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 regulation.

   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 evaluated carefully for appropriate disposition.

In 1997, ORI received 166 queries, a 15 percent decrease from the 196 queries received in 1996. The disposition of the queries is presented in table A 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 166 queries made to ORI in 1997, 52 were assessed in detail for a possible inquiry or investigation, 18 were referred to other agencies, 96 were closed without further action and 3 were referred to other agencies following detailed ORI assessment. Forty-seven of the fifty-two allegations (90%) that required in-depth review by ORI staff were resolved with an average processing time of 52 days (time from assignment to closure or the opening of a formal case). The other five cases were still under review at the end of the calendar year. Twenty-one of the forty-seven completed assessments resulted in formal cases.

Table A: Initial Disposition of Queries in 1997

Pre-Inquiry Assessment	52
No Action Possible Now Or No Action	96
Referred to Other Agencies	18
TOTAL	166

Cases

In 1997, 14 of the 29 closed misconduct cases resulted in sustained findings of scientific misconduct or PHS administrative actions. At the end of the calendar year, ORI had 35 formal cases and 5 allegations under review, an all-time low.

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

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 1997, ORI accepted nine institutional reports on inquiries that did not recommend investigations. Falsification was the most frequent allegation examined in the inquiries (seven). ORI requested that six institutions conduct inquiries, accepted nine reports, and carried seven cases into 1998.

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 1997 monitoring 35 investigations at institutions. During 1997, 18 institutional investigations were opened and 27 were closed. Twenty-six investigations were carried into 1998.

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, *e.g.*, a multicenter clinical trial. ORI opened one extramural inquiry because the respondent was president of a small business.

ORI investigations: ORI conducts 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 two investigations; one was intramural and the other involved multicenter clini-

cal trials. The two open investigations carried into 1998 were intramural cases.

Table B: ORI Scientific Misconduct Caseload by Case Type during 1997

Case Type	*Forwarded from 1996*	*Opened in 1997*	*Closed in 1997*	*Carried into 1998*
Institutional Inquiries	10	6	9	7
Institutional Investigations	35	18	27	26
ORI Inquiries	0	1	1	0
ORI Investigations	3	1	2	2
TOTAL	48	26	39	35

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. One investigation was administratively closed by ORI in 1997. This case is included in the statistical profile of closed investigations and is considered to be a case in which there is no finding of misconduct.

II. 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 PHS research funds are only awarded to eligible institutions. An institution is eligible when it has an active assurance on file with ORI stating that it has developed and will comply with an administrative process for responding to allegations of scientific misconduct in PHS-supported research that complies with the Federal regulation (42 C.F.R. Part 50, Subpart A). An institution establishes an assurance by filing an initial assurance form or signing the face page of the PHS grant application form revised in 1996. Institutions keep their assurance active by submitting the Annual Report on Possible Research Misconduct, submitting their misconduct in science policy upon request by ORI, revising their misconduct in science policy when requested by ORI, and complying with the Federal regulation.

The Assurance Program meets its responsibilities by maintaining the assurance database, auditing awards to institutions, gathering and summarizing information from institutions in their Annual Report on Possible Research Misconduct, and reviewing institutional policies and procedures in collaboration with the Compliance Review Program.

Assurance Database

Maintaining an accurate assurance database is essential to the successful operation of the assurance program because the database is used by ORI and funding agencies to determine the eligibility of institutions to received PHS research funding. In 1997, three new actions were taken to improve the accuracy of the database. First, an effort was begun to develop an e-mail network to facilitate communications with institutions that have an assurance. Second, ORI revised the list of activity codes that do not constitute research under the misconduct regulation. Third, ORI collaborated with NIH in developing an electronic bar to making awards to institutions without an active assurance. ORI also continued to send cutoff letters to institutions that failed to establish an assurance.

As of December 31, 1997, there were 3,674 active assurances on file in ORI, including 168 from 30 foreign coun-

tries. During 1997, 415 institutions filed their initial assurance. **ORI deleted 272 institutions because their assurance was inactivated**. Seventy-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 201 assurances because the institutions did not submit their Annual Report on Possible Research Misconduct, did not submit a copy of their 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.

All of these changes had little impact on the total assurance database in 1997. (See table C.) The total number of institutions with an assurance increased by 159. Categorically, institutions of higher education increased by 5, research organizations, institutes, foundations and laboratories decreased by 2, independent hospitals decreased by 22, educational organizations other than higher education decreased by 1, the small business category increased by 174, and unclassified increased by 5. The largest gain was in the small business category; the largest loss was in the independent hospitals category.

Table C: Type of Institution with Active Assurance by Frequency, December 31, 1997

Type of Institution	*Frequency*
Institutions of Higher Education	881
Research Organizations, Institutes, Foundations and Laboratories	321
Independent Hospitals	291
Educational Organizations Other Than Higher Education	23
Other Health, Human Resources, and Environmental Services Organizations	389
Other (small business)	1,757
Unclassified	12
TOTAL	3,674

E-Mail Network

A request for the e-mail address of the signing official was added to the 1997 Annual Report on Possible Research Misconduct as the initial step in establishing an electronic network that will facilitate communications with institutions that have an assurance. An electronic network will permit ORI to efficiently and rapidly inform all institutions or various subsets of institutions about assurance program requirements and other ORI activities. For example, the E-mail network could be used to request misconduct policies from all institutions that indicated they did not have such a policy on the Annual Report form. Notifications of new publications, guidelines, conferences and workshops could also be easily communicated.

Revised Activity Code List

The Federal regulation only covers PHS funding for research, research training, cooperative agreements and related research activities. Support for numerous other activities does not come under the regulation—conference grants, demonstration projects, clinical training. In 1997, ORI revised the "List of Activity Codes Not Supporting Research" originally developed in 1990. The activity code is a three-digit designation (R01, P01, T32) that identifies the type of project being supported. The original activity code list was reviewed by Agency Research Integrity Liaison Officers at all PHS agencies to determine which activity codes did or did not support research. ORI revised the list to ensure that assurances were requested only from institutions that received support under activity codes defined as research. The revised "List of Activity Codes Not Supporting Research" was adopted on October 10, 1997.

Bar on NIH awards

The initial step taken to prevent awards to institutions without an assurance was a message that appeared on the computer screen informing the grant officer to contact ORI before proceeding with an award, but further processing of the award was not blocked. An audit of NIH awards made from October 1995 to March 1997 indicated that 56 awards had been made to 36 institutions without an assurance. Consequently, ORI requested that NIH institute an electronic bar to awards to institutions without an assurance. A policy statement was drafted by the NIH Grants Policy Office and subsequently approved by the NIH Grants Management Advisory Committee on November 19, 1997. When the bar is implemented in 1998, a message will appear on the computer screen informing the grants officer that an award cannot be made to the institution until the institution complies with the Federal regulation related to scientific misconduct. The bar will prevent the release of funds to the institution until the ORI assurance database indicates that the institution has an assurance.

Cutoff Letters

Besides preventing awards to ineligible institutions, the assurance program must also contend with institutions that fail to establish or maintain an assurance after re-

ceiving funding. In 1996, ORI in collaboration with NIH adopted a new procedure for securing compliance from such institutions. These institutions are notified by letter that ORI will recommend that NIH suspend current support and withhold all future support to them if they fail to comply with the regulation 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 40 institutions in 1997; 28 institutions have subsequently complied; suspension of funding may be required against 12 institutions. ORI takes this compliance action after institutions have failed to respond to two requests for the required material.

Audit of Grant Awards

To further ensure that PHS research funds are awarded only to eligible institutions, ORI periodically audits two PHS systems that are used to record and track grant information, the Information for Management, Planning, Analysis and Coordination System (IMPAC) and the Grants Management Information System (GMIS). The IMPAC system is mainly used by NIH. All grant applications are entered directly into the IMPAC system when received. There is a check in the system against the assurance database. During the processing of a grant to an ineligible institution, the grant processor sees a flag in the system and the assurance program receives an e-mail message, noting that the grantee organization does not have a valid misconduct in science assurance.

The GMIS system contains information about grants that have been awarded by PHS agencies. All eight PHS agencies may have grants included in the GMIS, but it is mostly non-NIH funding that is listed. The information in GMIS comes from many different sources (the various PHS agencies that use different computer systems) and is not uploaded until a grant has been funded. At that time, it is too late to put a hold on the grant, since it has already been released. The check for active misconduct in science assurances can only be done retroactively.

a) IMPAC Awards

In 1997, an audit of the IMPAC system indicated that awards were made to 30 ineligible institutions. ORI requested an initial assurance from these institutions and notified the appropriate grants management staff in the PHS agencies about the problem. As of December 31, 1997, all 30 institutions were in compliance.

b) GMIS Awards

A preliminary analysis of fiscal year 1996 GMIS grants showed that 155 research grants totaling over $43 million were awarded to 117 institutions that did not have an assurance. A list of grants for each PHS agency was sent to the respective ARILO, asking for comments and clarification. Responses were received from all PHS agencies. Only CDC and FDA defined some of their grants as research. The other PHS agencies stated that the activity codes involved do not support research. After this review, 33 grants to 26 institutions totaling $11.2 million remained. Four codes were added to the "List of Activity Codes Not Supporting Research" and the institutions were brought into compliance.

Annual Reports on Possible Research Misconduct

To keep its assurance active, each institution must submit to ORI an Annual Report on Possible Research Misconduct (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 1996 Annual Report forms were mailed in January 1997 to the 3,310 institutions that had an assurance on file with ORI as of December 1, 1996.

Completed Annual Reports were received from 2,937 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 1996 report identified 282 institutions whose assurance was inactive and 179 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 638 institutions (21%). Institutions named 478 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 D.

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

Institutional Policy Reviews

ORI processed 612 institutional policies during 1997. Five hundred and two policies were requested in 1997; the other 110 policies were forwarded from 1996. In 1997, institutional policies were requested for the ORI annual review of a 5 percent sample of institutional policies, as followup activities to the 1996 Annual Report of Possible Research Misconduct, and the parent/affiliate institutions study (see below). ORI closed 338 reviews in 1997; 274 remain open. The closed reviews included 290 accepted policies and 48 inactivated assurances because policies were not submitted. Seventy-one percent of the accepted policies did not require revision. Two hundred and sixty-five of the 274 open reviews require institutional action before further progress can be made. Seventy-four percent of the policies under review require revision.

Policy Review Database

A database, GenRev, was established in 1997 to consolidate information on the numerous reviews conducted by the assurance and compliance programs. The database contains relevant information on the reviews, such at the initial outcome of the review, the number of revisions required, and the policy approval date. As of January 8, 1998, GenRev contained information on 1,006 policy reviews conducted by ORI primarily since 1995. Seven hundred and fifty-three reviews are completed; 253 are open.

Parent/Affiliate Study

Each institution that applies for or receives PHS research support is required to establish an administrative policy for responding to allegations of scientific misconduct that complies with the Federal regulation. However, 266 institutions are involved in a parent/affiliate relationship in which the parent policy is supposed to cover the affiliates. This population includes 80 parent institutions and 186 affiliates. ORI requested policies from the parent institutions to answer two questions: (1) Does the parent policy comply with the regulation? (2) Does the parent policy provide an administrative process that is applicable to the affiliate institutions? Seventy-eight policies have been reviewed for compliance with the regulation; 24 complied, 54 did not. The remaining two institutions will have their assurance inactivated if they fail to submit their policy.

In 1998, the policies will be analyzed to determine whether the administrative process described is applicable to the affiliates. A report will be sent to each unit of analysis—a parent and its affiliates—indicating whether the parent policy meets the regulatory requirements and is applicable to all affiliates. If not, the report will explain the regulatory provisions that are not adequately reflected and list needed changes. In addition, each affiliate will have to indicate that it has adopted the parent policy.

Compliance Cases

In 1997, the ORI compliance caseload was reduced to 1 by closing 11 cases and opening 2. One case was carried into 1998. (See table D.) Compliance cases involve compliance reviews of institutional handling of an allegation of scientific misconduct and/or retaliation complaints from whistleblowers.

A 12-month standard for completing compliance reviews and retaliation complaints was adopted in 1997. The average time for completing six compliance reviews was 16.3 months, primarily because of a complex case opened in late 1995 and closed in 1997. Cases initiated in 1996 or 1997 and completed in 1997 took 8.5 months from receipt of case to completion. Compliance reviews initiated and completed in 1997 took 6 months. The five retaliation cases closed in 1997 took an average of 23.6 months to complete. Two cases were originally opened in 1994 and required extensive interaction between institutional officials and ORI to close. A case opened in 1995 took 18 months while two retaliation cases opened in 1996 were closed in 14 and 10 months respectively. Summaries of closed compliance reviews and retaliation cases may be found in Appendix F.

Table D: Summary of Compliance Cases, 1997

Type of Case	*Forwarded from 1996*	*Opened in 1997*	*Closed in 1997*	*Carried to 1998*
Retaliation Complaints	4	0	3	1
Complaints/Reviews	4	1	5	0
Compliance Reviews	2	1	3	0
TOTAL	10	2	11	1

Study of Inquiry Reports

A study of inquiry reports not submitted to ORI was undertaken in 1997 to determine whether (1) the inquiries reported by institutions on the Annual Report on Possible Research Misconduct came under ORI jurisdiction, (2) the inquiry reports contained sufficient information to decide whether an investigation was warranted, (3) the inquiries were conducted in compliance with the PHS regulation, and (4) more technical assistance should be provided on the conduct of inquiries. Twenty-one reports submitted by 16 institutions were analyzed. A draft report was completed in 1997; the final report will be completed in 1998.

Implementation of Administrative Actions

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, 1997, the names of 194 individuals were in the system. ORI had listed 69 names and the FDA had listed 125 names. During the year, ORI added 12 names and removed 14 while 23 names were added to the FDA system. On December 31, 1997, the names of 215 individuals were in the system, 67 listed by ORI and 148 listed by FDA.

ORI added 12 names because 9 respondents agreed to a voluntary exclusion agreement, and 3 were found to have committed scientific misconduct in institutional reports to ORI. Fourteen names were removed during the year, 11 because the term of the administrative actions expired, 2 because ORI did not concur with the institutional findings of misconduct, and 1 because an institution reversed its scientific misconduct finding on appeal.

Of the 67 names in the system at year end, 63 individuals have had administrative actions imposed by ORI, and 4 remain as a result of an institutional report in which there was a finding of scientific misconduct.

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

The 148 names listed by FDA on December 31, 1997, were due to 47 FDA debarments, 75 disqualifications and 26 restrictions on the use of investigational products.

In 1997, the FDA began to publish on the Internet a Debarment list as well as a Disqualified/ Restriction/Assurance list for clinical investigators sanctioned by the FDA. Because of the overlap in the FDA lists and the PHS Administrative Actions Bulletin Board (AABB), which is also available on the internet, the PHS AABB carried the FDA information only until the end of 1997. Thereafter, only information regarding individuals sanctioned by ORI will be listed on the AABB, and information regarding FDA sanctions can be viewed separately on the FDA internet sites.

III. EDUCATION AND OUTREACH

ORI educational and outreach activities continued to expand in 1997. Two new publications were produced and development began on three others. Five workshops were held; planning began for three more, and additional proposals were solicited. An effort was launched to make the ORI home page more informative, attractive, and user-friendly. A preliminary analysis of institutional research integrity policies, statements and guidelines was begun to develop material for a campaign to promote research integrity. In addition, ORI staff made 46 presentations and published two articles. Fifteen notices were published in the *Federal Register*.

Publication Program

The new publications added to the ORI publication portfolio were the *ORI Handbook for Institutional Research Integrity Officers*, the *ORI Annual Report - 1996* and the *Report on the 1996 Annual Report on Possible Research Misconduct.* Preparation of the *ORI Handbook* began in 1995. It was submitted for review to 51 institutions and organizations in 1996. In 1997, the handbook was revised and sent to about 2,000 institutions, professional associations, PHS research integrity officers and other interested persons. The *ORI Annual Report - 1996* is the fourth report produced by ORI on it activities. The *Report on the 1996 Annual Report* is the second publication in this series that details the methodology and results of this mandated annual survey of institutions that have an assurance. Detailed descriptions of these reports may be found in Appendices D and G.

Publications under development in 1997 were *Guidelines for Responsible Whistleblowing*, *Guidance for Journal Editors*, and *Guidelines for Institutions Investigating Allegations of Possible Misconduct in Clinical Research*. The whistleblowing guidelines provide information on the criteria that PHS uses for pursuing scientific misconduct cases, the development and reporting of allegations, the whistleblower's role in inquiries and investigations, protection against alleged retaliation, and other matters. A draft of the whistleblowing publication was completed in 1997 and submitted for Departmental review. The guidance for editors suggests procedures for a collaborative effort between journal editors and ORI in addressing alleged scientific misconduct in manuscripts submitted or published in journals and the promotion of research integrity. A draft of the guidance for editors will be submitted for review by editors and the Department in 1998. The guidance for clinical research includes cases involving multicenter clinical trials, and outlines the special requirements for investigations involving patient records, the multiple sources of information available

in these cases, and other Federal entities that may need to be informed and involved in the investigation. The clinical case guidelines will be submitted for Departmental review in 1998.

ORI received 900 requests for its publications and other resource materials in 1997, compared to 1,275 in 1996. See Appendix H for a complete list of available resource material. The list also is posted on the ORI home page at http://ori.dhhs.gov.

Workshop Program

ORI reactivated and restructured its workshop program in 1997. Five workshops were held; three extramural and two intramural. The program solicited institutional co-sponsors for the first time and added the promotion of research integrity and the prevention of scientific misconduct to the previous program goals—facilitating the handling of allegations of scientific misconduct and compliance with the regulation.

In the December 1997 issue of its newsletter, ORI solicited proposals from institutions, professional associations, and scientific societies that wish to collaborate with ORI in developing a conference or workshop that addresses either handling scientific misconduct allegations or the promotion of research integrity.

Extramural Workshops

ORI conducted three extramural workshops in 1997. These are discussed in the "Highlights" section beginning on page one.

ORI and University of Florida Workshop

The ORI and the University of Florida co-sponsored a workshop on research integrity issues on April 15, 1997, in Gainesville. This was the first workshop that ORI has done jointly with an institution. Staff from the University of Florida and ORI each presented three sessions and two other sessions were jointly presented. Fifty-five representatives of fourteen public and private institutions in Florida and Georgia attended. ORI also made a presentation on research integrity to about 35 graduate students on April 14.

Tuskegee Introductory Workshop

ORI and Tuskegee University jointly sponsored an introductory workshop for institutional misconduct officials on November 13, 1997, at the Alabama institution. Besides Tuskegee University staff, the 47 attendees represented institutions and organizations in Alabama, Georgia, Mississippi, Arizona, New Jersey and Virginia.

ORI staff made presentations on the evolving approaches to scientific misconduct and research integrity, the maintenance of institutional eligibility for funding, the conduct of inquiries and investigations, Federal oversight of investigations, the protection of respondents and whistleblowers, the implementation of administrative actions, and the disclosure of case information. Tuskegee staff served as moderators of open discussion sessions and as panelists. Additionally, attendees from three institutions served as panelists.

Introductory Workshop for Institutional Research Integrity Officers

Seventy-six representatives from public and private institutions, research institutes, State governments, professional associations, and PHS agencies attended the ORI's first introductory workshop for institutional officials held at the Natcher Center on the NIH campus on June 6, 1997. The workshop reviewed the general responsibilities of institutional misconduct officials and highlighted the specific requirements that institutions need to fulfill in investigating allegations of misconduct involving research supported by PHS funds. Three discussion sessions scheduled throughout the day permitted participants and ORI staff to share their views on research integrity issues. The highly favorable evaluations indicated that ORI should offer these workshops at various locations around the country.

PHS Workshops

Update Workshop for PHS Research Integrity Officers

ORI held its annual update workshop on January 14, 1997, to inform more than 30 PHS agency representatives about the latest developments related to scientific misconduct. Among the topics addressed by ORI staff were the accomplishments of ORI since 1992, management of the caseload, protection of good faith whistleblowers, compliance activities, the Freedom of Information Act, and the Privacy Act.

Refresher Workshop for NIH Extramural Program Staff

More than 70 NIH extramural program staff attended a continuing education course on "Scientific Misconduct: Who Does What?" on July 28, 1997. ORI speakers briefed participants on the office's current caseload,

oversight activities, and educational programs. Participants also heard the latest developments in the lawsuit concerning institutional immunity in misconduct cases.

Other subjects discussed in the half-day session included the role of NIH extramural staff in reporting allegations and implementing administrative actions, and how NIH staff will be notified about the resolution of cases. ORI staff also reviewed the compliance requirements for extramural institutions and reiterated the need for confidentiality in misconduct cases.

ORI Home Page

A major redevelopment effort was initiated in 1997 to make the ORI home page more informative, attractive, and user-friendly. A development committee held its first meeting in December to outline the task. The new home page is expected to be completed in 1998. Created in 1995, the ORI home page continues to be a quick, effective, and inexpensive method for disseminating ORI resource materials, especially the ORI Model Policy. Besides newsletter issues and ORI annual reports, the new publications noted above were uploaded. In early 1998, the ORI home page address was shortened to **http://ori.dhhs.gov**.

Presentations

Barbara Bullman, Policy Analyst, DPE, participated in two sessions of the Update Workshop for PHS Research Integrity Officers held at NIH on January 14, 1997. She spoke about protection of good faith whistleblowers and general procedures concerning the Privacy Act and FOIA.

John Butler, Compliance Review Coordinator, DPE, participated in two sessions of the Update Workshop for PHS Research Integrity Officers held at NIH on January 14, 1997. He explained ORI's compliance activities and gave case examples of institutions protecting good faith whistleblowers.

John Butler, Compliance Review Coordinator, DPE, participated in two sessions of the ORI Introductory Workshop for Institutional Misconduct Officials at NIH on June 6, 1997. He spoke about guidelines and options for responding to retaliation complaints and the PHS administrative actions bulletin board.

Marcus Christ, Chief, Research Integrity Branch, OGC, gave an update on misconduct case hearings during the Update Workshop for PHS Research Integrity Officers held at NIH on January 14, 1997.

Marcus Christ, Chief, Research Integrity Branch, OGC, participated in three sessions of the ORI Introductory Workshop for Institutional Misconduct Officials at NIH on June 6, 1997. Mr. Christ addressed legal issues related to responding to misconduct allegations, to Federal oversight and resolution of cases, and protecting complainants and respondents.

Marcus Christ, Chief, Research Integrity Branch, OGC, gave a presentation on *qui tam* suits, the Angelides case, and confidentiality issues for the ORI update for NIH Extramural Scientist Administrators on July 28, 1997.

Marcus Christ, Chief, Research Integrity Branch, OGC, discussed the legal implications of institutions investigating allegations of misconduct in light of the Federal Government's position in the Angelides litigation and institutional obligations during the Science and Technology section of the American Bar Association's Annual Meeting in San Francisco, CA on August 4, 1997.

Marcus Christ, Chief, Research Integrity Branch, OGC, gave a presentation on the DAB hearings to the NIH Committee on Scientific Conduct and Ethics on September 26, 1997.

Marcus Christ, Chief, Research Integrity Branch, OGC, participated in three panel discussions during the ORI Workshop for Institutional Misconduct Officials at Tuskegee University in Tuskegee, AL on November 13, 1997. He spoke about legal issues related to responding to allegations of misconduct, Federal oversight and resolution of cases, and avoiding problems in disclosure of case information.

Alicia Dustira, Deputy Director, DPE, spoke about educational resources available from ORI during the Update Workshop for PHS Research Integrity Officers held at NIH on January 14, 1997.

Alicia Dustira, Deputy Director, DPE, outlined the different ways that institutions need to keep their ORI assurances active at the ORI Introductory Workshop for Institutional Misconduct Officials at NIH on June 6, 1997.

Alicia Dustira, Deputy Director, DPE, served as a panel member and discussed the role of ORI in resolving ethical disputes during a workshop organized by Sigma Xi, The Scientific Research Society, as part of its Annual Meeting in Crystal City, VA on November 22, 1997.

Gail Gibbons, Attorney, OGC, spoke about legal issues related to the Privacy Act and FOIA at the Update Workshop for PHS Research Integrity Officers held at NIH on January 14, 1997.

Dorothy Macfarlane, Acting Director, DRI, provided an update on the ORI caseload and ORI's role in misconduct cases at the Update Workshop for PHS Research Integrity Officers held at NIH on January 14, 1997.

Dorothy Macfarlane, Acting Director, DRI, discussed identifying and preventing scientific misconduct at a workshop during the Winter Conference on Brain Research in Breckenridge, CO on January 27, 1997.

Dorothy Macfarlane, Acting Director, DRI, made a presentation on research integrity to about 35 graduate students at the University of Florida in Gainesville, FL on April 14, 1997.

Dorothy Macfarlane, Acting Director, DRI, participated in two sessions of the regional Research Integrity Workshop co-sponsored by the University of Florida and ORI in Gainesville, FL on April 15, 1997. She spoke about ORI processes for responding to misconduct allegations, and discussed balancing confidentiality requirements with State open records laws.

Dorothy Macfarlane, Acting Director, DRI, gave a lecture on research integrity and research misconduct in clinical trials as part of the Lombardi Cancer Center Developmental Therapeutics Lecture Series in Washington, D.C. on June 4, 1997.

Dorothy Macfarlane, Acting Director, DRI, participated in three sessions of the ORI Introductory Workshop for Institutional Misconduct Officials at NIH on June 6, 1997. Dr. Macfarlane spoke about institutional notification and reporting requirements in misconduct cases, possible PHS administrative actions, and elements of supervisory plans.

Dorothy Macfarlane, Acting Director, DRI, gave a presentation on the role of NIH staff in reporting allegations, notifications about misconduct case openings, and the resolution of cases for the ORI update for NIH Extramural Scientist Administrators on July 28, 1997.

Dorothy Macfarlane, Acting Director, DRI, gave a presentation on the evolution of the definition of misconduct, allegation assessment, and ORI case oversight to the NIH Committee on Scientific Conduct and Ethics on September 26, 1997.

Dorothy Macfarlane, Acting Director, DRI, participated in three panel discussions during the ORI Workshop for Institutional Misconduct Officials at Tuskegee University in Tuskegee, AL on November 13, 1997. She spoke about responding to allegations of misconduct, Federal oversight and resolution of misconduct cases, and administrative actions that may be imposed by PHS or an institution.

Samuel Merrill, DRI Investigator/Scientist, moderated two open discussion sessions during the ORI Workshop for Institutional Misconduct Officials at Tuskegee University in Tuskegee, AL on November 13, 1997. One session dealt with institutional experiences and perspectives on responding to allegations, and the other covered approaches and experiences in resolving cases.

Samuel Merrill, DRI Investigator/Scientist, discussed ethics in scientific and medical research at the Society for Neuroscience Annual Meeting in New Orleans, LA, on October 27, 1997.

Chris Pascal, Acting Director, provided opening remarks and made two presentations during the Update Workshop for PHS Research Integrity Officers held at NIH on January 14, 1997. He spoke about the status of various external reports on ORI and discussed handling press inquiries in light of Privacy Act and FOIA requirements.

Chris Pascal, Acting Director, gave a presentation on the definition of misconduct, institutional responsibilities, investigations, and PHS administrative actions for the NIH Extramural Scientist Administrator Seminar Series on February 27, 1997.

Chris Pascal, Acting Director, participated in three sessions of the regional Research Integrity Workshop cosponsored by the University of Florida and ORI in Gainesville, FL on April 15, 1997. Mr. Pascal gave an historical perspective and led a discussion of current approaches to responding to misconduct, reviewed whistleblower protection issues, and discussed approaches for rehabilitating exonerated respondents.

Chris Pascal, Acting Director, made a presentation on research integrity to about 35 graduate students at the University of Florida in Gainesville, FL on April 14, 1997.

Chris Pascal, Acting Director, presented an overview of institutional regulatory requirements and the Federal-institutional partnership at the ORI Introductory Workshop for Institutional Misconduct Officials at NIH on June 6, 1997.

Chris Pascal, Acting Director, gave a presentation on ORI's caseload, oversight activities, and educational efforts for the ORI update for NIH Extramural Scientist Administrators on July 28, 1997.

Chris Pascal, Acting Director, was interviewed by ZDF German television for a brief news piece about ORI functions and activities on September 15, 1997.

Chris Pascal, Acting Director, gave a presentation on approaches to misconduct and basic principles for extramural investigations to the NIH Committee on Scientific Conduct and Ethics on September 26, 1997.

Chris Pascal, Acting Director, gave a presentation on institutional compliance, misconduct cases and findings, and legal challenges for the NIH Extramural Scientist Administrator Seminar Series on November 7, 1997.

Chris Pascal, Acting Director, provided opening remarks and talked about avoiding problems in disclosure of case information during the ORI Workshop for Institutional Misconduct Officials at Tuskegee University in Tuskegee, AL on November 13, 1997.

Peter Poon, Attorney, OGC, spoke at two sessions of the ORI Introductory Workshop for Institutional Misconduct Officials at NIH on June 6, 1997. Mr. Poon talked about legal issues concerning retaliation complaints and avoiding problems in disclosing misconduct case information.

Alan Price, DRI Investigator/Scientist, gave an update on issues and types of interactions with university officials at ORI as part of a panel discussion at a practicum on responding to allegations of misconduct conducted by the Association of American Medical Colleges and the American Association for the Advancement of Science in San Diego, CA on January 28, 1997.

Alan Price, DRI Investigator/Scientist, gave a presentation on opening institutional inquiries and investigations at the ORI Introductory Workshop for Institutional Misconduct Officials at NIH on June 6, 1997.

Alan Price, DRI Investigator/Scientist, gave a presentation to a focus group on anonymity in whistleblowing for the American Association for the Advancement of Science in Washington, D.C. on June 18, 1997.

Larry Rhoades, Director, DPE, spoke about ORI's assurance program at the Update Workshop for PHS Research Integrity Officers held at NIH on January 14, 1997.

Larry Rhoades, Director, DPE, participated in two sessions of the regional Research Integrity Workshop cosponsored by the University of Florida and ORI in Gainesville, FL on April 15, 1997. He gave an historical perspective and participated in a discussion of current approaches to responding to misconduct, and discussed approaches for rehabilitating exonerated respondents.

Larry Rhoades, Director, DPE, participated in three sessions of the ORI Introductory Workshop for Institutional Misconduct Officials at NIH on June 6, 1997. Dr. Rhoades explained what a research integrity officer is, how institutions develop policies and procedures for handling misconduct allegations, and ways to protect complainants and respondents.

Larry Rhoades, Director, DPE, gave a presentation on ORI's compliance program for the ORI update for NIH Extramural Scientist Administrators on July 28, 1997.

Larry Rhoades, Director, DPE, gave a presentation on the ORI education program and protection of whistleblowers to the NIH Committee on Scientific Conduct and Ethics on September 26, 1997.

Larry Rhoades, Director, DPE, made presentations in two sessions of the ORI Workshop for Institutional Misconduct Officials at Tuskegee University in Tuskegee, AL on November 13, 1997. He spoke about maintaining funding eligibility, submitting an assurance, developing policies and procedures, submitting the ORI annual report, complying the PHS regulation, and protecting complainants and respondents. He also moderated an open discussion on institutional experiences in protecting complainants and respondents.

Mary Scheetz, Program Analyst, DPE, discussed responses and critical issues related to research integrity and scientific misconduct as part of a panel presentation at the 40th Annual Council of Biology Editors Meeting, in Philadelphia, PA on May 6, 1997.

Barbara Williams, DRI Investigator/Scientist, gave a presentation on selecting committees, compiling testimony, and recordkeeping in misconduct cases at the ORI Introductory Workshop for Institutional Misconduct Officials at NIH on June 6, 1997.

Published Articles

Dustira, Alicia K. "The Federal Role In Influencing Research Ethics Education and Standards in Science." *Professional Ethics* 5 (1&2), Spring/Summer 1996 [issued October 1997].

Scheetz, M.D. "Authorship Controversies: A Call for CBE Standards." *CBE Views 1997*; 20(4): 125-127.

Federal Register Notices

Findings of Scientific Misconduct. Notice. 62 Fed. Reg. 66372-66373 (Dec. 18, 1997). [Imam]

Findings of Scientific Misconduct. Notice. 62 Fed. Reg. 53432 (Oct. 7, 1997). [Shang]

Findings of Scientific Misconduct. Notice. 62 Fed. Reg. 49014-49015 (Sept. 18, 1997). [Leonhard]

Findings of Scientific Misconduct. Notice. 62 Fed. Reg. 44280-44281 (Aug. 20, 1997). [Jiao]

Findings of Scientific Misconduct. Notice. 62 Fed. Reg. 44281-44282 (Aug. 20, 1997). [London]

Findings of Scientific Misconduct. Notice. 62 Fed Reg. 42558 (Aug. 7, 1997). [Shaprio]

Findings of Scientific Misconduct. Notice. 62 Fed. Reg. 37921-37922 (July 15, 1997). [Hajra]

Findings of Scientific Misconduct. Notice. 62 Fed. Reg. 32616 (June 16, 1997). [Fugang Li]

Findings of Scientific Misconduct. Correction. 62 Fed. Reg. 26515-26516 (May 14, 1997). [Sun]

Findings of Scientific Misconduct. Notice. 62 Fed. Reg. 23779 (May 1, 1997). [McCown]

Findings of Scientific Misconduct. Notice. 62 Fed. Reg. 23246 (April 29, 1997). [Huelskamp]

Findings of Scientific Misconduct. Notice. 62 Fed. Reg. 22950 (April 28, 1997). [Sun]

Findings of Scientific Misconduct. Notice. 62 Fed. Reg. 18631-18632 (April 16, 1997). [Misra]

Findings of Scientific Misconduct. Notice. 62 Fed. Reg. 15712-15713 (April 7, 1997). [Portuese]

Findings of Scientific Misconduct. Notice. 62 Fed. Reg. 7787 (Feb. 20, 1997). [Boone]

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, 5600 Fishers Lane, 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.

There were 90 FOIA requests received in 1997 and 24 were forwarded from 1996. This is an increase from 79 in 1996. Responses to 84 requests were completed and 14 were carried into 1998. The number of requests represents a 14 percent increase over 1996 and is the second highest number since 1994.

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, at 5515 Security Lane, Suite 700, Rockville, MD 20852. 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.

Twelve requests for information were received under the Privacy Act in 1997. All requests received responses. This represents a drop of 37% from the 19 requests received in 1996.

This section presents a descriptive analysis of the 29 investigations closed during 1997 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

Twenty-eight of the twenty-nine investigations closed in 1997 involved PHS extramural research programs. The research involved in the investigations was supported by 19 NIH institutes. Fourteen investigations (48 percent) resulted in a misconduct finding; 15 investigations (52 percent) did not.

Table 1: Investigation Outcome by Type of PHS Research Program, 1997

PHS Research Program Type	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
Extramural	14	13	1	28
Intramural	0	1	0	1
TOTAL	14	14	1	29

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." Ninety-three percent of the investigations closed were conducted exclusively by institutions. One extramural investigation was conducted by ORI at the request of the institution, and the other ORI investigation was intramural.

Table 2: Investigation Outcome by Performer of Investigation, 1997

Performer	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
Institutional	14	12	1	27
ORI	0	2	0	2
TOTAL	14	14	1	29

Institutional Setting

Sixty-nine percent of the investigations were conducted at medical schools. The 29 investigations were conducted by 31 institutions. Within institutions, the investigations involved such departments as anatomy, biology, biostructure and function, chemistry, dentistry, dermatology, epidemiology, gene therapy, molecular biology, obstetrics and gynecology, oncology, pathology, pediatrics, psychiatry, psychology, public opinion laboratory, surgery, and veterinary medicine.

Table 3: Investigation Outcome by Institutional Setting, 1997

Institutional Setting	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
Medical School	6	12	0	18
Hospital	1	0	0	1
Research Institute	3	0	0	3
Intramural	0	1	0	1
Other	4	1	1	6
TOTAL	14	14	1	29

Funding Mechanisms

The 13 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 (R01) was the dominant mechanism. However, the mechanisms also include program projects (P01), center core grants (P30), specialized centers (P50), small business innovation research grants (R44), cooperative agreements (U01), 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), research scientist development awards (K02), clinical investigator awards (K08), and first independent research support and transition (FIRST) awards (R29). The investigations were also concerned with research and development contracts (N01). A single mechanism was involved in 16 investigations; 2 mechanisms in 7 investigations, and 3 mechanisms in 5 investigations.

Table 4: Investigation Outcome by Funding Mechanism, 1997

Funding Mechanism	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
RO1	10	11	1	22
R29	2	0	0	2
R44	1	0	0	1
PO1	2	3	0	5
P30	1	0	0	1
P50	1	1	0	2
F32	0	1	0	1
KO2	1	0	0	1
KO8	1	0	0	1
T32	3	1	0	4
UO1	0	1	0	1
U10	0	3	0	3
N01	0	2	0	2
TOTAL	22	23	1	46

Type of Allegation

Allegations of falsification and/or fabrication accounted for 89 percent of the investigations closed and 93 percent of the misconduct findings in 1997. Falsification either alone or in combination with fabrication or plagiarism provided the basis for 22 investigations (76 percent) and 10 misconduct findings (71 percent). Fabrication alone or in combination with falsification or plagiarism accounted for 13 investigations (45 percent) and 8 misconduct findings (57 percent). Plagiarism alone or in combination with falsification or fabrication accounted for five investigations (17 percent) and two misconduct findings (14 percent).

Table 5: Investigation Outcome by Type of Allegation, 1997

Allegation	*Misconduct*	*No Misconduct*	*Admin.Closure*	*Total*
Fabrication	3	1	0	4
Falsification	4	7	1	12
Plagiarism	1	2	0	3
Fabrication/ Falsification	5	3	0	8
Falsification/ Plagiarism	1	0	0	1
Fabrication/ Falsification Plagiarism	0	1	0	1
TOTAL	14	14	1	29

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 29 closed investigations. In the investigations that resulted in misconduct findings, institutions reported sanctions against seven of the eight respondents. Three respondents had their employment terminated, one was subject to monitoring, one was suspended without pay, one was dismissed from medical school and one was required to participate in a bioethics program.

Institutions reported taking actions against seven respondents who were not found to have committed scientific misconduct under the PHS definition. Institutional investigations may include charges unrelated to the PHS definition of misconduct. Also, under their plenary authority, institutions may adopt broader or narrower definitions of scientific misconduct for use internally and may impose administrative actions pursuant to findings made under those definitions. These actions included a letter of reprimand, monitoring of research, retraction or correction of an article, and termination of employment.

Table 6: Investigation Outcome by Institutional Action, 1997

Institutional Action	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
Letter of Reprimand/ Censure	0	1	0	1
Monitoring of Research	1	1	0	2
Retraction/Correction of Article	0	1	0	1
Individual Counseled	0	1	0	1
Suspension With or Without Pay	1	0	0	1
Terminated Employment	3	1	1	5
Grant Withdrawn	0	1	0	1
Dismissed from Medical School	1	0	0	1
Participates in Bioethics Program	1	0	0	1
TOTAL	7	6	1	14

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 32 administrative actions against respondents in the 14 misconduct cases. Eight respondents were debarred from receiving Federal grants, contracts, and cooperative agreements for periods ranging from 3 to 5 years. Five were debarred for 3 years; one for 4 years; and one for 5 years. Thirteen respondents were prohibited from serving on PHS advisory committees, boards, or peer review groups for periods ranging from 3 to 5 years. One respondent was prohibited for 2 years, nine for 3 years; two for 4 years, and one for 5 years. Institutions employing two 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 3 years. Institutions employing two respondents were required to submit certification to the funding agency and ORI for a period of 3 years that the data submitted by the respondent in grant applications existed and was accurately represented. An institutional official must endorse the respondent's certification and forward the endorsed certification to the funding agency and the ORI. Two respondents were required to retract an article.

Table 7: Frequency of Type of Government Action, 1997

Government Action	*Frequency*
Debarment	8
Prohibition from Advisory Committees	13
Supervision of Duties	5
Certification of Data	2
Certification of Contributors	2
Retraction/Correction	2
TOTAL	32

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. Eighty-six percent of the misconduct findings were against junior personnel. The most frequent targets of allegations were professors (11), postdoctoral fellows (6), and assistant professors (4). Allegations were most frequently supported against postdoctoral fellows (67 percent). Allegations were least often supported against professors (9 percent).

Table 8: Investigation Outcome by Academic Rank of Respondent, 1997

Respondents' Academic Rank	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
Professor	1	10	0	11
Associate Professor	1	1	0	2
Assistant Professor	2	2	0	4
Postdoctoral Fellow	4	1	1	6
Student	2	0	0	2
Research Assistant/Assoc.	2	1	0	3
None	2	2	0	4
TOTAL	14	17	1	32*

*Note: One case had two respondents and one case had three respondents.

Academic Degree of Respondents

Eighty-one percent of the respondents held doctorates; 50 percent held a Ph.D. degree; 31 percent held an M.D. degree; and 16 percent held either a B.A. or M.A. degree. Forty-three percent of the individuals found guilty of scientific misconduct held a Ph.D. degree. Allegations were most frequently supported against respondents with masters degrees (100 percent).

Table 9: Investigation Outcome by Highest Degree of Respondent, 1997

Respondents' Highest Degree	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
Ph.D.	7	9	0	16
M.D.	3	7	0	10
M.A.	2	0	0	2
B.A.	2	0	1	3
Unknown	0	1	0	1
TOTAL	14	17	1	32*

* Note: One case had two respondents and one case had three respondents.

Gender of Respondent

Seventy-two percent of the allegations were made against males and more allegations were supported against males (48%) than females (33%).

Table 10: Investigation Outcome by Gender of Respondent, 1997

Gender	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
Male	11	12	0	23
Female	3	5	1	9
TOTAL	14	17	1	32*

* Note: One case 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 1997 closed investigations covered a broad range. The most frequent relationship was colleague (12), followed by principal investigator (4).

Table 11: Investigation Outcome by Relationship of Complainant to Respondent, 1997

Position of Complainant	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
Lab Chief, Research Director, Dept. Chair, P.I., Supervisor, Employer, or Mentor	10	1	112	
Colleague	4	8	0	12
Employee, Lab Tech, Postdoctoral Student, or Student	1	3	0	4
Reviewer of Grant Application	1	0	0	1
No Relationship	0	1	0	1
Unknown	0	3	0	3
TOTAL	16	16	1	33*

*Note: One case had two respondents and one case had three respondents. Three cases had two complainants.

Academic Rank of Complainants

Senior personnel (professor, associate professor) appear to make allegations more often than junior personnel, accounting for 57 percent of the complainants. Twenty-seven percent of the complainants were unknown or anonymous.

Table 12: Investigation Outcome by Academic Rank of Complainant, 1997

Complainants' Academic Rank	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
Professor	6	6	1	13
Associate Professor	4	2	0	6
Assistant Professor	1	2	0	3
Postdoctoral Fellow	1	1	0	2
Unknown or anonymous	4	5	0	9
TOTAL	16	16	1	33*

*Note: Three cases had two complainants.

Academic Degree of Complainants

Eighty-five percent of the complainants held either an M.D. or Ph.D. degree.

Table 13: Investigation Outcome by Highest Degree of Complainant, 1997

Complainant's Degree	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
Ph.D.	11	5	1	17
M.D.	5	6	0	11
No Degree	0	1	0	1
Unknown	0	4	0	4
TOTAL	16	16	1	33*

*Note: Three cases had two complainants.

Complainants' Gender

More complainants were male (79%) than female.

Table 14: Investigation Outcome by Gender of Complainant, 1997

Gender	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
Male	14	11	1	26
Female	2	1	0	3
Unknown	0	4	0	4
TOTAL	16	16	1	33*

*Note: Three cases had two 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 15, the length of the inquiry 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, 15 inquiries (52 percent) were completed within the required 60-day period. The shortest took 3 days, the longest 397 days.

Table 15: Investigation Outcome by Length of Inquiry, 1997

Inquiry Length	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
Fewer than 30 days	4	4	0	8
30-60 days	4	2	1	7
61-90 days	1	1	0	2
91-120 days	2	2	0	4
121-150 days	1	1	1	3
More than 150 days	2	2	1	5
TOTAL	14	12	3	29

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 16, 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. Eleven investigations (37 percent) were completed within 120 days. The shortest investigation took 5 days and the longest investigation took 898 days.

Table 16: Investigation Outcome by Length of Investigation, 1997

Investigation Length	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
120 days or fewer	8	3	0	11
121-180 days	3	4	0	7
181-240 days	1	0	1	2
241-300 days	1	3	0	4
More than 300 days	1	4	0	5
TOTAL	14	14	1	29

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 eight members to provide this expertise. The modal size was one.

Table 17: Investigation Outcome by Size of Inquiry Panel, 1997

Number of Panel Members	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
One	7	3	1	11
Two	3	2	0	5
Three	3	4	0	7
Four	0	3	0	3
Six	1	1	0	2
Eight	0	1	0	1
TOTAL	14	14	1	29

Size of Investigation Panels

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

Table 18: Investigation Outcome by Size of Investigation Panel, 1997

Number of Panel Members	*Misconduct*	*No Misconduct*	*Admin. Closure*	*Total*
One	4	1	1	6
Two	2	1	0	3
Three	4	5	0	9
Four	1	3	0	4
Five	1	3	0	4
Six	0	1	0	1
Seven	2	0	0	2
TOTAL	14	14	1	29

Fabrication

Christopher Leonhard, Dartmouth College (DC): Based upon an investigation conducted by DC, information obtained by ORI during its oversight review, and his own admission, ORI found that Mr. Leonhard, a former graduate student in the Department of Psychology, DC, engaged in scientific misconduct in biomedical research supported by two grants from the National Institute of Mental Health. Specifically, Mr. Leonhard fabricated experimental records and falsely represented them to his supervisor as being results obtained from multiple electrophysiological screening sessions conducted on eight animals, and fabricated two surgical records as evidence of experimental preparations (implantation of indwelling electrodes) on two animals, which in fact had not been done.

Mr. Leonhard accepted the ORI finding and entered into a Voluntary Exclusion Agreement with ORI in which he voluntarily agreed, for the 3-year period beginning September 8, 1997, 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 or that submits a report of PHS-funded research in which he is involved, must concurrently submit a plan for supervision of his duties. The experimental records did not appear in any publications.

Enrico Portuese, University of Pittsburgh (UP): Based upon an investigation conducted by UP, information obtained by the ORI during its oversight review, and Mr. Portuese's own admission, ORI found that Mr. Portuese, a former graduate student in the Department of Epidemiology, Graduate School of Public Health, UP, engaged in scientific misconduct by fabricating research data in biomedical research supported by two grants from the National Institute of Diabetes and Digestive and Kidney Diseases. Specifically, Mr. Portuese fabricated data in a study of angiotensin-converting enzyme polymorphism and complications from insulin-dependent diabetes mellitus. In addition, he fabricated genetic data on lipoprotein lipase polymorphisms as related to diabetes complications and risk factors. These fabricated data were included in tables prepared by Mr. Portuese and presented by him to his doctoral committee in October 1996.

Mr. Portuese accepted the ORI finding and entered into a Voluntary Exclusion Agreement with ORI in which he voluntarily agreed, for the 3-year period beginning March 25, 1997, 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 to ORI for supervision of his duties. None of the fabricated data in question has been published, presented at a scientific meeting, or used in any grant applications.

Xiaomin Shang, Ph.D., University of Texas Southwestern Medical Center (UTSMC): Based upon a report from the UTSMC, information obtained by ORI during its oversight review, and his own admission, ORI found that Dr. Shang, a former postdoctoral fellow student in the Department of Obstetrics and Gynecology, UTSMC, engaged in scientific misconduct arising out of certain biomedical research supported by a training grant from the National Institute of Child Health and Human Development (NICHD). Specifically, Dr. Shang fabricated a chemiluminescent film of a Western blot by using a physical mask to alter the prior results showing lack of antibody specificity to a human steroid metabolizing isozyme, rather than replicating an experiment as requested by his mentor.

Dr. Shang accepted the ORI finding and entered into a Voluntary Exclusion Agreement with ORI in which he voluntarily agreed, for the 3-year period beginning September 29, 1997, 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 or that submits a report of PHS-funded research in which he is involved must concurrently submit a plan for supervision of his duties. The fabricated data were not published.

Falsification

Shoushu Jiao, M.D., University of Wisconsin (UW): Based upon reports from UW, as well as information obtained by ORI during its oversight review, ORI found that Dr. Jiao, former Research Associate, Department of Pediatrics, UW, engaged in scientific misconduct by falsifying and creating laboratory records while conducting biomedical research. The data in these records were reported in a National Institute of Neurological Disorders and Stroke (NINDS) grant application to support a request for PHS funding. Based on the factual findings in the reports, the following article has been retracted: Jiao, S., Gurevich, V., & Wolff, J.A. "Long-term correction of rat model of Parkinson's disease by gene therapy." *Nature* 362:450-453, 1993.

Dr. Jiao entered into a Voluntary Exclusion Agreement with ORI in which he voluntarily agreed, beginning August 8, 1997, (1) to exclude himself from any Federal grants, contracts or cooperative agreements for 3 years, (2) to exclude himself from serving in any advisory capacity to the PHS for 4 years, and (3) that any institution that submits an application for PHS support for a research project on which Dr. Jiao'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 to the funding agency for 1 year following the 3-year exclusion.

Jill A. London, Ph.D., University of Connecticut Health Center (UCHC): Based upon a report from the UCHC, as well as information obtained by ORI during its oversight review, ORI found that Dr. London, former Assistant Professor, Department of Biostructure and Function, School of Dental Medicine, UCHC, engaged in scientific misconduct by intentionally falsifying data in conjunction with applying for and reporting research supported by the National Institute of Neurological Disorders and Stroke (NINDS) and the National Institute on Deafness and Other Communication Disorders (NIDCD).

Specifically, ORI found that Dr. London's grant applications and articles contained numerous falsifications:

(1) Figures 6, 7, and 8 in a paper (London, J.A. & Cohen, L.B. "High time resolution, multi-site optical measurement of vertebrate somatosensory cortex during epileptiform discharges and vertebrate gustatory cortex." *Optical Methods in Neurobiology*, pp. 61-78, 1988.) prepared for the 11th Annual Meeting of the European Neuroscience Association (hereafter referred to as the European Neuroscience paper) that cited support by NINDS, NIH grants R01 NS08437 and P01 NS16993;

(2) Figure 1A in a paper (London, J.A., "Optical recording of activity in the hamster gustatory cortex elicited by electrical stimulation of the tongue." *Chemical Senses* 15:137-143, 1990.) that cited support by NINDS, NIH grants R01 NS08437 and P01 NS16993; Figure 1A was found to be very similar or identical to Figure 7 of the European Neuroscience paper in #1 above;

(3) Figures 10 to 13 in grant application 2 P50 DC00168-14, "Connecticut Chemosensory Clinical Research Center," submitted to NIDCD, NIH on January 28, 1994; these figures also appear as Figures 4 to 7 in grant application 2 P50 DC00168-14A1, submitted to NIDCD, NIH on September 28, 1994;

(4) Figures 2, 8, and 9 in grant application 1 R01 DC01752-01, "Optical recording of hamster gustatory cor-

tex activity," submitted to NIDCD, NIH on January 29, 1992; these figures were the same as Figures 11, 12, and 13, respectively, in grant application 2 P50 DC00168-14 (see #3 above);

(5) Figures supplied for Figures 1 and 3 in grant application 1 F32 NS09601-01, "Modular response patterns in hamster gustatory cortex," submitted to NINDS, NIH on August 3, 1993; these figures were the same as Figures 10 and 11, respectively, in grant application 2 P50 DC00168-14 (see #3 above);

(6) Figure 3 of a handout that Dr. London provided during an NIH site visit on April 25, 1994, conducted in conjunction with the review of grant application 2 P50 DC00168-14; the top and bottom portions of Figure 3 of the site visit handout were very similar or identical to Figures 6 and 7, respectively, of the European Neuroscience paper (see #1 above), and approximately 115 of the 125 traces appearing in each of the figures showed identities, with one or two "active" traces being identical;

(7) Figures 1, 2, and 3 in a paper (London, J.A. & Wehby, R.G. "Classification of inhibitory responses of hamster gustatory cortex." *Brain Research* 666:270-274, 1994.) that cited support by NIDCD, NIH grants P50 DC00168 and T32 DC00025; and

(8) Nine figures included in a manuscript (London, J.A. & Wehby, R.G. "Excitatory neural responses in the hamster gustatory cortex." Submitted to *Brain Research*, 1996.) that cited support by NIDCD, NIH grants P50 DC00168 and T32 DC00025.

Dr. London accepted the ORI finding and entered into a Voluntary Exclusion Agreement with ORI in which voluntarily agreed, for the 5-year period beginning August 8, 1997, to exclude herself from any Federal grants, contracts or cooperative agreements and to exclude herself from serving in any advisory capacity to the PHS.

Dr. London is required to submit a letter to:

Chemical Senses requesting a retraction of the following article: London, J.A. "Optical recording of activity in the hamster gustatory cortex elicited by electrical stimulation of the tongue." *Chemical Senses* 15:137-143, 1990;

Brain Research requesting a retraction of the following article: London, J.A., & Wehby, R.G. "Classification of inhibitory responses of the hamster gustatory cortex." *Brain Research* 666:270-274, 1994; and

Optical Methods in Neurobiology requesting a retraction of Section V, Results – Hamster of the following article: London, J.A., & Cohen, L.B. "High time resolution, multisite optical measurement of vertebrate somatosensory cortex during epileptiform discharges and vertebrate gustatory cortex." *Optical Methods in Neurobiology*, pp. 61-78, 1988, prepared for the 11th Annual Meeting of the European Neuroscience Association.

William G. McCown, Ph.D., Integra, Inc.: Based upon a report forwarded to the ORI by Compass Information Services, Inc., and information obtained by ORI during its oversight review, ORI found that Dr. McCown, former Project Director at Integra, Inc. (now Compass Information Services, Inc.), engaged in scientific misconduct by falsifying answer sheets for an "Item Count Substance Abuse Survey" supported by a grant from the National Institute on Drug Abuse.

Dr. McCown entered into a Voluntary Exclusion Agreement with ORI in which he does not admit to any acts of scientific misconduct but voluntarily agreed, for the 3-year period beginning April 17, 1997, 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 to ORI for supervision of his duties. No scientific publications were required to be corrected.

Weidong Sun, M.D., Ph.D., Medical College of Pennsylvania (MCP) and Hahnemann University (HU): Based upon a report forwarded to the ORI by MCP and HU as well as information obtained by ORI during its oversight review, ORI found that Dr. Sun, a former graduate student in the Department of Neuroscience, MCP and HU, engaged in scientific misconduct by falsifying data in conducting and reporting research supported by a grant from the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). The research also was reported in applications requesting funding from NIAMS and the National Institute of Diabetes and Digestive and Kidney Diseases. Specifically, Dr. Sun falsified data by misrepresenting cloned DNA sequences from chicken non-muscle myosin as an isoform of neuronal myosin II from rat brain. The falsified DNA was included in the following publications and nucleotide sequences in GenBank and EMBL databases:

Sun, W.D., & Chantler, P.D. "Cloning of the cDNA encoding a neuronal myosin heavy chain from mammalian brand and its differential expression within the central

nervous system." *Journal of Molecular Biology* 224(4):1185-1193, 1992;

Sun, W.D., & Chantler, P.D. "A unique cellular myosin II exhibiting differential expression in the cerebral cortex." *Biochemical and Biophysical Research Communications* 175(1):244-249, 1991;

Sun, W., Chen, X., & Chantler, P.D. "Inhibition of neuritogenesis by antisense arrest of the expression of a specific isoform of brain myosin II." *Journal of Muscle Research and Cell Motility* 15:184-185, 1994;

M64596, "Rat myosin II mRNA, 3' end." [RETMYOSII];

M80591, "Rat neuronal myosin heavy chain mRNA, 3' end." [RATMYOH3E];

M94962, "Rattus rattus neuronal myosin heavy chain gene promoter sequence." [RATMYOPRO]; and

X62659, S98128, "R.rattus MRNA for brain neuronal myosin heavy chain." [RRNMYOHC].

Dr. Sun accepted the ORI finding and entered into a Voluntary Exclusion Agreement with ORI in which he voluntarily agreed, for the 3-year period beginning April 17, 1997, to exclude himself from any Federal grants, contracts, or cooperative agreements and to exclude himself from serving in any advisory capacity to the PHS. Retraction of the 1992 *Journal of Molecular Biology* article was published in 1997 in Volume 268(2), page 585.

Fabrication/Falsification

James B. Boone, Jr., Ph.D., University of Missouri-Columbia (UMC): Based upon an investigation conducted by UMC, information obtained by ORI during its oversight review, and Dr. Boone's own admission, ORI found that Dr. Boone, former Research Assistant Professor, Department of Veterinary Biomedical Sciences at UMC, engaged in scientific misconduct by fabricating and falsifying data in biomedical research supported by a grant from the National Heart, Lung, and Blood Institute. Specifically, Dr. Boone fabricated the weights of individual, isolated muscles that, in fact, had not been separated by dissection, and falsely presented unrelated gamma counter results as having been obtained from the same individual muscles. He presented these data to his laboratory director as the results from two experiments that Dr. Boone admitted he did not finish. He committed additional falsifications in conducting research, including presenting: (1) a computer spread sheet that used the above-described sets of the fabricated primary data of muscle weights and the falsified gamma counter results to generate false computations of blood flow in separate muscles; (2) a computer spread sheet for the statistical computations of the data from the two sets of fabricated and falsified reduced data; and (3) a histogram derived from the falsified reduced data that showed significant differences in some of the fabricated experimental measurements on individual muscles.

Dr. Boone accepted the ORI finding and entered into a Voluntary Exclusion Agreement with ORI in which he voluntarily agreed, for the 3-year period beginning February 10, 1997, 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 to ORI a plan for supervision of his duties. No scientific publications were required to be corrected.

Amitav Hajra, University of Michigan (UM): Based upon a report from UM, information obtained by the ORI during its oversight review, and Mr. Hajra's own admission, ORI found that Mr. Hajra, a former UM graduate student, engaged in scientific misconduct by falsifying and fabricating research data in five published research papers, two published review articles, one submitted but unpublished paper, in his doctoral dissertation, and in a submission to the GenBank data base. Mr.Hajra's doctoral training and research was supported by PHS grants, and his experiments were conducted at NIH's National Center for Human Genome Research (NCHGR). Mr. Hajra began his graduate research at the University of Michigan with Dr. Francis Collins as his mentor. When Dr. Collins later accepted the position of director of the NCHGR and established a research laboratory at the NIH, Mr. Hajra continued his research on the NIH campus.

The possibility that data had been fabricated or falsified first came to the attention of Dr. Collins when an editor informed him that reviewers of a manuscript had questioned the authenticity of a figure. When intervening events and a survey of laboratory notebooks and other data confirmed deep concerns, Dr. Collins confronted the student who admitted to fabricating major portions of his dissertation research and related research publications. The UM, NIH and ORI were notified. Dr. Collins also submitted retractions and corrections of the relevant publications and databases. ORI asked the UM, where Mr. Hajra was completing his final year of medical school, to conduct a formal investigation.

The following research reports (1-5) and review articles (6-7) contained falsified and fabricated data:

(1) Hajra, A., Collins, F.S. "Structure of the leukemia-associated human CBFB gene." *Genomics* 26(3):571-579, 1995. Retraction published in *Genomics* 38:107,1996.

(2) Hajra, A., Liu, P.P., Speck, N.A., Collins, F.S. "Over expression of core-binding factor (CBF) reverses cellular transformation by the CBFß-smooth muscle myosin heavy chain chimeric oncoprotein." *Molecular and Cellular Biology* 15(9):4980-4989, 1995. Retraction published in *Molecular and Cellular Biology* 16:7185, 1996.

(3) Hajra, A., Liu, P.P., Wang, Q., Kelley, C.A., Stacy, T., Adelstein, R.S., Speck, N.A., and Collins, F.S. "The leukemic core binding factor ß-smooth muscle myosin heavy chain (CBFß-SMMHC) chimeric protein requires both CBFß and myosin heavy chain domains for transformation of NIH 3T3 cells." *Proc. Natl. Acad. Sci. USA* 92(6):1926-1930, 1995. Retraction published in *Proc. Natl. Acad. Sci. USA* 93:15523, 1996.

(4) Wijmenga, C., Gregory, P.E., Hajra, A., Schröck, E., Ried, T., Eils, R., Liu, P.P., and Collins, F.S. "Core binding factor ß-smooth muscle myosin heavy chain chimeric protein involved in acute myeloid leukemia forms unusual nuclear rod-like structures in transformed NIH 3T3 cells." *Proc. Natl. Acad. Sci. USA* 93(4):1630-1635, 1995. Correction published in *Proc. Natl. Acad. Sci. USA* 93:15522, 1996.

(5) Liu, P.P., Wijmenga, C., Hajra, A., Blake, T.B., Kelley, C.A., Adelstein, R.S., Bagg, A., Rector, J., Cotelingham, J., Willman, C.L., and Collins, F.S. "Identification of the chimeric protein product of the CBFB-MYH11 fusion gene in inv(16) leukemia cells." *Genes, Chromosomes, and Cancer* 16:77-87, 1996. Correction published in *Genes, Chromosomes, and Cancer* 18:71, 1997.

(6) Hajra, A., Liu, P.P., and Collins, F.S. "Transforming properties of the leukemic Inv(16) fusion gene CBFB-MYH11." in "Molecular Aspects of Myeloid Stem Cell Development." in L. Wolff and A.S. Perkins, eds. *Current Topics in Microbiology and Immunology* ("*Current Topics*"), volume 211: *Molecular Aspects of Myeloid Stem Cell Development*, Springer-Verlag, Berlin and New York, 1996. pp. 289-298. The *Current Topics* volume has no mechanism for publishing retractions but the series editor has been notified.

(7) Liu, P.P., Hajra, A., Wijmenga, C., and Collins, F.S. "Molecular pathogenesis of the chromosome 16 inversion in the M4Eo subtype of Acute Myeloid Leukemia." *Blood* 85: 2289-2302, 1995. Correction published in *Blood* 89:1842, 1997.

Mr. Hajra submitted a fabricated nucleotide sequence: U22149, "Human leukemia-associated core binding factor subunit CBFbeta (CBFB) gene, promoter region and partial CDS." GenBank (NCBI, NLM, NIH). This database entry was removed in Sept. 1996. The majority of data reported in Mr. Hajra's dissertation, "Transformation properties of the leukemic CBFß-SMMHC chimeric protein," was fabricated. He also fabricated and falsified original research data in a manuscript submitted for publication to *Oncogene* but withdrawn prior to publication.

Mr. Hajra was found to be solely responsible for the data falsification and fabrication and no patients were involved in the research. Mr. Hajra accepted the ORI finding and entered into a Voluntary Exclusion Agreement in which he voluntarily agreed, for the 4-year period beginning July 7, 1997, to exclude himself from any Federal grants, contracts or cooperative agreements and to exclude himself from serving in any advisory capacity to the PHS.

Ann Marie Huelskamp, M.H.S., The Johns Hopkins University School of Medicine (JHUSM): Based upon a report forwarded to ORI by JHUSM, information obtained by ORI during its oversight review, and Ms. Huelskamp's own admission, ORI found that Ms. Huelskamp, a research program coordinator in the JHUSM Oncology Center engaged in scientific misconduct by fabricating patient interview data for a study of quality of life measures in cancer patients. The research was supported by a grant from the National Cancer Institute. ORI also found that Ms. Huelskamp engaged in scientific misconduct by falsifying patient status data by failing to update the status of treated breast cancer patients and misrepresenting data from previous contacts as the updated status for a study. These data were reported in an NCI grant application and gave the appearance that some patients' outcomes were more favorable than they actually were.

Ms. Huelskamp accepted the ORI finding and entered into a Voluntary Exclusion Agreement with ORI in which she has voluntarily agreed, for the 3-year period beginning April 17, 1997, 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 to ORI for supervision of her duties. No scientific publications were required to be corrected.

Fugang Li, Ph.D., University of Oklahoma Health Sciences Center (UOHSC): Based upon a report from the University of Oklahoma, information obtained by ORI during its oversight review, and Dr. Li's own admission, ORI found that Dr. Li, a former postdoctoral fellow in the

Department of Biochemistry and Molecular Biology, UOHSC, engaged in scientific misconduct by fabricating and falsifying data in conducting and reporting research supported by a grant from NIH's National Heart, Lung and Blood Institute. Specifically, Dr. Li fabricated and falsified data in a study involving the characterization of glycoprotein binding to P-selection on the surface of human leukocytes. The questioned data were included in a manuscript that was withdrawn prior to publication. Dr. Li accepted the ORI finding and entered into a Voluntary Exclusion Agreement with ORI in which he voluntarily agreed, for the 3-year period beginning June 3, 1997, to exclude himself from any Federal grants, contracts or cooperative agreements and to exclude himself from serving in any advisory capacity to the PHS. No scientific publications were required to be corrected.

David N. Shapiro, M.D., St. Jude Children's Research Hospital (SJCRS): Based upon a report from SJCRS as well as information obtained by ORI during its oversight review, ORI found that Dr. Shapiro, former faculty member, SJCRS, engaged in scientific misconduct by falsifying the authorship of five publications listed in his biographical sketches in several NIH grant applications. Specifically, Dr. Shapiro listed himself as an author when he was not. Dr. Shapiro also fabricated data for Figures 5 and 7 in the following publication: Sublett, J.E., Jeon, I.S., & Shapiro, D.N. "The aveolar rhabdomyosarcoma PAX3/FKHR fusion protein is a transcriptional activator." *Oncogene* 11:545-552, 1995. Dr. Shapiro has submitted a letter to *Oncogene* requesting retraction of these figures.

Dr. Shapiro accepted the ORI finding and entered into a Voluntary Exclusion Agreement in which he voluntarily agreed, beginning July 29, 1997, to: (1) exclude himself from any Federal grants, contracts or cooperative agreements for 2 years; (2) exclude himself from serving in any advisory capacity to the PHS for 3 years; and (3) that any institution that submits an application for PHS support for a research project on which his participation is proposed or that uses him in any capacity on PHS-supported research must concurrently submit a plan for supervision of his duties to the funding agency for approval for 1 year following the 2-year exclusion.

Falsification/Plagiarism

Manoj Misra, Ph.D., Dartmouth College (DC): Based upon the ORI review of a report forwarded to ORI by DC, Dr. Misra's admission of certain facts in that report, and ORI's own analysis, ORI found that Dr. Misra, a former postdoctoral research associate in Department of Chemistry, DC, engaged in scientific misconduct by intentionally altering laboratory notebook data entries for research supported by a grant from the National Institute of Environmental Health Sciences. Specifically, Dr. Misra altered laboratory notebook data entries in two instances in an effort to conceal prior manipulations of that data without disclosure or explanation to the principal investigator or anyone else. The experiment at issue involved an assay of the chemical activity of a carcinogen, and Dr. Misra's change in the readings of the "control" experiment, in which no carcinogen was present, changed the results.

Dr. Misra accepted the ORI finding and entered into a Voluntary Exclusion Agreement with ORI in which he voluntarily agreed, for the 3-year period beginning April 7, 1997, 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 to ORI for supervision of his duties. No scientific publications were required to be corrected.

Plagiarism

S. Ashraf Imam, Ph.D., University of Southern California (USC): Based on a report from USC, as well as information obtained by ORI during its oversight review, ORI found that Dr. Imam, an Associate Professor in the Department of Pathology, USC, engaged in scientific misconduct by including plagiarized material in a grant application submitted to the National Cancer Institute (NCI).

Specifically, Dr. Imam's grant application contained extensive paraphrasing of the text of another researcher's independent grant application to a State agency. Dr. Imam had been given that application by a colleague in confidence. The colleague was a reviewer on the State grant application and requested that Dr. Imam evaluate it and return the application to him. The other researcher's application was subsequently funded. Dr. Imam paraphrased or copied into his NCI application all of the other researcher's specific aims, the background on proposed methods, the experimental design and research plan, and most of the references; only the preliminary results sections of Dr. Imam's application were different.

Dr. Imam has accepted the ORI finding and entered into a Voluntary Exclusion Agreement with ORI in which he voluntarily agreed, for the 3-year period beginning December 8, 1997, to exclude himself from any Federal grants, contracts or cooperative agreements and to exclude himself from serving in any advisory capacity to the PHS. No scientific publications were required to be corrected.

Fabrication: The respondent allegedly fabricated data obtained from subjects in a nationwide health survey study. The institutional investigation concluded that errors in data entry could have occurred and that there is insufficient evidence to support a finding of scientific misconduct. ORI concurred with the institution's finding.

Falsification: A researcher was charged with allegedly falsifying research results in three versions of an unpublished manuscript. Both the institution and ORI found a number of discrepancies that lent credence to the allegation of data falsification. However, because the discrepancies between the representations of the parties cannot be resolved due to the age of the research and the absence of the original histology slides upon which the complainant and respondent reportedly based their analyses, ORI does not find that there is sufficient substantive evidence to make a finding of scientific misconduct on the part of the respondent in this case.

Falsification: The respondents were charged with possible falsification of research accomplishments by publishing the same research results in multiple papers and possible falsification of figures in three publications. For the issue of possible falsification of research accomplishments, the institutional investigation panel concluded that the practice of duplicate publication is unacceptable in reporting research within the scientific community and found that the respondents had committed scientific misconduct. However, ORI generally does not consider such duplication in publications (which amounts to "self-plagiarism" of results) to constitute "plagiarism" under the PHS definition of scientific misconduct. ORI further concluded that this is a matter that involves standards for scholarship and that adherence to these standards is appropriately handled by the institution. Regarding the possible falsification of figures in three publications, ORI concurs with the institution's conclusions that insufficient evidence exists to determine intent, identify responsibility, or assess the significance of any misrepresentation, or to make a finding of scientific misconduct. Thus, ORI did not make a finding of scientific misconduct under the PHS definition in this case.

Falsification: A co-worker alleged that the respondent had falsified data in a published paper and for continuing research supported by PHS funds. ORI conducted an investigation into the matter. ORI found that bias in data selection may have occurred, but there was insufficient evidence to determine a deliberate intent to deceive on the part of the respondent. Further, ORI identified a lack of formal training of the research staff in the research area and weaknesses in the study design

and implementation that may have contributed to any data selection bias. Thus, ORI did not make a finding of scientific misconduct.

Falsification: The respondent allegedly falsified the status of three manuscripts as "submitted" in a fellowship application to NIH. The institution determined that the respondent had committed "academic misconduct." ORI accepted the facts developed in the institution's report as final investigative findings and concurred with the institution's findings that the citations were inaccurate and the respondent's actions were inappropriate. However, in this instance, ORI did not find the deviations from accepted practices sufficiently serious to make a finding of scientific misconduct under the PHS definition.

Falsification: The respondent was charged with falsely representing rat or mouse muscle fibers as chicken embryo muscle fibers in a published paper. The institution's investigation concluded that (1) misrepresentation did occur in one figure in the paper; (2) the source and preparation of the tissue in the electronmicrographs in question should have been accurately described; and (3) the misrepresentation should be corrected in the literature. Based on ORI's review of the institution's investigation report and accompanying material as well as additional material obtained from the institution and from the respondent, ORI accepts the institution's report. However, because of the minor nature of the apparent misrepresentation and evidence that the body of the research on which the paper was based was not in doubt, ORI did not believe the matter warranted PHS action and did not make a finding of scientific misconduct under the PHS definition.

Falsification: A co-worker alleged that the respondent had falsified data reported in a published paper and in two contract proposals. The institutional investigation concluded that inadequate record keeping and a lack of standardized and consistent methods for evaluating patient data led to data discrepancies. The institution determined that there was insufficient evidence to warrant a finding of scientific misconduct but recommended that corrective measures be taken and that the journal editor be notified about the errors and inconsistencies in the published paper. ORI concurred with the institution's finding and recommendations.

Falsification: The respondent allegedly falsified statements about the extent of his research on gene expression in cultured cells in an abstract submitted for publication and oral presentation at a professional society meeting. The institution determined that the respondent's actions were wrong but not serious enough to warrant a finding of scientific misconduct given the junior status of the respondent, his immediate acknowledgment of his error in judgment, and the limited impact of an abstract that had been printed but withdrawn prior to presentation. ORI accepted the institution's conclusion and did not make a finding of scientific misconduct.

Fabrication/Falsification: The respondents allegedly had fabricated and falsified data involving the expression of antigens on animal cells, using antigenized antibodies and related immunological techniques. The institutional investigation determined that falsification or fabrication had occurred. ORI accepted the institution's factual findings and conclusion. However, ORI was unable to determine who was responsible and, therefore, did not make a finding of scientific misconduct.

Falsification/Fabrication: It was alleged that the respondents knowingly reported falsified or fabricated data in a series of manuscripts and publications. The data in question was related to subjects made eligible for the relevant studies by intentional falsifications and fabrications on the part of one of the participating physicians in a number of multicenter trials. ORI did not make a finding of scientific misconduct in this matter.

Falsification/Fabrication: The respondent allegedly falsified or fabricated the records of telephone call attempts to collect data from new mothers in conjunction with a federally funded program to determine risk factors for new mothers and babies. The institution conducted an investigation into the matter and determined that there was not sufficient evidence of falsification or fabrication on the part of the respondent or his staff to warrant a finding of scientific misconduct. Although the evidence indicated that there was an unusually large number of calls without subject contact and there were discrepancies between the official records and the worksheets, there was no clear evidence of a monetary incentive for fabricated phone calls. Furthermore, there was a possible explanation for the discrepancies between the official records and phone worksheets. Therefore, ORI accepted the institution's finding that there was insufficient evidence to make a finding of scientific misconduct.

Plagiarism: A colleague alleged that the respondent had plagiarized material from a grant application and had included the plagiarized material without attribution in another grant application. The institutional investigation determined that the respondent had copied portions of the complainant's grant application. However, the institution concluded that a preponderance of the evidence did not establish that the respondent had intentionally used the material without appropriate permission or

attribution. The institution also noted that considerable differences of opinion exist regarding the standards for permission, citation, and acknowledgment of other people's contributions to grant applications, as opposed to publications, and that there was a perception among the departmental faculty that applications were communally owned and their content commonly shared. Thus, the institution did not find sufficient evidence of intent to deceive to make a finding of scientific misconduct. ORI concurred with the institution's finding.

Plagiarism: The respondent was charged with plagiarizing background material from a clinical protocol and using the plagiarized material in an appendix to a grant application. The institution made a finding of scientific misconduct against the respondent. ORI accepted the institution's finding that the respondent committed plagiarism under the institution's standards. However, because the plagiarism was limited to background material, and because additional information submitted to ORI suggested the copying of text may have resulted from a misunderstanding rather than an intent to deceive, ORI did not make a finding of scientific misconduct under the PHS definition. Finally, because the institution has taken adequate actions to protect PHS-supported research and research applications, ORI will not take any further action in this matter.

Fabrication/Falsification/Plagiarism: The respondent allegedly deviated from Federal policies, the University's policies, and established standards of conduct in connection with the production, distribution, and clinical testing of investigational drugs for a number of years. Specifically, the respondent allegedly (1) administered investigational drugs without the patients' informed consent and the University's Institutional Review Board's (IRB) approval; (2) failed to monitor and report serious adverse events related to administering the investigational drugs; (3) used investigational drugs to treat patients not entered on investigational protocols; and (4) falsified a colleague's credentials in a National Institute of Health (NIH) grant application. For the first three issues, the University concluded that the respondent had committed scientific misconduct by seriously deviating from practices commonly accepted within the scientific community for proposing, conducting, or reporting research. The Food and Drug Administration (FDA) and the Office of Protection from Research Risks (OPRR) took action related to these findings under their relevant regulations. ORI reviewed the available evidence and determined that consistent with 42 C.F.R. § 50.101 and prior NIH policy, no further action was required by ORI, and ORI did not make a finding of scientific misconduct under the PHS definition. This conclusion did not affect the University's findings that the respondent committed academic misconduct as defined in the University policies and procedures or the actions taken by FDA and OPRR. For the fourth issue, the University determined that the allegation could not be substantiated by the evidence and did not make a finding of scientific misconduct. ORI accepted this finding.

In 1996, 88 institutions reported misconduct activities—receipt of an allegation, or conduct of an inquiry and/or investigation—in their Annual Report on Possible Research Misconduct. Fifty-four of these institutions opened 70 new cases in 1996; the other institutions were still responding to allegations received earlier. The level of misconduct activity declined between 1995 and 1996, but remained comparable to the activities reported in 1993 and 1994.

The institutions also reported receiving the highest number of allegations to date (127) and the highest number of three types of misconduct—fabrication, plagiarism, and other practices.

The 70 new cases opened by the institutions resulted in 61 inquiries and 25 investigations. Some cases were closed following a preliminary assessment of the allegations or were received too late in the year to begin an inquiry. The number of inquiries and investigations conducted in 1996 was less than in 1995, but comparable to the numbers in 1993 and 1994.

Efforts to restore the reputation of exonerated respondents were reported by 70 of the 88 institutions reporting misconduct activities. Maintaining confidentiality was the most frequent action cited (60 cases). Letters were sent to parties involved in the case informing them that misconduct was not found in 45 cases. Material related to the allegation was not placed in or was removed from personnel files in 13 cases. In two cases, articles were published in campus newsletters or newspapers.

Eighty-one of the eighty-eight institutions that reported misconduct activity reported taking action to protect the whistleblower. The most common actions taken to protect whistleblowers were: maintaining confidentiality (62 cases); establishing a policy prohibiting retaliation (39); cautioning the respondent against retaliating (30); monitoring for retaliation (26); reminding department chairs and deans about protections afforded to complainants (26); and informing appropriate officials that allegations were made in good faith (20).

Eighty-nine percent of the responding institutions indicated that they had the required policies for handling allegations of scientific misconduct. Three hundred and forty-two institutions (11 percent) either indicated that they did not have the required policy or did not answer the question. However, 163 of these institutions have a policy on file with ORI and will be so informed. Policies were requested for review from the remaining 179 institutions for which ORI has no policy.

Two institutions failed to report the opening of investigations in 1996 compared to four in 1995 and two in 1994. ORI asked the institutions to submit reports on those investigations.

Two hundred and eighty-two assurances were inactivated, including 201 institutions that did not return their Annual Reports or submit the required misconduct policies and 71 institutions that voluntarily withdrew their assurances rather than submit the Annual Report. Small businesses accounted for 66 percent of the inactivated assurances; higher education accounted for 8.5 percent.

The 1996 Annual Report records the highest response rate (89 percent) to date in the shortest amount of time because of the excellent cooperation received from institutions. The response rate was 4 percent higher than the previous high recorded for the 1995 Annual Report.

The 1996 Annual Report form was sent on January 14, 1997, to 3,310 institutions including 141 foreign institutions that had an assurance on file with ORI as of December 1, 1996. Seventy- three percent of the institutions responded by the March 3 deadline. A second mailing produced an additional 524 responses by the March 31 final deadline. Previous surveys had been completed in April, May or June.

Six hundred and thirty-eight institutions (21 percent) changed their responsible official and/or their address. Four hundred and seventy-eight officials and 198 addresses were new. Thirty-eight of these institutions made both changes.

The Annual Report survey continues to encounter problems with (1) the initial response rate, (2) erroneous or confusing responses regarding the availability of policies, the identity of the responsible official, and the name of the organization, and (3) unanswered questions.

CIVIL LITIGATION

U.S. ex rel. Karuturi* v. *John Wayne Cancer Institute, et al., No. 95-7939-CMB (C.D. Cal., filed Nov. 21, 1995). Dr. Satyanarayana Karuturi filed this *qui tam* action under the False Claims Act (FCA), 31 U.S.C. § 3730(b), 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 United States declined to intervene, and Dr. Karuturi elected to pursue his complaint independently. On March 4, 1997, the case was dismissed on jurisdictional grounds without prejudice for all defendants except the University of California at Los Angeles. Dr. Karuturi then filed an amended complaint, and the case was still pending at the end of 1997. On January 20, 1998, the district court dismissed all the claims in the suit against the individual defendants and St. John's Hospital and Health Center. However, the court denied a motion to dismiss claims against the John Wayne Cancer Institute under: 1) the False Claims Act; and 2) for wrongful termination under 31 U.S.C. § 3730 (h). No trial date has been scheduled.

Fisher* v. *University of Pittsburgh, et al., No 94-1160 (W.D. Pa., filed Dec. 18, 1995). Dr. Bernard Fisher filed a complaint against the University of Pittsburgh, ORI and several other HHS agencies and officials, and others. 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 actions, in addition to an ORI scientific misconduct investigation and the placement of annotations in MEDLINE® and CANCERLIT® on certain NSABP articles, 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. ORI issued its report on the misconduct investigation on February 28, 1997, which did not make a finding of scientific misconduct by Dr. Fisher or the other respondents. In March 1997, the government filed briefs moving to dismiss the case, and the court dismissed those charges which were the same as those previously dismissed in 1996 in *Fisher* v. *National Institutes of Health*, 934 F. Supp. 464 (D.C. 1996). On August 27, 1997, all

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[1]OGC tracks all civil and criminal litigation cases related to ORI's mission. Many cases, especially those in which ORI is named a party, require active participation with the Department of Justice, including sharing of information, discovery, the taking of depositions, preparation of briefs and pleadings, and strategy decisions. The litigation summaries provided here do not include *qui tam* cases which are under seal and, therefore, are not yet publicly reported, cases in which ORI has only a peripheral interest, nor cases in which a complaint has not yet been filed or an indictment issued.

parties entered into a settlement agreement, and the case was dismissed with prejudice. Neither ORI nor NIH admitted liability or wrongdoing. The case is now closed.

Needleman* v. *Varmus, No. 92-0749 (W.D. Penn., filed Dec. 4, 1992); No. 96-3351 (3rd Cir.). Dr. Herbert L. Needleman filed a 14-count class action against ORI, 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 did not find Dr. Needleman guilty of scientific misconduct, and ORI accepted the University's report. Although in 1994, the district court dismissed the case against the Federal defendants, two counts remained against the University defendants. In 1996, the court dismissed Dr. Needleman's procedural and substantive due process claim under 42 U.S.C. § 1983, and declined to exercise supplemental jurisdiction over his pendent State claim for breach of contract. Dr. Needleman appealed to the U.S. Court of Appeals for the Third Circuit, and on August 4, 1997, the appellate court affirmed the lower court's ruling in full. Although Dr. Needleman failed to raise his First Amendment claims in his Notice of Appeal, the Third Circuit court agreed that Dr. Needleman had not shown that the University was an agent of the Federal government for purposes of a First Amendment claim, and the misconduct investigation did not violate due process. Lastly, the appellate court affirmed as moot the earlier district court dismissal of all claims against the Federal defendants. Dr. Needleman did not apply for a writ of *certiorari* from the U.S. Supreme Court within the required 90-day period, and the case is now closed.

Popovic* v. *United States, et al., No. PJM-96-3106 (D. Md., filed Oct. 3, 1996). Dr. Mikulas Popovic brought a complaint under the Federal Tort Claims Act, 28 U.S.C. § 2671, *et seq.*, alleging negligence, invasion of privacy, intentional infliction of emotional distress, refusal to hire for reasons contrary to public policy, and due process violations against the United States. Dr. Popovic also brought claims of due process violations against the former director of the Office of Scientific Integrity (OSI), ORI's predecessor agency. Dr. Popovic alleged that these actions occurred as a result of the scientific misconduct investigation conducted by OSI and ORI. ORI had made findings of misconduct against Dr. Popovic which were reversed by the HHS Departmental Appeals Board (DAB). On April 21, 1997, the district court partially granted the defendants' motion for summary judgment, dismissing three counts of the complaint. The court then ordered supplemental briefing on the intentional infliction of emotional distress and due process counts, and Dr. Popovic filed an amended complaint on the three counts previously dismissed. On February 27, 1998, the U.S. District Court for the District of Maryland granted the defendant's motion for summary judgement by dismissing the remaining two counts and refused Dr. Popovic's request to reconsider the dismissal of the previously dismissed counts. On March 25, 1998, Dr. Popovic appealed the dismissal.

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. Erdem I. Cantekin filed this *qui tam* action under the False Claims Act (FCA), 31 U.S.C. § 3730(b), against the University and others (No. 91-0715). Dr. Cantekin alleged that the defendants defrauded the United States by making false financial disclosure statements in applications for Federal grants. The United States declined to intervene. 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 HHS released some materials. The FOIA case was dismissed in 1995. In 1997, the district court dismissed Dr. Cantekin's pre-October 27, 1986, FCA claims because prior to a 1986 Amendment, the FCA required dismissal of *qui tam* suits based on information already in the government's possession. The court noted that Dr. Cantekin failed to submit any evidence that rebutted the defendants' assertion, supported by affidavit, that the government was aware of the alleged conduct before October 1986. The court further dismissed Dr. Cantekin's consolidated State whistleblower action as time-barred, his Federal whistleblower action under 31 U.S.C. § 3730 against the individual defendants, his claim of civil conspiracy, and his claim for breach of contract. The court then ordered the parties to submit a statement of the remaining claims, including Dr. Cantekin's "scientific fraud claim." The case remains pending.

Raz* v. *United States, No. 96-2422 (W.D. La., filed Oct. 17, 1996). In 1995, Mr. Yoram Raz filed a *pro se* civil action against Louisiana State University Medical Center (LSUMC) and ORI after ORI accepted LSUMC'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, Mr. Raz sought money damages in addition to an injunction to require ORI to reopen an investigation against the exonerated scientific misconduct respondent. The U.S. magistrate judge dismissed Mr. Raz' action without prejudice, ruling that to the extent his claim was a tort action, it must be brought under the Federal Tort Claims Act (FTCA), 28 U.S.C. § 2671, *et*

seq. In 1996, Mr. Raz filed an administrative FTCA claim and, after 6 months elapsed without a Departmental response to his claim, the plaintiff brought a second suit under the FTCA against the United States, in the same district court, stating the same claims and requests for an injunction and money damages as in the first action. On January 21, 1997, the magistrate judge recommended dismissal of the matter, and on May 22, 1997, the district court dismissed the action with prejudice. Mr. Raz appealed the dismissal to the U.S. Court of Appeals for the Fifth Circuit, and on November 14, 1997, the appellate court affirmed the lower court's dismissal. The case is now closed.

Polsby* v. *Shalala, Consolidated CA No. DKC-88-2344 (D. Md., filed Aug. 10, 1988); No. 96-1793 (4th Cir.). Dr. Maureen Polsby originally alleged violations of the Civil Rights Act of 1964 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, even though an NIH inquiry determined that there was no basis for such an investigation. Dr. Polsby then sought discovery from ORI regarding the ORI files, and ORI requested a protective order from the court before it would release any records. The court failed to rule on this issue, and in 1996 the case went to trial. The Judge ruled in favor of HHS concluding that Dr. Polsby had failed to prove her claims of gender discrimination. Dr. Polsby then 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. *University of Alabama, et al., No. N-93-158 (D. Md., filed 1993); No. 95-2811 (appeal). After ORI declined to pursue Dr. Pamela Berge's allegations of scientific misconduct, she filed this *qui tam* action under the False Claims Act (FCA), 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, and 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 and was awarded treble damages against the University and damages and penalties against the other defendants. The University of Alabama appealed to the U.S. Court of Appeals for the Fourth Circuit, and several institutions and associations filed supporting *amicus curiae* briefs. The Department of Justice (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. The Government also rejected the arguments of several *amici* that the FCA should not be applicable to scientific misconduct issues by 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 FCA claim. On January 22, 1997, the Fourth Circuit reversed the lower court's decision and found in favor of the University defendants on the merits. However, the appellate court denied the University's jurisdictional arguments and agreed with the government that the FCA is applicable to matters of scientific misconduct, and State instrumentalities are not shielded from such liability by the Eleventh Amendment of the U.S. Constitution. 104 F.3d 1453 (4th Cir 1997). On October 14, 1997, the U.S. Supreme Court denied Dr. Berge's petition for *certiorari* without discussion. The case is now closed.

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 (BCM), filed a lawsuit against BCM and several of its employees in Texas State court, seeking damages on various grounds surrounding his employment dismissal by BCM. BCM had dismissed Dr.Angelides after an investigation committee determined that he had committed scientific misconduct by falsifying and fabricating research data in five grant proposals to NIH and five published scientific papers. In 1996, BCM removed the case to Federal court, arguing that the case involved the construction of Federal law relating to BCM'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. However, the Federal court then, *sua sponte*, remanded the case back to the State court for further proceedings based upon the lack of a Federal question. BCM appealed to the U.S. Court of Appeals for the Fifth Circuit, and the Department of Justice, following consultation with ORI and HHS, filed an *amicus curiae* brief with the Fifth Circuit, supporting BCM'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. Therefore, the government argued that BCM's Federal obligations insulated it from Dr. Angelides' defamation claims. On July 11, 1997, the Fifth Circuit court 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 has set a trial date for September 1998, and the case 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 previously recovered grant funds from the University of Pittsburgh through a negotiated settlement based upon ORI's 1993 finding of scientific misconduct against Dr. Poisson. The suit is still pending against St. Luc.

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). Dr. Paulo del Guercio filed this *qui tam* action under the False Claims Act (FCA), 31 U.S.C. § 3730(b). He claimed that the Board of Regents of the University of California at San Diego made false statements in several grant applications submitted by the University of California at San Diego on behalf of the codefendants, the principal investigators on several PHS grants for investigating new types of vaccination and immunotherapy. On October 14, 1997, all parties entered into settlement and release agreements, and the University agreed to pay $135,000 to the United States to settle the case. From that amount, the United States agreed to pay Dr. del Guercio $10,125 as his share of the proceeds, and the University also agreed to pay $30,000 of his attorneys' fee and expenses. The case is now closed.

U.S. ex rel. Lucinda C. Scott* v. *Dr. Robert J. McKenna, Jr., et al., No. 96-5176CBM (C.D. Ca., filed July 25, 1996). Ms. Scott filed this *qui tam* action under the False Claims Act (FCA), 31 U.S.C. § 3730(b), *pro se,* against Dr. Robert J. McKenna, Jr., and other defendants including various physicians, nurses, hospitals, and the University of California at Irvine. Ms. Scott alleged that false claims were submitted to the Health Care Financing Administration (HCFA), NIH, and the Department of Energy. She claimed that the defendants inappropriately billed HCFA for unapproved lung reduction surgery and misrepresented specifics about the surgical procedure, including mortality rates. She also filed a scientific misconduct allegation with ORI. However, ORI determined that only one of the named defendants had submitted a grant application to the NIH, and none of these grant applications were funded. On March 27, 1997, the United States declined to intervene, and the seal on the complaint was subsequently lifted. Ms. Scott elected to pursue the case independently. The defendants filed a Motion to Dismiss; however, the Court has not acted upon it, and the case remains open.

U.S. ex rel. Sharma* v. *University of Southern California, et al., Civ. No. 96-4050 (C.D. Cal. filed June 14, 1996). Dr. Ramesh C. Sharma, filed this *qui tam* action under the False Claims Act (FCA), 31 U.S.C. § 3730(b), alleging that Dr. Dieter Kramsch and the University of Southern California (USC) submitted falsified experimental results and/or methodology about studies exploring the treatment of atherosclerosis in several PHS grant applications. Dr. Sharma also alleged that Dr. Kramsch and USC conducted experiments on animal subjects that had not been approved by the institution's animal care and use committee, and they submitted falsified protocol synopses describing research conducted on animal subjects. In July 1997, the United States declined to intervene. Dr. Sharma has elected to pursue his complaint independently, and the case remains open.

Hasan M. Jalisi, et al.* v. *The Cleveland Clinic Foundation, et al., No. 1:96 CV 1406 (D.C. Ohio, filed June 28, 1996). Dr. Jalisi, a former employee of the Cleveland Clinic Foundation (CCF), filed a suit against CCF, his former lab chief at CCF, and other CCF employees. He alleged: violations of 15 U.S.C. § 1125(a) (false designations of origin, false descriptions, and dilution forbidden) by misrepresenting Dr. Jalisi's research and breaching promises and representations; breach of an employment agreement; failure to follow the Federal regulations on scientific misconduct; intentional interference with Dr. Jalisi's career and prospective economic advantages; retaliation against a whistleblower; defamation; unfair competition; and discriminatory pay practices. The defendants countersued, alleging, among other things, defamation, interference, and emotional distress. ORI had previously reviewed Dr. Jalisi's allegations of scientific misconduct and administratively closed the case because no connection with PHS funding could be found. CCF requested that the ORI Acting Director provide an affidavit regarding the extent of ORI's jurisdiction over extramural scientific misconduct cases for which there is no PHS funding. ORI provided the affidavit in December 1997, and the case remains pending.

The following are summaries of all compliance and retaliation cases closed during 1997.

Compliance

This case was initiated based on a complaint by a respondent that institutional officials violated Federal regulatory requirements during their investigation of him. The respondent alleged that the following actions constituted noncompliance with the requirement codified at 42 C.F.R. Part 50, Subpart A: 1) failure to interview the complainant in person, 2) attempts by the institutional counsel to influence a witness to change his testimony, 3) the refusal of the institution to extend the investigation deadline, 4) providing the inquiry report, prepared by a separate inquiry committee, to the investigation committee, 5) conflict of interest on the part of an institutional counsel regarding her involvement in a separate employment dispute initiated by the respondent, 6) the imposition of an unfair burden of proof regarding the respondent's counter allegations, 7) delay by institutional officials in the production of documents necessary for the respondent's defense, and 8) failure by the Provost to review the respondent's comments to the investigation report. Each issue was fully examined, and included an extensive review of documentation, including interview transcripts, gathered as part of the institutional misconduct investigation. A number of actions taken by the institution were clearly within their discretion in a misconduct investigation (telephonic vs. in-person interview, deadline adherence, the requirement that documentation be provided to support counter claims, and the sharing of the inquiry report with the investigation committee), while the other allegations were not supported by the record. ORI concluded that there was no insufficient evidence to support the respondent's claims that the various actions by institutional officials during the misconduct investigation violated provisions of the Federal regulation.

Compliance

A compliance review was conducted because documentation from an ongoing scientific misconduct investigation at the institution suggested that there could be procedural deficiencies in the institutional process. Also, the institution had experienced compliance problems with previous misconduct inquiries and investigations and was 2 years delinquent in revising its policies and procedures in response to an ORI policy review. The review raised concerns about the institutional implementation of the Federal misconduct regulation. Specifically, the institution had delayed the initiation of an inquiry for seven months while attempting to resolve the sus-

pected scientific misconduct through a legal settlement. The institution acknowledged that there had been a delay with initiating the inquiry but indicated that other dispute resolution processes were available for addressing conflicts. The institution was informed that this alternate dispute resolution process is not an acceptable alternative when allegations of scientific misconduct are raised and involve PHS funded research. The institution responded positively to ORI's request for a plan to ensure that the policies would be revised and implemented in compliance with the Federal regulation. As part of the policy revision, the institution created a new staff position for Director of Research Ethics and Regulatory Compliance, one of whose responsibilities is to monitor the progress of inquiries into allegations of misconduct and ensure that they proceed in a timely manner. The institution's revised policies and procedures have been reviewed by ORI and are now in compliance.

Compliance

A compliance review of an institutional misconduct process was initiated in response to a claim that the respondent was not afforded due process during an ongoing investigation. This review examined both the alleged lack of due process and the institutional policies and procedures for compliance with the Federal regulation. The respondent's attorney claimed that his client was not interviewed nor afforded the opportunity to comment on the inquiry or investigation reports. ORI considers such omissions in the inquiry and investigation process significant; however, ORI subsequently determined that PHS did not have jurisdiction in the misconduct matter, and therefore the institution was not required to follow the provisions of the Federal regulation in its review. The ORI review of the institution's scientific misconduct policies for compliance with the Federal regulation did find a number of deficiencies, and a report summarizing the findings was forwarded to the institution. The institution made the suggested changes to its policy and submitted its revised policies to ORI, which ORI then reviewed and approved.

Compliance

A respondent in a scientific misconduct case allegedly threatened to retaliate against the complainants who made allegations of scientific misconduct against him by threatening to make a counter scientific misconduct allegation against one of the complainants and threatening the denial of tenure to the other. ORI contacted the institution and expressed concern over the possibility of whistleblower retaliation which was documented in statements relayed to ORI. A compliance review was initiated to address the whistleblowers concerns and to review the institution's policies and procedures for compliance with the Federal regulation. Institutional officials assured ORI that they were monitoring the potential retaliation and would take appropriate steps to prevent any retaliation against the whistleblowers. ORI's review of the institutional policies and procedures noted various deficiencies and a report was forwarded to the institution for their review and action. Institutional officials agreed to follow the ORI Model Policy for dealing with allegations of scientific misconduct until their revised policy is adopted by the institution.

Compliance

A system wide compliance review was conducted on a State educational system because some of the campus affiliates failed to properly conduct inquiries and investigations of scientific misconduct allegations. The system includes 12 separate campuses that until recently were covered under a system-wide set of misconduct policies and procedures. When the chancellor subsequently decentralized this function, each affiliate was encouraged to develop a policy tailored specifically to its own campus. ORI reviewed the policies and procedures established at each campus and determined that revisions were required on the policies and procedures of all the campuses. Nine of the twelve campuses have revised their policies and procedures to bring them into compliance with the Federal regulation. The remaining three campuses have agreed to use the ORI Model Policy pending the submission to and approval by ORI of their revised policies and procedures.

Retaliation

A junior researcher at a research institute claimed that she suffered retaliation as a result of making allegations of scientific misconduct against her supervisor. The researcher claimed that as a result of her allegations, her salary support was terminated prematurely, the working environment at the research institute became increasingly hostile, and she was moved to a smaller work area, which limited her access to necessary laboratory equipment. ORI contacted institutional officials regarding these allegations of retaliation, and advised the officials to review the matter, as institutions bear the primary responsibility for the investigation of alleged retaliation. The institution chose to implement the ORI whistleblower guidelines in the investigation of the retaliation complaint, and concluded that the evidence did not support a finding that retaliation had occurred. ORI reviewed the institution's report and determined that the institution substantially followed the investigative process con-

tained in the ORI whistleblower guidelines, and therefore satisfied its regulatory requirement for addressing whistleblower complaints.

Retaliation

This case was referred to DPE from DRI for review of possible retaliation. A researcher asserted that an allegation of scientific misconduct was made against him by a former Chairman in retaliation for an earlier allegation of financial misconduct. A review of the file indicated that ORI did not have jurisdiction in this case. The case was administratively closed.

Retaliation

The complainant alleged, that as a result of making allegations of scientific misconduct against a member of his laboratory, he was removed from his position as laboratory chief at the research center, and ultimately was dismissed. The complainant also claimed that his wife initially discovered the alleged misconduct that he reported, and therefore she should also be protected as a whistleblower in this case. His wife was also dismissed subsequent to the allegations being made.

Officials at the institution were contacted, and informed of their obligation to protect the position and reputation of individuals that make allegations of scientific misconduct in good faith. They were asked to investigate the claims of retaliation made by the complainants. The institutional officials reviewed the documentation provided by the complainants, as well as other documentation that remained in their files. The institutional officials concluded, based on this review, that the actions that led up to the dismissal of the complainant and his wife were based on serious financial pressures at the research center, which were documented prior to the date the alleged misconduct was reported. The institution provided additional documentation to support their conclusions, including evidence that the complainants were each notified that their positions were in jeopardy prior to the allegations of scientific misconduct.

ORI reviewed all the materials relevant to the complaint, and agreed with the institution's assessment that the actions taken did not appear to be in retaliation for the misconduct allegations, given the sequence of events and circumstances prior to the time the allegations were made. In accordance with ORI procedures, the complainants were provided with the institution's assessment, including the supporting documentation, and asked to provide comments. ORI evaluated the comments provided, and concluded that no new substantive evidence had been produced by the complainants in support of their claim. The case was then closed with no further ORI action.

Retaliation/Compliance

A visiting professor and an assistant professor contacted ORI with complaints of institutional retaliation for 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 settlement of the lawsuit mooted out the retaliation claim, 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, 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 law suit against the institution. ORI informed the assistant professor that if the lawsuit was filed, ORI would consider it an election of remedies by the complainant in lieu of the institutional process. The lawsuit was served before the institutional process was initiated, and the case was closed.

Retaliation/Compliance

In this case, a postdoctoral fellow was told by her laboratory director that she was fired for contacting the Chair of the institution's Postdoctoral Training Grant Committee as well as ORI regarding possible scientific misconduct on the part of a research technician working in the same lab. She had raised these same concerns to the laboratory director previously, and only contacted ORI when she concluded that no formal action would be taken to investigate her complaint. ORI contacted senior officials at the institution regarding this retaliatory action taken against the complainant, and those officials assured ORI that this individual could not be fired by her laboratory director for reporting possible scientific misconduct, and her position was secure. Over the next few weeks, the complainant was provided space outside her laboratory to continue her work. The intention of this move was to provide a "cooling off" period for both individuals. The complainant subsequently was allowed to rejoin her laboratory, but found the atmo-

sphere to be intolerable. The complainant told institutional officials that she wanted to be removed immediately from the laboratory, and asked that she be allowed to take her fellowship elsewhere. Institutional officials stated that they would support the complainant's fellowship, even at another institution. However, before any official action was taken on this request, the complainant resigned her position prior to the end of her fellowship, and left the institution.

While the complainant's position and reputation did appear to be adversely affected by her actions in reporting alleged scientific misconduct, the institutional officials had taken a number of steps to protect the complainant and ORI found that the institution met the regulatory requirements. ORI also recommended that the institution develop and implement new policies and procedures to prevent and respond to any future retaliation against good faith whistleblowers.

Retaliation/Compliance

This case was initiated on the basis of concerns regarding potential compliance issues that were raised during the ORI oversight review of an institutional misconduct inquiry. The issues included 1) inappropriate interactions among decisionmakers, the inquiry committee and the respondent, 2) the failure to record or provide transcripts of interviews and information to ORI, 3) possible recrimination against the complainant, and 4) scope of the inquiry. The review found no evidence to support the claims that institutional officials may have inappropriately influenced individuals involved in the inquiry process or took recriminatory acts against the complainant. Regarding the recording of interviews, there is no Federal requirement that this be done during an inquiry. And although the institution inquiry report was augmented with three additional assessments in response to ORI questions, ORI was ultimately satisfied that all the pertinent issues were covered during the inquiry process, negating the need for the institution to open an investigation.

The *ORI Handbook for Institutional Research Integrity Officers* is divided into five sections: 1) Introduction; 2) Institutional Responsibilities; 3) ORI Oversight; 4) ORI Outreach; and 5) Appendices.

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

The PHS oversight section covers: 1) the ORI mission structure; 2) other PHS offices that handle research abuses; 3) institutional referrals; 4) oversight of institutional inquiries and investigations; 5) conduct of inquiries and investigations at institutions; 6) determinations of misconduct, administrative actions, and the hearing process; 7) defining plagiarism; 8) the assurance program; 9) the Annual Report on Possible Research Misconduct; 10) institutional compliance reviews; 11) review of retaliation complaints; 12) implementation of PHS/DHHS administrative actions; and 13) the PHS ALERT system.

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

The appendices contain documents and forms related to the institutional responsibilities and PHS oversight functions detailed above including the Federal regulation, model policy and procedures for responding to allegations of scientific misconduct, guidelines for a DAB hearing and responding to retaliation complaints, legal decisions and rulings, and the Annual Report form.

The text of the handbook and many of the appendices are available on the ORI Home Page at http://ori.dhhs.gov.

General Information

_____ **Which Office Handles What Type of Research Abuse.** Explains the different Federal offices that are concerned with abuses of the research process.

_____ **HHS Fact Sheet on Promoting Integrity in Research.** Describes the system that the Department of Health and Human Services currently uses to promote integrity in biomedical and behavioral research supported or conducted by agencies of the U.S. Public Health Service. Dated February 28, 1997.

_____ ***ORI: An Introduction.*** Describes the structure and functions of the Office of Research Integrity. Includes professional staff, their positions and qualifications, as well as the address and telephone numbers for the various divisions. Printed in September 1993.

Regulations and Guidelines

_____ ***Responsibility of PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science.*** Public Health Service (PHS) regulation 42 C.F.R. Part 50, Subpart A that requires each institution that applies for a research, research-training, or research-related grant or cooperative agreement under the Public Health Service Act to have established uniform policies and procedures for investigating and reporting instances of alleged or apparent scientific misconduct.

_____ **Guidelines for the Conduct of Research Within the Public Health Service.** Intended to provide a framework for the fair and open conduct of research without inhibiting scientific freedom and creativity. The guidelines indicate what is commonly considered appropriate scientific conduct in PHS intramural research, research training, and related activities. Issued on January 1, 1992.

_____ **General Procedures and Inquiry Instructions for Scientific Misconduct in Intramural Research.** Serves as a reference book for handling allegations of misconduct in science involving PHS intramural research. Issued April 21, 1994.

_____ **ORI Model Policy and Procedures for Responding to Allegations of Scientific Misconduct.** Intended as guidance only. The model policy was

designed primarily for use by institutions that are developing or refining their policies and procedures for handling scientific misconduct cases where ORI has jurisdiction. The model procedures were designed to provide more detailed guidance on how to conduct inquiries and investigations in cases where ORI will review and follow up on actions that the institution decides to take. Also available on diskette in WP5.1, WP6.1, or ASCII format (please specify).

_____ **ORI Guidelines for Institutions and Whistleblowers**. Intended to provide guidance in responding to possible retaliation against whistleblowers in cases involving PHS extramural research and provide information to whistleblowers regarding the appropriate method for submitting a retaliation complaint.

_____ **ORI Handbook for Institutional Research Integrity Officers.** Designed as a reference work for extramural institutional officials who have responsibility for handling allegations of misconduct involving PHS research. Dated February 1997.

_____ **Support of Research Integrity Meetings**. Guidance for developing proposals requesting ORI support for research integrity meetings. ORI seeks proposals from institutions, professional associations, and scientific societies that wish to collaborate with ORI to co-sponsor a conference or workshop on handling scientific misconduct allegations or the promotion of research integrity. Includes instructions and an application form.

ORI Position or Information Papers

_____ **"The Whistleblower's Conditional Privilege to Report Allegations of Scientific Misconduct."** Prepared by ORI lawyers, Position Paper #1 describing protections for whistleblowers in defamation suits.

_____ **"ORI Addresses Ten Issues in Inquiries and Investigations."** ORI Position Paper #2 that summarizes the PHS position on issues concerning allegations of misconduct in PHS-supported research. Based on a series of articles published in the ORI Newsletter.

_____ **Institutional Compliance Reviews**. Information paper that explains ORI Compliance Reviews, including the purpose of the reviews, details about the two basic parts of the review as well as detailing the specific issues examined in the review process.

Reports

_____ **Workshop on Data Management in Biomedical Research**. Report of a workshop held in April 1990. Single copies are available.

_____ **ORI/AAAS Conference on Plagiarism and Theft of Ideas**. Summary report of conference held on June 21-22, 1993. Single copies may be requested or the report is available on diskette in WP5.1, WP6.1, or ASCII format (please specify).

_____ **Integrity and Misconduct in Research**. 1995 Report of the Commission on Research Integrity to the Secretary of Health and Human Services, the House Committee on Commerce and the Senate Committee on Labor and Human Resources.

_____ **Consequences of Whistleblowing**. Report on the study of the "Consequences of Whistleblowing for the Whistleblower in Misconduct in Science Cases" conducted by the Research Triangle Institute. Single copies of the report may be requested.

_____ **Consequences of Being Accused of Misconduct**. Report on the "Survey of Accused but Exonerated Individuals in Research Misconduct Cases" conducted by the Research Triangle Institute.

_____ **Report on 1996 Annual Report on Possible Research Misconduct**. The report summarizes the information that extramural institutions filed with ORI to maintain their active assurances and the actions that were taken as a result of those submissions.

_____ **Managing Integrity in Research: Conference Summary.** A report on a conference co-sponsored by the University of Michigan and ORI that was held in Ann Arbor, Michigan on February 10-11, 1998.

Regular ORI Publications

_____ **Annual Reports**. Annual reports starting in 1994 describe ORI's significant accomplishments during the calendar year. Single copies of the 1993

ORI Annual Report and the Biennial Report from 1991-92 are also available upon request.

_____ ***ORI Newsletter***. Quarterly publication of ORI. The *ORI Newsletter* is sent to PHS agencies and all applicant and awardee institutions that hold an active assurance with ORI and is meant to facilitate common interests in handling allegations of scientific misconduct and promoting integrity in PHS-supported research.

***Available on ORI Internet Home Page:**

http://ori.dhhs.gov

To request copies, contact:

The Office of Research Integrity
Division of Policy and Education
5515 Security Lane, Suite 700, Rockville, MD 20852
Telephone: (301) 443-5300; FAX: (301) 443-5351
Internet:requests@osophs.dhhs.gov

ARILO	Agency Research Integrity Liaison Officer
DAB	Departmental Appeals Board
DPE	Division of Policy and Education, ORI
DRI	Division of Research Investigations, ORI
GMIS	Grants Management Information System
HHS	Department of Health and Human Services
IMPAC	Information for Management, Planning, Analysis and Coordination computerized information system on HHS extramural programs
NIH	National Institutes of Health
OGC	Office of the General Counsel
ORI	Office of Research Integrity
OSI	Office of Scientific Integrity (ended in 1992)
PHS	Public Health Service

Table A: Initial Disposition of Queries in 1997
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Appendix A

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