OFFICE OF RESEARCH INTEGRITY 1996 HIGHLIGHTS

Responding 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 encouraging their participation in and assessment of this collective enterprise. The more significant events of 1996 are summarized below. Additional information about ORI's program activities may be found in the chapters and appendices that follow.

Continued Improvement in Case Management

In 1996, ORI closed 49 misconduct cases and handled 196 allegations of scientific misconduct. Of the 49 closed cases, 17 resulted in findings of scientific misconduct or PHS administrative actions and one was overturned by the Department of Health and Human Services' (HHS) Departmental Appeals Board following a request for a hearing by the accused scientist.

Of the 196 new allegations made to ORI in 1996, 62 were assessed in depth for a possible inquiry or investigation. Eighty percent (80%) of these 62 allegations were resolved in 1996 with an average processing time of 29 days. The other 20% were still pending at year-end. ORI has dramatically reduced the average length of time for assessing allegations from more than 200 days in 1992.

In 1996, ORI focussed on the quality and timeliness of its case investigations, oversight, and resolution. At the end of the year, ORI had 48 formal cases and 13 allegations under review, an all-time low. This is a tremendous improvement from where ORI started in 1992 with a backlog of 70 plus cases and over 600 unresolved allegations. Currently, ORI's processing time for formal cases averages 10-12 months.

Since beginning operation in 1992, ORI made findings of scientific misconduct or imposed administrative actions in 68 cases. During that same time, an additional three findings were overturned on appeal, one was withdrawn, and two cases were settled without a finding of misconduct following an appeal. Hence overall, 92% (68/74) of ORI's misconduct findings and administrative actions became final between 1992 and 1996.

ORI has closed more than 200 cases and over 1,500 allegations of scientific misconduct since 1992. Of the 200 cases closed, approximately one-third of those cases resulted in findings of misconduct and PHS administrative actions. In addition, based on a thorough and objective review of the facts, ORI has declined to make a PHS finding in an additional 10 cases where an

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

institution conducted an investigation and found misconduct under its own standards.[2] This is consistent with ORI's careful efforts to apply the applicable PHS legal standard for misconduct and to protect the rights of the accused.

Of the 68 misconduct findings and administrative actions, 44 were based on cases opened after June 1992 and fully developed by ORI under its own standards and procedures. None of these findings has been reversed.[3]

ORI has made special efforts in recent years to expedite its resolution of misconduct cases and allegations, while maintaining the high quality of its case analysis and assessment. This effort requires a careful balance of vigorous efforts to protect the integrity of PHS-sponsored research and the rights of the accused. ORI will continue to monitor its efforts to maintain this balance and take corrective actions as appropriate.

ORI Investigative Efforts Support Clinical Research

Because there is close monitoring of clinical research, routine reviews of data continue to uncover instances of data falsification and fabrication in clinical trials conducted to test new treatments for serious and life-threatening diseases.

One of the clinical cases closed during 1996 involved a study of a rare form of eye cancer. The investigation revealed over 200 falsified data items on study forms submitted by a respondent at one of the study sites for the clinical trial. Although most of the falsified information related to the dates on which tests or examinations were performed or the certification status of the person performing the evaluation, the false information made it appear that the requirements of the study had been followed when in fact they had not. The falsified information also suggested that every patient had been evaluated by a radiation therapist prior to entry in the study, when these assessments had not taken place. Since some parts of the study included radiotherapy as a treatment, it was important that the patient's suitability for this treatment be evaluated prior to entry on the study. Since the study is ongoing and no results have been reported, the falsified and fabricated information was corrected in the study database and will not affect analyses and outcomes of the study.

In another clinical case, a nurse who was collecting and reporting data for trials of treatments in AIDS patients was found to have falsified data by reporting that tests had been done when they had not. For instance, a report of an X-ray for one patient was represented as the report for two

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[2]This is not tantamount to a "reversal" of an institutional finding of misconduct, but rather a decision not to make a PHS/HHS finding. Institutions may have different standards or definitions that support an institutional finding of misconduct independent of ORI's decision.

[3]In 1997, one case was appealed to the Departmental Appeals Board and is still pending. *In re Kimon J. Angelides, Ph.D.*, DAB No. A-97-98.

other patients in order to prove that the necessary test had been done to assure the patients were eligible to enter a study. Because of the confidential nature of study records for these AIDS patients, permanent identifiers had been removed from reports of tests and replaced with labels with study numbers. The same test report had been duplicated and used for multiple patients by attaching different labels to the copies.

In a third clinical case, it was the nurse coordinator who identified data that had been fabricated by a physician in retrospective studies of patients he had treated for gynecological conditions. After the nurse coordinator questioned data she was analyzing, an investigation revealed that the physician had falsified and added information in patient medical records and fabricated notes for examinations that had never taken place. Two earlier publications were retracted when the investigation committee determined that the majority of the data were fabricated.

In two additional cases involving clinical research, ORI agreed that investigations uncovered instances of incorrect data reporting. However, in both cases the training and supervision of the individuals who had been responsible for data reporting had been so deficient that ORI concluded that the misreporting was not intentional.

Mentor Falsifies Student's Data

One case closed during 1996 illustrated that misconduct on the part of a mentor can create significant problems for his students. A scientist altered results obtained by a graduate student in the laboratory by generating a graph for the student, purportedly using the student's laboratory notebook data. Thus, the investigation committee found a falsified graph in the student's laboratory notebook. The respondent further falsified this graph until a total of 34 out of the 42 points on a second graph were "non-data." The committee found this second graph in the thesis of the student, for whom the respondent was thesis advisor. The student, who had been unaware that the data had been falsified, was required to correct his thesis and publication of his thesis research was delayed. Both versions of these falsified graphs were submitted, successively, in the respondent's competing grant applications as support for the respondent's hypothesis regarding the mechanism of action of a co-enzyme. In another instance of falsification, the respondent took other data generated by a student and represented them in his grant application as having come from an entirely different experiment from that performed by the student.

ORI Finding Reversed

On June 21, 1996, the HHS Departmental Appeals Board decided that the evidence did not support a finding that Dr. Thereza Imanishi-Kari had engaged in scientific misconduct by falsifying and fabricating data in a scientific article published in the Journal *Cell*, in notebook data submitted to the National Institutes of Health (NIH) supporting that article, and in grant applications. The Board ruled that ORI had not proved by a preponderance of the evidence that fabrication or falsification had occurred. The decision rested largely upon the Board's rejection of testimony by the U.S. Secret Service that much of the data submitted by Dr. Imanishi-Kari to

support the paper had been deliberately fabricated.

Institutional Liability for Investigating and Reporting Misconduct—Is There Federal Immunity?

In 1996, a major legal and policy issue arose that threatened ORI's partnership with research institutions receiving PHS research funds. In this partnership, the institutions have assumed the obligation of investigating and reporting allegations of scientific misconduct to ORI.

In August 1995, Kimon Angelides, Ph.D., formerly a research scientist at the Baylor College of Medicine, filed a lawsuit against Baylor and several of its employees in Texas State court seeking damages for several alleged torts arising out of his employment dismissal by Baylor. Dr. Angelides' claims included alleged defamation by Baylor officials and committee members who investigated allegations of scientific misconduct by Dr. Angelides and reported their findings of misconduct to ORI. The case was later removed to Federal court.

After the defendant's attempt to have the case dismissed was rejected by the Federal district court in 1996, ORI and HHS asked the Department of Justice to file an *amicus curiae* brief in the case, asserting the legal argument that Federal statute and regulations require research institutions and staff to investigate and report alleged misconduct to ORI, thus shielding them from liability under State law. ORI relies on extramural institutions, such as Baylor, to conduct over 90% of the investigations into alleged misconduct that occur under PHS research grants, cooperative agreements, and contracts. Exposing the institutions and their scientists who assist in the investigations to legal liability for their actions would severely limit ORI's ability to rely on institutional cooperation.

Following dismissal in Federal district court, the defendants appealed the court's ruling to the United States Court of Appeals for the Fifth Circuit. In its *amicus* brief supporting the appeal, the Federal government asserted that the preemptive requirements of Federal law, which mandate the reporting of misconduct investigations to ORI, provide no basis for State tort liability in defamation: "These federal requirements preempt state tort liability for such actions since compliance with state and federal requirements is a practical impossibility and state tort liability stands as an obstacle to the accomplishment of the full purposes and objectives of Congress."

In July 1997, the 5th Circuit denied the appeal on jurisdictional grounds, although the defendant's Federal immunity argument remained open and could be raised in State court. At press time, DHHS was considering whether further legal action by the Department of Justice was appropriate. If protection against institutional liability cannot be successfully asserted in court, ORI will consider whether a regulatory or statutory response is appropriate. A summary of the *Angelides* lawsuit and other civil cases related to scientific misconduct is included at Appendix E.

Privacy Act Claim Against ORI Dismissed

ORI's policy to keep open investigations as confidential as possible to protect both the involved parties and the integrity of the investigation was vindicated in a case both decided and affirmed on appeal in 1996. In a suit brought by Bernard Fisher, M.D., the U.S. District Court for the District of Columbia dismissed claims that the Department, NIH, and ORI had violated the Privacy Act by publicly disclosing information from ORI's files that should have been confidential. The Court held that the plaintiff had not provided any evidence that the alleged public statements were based on information obtained from ORI's files. *Fisher* v. *NIH*. The Court also ruled that the Privacy Act was not violated by annotations placed on scientific publications on library databases because the annotations were not about the plaintiff but about the subject matter of the articles. The D.C. Circuit Court of Appeals agreed and dismissed the plaintiff's appeal without comment.

False Claims Suit Reversed

Several cases filed as *qui tams* under the False Claims Act have been related to scientific misconduct issues. In 1995, a federal District Court awarded the United States and the relator, Dr. Pamela Berge, damages and penalties for violations of the Act in *U.S. ex rel. Berge* v. *University of Alabama*. The U.S. had originally declined to participate in this *qui tam* case against the University of Alabama and several researchers, a decision based in part on ORI's, NIH's, and the Office of Inspector General's OIG recommendations. ORI had previously reviewed some of Dr. Berge's allegations in the context of the PHS definition of scientific misconduct and determined that it did not have jurisdiction because her claims involved authorship or collaboration disputes and not plagiarism.

However, in 1996, the U.S. intervened after the defendants appealed and several universities and associations filed *amicus curiae* briefs raising, among other issues, constitutional and jurisdictional arguments and also questioned whether scientific misconduct "disputes" were covered by the Act. The U.S., while specifically declining to comment on the merits of the claims, rebutted these arguments by supporting the constitutionality of the Act, the standing of the *qui tam* relator, Dr. Berge, to bring the claims, and the ability of the U.S. as the real party in interest to sue the States, *i.e.*, the state university, under the Act. The U.S. also argued that "all manner of scientific misconduct . . . may give rise to a legitimate False Claims Act claim." It also noted that the scope and burdens of proof differed between ORI and False Claims Act cases, meaning that a specific set of facts could constitute misconduct and not a false claim or vice-versa.

In January of 1997, the Fourth Circuit Appellate Court reversed the lower court's decision, holding that Dr. Berge had presented insufficient evidence of false statements or of the government's reliance on the statements in making funding decisions in order to find liability against the university. It did not specifically determine whether scientific misconduct had occurred. In reaching this decision on the merits, the Court noted ORI's policy that "plagiarism does not include credit disputes." Because the Court based its decision on the merits, it did not rule directly on the constitutional arguments. With respect to the jurisdictional issues, however, the Court noted that, as the U.S. was the real party in interest in the case, it stated that Dr. Berge had standing, and that the States had no Eleventh Amendment immunity from being sued.

ORI Studies: Exonerated Scientists and Institutional Inquiries

In 1996, ORI completed its study of scientists who were accused, but exonerated, of charges of scientific misconduct and initiated a study assessing the quality of institutional inquiries.

The study of accused but exonerated respondents was undertaken because some researchers who have been subjected to unconfirmed allegations of misconduct have claimed that their reputations and careers had been seriously damaged by the allegations. The study of the "Consequences of Being Accused of Scientific Misconduct" was commissioned by ORI in 1995 to evaluate the impact an allegation of misconduct had on the reputation and career of scientists and to determine whether further policy development was needed.

The study findings were based on a 50 percent response rate (54 of 108) to a survey of exonerated respondents that were involved in ORI cases closed prior to 1995. The majority of exonerated respondents perceived that an accusation of scientific misconduct had a mostly neutral impact on their careers, professional activities, and personal lives. However, a sizeable minority perceived the impact of the allegations as negative. Less than half of the respondents were satisfied with the handling of their cases, the restoration of their reputations, and the maintenance of confidentiality.

Sixty percent of respondents reported experiencing one or more negative consequences of being accused of scientific misconduct even though the allegation was unsupported. Seventeen percent reported experiencing severe consequences—loss of position, promotions, or salary increases. Forty percent reported no negative consequences. Thirty-nine percent of the respondents were dissatisfied with the efforts made by their institution to restore their reputation, and more than a third of respondents (36%) stated that institutions failed to maintain confidentiality. More information on the study results may be found in Appendix H.

ORI initiated a retrospective study of institutional scientific misconduct inquiries that did not proceed to an investigation and were not reported to ORI. The purposes of the study include gaining insight into the implementation of the Federal regulation (42 C.F.R. Part 50, Subpart A) by institutions, and identifying the types of technical assistance and educational efforts, if any, ORI may be able to offer. Study results will be reported as aggregated, nonidentifiable data in an ORI report which will be reported in the *ORI Newsletter*.

ORI Policy Reviews Ensure Compliance, Offer Technical Assistance

In 1996, ORI requested 226 institutional policies and procedures in order to evaluate their compliance with the regulatory requirements. Reviews for 168 institutions were completed and the remainder were carried over to 1997. In the majority of cases, ORI found one or more deficiencies in the institutional policy and requested revisions. The most common problems with the policies were: failure to cover all research staff, including nonfaculty staff and students; failure to cover all significant components of the PHS definition of scientific misconduct; and

omission of critical elements of inquiries and investigations, such as the need for appropriate expertise and avoiding conflicts of interest. Occasionally, ORI also offered suggestions on an institution's policy and procedures that may prove helpful to the institution but are not required by the PHS regulation. In several cases, institutional officials responded that ORI's review was helpful.

ORI Model Policy Frequently Adopted by Institutions

ORI developed the *ORI Model Policy and Procedures for Responding to Allegations of Scientific Misconduct* (ORI model) in 1995 to respond to the numerous requests it receives every year for a sample policy that would meet the regulatory requirements. Since it began reviewing policies in 1995, ORI has accepted a total of 270 institutional policies. Sixty-eight of those institutional policies were based on the ORI model, or 25% of the total accepted since 1995.

The ORI model is written from the institution's perspective and provides options in several places. Although the model is tightly related to PHS requirements, institutions are welcome to adapt the model to broaden its coverage and applicability to agencies other than PHS.

ORI Provides Detailed Guidance to Institutional Officials

In 1995, ORI began preparing a detailed guidance document for institutional officials, entitled *ORI Handbook for Institutional Research Integrity Officers*. In 1996, 51 institutions and organizations reviewed the *Handbook* and it was extensively revised based on the comments received. It was finalized in early 1997 and sent to approximately 2,000 institutions, professional associations, PHS research integrity officers, and other interested persons.

The *Handbook* provides a comprehensive set of ORI guidance documents in one place and is intended for use by institutional officials who are responsible for handling research integrity issues for the institution and reporting alleged misconduct to ORI. Included in the *Handbook* are the PHS regulations, ORI's guidance on whistleblower retaliation, model policies and procedures for institutions, assurance and report forms, the Departmental Appeals Board (DAB) procedures for misconduct cases, and a summary of several relevant DAB and court rulings. Also included is an entirely new overview of institutional and ORI responsibilities.

Policy Issues Under Development

At year end, several outstanding policy issues were still under development.

During 1996, a workgroup chaired by the Secretary's senior advisor on science policy reviewed 33 recommendations on research integrity issues made by the Commission on Research Integrity. A report issued by the workgroup recommended that the Department adopt many of the recommendations but defer action on others, such as a proposed new definition of scientific misconduct. This latter issue was also being reviewed by the White House Office of Science and

Technology Policy, which was considering a government-wide definition.

A separate workgroup on whistleblower protections chaired by ORI reviewed the Commission's recommendations on whistleblowers. The workgroup's recommendations were incorporated into a draft regulation on whistleblower protections, which was submitted for Departmental clearance in 1997.

Final Departmental decisions on the draft whistleblower regulation and the Commission recommendations were still pending at press time.

CONTENTS

I. SCIENTIFIC MISCONDUCT

The investigative workload associated with allegations of scientific misconduct includes queries, cases, and administrative closures. Queries are potential 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).

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 the PHS regulations.

   ORI must assess whether the action reported, if found to be true, would represent "fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research."

   Many queries involve questions of "honest differences in interpretations or judgments of data" which are specifically excluded under the PHS definition. 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.

   ORI may request additional information from the person initiating the query, if the person is identified. If an allegation is made anonymously, and there is not adequate information to proceed, ORI 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 15-20 percent of the queries received result in a formal case being opened by ORI, all queries must be carefully evaluated for appropriate disposition.

In 1996, ORI received 196 queries, a 20 percent decrease from the 244 queries received in 1995. The disposition of the queries are presented in Table 1 below. 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.

Of the 196 queries made to ORI in 1996, 62 were assessed in detail for a possible inquiry or investigation, 39 were referred to other agencies, 92 were closed without further action and three were referred to other agencies following detailed ORI assessment. Fifty-two of the sixty-two allegations (84%) that required in-depth review by ORI staff were resolved with an average processing time of 29 days (time from assignment to closure or the opening of a formal case). The other 10 cases were still under review at the end of the calendar year. The average length of time for assessing allegations has been dramatically reduced by ORI from more than 200 days in 1992.

Table 1: Disposition of Queries in 1996

Pre-Inquiry Assessment	62
No Action Possible Now Or No Action	92
Referred to Other Agencies	39
Pre-Inquiry Assessment/Referred to Other Agencies	3
TOTAL	196

Cases

In 1996, 17 of the 49 closed misconduct cases resulted in sustained findings of scientific

misconduct or PHS administrative actions; another misconduct finding was reversed by the DAB. At the end of the calendar year, ORI had 48 formal cases and 13 allegations under review, an all-time low. ORI had also reduced the pre-1995 backlog to eight cases.

The ORI caseload is divided into four elements: (1) institutional inquiries, (2) institutional investigations, (3) ORI inquiries, and (4) ORI investigations.

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

During 1996, ORI accepted 10 institutional reports on inquiries that did not recommend investigations. Falsification was the most frequent allegation examined in the inquiries (six), followed by plagiarism (three), and fabrication and falsification (one). ORI began 1996 monitoring 13 institutional inquiries. During 1996, ORI requested that 16 institutions conduct inquiries, accepted 10 reports, and carried 19 cases into 1997.

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, and provided a basis for a PHS finding of misconduct. ORI began 1996 monitoring 37 investigations at institutions. During 1996, 23 institutional investigations were opened and 34 were closed. Twenty-six investigations were carried into 1997.

ORI inquiries: ORI reviews all inquiries conducted into allegations of scientific misconduct within the PHS intramural research programs. In addition, ORI conducts inquiries at extramural institutions if ORI determines there is a need to do so, *i.e.*, a multi-center clinical trial. ORI closed one extramural inquiry in 1996, which was begun in 1995.

ORI investigations: ORI conducts all investigations into allegations of scientific misconduct in the PHS intramural research programs. In addition, ORI conducts investigations at extramural institutions if the case involves special circumstances. ORI closed four extramural investigations; two were begun by ORI's predecessor, the Office of Scientific Integrity (OSI), and two involved multi-center clinical trials. The three open investigations carried into 1997 included two intramural cases and one extramural case that was opened by OSI.

Table 2: ORI Scientific Misconduct Caseload by Case Type during 1996.

Case Type	Forwarded from 1995	Opened in 1996	Closed in 1996	Carried into 1997
Institutional Inquiries	13	16	10	19
Institutional Investigations	37	23	34	26
ORI Inquiries	1	0	1	0
ORI Investigations	7	0	4	3
TOTAL	58	39	49	48

Administrative Closures

A case may be administratively closed when ORI concludes that no PHS funds or applications were involved, or that continuing effort will not produce sufficient evidence to resolve a case satisfactorily or further review indicates that the allegation does not fall under the PHS definition of scientific misconduct. Four cases were administratively closed by ORI in 1996. 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. See Appendix D for case summaries.

INSTITUTIONAL COMPLIANCE

The PHS regulation on misconduct in science places several requirements on institutions receiving funds under the PHS Act. ORI monitors institutional compliance with these regulatory requirements through two programs: the Assurance Program and the Compliance Review Program.

A. 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, 1996, there were 3,515 active assurances on file in ORI, including 154 from 29 foreign countries. During 1996, 363 institutions filed their initial assurance with ORI. Institutions file their initial assurance by signing the face page of the grant application or by submitting the initial assurance form. ORI deleted 471 institutions because their assurance was inactivated. One hundred and twenty-one institutions voluntarily withdrew their assurance 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 withdrew the remaining 350 assurances because the institutions did not submit their Annual Report on Possible Research Misconduct, did not submit a copy of its policies and procedures for responding to allegations of research misconduct upon request, or did not have policies and procedures that complied with the PHS regulation.

Table 3: Type of Institution with Active Assurance by Frequency, December 31, 1996

Type of Institution	Frequency
Institutions of Higher Education	876
Research Organizations, Institutes, Foundations and Laboratories	323
Independent Hospitals	313
Educational Organizations Other Than Higher Education	24
Other Health, Human Resources, and Environmental Services Organizations	389
Other (small business)	1,583
Unclassified	7
TOTAL	3,515

Cutoff Letters

ORI adopted a new procedure for securing compliance from funded institutions that failed to respond to repeated requests for material required to establish or maintain an assurance. These institutions were notified by letter that ORI would recommend that NIH suspend current support and withhold all future support to them if they failed to establish active assurances by submitting the requested materials within 60 days. The required materials may be the Annual Report, an initial assurance form, a requested policy, or a revised policy. ORI took this compliance action against three institutions in 1996; all three institutions responded positively. Under this new policy, ORI takes this compliance action after institutions have failed to respond to two requests.

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 1996, an audit indicated that awards were made to 26 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, 1996, an assurance was received from 19 institutions and 7 grants expired.

Annual Reports on Possible Scientific Misconduct

To keep its assurance active, each institution must submit to 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.

The 1995 Annual Report forms were mailed in January 1996 to the 3,341 institutions that had an assurance on file with ORI as of December 1, 1995. The Federal government shutdown caused the Annual Reports to be mailed two weeks later than usual.

Responses were received from 2,968 institutions for a response rate of 89 percent. One hundred and twenty-one of those institutions (4%) voluntarily withdrew their assurances and, therefore, did not file an annual report form with ORI. The Annual Report survey provides essential information for administering the assurance program. The 1995 report identified 471 institutions whose assurance was inactive and 111 institutions that did not have the required policies and procedures for handling allegations of scientific misconduct. In addition, it provided corrected information on the name of the responsible official or the institutional addresses of 645 institutions (21%). Institutions named 541 new responsible officials.

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. For a summary of the results of the survey, see Appendix E.

B. Compliance Review Program

The Compliance Review Program 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 Program responds to retaliation complaints from complainants and monitors the implementation of PHS administrative actions by institutions and PHS agencies.

1996 Compliance Cases

ORI carries out several activities aimed at ensuring institutional compliance with the PHS regulation related to scientific misconduct. In 1996, ORI closed 12 cases involving retaliation complaints and/or compliance reviews and opened six. Ten cases were carried into 1997.

Most cases originate during the ORI oversight of misconduct investigations. ORI is contacted directly by those whistleblowers alleging retaliation.

Table 4: Summary of Compliance Review Cases

Type of Case	Forwarded From 1995	Opened In 1996	Closed In 1996	Forwarded to 1997
Retaliation Complaints	5	3	4	4
Compliance Reviews	7	3	6	4
Complaints/ Reviews	4	0	2	2
TOTAL	16	6	12	10

Compared with 1995, the new activity was reduced by more than half, 13 new cases in 1995 versus 6 cases in 1996. Summaries of closed compliance reviews and retaliation cases may be found in Appendix F.

The program emphasis over the last three years has changed from comprehensive review of a limited number of institutions to more focused reviews of specific institutional compliance issues as they are received. Routine examination of the institutional process involves significant staff time, and the resulting reports have had limited impact on the program. The emphasis during 1996 has been to review more policies and procedures, particularly those associated with case openings, to raise the percentage of institutional policies and procedures that comply with the various provisions of the Federal regulation. More time and effort now is being spent evaluating cases when they are received or referred to determine whether there is ORI jurisdiction and sufficient significance to warrant ORI action before a case is opened. Cases that involve allegations of retaliation are referred back to the institution for resolution.

Institution Uses ORI Guidelines for Retaliation Complaint

Guidelines developed by ORI to assist institutions in responding to retaliation complaints from whistleblowers in scientific misconduct cases were used by an institution for the first time in 1996.

The institution elected to conduct an investigation rather than submit the complaint to arbitration or reach a settlement with the two whistleblowers. The investigation was conducted by a committee composed of three full-time tenured faculty members. During the 4-month investigation, the committee interviewed 22 individuals including the whistleblowers and all of the alleged retaliators, and reviewed more than 1,650 pages of documents. The finding of no retaliation was reported in an extensive, well-documented report that included comments from the whistleblowers.

ORI found that the institution had substantially complied with the process outlined in the guidelines and informed the institution that it had met its obligation to undertake diligent efforts to protect the positions and reputations of the whistleblowers.

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; or (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, 1996, the names of 197 individuals were in the system. ORI had listed 68 names and the FDA had listed 129 names. During the year ORI added 15 names and removed 14, while the FDA removed 4 names. On December 31, 1996, the names of 194 individuals were in the system, 69 listed by ORI and 125 listed by FDA.

ORI added 15 names because 7 respondents agreed to a voluntary exclusion agreement, and 8 were found to have committed scientific misconduct in institutional reports to ORI. Fourteen names were removed during the year, 10 because the term of the administrative actions expired, 2 because ORI did not concur with the institutional findings of misconduct, 1 because additional

evidence showed there was no PHS jurisdiction in the matter, and 1 name was removed as a result of a reversal of the ORI misconduct finding by the DAB.

Of the 69 names in the system at year end, 60 individuals have had administrative actions imposed by ORI, and 9 remain as a result of an institutional report in which there was a finding of scientific misconduct.

During 1996, five individuals whose names had been entered as a result of an institutional report were subsequently subjected to an administrative action, with all five agreeing to a voluntary exclusion.

The 125 names listed by FDA on December 31, 1996, were due to 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 deleted four names in 1996 because the administrative actions had expired.

III. EDUCATION AND OUTREACH

ORI educational and outreach activities were curtailed by budget constraints in 1996. Nevertheless, ORI was able to (1) make two additions to its publication program; (2) continue the development of a third new publication, and (3) expand the ORI home page. In addition, an ORI publication was given recognition by the Department and the AAAS video project supported by ORI was completed. ORI staff made six presentations and published three articles and a letter. Seventeen notices and one correction were published in the *Federal Register*.

Publication Program

ORI continued its popular publication program in 1996. ORI has developed publications to help improve institutional compliance with the PHS regulation on research misconduct, institutional capabilities to handle allegations of research misconduct, and protection of whistleblowers. A complete list of available resource material is posted on the ORI home page located at http://www.dhhs.gov/phs/ori.

The number of requests for ORI resource materials more than doubled from 548 in 1995 to 1,275 in 1996 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.*

The new publications are the *Survey of Accused but Exonerated Respondents in Research Misconduct Cases* and the *Report on the 1995 Annual Report on Possible Research Misconduct.* Highlights of the findings of the accused study may be found in the Highlights section, with a more detailed description contained in Appendix G. The report on the annual reports filed by 2,847 institutions provides information on the institutional population that have submitted assurances to ORI, the number of allegations received and inquiries and investigations conducted, the efforts made to restore the reputation of exonerated individuals and protect whistleblowers, the problems encountered in conducting the annual survey and the proposed solutions to those problems. The executive summary of the report may be found in Appendix E.

ORI Home Page

The ORI home page, created in 1995, proved to be a quick, effective, and inexpensive method for disseminating ORI resource materials in 1996, especially the ORI Model Policy. The home page received about 300 hits per month. Besides newsletter issues and ORI annual reports, the two new publications noted above and the *Report of the Commission on Research Integrity* were uploaded. In addition, the original address of the ORI home page was shortened to **http://www.dhhs.gov/phs/ORI**.

Whistleblower Study

The *Consequences of Whistleblowing for the Whistleblower in Misconduct in Science* project completed in 1995 was selected as 1 of 11 HHS evaluations to be summarized in a special chapter of the Department's first annual report on evaluations. These evaluations were recognized for their quality and potential use by the health and human services research and practice communities.

AAAS Videos

The American Association for the Advancement of Science (AAAS) produced a series of five 10-minute videos for use in educational programs and discussions in 1996 to help scientists assess their responsibilities for maintaining the quality and integrity of their research. Financial support was provided by the NIH, ORI, and the Agricultural Research Service. ORI provided funding in 1993 for development of the first two video scripts, and a staff member served on the advisory committee that oversaw production of the videos.

The videos dramatize hypothetical situations in research that raise ethical issues, but leave them unresolved in order to stimulate discussion. Among the topics addressed are issues such as the role and responsibilities of mentors and lab chiefs, determination of authorship, allocation of credit, data selection, whistleblowing, handling privileged information, as well as practices relating to the retention, sharing, and reporting of data. A resource guide accompanies the series that includes discussion questions and a bibliography of related subject matter.

Copies of the videos or the discussion and resource guide may be ordered[4] from Science Integrity Videos, AAAS Directorate for Science and Policy Programs, 1200 New York Avenue, N.W., Washington, D.C. 20005; Fax: (202) 289-4950.

Presentations

Richard D. Broadwell, DRI Investigator/Scientist, discussed interpreting the potential for transcytosis of macromolecules through the blood-brain fluid barriers at the conference "Understanding the Blood-Brain Barrier and Its Implications for Drug Targeting Strategies" in London, England on November 14-15, 1996.

Alicia K. Dustira, DPE Deputy Director, discussed the Federal role in ethics education and standards as part of a Panel Presentation on Ethical Standards for Science and Engineering at the AAAS Annual Meeting in Baltimore, Maryland on February 11, 1996.

Stephen M. Godek, OGC Attorney, described the duties and functions of ORI and provided

[4]Lists are neither exhaustive nor all inclusive. Nor, should any of the items listed or described be even remotely construed as being favored or endorsed by the Government.

advice to institutional counsel at a conference focussing on legal issues affecting academic medical centers and other institutions that was sponsored by the American Academy of Healthcare Attorneys of the American Hospital Association in Rosslyn, Virginia on January 18, 1996.

Chris B. Pascal, Acting ORI Director, presented "Whistleblower Issues in Scientific Misconduct" at the Annual Meeting of the Society of Research Administrators in Toronto, Canada on October 7, 1996.

Chris B. Pascal, Acting ORI Director, addressed the definition of scientific misconduct and the recommendations of the Commission on Research Integrity at the National Human Subject Protections Education Workshop at Emory University in Atlanta, Georgia on April 12, 1996.

Lawrence J. Rhoades, DPE Director, served as a discussant at the premiere showing of the AAAS Videos on Integrity in Scientific Research in Washington, D.C. on July 17, 1996.

Published Articles

Baker-Cairns, B.J., Sloan, D.J., Broadwell,* R.D., Puklavec, M., and Charlton, H.M "Contributions of donor and host blood vessels in CNS allografts." *Experimental Neurology* 142:36-46, 1996.

Broadwell, R.D.,* Baker-Cairns, B.J., Friden, P.M., Oliver, C., and Villegas, J.C. "Transcytosis of protein through the mammalian cerebral epithelium and endothelium. III. Receptor-mediated transcytosis through the blood-brain barrier of blood-borne transferrin and antibody against the transferrin receptor." *Experimental Neurology* 142:46-65, 1996.

Soskolne, C. and Macfarlane, D.K.* "Scientific misconduct in epidemiological research." In *Ethics in Epidemiology*, February 1996.

Price, A.R. "Federal actions against plagiarism in research." *Journal of Information Ethics* 5(1):34-51, 1996.

*****ORI staff

Federal Register Notices

Findings of Scientific Misconduct. 61 Fed. Reg. 1765, Jan. 23, 1996. Paruchuri
Findings of Scientific Misconduct. 61 Fed. Reg. 10584, March 14, 1996. Daubert
Findings of Scientific Misconduct. 61 Fed. Reg. 11010, March 18, 1996. Lee
Findings of Scientific Misconduct. 61 Fed. Reg. 15806, April 9, 1996. Abbs
Findings of Scientific Misconduct. 61 Fed. Reg. 16803-16804, April 17, 1996. Farooqui
Findings of Scientific Misconduct. 61 Fed. Reg. 16804, April 17, 1996. Vardi
Findings of Scientific Misconduct. 61 Fed. Reg. 17705, April 22, 1996. Gans

Findings of Scientific Misconduct. 61 Fed. Reg. 19295, May 1, 1996. Friedman
Findings of Scientific Misconduct. 61 Fed. Reg. 24798, May 16, 1996. Washabaugh
Findings of Scientific Misconduct. 61 Fed. Reg. 29103-29104, May 16, 1996. Fossel
Findings of Scientific Misconduct. 61 Fed. Reg. 32826-32827, June 26, 1996. Altman
Findings of Scientific Misconduct. 61 Fed. Reg. 33744-33745, June 28, 1996. Kumar
Findings of Scientific Misconduct. 61 Fed. Reg. 39461-39462, July 29, 1996. Abdulahi
Correction. 61 Fed. Reg. 55152, Oct. 24, 1996. Friedman
Findings of Scientific Misconduct. 61 Fed. Reg. 56962-56963, Nov. 5, 1996. Harrington
Notice of Settlement. 61 Fed. Reg. 57436, Nov. 6, 1996. Yuan
Findings of Scientific Misconduct. 61 Fed. Reg. 58883, Nov. 19, 1996. Whitters
Findings of Scientific Misconduct. 61 Fed. Reg. 63849-63850, Dec. 2, 1996. Li

INFORMATION AND PRIVACY

Freedom of Information Act

The Freedom of Information Act (FOIA), 5 U.S.C. § 552, allows the public access to ORI records while protecting certain information that falls within one of the Act's nine exemptions.

ORI records are primarily subject to exemptions 5, 6, and 7 of the FOIA. 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, Darlene Christian, Parklawn Building, Room 13 C 24, Rockville, MD 20857. The request must reasonably describe the records sought so that the agency official is able to locate the records with a reasonable amount of effort. Some requests may be subject to review, search and duplication costs.

Requests for ORI documents decreased 20 percent this year, falling from 98 requests in 1995 to 79 requests in 1996, the same number received in 1994. Responses to 82 requests were completed and 17 requests were carried into 1997.

Privacy Act

The purpose of the Privacy Act of 1974, 5 U.S.C. § 552a, is to balance the needs of the government to maintain information about individuals with the rights of the individual to be protected against unwarranted invasions of their privacy stemming from federal agencies collection, maintenance, use, and disclosure of personal information about the individual. Under the Privacy Act, an agency is required to publish a notice of its system of records when the information in the system is information about an individual that is retrieved by a personal identifier.

The records in ORI files are part of a system of records that was published in the *Federal Register* on January 6, 1995 (60 Fed. Reg. 2140). However, these records are specifically exempted from specific provisions of the Privacy Act regarding notification, access, and correction and amendment of records requests by the subject of the records. Nonetheless, each request for access is reviewed on a case-by-case basis. Additionally, if the records are denied under the Privacy Act for reasons of the exemptions, the subject of the records may still be entitled to obtain access to his or her records or portion thereof under the provisions of the Freedom of Information Act.

A Privacy Act request should be made to the system manager, Acting Director, Division of Research Investigations, ORI or the Privacy Act Officer, ORI. For a request to fall within the purview of the Privacy Act, it must be from the subject of the records or his or her legal

representative.

Nineteen requests for information were received under the Privacy Act in 1996. All requests received responses.

APPENDICES

Appendix A: Closed Investigations: Statistical Profile

This section presents a descriptive analysis of the 38 investigations closed during 1996 under the following headings: (1) Setting of Closed Investigations, (2) Type of Allegation, (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: (a) Type of PHS Research Program, (b) Performer of Investigation, (c) Institutional Setting, and (d) Funding Mechanism.

Type of PHS Research Program

All 38 investigations closed in 1996 involved PHS extramural research programs. The research involved in the investigations was supported by 16 NIH institutes. Seventeen investigations (45 percent) resulted in a misconduct finding; 21 investigations (55 percent) did not.

Table 5: Investigation Outcome by Type of PHS Research Program, 1996

PHS Research Program Type	Misconduct	No Misconduct	Admin. Closure	Total
Extramural	17	19	2	38
Intramural	0	0	0	0
TOTAL	17	19	2	38

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." Eighty-nine percent of the investigations closed were conducted exclusively by institutions. Two extramural investigations were begun by institutions, but subsequently taken over by OSI before being closed by ORI. Two other extramural investigations were conducted by ORI because they involved multi-center clinical trials.

Table 6: Investigation Outcome by Performer of Investigation, 1996

Performer	Misconduct	No Misconduct	Admin. Closure	Total
Institutional	15	17	2	34
Institutional/ORI	1	1	0	2
ORI	1	1	0	2
TOTAL	17	19	2	38

Institutional Setting

Ninety-two percent of the investigations were conducted in two institutional settings: medical schools (79 percent) and hospitals (13 percent). The 38 investigations were conducted by 33 institutions. One institution with several affiliates conducted four investigations; two institutions conducted two investigations each. One investigation was conducted consecutively by two institutions. Within institutions, the investigations involved such departments as biochemistry, biology, cardiology, dermatology, microbiology and immunology, molecular biology and biochemistry, molecular endocrinology, neurology, obstetrics-gynecology, oncology, otolaryngology, pathology, pediatrics, pharmacology, physiology, psychiatry, psychology, and radiology.

Table 7: Investigation Outcome by Institutional Setting, 1996

Institutional Setting	Misconduct	No Misconduct	Admin. Closure	Total
Medical School	12	17	1	30
Hospital	4	1	0	5
Health Science Center	0	0	1	1
Research Institute	1	0	0	1
Clinical Center	0	1	0	1
TOTAL	17	19	2	38

Funding Mechanisms

The 12 funding mechanisms involved in the closed investigations support grants, contracts or cooperative agreements, awarded to individuals or institutions to support basic or clinical research projects, programs or centers or to develop new researchers or support distinctly superior researchers. The traditional research grant (RO1) was the dominant mechanism. However, the mechanisms also include program projects (PO1), the general clinical research centers program (MO1), center core grants (P30), specialized centers (P50) and cooperative clinical research (U10). In addition, mechanisms for training and developing researchers are involved—institutional national research service award (T32), postdoctoral individual national research service awards (F32), clinical investigator awards (KO8), and first independent research support and transition (FIRST) awards (R29) as well as the method to extend research in time (MERIT) award (R37) to distinctly superior researchers. The investigations were also concerned with research and development contracts (NO1). A single mechanism was involved in 23 investigations; 2 mechanisms in 12 investigations, and 3 mechanisms in 3 investigations.

Table 8: Investigation Outcome by Funding Mechanism, 1996

Funding Mechanism	Misconduct	No Misconduct	Admin. Closure	Total
RO1	12	24	1	37
R29	0	1	0	1
R37	2	0	0	2
PO1	1	1	0	2
P30	2	0	0	2
P50	0	1	0	1
F32	1	0	0	1
K08	0	1	0	1
T32	1	2	1	4
MO1	1	0	0	1
NO1	1	1	0	2
U10	1	1	0	2
TOTAL	22	32	2	56

Type of Allegation

Allegations of falsification and/or falsification accounted for 92 percent of the investigation closed and 94 percent of the misconduct findings in 1996. Falsification either alone or in combination with fabrication or plagiarism provided the basis for 31 investigations (82 percent) and 14 misconduct findings (82 percent). Fabrication alone or in combination with falsification accounted for 15 investigations (39 percent) and 9 misconduct findings (52 percent). Plagiarism alone or in combination with falsification or serious deviations accounted for 4 investigations (11 percent) and 2 misconduct findings (12 percent).

Table 9: Investigation Outcome by Type of Allegation, 1996

Allegation	Misconduct	No Misconduct	Admin. Closure	Total
Fabrication	2	0	1	3
Falsification	6	11	1	18
Plagiarism	1	0	0	1
Fabrication/ Falsification	7	5	1	13
Falsification/ Plagiarism	1	1	0	2
Plagiarism/ Serious Deviations	0	1	0	1
TOTAL	17	19	2	38

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 17 actions related to the 38 closed investigations. In the 17 investigations that resulted in misconduct findings, only nine institutions reported sanctions against the respondents. Eight respondents had their employment terminated; the research of the ninth respondent was subjected to monitoring. Five institutions reported taking sanctions against respondents who were not found to have committed misconduct. Several respondents in one investigation were given letters of reprimand and prohibited from serving on review committees because of errors and negligence found in the preparation of a grant application. The grant applications of another respondent were subjected to monitoring because the investigation found a pattern of sloppiness and

inattention to critical details in his applications. In the third instance, the respondent was required to retract an article because he falsified the description of the methodology. The employment of a another respondent was terminated because the investigation concluded that he did not understand the recording device used in the research or the theory guiding the research. One institution reported taking actions against the respondent in one case, but did not specify what those actions were.

Table 10: Investigation Outcome by Institutional Action, 1996

Institutional Action	Misconduct	No Misconduct	Admin. Closure	Total
Letter of Reprimand/ Censure	0	1	1	2
Monitoring of Research	1	1	0	2
Retraction/ Correction of Article	0	1	0	1
Prohibited from Serving on Review Committees	0	1	0	1
Removed from Administrative Post	0	1	0	1
Terminated Employment	8	1	1	10
TOTAL	9	6	2	17

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 43 administrative actions against respondents in the 17 misconduct cases. Two actions were taken against 11 respondents; 3 against 3 respondents; and 4 against 3 respondents. The actions were based on 17 voluntary exclusion or settlement agreements.

Thirteen respondents were debarred from receiving Federal grants, contracts, and cooperative agreements for periods ranging from 18 months to 4 years. Seven were debarred for 3 years; four for 2 years; one for 4 years, and one for 18 months. All 17 respondents were prohibited from serving on PHS advisory committees, boards, or peer review groups for periods ranging from 2 to 4 years. Fifteen respondents were prohibited for 3 years; one for 4 years, and one for 2 years. Institutions employing eight respondents were required to submit to the funding agency and ORI a plan for supervising the participation of the respondents in any PHS-supported research for periods ranging from 1 to 3 years. Four respondents were required to be supervised for 3 years; one for 2 years and three for 1 year. Supervision actions lasting less than 3 years began after the debarment period ended. Institutions employing three respondents were required to submit certification to the funding agency and ORI for periods ranging from 1 to 3 years that the data submitted by the respondent in grant applications existed and was accurately represented. A certification for 1 year began after the debarment period ended. One respondent was required for 3 years to submit a certification to his institution that the work of others contained in each document, application, or report he or she submitted to a PHS component was properly attributed. An institutional official must endorse the respondent's certification and forward the endorsed certification to the funding agency and the ORI. One respondent was required to retract an article; four other respondents had already withdrawn their manuscripts or retracted articles.

Table 11: Frequency of Type of Government Action

Government Action	Frequency
Debarment	13
Prohibition from Advisory Committees	17
Supervision of Duties	8
Certification of Data	3
Certification of Contributors	1
Retraction/Correction	1
TOTAL	43

Respondents

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

Academic Rank of Respondents

The majority of allegations and misconduct findings were made against junior personnel (assistant professors, postdoctoral fellows, students and technicians) rather than senior personnel. Fifty-

nine percent of the respondents were junior personnel. Seventy-one percent of the misconduct findings were against junior personnel. The most frequent targets of allegations were postdoctoral fellows (13), associate professors (10), professors (8) and technicians (7). Allegations were most frequently supported against postdoctoral fellows (62 percent), technicians (43 percent) and associate professors (40 percent). Allegations were least often supported against professors (13 percent).

Table 12: Investigation Outcome by Academic Rank of Respondent, 1996

Respondents' Academic Rank	Misconduct	No Misconduct	Admin. Closure	Total
Professor	1	7	0	8
Associate Professor	4	6	0	10
Assistant Professor	0	2	0	2
Postdoctoral Fellow	8	3	2	13
Student	1	2	0	3
Technicians	3	5	0	8
TOTAL	17	25	2	44*

* Note: Four cases had two respondents and one case had three respondents.

Respondents' Degrees

Eighty-six percent of the respondents held doctorates; 59 percent held a Ph.D. degree; 23 percent held an M.D. degree; and 2 percent each held a D.V.M. degree or D.D.S. degree. Sixty-five percent of the individuals found guilty of scientific misconduct held a Ph.D. degree. Allegations were most frequently supported against persons holding an M.A. degree (100 percent), registered nurse degree (67 percent) and Ph.D. degree (42 percent).

Table 13: Investigation Outcome by Highest Degree of Respondent, 1996

Respondents' Academic Rank	Misconduct	No Misconduct	Admin. Closure	Total
Ph.D.	11	13	2	26
M.D.	2	8	0	10
D.V.M.	2	1	0	1
D.D.S.	0	1	0	1
R.N.	2	1	0	3
M.A.	2	0	0	2
Unknown	0	1	0	1
TOTAL	17	25	2	44*

*Four cases had two respondents and one case had three respondents.

Gender of Respondent

Allegations were more often made against males than females. Sixty-one percent of the respondents were males. However, allegations against females were more often supported (44 percent vs 37 percent). Nevertheless, more misconduct findings were made against males than females (59 percent vs 41 percent).

Table 14: Investigation Outcome by Gender of Respondent, 1996

Gender	Misconduct	No Misconduct	Admin. Closure	Total
Male	10	17	0	27
Female	7	7	2	16
Unknown	0	1	0	1
TOTAL	17	25	2	44*

* Four cases had two respondents and one case had three respondents.

Complainants

Complainants are described by (1) relationship to respondents, (2) academic rank, (3) highest academic degree, and (4) gender. The description is somewhat tentative because of the amount of missing data.

Relationship to Respondents

The relationships that existed between complainants and respondents in the 1996 closed investigations covered a broad range. The most frequent relationship was colleague, followed by laboratory chief.

Table 15: Investigation Outcome by Relationship of Complainant to Respondent, 1996

Position of Complainant	Misconduct	No Misconduct	Admin. Closure	Total
Associate Vice Chancellor	0	1	0	1
Laboratory Chief	3	2	1	6
Co-Author	1	0	0	1
Colleague	5	11	3	19
Dean of Institution	0	1	0	1
Employer	0	1	0	1
Graduate Student	3	0	0	3
Other Institutional Official	1	2	0	3
Mentor	1	0	0	1
Principal Investigator	1	1	1	3
Reviewer of Grant Application	1	1	0	2
Unknown	3	1	0	4
TOTAL	19	21	5	45*

*Two cases had two complainants, one case had three complainants, and one case had four complainants.

Complainants' Academic Rank

Senior personnel (dean, professor, associate professor) appear to make allegations more often than junior personnel.

Table 16: Investigation Outcome by Academic Rank of Complainant, 1996

Rank of Complainant	Misconduct	No Misconduct	Admin. Closure	Total
Dean	0	1	0	1
Professor	3	6	2	11
Associate Professor	2	4	1	7
Assistant Professor	1	3	1	5
Postdoctoral Fellow	1	2	0	3
Student	3	0	0	3
Unknown	9	5	1	15
TOTAL	19	21	5	45*

*Two cases had two complainants, one case had three complainants, and one case had four complainants.

Complainant's Degree

Most complainants held either an M.D. or Ph.D. degree.

Table 17: Investigation Outcome by Highest Degree of Complainant, 1996

Degree of Complainant	Misconduct	No Misconduct	Admin. Closure	Total
Ph.D.	5	12	4	21
M.D.	6	6	1	13
R.N.	1	0	0	1
B.A.	3	0	0	3
No Degree	1	0	0	1
Unknown	3	3	0	6
TOTAL	19	21	5	45*

*Two cases had two complainants, one case had three complainants, and one case had four complainants.

Complainants' Gender

More complainants were male than female.

Table 18: Investigation Outcome by Gender of Complainant, 1996

Gender	Misconduct	No Misconduct	Admin. Closure	Total
Male	11	15	5	31
Female	3	3	0	6
Unknown	5	3	0	8
TOTAL	19	21	5	45*

*Two cases had two complainants, one case had three complainants, and one case had four complainants.

Length of Inquiry

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 19, 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, 19 inquiries (50 percent) were completed within the required 60-day period. The shortest inquiry took 3 days, the longest inquiry took 970 days.

Table 19: Investigation Outcome by Length of Inquiry, 1996

Inquiry Length	Misconduct	No Misconduct	Admin. Closure	Total
Fewer than 30 days	6	9	0	15
30-60 days	3	0	1	4
61-90 days	1	3	1	4
91-120 days	3	1	0	4
121-150 days	1	0	0	1
More than 150 days	3	6	0	9
Unknown*	1	0	0	1
TOTAL	17	19	2	38

*The inquiry report did not contain the date of the first panel meeting and/or the inquiry report was not dated.

Length of Investigation

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 20, 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. Thirteen investigations (34 percent) were completed within 120 days. The shortest investigation took 4 days and the longest investigation took 2,231 days.

Table 20: Investigation Outcome by Length of Investigation, 1996

Investigation Length	Misconduct	No Misconduct	Admin. Closure	Total
120 days or fewer	7	5	1	13
121-180 days	4	5	1	10
181-240 days	1	1	0	2
241-300 days	1	3	0	4
More than 300 days	4	5	0	9
TOTAL	17	19	2	38

Size of Inquiry 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 size was three.

Table 21: Investigation Outcome by Size of Inquiry Panel, 1996

Number of Panel Members	Misconduct	No Misconduct	Admin. Closure	Total
One	4	3	0	7
Two	1	3	0	4
Three	9	10	1	20
Four	2	0	1	3
Five	1	2	0	3
Six	0	1	0	1
TOTAL	17	19	2	38

Size of Investigation Panels

The size of the investigative committees ranged from one to six members. The modal size was three.

Table 22: Investigation Outcome by Size of Investigation Panel, 1996

Number of Panel Members	Misconduct	No Misconduct	Admin. Closure	Total
One	1	0	0	1
Two	1	2	0	3
Three	9	10	2	21
Four	4	0	0	4
Five	2	4	0	6
Six	0	3	0	3
TOTAL	17	19	2	38

Appendix B: Summaries of Closed Investigations Resulting in Findings of Misconduct or PHS Administrative Actions

Fabrication

Yi Li, University of Illinois, Urbana-Champaign (UI-UC): Based upon an investigation conducted by` the UI-UC, information obtained by ORI during its oversight review, and Mr. Li's own admission, ORI found that Mr. Li, while a candidate for a Ph.D. degree in the Neuroscience Program at the UI-UC, engaged in scientific misconduct by fabricating an experimental study and results for research represented in an abstract prepared for submission for presentation at a national meeting. The research was supported by a grant from the National Institute on Aging, NIH. The fabricated abstract and results addressed an electrophysiological study of the behavioral correlates for long-term potentiation in the motor cortex of the central nervous system of freely moving rats.

Mr. Li accepted the ORI finding and entered into a Voluntary Exclusion Agreement with ORI in which he voluntarily agreed, for a 3-year period beginning November 18, 1996, to exclude himself from serving in any advisory capacity to the PHS and that any institution that submits an application for PHS support for a research project on which his participation is proposed or which uses him in any capacity on PHS-supported research must concurrently submit a plan for supervision of his duties. The fabricated abstract was not published nor used in any grant applications.

Danya J. Vardi, Harvard Medical School (HMS): Based on an investigation conducted by the institution as well as information obtained by ORI during its oversight review, ORI found that Danya J. Vardi, former HMS Research Associate in Psychology in the Department of Psychiatry at the Massachusetts Mental Health Center and former part-time Research Assistant at the Cambridge Hospital, committed scientific misconduct. ORI found that Ms. Vardi fabricated subject responses regarding recall and recognition of words having an emotional valence in research supported by a PHS grant entitled "Psychophysiologic study of child abuse imagery in adults" at the Manchester New Hampshire VA Research Center.

Ms. Vardi entered into a Voluntary Exclusion Agreement with ORI in which she voluntarily agreed, for a 3-year period beginning March 28, 1996, to exclude herself from any Federal grants, contracts, or cooperative agreements, and from serving in any advisory capacity to the PHS. No scientific publications were required to be corrected.

Falsification

Gail L. Daubert, R.N., Northwestern University (NU): Based on an investigation conducted by DRI, ORI found that Ms. Daubert, while serving as clinic coordinator for the Collaborative Ocular Melanoma Study (COMS) at NU, committed scientific misconduct by falsifying clinical

trial data. The multi-center COMS (which is supported by NIH) involves research on the treatment of choroidal melanoma, a rare form of eye cancer. The study is still ongoing, and no results have been published. ORI found that Ms. Daubert falsified 211 data items, including falsely reporting that a radiation oncologist had evaluated patients prior to randomization, falsely reporting laboratory blood test results were normal when the results were abnormal, falsely reporting that dates for patient visits or procedures had been performed within the specified protocol window when the actual date was outside the protocol window, and falsely reporting that a COMS certified examiner had performed an evaluation or procedure when a non-certified examiner had performed the task. Ms. Daubert entered into a Voluntary Exclusion Agreement with ORI in which she did not admit to any acts of scientific misconduct, but she agreed voluntarily for the 3-year period beginning March 4, 1996, to exclude herself from: (1) Federal grants, contracts, and cooperative agreements, with limited exceptions; and (2) to exclude herself from serving in any advisory capacity to the PHS.

Eric T. Fossel, Ph.D., Beth Israel Hospital/Harvard Medical School (BIH/HMS): Based on ORI's analysis of the relevant evidence and conclusions submitted by the Harvard Medical School Committee on Faculty Conduct, ORI found that Dr. Fossel, former Harvard Medical School Associate Professor of Radiology at Beth Israel Hospital, committed scientific misconduct by reporting falsified research results in a PHS grant application. Specifically, Dr. Fossel altered nuclear magnetic resonance (NMR) data in the Multi-center Breast Trial (MCBT) such that the NMR test, purporting to detect from a patient's blood sample a predisposition toward malignancy or a relapse, appeared to be more accurate, sensitive, and specific than was actually the case. Premised on these falsely reported results, Dr. Fossel proposed in a PHS grant application that the National Cancer Institute provide funds to complete the MCBT. Dr. Fossel entered into a Voluntary Exclusion Agreement with ORI in which he voluntarily agreed, for the 3-year period beginning May 9, 1996, to exclude himself from any Federal grants, contracts, and cooperative agreements, and from serving in any advisory capacity to the PHS.

Melissa A. Harrington, Ph.D., University of Texas Southwestern Medical Center (UTSMC): Based upon an investigation conducted by the UTSMC, information obtained by ORI during its oversight review, and Dr. Harrington's own admission, ORI found that Dr. Harrington, former postdoctoral research fellow, Department of Pharmacology at the UTSMC, engaged in scientific misconduct by falsifying the methodology and figures in a manuscript that was accepted for publication in the *Journal of Neuroscience* ("$G_{\alpha q}$ and $G_{\beta\gamma}$ open two Bradykinin-gated potassium channels via a membrane-delimited pathway"). The research was supported by a National Institute of General Medical Sciences grant. The *Journal of Neuroscience* manuscript was withdrawn and was never published. Dr. Harrington accepted the ORI finding and entered into a Voluntary Exclusion Agreement with ORI in which she voluntarily agreed, for the 3-year period beginning October 23, 1996, to exclude herself from serving in any advisory capacity to the PHS; and that any institution that submits an application for PHS support for a research project on which her participation is proposed or which uses her in any capacity on PHS-supported research must concurrently submit a plan for supervision of her duties. The

supervisory plan must be designed to ensure the scientific integrity of Dr. Harrington's research contribution. The institution must submit a copy of the supervisory plan to ORI.

Durga K. Paruchuri, Ph.D., University of North Carolina, Chapel Hill (UNC): Based on an investigation conducted by UNC, and information obtained during its oversight review, the ORI concluded that Dr. Paruchuri committed scientific misconduct by falsifying research records and falsely reporting to her supervisor and in a grant application submitted to the PHS that she had produced a clone of meningococcal bacteria transferrin binding protein 1, labeled "pUNCH 701," and used it to obtain a second clone, "pUNCH 702." Furthermore, ORI accepted the UNC finding that Dr. Paruchuri falsified research records at the Lineberger Cancer Research Center oligonucleotide synthesis facility in an attempt to support her false claim. Dr. Paruchuri accepted the ORI findings and voluntarily agreed to exclude herself for a 2-year period beginning December 21, 1995, from Federal grants, contracts, and cooperative agreements. Dr. Paruchuri further agreed that for a period of 1 year, in addition to and immediately following the 2-year exclusion period, any institution which submits an application for PHS support for a research project on which her participation is proposed, or which uses her in any capacity on PHS-supported research, or which submits a report of PHS-funded research in which she is involved, must concurrently submit a plan of supervision and certification of data accuracy. Dr. Paruchuri also agreed to exclude herself voluntarily from serving in any advisory capacity to the PHS for a period of 3 years beginning December 21, 1995.

Eric Whitters, Ph.D., University of Oregon (UO): Based upon a UO investigation as well as his own admission, ORI found that Dr. Whitters, a former postdoctoral fellow at the Institute of Molecular Biology at UO, engaged in scientific misconduct by fabricating experimental results that involved the selective growth of yeast strains that he represented as having temperature-sensitive phenotypes. The research was supported in part by a grant from NIH's National Institute of General Medical Sciences. Dr. Whitters accepted the ORI finding and entered into a Voluntary Exclusion Agreement with ORI in which he voluntarily agreed, for the 3-year period beginning November 6, 1996, to exclude himself from any Federal grants, contracts, and cooperative agreements and from serving in any advisory capacity to the PHS. The research at issue did not affect any published research and was not included in any grant application.

Gang Yuan, Fox Chase Cancer Center (FCCC): ORI entered into a Voluntary Exclusion Agreement with Mr. Yuan, a former laboratory technician at FCCC. The agreement resolved ORI's proposed administrative actions against Mr. Yuan which were based on allegations concerning research data generated at FCCC. The data became the subject of an investigation conducted by FCCC and an ORI oversight review. The data at issue were included in a grant application submitted to the National Institute of General Medical Sciences of NIH and in a manuscript submitted to, but not published by, the journal *Biochemistry*. Mr. Yuan disagreed with the allegations, but to settle the matter he voluntarily agreed, without admitting to guilt,

for the 2-year period beginning October 25, 1996, to exclude himself from any Federal grants, contracts, and cooperative agreements, and from serving in any advisory capacity to the PHS.

Plagiarism

Jamal Z. Farooqui, Ph.D., University of Cincinnati College of Medicine (UCCM): Based on an investigation conducted by the institution as well as information obtained during its oversight review, ORI found that Dr. Farooqui, while a Research Associate Professor, Department of Dermatology at UCCM, committed scientific misconduct by plagiarizing material in a PHS grant application from an application another researcher had submitted to the National Science Foundation (NSF). Dr. Farooqui received the NSF application from another faculty member at UCCM while that application was undergoing confidential peer review. Dr. Farooqui included the plagiarized material in the "Prospective Significance" and "Methodology" sections of his application entitled "Proopimelanocortin expression in human epidermis," submitted to the National Institute of Arthritis and Musculoskeletal and Skin Diseases. Dr. Farooqui entered into a Voluntary Exclusion Agreement with ORI in which he voluntarily agreed, for the 3-year period beginning April 3, 1996, that he will (1) certify in every PHS research application or report that all contributors to the application or report are properly cited or otherwise acknowledged, that an institutional official must endorse the certification, and that the institution must send a copy of the certification to ORI and (2) exclude himself from serving in any advisory capacity to the PHS. No scientific publications were required to be corrected as part of the agreement.

Fabrication/Falsification

James H. Abbs, Ph.D., University of Wisconsin-Madison: Based on its own investigation, ORI found that Dr. Abbs engaged in scientific misconduct by falsifying and fabricating certain figures and research results supported by PHS grants and reported in "Orificial motor control impairment in Parkinson's disease" (*Neurology* 37:394-398, 1987). ORI found that Dr. Abbs falsified Figure 1 in the *Neurology* paper, which displays orificial motor control instability in a Parkinson's disease patient reported as nontremorous, by: (1) tracing the waveforms from those of a tremorous patient that had previously been published as Figure 6 in the *Journal of Speech and Hearing Research* (26:616-621, 1983); (2) eliminating the apparent tremors from the waveforms depicted in Figure 6; (3) falsifying the standard force levels and structures from those of Figure 6; and (4) misrepresenting the identity of the actual subject reported in Figure 1. ORI also found that Dr. Abbs falsified and fabricated the data for Figures 2 and 4 in the *Neurology* paper by: (1) falsifying the number of trials run on each subject; (2) misrepresenting the number of measurements made on each of the waveforms; and (3) fabricating the numbers used to calculate the force instability results.

Dr. Abbs and ORI agreed to resolve the case through a settlement agreement, which the parties agreed should not be construed as an admission of liability or wrongdoing on the part of Dr. Abbs. As part of the agreement, Dr. Abbs submitted a letter to ORI in which he addressed each of ORI's findings and explained in more detail the reasons for his decision to settle this

matter on these terms. Dr. Abbs voluntarily agreed, for a 3-year period beginning March 28, 1996: (1) to exclude himself from serving in any advisory capacity to PHS; (2) that any institution which submits an application for PHS support for a research project that proposes Dr. Abbs' participation or that uses Dr. Abbs in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which Dr. Abbs is involved, must concurrently submit a plan for supervision of his duties, designed to ensure the scientific integrity of his research; and (3) that any institution employing Dr. Abbs be required to submit, in conjunction with each application for PHS funds or report of PHS funded research in which Dr. Abbs is involved, a certification that the data provided by Dr. Abbs are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application or research report. Dr. Abbs also agreed to submit a letter to the journal *Neurology* forwarding ORI's investigation report and advising it of ORI's request to retract the *Neurology* paper.

Robert J. Altman, M.D., University of California at San Francisco (UCSF): Based on an investigation conducted by the institution as well as information obtained by ORI during its oversight review, ORI found that Dr. Altman, Research Fellow, Department of Obstetrics, Gynecology, and Reproductive Sciences, UCSF, committed scientific misconduct by fabricating and falsifying data in research supported by two NIH grants. Specifically, Dr. Altman fabricated an experiment related to an ovarian cell line injected intraperitoneally into 12 nude mice. The resulting data were reported in: (1) a manuscript in page proof entitled "Inhibiting vascular endothelial growth factor arrests growth of ovarian cancer in an intraperitoneal model" (*Journal of the National Cancer Institute*); (2) a manuscript entitled "Vascular endothelial growth factor is essential for human ovarian carcinoma growth in vivo," submitted to the *Journal of Clinical Investigation* (*JCI* manuscript); and (3) a published abstract entitled "Vascular endothelial growth factor is essential for ovarian cancer growth in vivo" (*Society for Gynecologic Investigation*, abstract #079). Further, in the *JCI* manuscript, Dr. Altman (1) falsified the number of subjects with ovarian tumors from whom he obtained sections of tissue for examination of the expression of vascular endothelial growth factor (VEGF) purportedly by both *in situ* hybridization and immunohisto-chemistry, and (2) falsely reported that VEGF expression was examined by *in situ* hybridization and immunohistochemistry in papillary serous- (n=7) and mucinous-(n=5) cystadeno-carcinomas, when the number of surgical cases involving papillary serous tumors was four and the number of mucinous tumors was zero. Dr. Altman examined VEGF expression in only three papillary serous tumor specimens, one specimen both *in situ* and by immunohistochemistry and the remaining two solely by immunohistochemistry. Dr. Altman entered into a Voluntary Exclusion Agreement with ORI in which he voluntarily agreed, for the 3-year period beginning June 11, 1996, to exclude himself, with limited exceptions, from any Federal grants, contracts, and cooperative agreements, and from serving in any advisory capacity to the PHS.

Andrew Friedman, M.D., Harvard Medical School (HMS): Based on a report from HMS and Dr. Friedman's admission, ORI found that Dr. Friedman, former HMS Associate Professor of Obstetrics, Gynecology, and Reproductive Biology at the Brigham and Women's Hospital (BWH), committed scientific misconduct by falsifying and fabricating data in research supported in part by a PHS grant to the BWH General Clinical Research Center. Between 1992 and 1995, Dr. Friedman altered and fabricated information in permanent patient medical records and notes by changing dates, changing and adding text, and fabricating notes for clinical visits that did not occur. Dr. Friedman admitted that he had falsified and fabricated approximately 80 percent of the data in research reports published in Friedman, A.J. and Thomas, P.P. "Gonadotrophin-releasing hormone agonist plus estrogen-progestin 'add-back' therapy for endometriosis-related pelvic pain." *Fertility and Sterility* 30:236-41, 1993, in Friedman, A.J. and Thomas, P.P. "Does low-dose combination oral contraceptive use affect uterine size or menstrual flow in premenopausal women with leiomyomas?" *Obstetrics and Gynecology*, pp. 631-635, 1995, and in an unpublished manuscript. Dr. Friedman entered into a Voluntary Exclusion Agreement with ORI in which he voluntarily agreed (1) for the 3-year period beginning April 19, 1996, with limited exceptions, to exclude himself from any Federal grants, contracts, and cooperative agreements; (2) that for a period of 2 years immediately following the 3-year voluntary exclusion above, any institution that submits an application for PHS support for a research project on which Dr. Friedman's participation is proposed or that uses him in any capacity on PHS supported research must concurrently submit a plan for supervision of his duties; the supervisory plan must be designed to ensure the scientific integrity of Dr. Friedman's research contribution, and the institution must submit a copy of the plan to ORI; and (3) to exclude himself from serving in any advisory capacity to the PHS.

A statement retracting the article entitled "Gonadotrophin-releasing hormone agonist plus estrogen-progestin 'add-back' therapy for endometriosis-related pelvic pain" has been published in *Fertility and Sterility* (65(1):211, January 1996) and a statement retracting the article entitled "Does low-dose combination oral contraceptive use affect uterine size or menstrual flow in premenopausal women with leiomyomas?" has been published in *Obstetrics and Gynecology* (85(5):728, November 1995).

Joan Gans, R.N., Denver Department of Health and Hospitals (DDHH): Based on an audit of records conducted by NIH and Ms. Gans' admission, ORI found that Ms. Gans, while employed at the Denver Community Program for Clinical Research on AIDS at the Department of Public Health, DDHH, committed scientific misconduct by falsifying and fabricating data related to patients entered on clinical trials. The research was supported by an NIH contract. Ms. Gans entered into a Voluntary Exclusion Agreement with ORI in which she voluntarily agreed: (1) to exclude herself, with limited exceptions, from Federal grants, contracts, and cooperative agreements for a period of 2 years beginning April 4, 1996; (2) that for a period of 1 year immediately following the 2-year voluntary exclusion above, any institution that submits an application for PHS support for a research project on which Ms. Gans' participation is proposed or that uses her in any capacity in PHS-supported research must concurrently submit a plan for supervision of her duties, the supervisory plan must be designed to ensure the scientific integrity

of Ms. Gans' research contribution, and the institution must submit a copy of the plan to ORI; and (3) to exclude herself from serving in any advisory capacity to the PHS for a period of 3 years beginning April 4, 1996. No scientific publications were required to be corrected as part of the agreement. The questioned data will be excluded before any findings of the affected clinical trials are reported.

Vipin Kumar, Ph.D., California Institute of Technology (CIT): Based upon a report forwarded to ORI by CIT as well as information obtained by ORI during its oversight review, ORI found that Dr. Kumar, formerly a scientist at CIT, engaged in scientific misconduct in biomedical research supported by PHS funds. Specifically, ORI found that Dr. Kumar committed scientific misconduct by: (1) falsifying and/or fabricating Figures 2a and 2b in a scientific paper published in the *Journal of Experimental Medicine*, 170:2183-2188 (1989) (*JEM* paper); and (2) falsifying and/or fabricating Figure 5b of a manuscript that was submitted for publication to the journal *Cell* (*Cell* manuscript). ORI also accepted the CIT conclusions that: (1) Figure 2c of the *JEM* paper was presented in a misleading fashion; and (2) Dr. Kumar made materially misleading statements in a paper published in the *Proceedings of the National Academy of Science* (*PNAS*) 87:1337-1341 (1990). The *Cell* paper was withdrawn and the *JEM* and *PNAS* papers were retracted prior to ORI's findings.

The case was resolved through a negotiated settlement and limited voluntary exclusion agreement, which the parties agreed shall not be construed as an admission of liability or wrongdoing on the part of the Dr. Kumar. He also submitted a letter to ORI in which he summarizes his response to ORI's findings. Dr. Kumar voluntarily agreed: (1) for the 3-year period beginning June 19, 1996, to exclude himself from serving in any advisory capacity to the PHS and that any institution that uses Dr. Kumar in any capacity on PHS-supported research must concurrently submit (a) a plan for supervision of his duties designed to ensure the scientific integrity of his research and (b) a certification that the data provided by Dr. Kumar are based on actual experiments or are legitimately derived and that the data, procedures and methodology are accurately reported in the application or research report; and (2) for the 18-month period beginning June 19, 1996, to exclude himself, with limited exceptions, from Federal grants, contracts, and cooperative agreements.

Cathy Q. Lee, Ph.D., Massachusetts General Hospital (MGH): ORI found that Dr. Lee, Postdoctoral Fellow, Molecular Endocrinology Laboratory at the MGH, committed scientific misconduct by engaging in falsification and fabrication of research data incorporated in a manuscript prepared for submission (but not submitted) to the *EMBO Journal* (Lee, C.Q., Yun, Y., and Habener, J.F. "Transactivation of functions of cAMP-responsive transcription factor CREB-327 mediated by amphiphatic helical domains flanking the requisite serine-119 phosphorylated by protein kinase-A.") and by engaging in improper data selection and falsification of data published in the *EMBO Journal* (Lee, C.Q., Yun, Y., Hoeffler, J.P., and Habener, J.F. "Cyclic-AMP responsive transcriptional activation of CREB-327 involves interdependent phosphorylated subdomains." *EMBO Journal* 9:4455-4465, 1990.). This research was supported by a PHS grant. Dr. Lee entered into a Voluntary Exclusion Agreement with ORI in settlement

of ORI's finding of scientific misconduct and voluntarily agreed: (1) to exclude herself, with limited exceptions, from any Federal grants, contracts, and cooperative agreements for a 2-year period beginning on February 28, 1996; (2) that for a period of 1 year beginning immediately after the 2-year voluntary exclusion above, any institution that submits an application for PHS support for a research project on which Dr. Lee's participation is proposed or which uses Dr. Lee in any capacity on PHS supported research, must concurrently submit a plan for supervision of her duties. The supervisory plan must be designed to ensure the scientific integrity of Dr. Lee's research contribution, and the institution must submit a copy of the supervisory plan to ORI; and (3) to exclude herself from serving in any advisory capacity to the PHS for a period of 3 years beginning on February 28, 1996. A letter retracting the article entitled "Cyclic-AMP responsive transcriptional activation of CREB-327 involves interdependent phosphorylated subdomains" was published in the *EMBO Journal* 13:2736, 1994.

Michael W. Washabaugh, Ph.D., Johns Hopkins University (JHU): Based on an investigation conducted by the institution as well as information obtained by ORI during its oversight review, ORI found that Dr. Washabaugh, Associate Professor of Biochemistry, Department of Biochemistry, School of Hygiene and Public Health, JHU, committed scientific misconduct by reporting falsified and/or fabricated research data in two NIH grant applications. Specifically, Dr. Washabaugh (1) reported falsified results of experiments concerning the number of DTNB (5, 5'-dithiobis [2-nitrobenzoate]) reactive thiols in native thiamin-binding protein in a grant application entitled "Mechanism of a periplasmic permease," and (2) reported falsified and/or fabricated portions of data presented in two separate figures to support his hypothesis of thiamin binding to thiamin binding protein in grant applications entitled "Mechanism of a periplasmic permease" and "Mechanisms of enzymic and non-enzymic thiamin reactions."

Dr. Washabaugh entered into a Voluntary Exclusion Agreement with ORI in which he voluntarily agreed, for the 4-year period beginning May 7, 1996, to exclude himself, with limited exceptions, from any Federal grants, contracts, cooperative agreements and serving in any advisory capacity to the PHS. No scientific publications were required to be corrected as part of the agreement.

Falsification/Plagiarism

Yahya Abdulahi, Ph.D., Clark Atlanta University (CAU): Based on the institution's report and ORI's own analysis, ORI found that Dr. Abdulahi, former Research Scientist, Department of Biology, CAU, committed scientific misconduct by plagiarizing words and concepts from a publication in the *Journal of Environmental Health* and by misrepresenting data in sections of a PHS grant application. Specifically, Dr. Abdulahi's grant application contained extensive and significant plagiarism in the "Description," "Background and Significance," "Experimental Design and Methods," and "Literature Cited" sections and contains plagiarism and misrepresentation of data in the "Preliminary Studies" section. Dr. Abdulahi's actions were serious in that the plagiarism involved (1) the use of extensive sections of a publication without attribution, (2) misrepresented data, and (3) expropriation of the study concept. Dr. Abdulahi entered into a Voluntary Exclusion Agreement with ORI in which he voluntarily agreed, for the 3-year period

beginning July 16, 1996, to exclude himself, with limited exceptions, from any Federal grants, contracts, and cooperative agreements, and serving in any advisory capacity to the PHS. No publications were required to be corrected as part of the agreement.

Appendix C:
Summaries of Closed Investigations Not Resulting in Findings of Misconduct

Generally, ORI protects the identity of exonerated respondents. However, ORI may reveal identifying information when the exonerated individual requests such action to restore his or her reputation or when other unusual circumstances occur, such as the filing of a public lawsuit. In addition, all cases appealed to the HHS Departmental Appeals Board (DAB) become public. One DAB case is summarized below.

Fabrication: A supervisor accused a visiting post-doctoral research fellow of fabricating test scores on mice. The supervisor requested that the fellow perform tests and record scores while the supervisor was absent from the lab. Upon return to the lab the supervisor found discrepancies in the recorded data. The supervisor queried the respondent about the test score discrepancy and the respondent stated that there must have been a mistake. The respondent submitted a written statement indicating that a mistake had been made, that it had not been deliberate, and offered to resign from the institution. The respondent subsequently retracted the claim of having made a mistake after reviewing in detail the laboratory records; she stated that the mice had been present and that the appropriate tests were conducted. The supervisor later submitted a formal allegation of scientific misconduct. An inquiry committee reviewed the allegation and recommended an investigation. The investigation committee concluded that although there was no malicious intent involved, the recorded data were fabricated and not the result of honest error. ORI found that the evidence was insufficient to support a finding of scientific misconduct under the PHS definition because available information was inconclusive as to whether the mice were available for testing, and whether the research fellow intentionally fabricated the test scores for the mice. ORI accepted the institution's report, but did not make a finding of scientific misconduct.

Falsification: A research professor was accused by two students in his laboratory of falsifying the unpublished results of an experiment they were conducting under his supervision. The students claimed that the researcher modified the initial experiments, performing duplicate experiments rather than triplicate, and fabricated results. The researcher was also accused of falsifying the results of another experiment that the student claimed could not possibly be true, as she had prepared the materials for the experiment incorrectly. An institutional inquiry determined that an investigation was warranted. During the investigation, the respondent answered that his decision to modify the initial experiment was sound, and the investigation committee agreed, noting that the students did not have the same understanding of the experiment as the respondent, and they may have misinterpreted his actions. Regarding the second experiment, the investigation committee was not able to substantiate the experiment the student claimed to have conducted; there were no written records of the experiment in the students' notebook, the students' recollection of the experimental process was inconsistent with other facts, and the respondent claimed never to have been involved in the purported experiment. The investigation committee was not able to resolve this issue, based on the lack of documentation to support the students' claim. The investigation committee concluded that there was insufficient evidence to indicate that scientific misconduct had occurred, and ORI concurred with this decision.

Falsification: Co-authors were accused of falsifying data on subjects and measurements presented in a table in their published paper by another researcher who was familiar with the reported experiments. An institutional investigating committee concluded that scientific misconduct had occurred because the co-authors offered no credible explanation for the discrepancies that existed between the data presented in the published article and the data presented in draft versions. However, the committee was unable to assign responsibility for the misconduct to any particular individual because the primary data were not retained, contradictory testimony could not be resolved, a key witness died, an author left the country, and considerable time had expired between the conduct of the research and the institutional investigation that led to a finding of scientific misconduct. The committee recommended withdrawal of the article and implementation of a publication policy designed to prevent such problems. ORI concluded that while falsification of data may have occurred, it was not possible to assign responsibility. Accordingly, ORI accepted the institutional report, and did not make a finding of scientific misconduct.

Falsification: The respondent was accused of falsifying research data in her dissertation by a research associate. The respondent denied altering the data and asserted that the whistleblower with whom she had an acrimonious relationship was responsible for the altered data because he was the only other person who knew enough about her study to alter the data. The whistleblower claimed that the copies of the scintillation counter printouts from the respondent's experiments he had been secretly monitoring did not show the positive results the respondent was reporting. The respondent had discarded the original printouts after her dissertation was accepted and she was told to clean out her office for the next student. Institutional officials unsuccessfully attempted to recover potentially deleted/altered files of scintillation counter data stored on the computer hard disk. The investigation committee concluded that the data were falsified and that both the respondent and the whistleblower had the opportunity to do so. The committee also concluded that the respondent had a motive to change the data because she was having difficulty in demonstrating a positive antagonist effect which was a fundamental requirement for acceptance of her dissertation. In addition, the investigation committee identified other important errors in the respondent's investigations and dissertation research which favorably influenced her results. The committee made a finding of scientific misconduct against the respondent. During its oversight review, ORI noticed that the respondent had told the investigation committee that she could not recalculate her data because the software program used in her research was missing from the laboratory computer. In responding to an ORI query, the institution reported that the whistleblower had downloaded the software to prevent the respondent from making further alterations in the data. The respondent claimed the format of the restored software had been altered, suggesting that the source code governing the program operation had been changed. ORI concluded that the downloading of the software had compromised the only tangible evidence available in the case. ORI determined that insufficient tangible evidence existed to assign responsibility for the falsified data and did not make a finding of scientific misconduct.

Falsification: A researcher was accused by lab members of falsifying results presented in a graph in a progress report to a private foundation for research that was jointly sponsored by a NIH

grant. An inquiry committee was convened and discovered an additional issue involving possible falsification of a letter submitted to the NIH in support of a grant application. The investigation committee learned that the respondent directed a student to cut and paste new text into a pre-existing letter of support regarding the use of animal subjects in proposed research. The researcher admitted that changes were made to the letter of support, but said they were made because the writer of the support letter was not available to provide a revised letter. The researcher contacted the author of the support letter to discuss the changes to the letter and the author concurred with the changes the researcher had made. The second instance of alleged falsification pertained to data points in a graph for a progress report submitted to the foundation and the NIH. The respondent admitted to exaggerating the data but stated that an opportunity to explain the variance of data to the investigation committee was not afforded. The institution determined that the respondent did commit scientific misconduct on both accounts. At the request of the institution, the respondent agreed to resign. ORI concluded that, while the support letter was altered, falsification had not occurred because the researcher did not misrepresent the views of the author of the support letter. Secondly, ORI reviewed the data submitted to the NIH and found that there was no evidence of falsification in the PHS grant application. ORI accepted the institutional report, finding that the institution handled the matter appropriately and determined that no further action was necessary.

Falsification: A visiting postdoctoral associate and co-author alleged that a researcher falsified experiments and results reported on mice in versions of two manuscripts submitted repeatedly for publication. The inquiry committee determined that several of the concerns raised were differences of opinions and judgements, although further investigation was necessary. The respondent claimed that the discrepancy was due to a co-author's error, and the respondent had not been informed of the error until the allegation of scientific misconduct was made. The investigation committee determined that the respondent did not provide a credible explanation as to what he knew about the deaths of the mice, since he gave contradictory explanations at different times. In a related study, another allegation was made that the same respondent falsified methods and failed to describe treatments given to the mice undergoing experimentation. The investigation committee found that the respondent had collapsed data, and concluded that the issue was a matter of scientific judgement, not one of scientific misconduct. However, the investigation committee also concluded that the respondent had committed scientific misconduct by falsifying data, failing to include important information, and manipulating data to advance an hypothesis. The committee noted that no papers containing questioned data had been published in peer-reviewed journals. The committee recommended that unless the data could be verified and validated, they should not be published. The respondent refuted the conclusion, noting that the miscoding of mice did not have any meaningful effect upon the results, interpretations or conclusions in the unpublished manuscript. After reviewing the investigation committee's report, the institutional official concluded that there was insufficient evidence to find misconduct, and ORI concurred with the latter decision because it concluded that the respondent's explanations were plausible. The respondent was not an expert in the area, and a combination of poor scientific practice, failed communications with his co-authors, sloppiness, negligence, and error could have contributed to the misstatements in the papers. Further, the respondent submitted

corrections that were published. Therefore, ORI did not find sufficient evidence to make a finding of scientific misconduct.

Falsification: A part-time researcher was accused of fabricating data in a published abstract and in two NIH grant applications. The institutional investigation determined that the respondent was deficient in knowledge of the experimental recording device and in the theory of the experiment, and therefore it was unlikely that he intentionally falsified the data. In its review of the institution's report, ORI found the investigative committee's explanations to be credible. ORI concurred with the institution that there was insufficient evidence to support a finding of scientific misconduct.

Falsification: A graduate student was alleged to have falsified research results by deliberately contaminating ("spiking") solutions with sodium and included the falsified data in a publication. The institution conducted an inquiry and investigation and submitted a report to ORI; it concluded that scientific misconduct had occurred, but was unable to determine who was responsible for the misconduct. In ORI's oversight, audiotapes and transcripts of the interviews of witnesses were reviewed. ORI observed that if the contaminations were deliberate, the responsible individual(s) would have to have been extremely knowledgeable about the experiments in order to be able to perform two almost-concurrent manipulations. ORI accepted the institution's conclusion that, although there were discrepancies in the data, there was not sufficient evidence to conclude that the graduate student had committed scientific misconduct. ORI recommended that the institution encourage the journal editor to publish a statement correcting the record regarding the published paper.

Falsification: A research professor was accused of falsifying photographic data that was prepared and submitted as supplemental material for a grant application to NIH. In response to a suggestion by the NIH study section that additional photographs would be helpful in the review of his grant, the respondent directed members of his laboratory staff, including the complainant, to prepare a submission to NIH, including a number of photographs, following a handwritten draft he had prepared. Shortly thereafter, the respondent began a trip abroad and was not available to review and approve the final figure for submission to NIH. In his absence, the materials were assembled and sent to NIH; subsequent to the submission, the complainant informed institutional officials that the photographs submitted to NIH were incorrectly labeled. Upon his return, the respondent was questioned by institutional officials regarding the mislabeled photographs, and he provided a written response as requested. Following the submission of his response to the allegations, an inquiry committee was formed to explore the allegations further, and it recommended that an investigation be initiated. At about the same time, the respondent made counter-allegations against the complainant, alleging the complainant had altered data in his laboratory notebook. The investigation committee determined that the photographs submitted to NIH did not match the figure legend, and it concluded that the respondent was guilty of scientific misconduct by causing the submission of false material to NIH. The Investigation committee also concluded that one of the respondent's laboratory staff also was guilty of scientific misconduct for his role in the submission of the questionable materials to NIH. Although the Investigation

committee did acknowledge that the complainant also was aware that the respondent intended to submit inaccurate data, it did not investigate the complainant's conduct because the Inquiry committee had not recommended an investigation of that issue. Furthermore, the Investigation committee did not find evidence to support the respondent's counter-allegation against the complainant. ORI concluded that, given the breakdown in coordination and communication among the individuals responsible for the preparation of the supplemental information, it was plausible that errors and oversights in the handling of the materials may have occurred, which would constitute honest error, and so ORI determined that there was insufficient evidence to make a finding of misconduct under the PHS definition.

Falsification: Two former collaborators alleged that a faculty researcher had knowingly reported results that were obtained by unreliable methods and had concealed some details of those methods in preparing abstracts, papers, and PHS grant applications. Specifically, the researcher was alleged to falsified the description of the methodology in a publication by selectively reporting research methods and reporting methods that he knew did not work. The institution conducted an inquiry and investigation into the matter and the committee found "research dishonesty" on the part of the respondent. However, the institution did not accept this conclusion and found that the respondent's actions did not constitute scientific misconduct. ORI reviewed the institution's report, and the respondent's poor record keeping, his lack of familiarity with some of the research methods, and his failure to maintain communication about the methods and results with his collaborators. ORI determined that the matter was not sufficiently serious to warrant an ORI finding of scientific misconduct in this case.

Falsification: ORI reviewed an institution's report of an investigation into alleged falsified information regarding the isolation and identification of a breast cancer tumor marker and its potential in cancer prognosis. The alleged falsifications occurred in a published article and an unfiled patent application. The investigation committee reviewed the immunohistologic and clinical data and analyses in detail. Of 79 sets of case records examined, the committee found problems with approximately one-third but no bias which favored the authors' hypothesis. Thus, the committee found numerous errors and mistakes, but no evidence of intentional misrepresentation. Overall, the committee found that the evidence for the clinical utility of the marker was ambiguous but that this was not uncommon in studies of this type. While ORI did not evaluate all technical aspects of the research, it reviewed the record of the investigation and accepted the investigation's overall conclusion that there was insufficient evidence of intentional misrepresentation to find scientific misconduct.

Falsification: The respondent was accused of falsifying eligibility forms for a multicenter clinical trial on which she was the lead nurse coordinator. The institutional investigation concluded that she had been responsible for one instance of data alteration, which she claimed she had made based on her knowledge about the patient. The committee determined that this one instance had been an error in judgment resulting from inadequate training with regard to data reporting requirements and inadequate supervision. Thus, the institution did not make a finding of scientific misconduct in this case. ORI concurred with the institution and did not make a finding of

scientific misconduct.

Fabrication/Falsification: Based on an investigation conducted by the former Office of Scientific Integrity and ORI's review of that investigation, ORI charged Dr. Thereza Imanishi-Kari of Tufts University with multiple counts of falsification and fabrication of data in a published paper and NIH grant applications. The research in question was conducted by Dr. Imanishi-Kari while she was at the Massachusetts Institute of Technology. Evidence supporting the charges was based on forensic analysis prepared by the United States Secret Service, expert statistical analysis, expert scientific analysis, and factual testimony. Dr. Imanishi-Kari requested a hearing regarding the ORI findings. The HHS Departmental Appeals Board (DAB) held a lengthy hearing and issued a written decision overturning the ORI findings of scientific misconduct. The DAB decision found that the published research of Dr. Imanishi-Kari contained many flaws and errors, but that the weight of the evidence did not support the forensic, statistical, and scientific findings of fraud or intentional misrepresentation. Copies of DAB decisions may be obtained by calling the DAB at 202-690-5501 or are available on the Internet at http://www.os.dhhs.gov/progorg/dab/dab_search.html.

Fabrication/Falsification: A former fellow was accused of fabrication or falsification of data when the laboratory director and a graduate student were unable to replicate his findings and available relevant data were inconsistent with his reported and unpublished results. The suspected results were published in five articles and presented at seminars. The respondent initially reported that some of his notebooks had been lost during his moves. Other data sources suggested by the respondent were unable to produce any relevant data. An institutional inquiry recommended an investigation. During the investigation, the respondent produced two notebooks which contained data that likely formed the basis for at least some of the published results and a summary report of equipment charges that indicated he had conducted numerous additional experiments that were not included in the institutional database. The respondent also informed the laboratory director and graduate student about the technical difficulties involved in doing this research which may have interfered with the replication of his findings. He called attention to some of these difficulties in a correction that was published to one article before the allegation was made. The committee could neither prove nor disprove the respondent's claim that the discrepancy between the labeling on plots on a composite slide and the original computer plots was a result of inadequate labeling of the original computer plots. The institution concluded there was insufficient evidence to find scientific misconduct. ORI concurred with the decision.

Fabrication/Falsification: Two respondents were charged with falsifying their academic titles and the submission and/or publication status of numerous research manuscripts in numerous grant applications. One of the respondents accepted responsibility for the misstatements and the institutional investigation found that there was a clear pattern of sloppiness and inattention to critical details on the part of that respondent, but no compelling case for finding scientific misconduct against either respondent. The institution took remedial actions to correct the falsifications. ORI concurred with the institution's finding and determined that insufficient evidence existed to warrant a PHS finding of scientific misconduct.

Fabrication/Falsification: ORI investigated allegations that research data reported on forms for a multi-site clinical trial contained possibly falsified and fabricated results. Discrepancies in the reporting of research data by one of the sites was reported to ORI by a NIH research integrity officer. Protocol monitors had performed a routine clinic monitoring site visit and found the following discrepancies: (1) consent forms for enrollment that were dated after the date of random treatment assignment for four patients; (2) of the 21 audited records, the audit team was unable to document required meetings of medical specialists with four patients prior to their random treatment assignment; (3) one patient may not have received the complete oncologic evaluation to rule out a particular disease prior to enrollment; and (4) in the case of four follow up examinations for four patients, there were no records that the examinations and procedures reported by the clinic coordinator had taken place. ORI opened a formal investigation approximately a month after it began reviewing the records as part of its inquiry into the allegations. After reviewing the records and interviewing staff at the institution, ORI concluded that the data discrepancies were most likely the result of ignorance, unintentional error, and careless reporting of research data. These conclusions were based on the following: (1) the clinic coordinators did not have a thorough working understanding of the protocol; (2) in many cases, outside physicians filled in the research forms rather than certified staff; (3) outside physicians telephoned the institution with the results of procedures without maintaining the documentation to support the data; (4) equipment malfunctioned; and (5) there was a lack of supervision of the clinic coordinators' performance. Therefore, ORI did not make a finding of misconduct in this case.

Fabrication/Falsification: A faculty researcher was accused by a post-doctoral fellow in his lab of fabricating and falsifying research results. The postdoctoral fellow had reviewed the respondent's recent program project grant, noting that there was an inconsistency in a figure and the associated text and that the availability of an experimental substance had been misrepresented. Based on a review of these allegations, the Associate Dean initiated an inquiry. The inquiry committee, after interviews with the respondent, complainant, and others, raised additional concerns regarding possible unsubstantiated claims in the respondent's grant applications, and an investigation was recommended. During the course of the investigation, the respondent acknowledged that he had made an error and transposed the labels on a figure in a grant application. The investigation committee noted that the issue was minor, and that the correct information would have been more impressive in the grant application. Other allegations were found to be without merit by the investigation committee because the complainant apparently was

unaware of previous work performed by the respondent and his colleagues, and the complainant did not have adequate knowledge of the properties of some of the experimental materials. Other claims that the respondent made in various grant applications were judged to be either over-interpretations or exaggerations, but did not constitute scientific misconduct. The Investigation committee acknowledged that the respondent's project was both experimentally difficult as well as scientifically exciting, and that the lack of experience and expertise on the part of the respondent and the post-doctoral researcher may have contributed to the misinterpretation of experimental results. ORI concurred with the institutional finding that there was insufficient evidence to warrant a finding of scientific misconduct.

Falsification/Plagiarism: The respondent was charged with plagiarizing and falsifying research data included in an unpublished manuscript. The institutional investigation concluded that, although the respondent had used misleading phraseology in the questioned manuscript, a misunderstanding and miscommunication had occurred between two colleagues. Thus, the institution found that insufficient evidence existed to make a finding of scientific misconduct in this case. ORI concurred with the institution's report and conclusions and found insufficient evidence to make a finding of scientific misconduct.

Plagiarism/Serious Deviation from Accepted Practices: Five faculty researchers were alleged to have misused the grant review process by plagiarizing several sentences or passages in a grant application submitted to the PHS after one of the researchers served as a reviewer of a different grant application from another institution. ORI brought the allegations to the attention of the institution, and the institution conducted an inquiry and investigation into the matter. In reviewing the institution's report and the supporting evidence presented, ORI accepted the institution's finding that incorporation of identical wording about a proposed program from the reviewed application into the text of the application in question was the result of a series of errors and negligence on the part of several individuals, but did not rise to the level of scientific misconduct. Therefore, ORI did not find scientific misconduct under the PHS definition on the part of any of the individuals involved in the preparation of the grant application.

Appendix D: Administrative Case Closures

Two cases involved alleged plagiarism. In one case, the respondent was accused of publishing an article containing data and concepts plagiarized from a grant application and appended manuscript. Access to this information could have been obtained during the review of the application/manuscript at NIH or review of the manuscript which also was submitted to a journal by the complainant. ORI determined that the alleged plagiarism did not occur during the NIH review process because the time interval between the receipt of the application for review and submission of the respondent's article to the journal was too short to permit the respondent to conduct the research and prepare the article. ORI closed the case because plagiarism that may occur during a review process conducted by a professional society is outside ORI jurisdiction. However, ORI informed the complainant that it would share with the journal editor the information developed during its review if the journal pursued the allegation further. In the second case of alleged plagiarism, the respondent was accused of plagiarizing background material from a thesis and publication and submitting it in a contract proposal to NIH. The institution identified on the proposal denied any knowledge of or responsibility for the proposal. The proposal was signed by the respondent who had no formal association with the institution. A letter co-signed by the respondent and a program official of the institution indicated the failure to properly cite the material was an innocent mistake made by a foreign graduate student. ORI declined to pursue the allegation under the PHS definition, but referred the false statements to the Inspector General who declined the case because the proposal was unfunded.

Two other cases did not involve PHS funds or applications for funds, and therefore ORI did not have jurisdiction in these cases.

Appendix E:

SCIENTIFIC MISCONDUCT RELATED LITIGATION DURING 1996

U.S. ex rel. Karuturi* v. *John Wayne Cancer Institute, et al., No. 95-7939-CMB(BQRx) (C. D. Cal., filed Nov. 21, 1995). Relator, Dr. Karuturi, filed this *qui tam* complaint under the False Claims Act alleging that the defendants submitted false claims for payment to the National Cancer Institute (NCI) by failing accurately to describe research results in grant applications and progress reports submitted to NCI. The Department of Justice (DOJ) declined to intervene in this action on July 29, 1996, on behalf of the United States, and the National Institutes of Health (NIH). Dr. Karuturi elected to pursue his complaint independently. Defendants filed a motion to dismiss arguing that Dr. Karuturi failed to state a claim under the False Claims Act because he presented no evidence of knowing fraud, and because his allegations concern a scientific dispute, which they alleged could not constitute a false claim. Defendants further argued that Dr. Karuturi's remaining claims of wrongful termination had already been fully litigated by the Superior Court of the State of California for the County of Los Angeles, which ruled in favor of the defendants on a motion for summary judgment. The DOJ filed an *amicus curiae* brief regarding the defendants' motion to dismiss to inform the court of the Government's position that, contrary to the defendants' position, scientific disputes may give rise to false claims under the False Claims Act. In 1997, several counts were dismissed on jurisdictional grounds. The case is still pending.

Fisher* v. *NIH, et al., No. 96-5252 (D.C. Cir.). Dr. Fisher, the former Chair and current Science Director of the National Surgical Adjuvant Breast and Bowel Project (NSABP), filed a 12-count action against the Office of Research Integrity and various other HHS agencies and officials alleging violations of the Privacy and Administrative Procedure Acts. He sought injunctive relief and damages. On June 25, 1996, the United States District Court for the District of Columbia ruled in favor of the Secretary by dismissing all claims filed against HHS. The court's written decision issued August 13, 1996, which summarized the bench decision, granted HHS' motion for summary judgement and denied Dr. Fisher's motions. On November 27, the D.C. Circuit Court of Appeals, *per curium*, granted the government's motion for summary affirmance of the lower court's dismissal and dismissed as moot the non-party motion to allow *amicus*. 1996 U.S. App. LEXIS 41629. The issuance of the court's order implementing the affirmance and dismissal was withheld pending disposition of Dr. Fisher's petition for rehearing. In 1997, in an unpublished decision, the D.C. Circuit Court denied the petition for rehearing, 1997 U.S. App. LEXIS 19092, and the case was dismissed with prejudice.

Fisher* v. *University of Pittsburgh, et al., No 94-1160 (W.D. Penn, filed Dec. 18, 1995). Dr. Fisher filed an amended complaint adding the Office of Research Integrity and several other HHS agencies and officials to a complaint he originally filed against the University of Pittsburgh and others. By order dated December 31, 1995, the court approved the addition of the HHS parties. Dr. Fisher alleged that the University worked in conjunction with HHS to remove him from his position with the National Surgical Adjuvant Breast and Bowel Project (NSABP) and as principal investigator on various PHS grants. He further alleged that these and other actions,

including the placement of annotations in MEDLINE® and CANCERLIT® on certain NSABP articles [see *Fisher* v. *NIH*, *supra*], resulted in an impingement of his constitutional rights including freedom of association, free speech, and due process as well as violations of Federal regulations. He sought damages against the nongovernment defendants and injunctive relief. The discovery, including depositions, was largely concluded by the end of 1996. In 1997, the United States District Court for the Western District of Pennsylvania granted defendants' motions to dismiss several of the claims, and the remainder were dismissed with prejudice by the court after the parties entered into a settlement agreement. Under the terms of the agreement the government did not pay damages to Dr. Fisher, but $300,000 in monies from NIH were contributed toward attorney fees. ORI and NIH admitted no liability or wrongdoing.

Needleman* v. *Varmus, No. 92-0749 (W.D. Penn., filed Dec. 4, 1992); No. 96-3351 (3rd Cir). Dr. Needleman filed a 14-count class action against the Office of Research Integrity, the University of Pittsburgh, and various government and university officials, seeking injunctive relief and damages. He alleged that his constitutional rights were violated in the course of the University's scientific misconduct investigation against him. The University had not found Dr. Needleman guilty of scientific misconduct, and ORI accepted the University's report. On November 23, 1994, the U.S. District Court for the Western District of Pennsylvania granted Federal defendants' motion to dismiss this case against them on all counts. Two counts remained against the University defendants, however, and the court denied the Federal defendants' Motion for Final Judgement pending resolution of those counts. On May 22, 1996, the court finally addressed the two remaining counts by granting the University's motion for summary judgement as to Dr. Needleman's procedural and substantive due process claim under 42 U.S.C. § 1983, and by declining to exercise supplemental jurisdiction over his pendent state claim of breach of contract. In June 1996, Dr. Needleman appealed the court's rulings, including the dismissal of the Federal defendants, to the U.S. Court of Appeals for the Third Circuit. In 1997, in an unpublished opinion, the Third Circuit affirmed the dismissal of the district court's order dismissing the Federal defendants.

U.S. ex rel. Cantekin* v. *University of Pittsburgh, et al., No. 91-0715 (W.D. Pa., filed May 1991); *Cantekin* v. *DHHS*, No. 93-2044 (W.D. Pa., filed Dec. 1993). Dr. Cantekin filed a *qui tam* action under the False Claims Act against the University and others (No. 91-0715) in which the Government declined to intervene. In his complaint, Dr. Cantekin alleged that the defendants defrauded the United States by making false financial disclosure statements in applications for federal grants. In conjunction with the *qui tam* action, Dr. Cantekin submitted a Freedom of Information Act (FOIA) request for ORI files. He appealed ORI's denial of his FOIA request (No. 93-2044), and on June 9, 1994, released some materials pursuant to FOIA and ORI's policy determination. The FOIA case was dismissed on November 14, 1995, but the *qui tam* is pending.

Raz* v. *United States, No. 96-2422 (W.D. La., filed Oct. 17, 1996). On August 21, 1995, Yoram Raz filed a *pro se* civil action against Louisiana State University Medical Center (LSUMC) and ORI which had accepted LSMU's finding that further investigation was not warranted with respect to a scientific misconduct allegation raised by Mr. Raz in 1992. Alleging that ORI was

negligent in handling the misconduct inquiry, the plaintiff sought money damages in addition to an injunction for ORI to reopen an investigation against the exonerated scientific misconduct respondent. On December 14, 1995, the U.S. magistrate judge dismissed plaintiff's action without prejudice. To the extent that plaintiff's claim sounded in tort, the court ruled that it must be brought under the Federal Tort Claims Act (FTCA); the plaintiff, however, had not filed an administrative claim prior to initiation of the suit, as required by the FTCA. With respect to the plaintiff's theory that he was a third party beneficiary of a contract between ORI and LSUMC, the court ruled that the proper venue of a contract claim against the government is the United States Court of Federal Claims. Plaintiff proceeded to file an administrative FTCA claim on March 27, 1996. After six months elapsed without a Departmental response to his claim, plaintiff brought a second suit under the FTCA against the United States, in the same district court, stating the same claims and prayer for relief as in the first action. The United States filed a motion to dismiss the new suit on November 4, 1996, arguing *inter alia* that alleged violations of Federal law are not actionable under the FTCA. In 1997, in an unpublished decision, the U.S. District Court for the Western District of Louisiana dismissed the case with prejudice.

Polsby* v. *Shalala, Consolidated CA No. DKC-88-2344 (D. Maryland, filed Aug. 10, 1988); No. 96-1793 (4th Cir.). Dr. Polsby originally alleged violations of the Civil Rights Act of 1954 by NIH. However, she expanded her claim to assert that a contributing factor to the alleged violations was ORI's failure to initiate a scientific misconduct investigation. The case went to trial, and on March 28, 1996, at the conclusion of the trial, the Judge ruled in favor of HHS concluding that Dr. Polsby had failed to prove her claims of gender discrimination. On June 13, 1996, Dr. Polsby appealed to the U.S. Court of Appeals for the Fourth Circuit *pro se*. The case is still pending.

U.S. ex rel. Berge* v. *Univ. Alabama, et al., No. N-93-158 (D. Md., filed 1993); No. 95-2811 (4th Cir.). After ORI declined to pursue Dr. Berge's scientific misconduct allegations, she filed this litigation under the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b), seeking both damages and civil penalties. She charged that the University of Alabama, through the individual defendants, obtained funding from NIH by making false claims in various grant applications. She also asserted a number of pendent state law claims. The United States declined to intervene. Nevertheless, Dr. Berge obtained a jury verdict in her favor. The jury awarded $550,000 in False Claims Act damages against the University that were trebled under the provisions of the False Claims Act to $1.6 million; other damages and penalties were also imposed against the defendants both jointly and severally. The University of Alabama appealed, and several institutions and associations filed supporting *amicus* briefs. DOJ, after consultation with HHS, also filed an *amicus* brief on several issues including the constitutionality of the *qui tam* provision and its applicability to the states. DOJ also rejected in its brief the arguments of several *amici* that the False Claims Act should not be applicable to scientific misconduct issues noting that all manner of scientific misconduct, *e.g.*, the falsifying of data or the misrepresentation of results to secure a grant—may give rise to a legitimate False Claims Act claim. The appellate court held a hearing on the matter on December 4, 1996. In 1997, the Fourth Circuit reversed the lower court's decision and held that the district court erred when it improperly denied the

defendant's motion for judgment as a matter of law. 104 F. 3rd 1453 (4th Cir. 1997). Dr. Berge's petition for *certiorari* to the U.S. Supreme Court was also denied.

Angelides* v. *Baylor College of Medicine, et al., No. 95-24248 (11th D.C. Harris County, Tex., filed Aug. 29, 1995); No. H-95-4640 (S.D. Tex.); No.95-042305 (11th D.C. Harris County, Tex.); No 96-20618 (5th Cir.). Dr. Angelides, formerly a research scientist at Baylor College of Medicine (Baylor), filed a lawsuit against Baylor and several of its employees, in Texas state court, seeking damages for various elements surrounding his employment dismissal by Baylor. Dr. Angelides was dismissed by Baylor after an investigation committee determined that he had committed scientific misconduct by falsifying and fabricating research data in four grant proposals to NIH and five published scientific papers. Baylor successfully removed the case to Federal court arguing that the case involved the construction of Federal law relating to Baylor's obligations under the scientific misconduct provisions of Section 493 of the Public Health Service Act. 42 U.S.C. § 289b; 42 C.F.R. Part 50, Subpart A. Baylor then filed a motion to dismiss the complaint on the grounds that the actions complained of were carried out by the defendants as required by the Federal statute and regulations. On June 13, 1996, the Federal district court denied the motion to dismiss and, *sua sponte*, remanded the case back to the state court for further proceedings based upon the lack of a Federal question. Baylor appealed to the U.S. Court of Appeals for the Fifth Circuit, and DOJ, following consultation with ORI and HHS, filed an *amicus curiae* brief with the Fifth Circuit supporting Baylor's argument that it was under a Federal regulatory obligation to investigate the allegations of misconduct levied against Dr. Angelides and to report those findings to ORI, and therefore, the institution's Federal obligations insulated it from Dr. Angelides' defamation claims. In 1997, the Fifth Circuit dismissed the appeal for lack of appellate jurisdiction, but noted that these issues could be reviewed by the Texas state court. 117 F.3d 830 (5th Cir. 1997). The State court proceeding is still pending.

U.S.A.* v. *Hôpital Saint-Luc, et al., No. 500-05-005930-951 (filed 1995). The U.S. Government filed breach of contract claims in Superior Court for the District of Montreal, Province of Quebec, Canada, against St. Luc Hospital and the University of Pittsburgh seeking recovery of PHS grant funds related to breast cancer research fabricated by a St. Luc researcher, Dr. Roger Poisson. NIH recovered grant funds from the University of Pittsburgh through a negotiated settlement based upon ORI's finding of scientific misconduct against Dr. Poisson. The suit is still pending.

U.S. ex rel. del Guercio* v. *Board of Regents of the University of California, et al., No. CA 950994 (LSP) (S.D. Cal., filed June 1995). Relator Dr. del Guercio, alleged in this *qui tam* filed under the provisions of the False Claims Act, 31 U.S.C. § 3729, that the Board of Regents of the University of California made false statements in several grant applications submitted by the University of California at San Diego on behalf of codefendants, the principal investigators on several PHS grants. On December 27, 1996, the United States intervened in this *qui tam* case, and notified the court that it would file an amended complaint alleging that the defendants violated the False Claims Act, by submitting falsified data and citing to a manuscript containing additional falsified data in grant applications and progress reports to the NIH. The case was

settled in 1997, pursuant to which the university agreed to pay the United States $135,000; $10,125 of this amount to be paid to the relator, Dr. delGuercio, and also to pay $30, 000 of the relator's attorney's fees and expenses.

Appendix F:
Executive Summary: Report on 1995 Annual Report on Possible Research Misconduct

This report describes the conduct and results of the 1995 Annual Report on Possible Research Misconduct. It presents the legal basis for requiring institutions to submit the report, the changes that were made to the report in 1995, the data collected, the follow-up actions taken, the problems encountered, proposed solutions, and emerging issues.

The Annual Report form was sent to 3,341 institutions on January 29, 1996. By April 19, 1996, the submission deadline, 2,847 institutions (85 percent) returned their reports. Considerable staff effort was saved by shifting the responsibility for submitting the Annual Report to the institutions and dropping the second follow-up effort—phone calls and faxes to the delinquent institutions. By June 18, 1996, 164 additional Annual Reports were submitted raising the number of reports received to 2,968 (89 percent).

Annual Reports covering 396 institutions were not returned; another 121 institutions voluntarily withdrew their assurances and did not have to submit the Annual Report. These 517 institutions were inactivated, making them ineligible for PHS research funding. Deleting 517 institutions from the ORI Assurance Database only resulted in small percentage shifts among the types of organizations that comprise the total population.

A record number of institutions (96) reported that they were responding to allegations of scientific misconduct in 1995. Sixty-one institutions received new allegations of scientific misconduct in 1995; 47 institutions were continuing to process allegations made in 1994 or before, and 12 institutions were responding to allegations made both prior to and in 1995. No unreported investigations were detected this year as has been the case in previous years.

The 96 institutions conducted 113 inquiries and 68 investigations in 1995, including 70 inquiries and 31 investigations stemming from new allegations. The new charges alleged fabrication, 24; falsification, 46; plagiarism, 13; and other practices, 21.

Ninety-five percent of the institutions reported that they had policies and procedures for handling misconduct allegations. Policies and procedures were requested from 111 institutions, including 71 small businesses, that reported they did not have such policies and procedures or did not answer the pertinent question.

Three methods are primarily used by institutions to inform faculty, staff, technicians, fellows and graduate students about their policies and procedures for responding to allegations of scientific misconduct—handbooks/manuals, all-hands memoranda, and orientation sessions.

Institutions took 2 to 9 actions in 70 of 113 cases to protect the position and reputation of individuals who made scientific misconduct allegations in good faith. These actions fall in four categories: (1) establishing policies and procedures related to retaliation; (2) preventive activities,

(3) protecting positions, and (4) protecting reputations.

Institutions attempt to restore the reputation of exonerated individuals by maintaining confidentiality during the inquiry and/or investigation, informing parties involved that misconduct was not found, and purging personnel files of any material related to the allegation.

Changes in the 1995 Annual Report form and transmittal letter were successful in reducing the non-response rate on two questions asking about the availability of policies and procedures, 56 percent, and the dissemination of policies and procedures, 54 percent. In addition, the number of unsigned forms was reduced by 33 percent.

Results from the Annual Report required a major updating of the ORI Assurance Database. Six hundred and sixty-five institutions (23 percent) reported changes in the name of the responsible official or the institutional address. Four hundred and ninety-four assurances (15 percent) covering 517 institutions were inactivated.

Further actions will be taken to increase the response rate and number of completed forms received in the 1996 Annual Report.

Five emerging issues were noted in the conduct and analysis of the Annual Report:

- **Content of the Annual Report**: The content of the Annual Report will be examined to determine whether it can more effectively serve as a vehicle for checking institutional compliance, educating institutions, and collecting information. ORI intends to examine the yield of current questions and consider additional questions on administrative actions taken by institutions, efforts made to promote research integrity, the frequency of bad faith allegations, and the appointment of institutional research integrity officers.

- **Compliance by Small Businesses**: Small businesses account for very few allegations of scientific misconduct. Consequently, follow-up compliance activities to the Annual Report focused on other types of institutions. However, a recent NSF OIG report which described several serious financial and accountability problems found in small businesses suggests that it may be prudent to pay more attention to compliance by small businesses. Policies and procedures were requested from 71 small businesses as a result of their responses to questions in the Annual Report.

- **Responsible Officials**: The responsible official is the primary contact person at an institution for ORI. The turnover rate among these officials is high, about 18 percent a year. In addition, the role of the assigned institutional official is often unclear. ORI is promoting the appointment of institutional research integrity officers with assigned responsibilities to address this problem. ORI distributed a *Handbook for Institutional Research Integrity Officers* in 1997 that will quickly inform a new appointee about the responsibilities of the position. ORI is also planning workshops for these individuals.

- **Protection of Whistleblowers**: Institutional efforts to protect whistleblowers are very uneven. Institutions take from zero to nine actions per case. There appears to be no accepted set of procedures for protecting whistleblowers. ORI is gathering information on whistleblowing for a possible publication on what whistleblowers can do to protect themselves. ORI continues to provide information to institutions on what other institutions are doing to protect whistleblowers to further the establishment of a common set of procedures. In addition, ORI is developing a regulation on the protection of whistleblowers.

- **Restoration of Reputations**: Institutions do not appear to be very active in restoring the reputation of respondents exonerated of scientific misconduct. The following factors complicate this task: First, the respondent may not want any action taken. Second, the institution may not want to restore the reputation of a respondent because other violations or poor performance was found. Third, the methodology for restoring reputations is underdeveloped. ORI intends to explore the literature on the restoration of reputations and continue to provide institutions with information about what other institutions are doing to restore reputations to further the development of a common set of procedures.

The full report is available from ORI's home page at http://www.dhhs.gov/phs/ori

Appendix G: Compliance Review Case Summaries

The following are summaries of all retaliation cases closed since the Compliance Review Program began in 1994, and all compliance cases closed during 1996.

Retaliation: The complainant claimed that his reputation was severely damaged and he was forced to resign his position as chairman of his department as a result of his bringing allegations of scientific misconduct against a faculty member at his institution. ORI requested that the institution investigate the complainant's claims, and the institution appointed an investigative committee to review the matter. The institution conducted an extensive review, and concluded that the institution was responsible for many of the adverse actions suffered by the complainant as a result of his making allegations. The institution implemented a number of remedies, including developmental leave for a full year, start-up research funds, and a written announcement to the faculty stating that the complainant acted properly in making the allegation. The institution also accepted a committee recommendation that as a way to prevent future retaliation, an official was to meet with the complainant on a semiannual basis.

Retaliation: The complainant claimed that the keys to his lab and a personal file cabinet were confiscated and he was sent a "lay off" notification because he made allegations of scientific misconduct against his supervisor. His supervisor also wrote to the complainant's former employer stating that the complainant falsified documents, sabotaged experiments, and breached patient confidentiality in an attempt to terminate the complainant's pension privileges. ORI contacted the institution and asked officials to explain the actions they intended to take in response to these retaliatory actions, and how they intended to prevent it from happening again.

The institution directed the respondent to cease such actions, and filed a formal complaint against the respondent for violation of the institution's policies and procedures, as well as the Faculty Code of Conduct. In terms of protecting the complainant, institutional officials extended his appointment for an additional year while the misconduct investigation was ongoing, and moved him twice to avoid interaction with the respondent. A letter was also sent to the former employer, stating that the allegations made by the respondent were not true. This protection was provided despite the complainant also being named as a respondent in the misconduct case he initially reported. The complainant's employment was terminated at the conclusion of the misconduct investigation, based on his admitted misconduct, but this action was not considered to be retaliatory.

Retaliation: The complainant made misconduct allegations against a fellow faculty member at a private university and subsequently claimed that he lost his department chairmanship as a result of making those allegations. The record shows that the complainant was accused of scientific misconduct prior to making allegations against the fellow faculty member in a separate case. The institution conducted a review of non-PHS issues, and found that the complainant's conduct violated its institutional standards. After the complainant filed a civil suit, the institution and the complainant entered into a settlement agreement.

ORI determined that there was insufficient evidence that the institution retaliated against the complainant. Therefore, ORI did not refer this allegation back to the institution for further consideration.

Retaliation: The alleged retaliatory actions against the complainant in this case included: (1) making counter allegations of scientific misconduct against the complainant, (2) accusing the complainant of sabotage in a NIH grant application, (3) attempting to prevent the complainant from utilizing grant supported equipment, citing "personal irreconcilable conflicts", and (4) threatening the complainant's continued employment. Another official at the institution alleged that charges of scientific misconduct were made against the official, potentially in bad faith, by certain respondents in this case in retaliation for his role in forwarding the initial allegations made by the complainant to the appropriate institutional officials.

This case was unusual, as the complainant was also a respondent accused of scientific misconduct. Institutional officials were required to pursue the scientific misconduct allegations against the complainant and others, as well as respond to alleged retaliatory acts by the co-respondents against the complainant and another institutional official. The record in this case showed possible evidence to support the claims that the complainant and another institutional official suffered retaliation by the co-respondents.

ORI asked the institution to investigate the matter and to provide ORI with a report describing the processes the institution had in place to protect good faith whistleblowers, and to explain the actions the institution would take to address the current retaliation complaints and to prevent future retaliation. The institution provided the requested report, and concluded that the actions of the respondents "had the appearance of being motivated by such retaliation, and they were directed to cease." The respondents were also informed that "if further inquiry into their actions determined that retaliation had occurred, or if additional retaliatory acts occur at any subsequent time, disciplinary action would be taken."

The institution took a number of steps in response to the retaliatory acts, including the continuance of the complainant's salary support and moving her to another laboratory. The institution also directed the respondents to remove inflammatory and false statements about the complainant in a NIH grant application. Based on the documentation provided in this case, ORI judged the actions of this institution to be appropriate, thus fulfilling the regulatory requirement for protecting good faith complainants.

Retaliation: In this case, an individual claimed that she was forced, through intimidation, threats, and persistent harassment, to resign her position at the institution, and the institution failed to take action to protect her funded research after she raised allegations of scientific misconduct against a faculty member. Once ORI staff determined that ORI had jurisdiction, the institution was asked to conduct an independent review of the matter. ORI provided the institution with a copy of the *ORI Guidelines for Institutions and Whistleblowers: Responding to Possible Retaliation Against Whistleblowers in Extramural Research* (ORI Guidelines) for guidance in investigating or

arbitrating the dispute.

The institution chose to investigate the matter, rather than submit the issues to arbitration, and provided a final report to ORI that did not find that retaliation had occurred. ORI reviewed the report and determined that the institution followed the process described in the ORI guidelines, thereby satisfying the requirements of the Federal regulation.

Retaliation: The complainant claimed that officials at the university where he received his doctorate were providing negative or false letters of recommendation in retaliation for his raising allegations of scientific misconduct. ORI staff contacted recipients of the letters, and they indicated that they did not perceive the contents as negative. The recipients also indicated that their hiring decisions were based on personal impressions developed during interviews and presentations; the letters had little or no impact on their hiring decision. Because there was insufficient evidence to pursue this allegation, the case was closed with no referral to the institution. The institution was reminded, however, of its general regulatory obligation to protect good faith whistleblowers.

Retaliation: In this case, the complainant had filed a lawsuit against the institution alleging that he was fired for making an allegation of scientific misconduct. The complainant also brought his retaliation complaint to ORI's attention. ORI suggested that arbitration be used to resolve the conflict and offered to fund partially the arbitration as a test of the approach being considered for possible inclusion in a notice of proposed rulemaking. The complainant and the institution set the arbitration mechanism in motion but reached a settlement before a hearing was held.

Retaliation: The complainant made allegations of scientific misconduct against officials at a research center and later claimed that he was dismissed in retaliation for making those allegations. An initial review of the record showed that the date of the complainant's dismissal was three months prior to his making allegations, and his performance had been an issue of concern for institutional officials at least one month earlier than that. The complainant was informed of ORI's initial assessment, and told that in order for ORI to pursue his complaint further, it would need substantive documentation showing some linkage between his dismissal and his allegations. Additional information was provided, and ORI was still unable to find a documented link between his making the allegations and his dismissal. The complainant was then informed that because he was unable to provide adequate documentation to support his claim, and because he did not identify any individuals who could corroborate his claim, ORI closed the case with no further action.

Retaliation: The complainant claimed that he was being subjected to threats and blackmail by the respondent, as a result of his making allegations of misconduct. The complainant was informed that ORI needed additional information regarding his retaliation complaint in order to pursue the matter further. The requested information included the nature of the adverse actions that resulted from his misconduct complaint, the date of the alleged allegation, the identity of the individual(s) that took the retaliatory actions, the name of the individual to whom he reported the alleged

retaliation, and any additional information relevant to the complaint. The complainant did not respond to our initial request for additional information, or to a follow-up request. Based on the lack of specific information regarding the complaint of alleged retaliation, no further action was taken and the case was closed.

Retaliation: The complainant, a research fellow, reported concerns regarding certain data being collected for a research program. These concerns prompted the initiation of an inquiry. About the same time the complainant raised these concerns, the complainant was removed from her position in the laboratory, and no alternative work assignment was provided. The complainant believed that her removal from the laboratory was in retaliation for raising allegations of misconduct. ORI contacted the officials and asked that the situation be reviewed with a possible solution being the transfer of the complainant to another laboratory that would provide a meaningful and supportive training experience, consistent with her position as a research fellow. With the assistance of institutional officials, the complainant was placed in another lab, and reported to ORI that, with only minor exceptions, she was satisfied with the new position in another laboratory. Contact with the complainant was maintained during the course of the scientific misconduct investigation to monitor the ongoing institutional effort to protect her as the whistleblower.

Retaliation: The complainant claimed that she was dismissed from her job in retaliation for raising allegations of misconduct regarding PHS supported research carried out at a research institute affiliated with a local hospital. This individual submitted extensive documentation to support her claims, and was interviewed by ORI staff regarding her allegations. A review of the documentation submitted found that none of the specific issues raised by the complainant fell within the PHS definition of scientific misconduct, and therefore, were outside the jurisdiction of ORI. However, a number of these issues were substantive and were referred to other PHS organizations for follow-up, including the FDA, the NIH Office for Protection from Research Risks, and the NIH Office of Management Assessment, a financial review group at NIH. Because the allegations made by this individual fell outside the PHS definition of scientific misconduct, there was no regulatory obligation under 42 C.F.R. Part 50, Subpart A, for the institution to protect her position and reputation as a whistleblower. Because of this lack of jurisdiction, ORI did not pursue her retaliation complaint.

Retaliation: This case involved an initial assessment of complaints of possible retaliation against two different individuals employed by a State Department of Health. The complaints were forwarded to ORI by an attorney representing both individuals. As part of an initial evaluation of retaliation claims, ORI reviews the claim to determine if the allegations of scientific misconduct fall within the PHS definition, if there was PHS support involved, and whether there is a link between the alleged adverse action and the misconduct allegation.

One individual claimed she was retaliated against for making two separate allegations of scientific misconduct. In the first instance she claimed, among other things, that the P.I. on the grant on which she was working falsified authorship on a research report. ORI did not pursue this

allegation primarily because the complainant was unwilling or unable to provide specific information to support her allegations. Moreover, because ORI could not document jurisdiction in this matter, it did not have the regulatory authority to pursue the alleged retaliation. In her second allegation, this individual claimed that her credentials were purposely misstated on a grant application, which if true, might constitute scientific misconduct. In reviewing the record associated with this allegation, ORI found that the complainant only became aware of the mistake on the summary statement regarding her credentials in late 1995, which was long after the purported adverse actions were taken against her. Because there was no credible connection between the purported adverse actions and her allegations, ORI did not pursue her claim of retaliation.

The second complainant made allegations and provided documentation regarding alleged safety violations at the State Department of Health. After reviewing the documentation provided, ORI determined that these issues were outside the PHS definition of scientific misconduct, and ORI therefore did not have a basis to pursue this individual's allegations of possible retaliation.

Retaliation: This case was initially opened based on a telephone conversation in which the complainant alleged that his termination for cause was actually retaliation for making allegations of scientific misconduct. He alleged that he was not given proper credit on a paper authored by a 4th-year resident in his laboratory. In response to this contact, ORI wrote to the institution to request information related to its handling of the allegation, and reminded the institution of its obligation to protect whistleblowers. The institution, in response to ORI's request, provided information related to the disputed authorship, and also provided information supporting its position that the complainant's dismissal was unrelated to his allegations. Based on the lack of credible evidence to support the complainant's allegation of retaliation, no further action was taken and the case was closed.

Retaliation: A researcher submitted retaliation complaints to ORI for review, claiming that in response to his making allegations of scientific misconduct, his institution denied him promotions, reduced his laboratory space, failed to take appropriate action against a student who had verbally confronted him, and denied him certain privileges for having appeared before the Commission on Research Integrity. ORI reviewed the documentation associated with the case and determined that a majority of the alleged retaliatory actions against the complainant predated the 1989 Federal regulation. ORI notified the complainant of this assessment, noting that institutions were not required under the regulation to process retaliation complaints that predated the Federal regulation. ORI also informed him that in accordance with its standard procedure in addressing retaliation complaints, it was prepared to refer the post-1989 allegations of retaliation to the institution for review under the regulations, which obligate the institution to protect good faith whistleblowers. The complainant was not satisfied with the exclusion of many of his earlier complaints, nor was he willing to accept ORI's intended referral of the case back to the institution, insisting instead that ORI conduct an independent investigation into his retaliation complaints. Since an ORI investigation was not a viable option, and the complainant was

unwilling to involve his institution in an investigation of his complaint, no further actions could be taken by ORI, and the case was closed.

Compliance: In this case, minor irregularities were noted in an institutional investigation, and because this institution had had several other cases of alleged misconduct, an initial decision was made to review all the recent cases for compliance. Because of other priorities, and the relative minor shortcomings that were noted during this review, the case was administratively closed in February 1996.

Compliance: A compliance review was initially opened for the purpose of reviewing the institutional response to a series of misconduct investigations, many of which had been criticized by Congress and others as being inadequate. An initial part of the review involved an assessment of the institution's policies and procedures for dealing with scientific misconduct, which recently had been revised, and were found to be satisfactory by ORI. The planned comprehensive review of the actual process employed by institutional officials in the investigation of numerous scientific misconduct allegations was scaled back due to a number of factors, including the creation of the position of a Research Integrity Officer at that institution which effectively centralized the response to misconduct allegations, the improvement in the conduct of more recent cases, and a reassessment of the value in reviewing older cases, some of which predated the establishment of ORI. Based on these factors, the compliance case was administratively closed in April 1996.

Compliance: An institutional compliance review was initiated based on the failure of the institution to notify ORI prior to the initiation of the investigation. The full compliance review involved a review of institutional policies and procedures, as well as an assessment of the institutional process in dealing with the misconduct allegations. The policies and procedures were found to be inadequate, and institutional officials were asked to make revisions to bring the policies and procedures into compliance with the Federal regulation, which they did. Regarding the conduct of the inquiry and investigation, ORI found that the institution generally complied with its policies and procedures and the Federal regulation, with the exception of its failure to notify ORI at the time it initiated the investigative portion of the process.

Compliance: The complainant criticized the process utilized by the institution, claiming that neither he nor the respondent were interviewed during the inquiry process, and no other witnesses were called. He also complained that he was not provided a copy of the inquiry report. The complainant further stated that with one single exception, there were no officials at the institution who were aware of the misconduct policies and procedures, and the institution therefore was not responsive to the requirements of the Federal regulation. There is no Federal requirement that the complainant, or anyone else, be interviewed at the inquiry stage, or that the institution provide the complainant with a copy of the inquiry report. Furthermore, a review of the institutional policies and procedures found that they did not contain any more specific requirements beyond those in the Federal regulation regarding interviews or distribution of inquiry reports. The alleged lack of knowledge by faculty or administrators of the provisions (or existence) of the Federal regulation was not pursued because of lack of supporting documentation. Independent of the complainant's

charges, ORI requested and reviewed the institution's policies and procedures. Numerous deficiencies were noted, and the institution was asked to modify its procedures to bring them into compliance with the Federal regulations, which it did. Because of the lack of adequate documentation to support his claim of institutional non-compliance with the Federal regulation, no further action was taken by ORI regarding compliance, and this case was closed.

Compliance: This case was selected for a policy review based on an institutional decision to terminate its process at the inquiry stage based on an admission of scientific misconduct by the respondent. Institutional officials reported to ORI that their policies and procedures did not identify a separate process for dealing with instances of admitted scientific misconduct, and they concluded that no further investigation was necessary because of the admission. This issue was dealt with separately as a part of the ORI oversight of the institutional scientific misconduct investigation. ORI also requested that the institution provide its most current policies and procedures for review, and ORI found that a number of provisions of the Federal regulation were not adequately represented in the institutional policies and procedures. ORI noted the deficiencies in a report, and asked that the institution revise its policies and procedures to eliminate the noted deficiencies. The institution revised its policies, and these revised policies were found by ORI to comply with the Federal regulation.

Compliance: This case was reviewed in response to an internal oversight review of a scientific misconduct investigation conducted by an institution. A compliance review of institutional policies demonstrated that the policies incorporated the basic elements of the Federal regulation; however, according to the ORI oversight report, there were two elements in the institution's policies that could circumvent the intent of the Federal regulation. One element involved the institution's ability to dismiss a scientific misconduct allegation despite an inquiry that recommends further investigation, and the other element specified "clear and convincing" as the standard of proof used for institutional determinations of scientific misconduct. It was determined that these elements did not violate any provision of the Federal regulation, although ORI reminded the institution that misconduct must be reported to ORI under the "preponderance of the evidence" standard. Based on this assessment, no further review was warranted and the case was closed.

Compliance/Retaliation: A visiting professor and an assistant professor contacted ORI with complaints of institutional retaliation for their making allegations of scientific misconduct. In addition to the allegations, these individuals also claimed that the institutional process for dealing with their misconduct allegations was flawed. The visiting professor also had filed a lawsuit against the institution, which included issues related to his claim of retaliation. The lawsuit eventually was settled, and ORI was so informed. Because this action represented an acceptable remedy to a retaliation complaint consistent with the intent of the current Federal regulation, ORI did not pursue this retaliation complaint further.

The assistant professor independently submitted documentation to ORI in support of his retaliation complaint, which included being deprived of access to computer labs and the deletion

of computer accounts, not being able to have access to work completed or tools developed during preceding months, being locked out of and having no office for several months, being deprived of teaching duties, and being denied access to a communication system that he had developed. This individual also informed ORI that he intended to file a lawsuit against the institution. ORI informed the assistant professor that if the lawsuit was filed, under its Whistleblower Guidelines ORI would not ask the institution to take additional actions, such as initiation of an institutional investigation, to satisfy its regulatory requirement to protect whistleblowers. Although the assistant professor initially stated that he intended to compel the institution to conduct an investigation of his retaliation complaint, the lawsuit was served before the institutional process was initiated, and ORI closed the case.

Compliance/Retaliation: This case was referred to ORI and involved allegations of possible scientific misconduct (plagiarism) as well as possible retaliation against the complainant, a postdoctoral fellow. A review of the materials provided disclosed that there was no identifiable PHS funding associated with the questioned research, and therefore ORI did not have the regulatory authority to pursue the retaliation complaint. Accordingly, the complainant was notified and the case was closed.

Appendix H: Consequences of Being Accused of Misconduct: Report of a Study

The study of the "Consequences of Being Accused of Scientific Misconduct" was commissioned by ORI in 1995 to evaluate the impact an allegation of misconduct had on the reputation and career of scientists and to determine whether further policy development was needed.

Originally, the survey included individuals against whom misconduct was found, but the misconduct group was dropped from the study because the expected response rate would not produce the minimum sample size (N=30) required by OMB. Consequently, the project title was changed to a "Survey of Accused but Exonerated Individuals in Research Misconduct Cases." The study completed by the Research Triangle Institute in 1996 analyzed responses from 54 respondents involved in closed cases that did not result in a misconduct finding under the PHS definition.

The majority of exonerated respondents perceive an accusation of scientific misconduct as having a mostly neutral impact on their careers, professional activities, and personal lives. However, a sizeable minority perceive the impact as negative, especially when they experienced severe negative consequences.

Less than half of the respondents were satisfied with the handling of their cases, the restoration of their reputations, and the maintenance of confidentiality.

Sixty percent of the respondents reported experiencing one or more negative consequences of being accused of scientific misconduct even though the allegation was unsupported; 17 percent reported severe consequences—loss of position, promotions or salary increase; 43 percent reported less severe consequences—threatened lawsuits, additional allegations, ostracism, reduction in research or staff support, delays in processing manuscripts or grant applications, and pressure to admit misconduct. Forty percent reported no negative consequences.

Ninety percent of the respondents who reported negative consequences indicated that the negative actions began during the inquiry and/or investigation and 65 percent reported the negative actions continued after the final determination. Institutional officials were cited as the major source of severe negative actions. Complainants were cited as the most frequent source of negative action—severe and less severe.

The overall impact of the allegation on their careers was viewed as neutral by 57 percent, negative by 39 percent, and positive by 4 percent. The most frequently mentioned career dimensions viewed as negatively affected by the allegation were professional reputation, 46 percent; job mobility, 30 percent; and networking 24 percent. Professional activities negatively affected were presenting papers, 39 percent; research, 37 percent; chairing sessions, 30 percent; and serving in elected offices, 28 percent. In their personal lives, negative impacts were seen on mental health, 78 percent; physical health, 48 percent; self-esteem, 46 percent, self-identity, 39 percent; and

spouse/partner, 37 percent. Positive effects were seen primarily on self-esteem, 11 percent, and friends, 11 percent.

Almost all of the respondents (94%) were still conducting research. Seventy-one percent were still working in the institution where they were accused of scientific misconduct. Seventy-five percent of the respondents who changed institutions thought the change was desirable. Nevertheless, 39 percent thought it was likely that there is a continuing stigma attached to being accused of misconduct; 54 percent thought it unlikely, and 11 percent did not know.

As many respondents were satisfied (44%) as dissatisfied with the handling of their cases. Major sources of dissatisfaction concerned the opportunity to review reports, protection against conflicts of interest, length of investigation, length of inquiry, confidentiality of proceedings, opportunity to defend themselves, and notification of allegations.

Thirty-nine percent of the respondents were dissatisfied with the efforts made by their institution to restore their reputation. Thirty institutions did nothing to restore the reputation of the respondent; four did so at the request of the respondent. Only nine respondents reported that their institution consulted with them about measures that could be taken to restore their reputations.

Nearly half of the respondents (47%) believed that their institution did all it could to maintain confidentiality. More than a third of the respondents (36%) stated that institutions failed to maintain confidentiality. Breaches in confidentiality were primarily attributed to the duration of the inquiry and/or investigation and information leaks.

These findings are based on responses from 54 of 108 respondents involved in closed cases prior to 1995 that did not result in a finding of scientific misconduct under the PHS definition. ORI records indicate that institutions impose administrative actions on some individuals exonerated of scientific misconduct because the investigation finds violations of other rules governing their behavior or inadequate job performance. Respondents in this study were not asked to indicate whether any of their reported consequences were due to such findings. However, three respondents reported that they were found to have committed other types of academic or professional misconduct.

Copies of the full survey report are available upon request or from ORI's home page, http://www.dhhs.gov/phs/ori.

Appendix I: Additional Information About the Office of Research Integrity

ORI Mission

ORI was established in June 1992 by the Assistant Secretary for Health to oversee and direct the PHS research integrity effort.[1] 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 of 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.

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[1]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.

- 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, conducts investigations in PHS intramural programs, and assists OGC in representing ORI before the DAB. The OGC branch provides legal advice on all ORI activities, defends ORI in civil litigation, and represents ORI before the DAB.

Staff Changes

Chris B. Pascal, J.D., Director, Division of Research Investigations (DRI), was named as Acting Director of ORI when Lyle W. Bivens, Ph.D. retired on March 31, 1996.

Mr. Pascal served as Chief, Research Integrity Branch, Office of the General Counsel, from 1992 to 1995 when he became Director, DRI. Marcus Christ was appointed Chief of the Research Integrity Branch when Mr. Pascal became DRI Director. Dorothy K. Macfarlane, M.D., was appointed as Acting Director of the Division of Research Investigations (DRI) to replace Mr. Pascal.

Appendix J: Abbreviations

DAB	Departmental Appeals Board
DPE	Division of Policy and Education, ORI
DRI	Division of Research Investigations, ORI
FDA	Food and Drug Administration
FOIA	Freedom of Information Act
HHS	Department of Health and Human Services
NSF	National Science Foundations
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

Appendix K: List of Tables