Office of Research Integrity

Annual Report 2004

May 2005

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

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Highlights of 2004 ORI Annual Report

The Office of Research Integrity (ORI) is a component of the Office of Public Health and Science (OPHS) that is in the Office of the Secretary (OS) within the Department of Health and Human Services (HHS). The ORI mission focuses on (1) oversight of institutional handling of research misconduct allegations involving research, research training or related research activities supported by the Public Health Service (PHS), (2) education in the responsible conduct of research (RCR), (3) prevention of research misconduct, and (4) compliance with the PHS regulation 42 CFR Part 50, Subpart A.

Regulations

- Published the proposed changes to the research misconduct regulation in April 2004 to implement the new Federal definition of research misconduct adopted by the Office of Science and Technology Policy, policy changes adopted by HHS in the past few years, and needed revisions and updates to the regulation that was published in 1989. All comments were carefully reviewed, and a number of substantive changes and clarifications have been proposed. The final rule was approved by HHS and submitted to the Office of Management and Budget (OMB) for review.

Responding to Research Misconduct Allegations

- Found research misconduct in 8 of the 23 cases closed. Four misconduct findings involved fabrication and falsification, 2 involved falsification, 1 involved falsification and plagiarism and 1 involved fabrication, falsification and plagiarism. The percentage of closed cases that produced PHS misconduct findings and administrative actions for 2004 (35 percent) was slightly lower than the historical average of 37 percent. However, 75 percent of the 30 cases pending in ORI at the end of 2004 with institutional determinations involve research misconduct findings.

- Recommended the following administrative actions to the Assistant Secretary for Health (ASH) in the 8 cases that resulted in research misconduct findings: debarment/voluntary exclusion from receipt of federal funds for 3 years, 6 respondents; supervision plans for 3 years, 2 respondents; prohibition from serving in any advisory capacity to PHS for 3 years, 8 respondents. All recommendations were accepted by the ASH.

- Received the highest number of allegations (267) since the tracking of allegations began in 1989. The new mark represented a 50 percent increase over 2003. Opened 30 new cases with 51 cases carried into 2005. Forty-four cases were carried into 2004.

- Completed its oversight in 19 of 23 closed cases (83 percent) within the ORI goal of 8 months. Mean completion time for closed cases was 6 months, median 4 months, range 1-22 months. Oversight involves reviewing reports, obtaining additional information from the institution, completing the ORI analysis, negotiating any PHS findings and administrative actions, and closing the cases. Institutions took a mean of 10.3 months after notifying ORI that they were launching an investigation (median 7 months; range 1-39 months) to complete their actions.

- Offered Rapid Response for Technical Assistance (RRTA) formally to 10 institutional officials in cases opened in 2004, 9 accepted; 6 of them were new clients, requesting from ORI specific and substantive advice, including advice on the handling of allegations and respondents and the sequestration of evidence during their assessment or inquiry stages. Of the 23 cases closed by ORI in 2004, ORI had provided RRTA during the early stages for 8 of them. ORI additionally provided RRTA to 42 institutional officials who called ORI during their assessment or inquiry stages, before reporting any case formally to ORI; some of these institutions called ORI two or more times for assistance.

Education and Prevention

- Funded 9 more instructional resources through the Responsible Conduct of Research (RCR) Resource Development Program raising to 39 the number of projects supported since 2002. Eleven completed resources were posted on the ORI web site for use in RCR education programs at institutions and research organizations around the world.

- Held the second annual RCR Expo in conjunction with the Annual Meeting of the Society of Research Administrators International. Fourteen developers of RCR resources exhibited their creations including 7 universities, 1 college, 2 hospitals, 2 associations, 1 commercial firm, and 1 government agency.

- Made awards to 5 academic societies to develop and institutionalize RCR infrastructure, activities, and educational programs into the culture of the societies and the disciplines they represent. In its first 2 years, The RCR Program for Academic Societies, a collaboration between the Association of American Medical Colleges and ORI, supported 20 projects submitted by 18 academic societies.

- Created the RCR Program for Graduate Schools to promote the institutionalization of RCR education programs for graduate students and faculty. Awards were given to 10 institutions to develop demonstration

projects designed to reach that goal; another 25 institutions are participating in the program as affiliated institutions. The program is a collaboration between the Council of Graduate Schools and ORI.

- Negotiated the printing of 5,000 additional copies of the *ORI Introduction to the Responsible Conduct of Research* by the Government Printing Office to replenish its stock after the initial 1,000 copies were rapidly sold. As of December 30, 2004, more than half (2,565) of the additional copies were sold. The 165-page book is posted on the ORI web site for reading on-line or downloading.

- Seven conferences or workshops related to research integrity, the responsible conduct of research and research misconduct were supported by ORI in collaboration with 4 universities, 2 medical schools, 3 academic societies, 3 institutional associations, and the Office for Human Research Protections.

- Redesigned the ORI web site to improve organization, navigation, access and visual appeal. Actively promoted the web site to principal investigators, research training officers, RCR instructors, research integrity officers, and responsible institutional officials.

- Increased the audience for the ORI web site dramatically. The number of visits to the ORI web site tripled (74,602 to 219,525) between FY 2003 and FY 2004, unique visitors doubled from 38,359 to 92,076, and repeat visitors tripled from 7,855 to 24,490. Besides the United States, visitors were from 18 other countries.

- Held exhibits at annual meetings of 5 academic societies and professional associations during 2004 to increase contact and generate a dialogue with members of the research and academic communities.

- Made 63 presentations at conferences, workshops, meetings of professional associations and academic societies, universities, medical schools, research institutes, hospitals, civic clubs, and Federal agencies.

Research on Research Integrity and Research Misconduct

- Completed 2 studies in the ORI intramural research program: *Closed Investigations into Misconduct Allegations Involving Research Supported by the Public Health Service: 1994-2003* and *Institutional Research Misconduct Activity: 1992-2001*. Both studies were conducted by ORI staff. ORI also awarded a contract to the Research Triangle Institute to conduct a study of institutional research integrity officers and submitted a proposal to HHS for a study of institutional infrastructure supporting mentoring programs.

- Made five awards in the extramural program through the Research on Research Integrity (RRI) Program increasing the number of studies supported in the 4 four years to 27. The program has produced 10 published articles, including 5 in 2004.

- Held the third biennial Research Conference on Research Integrity in San Diego. Over 70 presentations were made during the conference, including several by researchers supported by the RRI Program.

Institutional Compliance

- Completed the 2003 Annual Report on Possible Research Misconduct in which institutions reported the highest level of research misconduct activity since 1993. One hundred and six institutions reported opening 105 new cases in response to 136 allegations.

- Inactivated assurances for 480 institutions or organizations for failing to submit the calendar year 2003 Annual Report on Possible Research Misconduct by the March 31, 2003, deadline.

- Processed 130 institutional policies on handling allegations of research misconduct, requested 150 institutional policies for review, and increased the number of completed reviews to 2,377.

- Opened 9 compliance cases and closed 8 compliance cases. Two cases involved institutional handling of an allegation of scientific misconduct; 6 cases concerned retaliation complaints from whistleblowers.

Information and Privacy

- Received 43 Freedom of Information Act (FOIA) requests; 35 were closed. Two Privacy Act requests were also received; 1 was closed.

I. Responding to Research Misconduct Allegations

Introduction

ORI maintains oversight of institutional handling of research misconduct allegations through its Division of Investigative Oversight (DIO). Research misconduct investigations conducted by PHS awardee institutions and PHS agencies are reviewed by DIO staff for timeliness, objectivity, thoroughness and competence. On the basis of those reviews, DIO makes recommendations on findings and administrative actions to the Director, ORI, who then submits proposed findings and administrative actions to the Assistant Secretary for Health. The DIO staff also assists the Office of the General Counsel (OGC) in preparing cases that will be heard by the Research Integrity Adjudications Panel of the Departmental Appeals Board, HHS; organizes conferences and workshops on the handling of research misconduct allegations; provides assistance and advice to institutions on the conduct of inquiries and investigations through the Rapid Response for Technical Assistance Program (RRTA); and provides information on HHS policies and procedures, as requested, to individuals who have made an allegation or have been accused of research misconduct.

Allegations

ORI staff assesses each allegation received directly by ORI or indirectly through reports from institutions and the National Institutes of Health (NIH) 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 CFR 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 Office of the Inspector General, HHS).

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 at this phase.

In 2004, ORI handled 268 allegations; 267 were received in 2004; the other was received in late 2003 but assessed in 2004. The disposition of the allegations received by ORI are presented in Table 1. 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 jurisdiction or meet these criteria, (2) cannot be referred to another agency, or (3) are resolved through further review and information. Other allegations are referred to other Federal agencies or offices when they involve concerns about the use of humans or animals in research, financial issues, research funded or regulated by other agencies, etc. No action is possible for ORI if an allegation contains insufficient specific information to permit another disposition.

Table 1: Disposition of Allegations Received Directly by ORI, 2004

Handling of allegations – outcome in ORI		*Number of allegations*
Pre-inquiry assessment by ORI of allegations:		64
that were made to ORI directly	46	
that were made to NIH initially	18	
No action possible now or no action		172
Referred to other Federal agencies		25
Handled by NIH (for other allegations made to NIH)		7
TOTAL		268

Of the 268 allegations processed by ORI in 2004, 64 were assessed by ORI in detail for a potential inquiry or investigation; 25 were immediately referred to other agencies (Table 1). Thirty assessments resulted in the opening of formal cases; 34 allegations were administratively closed/and or assessed (Table 2). Assessments of the allegations that resulted in new cases took an average of 15 days; those that resulted in administrative closures took 29 days. Forty-two assessments were resolved by ORI within 25 days; the mean time was 8 days. 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 18 allegations that were made directly to NIH by complainants (Table 1). The number of allegations that ORI received in 2004 (267) was 50 percent higher than that for the prior year (179). The number of allegations that were the subject of formal pre-inquiry assessments by ORI (64) increased by 74 percent over the number assessed (38) in 2003.

Table 2: Time for Conduct of Pre-inquiry Assessments by ORI, 2004

Outcome of ORI assessment	*Number of new allegations*	*Total days for resolution*	*Distribution of resolution times (days)*			
			Mean	*Median*	*Mode*	*Range*
Opened formal case	30	455	15	7	1 & 7	1-120
Administratively closed	34	1001	29	8.5	1	1-212
Unresolved at end of year 2004	0	–	–	–	–	–
TOTAL	64	1456	23	–	–	1-212

Processing of Closed Cases

ORI closed 23 cases in 2004, including 7 inquiries and 16 investigations. The average duration of 16.3 months for an open case was split between institutional actions (10.3 months) and ORI oversight and actions (6.0 months) (Table 3). Nineteen (19) cases (83 percent of total number) were closed by ORI within 8 months of the institutional actions being completed.

Table 3: Duration of Research Misconduct Cases Closed by ORI, 2004 (N= 23)

Site of action during case	*Distribution of resolution times (months)*			
	Mean	*Median*	*Mode*	*Range*
Institution	10.3	7	4	1-39
ORI	6.0	4	2	1-22
Total time	16.3	12	21	3-42

The action period for the 7 institutional inquiries included their inquiry and adjudication phases, and for 16 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 that is requested by the respondent before the HHS Departmental Appeals Board; there were none this year).

In the case that took 22 months for ORI to resolve, there was an ongoing state criminal prosecution of the respondent, an assistant research scientist, that went on for two years before final judgement of felony theft by the court and its requirement for financial restitution; ORI delayed, until the court case was ready for closure, its pursuit of a voluntary agreement with a finding of scientific misconduct for fabrication of degree credentials in four NIH grant applications and at least four autistic family interviews. [ORI closed a similar case involving a senior interviewer who fabricated 50 to 150 interviews of mental health patients, based in part on written admission to local police, in a case that the local prosecutor declined to pursue.]

In a case that took 17 months for ORI to resolve, the institution assigned a new official, who had not been involved in the case, to handle ORI's questions and

requests for documentation. It took her a year to orient herself and to reconstitute the evidence, as well as to provide summaries and transcripts of interviews, for ORI analyses and findings of scientific misconduct against a clinical research associate for fabrication of clinical and study records for 35 prostate cancer patients.

One case was closed in 2004 with a three-way agreement, after a written admission to plagiarism and falsification of images on malaria drug development by the respondent, an assistant professor, who waived the need for further investigation. Six other such three-way agreements had been negotiated in prior years by the Office of General Counsel, HHS, with institutional counsels and respondents' attorneys. Institutional officials are encouraged to call ORI early in the conduct of cases in which there are full admissions of misconduct and the respondent appears to be ready to settle the case quickly.

Caseload and Outcomes

The ORI caseload is divided into two elements: institutional inquiries and institutional investigations. The origin of cases differ. Some are based on allegations made directly to ORI or transmitted to ORI by NIH. Cases may also originate from allegations made directly to institutions and reported to ORI in inquiry or investigation reports. ORI carried forward 44 cases from 2003, and opened 30 new cases and closed 23 cases during 2004. At the end of calendar year 2004, ORI had 51 active formal cases divided between inquiries and investigations (Table 4).

Table 4: ORI Research Misconduct Caseload by Case Type, 2004

Case type	*Forwarded from 2003*	*Opened in 2004**	*Closed in 2004*	*Carried into 2005*
Institutional inquiry	19	3	7	15
Institutional investigation	25	27	16	36
TOTAL	44	30	23	51

* The number of cases opened has been adjusted to compensate for the movement of cases from the inquiry stage to the investigation stage to avoid double-counting.

In 2004, 8 of the 16 investigation cases closed by ORI resulted in sustained findings of scientific misconduct and PHS administrative actions against the respondent (Table 5). Summaries of these cases may be found in Appendix A. Summaries of the 8 investigations closed by ORI that did not result in findings of scientific misconduct are located in Appendix B.

Institutional inquiries: Under the PHS regulation, institutions are not routinely required to report the conduct of inquiries to ORI unless they result in investigations. 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 routinely submit inquiry reports to ORI (many are equivalent to reports of investigations, making findings). Any inquiry that results in a finding of misconduct, e.g., from a respondent's admission, should be promptly reported to ORI. ORI reviews these reports to determine whether the conduct of the inquiry complied with the PHS regulation and was thorough, competent, and objective.

During 2004, ORI accepted 7 institutional inquiry reports that did not recommend further investigation (Table 5). The inquiries involved two allegations of falsification, two of fabrication, two of fabrication and falsification, and one of falsification and plagiarism. ORI carried 15 such institutional inquiries into 2005.

Institutional investigations: Institutions are required by the PHS regulation to report to ORI at the initiation of an investigation and to submit a report to ORI upon completion of the investigation. ORI reviews the reports to determine whether the conduct of the investigation complied with the PHS regulation; was thorough, competent, and objective; and provided a basis for a PHS finding of misconduct. ORI began 2004 with 25 investigations carried forward from 2003. During the year, 27 new institutional investigations were opened; 16 investigations were closed (Table 4). Of these 16 closed investigations, 8 involved ORI findings of scientific misconduct; 8 did not have such findings. Of the total of 23 cases closed in 2004, 35 percent (8 cases) involved findings of scientific misconduct, which is close to the historical average of about 37 percent of ORI cases with such findings (Table 5). The number of 2004 research misconduct findings was below the historical average of 13.

There were 36 active investigation cases carried into 2005. About 75 percent of the cases with institutional decisions that ORI carried over in 2005 included institutional findings of misconduct.

Table 5: Outcome of Research Misconduct Cases Closed by ORI, 2004 (N= 23)

Case type	*Outcome of cases*				
	No investigation	*No misconduct*	*Misconduct finding*	*Admin. closed*	*Total*
Institutional inquiry	7	0	0	0	7
Institutional investigation	0	8	8	0	16
ORI inquiry or investigation	0	0	0	0	0
TOTAL	7	8	8	0	23

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 were none in 2004.

Types of Allegations and Administrative Actions

Types of Allegations Involved in Cases Closed: Falsification or fabrication was involved in all 23 cases closed in 2004. No closed case was based solely on plagiarism. Seven cases were closed at the inquiry stage; 16 at the investigative stage. Seventy-eight percent of the closed cases involved falsification or fabrication, alone or in combination. Falsification alone or in combination with fabrication produced 6 of the 8 research misconduct findings. Closed cases dealing with fabrication alone did not produce any research misconduct findings. Three cases involving plagiarism with falsification or fabrication resulted in one misconduct finding. The remaining misconduct finding was made in a case involving plagiarism, falsification, and fabrication. (Table 6).

Table 6: Types of Allegations Involved in Closed Cases and Research Misconduct Findings

Allegation	*Inquiry*	*Investigation*	*ORI findings or PHS administrative actions*
Fabrication	2	1	0
Falsification	2	5	2
Falsif./Fabric.	2	6	4
Falsif./Plag.	1	2	1
Fabric./Plag.	0	1	0
Falsif./Fabric./Plag.	0	1	1
Plagiarism	0	0	0
TOTAL	7	16	8

PHS Administrative Actions Imposed in Closed Cases: A range of administrative actions is used by the PHS to protect public funds 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 non-financial, from the Federal Government for a set period.

For the 8 cases in 2004 in which ORI misconduct findings or PHS administrative actions were imposed, 6 persons were debarred or voluntarily excluded, each for 3 years. Other administrative actions imposed on respondents in these 8 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 [8 persons]; (b) participation in PHS-funded research is 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 [2 persons]; and (c) retraction of one published article (Table 7).

Table 7: PHS Administrative Actions Imposed in Closed Investigations with Misconduct Findings or Administrative Actions, 2004

PHS administrative actions	*Duration*	*Number of such actions*
Debarment or voluntary exclusion	3 years	6
Prohibition from serving as an advisor for PHS	3 years	8
Supervision plan required	3 years	2
Respondent required to or did retract articles	–	1

In one case, after ORI's finding of scientific misconduct and debarment of a former foreign postdoctoral fellow, for extensive falsification of data in a manuscript submitted for publication, the home country rescinded the doctoral degree and required repayment of the funds that had been provided by the country for the postdoctoral fellowship.

Rapid Response for Technical Assistance Program (RRTA)

In 1999-2000 ORI created 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; (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; (12) advising on potential whistleblower and confidentiality issues; (13) helping with contacts to national databases (such as Genbank); and (14) assisting journal editors with papers that require correction or retraction.

Among the 30 new cases opened in 2004, the Division of Investigative Oversight (DIO) made 10 RRTA offers to these institutions, and officials from 9 of them called ORI for substantive technical, administrative, or legal information. ORI also provided RRTA help to institutions for which ORI had opened cases in the previous year; of the 23 cases closed by ORI in 2004, ORI had provided RRTA to 8 of them at the early stages of their process.

ORI additionally provided RRTA to 42 institutional officials who called ORI during their assessment or inquiry stages, before reporting formally any case to ORI, seeking assistance on handling evidence, strategic approaches to allegations and interviews, and general advice. Some of these institutions called ORI two or more times for assistance.

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. Forty-eight (48) institutions were provided with RRTA in 2004, up from 26 in the prior year.

Challenging problems for institutions include voluminous or missing evidence, multi-center clinical sites, involvement of outside parties with an interest in the case, and premature or incomplete "admissions." ORI staff will provide such RRTA help (phone DIO at 240-453-8800) over the telephone or on-site.

II. Education and Prevention

ORI conducts its education and prevention activities primarily through the Division of Education and Integrity (DEI). Those activities include the RCR Resource Development Program, RCR Expo, RCR Program for Academic Societies, RCR Program for Graduate Schools, conferences and workshops, a web site, exhibits, and publications.

RCR Resource Development Program

ORI created the RCR Resource Development Program in FY 2002 to support the creation of RCR instructional materials by the research community that may be used by various institutions and organizations requesting or receiving research funds from the PHS. In addition to creating instructional resources, this program has sparked interest in RCR at private and public research institutes.

ORI received 14 finished products from 17 projects funded in 2003. One project was terminated by ORI because the project director left the institution while two projects received no-cost extensions to complete development. Finished products include several web-based RCR resources, a guidebook, and video vignettes. All finished products were exhibited at the ORI-sponsored RCR Expo which was held in conjunction with the 2004 Society of Research Administrators (SRA) International Annual Meeting.

In 2004, ORI received 24 proposals in response to a request for applications. Nine new projects were awarded for a total of $225,000 ($25,000 per project). The awardees included 6 universities, 1 college, 1 hospital, and 1 commercial firm. These projects will create several Internet-based materials, an assessment tool to evaluate RCR programs, and a computer-based tool designed to help improve the quality of peer reviews. Projects will provide training and education materials for culturally diverse researchers, training resources for community agencies, and education for the social sciences. Project titles, project director, and awardee institutions for the 2004 awards follow:

Online Education on the Responsible Conduct of Research: Oversight of Data Management
Meghan Coulehan, Clinical Tools, Inc.

RCR Educational Program for Administrative Staff Members
Stephen Erickson, Boston College

Teaching RCR with Humans (RCRH)
Stanley Korenman, University of California-Los Angeles

Active Learning Online on Responsible Mentoring and Collaboration
Murali Krishnamurthi, Northern Illinois University

Basic Training in Research Design Concepts for Novice Research Staff
Camille Nebeker, San Diego State University

Assessment Tools for Evaluating University RCR Programs
Lynne Olson, Ohio State University

The Development of RCR Internet-based E-seminars on Collaborative Science and Data Management
Daniel Vasgird, Columbia University

Computer-based Tool for Peer Review: Evaluating Data Analyses
Min Qi Wang, University of Maryland

Mentoring International Postdocs: Working Together to Advance Science and Careers
Wendy Williams, Children's Hospital of Philadelphia

RCR Expo

ORI held the 2004 RCR Expo on October 25-27, 2004, at Salt Lake City, Utah, in conjunction with the annual meeting of the Society of Research Administrators International.

The RCR Expo enabled creators of RCR resources to display, demonstrate, and discuss their products while providing potential users with an opportunity to review those resources and discuss their needs, options, and desires, thereby generating a dialogue among and between creators and users of RCR resources. The Expo provided an opportunity to display RCR products to over 1,400 research administrators and researchers.

Exhibitors focused one or more of the RCR core areas: (1) data acquisition, management, sharing, and ownership; (2) mentor/trainee responsibilities; (3) publication practices and responsible authorship; (4) peer review; (5) collaborative science; (6) human subjects; (7) research involving animals; (8) research misconduct, and (9) conflict of interest and commitment. Below is a list of institutions that exhibited at the Expo:

American Association of Laboratory Animal Science. Nicole Duffee and Pam Greebel. An interactive web course for training researchers on the handling of laboratory mice. Issues covered in this project include advanced handling of mice such as intra-operative care and monitoring, blood collection, post-operative care, anesthetics, analgesics, and euthanasia.

Association for Research Integrity. Tim Raynor. PHSTrainer.com. An online program that documents compliance with PHS policies on Instruction in the Responsible Conduct of Research and Human Subject Assurance Training.

Bryn Mawr College. *Educating Staff in Community Agencies about Human Subjects.* Leslie Alexander and Ken Richman. A web-based tool for training individuals in community agencies about the use of human subjects in research. The resource is targeted to low-income communities and is available in English and Spanish. Specific issues covered include assessing social, psychological, and legal risks; voluntary participation throughout a study; and maintaining confidentiality of research data.

Children's Hospital of Philadelphia. *A Guidebook for Teaching Selected RCR Topics to Culturally Diverse Trainee Groups.* Madeline Alexander and Wendy Reed Williams. A guidebook specifically tailored to provide training in data management, research misconduct, and intellectual property to international postdocs and culturally diverse students.

Columbia University. *The Development of RCR Internet-based E-seminars on Mentor/Trainee Responsibilities and Conflict of Interest.* Daniel Vasgird and Joyce Plaza. Two training e-seminars that require learners to develop problem solving and critical thinking skills related to mentoring and conflict of interest. Interactive multi-media seminars include video, audio, and text.

Northern Illinois University. *RCR for the Rest of Us.* Jeffrey Hecht. A CD-ROM created to train researchers in the social sciences about the responsible conduct of research. The CD-ROM contains video presentations and a graphically-appealing HTML interface to address issues in RCR as they pertain to non-biomedical research.

Northern Illinois University. *Online Decision Instruction on Data Integrity.* Murali Krishnamurthi. A web-based learning module that addresses data acquisition, data management, data sharing, and data ownership. The materials were developed using the Kolb Learning Cycle as a model for learning.

Office of Human Research Protections. Department of Health and Human Services. Shirley Hicks and Darlene Ross. Instructional material designed to further the protection of human research subjects.

RCR Educational Consortium. Michael Kalichman. The RCREC is a non-profit, non-governmental consortium of institutions and organizations. The mission of the RCREC is to provide leadership to the research community in identifying, developing, and promoting programs of education in the responsible conduct of research.

St. Jude Children's Research Hospital. *Education Clinical Staff on Clinical Research Data.* Cheryl Chanaud. A web site designed to teach hospital clinical staff about the management of research data. The learning materials allow clinical staff to distinguish the importance of medical documentation as research data, proper data collection methods as they apply to research, and the importance of protocol compliance on research data. Online quizzes evaluate knowledge gain among users.

St. Louis University. *Behavioral Health Research: An Ethics Case Compendium and Instructional Method.* James Dubois and Angie Dunn. An Internet training tool for instructing researchers on the use of human subjects in behavioral research. The tool contains a collection of ethics cases in behavioral health research, instructional materials to improve ethical decision making, and a bibliography of ethics information.

Syracuse University. *Video Vignettes to Foster the Mentor/Trainee Relationship.* Derina Sara Samuel. Video vignettes focused on the mentor/trainee relationship. A guide accompanies the vignettes to direct and encourage discussion on the scenarios presented in the videos. The video vignettes and discussion guide will be available via Internet and DVD-ROM.

University of Alabama-Birmingham. *A Documentary Film: A Round Table on Mentoring and Authorship.* Sara Vollmer. A 1-hour video addressing mentoring and authorship that features discussion between principal investigators and graduate students, acted scenarios about lab dilemmas, and interviews.

University of Texas Health Science Center. *Web-based Course on Conflicts of Interest in Research.* Melissa Proll. An Internet-based education tool to help researchers increase skills to recognize, disclose, and manage conflicts of interest in research. Case-based pedagogy is used that requires users to play the role of a Conflict of Interest Committee member developing a plan to address research conflicts arising from investigator and institutional financial interests. Information to support the user in developing the plan include 6 streaming-video vignettes showing different constituencies' perspectives/concerns about the conflicts. The vignettes are accompanied by resource materials with relevant background information.

RCR Program for Academic Societies

Recognizing the instrumental role that academic societies play in establishing and upholding normative standards of research professionalism, the Association of American Medical Colleges (AAMC) and ORI entered into a cooperative agreement in 2002 to encourage academic societies to provide leadership to the research community through initiatives designed to promote the responsible conduct of research. The overarching goal of the program is to assist academic societies in

developing, and mainstreaming or institutionalizing, RCR infrastructure, activities, and educational programs into the culture of the societies and disciplines. All academic societies with U.S. headquarters, whose mission includes advancing biomedical and behavioral research, or medical education, are eligible for this program.

Reports by the National Academy of Sciences (NAS) and the Institute of Medicine (IOM) have recommended that academic societies play a greater role in promoting the responsible conduct of research. In *Responsible Science: Ensuring the Integrity of the Research Process*, the NAS recommended that "scientific societies and scientific journals should continue to provide and expand resources and forums to foster responsible research practices and to address misconduct in science and questionable research practices."

In *The Responsible Conduct of Research in the Health Sciences*, the IOM recommended that scientific organizations "develop educational and training activities and materials to improve the integrity of research…assist universities in identifying substandard research and training practices that compromise the integrity or quality of research…develop policies to promote responsible authorship practices, including procedures for responding to allegations or indications of misconduct in published research or reports submitted for publication."

Awards for the program are provided to fund academic societies to specifically address some, or all, of the nine core components of the responsible conduct of research: (1) data acquisition, management, sharing, and ownership; (2) mentor/trainee responsibilities; (3) publication practices and responsible authorship; (4) peer review; (5) collaborative science; (6) human subjects; (7) research involving animals; (8) research misconduct; and (9) conflicts of interest and commitment. Of special interest are projects focused on developing guidelines, standards, policies, publications (including RCR articles in journals, newsletters, and on society web sites), committees, annual conferences, core competencies, curricula, and other instructional resources related to the core RCR components.

Five awards were made in 2004. In its first 2 years, the program has made 20 awards to 18 academic societies. The program offers awards up to $50,000. Academic societies receiving awards and project titles follow:

The Gerontological Society of America. *Guidebook for Multi-disciplinary Clinical Geriatric Researchers.*

Society of Teachers of Family Medicine. *Primary Care Research Participant Protection Project.*

Society for Academic Emergency Medicine. *Research Integrity in Emergency Medicine.*

American Occupational Therapy Association. *Promoting Research Integrity in the Next Generation of Occupational Therapy Researchers Curriculum.*

Research and Assessment Corporation for Counseling/National Board for Certified Counselors, Inc. *Training Module on Research Integrity for Researchers in Counseling.*

RCR Program for Graduate Schools

Ten institutions received awards in September 2004 to develop demonstration projects designed to institutionalize RCR education for graduate students and faculty through a two-year collaboration between the Council of Graduate Schools (CGS) and ORI.

Thirty-five institutions submitted applications to the program by the August 20, 2004, deadline.

The following institutions received awards of $15,000 each to develop the demonstration projects; each institution is providing additional funding:

- Arizona State University
- Duke University
- Florida State University
- New York Medical College
- Old Dominion University
- University of Kansas
- University of Missouri-Columbia
- University of New Hampshire
- University of Rhode Island
- University of Utah

The 25 institutions that did not receive awards have remained in the project as "affiliates." "Most of these institutions continue to plan some level of RCR activity using their own institutional funds, and many have already begun RCR projects," Dean Paul Tate, CGS Project Director, said. "These institutions have been invited to participate in electronic discussions with each other and with the institutions receiving awards, to attend sessions on RCR at CGS national meetings, to share what they have learned about RCR training with awardees and other affiliates, and to provide data for the CGS publication on the project after its completion."

This collaborative effort is expected to develop a corps of graduate deans that will exercise continuing leadership in RCR education. Additionally, a monograph on the demonstration projects and results will be published.

Conferences and Workshops

December 2-3, 2004
Developing Policy on Institutional Conflict of Interest Conference
Las Vegas, NV
Co-sponsors: University of Nevada-Las Vegas, Association of American Universities (AAU), Association of American Medical Colleges (AAMC), American Association for the Advancement of Science (AAAS), National Association of State Universities and Land Grant Colleges (NASULGC), and Office for Human Research Protections

November 12-14, 2004
Research Conference on Research Integrity
San Diego, CA
Co-sponsors: University of California-San Diego, AAMC, AAAS, Merck Research Laboratories

October 14-15, 2004
Research Integrity and Financial Conflicts of Interest in Clinical Research: Legal Issues and Requirements
Charlottesville, VA
Co-sponsors: University of Virginia School of Medicine, Center for Biomedical Ethics

June 28-29, 2004
The RCR Summit: A National Dialogue on Future Directions of RCR
East Lansing, MI
Co-sponsor: Michigan State University

April 13-14, 2004
Responsible Conduct of Research in Psychological Science
Washington, DC
Co-sponsor: American Psychological Association

March 22, 2004
Does Funding Source Influence Research Integrity?
Baltimore, MD
Co-sponsor: Society of Toxicology

March 19-20, 2004
Promoting the Responsible Conduct of Research: What It Means to the Research Enterprise
Winston-Salem, NC
Co-sponsors: Winston-Salem State University, Wake Forest University School of Medicine

ORI Web Site

The ORI web site is the pre-eminent web site in the world on the responsible conduct of research, research integrity, and research misconduct. In FY 2004, the web site had 219,525 visits by 92,076 unique visitors. Repeat visitors totaled 24,490. The web site averaged 599 visits per day with the average visit lasting 18 minutes. Sixty-nine percent of the visits were from individuals within the United States; 10 percent were international visits from Canada, the United Kingdom, Australia, China, Germany, Japan, the Netherlands, South Korea, Philippines, France, India, Singapore, Israel, Poland, Malaysia, Hong Kong, Italy, and Sweden. During FY 2004, significant improvements were made to the web site including: the addition of intramural and extramural research sections; posting of 11 responsible conduct of research educational products; creation of sections for the RCR Program for Academic Societies, the RCR Program for Graduate Schools, and RCR bibliography. The complete text of *ORI Introduction to the Responsible Conduct of Research* was made available through the ORI web site, along with creating a mechanism for educational product feedback and solicitations for contributions to the *ORI Newsletter*.

The title of the posted projects, their project director, and institutions follow:

Online RCR Study Guide, Julie Simpson, University of New Hampshire.

Online Research Ethics Course, Deni Elliot, University of Montana.

Program for Education and Evaluation in Responsible Research and Scholarship (PEERRS), Fawwaz Ulaby, University of Michigan.

Biomedical Research Integrity Cases, Wylie Burke and Kelly Fry-Edwards, University of Washington.

Ethical Dilemmas in Research Integrity, Claire Gutkin, MetaLinker.

Conflicts of Interest, Ruth Fischbach, Columbia University.

Conflicts of Interest, Mark Tumeo, Cleveland State University.

Mentoring, Daniel Vasgird and Joyce Plaza, Columbia University.

In the Lab: Mentors and Students Behind the Scenes, Harold Kincaid and Sara Vollmer, University of Alabama-Birmingham.

Contemporary Science, Values and Animal Subjects in Research, Nell Kriesberg and Joseph Herkert, North Carolina State University.

Avoiding Plagiarism, Self-Plagiarism, and Other Questionable Writing Practices: A Guide to Ethical Writing, Miguel Roig, St. Johns University.

Exhibits

ORI held exhibits at annual meetings of five academic societies and professional associations during 2004 to increase contact and generate a dialogue with members of the research and academic communities.

Exhibits were held at the following meetings: Biophysical Society, Baltimore, in February; Experimental Biology, Washington, DC, in April; American Society of Biochemistry and Molecular Biology, Boston, in June; the Society of Research Administrators International, Salt Lake City, in October; and the National Council of University Research Administrators, Washington, DC, in November.

ORI began its exhibit program in 2000. The exhibits allow ORI staff to talk to researchers, research administrators, postdocs, graduate students and professional association officials about the responsible conduct of research, the handling of research misconduct allegations, the maintenance of institutional eligibility for receiving PHS funding, the availability of RCR instructional materials, the sponsorship of conference and workshops, and the ORI research programs.

Scientific societies and professional and institutional associations that are interested in an ORI exhibit at their meeting should call ORI at 240-453-8400.

Publications

To help institutions develop responsible conduct of research (RCR) training programs, ORI published a basic *Introduction to the Responsible Conduct of Research* in January 2004. The 164-page book provides a brief overview of nine key areas of responsibility written primarily for beginning researchers. Five thousand complimentary copies were sent to key institutional officials and members of ORI's RCR Listserve. Another one thousand copies were sold through the Government Printing Office.

Before reprinting, the volume was revised and reformatted. In June 2004, two thousand complimentary copies of the new edition were sent to researchers involved in research training and another five thousand copies offered for sale through the Government Printing Office. By the end of the year, 2,565 copies had been sold and another 1,000 copies downloaded for free from the ORI web site. ORI also received requests to translate the *Introduction to the Responsible Conduct of Research* into Japanese and Chinese. The translations will appear in 2005.

Staff Presentations

Nancy Davidian, Clinical Case Expert, DIO, "Working with the ORI as a RIO," Extramural Research Integrity Officers, NIH, Bethesda, MD, November 3, 2004.

Carolyn R. Fassi, Educational Specialist, DEI, "Responsible Conduct of Research Program for Academic Societies," AAMC Council of Academic Societies, Spring Meeting, Santa Monica, CA, March 14, 2004.

Carolyn R. Fassi, Educational Specialist, DEI, "Enhancing Graduate Research, Education, and Training with Responsible Conduct of Research (RCR) Education and Training Resources," a roundtable discussion, and "Education and Training in RCR: What Some Institutions Are Offering," a poster session at the AAMC GREAT Group Annual Meeting, Austin, TX, April 25, 2004.

Susan Garfinkel, Scientist-Investigator, DIO, "Scientific Misconduct: The Role of ORI and the Scientist," Holland Laboratory 2004 Research Ethics Program, American Red Cross, Gaithersburg, MD, April 29, 2004.

Samuel Merrill, Scientist-Investigator, DIO, "Responsible Research: Protecting Human Subjects, Protecting Investigators," University of Tennessee College of Medicine, Chattanooga Unit, Chattanooga, TN, February 27, 2004.

Samuel Merrill, Scientist-Investigator, DIO, "The Role of the Office of Research Integrity in Handling Allegations of Scientific Misconduct," a roundtable presentation at the Fourth Annual Medical Research Summit, Baltimore, MD, April 23, 2004.

Chris B. Pascal, Director, ORI, "Institutional Standards and Research Accountability: Misconduct, Protection of Human Subjects, and More," ESA Seminar Series, NIH, Bethesda, MD, March 12, 2004.

Chris B. Pascal, Director, ORI, "Introductory Remarks: Overview of ORI Mission, Programs, and Resources" and "Themes in Research Integrity," Winston Salem State University/Wake Forest School of Medicine Research Integrity Conference – Promoting Responsible Conduct of Research: What It Means to the Research Enterprise, Winston Salem, NC, March 19-20, 2004.

Chris B. Pascal, Director, ORI, "ORI Views on Conflict of Interest and Other Ethical Conflicts" and "Discuss Case Studies of Conflict of Interest Issues," Workshop on RCR in Psychological Science, American Psychological Association Annual Meeting, Washington, DC, April 13-14, 2004.

Chris B. Pascal, Director, ORI, "Overview of Research Integrity" and "Rights and Obligations of Whistleblowers," Responsible Conduct in Research, University of Maryland, College Park, MD, April 14-15, 2004.

Chris B. Pascal, Director, ORI, "Federal Update: Overview of Research Misconduct and Integrity," and conducted an RCR Workshop, Washington University Medical Center – National Human Subjects Protection Conference, Saint Louis, MO, April 19-20, 2004.

Chris B. Pascal, Director, ORI, "Revised PHS Regulations on Research Misconduct," a briefing for the AAMC, AAU, and the Council on Government Relations, Washington, DC, April 27, 2004.

Chris B. Pascal, Director, ORI, "Revised PHS Regulations on Research Misconduct," a briefing for the Federation of American Societies for Experimental Biology, Rockville, MD, May 14, 2004.

Chris B. Pascal, Director, ORI, "ORI Mission: How We Protect the Public Trust in Research Integrity" and "Discussion of Revised Research Misconduct Regulations," meeting of the AAMC Advisory Board, Washington, DC, May 19, 2004.

Chris B. Pascal, Director, ORI, "Research Integrity and RCR for Human Subjects," NIH Regional Seminar, Seattle, WA, June 23-26, 2004.

Chris B. Pascal, Director, ORI, "The Importance of RCR Education in NIH Training Grants," NIH Training Grant Officers Meeting, Bethesda, MD, July 14, 2004.

Chris B. Pascal, Director, ORI, "Research Misconduct and the Responsible Conduct of Research," Japanese TV Interview, NHK-TV, Rockville, MD, July 15, 2004.

Chris B. Pascal, Director, ORI, "The Onus of Compliance" and "Not Too Hot, Not Too Cold, But Just Right: A Dialogue on the Revised PHS Misconduct Regulations," National Council of University Research Administrators (NCURA), Providence, RI, July 25-28, 2004.

Chris B. Pascal, Director, ORI, "Common Compliance Issues for ORI," Alliance of Small Institution Sponsored Program Administrators, 2nd Annual Retreat, Jackson, NH, September 12-14, 2004.

Chris B. Pascal, Director, ORI, "Overview of Research Misconduct and Research Integrity" and "Case Studies on Research Misconduct," American Association of State Colleges and Universities meeting, Washington, DC, September 18-19, 2004.

Chris B. Pascal, Director, ORI, "Overview of the ORI Mission" and "ORI Views on Conflicts of Interest," Research Integrity Conference, University of Virginia, Charlottesville, VA, October 14-15, 2004.

Chris B. Pascal, Director, ORI, "Legal Issues in Research Integrity for Institutions, Investigators, and Administrators," Society of Research Administrators (SRA) International Annual Meeting, Salt Lake City, UT, October 23-27, 2004.

Chris B. Pascal, Director, ORI, "Strategies to Maintain Integrity in Clinical Research" and "Strategies for Improving Public Trust and Participation in Clinical Trials/Research," Emory University School of Medicine Clinical Trials Office, Atlanta, GA, October 28, 2004.

Chris B. Pascal, Director, ORI, "New ORI Regulations on Research Misconduct," NCURA Annual Meeting, Washington, DC, November 3, 2004.

Chris B. Pascal, Director, "Federal Update: Overview of Research Integrity and Research Misconduct," "Legal Issues in Research Misconduct and Integrity," and "Introduction to the Responsible Conduct of Research," Office for Human Research Protections National Conference – Partnership in Human Subject Protections, University of Medicine and Dentistry of New Jersey, Newark, NJ, November 11-13, 2004.

Alan R. Price, Director, DIO, "Office of Research Integrity and Its Regulatory Status," Hawaiian Chapter of the Society for Research Administrators International and the Office for Human Research Protections (OHRP) conference, Honolulu, HI, February 10, 2004.

Alan R. Price, Director, DIO, "Investigating Allegations and Preventing Scientific Misconduct in Research – An ORI Perspective," a panel presentation at the Hawaiian Chapter of the Society for Research Administrators International and the OHRP conference, Honolulu, HI, February 11, 2004.

Alan R. Price, Director, DIO, "Avoiding 'Plagiarism' Allegations Due to Authorship and Credit Disputes," a panel presentation at the Hawaiian Chapter of the SRA International and OHRP conference, Honolulu, HI, February 11, 2004.

Alan R. Price, Director, DIO, "Case Studies of Authorship Disputes That Came to ORI," Conference on Research Integrity, University of Maryland, College Park, MD, April 14, 2004.

Alan R. Price, Director, DIO, "Who Commits Fraud? Are Some Scientists Any Different from a Few Business Leaders?" a talk to the Potomac Rotary Club, Potomac, MD, April 21, 2004.

Alan R. Price, Director, DIO, "Curbstoning as Research Misconduct?" Big Ten Committee on Institutional Cooperation meeting of Research Integrity Officers, Chicago, IL, April 30, 2004.

Alan R. Price, Director, DIO, "Avoiding Plagiarism and Misconduct," a panel talk at the Duke University Medical Center to a faculty group interested in research integrity, Durham, NC, June 11, 2004.

Alan R. Price, Director, DIO, "ORI Cases and Regulations," a panel talk at the National Association of College and University Attorneys, Vancouver, British Columbia, Canada, June 17, 2004.

Alan R. Price, Director, DIO, "Is 'Curbstoning' in Surveys 'Research Misconduct'?" a panel talk at the American Statistical Association's Joint Statistical Meeting, Toronto, Ontario, Canada, August 11, 2004; published as "Curbstoning in Survey Research and Required Reporting to the Office of Research Integrity," *2004 Proceedings of the American Statistical Association, Statistical Methods Section* [CD-ROM].

Alan R. Price, Director, DIO, "Is 'Curbstoning' in Surveys Considered to Be 'Research Misconduct'?" a talk to the staff of Research Triangle Institute, Research Triangle Park, NC, December 7, 2004.

Lawrence J. Rhoades, Director, DEI, "Responsible Conduct of Research," Recognizing and Protecting Vulnerable Subjects: Theory, Practice and Compliance, sponsored by OHRP in Orlando, FL, April 1, 2004.

Lawrence J. Rhoades, Director, DEI, "Responsible Conduct of Research," University of Maryland Research Integrity Conference in College Park, MD, April 14, 2004.

Lawrence J. Rhoades, Director, DEI, "Research Administrators and RCR," NCURA Region 1 meeting in Sturbridge, MA, May 4, 2004.

Lawrence J. Rhoades, Director, DEI, "RCR Summit: Why Are We Here?" RCR Summit Conference: Responsible Conduct of Research Education, Michigan State University, East Lansing, MI, June 28, 2004.

Lawrence J. Rhoades, Director, DEI, "Graduate Education: Anticipatory Socialization," Council of Graduate Schools Summer Workshop on Graduate Education and the Responsible Conduct of Research, San Juan, Puerto Rico, July 13, 2004.

Lawrence J. Rhoades, Director, DEI, "Research Management: The Responsible Conduct of Research," SRA International annual meeting, Salt Lake City, UT, October 25, 2004.

Lawrence J. Rhoades, Director, DEI, "RCR: Where Are We, What Are We Doing?" NCURA annual meeting, Washington, DC, November 1, 2004.

Lawrence J. Rhoades, Director, DEI, "New Institutional Research Misconduct Activity: 1992-2001" and "ORI Closed Research Misconduct Investigations: 1994-2003," third biennial Research Conference on Research Integrity, San Diego, CA, November 12, 2004.

Lawrence J. Rhoades, Director, DEI, "Institutional Environments and the Responsible Conduct of Research," Developing Policy on Institutional Conflict of Interest, Las Vegas, NV, December 2, 2004.

Lawrence J. Rhoades, Director, DEI, "RCR Resource Development Program," workshop on Ethics and the Responsible Conduct of Research during the annual meeting of the Council of Graduate Schools, Washington, DC, December 8, 2004.

Sandra Titus, Director, Intramural Research, DEI, "Research Mentoring," Brigham and Women's Hospital, Boston, MA, June 3, 2004.

Sandra Titus, Director, Intramural Research, DEI, "When Research Mentoring Fails," Duke University Medical School, Durham, NC, June 10, 2004.

Sandra Titus, Director, Intramural Research, DEI, "Descriptive Study: Research Integrity Measures Used in Biomedical Laboratories" and "Laboratory Directors' Views on Mentoring and Absentee Mentoring," third biennial Research Conference on Research Integrity, San Diego, CA, November 12, 2004.

Sandra Titus, Director, Intramural Research, DEI, "Mentoring and Supervising the Research Process," Research Triangle Institute, Research Triangle Park, NC, December 7, 2004.

Federal Register Notices

1) Findings of Scientific Misconduct. Notice. 69 Fed. Reg. 7488-7489 (February 17, 2004). [Pat J. Palmer]

2) Findings of Scientific Misconduct. Notice. 69 Fed. Reg. 8446 (February 24, 2004). [Bernd Hoffmann, Ph.D.]

3) Findings of Scientific Misconduct. Notice. 69 Fed. Reg. 16541-16542 (March 30, 2004). [Vickie L. Hanneken, R.N.]

4) Findings of Scientific Misconduct. Notice. 69 Fed. Reg. 35629 (June 25, 2004). [Regina D. Horvat, Ph.D.]

5) Findings of Scientific Misconduct. Notice. 69 Fed. Reg. 43420-43421 (July 20, 2004). [Tirunelveli S. Ramalingam, Ph.D.]

6) Findings of Scientific Misconduct. Notice. 69 Fed. Reg. 48246 (August 9, 2004). [Nancy J. Strout, Ph.D.]

7) Findings of Scientific Misconduct. Notice. 69 Fed. Reg. 58445 (September 30, 2004). [Charles N. Rudick]

8) Findings of Scientific Misconduct. Notice. 69 Fed. Reg. 67737 (November 19, 2004). [Ali Sultan, M.D., Ph.D.]

Other Federal Register Notices

1) Public Health Service Policies on Research Misconduct. NPRM. 69 Fed. Reg. 20778-20803 (April 16, 2004).

III. Research on Research Integrity and Research Misconduct

Intramural Research Program

The intramural research program within ORI focuses on institutional implementation of the research misconduct regulation and research misconduct. The studies, primarily descriptive, are done under contract with research organizations or 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 Research section. The intramural research program also works with extramural researchers who are interested in analyzing data that are available in ORI databases or case files. Two studies were completed in 2004, while five others were continuing or starting.

Completed Studies

Closed Investigations Into Misconduct Allegations Involving Research Supported by the Public Health Service: 1994-2003

This study, conducted by ORI staff, analyzed 259 research misconduct investigation cases involving research supported by the PHS that were closed by ORI from 1994-2003 inclusive. Data for this secondary analysis were collected from the research misconduct case database maintained by ORI to administratively track the progress made in processing cases. Variables included in the analysis were frequency of allegations; types of misconduct; organizational locations of misconduct activity; academic rank, highest degree, and gender of respondents and whistleblowers; frequency of misconduct and no misconduct findings; administrative actions taken by the PHS and institutions; size of inquiry and investigation panels, and length of inquiries and investigations.

Findings: A substantial decrease in allegations, cases, and misconduct findings occurred between the first and second half of the 10-year period. Misconduct investigations were increasingly centered in medical schools. Male Ph.D.'s played the predominant role as whistleblowers and respondents throughout the 10-year period. Whistleblowers were primarily faculty: professors, associate professors, and assistant professors. Fifty-two percent of the respondents were faculty in the first five-year period compared to 34 percent in the second five-year period. More misconduct findings were made against non-faculty (67 percent) than faculty (32 percent). Sixty-five percent of the 133 persons against whom a research misconduct finding was made were debarred from receiving federal funds. Institutions completed 59 percent of the inquiries within the 60-day regulatory standard and 34 percent of the investigations within the 120-day regulatory standard.

Institutional Research Misconduct Activity: 1992-2001

This study, conducted by ORI staff, analyzed the research misconduct activity (receipt of an allegation or conduct of an inquiry or investigation) involving PHS-supported research reported by institutions in their Annual Report on Possible Research Misconduct from 1992-2001. Variables in the analysis were number of allegations received and inquiries and investigations conducted, types of research misconduct alleged, number of years misconduct activity reported, number of misconduct findings, and rank on NIH funding ladder.

Findings: The number of institutions reporting research misconduct activity for the first time increased steadily over the 10-year period but at a declining rate. Total number of institutions reporting research misconduct activity was 248. About 4,000 to 4,500 institutions/organizations file Annual Reports on Possible Research Misconduct but about half are small businesses. The number of years institutions reported activity ranged from zero to 10. Most institutions reported activity only in one year (57.5 percent); about 6 percent reported activity in 6 or more years. The total number of allegations reported by institutions over the 10-year period ranged from zero to 20. Slightly more than half of the institutions (51 percent) reported only one allegation; 32 percent of the institutions reported received from 2 to 5 allegations; 13 percent received 6 to 10 allegations, and 4 percent received 10-20. Although the reported research misconduct activity is concentrated in the top 75 funded institutions, institutions throughout the funding hierarchy report such activity.

Studies in Progress

Reporting Suspected Research Misconduct in Biomedical and Behavioral Research

This study conducted by The Gallup Organization is aimed at estimating the incidence of suspected research misconduct in biomedical and behavioral research. The questionnaire was revised to respond to comments from the research community and HHS. The OMB clearance process is underway. The study is expected to be completed in 2006.

Institutional Research Integrity Officer (RIO) Study

This study, conducted by the Research Triangle Institute, is focused on the administrators responsible for implementing the PHS research misconduct regulation (42 CFR Part 50, Subpart A). The study will examine the responsibilities, authority, qualifications, training, organizational location, role set, resources, and turnover rates of individuals in this critical position. The study will also examine how individual and institutional factors influence the preparedness of the RIO to handle misconduct allegations and the promotion of research integrity. Half of the sample will come

from the top 100 NIH-funded institutions and the remaining population will be drawn from the other 1,600 educational or research institutions. The study is expected to be completed in 2006.

Misconduct by Postdocs: Has the Mentor Been Supervising?

ORI staff is analyzing about 60 research misconduct cases involving postdocs and research associates to determine what type of relationship the respondents had with their mentor. The case files are being examined to determine whether mentors supervised and examined original data. Other variables being examined are whether the respondent was under any stress to meet a deadline, whether the laboratory had difficult interpersonal behaviors, and the response of the investigation committee in terms of examining whether the mentor provided a good research environment. The study is expected to be completed in 2005.

Proposed Research

Institutional Role in Promoting Research Mentoring

ORI has submitted a proposal to HHS for a study of the infrastructure institutions have developed to promote, support, reward, and evaluate the research mentoring of graduate students, postdocs, and junior faculty. Rather than being focused on the mentor-mentee relationship, this study will examine the policies and procedures for selecting, replacing, training, evaluating, and rewarding mentors. Funding was received in March 2005. The study is expected to be completed in 2007.

Extramural Research Program – Research on Research Integrity (RRI)

ORI established its extramural research program, Research on Research Integrity, in 2000 in collaboration with the National Institute of Neurological Disorders and Stroke (NINDS). Since then, the National Institute of Nursing Research (NINR) and the National Institute on Drug Abuse (NIDA) have joined the program. The grant program was created to foster empirical research on societal, organizational, group, and individual factors that affect, both positively and negatively, integrity in research.

Research on Research Integrity Program

Five awards were made by the RRI Program in 2004 increasing the number of studies supported in the first 4 years to 27. Abstracts are posted on the Research page of the ORI web site.

The program received the highest number of applications (53) in 2003, almost doubling the previous high of 31. Maximum direct costs were increased from $100,000 to $250,000 per year, and the project period was extended from 2 to 3 years.

Previously, funding for the applications came from the NINDS, the NINR, the NIDA, and ORI. This year ORI is funding four grants and partially funding the fifth grant with NINR. Funding for continuation awards is provided by NINDS, NINR, NIDA, and ORI. Total funding for the round (new and continuations) totaled $1.9 million, which is on par with the funding awarded in the third round. ORI provided $1.36 million for the third round; NINR provided $284,500; NIDA provided $167,000 and NINDS provided $151,600.

Grant titles, principal investigators, and institutions for the 2004 awards follow:

Authorship and Conflicts of Interest in Clinical Trials, William Gardner, Children's Research Institute, Ohio State University.

Competition between Science and Care in Clinical Trials, Charles W. Lidz, University of Massachusetts Medical School.

Environmental and Educational Influences on Scientists' Ethical Decisions, Michael D. Mumford, University of Oklahoma.

Monitoring Fidelity to Promote Research Integrity, Sheila J. Santacroce, Yale University School of Nursing.

Defining the Learning Curve in Research Trials, Jeffrey M. Taekman, Duke University.

RRI Publications

The following 10 journal articles were published in 2003-2004 by principal investigators of grants supported by the RRI program:

Boyd, EA, MK Cho, and LA Bero. "Financial Conflict-of-Interest Policies in Clinical Research: Issues for Clinical Investigators." *Academic Medicine* 78, no. 8 (2003): 769-74.

Boyd, EA, S Lipton, and LA Bero. "Implementation of Financial Disclosure Policies to Manage Conflicts of Interest." *Health Affairs* (Milwood) 23, no. 2 (2004): 206-14.

Djulbegovic, B., A Cantor, and M Clarke. "The Importance of Preservation of the Ethical Principle of Equipoise in the Design of Clinical Trials: Relative Impact of the Methodological Quality Domains on the Treatment Effect in Randomized Controlled Trials." *Accountability in Research* 10, no. 4 (2003): 301-15.

Djulbegovic, B. “Well Informed Uncertainties About the Effects of Treatment: Paradox Exists in Dealing with Uncertainty.” *British Medical Journal* 328, no. 7446 (2004): 1018.

Gaddis, B, W Helton-Fauth, G Scott, A Shaffer, S Connelly, and M Mumford. “Development of Two Measures of Climate for Scientific Organizations.” *Accountability in Research* 10, no. 4 (2003): 253-88.

Helton-Fauth, W, B Gaddis, G Scott, M Mumford, L Devenport, S Connelly, and R Brown. “A New Approach to Assessing Ethical Conduct in Scientific Work.” *Accountability in Research* 10, no. 4 (2003): 205-28.

Liaschenko, J, and DA DeBruin. “The Role of Nurses in Ensuring the Responsible Conduct of Clinical Trials.” *Minnesota Medicine* 86, no. 10 (2003): 35-36.

Lipton, S, EA Boyd, and LA Bero. “Conflicts of Interest in AcademicResearch.” *Accountability in Research* 11, no. 2 (2004): 83-102.

Macrina, FL, Funk CL, Barrett K. Effectiveness of Responsible Conduct of Research Instruction: Initial Findings. *Journal of Research Administration* 35, no. 2 (2004): 6-12.

Soares, HP, S Daniels, A Kumar, M Clarke, C Scott, S Swann, and B Djulbegovic. “Bad Reporting Does Not Mean Bad Methods for Randomised Trials: Observational Study of Randomised Controlled Trials Performed by the Radiation Therapy Oncology Group.” *British Medical Journal* 328, no. 7430 (2004): 22-4.

Research Conference on Research Integrity

ORI held its 3rd Research Conference on Research Integrity at the Paradise Point Resort, San Diego, CA, on November 12-14, 2004. One hundred and sixty-five persons attended, with representation from 8 foreign countries.

The conference was co-hosted with the Department of Bioethics, University of California, San Diego, and co-sponsored by the AAAS, AAMC, NIH, and Merck Research Laboratories.

Over 70 presentations and posters were presented during the 2-day conference. Research was reported on misconduct and questionable research practices; authorship and publication issues; conflict of interest, data management and data sharing, the influence of the research environment on research behavior; human subject research (IRBs, informed consent, and clinical trials); and mentoring and responsible conduct of research education. Several of the presentations reported findings from the Research on Research Integrity Program, which gave its first awards in 2001.

IV. Institutional Compliance

The PHS regulation on misconduct in science (42 CFR Part 50, Subpart A) places several requirements on institutions receiving funds under the PHS Act. ORI monitors institutional compliance with these regulatory requirements through two programs, the Assurance Program and the Compliance Review Program.

Assurance Program

The Assurance Program is responsible for ensuring that PHS research funds are awarded only 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 (Annual Report), 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, and reviewing institutional policies and procedures in conjunction with the Compliance Review Program.

In 2001, ORI switched to electronic submission of the Annual Report beginning with the report for CY 2000 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 to determine the eligibility of institutions to receive PHS research funds.

The number of institutional assurances on file with ORI increased by 167 during 2004 to 4,430. Six hundred and forty-seven institutions were added to the assurance database; 599 had filed their initial assurance and 48 reestablished their assurance by submitting their Annual Report on Possible Research Misconduct for 2002 and 2003. Four hundred and eighty assurances were inactivated, 406 for failing to submit their Annual Report in 2004 and 74 at the request of the institution or because duplicate records existed.

Table 8: Number and Type of Institutions With Active Assurances, 2003

Type of institution	*Number*	*Change*
Institutions of Higher Education	953	+25
Research Organizations, Institutes, Foundations, and Laboratories	363	+18
Independent Hospitals	294	+ 17
Educational Organizations, Other Than Higher Education	25	+ 2
Other Health, Human Resources, and Environmental Services Organizations	420	+22
Other (small businesses)	2,375	+83
TOTAL	4,430	+167

Institutional Misconduct Policy Reviews

ORI completed 130 policy reviews in 2004. Seven policy reviews were carried into 2004; another 150 institutional research misconduct policies were requested for review. One hundred and twenty institutional policies were accepted as submitted; 10 others were accepted after revision, and one institutional assurance was inactivated because the institution requested inactivation of its assurance. Twenty-six reviews were carried into 2005; four of these policies are pending review; 20 policies are being revised by institutions, and two institutions have not submitted their policies. Since 1995, ORI has reviewed 2,377 institutional policies.

Annual Report 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 2003 Annual Report began in January 2004 for the 4,263 institutions that had an assurance on file with ORI as of December 31, 2003.

Completed Annual Reports were received from 3,511 institutions for a response rate of 82 percent. ORI inactivated 752 assurances, including for 711 institutions that did not return their Annual Reports by the March 31 deadline, and 41 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 2003 report identified 19 institutions that did not have the required policies and procedures for handling allegations of scientific misconduct.

The Annual Report form requested institutions to report on the availability of policies and procedures for responding to allegations of research misconduct, the number of allegations of research misconduct received, and the number of inquiries and investigations conducted.

Reported Misconduct Activity

The amount of research misconduct activity reported by institutions in their 2003 Annual Report on Possible Research Misconduct substantially exceeds the averages for four categories for the previous 10 years (1993-2002) and establishes new highs for three categories (Table 9).

One hundred and six institutions reported starting or continuing research misconduct activity in their 2003 reports; 82 institutions reported opening new cases; institutions reported receiving 136 new allegations; and opening 105 new cases. The 10-year averages for those categories are 81, 55, 105, and 69, respectively.

The new highs were established in the number of institutions reporting new and/or continuing research misconduct activity, the number of institutions opening new cases, and the number of new cases opened.

Research misconduct activity is defined as receipt of an allegation or the conduct of an inquiry or investigation in the reporting year or before the reporting year. Reportable activities are limited to alleged research misconduct involving PHS-supported research, research training, or other research-related activities.

The 106 institutions that reported research misconduct activity resulting from allegations received during or before 2003 conducted 122 inquiries and 55 investigations in 2003.

Eighty-two of the 106 institutions reported opening 105 new cases in 2003 upon receipt of 136 allegations. Institutions received 48 allegations of falsification; 34 of plagiarism; 30 of fabrication; and 24 others. These allegations resulted in 76 inquiries and 19 investigations in 2003.

Institutions reporting new cases included higher education, 61; research organizations, 7; health organizations, 7; independent hospitals, 5; and small businesses, 2.

Table 9: Number of Institutions Reporting Misconduct Activities, Institutions Reporting New Cases, New Allegations, and New Cases: 1993-2003

Year	*Institutions reporting activity*	*Institutions reporting new cases*	*New allegations*	*New cases*
2003	106	82	136	105
2002	99	71	163	83
2001	78	61	127	72
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
1993	73	53	86	77

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.

Compliance Cases

Compliance cases involve compliance reviews of institutional handling of an allegation of scientific misconduct or retaliation complaints from the whistleblower. In 2004, nine compliance cases were opened and eight were closed. Two closed cases involved institutional handling of an allegation of scientific misconduct; 6 cases concerned retaliation complaints from whistleblowers. Nine compliance cases were carried into the year, and 10 were still open at the end of the year (Table 10).

Table 10: Summary of Compliance Cases, 2004

Case type	*Forwarded from 2003*	*Opened in 2004*	*Closed in 2004*	*Carried into 2005*
Compliance	4	2	2	4
Retaliation	5	7	6	6
TOTAL	9	9	8	10

Institutional Handling of Allegations

The two closed compliance cases involved the institutional handling of allegations.

Respondent Restored

In this case, early in the inquiry process, the respondent was publicly suspended, and claimed that he was subsequently coerced into resigning his position. The institution ultimately determined there was insufficient evidence to proceed to an investigation, and the process was terminated at the inquiry stage. During its oversight of the institutional inquiry, ORI questioned the actions taken against the respondent, and reminded the institution that under the PHS regulation, it had an obligation to "undertake diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when the allegations are not confirmed." ORI worked with both the respondent and institutional official to develop a public statement clarifying the institutional finding regarding the alleged scientific misconduct, and helped to facilitate the transfer of the respondent's research to another institution.

Interviewers Can Commit Research Misconduct

In this case, ORI initially became aware through a news article of possible falsification of data by interviewers in a behavioral study. When contacted by ORI, the institution claimed that institutional review committee had not been informed of the allegations, and ultimately agreed to conduct an inquiry into this matter and report back to ORI. The institutional inquiry report concluded that possible misconduct by a number of interviewers did not fall under the PHS definition of research misconduct, as they were not members of the research community. The basis of this conclusion contrasted with information that ORI and its counsel had previously provided to this institution. After an in-person meeting with ORI, institutional officials reopened this review to further investigate this matter. While the institution did find evidence of misconduct against one interviewer, its inability to make contact with any other interviewer, the passage of time, and the untimely purge of study records

devalued its findings, and limited ORI's ability to pursue any misconduct findings. As part of a post-investigation compliance action, ORI carefully reviewed the institution's misconduct policies and made several suggestions to strengthen its future effectiveness.

Retaliation Complaints

In 2004, ORI closed 6 retaliation complaints from whistleblowers. Five complaints were closed because the alleged misconduct did not fall under the PHS definition of research misconduct, the research involved was not supported by the PHS, or the adverse treatment of the whistleblower preceded the allegation of research misconduct or did not negatively affect the terms or conditions of the whistleblower's status at the institution. This includes, but is not limited to, his or her employment, academic matriculation, awarding of degree, or institutional relationship established by grant, contract, or cooperative agreement.

In the remaining case, the complainant claimed that in response to his bringing allegations of research misconduct, institutional officials locked him out of his laboratory, declined to renew his employment contract, prevented him from accessing frozen cells associated with his research, and locked his e-mail account. ORI asked the institution to assess this complaint of alleged retaliation, which it did and submitted a report to ORI. While these allegations were under review by ORI, the complainant filed a civil complaint against the institution, and the retaliation claims were included in this action. On the basis of this action by the complainant, and consistent with ORI guidelines, ORI concluded that the institution had no further obligation to address the retaliation allegations, and the case was closed.

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.

The ALERT system was computerized in 1994 to facilitate checks of individuals in the above categories against incoming applications, pending awards, and proposed appointments to PHS advisory committees, boards, and peer review groups. Listing

in the PHS ALERT system does not necessarily debar or exclude individuals from receiving support or serving in an advisory capacity to the PHS unless a PHS administrative action imposed on them specifically requires it.

On January 1, 2004, ORI listed the names of 63 individuals in the ALERT system. During the year, ORI added 10 and removed 12 names. On December 31, 2004, the names of 61 individuals were in the system.

ORI added 10 names because those individuals were found to have committed scientific misconduct in institutional reports to ORI. Ten names were removed during the year because the term of the PHS administrative actions expired, and 2 names were removed when ORI did not recommend a finding of scientific misconduct after reviewing an institutional misconduct investigation report.

Of the 61 names in the system at year end, 41 individuals had PHS administrative actions imposed, and 20 remained as a result of an institutional report in which there was a finding of research misconduct.

Table 11: Summary of PHS ALERT System Activity, 2004

	Total
As of January 1, 2003	63
Addition	10
Action Expired/Removed	12
As of December 31, 2003	61

When individuals in the PHS ALERT system have an ORI research misconduct finding made against them and/or have PHS administrative actions imposed on them, they are also listed on the PHS Administrative Actions Bulletin Board (AABB), a public system of records that may be accessed through the ORI web site at http: //ori.dhhs.gov/html/misconduct/administrative_actions.asp. Information on each individual in the system is limited to name, social security number, date of birth, type of misconduct, the name of the institution that conducted the investigation, a summary of the administrative actions imposed as a result of the misconduct, and the effective and expiration dates of the administrative actions.

V. Information and Privacy

The number of requests for information under the Freedom of Information Act (FOIA) and the Privacy Act increased in 2004.

- ORI received 43 FOIA requests in 2004; 35 were closed. In 2003, ORI received and responded to 34 requests.

- ORI received 2 Privacy Act requests in 2004, 1 was closed. In 2003, ORI received and responded to 1 request.

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 17A-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. A notice was published in the *Federal Register* on January 6, 1995 (60 Fed. Reg. 2140), announcing the establishment of the system of records. However, these records are specifically exempted from express provisions of the Privacy Act regarding notification, access, and correction and amendment of record requests by the subject

of the records. Nonetheless, each request for access is reviewed on a case-by-case basis. Additionally, if the record requested is denied under the Privacy Act because of an exemption, the subject of the records may still be entitled to obtain access to his or her records, or portions thereof, under the provisions of FOIA.

A Privacy Act request should be made to the Privacy Act Officer, ORI, at 1101 Wootton Parkway, Suite 750, Rockville, MD 20852. A request under the purview of the Privacy Act must be made by the subject of the records or his or her legal representative.

Summaries of Closed Investigations Resulting in Findings of Research Misconduct or Administrative Actions – 2004

Vickie L. Hanneken, R.N., Decatur Memorial Hospital: Based on the report of an investigation conducted by Decatur Memorial Hospital (DMH) and additional analysis conducted by the Office of Research Integrity in its oversight review, the U.S. Public Health Service (PHS) found that Vickie L. Hanneken, R.N., former Clinical Research Associate, DMH, engaged in scientific misconduct in research that was part of a Southwest Oncology Group prostate cancer prevention clinical trial supported by a National Cancer Institute (NCI), National Institutes of Health (NIH), cooperative agreement U10 CA45807 under the Central Illinois Clinical Community Oncology Program. PHS found that the respondent engaged in scientific misconduct by falsifying or fabricating data in the clinical/study records of 35 participants in the Selenium and Vitamin E Cancer Prevention Trial (SELECT) at Decatur Memorial Hospital, with a total of 60 separate acts, which included:

- falsification of the laboratory reports on PSA concentration for 12 participants;
- fabrication of the laboratory reports on PSA concentration for 2 participants;
- falsification of the physician's and nurse's records for 10 participants;
- fabrication of the nurse's records for 2 participants;
- falsification of data on patients' history and physical forms for 21 participants; and
- entry of falsified data into the SWOG computerized database for 13 participants.

No publications were affected, and all false data were removed from the database or corrected.

Ms. Hanneken has entered into a Voluntary Exclusion Agreement in which she has voluntarily agreed for a period of three (3) years, beginning on March 15, 2004: (1) to exclude herself from any contracting or subcontracting with any agency of the U.S. Government and from eligibility or involvement in nonprocurement programs of the U.S. Government as defined in the debarment regulations at 45 CFR Part 76; and (2) to exclude herself from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

Bernd Hoffmann, Ph.D., University of Medicine and Dentistry of New Jersey: Based on two inquiry/investigation reports from the University of Medicine and Dentistry of New Jersey (UMDNJ) and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Bernd Hoffmann, Ph.D., former Postdoctoral Fellow and Adjunct Assistant Professor, Department of Pharmacology at UMDNJ, engaged in scientific misconduct in research supported by National Institutes of Health (NIH) grant 2 R01 GM052309-05. PHS found that Dr. Hoffmann engaged in scientific misconduct by falsifying and fabricating research data in a manuscript entitled "LIS1/NUDF and CLIP-170 are required for dynein-mediated vesicle transport on microtubules" that had been submitted to the *Journal of Cell Biology (JCB)*, but was withdrawn before publication. Specifically, respondent:

- falsified data values on the second line from the bottom of Table IV; for example, the correct number under "Bound" in the first column was only one-third of that shown (325) in the manuscript;

- falsified data by erasing a band of approximate molecular weight 15KD from Figure 5A in the manuscript; and

- falsified a related movie film available on the Internet by altering the movement of the vesicles.

PHS also found that Dr. Hoffmann engaged in scientific misconduct by falsifying and fabricating research data in a published paper entitled "The LIS1-related Protein NUDF of *Aspergillus nidulans* and its Interaction Partner NUDE Bind Directly to Specific Subunits of Dynein and Dynactin and to Alpha- and Gamma-Tubulin" that had been published in the *Journal of Biological Chemistry (JBC)* at 276:38877-38884, 2001. Specifically, Respondent:

- falsified Figure 5A left, Western blot with the alpha tubulin antibody for incubated proteins (+E+gamma+alpha); the lower right band was reused twice in Figure 2A. In Figure 5A, it was used as gamma tubulin band for the coprecipitation experiment with NUDF-Prot.S and as NUDE for the coprecipitation experiments with NUDG (CDLC)-Flag;

- falsified Figure 5A left, NUDF Western blot with the alpha tubulin antibody for incubated proteins (+E+gamma+alpha); the lower left band was reused in Figure 2A as alpha tubulin in the coprecipitation experiment with NUDF-Prot.S; and

- falsified Figure 4A left, NUDF and for the interaction between the two proteins NUDA and NUDF, pulled out with NUDA-FLAG-agarose, had been used at several other places such as Figure 5A left, left gamma tubulin band,

Figure 5B left, NUDE band for the interaction E + alpha, and Figure 5B right, NUDE band for the interaction E + K (ARP1).

Dr. Hoffmann has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed for a period of three (3) years, beginning on January 30, 2004: (1) to exclude himself from any contracting or subcontracting with any agency of the U.S. Government and from eligibility or involvement in nonprocurement programs of the U.S. Government referred to as "covered transactions" as defined in the debarment regulations at 45 CFR Part 76; (2) to exclude himself from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and (3) to draft a letter of retraction and send it to ORI, along with the signed Agreement. The draft letter requested the retraction of the *JBC* paper published at 276:38877-38884, 2001, and stated that he falsified and fabricated data in Figures 2A, 4A, 5A, and 5B. Upon ORI approval of the draft letter, respondent agreed to send the final retraction letter to the Editor of *JBC*.

Regina D. Horvat, Ph.D., Northwestern University: Based on the report of an inquiry conducted by Northwestern University (NU Report), the respondent's admission, and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Regina D. Horvat, Ph.D., former Postdoctoral Fellow, Department of Cell and Molecular Biology at NU, engaged in scientific misconduct in research supported in part by the following National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH), grants: F32 HD041309, RO1 HD38060-01A1, and T32 HD007068."[1] Specifically, PHS found that:

- Dr. Horvat falsified a Western blot of an immunoprecipitation (IP) assay presented as Figure 5B in a manuscript ("Inhibition of Luteinizing Hormone Receptor Desensitization Suppresses the Induction of Ovulatory Response Genes in Granulosa Cells") submitted to *Molecular Endocrinology*. Dr. Horvat falsely labeled an autoradiogram in her laboratory notebook with a piece of tape to misrepresent the data from a different IP experiment that was actually conducted on October 31, 2001, as the experiment described in Figure 5B. Further, Dr. Horvat falsely used Figure 5B in an oral presentation at a national scientific meeting; and

- Dr. Horvat falsified the intensity of the band in Lane 6 of a luteinizing hormone receptor (LHR) Western blot experiment to quantitate the level of LHR immunoprecipitated with an arrestin2 antibody in cells treated with

[1] The T32 award cited in the manuscript was T32 HD21021. A search of the CRISP database showed the correct grant number was T32 HD007068.

hCG for 30 minutes in the PowerPoint figure, prepared in response to the initial review of the *Molecular Endocrinology* manuscript. This manuscript was withdrawn.

Dr. Horvat has entered into a Voluntary Exclusion Agreement in which she has voluntarily agreed for a period of three (3) years, beginning on June 2, 2004: (1) to exclude herself from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and (2) that any institution which submits an application for PHS support for a research project on which the respondent's participation is proposed or which uses the respondent in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which the respondent is involved, must concurrently submit a plan for supervision of the respondent's duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of the respondent's research contribution. Respondent agrees to ensure that a copy of the supervisory plan is also submitted to ORI by the institution. Respondent agrees that she will not participate in any PHS-supported research until such a supervision plan is submitted to and accepted by ORI.

Pat J. Palmer, University of Iowa: Based on the report of an investigation conducted by the University of Iowa (UI Report), the respondent's guilty plea in a state criminal case, and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Pat J. Palmer, former Assistant Research Scientist at UI, engaged in scientific misconduct (1) in research supported by National Institutes of Health (NIH) grant R01 MH55284 entitled "Collaborative Linkage Study of Autism"; (2) in grant proposals 1 R10 MH55284-01, 2 R01 MH55284-04 (both entitled "Collaborative Linkage Study of Autism"), 1 R01 DC05067-01, and 1 R55 DC05067-01A1 (both entitled "The Genetics of Specific Speech and Language Disorders"); and (3) in obtaining salary support from postdoctoral training grant T32 MH14620. PHS found that Ms. Palmer engaged in scientific misconduct by: (1) fabricating interview records for at least six interviews of autism patient families; (2) fabricating her claims for a B.S. from the University of Northern Iowa, a M.S./M.P.H. from the University of California at Berkeley, and a Ph.D. in Epidemiology/Bio-statistics from the University of Iowa in biographical sketches that were submitted to NIH in four grant applications (see above); and (3) fabricating her claim that she obtained a Ph.D. in Epidemiology/Bio-statistics from the University of Iowa in the biographical sketches of a training grant application, so she received salary support from July 1995 through June 1998 for postdoctoral training under NIH training grant T32 MH14620.

Ms. Palmer also engaged in dishonest conduct that demonstrates that she is not presently responsible to be a steward of Federal funds. She falsified that she was a coauthor of several published articles, by inserting her name or replacing another

name with her name on 10 articles listed in her biographical sketch for four NIH grant applications (see above):

(a) Canby, C.A., [**Palmer, P.J.**], & Tomanek, R.J. "Role of lowering arterial pressure on maximal coronary flow with and without regression of cardiac hypertrophy." *American Journal of Physiology* 257:H1110-H1118, 1989.

(b) Stegink, L.D., Brummel, M.C., Filer, L.J., Jr., & [**Palmer, P.J.**, replaced Baker, G.L.]. "Blood methanol concentrations in one-year old infants administered grade [sic] doses of aspartame." *Journal of Nutrition* 113:1600-1606, 1983.

(c) Stegink, L.D., Koch, R., [**Palmer, P.J.**, replaced Blaskovics, M.E.], Filer, L.J., Jr., Baker, G.L., & McDonnell, J.E. "Plasma phenylalanine levels in phenylketonuric heterozygous and normal adults administered aspartame at 34mg/kg body weight." *Toxicology* 20:81-90, 1981.

(d) Stegink, L.D., Brummel, M.C., [**Palmer, P.J.**, replaced McMartin, K.], Martin-Amat, G., Filer, L.J., Jr., Baker, G.L., & Tephly, T.R. "Blood methanol concentrations in normal adult subjects administered abuse doses of aspartame." *Journal of Toxicology & Environmental Health* 7:281-290, 1981.

(e) Stegink, L.D., Reynolds, W.A., Pitkin, R.M., Cruikshank, D.P., & [**Palmer, P.J.**]. "Placental transfer of taurine in rhesus monkeys." *American Journal of Clinical Nutrition* 24:2685-2692, 1981.

(f) Stegink, L.D., Filer, L.J., Jr., Baker, G.L., & [**Palmer, P.J.**, replaced Brummel, M.C.]. "Plasma and erythrocyte amino acid levels of adult humans given l00mg/kg body weight aspartame." *Toxicology* 14:131-140, 1979.

(g) Weiss, N.S., Szekely, D.R., Austin, D.F., & [**Palmer, P.J.**]. "Increasing incidence of endometrial cancer in the United States." *New England Journal of Medicine* 294:1259-1262, 1976.

(h) Elwood, E.K., & [**Palmer, P.J.**, replaced Apostolopoulos, A.X.]. "Analysis of developing enamel of the rat. II.Electrophoretic and amino acid studies." *Clinical Metabolic Studies* [sic] [should be *Calcified Tissue Research*] 17: 327-335, 1975.

(i) Aronow, W.S., Goldsmith, J.R., Kern, J.C., Cassidy, J., [**Palmer, P.J.**], Johnson, L.L., Adams, W., & Nelson, W.H. "Effect of smoking cigarettes on

cardiovascular hemodynamics." *Archives of Environmental Health* 28, 330-332, 1974.

(j) Seltzer, C.C., Friedman, G.D., Siegelaub, A.B., & [**Palmer, P.J.**, replaced Collen, M.F.]. "Smoking habits and pain tolerance." *Archives of Environmental Health* 29,170-172, 1974.

Ms. Palmer has entered into a Voluntary Exclusion Agreement in which she has voluntarily agreed for a period of three (3) years, beginning on January 26, 2004: (1) to exclude herself from any contracting or subcontracting with any agency of the U.S. Government and from eligibility or involvement in nonprocurement programs of the U.S. Government referred to as "covered transactions" as defined in the debarment regulations at 45 CFR Part 76; and (2) to exclude herself from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

Tirunelveli S. Ramalingam, Ph.D., California Institute of Technology: Based on the report of an investigation conducted by the California Institute of Technology (CIT Report) and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Tirunelveli S. Ramalingam, Ph.D., former Postdoctoral Fellow, Division of Biology at CIT, engaged in scientific misconduct in research supported by National Institute for Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), grant 1 R01 AI41239-01, "Neonatal Fc receptor/IgG interaction." Specifically, PHS found that:

A. Respondent plagiarized Figures 6a and 7a from: Dustin, M.L. "Adhesive Bond Dynamics in Contacts between T Lymphocytes and Glass-supported Planar Bilayers Reconstituted with the Immunoglobulin-related Adhesion Molecule CD58." *J. Biol. Chem.* 272:15782-15788, 1997 (hereafter referred to as the "*JBC* 1997 paper").

B. Respondent also falsified Figures 6a and 7a from the *JBC* 1997 paper by electronically manipulating the images and representing them as a different experiment in Figure 6 of NIH grant application 2 R01 AI41239-06A1 entitled "Analysis of the Neonatal Fc Receptor/IgG Interaction."

C. Respondent fabricated timed experimental data obtained from using the fluorescense recovery after photobleaching (FRAP) technique in Figure 7 (upper and lower panels) in a draft manuscript: "IgG can bridge between adjacent membranes containing the neonatal Fc receptor (FcRn): Implications for FcRn-mediated transport of IgG."

The draft manuscript was not submitted for publication; however, because of the laboratory's inability to verify scientific experiments conducted by Dr. Ramalingam, two of his other papers, published in *Nature Cell Biology* in 2000 and *EMBO Journal* in 2002, were retracted.

Dr. Ramalingam has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed for a period of three (3) years, beginning on July 2, 2004: (1) to exclude himself from any contracting or subcontracting with any agency of the U.S. Government and from eligibility or involvement in nonprocurement programs of the U.S. Government referred to as "covered transactions" as defined in the debarment regulations at 45 CFR Part 76; and (2) to exclude himself from serving in any advisory capacity to the PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

Charles N. Rudick, Northwestern University: Based on the report of an investigation conducted by Northwestern University (NU Report) and additional analysis conducted by ORI in its oversight review, PHS found that Charles N. Rudick, Graduate Student, Department of Neurobiology and Physiology at NU, engaged in scientific misconduct in research supported by National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH), grant R29 NS37324, "Estrogen-induced hippocampal seizure susceptibility," and National Institute of General Medical Sciences (NIGMS), NIH, grant T32 GM08061, "Cellular and Molecular Basis of Disease Training Program." Specifically, PHS found that Mr. Rudick falsified illustrations in Photoshop pertaining to unpublished traces of electrophysiological recordings of inhibitory postsynaptic currents.

Mr. Rudick has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed for a period of three (3) years, beginning on September 14, 2004: (1) to exclude himself from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and (2) that any institution which submits an application for PHS support for a research project on which the respondent's participation is proposed or which uses the respondent in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which the respondent is involved, must concurrently submit a plan for supervision of the respondent's duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of the respondent's research contribution. Respondent agrees to ensure that a copy of the supervisory plan is also submitted to ORI by the institution. Respondent agrees that he will not participate in any PHS-supported research until such a supervision plan is submitted to and accepted by ORI.

Ali Sultan, M.D., Ph.D., Harvard School of Public Health: On October 19, 2004, the U.S. Public Health Service (PHS) entered into a Voluntary Exclusion Agreement with the President and Fellows of Harvard College (Harvard) and Ali Sultan, M.D., Ph.D., former Assistant Professor of Immunology and Infectious Diseases at the Harvard School of Public Health (HSPH). Based on HSPH's inquiry report, the respondent's admission, and additional analysis conducted by ORI in its oversight review, PHS found that Dr. Sultan engaged in scientific misconduct in research funded by National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), grant 1 P01 AI060332-01, "Chemical genetics and malaria drug development," Subproject 2, "Screening of target-rich environment." Specifically, PHS and Harvard found that: (1) Dr. Ali Sultan plagiarized text, plagiarized three figures showing results of an immunofluorescence assay, a phosphorimage, and Northern blot analysis (Figures 3, 4, and 5, respectively), and falsified the data as results of experiments on *Plasmodium bergheii*, instead of *P. falciparum* as reported in a subproject of the PHS grant application 1 P01 AI060332-01, "Chemical genetics and malaria drug development;" and (2) Dr. Ali Sultan fabricated portions of an e-mail from his postdoctoral student that he presented to the HSPH inquiry committee purportedly to falsely implicate the student in the submission of the plagiarized materials for the grant application.

The Voluntary Exclusion Agreement states that for a period of three (3) years, beginning on October 19, 2004: (1) Dr. Sultan agreed to exclude himself from any contracting or subcontracting with any agency of the U.S. Government and from eligibility or involvement in nonprocurement programs of the U.S. Government as defined in the debarment regulations at 45 CFR Part 76; and (2) Dr. Sultan agreed to exclude himself from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

Nancy J. Strout, Ph.D., University of Southern Maine: Based on the report of an inquiry conducted by the University of Southern Maine (USM) and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Nancy J. Strout, Ph.D., former interviewer, USM, engaged in scientific misconduct in research supported by Substance Abuse and Mental Health Services Administration (SAMHSA) cooperative agreement UD1 SM52362, "Maine evaluation of consumer-operated services." Specifically, PHS found that the respondent engaged in scientific misconduct by fabricating interview data for at least 50 interviews of human subjects enrolled in the Maine Evaluation of Consumer-Operated Services Project for mental health services, and possibly up to 150 interviews or more (based on calculations performed by USM), causing the project to nullify all 346 interviews because of her involvement at one or more stages with the subjects. PHS also found that the respondent is not presently responsible to be a steward of Federal funds because she falsified invoices for interviews and receipts for

interview incentive payments in pursuit of a fraudulent scheme to obtain payment for services she did not render.

Dr. Strout has entered into a Voluntary Exclusion Agreement in which she has voluntarily agreed for a period of three (3) years, beginning on July 23, 2004: (1) to exclude herself from any contracting or subcontracting with any agency of the U.S. Government and from eligibility or involvement in nonprocurement programs of the U.S. Government as defined in the debarment regulations at 45 CFR Part 76; and (2) to exclude herself from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

Summaries of Closed Inquiries and Investigations Not Resulting in Findings of Research Misconduct – 2004

Falsification: The respondent, an interviewer, allegedly falsified or fabricated interviews in a study involving sexually transmitted disease. The questioned research was supported by a National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH), grant and a National Institute of Mental Health (NIMH), NIH, grant. The institution concluded that the respondent had falsified eight interviews. ORI accepted the institution's investigation report as meeting the reporting requirement to ORI. However, because of a lack of adequate documentation, ORI declined to pursue a finding of scientific misconduct in this matter.

Falsification: The respondent, an assistant professor, allegedly knowingly reported falsified data from a published paper that had been retracted in a grant application submitted to the National Institute of Mental Health (NIMH), National Institutes of Health (NIH). The questioned research involved behavior of primates. The institution conducted an investigation. The institution concluded that the respondent's failure to discuss and properly cite the retraction of the questioned paper in the grant application seriously deviated from commonly accepted practices in the scientific community and thereby constituted scientific misconduct. However, ORI found that there was insufficient evidence of falsification under the PHS definition. Because of weakness of the evidence and the lack of testimony from important witnesses, ORI declined to pursue a finding of scientific misconduct. However, ORI recognized that this does not impact on the findings of misconduct made under institutional standards.

Falsification: The respondent, a professor, allegedly falsified academic credentials in grant applications submitted to the National Institutes of Health (NIH). The questioned research involved the effects of a chemical on organ function. The institution conducted an investigation into the matter. The institution concluded that there were numerous errors and misstatements included in the questioned grant applications that by themselves were relatively trivial, but collectively, these errors might have been material to funding decisions. However, the institution could not determine with certainty that the errors and misstatements were intentional and did not find him guilty of misconduct. The institution did take administrative actions against the respondent. While ORI does not countenance either intentional or reckless behavior in falsely reporting academic credentials in grant applications, whether significant or not, ORI concurred with the institution and did not make a finding of scientific misconduct in this case. Nonetheless, ORI recognized the authority of the institution to establish and implement its own institutional standards for integrity in science.

Falsification: The respondents, a professor and an associate professor, allegedly falsified research data in a study involving measuring a ligand-neurotransmitter in blood of human subjects. The questioned research was supported by two National Institute of Mental Health (NIMH), National Institutes of Health (NIH), grants. The institution conducted an inquiry into the matter. The institution concluded that there was no substantial evidence of possible fraud or deliberate scientific misconduct; thus, no further investigation was warranted. ORI accepted the institution's determination that a formal investigation was not warranted in this case.

Falsification: The respondent, a clinical coordinator, allegedly falsified subject records in a clinical drug trial on disease prevention. The questioned research was supported by a National Cancer Institute (NCI), National Institutes of Health (NIH), cooperative agreement. The institution conducted an investigation. The institution concluded that dates had been altered in the records for two study participants and found misconduct. However, because of the lack of sufficient evidence of the respondent's intent to deceive, the small fraction of the total data in the study that was apparently altered, and the fact that the date changes would not have changed participants' eligibility because of other problems with their records, ORI declined to pursue a PHS finding of scientific misconduct. Nonetheless, ORI recognized the authority of the institution to establish and implement its own institutional standards for integrity in science and to make findings on issues that include and go beyond those considered by ORI in this matter.

Fabrication: The respondent, a research interviewer, allegedly fabricated data for a human subject participant in a study involving diabetes research. The study in question was supported by a National Institute of Diabetes and Digestive and Kidney Disorders (NIDDK), National Institutes of Health (NIH), cooperative agreement. The institution conducted an inquiry into the matter and concluded that the evidence in this case did not warrant further investigation or a finding of research misconduct under PHS standards. ORI concurred with the institution's determination.

Fabrication: The respondents, both professors, allegedly fabricated research data in a manuscript submitted for publication on the fertility of mice with knock-out mutations in a hormone receptor gene. The questioned research was supported by a National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH), grant and a National Institute of Arthritis and Musculoskeletal Skin Diseases (NIAMS), NIH, grant. The institution conducted an inquiry into the matter. The institution concluded that the documentation was incomplete and that the evidence was insufficient to investigate further. ORI concurred with the institution's determination that there was insufficient evidence to warrant further investigation.

Plagiarism: The respondent, an associate professor, allegedly plagiarized an idea for research presented by another researcher in the same department and included the plagiarized idea in a grant application submitted to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH). The questioned research involved development of a drug to treat a common debilitating disease. The institution conducted an investigation into the matter. The institution concluded that the allegation of theft of an idea was unfounded and did not make a finding of scientific misconduct. ORI accepted the institution's conclusion and did not find scientific misconduct on the part of the respondent.

Falsification/Fabrication: The respondent, a professor, allegedly falsified and/or fabricated data in two published papers and two manuscripts submitted for publication. The research involved the conduct of gene expression in a family of proteins. The questioned papers and manuscripts were supported by National Institute for Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), and National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), NIH, grants. The institution conducted an investigation into the matter and concluded that the respondent had engaged in research misconduct by falsifying and fabricating research results by computer manipulation. ORI accepted the institution's report for purposes of closing its oversight review. However, ORI did not find sufficient credible evidence to support a finding of scientific misconduct against the respondent. Thus, ORI declined to make a PHS finding in this case. Nonetheless, ORI recognized the authority of the institution to establish and implement its own institutional standards for integrity in science.

Falsification/Fabrication: The respondent, a professor, allegedly falsified and/or fabricated research data included in two National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH), grant applications. The questioned research involved immunological approaches to prevention of drug addiction. The institution conducted an inquiry into the matter. The institution concluded that while an honest error had occurred, and there were administrative problems in laboratory management that needed to be corrected, there was no evidence of possible scientific misconduct that would warrant an investigation. ORI accepted the institution's conclusion that no investigation was warranted.

Falsification/Fabrication: The respondent, a professor, allegedly falsified data and/or fabricated information included in a National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH), grant application and in two publications on the cloning and expression of a mammalian immunoglobulin family gene. The questioned publications cited support from two NICHD, NIH, grants, a National Heart, Lung, and Blood Institute (NHLBI), NIH, grant, and a National Institute of General Medical Sciences (NIGMS), NIH, grant. The institution

conducted an assessment into the matter and concluded that further inquiry or investigation was not warranted. ORI concurred with the institution's determination.

Plagiarism/Falsification: The respondent, a senior research pathologist and adjunct research associate professor, allegedly plagiarized and falsified part of the Preliminary Results section of a grant application submitted to the National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH). The research involved degeneration of an organ in a mouse model. The institution conducted an inquiry and an investigation into the matter. The institution determined that there was insufficient evidence to conclude that the respondent had committed plagiarism or falsification. ORI concurred with the institution's determination that there was insufficient evidence to conclude that the respondent had committed scientific misconduct. Rather the respondent's inaccurate use of others' data appears more likely to have been a series of honest errors and a failure to carefully review the final grant application.

Plagiarism/Falsification: The respondent, an associate professor, allegedly plagiarized information from a manuscript under review and/or falsified data on cloning a gene from tumor cells described in a paper submitted to a journal. The questioned research was supported by two National Cancer Institute (NCI), National Institutes of Health (NIH), grants. The institution conducted an investigation. The institution concluded that while the respondent failed to protect the confidentiality of a confidential communication and was lax in maintaining appropriate documentation of his research results, these infractions did not constitute misconduct. The institution implemented administrative actions for the respondent because of deficiencies in maintaining accurate data and notebooks as well as other lax procedures. ORI accepted the institution's conclusion that there was insufficient evidence to make a finding of falsification or plagiarism against the respondent.

Plagiarism/Falsification: The respondent, an assistant professor, allegedly plagiarized and/or falsified data in grant applications submitted to the National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), from data found in two publications. The questioned research involved an in vitro transcription system with DNA or chromatin templates. The institution conducted an inquiry into the matter. The institution concluded that while honest errors that reflect a carelessness on the part of the respondent had occurred, this did not constitute scientific misconduct and further investigation was not warranted. ORI accepted the institution's determination that no further investigation was warranted.

Research Misconduct Related Litigation During 2004[1]

CIVIL LITIGATION – Open Cases

***Justin D. Radolf v. University of Connecticut Health Center,* et al.** (No. 303CV242) (D. Conn., filed March 21, 2003). On March 21, 2003, plaintiff Justin D. Radolf, M.D., filed a motion for preliminary injunction seeking to enjoin a University of Connecticut Health Center (UCHC) investigation concerning allegations that plaintiff falsely reported time and effort reports to the National Institutes of Health (NIH). Plaintiff alleged that the investigation was spawned by a vengeful motive to intimidate and threaten him for his refusal to accede to UCHC's unlawful attempt to encumber the funds by paying an unwarranted proportion to the plaintiff's research associate. A recommended ruling was issued to deny injunctive relief, from which plaintiff has appealed. On December 29, 2003, the court upheld the magistrate's recommended ruling denying plaintiff's request to enjoin UCHC's investigation.

The parties' summary judgment motions were filed and argued on January 31, 2005.

Justin D. Radolf v. Peter J. Deckers (No. 303CV672) (D. Conn., filed April 14, 2003). On March 10, 2003, the Public Health Service (PHS) entered into a Voluntary Exclusion Agreement with Justin D. Radolf, M.D., who is a Professor at the University of Connecticut Health Center (UCHC). Under the terms of his PHS agreement, Radolf agreed to accept supervision by any institution employing him until March 9, 2008. UCHC, Dr. Radolf's current employer, developed a supervision plan proposing restrictions in addition to those mandated by the PHS agreement.

Dr. Radolf is seeking judicial review of UCHC's additional restrictions. On April 14, 2003, Radolf filed a complaint and a motion for a preliminary injunction in the U.S. District Court in the District of Connecticut against Peter Deckers, in his official capacity as the Executive Vice President and Dean of the School of Medicine at UCHC. The complaint alleges general deprivation of Radolf's constitutional right to due process of law in violation of the Fourteenth Amendment.

Radolf alleges that the defendant unlawfully (1) removed the plaintiff from any academic and/or administrative leadership position on behalf of UCHC; (2) expelled the plaintiff from the existing academic/departmental structure of UCHC; (3) negated

[1] The HHS Office of the General Counsel tracks all civil and criminal litigation related to ORI's mission. Many cases, especially those in which HHS is a named party, require legal support to the Department of Justice (DOJ). This includes drafting litigation summaries and reports, drafting discovery requests and responses, preparing briefs and pleadings, and developing legal strategy. The litigation summaries included in this Annual Report exclude *qui tam* cases that are under seal and hence confidential, pending DOJ civil and criminal investigations, and cases in which ORI has only a peripheral interest.

the plaintiff from existing departmental appointments; (4) imposed upon the plaintiff four additional years of academic probation; (5) expunged the plaintiff's name from the list of available mentors for new M.D./Ph.D. candidates; and (6) revoked the plaintiff's appointment to the Steering Committee of the M.D./Ph.D. program.

Both of the preceding cases involving Dr. Radolf were consolidated.

Marguerite M. Kay v. Peter Likins, et al. (No. Civ. 02-307) (D. Ariz., removed from Ariz. Super. Ct., June 20, 2002). In this companion case to three previous cases, Dr. Marguerite M. Kay seeks review of the University of Arizona's final decision terminating her employment as a faculty member. Dr. Kay had been subject to several previous research misconduct and termination hearings that one of the court cases ordered redone due to procedural deficiencies. This suit focuses on the most recent research misconduct and termination hearings by the University of Arizona's Committee on Academic Freedom and Tenure, which found scientific misconduct and recommended dismissal, and the concurring decisions by the University's president.

Defendants named in the suit include the University's president and provost and their spouses, members of the Committee on Academic Freedom and Tenure and their spouses, and the State of Arizona Board of Regents. Dr. Kay alleges denial of her property interest in her employment and liberty interest in her name without procedural or substantive due process, breach of contract, and tortious interference with her employment relationship. She has requested reinstatement, back pay, and compensatory and punitive damages.

The Federal district court dismissed the case without prejudice in April 7, 2003. Dr. Kay filed an amended complaint on May 5, 2003. The court dismissed the amended complaint on January 22, 2004. The parties are now briefing Dr. Kay's appeal, which was docketed in the U.S. Court of Appeals for the Ninth Circuit on March 12, 2004.

CRIMINAL LITIGATION – Open Cases[2]

State of Iowa v. Pat J. Palmer (FECR 062994) (Iowa Distr. Ct.). After the University of Iowa's Research Misconduct Committee found Pat J. Palmer responsible for misconduct, the Johnson County, Iowa prosecutor charged Ms. Palmer with three criminal counts: one count of felony theft and one count of tampering with records, both arising from false claims of automobile mileage of approximately $53,000 charged against a University of Iowa research grant; and one count of falsifying her

[2] The criminal litigation list does not include ongoing criminal matters which are still in the investigational stages, or those for which no indictment has been sought.

academic record in an employment application by falsely claiming to have received an undergraduate degree from the University of Northern Iowa, two masters degrees from the University of California at Berkeley, and dual doctorate degrees from the University of Iowa.

On October 30, 2003, Palmer pled guilty in the Johnson County District Court to the counts of theft in the first degree (violation of Iowa Code §§ 714.1(3), 714.2(1)) and falsifying academic degrees (in violation of Iowa Code § 715A.6A). The court sentenced Palmer to three years of supervised probation and a $1,000 fine on the first count, one year of supervised probation and a $250 fine on the second count, and $18,976.80 restitution for falsified travel vouchers. ORI made PHS findings of research misconduct in 2004. See Appendix A.

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