In an earlier decision, the court dismissed Dr. Hiserodt's Administrative Procedure Act and due process claims. Dr. Hiserodt has appealed the dismissal of his civil suit to the United States Third Circuit Court of Appeals where it is now pending.

McCutchen v. DHHS

The D.C. Circuit Court of Appeals ruled on August 5, 1994, that ORI is not required to disclose publicly the names of respondents and complainants in cases where there has been no finding of scientific misconduct. *Charles W. McCutchen* v. *DHHS*, 30 F. 3rd 183 (D.C. 1994). The Circuit Court reversed in part and affirmed in part the decision of the D.C. District Court in which Dr. McCutchen sought a list of all ORI investigations under the Freedom of Information Act (FOIA). ORI does not release the names of respondents and complainants in cases where there is no finding of scientific misconduct.

The Circuit Court found that both respondent and complainant names could be withheld in "no misconduct" cases under Exemption 7(C) of FOIA which allows withholding of "records or information compiled for law enforcement purposes . . . ." 5 U.S.C. § 552(b)(7)(C). For both respondents and complainants in "no misconduct" cases, the court found that the substantial privacy interest in withholding their names outweighed the public interest in releasing the names.

Needleman v. Healy

In 1994, the U.S. District Court for the Western District of Pennsylvania dismissed civil claims brought by Dr. Herbert Needleman challenging ORI's procedures for conducting scientific misconduct investigations. *Needleman* v. *Healy*, C.A. No. 92-0749 (W.D. Pa., November 23, 1994). Earlier in the year, ORI had accepted the report of the University of Pittsburgh that did not find scientific misconduct on the part of Dr. Needleman and filed a motion for dismissal in the district court. The court granted the Government's motion on all counts.

PART IV: SCIENTIFIC MISCONDUCT

The investigative workload associated with allegations of scientific misconduct includes queries, cases, and hearings. Queries represent the initial contact with a potential complainant to determine whether a case exists. The ORI caseload includes oversight and review of institutional inquiries and investigations and the conduct of inquiries and investigations in the PHS intramural program or at extramural institutions under special circumstances (e.g., when the institution is unable to do the inquiry or investigation or multiple institutions are involved). Hearings result when a respondent appeals an ORI finding of scientific misconduct to the DAB.

QUERIES

Each query received by ORI is assessed against the criteria which must be met in order to open a case. These criteria are:

1. The research in which the alleged misconduct took place must be supported by PHS funds or involve an application for PHS funds.

A search is made of computer records for PHS grants, contracts and cooperative agreements. Relevant grant applications and/or publications are obtained to determine the source of support.

2. The alleged misconduct meets the definition of scientific misconduct set forth in PHS regulations.

ORI must assess whether the action reported, if found to be true, would represent "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."

Many queries involve questions of "honest differences in

interpretations or judgments of data," which are specifically excluded under the PHS definition (45 C.F.R. § 50.102). If the allegation involves possible financial misconduct, non-ORI regulatory violations, criminal acts, or civil matters (e.g., Equal Employment Opportunity violations or harassment claims), ORI refers the query to the appropriate office or agency. If it involves a credit or authorship dispute, ORI refers it to the responsible institution for resolution.

3. There must be adequate information to proceed with an inquiry.

ORI may request additional information from the person initiating the query, if the person is identified. If an allegation is made anonymously, and there is not adequate information to proceed, ORI opens a file and waits to see whether additional information will be forthcoming.

Review of information available to ORI (such as grant applications, review summary statements, or correspondence with the funding agency) may result in a simple resolution to the query or allegation if it is found to have arisen because of a misunderstanding or incomplete information. Queries which meet the three criteria listed above may lead to ORI requesting an institution to conduct an inquiry, or ORI opening its own inquiry.

Thus, although only about 15% of the queries received result in a case being opened by ORI, all queries must be carefully evaluated for appropriate disposition.

Table 1: Disposition of Queries to ORI in 1994

Queries:	185
Intramural program	28
Extramural program	157
Referred to other agencies:	24
Resulted in inquiries/investigations:	38

CASES

ORI opens a case only when it determines that the allegation involves PHS-supported research or an application for PHS support and the alleged conduct falls within the definition of scientific misconduct stated in the PHS regulation. The ORI caseload is divided into four elements: (1) institutional inquiries, (2) institutional investigations, (3) ORI inquiries, and (4) ORI investigations. ORI began 1994 with 73 cases. During the year, ORI opened 38 cases and closed 44, excluding the six administrative closures described below. Sixty-seven cases were forwarded into 1995.

Administrative Closures

As part of its effort to reduce its inherited backlog, ORI administratively closed six investigations in 1994 that were effectively closed by the former Office of Scientific Integrity (OSI) as early as 1990. These cases had remained "open" because OSI had not taken formal close-out steps in the cases.

Five of the six investigations involved findings of scientific misconduct. In each of these cases, the finding of scientific misconduct was made by an institutional investigation committee. In four cases, OSI had accepted the institutional finding and notified the respondent. In the fifth case, the respondent reportedly died in his home country shortly after the institution submitted its report to OSI. In the sixth case, OSI had previously notified the respondent that it had reviewed the institutional investigation which did not find scientific misconduct. ORI determined that there was insufficient evidence to pursue the matter.

These cases are not included in the caseload for 1994 because the cases were completed in the period 1990-92, although formal close-out action had not been taken. Consequently, four cases were closed effective in 1990 and one each was closed effective in 1991 and 1992. These cases are not included in the summary section and the statistical profile for 1994.

Another case was closed administratively because ORI determined that some of the allegations did not fall within the PHS definition of scientific misconduct and insufficient evidence was available to make a determination on the remaining issue. This case was closed effective in 1994 and is included in the statistical profile.

Table 2: ORI Caseload by Case Type During 1994

Case Type	Forwarded From 1993*	Opened In 1994	Closed In 1994	Carried Into 1995
Institutional Inquiries	16	13	17	12
Institutional Investigations	39	17	18	38
ORI Inquiries	1	3	1	3
ORI Investigations	17	5	8	14
TOTAL	73	38	44	67

* Case type totals forwarded from 1993 are slightly different than those reported in the 1993 annual report. Inquiries and subsequent investigations (whether ORI or institutional) moved from one

category to another throughout the year. These changes are reflected in this table and accurately show the current status of those cases. The total number of cases forwarded from 1993 and the total number of cases closed in 1994 do not include the six cases administratively closed by ORI effective in 1990-92.

Institutional Inquiries

Under the PHS regulation, institutions are not required to report the conduct of inquiries to ORI unless they result in investigations. ORI may become involved in institutional inquiries when ORI receives an allegation directly from the complainant and then asks the institution to conduct the inquiry; under these circumstances, the institution is required to report the outcome of the inquiry to ORI. ORI then reviews the report to determine whether the conduct of the inquiry complied with the PHS regulation and was thorough, competent, and objective.

During 1994, ORI closed 17 institutional inquiries that did not recommend investigations. Four of the inquiries were administratively closed by ORI due to a lack of PHS jurisdiction. Seven of the remaining 13 inquiries involved allegations of plagiarism in grant applications, a manuscript, published papers, and reports. Six inquiries involved allegations of falsification in published papers and abstracts and in grant progress reports.

ORI began 1994 monitoring 16 institutional inquiries. During 1994, ORI opened 13 institutional inquiries, closed 17, and carried 12 into 1995.

Institutional Investigations

Institutions are required by the PHS regulation to report to ORI the initiation of an investigation and to submit a report to ORI upon completion of the investigation. ORI reviews the report to determine whether the conduct of the investigation complied with the PHS regulation and was thorough, competent, and objective.

ORI started 1994 monitoring 39 institutional investigations. Institutions began another 17 investigations during 1994. ORI closed 18 institutional investigations and carried 38 investigations into 1995. An ORI case is closed when ORI takes final action in response to an institutional investigation, i.e., finds no misconduct or finds misconduct and imposes appropriate administrative actions. If the respondent requests a hearing, the case is closed following the DAB decision.

ORI Inquiries

ORI reviews all inquiries conducted into allegations of scientific misconduct within the PHS intramural research programs. In addition, ORI conducts inquiries at extramural institutions if ORI determines there is a need to do so, i.e., a multi-center clinical trial. One inquiry was carried into 1994, three were opened and one was closed during the year. Three inquiries were forwarded into 1995; one intramural and two extramural.

ORI Investigations

ORI conducts all investigations into allegations of scientific misconduct in the PHS intramural research programs. In addition, ORI conducts investigations at extramural institutions if the case involves special circumstances.

ORI began 1994 with 17 investigations underway. During the year, ORI opened five investigations and closed eight. Fourteen cases were forwarded into 1995, five intramural and nine extramural.

Hearings

Under interim procedures established by the PHS in 1992, an individual against whom ORI makes a finding of scientific misconduct may request a hearing before the DAB within 30 days of receipt of the ORI notice of findings and proposed administrative actions. During a hearing, the respondent has an opportunity to be represented by counsel, to question any evidence and witnesses presented by PHS, and to present evidence and witnesses in rebuttal to the findings and proposed administrative actions.

Two hearing requests before the DAB were concluded in 1994; one hearing request was forwarded to 1995. In the only DAB decision issued in 1994, the DAB affirmed the finding of scientific misconduct and the administrative actions imposed on the respondent. (See Summary of Hearing for details.) In the other case, the hearing request was dismissed when the respondent, the institution, and ORI reached a settlement.

Summaries of Closed Investigations

Twenty-six investigations were closed by ORI in 1994: institutions conducted 18; ORI conducted eight. The investigations resulted in 11 findings of misconduct or administrative action, 14 findings of no misconduct, and one administrative closure. Summaries of the 25 cases with findings are presented below.

INVESTIGATIONS RESULTING IN FINDINGS OF SCIENTIFIC MISCONDUCT OR ADMINISTRATIVE ACTIONS

Fabrication:

Jacqueline Edberg, Villanova University. ORI reviewed an investigation conducted by Villanova University into possible scientific misconduct on the part of Ms. Edberg, a former Master's degree student in the psychology department at the university. ORI concluded that Ms. Edberg committed scientific misconduct by fabricating data in two experiments for a project supported by the National Institute of Mental Health. Ms. Edberg has been debarred from eligibility for and involvement in grants, other Federal assistance awards, and contracts and has been excluded from serving on PHS advisory committees, boards, or peer review groups for a three-year period beginning October 20, 1994. The fabricated data did not appear in any scientific publication.

Falsification:

John L. Ninnemann, Ph.D., University of Utah/University of California, San Diego. On July 22, 1994, ORI settled scientific misconduct charges against Dr. Ninnemann, formerly of the University of Utah and the University of California, San Diego, that resulted in his retraction or correction of several articles related to immunosuppression. Although Dr. Ninnemann has not admitted that he falsified and misrepresented scientific experiments in grant applications and publications in the 1970s and 1980s, he has agreed to be excluded from eligibility for all Federal grants, contracts, and cooperative agreements for three years and from serving on any PHS advisory committees, boards, or peer review groups for three years. In addition, he agreed to submit letters of retraction for five scientific articles and letters of correction for four additional scientific articles.

Following the settlement, Dr. Ninnemann submitted letters of retraction for the following five articles:

"Melanoma-Associated Immunosuppression Through B Cell Activation of Suppressor T Cells," *Journal of Immunology*, 120: 1573-1579 (1978).

"Induction of Prostaglandin Synthesis-Dependent Suppressor Cells with Endotoxin: Occurrence in Patients with Thermal Injuries," *Journal of Clinical Immunology*, 3:142-150 (1983).

"Immunosuppression Following Thermal Injury through B Cell Activation of Suppressor T Cells," *The Journal of Trauma*, Vol. 20, 3:206-213 (1980).

"Isolation of Immunosuppressive Serum Components Following Thermal Injury," *The Journal of Trauma*, Vol. 22, 10:837-844 (1982).

"Participation of Prostaglandin E in Immunosuppression Following Thermal Injury," *The Journal of Trauma*, Vol. 24, 3:201-7 (1984).

Dr. Ninnemann also submitted letters of correction for the following four articles:

"Hemolysis and Suppression of Neutrophil Chemotaxis by a Low Molecular Weight Component of Human Burn Patient Sera," *Immunology Letters*, 10:63-69 (1985).

"Reversal of SAP-induced Immunosuppression and SAP Detection by a Monoclonal Antibody," *The Journal of Trauma*, Vol. 27, 2:123-6 (1987).

"Definition of a Burn Injury-induced Immunosuppressive Serum Component." *The Journal of Trauma*, Vol. 25, No. 2:113-7 (1985).

"Immunosuppression Activity of C1Q Degradation Peptides," *The Journal of Trauma*, Vol. 27:119-122 (1987).

Mark S. Chagnon, Sc.D., Molecular BioQuest, Inc. ORI found that Dr. Chagnon had engaged in scientific misconduct by misrepresenting his academic credentials in five research grant applications submitted to the NIH. Dr. Chagnon falsely claimed to have completed undergraduate and graduate studies in chemistry at the Massachusetts Institute of Technology (MIT), Lowell University (Lowell Institute of Technology), and Northeastern University. ORI also concluded that Dr. Chagnon falsely claimed to have earned an M.S. degree in organic chemistry from MIT. ORI found that Dr. Chagnon was never enrolled as an undergraduate or graduate student at MIT. Dr. Chagnon does not possess a degree from any officially recognized institution of higher learning. ORI also concluded that a separate claim that he had conducted graduate studies also constitutes falsification. Although he neither admits nor denies the ORI finding of scientific misconduct, Dr. Chagnon has agreed to a Voluntary Exclusion and Settlement Agreement under which he is excluded from contracting or subcontracting and from eligibility for or involvement in grants and cooperative agreements of the U.S. government and may not serve on PHS advisory committees, boards, or peer review groups for a three-year period beginning June 28, 1994.

Gerald Leisman, Ph.D., New York Chiropractic College. The ORI reviewed an investigation conducted by the New York Chiropractic College into possible scientific misconduct by Dr. Leisman, a former faculty member. ORI found that Dr. Leisman committed scientific misconduct by misrepresenting his academic credentials

and professional experience and awards in an application for PHS research funds. Based upon information obtained by ORI during its oversight review, the ORI found that Dr. Leisman falsely claimed: 1) to have earned a M.D. degree from the University of Manchester (England) in 1972; 2) to have held the position of Professor, Neurology and Biomedical Engineering, Harvard University Medical School (June 1982 to January 1987); and 3) to have been awarded inventorship or co-inventorship of thirteen U.S. patents. Dr. Leisman accepted the ORI findings and agreed to a Voluntary Exclusion and Settlement Agreement under which he is excluded from contracting or subcontracting and from eligibility for or involvement in grants and cooperative agreements of the U.S. government and may not serve on PHS advisory committees, boards, or peer review groups for a three-year period beginning November 28, 1994.

Annmarie Surprenant, Ph.D., Oregon Health Sciences University. An investigation conducted by the Oregon Health Sciences University (OHSU) found that Dr. Surprenant had misrepresented her academic credentials in a grant application for PHS research funds by falsely stating that she had earned an M.D. degree from the University of Illinois, Chicago in 1976. As a result of the OHSU investigation, Dr. Surprenant resigned from the OHSU faculty. Based upon the OHSU report, as well as the information obtained by ORI during its oversight review, ORI found that Dr. Surprenant engaged in scientific misconduct by falsely claiming in three PHS research grant applications to have earned an M.D. degree. Dr. Surprenant accepted the ORI finding and agreed to a Voluntary Exclusion and Settlement Agreement under which she is excluded from contracting or subcontracting and from eligibility for or involvement in grants and cooperative agreements of the U.S. government and may not serve on PHS advisory committees, boards, or peer review groups for a three-year period beginning June 8, 1994.

<u>Plagiarism</u>:

Gerald I. August, Ph.D., University of Minnesota. ORI reviewed an investigation conducted by the University of Minnesota into possible scientific misconduct on the part of Dr. August, an associate professor of psychiatry in the medical school. The university concluded that Dr. August committed scientific misconduct by plagiarizing materials in a PHS grant application which he obtained as a member of a PHS Special Study Section. ORI concurred with the university's findings. Dr. August accepted the misconduct finding and agreed to a Voluntary Exclusion and Settlement Agreement under which, for a five-year period beginning May 6, 1994, he (1) will not serve on PHS advisory committees, boards, or peer review groups, and (2) will submit a certification with each document, application, or report he submits to a PHS

component that the work of others contained in the document, application, or report is properly attributed.

Fabrication/Falsification:

Keith A. Caruso, Cornell University. An inquiry conducted by Cornell University Medical College found that Dr. Caruso, while a medical student in the department of psychiatry, altered, fabricated, and destroyed primary laboratory data while learning techniques for insulin receptor binding on erythrocytes at the Columbia College of Physicians and Surgeons; this work was supported by grants from the National Institute of Mental Health. Dr. Caruso admitted to these acts of alteration, falsification, and destruction of primary data. ORI has accepted the university's findings and the administrative actions previously imposed by Cornell University. Dr. Caruso has signed an agreement with ORI accepting the finding of scientific misconduct. This agreement was made final on April 6, 1994. ORI determined that the university's administrative actions were sufficient and did not imposed any further PHS actions. The fabricated data did not appear in any scientific publications.

Pantelis Constantoulakis, Advanced BioScience Laboratories, Inc. An investigation conducted by Advanced BioScience Laboratories (ABL) found that Mr. Constantoulakis had committed scientific misconduct by falsifying and fabricating data in biomedical research supported by a contract with the National Cancer Institute and by misrepresenting his academic credentials for purposes of his employment under the contract. Mr. Constantoulakis was at that time an employee of ABL at the Frederick Cancer Research and Development Center. ORI concurred with the factual findings and conclusions of the ABL report. Mr. Constantoulakis accepted the misconduct finding and agreed to a Voluntary Exclusion and Settlement Agreement under which Mr. Constantoulakis is excluded from contracting or subcontracting and from eligibility for or involvement in grants and cooperative agreements of the U.S. government and may not serve on PHS advisory committees, boards, or peer review groups for a five-year period beginning August 2, 1994. One published paper, "Inhibition of Rev-mediated HIV-1 Expression by an RNA Binding Protein Encoded by the Interferon-inducible 9-27 Gene." *Science*, 259:1314-1318 (1993), was retracted (*Science*, 264:492) as a result of the misconduct finding.

David F. Eierman, Ph.D., University of North Carolina at Chapel Hill. An investigation was conducted by the University of North Carolina at Chapel Hill into possible scientific misconduct on the part of Dr. Eierman, a former research assistant at the university. Based in part on Dr. Eierman's admission, the university concluded that he committed scientific misconduct by falsifying or

fabricating data in biomedical research supported by two PHS grants. The ORI accepted the university's conclusions and found that Dr. Eierman engaged in scientific misconduct.

Dr. Eierman has fully cooperated with the university and ORI in this matter and has signed a Voluntary Exclusion and Settlement Agreement under which he is excluded from contracting or subcontracting and from eligibility for or involvement in grants and cooperative agreements of the U.S. government and may not serve on PHS advisory committees, boards, or peer review groups for a three-year period beginning December 12, 1994. The fabricated and falsified data were reported in two manuscripts that were never published and in Figure 3 of "$ß_1$ and $ß_2$ Integrin Subunit Regulation of the Monocyte Inflammatory Response," Cellular and Cytokine Networks in Tissue Immunity (M. Meltzer, and A. Mantovani, Eds.). (1991). New York: Wiley-Liss.

John C. Hiserodt, M.D., Ph.D., University of Pittsburgh. An inquiry conducted by the University of Pittsburgh and an investigation conducted by the ORI found that Dr. Hiserodt deliberately and knowingly falsified four figures and one table in two research grant applications submitted to the NIH, and deliberately and knowingly fabricated a laboratory notebook to cover-up the falsifications in the grant applications. In reporting research results on antigen recognition by natural killer cells, Dr. Hiserodt falsely reported that a purportedly unique protein had a molecular weight of 48 kilodaltons by altering photographs of autoradiograms, falsely reported that this protein had been found in human cells, falsely reported the results of a gene sequence in response to questions raised by NIH grant reviewers about his experimental findings, and fabricated a laboratory notebook to cover-up the falsified research when questions about it were raised by investigating officials. Dr. Hiserodt has been debarred from receiving Federal grant or contract funds for a period of five years beginning March 9, 1994. In addition, any institution receiving PHS research support involving Dr. Hiserodt must monitor the accuracy of his research for an additional two-year period following the five-year debarment (for a total period of seven years) beginning March 9, 1999. He has also been prohibited from serving on PHS advisory committees, boards, or peer review groups for seven years beginning February 25, 1994. Dr. Hiserodt is also required to request correction of the article "The Expression and Functional Involvement of Laminin-like Molecules in Non-MHC Restricted Cytotoxicity by Human Leu-19+/CD3-Natural Killer Lymphocytes," *Journal of Immunology*, 141: 3318-23, 1988, to indicate that Figure 2 in the article may not be relied upon. Dr. Hiserodt's appeal to the DAB was denied and the debarment and PHS administrative actions were affirmed. See Summary of Hearing on page 15.

Anand Tewari, M.D., Stanford University. ORI conducted an investigation into possible scientific misconduct on the part of Dr. Tewari while he was a postdoctoral fellow in the Department of Surgery, Stanford University School of Medicine. ORI concluded that Dr. Tewari committed scientific misconduct in clinical research supported by an NIH grant by fabricating ophthalmologic examination results; fabricating and falsifying blood gas data; fabricating and falsifying values for glycerol determinations; falsifying standard errors and including fabricated data on platelet counts in a published article, "Effects of interleukin-1 on platelet counts" [*The Lancet* 336:712-714 (1990)] and related abstracts; and providing to his supervisor summaries of data that included falsified and fabricated data, which were used in a PHS grant application. Dr. Tewari accepted the ORI findings and agreed to a Voluntary Exclusion and Settlement Agreement under which he is excluded from contracting or subcontracting and from eligibility for or involvement in grants and cooperative agreements of the U.S. Government and may not apply for Federal grant or contract funds (except for non-research training or the practice of clinical medicine) and may not serve on PHS advisory committees, boards, or peer review groups for a five-year period beginning March 1, 1994. The published article containing the falsified and fabricated data, was retracted on August 22, 1992 [*The Lancet*, 340:496].

INVESTIGATIONS NOT RESULTING IN FINDINGS OF MISCONDUCT

Fabrication: A co-author alleged that her colleague had fabricated a figure in a manuscript submitted for publication. An investigation conducted by the institution determined that the disputed figure was not a true representation of the experimental data. The respondent explained that the figure was a montage containing twelve lanes, four lanes for each of three proteins. The respondent said final workprints for six lanes were initially provided to the artist for mounting while a second set of experiments were conducted to obtain satisfactory workprints for the other six lanes. The artist testified that while he was waiting for the second set of workprints he completed the figure by using interim workprints in a paste-up. He said he intended to replace the interim workprints with the final workprints which he never received. The second set of experiments was conducted by a fellow in the laboratory and the results were presented to the photographer who apparently did not provide the artist with final workprints. The respondent did identify original autoradiograms and workprints for 11 of the 12 lanes. Other figures in the original manuscript confirmed results illustrated in three of the lanes. The data in the disputed figure were also confirmed in a replication of the original experiments by another co-author of the paper. The investigating committee concluded that the respondent

failed to exercise proper oversight in coordinating activities related to data presentation in the manuscript, but did not fabricate the data in the figure. ORI concurred with the institution's finding of no scientific misconduct.

Fabrication: A technician in a clinical trial was charged with fabricating data on a subject form. Subject forms could not be completed unless the subject visited the medical center because the study protocol required specialized procedures to be followed in obtaining repeated measurements. The respondent completed the form with single measures of blood pressure and weight obtained from the subject during a phone conversation. She said she was advised by the study coordinator to complete the form in this manner. An institutional investigation concluded that the respondent had made a serious misjudgment in failing to follow the protocol methodology. The committee found no attempt to deceive because the respondent indicated on the form that the data were obtained by phone. She also volunteered this information in a phone conversation with the data coordinating center. The data were withdrawn from the study database. The committee concluded that the technician was inadequately supervised. A data audit conducted by the data coordinating center found additional errors and concluded that the medical center staff was careless in data collection and correction. ORI concurred with the institution's finding of no scientific misconduct.

Falsification: A laboratory chief alleged that a postdoctoral fellow falsified data in several figures contained in a manuscript prepared for publication and an abstract submitted to a scientific meeting. The complainant filed the allegation after the respondent, who had returned to his native country, had failed to adequately answer questions raised by the complainant. An institutional investigation found that in one figure the dot blot was presented upside down and backwards, the concentrations cited in the legend were incorrect, and the normalization probe was misidentified. In another figure, the dot blot was cut to eliminate a lane that did not support the hypothesis, but the cut was so obvious that it would not deceive others. In a third figure data were attributed to the wrong experiment. The respondent claimed he made the errors because he did not adequately understand the studies he was conducting and he was under great pressure to complete the manuscript before returning home. The investigation committee concluded that the problematic figures represented extremely sloppy preparation of the manuscript and abstract rather than deliberate attempts to deceive. The manuscript was not submitted for publication and the abstract was withdrawn. ORI concurred with the institution's finding of no scientific misconduct.

Falsification: A research assistant professor was charged with falsifying his credentials in grant applications to NIH for 11 years by claiming he had a bona fide Ph.D. from Northwestern University in Illinois. An institutional inquiry concluded the respondent misrepresented his credentials because the respondent held a mail-order doctorate from Northwestern College of Allied Sciences in Tulsa, Oklahoma which was never licensed or accredited by the Regents of Higher Education of the State of Oklahoma. However, the institution considered this misrepresentation to be academic misconduct and not scientific misconduct. ORI determined that the misrepresentation fell under the PHS definition of scientific misconduct and initiated an investigation. ORI concluded that it could not be determined by a preponderance of the evidence that the respondent was responsible for the submission of the false credentials in the NIH grant applications. The respondent provided the institution with a transcript and certificate from Northwestern College showing the awarding of the Ph.D. in 1976. Subsequently, material submitted with grant applications listed the respondent as having a Ph.D. from Northwestern University in Illinois. The respondent said he did not prepare nor did he see the materials submitted with the applications. ORI concluded that it was credible that the persons responsible for the administration of the grant applications had completed these forms for the respondent without his review or approval. The excess personnel costs charged to grants for the respondent's services were part of a $219,686 repayment the institution made to NIH.

Falsification: An anonymous letter charged a professor with falsifying data in several publications. In the first allegation, the respondent was charged with using the same figure to represent the outcome of different experiments in two publications. An institutional investigation examined the original data and found unequivocal differences in the two experiments. However, when the graphs were photographically reduced, the figures appeared quite similar, but not identical. The second allegation claimed the respondent falsified the recovery of H3-labeled norepinephrine because he claimed the same recovery for different experiments published in different journals. The investigation found that a standard recovery rate was determined for each batch of H3-norepinephrine and that rate was cited for every experiment using material from that batch. The third allegation claimed the respondent cited the same recovery rate for experiments using 10 and 20 nanograms of material. The investigation concluded that citing these amounts was an error because 20 micrograms of material was consistently used for standardization. ORI concurred with the institution's finding of no scientific misconduct.

Falsification: A reviewer noticed that a grant application submitted by the respondent in 1992 had a figure depicting the effects of one compound on platelet aggregation that was very similar to a figure in an application the respondent submitted in 1991 that showed the effect of another compound on platelet aggregation. ORI asked the institution to look into the matter. During an ensuing investigation, the respondent said that he had given an unlabeled figure which he thought represented the effects of the compound that was reported in the 1992 application to an artist for labeling. However, the figure actually represented the effects of the compound reported in the 1991 application. The original recordings for both compounds were obtained by the investigation committee and the experiments were independently replicated. The investigation committee concluded that the falsified figure was the result of an error. The committee also concluded that the failure of the respondent to adequately check the figures when they were initially called into question by the reviewers represented professional negligence and constituted scientific misconduct under the institution's standards. ORI concurred with the institution's finding of no scientific misconduct under the PHS definition.

Falsification: Senior collaborators alleged that the respondent had falsely claimed success with a technique in a grant application despite the absence of data to support his conclusions. In the application, the respondent reported success in an important pilot experiment using the technique and cited the data shown in an accompanying figure. However, the figure was not included in the application. The institutional investigation committee found that the respondent had been asked by NIH to provide the missing figure. The respondent told NIH that he had removed the figure because the experiment he conducted at another institution was flawed but he had forgotten to remove the text referring to the figure. Instead of the requested figure, the respondent furnished NIH with data from a different but closely related experiment conducted by a prospective collaborator. The respondent told the investigation committee that the text citation of the figure was simply a "placeholder" for results of planned experiments. The investigation committee found the respondent's practice of using "placeholder text" to be highly inadvisable and concluded that the respondent had been extremely negligent in allowing the "false text" to be submitted to NIH. ORI concurred with the institution's finding of no scientific misconduct.

Falsification: Two researchers alleged that the respondent had falsified research affecting a significant public health issue through biased selection of control variables and subjects and falsification of methodology and results. An institutional investigation concluded that the respondent had not biased the

research results. However, the investigation committee recommended that the respondent correct the description of the study procedures that had been published and make the complete data set available to any interested scholar. In reviewing the case, ORI found that the study procedures were inaccurately reported and that three points were misplotted on a graph supporting the hypothesis. ORI concluded that this evidence was insufficient for a finding of scientific misconduct, so it accepted the institutional determination and supported the committee recommendations.

Falsification: A research nurse alleged that a researcher used inappropriate criteria for randomization and exclusion of patients in a clinical trial. An institutional inquiry concluded that the methods used by the researcher in conducting the trial were inadequate but did not constitute scientific misconduct. The inquiry committee noted that problems of bias are often encountered when a clinical study is conducted by a single investigator, especially when randomized patients are disqualified retrospectively and the eligibility criteria of the study are changed as the trial progresses. The study was underway for seven years when the allegations were made. The inquiry committee concluded that the study did not reflect the research standards of the institution. It recommended that a manuscript be revised to include all patients registered in the study with detailed explanations of why some cases were excluded and that the work of the researcher be monitored for a minimum of three years. OSI opened an investigation because it found that available evidence indicated that further investigation was warranted. After a panel of experts reviewed the case, ORI concluded the researcher had little or no training in clinical trial design or methodology, nor understanding of the profound effect that retrospective exclusion could have in biasing the results of a small study. ORI accepted the finding of the institutional inquiry and closed its investigation.

Falsification: A postdoctoral fellow alleged that a Ph.D. candidate had changed data in a laboratory notebook more than two years after the original entries were made without any postdating or other explanation for the changes. These data were included in a manuscript submitted for publication and in two reports to NIH. The respondent admitted altering the data but claimed he was correcting an error in his notebook, not falsifying data. He acknowledged that he should have followed laboratory procedures and annotated the entries to indicate they were being made to reflect other records and his recollections of the earlier results. The institutional investigating committee concluded that scientific misconduct had occurred because the respondent could not provide direct evidence to support the changed data. The committee concluded that the alteration in the data was necessary to make the

presentations and publications by the respondent credible. After reviewing the institutional report, the ORI concluded that the respondent's explanation that he was retroactively correcting an error that he had made in recording the original data was credible. Although unable to provide exact documentation for the altered data, the ORI noted the respondent was able to provide other records that made his explanation plausible. The ORI further noted that the respondent used a different color ink (blue over black) for the changes, thereby, making it readily recognizable that the data had been changed after the postdoctoral fellow had seen the original data in the notebook. Consequently, ORI found that a preponderance of evidence did not support a finding of misconduct.

Fabrication/Falsification: An investigation into violations of animal care and housing regulations recommended that the work of the respondent be examined for scientific misconduct. An institutional investigation found falsification and fabrication of data in laboratory notebooks, clinical laboratory log books, published and submitted papers, case report forms, abstracts, and a grant application. During the institutional investigation, a postdoctoral fellow working for the respondent took sole responsibility for the falsified and fabricated data. However, the investigation committee criticized the respondent for poorly supervising the fellow and the laboratory. The respondent resigned his position at the institution. ORI concurred with the institution's finding of no scientific misconduct.

Fabrication/Falsification: An allegation of unauthorized use of radioisotopes was made to the U.S. Nuclear Regulatory Commission against a director of a research institute. During an investigation conducted by the Office of Inspector General (OIG), two institute staff members charged the director with fabricating and falsifying data in two grant applications submitted to NIH. One complainant alleged that the respondent fabricated preliminary experimental data in one application because no research using radioactive chromium was done at the institute. The other complainant alleged that the respondent instructed her to falsify data from spinal cord injury experiments in constructing a graph for the second application. During an institutional inquiry (conducted while the OIG investigation was underway), the respondent produced data for some tables in the applications, but not for others. The institution concluded there was insufficient evidence to proceed to an investigation. The OIG asked OSI for assistance in investigating the alleged scientific misconduct, and at the request of OSI, issued an administrative subpoena for the respondent's notebooks. Another notebook was presented by a complainant. During the OSI investigation, the respondent produced records showing that he had authorization to use radioactive chromium at another institution and a notebook containing

experiments using the isotope. The OSI also determined that the graph depicting results of spinal cord injury experiments was falsified. However, OSI could not prove that the respondent instructed the complainant to do so. ORI found no scientific misconduct.

Falsification and Plagiarism: A department chairman alleged that a collaborator had falsely described his methodology in abstracts, violated patient confidentiality, used data from other investigators without their permission, failed to get informed consent, failed to be collegial, and abused co-workers. The respondent provided extensive information which led a university inquiry to conclude that the respondent had used careless research methods but had not committed scientific misconduct. During its review OSI, the predecessor to ORI, became concerned about the definition of scientific misconduct and the standard of proof employed by the institution. Upon further review, ORI concluded that only two allegations fell within the PHS definition of scientific misconduct: falsely describing the methodology used in the study and using data in abstracts and manuscripts without permission from collaborators. ORI determined that the respondent did show collaborators' materials prior to submission of abstracts and manuscripts, but ORI was unable to determine whether permission to use the data was obtained and thus found no scientific misconduct on this issue. ORI also determined that the methodology issue concerned patient confidentiality rather than falsification of methodology. ORI referred the issues concerning patient confidentiality and informed consent to the Office of Protection from Research Risks (OPRR).

Plagiarism and Other: A professor accused a graduate student of plagiarism and serious deviation from practices that are commonly accepted within the scientific community for proposing, conducting, or reporting research because she sequestered data from a collaborative project for 15 months and published the data without the consent of her collaborators. Three faculty advisors were also charged with scientific misconduct because they assisted the respondent to prepare the manuscript for publication. An institutional investigation committee, composed entirely of members from outside the institution, found the graduate student had committed scientific misconduct by sequestering the data and publishing the data without the consent of her collaborators. The investigation committee recommended that an investigation be conducted into the role the faculty advisors played in the publication of the data. ORI supported the finding of misconduct against the graduate student for sequestering the data. However, ORI concluded that the graduate student and faculty advisors committed an error in judgment rather than scientific misconduct by publishing the sequestered data without the consent of the

collaborators because senior administrators at the institution supported the right of the graduate student to publish the data. The graduate student requested a hearing before the Departmental Appeals Board on the misconduct finding stemming from the sequestration of data. Prior to the hearing, ORI and the institution reached a settlement with the graduate student in which ORI and the institution withdrew their misconduct findings and the graduate student acknowledged that her conduct was improper, that PHS had authority over any PHS-supported research in which she may engage, and that the institution had a right to supervise her research program. She also agreed to follow all institutional and Federal requirements for the retention and provision within the laboratory of data, research materials, and analyses. The latter condition implemented the administrative action which ORI proposed in conjunction with its original finding of misconduct.

SUMMARY OF HEARING

John C. Hiserodt, M.D., Ph.D., University of Pittsburgh.
The DAB affirmed the finding of scientific misconduct and the PHS administrative actions imposed on Dr. Hiserodt and recommended that the Deputy Assistant Secretary for Grants and Acquisition Management impose a five-year debarment. Dr. Hiserodt's subsequent motion for reconsideration of the debarment was denied by the Deputy Assistant Secretary for Grants and Acquisition Management. See case summary on page 11.

In affirming the ORI misconduct findings, the DAB stated that Dr. Hiserodt violated fundamental standards of conduct and that the government had an obligation to award its limited Federal research monies only to those individuals it determines will use those funds responsibly. In reaching this conclusion, the DAB stated that Dr. Hiserodt's actions constituted scientific misconduct under the 1989 regulations. In addition, the DAB found that those actions occurring prior to the effective date of the regulations were scientific misconduct under the applicable and widely-recognized professional standard which predated the regulations. It noted that both prior to and subsequent to the adoption of the 1989 regulations, applicants for research funds have had a duty to honestly and truthfully report the experimental results on which they premise their applications. The DAB stated that Dr. Hiserodt "engaged in an unremitting pattern of behavior evidencing indifference to the truth."

Dr. Hiserodt's contention that there was no PHS jurisdiction because both applications were unfunded was also rejected by the DAB. The DAB noted that the broad purpose of the scientific misconduct statute is to protect the integrity of the grant programs and that the event which triggered the authority to

investigate was the filing of the applications. Furthermore, Dr. Hiserodt's actions fell within the debarment regulations because his conduct demonstrated a lack of present responsibility. The DAB found that ORI has jurisdiction over a fabricated notebook because it was an integral component of Dr. Hiserodt's attempt to persuade NIH to fund the grant applications, since he had prepared it to convince the University of Pittsburgh that allegations of scientific misconduct against him were unfounded. The fabrication of the notebook was also relevant to the question of Dr. Hiserodt's integrity with respect to whether he is presently responsible to receive Federal funds. Debarment, the DAB stated, is not a punishment but a remedy which is designed to protect federally funded programs from individuals who have shown by their conduct that they are not trustworthy to deal with program funds. Dr. Hiserodt's argument that the term of debarment should be shortened because he had been "effectively debarred" during the investigation was rejected.

CLOSED INVESTIGATIONS - STATISTICAL PROFILE

This section presents a descriptive analysis of the investigations closed during 1994 under 9 headings: (1) Setting of Closed Investigations, (2) Allegations, (3) Institutional Actions, (4) Government Actions, (5) Respondent, (6) Complainant, (7) Length of Inquiries, (8) Length of Investigations, and (9) Size of Panels. Investigative outcomes are based on the final disposition of the case including the result of any hearing. For the first time the tables in this section contain a column for cases administratively closed by ORI without a finding.

Setting of Closed Investigations

The setting of closed investigations is described from four perspectives: (1) PHS Research Program, (2) Institutional Setting, (3) Funding Mechanism, and (4) Performer of the Investigation.

PHS Research Program

All except one of the 26 investigations closed in 1994 involved PHS extramural research programs in 14 NIH institutes. The intramural investigation involved an employee working in a Federal research facility for a company under contract with an NIH institute. Forty percent of the extramural investigations concluded with a finding of scientific misconduct; the lone intramural investigation also found misconduct.

Table 3: Outcome of Investigations by PHS Research Program, 1994

Program	Misconduct	No Misconduct	Admin Closure	Total
Extramural	10	14	1	25
Intramural	1	0	0	1
TOTAL	11	14	1	26

Institutional Setting

Twenty-six institutions were involved in the investigations closed in 1994. Twenty-three institutions handled a single investigation; three institutions were involved in two investigations each. Twenty-four investigations were conducted within a single institution; two investigations covered two institutions each. Investigations occurred primarily in medical schools. Other sites were research institutes, a hospital, and a biotechnology corporation. Within institutions, the investigations involved: departments of anesthesiology, biochemistry, biology, digestive disease, internal medicine, nephrology, neurology, obstetrics and gynecology, pathology, physiology, psychiatry, and surgery.

Table 4: Outcome of Investigations by Institutional Setting, 1994

Setting	Misconduct	No Misconduct	Admin Closure	Total
Medical School	8	12	1	21
PHS Intramural	1	0	0	1
Research Inst	1	1	0	2
Hospital	0	1	0	1
Biotech Corp	1	0	0	1
TOTAL	11	14	1	26

Funding Mechanisms

Twelve funding mechanisms were involved in the closed investigations. As expected, the traditional research grant, RO1, was predominant. Other mechanisms involved in the closed investigations were small research grants (RO3), first independent research support and transition (FIRST) awards (R29), small business innovation research grants (R43), research program projects (PO1), specialized centers (P50), postdoctoral individual national research service awards (F32), institutional national research service awards (T32), general clinical research centers (MO1), biomedical research support grants (SO7), cooperative agreements (UO1) and contracts. Sixteen investigations involved single grants; nine investigations involved from two to four

grants.

Table 5: Outcome of Investigations by Funding Mechanism, 1994

Funding Mechanism	Misconduct	No Misconduct	Admin Closure	Total
RO1	11	12	2	25
RO3	0	1	0	1
R29	0	1	0	1
R43	1	0	0	1
PO1	0	3	0	3
P50	0	2	0	2
F32	1	0	0	1
T32	1	0	0	1
MO1	1	1	0	2
SO7	0	2	0	2
UO1	0	1	0	1
Contract	1	0	0	1
TOTAL	16	23	2	41

Performer of Investigation

The PHS regulation assigns the primary responsibility for conducting inquiries and investigations into allegations of scientific misconduct to applicant and awardee institutions. However, the regulation reserves the right of the Department "to perform its own investigation at any time prior to, during, or following an institution's investigation". Seventeen of the 25 extramural investigations closed in 1994 involved only the institutions; seven investigations involved both institutions and ORI; and one investigation involved only ORI. ORI entered one investigation at the request of the Office of the Inspector General; another at the request of the Department of Justice, and third at the request of the institution because the respondent and complainant had filed lawsuits against the institution. ORI entered the fourth investigation because it concluded that the institution had prematurely terminated the investigation and the respondent was challenging the institutional process. In the fifth investigation, the institution declined to conduct an investigation after an inquiry concluded that the respondent had committed misconduct. The subsequent ORI investigation concluded that there was insufficient evidence to show that the respondent was responsible for the misconduct. In the sixth case, an investigation into allegations against one respondent resulted in an admission of guilt by another person. The institution declined to open an investigation focused on the second individual who had left the institution, so ORI did. In the seventh case, OSI felt that some additional issues needed to be investigated before the

institution's decision not to proceed to an investigation was accepted. ORI looked into those issues and affirmed the institution's decision. ORI conducted the remaining extramural investigation because it involved a small business that did not have appropriate personnel to handle the investigation.

Table 6: Outcome of Investigations by Performer of Investigation, 1994

Performer	Misconduct	No Misconduct	Admin Closure	Total
Institutional	6	11	0	17
Institutional/ORI	3	3	1	7
ORI	2	0	0	2
TOTAL	11	14	1	26

Allegations

Allegations of fabrication and/or falsification provided the basis for 24 of the 26 investigations (92 percent) and 10 of the 11 findings of misconduct (91 percent). Allegations of plagiarism occurred in three investigations. Only one case involved an allegation of "other practices" and it was combined with plagiarism. Falsification was involved in 21 investigations; 12 as a solo allegation, seven in combination with fabrication, and two in combination with plagiarism, making falsification the most frequent allegation occurring in these investigations. Fabrication was involved in 10 investigations; three as a solo allegation and seven in combination with falsification. Allegations combining fabrication and falsification were most frequently supported by the investigations (71 percent).

Table 7: Outcome of Investigations by Type of Allegation, 1994

Allegation	Misconduct	No Misconduct	Admin Closure	Total
Fabrication	1	2	0	3
Falsification	4	8	0	12
Plagiarism	1	0	0	1
Fab/Falsification	5	2	0	7
Falsifi/Plag	0	1	1	2
Plagiarism/Other	0	1	0	1
TOTAL	11	14	1	26

Institutional Actions

The PHS regulation on misconduct in science requires institutions

to impose appropriate sanctions on individuals when the allegation of misconduct has been substantiated. Institutions are known to have imposed seven sanctions in six of the 11 misconduct cases and four sanctions in three of the 14 no misconduct cases. In one misconduct case, the institution required the respondent to take ethics training and engage in community service. Institutions also terminated the employment of the respondent in four misconduct cases and issued a letter of reprimand in another. In the first no-misconduct case, the institution suspended a research associate with pay for 30 days and issued a letter of reprimand for retroactively altering data in a notebook without postdating or explaining the change. In another no misconduct case, an institution issued a letter of reprimand to a respondent for professional negligence in failing to adequately check figures in a grant application that was called into question by reviewers. In the third no misconduct case, the institution withheld a pay increase from the respondent for whom false credentials were claimed in grant applications submitted by the institution.

Table 8: Outcome of Investigations by Institutional Action, 1994

Institutional Action	Misconduct	No Misconduct	Admin Closure	Total
Letter of Reprimand	1	2	0	3
Ethics Training	1	0	0	1
Community Service	1	0	0	1
Pay Increase Withheld	0	1	0	1
Suspension with Pay	0	1	0	1
Terminated Employment	4	0	0	4
TOTAL	7	4	0	11

Government Actions

The PHS regulation on misconduct in science also recognizes the authority of DHHS to impose administrative actions of its own on investigators and institutions for violating the regulation. The Department and the PHS took 23 administrative actions against respondents in the 11 misconduct cases. Nine of the 11 respondents found to have committed scientific misconduct were debarred from receiving Federal grants, contracts, and cooperative agreements for periods of three to five years. Ten respondents were prohibited from serving on PHS advisory committees, boards, or peer review groups for periods of three to seven years. In addition, any institution employing one of the above respondents is required to monitor the accuracy of his research for two years beyond the debarment. All nine respondents were found to have falsified and/or fabricated data or credentials. The invalid data were used in articles, abstracts, a book, and grant applications. The false

credentials were presented in grant applications. One respondent was required, for a period of five years, to submit a certification that the work of others contained in each document, application or report he submits to a PHS component is properly attributed. Although only two respondents were required to correct the scientific literature, two other respondents retracted their published works.

Table 9: Frequency of Type of Government Action, 1994

Govt Actions	Frequency
Debarment	9
Adv Committee	10
Certification	1
Correcting Literature	2
Monitoring Research	1
TOTAL	23

Respondents

The respondents are described by (1) Academic Rank, (2) Highest Academic Degree, and (3) Gender.

Respondents' Academic Rank

Respondents in the 26 investigations closed in 1994 ranged from technician to professor. Allegations were made more frequently against senior personnel (professors and assoc. professors) than junior personnel, 58 percent to 38 percent. However, allegations were more often supported against junior personnel than senior personnel, 50 percent to 33 percent. Allegations against graduate students were most frequently supported (67 percent).

Table 10: Outcome of Investigations by Academic Rank of Respondent, 1994

Respondent	Misconduct	No Misconduct	Admin Closure	Total
Professor	0	3	0	3
Assoc Prof	5	6	1	12
Fellow	2	2	0	4
Grad Student	2	1	0	3
Technician	1	2	0	3
Not Applicable	1	0	0	1
TOTAL	11	14	1	26

Seventy-three percent of the accused respondents held a doctorate,

42 percent held an M.D., and 35 percent held a Ph.D. One respondent held an M.D. and a Ph.D. Other respondents held a master's or a bachelor's degree. The remaining respondent held no degree. Of the respondents found guilty of scientific misconduct, 64 percent held doctorates, 55 percent held Ph.D.s, 18 percent held M.D.s. Allegations against respondents with Ph.D.s were most frequently supported (67 percent).

Table 11: Outcome of Investigations by Highest Academic Degree of Respondent, 1994

Degree	Misconduct	No Misconduct	Admin Closure	Total
PhD	5	3	0	8
MD	1	8	1	10
MD/PhD	1	0	0	1
MS	0	1	0	1
BS	1	1	0	2
BA	2	1	0	3
None	1	0	0	1
TOTAL	11	14	1	26

Respondents' Gender

Eight-five percent of the accused respondents were male. Male respondents also constituted 82 percent of the individuals found guilty of scientific misconduct. However, allegations against female respondents were more frequently supported, 50 percent to 43 percent.

Table 12: Outcome of Investigations by Gender of Respondent, 1994

Respondent	Misconduct	No Misconduct	Admin Closure	Total
Male	9	12	1	22
Female	2	2	0	4
TOTAL	11	14	1	26

<u>Complainants</u>

Complainants are described by (1) Relationship to Respondents, (2) Academic Rank, (3) Highest Academic Degree, and (4) Gender. There was a single complainant in 23 investigations. The other three investigations had two complainants each.

Relationship to Respondents

The relationships that existed between complainants and respondents in the 1994 closed investigations covered a broad range. The most frequent relationship was supervisory - dean, department chair, lab chief, and supervisor. Peers were the second largest group - colleagues and reviewers. Subordinates were the smallest group - research assistant and technician. In one case, the complainant was a lawyer for a competing firm.

Table 13: Outcome of Investigations by Relationship of Complainant to Respondent, 1994

Complainant	Misconduct	No Misconduct	Admin Closure	Total
Dean	1	1	0	2
Department Chair	0	2	0	2
Lab Chief	2	2	0	4
Supervisor	2	0	0	2
Colleague	0	4	0	4
Reviewer	1	3	0	4
Research Asst	1	0	0	1
Technician	1	2	1	4
Other	1	0	0	1
Unknown	3	2	0	5
TOTAL	12	16	1	29

Complainants' Academic Rank

The complainants spanned the academic rank structure. Fifteen complainants were senior personnel (dean, professor, associate professor); six were junior personnel. The academic rank for eight complainants was unknown.

Table 14: Outcome of Investigations by Academic Rank of Complainant, 1994

Rank	Misconduct	No Misconduct	Admin Closure	Total
Dean	1	1	0	2
Professor	2	7	0	9
Assoc. Professor	2	2	0	4
Fellow	0	1	0	1
Grad Student	1	0	0	1
Nurse	0	1	0	1
Lab Technician	1	1	1	3
Unknown	5	3	0	8
TOTAL	12	16	1	29

Complainants' Highest Academic Degree

Nineteen complainants held doctorates; eight held Ph.D. degrees and 11 held M.D. degrees. One respondent held a master's degree; and two held bachelor's degrees. The highest academic degree of seven complainants was unknown.

Table 15: Outcome of Investigations by Highest Academic Degree of Complainant, 1994

Degree	Misconduct	No Misconduct	Admin Closure	Total
Ph.D.	1	7	0	8
M.D.	6	5	0	11
M.S.	0	0	1	1
B.S.	1	1	0	2
Unknown	4	3	0	7
TOTAL	12	16	1	29

Complainants' Gender

The complainants were mostly males. Fifteen complainants were males and seven were females. The gender of seven complainants was unknown.

Table 16: Outcome of Investigations by Gender of Complainant, 1994

Gender	Misconduct	No Misconduct	Admin Closure	Total
Male	7	8	0	15
Female	0	6	1	7
Unknown	5	2	0	7
TOTAL	12	16	1	29

Length of Inquiries

According to the PHS regulation, institutions are required to complete an inquiry "within 60 calendar days of its initiation unless circumstances clearly warrant a longer period". When a longer period is required, the circumstances warranting the longer period must be included in the inquiry report. However, the regulation does not stipulate the starting and ending points of an inquiry. In Table 17, the 60-day period was measured from the date on which the inquiry panel held its first meeting to the date of the inquiry panel report. Using this criteria, 15 inquiries (58 percent) were completed within the required 60-day period. The

length of inquiries ranged from five days to 390 days. The shortest inquiry involved falsified and fabricated laboratory data and academic credentials. The longest inquiry involved data from a clinical trial that was collected by the respondent at four institutions over an eight-year period.

Table 17: Outcome of Investigations by Length of Inquiry Recommending the Investigation, 1994

Inquiry Length	Misconduct	No Misconduct	Admin Closure	Total
0-60 days	7	8	0	15
61-90 days	2	2	0	4
91-120 days	1	1	0	2
121-150 days	1	0	0	1
Over 150 days	0	3	1	4
TOTAL	11	14	1	26

Length of Investigations

According to the PHS regulation, "an investigation should ordinarily be completed within 120 days of its initiation. This includes conducting the investigation, preparing the report of findings, making that report available for comment by the subjects of the investigation" and submitting the report to the ORI. If additional time is needed, the institution is required to request an extension from ORI. However, the regulation does not stipulate a starting point for investigations. In Table 18, the length of the investigation was measured from the date of the first meeting of the investigation committee to the date ORI received the report. Nine investigations (35 percent) were completed within 120 days. The length of an investigation ranged from 14 days to 1140 days. The shortest investigation followed the shortest inquiry and produced an admission of guilt. The longest investigation followed the longest inquiry and resulted in ORI affirming the institutional finding of no misconduct.

Table 18: Outcome of Investigations by Length of Investigation, 1994

Length	Misconduct	No Misconduct	Admin Closure	Total
0-120 days	6	3	0	9
121-180 days	2	1	0	3
181-240 days	0	3	0	3
241-300 days	1	1	0	2
Over 300 days	2	6	1	9
TOTAL	11	14	1	26

Size of Panels

The PHS regulation requires institutions to secure "necessary and appropriate expertise to carry out a thorough and authoritative evaluation of the relevant evidence in any inquiry or investigation." In conducting inquiries, institutions established panels ranged from one to six members to provide this expertise. The modal size of inquiry panels was one member; the median panel size was three members.

Table 19: Outcome of Investigations by Size of Inquiry Panel Recommending an Investigation, 1994

Members	Misconduct	No Misconduct	Admin Closure	Total
One	6	3	0	9
Two	1	1	0	2
Three	1	6	0	7
Four	2	2	1	5
Five	0	2	0	2
Six	1	0	0	1
TOTAL	11	14	1	26

The size of the investigative panels also ranged from one to six members. The modal and median size of investigative panels was three members.

Table 20: Outcome of Investigations by Size of the Investigative Panel, 1994

Members	Misconduct	No Misconduct	Admin Closure	Total
One	5	0	0	5
Two	2	2	0	4
Three	2	3	1	6
Four	1	4	0	5
Five	1	3	0	4
Six	0	2	0	2
TOTAL	11	14	1	26

PART V: INSTITUTIONAL COMPLIANCE PROGRAM

The PHS regulation on misconduct in science places several requirements on institutions receiving funds under the PHS Act. ORI monitors institutional compliance with these requirements through the following activities: (1) Assurance Program; (2) Annual Report of Possible Research Misconduct; (3) Institutional Compliance Reviews; (4) Allegations of Retaliation Against Whistleblowers; and (5) Implementation of PHS Administrative Actions.

ASSURANCE PROGRAM

To be eligible for PHS research funding, each institution that applies for or receives a grant, fellowship, or cooperative agreement must file an institutional assurance (PHS form #6315) with the ORI that makes two declarations:

(1) The institution has an administrative process for handling allegations of scientific misconduct that complies with the PHS regulation.
(2) The institution will follow its administrative process and the regulatory requirements when responding to allegations of misconduct in science.

As of December 31, 1994, there were 3,492 active assurances on file in ORI, including 180 from 28 foreign countries. During 1994, 389 institutions filed their initial assurance with the ORI. ORI deleted 169 institutions from its active assurance database, including 99 that failed to submit their Annual Report, thereby making those institutions ineligible to receive PHS funds.

In December 1994, the ORI active assurance database contained 847 institutions of higher education; 324 research organizations, institutes, foundations, and laboratories; 315 independent hospitals; 30 educational organizations other than higher

education; 458 other health, human resources, and environmental services organizations; 1494 small businesses; and 24 remained to be classified.

ANNUAL REPORT ON POSSIBLE SCIENTIFIC MISCONDUCT

In addition to filing an assurance, each institution with an active assurance is required to submit to the ORI an Annual Report on Possible Misconduct in Science (PHS form #6349) that provides aggregate information on allegations, inquiries, investigations, and other activities required by the PHS regulation. If the institution does not submit the required annual report, its institutional assurance lapses, and the institution is ineligible to apply for or receive PHS research funds.

Seventy-two institutions were responding to allegations of scientific misconduct in 1993, according to their annual reports. Fifty-three institutions received new allegations of scientific misconduct in 1993. Twenty-six institutions were continuing to process allegations made in 1992. Seven institutions were responding to allegations made in 1992 and 1993.

In their annual submission, institutions report the receipt of an allegation of scientific misconduct and the conduct of an inquiry and/or investigation. Reportable activities are limited to alleged misconduct involving PHS-supported research, research training, or other research-related activities.

Of the 53 institutions reporting new allegations in 1993, 37 were institutions of higher education; five were research organizations; eight were independent hospitals; two were other health, human resources, or environmental service organizations; and one was a small business.

Sixty-seven new cases were opened by the 53 institutions in 1993. The number of new cases opened by these institutions ranged from one to four. These cases involved 86 allegations, including 23 of fabrication, 29 of falsification, 15 of plagiarism, and 19 of other practices. Fifteen cases involved multiple allegations.

The 53 institutions conducted 63 inquiries and 26 investigations in 1993. The number of inquiries conducted by an institution ranged from none to four. The number of investigations conducted by an institution ranged from none to three.

INSTITUTIONAL COMPLIANCE REVIEWS

Institutional compliance reviews are designed to monitor institutional compliance with the initial assurance each

institution is required to file with ORI by the PHS regulation. In its assurance, an institution declares that it has established an administrative policy and process for responding to allegations of scientific misconduct that complies with the PHS regulation and that the institution will follow its policy and process when an allegation is made.

Institutional compliance reviews may contain one or two components depending on whether the review is limited to the administrative policy and process or extends to the conduct of an inquiry and/or investigation. The first component examines the institution's policy and process for adherence to the provisions of the PHS regulation. The second component examines the actual conduct of an inquiry and/or investigation of scientific misconduct to determine if the process utilized was consistent with the institution's own policy and process and the PHS regulation. A final report containing the results of the review is sent to the institution. The report may require actions by the institution to bring its written policy and process or actual handling of allegations of scientific misconduct into compliance with the PHS regulation.

Nine institutional compliance reviews were carried into 1994 from 1993. ORI opened 10 reviews during 1994 and closed 10 reviews. Nine reviews were carried into 1995. Initially, institutional compliance reviews originated from problems noted during ORI's oversight of institutional inquiries and investigations. In 1995, the ORI will begin to systematically sample administrative policies and processes for compliance with the PHS regulation.

In conducting compliance reviews, ORI has noticed that institutional policies and processes frequently are deficient in the following areas:

- Policy coverage. The institution's policies and procedures should apply to all individuals engaged in research that is supported by, or for which support is requested from the PHS, not just the faculty. This includes scientists, trainees, technicians, students, fellows, guest researchers, or collaborators.

- The purpose of the inquiry. The purpose of the inquiry committee is not to come to conclusions about whether or not misconduct occurred or who might be responsible. The inquiry should be limited to gathering information and determining whether the initial evidence indicates that an allegation or apparent instance of misconduct warrants an investigation.

- Role of the complainant. The role of the complainant is only to raise the question of possible misconduct. It is the institution's

responsibility to inquire into the matter and determine if it is an easily resolvable misunderstanding or whether it should be investigated further.

Once an allegation is made, the complainant should cooperate with the inquiry or investigation; he or she does not need to prove the case or provide the only source of expertise to counter the respondent's claims.

- Protection of the complainant. The institution is required to protect the position and reputation of the complainant. This includes preventing the respondent or others from acting in ways that damage the complainant's reputation.

- Appropriate expertise. If the inquiry committee requires additional expertise, it should be made available. Alternatively, the inquiry committee may recommend conducting an investigation to thoroughly examine the issues raised. Investigative committees should contain members with the appropriate expertise, or have experts available for consultation.

- Avoiding conflicts of interest. Institutions are required to "take precautions against real or apparent conflicts of interest on the part of those involved in the inquiry or investigation." Individuals involved in inquiries or investigations should have no relationships with the respondent or complainant that would prevent them from rendering a fair, impartial, and objective assessment of the evidence in the case.

- Confidentiality. Institutions are required to protect the privacy of those who in good faith report apparent misconduct, as well as afford other affected individuals confidential treatment to the maximum extent possible. The steps deemed necessary to maintain confidentiality should be outlined for those who conduct inquiries or investigations.

- Restoration of reputations. Institutions are required to undertake "diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed." It would be helpful if institutional procedures outlined the possible steps to be taken in these cases.

- Reporting requirements. Part 50.104 of the regulation outlines the reporting requirements to ORI. Many policies mention reporting certain information to funding agencies, but it should be noted that ORI is not a funding agency.

- Relevant dates. Institutional reports should note the relevant dates regarding the receipt of the allegation, the appointment of the inquiry and investigative committees, and the dates of the committee meetings. Each institutional report should also be dated.

ALLEGATIONS OF RETALIATION AGAINST WHISTLEBLOWERS

The PHS regulation requires institutions to undertake "diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations."

ORI began 1994 monitoring one allegation of retaliation; it received nine more allegations during the year. ORI intervened relatively early in several of these cases by consulting with the whistleblowers about their situation or concerns, requesting institutions to investigate the allegations, reminding institutions about their obligations to protect whistleblowers, and monitoring the steps taken by institutions to prevent or redress retaliatory actions.

Based on experience to date, ORI believes complainants should notify an institutional official or ORI about retaliatory action immediately after the incident occurs. Early notification provides the institution or ORI with the best opportunity to intervene.

IMPLEMENTATION OF ADMINISTRATIVE ACTIONS

The PHS regulation permits the Department to "impose sanctions of its own upon investigators or institutions based on authorities it possesses or may possess, if such action seems appropriate." The FDA also imposes administrative actions against researchers for violating regulated-research standards.

As shown in Table 9, the Department and the PHS impose a variety of administrative actions on individuals found to have committed scientific misconduct, including debarment from applying for or receiving Federal funds, prohibition from serving on PHS advisory committees, boards, and peer review groups, and submission of various certifications. In addition, the FDA disqualifies researchers for violating regulated-research standards.

The implementation of administrative actions is monitored through the PHS ALERT, a system of records under the purview of the Privacy Act. Individuals are entered into the PHS ALERT when: (1) ORI has made a finding of scientific misconduct concerning the individual; (2) the individual is the subject of an administrative action imposed by the Federal government as a result of a determination

that scientific misconduct has occurred; (3) the individual has agreed to voluntary corrective action as a result of an investigation of scientific misconduct; (4) ORI has received a report of an investigation by an institution in which there was a finding of scientific misconduct concerning the individual and ORI has determined that PHS has jurisdiction; and (5) FDA has determined that there is sufficient reason to believe that official action is warranted against the individual for violation of an FDA regulation governing research.

Information on each individual in the PHS ALERT is limited to name, social security number, date of birth, type of misconduct, the name of the institution that conducted the investigation, a summary of the administrative actions imposed as a result of the misconduct, and the effective and expiration dates of the administrative actions.

The PHS ALERT was computerized in 1994 to facilitate checks against incoming applications, pending awards, and proposed appointments to PHS advisory committees, boards, and peer review groups.

On January 1, 1994, the PHS ALERT listed 51 individuals who had been found to have committed scientific misconduct or against whom administrative actions were taken. During 1994, 140 were added; eight for scientific misconduct and 132 for FDA violations. Nineteen individual names were removed from the PHS ALERT in 1994 because the terms of the administrative actions imposed for scientific misconduct had expired; the case was administratively closed without the imposition of administrative actions; the finding of scientific misconduct had been overturned by ORI or the DAB, or the person died. On December 31, 1994, the PHS ALERT contained the names of 172 individuals sanctioned for scientific misconduct or violation of FDA regulations governing research.

PART VI: PUBLIC HEALTH SERVICE INTEGRITY PROGRAM

ORI continued to assist PHS agencies to develop their administrative structures and processes for handling allegations of scientific misconduct and promoting research integrity in 1994 by: (1) establishing the PHS Agency Research Integrity Liaison Officers (ARILOs) Committee; (2) holding a training workshop for ARILOs and their associates; and (3) making presentations to senior policy and management committees.

ARILO COMMITTEE

The PHS ARILO Committee is composed of the senior manager in each PHS agency who has primary responsibility for developing the administrative structures and processes within the agency for

responding to allegations of scientific misconduct and promoting research integrity.

In large agencies, the ARILO is assisted by an Agency Intramural Research Integrity Officer (AIRIO) for the intramural program, an Agency Extramural Research Integrity Officer (AERIO) for the extramural program, and Research Integrity Officers for each major component of the agency.

Two ARILO Committee meetings were held during 1994 to discuss policies and issues related to allegations of scientific misconduct and the promotion of research integrity.

TRAINING WORKSHOP ON INTRAMURAL INSTRUCTIONS

On May 18, 1994, ORI held a training workshop, "Ensuring Scientific Integrity in PHS Intramural Research Programs," at NIH for ARILOs, AIRIOs, AERIOs, and others involved in handling allegations of scientific misconduct and promoting research integrity.

Seventy-two individuals from all PHS agencies attended the workshop that covered the definition of scientific misconduct, the assessment of allegations, the conduct and reporting of inquiries, the protection of whistleblowers, and the promotion of research integrity. The workshop was focused on the conduct of inquiries because ORI handles all investigations of scientific misconduct in PHS intramural programs.

PRESENTATIONS

During 1994, ORI staff made several presentations on the PHS Research Integrity Program to senior policy and management committees in PHS agencies concerned with extramural program management, application review policy, grants management, contracts management, and program and project management.

PART VII: POLICY/PROCEDURAL DEVELOPMENT

Besides the policy and procedural developments noted in the Significant Accomplishments section, the ORI concentrated its policy and procedural efforts on: (1) providing administrative support for the Commission on Research Integrity; (2) responding to issues that have arisen in inquiries and investigations; (3) defining plagiarism; (4) developing and monitoring policy studies; (5) establishing its investigative files as a Privacy Act System of Records; and (6) modifying the PHS ALERT system to permit its computerization.

COMMISSION ON RESEARCH INTEGRITY

The Commission on Research Integrity is mandated by the NIH Revitalization Act of 1993 (Pub. L. 103-43) to make recommendations on the process developed by the PHS for responding to allegations of misconduct in research activities funded under the PHS Act.

The two-year charter of the Commission was signed by the Secretary of Health and Human Services on November 4, 1993. Appointment of Commission members by the Secretary was completed in May 1994.

The Commission held its first meeting on June 20, 1994; five more meetings followed before year's end, all in the Washington, D.C., metropolitan area. During these meetings, the Commission defined its mission, organized its efforts, and took testimony from respondents, whistleblowers, government officials, and attorneys.

The Commission is composed of Kenneth J. Ryan, M.D., Harvard Medical School, chairman; Carol Ann Kemp Aschenbrener, M.D., University of Nebraska Medical Center; Eugene H. Cota-Robles, Ph.D., University of California at Santa Cruz; Thomas M. Devine, J.D., Government Accountability Project, Washington, D.C.; Linda L. Emanuel, M.D., Ph.D., Harvard Medical School; C. Kristina Gunsalus, J.D., University of Illinois at Urbana-Champaign; Karl J. Hittelman, Ph.D., University of California at San Francisco; Drummond Rennie, M.D., University of California at San Francisco; Priscilla Ann Schaffer, Ph.D., Harvard Medical School; S. Andrew Schaffer, LL.B., New York University; Judith P. Swazey, Ph.D., The Acadia Institute, Bar Harbor, ME, and Carolyn Dickson Whitfield, Ph.D., Howard University.

ISSUES IN INQUIRIES AND INVESTIGATIONS

A variety of important issues have arisen in the course of inquiries and investigations conducted by extramural institutions into allegations of scientific misconduct. ORI presented its position on ten of these issues in 1994. It should be noted that for areas of conduct not covered by the PHS definition of misconduct in science, the statutory mandate and regulations do not replace the authority of extramural institutions to establish their own professional norms on the responsible conduct of research.

- Categories of Personnel Covered. Inquiries and investigations required by the ORI assurance program must be conducted on allegations of scientific misconduct brought against any individual involved in PHS-supported research. This includes postdoctoral fellows, residents, graduate students, undergraduate students, nurses, technicians, and other staff members. Institutional policies and procedures may not be limited only to faculty and professional staff. Policies and procedures which do not apply to

all individuals engaged in the research enterprise do not meet the requirements of either the institution's assurance to ORI or the PHS regulation and may place the institution's assurance in jeopardy.

- Confessions/Negotiated Pleas. Occasionally, an institution has accepted a "confession" or "negotiated plea" in lieu of a full investigation--especially when the respondent has left, or offered to leave, the institution as part of a negotiated settlement. Either of these actions may prevent the full extent of the misconduct from being discovered because the investigation may be terminated prematurely. Also, respondents have been known to withdraw or explain away their "confession" after the institutional report is sent to ORI. Thus, without the benefit of a full investigation, the ORI may not be able to protect adequately the PHS interest in the matter. Consequently, ORI requests that confessions be fully documented in the record, or alternatively that the institution contact ORI prior to settling the matter so that ORI can take steps to protect PHS interests.

- Standard of Proof. The evidentiary burden of proof used in investigating allegations of PHS scientific misconduct is a "preponderance of the evidence," which is the Federal government standard for civil and administrative adjudications. While an institution may choose another standard for its internal actions, ORI cannot accept either a misconduct or no misconduct finding based on any other standard. The preponderance of the evidence standard has been adopted by the Department for scientific misconduct hearings and debarment actions based on a finding of scientific misconduct. See Section XI of the Hearing Procedures for Scientific Misconduct, 59 Fed. Reg. 29809, 29811, June 9, 1994; 45 CFR 76.313(c)(1)and (2). Consequently, an institution must use this standard for investigations and findings forwarded to ORI.

- Panel Members. The names of the panel members in institutional inquiries and investigations must be included in the report to ORI. ORI has an oversight obligation to ensure that inquiries and investigations are free of conflicts of interest and bias and have appropriate expertise available. Panel members should be informed that their names could become available to the respondent and that they may be interviewed by ORI during its oversight process, an appeal by the respondent, or an institutional compliance review.

- Good Faith Whistleblowers. The question of what constitutes a good faith allegation of scientific misconduct continues to cause concern and confusion among institutions. Under the regulation, institutions must protect the positions and reputations of those

persons who, in good faith, make allegations of scientific misconduct [42 C.F.R. § 50.103(d)(13)]. A "good faith" allegation means that the whistleblower honestly believed that the allegation was true. Thus, an allegation may be made in good faith even if after investigation the allegation is not proven to be true, or even if the allegation was made for personal reasons, such as dislike of a colleague. However, an allegation is not in good faith if undertaken with reckless disregard for, or willful ignorance of, facts that would disprove the allegation. A whistleblower may not be retaliated against for making a good faith allegation.

- Ownership & Retention of Data. Research data generated under PHS funding generally is owned by the grantee institution, not the principal investigator or the researcher producing the data. The institution is the grantee and assumes legal and financial accountability for the awarded funds [See 42 C.F.R. §§ 50.102 and 52.2(e)]. Therefore, a grantee institution has not only the right, but the obligation to require a researcher to produce accurate supporting data not only for funded programs but also for grant applications. Additionally, grant regulations require an institution to retain records for specific lengths of time and to provide records on request to support a grant project [45 C.F.R. Part 74.53, 59 Fed. Reg. 43773, August 25, 1994]. Some institutions have also developed specific internal procedures defining the types of research records that must be kept, their form, and the length of time they must be retained. In conjunction with the regulations, policies such as these help to protect both institutions and responsible researchers in the event of an allegation of scientific misconduct.

- Institutional versus PHS standards. Scientific misconduct under the PHS standards must meet certain legal requirements which may be greater, lesser, or different from an institution's own internal standards. Therefore, in the course of an investigation, an institution may find conduct to be actionable under its own standards, even though the action does not meet the PHS definition of scientific misconduct. If ORI reaches a determination that a particular action does not fall within the PHS definition of scientific misconduct (as opposed to whether the action actually occurred), this PHS finding should not affect the institution's internal finding or any administrative actions that it imposes.

- Credentials and Publications. The falsification or fabrication of a researcher's credentials and publication list in an application for PHS funds can result in a finding of scientific misconduct. A review of credentials and publications during the peer review process may be critical to determining if an individual

is capable of performing the proposed research. Some researchers have listed degrees they did not earn or positions they have not held. Other researchers have listed publications as published, in press, accepted, or submitted when they were not. ORI considers this to be scientific misconduct under the PHS definition.

- Training Foreign Students. Foreign students and postdoctoral fellows involved in inquiries and investigations of scientific misconduct have told ORI that certain research policies in the U.S. are different from those in their home countries. They have noted that no one ever discussed these differences with them or told them that they were performing research in what was considered to be an inappropriate manner. It is possible that some allegations of misconduct could be avoided if these individuals received training in biomedical research ethics, and if their mentors and fellow researchers made a point of helping them to understand the research methods and practices that are appropriate.

- Provision of Counsel. ORI permits, but neither requires nor provides counsel for respondents, complainants, and other participants in misconduct proceedings. An institution must decide to whom it should provide counsel, and when such counsel should be provided. Some institutions routinely provide counsel for all or some parties while others provide none. If counsel is provided, care should be taken to prevent any potential conflicts of interest between the needs of the institution and that of the individual being provided with representation. For example, if an institution decides to provide a respondent with counsel, the institution's obligation to comply with the regulation and to cooperate with ORI investigations must not be compromised. ORI strongly recommends that outside counsel be provided in this instance. Also, while parties may arrange for their own counsel, reimbursement is not available from the Federal government under the Equal Access to Justice Act in hearings before the DAB.

DEFINING PLAGIARISM

Although there is widespread agreement on including plagiarism as a major element of the definition of scientific misconduct, there remains considerable uncertainty about the definition of plagiarism itself. As the first step in clarifying the meaning of plagiarism, the ORI published its operational definition of the concept in the *ORI Newsletter* in December 1994:

> As a general working definition ORI considers plagiarism to include both the theft or misappropriation of intellectual property and the substantial unattributed textual copying of another's work. It does not include

authorship or credit disputes.

The theft or misappropriation of intellectual property includes the unauthorized use of ideas or unique methods obtained by a privileged communication, such as a grant or manuscript review.

Substantial unattributed textual copying of another's work means the unattributed verbatim or nearly verbatim copying of sentences and paragraphs which materially mislead the ordinary reader regarding the contributions of the author. ORI generally does not pursue the limited use of identical or nearly-identical phrases which describe a commonly-used methodology or previous research because ORI does not consider such use as substantially misleading.

However, many allegations of plagiarism involved disputes among former collaborators who participated jointly in the development or conduct of a research project, but who subsequently went their separate ways and made independent use of the jointly developed concepts, methods, descriptive language, or other product of the joint effort. The ownership of the intellectual property in many such situations is seldom clear, and the collaborative history among the scientists often supports a presumption that the products of the collaboration may be used by any of the former collaborators.

For this reason, ORI considers many such disputes to be authorship or credit disputes rather than plagiarism. Such disputes are referred to PHS agencies and extramural institutions for resolution.

POLICY STUDIES

ORI contracted with the Research Triangle Institute (RTI) in 1994 to conduct a study of the consequences of being accused of scientific misconduct.

ORI also contracted with RTI in 1993 to conduct a study of the consequences of whistleblowing for the whistleblower in scientific misconduct cases. Data analysis was underway at the end of 1994; the final report is due in June 1995.

Little information exists on the impact an allegation of scientific misconduct has on the employment, career, professional activities, and personal life of the accused. Some researchers who have been subjected to unconfirmed allegations of research misconduct have claimed that their reputations have been seriously damaged by such

allegations. Data on the impact of supported allegations are also minimal.

This project intends to systematically collect information from respondents involved in closed PHS scientific misconduct cases to determine what has happened to them since they were accused of misconduct. The study population should range between 100 and 150 individuals. A self-administered questionnaire will be used to collect the data. The ORI expects the final study results in 1995.

PRIVACY ACT SYSTEM OF RECORDS

The ORI converted its investigative files to a Privacy Act System of Records in 1994 to facilitate the storage and retrieval of information by the name of the respondent in each case.

The Privacy Act requires Federal agencies that maintain files that are retrieved by personal identifier (name, social security number, etc.) to formally establish a system of records and, among other things, to define the conditions under which information from those files may be disclosed. A notice describing the system of records was published on January 6, 1995, in the *Federal Register*, Vol. 60, No. 4, pp. 2140-2143.

MODIFICATION OF THE PHS ALERT SYSTEM

ORI modified the PHS ALERT system in 1994 to facilitate its use in the protection of public funds and the implementation of PHS administrative actions against individuals found to have committed scientific misconduct.

The names of individuals are entered in the system when they have been found to have committed scientific misconduct by an institutional or ORI investigation. They are removed from the system when the finding of misconduct is overturned by the ORI or the DAB or the term of the administrative action expires.

The modification permits the information in the PHS ALERT system to be computerized. Previously, the information only existed in hard copy. Computerization facilitates checking the names in the ALERT system against incoming applications, pending awards, and proposed advisory committee appointments. Computerization also enables the names of the individuals against whom PHS has imposed administrative actions to be accessed through an electronic bulletin board. The modification also permits the use of social security numbers of the subjects in the system.

A notice on the modification was published May 18, 1994, in the *Federal Register*, Vol. 59, No. 95, pp. 25953-25956.

PART VIII: EDUCATION AND OUTREACH

The education and outreach activities of ORI in 1994, included: publications, presentations, and published articles.

PUBLICATIONS

ORI continued its publication program in 1994. It includes the quarterly *ORI Newsletter* and an annual report. These publications are distributed to almost 3,500 institutions that have an active assurance on file with ORI and to 2,043 individuals who have requested the publications. ORI also produced other publications as needed--position or issue papers, conference reports, guidelines, instructions, or models.

During 1994, ORI filled more than 650 requests for such publications as *ORI Annual Report: 1993*; *ORI Biennial Report: 1991-1992*; "ORI: An Introduction;" "Guidelines for the Conduct of Research within the Public Health Service;" "Data Management in Biomedical Research: Report of a Workshop," and Position Paper #1: "The Whistleblower's Conditional Privilege to Report Allegations of Scientific Misconduct."

PRESENTATIONS

The following 19 presentations were made by ORI staff in 1994 at professional and scientific meetings and convocations, workshops and conferences, and colleges, universities, and medical schools:

Bivens, L.W. Roundtable on Handling Allegations of Misconduct and Questionable Practices. Convocation on Scientific Misconduct, National Academy of Sciences, Washington, DC, June 7, 1994.

Bivens, L.W. "The Office of Research Integrity: An Overview and a Look Ahead." New England Region 1, National Council of University Research Administrators, Boston, MA, October 20, 1994.

Bivens, L.W. Panel on Institutional Management of Allegations of Scientific Misconduct. National Council of University Research Administrators, National Meeting, Washington, DC, November 6, 1994.

Bivens, L.W. Panel on Responsible Conduct of Research. Society for Neuroscience, Miami Beach, FL, November 13, 1994.

Dustira, A.K., Parrish, D.M., Davidian, N.M. "Scientific Misconduct Investigation, Legal Landscape, Ethics." Virginia Polytechnic Institute and State University, Blacksburg, VA, January 14, 1994.

Krueger, J.W. Panel discussion on Misconduct in Science. Columbia University College of Physicians and Surgeons, New York, NY, October 8, 1994.

Krueger, J.W. "Myths, Misconduct, and the Office of Research Integrity." William Paterson State College, Paterson, NJ, October 24, 1994.

Macfarlane, D.K. "Research Integrity and Research Misconduct-A Tale of Two Cities." Georgetown University Medical Center, Washington, DC, September 21, 1994.

Macfarlane, D.K. "Research Integrity and Research Misconduct in Multicenter Trials." University of Maryland School of Medicine, Baltimore, MD, December 15, 1994.

Pascal, C.B. "Scientific Misconduct Issues." American Association for the Advancement of Science-American Bar Association Conference of Lawyers and Scientists, San Francisco, CA, February 20, 1994.

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PART IX: OTHER ACTIVITIES

FREEDOM OF INFORMATION ACT REQUESTS

The Freedom of Information Act (FOIA), 5 U.S.C. § 552, provides public access to ORI records except to the extent that the records are protected from disclosure by one or more of the FOIA's nine exemptions.

ORI records are primarily within the scope of exemptions 5, 6, and 7. Exemption 5 covers internal government communications and notices. Exemption 6 covers documents about individuals that, if disclosed, would constitute a clearly unwarranted invasion of personal privacy. Exemption 7 covers records that the government has compiled for law enforcement purposes.

A FOIA request for ORI records should be made to the PHS FOIA Officer. The request must reasonably describe the records sought so that the agency official is able to locate the record with a reasonable amount of effort. Some requests may be subject to review, search, and duplication costs.

Eighty-seven requests for ORI documents were made in 1994, primarily for ORI case reports. Seventy-nine requests were filled. Eight requests were carried into 1995.

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B. Abbreviations

ARILO	Agency Research Integrity Liaison Officer
DAB	Departmental Appeals Board
DHHS	Department of Health and Human Services
DPE	Division of Policy and Education, ORI
DRI	Division of Research Investigations, ORI
NIH	National Institutes of Health
OD	Office of Director
OGC	Office of the General Counsel
ORI	Office of Research Integrity
OSI	Office of Scientific Integrity (ended in 1992)
OSIR	Office of Scientific Integrity Review (ended in 1992)
PHS	Public Health Service