Office of Research Integrity

ANNUAL REPORT 2001

JULY 2002

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Secretary
Office of Public Health and Science

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Highlights of 2001 ORI Annual Report

POLICIES AND REGULATIONS

Proposed Whistleblower Regulation

The Department of Health and Human Services (Department) published a Notice of Proposed Rulemaking (NPRM) to implement Section 493(e) of the Public Health Service (PHS) Act, which required the Secretary to establish regulatory standards for preventing and responding to occurrences of retaliation taken against whistleblowers by entities that have a research misconduct assurance and by officials and agents of those organizations. The NPRM, 65 Fed. Reg. 70830 (Nov. 28, 2000), 65 Fed. Reg. 82972 (Dec. 29, 2000), is available on ORI's web site. ORI received 47 responses from whistleblower organizations, universities, professional associations, the media, a government agency, and individuals in 2001. ORI expects to recommend revisions to the Department in 2002.

Revised PHS Misconduct Regulations

A draft of the revised PHS misconduct regulations was submitted to Office of Public Health and Science (OPHS) and the Office of the Secretary (OS) for review in early 2002. The revised regulation incorporates the new Federal research misconduct policy published by the Office of Science and Technology Policy on December 6, 2000, formally adopts the policy changes made by the Department in 1999, and updates the regulation based on the past 10 years experience in implementing it.

RCR Policy

Implementation of the PHS Policy on Instruction in the Responsible Conduct of Research (RCR) published in the *Federal Register* on December 1, 2000, was suspended on February 21, 2001, to permit review of the substance of the policy as well as the process followed in its adoption. This suspension resulted from a congressional inquiry that questioned whether the requirement should have been processed as a proposed regulation rather than a policy.

During 2001, ORI undertook a series of meetings with professional and institutional associations and scientific societies to solicit additional comment on the

suspended policy. ORI also consulted with PHS agency representatives on the policy. Potential revisions to the RCR policy were still under consideration at the time this report went to press.

Governmentwide Suspension and Debarment NPRM

A Notice of Proposed Rulemaking to revise the regulations on the Governmentwide Nonprocurement Common Rule for debarment and suspension was published in early 2002, 67 Fed. Reg. 3266 (2002). ORI pursues more debarment cases than any other office within the Department, and an attorney in ORI's Research Integrity Branch of the Office of the General Counsel played a key role in drafting the revision.

A Notice of Proposed Rulemaking to revise the regulations on the Governmentwide Nonprocurement Common Rule for debarment and suspension was published in early 2002, 67 Fed. Reg. 3266 (2002).

OVERSIGHT OF ALLEGATIONS

Responding to Misconduct Allegations

More than half of the research misconduct cases (56 percent) closed by ORI in 2001 resulted in misconduct findings (see Graph 1). This represented more than a doubling of the rate of misconduct findings compared with the previous year, and far exceeding the historical average of 33 percent (see Graph 2). The 14 cases that ORI concluded with misconduct findings and/or administrative actions resulted in debarments or voluntary exclusions for 10 respondents ranging from 1-5 years; prohibition from serving as an advisor to PHS for all 14 respondents from 3-5 years; required supervision for 4 respondents for 3 years each, and citation certification of all contributions for 2 respondents for 2 years each. On average, two administrative actions were imposed on each respondent.

The misconduct findings and/or administrative actions involved 10 cases of falsification and/or fabrication of data, 3 cases of plagiarism in combination with fabrication or falsification, and 1 case of plagiarism.

In 2001, ORI opened 35 new cases and closed 25 cases, with 41 cases remaining open at the end of the calendar year, slightly more cases than ORI had in 2000. The total processing time for the 25 cases closed in 2001 averaged 14.6 months (9 months, median, and 4 months, mode). For institutions, processing time averaged 8.7 months (4 months, median, and 2 months,

mode). For ORI, processing time averaged 5.9 months (4 months, median, and 3 months, mode). Ten cases were closed with no misconduct findings or PHS administrative actions taken against any individuals (see summaries in Appendix B), and one case was closed administratively.

The number of allegations received by ORI has increased for 3 consecutive years from 112 in 1998, to 129 in 1999, to 173 in 2000, and to 196 in 2001. ORI has only received more than 196 allegations in a single year once since 1991—244 in 1995.

Research Misconduct Activity Increases

Institutions reported increased misconduct activity in their *Annual Report on Possible Research Misconduct* for the second consecutive year following a 3-year decline. Institutional annual reports were filed with ORI in early 2001. Eighty-two institutions reported misconduct activity in 2000 compared with 72 in 1999 and 67 in 1998. New cases were opened by 60 institutions in 2000 compared with 46 in 1999 and 41 in 1998.

Figure 1

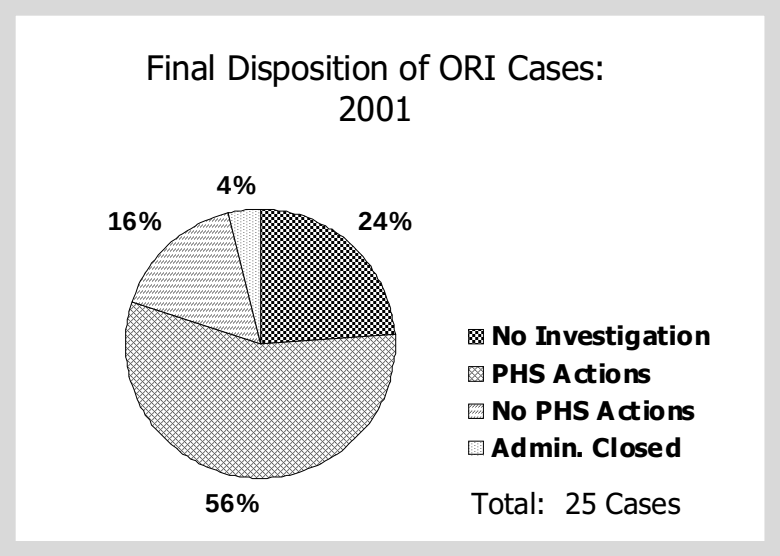
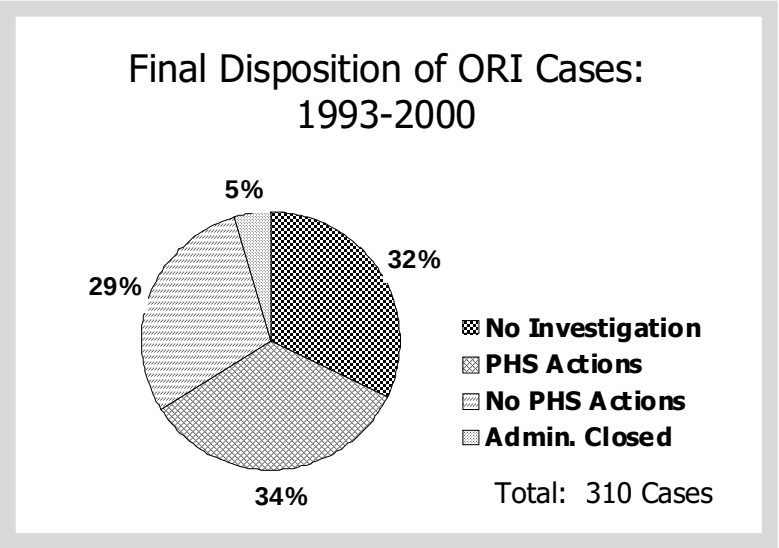


Figure 2



New cases resulted in 59 inquiries in 2000 compared with 51 in 1999 and 38 in 1998. The new cases also resulted in 18 investigations in 2000 compared with 9 The 103 new allegations received in 2000 were more than the 89 received in 1999 and the 69

received in 1998. The 62 new cases opened in 2000 was 1 less than in 1999, but 8 more than in 1998. Cases frequently involve more than one allegation.

Institutions are increasingly taking advantage of the technical assistance program begun in late 1999 by ORI.

The 82 institutions reporting misconduct activity in 2000 conducted 80 inquiries and 38 investigations in response to allegations made in 2000 and before. Sixty institutions opened new cases; 30 were completing old cases, and 8 were handling new and old cases. The number of inquiries conducted by an institution ranged from 0 to 2. The number of investigations conducted by an institution also ranged from 0 to 2.

Technical Assistance

Institutions are increasingly taking advantage of the technical assistance program begun in late 1999 by ORI to provide support for institutions responding to allegations of research misconduct, especially for the first time. In 2001, ORI offered technical assistance to 20 institutions and 10 accepted. Six other institutions asked for help on their own in 2001. Of the 16 institutions assisted in 2001, 8 were new clients. In 2000, ORI offered assistance to 12 institutions and 6 accepted. Nine other institutions initiated calls for help in 2000. A total of 15 institutions were assisted in 2000.

In one case, an ORI analyst spent a week at an institution providing assistance in organizing records. In another case, institutional officials and attorneys visited ORI to resolve questions over ORI jurisdiction and to obtain guidance in opening an inquiry. ORI also has provided assistance in analyzing possible image falsifications; informing a respondent about an allegation; developing investigative strategies; helping with the sequestration of data and other records; and addressing legal questions.

ORI offers assistance to institutions, even experienced ones, that are facing complex or difficult cases as well as to institutions handling their first case. ORI responds to calls for help from any institution or Federal agency.

EDUCATION AND PREVENTION

Conferences on Fostering Research Integrity and Handling Misconduct Allegations

ORI held 8 workshops or conferences in 2001, with an average attendance of nearly 90 participants at each meeting. Seven of these meetings were co-sponsored with universities, scientific societies, and professional associations.

On February 1, 2001, ORI held a workshop in Washington, DC, on implementing the Federal Research Misconduct Policy in collaboration with members of the Federal Research Misconduct Officials Network. On May 3-4, 2001, ORI co-sponsored a national conference with the American Speech-Language-Hearing Association in Rockville, MD, on promoting research integrity in communication sciences and disorders and related disciplines. ORI collaborated with The Johns Hopkins University School of Medicine to jointly sponsor a national conference on May 6-7, 2001, in Baltimore, MD, on creating effective compliance programs within academic institutions. On May 18-19, 2001, a national conference was held in Arlington, VA, on developing or improving institutional RCR programs, sponsored by ORI, Public Responsibility in Medicine and Research (PRIM&R), the Applied Research Ethics National Association (ARENA), the Association of American Medical Colleges (AAMC) and Tufts University School of Medicine. On May 30-31, 2001, ORI held its first national conference on legal issues and strategies for responding to research misconduct allegations, which was held in Washington, DC, and co-sponsored by the American Association for the Advancement of Science (AAAS), The Johns Hopkins University, and Howard University. ORI's first advanced investigative techniques workshop was co-sponsored by the Harvard Medical School and the University of Pittsburgh, and held on September 24-25, 2001, in Bethesda, MD. A regional conference on training in the responsible conduct of research was held on November 16-17, 2001, in Birmingham, AL, which ORI sponsored with the University of Alabama at Birmingham, East Carolina University, Meharry Medical College, Vanderbilt University, and Charles Stuart University (Canberra, Australia). On December 5, 2001, ORI sponsored a workshop on RCR instruction with the Council of Graduate Schools (CGS) in San Diego, CA.

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Publications

Educational Needs Assessment Study

This contract study concluded that RCR training is needed by principal investigators, research associates, postdocs, and graduate students, and resource materials are needed on scientific recordkeeping, data management, authorship, publication practices, conflicts of interest, intellectual property, and research misconduct. Training in handling research misconduct allegations is needed by vice presidents for research, science deans, department heads, and Research Integrity Officers (RIOs), and resource materials are needed on the requirements of proof, sequestering data, handling evidence, the development of investigational plans, and regulatory requirements. Study results and findings from "Office of Research

Integrity Education Program: A Needs Assessment" are available on the ORI web site in the Publications section under Studies/Reports.

Study of Guidelines for the Conduct of Research Adopted by Medical Schools

The *Analysis of Guidelines for the Conduct of Research Adopted by Medical Schools or Their Components* found considerably more medical schools provide written guidelines for the conduct of research for their faculty than in 1990. However, the majority of guidelines are narrowly focused and do not reflect much agreement on what topics guidelines should cover or what specific guidance should be offered. Conflict of interest was the most frequently addressed topic area in the guidelines. The final report from this contract study is available on the ORI web site in the Publications section under Studies/Reports.

ORI held exhibits or poster sessions at seven meetings of scientific societies or professional associations in 2001 to increase contact and generate a dialogue with members of the research and academic communities.

ORI Web Sites

A new section on comprehensive and specialized RCR instructional resources was added to the ORI web site in 2001. The instructional resources page may be accessed through the ORI home page located at **http://ori.hhs.gov** by selecting Programs and clicking on "RCR Instructional Resources" under RCR Education. Several comprehensive sources are listed as well as specialized resources on mentor/trainee responsibilities, collaborative science, human subjects, research involving animals, and conflict of interest and commitment.

The University of California at San Diego will be expanding the RCR web site located at **http://rcr.ucsd.edu** by adding new topic areas and downloadable course material to the site over the next 3 years, with support provided by ORI. A new interactive section of the web site will serve as a forum for exchanging ideas and information relevant to RCR instruction and will include a calendar of upcoming events.

Exhibits at Scientific and Professional Meetings

ORI held exhibits or poster sessions at seven meetings of scientific societies or professional associations in 2001 to increase contact and generate a dialogue with members of the research and academic communities. Exhibits or poster sessions were held at the following meetings: Experimental Biology 2001 in Orlando; Association of Clinical Research Professionals in San Francisco; American Society for Reproductive Medicine in Orlando; National Council of University Research Administrators in Washington, DC; American

Society for Cell Biology in Washington, DC; American Psychological Society in Toronto, Canada; and the Society of Research Administrators, in Vancouver, Canada.

Poster Program

Three sample posters on research integrity were developed and displayed in ORI exhibits at several scientific meetings to solicit comments from visitors to the exhibit booth. ORI expects to make at least one poster available in 2002.

Listservs

ORI created three listservs in 2001 to foster discussion and networking among interested parties. The institutional official listserv was created to exchange strategies and concerns about promoting research integrity and preventing research misconduct at institutions. The research listserv provides a forum for scholarly debate and encourages more research on the sociological, psychological, educational, organizational, and cultural factors that influence research integrity. The RCR instruction listserv promotes discussion and networking among researchers, research administrators, and RCR course instructors.

Resources for Education in the Responsible Conduct of Research

ORI was successful in getting the development of educational resources for training in the responsible conduct of research included in the omnibus solicitation for the Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) programs during 2001. Each program offers a maximum of $100,000 in total costs for Phase I projects. Two proposals were submitted in 2001, but neither were funded.

RCR Educational Consortium

A charter was developed for the Responsible Conduct of Research Educational Consortium (RCREC) that will promote and advocate RCR education as a central responsibility for any institution involved in research. ORI and the Office for Human Research Protections (OHRP) have supported development of this consortium.

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Liaison Activities

Seven of the eight conferences and workshops supported by ORI in 2001 resulted from collaborations with universities, scientific societies, and professional associations. ORI also held exhibits or poster sessions at seven scientific meetings in 2001.

Minority Initiatives

Howard University and Meharry Medical College were two historically black institutions that served as co-sponsors for ORI conferences in 2001.

Staff Publications

ORI staff published two articles on research integrity issues in 2001.

RESEARCH ACTIVITIES

Intramural Research

In 2001, one study was started, two studies were completed, and four were in progress.

New Studies

ORI contracted with the Gallup Organization to study how often research misconduct occurs. This study is scheduled to be completed in 2003. Gallup will collect data on the detection, reporting, investigation, and verification of alleged research misconduct from a large representative sample of principal investigators.

Completed Studies

See "*Study of Guidelines for the Conduct of Research Adopted by Medical Schools"* and *"Educational Needs Assessment Study"* summarized above.

Studies Underway

A contract study of the feasibility of creating consortia among institutions and professional organizations to assist institutions in fact-finding or other-

wise processing misconduct allegations is expected to be completed in early 2002.

ORI staff is preparing a report on a study of instructions to authors issued by 41 journals that published articles involved in findings of research misconduct.

The results of a draft report by the Institute of Medicine (IOM) on assessing integrity in research environments will be presented at a conference on October 10, 2002. Conceptual issues expected to be addressed in the IOM report include (1) defining "research environment" and "research integrity," (2) identifying elements of the research environment; (3) indicating how the elements may be measured; (4) distinguishing between those environmental elements that promote research integrity and those that do not; (5) suggesting appropriate methodology for collecting the data; (6) stipulating unit(s) of analysis; and (7) proposing appropriate outcome measures. IOM recommendations are also expected on ways to improve integrity in research institutions, including RCR education.

The survey of research integrity measures utilized in biomedical laboratories under contract with ORI is expected to be completed in 2003.

Extramural Research Program on Research Integrity

The Research on Research Integrity (RRI) Program, supported by National Institute of Neurological Disorders and Stroke (NINDS), National Institute of Nursing Research (NINR), and ORI, awarded seven grants in 2001. Total funding was about $1.03 million, which doubled the $500,000 ORI originally committed to the program, and represents a 28 percent funding rate. The RRI Program received 30 applications during the second round that closed on November 19, 2001, a 20 percent increase over the 25 applications received in the first round. Awards will be made in July 2002.

The Research on Research Integrity (RRI) Program, supported by National Institute of Neurological Disorders and Stroke (NINDS), National Institute of Nursing Research (NINR), and ORI, awarded seven grants in 2001.

ASSURANCE AND COMPLIANCE

ORI simplified the process and reduced the reporting burden associated with submitting the *Annual Report on Possible Research Misconduct* by switching to electronic submission in 2001. About 4,000 institutions must file the Annual Report to maintain their eligibility to receive research or research training funds from the PHS.

ORI reviewed 140 institutional policies on handling allegations of misconduct and inactivated assurances for 426 institutions for failure to submit an annual report for calendar year 2000.

Meeting Legal Challenges

ORI responded to several legal challenges during 2001, one of which is summarized below. For a more detailed discussion of this and other items, see Appendices A and C.

Marguerite Kay, M.D.* v. *Tolbert. This Federal case resulted in favorable rulings on the issue of qualified immunity for institutional officials who participate in research misconduct proceedings. Dr. Kay had filed suit against the University of Arizona, which had terminated her employment, and also against individual institutional employees, including members of the faculty investigation committee that had made findings of research misconduct against her. The District Court dismissed the case, holding that all the individual defendants were entitled to qualified immunity because at the time she was terminated, the law on this matter was unclear, and she had no clearly-established constitutional right to substantive due process protection. The court also held that the individual defendants were entitled to qualified immunity because they either did not cause the alleged due process violation (the termination without hearing) or they acted reasonably and relied in good faith on the termination process used on the advice of counsel.

I. Scientific Misconduct

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 of 2000, investigations in the Public Health Service (PHS) intramural program were conducted by the pertinent PHS operating division, e.g., National Institutes of Health (NIH) or the Centers for Disease Control and Prevention (CDC), and any extramural investigations requiring an HHS investigation would be conducted by the HHS Office of Inspector General (OIG).

Allegations

ORI staff assess each allegation received by ORI 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 misconduct, 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 initiates 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 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 may lead ORI to refer the allegation to the HHS Office of Inspector General).

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

In 2001, ORI received 196 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 (1) they do not fall under ORI jurisdic-

tion or meet the above 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 for ORI if an allegation contains insufficient specific information to permit another disposition.

Table 1:

Disposition of Allegations in ORI, 2001

Handling of allegations - outcome in ORI	*Number of allegations*
Pre-Inquiry Assessment by ORI of allegations:	
That were made to ORI directly	39
That were made to NIH initially	13
No Action Possible Now or No Action	106
Referred to other Federal agencies	25
Handled by NIH (for other allegations made to NIH)	13
TOTAL	196

Of the 196 allegations made to ORI in 2001, 52 were assessed in detail for a potential inquiry or investigation. Of the 196 allegations, 25 were immediately referred to other agencies, and 106 were closed without further action (Table 1). Of the 52 allegations that received a detailed assessment, 42 were resolved by ORI within 25 days from date of file assignment to date of administrative closure or of opening a formal case; the mean times were 24.3 and 10.8 days, respectively. Of the 50 ORI assessments completed in 2001, 33 (66 percent) resulted in formal cases being opened in ORI (Table 2). These data do not reflect the additional time taken by officials at NIH who handled (with advice, assessment, and assistance from ORI, as appropriate) the 26 allegations that were made directly to NIH by complainants (Table 1).

Table 2:

Time for Conduct by ORI of Pre-inquiry Assessments, 2001 (N=52)

Outcome of ORI assessment	*Number of allegations*	*Total days for resolution*	*Distribution of resolution times (days)*			
			Mean	*Median*	*Mode*	*Range*
Opened formal case	33	356	10.8	8	7	1–33
Administratively closed	17	413	24.3	14	1	1–116
Unresolved at end of year 2001	2	14	14.0	–	–	–
TOTAL	52	783	15.0	–	–	–

Cases Closed

ORI closed 25 cases in 2001, including 6 inquiries and 19 inquiries/investigations. The average duration of 14.6 months for an open case was split between institutional actions (8.7 months) and ORI oversight and actions (5.9 months) (Table 3).

Table 3:

Duration of Research Misconduct Cases Closed, 2001 (N=25)

Site of action during case	*Distribution of resolution times (months)*			
	Mean	*Median*	*Mode*	*Range*
Institution	8.7	4	2	1–80
ORI	5.9	4	3	1–23
TOTAL (Inst. & ORI)	14.6	9	4	4–86

The action period for the 6 institutional inquiries included their inquiry and adjudication phases, and for 19 institutional investigations included their inquiry, investigation, and adjudication phases.

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 required to make a PHS finding of misconduct (in some cases, the period may include a hearing requested by the respondent before the HHS Departmental Appeals Board; there were none this year).

In the single case that took 23 months for ORI to resolve, the institution had not reported the case to ORI since it was not PHS-funded. However, ORI learned of the case from a letter to the editor of a journal, retracting the questioned paper, and ORI determined that the falsified and fabricated data had been used in a PHS grant application, giving ORI jurisdiction. When ORI found that the institution's investigation had focused on exonerating a senior professor rather than thoroughly reviewing the evidence of scientific misconduct by a postdoctoral fellow, ORI had to do extensive work in obtaining and reviewing the research records to document the falsification and fabrication, which ORI used to negotiate a debarment agreement with the respondent and close the case.

In 2001, 14 of the 19 investigation cases closed by ORI resulted in sustained findings of scientific misconduct and PHS administrative actions against the respondent (Table 4). Summaries of these cases may be found in Appendix A. Summaries of the 10 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 (CY) 2001, ORI had 41 active formal cases, as well as 2 allegations, under review (Table 4).

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

In 2001, 14 of the 19 investigation cases closed by ORI resulted in sustained findings of scientific misconduct and PHS administrative actions against the respondent.

Table 4:

ORI Scientific Misconduct Caseload by Case Type, 2001

Case type	*Forwarded from 2000*	*Opened in 2001*	*Closed in 2001*	*Carried into 2002*
Institutional Inquiries	5	17	6	16
Institutional Investigations	26	18	19	25
TOTAL	31	35	25	41

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. Other institutions may submit inquiry reports to ORI (some 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 thorough, competent, and objective.

During 2001, ORI accepted six institutional inquiry reports that did not recommend further investigation (Table 5). Five cases involved allegations of falsification, and one dealt with alleged fabrication and falsification (see Table 6). ORI carried 16 such institutional inquiries into 2002, including one PHS intramural case opened in 2001.

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 deter-

mine whether the conduct of the investigation complied with the PHS regulation; was thorough, competent, and objective; and provided a basis for a PHS finding of misconduct. In 2001, ORI monitored 26 investigations at research institutions. During the year, 18 new institutional investigations were opened; 19 investigations cases were closed. Of these 19 closed cases, 14 involved ORI findings of scientific misconduct, 4 did not have such findings, and 1 was administratively closed by ORI. There were 25 active investigations carried into 2002.

ORI inquiries and investigations: Previously, ORI conducted inquiries or investigations 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. Given last year's HHS decision that Federal fact-finding should be done by the OIG, which has subpoena power, there were no ORI inquiries or investigations opened in 2001. OIG did not open any investigations related to ORI cases in 2001.

Table 5:

Outcome of Research Misconduct Cases Closed by ORI, 2001 (N=25)

Case Type	*Outcome of Case*				*Total*
	No investigation	*No misconduct*	*Misconduct finding*	*Admin. Closed*	
Institutional Inquiry	6	-	-	-	6
Institutional Investigation	-	4	14	1	19
ORI Inquiry or Investigation	-	-	-	0	
TOTAL	6	4	14	1	25

Types of Allegations Involved in Closed Cases: During 2001, of the 6 closed inquiries and 19 closed investigations, 6 inquiries and 15 investigations involved allegations of falsification, fabrication, or both. Of those 21 cases, 10 cases resulted in ORI findings and/or administrative actions. Four cases involved plagiarism, two of which also involved falsification, and one of which

also involved fabrication; all four of these cases led to ORI findings and/or administrative actions (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	0	4	2
Falsification	5	6	4
Plagiarism	0	1	1
Fab/Fals	1	5	4
Fab/Plag	0	1	1
Fals/Plag	0	2	2
TOTAL	6	19	14

PHS Administrative Actions Imposed in Closed Cases: A range of administrative actions are used by PHS to protect the public fisc and the integrity of PHS-funded research. Persons may be debarred or voluntarily exclude themselves for several reasons, including a criminal conviction, fraud, or serious misconduct. Once debarred or excluded, a person may not receive any form of assistance, financial or nonfinancial, from the Federal Government for a set period of time.

For the 14 cases in 2001 in which ORI findings or PHS administrative actions were imposed, 10 persons were debarred or voluntarily excluded for periods from 1 to 5 years. Other administrative actions imposed on respondents in these 14 closed cases included the following: (a) prohibition from serving in any advisory capacity to PHS, including service on PHS advisory committees, boards, and/or peer review committees or as a consultant for a specified period of time [14 persons]; (b) participation in any PHS-funded research subject to supervision requirements for a specified period of time, wherein the institution is required to submit a plan of supervision that will ensure the

scientific integrity of the individual's research contribution [4 persons]; and (c) submission by the respondent with each application or report a statement of certification, endorsed by an institutional official, that all contributors to the application or report are properly cited or otherwise acknowledged (not plagiarized) [2 persons] (Table 7).

Table 7:

PHS Administrative Actions Imposed in Closed Investigations with Misconduct Findings or Administrative Actions

PHS Administrative Actions	*Duration*	*Number of Such Actions*
Debarment or	1 year	2
Voluntary Exclusion	3 years	4
	5 years	4
Prohibition from Serving	3 years	9
as an Advisor for PHS	4 years	1
	5 years	4
Supervision Plan Required	3 years	4
Certification of Research Required	3 years	2
Retraction/Correction of the Literature	-	3

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 or warrant further action. There was one institutional investigation, included in the data above, that was administratively closed by ORI in 2001.

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) educating or assisting on 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 journal editors for papers that require correction or retraction.

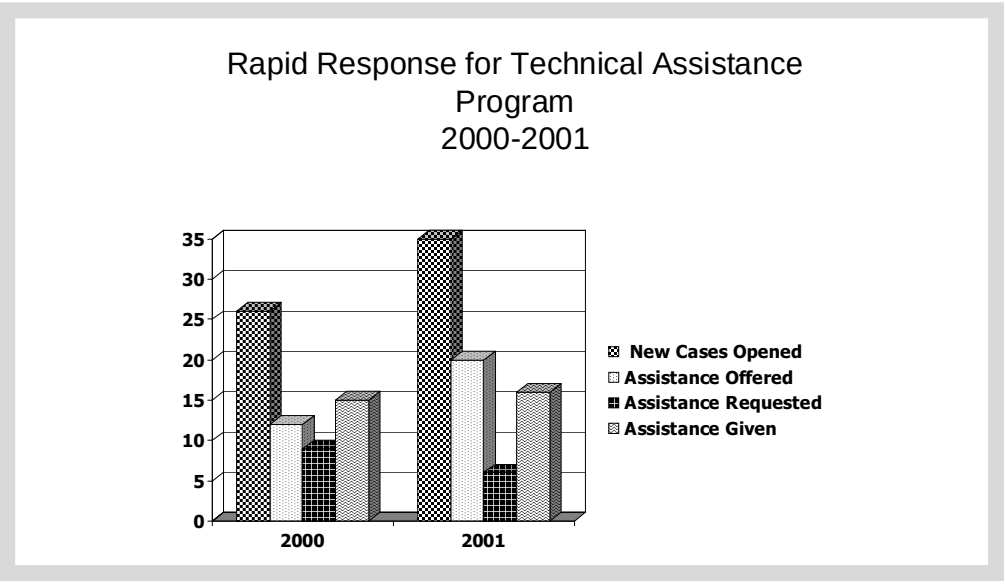
ORI created a Rapid Response for Technical Assistance (RRTA) program to provide aid to institutions conducting allegation assessments, inquiries, and investigations.

Among the 35 new cases opened in 2001, the Division of Investigative Oversight (DIO), ORI, made 20 RRTA offers to these institutions, and 10 accepted. Six other institutions asked for help on their own. Of the 16 institutions in 2001, 8 were new clients. In 2000, ORI offered assistance to 12 institutions; 6 accepted. Nine other institutions initiated calls for help. A total of 15 institutions were assisted in 2000 (Graph 3).

An additional team of officials and attorneys visited ORI to resolve questions over ORI jurisdiction and to obtain guidance in opening an inquiry. In three new cases, DIO provided image files and guidance to the institutional officials on programs and strategies that they could use for their analysis of possible image falsifications. An institution and another Federal agency, knowing of ORI's extensive experience in handling over 2,000 allegations, called ORI for strategic guidance on two other allegations that fell outside of PHS jurisdiction; ORI staff provided extensive on-site advice and sample documents to assist the latter agency.

In one new case, ORI provided RRTA on-site advice and assistance in informing the respondent and obtaining records for an inquiry at a university and its affiliated small business. In another new case, ORI staff accompanied Federal

Figure 3



program auditors to the institution on two occasions and provided the official with information of use to its inquiry. ORI also provided RRTA help to five institutions for which ORI had opened cases in the previous year; in one, a team like that cited above visited ORI to discuss investigative strategies.

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, involvement of outside parties, and premature or incomplete "admissions." ORI staff will provide such RRTA help over the telephone (call DIO at 301-443-5330) or on-site.

Federal Regulations

Regulation to Protect Whistleblowers

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 Secretary 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.

Among the 35 new cases opened in 2001, the Division of Investigative Oversight made 20 RRTA offers to these institutions, and 10 accepted.

The NPRM, 65 Fed. Reg. 70830 (Nov. 28, 2000), 65 *Fed Reg*. 82972 (Dec. 29, 2000), is available on ORI's web site. ORI received 47 responses from whistleblower organizations, universities, professional associations, the media, a government agency, and individuals during the comment period which closed in 2001. Once a detailed legal analysis of the comments is complete, ORI expects to make recommendations for revisions to the NPRM to the Department in 2002.

Revised PHS Misconduct Regulations

A draft of revised PHS misconduct regulations was submitted to Office of Public Health and Science and the Office of the Secretary for review in early 2002. The revised regulation incorporates the new Federal definition of misconduct and policies published by the Office of Science and Technology Policy in December 2000, formally adopts the policy changes made by the Department in 1999, and updates the regulation based on the past 10 years experience in implementing it.

Governmentwide Suspension and Debarment NPRM

An NPRM to revise the regulations on the Governmentwide Nonprocurement Common Rule for debarment and suspension was published in early 2002, 67 Fed. Reg. 3266 (2002). ORI pursues more debarment cases than any other office within the Department of Health and Human Services (HHS) and an attorney in ORI's Research Integrity Branch of the Office of the General Counsel played a key role in drafting the revision. The proposed rule is in plain language, and most of the substantive changes have to do with nonprocurement activities that focus on relationships between awarding

agencies and institutions receiving awards, rather than ORI or the debarred individual.

Policy Guidance and Technical Advice

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. A compilation of ORI's policies on 26 significant issues may be found at **http://ori.dhhs.gov/html/misconduct/inquiry_issues.asp**

Three articles, one dealing with a policy issue and two providing technical advice concerning statistical forensics, were published in the *ORI Newsletter* during 2001, and are reprinted below.

1. Concerns About Using Set-Up Experiments in Institutional Investigations

Several investigation reports transmitted to ORI from research institutions in recent years have included descriptions of experiments that were set up to try to detect additional fabrication or falsification of research results by the respondents. The set-up experiments (S-UEs) were arranged by complainants or institutional officials. Setting up experiments or asking respondents to repeat the experiments resulted in misconduct findings in the first three case examples given here. However, in other cases, the S-UEs failed to include safeguards, so the results were not useful in supporting an ORI finding of scientific misconduct. Furthermore, "repeating" the originally-claimed results in an experiment does not alone disprove an allegation that the original work was fabricated.

Most findings of scientific misconduct are not based on the implementation of S-UEs and S-UEs are not necessary to confirm scientific misconduct. The results of S-UEs will not be useful in confirming misconduct unless adequate safeguards are imposed to monitor the situation and document any evidence.

Case #1

An M.D./Ph.D. graduate student was suspected of fabricating data on experiments over several years. When asked to return to the laboratory to repeat the work on blinded samples, the student repeated the results in the presence of a coworker. However, when the laboratory director evaluated the materials used in the repeat experiments, the director found changes indicating the student had surreptitiously determined the contents of the "blinded" tubes before doing the new experiments. The student admitted doing so when challenged, and ORI obtained a debarment of the respondent from receiving Federal funds.

Case #2

A postdoctoral fellow was observed pipetting material into labeled scintillation vials before conducting an experiment. The complainant secretly counted the vials and found they had been "spiked" with radioactive material. The respondent apparently was conducting the research with unlabeled cells and discarding them. The complainant went to the laboratory director, who set up experiments with animals deliberately misidentified as being transgenic, but the fellow got the results that he had predicted if they were transgenic. The institution found scientific misconduct in this case and retracted four papers. Based on the institution's report, ORI obtained a debarment agreement.

Case #3

The institution found substantial evidence of falsification of data by a graduate student who had finished a doctoral thesis. The officials delayed awarding the degree, but allowed the student a year to try to repeat the allegedly falsified results in another laboratory. ORI informed the institution that getting the expected results would not constitute proof that the original experiments were actually done, since the student might have correctly predicted the results without actually conducting the original experiments. But the institution insisted that the student have the opportunity to repeat the protocol. However, the student ultimately was unable to do so (there was evidence the student had changed the labels on the new materials, too). ORI found sufficient evidence of multiple falsifications in the student's original research to warrant debarment.

Case #4

A group of postdoctoral and graduate students had individually raised concerns about some of the work that their professor did to complete the assays and report the results of the experiments that the students had initiated. So the students set up several experiments in which the biological samples were non-positive controls, but they told the professor that they were actual test samples. The professor got results that were consistent with those predicted by his theoretical model, but were impossible to achieve based on the actual samples. Unfortunately, the students did not inform the chairman, dean, or counsel in advance, and they could not prove later what the samples had contained. Although the evidence of other falsifications by the professor was sufficient for ORI to get a debarment agreement, ORI was not able to use the results of the S-UE to confirm scientific misconduct.

Case #5

A professor and a senior scientist suspected that a graduate student had spiked biological samples before testing, to guarantee achieving the predicted results. They notified university officials, and they arranged for the student to return to their laboratory to conduct controlled, blinded experiments under their close supervision. However, because they learned later that the student could have had overnight access to the room with the "blinded" samples, the student could have tested and decoded the samples before the supervised runs. In the end, the institution found that the evidence was insufficient to conclude that the student had committed scientific misconduct, and ORI agreed.

Case #6

A postdoctoral fellow was accused of manipulating instruments to get results that were "almost perfect" in physiological experiments on patient tissues. The laboratory chief set up experiments in which water was substituted for the biological agent in the solution that he planned for the fellow to use. When the new results came out as expected, he accused the fellow of falsifying all the results, and the fellow left the laboratory without responding. However, the investigation committee found that none of the new stock solution, made up to a standard volume, appeared to have been used. The fellow's notebooks indicated that a new vial of agent had been prepared, and the fellow testified that this new solution had been

used for the repeat experiments. The institution found insufficient evidence of misconduct, and ORI agreed.

ORI concludes from these examples that set-up experiments have sometimes been problematic, especially when the members of the laboratory conducting the S-UEs have not sufficiently documented the evidence or informed institutional officials who could independently monitor or confirm the actions. However, in other cases, the S-UEs have been used successfully to confirm suspicions about scientific misconduct and to obtain an admission from the respondent.

2. Statistical Forensics: One Digit Too Many!

When the original handwritten data contain only *three* decimal places, and the same data entered into a Microsoft Excel® spreadsheet appear with *four* decimal places, there is cause for suspicion. Where did that extra digit come from? And when that fourth digit is either a *zero* or a *five*, (and no other digit, e.g., *one* or *nine*) the suspicion is that division by *two* produced the fourth decimal digit. Thus, division by *two* of a decimal number whose last digit is *odd* leaves a remainder of *one-half* which produces an extra decimal digit, *five*. In contrast, when the last digit is even, there is no remainder and the extra digit is *zero*. Division by two yields no other extra digits.

In one case, these clues led investigators of ORI's Division of Investigative Oversight (DIO) to determine that the data for a third rat were fabricated by averaging the data for two others. This case concerned a study of the effect of rhythmic contractions of skeletal muscle in the hind limbs of rats where blood flow was measured at rest and during nerve stimulation. Measurements of blood flow and muscle weight were recorded.

The respondent presented results for six rats in a lab seminar. Sometime after that, a co-worker discovered that the original data sheets for two rats were blank. The respondent furnished the university with copies of tracings of continuous measurements, handwritten recorded data for muscles for six rats, and printouts of a Microsoft Excel® spreadsheet that contained blood pressure measurements and muscle weights for six rats.

DIO investigators concentrated on the measurements of muscle weight. The investigators observed that the entries in the spreadsheet for Rat-3 and Rat-6, purportedly copied from the handwritten data sheets, had an extra decimal digit. Therefore, the spreadsheet numbers had not been copied from the handwritten sheets. They further observed that the extra digit was either *five* or *zero*. This observation led to the hypothesis that the Rat-3 and Rat-6 measurements were the average of two measurements. Investigators then verified that the purported measurements for "Rat-3" and "Rat-6" were the averages of the corresponding measurements, respectively, for Rat-1 with Rat-2, and Rat-4 with Rat-5. This irrefutable demonstration that the weights for both Rat-3 and Rat-6 were fabricated by calculation facilitated the voluntary exclusion of the respondent from receiving Federal funds for 3 years.

3. Statistical Forensics: Check Rightmost Digits for Uniform Distribution

Numbers are often recorded beyond the repeatability of the experimental procedure. When counts or measurements are recorded to higher precision than can be repeated in replications of an experiment, the rightmost digits of the recorded numbers have little biological meaning. Consider a count of radioactivity for a biological preparation, for example, 5179. In a recount of the sample, or in a replication of the assay, it is unlikely that the rightmost digits will be the same. Thus, with three repetitions, 5179, 5118 and 5134 could be expected.

The rightmost digits of these three numbers differ. Thus xx **79** differs from xx **18**, and, in turn, both differ from xx **34**.

In large samples of numbers, such rightmost digits often occur with the same frequency, like lottery digits where each of the digits 0, 1, 2, . . . , 9 has the same expectation. Statistically speaking, rightmost digits are approximately uniformly distributed in many circumstances.

In one ORI case, the respondent's notebook contained fabricated counts as well as un-fabricated counts. For the fabricated counts the radioactive spots on the experimental sheets had not been excised and hence could not have been counted in the scintillation counter. The un-fabricated counts were supported by counter tapes.

Investigators from ORI's Division of Investigative Oversight (DIO) compared rightmost digits of fabricated and un-fabricated counts. The fabricated digits differed significantly from uniform. The un-fabricated digits did not so differ. (The respondent accepted voluntary exclusion from receiving Federal funds for 3 years.)

In another case, one column of a published table of numbers was not supported by notebook data. DIO investigators found that the rightmost digits of the unsupported column differed significantly from uniform. The rightmost digits of the supported columns did not so differ. (The paper was retracted, and in a related Department of Justice settlement, the Government recovered over $1 million from two universities.)

To succeed in fabricating data, the fabricator must make the leftmost digits exhibit the desired biological magnitudes. Rightmost digits, given little thought, may be subject to personal preferences of the moment, and hence not uniform. Even when instructed to "make up" numbers with uniform digits, many subjects appear unable to do so. (See "Data Fabrication: Can people generate Random Digits?" J.E. Mosimann, C.V. Wiseman and R.E. Edelman, *Accountability in Research*, 4, 31-55, 1995.)

In cases of scientific misconduct, un-scientific details, like rightmost digits, are worthy of attention.

II. Education and Prevention

ORI's education and prevention activities continued to expand in 2001. Noteworthy actions and achievements included:

- ORI held eight workshops or conferences in 2001, with six of these meetings co-sponsored with universities, scientific societies, and institutional associations. Four of the eight meetings focused on promoting research integrity or teaching responsible conduct of re search.

- Three publications were issued in 2001: (1) Educational Needs Assess ment; (2) Study of Guidelines for the Conduct of Research Adopted by Medical Schools; (3) *ORI Annual Report - 2000.*

- ORI held exhibits or poster sessions at seven meetings of scientific societ ies or professional associations in 2001, almost doubling the four held in 2000, to increase contact and generate dialogue with members of the research and academic communities.

- ORI is constructing a new section on instructional resources on its web site located at **http://ori.hhs.gov** to call attention to RCR materials cur rently available. It can be accessed by selecting Programs and clicking on "RCR Instructional Resources" under RCR Education.

- A 3-year contract with the University of California at San Diego (UCSD) will expand and update the web site located at **http://rcr.ucsd.edu** to add new topic areas and downloadable course materials.

- ORI created three new listservs in 2001 to foster discussion and network ing among institutional research integrity officers, responsible conduct of research instructors, or researchers studying research integrity, research misconduct, or the responsible conduct of research.

- ORI was successful in getting the development of educational resources for training in the responsible conduct of research in the omnibus solicita-

tion for Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) programs.

- Gave 78 staff presentations at conferences, workshops, or meetings, and published 2 articles.

RCR Policy

Implementation of the PHS Policy on Instruction in the Responsible Conduct of Research 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 implemented through a proposed regulation rather than a policy.

Implementation of the PHS Policy on Instruction in the Responsible Conduct of Research was suspended in February 2001.

A letter to ORI from Representative W.J. Tauzin, Chairman, Committee on Energy and Commerce, and Representative James C. Greenwood, Chairman-designate, Subcommittee on Oversight and Investigations, stated that the policy "appears to be a final substantive rule" and its adoption should have followed "the various statutes designed to ensure sound regulatory decisionmaking."

In his response, Chris Pascal, Director, ORI, gave the following reasons for issuing the RCR program as a policy:

- "The RCR policy is the outgrowth of a longstanding sentiment in the scientific community that efforts to enforce rules against research miscon duct should be coupled with programs to prevent such episodes from occurring in the first place." Two reports from the National Academy of Sciences and the report of the congressionally-mandated Commission on Research Integrity are cited.

- The RCR initiative fits into a pre-existing regulation that requires institu tions to "foster a research environment that discourages misconduct in all research . . ." 42 C.F.R. § 50.105. A key component of any institutional effort to promote such an environment would be an RCR program.

- The Secretary of Health and Human Services has the authority to impose additional conditions on awards. 42 C.F.R. § 52.9.

- The RCR policy lacks the normative standards typically associated with a substantive rule because the policy gives institutions broad discretion to determine how virtually every aspect of the educational program will be implemented.

- Extensive efforts were made to ensure that the extramural research community had ample notice and opportunity to comment on the draft RCR policy. Public comments were substantially incorporated into the revised policy.

Even though ORI believed that the RCR policy was appropriately issued, ORI agreed that its implementation should be delayed pending additional review within the Department.

A *Federal Register* notice published February 21, 2001, states 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."

During 2001, ORI undertook a series of meetings with scientific societies as well as professional and institutional associations to solicit additional comment on the suspended policy. ORI also consulted with PHS agency representatives on the policy.

Potential revisions to the RCR policy were still under consideration at the time this report was published.

ORI held eight workshops or conferences in 2001 that drew an average of 89 participants to each event.

Conferences and Workshops

ORI held a total of eight workshops or conferences in 2001. ORI co-sponsored six of these meetings with universities, scientific societies, and professional and institutional associations in 2001. Four of the eight meetings

focused on promoting research integrity or teaching the responsible conduct of research (RCR). These 8 meetings drew an average of 89 participants to each event.

Federal Research Misconduct Officials Workshop

ORI held a workshop on February 1, 2001, in Washington, DC, on implementing the Federal Research Misconduct Policy. Members of the Federal Research Misconduct Officials Network from 25 agencies attended the meeting. All Federal agencies supporting intramural and/or extramural research were to implement the Federal policy within 1 year of its publication in the *Federal Register* by the Office of Science and Technology Policy on December 6, 2000. An ORI staff member chaired the workshop planning committee.

"Promoting Research Integrity in Communication Sciences and Disorders and Related Disciplines"

ORI co-sponsored a national conference at the headquarters office of the American Speech-Language-Hearing Association (ASHA) in Rockville, MD, on May 3-4, 2001. Designed to educate researchers in communication sciences and disorders about the responsible conduct of research, the meeting targeted doctoral students, post-doctoral fellows, junior faculty and others early in their research careers. Fifty participants heard about conducting and publishing research, teaching students or junior faculty about the research process, and recognizing and reporting scientific misconduct. Lectures were followed by small group discussions.

"*Research Compliance: Challenges and Opportunities"*

ORI collaborated with the Johns Hopkins University School of Medicine to host a national conference on creating effective research compliance programs within academic institutions. The conference was held May 6-7, 2001, in Baltimore, MD, and drew 120 participants. Presentations on ways to foster a culture of compliance within institutions were followed by a set of concurrent workshops run twice on the second day. The six workshops topics were: teaching RCR, directing inquiries and investigations of research misconduct allegations, protecting human subjects, animal care and use, managing financial

conflicts of interest, and fiscal grants management. This was the first of a series of compliance conferences that ORI hopes to co-sponsor with major research institutions around the U.S. The conference summary is available on ORI's web site.

"Promoting Responsible Conduct of Research: Policies, Challenges, and Opportunities"

On May 18-19, 2001, ORI co-sponsored a national conference in Arlington, VA, with Public Responsibility in Medicine and Research (PRIM&R) on developing or improving institutional RCR programs. Other co-sponsors included the Applied Research Ethics National Association (ARENA), the Association of American Medical Colleges (AAMC) and Tufts University School of Medicine. This conference gave practical advice to 150 participants about existing and anticipated Federal requirements for RCR education. Conference proceedings should be available from PRIM&R next year.

"Legal Issues and Strategies in Responding to Research Misconduct Allegations"

Held in Washington, DC, on May 30-31, 2001, this national conference was co-sponsored by the American Association for the Advancement of Science (AAAS), The Johns Hopkins University, and Howard University. This was ORI's first conference on legal issues surrounding allegations of scientific misconduct and drew 135 participants. Changes in regulatory policy were explored and participants discussed the implications of litigation related to specific research misconduct cases.

Advanced Investigative Techniques Workshop

This national workshop was co-sponsored by ORI with the Harvard Medical School and the University of Pittsburgh, and was held September 24-25, 2001, at NIH in Bethesda, MD. There were 75 institutional officials from across the country who participated, with 15 speakers from ORI and 4 universities. The workshop provided education and technical guidance on issues such as strategic planning, addressing complicated issues, sequestering and evaluating complex records, using sophisticated investigative image analy-

ses or digit and statistical analyses, interviewing effectively, dealing with uncooperative respondents, and reaching supportable conclusions.

"Training in the Responsible Conduct of Research"

This regional conference was held on November 16-17, 2001, in Birmingham, AL, and drew 140 participants. Co-sponsors included the University of Alabama at Birmingham, East Carolina University, Meharry Medical College, Vanderbilt University, and Charles Stuart University (Canberra, Australia). The conference featured breakout sessions on identifying misconduct, authorship, data access and ownership, conflict of interest, and human subject protections.

"Workshop on Instruction in the Conduct of Research"

ORI co-sponsored this workshop with the Council of Graduate Schools (CGS) in San Diego, CA, on December 5, 2001. An ORI staff member spoke about RCR in two 2-hour sessions, as part of a series of workshops that CGS traditionally holds prior to its Annual Meeting. A total of 21 persons attended the workshop.

Exhibits at Scientific and Professional Meetings

ORI displayed exhibits or held poster sessions at seven meetings of scientific societies or professional associations in 2001 (almost doubling the four held in 2000) to increase contact and generate a dialogue with members. Several were held in collaboration with the Office for Human Research Protections (OHRP).

Exhibits were held at the following professional meetings: Experimental Biology 2001 in Orlando in March; Association of Clinical Research Professionals in San Francisco in April; American Society for Reproductive Medicine in Orlando in October; National Council of University Research Administrators in Washington, DC, in November; and the American Society for Cell Biology in Washington, DC, in December. ORI also held an exhibit at an OHRP workshop in Long Beach, CA, in July.

Poster sessions were held at the following meetings: American Psychological Society, Toronto, Canada in June; and the Society of Research Administrators, in Vancouver, Canada, in October.

The exhibits and poster sessions enable ORI staff to talk to researchers, research administrators, postdoctoral fellows, graduate students, and professional and institutional association officials about the research program on research integrity; the RCR education program; opportunities to collaborate with ORI in developing workshops and conferences; ORI studies, reports and publications; institutional policies for responding to allegations of research misconduct; and emerging issues.

Scientific societies and professional and institutional organizations interested in having ORI hold an exhibit or poster session at their meeting should contact ORI's Division of Education and Integrity at 301-443-5300.

ORI is constructing a new section on instructional resources on its web site to facilitate the teaching of the responsible conduct of research by calling attention to existing materials that could be used in such instruction.

Poster Program

A consultant developed a report for ORI that outlined options for creating a poster program on research integrity. The consultant also had an artist develop three sample posters which were included in ORI exhibits at several scientific meetings. The response to the posters was quite favorable. ORI expects to make at least one poster available for distribution in 2002.

Web Sites

ORI Web Site

ORI is constructing a new section on instructional resources on its web site to facilitate the teaching of the responsible conduct of research by calling attention to existing materials that could be used in such instruction. The instructional resources page may be accessed through the ORI home page located at **http://ori.hhs.gov** by selecting Programs and clicking on "RCR Instructional Resources" under RCR Education.

The material is categorized as *comprehensive resources* that cover or intend to cover more than one of the core instruction areas named in the suspended PHS

Policy on Instruction in the Responsible Conduct of Research and as *specialized resources* that address one of the core instruction areas. All of the materials may be accessed on the Internet; some require payment. Posting on the ORI web site does not imply ORI endorsement.

ORI has created three listservs to facilitate interaction among members of three communities: institutional research integrity officers (RIOs), RCR instructors, and researchers on research integrity.

Several *comprehensive resources* are listed as well as *specialized resources* on mentor/trainee responsibilities, collaborative science, human subjects, research involving animals, and conflict of interest and commitment. Specialized resources are still needed for the following topic areas: data acquisition, management, sharing and ownership; peer review; publication practices and responsible authorship; and research misconduct.

RCR Web Site

In September 2001, ORI awarded a 3-year contract to the University of California at San Diego (UCSD) to expand and update the web site located at **http://rcr.ucsd.edu** by adding new topic areas and downloadable course materials to the site. A new interactive section will also be created that will be a forum for exchanging questions, ideas, and information relevant to RCR instruction. The interactive portion of the site will include a calendar of upcoming events, such as workshops and conferences, and sections for news and discussion.

The domain will become a portal to the following four sections: (1) suggested goals, content, format, tools and evaluation of programs for teaching RCR; (2) instruction in the responsible conduct of research involving human participants; (3) instruction in the responsible conduct of research involving animal subjects; and (4) an interactive site as described above.

Listservs

ORI has created three listservs to facilitate interaction among members of three communities that play important roles in the handling of research misconduct allegations, the promotion of the responsible conduct of research (RCR), and the conduct of research on research integrity: institutional research integrity officers (RIOs), RCR instructors, and researchers on research integrity.

ORI would like to see these mechanisms provide collegial advice and support for the members of these communities and stimulate productive collaborations. ORI plans to make these listservs prime channels for communicating information to members of these communities.

The listserv for RIOs is called INSTI-OFFICIALS; for RCR instructors it is RCR-INSTRUCTION, and for researchers on research integrity it is RRI-PROGRAM. You can subscribe to these listservs by accessing the NIH listserv web site at **http://list.nih.gov** by clicking on Browse, selecting the name of the listserv, and providing your e-mail address and full name. Your subscription will be confirmed by e-mail, and you will receive instructions for participating in the listserv. When you access the listserv, you will be asked to create a password that will also be confirmed by e-mail.

Subscribers may post messages on the listservs for RIOS and RCR instructors. Messages on the listserv for researchers may only be posted by the listserv manager.

The listserv managers may be contacted at the following addresses: INSTI-OFFICIALS at instlist@osophs.dhhs.gov; RCR-INSTRUCTION at rcrlist@osophs.dhhs.gov, and RRI-PROGRAM at rri@osophs.dhhs.gov.

SBIR/STTR Resources for RCR Education

ORI was successful in getting the development of educational resources for training in the responsible conduct of research included in the omnibus solicitation for the Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) programs. The ORI Program Officer consulted with several organizations that indicated an initial interest in submitting proposals. The actual response to the two application deadlines (August 1 and December 1) was disappointing. Only two proposals were submitted and neither was funded.

The SBIR program is only open to small businesses. The STTR program allows collaboration between a small business and an academic institution. Funding for SBIR/STTR projects occurs in two phases. In Phase I, the technical/scientific merit and feasibility of the project must be established

along with the ability of the organization to carry the project through Phase II. Successful Phase I projects may apply for Phase II support to continue the work begun in Phase I.

ORI ACTIVELY SEEKS COLLABORATIONS WITH SCIENTIFIC SOCIETIES AND PROFESSIONAL AND INSTITUTIONAL ASSOCIATIONS.

Each program offers a maximum of $100,000 in total costs for Phase I projects. The SBIR program expects Phase I projects to be completed in 6 months; the STTR program, 1 year. The SBIR program offers a maximum of $750,000 for Phase II projects; the STTR program, $500,000. Each program expects the projects to be completed in 2 years.

Areas in which ORI would like additional resource development include: (1) data acquisition, management, sharing, and ownership; (2) mentor/trainee relationships; (3) publication practices and responsible authorship; (4) peer review; (5) collaborative science; (6) protection of human research subjects; (7) use of animals in research; (8) research misconduct; and (9) conflicts of interest and commitment.

RCR Educational Consortium

A charter was developed for the Responsible Conduct of Research Education Consortium (RCREC) that will promote and advocate RCR education as a central responsibility for any institution involved in research. ORI and OHRP have supported development of this consortium.

Liaison Activities

ORI actively seeks collaborations with scientific societies and professional and institutional associations. Seven of the eight conferences and workshops supported by ORI in 2001 were collaborations with the extramural research community. ORI also held exhibits or poster sessions at seven scientific meetings in 2001. ORI is establishing liaisons with 22 scientific societies and professional and institutional associations pertinent to its mission.

Minority Initiatives

ORI mailed 79 individually-addressed letters to minority-serving institutions holding active assurances with ORI to ask if these organizations would be inter-

ested in collaborating with ORI to co-sponsor workshops or conferences on the promotion of research integrity. By October 2001, 24 of the 25 institutions responding to the letter indicated they were interested in exploring possible collaborations with ORI. Followup telephone calls were made to each of these institutions to offer speakers or other assistance to their staff for handling misconduct allegations or fostering the responsible conduct of research.

Howard University and Meharry Medical College were two minority institutions that served as co-sponsors for ORI conferences or workshops in 2001.

Publications

Educational Needs Assessment Study

The study, "Office of Research Integrity Education Program: A Needs Assessment," was completed in November 2001. The study looked at educational needs in two areas: the responsible conduct of research (RCR) and the handling of research misconduct allegations. The sample for the RCR study was composed of 200 RCR instructors and 100 institutional research integrity officers (RIOs). The response rate was 51 percent. The sample for the research misconduct allegation survey was composed of 200 RIOs and the response rate was 57 percent. The study concluded that RCR training was needed by principal investigators, research associates, postdocs, and graduate students and resource materials were needed on scientific recordkeeping, data management, authorship, publication practices, conflicts of interest, intellectual property, and research misconduct. Training in handling research misconduct allegations is needed by vice presidents for research, science deans, department heads, and RIOs and resource materials are needed on the requirements of proof, sequestering data, handling evidence, the development of investigational plans, and regulatory requirements. The findings were published in an *ORI Newsletter* article in the December 2001 issue. The final report was posted on the ORI web site in December 2001.

Study of Guidelines on the Conduct of Research Adopted by Medical Schools

The final report on the "Analysis of Guidelines for the Conduct of Research Adopted by Medical Schools or Their Components" was completed in Sep-

tember 2001. The number of medical schools that have guidelines has increased from 13 percent to 78 percent since 1990. About two-thirds of the guidelines followed by medical schools were developed at the university level. Of the 98 guidelines analyzed, 41 cover no more than 2 topics; 32 guidelines were limited to conflicts of interest and intellectual property rights. The number of guidelines addressing each topic on which information was requested was: peer review, 8; publication practices, 16; mentoring, 23; authorship, 34; data management, 45; responsibilities of principal investigators, 48; intellectual property rights, 65; and conflicts of interest, 86. There appears to be little consensus on topics to be included in research guidelines or the behavior recommended under each topic. The findings were published in an *ORI Newsletter* article in the December 2001 issue, and the final report was posted on the ORI web site in December 2001.

The number of medical schools that have guidelines has increased from 13 percent to 78 percent since 1990.

RCR Self-Instruction Booklet

The RCR self-instruction booklet was delivered by the contractor in August 2001. The contract for the booklet was awarded in September 2000 to meet the training requirements of the PHS Policy on Instruction in the Responsible Conduct of Research (RCR) issued in December 2000 and suspended in February 2001. The booklet contains a chapter on each of the nine core instructional areas designated in the PHS policy—data acquisition, management, sharing and ownership; mentor/training responsibilities; publication practices and responsible authorship; peer review; collaborative science; human subjects; research involving animals; research misconduct; and conflict of interest and commitment. An initial review of the booklet by ORI staff indicated that reading the booklet would take much longer than the 2-3 hours originally estimated. ORI is considering what further steps are needed to complete the booklet.

2000 ORI Annual Report

The *ORI Annual Report - 2000* was published in September 2001, and posted on ORI's web site. Highlights of the annual report included a discussion of ORI policies and regulations, misconduct case activities, research issues, educational and web-based activities, and a summary of all misconduct cases and litigation.

Staff Presentations

Peter Abbrecht, Medical Expert, DIO, gave a presentation on "ORI Guidelines for Assessing Possible Research Misconduct in Clinical Research and Clinical Trials" at the NIH Extramural Program Management Council in Bethesda, MD, on May 8, 2001.

Peter Abbrecht, Medical Expert, DIO, gave presentations on "ORI Guidelines for Assessing Possible Research Misconduct in Clinical Research and Clinical Trials" and the "ALLHAT Case" at the workshop sponsored by ORI, Harvard Medical School, and the University of Pittsburgh on ORI Advanced Investigative Techniques for Research Misconduct held in Bethesda, MD, September 24-25, 2001.

Peter Abbrecht, Medical Expert, DIO, gave a presentation on "Overseeing Research Misconduct by the Office of Research Integrity" at the Barnett International Conference on Fraud and Misconduct in Clinical Research held in Tysons Corner, VA, on October 25, 2001.

Barbara Bullman, Policy Analyst, DEI, gave a presentation at Roswell Park Cancer Center on "Current and Future ORI Regulations and the Guidelines on the Responsible Conduct of Research" during the fifth meeting of the Cancer Trials and Protocol Review Conference in Buffalo, NY, on February 1, 2001.

Barbara Bullman, Policy Analyst, DEI, gave a presentation on "ORI and RCR - A Primer on Recent Developments" at the National Council of University Research Administrators (Region III) Meeting held in Fort Lauderdale, FL, on May 2, 2001.

Alicia Dustira, Deputy Director, DEI, gave a presentation on the "ORI Education Program in the Responsible Conduct of Research" at the conference sponsored by ORI and the American Speech-Language-Hearing Association (ASHA) on Promoting Research Integrity in Communication Sciences and Disorders and Related Disciplines held in Rockville, MD, on May 3, 2001.

Kay Fields, PHS Fellow and Investigator/Scientist, DIO, gave a presentation, "Dealing with Uncooperative Respondents," to a meeting of the Greater

Washington Area Consortium on Research Integrity, held at ORI on October 31, 2001.

Kay Fields, PHS Fellow and Investigator/Scientist, DIO, gave presentations entitled "A Model Investigation, ORI Review and DAB Decision" and "Dealing with Uncooperative Respondents" at the ORI Advanced Investigative Techniques for Research Misconduct Workshop for Institutional Officials sponsored by ORI, Harvard Medical School, and the University of Pittsburgh, held in Bethesda, MD, September 24-25, 2001.

Kay Fields, PHS Fellow and Investigator/Scientist, DIO, gave a presentation, "How Do We Distinguish Between Honest Error and Research Misconduct?" to the interdisciplinary faculty seminar on the Responsible Conduct of Science at Boston College, Boston, MA, on April 24, 2001.

Gail L. Gibbons, Deputy Chief Counsel, OGC, gave presentations on "Evidentiary Matters: Sequestration of Lab Records and Other Relevant Materials" and "Settlement Issues" at the Legal Issues and Strategies for Responding to Research Misconduct Allegations conference sponsored by ORI, AAAS, The Johns Hopkins University, and Howard University in Washington, DC, May 30-31, 2001.

Gail L. Gibbons, Deputy Chief Counsel, OGC, made presentations on the "Status of the Proposed Whistleblower Regulation" and "Guidelines for Respondents Accused of Research Misconduct in Research Supported by the Public Health Service" at the Annual Meeting of the Research Integrity Officers at NIH in Bethesda, MD, on June 13, 2001.

Stephen Godek, Attorney, OGC, made presentations on "Preparing the Investigation Report and Disclosure Responsibilities" and "Assessing Culpability and Proving Intent and Materiality" at the conference sponsored by ORI, AAAS, The Johns Hopkins University, and Howard University on Legal Issues and Strategies for Responding to Research Misconduct Allegations held in Washington, DC, on May 30, 2001.

Stephen Godek, Attorney, OGC, gave a presentation on how to prepare and

respond to scientific misconduct at the Texas Health Research Institute in Dallas, TX, on December 11, 2001.

John W. Krueger, Investigator/Scientist, DIO, gave a presentation on "Research Misconduct - The [NSF and the] ORI Experience" at a meeting entitled *Research Integrity - Who is Responsible?*, sponsored by University of South Alabama in Mobile, AL, on April 17, 2001.

John W. Krueger, Investigator/Scientist, DIO, gave a presentation on "Recognizing and Reporting Scientific Misconduct" at the conference sponsored by ORI and ASHA on Promoting Research Integrity in Communications Sciences and Disorders and Related Disciplines, held May 3-4, 2001, in Rockville, MD.

John W. Krueger, **Investigator/Scientist, DIO**, (1) gave a presentation on "ORI Image Analysis - General Approaches and Methods" (2) presented comments on an image case study presentation given by Dr. L. Wittie, SUNY, (3) presented case studies on "Dealing with Uncooperative Respondents,"and (4) presented case studies on working with experts and the Departmental Appeals Board at the ORI Advanced Investigative Techniques for Research Misconduct workshop, sponsored by ORI, Harvard Medical School, and the University of Pittsburgh, September 24-25, 2001, in Bethesda, MD.

Samuel Merrill, Jr., Investigator/Scientist, DIO gave a presentation on "Handling Research Misconduct" at the National Sponsored Programs Administrators Alliance of Historically Black Colleges and Universities 8th Annual Meeting in Nashville, TN, on June 7, 2001.

Samuel Merrill, Jr., Investigator/Scientist, DIO, gave a presentation on "How To Handle Research Misconduct Issues At the University Level" at North Carolina Central University in Durham, NC, on August 16, 2001.

Samuel Merrill, Jr., Investigator/Scientist, DIO, gave a presentation entitled "Overseeing Research Misconduct by the Office of Research Integrity: A Case Study" at Barnett International's Fraud & Misconduct in Clinical Research conference in Tysons Corner, VA, on October 25, 2001.

Samuel Merrill, Jr., Investigator/Scientist, DIO, made a presentation on "Research Integrity and Scientific Misconduct: Federal Definitions and Approaches" for the Minority Student Research Programs of California State University Dominguez Hills on November 15, 2001, and held mini-discussions with minority students on November 16, 2001.

Marshall A. Narva, Investigator/Scientist, DIO, made a panel presentation on "Teaching How to Respond Responsibly to Allegations or Observations of Research Misconduct" at the Promoting Responsible Conduct of Research: Policies, Challenges, and Opportunities conference held in Arlington, VA, and sponsored by ORI, PRIM&R, ARENA, AAMC, and the Tufts University School of Medicine on May 18, 2001.

Marshall A. Narva, Investigator/Scientist, DIO, gave a presentation on "Case Studies of 'Admissions' Claimed by Institutions that Could Not Be Used by ORI" at the workshop on ORI Advanced Investigative Techniques for Research Misconduct, sponsored by ORI, Harvard Medical School, and the University of Pittsburgh, and held in Bethesda, MD, on September 24, 2001.

Chris B. Pascal, Director, ORI, made a presentation on "Research Integrity" at the University of Tennessee Center for Health Services Research in Memphis, TN, March 1-3, 2001.

Chris B. Pascal, Director, ORI, made a presentation on "Research Integrity" at the NIH Regional Seminar at the University of Texas MD Anderson Cancer Center in Houston, TX, March 14-16, 2001.

Chris B. Pascal, Director, ORI, made a presentation on "ORI's Mission and Responsibilities and RCR" at the Spring Meeting of the National Council of University Research Administrators, Region I, held in Burlington, VT, April 29 to May 1, 2001.

Chris B. Pascal, Director, ORI, gave introductory remarks and made a presentation on the "Responsible Conduct of Research" at the conference sponsored by ORI and the Johns Hopkins University School of Medicine on Research Compliance: Challenges and Opportunities, held in Baltimore, MD, on May 6, 2001.

Chris B. Pascal, Director, ORI, gave welcoming remarks and made several presentations on the "Responsible Conduct of Research" at the conference sponsored by ORI, PRIM&R, ARENA, AAMC, and Tufts University School of Medicine on Promoting Responsible Conduct of Research: Policies, Challenges and Opportunities, held in Arlington, VA, May 18-19, 2001.

Chris B. Pascal, Director, ORI, gave opening remarks for the conference co-sponsored by ORI, AAAS, The Johns Hopkins University, and Howard University on Legal Issues and Strategies for Responding to Research Misconduct Allegations, held in Washington, DC, on May 30, 2001.

Chris B. Pascal, Director, ORI, made a presentation on "Research Integrity" at the NIH Regional Seminar at the Oregon Health and Science University, Portland, OR, June 6-9, 2001.

Chris B. Pascal, Director, ORI, gave opening remarks for the ORI Advanced Investigative Techniques Workshop, co-sponsored by ORI, Harvard Medical School, and the University of Pittsburgh that was held in Bethesda, MD, on September 24, 2001.

Chris B. Pascal, Director, ORI, gave three separate presentations on "Ensuring the Integrity of Research," "Research Integrity & Misconduct: Update from Federal Research Agencies Parts I and II," and "Responsible Research: Perspectives from ORI, NSF and VA" at the Society of Research Administrators (SRA) International Annual Meeting, Vancouver, BC, Canada, October 13-18, 2001.

Chris B. Pascal, Director, ORI, made a presentation on "What's New at the ORI" at the Greater Washington Area Consortium on Research Integrity, held in Rockville, MD, on October 31, 2001.

Chris B. Pascal, Director, ORI, made presentations on "Research Integrity Issues Relevant to the Principal Investigator" and "Federal Research Misconduct Policy from the PHS Perspective" at the Sigma Xi Forum on Ethics held in Albuquerque, NM, November 8-11, 2001.

Chris B. Pascal, Director, ORI, gave three separate presentations on "The Science of Research Integrity: A New Program and Implications for Institutions," "Responsible Conduct of Research: A Pilgrim's Progress," and "Federal Policy on Research Misconduct: Progress in Agency Implementations" at the NCURA's 43rd Annual Meeting, November 11-14, 2001, in Washington, DC.

Chris B. Pascal, Director, ORI, gave three separate presentations on "Conflict of Interest," "Defining Misconduct," and "Training and Prevention of Misconduct" at the Training in the Responsible Conduct in Research conference sponsored by ORI, the University of Alabama at Birmingham, East Carolina University, Meharry Medical College, Vanderbilt University, and Charles Stuart University, in Birmingham, AL, November 16-17, 2001.

Alan R. Price, Director, DIO, made a presentation at a workshop for the Federal Misconduct Officials Network held at the Department of Health and Human Services in Washington, DC, on February 1, 2001.

Alan R. Price, Director, DIO, gave a presentation on how to "Protect Yourself from Research Misconduct in Your Laboratory," a panel talk at the American Society for Biochemistry and Molecular Biology meeting, part of the Federation of American Societies for Experimental Biology Annual Meeting in Orlando, FL, on April 2, 2001.

Alan R. Price, Director, DIO, gave a presentation on "Compliance with Sequestration of Physical Evidence in Scientific Misconduct Cases for ORI" as part of panel talks at two breakout sessions at the conference sponsored by ORI and the Johns Hopkins University School of Medicine on Research Compliance: Challenges and Opportunities, held in Baltimore, MD, on May 7, 2001.

Alan R. Price, Director, DIO, gave a presentation on "Handling Plagiarism Cases in the Office of Research Integrity Vs. Collaborators' Authorship, Credit, and Intellectual Property Disputes" for a panel on "Whose Work Is It, Anyway? The Ethics of Scholarship" for the Health Care Management Division at the Academy of Management's annual meeting held in Washington, DC, on August 4, 2001.

Alan R. Price, Director, DIO, made a presentation on "Your Role as Program, Review, and Grants Officers in Reporting Allegations of Scientific Misconduct to NIH and ORI" to staff of the National Institute for Nursing Research, NIH, Bethesda, MD, on September 27, 2001.

Alan R. Price, Director, DIO, made a presentation on "ORI's Rapid Response for Technical Assistance (RRTA) Program" and served as chief organizer for the Office of Research Integrity for the ORI Advanced Investigative Techniques for Research Misconduct workshop, sponsored by ORI, Harvard Medical School, and the University of Pittsburgh that was held in Bethesda, MD, September 24-25, 2001.

Alan R. Price, Director, DIO, made presentations on "What Research Misconduct is Not for ORI" and "How to Protect Yourself from Research Misconduct in Your Laboratory" at the conference on Training in the Responsible Conduct of Research sponsored by ORI, the University of Alabama at Birmingham, East Carolina University, Meharry Medical College, Vanderbilt University, and Charles Stuart University, held in Birmingham, AL, on November 17, 2001.

Lawrence J. Rhoades, Director, DEI, made a presentation on the "PHS Policy on Instruction in the Responsible Conduct of Research" during a conference on "Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions" sponsored by the American Health Lawyers Association in Washington, DC, on January 25, 2001.

Lawrence J. Rhoades, Director, DEI, made a presentation on "ORI Education, Outreach, and Compliance Activities" during the Federal Research Misconduct Policy Implementation Workshop sponsored by the Office of Science and Technology Policy, the Federal Scientific Misconduct Officials Network, and ORI in Washington, DC, on February 1, 2001.

Lawrence J. Rhoades, Director, DEI, made a presentation on the "ORI Education Program in the Responsible Conduct of Research" at Clinical Research 2001 jointly sponsored by the General Clinical Research Center Program Directors Association, the American Federation for Medical Research, and the Association for Patient-Oriented Research in Arlington, VA, on March 11, 2001.

Lawrence J. Rhoades, Director, DEI, made a presentation on the "ORI Education Program in the Responsible Conduct of Research" during the spring meeting of the AAMC Council of Academic Societies in San Antonio, TX, on March 23, 2001.

Lawrence J. Rhoades, Director, DEI, made a presentation on the "ORI Education Program in the Responsible Conduct of Research" at the Experimental Biology 2001 meeting in Orlando, FL, on April 2, 2001.

Lawrence J. Rhoades, Director, DEI, made a presentation on the "ORI Education Program in the Responsible Conduct of Research" at the Research Compliance: Challenges and Opportunities conference sponsored by ORI and the Johns Hopkins Medical School in Baltimore, MD, on May 7, 2001.

Lawrence J. Rhoades, Director, DEI, made a presentation on "Research Integrity in Clinical Research" during a Clinical Gene Transfer Training Course sponsored by the American Society of Gene Therapy, the Mount Sinai School of Medicine, FDA, NIH, and OHRP in Seattle, WA, on May 30, 2001.

Lawrence J. Rhoades, Director, DEI, made a presentation on the "PHS Policy on Instruction in the Responsible Conduct of Research" during the annual meeting of the AAMC Group on Research Advancement and Development (GRAND) in Washington, DC, on June 4, 2001.

Lawrence J. Rhoades, Director, DEI, made a presentation on the "Office of Research Integrity: Compliance, Education and Prevention" during the annual meeting of the National Sponsored Programs Administrators Alliance of Historically Black Colleges and Universities in Nashville, TN, on June 7, 2001.

Lawrence J. Rhoades, Director, DEI, made a presentation on having a "Research Program on Research Integrity" at the Annual NIH Research Integrity Officers Meeting in Bethesda, MD, on June 13, 2001.

Lawrence J. Rhoades, Director, DEI, made two presentations and gave a graduate seminar on the "Responsible Conduct of Research" at the Dartmouth-Hitchcock Medical Center, Dartmouth College, and the Dartmouth Medical School in Hanover, NH, October 11-12, 2001.

Lawrence J. Rhoades, Director, DEI, made a presentation on the "Responsible Conduct of Research" to intramural researchers at the National Institute on Drug Abuse, Baltimore, MD, on November 7, 2001.

Lawrence J. Rhoades, Director, DEI, made a presentation on the "Responsible Conduct of Research" during a workshop on Research Integrity Programs in Graduate Education at the annual meeting of the Council of Graduate Schools, San Diego, CA, on December 5, 2001.

Mary D. Scheetz, Research Program Officer, DEI, made a presentation on the "Research Integrity Issues in the Publication of Research" at the conference sponsored by the American Speech-Language-Hearing Association and ORI on Promoting Research Integrity in Communications Sciences and Disorders and Related Disciplines, held in Rockville, MD, on May 3, 2001.

Mary D. Scheetz, Research Program Officer, DEI, made a presentation on the "Ethical and Quasi-Ethical Problems in Publication" at the 44th Annual Council of Science Editors Meeting held in Washington, DC, on May 6, 2001.

Mary D. Scheetz, Research Program Officer, DEI, made a presentation on "Science of Research Integrity: A New Program and Implications for Institutions" at the 43rd Annual Meeting, National Council of University Research Administrators in Washington, DC, on November 12, 2001.

Barbara R. Williams, Deputy Director, DIO, made a presentation at the Southwestern Oncology Group Continuing Education Annual Meeting in San Francisco, CA, on April 26, 2001.

Barbara R. Williams, Deputy Director, DIO, made a panel presentation on "Teaching How to Respond Responsibly to Allegations or Observations of Research Misconduct" at the conference "Promoting Responsible Conduct of Research: Policies, Challenges, and Opportunities" in Arlington, VA, on May 18, 2001.

Barbara R. Williams, Deputy Director, DIO, made presentations that covered three different topics at the workshop co-sponsored by ORI and

others on ORI Advanced Investigative Techniques for Research Misconduct held in Bethesda, MD, on September 24, 2001.

Published Articles

Pascal, C.B. "Federal Research Misconduct Policy from the Public Health Service Perspective," *2000 Sigma Xi Forum, New Ethical Challenges in Science & Technology,* pp. 104-106, (2001).

Pascal, C.B. "Research Integrity Issues Relevant to Principal Investigators." *2000 Sigma Xi Forum, New Ethical Challenges in Science & Technology*, pp. 73-77, (2001).

Federal Register Notices

OS. Findings of Scientific Misconduct. Notice. 66 Fed. Reg. 66417 (Dec. 26, 2001) [Valentin]

OS. Findings of Scientific Misconduct. Notice. 66 Fed. Reg. 64266 (Dec. 12, 2001) [Ruggiero]

OS. Findings of Scientific Misconduct. Notice. 66 Fed. Reg. 63709 (Dec. 10, 2001) [Xiong]

OS. Findings of Scientific Misconduct. Notice. 66 Fed. Reg. 59793 (Nov. 30, 2001) [Elster]

OS. Findings of Scientific Misconduct. Notice. 66 Fed. Reg. 54999 (Oct. 31, 2001) [Smith, S.]

OS. Findings of Scientific Misconduct. Notice. 66 Fed. Reg. 54012-54013 (Oct. 25, 2001) [Padgett]

OS. Findings of Scientific Misconduct. Notice. 66 Fed. Reg. 52137 (Oct. 12, 2001) [Arnold]

OS. Findings of Scientific Misconduct. Notice. 66 Fed. Reg. 49386-29387 (Sept. 27, 2001) [Sanchez]

OS. Findings of Scientific Misconduct. Notice. 66 Fed. Reg. 40288-40289 (Aug. 2, 2001) [Pandurangi]

OS. Findings of Scientific Misconduct. Notice. 66 Fed. Reg. 35982-35983 (July 10, 2001) [Jacoby]

OS. Findings of Scientific Misconduct. Notice. 66 Fed. Reg. 34200 (June 27, 2001) [Lin]

OS. Findings of Scientific Misconduct. Correction. 66 Fed. Reg. 33965 (June 26, 2001) [Saleh]

OS. Findings of Scientific Misconduct. Notice. 66 Fed. Reg. 27974-27975 (May 21, 2001) [Saleh]

OS. Findings of Scientific Misconduct. Notice. 66 Fed. Reg. 22231-22232 (May 3, 2001) [Sarker]

OS. Agency Information Collection Activities; Submissions for OMB Review; Comment Request. 1. Research Misconduct: An Inquiry into Etiology and Stigma—NEW. 66 Fed. Reg. 20309 (April 20, 2001).

OS. PHS Policy on Instruction in the Responsible Conduct of Research. Notice of suspension of "PHS Policy for Instruction in the Responsible Conduct of Research." 66 Fed. Reg. 11032-11033 (Feb. 21, 2001).

OS. Agency information collection activities: Submission for OMB Review; Comment Request. Office of Research Integrity Educational Program: A Needs Assessment—NEW. 66 Fed. Reg. 10304 (Feb. 14, 2001).

OS. Agency information collection activities: Proposed collections; Comment Request. *Proposed Project 1*. Organizing an Institutional Investigation Assistance Program: A Feasibility Study. 66 Fed. Reg. 8237-8238 (Jan. 30, 2001).

III. Research on Research Integrity and Misconduct in Science

INTRAMURAL RESEARCH

ORI has conducted an intramural research program since 1994. The studies are done under contract with research organizations or by ORI staff. Funding is provided by HHS or ORI. Information on the studies, completed and in progress, is available on the ORI web site in the Publications section under Studies/Reports.

In 2001, two studies were completed, one was initiated, and four were in progress. A study of the etiology of research misconduct was terminated because approval could not be obtained from the Office of Management and Budget (OMB).

In 2001, two studies were completed, one was initiated, and four were in progress.

A. Completed Studies

Medical School Research Guidelines

The *Analysis of Guidelines for the Conduct of Research Adopted by Medical Schools or Their Components* found considerably more medical schools provide some written guidelines for the conduct of research for their faculty to follow than in 1990. However, the majority of guidelines are narrowly focused, and do not reflect much agreement on what topics guidelines should cover, or what specific guidance should be offered. The final report is available on the ORI web site in the Publications section under Studies/Reports.

Guidelines from 98 of the 125 accredited U.S. medical schools were analyzed by R.O.W. Sciences, Inc., Rockville, MD, under contract with ORI. Eighty-one medical schools submitted guidelines upon request. The remainder of the 98 guidelines were obtained from medical school or university web sites. At a minimum, 78 percent of accredited medical schools had some guidelines for the conduct of research in 2000, compared with only 13 percent in 1990. Sixty-three percent of the guidelines were developed at the university level; 31 percent at the school level; and 6 percent were combinations of both levels.

Each medical school was asked to submit its guidelines on nine topics, eight of which are listed in Table 8, and on any other topic for which guidelines were available. Guidelines were provided in one additional area—intellectual property rights. No specific guidelines were submitted on two requested topics: collaborative research among scientists and laboratory management. When addressed, they were included in the topic areas of responsibilities of principal investigators, authorship, and data management.

Table 8

Number of Guidelines Discussing 8 Topics [N=98]

Topic	*Frequency*	*Percent*
Conflicts of Interest	86	87.8
Intellectual Property	65	66.3
Principal Investigator	48	49.0
Data Management	45	45.9
Authorship	34	34.7
Mentoring	23	23.5
Publication Practices	16	16.3
Peer Review	8	8.2

Conflict of interest was most frequently addressed in the guidelines; intellectual property rights was a distant second. These areas heavily reflect legal, regulatory, and financial concerns. The remaining six topics were each included in less than half of the guidelines.

About 32 percent of the guidelines were limited to conflicts of interest and/or intellectual property rights. Almost 43 percent of the guidelines were limited to 2 of the 8 topics; more than 61 percent covered 3 topics or fewer. Only two guidelines addressed all eight topics. (See Table 9.)

A content analysis examining behavioral recommendations made under the 8 topics found in the 98 guidelines produced 48 content areas. The number of content areas under each topic ranged from 3-12. (See Table 10.) On average, guidelines included about half of the total content areas cited under each topic.

Table 9:

Number of Topics Covered in Guidelines

Number of Topics	*Frequency*	*Percent*
One	16	16.3
Two	26	26.5
Three	18	18.4
Four	13	13.3
Five	9	9.2
Six	10	10.2
Seven	4	4.1
Eight	2	2.0
TOTAL	98	100.0

The study also indicated that the guidelines generally were not available in a single document or from a single source. Instead, the guidelines were present in multiple documents generated by various units within the institution and available at different locations.

Educational Needs Assessment

Results of an educational needs assessment, funded by ORI, indicate wide agreement among institutional research integrity officers (RIOs) and responsible conduct of research (RCR) instructors for the need for training in both RCR and managing of scientific misconduct allegations. The final report, *ORI Education Program: A Needs Assessment* is available on the ORI web site in the Publications section under Studies/Reports.

A large majority (90 percent) of the respondents answering the RCR needs assessment questionnaire agreed that RCR training was needed for all researchers including principal investigators, research associates, postdoctoral fellows, graduate students, and the institutional RIOs. A lesser majority felt that laboratory assistants and laboratory technicians should receive RCR training (66 percent and 68 percent, respectively).

Table 10:

Topics and Content Areas Cited under Each Topic in Research Guidelines

Topic	*# Content Areas Per Topic*	*Average # Per Guideline*	*Most Frequent Content Area Covered*
Data Management	5	2.0	Data retention; Ownership, sharing, access
Publication Practices	4	2.0	Multiple submissions; Duplicate publications
Authorship	5	2.2	Responsibilities; Qualifications
Peer Review	3	1.8	Confidentiality; Reviewer Responsibilities
Principal Investigator	4	1.6	Responsibilities; Qualifications
Mentoring	5	2.2	Responsibilities; Number of mentees
Conflicts of Interest	12	5.2	Definition; Disclosure process
Intellectual Property	10	4.0	Distribution of Revenue; Ownership

Concerning training in managing scientific misconduct allegations, more than 80 percent of the RIOs responding to the survey felt that the Vice President for Research, science deans, department heads, and RIOs should receive training. More than 70 percent reported that laboratory directors, inquiry committee chairs, and investigation committee chairs needed training, while 68 percent reported that principal investigators should receive it.

Under contract with ORI, the Center for Health Policy Studies collected information regarding the needs of extramural research organizations for educational materials and programs related to (1) responsible conduct of research and (2) managing scientific misconduct allegations.

The RCR educational needs assessment survey was administered to a sample of 200 RCR instructors and 100 RIOs. Surveys were sent by e-mail and participants were given three options for responding, including (1) completing a web survey, (2) printing, completing, and faxing an attachment that was sent with the e-mail, and (3) requesting a hard copy of the survey with a stamped, addressed envelope. Of the total RCR survey forms, 153 were completed and returned for a 51 percent response rate.

Regarding the need for training to manage scientific misconduct allegations, surveys forms were sent to a sample of RIOs representing 200 institutions. The sample consisted of 150 institutions that have experienced an allegation of misconduct in the past, and 50 other institutions. Options for responding were the same as for the RCR educational needs assessment survey. Of the total survey forms sent, 114, or 57 percent, were returned. Sixty percent of the RIOs from institutions that have experienced a research misconduct allegation returned a completed survey form.

Approximately 61 percent of the RCR survey responses indicated that more adequate instructional materials are needed in scientific recordkeeping and data management. More than 50 percent also selected authorship and publication practices, intellectual property, conflict of interest, and scientific misconduct as topics for which adequate educational materials were lacking. Overall, principal investigators and graduate students were the primary audiences needing more RCR educational materials.

When asked what are the top four topics that should be addressed in RCR training for researchers, more than 95 percent of the responses to this question indicated scientific misconduct, conflict-of-interest, authorship and publication practices, intellectual property, and peer review as the topics needing attention.

Approximately 65 percent of RIOs answering the scientific misconduct allegations survey agreed that more and better instructional materials are needed on the topic of requirements of proof. More than 62 percent also responded that more instructional materials were needed in protection against conflicts-of-interest and handling evidence and sequestering data, while nearly 60 percent indicated a need for materials in regulatory requirements and developing investigational plans.

B. New Study

Study on Incidence of Research Misconduct in Biomedical Research

ORI contracted with The Gallup Organization, Washington, DC, to conduct a study to answer a persistent and crucial question concerning research misconduct: How often does research misconduct occur? The study, *Incidence of Research Misconduct in Biomedical Research*, is scheduled for completion in 2003. This study will initiate a longitudinal database for measuring change in the incidence of research misconduct at 5-year intervals.

ORI contracted with The Gallup Organization, to conduct a study to answer a persistent and crucial questiona: How often does research misconduct occur?

The study addresses the frequency of misconduct by collecting data on the (1) detection, (2) reporting, (3) investigation, and (4) verification of alleged research misconduct. The design will try to avoid the methodological flaws of previous studies by (1) distinguishing between research misconduct and questionable research practices; (2) surveying a large representative sample of principal investigators; (3) limiting reporting to a standard time period; (4) minimizing the probability that the same incidents will be reported by more than one respondent; (5) covering numerous fields of science; (6) differentiating between alleged, reported, and verified research misconduct; and (7) generating a high response rate.

Data will also be collected on the general characteristics of the institution, department, accused, and the principal investigator. No information will be collected that would permit individuals or institutions to be specifically identified.

C. Studies in Progress

Fostering Integrity in Research Environments

The report on assessing integrity in research environments being prepared by the Institute of Medicine (IOM) under contract with ORI is expected to be completed in July 2002. The report will be presented to the research community during a conference tentatively scheduled for October 10, 2002, at the National Academy of Sciences. The report is expected to serve as a precursor to the development of a longitudinal database for tracking institutional and PHS efforts to foster integrity in research environments.

Conceptual issues expected to be addressed in the IOM report include (1) defining the concepts of "research environment" and "research integrity;" (2) identifying elements of the research environment; (3) indicating how the elements may be measured; (4) distinguishing between those environmental elements that promote research integrity and those that do not; (5) suggesting appropriate methodology for collecting the data; (6) stipulating unit(s) of analysis; and (7) proposing appropriate outcome measures.

The IOM report is also expected to identify specific steps that institutions can take to promote research integrity based on existing knowledge.

Research Integrity Measures in Biomedical Laboratories

The survey of research integrity measures utilized in biomedical laboratories being conducted by the American Institutes for Research, Washington, DC, is expected to be completed in 2003. The study is designed to determine the types of, and the extent to which, research integrity measures are utilized in biomedical research laboratories. The study population is composed of 5,000 randomly-chosen principal investigators (PIs) who have received support from NIH for the conduct of biomedical or behavioral research. In addition, data will be collected on the characteristics of the host institution, the laboratory, and the PI. The study is expected to establish a database that may be used for secondary analysis by other researchers interested in doing research on research integrity. The study is expected to be completed in 2003.

Instructions to Authors

ORI staff are preparing the final report on the study of instructions to authors issued by 41 journals to determine what provisions they contain that are related to scientific misconduct, research integrity, or the responsible conduct of research. Each journal in this study published articles for which corrections or retractions were requested subsequent to a scientific misconduct case. Among the provisions included in the analysis are referral of suspicious manuscripts, authorship qualifications, responsibility of authors, required

data deposit, financial disclosure, conflicts of interest, publication claims, corrections, and retractions. The report is expected to be issued in 2003.

Institutional Investigation Assistance Program: Feasibility Study

The final report on *An Institutional Investigation Assistance Program: A Feasibility Study* being conducted by ROW Sciences, Inc., under contract with ORI is expected to be issued in 2002. The study stems from a recommendation from the HHS Review Group on Research Misconduct and Research Integrity which states 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." The study was designed to address the following issues: (1) determine the interest in developing consortia among institutions and professional organizations, (2) assess the expected utilization of consortia, its cost, and methods for cost reimbursement, (3) stipulate the principles for organizing consortia, (4) suggest steps ORI may take to encourage the development of consortia, (5) determine whether the ORI on-site technical assistance program can be an effective means of assisting institutions in conducting their own fact-finding processes, and (6) determine whether the desired assistance could be provided through other mechanisms.

Etiology Study

ORI awarded a contract to Justice Research and Advocacy, Inc., in 1999 to conduct a study of the etiology of research misconduct and the stigma associated with such a finding. The data were collected from ORI's files of 92 cases in which there was a finding of research misconduct through December 2000. Initially the data for this study were to come from two sources. One source was interviews with respondents against whom a finding of research misconduct had been made by ORI. The other data source consisted of a review of ORI's case files on the same respondents. However, due to delays and the failure to obtain OMB approval to conduct the interviews, the study was modified to only employ case file reviews. The contractor completed the data gathering from the ORI case files in 2001 and was analyzing data for presentation to ORI in 2002.

Research Program on Research Integrity

The Research Program on Research Integrity (RPRI), a collaboration between ORI and the National Institute for Neurological Disorders and Stroke (NINDS) that was launched in 2000 made its first grant awards in September 2001. Seven research grant applications of the 25 submitted in response to the first request for application (RFA) were funded. The success rate was 28 percent, which is comparable to the success rate for all NIH grants.

THE RESEARCH PROGRAM ON RESEARCH INTEGRITY (RPRI) MADE ITS FIRST GRANT AWARDS IN SEPTEMBER 2001.

The 2-year awards were supported by the NINDS, the National Institute of Nursing Research (NINR), and ORI. Funding for the first year was approximately $1.03 million, which doubles the $500,000 originally committed to the program.

The awards demonstrate the interdisciplinary nature and broad spectrum of research on research integrity. Principal investigators are in psychology, clinical psychology, sociology, pharmacology, epidemiology, and higher education/administration. The studies will investigate conflicts of interest, data sharing, clinical trials, work-strain, quality assurance and organizational influences.

Thirty applications were received for the RPRI in response to a second RFA issued in May 2001. The new submissions represent a 20 percent increase over the 25 applications received in the first round. ORI has committed $1 million in fiscal year (FY) 2002 and requested $1.4 million for FY 2003. The new applications are scheduled for review in April 2002 and awards will be made in July 2002. The RPRI is supported by NINDS, NINR, and ORI.

IV. 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 2001 include:

- Improved the system to allow for the electronic submission of the *Annual Report on Possible Research Misconduct* for CY 2001.

- Completed the 2000 *Annual Report on Possible Research Misconduct* with a response rate of 77 percent. Sixty institutions reported opening 62 new scientific misconduct cases; a total of 82 institutions reported misconduct activities because of cases carried over from 1999. Eighty-nine percent of the responding institutions indicated they have the required policy for handling allegations of scientific misconduct.

- Inactivated assurances for 426 institutions for failure to submit an Annual Report for CY 2000.

- Processed 140 institutional policies on handling allegations of scientific misconduct, requested 86 institutional policies for review, and increased the number of completed reviews to 1,684.

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 science 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.

In 2001, ORI switched to electronic submission of the *Annual Report on Possible Research Misconduct* beginning with the report for CY 2000 to reduce the reporting burden on the 4,000 institutions required to file a report with ORI.

In 2001, ORI switched to electronic submission of the *Annual Report on Possible Research Misconduct* to reduce the reporting burden on the 4,000 institutions required to file a report with ORI.

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 funds.

As of December 31, 2001, there were 4,060 active assurances on file in ORI, including 219 from 35 foreign countries. During 2001, 429 institutions filed their initial assurance. ORI deleted 530 institutions because their assurance was inactivated. Eight duplicate assurance records were deleted. There were 96 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 426 assurances because the institutions did not submit their *Annual Report on Possible Research Misconduct*.

All of these changes had only slight impact on the total assurance database in 2001 (See Table 11). The total number of institutions with an assurance decreased by 87. Categorically, institutions of higher education decreased by 7; research organizations, institutes, foundations and laboratories decreased by 11; independent hospitals decreased by 17; educational organizations other than higher education decreased by 4; other health, human resources, environmental service organiza-

tions decreased by 9; the small business category decreased by 39; and unclassified was unchanged. The largest decline was in the small business category. Each category of institutions declined during CY 2001.

Table 11:

Type of Institution with Active Assurance by Frequency, 2001

Type of Institution	*Frequency*	*Change*
Institutions of Higher Education	908	-7
Research Organizations, Institutes, Foundations and Laboratories	326	-11
Independent Hospitals	273	-17
Educational Organizations, Other Than Higher Education	19	-4
Other Health, Human Resources, and Environmental Services Organization	397	-9
Other (small business)	2,137	-39
Unclassified	0	0
TOTAL	4,060	-87

E-Mail Network

The establishment of an e-mail network covering all institutions that have an active assurance is in place. About 92 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 ORI conferences/ workshops. Information regarding the implementation of the electronic transmission of the *Annual Report on Possible Research Misconduct* is also being provided to institutional contacts through 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 electronic submission of the 2000 Annual Report began in January 2001 for the 4,147 institutions that had an assurance on file with ORI as of December 31, 2000.

Completed Annual Reports were received from 3,178 institutions for a response rate of 77 percent. ORI inactivated 969 assurances, including 8 institutions that did not return their Annual Reports by the March 31 deadline, and 72 institutions that voluntarily withdrew their assurances rather than submit the Annual Report. Many assurances were reactivated later because annual reports were submitted after the due date. The 2000 report identified 185 institutions that did not have the required policies and procedures for handling allegations of scientific misconduct. With the electronic submission of the CY 2000 Annual Report, ORI no longer tracks changes in the institutional address or the responsible official.

Electronic submission of the *Annual Report on Possible Research Misconduct* was conducted for the first time with the CY 2000 report to reduce the reporting burden on 4,000 institutions.

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

Electronic submission of the *Annual Report on Possible Research Misconduct* was conducted for the first time with the CY 2000 report to reduce the reporting burden on 4,000 institutions.

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 form. 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.

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 3 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 is used as the primary means of notifying institutions of the new electronic annual reporting system, and to provide follow-up notices.

Over the past 3 years, ORI has been developing an e-mail network to allow it to disseminate information related to the ORI programs quickly and easily

Reported Misconduct Activity

Institutions reported increased misconduct activity in their *Annual Report on Possible Research Misconduct* for the second consecutive year following a 3-year decline. Institutional annual reports for CY 2000 were filed with ORI in early 2001. Eighty-two institutions reported misconduct activity in 2000 compared with 72 in 1999 and 67 in 1998. New cases were opened by 60 institutions in 2000 compared with 46 in 1999 and 41 in 1998.

New cases resulted in 59 inquiries in 2000 compared with 51 in 1999 and 38 in 1998. The new cases also resulted in 18 investigations in 2000 compared with 9 in 1999 and 7 in 1998.

The 103 new allegations received in 2000 were more than the 89 received in 1999 and the 69 received in 1998. The 62 new cases opened in 2000 was 1 less than in 1999, but 8 more than in 1998. Cases frequently involve more than one allegation.

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

The 103 new allegations included 24 of falsification, 37 of fabrication, 19 of plagiarism, and 23 others. Institutions reporting new cases include 45 in higher education, 7 research organizations, 5 independent hospitals, 2 small businesses, and 1 health organization.

The 82 institutions reporting misconduct activity in 2000 conducted 80 inquiries and 38 investigations in response to allegations made in 2000 and before. Sixty institutions opened new cases; 30 were completing old cases, and 8 were handling new and old cases. The number of inquiries conducted by an institution ranged from 0 to 2. The number of investigations conducted by an institution also ranged from 0 to 2.

Table 12:

Frequency of Institutions Reporting Misconduct Activities, Institutions Reporting New Cases, New Allegations, and New Cases Opened, 1994-2000.

Annual Report	*Institutions Reporting Activity*	*Institutions Reporting New Cases*	*New Allegations*	*New Cases*
2000	82	60	103	62
1999	72	46	89	63
1998	67	41	69	54
1997	73	48	92	64
1996	88	54	127	70
1995	96	61	104	81
1994	79	50	89	64

Bad Faith Allegations

Two institutions received one bad faith allegation each during 2000 according to their *Annual Report on Possible Research Misconduct*. Four allegations have now been reported by institutions since the question concerning these allegations was initially included in the 1997 Annual Report.

One institution determined that all six allegations included in a complaint "have possibly been filed in bad faith." The allegations were dismissed during

Table 13:

Frequency of Inquiries and Investigations Conducted in Response to New Allegations, 1994-2000

Annual Report	*Inquiries*	*Investigations*
2000	59	18
1999	51	9
1998	38	7
1997	56	19
1996	61	25
1995	70	31
1994	56	20

the preliminary assessment. No action was taken against the employee who left the institution prior to the bad faith determination. The other institution placed a copy of the final report of the research ethics committee, which concluded the allegation was made in bad faith, into the personnel file of the whistleblower.

The "ORI Model Policy for Responding to Allegations of Scientific Misconduct " states, "an allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation." Although institutions are not required to determine whether an allegation was made in bad faith, ORI requests data on bad faith allegations because of the concern within the scientific community about such allegations and because many institutional misconduct policies state that these acts are subject to disciplinary action.

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 140 institutional policies during 2001. ORI requested 86 policies in 2001; the other 54 policies were forwarded from 2000. ORI closed 102 reviews in 2001; 38 were carried into 2002. Of the 38 open reviews, 21 require institutional action before further progress can be made.

ORI PROCESSED 140 INSTITUTIONAL POLICIES DURING 2001.

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, 2001, GenRev contained information on 1,722 policy reviews conducted by ORI primarily since 1995. ORI completed 1,684 reviews; 38 are open.

Compliance Cases

Compliance cases involve compliance reviews of institutional handling of an allegation of scientific misconduct and/or retaliation complaints of the whistleblower. Assessments are cases where ORI has received an allegation or other information to suggest that retaliation may have occurred in a misconduct case.

In 2001, a total of 12 compliance cases were opened and 13 were closed. Nine compliance cases were carried into the year and 8 were still open at the end of the year.

Five compliance reviews were opened and five were closed in 2001. At the beginning of the year there were six open assessments; seven new assessments were opened during 2001, and eight were closed during 2001 (Table 14). Cases were closed primarily because ORI made a determination that it did not have jurisdiction, or the complain-

ant did not respond to ORI's request for additional documentation supporting the complaint.

Of the compliance cases closed during 2001, 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 initiated a civil suit against the institution, and the retaliation claims were included in this action. ORI acknowledges that a whistleblower may pursue any legal rights available for the resolution of the retaliation complaints, but once this election is made, the institution has no further obligation under the PHS regulation to address the retaliation allegations, therefore the case was closed. In another case, the institution was asked by ORI to examine retaliation complaints raised by a whistleblower, and it provided documentation that actions taken against that individual were in response to specific employment issues rather than misconduct allegations. Based on this response, ORI declined to pursue the matter further.

Table 14:

Summary of Compliance Cases, 2001

Case Type	*Forwarded from 2000*	*Opened in 2001*	*Closed in 2001*	*Carried into 2002*
Review	3	5	5	3
Assessment	6	7	8	5
TOTAL	9	12	13	8

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) PHS 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. The PHS ALERT is not a public system.

Of the 47 names in the system at year end, 35 individuals had PHS administrative actions imposed, and 12 remained as a result of an institutional report in which there was a finding of scientific misconduct.

The PHS Administrative Actions Bulletin Board is a public system. Information on each individual in the system is limited to name, 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 of individuals subject to PHS administrative actions against incoming applications, pending awards, and proposed appointments to PHS advisory committees, boards, and peer review groups.

On January 1, 2001, ORI listed the names of 45 individuals in the system. During the year, ORI added 19 and removed 17 names. On December 31, 2001, the names of 47 individuals were in the system.

ORI added these 19 names after 2 respondents agreed to a voluntary exclusion agreement, and 17 others were found to have committed scientific misconduct in institutional reports to ORI. Fifteen names were removed during the year because the term of the administrative actions expired, and two names were removed where ORI did not recommend a finding of scientific misconduct after reviewing an institutional misconduct investigation report.

Of the 47 names in the system at year end, 35 individuals had PHS administrative actions imposed, and 12 remained as a result of an institutional report in which there was a finding of scientific misconduct.

Table 15:

Summary of PHS ALERT System Activity, 2001

	PHS Actions	*Institutional Misconduc Finding*	*Total*
As of January 1, 2001			45
Additions	2	7	19
Action Expired/Removed	15	2	17
As of December 31, 2001	35	12	47

V. Information And Privacy

The number of requests for information under the Freedom of Information Act (FOIA) decreased in 2001. Privacy Act requests remained the same.

- ORI received 50 FOIA requests in 2001 compared with 59 in 2000 and 88 in 1999. Four requests were carried into 2001 compared with seven which were carried into 2000 and eight into 1999. The response rate for 2001 was a range between 1 day and 82 days, with a median of 10 days; mode was 1 day; and the average was slightly more than 12 days.

- Two Privacy Act requests were handled in 2001 compared with two in 2000 and four in 1999. All requests were completed in the year of receipt; none were carried into the next year. One request was completed in 14 days; the other in 33 days. The average response rate was 23 ½ days.

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.

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.

Appendix A

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

Steven F. Arnold, Ph.D., Tulane University (TU): Based on the TU investigation report dated July 16, 1999, and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Dr. Arnold, former Research Assistant Professor at the Center for Bioenvironmental Research at Tulane University Medical Center, engaged in scientific misconduct. Dr. Arnold committed scientific misconduct by intentionally falsifying the research results reported in Table 3 of a paper published in the journal *Science*[1] and by providing falsified and fabricated materials to investigating officials at Tulane University in response to a request for original data to support the research results and conclusions reported in the *Science* paper. In addition, PHS finds that there is no original data or other corroborating evidence to support the research results and conclusions reported in the *Science* paper as a whole. Specifically, PHS found that Dr. Arnold's research reported in the *Science* paper involved a finding that environmental chemicals, such as certain insecticides and hydroxylated polychlorinated biphenyls (PCBs), which have a weak estrogenic activity when acting alone, were up to 1,000 times more potent in mimicking estrogen when tested in combination. These research results and conclusions were important to the public health because they suggested that the Environmental Protection Agency (EPA) may need to adjust its guidelines on exposure limits to such chemicals. The *Science* paper was withdrawn July 25, 1997. See *Science* 277:462 (July 25, 1997). This research formed the basis of National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH), grant application 1 R29 DK52420-01, "Two Estrogen Binding Sites on the Estrogen Receptor."

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[1]Steven F. Arnold, Diane M. Klotz, Bridgette M. Collins, Peter M. Vonier, Louis J. Guillette, Jr., John A. McLachlan. "Synergistic Activation of Estrogen Receptor with Combinations of Environmental Chemicals." *Science* 272:1489-1492 (June 7, 1996) (hereafter referred to as the "*Science* paper").

Dr. Arnold entered into a Voluntary Exclusion Agreement (Agreement) with PHS in which he voluntarily agreed for 5 years beginning September 20, 2001, to exclude himself from any contracting, subcontracting, or involvement in grants and cooperative agreements with the U.S. Government and to exclude himself from serving in any advisory capacity to PHS. Dr. Arnold was cooperative with ORI and accepted responsibility for his actions, admitted to scientific misconduct, and conceded that there were no original data or other corroborating evidence to support the conclusions reported in the *Science* paper.

Jason Elster, Saint Louis University (SLU): Based on the SLU investigation report, Mr. Elster's admission, and additional analysis conducted by ORI in its oversight review, PHS found that Mr. Elster, former undergraduate research assistant, School of Public Health, SLU, engaged in scientific misconduct by falsifying or fabricating data in at least 8 of the 125 questionnaires he collected with support from Centers for Disease Control and Prevention (CDC) cooperative agreement U48 CCU710806, "Rural Chronic Disease Prevention Center." Specifically, the objective of the questionnaire was to assess the extent of media exposure by the community and opinions regarding local media coverage of health issues as well as to determine baseline health-related behavior. The intent of the study was to use this information in developing effective strategies for delivering information on disease prevention to the public. No publications were affected, but because of the removal of Mr. Elster's 125 questionnaires from the study, interviews with 125 new participants were required to achieve the sample size needed to have sufficient statistical power.

Mr. Elster entered into an Agreement with PHS in which he voluntarily agreed for 3 years, beginning November 13, 2001: to exclude himself from serving in any advisory capacity to the PHS and that any institution that submits an application for PHS support for a research project on which his participation is proposed or 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 Mr. Elster's research contribution. The institution must also submit a copy of the supervisory plan to ORI.

David R. Jacoby, M.D., Ph.D., Harvard Medical School (HMS) and Massachusetts General Hospital (MGH): Based on the HMS and MGH report and additional analysis conducted by ORI in its oversight review, PHS found that Dr. Jacoby, instructor, Department of Neurology, MGH, engaged in 15 acts of scientific misconduct by plagiarizing and falsifying research data taken from another scientist's different experiment in a published journal article for use in an grant application that was subsequently funded. Specifically, Dr. Jacoby plagiarized an image of a Southern blot analysis of genomic DNA that appeared as Figure 3A in Balagu , C., Kalla, M., & Zhang, W.-W. "Adeno-associated virus rep78 protein and terminal repeats enhance integration of DNA sequences into the cellular genome." *J. Virology* 71:3299-3306, 1997. Dr. Jacoby first falsified the image by adding molecular weight markers and lane labels that misrepresented the image as his own experimental data. He further falsified the image using computer software to intensify a band he claimed was a site-specific integration and to remove identifiable background spots present in the original image. The effect of Dr. Jacoby's falsifications was to misrepresent the image as data from his own experimental analysis of clonal cell lines derived from the infection of a human cell line with a recombinant hybrid virus incorporating two transgenes and adeno-associated virus genes into a herpes simplex virus amplicon. Dr. Jacoby's falsified image was material to his research because it supported his claim that the transgene DNA had integrated into the cell genome at a specific site. These plagiarized results were reported in (1) appendix material supporting an application for a Program Project Grant, Molecular Etiology of Early Onset Torsion Dystonia, 1 P01 NS37409-01A1, submitted by Dr. Jacoby's supervisor; Dr. Jacoby's supervisor relied upon falsified written and oral information provided to her by Dr. Jacoby in her description of his recent research progress; (2) three presentations by Dr. Jacoby's supervisor to colleagues at MGH in May 1998 regarding the status of the research in her laboratory; Dr. Jacoby's supervisor relied upon falsified written and oral information provided to her by Dr. Jacoby in her description of his recent research progress; and (3) a grant application to NIH for continuation of Dr. Jacoby's Clinical Investigator Award grant, 5 K08 NS01887-03. In addition, Dr. Jacoby subsequently altered the falsified image described above further by changing the location of the molecular weight markers to make it appear more consistent with the expected experimental results. Dr. Jacoby then submitted the plagiarized and falsified results to a MGH colleague, who included them in a presentation at

the First Annual Meeting of the American Society of Gene Therapy, held in Seattle, Washington, May 30, 1998. During the institutional investigation in 1998, Dr. Jacoby presented another falsified image as data from his own experiment. Specifically, he used computer software to scan Figure 3A in Balagu et al., and then alter the locations of three major bands in an effort to conceal the origin of the falsified image (i.e., Figure 3A) and to deceive investigating officials into believing that the results were from an independent experiment. Dr. Jacoby then used the different band locations as "evidence" of the differences between Figure 3A by Balagu et al. and the data purportedly from his own experiment by presenting the falsified image: (1) to the Chief of MGH's Neurology Service; (2) to a scientist assisting the Inquiry Committee by attempting to reproduce Dr. Jacoby's experiments; and (3) to the Inquiry Committee as data from his own independent experiment. After the institution concluded that Dr. Jacoby had engaged in scientific misconduct, Dr. Jacoby forged the signature of the institutional official for the MGH Grants and Contracts Office and knowingly included false and material information on his NIH non-competing renewal application for a Clinical Investigator Award, 5 K08 NS01887-05. Specifically, after ceasing to work in his supervisor's laboratory and after being told by his supervisor that she would no longer serve as his mentor on the Clinical Investigator Award, Dr. Jacoby (1) listed his former supervisor as his mentor on his 5 K08 NS 01887-05 application; (2) claimed that he was continuing to conduct grant-funded research in her laboratory; (3) forged the signature of the MGH institutional official to avoid detection by MGH; and the (4) submitted the completed application directly to NIH on or about August 1, 2000. Dr. Jacoby's actions amount to significant and serious falsifications in the proposing and reporting of research. His falsifications gave NIH reviewers inaccurate information for their evaluation of the progress made by the research group at MGH in its PHS-supported research. His falsifications also substantially hindered the progress of the PHS-funded research project. Finally, his falsifications induced NIH to award research funds for Dr. Jacoby's 5 K08 NS01887-05 grant at a time when he was no longer conducting research. Accordingly, PHS further found that Dr. Jacoby engaged in a pattern of dishonest conduct through the commission of 15 acts of data falsification and plagiarism, including additional steps taken to conceal the true nature and origin of the research data, that further demonstrated a lack of present responsibility to be a steward of Federal funds.

Dr. Jacoby entered into an Agreement with PHS in which he voluntarily agreed for 5 years beginning June 12, 2001, to exclude himself from any contracting, subcontracting, or involvement in grants and cooperative agreements with the U.S. Government, and to exclude himself from serving in any advisory capacity to PHS.

Kuie-Fu (Tom) Lin, D.V.M., Medical University of South Carolina (MUSC): Based on the MUSC report and additional analysis conducted by ORI in its oversight review, PHS found that Dr. Lin, a former graduate student, Department of Biochemistry and Molecular Biology at MUSC, engaged in scientific misconduct in research supported by the National Heart, Lung, and Blood Institute (NHLBI), NIH, grants R01 HS29397, "Regulation and Function of Renal Kallikrein," and R01 HL56686, "Gene Therapy in Experimental Hypertension and Renal Diseases." Specifically, PHS found that Dr. Lin engaged in scientific misconduct by (A) falsifying research on the expression and effect of the human atrial natriuretic peptide (ANP) gene in rats reported in *Hypertension* 26:847-853, 1995; Dr. Lin falsified data in the text on page 850 that described RT-PCR results shown in Figure 3 as obtained from multiple control and experimental rats, when only one rat was tested for each group; (B) falsifying research on the expression and effect of the human adrenomelullin (ADM) gene in rats reported in *Hypertension Research* 20:269-277, 1997; Dr. Lin falsified data in (a) Figure 2 on page 272 by reusing Figure 2 of the *Hypertension* paper cited in "A" above, and falsely relabeling it as being a test of ADM levels in experimental rats; (b) Table 1 on page 273 by stating concentrations of human ADM in experimental rat tissues without accounting for the high levels of endogenous cross-reactive rat ADM; and (c) Table 1 on page 273 by claiming that the levels of human ADM seen in rat tissues were obtained from four animals when the values were actually obtained from four serial dilutions of one sample; the journal published an erratum at 22(3):229, 1999; and (C) falsifying research on the expression and effect of the human ANP gene in rats reported in *Human Gene Therapy* 9:1429-1438, 1998; Dr. Lin falsified data in (a) Figure 3 on page 1431 by reusing Figure 2 of the *Hypertension* paper cited in "A" above, and falsely relabeling it as being based on the use of an adenovirus vector to deliver the ANP (gene rather than the use of "naked DNA" described in the earlier paper); (b) text on page 1433 that stated concentrations of human ANP in experimental rat tissues without accounting for the high levels of endogenous

cross-reactive rat ANP; and (c) Table 2 by making an inappropriate calculation for the renal blood flow (RFB) of the "AdCMV-LacZ" group by altering data (from animals that should not have been included because their venous flow was greater than their arterial flow), to falsely produce an average RBF value that was significantly different from the group receiving the ANP vector. All three of the questioned papers described gene therapy models in which the introduced gene lowered blood pressure in hypertensive or salt-sensitive rats. Dr. Lin's falsifications greatly enhanced the apparent expression and effects of the introduced ANP and ADM genes in the experimental rats.

Dr. Lin stated that he made honest mistakes and deeply regrets his unintentional errors in data handling. Dr. Lin entered into an Agreement with PHS in which he voluntarily agreed to exclude himself from any contracting, subcontracting, or involvement in grants and cooperative agreements with the U.S. Government, and to exclude himself from serving in any advisory capacity to PHS for 3 years beginning June 12, 2001. He agreed to submit letters of correction or retraction to (A) *Hypertension* 26:847-853, 1995: Requesting correction of the statement on page 850 to indicate that results on RT-PCR of tissue extracts were obtained with only one control and one experimental rat, rather than the four animals for each group claimed in the paper; (B) *Hypertension Research* 20:269-277, 1997: Requesting retraction of Table 1; the notice to the journal should state that the values for human ADM in Table 1 were incorrect because they did not account for the high level of endogenous ADM detected in control tissues by the RIA, and that only a single rat was tested rather than the four animals claimed; and (C) *Human Gene Therapy* 9:1429-1438, 1998: Requesting retraction of Figure 2 and correction of Table 2 to indicate that the renal blood flow value for the "Ad.CMV-LacZ (4% NaC1)" rats was falsified. The notice to the journal should state that Figure 2 was falsified because it was in large part a duplicate of a previously published figure and was falsified both because logit values were deliberately altered and because the results were obtained from experimental rats that were treated differently from those described in the paper. This statement should also note that the first paragraph on page 1433 contained misleading concentrations of human ANP in experimental tissues because they failed to account for the high level of cross-reactive endogenous ANP observed by the RIA used in control tissues. These correction and retraction requirements will

remain on the ALERT System until Dr. Lin sends, and ORI receives, copies of these letters that are consistent with the above language.

Shaan F. Munjee, M.S., Wake Forest University School of Medicine (WFUSM): Based on the WFUSM investigation report, and additional analysis conducted by ORI in its oversight review, PHS found that Shaan F. Munjee, M.S., former research fellow, Department of Cancer Biology at WFUSM, engaged in scientific misconduct by falsifying and fabricating data in research supported by NIDDK, NIH, grants 5 R29 DK52623-03 and 5 R29 DK52623-04, "PTHRP and prostate growth." Specifically, PHS found that Ms. Munjee falsified data relating to the signaling of protein kinase in prostate cancer cell lines. From March 2000 through October 2000, Ms. Munjee falsified and fabricated data in her notebook from experiments to misrepresent her productivity and the significance of her findings. Ms. Munjee reported the falsified and fabricated data in: (1) laboratory group meetings, a journal club, and a Cancer Biology retreat within WFUSM; (2) NIH grant application 5 R29 DK52623-04, "PTHRP and prostate growth"; and (3) an abstract submitted to the American Association for Cancer Research. Given the extensive nature of Ms. Munjee's data falsification and fabrication, none of her research can be considered reliable. Her actions adversely and materially affected the laboratory's ongoing research in prostate cancer by causing an unproductive avenue of research to be pursued and by preventing the principal investigator from submitting a competitive renewal application for a NIH grant. No publications required correction or retraction.

Ms. Munjee entered into an Agreement in which she voluntarily agreed for 3 years, beginning December 17, 2001, to exclude herself from any contracting, subcontracting, or involvement in grants and cooperative agreements with the U.S. Government, and to exclude herself from serving in any advisory capacity to PHS.

David A. Padgett, Ph.D., Ohio State University (OSU): Based on the OSU investigation report, Dr. Padgett's admissions, and additional analysis conducted by ORI in its oversight review, PHS found that Dr. Padgett, an Assistant Professor at the OSU College of Dentistry, engaged in scientific misconduct in grant application 1 R01 AG20102-01 submitted to the National

Institute of Aging, NIH. Specifically, PHS found that Dr. Padgett plagiarized and misrepresented as his own research data for Figures 1 and 2 of this NIH grant application, data which represented unpublished experiments originally conducted by a researcher at another institution for a private company. The plagiarism was a significant misrepresentation because the data appeared in the preliminary results section of the NIH grant application. Dr. Padgett used these experiments, which were relevant to the proposed research, to support the request for funding.

Dr. Padgett entered into an Agreement in which he voluntarily agreed for 3 years, beginning, October 4, 2001, to exclude himself from serving in any advisory capacity to the PHS, and that any institution that submits an application for PHS support for a research project on which his participation is proposed or 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. Padgett's research contribution. The institution must also submit a copy of the supervisory plan to ORI.

Raghoottama S. Pandurangi, Ph.D., University of Missouri--Columbia (UM-C): Based on the UM-C investigation report and additional analysis conducted by ORI in its oversight review, PHS found that Dr. Pandurangi, a former Research Assistant Professor at UM-C, engaged in scientific misconduct by plagiarizing and falsifying research data taken from journal article published by other scientists for use in supplementary materials of an NIH research grant application. Specifically, PHS found that Dr. Pandurangi plagiarized the images of data in Figures 2A and 2B and related text in supplemental material he submitted in connection with NHLBI, NIH, grant application 1 R01 HL62517-01A2, "Myocardial Viability by AII Receptor-99mTc Conjugates," in which he was the principal investigator. Specifically, Figures 2A and 2B and related text were plagiarized from Figures 7C and 7D of the following journal publication: Gibson, R., Beauchamp, H., Fioravanti, C., Brenner, N., and Burns, H.D. "Receptor Binding Radiotracers for the Angiotensin II Receptor: Radioiodinated [Sar^1, Ile^8]Angiotensin II." *Nuclear Medicine and Biology* 21:593-600, 1994. In addition, Dr. Pandurangi falsified the text in the supplement to his NIH grant application by claiming that Figures 2A and 2B represented a compound he had developed. Namely, he

claimed that Figure 2A represented radioionated compound ^{123}I-2C and Figure 2B represented radioionated compound ^{123}I-2C with nonradioactive compound 2C added as a competitor. However, Figures 2A and 2B were plagiarized from the figures in the above *Nuclear Medicine and Biology* article, which in reality represented radiolabeled [Sar^{1}, Ile^{8}]Angiotensin II, with compound L-158,809 as a blocker/competitor.

Dr. Pandurangi entered into an Agreement with PHS in which he voluntarily agreed beginning July 17, 2001, to exclude himself from any contracting, subcontracting, or involvement in grants and cooperative agreements with the U.S. Government for 1 year, his participation in any PHS-funded research is subject to supervision requirements for 3 years, to exclude himself from serving in any advisory capacity to PHS for 4 years.

Karen M. Ruggiero, Ph.D., Harvard University (HU): Based on the HU report, and related actions and findings by HU, as well as additional analysis conducted by ORI in its oversight review, PHS found that Dr. Ruggiero engaged in scientific misconduct by fabricating data in research supported by the NIH. Specifically, PHS and HU found that: (1) Dr. Ruggiero fabricated three experiments, including data reported as having been obtained from a total of 240 participants, published in the following paper: Ruggiero, K.M. & Marx, D.M. "Less pain and more to gain: Why high-status group members blame their failure on discrimination." *Journal of Personality and Social Psychology*, 77(4):774-784, 1999 (the "*JPSP* paper"). These experiments were also proposed in the "Research Plan" of an application submitted to the National Institute of Mental Health, NIH, by Dr. Ruggiero in September 1997 for grant 1 R03 MH58586-01, which was acknowledged as a source of support in the *JPSP* paper. Dr. Ruggiero admitted that she fabricated the data on the 240 participants in the *JPSP* paper. At her request, a notice of retraction of this paper appeared in the *Journal of Personality and Social Psychology* 81(2):178, 2001. (2) Dr. Ruggiero fabricated two experiments, including data reported as having been obtained from a total of 360 participants, published in the following paper: Ruggiero, K.M., Steele, J., Hwang, A., & Marx, D.M. "Why did I get a 'D'? The effects of social comparisons on women's attributions to discrimination." *Personality and Social Bulletin* 26(10):1271-1283, 2000 (the "*PSPB* paper"). These experiments were also proposed in the "Research Plan" of the application submitted by Dr. Ruggiero in September

1997 for grant 1 R03 MH58586-01, which was acknowledged as a source of support in the *PSPB* paper. Dr. Ruggiero admitted that she fabricated the data on the 360 participants in the *PSPB* paper. At her request, a notice of retraction of this paper appeared in the *Personality and Social Psychology Bulletin* 27(9):1237, 2001. (3) Dr. Ruggiero's admittedly fabricated research from the *JPSP* and *PSPB* papers was cited in and served as the basis for an NIH Individual National Service Award application, F32 MH12868-01 and -01A1, formerly F32 HD41874, "Status effects in perceptions of preferential treatment," submitted in August 2000 by one of Dr. Ruggiero's post-doctoral fellows, with Dr. Ruggiero listed as the sponsor. (4) In connection with a Harvard School of Public Health grant application to NIH, 1 R01 HL065220-01, "Measuring racial discrimination for health research," Dr. Ruggiero submitted a subcontract in September 2000 citing the admittedly fabricated research from the *JPSP* and *PSPB* papers in support of her qualifications to serve as a subcontractor. (5) In July 1999 and July 2000, Dr. Ruggiero cited and included as "Preliminary Studies" her admittedly fabricated, PHS-supported research from the *JPSP* and *PSPB* papers in applications, "The ironic status effect," that she submitted to the National Science Foundation.

Dr. Ruggiero agreed to exclude herself from any contracting, subcontracting, or involvement in grants and cooperative agreements with the U.S. Government for a period of 5 years beginning November 26, 2001, and to exclude herself from serving in any advisory capacity to PHS. She agreed to submit a letter, with a copy to ORI and HU, to the *Personality and Social Psychology Bulletin* requesting retraction of the following paper: Ruggiero, K.M. & Major, B.N. "Group status and attributions to discrimination: Are low- or high-status group members more likely to blame their failure on discrimination?" *Personality and Social Psychology Bulletin* 24:821-838, 1998. Dr. Ruggiero further agreed that the letter would state that the retraction is warranted "because serious questions exist concerning the validity of the data which relate solely to my own work and which do not implicate my coauthor in any way." She submitted a copy to ORI. (4) Dr. Ruggiero agreed to submit a letter, with a copy to ORI and Harvard, to *Psychological Science* requesting a retraction of the following paper: Ruggiero, K.M., Mitchell, J.P., Krieger, N., Marx, D.M., & Lorenzo, M.L. "Now you see it, now you don't: Explicit versus implicit measures of the personal/group discrimination discrepancy." *Psychological Science* 22:57-67, 2000. Dr. Ruggiero further agreed that the letter submitted

would state that the retraction is warranted "because I improperly excluded some participants who should have been included in the analyses and that this exclusion affected the reported results. Moreover, the improper exclusion of data was solely my doing and was not contributed to or known by my coauthors." She submitted a copy to ORI.

Ayman Saleh, Ph.D., University of Pittsburgh (UP): Based on the UP inquiry report and additional analysis conducted by ORI in its oversight review, PHS found that Dr. Saleh, former postdoctoral research associate, UP School of Medicine, engaged in scientific misconduct in research supported by the NIH. PHS found that Dr. Saleh falsified: (a) data for a manuscript which purported to show Western blots of rabbit Bcl-2 and tubulin; the blots were actually obtained from different experiments by another researcher using antibody against Hsp70 and against Bag-1, respectively; (b) the label on a Western blot for Bcl-2 that he presented to the inquiry committee as evidence that he had conducted the experiment at issue; the blot was actually from a different experiment by a coworker; (c) data for a laboratory figure purported to represent a rabbit PARP cleavage blot; the data was from another experiment, and the antibody to PARP was not available to Dr. Saleh at that time; (d) Western blot data on pcasp-9 and p37/p35 for a manuscript on Hsp27; the data represented experiments that could not be performed because the cell lines were unavailable at the time; and (e) Figure 2b, the panel that shows a Western blot of Casp-9(WT) in a publication by Srinivasa M. Srinivasula, Ramesh Hegde, Ayman Saleh, Pinaki Datta, Eric Shiozaki, Jijie Chais, Ryung-Ah Lee, Paul D. Robbins, Theresa Fernandes-Alnemri, Yigong Shi, and Emad S. Alnemri. "A conserved XIAP-interaction motif in caspase-9 and Smac/DIABLO regulates caspase activity and apoptosis." *Nature* 410(6824):112-116, 2001. The Figure 2b data were actually taken from a Western blot of Bcl-XL data, in which Dr. Saleh transposed the lanes. The experiments examined the regulation of programmed cell death (apoptosis), a process that is important to a better understanding of cancer. Figure 2b in the *Nature* paper represented a control experiment that confirmed the association of an X-linked gene to a particular type of apoptosis.

While neither accepting nor admitting to the findings of scientific misconduct, Dr. Saleh entered into an Agreement with PHS in which he voluntarily agreed for 3 years, beginning May 3, 2001, to exclude himself from any contracting,

subcontracting, or involvement in grants and cooperative agreements with the U.S. Government, and to exclude himself from serving in any advisory capacity to PHS.

David D. Sanchez, Public Health Foundation Enterprises, Inc. (PHFE): Based on the PHFE investigation report and additional analysis conducted by ORI in its oversight review, the PHS found that Mr. Sanchez, former research assistant for PHFE's California Emerging Infections Program (CEIP), engaged in scientific misconduct in research supported by CDC cooperative agreement U50 CCU915546-03. Specifically, PHS found that Mr. Sanchez engaged in scientific misconduct by falsifying and fabricating data in interview questionnaires involving 21 cases and 27 controls for the "Campylobacter Ethnicity Case Control Study," which he submitted to the CEIP coordinator. As a result of his actions, none of Mr. Sanchez' research could be considered reliable and the research project was terminated. Mr. Sanchez also falsified and fabricated an additional 15 data records relating to PHFE's "E. Coli O157 Case-Control Study," which he also submitted to the CEIP coordinator. Mr. Sanchez further engaged in a pattern of dishonest conduct that indicated that he is not presently responsible to be a steward of Federal funds. This pattern of behavior includes falsely claiming hundreds of hours on his time sheets submitted to CEIP for which he had not performed any work and repeatedly refusing to cooperate with the misconduct investigation. These actions adversely and materially affected CEIP's ability to determine risk factors for Campylobacter infections among Latino and Chinese-American children. No publications required correction.

Mr. Sanchez entered into an Agreement with PHS in which he voluntarily agreed for 3 years, beginning September 4, 2001, to exclude himself from any contracting, subcontracting, or involvement in grants and cooperative agreements with the U.S. Government, and to exclude himself from serving in any advisory capacity to PHS.

Malabika Sarker, M.B.B.S., M.P.H., University of Alabama at Birmingham (UAB): Based on the UAB investigation report and additional analysis conducted by ORI in its oversight review, the PHS found that Dr. Sarker, former doctoral fellow, Department of Epidemiology, School of Public Health, UAB, engaged in scientific misconduct by falsifying questionnaire data for

risk factors for sexually transmitted diseases (STDs) in Bangladesh for her dissertation. The research was supported by the Fogerty International Center, NIH, grant D43 TW01035, "UAB AIDS/HIV International Training & Research." The purpose of the research was to determine from questionnaires the lifestyle and personal history factors of subjects and correlate them to infection rates for STDs from use of laboratory tests. Dr. Sarker admitted that she falsified the coding of the questionnaire data relating to the occupations of the subjects and of their sexual partners to present statistically significant data regarding the risk factors for STDs. Dr. Sarker accepted the PHS finding and entered into an Agreement with PHS in which she voluntarily agreed for 3 years, beginning April 17, 2001, (1) to exclude herself 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 her participation is proposed or that uses her 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. Sarker's research contribution. The institution must also submit a copy of the supervisory plan to ORI.

Mr. Sherman Smith, University of California at San Francisco (UCSF): Based on the UCSF investigation report and information obtained by ORI during its oversight review, PHS found that Mr. Smith, former research technician, Division of Occupational and Environmental Medicine at UCSF, engaged in scientific misconduct by intentionally and knowingly fabricating and falsifying patient interview data as the sole interviewer in the PHS-funded UCSF Asthma Disability Study (Asthma Study). The UCSF Asthma Study was funded by NHLBI, NIH, grants K04 HL03225, R01 HL56438, and R29 HL48959, and National Institute for Occupational Safety and Health, CDC, grant R01 OH03480. Specifically, Mr. Smith intentionally falsified and fabricated the interviews of 107 patients in the Asthma Study. The falsification of the patient interviews was committed with an intent to deceive. This deception, in turn, had a material, negative impact on the Asthma Study in particular and on asthma research in general. The falsified and fabricated data were reported in ten publications, and fellow members of the Asthma Study Team spent more than 2 years correcting the research data and were required to submit retractions or corrections for all ten publications produced by the study.

PHS implemented the following administrative actions for the 5-year period beginning October 9, 2001: (1) Mr. Smith is prohibited from serving in any advisory capacity to PHS, and (2) he is debarred from any contracting, subcontracting, or involvement in grants and cooperative agreements with the U.S. Government.

Ms. Vilma Valentin, Boston University School of Medicine (BUSM): Based on the BUSM investigation report as well as additional analysis conducted by ORI in its oversight review, PHS found that Ms.Valentin, a former counselor and interventionist on the BUSM Inner City Asthma Study, engaged in scientific misconduct by fabricating records in research funded by two National Institute of Allergy and Infectious Diseases, NIH, cooperative agreements: U01 AI39776, "Data Coordinating Center for NCICAS II," and U01 AI39769, "Trial of Interventions to Reduce Asthma Morbidity." Specifically, PHS found that Ms. Valentin fabricated: (1) the data on three environmental intervention forms for visits that she allegedly made to two patients' homes in early and late August 1999; and (2) the reports of two telephone calls that she allegedly made to the two patients' families during the same period; these calls were not made. The study intervention included home visits, telephone calls, and advocacy letters, all of which were central to the research, which sought to evaluate the effectiveness of two interventions to reduce asthma severity. Thus, the data and reports could have had a substantive effect on the outcome of the research had the institution not corrected the research record.

While acknowledging the findings of scientific misconduct as set forth above and in the BUSM Report but without admitting liability or wrongdoing, Ms. Valentin entered into an Agreement in which she voluntarily agreed for 3 years, beginning December 5, 2001, to exclude herself from serving in any advisory capacity to the PHS; and her participation in any PHS-funded research is subject to supervision requirements. The supervisory plan must be designed to ensure the scientific integrity of Ms. Valentin's research contribution. The institution must also submit a copy of the supervisory plan to ORI.

Momiao Xiong, Ph.D., The University of Texas Health Science Center at Houston (UTHSCH): Based on the UTHSCH inquiry report, and any related actions and findings by UTHSCH, as well as additional analysis

conducted by ORI in its oversight review, PHS found that Dr. Xiong engaged in scientific misconduct by plagiarizing and fabricating data in National Institute of General Medical Sciences, NIH, grant application R01 GM64353-01, "Genetics of Human Pigmentation and Skin Response" (Pigmentation Application), on which he was a co-investigator. The plagiarized and fabricated data were essential to the scientific validity of the proposed research and were important for NIH's scientific evaluation of the Pigmentation Application. Dr. Xiong admitted his actions. Specifically, PHS and UTHSCH found that Dr. Xiong: (1) plagiarized text from another researcher's grant application, which Dr. Xiong had obtained during the NIH confidential review process and used without appropriate citation in the Pigmentation Application; and (2) falsified research in the Pigmentation Application by (a) falsely claiming that he had performed an extensive series of simulations to evaluate the power to detect genes influencing pigmentation traits by the proposed statistical analysis, and (b) falsely representing estimates from previous work on unrelated individuals as being appropriate for large families in the proposed research.

The Agreement states that beginning November 26, 2001, Dr. Xiong: (1) will not serve as a principal investigator on PHS grants for 1 year; (2) will exclude himself from serving in any advisory capacity to PHS for 3 years; and (3) agrees that for 3 years, he and any institution employing him are required to certify, in every PHS application or report in which Dr. Xiong is involved: (a) that all persons who contribute original sources of ideas, data, or research results to the applications or reports are properly cited or otherwise acknowledged; and (b) that the applications or reports do not contain any falsified, fabricated, or misleading information. This requires Dr. Xiong and the institution, with respect to Dr. Xiong's contributions to the application or report, to certify that all individuals (both within and outside the institution) who contributed to the application or report are acknowledged. The institution must also send a copy of the certification to ORI; and (4) accepts the following UTHSCH administrative actions: (a) Dr. Xiong must send a formal, written apology to the principal and co-investigators explicitly acknowledging his plagiarism from their grant application; (b) for a 1-year period starting October 11, 2001, Dr. Xiong may not: (i) submit, as a principal investigator, any new grant applications, including applications to any Federal, State, or local government agencies, as well as any private foundations or agencies; or

(ii) submit any publications without providing certification, co-signed by his immediate supervisor, that any manuscript for publication does not contain any plagiarized information or any falsified, fabricated, or misleading information; (c) for an additional 2 years, Dr. Xiong must similarly certify any grant application or publication; (d) for the next 3 years, to submit any grant application or publication, Dr. Xiong must have a signed statement from his immediate supervisor stating that the supervisor reviewed the materials and finds no indication of plagiarism, falsification or fabrication of data, nor any other form of scientific misconduct; (e) for the next academic year, Dr. Xiong is required to participate in a course in the responsible conduct of research, and in the year after completing the course, serve as a co-instructor in a small discussion group for all breakout sessions of the course; and (f) within 2 years, Dr. Xiong must write a formal essay, of publication quality, in English and Chinese, on plagiarism for submission to the Executive Vice President for Research, UTHSCH, and for publication.

Appendix B

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

Closed Inquiries:

Falsification: The respondent, a professor, allegedly falsified published data by biased selection of research results involving animal behavioral research. The research was supported by three National Institute of Aging), National Institutes of Health (NIH), grants, one National Institute of Drug Abuse, NIH, grant, and one National Heart, Lung, and Blood Institute (NHLBI), NIH, grant. The institution conducted an inquiry into the matter and concluded that although errors were made and reported in the questioned publication, there was insufficient evidence of scientific misconduct to warrant further investigation. The institution required that the authors of the publication in question inform the journal of the errors/omissions in the reporting of their work, and a letter of correction was published. ORI concurred with the institution's determination that there was insufficient evidence to warrant further investigation in this case.

Falsification: The respondents, a professor and an associate professor, allegedly falsified research data in research involving growth factors and anticancer drugs and included the questioned data in a published paper. The questioned research was supported by three grants from the National Cancer Institute (NCI), NIH. The institution conducted an inquiry into the matter and determined that there was insufficient evidence of misconduct to warrant an investigation under the institution's disciplinary rules. In conducting the inquiry, the committee confirmed the existence of the questioned data. In accepting the institution's conclusion, ORI examined two additional manuscripts that reproduced and extended the results and noted that no evidence was presented that confirmed the allegations.

Falsification: The respondent, a professor, allegedly falsified research results that were reported in a published paper on motor control in animals. The questioned paper cited support from the National Institute for Neurologi-

cal Disorders and Stroke, NIH. The institution conducted an inquiry into the matter and concluded that the facts of the case did not support the allegation of scientific misconduct and determined that no further investigation was warranted. ORI concurred with the institution's determination.

Falsification: The respondent, an associate professor, allegedly used false data for three figures in a research grant application submitted to the NCI, NIH. The questioned research involved the development of a high energy proton beam source and its exploitation to deliver therapeutic doses in radiation oncology. The institution conducted an inquiry into the matter and concluded that the evidence did not warrant an investigation into scientific misconduct. ORI determined that the evidence indicated that the misrepresentations of the figures in the questioned grant application were consistent with honest errors on the part of the respondent and concurred with the institution's conclusion that an investigation was not warranted.

Falsification: The respondent, a research nurse, allegedly falsified screening logs and patient questionnaires and activities records in a clinical research project involving problems of cancer patients. The questioned research was supported by grants from the National Institute of Nursing Research, NIH. The institution conducted an inquiry into the matter and concluded that while there were deficiencies in the screening process and in the data collection methodology, there was no evidence of scientific misconduct. ORI concurred with the institution's factual findings and determined that there was insufficient evidence to warrant an investigation.

Falsification: An anonymous complainant alleged that the respondents, who are associate professors, allegedly falsified data in recent publications by inappropriate selection of data, using different doses of radiation from case animals and control animals to ensure statistical significance in their published case-control studies. The questioned research was supported by five NCI, NIH, grants. The institution conducted an inquiry into the matter and concluded, after an exhaustive review of the primary data and interviews with the respondents, that there was no evidence of scientific misconduct. ORI accepted the institution's conclusion that there is insufficient evidence of falsification or fabrication to warrant any further investigation in this case.

Closed Investigations:

Fabrication: The respondent, a staff interviewer, allegedly fabricated records for two interviews on one day, in a behavioral research study involving sensitive behaviors, under a cooperative agreement funded by Centers for Disease Control and Prevention. The institution conducted an investigation into the matter. The respondent, who claimed to have conducted the interviews, failed to respond during the investigation. The institution concluded the respondent had fabricated the interview records and forged payment receipts for the two subjects. However, ORI concluded that the evidence may be insufficient to sustain a PHS finding of scientific misconduct. Therefore, ORI accepted the institution's factual findings, but did not make a finding of scientific misconduct in this case.

Falsification: The respondent, a research nurse, allegedly falsified research data for human subjects in a study involving hypertension and kidney disease. The study in question was supported in part by the National Institute for Diabetes and Digestive and Kidney Diseases (NIDDK), NIH. The institution conducted an inquiry into the matter and concluded that an investigation was warranted for certain issues not resolved by the inquiry. Upon completion of its investigation, the institution determined that the allegations were unfounded and recommended dismissal of the allegations. ORI accepted the institution's findings of fact and concluded that there was insufficient evidence to resolve definitively the allegations of falsification.

Falsification: The respondent, a graduate student, allegedly falsified research for a section of his doctoral dissertation in research on brain control of animal movements. The questioned research was supported by two National Institute of Mental Health, NIH, grants. The institution conducted an investigation into the matter and concluded that an electronic file containing data from the questioned research was copied and represented as data from an independent experimental measurement. However, it was not possible for the institution to determine who was responsible for the file being copied or whether the copying was intentional. Thus, the institution found that since neither the identity nor the intent of the responsible party could be established, no finding of scientific misconduct could be made. ORI concluded that the evidence was insufficient to determine whether duplication and misrepresenta-

tion of computer files represented an intentional and significant falsification of data for the limited set of control experiments in question. Given the inconsistencies in the evidence, ORI concurred with the institution's determination that the evidence was not sufficient to establish that the respondent was responsible, and ORI did not make a finding of scientific misconduct in this case.

Falsification/Fabrication: The respondent, a senior scientist and chief nurse, allegedly falsified and/or fabricated data on patient interview forms in a study involving surgical treatment of a disease. The study in question received funding from the NHLBI, NIH. The institution conducted an investigation and determined that the respondent had falsified dates on patient interview forms but had not falsified or fabricated any other information. Based on information gained from its extensive oversight review, ORI decided to close the matter without taking further action. Specifically, ORI considered: (1) the time lag of approximately 10 years between the alleged misconduct and the completion of the institutional process (including several appeals by the respondent); (2) the sufficiency of the administrative actions already imposed on the respondent by the institution to protect the integrity of the research record; and (3) the respondent's retirement and lack of current participation in Public Health Service research.

Appendix C

Scientific Misconduct Related Litigation During 2001[2]

Civil Litigation – Closed Cases

U.S. ex rel. Cantekin* v. *University of Pittsburgh, No. 91-0715 (W.D. Pa., filed May 1991). 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), 31 U.S.C. § 3729, 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 several of the claims. However, the court allowed 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 with respect to 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 this decision.

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[2]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, taking depositions, preparing briefs and pleadings, and assisting with 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.

In 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 District Court's dismissal of the post-October 1986 claims stating that there were genuine factual disputes that precluded summary judgment on whether the defendants knowingly submitted a false claim. The court stated that there was a question of fact regarding the researcher's state of mind, that the NIH grant application instructions were clear that a researcher must disclose other support, and that 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 2000, the Third Circuit returned the case to the District Court for action, and Dr. Cantekin filed a petition for *certiorari* with the U.S. Supreme Court (Docket 00-282), which the Court denied. 21 S. Ct. 192 (2000). In 2001, the Department of Justice approved a private settlement agreement between Dr. Cantekin and the University, which the District Court approved and dismissed both the private claims and the *qui tam* action. This case is now closed.

U.S. ex rel. Lucinda C. Scott* v. *Dr. Robert J. McKenna, Jr., No. 96-5176CBM (C.D. Ca., filed July 25, 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), 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, but ORI determined that only one of the named defendants had submitted a grant application to the NIH and that none of his grant applications were funded. In 1997, based on recommendations from ORI, the National Heart, Blood and Lung Institute, NIH, Office for Protection from Research Risks, and the National Center for Research Resources, 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 court set a tentative trial date. The government reconsidered whether to intervene. After the defendants filed several motions for summary judgment, the parties settled with no recovery for the United States in exchange for a waiver of costs against the relator. This case is now closed.

U.S. ex rel. Streed* v. *The Regents of the University of California, et al., No. 97 CV0443K (RBB) (D.S. Cal. 1997). Relator, Thomas B. Streed, Ph.D., filed a *qui tam* action under the FCA, against the University of California, Immusol Inc., Pfizer Inc., and several individual investigators. 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, NIH and ORI recommended that the government not intervene in this case, the United States declined to intervene, and the court lifted the seal. In 1999, the court granted the defendants' motion to dismiss the complaint, but permitted Dr. Streed to refile an amended complaint which included new allegations about violations of the First Amendment. The court then dismissed the University as a defendant because a U.S. Supreme Court case determined that State agencies may not be sued by a *qui tam* relator under FCA. In 2001, at the request of the parties, the judge dismissed the case without prejudice to the government. The case is now closed.

Marguerite Kay, M.D.* v. *State of Arizona Board of Regents, No. 328309 (Sup. Ct. of Arizona, filed Aug. 17, 1998). Dr. Kay filed suit against the University of Arizona in State court claiming wrongful discharge and violation of the Arizona Administrative Procedure Act (APA), 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 employment in 1998. Dr. Kay had previously filed in Federal Court for a restraining order claiming violation of substantive and due process on similar grounds; that case was dismissed.

In 1999, the State court ruled that the University had 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. She appealed the failure to reinstate or grant back pay. The University reinstated Dr. Kay, refired her, and she administratively appealed the new firing. Both parties appealed the Court of Appeals' decision to the Arizona State Supreme Court, which granted the University's petition for rehearing. In September 2001, the Arizona Supreme Court vacated the lower appellate court decision and held that a 1996 amendment to the Arizona APA did not confer jurisdiction for a reviewing court to order the reinstatement of a terminated public employee based on irregularities in an agency's administrative decision. However, based on the lower court's decision, and before the Arizona Supreme Court ruled, the University had reinstated Dr. Kay, paid her more than $100,000 in back pay, and commenced a new scientific misconduct proceeding. The state case is now ended.

Civil Litigation – Open Cases

Marguerite Kay, M.D.* v. *Tolbert, No. 290-TUC-JMR (D. Az. March 30, 2001). In this companion case to the above closed case, *Kay* v. *Arizona State Board of Regents*, Dr. Kay filed a breach of contract and section 1983 suit in State court, suing the University of Arizona and institutional employees, including members of the investigation committee, for damages

relating to the scientific misconduct investigation against her. The University removed the case to Federal Court, and the District Court dismissed it. The Federal Court granted the defendants' motion for summary judgment and dismissed the case with prejudice, awarding costs against Dr. Kay. The District Court held that many of the issues raised by Dr. Kay were *res judicata* because of the decisions in her prior lawsuits. Relying on *Harlow* v. *Fitzgerald*, 457 U.S. 800 (1982), the court also held that all the individual defendants were entitled to qualified immunity. With respect to Dr. Kay's substantive due process claims, the court held that the defendants were entitled to qualified immunity because at the time she was terminated, the law on this matter was unclear, and she had no clearly established constitutional right to substantive due process protection. With respect to her due process claims, the court held that the individual defendants were entitled to qualified immunity because they either did not cause the due process violation (the termination without hearing) or they acted reasonably and relied in good faith on the termination process used on the advice of counsel. Dr. Kay appealed the District Court decision to the Ninth Circuit Court of Appeals. At the end of 2001, the parties had submitted written briefs and were awaiting the scheduling of oral argument.

U.S. ex rel. Gene Ioli* v. *Regents of the University of California, John Hiserodt, et al., No. SACV 98-473 GLT (C.D. Cal., filed June 1998). The Relator, Dr. Gene Ioli, filed this *qui tam* suit under the False Claims Act, 31 U.S.C. § 3730, against the Regents of the University of California, Dr. John Hiserodt, and others. Dr. 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. Dr. 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 Federal government declined to intervene in the case, and the District Court lifted the seal. Based upon the U.S. Supreme Court decision in *Vermont Agency of Natural Resources* v. *U.S. ex rel. Steven*, which held that a private individual may not bring suit in Federal Court on behalf of the United States against a State under the False Claims Act, the court dismissed the *qui tam* suit as to the Regents of the University of California.

The court dismissed one of the individual defendants from the case for the counts involving the alleged false claims, but he is still a defendant for claims of whistleblower retaliation against the Relator. However, the court denied the motion to dismiss Dr. Hiserodt as a defendant. The trial is scheduled for Spring 2002.