

# Highlights of 2000 ORI Annual Report

## POLICIES AND REGULATIONS

### Proposed Regulation

On November 28, 2000, the Department published a Notice of Proposed Rulemaking (NPRM) to implement statutory protections for whistleblowers who make good faith allegations of research misconduct. The NPRM is at 65 Fed. Reg. 70830 (2000) and is available on ORI's web site. The NPRM requested comments by January 29, 2001. ORI is analyzing the comments in preparation to recommending appropriate revisions to the Department. See Chapter 1, page 5 for more details.

### Policy Change

Implementation of the PHS Policy on Instruction in the Responsible Conduct of Research (RCR), announced on December 1, 2000, was suspended in February 2001 to permit review of the substance of the policy and the process followed in its adoption in response to a congressional inquiry that questioned whether the requirement should have been processed as a proposed regulation rather than a policy. A *Federal Register* notice published on February 21, 2001, stated that “[p]ending completion of that review, institutions that might otherwise be subject to the RCR policy are under no obligation to implement the policy unless further public notice is issued in the *Federal Register*. Any future PHS action taken to implement the RCR policy would provide extended implementation time frames that take into consideration this suspension.” The letter from Representatives W.J. “Billy” Tauzin and James Greenwood, the response by Chris Pascal, Director of ORI, and the *Federal Register* notice are posted on the ORI web site.

## OVERSIGHT OF ALLEGATIONS

### Responding to Misconduct Allegations

In 2000, ORI opened 26 new cases and closed 27 cases, with 31 cases remaining open at the end of the calendar year, slightly fewer cases than ORI had in 1999. Of the 27 cases closed by ORI, 7 cases resulted in sustained findings of scientific misconduct or PHS administrative actions against the respondents, 6 involving falsification or fabrication of data. One case involved plagiarism; it was handled as an ORI investigation (initiated in 1999), finding an applicant had plagiarized images from the Internet for a small business innovation research grant. The other 26 cases involved institutional inquiries or investigations. The percentage of PHS findings of misconduct and PHS actions for Year 2000 (26%) was somewhat below the historical average; PHS has found scientific misconduct in about one-third of the cases subject to ORI oversight.

For the 27 cases of inquiries or investigations reviewed and closed by ORI in 2000, institutions took a mean of 8.7 months after their notification of ORI (median, 4 months; range, 1 to 41 months) to complete their actions. ORI took a mean of 6.2 months (median, 4 months; range 1 to 27 months) to complete its oversight review. See Chapter 1, page 2 for more details.

ORI offered Rapid Response for Technical Assistance (RRTA) formally to 12 institutional officials in the 26 cases opened by ORI in 2000. Six of these officials called ORI for specific and substantial advice, from the handling of allegations and respondents and sequestration of evidence to the technical analysis of images and digits, using ORI-developed forensic techniques. In one complex clinical data case, an ORI analyst spent a week at the institution providing RRTA as requested by the institution, indexing and analyzing the questioned and related records, to strengthen the evidentiary basis for the

scientific misconduct findings proposed in the institutional investigation report. Officers from another nine institutions independently called ORI for RRTA help on their cases.

### **Misconduct Activity Increases**

A 3-year decline in research misconduct activity was reversed in 1999 as institutions reported a moderate increase in such activity in their Annual Reports on Possible Research Misconduct, which were filed with ORI in early 2000. Seventy-two institutions reported misconduct activity in 1999. Eighty-nine new allegations, which were received by 46 institutions, resulted in the opening of 63 new cases. There were 34 institutions still processing allegations made prior to 1999 and 8 institutions were responding to allegations made prior to and during 1999. The 63 new cases resulted in 51 inquiries and 9 investigations by the end of 1999. Some cases were closed following a preliminary assessment of the allegations or the allegations were received too late to begin or complete an inquiry or investigation that year.

## **RESEARCH ACTIVITIES**

### **New Research Program Launched**

Twenty-five grant applications were submitted in response to a request for applications for the Research Program on Research Integrity published on August 14, 2000, in the *NIH Guide for Grants and Contracts*. ORI committed \$500,000 in Fiscal Year (FY) 2001 to the program and requested \$1 million for FY 2002.

The research program is a collaboration between the National Institute for Neurological Disorders and Stroke (NINDS) and ORI. NINDS reviews the applications, manages the grants, and provides additional funding. The grant applications were reviewed in April 2001. Up to seven awards were expected to be made in FY 2001. The request for applications for the second round was published by NIH in May 2001. The submission deadline was set for November 19, 2001. The National Institute of Nursing Research joined the collaboration in the second year.

### **Other Research Projects Completed and Planned**

A study of institutional misconduct policies was completed in September 2000 under a contract with the Center for Health Policy Studies, and the study results were posted on the ORI web site in 2001. The Center for Health Policy Studies also is assessing the educational needs of the extramural community, and the results of that study will be used to develop a strategic plan for ORI's education program. A study of the etiology of research misconduct was initiated in 2000 to answer the questions of why researchers commit misconduct and what impact a finding of misconduct has on the career of a researcher. An analysis of medical school guidelines for the conduct of research was initiated in 2000, and will determine the topics covered by the guidelines and what behavior is recommended. ORI is also conducting a content analysis of the instructions to authors published in 41 journals to determine whether those instructions address research integrity issues. A study of the feasibility of developing consortia to assist institutions in investigating misconduct allegations was begun in 2000, with data collection expected in 2001.

### **Popular Research Conference on Research Integrity Held**

On November 18-20, 2000, ORI held its first research conference where participants discussed scholarly information on research integrity issues. The goal of the national conference was to provide a forum for scholarly discussions and to encourage more research on the sociological, psychological, educational, organizational, and cultural factors that positively or negatively influence integrity in research. Two hundred and twenty people participated in the conference and registration was stopped

several weeks before the conference because it was oversubscribed. See Chapter 2, page 10 for more details.

## EDUCATION AND PREVENTION

### Conferences on Fostering Research Integrity and Handling Misconduct Allegations

ORI also conducted three other national conferences in 2000. On March 24, 2000, ORI co-sponsored a live satellite video teleconference with the National Council of University Research Administrators on making the right moves in misconduct investigations. A conference on the roles and activities of scientific societies in promoting research integrity was held on April 10-11, 2000, co-sponsored by the American Association for the Advancement of Science (AAAS). Also co-sponsored by AAAS, a third conference on practical approaches to responding to allegations of research misconduct was held on June 4-5, 2000. A summary of the video conference and conference proceedings for the April meeting were posted on ORI's web site.

### ORI Traveling Exhibit Launched

ORI sponsored exhibits at four annual meetings of scientific societies and professional associations in 2000 to increase contact and generate a dialogue with members of the research and academic communities. Exhibits were held during meetings of the National Council of University Research Administrators in November, the Association of American Medical Colleges Group on Graduate Research Education and Training in October, the American Sociological Association in August, and the American Association for the Advancement of Science in February.

### RCR Self-Instruction Booklet Planned

A self-instruction booklet on the responsible conduct of research (RCR) for individuals supported by PHS research or research training funds is being developed with support from ORI. Besides the text, each unit will contain exercises, resources, and a test. Core topics will include: (1) data acquisition, management, sharing, and ownership, (2) mentor/trainee responsibilities, (3) publication practices and responsible authorship, (4) peer review, (5) collaborative science, (6) human subjects, (7) research involving animals, (8) research misconduct, and (9) conflict of interest and commitment.

### ORI Web Site Redesigned

Visitors to the new, redesigned ORI web site that went on-line in September 2000 should have found it easier to access the information they seek because numerous routes were built into the home page to quickly identify the location of the desired information. Eight buttons at the top of the home page access information **about ORI** including its mission, history, professional staff, and contact numbers; provide the latest **news**; allow **searches**; present a **site map**, provide **FOIA** information and permit a return to the **home** page from anywhere in the site. Five additional buttons along the left side of the page address the process for **handling misconduct**, describe **ORI programs**, list **publications** available from ORI, identify additional **resources**, and list relevant **policies/regulations/statutes**. Each button has a drop-down menu that further specifies the content of the category. In addition, the home page text provides direct links to information on more than 18 topics that frequently draw individuals to the web site. ORI's home page address is <http://ori.hhs.gov>.

### New RCR Web Site Becomes Operational

A new web site designed to assist institutions in creating or revising programs in the responsible conduct of research (RCR) went on line in November 2000. The web site focuses on resources and training in the responsible conduct of research. A background section includes an overview of the goals of RCR training,

as well as contact information for individuals and institutions relevant to various dimensions of RCR. Recommended resources include texts useful for courses in RCR, material on ethical decisionmaking, and information relevant to the practical aspects of ethics for research scientists. The training section includes descriptions of formats for training programs in RCR, links to several established courses, selected cases available for discussion on a variety of topics typically included in RCR courses, and suggestions for program evaluation. The RCR web site is located at <http://rcr.ucsd.edu>.

### **Funding Available for RCR Resources**

The development of resources for education in the responsible conduct of research (RCR) was included in the omnibus solicitation for the Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) programs that was issued in early 2001. The web site address is <http://grants.nih.gov/grants/funding/sbirsttr1/index.htm>.

### **IOM Study**

ORI has also commissioned the Institute of Medicine, part of the National Academies of Sciences, to prepare a report on the conceptual issues related to assessing integrity in research environments as a precursor to developing a longitudinal database for tracking institutional and PHS efforts to foster integrity in research. See Chapter 2, page 12 for more details.

## **ASSURANCE AND COMPLIANCE**

### **Ensuring Regulatory Compliance**

ORI processed a total of 379 institutional policies on handling allegations of scientific misconduct in 2000, closing 320 reviews and carrying 59 reviews into 2001. The closed reviews accepted 282 policies and inactivated 38 assurances because policies were not submitted. Of the 59 open reviews, 29 required institutional action before further progress could be made. For details, see Chapter 3.

### **Planning Begins for Electronic Submission of the Annual Report**

Steps were taken during the past year to develop and implement an electronic system for the submission of the *Annual Report on Possible Research Misconduct*. The electronic system was designed to allow institutions to access and update their institutional assurance record at any time during the year, and allow them to complete the annual report on-line during the reporting period. In order to test the system prior to implementation, ORI contacted 50 organizations in September 2000 and requested that they participate in testing the program. Based on the feedback from the institutions that agreed to participate, modifications were made to both the electronic program and the instructions.

## **MEETING LEGAL CHALLENGES**

### **Dr. Dreyer DAB Hearing Terminated After Settlement**

On November 15, 2000, the PHS found that Dr. Dreyer intentionally fabricated data to support his claim that Meniere's disease, a progressive disease causing irreparable hearing loss, was caused by an elevated level of the amino acid glutamate and could be treated with drugs called glutamate antagonists. Dr. Dreyer appealed the findings and proposed administrative actions to the Departmental Appeals Board. About half-way through the hearing, Dr. Dreyer agreed to a settlement in which he voluntarily excluded himself from receiving Federal funding and serving the PHS in any advisory capacity for 10 years. See Appendix A for more details.

## **Thomas Jefferson University Settles Qui Tam Case**

On June 6, 2000, in *U. S. ex rel. Yong Wu v. Jefferson Medical College*, the District Court for the Eastern District of Pennsylvania approved a global settlement agreement on a number of grant related matters, including this *qui tam* proceeding. With respect to the *qui tam* portion of the settlement, Thomas Jefferson University (TJU) agreed to return \$450,000 in NIH grant funds and to correct the scientific literature. The matter involved research data which the United States claimed was false, fabricated, or nonexistent and was used to support TJU's application for, and continued funding of, gene therapy research into the inhibition of the HIV virus. ORI and OGC staff worked closely on the case for over 2 years with the U.S. Attorney's office.

## **ORI STAFF**

### **ORI Director Appointed**

Chris B. Pascal, J.D., Acting Director, ORI, for more than 4 years, was appointed Director, ORI, by Dr. David Satcher, Assistant Secretary for Health and Surgeon General (ASH/SG) on August 14, 2000, following a national search that produced 17 candidates. Following his appointment, Mr. Pascal named Alan R. Price, Ph.D., as the Director, Division of Investigative Oversight (DIO), and Barbara Williams, Ph.D., as Deputy Director, DIO. Each held their respective positions in an acting capacity since May 1999. In addition, Mr. Pascal named Dr. Price and Lawrence J. Rhoades, Ph.D., Director, Division of Education and Integrity (DEI), as Associate Directors, ORI.

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## I. SCIENTIFIC MISCONDUCT

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For ORI, the investigative workload associated with allegations of scientific misconduct includes handling allegations, cases, and administrative closures. The ORI caseload includes oversight and review of institutional inquiries and investigations as well as the conduct of inquiries and investigations for extramural institutions under special circumstances (*e.g.*, when the institution is unable or unwilling to do the inquiry or investigation). As of this year, investigations in the Public Health Service (PHS) intramural program were conducted by the pertinent PHS operating division (*e.g.*, NIH or CDC), and any extramural allegations requiring an HHS investigation would be conducted by the HHS Office of Inspector General (OIG).

### A. Allegations

Each allegation received by ORI is assessed to determine whether it meets the criteria for opening a formal case in ORI. These criteria are:

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

ORI searches agency computer records as well as publications involving the respondent for potentially related PHS grants, fellowships, contracts, or cooperative agreements. ORI obtains the relevant grant applications and/or publications to determine whether there was a PHS source of support for the questioned research.

2. The alleged misconduct must meet the definition of scientific misconduct set forth in the PHS regulation (42 C.F.R. Part 50, Subpart A).

ORI assesses 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.”

ORI finds that many allegations involve questions of “honest differences in interpretations or judgments of data” that are specifically excluded from the PHS definition. Also, ORI finds that some “plagiarism” allegations are actually authorship or credit disputes between former collaborators, which ORI does not consider under this definition. If the allegation involves possible financial miscon-

duct, other regulatory violations, criminal acts, or civil matters (such as harassment claims), ORI refers the allegation to another appropriate Federal office or agency.

3. There is sufficient information about the alleged misconduct to proceed with an inquiry.

ORI may request that the person who initiated the allegation provide further information or documentation to ORI. However, if an allegation is made anonymously or there is not adequate information available to proceed, ORI opens a tracking file and waits to see whether additional information is forthcoming or can be requested from the complainant or other sources.

ORI's review of the information available (such as grant applications, review summary statements, or correspondence with the funding agency) may result in a simple resolution of the allegation. Some allegations are found to have arisen because of a misunderstanding or incomplete information being available to the complainant. However, substantive allegations that meet the above three criteria will lead ORI to request an institution to conduct an inquiry or for ORI to refer the allegation to the HHS Office of Inspector General (OIG).

Although typically only about 15-20 percent of the allegations received by ORI result in a formal case being opened, all the allegations received are evaluated carefully for an appropriate disposition. Many assessments require appreciable ORI staff work at this phase. In some instances, ORI requests preliminary information about a potential case from an institution.

In 2000, ORI received 173 allegations. The disposition of the allegations received by ORI are presented in Table 1 below. Allegations become active cases when the criteria outlined above are met. Some allegations are administratively closed when ORI finds that they (1) do not fall under ORI jurisdiction or meet these criteria, (2) cannot be referred to another agency, or (3) are resolved through further review and information. Other allegations are referred to other Federal agencies or offices when they involve concerns about the use of humans or animals in research, financial issues, research funded or regulated by other agencies, etc. No action is possible by ORI when an allegation does not contain sufficient specific information to permit another disposition.

Table 1: **Disposition of Allegations in ORI, 2000**

<i>Handling of allegations—outcome in ORI</i>	<i>Number of allegations</i>
Pre-Inquiry Assessment of allegation	36
No Action Possible Now or No Action	101
Referred to other Federal agencies	14
Handled by Agency (for allegations made to PHS Agency)	22
<b>TOTAL</b>	<b>173</b>

Of the 173 allegations made to ORI in 2000, 36 were assessed in detail for a potential inquiry or investigation. Of the 34 ORI assessments completed in 2000, 23 (68%) resulted in formal cases being opened in ORI. Of the 173 allegations, 14 were immediately referred to other agencies, and 101 were closed without further action. Of the 36 allegations that required a detailed assessment, 32 were resolved by ORI within 30 days (from date of file assignment to date of administrative closure or opening of a formal case; see Table 2). This data does not reflect the time taken by officials at the National Institutes of Health (NIH) who handled (with advice, assessment, and assistance from ORI as appropriate) the 22 allegations that were made directly to NIH by complainants (Table 1).

### **B. Cases Closed**

ORI closed 27 cases in 2000, including 13 inquiries and 14 inquiries/investigations. The average duration of 14.9 months for an open case was split between institutional actions (8.7 months) and ORI oversight and actions (6.2 months) (see Table 3).

The action period for the 13 institutional inquiries included their inquiry and adjudication phases, and for 13 institutional investigations included their inquiry, investigation, and adjudication phases. One additional investigation, involving a small business, was conducted by ORI in 2000, the last such investigation given HHS's new policy. Another inquiry, involving allegations against an officer of a small business, was conducted for ORI by agreement with another local research institution that had affiliations with local small research businesses.

The action period for ORI oversight includes a detailed review of each institution's inquiry and/or investigation. ORI often makes requests to the institution for more information and analysis, or for explanation by the officials of the basis for their decision on whether misconduct occurred. Additional ORI analysis often is

Table 2: **Time for Conduct by ORI of Pre-inquiry Assessments, 2000 (N=36)**

<i>Outcome of ORI assessment</i>	<i>Number of allegations</i>	<i>Total days for resolution</i>	<i>Distribution of resolution times (days)</i>			
			<i>Mean</i>	<i>Median</i>	<i>Mode</i>	<i>Range</i>
Opened formal case	23	374	16.2	3	8	2 - 112
Administratively closed	11	172	15.6	8	1	1 - 50
Unresolved at end of year 2000	2	27	13.5	–	–	–
<b>TOTAL</b>	<b>36</b>	<b>573</b>	<b>15.9</b>	<b>–</b>	<b>–</b>	<b>–</b>

Table 3: **Duration of Research Misconduct Cases Closed, 2000 (N=27)**

<i>Site of action</i>	<i>Distribution of resolution times (months)</i>			
	<i>Mean</i>	<i>Median</i>	<i>Mode</i>	<i>Range</i>
Institution	8.7	4	2	1 - 41
ORI	6.2	4	3	1 - 27
<b>TOTAL</b> (Inst. & ORI)	<b>14.9</b>	<b>10</b>	<b>10</b>	<b>2 - 54</b>

Table 4: **ORI Scientific Misconduct Caseload by Case Type, 2000**

<i>Case type</i>	<i>Forwarded From 1999</i>	<i>Opened in 2000</i>	<i>Closed in 2000 into 2001</i>	<i>Carried</i>
Institutional inquiries	12	8	13	7
Institutional investigations	19	18	13	24
ORI inquiries	0	0	0	0

required to make a PHS finding of misconduct. In some cases, the period includes a hearing requested by the respondent before the Departmental Appeals Board (DAB).

One case closed in 2000 went to a DAB hearing. The ORI and DAB process took 27 months from the date of the institutional decision. Although the DAB hearing was initiated, the case was not decided by the DAB because the respondent and ORI agreed on a voluntary exclusion, which included debarment of the respondent, prohibition from him serving on PHS advisory boards, and prohibition from him being a mentor, all for a period of 10 years (see case summary in Appendix A).

In 2000, 7 of the 14 investigation cases closed by ORI resulted in sustained findings of scientific misconduct and/or PHS administrative actions against the respondent. Summaries of these cases may be found in Appendix A. Summaries of the seven investigations closed by ORI that did not result in findings of scientific misconduct may be found in Appendix B. At the end of calendar year 2000, ORI had 31 active formal cases, as well as 2 allegations, under review.

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

*Institutional inquiries:* Under the PHS regulation, institutions are not routinely required to report the conduct of inquiries to ORI unless they result in investigations. However, 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. Some institutions routinely submit inquiry reports to ORI and, in some cases, these reports are equivalent to reports of investigations, making findings. ORI reviews these reports to determine whether the conduct of the inquiry complied with the PHS regulation and was timely, thorough, competent, and objective.

During 2000, ORI accepted 13 institutional inquiry reports that did not recommend further investigation. Seven cases involved allegations of falsification, three dealt with alleged fabrication and falsification, one considered alleged fabrication, one involved allegations of falsification and plagiarism, and one had alleged plagiarism. ORI carried five such institutional inquiries into 2001, including two PHS intramural cases opened in 2000.

Table 5: **Outcome of Research Misconduct Cases Closed by ORI, 2000 (N=27)**

Case Type	Outcome of Case				Total
	No Investigation	Misconduct Misconduct Admin. Actions*	Admin. Finding/	Closed	
Institutional Inquiry	12	-	-	1	13
Institutional Investigation	-	6	6	1	13
ORI Investigation	-	-	1	-	1
<b>TOTAL</b>	12	6	7	2	27

\*Includes cases resolved through negotiations where administrative actions were imposed without a PHS finding of scientific misconduct.

*Institutional investigations:* Institutions are required by the PHS regulation to report to ORI at the initiation of an investigation and to submit a report to ORI upon completion of the investigation. ORI reviews the reports to determine whether the conduct of the investigation complied with the PHS regulation, was timely, thorough, competent, and objective, and provided a reasonable basis for a PHS finding of misconduct. In 2000, ORI continued to monitor 13 investigations at research institutions. During the year, 18 new institutional investigations were opened, and 13 investigations were closed. There were 24 active investigations carried into 2001.

*ORI inquiries:* Previously, ORI conducted inquiries at extramural institutions if ORI determined that there was a need to so, e.g., a case involving a multi-center clinical trial or a small business. There were no ORI inquiries opened in 2000, given a new HHS policy that Federal investigations should be done by the HHS OIG, which has subpoena power.

*ORI investigations:* One ORI investigation, initiated in 1999, was closed in 2000 with a finding of scientific misconduct for plagiarism. The case involved plagiarism from Internet sources for a grant application from a small business, which could not conduct the investigation itself, given the unavoidable conflicts of interest of its officers.

**C. Administrative Closures**

A formal ORI case file may be administratively closed when ORI later concludes that no PHS funds or applications were actually involved, that continuing effort will not produce sufficient evidence to resolve a case satisfactorily, or that after additional review, ORI determines that the allegation did not fall under the PHS definition of

scientific misconduct nor warrants further action. There were two cases, one institutional inquiry and one institutional investigation, included in the data above that were administratively closed by ORI in 2000.

**D. Types of Allegations Involved**

During 2000, of the 13 closed inquiries and 14 closed investigations, 11 inquiries and 12 investigations involved allegations of falsification, fabrication, or both. Of those 23 cases, 6 cases resulted in ORI findings and/or administrative actions. Four cases involved plagiarism, two of which also involved falsification. Of these four, one led to ORI findings and administrative actions. (See Table 6).

Table 6: **Types of Allegations Involved in Closed Inquiries and Investigations and Their Outcomes**

Allegation	Inquiry	Investigation	ORI Findings or PHS Administrative Actions
Fabrication	1	2	1
Falsification	7	8	4
Plagiarism	1	1	0
Fab/Fals	3	2	1
Fab/Plag	0	0	0
Fals/Plag	1	1	1
<b>TOTAL</b>	13	14	7

## E. PHS Administrative Actions Imposed

A range of administrative actions are used by the PHS to protect the public fisc and the integrity of PHS-funded research. Persons may be debarred or voluntarily exclude themselves from grants, contracts, and cooperative agreements for several reasons, including a criminal conviction, fraud, or serious scientific misconduct. Once debarred or excluded, a person may not receive this assistance from the Federal Government for a set period of time.

In 2000, five persons were debarred or voluntarily excluded. Other administrative actions imposed on respondents in 7 scientific misconduct cases closed in 2000 included the following: (a) prohibition from serving in any advisory capacity to PHS, including service on a PHS advisory committees, boards, and/or peer review committees or as a consultant for a specified period of time [6 persons]; (b) participation in any PHS-funded research is subject to supervision requirements for a specified period of time, where the institution is required to submit a plan of supervision that will ensure the scientific integrity of the individual's research contribution [2 persons]; (c) the respondent must submit with each application or report a statement of certification, endorsed by an institutional official, that all contributors to an application or report are properly cited or otherwise acknowledged (not plagiarized) [1 person]; and (d) agreement to not serve as a mentor to any graduate student, fellow, or other individual who applies for or receives PHS funding [1 person]. (See Table 7.)

## F. Policy Issues and Regulations

In 2000, the Assistant Secretary for Health decided that allegations of scientific misconduct received by PHS agencies should be referred by the agencies to the extramural institutions for inquiry and reporting to ORI. This change was considered by PHS to be consistent with the decisions of the HHS Review Group on Research Misconduct and Research Integrity, which assigned to the PHS agencies authority for handling allegations of misconduct in the intramural programs, subject to ORI oversight. ORI continues to handle the great majority of allegations which come directly to ORI, provides oversight for any allegations referred by PHS agencies to the institutions, and confers with the agency on all cases prior to agency referral.

### *Proposed Regulation*

On November 28, 2000, the Department published a Notice of Proposed Rulemaking (NPRM) to implement Section 493(e) of the PHS Act, which required the Sec-

Table 7: **PHS Administrative Actions Imposed in Closed Investigations**

<i>PHS Administrative Actions</i>	<i>Duration</i>	<i>Number of Such Actions</i>
Debarment	2 years	1
	3 years	1
	5 years	2
	10 years	1
Prohibited from Serving as an Advisor to PHS	2 years	1
	13 years	3
	5 years	1
	10 years	1
Supervision Plan Required	1 year	1
	3 years	1
Certification of Research Required	3 years	1
Mentoring of Students Prohibited	10 years	1

retary to establish regulatory standards for preventing and responding to occurrences of retaliation taken against whistleblowers by entities which have a research misconduct assurance and by those entities' officials and agents. Under the NPRM, the entities, their officials and agents would be prohibited from retaliating against an employee with respect to the terms and conditions of employment when the employee has in good faith (1) made an allegation that the entity or its officials or agents, has engaged in, or failed to respond adequately to an allegation of research misconduct, or (2) cooperated with an investigation of such an allegation. The NPRM is at 65 Fed. Reg. 70830 (2000) and is available on ORI's web site. The NPRM requested comments by January 29, 2001.

### *Policy Guidance*

To help provide guidance to individuals and institutional officials responsible for handling misconduct allegations, significant issues raised during ORI's oversight of institutional investigations are discussed and ORI's position explained in occasional articles in ORI's quarterly newsletter.

Two such issues were published in the *ORI Newsletter* during 2000, and are reprinted below. A compilation of ORI's position on other significant issues

may be found at [http://ori.dhhs.gov/html/misconduct/inquiry\\_issues.asp](http://ori.dhhs.gov/html/misconduct/inquiry_issues.asp)

### 1. PHS Funding Jurisdiction in Scientific Misconduct Cases Explained

An important preliminary issue in scientific misconduct cases is whether there is Public Health Service (PHS) funding jurisdiction that would allow ORI to exercise its oversight responsibilities. While there are many possible funding and misconduct scenarios, the general principles discussed below may provide valuable guidance for institutions and individuals alike.

The PHS Act gives ORI oversight responsibility for anyone applying for financial assistance (*i.e.*, a grant, contract, or cooperative agreement) from the PHS for any biomedical or behavioral research program. Although in most cases the PHS funding agency is the National Institutes of Health, it may be any of the seven PHS agencies (*e.g.*, the Centers for Disease Control and Prevention). Under the PHS scientific misconduct regulations, ORI's authority extends to "allegations of misconduct in science in connection with PHS-sponsored biomedical and behavioral research" as well as to "alleged or apparent misconduct involving research or research training, applications for support of research or research training, or related research activities that are supported with funds made available under the PHS Act." 42 C.F.R. §§ 50.101(a) and 50.103(a)(1).

The following are examples of situations where ORI would have jurisdiction in a misconduct case:

- Research funded by PHS grants, contracts, and cooperative agreements.
- Applications for PHS-funded grants, whether or not the grants are funded.
- Applications for PHS-funded grants that are withdrawn either before or after funding.
- Research data submitted in progress or final reports on funded grants.
- Materials submitted by a respondent during an inquiry or investigation that are falsified or fabricated even if no scientific misconduct is ultimately found in the underlying research.
- Research not conducted with PHS funds if the data from that research are then used in or referenced in

PHS-related grant applications or progress or final reports.

- Research data included in publications that cite PHS support.

Another closely related issue is who makes the decision on PHS funding jurisdiction. Initially, the institution has the responsibility to make an independent determination of PHS funding jurisdiction that does not rely solely on the representations of either the respondent or the complainant. While complainants are often in a good position to provide helpful information to the institution regarding the existence of PHS funding, and should always make an effort to assist in the determination, they are not required to prove this issue. However, a respondent who affirmatively claims that the subject matter of the alleged scientific misconduct does not involve any PHS funding should be required to establish this claim.

An institution's decision regarding PHS jurisdiction, however, is not determinative of the issue nor is it binding on ORI. As part of ORI's responsibility for determining whether an institution is complying with its assurance, ORI may request, and the institution is obligated to provide, reasonable evidence that PHS funding jurisdiction is or is not involved in any particular case. ORI is authorized to and does review the institution's conclusion regarding the involvement of PHS support.

Any party or institution with questions about a PHS funding issue may contact ORI's Division of Investigative Oversight for further assistance. From *ORI Newsletter*, Vol. 8, No. 3, p. 3.

- Inquiry Versus Investigation Stages in Scientific Misconduct Cases

When examining allegations of scientific misconduct, institutions have an obligation to conduct an initial inquiry, and, if warranted, a thorough investigation in accordance with Public Health Service (PHS) standards. 42 C.F.R. Part 50, Subpart A. This article discusses some procedural and substantive considerations in examining allegations of scientific misconduct in inquiries and investigations.

After receiving a good faith allegation of scientific misconduct, an institution will usually open an inquiry to gather general information and make initial findings of fact to determine whether the allegation has substance and there is sufficient evidence to warrant an investigation. Sometimes, however, when there is sufficient evidence already at hand, for example as the result of an

audit of a clinical trial, the institution may move directly to the investigation stage. If the inquiry uncovers evidence of “fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community,” the institution should move quickly to a full investigation. See 42 C.F.R. § 50.102. In general, absent full admissions, inquiries should not be used to make findings on whether scientific misconduct itself has occurred.

On occasion, ORI receives an inquiry report in which either the committee has conducted the equivalent of an investigation and made specific findings or which is obviously the result of a negotiated agreement. These reports may violate the PHS regulation and cause substantial difficulties for ORI’s oversight. Findings made at the inquiry stage are all too frequently incomplete because the record has not been fully developed, and negotiated agreements violate the PHS regulation, if made without ORI’s advance approval. Both instances may deprive ORI of the facts necessary to determine whether there has been an adverse effect on the PHS sponsored research, and the institution may need to reopen its case and initiate an investigation.

Instead of short circuiting the process, once an institution has determined that there is some evidence of possible misconduct, a thorough investigation should be conducted to analyze “all documentation, including but not necessarily limited to relevant research data and proposals, publications, correspondence, and memoranda of telephone calls.” 42 C.F.R. § 50.103. Only after this process is complete should the investigation committee turn to an analysis of whether the charges meet the burden of proof under the PHS definition of scientific misconduct.

Even if the record is relatively complete at the inquiry stage, the PHS regulation normally gives respondents the opportunity to have a full investigation before any findings are made against them. Most institutional policies have this same requirement. This multiple stage process has also been endorsed by the Federal Office of Science and Technology Policy which has stated that the investigation is “the formal examination and evaluation of the relevant facts leading either to dismissal of the case or a recommendation for a finding of research misconduct.” Proposed Federal Policy on Research Misconduct To Protect the Integrity of the Research Record, 64 Fed. Reg. 55722, 55724 (Oct. 14, 1999). From *ORI Newsletter*, Vol. 8, No. 4, p. 5.

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## II. EDUCATION AND PREVENTION

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ORI's education and prevention activities dramatically expanded in 2000. Noteworthy actions and achievements included:

- Conducted 4 national conferences, a meeting of the Federal Research Misconduct Officials Network, and monthly meetings of Agency Research Integrity Liason Officers (ARILOs), involving a total of 2,000 participants. Conference summaries or proceedings were issued or planned for three of the national conferences.
  - Launched the redesigned ORI web site.
  - Launched a new web site providing resources for instruction in the responsible conduct of research.
  - Commissioned the Institute of Medicine to prepare a report on the conceptual issues related to assessing integrity in research environments as a precursor to the development of a longitudinal database for tracking institutional and PHS efforts to foster integrity in research.
  - Contracted with the American Institutes for Research of Washington, DC, to evaluate the measures that are being utilized to prevent misconduct and promote research integrity in the biomedical research laboratory.
  - Continued development of a research program focusing on key elements of research integrity and misconduct in science. A study of institutional misconduct policies was completed in September 2000.
- Collaborated with NIH to develop a grant program
- to develop resources for education in the responsible conduct of research.
  - Sponsored exhibits at four annual meetings of scientific societies and professional associations.
  - Created a new technical assistance program to assist institutions in developing high quality and well-documented investigation reports and to help resolve scientific misconduct cases promptly.
  - Gave 43 presentations at conferences, workshops, or meetings and published 8 articles.

## A. Conference and Workshop Program

ORI conducted four national conferences in 2000. All of these conferences were co-sponsored with professional associations or scientific societies.

### *“Making the Right Moves in Handling Misconduct Allegations”*

A live satellite video teleconference was broadcast to 88 locations in the U.S. on March 24, 2000. Co-sponsored by the National Council of University Research Administrators, the 4.5 hour broadcast had an estimated audience participation of 1,500 research administrators and faculty in universities, research centers, and hospitals. Topics included defining research misconduct, reviewing the process of handling allegations, gathering evidence, conducting a preliminary inquiry, and details and results of the investigation process. This was the first time ORI used teleconferencing as a communication technique, and feedback was overwhelmingly positive. ORI staff also drafted a summary of the teleconference presentations and posted the summary on ORI’s web site.

### *“The Role and Activities of Scientific Societies in Promoting Research Integrity”*

On April 10-11, 2000, ORI co-sponsored a conference on the role and activities of scientific societies in promoting research integrity in Washington, DC, in collaboration with the American Association for the Advancement of Science (AAAS). The conference drew 90 participants. A conference summary was issued in July, which encouraged societies to develop better standards of practice, to publicize their codes of conduct, and to use annual meetings to educate members about the responsible conduct of research. The summary may be found on ORI’s web site.

### *“Practicum on Responding to Allegations of Research Misconduct”*

On June 4-5, 2000, ORI co-sponsored a practicum on responding to allegations of misconduct in St. Charles, IL, with the AAAS. Ninety participants took part in lively discussions that emphasized practical approaches and included discussion of a mock case.

### *“Research on Research Integrity Conference”*

On November 18-20, 2000, ORI held its first research conference where participants discussed scholarly information on research integrity issues. The goal of the conference was to provide a forum for scholarly debate and to encourage more research on the sociological, psychological, edu-

cational, organizational, and cultural factors that positively or negatively influence integrity in research. Over 200 researchers, administrators, and policymakers attended the conference in Bethesda, MD, and registration had to be stopped several weeks before the conference because it was oversubscribed. About 85 abstracts were submitted and nearly 70 persons presented during plenary, concurrent, and poster sessions. A half-day grant writing workshop immediately followed the conference. The conference was co-sponsored by AAAS, the Association of American Medical Colleges, NIH and the National Science Foundation. Conference materials, including abstracts, a review of the literature, and bibliography were available on the ORI web site after the conference. Many of the papers presented at this conference will be published in conference proceedings in 2001.

## B. Publications

ORI distributed a new publication on *Managing Allegations of Scientific Misconduct: A Guidance Document for Editors* in February 2000 to 1,200 members of the Council of Science Editors, an international organization of editors and other individuals involved in journal and other academic publications. The document also was sent to scientific societies, professional organizations, and institutional associations. The publication provides guidance for journal editors and their staffs on reporting manuscripts where misconduct is suspected, facilitating the investigation of misconduct allegations, improving correction of the literature, and promoting research integrity. Copies are available upon request or from ORI’s web site.

ORI published its Annual Report for calendar year 1999 in August 2000 and distributed it to all institutions, except small businesses, that have an assurance on file with ORI, as well as to professional and scientific societies, the media, the network of Federal misconduct officials, PHS research integrity officers, and included it in the Quarterly Report to the Secretary for the third quarter. The annual report contained a listing of significant accomplishments, summaries of closed investigations, summaries of scientific misconduct related litigation, compliance review case summaries, and descriptions of ORI educational activities. Information in the report may be used in courses and seminars on the responsible conduct of research. The report is available on the ORI web site.

ORI published 4 issues of the *ORI Newsletter* in 2000, including a 12-page edition in September 2000. Major articles in 2000 covered ORI’s new rapid response for technical assistance program, additional scientific eth-

ics training being required by the Centers for Disease Control and the Agency for Toxic Substances and Disease Registry, ORI's increased emphasis on education and prevention of misconduct, announcement of a new web site resource for instruction in the responsible conduct of research (RCR), development of a proposed regulation for the protection of whistleblowers, the availability of a new grant program to conduct research on research integrity, and settlement of the Dreyer case.

Sigma Xi, The Scientific Research Society, published a 75-page proceedings document on the workshop on "Ethical Challenges and Practical Solutions for Managers in Research" which was held on September 10, 1999, in Albuquerque, NM, and co-sponsored by ORI. Research managers from academia and national laboratories made presentations. ORI staff members presented "ORI Views on Building a System of Research Integrity" and chaired a panel discussion on "Institutional and Government Interactions." The availability of this publication was announced in the *ORI Newsletter* and on the ORI web site.

A self-instruction booklet on the responsible conduct of research (RCR) for individuals supported by PHS research or research training funds is being developed with support from ORI. Besides the text, each unit will contain exercises, resources, and a test. Core topics will include: (1) data acquisition, management, sharing, and ownership, (2) mentor/trainee responsibilities, (3) publication practices and responsible authorship, (4) peer review, (5) collaborative science, (6) human subjects, (7) research involving animals, (8) research misconduct, and (9) conflict of interest and commitment.

### C. Web Sites

#### *ORI Web Site*

The completely redesigned ORI web site [<http://ori.hhs.gov>] went on-line in September 2000. The refurbished site is more attractive and features additional information, better organization, and improved navigation. Numerous routes have been built into the site to help users quickly identify the location of the desired information.

Eight buttons at the top of the home page access information **about ORI** including its mission, history, professional staff, and **contact** numbers; provide the latest **news**; allow **searches**; furnish a **site map**, provide information about the HHS **privacy**

policy; link to instructions for requesting information under **FOIA** (Freedom of Information Act); and permit a return to the **home** page from anywhere in the site.

Five additional buttons along the left side of the page address the process for **handling misconduct**, describe **ORI programs**, list **publications** available from ORI, identify additional **resources**, and provide links to relevant **policies, regulations, and statutes**. Each side button has a drop down menu that further specify the content of the category. Two other features: "Breaking News" and "Featured Attraction" highlight significant developments. In addition, the home page provides "Quick Links" to information on 25 topics that frequently draw individuals to the web site.

#### *RCR Web Site*

A new web site, "Online Resource for RCR Instruction," went on-line on November 1, 2000, and provides resources for instruction in the responsible conduct of research (RCR). The web site, developed with support from ORI, is hosted by the University of California-San Diego, and is located at <http://rcr.ucsd.edu>.

The web site contains five main sections: (1) Goals: Goals for Responsible Conduct of Research Instruction; (2) Content: Suggested RCR topics, with descriptions and reading lists; (3) Formats: Descriptions and examples of formats for RCR instruction; (4) Tools: Texts, cases and contacts suggested for use by RCR instructors; and (5) Evaluation: An overview and examples of ways to evaluate and possibly improve the quality of RCR instruction.

### D. Education in the Responsible Conduct of Research (RCR)

Implementation of the PHS Policy on Instruction in the Responsible Conduct of Research (RCR), announced on December 1, 2000, was suspended in February 2001 to permit review of the substance of the policy and the process followed in its adoption in response to a congressional inquiry that questioned whether the requirement should have been processed as a proposed regulation rather than a policy. A *Federal Register* notice published on February 21, 2001, stated that "[p]ending completion of that review, institutions that might otherwise be subject to the RCR policy are under no obligation to implement the policy unless further public notice is issued in the *Federal Register*. Any future PHS action taken to implement

the RCR policy would provide extended implementation time frames that take into consideration this suspension.” The letter from Representatives W.J. “Billy” Tauzin and James Greenwood, the response by Chris Pascal, Director of ORI, and the *Federal Register* notice may be found ORI’s web site at [http://ori.dhhs.gov/html/programs/rcr\\_requirements.asp](http://ori.dhhs.gov/html/programs/rcr_requirements.asp).

The development of resources for education in the responsible conduct of research (RCR) was included in the omnibus solicitation for the Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) programs that was issued in early 2001. The SBIR program is only open to small businesses. The STTR allows collaboration between a small business and an academic institution. Resources produced through these grants must be sold. The web site address is <http://grants.nih.gov/grants/funding/sbirsttr1/index.htm>.

## **E. Research Program**

### *Research on Research Integrity*

A Request for Applications for the Research Program on Research Integrity was published on August 14, 2000, in the *NIH Guide for Grants and Contracts*. Twenty-five grant applications were submitted to the Research on Research Integrity Program by the December 15, 2000, deadline. The total funding requested for the applications exceeded \$5 million. Another request for applications was expected to be issued in early 2001 to solicit a second round of grant applications. ORI committed \$500,000 in FY 2001 to the program and requested \$1 million for the program in FY 2002. Three to five grants may be funded each year. Applicants may request up to a 2-year project period and direct costs up to \$100,000 per year.

### *Assessing Integrity in Research Environments*

ORI commissioned the Institute of Medicine (IOM) to prepare a report on the conceptual issues related to assessing integrity in research environments as a precursor to the development of a longitudinal database for tracking institutional and PHS efforts to foster integrity in research. The report will address the following conceptual problems associated with assessing integrity in research environments: (1) define the concept “research environment”, (2) define the concept “research integrity”, (3) identify elements of the research environment, (4) distinguish between elements that promote research integrity and those that do not, (5) stipulate the unit(s) of analysis; (6) indicate how the elements may be mea-

sured; (7) suggest appropriate methodology for collecting the data; and (8) cite appropriate outcome measures. Development of a longitudinal database that tracks the state of integrity in research environments requires these conceptual problems to be solved. To prepare the report, IOM will review the literature, appoint a study committee, commission scholarly papers, and solicit comments from the research community. The study is expected to be completed in early 2002.

### *Survey of Research Integrity Measures Utilized in Biomedical Research Laboratories*

ORI contracted with the American Institutes for Research of Washington, DC, to evaluate the measures that are being utilized to prevent misconduct and promote research integrity in the biomedical research laboratory. The study population will be 5,000 randomly chosen principal investigators who have received support from the Public Health Service for the conduct of biomedical or behavioral research. A self-administered questionnaire will request information on the research integrity measures utilized in the laboratory such as guidelines for the conduct of research, standards for recording and retaining data, the review of raw data and notebooks, regular presentations in the laboratory of ongoing research, the ratio of mentors to mentees, guidelines for authorship and collaborative research, publication practices, and clearance procedures for abstracts, presentations, manuscripts and proposals. In addition, data will be collected on characteristics of the institutional setting, the laboratory, and the principal investigator. The data will be analyzed to determine (1) the extent to which research integrity measures are utilized in the laboratories, (2) which research measures are used, and (3) the characteristics of the institution, laboratory, and principal investigator that may affect their use.

### *Study of Institutional Misconduct Policies*

The Analysis of Institutional Policies for Responding to Allegations of Scientific Misconduct was completed on September 29, 2000, under a contract with the Center for Health Policy Studies of Columbia, MD. This content analysis of 156 institutional policies for responding to allegations of scientific misconduct reveals the range of approaches institutions have taken to the 18 issues that are generally addressed in such policies. The analysis indicates the range and frequency of options employed in providing guidance on each issue. Best practices are also cited for each issue. ORI plans to use the study results in the development of a web-based module designed to assist institutions to make their policies more effective. Results were posted on the ORI web site in

2001 at <http://ori.dhhs.gov/html/publications/polantitle.htm>.

#### *Other Research Projects*

ORI intends to expand its educational efforts related to the promotion of research integrity, the responsible conduct of research, and the prevention of research misconduct. To help in planning this expansion, the Center for Health Policy Studies of Columbia, MD, is assessing the educational needs of the extramural research community to see how those needs may be addressed through conferences, publications, the ORI web site, CD-ROM, web-based courses, and so on. The needs assessment is utilizing focus groups and a survey, and the results will be used to develop a strategic plan for the educational program.

An ORI-sponsored study being conducted by Justice Research and Advocacy, Inc., of Columbus, OH, about the etiology and stigma of research misconduct is addressing two questions: Why do researchers commit misconduct? What impact does a finding of misconduct have on the career of a researcher? The study population includes more than 100 researchers or research personnel against whom the PHS has made a finding of scientific misconduct since 1992. Results of the study will be submitted to refereed journals for publication and will be used in the ORI education program. This study complements the previous ORI study on the effect of misconduct allegations on exonerated respondents.

R.O.W. Sciences, Inc., of Rockville, MD, has a contract with ORI to analyze the guidelines on the conduct of research from 98 of the 125 medical schools in this country. This study will determine what topics are covered by the guidelines, and what behavior is recommended by the guidelines. Following completion of the study, ORI intends to hold a conference to discuss the study results. Data collection ended on December 8, 2000, and the study should be completed in 2001.

ORI is conducting a content analysis of the instructions to authors published in 41 journals that have published articles involved in scientific misconduct cases to determine whether those instructions address research integrity issues. Among the issues to be included in the analysis are the referral of suspect manuscripts for possible misconduct assessment, authorship, conflicts of interest, access to data, and retractions/corrections. Preliminary results were presented during the Research Conference on Research Integrity held on November 18-19, 2000. The final report will be in the conference proceedings.

An ORI-sponsored study on the feasibility of organizing an institutional investigation assistance program stemmed from a recommendation of the HHS Review Group on Research Misconduct and Research Integrity which stated that "HHS should encourage the development of consortium-based approaches to be used by awardee institutions that do not have the capacity to conduct the fact-finding process, or at which there is otherwise inadequate institutional or organizational capacity." By the end of 2000, R.O.W. Sciences, Inc., of Rockville, MD, had revised the study design, developed and tested the questionnaire, and had constructed the analytical framework, database structure, and dummy tables.

#### **F. Educational Networks**

##### *PHS Research Integrity Officers Network*

The PHS Research Integrity Officers Network had its busiest year in 2000, especially the Agency Research Integrity Liaison Officers (ARILOs) component. The ARILOs met monthly at ORI to develop the PHS policy on instruction in the responsible conduct of research that was announced on December 6, 2000. Membership in the network became more important this year as agencies can now respond directly to allegations they receive (in coordination with ORI). Network members were alerted to significant upcoming events, such as the publication of the Notice of Proposed Rule Making on the protection of whistleblowers and the new Federal Policy on Research Misconduct. Network members were asked to comment on proposed research projects, and new members were invited to orientation sessions at ORI.

##### *Federal Research Misconduct Officials Network*

The Federal Research Misconduct Officials Network held a meeting on February 1, 2001, to discuss the implementation of the Federal Policy on Research Misconduct. Some 41 representatives from about 18 agencies discussed their research misconduct policies and problems during a meeting held on April 28, 2000. During the year, network members have been informed about significant events and sent ORI publications. Network membership was posted on the ORI web site to assist individuals in channeling their concerns and allegations to other agencies.

### *Collaborations with Professional Associations and Scientific Societies*

ORI sponsored exhibits at four annual meetings of scientific societies and professional associations in 2000 to increase contact and generate a dialogue with members of the research and academic communities. Exhibits were held during meetings of the National Council of University Research Administrators in November, the Association of American Medical Colleges Group on Graduate Research Education and Training in October, the American Sociological Association in August, and AAAS in February. ORI staff made several presentations at meetings of these organizations.

### **G. Rapid Response for Technical Assistance Program (RRTA)**

ORI created in 1999-2000 a Rapid Response for Technical Assistance (RRTA) program to provide aid to institutions conducting allegation assessments, inquiries, and investigations. RRTA from ORI includes: (1) rapidly reviewing institutional procedures to identify problem areas; (2) advising or assisting in sequestration and inventory of physical or computer evidence; (3) advising on case strategy, including legal issues; (4) outlining specific PHS issues; (5) providing PHS grant applications; (6) assisting with sophisticated analytical techniques for image comparisons and statistical or digit analyses of data to prove falsification or fabrication; (7) suggesting collateral evidence to confirm or refute questioned claims; (8) advising on "missing" records; (9) assisting in locating experts; (10) developing strategies to prevent incomplete or withdrawn "admissions;" (11) informing other Federal agencies; (12) notifying or requesting help from other institutions; (13) advising on potential whistleblower and confidentiality issues; (14) helping with contacts to national databases (such as Genbank); and (15) assisting with journals on papers that require correction or retraction.

Among the 26 new cases opened in 2000, the Division of Investigative Oversight (DIO), ORI, made 12 RRTA offers to institutions, and 6 officials called DIO for substantive advice. Officials from 9 other institutions independently asked DIO for assistance; 3 others called ORI about allegations outside of PHS jurisdiction, knowing of DIO's extensive experience in handling over 2,000 allegations.

In three of these cases, ORI provided RRTA on-site at the institution. In the first, a DIO scientist met with officials and the committee at its formative stage, pro-

viding strategic planning advice on sequestering and analyzing records. In the second, ORI scientists and counsel provided direct assistance with the institution's notification of the respondent and sequestration of research records from an office and home. In the third, an official requested a DIO analyst to spend a week at the institution, indexing and documenting the questioned records from the investigation and identifying additional relevant records, and another DIO analyst searched for subjects in national databases, to provide evidence on the alleged fabrication of interview records, both substantially strengthening the institution's findings.

ORI intends for its RRTA program to facilitate institutional efforts to obtain high quality and well-documented investigation reports and to help resolve scientific misconduct cases promptly. Challenging problems include voluminous or missing evidence, multi-center clinical sites, and premature or incomplete "admissions." ORI staff will provide such RRTA help (phone DIO at 301-443-5330) over the telephone or on-site.

### **H. Presentations**

**John Dahlberg, Investigator-Scientist, DIO, and John Krueger, Investigator-Scientist, DIO** moderated a breakout session on investigative methods at the AAAS-ORI Meeting, "Responding to Allegations of Research Misconduct, Inquiry, Investigation, and Outcomes: A Practicum" in St. Charles, IL, on June 5, 2000.

**Alicia Dustira, Deputy Director, DEI**, gave a presentation on "Applying the Federal Definitions of Misconduct: More Changes in HHS Policies and Regulations" as part of a live video satellite conference co-sponsored by ORI and the National Council of University Research Administrators (NCURA) entitled "Making the Right Moves in Handling Misconduct Allegations," broadcast from Washington, DC, on March 24, 2000.

**Alicia Dustira, Deputy Director, DEI**, moderated a session on "Establishing Institutional Policies and Procedures for Research Misconduct" at the AAAS-ORI Meeting, "Responding to Allegations of Research Misconduct, Inquiry, Investigation, and Outcomes: A Practicum" in St. Charles, IL, on June 4, 2000.

**Alicia Dustira, Deputy Director, DEI**, moderated a session on "Research Integrity as an International Concern" at ORI's "Research Conference on Research Integrity," in Bethesda, MD, on November 20, 2000.

**Caroline Elmendorf, Chief Counsel, RIB, OGC**, gave a presentation on “Scientific Misconduct Investigations and the Federal Oversight Perspective” at the AAAS-ORI Meeting, “Responding to Allegations of Research Misconduct, Inquiry, Investigation, and Outcomes: A Practicum” in St. Charles, IL, on June 5, 2000.

**Caroline Elmendorf, Chief Counsel, RIB, OGC**, participated on a panel discussion during a video teleconference co-sponsored by ORI and NCURA entitled “Making the Right Moves in Handling Research Misconduct Investigations,” broadcast from Washington, DC, on March 24, 2000.

**Kay Fields, Scientist Investigator, DIO**, gave a talk on May 10, 2000, at Temple University Graduate School entitled “Plagiarism and Intellectual Property Interests of Scientists: What’s New? The ORI Perspective.”

**Gail Gibbons, Deputy Chief Counsel, RIB, OGC**, gave a talk on “Scientific Integrity and the National Institutes of Health Policy Updates and Whistle Blowing Issues,” on May 9, 2000, at the Ohio State University Health Sciences Center.

**Gail Gibbons, Deputy Chief Counsel, RIB, OGC**, gave a presentation entitled “Update on Revision of Suspension and Debarment Regulation,” July 20, 2000, for the Executive Committee on Grants Administration Policy, HHH Bldg., in Washington, DC.

**Gail Gibbons, Deputy Chief Counsel, RIB, OGC**, gave a presentation entitled “How to Prevent Things From Going Wrong and What to Do When They Do” at a conference on “University Research Activities: Compliance, Partnering, and Intellectual Property” sponsored by the National Association of College and University Attorneys, in cooperation with the NCURA in Baltimore, MD, on November 2, 2000.

**John Krueger, Scientist Investigator, DIO**, gave a presentation on “Images as Evidence: Forensic Examination of Scientific Images,” at the ORI sponsored “Research Conference on Research Integrity,” in Bethesda, MD, on November 20, 2000.

**Samuel Merrill, Jr., Scientist Investigator, DIO**, gave a presentation at Howard University School of Medicine for their “Neuroscience Seminar Series” entitled “Ethnics in Biomedical Research.” in Washington, DC, on May 2, 2000.

**Samuel Merrill, Jr., Scientist Investigator, DIO**, gave a presentation at the 7th Annual National Sponsored Programs Administrators Alliance of Historical Black Colleges and Universities (HBCUs) on ORI investigative oversight activities in Arlington, VA, on June 9, 2000.

**Samuel Merrill, Jr., Scientist Investigator, DIO**, participated in a panel discussion for the Minority Neuroscience Fellowship Program, National Institute of Mental Health, entitled “Bioethnics in Scientific Research,” held for the Society for Neuroscience, New Orleans, LA, on November 6, 2000.

**Samuel Merrill, Jr., Investigator-Scientist, DIO**, made a presentation at the Eastern Cooperative Oncology Group (ECOG), Clinical Research Associate (CRA) Education Symposium entitled, “Scientific Misconduct: Allegations and Consequences; Research Integrity Initiatives” in Miami, FL, on November 18, 2000.

**Samuel Merrill, Jr., Investigator-Scientist, DIO**, made a presentation at the ECOG, CRA CORE Committee entitled, “Scientific Misconduct: Case Studies” in Miami, FL, on November 19, 2000.

**Chris B. Pascal, Director, ORI**, gave opening remarks at the AAAS-ORI Conference on the Role and Activities of Scientific Societies in Promoting Research Integrity, entitled “ORI Update,” in Washington, DC, on April 10, 2000.

**Chris B. Pascal, Director, ORI**, gave a presentation entitled “Definition and Procedures for Handling Misconduct,” at the University of Maryland in College Park, MD, on April 24, 2000.

**Chris B. Pascal, Director, ORI**, made presentations on “The Proposed Federal Definition and Policy on Research Misconduct” and as part of a panel on “Outcomes Following Misconduct Investigations,” during the AAAS-ORI Practicum on Responding to Allegations of Research Misconduct held in St. Charles, IL, on June 4-5, 2000.

**Chris B. Pascal, Director, ORI**, gave a presentation on “Research Integrity,” during an NIH Regional Seminar at Cornell University in Ithaca, NY, on July 13-14, 2000.

**Chris B. Pascal, Director, ORI**, made a presentation entitled “Draft Policy on the Responsible Conduct of Research (RCR),” to the Federal Demonstration Partnership in Washington, DC, on September 19, 2000.

**Chris B. Pascal, Director, ORI**, gave a presentation on the “Draft Policy on Instruction in the Responsible Con-

duct of Research (RCR),” for NIH staff at “Human Subjects Policy Update: A Symposium,” in Bethesda, MD, on October 16, 2000.

**Chris B. Pascal, Director, ORI**, made a presentation on the “Draft Policy on Instruction in the Responsible Conduct of Research (RCR),” as part of the Society of Research Administrators’ Annual Meeting, held in St. Louis, MO, on October 23, 2000.

**Chris B. Pascal, Director, ORI**, gave an “ORI Update” and a presentation on “The Proposed Federal Definition and Policy on Research Misconduct,” AAAS-ABA National Conference of Lawyers and Scientists, in Washington, DC, on November 3, 2000.

**Chris B. Pascal, Director, ORI**, gave a presentation on “The Proposed Federal Definition and Policy on Research Misconduct,” at the NCURA 42<sup>nd</sup> Annual Meeting, held in Washington, DC, on November 6, 2000.

**Chris B. Pascal, Director, ORI**, made presentations on “The Proposed Federal Definition and Policies on Research Misconduct,” and “PHS Policy on Instruction in the Responsible Conduct of Research,” at the Sigma Xi Annual Meeting, Albuquerque, NM, on November 9, 2000.

**Alan Price, Director, DIO**, gave a panel presentation on “Handling Scientific Misconduct Cases” for the NCURA teleconference on Making the Right Moves in Research Misconduct Inquiries, in Washington, DC, on March 24, 2000.

**Alan Price, Director, DIO**, gave a panel presentation on “Sequestration and Handling Physical Evidence in Scientific Misconduct Cases for ORI,” at the AAAS conference “Responding to Allegations of Research Misconduct: A Practicum” in St. Charles, IL, on June 4, 2000.

**Alan Price, Director, DIO**, gave a talk on “Who are the Victims of Research Misconduct, and What are Your ‘Rights’ as a Research Student?” at the University of Oklahoma Health Science Center, Oklahoma City, OK, on December 8, 2000.

**Alan Price, Director, DIO**, gave a presentation on “How to Protect Yourself from Research Misconduct in Your Laboratory” at the Oklahoma Medical Research Foundation, Oklahoma City, OK, on December 8, 2000.

**Lawrence J. Rhoades, Director, DEI**, gave a presentation on “Research Integrity in Biomedical Research” at

the NIH Extramural Staff Training Core Curriculum Course #4 that addressed institutional issues in Bethesda, MD, on March 6, 2000.

**Lawrence J. Rhoades, Director, DEI**, gave a presentation on “The Proposed Federal Definition of Research Misconduct and Other Changes” during a satellite video conference on “Making the Right Moves in Handling Misconduct Allegations” broadcast from Washington, DC, and co-sponsored by NCURA and ORI on March 24, 2000.

**Lawrence J. Rhoades, Director, DEI**, gave a presentation on “Research Integrity” during the NIH Regional Seminar on Program Funding and Grants Administration in Kansas City, MO, on June 1, 2000.

**Lawrence J. Rhoades, Director, DEI**, gave a presentation on “Establishing Institutional Policies and Procedures for Responding to Research Misconduct” during “A Practicum on Responding to Allegations of Research Misconduct: Inquiry, Investigation, and Outcomes”, co-sponsored by AAAS and ORI in St. Charles, IL, on June 4, 2000.

**Lawrence J. Rhoades, Director, DEI**, gave a presentation on the education, research, and prevention activities of ORI during the 7<sup>th</sup> Annual Meeting of the National Sponsored Programs Administrators Alliance of HBCUs in Arlington, VA, on June 9, 2000.

**Lawrence J. Rhoades, Director, DEI**, gave a presentation on “Research Misconduct and Research Integrity” during the NIH Extramural Seminar for Summer 2000 in Bethesda, MD, on July 12, 2000.

**Lawrence J. Rhoades, Director, DEI**, gave a presentation on “Research Misconduct” at the TriService Nursing Research Program Post-Award Workshop in Rockville, MD, on July 27, 2000.

**Lawrence J. Rhoades, Director, DEI**, gave a presentation on “The Draft RCR Policy” at the AAMC Graduate Education and Training Conference in Savannah, GA, on October 17, 2000.

**Lawrence J. Rhoades, Director, DEI**, gave a presentation on “The Draft RCR Policy” at an University Compliance Program Workshop sponsored by the National Association of College and University Business Officers in Washington, DC, on October 27, 2000.

**Mary Scheetz, Program Analyst, DEI**, served as moderator for an Ethics and Human Genetics panel at the 9<sup>th</sup> An-



nual Association for Practical and Professional Ethics in Washington, DC, on February 25, 2000.

**Mary Scheetz, Program Analyst, DEI**, served as a panel member in a session entitled “Guidelines for Authors: What’s New?” at the 43rd Annual Council of Science Editors Meeting in San Antonio, TX, on May 8, 2000.

**Mary Scheetz, Program Analyst, DEI**, presented “Instructions to the Author: An Integrity Issue” at the First Research Conference on Research Integrity in Bethesda, MD, on November 19, 2000.

**Barbara R. Williams, Deputy Director, DIO, and Peter H. Abbrecht, M.D., Ph.D., Expert Medical Consultant to ORI**, made a presentation titled “Office of Research Integrity (ORI) Handling of Allegations of Scientific Misconduct in Public Health Service-Sponsored Clinical Research and Case Studies Involving Liason with the FDA” at a Perexel Conference on Fraud and Misconduct in Clinical Research in Philadelphia, PA, on November 30, 2000.

## I. Published Articles

**Pascal, C.B.** “Research Integrity: The ORI View,” *Proceedings of Public Responsibility in Medicine and Research (PRIM&R) Conference on Responsibility in Research*, pp. 6-13 (2000).

**Pascal, C.B.** “Promoting Responsible Conduct and Preventing Misconduct: Institutional Approaches,” *Proceedings of Public Responsibility in Medicine and Research (PRIM&R) Conference on Responsibility in Research*, pp. 192-203 (2000).

**Pascal, C.B.** “New PHS Policy on Instruction in the Responsible Conduct of Research,” *NCURA Newsletter*, Vol. XXXII, No. 3, July/August 2000.

**Pascal, C.B.** “Scientific Misconduct and Research Integrity for the Bench Scientist,” *Proceedings of the Society for Experimental Biology and Medicine*, Vol. 224, No. 4, pp. 220-230 (2000).

**Price, A.R.** “Institutional and Government Interactions” in proceedings for a workshop on *Ethical Challenges and Practical Solutions for Managers in Research* co-sponsored by Sigma Xi, The Scientific Research Society and ORI. Published by Sigma Xi in February 2000, pp. 53-83.

**Rhoades, L.J.** “The American Experience: Lessons Learned,” *Science and Engineering Ethics* (6) 1: 95-107.

**Rhoades, L.J.** and Gorski, A. “Scientific Misconduct: An International Perspective,” *Science and Engineering Ethics* (6) 1:5-10.

**Rhoades, L.J.** “ORI Views on Building a System of Research Integrity” in proceedings for a workshop on *Ethical Challenges and Practical Solutions for Managers in Research* co-sponsored by Sigma Xi, The Scientific Research Society and ORI. Published by Sigma Xi in February 2000, pp. 7-15.

Petrovecki M. and **Scheetz, M.D.** “Croatian Medical Journal Introduces Culture, Control, and the Study of Research Integrity,” *Croatian Med. J.* 2001; 42(1): 7-13.

## J. Federal Register Notices

HHS. Notice of Proposed rulemaking; technical correction. Public Health Service Standards for the Protection of Research Misconduct Whistleblowers. 65 Fed. Reg. 82972-82973 (Dec. 29, 2000).

OS. Findings of Scientific Misconduct. Notice. 65 Fed. Reg. 77383 (Dec. 11, 2000). [Hartzer]

OS. Announcement of “Final PHS Policy for Instruction in the Responsible Conduct of Research.” 65 Fed. Reg. 76647 (Dec. 7, 2000).

OSTP. Federal Policy on Research Misconduct; Preamble for Research Misconduct Policy. Notification of Final Policy. 65 Fed. Reg. 76260-76264 (Dec. 6, 2000).

HHS. Public Health Service Standards for the Protection of Research Misconduct Whistleblowers. Notice of Proposed Rulemaking. 65 Fed. Reg. 70830-70841 (Nov. 28, 2000).

OS. Findings of Scientific Misconduct. Notice. 65 Fed. Reg. 70915-70916 (Nov. 28, 2000). [Dreyer]

OS. Findings of Scientific Misconduct. Notice. 65 Fed. Reg. 61170 (Oct. 16, 2000). [French]

OS. Findings of Scientific Misconduct. Notice. 65 Fed. Reg. 59848 (Oct. 6, 2000). [Garey]

OS. Agency Information Collection Activities: Proposed Collections; Comment Request. 65 Fed. Reg. 55252-55253 (Sept. 13, 2000.) *Proposed Project 2*. Office of Research Integrity (ORI) Educational Program: A Needs Assessment.

OS. Findings of Scientific Misconduct. Notice. 65 Fed. Reg. 54852-54853 (Sept. 11, 2000). [Simmons]

OS. Agency Information Collection Activities: Proposed Collections; Comment Request. 65 Fed. Reg. 52120 (Aug. 28, 2000.) *Proposed Project 1*. Research Misconduct: An Inquiry into Etiology and Stigma.

OS. Notice of Availability. Extension of comment period on “PHS Policy for Instruction in the Responsible Conduct of Research” 65 Fed. Reg. 49809 (Aug. 15, 2000.)

OS. Notice of Availability. “PHS Policy for Instruction in the Responsible Conduct of Research; Availability of New Draft” 65 Fed. Reg. 45381 (July 21, 2000.)

OS. Findings of Scientific Misconduct. Notice. 65 Fed. Reg. 41468 (July 5, 2000.) [Qian]

OS. Findings. Notice. 65 Fed. Reg. 39149-39150 (June 23, 2000). [Duan]

OS; OPHS. Statement of Organization, Functions, and Delegations of Authority. [Policy changes: ASH will propose findings of research misconduct and administrative actions; direct investigations now made by intramural components and OIG; ORI focus on education and prevention.] 65 Fed. Reg. 30600-30601 (May 12, 2000).

OS. Agency Information Collection Activities; Proposed Collections; Comment Request. Proposed Project 1. Analysis of Guidelines for the Conduct of Research Adopted by Medical Schools or their Components. 65 Fed. Reg. 9269-2970 (Feb. 24, 2000).

### III. INSTITUTIONAL COMPLIANCE

The PHS regulation on misconduct in science (42 C.F.R. Part 50, Subpart A) places several requirements on institutions receiving funds under the PHS Act, 42 U.S.C. § 289b. ORI monitors institutional compliance with these regulatory requirements through two programs, the Assurance Program and the Compliance Review Program. Notable actions and achievements in 2000 include:

- Completed the 1999 Annual Report on Possible Research Misconduct with a response rate of 84 percent. Forty-six institutions reported opening 63 new scientific misconduct cases; a total of 72 institutions reported misconduct activities because of cases carried over from 1998. Ninety-three percent of the responding institutions indicated they have the required policy for handling allegations of scientific misconduct.
- Inactivated assurances for 521 institutions for failure to submit an Annual Report, and inactivated assurances for 16 institutions for not submitting an institutional policy as requested.
- Processed 379 institutional policies on handling allegations of scientific misconduct; requested 269 institutional policies for review, and increased the number of completed reviews to 1,593.
- Completed the development of a system to allow for the electronic submission of the Annual Report on Possible Research Misconduct for calendar year 2000.

#### 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 PHS regulation. 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 sci-

ence policy when requested by ORI, and complying with the PHS 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 conjunction 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 receive PHS research funding.

As of December 31, 2000, there were 4,147 active assurances on file in ORI, including 203 from 32 foreign countries. During 2000, 517 institutions filed their initial assurance. ORI deleted 344 institutions because their assurance was inactivated. Eleven duplicate assurance records were deleted. There were 135 institutions that 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 198 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 only slight impact on the total assurance database in 2000 (see Table 8). The total number of institutions with an assurance increased by 197. Categorically, institutions of higher education increased by 21; research organizations, institutes, foundations and laboratories increased by 10; independent hospitals increased by 4; educational organizations other than higher education decreased by 1; other health, human resources, environmental service organizations increased by 8; the small business category increased by 155; and unclassified increased by 3. The largest gain was in the small business category.

Table 8 **Type of Institution with Active Assurance by Frequency, 2000**

<i>Type of Institution</i>	<i>Frequency</i>	<i>Change</i>
Institutions of Higher Education	915	+21
Research Organizations, Institutes, Foundations and Laboratories	337	+10
Independent Hospitals	290	+4
Educational Organizations, Other Than Higher Education	23	-1
Other Health, Human Resources, and Environmental Services Organization	406	+8
Other (small business)	2,176	+155
Unclassified	0	+3
<b>TOTAL</b>	<b>4,147</b>	<b>+197</b>

#### *E-Mail Network*

The effort to establish an e-mail network covering all institutions that have an active assurance is progressing well. About 89 percent of the institutions have submitted e-mail addresses for their responsible official. The e-mail network enables ORI to quickly contact institutional officials individually or *en masse*. It has been used to inform institutional officials about upcoming conferences/workshops. Information regarding the implementation of the Electronic Transmission of the Annual Report on Possible Research Misconduct will also be provided to institutional contacts via the e-mail network.

#### *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 1999 Annual Report forms were mailed in January 2000 to the 3,767 institutions that had an assurance on file with ORI as of December 1, 1999.

Completed Annual Reports were received from 3,164 institutions for a response rate of 84 percent. ORI inactivated 603 assurances, including 521 institutions that did not return their Annual Reports by the March 31 deadline and 82 institutions that voluntarily withdrew their assurances rather than submit the Annual

Report. Many assurances were reactivated because annual reports were submitted after the due date. The 1999 report identified 105 institutions that did not have the required policies and procedures for handling allegations of scientific misconduct, and assurances were inactivated for 16 institutions that did not submit their misconduct policies as requested. In addition, the 1999 report provided corrected information on the name of the responsible official or the institutional addresses of 646 institutions (17%). Institutions named 470 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, and (3) the number of bad faith allegations received.

#### *Electronic Submission of Annual Report*

Steps were taken during the past year to develop and implement an electronic system for the submission of the Annual Report on Possible Research Misconduct.

Previously, ORI would prepare and mail a hard copy of the annual report to all institutions with active assurances, with instructions for those institutions to update their institutional profile (name, address, phone, fax, and e-mail), and to report any misconduct activity that may have occurred in the reporting period. As these reports were returned, ORI would update its Assurance program database to record any changes in the institutional profile, as well as any misconduct information that was reported.

The electronic system was designed to allow institutions to access and update their institutional assurance record at any time during the year, and allow them to complete the annual report on-line during the reporting period. The ORI assurance database would then be automatically updated with the information submitted. In implementing this electronic system, ORI eliminated the need to prepare and mail a hard copy report to all active institutions, and the burden of updating each record with the information returned with the annual report. The system also reduced the burden on reporting institutions by providing them with a straightforward on-line reporting system that eliminated the need to prepare and return a hard copy of the annual report.

In order to test the system prior to implementation, ORI contacted 50 organizations in September 2000 and requested that they participate in testing the program.

Based on the feedback from the institutions that agreed to participate, modifications were made to both the electronic program and the instructions.

One aspect of another Assurance Program initiative that is key to the success of the electronic submission system is the e-mail network. Over the past 2 years, ORI has been developing an e-mail network to allow it to disseminate information related to the ORI programs quickly and easily through the e-mail system. This e-mail network will also be used as the primary means of notifying institutions of the new electronic annual reporting system, and to provide follow-up notices.

#### *Reported Misconduct Activity*

According to their 1999 Annual Report on Possible Research Misconduct, which was filed in 2000, 63 new scientific misconduct cases were opened in 1999 by 46 institutions that conducted 51 inquiries and 9 investigations in response to 89 allegations.

A total of 72 institutions responded to allegations in 1999 because 26 institutions were continuing to investigate allegations received before 1999, while 8 were dealing with allegations made prior to and in 1999.

In their submissions, institutions report the receipt of allegations of scientific misconduct, the type of misconduct, and the conduct of an inquiry and/or investigation. Reportable activities are limited to alleged misconduct that falls under the PHS definition of scientific misconduct and involves research supported by the PHS.

Of the 46 institutions reporting new allegations in 1999, 41 were institutions of higher education, 4 were research organizations, and 1 was a health organization.

The 89 new allegations reported in 1999 included 21 of fabrication, 37 of falsification, 13 of plagiarism, and 18 of other serious deviations. The number of new cases opened by the 46 institutions ranged from 0 to 3.

#### **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 379 institutional policies during 2000. ORI requested 269 policies in 2000; the other 110 policies were forwarded from 1999. ORI closed 320 reviews in 2000; 59 were carried into 2001. The closed reviews included 282 accepted policies and 38 inactivated assurances because policies were not submitted. Of the 59 open reviews, 29 require institutional action before further progress can be made.

### *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 as the initial outcome of the review, the number of revisions required, and the policy approval date. As of December 31, 2000, GenRev contained information on 1,652 policy reviews conducted by ORI primarily since 1995. ORI completed 1,593 reviews; 59 are open.

### *Compliance Cases*

In 2000, the ORI compliance caseload was increased by two, for a total of three open cases at the end of the year. Compliance cases involve compliance reviews of institutional handling of an allegation of scientific misconduct and/or retaliation complaints of the whistleblower.

At the beginning of the year there were 2 open assessments, 14 new assessments were opened during 2000, and 10 assessments were closed during 2000. Cases were closed primarily because ORI made a determination that it did not have jurisdiction, or the complainant did not respond to ORI's request for additional documentation supporting the complaint.

Of the compliance cases closed during 2000, two involved retaliation complaints. In one case, the complaint was referred by ORI to the institution for investigation. While the investigation was still ongoing, the whistleblower decided to withdraw the complaint. Based on this request, and with ORI concurrence, the investigation was terminated and the case was closed. In the other case, the whistleblower had filed a civil suit against his former institution prior to making his retaliation complaint to ORI, and the alleged retaliatory acts were included among his complaints. Since the retaliation issues had already been examined as part of this suit, and a settlement accepted by both parties, ORI declined to pursue it further.

Table 9: **Summary of Compliance Cases, 2000**

<i>Case Type</i>	<i>Forwarded from 1999</i>	<i>Opened in 2000</i>	<i>Closed in 2000</i>	<i>Carried into 2001</i>
Compliance Review	1	5	3	3
Assessment	2	14	10	6
<b>TOTAL</b>	3	19	13	9

### *Implementation of ORI Administrative Actions*

The implementation of ORI 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, or (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.

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, 2000, ORI listed the names of 48 individuals in the system. During the year, ORI added 10 and removed 13 names. On December 31, 2000, the names of 45 individuals were in the system.

ORI added these 10 names after 2 respondents agreed to a voluntary exclusion agreement, and 8 others were found to have committed scientific misconduct in institutional reports to ORI. Twelve names were removed during the year because the term of the administrative actions expired, and one name was removed where ORI did not make a finding of scientific misconduct after reviewing an institutional misconduct investigation report.

Of the 45 names in the system at year end, 37 individuals have had administrative actions imposed by ORI, and 8 remained as a result of an institutional report in which there was a finding of scientific misconduct.

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## IV. INFORMATION AND PRIVACY

The number of requests for information under the Freedom of Information Act (FOIA) decreased in 2000. Privacy Act requests also declined.

- ORI received 59 FOIA requests in 2000 compared with 88 in 1999 and 52 in 1998. Seven requests were carried into 2001 compared with 8 which were carried into 1999 and 24 into 1998.
- Two Privacy Act requests were handled in 2000 compared with four in 1999 and eight in 1998. All requests were completed in the year of receipt; none were carried into the next year.

### A. Freedom of Information Act

The Freedom of Information Act (FOIA), 5 U.S.C. § 552, as amended, allows the public access to Federal agency records, except to the extent that those records, or portions thereof, are protected from disclosure by one or more of the nine FOIA 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 17-A-46, 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.

### B. 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 agency 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 about

an individual that is retrieved by a personal identifier.

The inquiry and investigative 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 express 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 portions thereof, under the provisions of the Freedom of Information Act.

A Privacy Act request should be made to the Privacy Act Officer, ORI, at 5515 Security Lane, Suite 700, Rockville, MD 20852. A request under the purview of the Privacy Act must be made by the subject of the records or his or her legal representative.

**Summaries of Closed Investigations Resulting in Findings of Scientific Misconduct or Administrative Actions**

**Lingxun Duan, M.D., Thomas Jefferson University (TJU):** In a case related to a Global Settlement Agreement in a *qui tam* suit between the United States and TJU, and based on an oversight review conducted by the Office of Research Integrity (ORI), the U.S. Public Health Service (PHS) entered into a Voluntary Exclusion Agreement (Agreement) with Dr. Duan, former Research Assistant Professor of Medicine, Division of Infectious Diseases, Department of Medicine, TJU. The PHS alleged that Dr. Duan engaged in scientific misconduct by reporting research that was inconsistent with original data or could not be supported because original data were not retained. Dr. Duan denied all allegations of scientific misconduct and contended that some of his original data is missing. The research in question was supported by a National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), grant, R01 AI36552, entitled “Intracellular antibodies and HIV 1.” Specifically, the research in question was reported in an NIAID, NIH, grant application; in an FDA-approved phase I gene therapy investigational new drug (IND) application entitled “Intracellular immunization against HIV-1 infection using an anti-rev single chain variable fragment (SFV);” and in two publications: (1) Duan, L., Bagasra, O., Laughlin, M.A., Oakes, J.W., & Pomerantz, R.J., “Potent inhibition of human immunodeficiency virus type I replication by an intracellular anti-Rev single chain antibody,” *Proc. Natl. Acad. Sci. USA* 91:5075-5079, 1994; and (2) Levy-Mintz, P., Duan, L., Zhang, H., Hu, B., Dornadula, G., Zhu, M., Kulkosky, J., Bizub-Bender, D., Skalka, A.M., and Pomerantz, R.J., “Intracellular expression of single-chain variable fragments to inhibit early stages of the viral life cycle by targeting human immunodeficiency virus type 1 integrase,” *J. Virol.* 70:8821-8823, 1996.

Under the terms of the Agreement, Dr. Duan voluntarily agreed, beginning June 7, 2000: (1) to exclude himself from any contracting, subcontracting, or involvement in grants and cooperative agreements with the U.S. Government for a period of 2 years; (2) that for 1 year after the conclusion of the voluntary exclusion period, his participation in any PHS-funded research is subject to supervision requirements; and (3) to exclude himself from serving in any advisory capacity to PHS, for a period of 2 years. Dr. Duan also agreed that he will not oppose the submission to journals of a statement summarizing the current state of the science with respect to the scientific matters

at issue relating to grant R01 AI36552, which was jointly agreed to by TJU and the United States in the Global Settlement Agreement.

**Evan B. Dreyer, M.D., Ph.D., Massachusetts Eye and Ear Infirmary (MEEI) and Harvard Medical School (HMS):** Based on the findings and evidence documented in a report, dated November 17, 1997, by a joint inquiry panel and additional information obtained by the Office of Research Integrity (ORI) during its oversight review, the PHS issued its findings on April 14, 2000, that Dr. Dreyer, former HMS Associate Professor of Ophthalmology at MEEI, engaged in scientific misconduct by falsifying or fabricating experimental results. These results were included in National Institute on Deafness and Other Communication Disorders (NIDCD), NIH, grant application K08 DC00131-01A1. Specifically, Dr. Dreyer falsified or fabricated experimental results to support the hypothesis that elevated levels of the amino acid glutamate play a role in Meniere's disease and reported these falsified or fabricated results in six documents:

1. an NIH grant application, K08 DC0013 1-01A1, "Glutamate toxicity in endolymphatic hydrops," submitted to NIH for a Mentored Clinical Scientist Development Award in July 1996. PHS found that the experimental results for 19 amino acids reported in Table 2 and the text (pp. 58-59) were falsified or fabricated.
2. an abstract, Cliff A. Megerian, M.D., Michael J. McKenna, M.D., Joseph B. Nadol, Jr., M.D., and Evan B. Dreyer, M.D., Ph.D. "Elevated Perilymphatic Glutamate and Type-1 Spiral Ganglion Cell Loss in the Hydropic Ear," submitted on August 1, 1996, for the Triological Society Eastern Division Meeting scheduled for early February 1997. PHS found that the text reports the same falsified or fabricated experimental results for the amino acid glutamate that were reported in the K08 DC00131-01A1 grant application to support the conclusion that elevated levels of glutamate may play a role in Meniere's disease.
3. a manuscript, Cliff A. Megerian, M.D., Michael J. McKenna, M.D., Joseph B. Nadol, Jr., M.D., Barbara J. Burgess, B.A., David Zurakowski, Ph.D., and Evan B. Dreyer, M.D., Ph.D. "Elevated Perilymphatic Glutamate and Type-1 Spiral Ganglion Cell Loss in the Hydropic Ear." PHS found that Table 1 and the text (pp. 2 and 8) contained the same falsified or fabricated experimental results that were reported in the K08 DC00131-01A1 grant application.
4. a draft NIH grant application, listing Dr. Dreyer as Principal Investigator, in which Table 2 and the text of the draft NIH grant application contained the same experimental results that the PHS found were falsified or fabricated in K08 DC00131-01A1.
5. two computer spreadsheets, which contained the same results that the PHS found were falsified or fabricated in the K08 DC00131-01A1.
6. magneto-optical computer disk, which contained files with 21 fabricated chromatograms of amino acid elution patterns. On January 21, 1997, Dr. Dreyer provided the computer disk to MEEI officials in response to requests for the primary data and laboratory notebooks supporting the amino acid results reported in the documents described above. On April 7 and May 21, 1997, Dr. Dreyer admitted that he fabricated each of the 21 chromatograms.

On May 10, 2000, Dr. Dreyer appealed the proposed PHS findings and administrative actions to the HHS Departmental Appeals Board ("DAB"), DAB Docket No. A-2000-72, "which commenced a *de novo* hearing to consider the charges of scientific misconduct." Although the hearing was scheduled to run 3 weeks, on November 13, 2000, Dr. Dreyer entered into a Voluntary Exclusion Agreement (Agreement) with PHS in which he agreed to withdraw his appeal of the PHS findings of scientific misconduct against him. On November 17, 2000, the DAB dismissed the case.

Under the terms of the Agreement, Dr. Dreyer did not admit that he falsified or fabricated the results at issue, but he recognized that if the DAB case proceeded to conclusion, there was sufficient evidence upon which the DAB may make a finding of scientific misconduct. However, with respect to material identified in item 6 above, Dr. Dreyer admitted that he fabricated the 21 chromatograms contained in the magneto-optical computer disk that he provided to institutional officials after questions were raised about his research. He further admitted that the fabrication of the data on the disk amounts to scientific misconduct.

Dr. Dreyer voluntarily agreed for a period of 10 years beginning November 15, 2000, to exclude himself from: (1) any contracting, subcontracting, or involvement in grants and cooperative agreements with the U.S. Government; (2) serving as a mentor to any graduate student, fellow, or other individual who ap-

plies for or receives Federal funding; and (3) serving in any advisory capacity to PHS. The Agreement, however, does not apply to Dr. Dreyer's practice of clinical medicine as a licensed practitioner or to Federal funds used for purposes of teaching or training medical students, residents, or fellows, in clinical medical matters.

**Randall P. French, Ph.D., Fox Chase Cancer Center (FCCC):** Based on the report of an investigation conducted by FCCC and additional analysis by ORI in its oversight review, the PHS found that Dr. French, postdoctoral associate, FCCC, engaged in scientific misconduct by fabricating published research supported by National Cancer Institute (NCI), NIH, grants T32 CA09035 and P30 CA06927. Specifically, Dr. French fabricated research results published in *Developmental Biology* 217:62-76, 2000, by falsely claiming in the text and Table 1 that he had assayed mouse embryos transgenic for a modified DNA construct (cG5/lacZ-F) for a study on the expression of cGATA-5 transcription factor during heart development in mice. An erratum replacing the fabricated data was published by the authors in *Developmental Biology* 223:463, 2000.

Dr. French accepted the PHS finding and entered into a Voluntary Exclusion Agreement with the PHS in which he voluntarily agreed for a period of 3 years beginning September 28, 2000: (1) to exclude himself from serving in any advisory capacity to the PHS; and (2) 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. The supervisory plan must be designed to ensure the scientific integrity of Dr. French's research contribution. The institution must also submit a copy of the supervisory plan to ORI.

**Caroline E. Garey, Boston College (BC):** Based on the Report and Addendum of the Boston College Research Misconduct Investigation Committee and additional analysis conducted by ORI in its oversight review, the PHS found that Ms. Caroline E. Garey, former doctoral student, BC, engaged in scientific misconduct by falsifying research supported by National Institute of Neurological Disorders and Strokes (NINDS), NIH, grant R01 NS23355. Specifically, as a BC graduate student, Ms. Garey falsified restriction fragment length polymorphism (RFLP) data for ABP and DBA backcross mice DNA samples by misrepresenting results from multiple assays of identical backcross ABP DNA samples as being from

different animals and misrepresenting the autoradiograms of backcross ABP DNA samples as the results from experiments on backcross DBA mice. Ms. Garey reported this falsified data in her doctoral dissertation, "Defect in the ceruloplasmin gene associated with epilepsy in the EL mouse," and in an article in *Nature Genetics* 6:426-431, 1994. She caused her falsified data to be reported by her laboratory director in NINDS, NIH, grant application 2 R01 NS23355-08A1 and at an international workshop on epilepsy on September 24, 1994. Ms. Garey also fabricated a translation table that she used to assign falsified RFLP data to individual backcross DBA mice. As a result of falsifying these assays over a minimum of two and one-half years, none of Ms. Garey's research can be considered reliable and the *Nature Genetics* publication has been retracted. These actions adversely and materially affected the laboratory's ongoing research on the genetic causes of epilepsy. Ms. Garey also has engaged in a pattern of dishonest conduct that indicates that she is not presently responsible to be a steward of Federal funds. This pattern of behavior includes (1) a history of falsely claiming that she has performed scientific experiments when she has not, and (2) repeated instances in which she has misrepresented her credentials to prospective employers, colleagues, customers, and the general public as including a Ph.D. degree even though BC refused to grant her a doctoral degree because of her scientific misconduct. The publication affected is: Garey, C.E., Schwarzman, A.L., Rise, M.L., & Seyfried, T.N. "Ceruloplasmin gene defect associated with epilepsy in EL mice." *Nature Genetics* 6:426-431, 1994 (retracted in *Nature Genetics* 11:104, 1995).

While Ms. Garey does not admit the allegations of scientific misconduct, she entered into a Voluntary Exclusion Agreement with the PHS in which she voluntarily agreed for a period of 5 years beginning September 25, 2000: (1) to exclude herself from any contracting, subcontracting, or involvement in grants and cooperative agreements with the U.S. Government; and (2) to exclude herself from serving in any advisory capacity to PHS.

**Michael K. Hartzler, Ph.D., Oakland University (OU):** Based on the report of an investigation conducted by OU and additional analysis conducted by ORI during its oversight review, PHS found that Dr. Hartzler, former Associate Professor of Biomedical Sciences, Eye Institute, OU, engaged in scientific misconduct by falsifying the status of support materials in eight National Eye Institute (NEI), NIH, grant applications. Specifically, Dr. Hartzler falsified the status of 11 manuscripts in 8 grant applications by listing them as "accepted" or "in press" when the papers had either not been subsequently published or had been rejected. The repetition of these

actions over several years indicates a pattern of knowingly misrepresenting the research record. Dr. Hartzler accepted the PHS finding and entered into a Voluntary Exclusion Agreement with the PHS in which voluntarily agreed for a period of 3 years beginning November 20, 2000: (1) to submit with each PHS research application, continuing application, or report, a statement of certification, endorsed by an institutional official, that all manuscripts or publications are properly and accurately cited in the application; the institution must also submit a copy of the certification to ORI; and (2) to exclude himself from serving in any advisory capacity to PHS.

**Mr. Jin Qian, New Dimensions Research and Instrument, Inc. (NDRI):** Based on an investigation by ORI, the PHS made a final finding of scientific misconduct against Mr. Qian, Executive Manager for Corporate Planning and Research, NDRI, committed scientific misconduct by plagiarizing research results and text from other investigators in an application to the National Institute of Neurological Disorders and Stroke (NINDS), NIH, for a Small Business Innovation Research (SBIR) award, “Glass-based neurochip system,” 1 R43 NS39266-01. Based on ORI’s analysis, the PHS found that Mr. Qian: (1) used research images and descriptions posted on the Internet to create seven figures in the application and used that material, its associated text, and text from other publications obtained from the Internet without attribution; (2) misrepresented research results in two of the plagiarized figures as exemplar applications of NDRI’s proprietary technology; and (3) misrepresented his research bibliography in that application and to ORI staff during the investigation. These actions constitute falsifications in the proposing of research because their collective effect was to falsify the basis on which NIH reviewers determine whether NDRI could achieve the goals of the proposed project.

Mr. Qian accepted the PHS finding and entered into a Voluntary Exclusion Agreement with the PHS in which he voluntarily agreed for a 3-year period beginning June 12, 2000: (1) to exclude himself from any contracting, subcontracting, or involvement in grants and cooperative agreements with the U.S. Government; and (2) to exclude himself from serving in any advisory capacity to PHS.

**William A. Simmons, Ph.D., University of Texas Southwestern Medical Center (UTSMC):** Based on the UTSMC report and additional ORI analysis in its oversight review, the PHS found that Dr. Simmons engaged in scientific misconduct by falsifying research supported by National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), NIH grant R01 DK47692, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), NIH, grants R01 AR38319 and P01 AR09989, National Institute of Allergy and Infectious Diseases (NIAID), NIH, grant R01 AI42860, and NCI, NIH, grant T32 CA09082.

Specifically, while a graduate student and postdoctoral fellow at UTSMC, Dr. Simmons manipulated results of cytotoxic T-lymphocyte assays by adding predetermined amounts of radioactivity to scintillation counting vials rather than carrying out the assays as claimed. As a result of falsifying these assays over a minimum of 5 years, none of Dr. Simmons research can be considered reliable and the publications identified below have been retracted or corrected. The falsified research also was reported in the 1 R01 AI42860-01 grant application, “A new MHC locus influencing class I peptide display.” Additionally, Dr. Simmons was responsible for falsifying Figure 3 published in *J. Immunol.* 159:2750-2759, 1997, by substituting preparations of chemically synthesized oligopeptide for natural peptides obtained from T cells isolated from B27 transgenic rats. These actions adversely and materially affected the laboratory’s ongoing research into the role that human histocompatibility leukocyte antigens play in the development of disease.

The publications affected are:

- Simmons, W.A., Summerfield, S.G., Roopenian, D.C., Slaughter, C.A., Suberi, A.R., Gaskell, S.J., Bordoli, R.S., Hoyes, J., Moomaw, C.R., Colbert, R.A., Leong, L.Y., Butcher, C.W., Hammer, R.E., & Taurog, J.D. “Novel HY peptide antigens presented by HLA-B27.” *J. Immunol.* 159:2750-2759, 1997 (retracted).
- Simmons, W.A., Leong, L.Y., Satumtira, N., Butcher, G.W., Howard, J.C., Richardson, J.A., Slaughter, C.A., Hammer, R.F., & Taurog, J.D. “Rat MHC-linked peptide transporter alleles strongly influence peptide binding by HLA-B27 but not B27-associated inflammatory disease.” *J. Immunol.* 156:1661-1667, 1996 (retracted).

- Simons, W.A., Roopenian, D.C., Summerfield, S.G., Jones, R.C., Galocha, B., Christianson, G.J., Maika, S.D., Zhou, M., Gaskell, S.J., Bordoli, R.S., Ploegh, H.L., Slaughter, C.A., Lindahl, K.F., Hammer, R.E., & Taurog, J.D. "A new MHC locus that influences class I peptide presentation." *Immunity* 7:641-651, 1997 (retracted).
- Simmons, W.A., Taurog, J.D., Hammer, R.E., & Breban, M. "Sharing of an HLA-B27-restricted H-Y antigen between rat and mouse." *Immunogenetics* 38:351-358, 1993 (retracted).
- Zhou, M., Sayad, A., Simmons, W.A., Jones, R.C., Maika, S.D., Satumtira, N., Dorris, M.L., Gaskell, S.J., Bordoli, R.S., Sartor, R.B., Slaughter, C.A., Richardson, J.A., Hammer, R.F., & Taurog, J.D. "The specificity of peptides bound to human histocompatibility leukocyte antigen (HLA)-B27 influences the prevalence of arthritis in HLA-B27 transgenic rats." *J. Exp. Med.* 188:877-886, 1998 (published erratum).

Mr. Simmons accepted the PHS findings and entered into a Voluntary Exclusion Agreement with PHS in which he voluntarily agreed for a period of 5 years beginning on August 22, 2000, to (1) to exclude himself from any contracting, subcontracting, or involvement in grants and cooperative agreements with the U.S. Government; and (2) exclude himself from serving in any advisory capacity to PHS.

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### Summaries of Closed Inquiries and Investigations Not Resulting in Findings of Scientific Misconduct

#### Closed Inquiries

**Fabrication:** The respondent, a professor, allegedly fabricated linkage data on a human disease for a figure in a published paper. The questioned research was supported by grants from the National Heart, Lung, and Blood Institute (NHLBI), National Center for Research Resources (NCRR), and National Center for Human Genome Research (NCHGR), of the National Institutes of Health (NIH). The institution conducted an inquiry into the matter and determined that this case involved a dispute between two collaborators involving a third party, with no evidence found of misrepresentation of results. The institution concluded that no further investigation was warranted. ORI accepted the institution's conclusion.

**Falsification:** A reviewer of a Small Business Innovation Research (SBIR) grant application to the NIH alleged that the application, which contained two pages of theory-equations and text marked "proprietary," was plagiarized from a conference proceedings paper by other investigators. As the respondent was the president of the small business, ORI arranged for another local institution to conduct the inquiry. The inquiry committee found that there was insufficient evidence to warrant further investigation. The committee accepted as plausible the respondent's claims: (1) that he had been given the questioned, unattributed text by a postdoctoral fellow who wanted to work with him, but left the country and could not be located, and that the respondent used the material without knowing that it came from another source; and (2) that the material had been accidentally copied onto pages marked "proprietary" by outside staff in a rush to meet the submission deadline, and other related applications did not contain this error. In its oversight review, ORI found that the copied text was background/methods material lacking much significance for the research proposed in the SBIR application. Furthermore, upon being informed, the applicant immediately submitted to NIH alternative text with appropriate citations for his pending applications. Therefore, ORI concurred with the inquiry committee's conclusion that there was insufficient evidence to warrant further investigation.

**Falsification:** The respondent, a staff investigator, allegedly falsified the results of experiments in a publication involving research on human and animal viruses.

The research was supported by three grants from the National Institute of Allergy and Infectious Diseases (NIAID), NIH. The institution conducted an inquiry into the matter and determined that there was insufficient evidence to warrant further investigation. However, the institution recommended that the authors of the questioned publication submit an erratum to correct errors in the publication and that the respondent be counseled about improving data management practices. ORI accepted the institution's conclusion that there was insufficient evidence available to warrant further investigation.

**Falsification:** The respondents allegedly falsified and/or fabricated the results in three published papers on the development of virus-induced disease in animal ears. The research was supported by three grants from the National Institute on Deafness and Other Communication Disorders (NIDCD), NIH. The institution conducted an inquiry into the matter and determined that there was insufficient evidence to warrant further investigation. The authors had acknowledged in the paper that mechanical damage had occurred in the viral-injection process. ORI considered this adequate notice that data from these damaged ears were included in the paper and found there was sufficient scientific justification for inclusion of the data, thus refuting the alleged falsification. ORI concurred with the institution's determination in this case.

**Falsification:** The respondent, an assistant professor, allegedly falsified the publication status of manuscripts listed in his biographical sketch in two NIH grant applications. The institution conducted an inquiry into the matter. The institution found it plausible that the respondent's inconsistencies in listing papers had resulted from errors in cutting and pasting from previous documents, from typographical errors (getting the wrong journal name and year), and from errors in judgment in preparing the biographical sketches, rather than an intent to deceive the reviewers. ORI accepted the institution's inquiry report, and ORI concluded that there was insufficient evidence on the part of the respondent to warrant further investigation.

**Falsification:** The complainant alleged that the three respondents had included falsified data in a table of a published paper on the effects of transplants on recovery from spinal cord injury in rats since the complainant's experiments gave different results. The work was supported by an NIH grant. The institution conducted an inquiry into the matter and concluded that the complainant had not documented his experiments to permit a comparison with the published data, so no further examination of the data was necessary. Two of the respondents and another witness expressed confidence in the published re-

sults. ORI concurred with the institution that there was insufficient evidence of scientific misconduct to warrant further investigation.

**Falsification:** The respondent, an associate professor at two institutions, allegedly falsified data in two publications on the three-dimensional structure of a protein and the cloning of its gene that were supported by NIH grants. The institution conducted an inquiry into the matter and concluded that, based on the evidence of experiments performed at a new institution by the respondent, there was insufficient evidence to warrant further investigation. ORI concurred with the institution's conclusion.

**Falsification:** The institution conducted an inquiry into whether the respondent, a research assistant, had falsified patient interview data for a pilot study of drug effects on human beings and entered the allegedly false data into a computer system. The research was sponsored by an NIH cooperative agreement. Because the contractor had erased the computer files before the inquiry began, the complainant refused to be interviewed, and the inquiry did not identify any additional reliable evidence to confirm the allegation, the inquiry committee determined that there was insufficient evidence to support moving to an investigation. However, because of concerns for the accuracy of the questioned data, the institution and the contractor did not include that data in the study's final conclusion and analysis. ORI's oversight concluded that further investigation was unlikely to produce additional credible evidence of falsification. Therefore, ORI concurred with the institution's conclusion that a formal investigation was not warranted.

**Falsification:** The respondent, an assistant professor, allegedly falsified data in a published paper and in an NIH grant application. The questioned research involved the cloning of genes in the regulation of signal transduction. The institution conducted an inquiry and determined that there was insufficient evidence to warrant further investigation. The institution concluded that the complainant may have misunderstood the nature of the previously isolated clones and the reason that the complainant had been requested to isolate new clones. ORI concurred with the institution's determination in this matter.

**Falsification:** An audit of clinical records suggested that unknown persons may have falsified patient eligibility data in a cancer prevention trial. The research was supported by an NIH cooperative agreement. The institution conducted an inquiry into the matter and determined that an investigation into possible falsifi-

cation of patient records was not warranted. In one instance, the patient or spouse may have altered the records to increase the patient's chance of enrollment in the trial, but the evidence was insufficient to prove this. In another case, the patient apparently had been registered in error, given reports of recurrent disease. ORI concurred with the institution's determination that there was insufficient evidence to warrant further investigation.

**Fabrication/Falsification:** The respondent, an associate research scientist, allegedly fabricated or falsified interview data in research involving treatment of cocaine abusers. The questioned research was supported by an NIH grant, and the data were presented as results of a pilot study in an NIH grant application. The institution conducted an inquiry into the matter and concluded that there was insufficient evidence to warrant further investigation. ORI accepted the institution's conclusion.

**Fabrication/Falsification:** The respondent, a research assistant, allegedly falsified or fabricated telephone interview data in research on the effectiveness of various therapeutic interventions for substance abuse. The research was supported by three grants from the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and the National Institute on Drug Abuse (NIDA), NIH. The institution conducted an inquiry and concluded that the inability of four subjects to recall being interviewed by the respondent was insufficient evidence to warrant further investigation. Assessment of available telephone logs or the questioned interview forms themselves was inadequate to provide any useful independent information. There were also mixed opinions by the project research staff about the reliability of such recall by the subjects involved. ORI concurred with the institution's conclusion.

#### *Closed Investigations*

**Falsification:** The respondent, a research assistant professor, allegedly falsified information about the treatment of 1 of 20 subjects included in draft material for an abstract, a publication, and an NIH grant progress report. The institution originally informed ORI that the respondent had admitted to acts that constituted scientific misconduct. However, on being contacted by ORI, the respondent denied making any such admission and appealed the institution's initial conclusion. Subsequently, the institution decided to conduct an investigation into the matter. Its report concluded that the respondent had believed the data included were accurate; therefore, the insti-

tion did not make a finding of scientific misconduct. ORI accepted the institution's report. However, given the numerous discrepancies in the testimony of the principals and some of the witnesses, as well as the absence of documentation for the research materials in question, ORI considers several significant factual matters in this case to be unresolvable and does not make a finding of scientific misconduct.

**Falsification:** The respondent, an associate professor, allegedly falsified research on genes and enzymes involved in detoxification of organic compounds in humans. The research was supported by an NIH grant, and preliminary data from this research was included in an NIH grant application and two publications. The institutions with which the respondent was affiliated conducted an investigation into the matter. The institutions concluded that there was a lack of sufficient evidence to conclude that the respondent had falsified or fabricated research. However, the institutions found the respondent's publication of data, for which there was no longer any record, represented a significant deviation from commonly accepted scientific practice. ORI conducted an oversight review and determined that there was insufficient evidence to determine whether or not the respondent falsified the research. The institutions had required the respondent to retract the two papers, and publications from other laboratories had refuted those findings, so ORI determined that no additional PHS action was warranted. Thus, there is no PHS finding of scientific misconduct in this case.

**Falsification:** The respondent, an associate professor, allegedly falsified results in research involving growth factors in the repair of damaged tissues and included these results in two publications. The research was supported by an NIH grant. The institution conducted an investigation into the matter. The institution concluded that the respondent had been negligent in reporting the results of the research and had made significant errors, and the institution issued a reprimand. However, the institution did not find that the respondent committed scientific misconduct under the PHS definition. ORI concurred with the institution's determination and did not make a finding of scientific misconduct in this case.

**Falsification:** The respondent, a nurse coordinator, allegedly falsified dates of patient treatments or procedures on research documents, including Case Report Forms, in a multicenter clinical trial involving research on bladder cancer. The clinical trial was supported in part by an NIH cooperative agreement. The institution conducted an investigation into the matter and con-

cluded that insufficient evidence existed to make a finding of scientific misconduct against the respondent. ORI concurred with the institution's determination and did not make a finding of scientific misconduct in this case.

**Fabrication/Falsification:** The respondent, a professor, allegedly falsified or fabricated research results on transgenic mice and included the questioned results in a table in a published paper. The questioned research was supported by two grants from the NHLBI, NIH, and was included in a grant application and a renewal grant application submitted to the NIAID, NIH. The institution conducted an investigation into the matter and found research records to support the published results. The institution concluded that there was no research misconduct on the part of the respondent. ORI accepted the institution's conclusion and found insufficient evidence to make a finding of scientific misconduct in this case.

**Falsification/Plagiarism:** The respondent, a professor, allegedly copied and falsified material from a former student's grant application, including a portion of a statement about imaging equipment, into his own grant application submitted to the NIH. The institution conducted an investigation into the matter, which concluded that the respondent had committed research misconduct by misrepresenting his ability to conduct the research outlined in his grant application and falsifying information in the application. However, ORI did not make a finding of scientific misconduct in this case because ORI does not consider the alleged use of a former collaborator's material to fall under ORI's definition of plagiarism. As indicated in the institution's report, whether the misrepresentation was willfully or carelessly performed could not be determined; ORI found that the evidence of the respondent's intent to falsify the disputed statement and to deceive the NIH reviewers was mixed.

### Scientific Misconduct Related Litigation During 2000<sup>1</sup>

#### Civil Litigation

*U.S. ex rel. Dreyer v. Massachusetts Eye & Ear Infirmary*, C.A. No. 99 CV11948JLT (D. Mass., filed 1999). The Relator, Dr. Dreyer, filed this *qui tam* suit under the False Claims Act, 31 U.S.C. § 3730, against the Massachusetts Eye and Ear Infirmary (MEEI) and others. He alleged that: (1) the defendants falsely certified compliance with NIH K-series grants as to the amount of time spent on grant related activities; (2) one of the defendants falsely certified compliance with the amount of time spent on his own NIH grants; (3) grant fraud was widespread at MEEI; and (4) items had been “up coded” for ophthalmological examinations performed at MEEI for reimbursement under Medicare. Dr. Dreyer also alleged that he reported this fraud to MEEI in 1997 and that in response, MEEI brought the charges of PHS scientific misconduct against him. In September 2000, after the government declined to intervene, the District Court unsealed the case, and Dr. Dreyer and the United States agreed to request voluntary dismissal of the case without prejudice. However, under the terms of Dr. Dreyer’s Voluntary Exclusion Agreement with the PHS (see discussion at Appendix A), Dr. Dreyer and the United States filed an amended notice of voluntary dismissal on December 4, 2000, in which Dr. Dreyer consented to the dismissal of his complaint with prejudice. Pursuant to 31 U.S.C. § 3730(b)(1), the Court dismissed the complaint without prejudice as to the United States. The case is now closed.

*U. S. ex rel. John Anderson v. University of Michigan*, No. 99-72948 (E.D. Mich., filed 1999). In July 2000, the District Court dismissed this case *sua sponte* for the Relator’s failure to prosecute. In February 2000, shortly after the United States declined to intervene, the District Court lifted the seal in this *qui tam* action. The Relator, John Anderson, had alleged that the University of Michigan, Wayne State University, and others violated the False Claims Act. Mr. Anderson’s allegations included charges

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<sup>1</sup>OGC tracks all civil and criminal litigation cases related to ORI’s mission. Many cases, especially those in which ORI is a named 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.

that the defendants: 1) made false statements and presented fabricated data in proposals to NIH; 2) plagiarized his research and used it to support an NIH funding proposal; 3) improperly received funding from both NIH and another source to conduct the same research; 4) misappropriated Federal research funds in violation of the NIH grant regulations; 5) failed to comply with ORI's assurance program and applicable research integrity policies and made false statements to ORI regarding compliance; 6) made false statements and plagiarized data in a NIH SBIR application; 7) threatened and retaliated against the Relator for reporting the alleged misconduct; 8) discriminated against the Relator on the basis of a perceived serious mental impairment; and 9) failed to follow the uniform administrative requirements for grant awards. The case is now closed.

*U. S. ex rel. Yong Wu v. Jefferson Medical College*, (E.D. Pa., filed 1997). In January 2000, the District Court for the Eastern District of Pennsylvania lifted the seal in this *qui tam* proceeding to enable the United States and Thomas Jefferson University (TJU) to conduct settlement negotiations. The Relator, Yong Wu, Ph.D., a former employee of TJU, filed this *qui tam* action against Jefferson Medical College, Dr. Lingxun Duan, and Dr. Roger Pomerantz alleging violations of the False Claims Act (FCA). Dr. Wu claimed that the defendants: (1) fabricated and falsified data in their conducting and reporting research; (2) filed NIH grant applications on a pseudogene on which they intended to conduct clinical trials for HIV; and (3) violated the whistleblower provision of the FCA. On June 6<sup>th</sup>, the District Court approved a global settlement agreement of this case and another involving NIH grants. With respect to this *qui tam*, TJU agreed to return \$450,000 in NIH grant funds and to correct the scientific literature. In a related matter, Dr. Duan, one of the defendants, agreed to accept a 2-year debarment followed by a year of supervision for any PHS-funded research (see Appendix A). The case is now closed.

*U.S. ex rel. Gene Ioli v. University of California*, No. SACV 98-473 GLT (C.D. Cal., filed 1998). The Relator, Mr. Gene Ioli, filed this *qui tam* suit under the False Claims Act (FCA) against the University of California, Dr. John Hiserodt, and others. Mr. Ioli alleged, among other things, that Dr. Hiserodt violated the terms of his 5-year debarment for committing scientific misconduct by directing the PHS-supported research of others at the University of California at Irvine. Mr. Ioli further alleged that the University of California falsely certified compliance with NIH grant requirements in a grant application to the National Cancer Institute. The United States declined to intervene, and the District Court lifted the seal. Based

upon the recent U.S. Supreme Court decision in *Vermont Agency of Natural Resources v. U.S. ex rel. Steven*, which held that State agencies may not be sued by a *qui tam* relator under FCA, the District Court dismissed the *qui tam* suit as to the Regents of the University of California. The Court did not dismiss the other individual defendants, and the case continues against them.

*U.S. ex rel. Streed v. University of California*, No. 97 CV0443K (RBB) (D.S. Cal., filed 1997). The Relator, Thomas B. Streed, Ph.D., filed this *qui tam* action under the False Claims Act (FCA) against the University of California, Immusol Inc., Pfizer Inc., and several individual scientists. Dr. Streed alleged that the defendants: 1) illegally imported and conducted research using NIH grant funds on "human neurological disease;" 2) contaminated other NIH-funded research materials with the imported material; 3) improperly transferred NIH grant funds and medical technology to Immusol; 4) improperly used NIH funds to pay defendants for work done at Immusol; 5) filed patent applications without disclosing to the Government that the inventions were made using NIH grant funds; 6) failed to disclose to NIH conflicts of interest in conducting grant reviews and administering grant funds; 7) made false statements to NIH about compliance with environmental and health safety regulations and safety records; and 8) fabricated research data. In 1998, the United States declined to intervene, and the District Court lifted the seal. In 2000, the Court dismissed the University of California as a defendant pursuant to *Vermont Agency of Natural Resources v. U.S. ex rel. Steven*, the U.S. Supreme Court case which held that State agencies may not be sued by a *qui tam* relator under FCA. The Relator then filed his third amended complaint, and the case continues.

*Marguerite Kay, M.D. v. State of Arizona Board of Regents*, No.328309 (Sup. Ct. of Arizona, filed 1998). Dr. Kay filed this suit against the University of Arizona in State court claiming wrongful discharge and violation of the Arizona Administrative Procedure Act, A.R.S. § 12-901, *et seq.*, and the United States and Arizona Constitutions. She claimed the alleged violations occurred because the University terminated her employment as a tenured professor without providing her with the required substantive or procedural due process and without adherence to the policies of the State Board of Regents. The University had conducted several investigations and found that Dr. Kay had committed, among other internal institutional charges, PHS scientific misconduct. After the inquiry, investigations, and subsequent public administrative hearing, the institution terminated her in 1998. In 1999, the State District Court ruled that the University failed

procedurally to follow its policies for termination of faculty and remanded the termination matter back to the University. However, the court held it did not have jurisdiction to order her reinstatement or back pay. The court dismissed the rest of Dr. Kay's complaint but awarded her reasonable attorneys' fees and costs. The University reinstated Dr. Kay, refired her, and she administratively appealed the new firing. The University's conciliation procedures did not produce a settlement, and the administrative rehearing on the scientific misconduct and termination matters began again. The Arizona Court of Appeals then ruled that the lower court judge had the authority to consider the reinstatement issue and sent that issue back to the district court. Both parties appealed the Court of Appeals' decision to the Arizona State Supreme Court, which had not yet ruled by the end 2000. The case continues.

***U.S. ex rel. Karuturi v. John Wayne Cancer Institute***, No. 95-7939-CMB (C.D. Cal., filed 1995). The Relator, Dr. Satyanarayana Karuturi, a former researcher at the John Wayne Cancer institute (JWCI), filed this *qui tam* complaint under the False Claims Act (FCA) alleging that JWCI, St. Johns Medical Center, the University of California at Los Angeles, and two JWCI researchers submitted false claims for payment to the National Cancer Institute by failing accurately to describe research results in grant applications and progress reports submitted to the Institute. JWCI performed an inquiry and found insufficient evidence to proceed to an investigation on Dr. Karuturi's allegations of scientific misconduct or retaliation for reporting misconduct. ORI's oversight concurred with these findings. In 1996, the United States declined to intervene, and Dr. Karuturi pursued his complaint independently. In 1998, the District Court dismissed all defendants except JWCI and all claims except for the FCA charges on specified grant applications and the wrongful termination claim under the whistleblower section of the FCA, 31 U.S.C. § 3730(h). The Court granted JWCI's motion for summary judgment and dismissed all remaining claims in the case, and Dr. Karuturi appealed. After the Ninth Circuit Court of Appeals denied his request to waive filing fees based on *pro se* status, he withdrew the appeal. The case is now closed.

***U.S. ex rel. Cantekin v. University of Pittsburgh***, No. 91-0715 (W.D. Pa., filed May 1991). The Relator, Dr. Cantekin, a researcher at the University of Pittsburgh, filed an action against the University and individual employees of the University, under the *qui tam* provision of the False Claims Act (FCA), alleging that they defrauded the United States by making false financial disclosure statements in applications for Federal grants. The United States declined to intervene, and the District Court dismissed sev-

eral of the Relator's claims. However, the court allowed the Dr. Cantekin to go forward on his Federal whistleblower action against the University and his post-October 1986 FCA claims. In 1998, the court granted the University defendant's motion for summary judgment on the remaining FCA claims, holding that the defendant researcher at issue lacked the requisite intent and did not "knowingly" submit false or fraudulent information to the Government. The court also ruled that the NIH grant application and instructions were unclear and subject to varying interpretations with respect to what was required in the "other support" section. Further, the researcher's disclosure in earlier applications and in a 1987 letter, negated any possible finding that he knowingly submitted a false or fraudulent claim. Thus, the court held that there was insufficient evidence in the record to create a genuine issue of material fact to support the Relator's claims. Dr. Cantekin appealed.

In a 1999, the Third Circuit affirmed the lower court's dismissal of the pre-October 1986 FCA claims although on different grounds. However, the court reversed the lower court's dismissal of the post-October 1986 claims stating that there were genuine factual disputes that preclude summary judgment on whether the defendants knowingly submitted a false claim. The Circuit Court held that: (1) there was a question of fact regarding the researcher's state of mind; (2) the NIH grant application instructions were clear that a researcher must disclose other support; and (3) because the 1987 letter was sent after the researcher was under investigation and was not disseminated to the grant reviewers for consideration, it was not exculpatory nor did the grant reviewers have access to the information in the letter. 192 F.3d 402 (3rd Cir. 1999). In October 2000, the U.S. Supreme Court denied Dr. Cantekin's petition for *certiorari*. 121 S.Ct. 192 (2000). The case continues on the remaining issues.

***U.S. ex rel. Lucinda C. Scott v. Dr. Robert J. McKenna, Jr.***, No. 96-5176CBM (C.D. Cal., filed 1996). The Relator, Ms. Scott, filed this *qui tam* action under the False Claims Act (FCA), *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), the NIH, and the Department of Energy. Ms. Scott 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 his grant applications were funded. In 1997, the United States declined to intervene, the court

lifted the seal, and Ms. Scott pursued the case independently. In 1998, the district court dismissed, with prejudice, the relator's claims against the University of California at Irvine and the Tustin Rehabilitation Hospital, but declined to dismiss the claims against Dr. McKenna and other named physicians and hospitals. The Relator filed an amended complaint, and the United States is reconsidering whether to intervene. The case continues.