OFFICE OF RESEARCH INTEGRITY

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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CONTENTS

PART I: INTRODUCTION

The effort to respond effectively to research misconduct requires the cooperation and support of numerous individuals and organizations: Public Health Service (PHS) applicant and awardee institutions, scientists, professional associations, Congress, government officials, Federal research agencies, and the general public. The Office of Research Integrity (ORI) publishes this annual report[1] to inform these audiences about the effort made each year to protect the integrity of biomedical and behavioral research, thereby, facilitating their participation in and assessment of this collective enterprise.

ORI Mission

ORI[2] was established in June 1992 by the Assistant Secretary for Health to oversee and direct the PHS research integrity effort.[3] ORI became an independent entity established by statute within the Department of Health and Human Services (HHS) in June 1993 with the Director, ORI, reporting to the Secretary of Health and Human Services (Section 493 of the Public Health Service Act, 42 U.S.C. 289b). A reorganization within HHS in October 1995 placed ORI in the Office of Public Health and Science (OPHS) within the Office of the Secretary for Health and Human Services. OPHS is headed by the Assistant Secretary for Health.

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; protect whistleblowers from retaliation; and ensure institutional compliance with PHS regulations.

- 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 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), HHS.

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 retaliation complaints from 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 allegations of scientific misconduct, 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.

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[1] This is the third ORI Annual report. Previous reports also include the *ORI Biennial Report: 1991-92* and *Scientific Misconduct Investigations: 1989-90*.

[2] 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 enacted 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.

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

PART II: SIGNIFICANT ACCOMPLISHMENTS

Among the significant accomplishments achieved by ORI in 1995 were (1) closing a record number of cases, (2) improving case management, (3) finalizing the ORI model policy and procedures for responding to allegations of scientific misconduct, (4) beginning a systematic review of institutional policies and procedures, (5) issuing guidelines for responding to retaliation against complainants, (6) completing a study of the consequences of whistleblowing, (7) developing a handbook for institutional research integrity officers, (8) establishing the administrative actions bulletin board, (9) recovering funds, and (10) creating a Home Page on the World Wide Web.

Record Case Closings

In 1995, ORI continued to increase the number of misconduct cases it closes annually. Fifty-eight cases were closed compared to 44 cases in 1994, a 32 percent increase. The 1995 total more than doubled the number of misconduct cases (28) closed in 1993, the first full year of ORI operations. This increased productivity reduced the pre-1993 case backlog by 75 percent, resulting in the closing of nine of 12 cases. ORI reduced the number of misconduct cases (58) carried into 1996, compared to 67 cases carried into 1995 even though a record number of new cases (49) were opened in 1995.

In addition, ORI increased its compliance case closings by 40 percent, closing 14 cases compared to 10 in 1994. Nine of the compliance case closings in 1995 involved retaliation complaints; the cases closed in 1994 were all compliance reviews. ORI carried 16 compliance cases into 1996 compared to 17 cases in 1995.

Case Management

Besides closing a record number of cases, ORI continued to improve other aspects of case management. ORI decreased the average time for assessing queries and shortened the process for closing cases. Queries are putative allegations of scientific misconduct and represent the initial contact with a complainant to determine whether a case exists.

Assessment time for queries was decreased by assigning a program analyst to assist the Deputy Director, DRI, in the initial triage and response to queries. As a result, 91 percent of the complainants who filed 244 queries in 1995 received an initial response within one week. One hundred and fifteen queries required ORI to conduct preinquiry assessments to determine whether the queries constituted allegations within ORI jurisdiction.

Other queries were referred to other offices (such as offices for human subjects or fiscal issues), fell outside the PHS definition of misconduct or did not involve PHS funds or

applications, or were closed due to lack of sufficient information to proceed. A more complete discussion of the resolution process for queries is included under "PART IV: Scientific Misconduct" on page 10.

Of the 115 queries leading to a preinquiry assessment, 106 were assigned to an investigator for in-depth review within two weeks of receipt. Eighty-one preinquiry assessments were completed in 1995; 34 were carried into 1996. The completed preinquiry assessments resulted in 31 new cases.

The case closing process was shortened by negotiating Voluntary Exclusion or Voluntary Settlement Agreements when scientific misconduct was found. In 1995, ORI negotiated 15 Voluntary Exclusions or Settlements compared to eight in 1994, an increase of 87 percent. These agreements shorten the closing process because the respondents voluntarily accept the misconduct finding and administrative actions thereby negating the need for preparation of a formal charging document, notification of findings and proposed administrative actions, and a hearing. In addition, in some cases an ORI final report is not needed, such as in those cases where ORI relies on an investigation and finding of misconduct made by an extramural institution.

Model Policy and Procedures

The *ORI Model Policy and Procedures for Responding to Allegations of Scientific Misconduct* were issued in April 1995. The Model Policy provides guidance to institutions in establishing the administrative policy and process required by the PHS regulation.[4] To be eligible for PHS funding, institutions must provide an assurance to ORI that they have established and will follow an administrative policy and process that complies with the PHS regulation. The Model Procedures provide detailed guidance that institutions may adopt for conducting inquiries and investigations into allegations of scientific misconduct and preparing the required reports. This document is available on the ORI Home Page on the World Wide Web.

Systematic Review of Policies and Procedures

In 1995, ORI initiated a systematic process for reviewing institutional policies and procedures for responding to allegations of scientific misconduct.

The annual process involves a five percent sample of institutions that have an active assurance on file with ORI declaring that they have established and will follow an administrative process for responding to allegations of scientific misconduct that complies with the Federal regulation.

The process calls for ORI to request policies and procedures from the sample during the first quarter of the year and report the results of its evaluation to the institutions by the end of the year. Each institution is sent a letter stating whether its policies and procedures comply with the regulation when the evaluation is completed. If the policies and procedures are deficient, an accompanying report cites the provisions of the regulation that are not adequately reflected in the document. Institutions are given 90 days to submit their revised policies and procedures to maintain their eligibility for PHS research funding.

Guidelines for Responding to Retaliation

ORI developed guidelines that contain recommended options which PHS applicant and awardee institutions may use to respond to retaliation complaints, thereby meeting their obligation under the PHS regulation to protect good faith whistleblowers.

The *ORI Guidelines for Institutions and Whistleblowers: Responding to Possible Retaliation Against Whistleblowers in Extramural Research* serve as interim guidance until the regulation on the protection of whistleblowers mandated by the NIH Revitalization Act of 1993 is established. At this time the guidelines are available on request and on the ORI Home Page on the World Wide Web. The guidelines are included in the *ORI Handbook for Institutional Research Integrity Officers* that will be sent to all institutions that have an active assurance on file with ORI, excluding small businesses. (See page 5.)

Institutions that follow these guidelines in handling retaliation complaints will be considered by ORI to be in compliance with the current regulation. However, institutions are not required to adopt these procedures; they may devise their own procedures to meet their regulatory obligation.

Under the recommended guidelines, institutions must report all retaliation complaints to ORI within 10 working days of receipt, permit the whistleblower to request interim protection, and necessitate the appointment of a responsible official to handle retaliation complaints.

The guidelines offer institutions two options for handling retaliation complaints--investigation or arbitration. If the whistleblower declines the option proposed by the institution, the institution may, but is not required to, propose the alternative option. If the whistleblower does not accept the proposed option or options, the whistleblower may pursue any other legal remedies available to resolve the retaliation complaint, but ORI will deem the institution to have met its regulatory requirement.

An investigation should be conducted according to the guidelines by a panel of at least three persons who have the appropriate expertise and no conflicts of interest. Appropriate remedies must be adopted if retaliation is found and a report of the investigation must be sent to ORI. If the institution has substantially conformed to the guidelines, ORI will not review the merits of the institutional determination.

If arbitration is selected, the parties must sign an agreement that the retaliation dispute will be decided by final and binding arbitration and must identify the presiding arbitrator and designated arbitration association. The institution and the whistleblower must agree on the choice of arbitrator. The institution must send a copy of the final arbitration award to ORI.

In lieu of the two options, a settlement may be reached between the institution and the whistleblower at any time in the proceedings, even after an investigation or arbitration is underway. If a settlement is reached, the institution must send to ORI a statement signed by an institutional official and the whistleblower indicating that the retaliation complaint has been resolved. ORI does not require a copy of the actual terms of the settlement. However, the settlement may not restrict the whistleblower from cooperating with any investigation of an allegation covered by the PHS regulation. Whatever procedure is adopted, it should be completed within 180 days of the date the complaint was filed.

Study of Consequences of Whistleblowing

The study of the consequences of whistleblowing for the whistleblower that ORI commissioned in 1993 was completed by the Research Triangle Institute. The study of 68 whistleblowers involved in closed PHS misconduct in science cases concluded that whistleblowers are highly likely to experience one or more negative consequences as a result of their whistleblowing, but most perceived those consequences to have had a neutral impact on their careers, professional activities, and personal lives.

Sixty-nine percent of the whistleblowers reported experiencing at least one negative outcome; 31% experienced none. Twenty-five percent reported serious consequences such as loss of position or denial of tenure, promotions, or salary increases.

About 62% of the whistleblowers perceived their whistleblowing to have had a neutral impact on their careers, professional activities and personal lives; about 28% perceived a negative impact; and 10% perceived a mixed (positive and negative) impact.

Although few whistleblowers perceived positive consequences, 68% would make another allegation, 12% probably would, 10% were uncertain, and 10% would not.

Other negative consequences noted by whistleblowers include reduction in research support or travel funds, counter allegations, delays in reviewing manuscripts or processing grant applications, and ostracism.

Whistleblowers attributed the negative consequences to institutional officials, respondents, colleagues, and professional societies. The most serious consequences were most frequently attributed to institutional officials.

Whistleblowers experienced the negative consequences while the institution was responding to their allegations and after the inquiry or investigation was completed. Negative consequences were experienced whether or not the allegation was substantiated.

Whistleblowers perceived negative career effects more frequently on their reputations, promotions, research, income, job mobility, and collaborations. Negative effects on professional activities were perceived more frequently on research, collegial relations, committee memberships, and the chairing of sessions at professional meetings. In their personal lives, the negative effects were perceived more frequently on their mental health, finances, physical health, and spouse.

Negative consequences reduced the willingness of whistleblowers to blow the whistle again, but did not extinguish the willingness to do so. More than half of the whistleblowers who experienced severe negative consequences reported that they would blow the whistle again.

Although positive consequences of whistleblowing were seldom cited, one in four whistleblowers reported a positive impact on their self-esteem.

A copy of the report on "Consequences of Whistleblowing for the Whistleblower in Misconduct in Science Cases" is available from ORI on diskette or in hard copy. Please specify the format preference for your diskette: WordPerfect 5.1 or 6.1 or ASCII. The report is also available on the ORI Home Page on the World Wide Web.

Handbook for Institutional Research Integrity Officers

ORI has developed a handbook for the official in PHS awardee and applicant institutions who is responsible for creating and implementing policies and procedures required by the Federal regulation on handling allegations of scientific misconduct. Depending on the availability of funding, the handbook is scheduled to be sent to all institutions that have an active assurance on file with ORI in 1996.

ORI produced the *PHS Handbook for Institutional Research Integrity Officers* because the low frequency at which allegations of scientific misconduct occur and the high turnover rate in institutional officials responsible for misconduct policy (17 percent in 1994) make it difficult for institutions to develop the expertise required to respond to such allegations in an objective, thorough, and competent manner.

The handbook is divided into five sections: (1) Institutional Responsibilities; (2) Legal Rulings, (3) PHS Oversight, (4) PHS Outreach, and (5) Appendices.

The institutional responsibilities section describes the obligations that institutions assume by applying for or receiving PHS research funds: (1) Developing an administrative process for responding to allegations of scientific misconduct; (2) submitting an assurance; (3) keeping an assurance active; (4) responding to allegations of scientific misconduct; (5) restoring reputations of exonerated respondents; (6) protecting the positions and reputations of complainants; (7) cooperating with the ORI; (8) fostering research integrity, (9) informing scientific and administrative staff about the institution's policies and procedures for responding to allegations of scientific misconduct, and (10) implementing PHS/HHS administrative actions.

Court decisions and DAB rulings affecting the handling of allegations of scientific misconduct are reported in the legal rulings section.

The PHS oversight section covers (1) the ORI mission and structure; (2) other PHS offices that handle research abuses; (3) oversight of institutional inquiries and investigations; (4) conduct of inquiries and investigations at institutions; (5) determinations of misconduct, administrative actions, and the hearing process; (6) the assurance program; (7) the Annual Report on Possible Research Misconduct; (8) institutional compliance reviews; (9) review of allegations of retaliation against complainants; (10) implementation of PHS/HHS administrative actions; (11) the PHS ALERT System, and (12) defining plagiarism.

The PHS outreach section reports on the mechanisms used by ORI to keep institutions, the scientific community, and the public informed about PHS efforts to handle scientific misconduct and promote research integrity including: (1) Publications; (2) conferences and workshops; (3) speakers; (4) responses to Freedom of Information Act requests; (5) *Federal Register* notices; (6) public notices; (7) notification to journal editors; (8) press releases, and (9) electronic bulletin boards.

The appendices contain documents and forms related to the institutional responsibilities and PHS oversight including the Model Policy and Procedures and the guidelines for responding to retaliation against whistleblowers.

Administrative Actions Bulletin Board

The PHS Administrative Actions Bulletin Board was established in 1995 to assist PHS agencies and extramural institutions in implementing administrative actions imposed on individuals for scientific misconduct or violations of FDA regulations governing research.

The new electronic bulletin board provides current information on PHS administrative actions. Each entry for scientific misconduct includes the name of the individual, the name of the institution where the misconduct was investigated, the type of misconduct found, the administrative actions imposed, and the starting and ending dates for the administrative actions. Relevant information on FDA violations is also provided.

The information included in the bulletin board is meant to be used by PHS program, scientific review, committee management, and grant and contract officials, and administrators at PHS applicant institutions to assist in the enforcement of PHS administrative actions. The new bulletin board was developed in collaboration with the Division of Research Grants, NIH.

Access to the bulletin board can be obtained through a modem, NIHnet, or INTERNET. The information can be viewed and/or downloaded. Specific instructions on accessing and downloading information on the bulletin board were published in the *NIH Guide for Grants and Contracts*, Volume 24, Number 7, on February 24, 1995. Technical questions on accessing the bulletin board should be directed to Ms. Jo Ann Wingard of the NIH Division of Research Grants by phone at 301-594-7090 or by E-mail at CJA@DRGPO.DRG.NIH.GOV.

Recovery of Funds

ORI notifies PHS agencies about scientific misconduct cases which may provide a basis for seeking a recovery of grant funds. In 1995, the NIH recovered $296,478 from one institution involved in a scientific misconduct case.[5] The funds were recovered because the principal investigator conducted no research under his grant for more than three years but submitted progress reports to NIH that did not present accurate descriptions of his performance. The principal investigator claimed his nonperformance was due to illness. In 1994, two scientific misconduct cases resulted in the recovery of $1.228 million from three institutions by the NIH.

Home Page

ORI has developed a Home Page on the World Wide Web to facilitate access by institutional officials, scientists, and the public to information about ORI activities.

The Home Page contains information about the mission and structure of ORI, telephone and fax numbers, back issues of the *ORI Newsletter*, position papers on issues concerning allegations of scientific misconduct and protections available to whistleblowers in defamation suits, and brief descriptions of other available ORI publications.

The Home Page also provides instructions for retrieving several larger ORI publications or downloading the compressed text from the Home Page. These documents include ORI's model policy and procedures for extramural institutions, back issues of ORI's Annual Reports, the report on the 1993 ORI/AAAS Conference on Plagiarism and Theft

of Ideas, the Report of the Commission on Research Integrity, and the Report on the Study of the Consequences of Whistleblowing for the Whistleblower in Misconduct in Science Cases. Additional publications that are not available electronically are also listed, along with information on how to request them by
E-mail or otherwise. ORI's Home Page address is **http://phs.os.dhhs.gov/phs/ori/ori_home.html**.

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[4] 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.

[5] A *qui tam* suit involving NIH grant funds resulted in a Federal judge ordering an institution to pay $1.65 million to the Federal government. The complainant may be entitled to up to 30 percent of that award because the Federal government did not join in the suit. The institution has appealed.

PART III: RESOLUTION OF MAJOR LEGAL ISSUES

Two significant legal decisions were rendered in 1995 involving misconduct cases handled by the ORI. One decision was made by the U.S. Court of Appeals for the Third Circuit; the other was made by the DAB. Both decisions supported ORI procedures and authorities in protecting research integrity in PHS-funded programs.

Hiserodt* v. *Shalala, et al.

On July 5, 1995, the U.S. Court of Appeals for the Third Circuit affirmed a U.S. District Court order dismissing claims filed by John C. Hiserodt, M.D., Ph.D. against ORI and others. Dr. Hiserodt had sought declaratory and injunctive relief from ORI's investigation and finding that he had committed scientific misconduct in connection with two research grants from the NIH. Because the Third Circuit's order summarily affirmed the district court's decision, the district court's opinion represents the only discussion of the merits of the case.

In upholding ORI's position, the district court rejected Dr. Hiserodt's contention that the three-year investigation and hearing process constituted an "inordinate delay" in violation of the due process guarantees of the U.S. Constitution. The court also held that Dr. Hiserodt did not hold a protected "property" interest in the receipt of federal research funds by virtue of his status as the principal investigator because he does not possess a legitimate claim of entitlement to the research funds, which belong to the grantee institution and not the principal investigator, and because the decision to award or transfer research funds lies solely within the discretion of the Secretary. Similarly, the court held that Dr. Hiserodt did not have a protected "liberty" interest in his "reputation, good name, and standing in the scientific community" because there was no evidence that allegedly stigmatizing information about Dr. Hiserodt's scientific misconduct was ever published outside of the PHS during the investigation.

The district 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." Finally, the district court held that the ORI investigation and finding of scientific misconduct was not barred under the doctrine of administrative *res judicata* because the PHS scientific misconduct regulations provide that ORI reserves the right to perform its own investigation at any time prior to, during, or following an institution's investigation.

In an earlier decision, the district court had dismissed other due process claims brought by Dr. Hiserodt under the Administrative Procedure Act.

***In the Matter of Catherine Kerr*, DAB No. A-95-123**

ORI found that Catherine Kerr, a data manager for the Breast Cancer Prevention Trial (BCPT) in Montreal, Canada, had fabricated or falsified results in a PHS supported study. Ms. Kerr requested a *de novo* hearing before the DAB regarding ORI's finding of scientific misconduct and the recommended administrative actions against her. Subsequently, Ms. Kerr moved to dismiss the matter on jurisdictional grounds. On August 16, 1995, the DAB denied Ms. Kerr's motion to dismiss, finding that ORI had authority to pursue misconduct cases that arise outside the territorial limits of the United States, contrary to the territorial principle of international law asserted by Ms. Kerr. The DAB found that all institutions and individuals who apply for or receive PHS research funds, regardless of where they are physically located, are subject to the scientific misconduct regulations. Secondly, the DAB agreed with ORI that Ms. Kerr's role as a data manager for the BCPT was covered by the scientific misconduct regulations as she was responsible for the reporting of research data. The DAB affirmed that, under the regulations, the potential for misconduct in science is not narrowly limited to "researchers" or "scientists," but extends to all employees or persons within a covered institution's control.

The investigative workload associated with allegations of scientific misconduct includes queries, cases, and hearings. Queries are putative allegations of scientific misconduct and represent the initial contact with a 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 or unwilling 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.

   DRI 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. If the allegation involves possible financial misconduct, regulatory violations, criminal acts, or civil matters (e.g., harassment claims), ORI refers the query to the appropriate office or agency. If it involves a credit or authorship dispute, ORI refers the allegation to the responsible institution for resolution.

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

   DRI 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 initiates 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 of 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.

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

In 1995, ORI received 244 queries, a 32 percent increase over the 184 queries received in 1994. The disposition of the queries are presented in Table 1. Queries become active cases when the criteria outlined above are met. Queries are administratively closed when the allegation does not fall under ORI jurisdiction and cannot be referred to another agency or is resolved through further inquiry and information. Queries may be referred to other agencies when the potential allegation concerns the use of humans and animals in research, financial issues, research funded by other agencies, and so on. No action is possible when a query does not contain sufficient specific information to permit another disposition to be made.

Table 1: Disposition of Queries to ORI in 1995

Disposition	*Frequency*
Resulted in Inquiries/Investigations	31
Administratively Closed	50
Referred to Other Agencies	30
No Action Possible	99
Remained to be Assessed	34
TOTAL	244

Cases

The ORI opens a formal case only when it determines that the allegation involves PHS-supported research or an application for PHS support and the alleged conduct appears to fall 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 1995 with 67 cases. During the year, ORI opened a record 49[6] cases and closed a record 58 cases, including the three administrative closures described below. Fifty-eight cases were forwarded into 1996, thirteen percent less than carried into 1995.

Administrative Closures

A case may be administratively closed when ORI concludes that continuing effort will not produce sufficient evidence to resolve a case satisfactorily. Three cases were administratively closed by ORI in 1995. These cases are included in the statistical profile of closed investigations and are considered to be cases in which there is no finding of misconduct.

In one case the institution found scientific misconduct because the respondent had submitted data in PHS grant applications that were collected from human subjects whose consent forms were forged. ORI was unable to establish its jurisdiction in this case because it could not match the data collected from the subjects associated with the questioned consent forms with the data the respondent submitted in the grant applications. In addition, ORI concluded that the institution did not provide sufficient evidence to show that the respondent personally forged the consent forms.

In the second case the complainant alleged that the respondent reported in several publications that the same electron spin resonance spectrum was the result of different experimental conditions. The respondent claimed the spectra were representative of the spectral information obtained under the experimental conditions described in the articles. The institution investigated the allegation for three years without producing a finding. ORI administratively closed the case because the primary data which were essential to demonstrating that the experiments took place or that the published scans were representative of the experimental conditions described in the articles were reportedly stolen between the time the allegation was made and the time the institution attempted to secure the data for an investigation.

The third case was closed because the alleged psychiatric problems of the respondent prevented fruitful pursuit of the case. Further, the respondent retracted the published article under investigation and was not engaged in PHS-supported research at the time of closure. A questionable document submitted by the respondent during the investigation was referred to the OIG for action.

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[6] The previous record was 38 in 1994.

Table 2: ORI Scientific Misconduct Caseload by Case Type during 1995

Case Type	*Forwarded From 1994**	*Opened In 1995*	*Closed In 1995*	*Carried Into 1996*
Institutional Inquiries	12	19	14	17
Institutional Investigations	40	27	32	35
ORI Inquiries	2	3	3	2
ORI Investigations	13	0	9	4
TOTAL	67	49	58	58

* Case type totals forwarded from 1994 are slightly different than those reported in the 1994 annual report. Inquiries and subsequent investigations (whether ORI or institutional) are 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.

Institutional Inquiries

Under the PHS regulation, institutions are not routinely required to report the conduct of inquiries to ORI unless they result in investigations. The 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. The 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 1995, ORI closed 14 institutional inquiries that did not recommend investigations. Falsification was the most frequent allegation examined in the inquiries (seven) followed by falsification and fabrication, three; fabrication, two; falsification and plagiarism, one, and fabrication and other practices, one. ORI began 1995 monitoring 12 institutional inquiries. During 1995, ORI opened 19 institutional inquiries, closed 14, and carried 17 into 1996.

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. The ORI reviews the report to determine whether the conduct of the investigation complied with the PHS regulation and was thorough, competent, and objective.

The ORI started 1995 monitoring 40 institutional investigations. Institutions began another 27 investigations during the year. ORI closed 32 institutional investigations and carried 35 investigations into 1996. An ORI case is closed when ORI takes final action in response to an institutional investigation, i.e., finds no misconduct or finds misconduct with appropriate administrative actions. If the respondent requests a hearing, the case is closed following the DAB decision and, in cases recommending debarment, after a final decision is rendered by the debarring official, the Assistant Secretary for Management and Budget.

ORI Inquiries

The 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. Two inquiries were carried into 1995, three were opened and three were closed during the year. Two inquiries were forwarded into 1996.

ORI Investigations

The 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 1995 with 13 investigations underway. During the year, ORI opened no investigations and closed nine. Four cases were forwarded into 1996, two intramural and two 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.

One hearing was requested in 1995, but the request was withdrawn by the respondent when the DAB ruled in favor of ORI on a prehearing motion challenging ORI's jurisdiction over the respondent. (See Resolution of Major Legal Issues on page 8.) One hearing, requested in 1994, was held in 1995; the decision is pending. (See Summary of Hearing on page 21.)

Summaries of Closed Investigations

Forty-one investigations were closed by ORI in 1995, institutions conducted 32; ORI conducted nine. The investigations resulted in 24 findings of misconduct; 14 findings of no misconduct, and three administrative closures. Summaries of the 38 cases with findings are presented below under two headings: (1) Investigations Resulting in Findings of Scientific Misconduct and (2) Investigations Not Resulting in Findings of Misconduct.

Investigations Resulting in Findings of Scientific Misconduct

Fabrication

Aaron Apte, Stanford University (SU): ORI reviewed an investigation conducted by SU into possible scientific misconduct on the part of Mr. Apte, a former technician in the Division of Cardiovascular Medicine. ORI concluded that Mr. Apte fabricated research data by cutting from a former coworker's notebook a scintillation counter printout, pasting it into his own notebook, and representing it as his own results from a different experiment on the binding of angiotensin to transfected cells. Mr. Apte was debarred from eligibility for and involvement in grants as well as other assistance awards and contracts from the Federal Government for a period of three years beginning January 26, 1995. The fabricated research did not appear in any publications.

Gloria Clayton, R.N., Ed.D., Medical College of Georgia (MCG): ORI reviewed an investigation conducted by MCG into possible scientific misconduct on the part of Dr. Clayton, Professor of Adult Nursing, MCG. ORI found that Dr. Clayton fabricated the existence of subjects and associated data under a subcontract with the Gerontology Center at the University of Georgia for research entitled "Adaptation and Mental Health of the Oldest Old," supported by the National Institute of Mental Health. Dr. Clayton, who admitted this fabrication, accepted the ORI findings and agreed to a Voluntary Exclusion Agreement. Under the Agreement, Dr. Clayton is not eligible to apply for or receive any Federal grant or contract funds or to serve on any PHS advisory committee, board or peer review committee for a three-year period beginning May 25, 1995. In addition, Dr. Clayton agreed to cooperate with the University of Georgia and MCG in the submission of letters of correction to appropriate journals for publications shown to contain the fabricated data.

Victoria Santa Cruz, University of Arizona (UA): Based on a UA investigation, ORI found that Ms. Santa Cruz, former Program Coordinator, College of Nursing, engaged in scientific misconduct by fabricating interview data on a questionnaire intended for use in two studies.

Ms. Santa Cruz did not contest the ORI findings or administrative actions, which require that, for a period of three years, any institution that proposes her participation in PHS-supported research must submit a supervisory plan designed to ensure the scientific integrity of her contribution. Ms. Santa Cruz was also prohibited from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of three years beginning December 14, 1995. Because the studies involved are ongoing, no publications were affected by the fabricated data, and no clinical treatment has been based on the results of the studies.

Richard Thwaites, University of North Texas Health Science Center at Fort Worth (UNTHSC): Based on an investigation conducted by UNTHSC, ORI found that Mr. Thwaites, former medical student, engaged in scientific misconduct by fabricating data in a clinical trial study.

Mr. Thwaites entered into a Voluntary Exclusion Agreement with ORI in which he accepted ORI's finding and, for the three year period beginning October 3, 1995, has voluntarily agreed to (1) exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement transactions (e.g., grants and cooperative agreements) of the United States Government, as defined in 45 C.F.R. Part 76 and 48 C.F.R. Subparts 9.4 and 309.4 (Debarment Regulations); and (2) exclude himself from serving in any advisory capacity to the PHS, including service on any PHS advisory committee, board, and/or peer review committee, or as a consultant. No scientific articles were published that relied on the fabricated data.

James Urban, M.D., Ph.D., California Institute of Technology (CIT). ORI found that Dr. Urban engaged in scientific misconduct based on a CIT investigation which concluded that Dr. Urban committed serious errors in judgment and scientific misconduct in connection with fabricating certain research data in two scientific papers that were published in the journal *Cell*. The first paper is J. Urban, V. Kumar, D. Kono, C. Gomez, S. Horvath, J. Clayton, D. Ando, E. Sercarz, and L. Hood, "Restricted Use of T Cell Receptor V Genes on Murine Autoimmune Encephalomyelitis Raises Possibilities for Antibody Therapy," *Cell* 54:577-592 (1988). The second paper is J.L. Urban, S.J. Horvath and L. Hood, "Autoimmune T Cells: Immune Recognition of Normal and Variant Peptide Epitopes and Peptide-based Therapy," *Cell* 59:257-271 (1989). Specifically, the CIT report states that Dr. Urban admitted that he fabricated two control lanes reported in Figure 5 of the *Cell* 54 paper. With respect to the *Cell* 59 paper, the CIT report states that Dr. Urban admitted that he circulated draft copies of the manuscript that contained fabricated data in order to circumvent both the internal and external review processes.

Dr. Urban accepted the ORI findings and agreed to exclude himself voluntarily, for a period of three years beginning June 2, 1995, from any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement transactions (e.g., grants and cooperative agreements) of the United States Government as defined in 45 C.F.R. Part 76 and 48 C.F.R. Subparts 9.4 and 309.4 (Debarment Regulations). This voluntary exclusion does not apply to Dr. Urban's current or future practice of clinical medicine or training, whether as a resident, fellow, or licensed

practitioner, unless that practice involves the proposing, conducting, or reporting of biomedical or behavioral research or research training. Dr. Urban also agreed to exclude himself voluntarily from serving on any PHS advisory committees, boards, and/or peer review committees for the same three-year period.

ORI acknowledges that Dr. Urban cooperated with the CIT Investigation Committee during its investigation of allegations of scientific misconduct and with ORI in its resolution of this matter.

Falsification

Catherine Coyle, ISOLAB, Inc. An investigation conducted by ISOLAB found that Ms. Coyle, a former laboratory technician, falsified and misreported the results of assays for fetal hemoglobin data generated for Johns Hopkins' Multicenter Study of Hydroxyurea in Sickle Cell Anemia under a cooperative agreement. Ms. Coyle admitted that she misrepresented data submitted to the Johns Hopkins clinical hydroxyurea study. There were no publications involved. Ms. Coyle executed a Voluntary Exclusion and Settlement Agreement in which she agreed not to apply for Federal grant or contract funds and will not serve on PHS advisory committees, boards or peer review groups for a three-year period beginning March 27, 1995.

Terence S. Herman, M.D., Dana Farber Cancer Institute/Harvard Medical School (DFCI/HMS): ORI reviewed an investigation conducted by DFCI/HMS into possible scientific misconduct on the part of Dr. Herman while he was an employee of that institution. ORI concurred with the factual findings in the institution's report, and found that Dr. Herman committed scientific misconduct by falsely reporting in a published article that research had been conducted according to a stated protocol when, in fact, Dr. Herman knew at the time that the protocol for tumor measurements had not been carried out exactly as described.

Dr. Herman accepted the misconduct finding as part of a Voluntary Settlement Agreement under which, for a period of three years, any institution which submits an application for PHS support for a clinical research project on which his participation is proposed or which uses him in any capacity on PHS supported clinical research must concurrently submit a plan for supervision of his duties. The supervisory plan must be designed to ensure the scientific integrity of Dr. Herman's research contribution. Dr. Herman also was prohibited from serving on any PHS advisory committee, board, or peer review committee for a period of three years beginning March 30, 1995. He has agreed to submit a letter to the *International Journal of Radiation Oncology, Biology, Physics* requesting retraction of that portion of the article dealing with tumor response (Herman, et al., A Phase I-II Trial of Cisplatin, Hyperthermia and Radiation in patients with Locally Advanced Malignancies. *Int. J. Radiation Oncology Biol. Phys.* 17:1273-1278; 1989).

Harry L. June, Ph.D., Indiana University-Purdue University at Indianapolis (IUPI): Based on an IUPI investigation, ORI found that Dr. June committed scientific misconduct by falsifying three letters of recommendation submitted with and in support of a First Independent Research Support and Transition (FIRST) Award application to the PHS.

Dr. June entered into a Voluntary Exclusion Agreement with ORI in which he accepted ORI's finding and agreed to exclude himself voluntarily, for the three-year period beginning November 21, 1995, from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

In addition, Dr. June voluntarily agreed to accept the administrative sanctions imposed by IUPI, which include requirements that Dr. June: (1) take a course in research ethics; (2) be supervised by a senior faculty member for not less than three years; and (3) submit all grant applications to his supervisor for review for at least one month prior to the agency deadline and to the Dean's office at least two weeks prior to the agency deadline. No scientific publications were required to be corrected.

James T. Kurtzman, M.D., University of California at San Francisco (UCSF). An investigation conducted by UCSF found that Dr. Kurtzman, a former Resident/Fellow in the Department of Obstetrics, Gynecology, and Reproductive Sciences, falsified results of research on the kinetics of nitric oxide synthase in cells and homogenates of human myometrial tissue in pregnant women. Dr. Kurtzman admitted that he had altered data in eight experiments that he performed during December 1993 and January 1994. Dr. Kurtzman reported that he had conducted the enzyme assays and entered the data into a computer-based spreadsheet, but then changed the data to generate graphs that would reproduce the type of results that he had submitted earlier to the *Journal of Clinical Investigation*. The paper was not published. Dr. Kurtzman executed a Voluntary Exclusion and Settlement Agreement in which he has agreed not to apply for Federal grant or contract funds and will not serve on PHS advisory committees, boards or peer review groups for a three-year period beginning March 18, 1995. The voluntary exclusion, however, shall not apply to Dr. Kurtzman's future training or practice of clinical medicine whether as a resident, fellow, or licensed practitioner, as the case may be, unless that practice involves federally funded research or the direct receipt of an award for federally funded research training.

Ruth Lupu, Ph.D., Georgetown University Medical Center (GUMC): Based on a GUMC investigation, ORI found that Dr. Lupu committed scientific misconduct by submitting a false letter of collaboration in an unfunded application to the PHS. Letters of collaboration are a significant factor in the evaluation of applications.

Dr. Lupu entered into a Voluntary Exclusion Agreement with ORI in which she accepted ORI's finding and agreed to exclude herself voluntarily, for the period beginning December 6, 1995, and ending January 30, 1997, from serving in any advisory capacity to PHS, including service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

In addition, Dr. Lupu voluntarily agreed to accept the administrative sanctions imposed by GUMC, which include requirements that: (1) a letter of reprimand be issued and retained in her personnel file for two years; and (2) her future grant applications, proposals, and other publications be subject to special monitoring and review for two years. No scientific publications were required to be corrected.

Tetsuya Matsuguchi, M.D., Ph.D., Dana-Farber Cancer Institute/Harvard Medical School (DFCI/HMS): Based on a DFCI/HMS investigation, ORI found that Dr. Matsuguchi, formerly a HMS Research Fellow at DFCI, committed scientific misconduct by intentionally falsifying data by artificially darkening one band each on two autoradiographs in figures that he had prepared for a presentation at an intramural research seminar and by altering three bands on the print of an immunoblot included in Figure 2A of a paper published in the *EMBO Journal*.

Dr. Matsuguchi entered into a Voluntary Exclusion Agreement with ORI in which he accepted ORI's finding and agreed to exclude himself voluntarily, for the three-year period beginning November 3, 1995 (1) from any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, Federal nonprocurement transactions (e.g., grants and cooperative agreements), of the United States Government, as defined in 45 C.F.R. Part 76 and 48 C.F.R. Subparts 9.4 and 309.4 (Debarment Regulations); and (2) from serving in any advisory capacity to PHS, including on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

The voluntary exclusion, however, does not apply to Dr. Matsuguchi's future training or practice of clinical medicine whether as a medical student, resident, fellow, or licensed practitioner unless that practice involves research or research training.

Dr. Matsuguchi has agreed to submit a letter to the *EMBO Journal* requesting correction of the article entitled "Tyrosine phosphorylation of $p85^{Vav}$ in myeloid cells is regulated by GM-CSF, IL-3, and Steel factor and is constitutively increased by $p210^{BCR/ABL}$" (*EMBO Journal* 14:257-265, 1995).

Farooq A. Siddiqui, Ph.D., Roswell Park Cancer Institute (RPCI): ORI completed an investigation into possible scientific misconduct on the part of Dr. Siddiqui while he was an employee of RPCI. ORI found that Dr. Siddiqui committed scientific misconduct by misrepresenting data in a published article.

Dr. Siddiqui entered into a Voluntary Settlement Agreement under which, for a period of two years, he will not apply as a principal or coprincipal investigator in any nonprocurement transactions (grants and cooperative agreements) or as a principal or coprincipal in any contract or subcontract with the United States Government. Dr. Siddiqui also was prohibited from serving on any PHS advisory committee, board, and/or peer review committee for a period of two years. Also, for a two-year period the institution where he is employed will supervise his performance of work on any covered transaction including a periodic review of primary data, and certify the accuracy of any such data used in any PHS grant application, contract proposal, or which is otherwise publicly reported. He agreed to submit a letter to the journal *Biochemica et Biophysica Acta (BBA)* to retract the article entitled "Purification and Immunological Characterization of DNA Polymerase-alpha from Human Acute Lymphoblastic Leukemia Cells" (*BBA*, 745:154-161, 1983).

Jose R. Sotolongo, Jr., M.D., Mount Sinai Medical Center (MSMC), New York: Based on an MSMC investigation, ORI found that Dr. Sotolongo, formerly of MSMC, committed scientific misconduct by falsifying research involving guanabenz treatment of spinal cord injured cats presented in a PHS grant application.

Dr. Sotolongo entered into a Voluntary Exclusion Agreement with ORI in which he accepted ORI's finding and agreed to exclude himself voluntarily, for the three year period beginning July 3, 1995, from: (1) applying for or receiving any Federal grant or contract funds; and (2) serving in any advisory capacity to the PHS, including service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

The voluntary exclusion, however, does not apply to Dr. Sotolongo's future training or practice of clinical medicine as a licensed practitioner unless that practice involves research or research training. No scientific publications were required to be corrected.

John J. Tomasula, Mount Sinai Medical Center (MSMC), New York: Based on an MSMC investigation, ORI found that Mr. Tomasula, formerly of MSMC in New York, committed scientific misconduct by falsifying research involving guanabenz treatment of spinal cord injured cats reported in a PHS grant application. Additionally, ORI found that Mr. Tomasula had falsified his credentials on three PHS grant applications in which he claimed to have a Ph.D. degree from Northwestern University when, in fact, he had obtained a mail-order degree from Northwestern College of Allied Sciences in Oklahoma, an unaccredited, now-defunct "institution."

Mr. Tomasula entered into a Voluntary Exclusion Agreement with ORI in which he accepted ORI's finding and agreed to exclude himself voluntarily, for the three year period beginning June 29, 1995, from: (1) applying for or receiving any Federal grant or contract funds; and, (2) serving in any advisory capacity to the PHS, including service on any PHS advisory committee, board, and/or peer review committee, or as a consultant. No scientific publications were required to be corrected.

Weishu Y. Weiser, Ph.D., Brigham and Women's Hospital/Harvard Medical School (BWH/HMS): Based on a BWH/HMS investigation, ORI found that Dr. Weiser, formerly of BWH/HMS, committed scientific misconduct by falsifying data in biomedical research supported by two PHS grants.

Dr. Weiser entered into a Voluntary Exclusion Agreement with ORI in which she accepted ORI's finding and agreed to exclude herself voluntarily, for the three year period beginning October 19, 1995, from (1) participating in any Federal contracts or subcontracts and from eligibility for or involvement in Federal nonprocurement transactions (e.g., grants and cooperative agreements), as covered in 45 C.F.R. Part 76 and 48 C.F.R. Subparts 9.4 and 309.4 (Debarment Regulations); and (2) serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

She also agreed to submit a letter to the *Journal of Immunology* and to the *Proceedings of the National Academy of Sciences* to retract the articles entitled "Human recombinant migration inhibitory factor activates human macrophages to kill *Leishmania donovani*" (*Journal of Immunology* 147:2006-2011, 1991), "Recombinant migration inhibitory factor induces nitric oxide synthase in murine macrophages" (*Journal of Immunology* 150:1908-1912, 1993), and "Recombinant human migration inhibitory factor has adjuvant activity" (*Proceedings of the National Academy of Sciences* 89:8049-8052, 1992).

Plagiarism

Alan L. Landay, Ph.D., Rush-Presbyterian-St. Luke's Medical Center (RPSLMC), Chicago: Based on an RPSLMC investigation, ORI found that Dr. Landay, Associate Professor, Department of Immunology/Microbiology, engaged in scientific misconduct involving two instances of plagiarism in publications related to two PHS grants.

Dr. Landay entered into a Voluntary Settlement Agreement with ORI in which he accepted ORI's finding and, for the two year period beginning August 8, 1995, voluntarily agreed to (1) exclude himself from serving in any advisory capacity to PHS, including service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and (2) certify in every PHS research application or report that all contributors to the application or report are properly cited or otherwise acknowledged. The certification by the Respondent must be endorsed by an institutional official. A copy of the endorsed certification is to be sent to ORI by the institution.

ORI acknowledges that Dr. Landay cooperated with the institutional investigation and the ORI review, accepted responsibility for his actions, and appropriately corrected the scientific literature. The two published papers (Coon, J.S., Landay, A.L., & Weinstein, R.S. "Advances in flow cytometry for diagnostic pathology." *Laboratory Investigations* 57:453-479, 1987; and Landay, A., Hennings, C., Forman, M., & Raynor, R. "Whole blood method for simultaneous detection of surface and cytoplasmic antigens by flow cytometry." *Cytometry* 14:433-440, 1993) that contained plagiarized text have been corrected (Landay, A. Correspondence. *Laboratory Investigations* 70:134, 1994; and Landay, A., Jennings, C., Forman, M., & Raynor, R. Correction. *Cytometry* 14:698, 1993).

Oscar R. Rosales, M.D., Yale University School of Medicine (YUSM): Based on a YUSM investigation, ORI found that Dr. Rosales, Assistant Professor of Medicine (Cardiology), committed scientific misconduct by plagiarizing and intentionally misrepresenting research in an application for PHS support.

Dr. Rosales entered into a Voluntary Settlement Agreement with ORI in which he accepted ORI's finding and, for the three year period beginning August 2, 1995, voluntarily agreed to (1) exclude himself from serving in any advisory capacity to the PHS, including service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and (2) certify in every PHS research application or report that all contributors to the application or report are properly cited or otherwise acknowledged. This certification must be endorsed by an institutional official, and the institution must send a copy of the certification to ORI.

Fabrication and Falsification

Daniel P. Bednarik, Ph.D., Centers for Disease Control and Prevention (CDC): Based on an investigation conducted by its Division of Research Investigations, ORI found that Dr. Bednarik engaged in scientific misconduct by fabricating and falsifying research data in two scientific manuscripts that were submitted for publication. One paper, entitled "Expression of the human (cytosine-5) methyltransferase is regulated by alternative mRNA splicing," was not accepted and the other, entitled "Indirect evidence for an EBV-HIV hybrid virus: Human immunodeficiency virus type 1 and Epstein-Barr virus genome association," was withdrawn before review. Dr. Bednarik is a former employee of CDC, and the research was done while he was employed by CDC.

Dr. Bednarik and ORI entered into a Voluntary Exclusion Agreement, wherein Dr. Bednarik agreed not to appeal ORI's jurisdiction or its findings and further voluntarily agreed (1) to exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement transactions (e.g., grants and cooperative agreements) of the United States Government, as defined in 45 C.F.R. Part 76 and 48 C.F.R. Subparts 9.4 and 309.4 (Debarment Regulations) for a period of two years, beginning on October 30, 1995; (2) that any institution employing the respondent be required to submit, in conjunction with each application for PHS funds or report of PHS funded research in which the respondent is involved, a certification that the data provided by the respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application or report for a period of one year following his exclusion; (3) that any institution that submits an application for PHS support for a research project that proposes the respondent's participation or that uses the respondent in any capacity on PHS supported research, must concurrently submit a plan for supervision of the respondent's duties, designed to ensure the scientific integrity of Dr. Bednarik's research, for a period of one year following his exclusion; and (4) to exclude himself from serving in any advisory capacity to the PHS, including service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of three years, beginning on October 30, 1995.

Denise R. Conrad, University of Iowa (UI): ORI reviewed an investigation conducted by the UI into possible scientific misconduct on the part of Ms. Conrad, formerly a Research Assistant in the Department of Preventive Medicine, College of Medicine. Checks and balances established by the research team, at the inception of the research, resulted in the early discovery of possible falsification of documents and misconduct. ORI found that Ms. Conrad committed scientific misconduct by fabricating or falsifying data on questionnaires. Ms. Conrad accepted the ORI findings and agreed to a Voluntary Exclusion Agreement under which Ms. Conrad is not eligible to apply for or receive any Federal grant or contract funds for a three-year period beginning April 10, 1995. The research study was in no way adversely affected by the fabricated or falsified data, as such data were not used in any way, and the data did not appear in any publication.

Barbara Jones, St. Mary's Hospital (SMH), Montreal: ORI conducted an investigation into possible scientific misconduct on the part of Ms. Jones while a data coordinator at SMH. ORI concluded that Jones committed scientific misconduct by falsifying and fabricating the dates of tests or examinations required prior to study entry for two women entered on the Breast Cancer Prevention Trial (BCPT). The BCPT is coordinated by the National Surgical Adjuvant Breast and Bowel Project (NSABP). Because the BCPT is still in progress, no conclusions or results have been published and no clinical recommendations have been based on the results of the study.

Ms. Jones did not contest the ORI findings or administrative actions which require that, for a period of three years, any institution which proposes Ms. Jones' participation in PHS-supported research must submit a supervisory plan designed to ensure the scientific integrity of her contribution. Ms. Jones was also prohibited from serving in any advisory capacity to the PHS for a period of three years beginning June 8, 1995.

Catherine Kerr, St. Mary's Hospital (SMH), Montreal: ORI conducted an investigation into possible scientific misconduct on the part of Ms. Kerr while she was a data coordinator at SMH. ORI concluded that Ms. Kerr committed scientific misconduct by falsifying and fabricating the dates of tests or examinations required prior to study entry for one woman entered on the Breast Cancer Prevention Trial (BCPT). She also fabricated laboratory results and falsified dates of laboratory tests used to follow the progress of another woman entered on the trial. The BCPT is coordinated by the National Surgical Adjuvant Breast and Bowel Project (NSABP). Because the BCPT is still in progress, no conclusions or results have been published and no clinical recommendations have been based on the results of the study.

Ms. Kerr originally appealed but later withdrew her request for a hearing on the ORI findings and administrative actions, which require that, for a period of three years beginning September 6, 1995, any institution that proposes Ms. Kerr's participation in PHS-supported research must submit a supervisory plan designed to ensure the scientific integrity of her contribution. Ms. Kerr is also prohibited from serving in any advisory capacity to PHS the same three-year period. (See page 9.)

Nicholas Y. Lorenzo, M.D., Mayo Foundation (MF), Rochester, MN: Based on an MF investigation, ORI found that Dr. Lorenzo, formerly of the MF, committed scientific misconduct by falsifying and fabricating data incorporated in an abstract submitted for presentation at a professional meeting.

Dr. Lorenzo entered into a Voluntary Exclusion Agreement with ORI in which he accepted ORI's finding and agreed to exclude himself voluntarily, for the three year period beginning October 16, 1995, from (1) any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement transactions (e.g., grants and cooperative agreements) of the United States Government, as defined in 45 C.F.R. Part 76 and 48 C.F.R. Subparts 9.4 and 309.4 (Debarment Regulations); and (2) serving in any advisory capacity to PHS, including service on any PHS advisory committee, board, and/or peer review committee, or as a

consultant. The above voluntary exclusion, however, does not apply to Dr. Lorenzo's future training or practice of clinical medicine whether as a medical student, resident, fellow, or licensed practitioner unless that practice involves research or research training. The abstract was withdrawn prior to publication, and thus, no correction of the literature was required.

Celia Ryan, R.N., University of Pittsburgh (UP): ORI reviewed a UP investigation into possible scientific misconduct by Ms. Ryan while an employee of the university. ORI concurred with the factual findings in the university report, and found that Ms. Ryan committed scientific misconduct by falsifying and fabricating interview data in a research project. Ms. Ryan accepted the misconduct finding and agreed to a Voluntary Exclusion and Settlement Agreement under which Ms. Ryan will not apply for, nor permit her name to be used on any application for Federal grant or contract funds, will not receive nor be supported by such funds, and will not serve on PHS advisory committees, boards, or peer review groups for a three-year period beginning January 11, 1995.

Vivian N. Tanner, Cleveland Clinic Foundation (CCF): ORI conducted an investigation into possible scientific misconduct on the part of Ms. Tanner while she was a clinic coordinator for the Collaborative Ocular Melanoma Study (COMS) at the CCF. ORI concluded that Ms. Tanner committed scientific misconduct by falsifying and fabricating clinical trial data on research data forms related to a multicenter study on the treatment of choroidal melanoma, a rare form of eye cancer. Due to these falsifications and fabrications, inaccurate clinical data were entered into the clinical trial database. These acts were committed over a period of several years, were material, and, therefore, were potentially detrimental to the study. Ms. Tanner has been debarred from eligibility for and involvement in grants as well as other assistance awards and contracts from the Federal Government for a period of three years beginning February 21, 1995. Because the COMS is an ongoing study, no publications were affected by the falsified or fabricated data, and no clinical treatment has been based on the results of the study.

Investigations Not Resulting in Findings of Misconduct

Generally, ORI protects the identity of exonerated respondents. However, ORI may reveal identifying information when the exonerated individuals requests such action to restore his or her reputation. Identifying information is included in the first summary as part of an effort to restore the reputation of an exonerated investigator in a case involving a clinical trial and media coverage. This summary was also published in the *Federal Register* and the *NIH Guide for Grants and Contracts.*

David Plotkin, M.D., Memorial Cancer Research Foundation of Southern California (MCRF), Los Angeles: ORI investigated allegations that clinical trial data forms submitted from the MCRF contained falsified and fabricated information. The data forms were submitted to the Statistical Office of the National Surgical Adjuvant Breast and Bowel Project (NSABP) located at the University of Pittsburgh. The NSABP project at MCRF received funding from the National Cancer Institute (NCI), with Dr. Plotkin as principal investigator.

In mid April 1994, the *Chicago Tribune* obtained a copy of an April 1990 NSABP Audit Report that indicated there was a "serious problem . . . with respect to the accuracy of the data reported to the NSABP" from the MCRF. A *Chicago Tribune* reporter reviewed records on some subjects entered on NSABP trials at MCRF and found apparent discrepancies between reported data and medical records. Much of the questioned data was related to the B-06 clinical trial which compared lumpectomy (with or without radiation therapy) to total mastectomy for the treatment of breast cancer.

ORI reviewed records and data on 59 patients reported to NSABP between 1973 and 1994 and did not find falsification, fabrication, or deliberate misrepresentation on the part of Dr. Plotkin or his staff. ORI found that many of the discrepancies originally identified by the NSABP and the *Chicago Tribune* were the result of a review of incomplete records, honest error on the part of one or more of the participating parties, or differences in interpretations or judgments of the facts.

Fabrication: A former postdoctoral fellow alleged that the respondent fabricated data in three papers and a grant application so that the data purportedly misrepresented the number of experiments performed and the averaged values in figures and tables. The institutional investigation committee did find evidence of fabricated data in one publication. However, the committee concluded there was no credible evidence that the respondent had participated in the misconduct. Instead, the committee believed the testimony of the respondent who reported that he relied on the complainant to draft the questioned publication and to prepare the data summaries. The committee concluded that the evidence indicates the complainant was responsible for the fabricated data. ORI accepted the institutional finding.

Falsification: The respondent was charged with falsifying data by inappropriately editing points on standard curves for hormone assays and publishing falsified data in one figure in each of two articles. The institutional investigation committee found scientific misconduct on both counts. During its oversight review, ORI found that the respondent had learned the inappropriate editing practice from her postdoctoral mentor and had not been told by her supervisors

to stop the practice which the respondent made no attempt to hide in her annotated notebooks. ORI also found that the respondent lacked the skill and understanding to properly use experimental methods and to analyze data. ORI concluded that there was insufficient evidence to support a finding of intentional falsification on either charge.

Falsification: A technician alleged that the laboratory chief falsely claimed in a grant application that his laboratory had identified three crucial reagents needed for a technique that would allow the laboratory to distinguish between the bacterium that caused a specific disease and other closely related bacteria that do not. The technician alleged that there was no authentic experimental basis for these claims of specificity for these reagents. An institutional inquiry which found no reason to conduct an investigation was considered inadequate by the former Office of Scientific Integrity (OSI) because the inquiry failed to examine notebook data and interview the complainant. OSI conducted its own inquiry and investigation. After reviewing the OSI investigation and conducting further analysis, ORI verified the OSI conclusion that there was insufficient scientific support to claim the reported specificity for the reagents. However, ORI did not find scientific misconduct because there was insufficient evidence to demonstrate a deliberate misrepresentation. ORI concluded that reasonable scientists could differ on whether the preliminary results showed sufficient promise of success to justify their presentation as initial observations, plans, and suggestive results in an application. In addition, no falsified or fabricated research data were presented in the application.

Falsification: A coinvestigator alleged that inconsistencies in the methodology and data reported by her colleague in several publications that were based on the same study indicated that they were falsified. An institutional inquiry concluded that there were problematic aspects of data management and reporting, but no evidence of deliberate deception or scientific misconduct. The complainant questioned the conclusions of the inquiry and the institution agreed to conduct an investigation. Four members of the investigation committee found that the conclusions in the questioned publications would not be weakened if all errors and other irregularities in data management were removed and they concluded there was no intent to deceive and no misconduct. One committee member dissented, holding that the irregularities were serious enough to constitute misconduct and, if there was no intent to deceive, that the respondent was incompetent to conduct independent research. During its review, ORI conducted further analysis to determine whether a pattern of inconsistencies could be identified. ORI's analysis demonstrated that there was no example of a repeated inconsistency associated with any variable examined. ORI concluded that, if any misrepresentation had occurred, it was likely due to honest error.

Falsification: Two colleagues alleged that three researchers had falsely reported the methodology and results of a clinical trial in a published article. An institutional investigation committee found numerous discrepancies between the protocol, the manner in which the study was conducted, and what was reported in the article. Besides containing numerous factual errors, the committee concluded that the article "described a careful prospective clinical study which was not carried out." However, the committee did not find misconduct because it found no intention to deceive. Instead, the committee attributed the respondent's actions to undertaking "a complex task of conducting a clinical investigation while lacking the knowledge and experience necessary to accomplish that task. The respondents' failure to understand the requirements of clinical research was underscored by the lack of any systematic data management or record keeping, essential elements of clinical investigation. Similarly, the respondents failed to understand that subjective clinical judgments, regardless of the clinical expertise of the investigators, do not substitute for more objective means of assessment when a protocol proposes and a paper reports that the more objective means were used . . ." A letter of correction submitted by the respondents was published by the journal. The institution established a committee of experienced clinical investigators to supervise the respondents' continuing clinical research and review their manuscripts prior to submission for publication. ORI accepted the disposition of the case by the institution.

Falsification: A researcher alleged that his colleague falsified results of a study by mislabeling blood samples. An investigative committee at the institution concluded that the wrongly-labeled samples seriously distorted the study results. However, the committee could not determine whether the mislabeling was performed intentionally or erroneously. Nor could it determine when, where or by whom the mislabeling was performed. The samples were collected and labeled in another country. Manipulation of the labels at the institutions in this country would have required an elaborate series of actions for which there was no evidence. The institution concluded there was insufficient evidence for a finding of scientific misconduct. ORI accepted that conclusion because of the low likelihood that credible evidence could be obtained to answer the remaining questions.

Plagiarism: Two colleagues accused the respondent who was a junior faculty member of plagiarizing their published article. All three researchers were part of the same department, but the complainants and the respondent had published separate articles on their separate projects. The project director told the three researchers to prepare an article for a special journal issue combining their previously published works and he assigned the respondent as first author. The respondent incorporated verbatim nearly the entire text of the article written by the complainants and their collaborators, who included the project director. Two citations to the complainants' workshop presentation were made, but the verbatim material was not enclosed in quotation marks. The complainants objected to the

designation of the respondent as first author and withdrew as co-authors. The article was published with no changes except that the respondent was the sole author. The institutional investigation committee found the respondent "guilty of publishing without adequate attribution verbatim material that had been previously published by other members of the . . . project." However, the committee also concluded that the respondent was guilty of a form of misconduct that does not amount to scientific misconduct under the PHS regulations. ORI accepted the institutional decision because of the special supervisory circumstances involved in the case.

Other Practices: In another aspect of the above case, the two colleagues also alleged that their project director engaged in a serious deviation from commonly accepted practices when, as their supervisor and the editor of a special journal issue, he accepted an article from a member of the department that plagiarized their work. An institutional investigation found that the respondent had instructed the complainants and another project member to prepare an article for a special journal issue he was editing, to combine articles published separately by the complainants and the other project member, and he assigned the latter as lead author for the new article. After reviewing the draft document, the complainants informed the project director that they objected to the text and the order of authorship and withdrew as coauthors. However, nearly the entire text of their article was incorporated verbatim into the combined article with two citations to a workshop presentation but no quotes. The article was published in the special issue with the other project member as sole author. The respondent claimed he did not review the manuscript before including it in the special issue. The institutional investigation committee found the respondent had failed to fulfill the responsibilities of a guest editor and had violated the faculty code of conduct by his uncollegial and unethical behavior toward his junior collaborators but that his actions did not constitute scientific misconduct under the PHS regulation. ORI accepted the institutional decision.

Fabrication/Falsification: A researcher alleged that a colleague used fabricated data in two tables intended for use in a poster presentation. While looking into this allegation, the inquiry committee found sufficient evidence to begin an investigation into whether the respondent falsely described the data collection technique in an abstract. The number of charges was increased during the investigation to include false reporting of data in two publications. The investigation committee did not find misconduct for the following reasons: (1) the poster was neither finalized nor presented in public; (2) the misrepresentation of the data collection technique in the abstract was considered an error because the stated technique was used to produce some data in the study; and (3) the publication of the inaccurate and misleading papers was due to egregious and unacceptable data and laboratory management practices. The investigation committee recommended that the abstract and publications be retracted and that appropriate actions be taken against the respondent and his supervisor who reportedly knew of the errors in the publications but failed to correct them. The reviewing faculty committee concluded that the respondent's conduct fell under the "other practices clause" of the PHS definition of scientific misconduct and recommended that his appointment not be renewed and that the supervisor be evaluated to determine whether she should continue as laboratory director. ORI determined that the abstract and one publication fell under PHS jurisdiction. ORI determined that insufficient evidence existed to find misconduct.

Fabrication/Falsification: A senior research associate accused two researchers of fabricating or falsifying experimental results reported in figures and tables in a grant application. The complainant claimed the data did not reflect the results he had obtained in a set of experiments. He further stated that he was the only person in the laboratory conducting those particular experiments because he was the only person permitted to handle radioactive isotopes. The investigation committee determined that where experimental records were available they were consistent with the data presented in the grant application. However, because much data had not been retained, it was not possible to determine whether the reported results were completely accurate. In addition, the committee found that other laboratory members also performed the questioned experiments even though they were not authorized to handle radioactive isotopes. The committee suggested that the complainant may not have known that particular experiments were being conducted by others because of his frequent and lengthy absences from the laboratory. The committee concluded there was insufficient evidence to find scientific misconduct, but recommended actions to be taken to improve record keeping and the handling and retention of data in the laboratory. The respondents appealed the recommended actions within the institution asserting that the record keeping and data handling and retention problems were limited to the experiments conducted by the complainant. A separate review of the laboratory concluded that record keeping was generally acceptable, but improvements could be made in some areas. The recommended actions were significantly reduced. ORI accepted the disposition of the case by the institution.

Fabrication/Falsification: A former postdoctoral fellow in the PHS intramural program alleged that her ideas and data had been plagiarized by four colleagues who failed to include her as a co-author on a submitted manuscript. An agency inquiry also raised the possibility of data fabrication and falsification in the submitted manuscript and concluded that an investigation was warranted. ORI determined that the alleged theft of ideas and failure to include the complainant as an author constituted an authorship dispute between collaborators and ORI referred it to the agency for resolution. ORI conducted an investigation into the alleged data fabrication and falsification by one of the co-authors. ORI found that purchase and mortality records for mice,

laboratory notebooks, handwritten tables, computer files, and testimony of witnesses demonstrated that the research had been conducted and accurately reported. ORI concluded that scientific misconduct did not occur.

Fabrication/Falsification/Plagiarism: Three colleagues accused the respondent of falsification, fabrication, and plagiarism in research publications, manuscripts, and grant applications. The institutional investigation committee found "substantial evidence" to support the allegations. During its oversight review, ORI found PHS funding was involved in only two of the allegations. ORI found insufficient evidence to conclude that the respondent had deliberately fabricated or falsified citations to published articles in a grant application. ORI also concluded that the subsequent use by the respondent of text from an article he coauthored did not constitute plagiarism.

Falsification/Plagiarism: An author charged that a colleague in the department had plagiarized from his book in writing journal articles. During the inquiry, the committee found that the respondent may have falsified his credentials in several grant applications, claiming he was an associate professor at a nearby university rather than an adjunct assistant professor. The institutional investigation committee found that the respondent had committed plagiarism because the citation of the book in the introductory section was not sufficient to indicate that the disputed text and table formats were taken from the book, but did not find misconduct because the questioned text was not considered to have materially affected the scientific conclusions of the article. The allegation of false credentials was dismissed because the resume files and biographical sketches were maintained by the editorial staff, so it could not be shown who was responsible for the misrepresentations. ORI considered the questioned text to be material but ORI concluded the presentation of the citation of the book relative to the questioned text demonstrated a lack of intent to deceive. In addition, ORI did not consider the limited use of identical or nearly-identical phrases which describe a commonly-used methodology to warrant finding plagiarism in this case. ORI also agreed with the institutional finding on the credentials allegation because the respondent did not completely control the selection of biographical information for applications and because he had always properly cited his position at his own institution, and indicated that the university positions were not full-time.

SUMMARY OF HEARING

Thereza Imanishi-Kari, Ph.D., Tufts University

Dr. Imanishi-Kari requested a hearing in late 1994 on the ORI findings that she had falsified and fabricated data in a journal article, in PHS grant applications, and in information submitted to Federal investigators. Attorneys for ORI filed approximately 700 exhibits comprising 19 notebooks for the hearing which lasted 27 days between June 12 and September 15. As required by the DAB, attorneys for ORI filed an extensive post-hearing brief and findings of fact and conclusions of law in late December and a reply to the respondent's post-hearing brief on March 1, 1996. Final arguments were entertained by the DAB on March 19, 1996. Just prior to issuance of this report, the DAB reversed the ORI findings of misconduct, primarily based on its rejection of extensive forensic evidence provided by the U.S. Secret Service.

CLOSED INVESTIGATIONS - STATISTICAL PROFILE

This section presents a descriptive analysis of the 41 investigations closed during 1995 under the following headings: (1) Setting of Closed Investigations, (2) Types of Misconduct, (3) Institutional Actions, (4) Government Actions, (5) Respondent, (6) Relationship between Complainant and Respondent, (7) Complainant, (8) Length of Inquiries, (9) Length of Investigations, and (10) Size of Panels. Investigative outcomes are based on the final disposition of the case including the result of any hearing.

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

Ninety-three percent of the 41 investigations closed in 1995 involved PHS extramural research programs in the Agency for Health Care Policy and Research and 12 NIH institutes. The intramural investigations involved the Centers for Disease Control and Prevention (CDC) and two NIH institutes. Sixty-one percent of the extramural investigations concluded with a finding of scientific misconduct; one of the three intramural investigations also found misconduct. Twenty-four of the 41 investigations resulted in a finding of misconduct.

Table 3: Outcome of Investigations by PHS Research Program, 1995.

Program	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
Extramural	23	13	2	38
Intramural	1	1	1	3
TOTAL	24	14	3	41

Institutional Setting

Thirty-four institutions were involved in the extramural investigations closed in 1995. Twenty institutions found misconduct; three institutions found misconduct twice. Twenty-eight institutions handled a single investigation; five institutions were involved in two investigations each. Thirty-

seven investigations were conducted within a single institution; one investigation covered two institutions. One medical school was involved in four investigations at affiliated institutions. Almost half of the investigations were conducted in medical schools; other prominent sites were hospitals and research institutes. Within institutions, the investigations involved such departments as biochemistry, biology, cell biology, experimental therapeutics, gerontology, immunology, internal medicine, medicine, neurology, obstetrics and gynecology, oncology, ophthalmology, pathology, pharmacology, psychology, psychiatry, radiology, surgery, and urology. Medical schools and hospitals accounted for two-thirds of the misconduct findings.

Table 4: Outcome of Investigations by Institutional Setting, 1995

Institutional Setting	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
Medical School	10	7	2	19
Hospital	6	2	0	8
Research Institute	3	3	0	6
Intramural	1	1	1	3
College/University	2	0	0	2
School of Nursing	1	0	0	1
Biotech Laboratory	1	0	0	1
Professional Association	0	1	0	1
TOTAL	24	14	3	41

Funding Mechanisms

Thirteen funding mechanisms were involved in the closed investigations. The traditional research grant, RO1, was involved in 66 percent of the investigations. Another mechanism of note is research program projects (PO1) at 12 percent. Other mechanisms involved in the closed investigations were cooperative clinical research grants (R1O), a U.S.-Japan Cooperative Program award (R22), first independent research support and transition (FIRST) awards (R29), small business innovation research grants, Phase II (R44), specialized centers (P50), research scientist development award—research (KO2), general clinical research centers (MO1), research and development contracts (NO1), biomedical research support grants (SO7), cooperative research project (UO1), and cooperative clinical research (U10). Thirty-three investigations involved a single mechanism; six investigations involved two mechanisms and two involved three.

Table 5: Outcome of Investigations by Funding Mechanism, 1995

Funding Mechanism	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
RO1	14	13	0	27
R10	0	1	0	1
R22	0	1	0	1
R29	1	0	1	2
R44	1	0	0	1
PO1	3	2	0	5
P50	0	2	0	2
KO2	0	1	0	1
MO1	0	1	0	1
NO1	0	1	0	1
SO7	1	0	0	1
UO1	1	0	0	1
U10	1	0	0	1
Intramural	0	1	2	3
Other	2	0	1	3
TOTAL	24	23	4	51

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." Thirty-two of the 38 extramural investigations closed in 1995 (84 percent) were conducted solely by the institutions; two investigations (five percent) involved both institutions and ORI; and four investigations (11 percent) involved only ORI. The two investigations that included institutions and ORI were taken over by the former Office of Scientific Integrity (OSI), in the first instance, because two institutions were involved, the investigating institution's process was deficient, and the complainant continued to challenge the institutional finding, and, in the second instance, because the investigating institution's process was deficient, forensic examination of the evidence was necessary, the respondent was a Federal employee, and the case was referred by the FBI through the OIG. ORI conducted four investigations at institutions because they were concerned with the fabrication and falsification of data in multi-center clinical trials.

Table 6: Outcome of Investigations by Performer of Investigation, 1995

Performer	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
Institutional	19	11	2	32
Institutional/ORI	1	1	0	2
ORI	4	2	1	7
TOTAL	24	14	3	41

Types of Misconduct

Allegations of fabrication and/or falsification provided the basis for 90 percent of the investigations closed in 1995. Fabrications and/or falsification accounted for 92 percent of the misconduct findings; 86 percent of the no misconduct findings, and 100 percent of the administrative closures. Falsification was involved in 31 cases; fabrication in 19 cases; plagiarism in five cases, and other misconduct in one case. Falsification occurred more frequently as a single allegation than in combination with fabrication or plagiarism. Fabrication occurred most frequently in combination with falsification. Respondents were found to have falsified data; protocols, letters of recommendation or collaboration, and credentials. Besides fabricating data respondents also fabricated subjects and dates of tests or examinations in clinical trials. The fabrication and/or falsification occurred in notebooks, questionnaires, published articles, grant applications, submitted manuscripts, and abstracts. Investigations most frequently supported singular allegations of fabrication (83 percent). Fifty-nine percent of the investigations resulted in a finding of misconduct.

Table 7: Outcome of Investigations by Type of Misconduct, 1995

Allegation	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
Fabrication	5	1	0	6
Falsification	10	5	2	17
Plagiarism	2	1	0	3
Other	0	1	0	1
Fabrication/Falsification	7	4	1	12
Falsification/Plagiarism	0	1	0	1
Fab/Fals/Plagiarism	0	1	0	1
TOTAL	24	14	3	41

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 reported 20 administrative actions in 13 misconduct cases and three no misconduct cases. In nine misconduct cases, the respondent resigned or was dismissed. In two misconduct cases, research conducted by the respondents was subjected to supervision. In another case the respondent was expelled from the degree program and prohibited from re-enrolling. Institutions also issued reprimands and required a respondent to correct a published article. In one no misconduct case in which the respondents failed to understand the requirements of clinical research, the institution established a committee of experienced clinical investigators to oversee research conducted by the respondents and review their manuscripts prior to submission. In another no misconduct case, the respondent was reprimanded for his uncollegial and unethical behavior toward his junior collaborators. In the third no misconduct case, the respondent was reprimanded because he failed to properly attribute the published work of his colleagues in an article he published.

Table 8: Outcome of Investigations by Reported Institutional Action, 1995

Institutional Action	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
Reprimand	3	2	0	5
Supervised Research	2	2	0	4
Prohibit Re-Enrollment	1	0	0	1
Correction of Articles	1	0	0	1
Terminated Employment	9	0	0	9
TOTAL	16	4	0	20

Government Actions

The PHS regulation on misconduct in science also recognizes the authority of HHS to impose administrative actions of its own on investigators and institutions for violating the regulation. The Department took 51 administrative actions against respondents in the 24 misconduct cases. A single administrative action was imposed on five respondents; two were imposed on 13 respondents, three on four respondents, and four on two respondents. Sixteen of the 24 respondents found to have committed scientific misconduct were debarred from receiving Federal grants, contracts, and cooperative agreements for periods of two to three years. Twenty-one respondents were prohibited from serving on PHS advisory committees, boards, or peer review groups for periods of two to three years. Institutions employing six respondents were required to submit a plan for supervising the participation of the respondents in any PHS supported research for a period of three years. An institution employing one debarred respondent was required to certify for one year after the debarment ended that the data submitted by the respondent in grant applications existed and was accurately represented. Two other respondents were required, for a period of three years, to submit a certification that the work of others contained in each document, application, or report he or she submitted to a PHS component is properly attributed. Five respondents agreed to retract or correct published articles.

Table 9: Frequency of Type of Government Action, 1995

Govt. Actions	*Frequency*
Debarment	16
Advisory Committee	21
Certification of Sources	2
Certification of Data	1
Supervised Research	6
Correction/Retraction	5
TOTAL	51

Respondents

The respondents are described by (1) academic rank, (2) highest academic degree, and (3) gender.

Respondents' Academic Rank

Respondents in the 41 investigations closed in 1995 ranged from technician to professor. Allegations were made slightly less often against senior personnel (professors and associate professors) than junior personnel, 47 percent to 53 percent. The most frequent targets of allegations were associate professors, assistant professors, technicians, and professors. Allegations were more often supported against junior personnel than senior personnel, 68 percent to 32 percent. Allegations against technicians and fellows were most frequently supported (100 percent). Technicians and fellows accounted for half of the misconduct findings.

Table 10: Outcome of Investigations by Academic Rank of Respondent, 1995

Respondent	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
Professor	2	4	1	7
Assoc. Professor	5	9	1	15
Asst. Professor	2	6	0	8
Research Instructor	1	0	0	1
Fellow	4	0	1	5
Res. Assoc./Asst.	1	1	0	2
Medical Student	1	0	0	1
Technician	8	0	0	8
TOTAL	24	20	3	47

Respondents' Highest Academic Degree

Seventy-four percent of the accused respondents held a doctorate; 38 percent held a Ph.D. degree, 34 percent held a M.D. degree, and 2 percent held an ED.D. Four respondents held a bachelor's degree; the degree held by eight respondents is unknown. Fifty-eight percent of the respondents found guilty of scientific misconduct held doctorates; 29 percent held M.D. degrees 25 percent held Ph.D. degrees; and four percent held ED.D. degrees. Allegations against respondents with bachelors' degrees were most frequently supported (100 percent).

Table 11: Outcome of Investigations by Highest Academic Degree of Respondent, 1995

Respondent	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
Ph.D*	6	9	3	18
M.D.	7	9	0	16
ED.D.	1	0	0	1
B.S.	4	0	0	4
Unknown	6	2	0	8
TOTAL	24	20	3	47

* Includes a Doctor of Science

Respondents' Gender

Seventy-four percent of the accused respondents were male. Male respondents also constituted 58 percent of the individuals found guilty of scientific misconduct. However, allegations against female respondents were more frequently supported, 83 percent to 40 percent. Forty percent of the females found to have committed scientific misconduct held coordinating positions—data, clinic, or program.

Table 12: Outcome of Investigations by Gender of Respondent, 1995

Respondent	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
Male	14	18	3	35
Female	10	2	0	12
TOTAL	24	20	3	47

Complainants

Complainants are described by (1) relationship to respondents, (2) academic rank, (3) highest academic degree, and (4) gender. There was a single complainant in 30 investigations. Two investigations had two complainants each. The number of complainants for the remaining nine investigations could not be determined.

Relationship to Respondents

The relationships that existed between complainants and respondents in the 1995 closed investigations covered a broad range. The most frequent relationship was collaborator followed by colleague, lab chief/research director, principal investigator, and reviewer. In two cases there was no relationship between the complainant and the respondent. The complainants were a lawyer and a reporter. The relationship between the complainant and the

respondent was unknown in ten investigations because five complainants made their allegations anonymously and the other five were made by inquiry committees, data coordinating centers, and PHS agencies without identifying an individual as the complainant.

Table 13: Outcome of Investigations by Relationship of Complainant to Respondent, 1995

Complainant	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
Dean	1	0	0	1
Department Chair	0	0	1	1
Lab Chief/Research Dir.	4	0	0	4
Principal Investigator	3	0	0	3
Collaborator	5	5	1	11
Colleague	1	4	0	5
Reviewer	2	1	0	3
Fellow	1	0	0	1
Research Asst.	1	0	0	1
Student	1	0	0	1
No Relationship	1	1	0	2
Unknown	6	3	1	10
TOTAL	26	14	3	43

Complainants' Academic Rank

The complainants spanned the academic rank structure. Nineteen complaints were senior personnel (dean, professor, associate professor) while eight were junior personnel. Two complainants, a lawyer and a reporter, did not hold academic rank. The academic rank of 14 complainants was unknown.

Table 14: Outcome of Investigations by Academic Rank of Complainant, 1995

Rank	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
Dean	1	0	0	1
Professor	8	0	1	9
Assoc. Professor	5	4	0	9
Asst. Professor	1	3	0	4
Fellow	0	1	0	1
Graduate Student	1	0	0	1
Research Associate	0	0	1	1
Technician	0	1	0	1
None	1	1	0	2
Unknown	9	4	1	14
TOTAL	26	14	3	43

Complainants' Highest Academic Degree

Twenty-six complainants held doctorates; 17 held Ph.D. degrees; eight held M.D. degrees; and one held a J.D. One complainant respondent held a master's degree; and two held bachelor's degrees. The highest academic degree of 14 complainants was unknown.

Table 15: Outcome of Investigations by Highest Academic Degree of Complainant, 1995

Degree	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
Ph.D.	10	5	2	17
M.D.	6	2	0	8
J.D.	0	1	0	1
M.S.	0	1	0	1
B.S.	2	0	0	2
Unknown	8	5	1	14
TOTAL	26	14	3	43

Complainants' Gender

The complainants were mostly males. Twenty-six complainants were males and five were females. The gender of 12 complainants was unknown. Investigations supported the allegations made by male and female complainants at about the same rate (62 percent vs. 60 percent).

Table 16: Outcome of Investigations by Gender of Complainant, 1995

Gender	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
Male	16	9	1	26
Female	3	1	1	5
Unknown	7	4	1	12
TOTAL	26	14	3	43

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 these criteria, 24 inquiries (59 percent) were completed within the required 60-day period. The length of inquiries ranged from two days to 392 days. The shortest inquiry involved a respondent who reported falsified data to a coordinating center in a clinical trial. The longest inquiry involved an allegation of plagiarism brought by two members of a project team against another team member. The shortest and longest inquiries recommended investigations.

Table 17: Outcome of Investigations by Length of Inquiry Recommending the Investigation, 1995

Inquiry Length	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
0-60 days	16	7	1	24
61-90 days	2	1	1	4
91-120 days	0	1	0	1
121-150 days	1	4	0	5
Over 150 days	5	1	1	7
TOTAL	24	14	3	41

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. Ten investigations (24 percent) were completed within 120 days. The length of an investigation ranged from 22 days to 2120 days. The shortest investigation examined the allegation of plagiarism which was the subject of the longest inquiry. The investigation resulted in a finding of no misconduct under the PHS definition of scientific misconduct. The longest investigation involved a claim by an investigator in a grant application that he had identified three reagents that were crucial to the development of a diagnostic technique. The investigation did not find misconduct.

Table 18: Outcome of Investigations by Length of Investigation, 1995

Length	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
0-120 days	6	4	0	10
121-180 days	7	3	0	10
181-240 days	3	0	1	4
241-300 days	2	2	1	5
Over 300 days	6	5	1	12
TOTAL	24	14	3	41

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 composed of one to six members to provide this expertise. The modal and median size of inquiry panels was three members.

Table 19: Outcome of Investigations by Size of Inquiry Panel Recommending an Investigation, 1995

Members	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
One	7	1	0	8
Two	4	0	2	6
Three	8	8	1	17
Four	2	3	0	5
Five	2	0	0	2
Six	1	2	0	3
TOTAL	24	14	3	41

The size of the investigative panels ranged from one to eight members. The modal size of investigative panels was three members; the median size was four.

Table 20: Outcome of Investigations by Size of the Investigative Panel, 1995

Members	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
One	3	0	0	3
Two	2	1	1	4
Three	8	4	1	13
Four	1	2	1	4
Five	6	2	0	8
Six	4	1	0	5
Seven	0	1	0	1
Eight	0	3	0	3
TOTAL	24	14	3	41

PART V: INSTITUTIONAL COMPLIANCE

The PHS regulation on misconduct in science places several requirements on institutions receiving funds under the PHS Act:

Section 50.103(a) of the regulation states: "Each institution that applies for or receives assistance under the Act for any project or program which involves the conduct of biomedical or behavioral research must have an assurance satisfactory to the Secretary that the applicant: (1) Has established an administrative process that meets the requirements of this Subpart, for reviewing, investigating, and reporting allegations of misconduct in science in connection with PHS-sponsored biomedical and behavioral research conducted at the applicant institution or sponsored by the applicant; and (2) Will comply with its own administrative process and the requirements of this Subpart."

Section 50.103(b) of the regulation states: "The institution's assurance shall be submitted to the [ORI], on a form prescribed by the Secretary, . . . and updated annually thereafter . . . An institution shall submit, along with its annual assurance, such aggregate information on allegations, inquiries, and investigations as the Secretary may prescribe."

Section 50.103(d)(13) states that institutional policies and procedures must provide for "undertaking diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed, and also undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations."

Section 50.103(c)(2) requires an institution to "inform its scientific and administrative staff of the policies and procedures and the importance of compliance with those policies and procedures."

ORI monitors institutional compliance with these requirements through two programs: the Assurance Program and the Compliance Review Program.

Assurance Program

The Assurance Program is responsible for ensuring that institutions that receive PHS funds have an active assurance on file with ORI. The Assurance Program meets its responsibilities by maintaining the Assurance Database, auditing awards to institutions, conducting the Annual Report on Possible Research Misconduct, and reviewing institutional policies and procedures in collaboration with the Compliance Review Program.

Assurance Database

As of December 31, 1995, there were 3,623 active assurances in the ORI Assurance Database, including 185 from 28 foreign countries. (See Table 21.) In 1995, 377 institutions filed initial assurances with the ORI, thereby becoming eligible to receive PHS research funds under the regulation.

TABLE 21: Type of Institution with Active Assurance by Frequency, December 31, 1995.

Type of Institution	*Frequency*
Institutions of Higher Education	881
Research Organizations, Institutes, Foundations and Laboratories	337
Independent Hospitals	324
Educational Organizations Other Than Higher Education	28
Other Health, Human Resources, and Environmental Services Organizations	469
Other (small business)	1569
Unclassified	15
TOTAL	3623

Two hundred and seventy-nine institutions became ineligible to receive PHS funds in 1995 because they permitted their assurances to become inactive. Fifty-eight of these institutions voluntarily withdrew their assurances because they (1) did not expect to apply for PHS funds, (2) did not conduct research, (3) merged with another institution, or (4) went out of existence. ORI inactivated the assurances of the 221 remaining institutions because they did not comply with the PHS regulation. (See Table 22.) Institutions may reactivate their assurance by complying with the regulation (i.e., submitting their Annual Report, providing their policies and procedures upon request, etc.).

Table 22: Number of Assurances Inactivated by Cause, 1995.

Cause	*Number of Institutions*
Failure to Return Annual Report	141
Failure to Submit Policies and Procedures	80
Voluntary Inactivation	58
TOTAL	279

Beginning in 1996, institutions will no longer be required to file their initial assurance with ORI by submitting a separate form (PHS form 6315). Instead, institutions will automatically submit their assurance when signing the face page of the revised PHS Grant Application Form 398. Similar revisions were made in 1994 to the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Program grant applications (PHS Form 6246).

Auditing Awards

Before making an award, PHS grant management officers are required to check the eligibility of the institution to receive funding by determining whether the institution is listed in the ORI Assurance Database. An institution may not be listed in the database because it did not file an assurance with ORI or it did not keep its assurance active by submitting the Annual Report on Possible Research Misconduct or it voluntarily inactivated its assurance. If the institution is not listed, the grant management officer notifies ORI which requests the appropriate document from the institution to establish its eligibility for funding.

In 1995, an audit indicated that awards were made to 42 ineligible institutions. ORI requested an initial assurance from these institutions and notified the appropriate grants management staff in PHS agencies about the problem. As of December 31, 1995, an assurance was received from 17 institutions.

Annual Reports on Possible Scientific Misconduct

To keep its assurance active, each institution must 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 becomes ineligible to apply for or receive PHS research funds.

Annual Report forms were mailed in January 1995 to the 3,204 institutions that had an assurance on file with ORI as of November 1, 1994. Responses were received from 3,018 institutions for a response rate of 94.2 percent. However, only 70 percent of the institutions returned their Annual Reports by the March 1 deadline.

The 1994 Annual Report survey indicated a high turnover rate among officials responsible for implementing policies and procedures for handling allegations of scientific misconduct. Seventeen percent of the institutions (535) changed their responsible official in 1994.

The Annual Report form requested institutions to report on (1) the availability of policies and procedures for responding to allegations of scientific misconduct, (2) the number of allegations of scientific misconduct received and the number of inquiries and investigations conducted, (3) actions taken to restore the reputation of exonerated respondents, (4) actions taken to protect the position and reputation of complainants, and (5) mechanisms used to inform faculty and administrative staff about the policies and procedures adopted by the institution to respond to allegations of scientific misconduct.

Availability of Policies and Procedures

Two hundred and seventy-three institutions indicated they did not have policies or procedures for responding to allegations of scientific misconduct or failed to answer the pertinent question on the Annual Report form. ORI asked these institutions, except for 89 small businesses, to submit their policies and procedures for review within 60 days, or risk losing their eligibility to receive PHS research funds.

Eighty-four institutions submitted their policies and procedures within 60 days and 20 institutions asked for additional time to develop policies and procedures. The assurances were inactivated for the remaining eighty institutions.

Allegations, Inquiries and Investigations

Seventy-nine institutions reported they were responding to allegations of scientific misconduct. Fifty institutions received new allegations of scientific misconduct in 1994. Forty-two institutions were continuing to process allegations made in 1993. Thirteen of the institutions were responding to allegations made in 1993 and 1994.

In their annual reports, institutions report the receipt of an allegation of scientific misconduct, the type of 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 50 institutions reporting new allegations in 1994, 39 were institutions of higher education; five were research organizations; one was an independent hospital; two were other health, human resources, or environmental service organizations; and three were small businesses.

Sixty-four new cases were opened by the 50 institutions in 1994. The number of new cases opened by these institutions ranged from one to four. These cases involved 89 allegations, including 23 of fabrication, 29 of falsification, 10 of plagiarism and 27 of other practices. Twenty-three cases involved multiple allegations.

The 79 institutions conducted 88 inquiries and 55 investigations in 1994 including 56 inquiries and 20 investigations stemming from new allegations. The number of inquiries conducted by an institution ranged from zero to eight. The number of investigations conducted by an institution ranged from zero to four.

Restoring Reputations

Institutions reported they rely heavily on the confidentiality of their administrative process for handling allegations of scientific misconduct to protect the reputation of accused individuals, but they also take additional steps to restore the reputation of exonerated individuals.

Federal regulations require institutions applying for or receiving PHS funds to "afford the affected individual confidential treatment to the maximum extent possible" and undertake "diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed."

Two steps frequently taken by institutions were described as follows: "Information of 'not found guilty of misconduct' is sent to all parties involved including complainant, respondent, witnesses, panel members, department chair, and national or state agency. Personnel file is cleaned of all documents regarding the allegations."

The information is usually contained in letters from the president, dean or other high level administrator. Besides those involved in the process, letters may be sent to "top administrators," professional societies, "home institution" or "all individuals whom the person was interested in having the information disseminated to." In a highly publicized case, the president, provost, and integrity officer issued public letters that were published in the university newspaper.

In one case, the exonerated individual was "relocated in a different environment with institutional funding for a fixed (18 month) period." In another case, the individual was counseled by the dean and associate dean for research. In a third case, the institution "provided defense in civil litigation."

Protecting Complainants

Institutions reported a range of actions taken to protect individuals who make allegations of scientific misconduct in good faith.

Federal regulation requires institutions that apply for or receive PHS funds to protect "to the maximum extent possible, the privacy of those who in good faith report apparent misconduct" and undertake "diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations."

Among the actions reported by the institutions were (1) protecting the identity of the complainant; (2) moving the complainant to another laboratory; (3) warning the accused against taking retaliatory actions; (4) investigating charges of retaliation; (5) monitoring for potential retaliatory action; (6) providing financial assistance to restore the complainant's research program; (7) publishing public letters from the president and provost in the university newspaper, and (8) informing appropriate officials that the allegation was made in good faith.

Additional actions are indicated in the following institutional reports:

- "Co-workers were cautioned to avoid negative behavior toward the complainant. They were told he was doing the 'right thing.' His identity has been protected except on a "need to know" basis. The complainant left . . . to go to another high quality academic experience elsewhere. He was assisted by the university."

- "In the one instance where such protection was required, the University prevented the attempt by the respondents to terminate the complainant, and the University continues to ensure the employment of this individual at another laboratory within the University."

- ". . . The Director of the Regulatory Compliance Office informed the complainant about state 'whistleblower statutes' and encouraged the complainant to maintain contact with the RCO, and the department chairman and college Dean were reminded of the protections afforded to the complainant."

- ". . . Special arrangements were made for the person who made the allegations (a postdoc) to use an alternate laboratory for completion of his experiments so as not to conflict with the person alleged to have committed scientific misconduct (the postdoc's supervisor). Finally, an administrative procedure was established for ensuring that the supervisor's letters of recommendation for the postdoc were not influenced by the postdoc's allegations of scientific misconduct."

Informing Faculty and Staff

Federal regulation requires an institution to inform "its scientific and administrative staff of the policies and procedures and the importance of compliance with those policies and procedures" as a general condition of compliance with its assurance.

Institutions reported various efforts to inform their scientific and administrative staff about their policies and procedures for responding to allegations of scientific misconduct involving PHS-supported behavioral and biomedical research.

The institutional efforts vary by the number of mechanisms employed, the populations covered, the amount of information distributed, the frequency of distribution, and the ease of access to the information.

The most popular mechanism employed by institutions is publication of their policies and procedures in one or more handbooks or manuals for faculty, staff, principal investigators, researchers, employees, graduate students and fellows, institutional review boards, administrators, and project directors.

Some institutions have developed pamphlets and brochures containing their policies and procedures and distributed them to all concerned. Other institutions have published a summary of their policies and procedures in newsletters that cover the entire institution or specialized groups such as administrators and principal investigators.

A few institutions have distributed the policies and procedures by memo to all faculty and staff and have required all members to sign a document certifying that they had read the document and agree to follow the principles.

Although most institutions have distributed the policies and procedures in hard copy, some have made their policies and procedures available electronically on their E-mail system, Internet home page, or electronic bulletin board.

Some institutions discussed their policies and procedures at Faculty Senate and research council meetings, orientation sessions for new employees, postdoctoral fellows and graduate students or during courses, seminars, and luncheon lecture series on research ethics or misconduct in science.

Many institutions make their policies and procedures available in several offices, including department heads, deans, and sponsored programs.

Policies and Procedures

ORI requested policies and procedures from 292 institutions for review in 1995. (See Table 23.) The policies and procedures were requested either because institutional officials indicated that their institutions did not have the required policies and procedures in response to a question on the 1994 Annual Report on Possible Research Misconduct or they failed to answer the question on the form. Policies and procedures also were requested in the newly-initiated annual five percent sample and as part of institutional compliance reviews.

Table 23: Number of Policies and Procedures Requested by Cause, 1995.

Cause	*Number of Policies and Procedures*
Indicated Did Not Have Policies/Procedures	114
Failed to Answer Question about Policies	70
Annual Sample for Review	92
Compliance Reviews	16
TOTAL	292

Annual Review Sample

ORI initiated a systematic process in 1995 for reviewing institutional policies and procedures for responding to allegations of scientific misconduct that have been established by institutions that apply for or receive PHS research funds in compliance with the PHS regulation.

Policies and procedures were requested from 92 institutions. Seventy-nine institutions submitted their policies and procedures for review; seven signed small organization agreements, five withdrew their assurance, and one institution did not respond. The nonresponsive institution has been informed that failure to submit the requested document will make it ineligible to receive PHS funds.

The review of the 79 submitted policies and procedures was completed on December 4, 1995. Policies and procedures from 14 institutions were found to comply with the provisions of the PHS regulation. The remaining 65 institutions were sent reports that noted the deficiencies in their policies and procedures and requested submission of a revised document in 90 days.

Compliance Review Program

The Compliance Review Program (CRP) is responsible for ensuring that institutions that apply for or receive PHS funds establish the required policies and procedures and comply with them and the PHS regulation in responding to allegations of research misconduct. In addition, the CRP responds to retaliation complaints from complainants and monitors the implementation of PHS administrative actions by institutions and PHS agencies.

Compliance Reviews

A compliance review generally is conducted when compliance problems are noted during ORI review of the inquiry and/or investigation conducted by the institution or when ORI receives an allegation of noncompliance. A compliance review may consist of one or more of the following components: (1) an analysis of the policies and procedures established by the institution, (2) an examination of the case file to determine the process actually followed by the institution in responding to an allegation of scientific misconduct, (3) a site-visit to review the institutional records and conduct interviews, or (4) other actions deemed appropriate to gather information regarding potential compliance issues.

The appropriate institutional official is informed about the initiation, purpose, and scope of a compliance review. If necessary, a copy of the most recent policies and procedures will be requested. Once the review had been completed, a draft report is sent to the appropriate institutional official for comment. After giving the institutional comments due consideration, the final report is prepared with the institutional comments included as an appendix. The final report is sent to the institution, and any additional follow-up related to recommended corrective actions is monitored.

On January 1, 1995, the Compliance Review program was actively reviewing 17 compliance cases. (See Table 24.) Of that total, seven were compliance reviews, eight involved retaliation complaints, and two were combinations of both. Over the twelve-month period, five additional compliance reviews were initiated, six retaliation complaints were received, and two combination reviews were opened. By December 31, 1995, five compliance reviews were completed and nine retaliation complaints were resolved. Sixteen cases were carried into 1996 including seven compliance reviews, five retaliation complaints, and two combinations.

Of the five compliance cases closed during 1995, three involved full reviews, examining the policies and procedures as well as the process, while two cases involved a review of only the institutional policies. The institutions agreed to revise their policies and procedures to eliminate the deficiencies noted in the compliance review reports.

Table 24: Compliance Review Caseload by Case Type, 1995

Case Type	*Forwarded From 1994*	*Opened In 1995*	*Closed In 1995*	*Forwarded To 1996*
Compliance Reviews	7	5	5	7
Retaliation Complaints	8	6	9	5
Compliance/Retaliation	2	2	0	4
TOTAL	17	13	14	16

Retaliation Complaints

The PHS regulation requires institutions to undertake "diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations," but does not indicate what constitutes such efforts. As noted in the Significant Accomplishments section, ORI has issued guidelines that suggest options which PHS applicant and awardee institutions and whistleblowers may use in resolving whistleblower retaliation complaints.

Cases involving retaliation complaints initially are assessed to determine whether ORI has jurisdiction, and whether there is a documented adverse action that could be attributed to the misconduct allegation. Of the nine retaliation complaints closed, four could not meet the above criteria. In one case, the alleged retaliatory act occurred before the individual made his allegation to ORI; in another case, staff was unable to corroborate a complainant's claim that the individual he made allegations against was instrumental in negatively influencing potential employers. The third case was closed because the respondent did not respond to a request for the additional information needed to assess the complaint. In the fourth case, the complainant withdrew the complaint.

Consistent with the intention of the Federal regulation that places primary responsibility for protecting complainants on institutions, ORI referred five retaliation complaints to institutions for appropriate action. In one case, an institutional investigation found that officials did retaliate against the complainant by forcing him to step down as department chairman. The institution did not reinstate him as department chairman. However, the institution provided the complainant with a 12-month development leave at full salary and additional funds for research equipment to assist him in reviving his research career. The institution also sent a memorandum to the college faculty acknowledging that the complainant acted properly in bringing the allegation. Another institution moved the complainant to a different laboratory, extended salary support for an extra year, warned the respondent to stop his retaliatory actions, and filed charges against the respondent for violating the faculty code of conduct. A third institution advised the respondents that disciplinary action would be forthcoming if they did not stop making unsupported allegations against the complainant; moved the complainant to another laboratory, extended her appointment, and assisted her in pursuing an appropriate position to continue her career. In an intramural case, a PHS agency transferred the complainant to another laboratory in a related project, ensuring that the individual was able to work in his or her field of interest. ORI also proposed using arbitration to resolve a retaliation complaint for the first time. The institution and the complainant reached a settlement before the arbitration began.

Of the currently open cases involving alleged retaliation, two institutions were asked to investigate the complaints. One report has been submitted and is currently under review. The other complaints are being assessed to determine ORI jurisdiction.

Implementation of Administrative Actions

Individuals found to have committed scientific misconduct in PHS-supported research may have administrative actions imposed on them by HHS as well as by their institutions. The regulation authorizes the Department to "impose sanctions of its own upon investigators or institutions based on authorities it possesses or may possess, if such actions seem appropriate." The FDA also imposes administrative actions against researchers for violating regulated-research standards.

The Department may impose administrative actions on a respondent: (1) when a settlement is reached through a Voluntary Agreement; (2) when the respondent does not request a hearing before DAB; or (3) when a DAB decision affirms the ORI misconduct finding.

One or more of the following administrative actions may be imposed when a misconduct finding is final. Although the modal time period for the imposition of administrative actions is generally three years, the time may be increased or decreased depending on the extent of the need to protect the Federal government in general and PHS programs in particular. Some of the considerations used in making this determination include the seriousness of the respondent's acts or omissions and any aggravating or mitigating factors. The effective time periods for PHS administrative actions are not retroactive, but begin when the administrative action is officially imposed.

Administrative actions are carried in the PHS ALERT System and on the PHS Administrative Actions Bulletin Board for the duration of the action.

Debarment

This action is intended to protect Federal funds by prohibiting the support or the involvement of the respondent in any capacity under a Federal grant, contract, or cooperative agreement, including serving as principal investigator, coprincipal investigator, research associate, research assistant, technician, consultant, contractor, and participating in all other types of covered transactions as defined in 45 C.F.R. Part 76 and 48 C.F.R. Subpart 9.4 for a specified period of time.

Prohibition Against Advisory Service

This action is intended to protect the PHS advisory system by prohibiting the respondent from serving in any advisory capacity to the PHS including service as an initial review group member, an ad hoc reviewer, a consultant, or an agency, institute, center or division board or council member for a specified period of time.

Required Certification of Sources

For a specified period of time, the respondent is required to certify in every PHS research application or report that all contributors to the application or report are properly cited or otherwise acknowledged. The certification by the respondent must be endorsed by an institutional official. A copy of the endorsed certification must be submitted to ORI by the institution. This action is intended to protect the integrity of applications and reports submitted to PHS research programs by assuring that the words and ideas expressed are those of the respondent (i.e., have not been plagiarized) and applies to all documents submitted to the PHS that involve the respondent. These documents include new, renewal, and continuation applications, and progress and final reports.

Required Certification of Data

For a specified period of time, any institution employing the respondent is required to submit, in conjunction with each application for PHS funds or report of PHS research in which the respondent is involved, a certification that the data provided by the respondent are based on actual experiments

or are otherwise legitimately derived, and that the data, procedures, and methodology are accurately reported in the application or report. A copy of the certification must be submitted to ORI by the institution. This action is intended to verify the integrity of the data submitted by the respondent to the PHS in applications and reports and covers new, renewal, and continuation applications, as well as progress and final reports.

Required Plan of Supervision

For a specified period of time, any institution which submits an application for PHS support for a research project on which the respondent's participation is proposed or which uses the respondent in any capacity on PHS-supported research, must concurrently submit a plan for supervision of the respondent's duties. The supervisory plan must be designed to ensure the scientific integrity of the respondent's research contribution. A copy of the supervisory plan must be submitted to ORI by the institution. This action is intended to protect the integrity of the PHS research and covers new, renewal, and continuation applications.

Retraction of Article

The respondent is required to submit a letter to a specified journal requesting retraction of a specified article within 30 days of notification of this action. This requirement is noted in the ALERT System until the respondent sends a copy of the retraction letter to ORI. This action is intended to ensure the accurate reporting of research supported by PHS funds. ORI also notifies the relevant journal of this action.

Correction of Article

The respondent is required to submit a letter within 30 days of notification of this action to a specified journal requesting correction of a specified article. This requirement is noted in the ALERT System until the respondent sends a copy of the correction letter to ORI. This action is intended to ensure the accurate reporting of research supported by PHS funds. ORI also notifies the relevant journal of this action.

Institutional Actions

If appropriate for the particular circumstances of a specific case, ORI may accept the administrative actions already imposed on a respondent by an institution and not impose additional PHS administrative actions.

PHS ALERT System

The implementation of administrative actions is monitored through the PHS ALERT, a system of records subject to the Privacy Act. Individuals are entered into the PHS ALERT System 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 system 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 system 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, 1995, the names of 172 individuals were in the system. ORI had listed 42 names and the FDA had listed 130 names. During the year ORI added 31 names and removed six while the FDA added four names and removed 5. On December 31, 1995, the names of 196 individuals were in the system; 67 listed by ORI and 129 listed by FDA.

ORI added the 31 names because seven respondents agreed to a voluntary exclusion agreement, one was debarred, three had other administrative actions imposed, and 20 were found to have committed scientific misconduct in institutional reports to ORI. Six names were removed because the term of the administrative actions expired.

Of the 67 names in the system at year end, 51 individuals have had administrative actions imposed by PHS, 15 remain as a result of an institutional report in which there was a finding of scientific misconduct, and one case involved an ORI finding of misconduct where proposed administrative actions have been deferred pending completion of a hearing to challenge ORI's findings.

During 1995, six individuals whose names had been entered as a result of an institutional report were subsequently subjected to administrative actions, with four agreeing to a voluntary exclusion.

The 129 names listed by FDA on December 31, 1995, were due to four debarments from Federal procurement, 30 FDA debarments, 73 restrictions on the use of investigational drugs, and 22 restrictions on the use of investigational products. In only one instance was there a concurrent listing by FDA and ORI. FDA added four names in 1995 because the individual was debarred by FDA and deleted five names because the administrative actions had expired.

PART VI: PHS RESEARCH 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 1995 by (1) holding an in-service training session for NIH Research Integrity Officers (RIOs) and (2) making presentations during in-service training workshops for NIH extramural program personnel.

NIH Research Integrity Officers

ORI met with Research Integrity Officers (RIOs) representing the extramural research programs of the institutes, centers, and divisions of the National Institutes of Health on October 5, 1995, to discuss the RIOs' role in the PHS Research Integrity Program.

Under the PHS Research Integrity Program, RIOs are responsible for establishing an administrative process to ensure that the following functions are performed within their organizational unit: (1) Reporting allegations of research misconduct received or identified; (2) cooperating with ORI reviews or investigations of extramural allegations concerning research misconduct, retaliation against complainants, or institutional noncompliance with the Federal regulation on research misconduct; (3) implementing administrative actions imposed on researchers found to have committed research misconduct; (4) verifying the eligibility of institutions to receive funding under the PHS Act, and (5) promoting research integrity.

During the meeting, ORI staff outlined the role that RIOs are expected to play during the following misconduct case stages: Queries, preliminary assessments, inquiries, investigations, oversight reviews, and hearings. In addition, RIOs were informed about provisions of the Federal regulation that obligate institutions applying for or receiving PHS funds to (1) file an assurance, (2) submit the Annual Report on Possible Research Misconduct, (3) protect complainants; (4) restore the reputation of exonerated respondents, and (5) implement PHS/HHS administrative actions imposed on individuals found to have committed scientific misconduct.

The meeting also covered mechanisms for keeping RIOs informed about the status and disposition of cases involving their organizational units. The relevance of the PHS Administrative Action Bulletin Board, the PHS ALERT System, and the ORI assurance database to their responsibilities were outlined.

Finally, ORI and NIH attorneys discussed the need for confidentiality in responding to allegations of scientific misconduct, the limitations placed on the dissemination of information about cases by the Privacy Act, the conditions under which recovery of funds may occur, and the increasing frequency of *qui tam* suits.

Presentations

During 1995, ORI staff made presentations at NIH during courses and workshops held for health science administrators, science review administrators, and extramural science administrators.

PART VII: POLICY AND PROCEDURAL DEVELOPMENT

In addition to finalizing the model policy and procedures for responding to allegations of scientific misconduct, developing guidelines for addressing retaliation complaints, and finalizing the study of the consequences of whistleblowing, ORI concentrated its policy and procedural efforts on (1) providing administrative support for the Commission on Research Integrity, (2) cooperating with the Government Accounting Office (GAO) review of ORI policies, procedures, and operations, and (3) monitoring the study of the consequences of being accused of scientific misconduct.

Commission on Research Integrity

The Commission on Research Integrity, 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, submitted its report on November 3, 1995 to the Secretary of Health and Human Services and Congress.

In its report, the Commission made numerous recommendations, including adopting a new PHS definition of research misconduct, developing a common Federal definition of research misconduct, requiring institutions to have an educational program on the responsible conduct of research, and incorporating principles expressed in a Whistleblower's Bill Of Rights into regulations. In addition, the Commission made numerous recommendations related to Federal structures and procedures for responding to scientific misconduct.

In 1995, the Commission held nine meetings, including regional meetings in San Francisco, Chicago, Boston, and Birmingham, Alabama. The two-year charter of the Commission expired on November 4, 1995.

A high-level departmental panel was established in November by the Secretary to review the recommendations made by the Commission and make recommendation to the Secretary for possible implementation by HHS. The panel includes senior representatives from PHS research agencies and the offices of the Secretary, Assistant Secretary for Planning and Evaluation, General Counsel, Inspector General, and Research Integrity. William Raub, Science Advisor, Office of the Assistant Secretary for Planning and Evaluation, chairs the panel whose report is expected in 1996.

In February 1996, the Commission report was sent to all institutions that have an assurance on file with the ORI, and to university libraries, professional and scientific associations, and the media.

Individuals desiring a copy of the report should contact Henrietta Hyatt-Knorr at ORI for information on its availability. E-mail: hhyatt@osophs.ssw.dhhs.gov. Fax: (301) 443-5351. Phone: (301) 443-3400. A copy of the report is also available from the ORI Home Page. (See page 6.)

Policy Studies

GAO Report

A report issued by the Government Accounting Office (GAO) in August 1995 concluded that ORI has improved its handling of scientific misconduct cases since it was established, but needed additional management tools to eliminate persistent delays in case handling.

The GAO study, requested by Senators Kassebaum, Cohen, and Pryor, was conducted between July 1994 and April 1995. The review focused on the assessment of 30 allegations received by ORI between June 1993 and December 1994 and the handling of 10 investigations that were opened after ORI was established in June 1992 and closed before April 1995. Four investigations were conducted by ORI; six were conducted by institutions and reviewed by ORI. The GAO made the following general conclusions:

- Policies and procedures adopted by ORI for handling scientific misconduct cases are consistent with investigation guidelines established by the President's Council on Integrity and Efficiency.

- ORI investigators documented the work performed and followed established procedures in screening allegations and handling misconduct investigations.

- ORI investigators appear to be making appropriate decisions on whether allegations merited examination beyond their initial screening.

- ORI investigators appeared to have followed proper procedures in reviewing extramural investigations.

- ORI has made progress in completing cases inherited from its predecessors, but a substantial backlog still exists.

- The screening of allegations, the conduct of ORI investigations, and the review of extramural investigations needs to be more timely.

The GAO report acknowledged that ORI had already taken steps to address the timeliness issue by establishing a tracking system for cases, initiating the use of voluntary agreements, assigning a program analyst to work on initial assessments, and educating intramural and extramural institutions on the handling of allegations of scientific misconduct. However, the GAO recommended that ORI employ strategic planning and resource assessments to decide how to most efficiently and effectively deploy its resources.

Prior to completion of the GAO review, ORI had already identified improved efficiency and timeliness in screening allegations and resolving cases as a high priority and taken several steps to make such improvements. See earlier discussions on case closings and case management under "Significant Accomplishments" on page 3.

Accused Study

The Research Triangle Institute began the study of the consequences of being accused of scientific misconduct in 1995 under contract with the ORI. The study was delayed by clearance procedures for the self-administered questionnaire.

The study focuses on individuals who were accused of scientific misconduct, but exonerated of the charge. Some researchers who have been subjected to unconfirmed allegations of scientific misconduct have claimed that their reputations have been seriously damaged by such allegations.

The study collected information from respondents involved in closed PHS scientific misconduct cases on the impact of such allegations on the employment, career, professional activities, and personal life of the accused. The study is expected to be completed by summer 1996.

PART VIII: EDUCATION AND OUTREACH

The education and outreach activities of ORI in 1995 included (1) the publication program, (2) the Conference Report on the ORI/AAAS Conference on Plagiarism and Theft of Ideas, (3) the British Broadcasting Company (BBC) program, (4) nine presentations, (5) three published articles, and (6) *Federal Register* notices.

Publication Program

ORI continued its publication program in 1995. 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 about 2,000 individuals who have requested the publications.

During 1995, ORI filled more than 548 requests for various resource materials including the *ORI Newsletter*, *ORI Annual Report*, guidelines for responding to retaliation complaints, the model policy and procedures for responding to allegations of scientific misconduct, the plagiarism conference report, the report on the consequences of whistleblowing, an introductory pamphlet on ORI, *Guidelines for the Conduct of Research within the Public Health Service*, and *Data Management in Biomedical Research.*

Plagiarism Conference Report

A 250-page report was issued on the ORI/AAAS Conference on Plagiarism and Theft of Ideas which was held at NIH on June 21-22, 1993. The report contains presentations made on the intellectual and historical development of plagiarism, the handling of plagiarism cases by institutions, the response of journal editors and funding agencies to plagiarism allegations arising during peer review, and the impact of the computers on the potential for plagiarism. Contributed papers are also included. Single copies are available in hard copy or diskette from ORI or on the ORI Home Page. Please specify diskette type: WordPerfect 5.1 or 6.1 or ASCII.

BBC Program

ORI outreach moved to the international level in 1995 when ORI staff participated in a television program discussing the development of procedures for handling allegations of scientific misconduct in Britain. The program was aired on March 13, 1995 by the BBC as part of its *Horizon* series. A short segment in the program described the ORI procedures for responding to allegations of scientific misconduct and included interviews with ORI staff.

Presentations

The following presentations were made by ORI staff in 1995 at professional and scientific meetings, courses and conferences, and at colleges, universities and medical schools:

Bivens, L.W. "The Role of the Office of Research Integrity in Dealing with Fraud." Short course on Fraud in Clinical Trials: Prevention, Detection and Consequences, Center for Clinical Trials, Johns Hopkins University, Baltimore, MD, June 16, 1995.

Godek, S.M. "Duties and Functions of ORI." Lecture to graduate students in biology at Princeton University, March 1995.

Krueger, J. "Allegations of Research Misconduct in U.S. Academic Institutions." Bioethics Center, University of Maryland-Baltimore, April 20, 1995.

Krueger, J. "ORI Investigations and Issues in Scientific Misconduct." Department of Biology, Iona College, New Rochelle, NY, October 16, 1995.

Macfarlane, D.K. "Conduct and Misconduct: The Integrity of Clinical Research." Annual meeting. Society for Clinical Trials. Seattle, WA, May 1, 1995.

Merrill, S. "Ethics in Scientific Research." Seminar for the Department of Chemistry, University of the District of Columbia, November 30, 1995.

Pascal, C.B. "International Research Concerns: Ethical Issues in the Protection of Human Subjects." Conference on Research Integrity Issues in the International Arena, Baltimore, MD, November 13, 1995. Sponsored by Johns Hopkins University, Howard University and NIH.

Rhoades, L.J. "Handling Misconduct Cases at HHS." Session on The Research Community, the Federal Government, and Misconduct in Science. Annual Meeting. American Sociological Association, Washington, D.C., August 23, 1995.

Scheetz, M.D. Moderated an Ethics for Lunch session on "Survival Skills for the Emerging Scientist" conducted for graduate students at the University of Pittsburgh, January 14, 1995.

Published Articles

*Broadwell, R.D., Belinda J. Baker, and William F. Hickey. "CNS Transplants and the Host Immune Response: The Blood-Brain Barrier and Immunological Privilege within the Mammalian Brain." *New Concepts of a Blood-Brain Barrier* edited by J. Greenwood, D. Begley, M. Segal, and S. Lightman. Plenum Press, 1995.

Kamp, T.M., Mitas, M., *Fields, K.L., Asch, S., Chin, H., Marban, E., and Nirenberg, M. "Transcriptional Regulation of the Neuronal L-Type Calcium Channel Alpha-1D Subunit Gene." *Cellular and Molecular Neurobiology*, 15, 307-326.

Poon, Peter. "Legal Protections for the Scientific Misconduct Whistleblower." *The Journal of Law, Medicine & Ethics*, 23(1):88-95, (Spring 1995).

*ORI staff

***Federal Register* Notices**

Office of the Secretary and Public Health Services; Statement of Organization, Functions, and Delegations of Authority. Vol. 60, No. 217, pp. 56605-56606, November 9, 1995.

Notification of Revised System of Records. Vol. 60, No. 4, pp. 2140-2143, January 6, 1995.

Completion of Investigation. Vol. 60, No. 121, p. 32684, June 23, 1995. Plotkin

Findings of Scientific Misconduct. Vol. 60, No. 13, p. 4169, January 20, 1995. Ryan
Findings of Scientific Misconduct. Vol. 60, No. 51, p. 14291, March 16, 1995. Tanner
Findings of Scientific Misconduct. Vol. 60, No. 54, p. 14943, March 21, 1995. Apte
Findings of Scientific Misconduct. Vol. 60, No. 76, p. 19750, April 20, 1995. Kurtzman
Findings of Scientific Misconduct. Vol. 60, No. 84, p. 21524, May 2, 1995. Conrad and Coyle
Findings of Scientific Misconduct. Vol. 60, No. 87, pp. 22401-22402, May 5, 1995. Herman
Findings of Scientific Misconduct. Vol. 60, No. 114, p. 31312, June 14, 1995. Jones
Findings of Scientific Misconduct. Vol. 60, No. 120, pp. 32555, June 22, 1995. Clayton
Findings of Scientific Misconduct. Vol. 60, No. 122, p. 32964, June 26, 1995. Siddiqui
Findings of Scientific Misconduct. Vol. 60, No. 132, p. 35749, July 11, 1995. Urban
Findings of Scientific Misconduct. Vol. 60, No. 143, pp. 38352-38353, July 26, 1995. Tomasula and Sotolongo
Findings of Scientific Misconduct. Vol. 60, No. 165, p. 44358, August 25, 1995. Rosales
Findings of Scientific Misconduct. Vol. 60, No. 176, p. 47390, September 12, 1995. Landay
Findings of Scientific Misconduct. Vol. 60, No. 178, p. 47748, September 14, 1995. Kerr
Findings of Scientific Misconduct. Vol. 60, No. 198, pp. 53377-53378, October 13, 1995. Thwaites
Findings of Scientific Misconduct. Vol. 60, No. 207, p. 54878, October 26, 1995. Lorenzo
Findings of Scientific Misconduct. Vol. 60, No. 220, p. 57448, November 15, 1995. Weiser

Findings of Scientific Misconduct. Vol. 60, No. 227, p. 58365, November 27, 1995. Bednarik
Findings of Scientific Misconduct. Vol. 60, No. 228, p. 58628, November 28, 1995. Matsuguchi
Findings of Scientific Misconduct. Vol. 60, No. 241, p. 64444, December 15, 1995. June
Findings of Scientific Misconduct. Vol. 60, No. 245, p. 66276, December 21, 1995. Lupu and Santa Cruz

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.

Requests for ORI documents increased 24 percent this year rising from 79 requests in 1994 to 98 requests in 1995. Responses to eighty requests were completed. Eighteen requests were carried into 1996.

APPENDIX

A. List of Tables

B. Abbreviations

ARILO	Agency Research Integrity Liaison Officer
CRP	Compliance Review Program
DAB	Departmental Appeals Board
DPE	Division of Policy and Education, ORI
DRI	Division of Research Investigations, ORI
FBI	Federal Bureau of Investigation
GAO	Government Accounting Office
HHS	Department of Health and Human Services
NIH	National Institutes of Health
OD	Office of Director
OGC	Office of the General Counsel
OIG	Office of the Inspector General
OPHS	Office of Public Health and Science
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