

# Office of Research Integrity

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# HIGHLIGHTS OF CY 2005 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 C.F.R. Part 93.

## Regulations

- Published the PHS Policies on Research Misconduct (42 C.F.R. Part 93) in the *Federal Register* on May 17, 2005. The new final rule implements the 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 updates the regulation published in 1989. The new regulation that became effective June 16, 2005, is on the ORI home page at <http://ori.hhs.gov>

## Responding to Research Misconduct Allegations

- Found research misconduct in 8 of the 22 cases closed. The types of misconduct involved in the findings were falsification 3, fabrication and falsification 2, fabrication 2, and plagiarism 1. The percentage of PHS misconduct findings and administrative actions in 2005 (36 percent) was comparable to the historical average of 37 percent. However, about 75 percent of the cases still pending in ORI with institutional determinations involve research misconduct findings.
- Imposed debarments on 75 percent of the respondents against whom a research misconduct finding was made, including a lifetime debarment for the first time. Four respondents were debarred for 3 years, and one was debarred for 2 years. All eight respondents were prohibited from serving in any advisory capacity to PHS for terms ranging from 3 years to a lifetime. Certification of work was imposed on two respondents, and supervision was imposed on one. The misconduct cases also led to the correction or retraction of 10 articles.
- Opened 30 cases in 2005, with 59 cases remaining open at the end of the calendar year, 8 more cases than ORI had in 2004. The number of allegations received by ORI (265 in 2005) was two fewer than in 2004, but represented nearly a 50 percent increase over the 2003 level.

- Completed oversight on 21 of the 22 closed cases within 1 year. For the 22 cases involving inquiries or investigations reviewed and closed by ORI in 2005, institutions took a mean of 8.4 months after notification of ORI (median 8 months; range 1-19 months) to complete their actions. ORI took a mean of 5.8 months (median 3 months; range 1-24 months) to review the reports, obtain additional information from the institution, complete the ORI analysis, negotiate any PHS findings and administrative actions, and close these cases.
- Offered Rapid Response for Technical Assistance (RRTA) formally to nine institutional officials in the cases opened by ORI in 2005, all of whom accepted assistance; three 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 22 cases closed by ORI in 2005, ORI had provided RRTA during the early stages to 8 of them. In addition, ORI provided RRTA to 56 institutional officials who called ORI during their assessment or inquiry stages, before reporting any case formally to ORI.

### **Education and Prevention**

- Funded 9 instructional resources through the Responsible Conduct of Research (RCR) Resource Development Program, raising to 48 the number of projects supported since 2002. Seven more completed resources were posted on the ORI web site for use in RCR education programs at institutions and research organizations around the world. A total of 18 resources were available on the ORI web site at the end of 2005.
- Held the third annual RCR Expo in conjunction with the annual meeting of the Society of Research Administrators International. Thirteen developers of RCR resources, including seven universities, one college, one hospital, one association, one commercial firm, one journal, and one e-mail service, exhibited their creations.
- Contracted with the Collaborative Institutional Training Initiative (CITI) Program to develop an RCR course covering seven of the nine core RCR instructional areas. The CITI-RCR Program will provide course site administration, technical support for administrators, and a help desk for learners. Instructional records will be maintained on a secure CITI Program dedicated server. Institutional administrators will be able to download instructional records for their learners from the course site. CITI was founded in 2000 to provide web-based instruction in human subject protection. Over 450 organizations worldwide are CITI members.

- Initiated a training program for Research Integrity Officers (RIOs), the institutional officials responsible for implementing the PHS Policies on Research Misconduct. ORI contracted with Michigan State University to produce an orientation video that presents an overview of the main responsibilities of RIOs. The video is expected to be completed in 2006.
- Made awards to 12 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 3 years, the RCR Program for Academic Societies, a collaboration between the Association of American Medical Colleges and ORI, supported 32 projects submitted by 30 academic societies.
- Supported four 1-day meetings of graduate deans from institutions participating in a project to institutionalize RCR education programs in graduate schools to discuss problems and issues encountered in developing their demonstration projects and the progress being made. These meetings were essential for the successful implementation of RCR education programs in the participating institutions, the development of an RCR leadership cadre of graduate deans, and the production of a monograph on best practices in establishing RCR education programs in graduate schools. The program is a collaboration between the Council of Graduate Schools and ORI.
- Sponsored eight conferences or workshops related to research integrity, the responsible conduct of research, and research misconduct in collaboration with nine universities, seven medical schools, one professional association, and four foreign and domestic government agencies.
- Increased the number of visits to the ORI web site by 50 percent (219,525 to 330,268) and the number of visitors by 31 percent (92,076 to 120,288) between FY 2004 and FY 2005 by aggressive marketing and effective web site management. Besides the United States, visitors were from 22 countries, compared to 18 countries in FY 2004.
- Granted permission for the publication in 2005 of Chinese and Japanese versions of the *ORI Introduction to the Responsible Conduct of Research*. Over 5,500 copies of the publication have been sold by the U.S. Government Printing Office, and more than 1,000 copies have been downloaded from the ORI web site since the booklet was published in 2004.
- Made 80 staff presentations at conferences, workshops, meetings of professional associations, institutional associations and academic societies, universities, medical schools, research institutes, hospitals, and federal agencies.

## **Research on Research Integrity and Research Misconduct**

- Awarded a contract through the intramural research program to the RAND Corporation for a study of institutional infrastructure and support for research mentoring. Studies of the reporting of suspected research misconduct, institutional RIOs, and misconduct by graduate students and postdocs are expected to be completed in 2006. The intramural program has also proposed a study of institutional efforts to educate their staffs about the PHS Policies on Research Misconduct.
- Made 7 awards in the extramural research program through the Research on Research Integrity (RRI) Program, increasing the number of studies supported in the first 5 years to 34. Four more PHS funding agencies have joined the program, increasing the total to eight. The program has produced 29 publications, including 10 in 2005.
- Began planning the fourth biennial Research Conference on Research Integrity, which will be held in Tampa, Florida, from December 1-3, 2006.

## **Institutional Compliance**

- Completed the 2004 Annual Report on Possible Research Misconduct in which 101 institutions reported they were responding to allegations of research misconduct received in 2004 or earlier. Sixty-three institutions reported receiving 120 new allegations in 2004 that resulted in the opening of 81 new cases.
- Inactivated assurances for 483 institutions or organizations for failing to submit the CY 2004 Annual Report on Possible Research Misconduct by the March 31, 2005, deadline.
- Processed 216 institutional policies on handling allegations of research misconduct, requested 128 institutional policies for review, and increased the number of completed reviews to 2,364.
- Opened two compliance cases and closed three compliance cases and carried three compliance cases into 2006.

## **Information and Privacy**

- Received 40 Freedom of Information Act (FOIA) requests; 38 were closed. One Privacy Act request was received and 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 Public Health Service (PHS) awardee institutions and PHS agencies, like the National Institutes of Health (NIH), 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. The DIO staff also assists the Office of the General Counsel (OGC) in preparing cases that will be heard by the Administrative Law Judges under the Department of Health and Human Services (HHS) Departmental Appeals Board system, 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 by ORI to determine whether it meets the criteria for opening a formal case in ORI. These criteria are:

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

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

2. The alleged misconduct must meet the definition of scientific misconduct set forth in the PHS regulation (42 C.F.R. Part 50, Subpart A); for allegations received after June 16, 2005, refer to 42 C.F.R. Part 93.

ORI assesses whether the action reported, if found to be true, would represent “fabrication, falsification or plagiarism.”

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, 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 2005, ORI received 265 allegations. The disposition of the allegations received by ORI is presented in Table 1 below. Allegations become active cases when the criteria outlined above are met. Some allegations are administratively closed when ORI finds that (1) they do not fall under ORI 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 by ORI, 2005**

<i>Handling of allegations – outcome in ORI</i>	<i>Number of allegations</i>
Pre-inquiry assessment by ORI of allegations:	64
that were made to ORI directly	44
that were made to NIH initially	20
No action possible now or no action	159
Referred to other Federal agencies	26
Handled by NIH (for other allegations made to NIH)	14
Received by NIH and referred to ORI	2
TOTAL	265

Of the 265 allegations made to ORI (or to NIH and reported to ORI) in 2005, 64 were assessed by ORI in detail for a potential inquiry or investigation; 30 assessments resulted in the opening of formal cases. Of these, 23 were from 2005 allegations and 7 were from prior year allegations. One of the allegations from 2005 developed into two cases. In total, 37 allegations were administratively closed and/or assessed (Table 2); 26 were referred to other agencies (Table 1).

Assessments of the allegations that resulted in new ORI cases took an average of 7 days; those that resulted in administrative closures took 11 days. Fifty-five assessments were resolved by ORI within 25 days; of these, the mean time was 6 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 20 allegations that were made directly to NIH by complainants (Table 1). The number of allegations that ORI received in 2005 (265) were about the same as that for the prior year (267). The number of all allegations that were the subject of formal pre-inquiry assessments in 2005 by ORI (64) remained the same.

**Table 2: Time for Conduct of Pre-inquiry Assessments by ORI, 2005**

<i>Outcome of ORI assessment</i>	<i>Number of new allegations</i>	<i>Total days for resolution</i>	<i>Distribution of resolution times (days)</i>			
			<i>Mean</i>	<i>Median</i>	<i>Mode</i>	<i>Range</i>
Opened formal case	30	220	7	7	7	1-26
Administratively closed/assessed	37	437	11	4	1	1-148
Unresolved at end of year 2005	5	–	–	–	–	1-127
TOTAL	72	657	18	–	–	1-148

### Processing of Cases Closed

ORI closed 22 cases in 2005, including 4 inquiries and 18 investigations. The average duration of 14.2 months for an open case was split between institutional actions (8.4 months) and ORI oversight and actions (5.8 months) (Table 3). Seventeen cases (77 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, 2005 (N= 22)**

<i>Site of action during case</i>	<i>Distribution of resolution times (months)</i>			
	<i>Mean</i>	<i>Median</i>	<i>Mode</i>	<i>Range</i>
Institution	8.4	8	4	1-19
ORI	5.8	3	2	1-24
Total time	14.2	13	7	2-43

The action period for the 4 institutional inquiries included their inquiry and adjudication phases, and for 18 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 was one appeal in 2005).

In 2005, 8 of the 18 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 10 investigations closed by ORI that did not result in findings of scientific misconduct are located in Appendix B.

### Caseload and Outcomes

The ORI caseload is divided into two elements: institutional inquiries and institutional investigations. ORI carried forward 51 cases from 2004, and ORI opened 30 new cases and closed 22 cases during 2005. At the end of CY 2005, ORI had 59 active formal cases divided between inquiries and investigations (Table 4).

**Table 4: ORI Research Misconduct Caseload by Case Type, 2005**

<i>Case type</i>	<i>Forwarded from 2004</i>	<i>Opened in 2005*</i>	<i>Closed in 2005</i>	<i>Carried into 2006</i>
Institutional inquiries	15	9	4	20
Institutional investigations	36	21	18	39
TOTAL	51	30	22	59

\*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.

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

During 2005, ORI accepted four institutional inquiry reports that did not recommend further investigation (Table 5). Three cases involved allegations of falsification; one dealt with alleged plagiarism. ORI carried 20 such institutional inquiries into 2006.

***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 2005 with 36 cases carried forward from 2004. During the year, 21 new institutional investigations were opened; 18 investigation cases were closed (Table 5). Of these 18 closed cases, 8 involved ORI findings of scientific misconduct; 10 cases did not have such findings. Of the total of 22 cases closed in 2005, 36 percent (eight 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).

There were 39 active investigation cases carried into 2005. About 75 percent of the cases with an institutional decision that ORI carried over in 2005 included institutional findings of misconduct.

**Table 5: Outcome of Research Misconduct Cases Closed by ORI, 2005**

<i>Case type</i>	<i>Outcome of case</i>				<i>Total</i>
	<i>No investigation</i>	<i>No misconduct</i>	<i>Misconduct finding</i>	<i>Admin. closed</i>	
Institutional inquiry	3	-	-	1	4
Institutional investigation	-	10	8	-	18
ORI inquiry or investigation	-	-	-	-	-
<b>TOTAL</b>	<b>3</b>	<b>10</b>	<b>8</b>	<b>1</b>	<b>22</b>

### **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 after additional review, ORI determines that the allegation did not fall under the PHS definition of scientific misconduct or warrant further action. There was one case administratively closed by ORI in 2005, in which the institutional assessment after the referral by ORI quickly demonstrated that a principal investigator accused of plagiarism in a grant application actually had the permission and encouragement of the source institution to use their results and text.

## Types of Allegations and Administrative Actions

**Types of Allegations Involved in Cases Closed:** During 2005, of the 4 closed inquiries and the 18 investigations closed with findings, all involved allegations of falsification, fabrication, or both (2 also involved some plagiarism). Of those 22 cases, 8 cases resulted in ORI misconduct findings and/or administrative actions (Table 6).

**Table 6: Types of Allegations Involved in Closed Inquiries and Investigations and Their Outcomes, 2005**

<i>Allegation</i>	<i>Inquiry</i>	<i>Investigation</i>	<i>ORI findings or PHS administrative actions</i>
Fabrication	-	2	2
Falsification	3	13	3
Falsif./Fabric.	-	2	2
Plagiarism	1	1	1
TOTAL	4	18	8

**PHS Administrative Actions Imposed in Closed Cases:** A range of administrative actions is used by PHS to protect the 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 eight cases in 2005 in which ORI misconduct findings or PHS administrative actions were imposed, one person was debarred for life; four persons were debarred or voluntarily excluded, each for 3 years; and one debarred for 2 years. Other administrative actions imposed on respondents in these eight 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 (seven 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 (one person); and correction and or retraction of articles (10 publications) (Table 7).

**Table 7: PHS Administrative Actions Imposed in Closed Investigations with Misconduct Findings or Administrative Actions, 2005**

<i>PHS administrative actions</i>	<i>Duration</i>	<i>Number of such actions</i>
Debarment or voluntary exclusion	lifetime	1
Debarment or voluntary exclusion	3 years	4
Debarment or voluntary exclusion	2 years	1
Prohibition from serving as an advisor for PHS	lifetime	1
Prohibition from serving as an advisor for PHS	4 years	1
Prohibition from serving as an advisor for PHS	3 years	5
Supervision plan required	3 years	1
Certification of work	3 years	1
Certification of work	2 years	1
# of respondents required to retract or correct articles	–	1

**Rapid Response for Technical Assistance Program (RRTA)**

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

Among the 30 new cases opened in 2005, the DIO/ORI made nine RRTA offers to the institutions, and officials from all of them called ORI for substantive technical, administrative, or legal advice. ORI also provided RRTA help to institutions for



which ORI had opened cases in the previous year; of the 22 cases closed by ORI in 2005, ORI had provided RRTA to 8 of them at the early stages of their process. ORI additionally provided RRTA to 56 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. Fifty-six institutions were provided with RRTA in 2005, up from 48 in the prior year. In total, ORI provided 78 RRTA responses in 2005.

Challenging problems for institutions include voluminous or missing evidence, multi-center clinical sites, involvement of aggressive outside parties, and premature or incomplete “admissions.” ORI staff will provide such RRTA help (phone DIO at 240-453-8800) over the telephone or on-site. More information on the RRTA program is at [http://ori.hhs.gov/misconduct/tech\\_assistance.shtml](http://ori.hhs.gov/misconduct/tech_assistance.shtml)



## 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 for use in the worldwide research community. In addition to creating instructional resources, this program has sparked interest in RCR at private and public research institutes.

ORI received 16 applications in 2005 in response to a request for proposals. Nine new projects were awarded for a total of \$225,000 (\$25,000 per project). The awardees included eight universities and one teaching hospital. These projects will create Internet-based assessment and instructional materials on peer review, data management, mentoring, and laboratory management.

Project titles, project directors, and awardee institutions for the 2005 awards follow:

*Peer Review Tool - Sample Size Determination for Experimental Studies*

Min Qi Wang, University of Maryland

*Promoting Responsible Peer Review and Publishing Through Interactive eLearning Experience*

Murali Krishnamurthi, Northern Illinois University

*Data Acquisition, Retention, Storage, Custody, Sharing, Ownership, Interpretation and Reporting*

Neil Mehta, Cleveland Clinic Foundation

*Utilizing Video Vignettes and Decision Tree Technology to Promote Responsible Conduct in Research Data Acquisition, Management, Sharing and Ownership*

Derina Samuel, Syracuse University

*Lab Management: Training and Education for the Principal Investigator and Associated Technical Personnel*

Dan Nordquist, Washington State University

*Development of a Web-Based Educational Intervention on Research Misconduct*

Melissa Proll, University of Texas Health Science Center - Houston

*Mentoring Relationships for Multi-cultural Populations*  
Wayne Patterson, Howard University

*Development and Testing of a Web-based Tutorial for Program Evaluation of RCR Education*  
Rebecca Henry, Michigan State University

*Baseline RCR Testing Program*  
Elizabeth Heitman, Vanderbilt University

ORI received six finished products in 2005 from nine projects funded in 2004. Three projects received no-cost extensions to complete development. Finished products include several web-based RCR resources, an RCR assessment program, and a prototype tool to assist the peer review process. All finished products were exhibited at the ORI-sponsored RCR Expo, which was held in conjunction with the annual meeting of the Society of Research Administrators (SRA) International in Milwaukee, Wisconsin, in October 2005. More information on the RCR Resource Development Program is at <http://ori.hhs.gov/education/rdp.shtml>

Seven resources were posted on the ORI web site in 2005, bringing the total number of instructional resources available to the worldwide research community to 18. The resources are at [http://ori.hhs.gov/education/rcr\\_resources.shtml](http://ori.hhs.gov/education/rcr_resources.shtml)

Project titles, project directors, and originating institutions or organizations for the RCR resources posted in 2005 follow:

*Ethics in Mental Health Research: Case Compendium*  
James DuBois, St. Louis University

*Ethics and Research in the Community*  
Leslie Alexander, Bryn Mawr College, and Ken Richmond, Massachusetts College of Pharmacy and Health Sciences

*Responsible Conduct in Data Management*  
Murali Krishnamurthi, Northern Illinois University

*Guidebook for Teaching Selected Responsible Conduct of Research Topics to a Culturally Diverse Trainee Group*  
Madeline Alexander and Wendy Reed Williams, The Children's Hospital of Philadelphia

*Research Conflicts of Interest Course*  
Melissa Proll, University of Texas Health Science Center - Houston

*Potential Conflicts of Interest: A Course for Researchers*

Jeffrey Kahn, University of Minnesota

*Reviewing and Managing Researchers' Conflict of Interest*

Jeffrey Kahn, University of Minnesota

**RCR Expo**

ORI held the third annual RCR Expo on October 16-17, 2005, in the Midwest Airlines Center in Milwaukee, Wisconsin, in conjunction with the annual meeting of the SRA 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. These activities generated a dialogue among and between creators and users of RCR resources. The Expo provided an opportunity to display RCR products to over 1,600 research administrators and researchers.

Exhibitors focused on 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 institutes that exhibited at the Expo and a description of the products showcased:

**Exhibitor:** Clinical Tools, Inc.

**Product:** An interactive, Internet-based course for the oversight of data management

The course includes background information on the topic, as well as tools and resources to help researchers oversee the management of data. The course contains information and suggestions about defining research staff roles and responsibilities related to data management and about establishing a communication plan. Interactive features, such as a self-quiz, case studies, and planning checklist, provide active learning.

**Exhibitor:** Boston College

**Product:** An RCR educational program for administrative staff members

The RCR educational program consists of materials designed to fill this gap in RCR education and to enhance the environment of research integrity of an institution that uses them. Using the program, research administrators will be able to (1) identify when situations present ethical conflicts, (2) reason among possible courses of action, and (3) effectively implement their best solution to the problem.

**Exhibitor:** University of California - Los Angeles

**Product:** An interactive web course on research with human subjects

The web course includes didactic text, illustrative scenarios, and a large annotated bibliography. Real-life scenarios are used for pedagogical objectives. The course book includes sections on Experimental Design, Consent, Oversight, Conflicts of Interest, International Research, Genetics, and Malfeasance–Misconduct.

**Exhibitor:** Northern Illinois University

**Product:** An active learning online course on responsible mentoring and collaboration

The modules use adult learning principles based on the Kolb Learning Theory and active learning principles, and make use of the relationships between the two topics. The modules contain a variety of activities such as games, quizzes, cases, and decision trees for engaging diverse learners.

**Exhibitor:** San Diego State University

**Product:** A web-based training course for community health workers and other novice research staff

The online course is targeted at community health workers who may have no or little experience in research. Basic knowledge of research methods is provided to ensure that protocols are carried out as intended.

**Exhibitor:** Ohio State University

**Product:** An assessment tool for evaluating university RCR programs

The assessment tool helps research administrators evaluate their institute's RCR programs. The computer-based instrument walks the administrator through specific components of an RCR program. The user is able to input information about personnel within the institution who perform RCR tasks. A final printout allows the institution to easily view strengths and weaknesses in the RCR program and gaps in the program.

**Exhibitor:** Columbia University

**Product:** Collaborative science and data management learning modules

Columbia University is in the midst of completing learning modules for all nine RCR topics and is completing the latest modules on Collaborative Science and Data Management. The modules combine content and pedagogy available in traditional classroom settings with compelling new multimedia techniques for presenting information. This resource uses a dynamic problem-oriented, case-based study approach.

**Exhibitor:** University of Maryland

**Product:** A computer-based tool for peer review: evaluating data analyses

The Peer Review Tool will be a comprehensive, computer-based instrument to facilitate the peer review process. In this phase of the project, the data analyses section is covered. The companion tool will help peer reviewers detect common and less frequent errors in statistical procedures, reporting, and analysis. The completed Peer Review Tool will cover all sections of a research paper, including the introduction, hypotheses, methods, data/results, and conclusions.

**Exhibitor:** Children's Hospital of Philadelphia

**Product:** A guidebook for mentoring international postdocs

The guidebook with video supplement addresses the special challenges associated with the training and career development of this large subgroup of postdocs. This electronic guidebook is divided into five content areas, with interactive elements and one or more videotaped vignettes illustrating common problems and alternative courses of action. This training guide is expected to be an effective method of identifying issues, raising awareness, and facilitating problem-solving, with the goal of promoting a positive mentoring environment for both mentor and trainee.

**Exhibitor:** University of Alabama - Birmingham

**Product:** A Documentary Film: A Round Table on Mentoring and Authorship

A 1-hour video addressing mentoring and authorship that features discussion between principal investigators and graduate students, acted scenarios about lab dilemmas, and interviews.

**Exhibitor:** RCREC - The RCR Educational Consortium

**Product:** Information about RCREC

RCREC is a non-profit organization dedicated to the promotion of responsible conduct of research. RCREC provided brochures about their programs as well as information for membership.

**Exhibitor:** JERHRE - *Journal of Empirical Research on Human Research Ethics*

**Product:** Online journal

JERHRE is a new journal on human research. The first issue was published in March 2006.

**Exhibitor:** Illuminata, Inc.

**Product:** E-mail service

Illuminata, Inc., exhibited its e-mail service, which provides weekly e-mail updates on current human research. Visitors to the exhibit were able to sign up for a 4-week free subscription.

### **Collaborative Institutional Training Initiative (CITI) Program**

ORI contracted with the CITI Program to develop a responsible RCR course that will be available to individuals, institutions, and organizations free of charge.

The RCR course will cover seven of the nine core RCR instructional areas: data acquisition, management, sharing, and ownership; mentor/trainee relationships; publication practices and responsible authorship, peer review, collaborative science, research misconduct, and conflict of interest. Courses on human subject protections and animal welfare are available through the ORI web site and elsewhere. The course is expected to be available in late 2006.

CITI was founded in 2000 by a consortium of investigators, administrators, and bioethicists to provide web-based instruction in human subject protection. More than 450 organizations worldwide are CITI members. Over 180,000 persons have taken its human subject protection course.

Any organization will be able to participate in the CITI–RCR program at no cost. CITI will customize courses for institutions to fit the needs of learner groups in the various sciences at the undergraduate, graduate, postdocs, and faculty levels. Individual learners will also be able to register for an RCR course at the CITI web site ([www.citiprogram.org](http://www.citiprogram.org)).

An RCR Developers Group will be created to monitor the course and conduct semi-annual reviews. CITI will offer continuing medical education (CME) or continuing education unit (CEU) credits through the University of Miami Office of Continuing Medical Education.

The CITI–RCR Program will provide course site administration, technical support for administrators, and a help desk for learners. Instructional records will be maintained on a secure CITI Program dedicated server. Institutional administrators will be able to download instructional records for their learners from the course site.

When learners complete the institutionally prescribed course, they will receive a completions report (transcript) describing the curriculum completed. Successful completion is based on attaining a score (determined by the institution) on the quizzes associated with each module.



## **Research Integrity Officer (RIO) Training Program**

ORI began creating a training program in 2005 for RIOs, the institutional officials who are responsible for implementing the PHS Policies on Research Misconduct (42 C.F.R. Part 93), to professionalize the role by defining essential functions and by codifying best practices.

As a first step, ORI contracted with Michigan State University (MSU) to produce a 1-hour orientation video that presents an overview of the main responsibilities of RIOs. The video is expected to be completed in 2006.

David Wright, who served as the RIO at MSU for 11 years, is serving as project director. Three other veteran RIOs are also participating in the video: Margaret Dale, Harvard University; Joe Corless, Duke University, and Todd Guttman, Ohio State University.

The video is being produced by Richard C. Tibbals and Brian Kusch, College of Communication Arts and Sciences, MSU, in collaboration with Ed Cheeney, Dennis Hart, and Holly Giesman of Cheeney Media Concepts.

The video will address administering institutional policies and procedures for handling allegations of misconduct; securing and safeguarding evidence; helping to protect whistleblowers; working with institutional counsel; liaising with those overseeing other regulatory areas, for example, protection of human subjects; handling complex cases that cross regulatory boundaries; and staffing and training inquiry and investigation committees.

The video will include interviews with experienced RIOs as well as senior ORI officials. Short scenarios of RIOs performing critical functions, for example, sequestering data, may also be included.

## **RCR Program for Academic Societies**

Twelve awards were made in 2005 by the RCR Program for Academic Societies to facilitate the institutionalization of infrastructure and activities within academic societies that will promote the responsible conduct of research by their members.

The program, a collaboration between the Association of American Medical Colleges and ORI, has supported 36 projects by 30 academic societies since the program began in 2002. Any academic society whose members conduct biomedical or behavioral research supported by the Public Health Service is eligible to apply. The program offers awards up to \$50,000.

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 should “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.”

The purpose of the awards is to provide funds to 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, and to mainstream or institutionalize RCR infrastructure, activities, and educational programs into the culture of the societies and disciplines.

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 resources related to the core RCR components.

A module on responsible literature searching, produced by the Association of Health Science Libraries and hosted by the University of Pittsburgh, may be accessed through the ORI home page. The code of ethics, “Ensuring Integrity for Research with Children,” was developed by the Ambulatory Pediatric Association. The statement was published in the January/February issue of *Ambulatory Pediatrics*. This policy statement is also available on the ORI home page. More information about the RCR Program for Academic Societies is at <http://ori.hhs.gov/education/pas.shtml>

Abstracts for all funded projects are posted on the ORI web site at [http://ori.hhs.gov/education/aamc\\_funded\\_13.shtml](http://ori.hhs.gov/education/aamc_funded_13.shtml). Academic societies receiving awards and project titles follow:

**AcademyHealth.** “Promoting AcademyHealth’s Ethical Guidelines for Health Services Research.”

**American Academy of Family Physicians.** “Continuing Medical Education and Conflicts of Interest.”

**The American College of Physicians.** “Training and Support in the Responsible Conduct of Practice-based Research in Internal Medicine.”

**The American Society for Clinical Pharmacology and Therapeutics.** “Workshop on Corporate Influence in Research.”

**American Speech-Language-Hearing Association.** “Enhancing Research Integrity: The Publication Process.”

**Association of Academic Physiatrists.** “An Enduring Multidisciplinary Curriculum for Responsible Conduct of Rehabilitation Research.”

**Association of Anatomy, Cell Biology and Neurology Chairs.** “Nobel Roundtable Discussion on the Impact of Large Interdisciplinary and Inter-institutional Consortia on Conflict of Interest and Scientific Misconduct.”

**Association of Rheumatology Health Professionals.** “Responsible Data Management in Research: Getting It Right the First Time.”

**The Endocrine Society.** “Workshop on Enhancing Integrity in Clinical Research.”

**Public Health Leadership Society.** “Public Health Research and the Public Health Code of Ethics.”

**Society for Academic Continuing Medical Education.** “Improving the Informed Consent Process.”

**The Society of Research Subject Advocates.** “Research Subject Advocates Development and Research Integrity Seminar.”

### **RCR Program for Graduate Schools**

ORI provided support in 2005 for four 1-day meetings of graduate deans from institutions participating in a project to institutionalize RCR education programs in

graduate schools. The purpose of the meetings was to discuss problems and issues encountered in developing the demonstration projects and the progress being made. These meetings were essential for the successful implementation of RCR education programs in the participating institutions, the development of an RCR leadership cadre of graduate deans, and the production of a monograph on best practices in establishing RCR education programs in graduate schools.

Two meetings involved graduate deans from the 10 institutions that received awards under the 2-year contract ORI awarded to the Council of Graduate Schools (CGS) in May 2004. The other two meetings were also open to representatives from the 25 institutions that did not receive awards but remain affiliated with the project.

The effort to institutionalize RCR education programs in graduate training will be extended, at least, until December 31, 2007, with support provided by the National Science Foundation (NSF). The ORI contract ends in May 2006. More information about the RCR Program for Graduate Schools is available at <http://www.cgsnet.org/Default.aspx?tabid=123>

### **Conferences and Workshops**

ORI held eight conferences or workshops in 2005. The workshops were organized in collaboration with universities, medical schools, professional organizations, and government agencies, foreign and domestic. More information about the conference and workshop program is available at <http://ori.hhs.gov/conferences/>

June 3-4

Responsible Conduct of Basic and Clinical Research  
Warsaw, Poland

Co-sponsors: Polish Academy of Sciences, Ministry of Science, Ministry of Health, Association of Pharmaceutical Companies

June 13-14

Promoting a Productive and Responsible Research Environment  
Sacramento, CA

Co-sponsor: University of California - Davis

June 16-17

The Research Coordinator: Strategies for Promoting Integrity in Clinical Research  
Bryn Mawr, PA

Co-sponsors: University of Pennsylvania School of Medicine, Thomas Jefferson University, and Drexel College of Medicine

August 4-5

Mentoring and Human Subjects' Protection

Little Rock, AR

Co-sponsors: University of Arkansas for Medical Sciences, Office for Human Research Protections (OHRP)

October 1

Plagiarism Across the Science Disciplines: An Exploration of the Parameters of Plagiarism in Scholarly and Scientific Publications

New York, NY

Co-sponsors: New York University School of Medicine, St. John's University, Columbia University College of Physicians and Surgeons, City University of New York

October 3-4

Workshop on Institutional Trustworthiness

Aspen, CO

Co-sponsors: University of Colorado, Baylor College of Medicine, Johns Hopkins University, University of Washington School of Medicine

October 20-21

Responsible Conduct of Research: Essentials for Research Success and Integrity

Pocatello, ID

Co-sponsors: Idaho State University, Boise State University, Idaho National Laboratory, Portneuf Medical Center, University of Idaho

December 3

"CSI" for Clinical Investigators: Making the Case for Integrity and Examining the Causes of Misconduct in Research

Boston, MA

Co-sponsor: Public Responsibility in Medicine and Research

### **ORI Web Site**

The number of visits to the ORI web site increased by 50 percent from 219,525 in FY 2004 to 330,268 in FY 2005. The web site attracted an average of 10,024 visitors per month, or 120,288 for the year, an increase of 31 percent over FY 2004. Besides the United States, the web site was accessed by visitors from 22 countries compared to 18 countries in FY 2004, an increase of 22 percent. The address for the ORI web site is <http://ori.hhs.gov>

## **Exhibits**

ORI planned to hold exhibits at four scientific meetings in 2005 to promote contact and generate dialogue with members of the biomedical and behavioral research communities. The only exhibit that was held, however, was at the Annual Meeting of the American Society for Microbiology in Atlanta from June 5-9, 2005. The program was suspended when its director took a position elsewhere in the government.

## **Publications**

The *ORI Introduction to the Responsible Conduct of Research* was published in Chinese and Japanese during 2005. The Japanese translation was published by Maruzen Co., Ltd., Tokyo. The text was translated by Shigeaki Yamazaki, Department of Library & Information Science, Aichi Shukutoku University. The Chinese version was translated by Nanyan Cao, who teaches a course on research ethics at Tsinghua University. The booklet was published by Tsinghua University Press.

Over 5,500 copies of the text have been sold since it was published in 2004, and more than 1,000 copies have been downloaded from the ORI web site. The publication is available at <http://ori.hhs.gov> for on-line reading or downloading. More information on ORI publications is at <http://ori.hhs.gov/publications/>

## **Staff Presentations**

**Peter Abbrecht, Medical Expert, DIO**, “Responding to Allegations of Research Misconduct,” a panel presentation at a conference on “Promoting a Productive and Responsible Research Environment,” Sacramento, CA, June 13, 2005.

**Peter Abbrecht, Medical Expert, DIO**, “Reporting Research Misconduct: A Workshop on ORI Clinical Research Vignettes” and “The Research Coordinator: Strategies for Promoting Integrity in Clinical Research,” Bryn Mawr, PA, June 17, 2005.

**Peter Abbrecht, Medical Expert, DIO**, “ORI Case Studies Session,” panel coordinator during a workshop on CSI for Clinical Investigators: Making the Case for Integrity and Examining the Causes of Misconduct in Clinical Research, Boston, MA, December 3, 2005.

**John Dahlberg, Microbiology Expert, DIO**, “Major Misconduct Case: Eric Poehlman, Ph.D., University of Vermont,” at the NIH Regional Seminar on Program Funding and Grants Administration, West Lafayette, IN, June 24, 2005.

**John Dahlberg, Microbiology Expert, DIO**, “Major Misconduct Case: Eric Poehlman, Ph.D.,” at the OIG Invitational Grant Fraud Training hosted by NSF’s Office of Inspector General, Arlington, VA, October 12, 2005.

**Nancy Davidian, Clinical Case Expert, DIO**, “The Office of Research Integrity and Research Misconduct in Clinical Activities,” at Campbell University, Department of Clinical Research, School of Pharmacy, Medical Ethics Class, Durham, NC, March 22, 2005.

**Nancy Davidian, Clinical Case Expert, DIO**, “ORI Clinical Research Misconduct Case Scenarios,” at CSI for Clinical Investigators: Making the Case for Integrity and Examining the Causes of Misconduct in Clinical Research, Boston, MA, December 3, 2005.

**Nancy Davidian, Clinical Case, Expert, DIO**, “The Role of the IRB Administrator Versus the Research Integrity Officer in Handling Allegations of Misconduct in Clinical Research,” panel presentation at the annual meeting of the Physicians for Responsibility in Medicine and Research, Boston, MA, December 4, 2005.

**Kay Fields, Scientist/Investigator, DIO**, “Publication Practices,” at a meeting on Enhancing Integrity Throughout Research: A Summit on Publication Practices, Responsible Authorship, Manuscript Content and the Peer Review Process, sponsored by American Speech-Language- Hearing Association and American Association of Medical Colleges, Rockville, MD, September 22, 2005.

**Kay Fields, Scientist/Investigator, DIO**, “Promoting Research Integrity: The Role of the Office of Research Integrity in Education,” presentation at the Dialogs Meeting of the Council on Undergraduate Research, Arlington, VA, April 18, 2005.

**John Krueger, Scientist/Investigator, DIO**, “Digital Manipulation of Images in Research and Scientific Misconduct,” Drake University, Des Moines, IO, March 3, 2005.

**John Krueger, Scientist/Investigator, DIO**, “Digital Manipulation of Images in Research and Scientific Misconduct,” Iowa State University, Ames, IO, March 4, 2005.

**John Krueger, Scientist/Investigator, DIO**, “Where Responsible Conduct of Research Meets Scientific Misconduct,” Iowa Health, Des Moines, IO, March 4, 2005.

**Samuel Merrill, Scientist/Investigator, DIO**, “The Role of the Office of Research Integrity and Clinical Misconduct Case Scenarios,” The Research Coordinator: Strategies for Promoting Integrity in Clinical Research, Bryn Mawr, PA, June 16, 2005.

**Samuel Merrill, Scientist/Investigator, DIO**, “Enhancing Integrity in Clinical Research and Comprehending Research Misconduct and Malfeasance,” panel presentation at the Endocrine Society Annual Meeting, San Diego, CA, June 3, 2005.

**Chris B. Pascal, Director, ORI**, “Common Compliance Issues for ORI” and “Overview of Compliance Activities: Relationships with OHRP, FDA,” Secretary’s Advisory Committee on Human Research Protections (SACHRP), Alexandria, VA, February 1, 2005.

**Chris B. Pascal, Director, ORI**, “The Federal Definition and Policies on Research Misconduct: Revised PHS Misconduct Regulations,” “Preview of RCR Educational Products,” and “Major Misconduct Case: Eric Poehlman, Ph.D., University of Vermont,” NIH Regional Seminar on Program Funding and Grants Administration, University of New Mexico, Albuquerque, NM, April 6-8, 2005.

**Chris B. Pascal, Director, ORI**, “ORI Views on Conflict of Interest—Why Does It Matter,” “Preview of RCR Educational Products,” and “Research Integrity,” OHRP, Protection of Human Subjects Conference, The Critical Path to New Medical Products: The Challenges in Protecting Human Subjects, Houston, TX, April 20-23, 2005.

**Chris B. Pascal, Director, ORI**, “Research Misconduct” and “Research Integrity,” NIH Extramural Scientist Administrator Seminar Series, Bethesda, MD, April 23, 2005.

**Chris B. Pascal, Director, ORI**, “Major Misconduct Case: Eric Poehlman, Ph.D. University of Vermont” and “Institutional Standards and Research Accountability: Misconduct, Protection of Human Subjects, and More,” St. Vincent Hospital Research Symposium, Indianapolis, IN, May 17-18, 2005.

**Chris B. Pascal, Director, ORI**, “Research Misconduct” and “Managing Data for Integrity,” The Responsible Conduct of Basic and Clinical Research, Warsaw, Poland, June 3-4, 2005.

**Chris B. Pascal, Director, ORI**, “Setting the Stage: What is Misconduct? What is Integrity?,” “New Research Misconduct Regulations, 42 CFR Part 93,” “Federal Oversight and Resolutions—What is the Role of the Federal Government,” and “Legal Issues in Research Integrity,” Promoting a Productive and Responsible Research Environment, Sacramento, CA, June 13-15, 2005.



**Chris B. Pascal, Director, ORI**, “Research Misconduct Case Studies” and “Research Integrity,” Office for Human Research Protections National Human Subjects Protections Conference, Protecting Human Subjects in a Changing Research Environment, Youngstown, OH, August 15-16, 2005.

**Chris B. Pascal, Director, ORI**, “Research Misconduct, RCR Education, and Research Program on Integrity,” TIES Conference, Aspen, CO, October 3-4, 2005.

**Chris B. Pascal, Director, ORI**, “Research Integrity” and “Mentoring and Training of Young Scientists,” Responsible Conduct of Research: Essentials for Research Success and Integrity, Pocatello, ID, October 20-21, 2005.

**Chris B. Pascal, Director, ORI**, “ORI Update: New Misconduct Regulations and Current Activities in Promoting the Responsible Conduct of Research,” In the Public Interest: Promoting and Supporting Research, Annual Meeting of the National Council of University Research Administrators, Washington, DC, October 30-November 2, 2005.

**Chris B. Pascal, Director, ORI**, “Research Misconduct” and “Research Integrity,” NIH Extramural Scientist Administrator Seminar Series, Bethesda, MD, November 4, 2005.

**Chris B. Pascal, Director, ORI**, “Ethics in Research,” “Scientific Misconduct,” and “Mentoring: Managing Data for Integrity,” 4th Symposium on Ethics and Integrity in Science and Research, San Juan, Puerto Rico, November 18, 2005.

**Alan Price, Director, DIO**, “How to Protect Yourself from Research Misconduct in Your Laboratory,” a talk at the University of Minnesota workshop on Promoting an Ethical Research Culture, Minneapolis, MN, March 9, 2005.

**Alan Price, Director, DIO**, “ORI and Clinical Research Integrity and Misconduct in Clinical Trials,” a talk at a seminar for clinical research staff at the University of Minnesota Medical School, Minneapolis, MN, March 9, 2005.

**Alan Price, Director, DIO**, “University Compliance with ORI’s Regulations on Misconduct,” a panel talk at the University of Minnesota Workshop on Promoting an Ethical Research Culture, University of Minnesota Medical School, Minneapolis, MN, March 9, 2005.

**Alan Price, Director, DIO**, “The Office of Research Integrity and NIH,” a panel talk for the Extramural Program Staff of the National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, May 11, 2005.

**Alan Price, Director, DIO**, “Clinical Research Misconduct and the Role of the Institutional Review Board (IRB),” a panel talk for the Annual Meeting of the National Association of IRB Managers, Detroit, MI, May 20, 2005.

**Alan Price, Director, DIO**, “Problems in Dealing with Privilege and Tenure Committees in Scientific Misconduct Investigations,” University of California System and Campuses Research Integrity Officers and Counsels, Sacramento, CA, June 12, 2005.

**Alan Price, Director, DIO**, “Responding to Allegations of Research Misconduct,” Promoting a Productive and Responsible Research Environment, Sacramento, CA, June 13, 2005.

**Alan Price, Director, DIO**, “Best Practices in Dealing with Inquiry and Investigation Committees,” Promoting a Productive and Responsible Research Environment, Sacramento, CA, June 13, 2005.

**Alan Price, Director, DIO**, “The Office of Research Integrity’s Findings of Plagiarism,” Plagiarism Across the Science Disciplines: An Exploration of the Parameters of Plagiarism in Scholarly and Scientific Publications, New York City, NY, October 1, 2005.

**Alan Price, Director, DIO**, “Research Misconduct: Highlights of Trends and Preventing Research Misconduct in the Laboratory,” Responsible Conduct of Research: Essentials for Research Success and Integrity, Pocatello, ID, October 20, 2005.

**Alan Price, Director, DIO**, “Curbstoning: Research Misconduct in Survey Research,” Responsible Conduct of Research: Essentials for Research Success and Integrity, Pocatello, ID, October 20, 2005.

**Alan Price, Director, DIO**, “The Office of Research Integrity and NIH,” a panel talk for the Extramural Program Staff of the National Center for Research Resources, NIH, Bethesda, MD, October 28, 2005.

**Alan Price, Director, DIO**, “ORI and Integrity in Clinical Research,” CSI for Clinical Investigators: Making the Case for Integrity and Examining the Causes of Misconduct in Research, Boston, MA, December 3, 2005.

**Alan Price, Director, DIO**, “Clinical Research Misconduct and the Role of the IRB,” Annual Meeting of the Physicians for Responsibility in Medicine and Research in Boston, MA, December 4, 2005.

**Lawrence J. Rhoades, Director, DEI**, “Plagiarism: A Concept Needing Explication,” Plagiarism Across the Science Disciplines: An Exploration of the Parameters of Scholarly and Scientific Publications, New York, NY, October 1, 2005.

**Lawrence J. Rhoades, Director, DEI**, “PHS Policies on Research Misconduct,” a meeting of the Native American Research Centers for Health Program, Rockville, MD, November 9, 2005.

**Mary D. Scheetz, Director, Extramural Research, DEI**, “Research on Research Integrity Grant Program Update,” Annual Meeting of the American Association of State Colleges and Universities, Washington, DC, March 22, 2005.

**Mary D. Scheetz, Director, Extramural Research, DEI**, “Enhancing Integrity Throughout Research: A Summit on Publication Practices, Responsible Authorship, Manuscript Content, and the Peer Review Process,” American Speech-Language-Hearing Association/American Association of Medical Colleges Joint Meeting, Rockville, MD, September 23, 2005.

**Mary D. Scheetz, Director, Extramural Research, DEI**, “Authorship and Publication Practices: Review and Updates.” Responsible Conduct of Research: Essentials for Research Success and Integrity, Pocatello, ID, October 20, 2005.

**Mary D. Scheetz, Director, Extramural Research, DEI**, “Research on Research Integrity,” Responsible Conduct of Research: Essentials for Research Success and Integrity, Pocatello, ID, October 21, 2005.

**Nicholas H. Steneck, Consultant**, “The Ethics of Research Integrity,” Responsible Conduct in Research Luncheon Series, Arizona State University, January 27, 2005.

**Nicholas H. Steneck, Consultant**, “Lunch with Author, ORI Introduction to the Responsible Conduct of Research,” Annual Meeting, Association for Professional and Practical Ethics, San Antonio, TX, February 25, 2005.

**Nicholas H. Steneck, Consultant**, “Ethics, Evaluation, and IRB: Challenges Created by Internet Technology,” Annual Meeting, the Eastern Evaluation Research Society, Absecon, NJ, April 19, 2005.

**Nicholas H. Steneck, Consultant**, “The Office of Research Integrity and the Responsible Conduct of Research,” Faculty and Administrator’s Network Sessions, National Conference on Undergraduate Research, Lexington, VA, April 21, 2005.

**Nicholas H. Steneck, Consultant**, “What Constitutes Responsible Conduct of Research?” The Responsible Conduct of Basic and Clinical Research, Warsaw, Poland, June 3-4, 2005.

**Nicholas H. Steneck, Consultant**, “Establishing an RCR Program,” The Responsible Conduct of Basic and Clinical Research, Warsaw, Poland, June 3-4, 2005.

**Nicholas H. Steneck, Consultant**, “ORI, RCR and Graduate Education,” Council of Graduate Schools Summer Workshop, Santa Fe, NM, July 12, 2005.

**Nicholas H. Steneck, Consultant**, “Responsible Conduct of Research: An Overview of the Nine Core Areas,” Responsible Conduct of Research: Essentials for Research Success and Integrity, Pocatello, ID, October 20-21, 2005.

**Nicholas H. Steneck, Consultant**, “Commentary: Research Ethics and Ethical Issues: Five Ways to Promote Responsible Research Through Graduate Education,” International Conference on Challenges to Innovation in Graduate Education, Toronto, Canada, November 5, 2005.

**Sandra Titus, Director, Intramural Research Program, DEI**, “Research Integrity Methods Reported by 3000 Principal Investigators,” Mentoring and Human Subjects’ Protection, Little Rock, AR, August 4, 2005.

**Sandra Titus, Director, Intramural Research Program, DEI**, “Research Integrity,” Howard University, Washington, DC, October 19, 2005.

**David E. Wright, Consultant**, “Misconduct in Clinical Research,” National Association of IRB Managers, Annual Meeting, Detroit, MI, May 20, 2005.

**David E. Wright, Consultant**, “Peer Review of Research: Current Issues, Best Practices and a Case of Abuse,” The Responsible Conduct of Basic and Clinical Research, Warsaw, Poland, June 3-4, 2005.

**David E. Wright, Consultant**, “The Research Integrity Officer: Evolution of Roles and Responsibilities,” Promoting a Productive and Responsible Research Environment, Sacramento, CA, June 13-14, 2005.

**David E. Wright, Consultant**, “Responding to Allegations of Misconduct in Research: Best Practices and Practices to Avoid,” Promoting a Productive and Responsible Research Environment,” Sacramento, CA, June 13-14, 2005.

**David Wright, Consultant, Jered C. Cornelison, Michigan State University, Sandra L. Titus, Ph.D., Director, Intramural Research Program, DEI**, “Mentoring and Research Misconduct: An Analysis of ORI Closed Cases,” Mentoring and Human Subjects’ Protection, Little Rock, AR, August 4, 2005.

**David Wright, Consultant, and Jered C. Cornelison, Michigan State University,**  
“Investigating Plagiarism in the Age of Electronic Publishing: Challenges for  
Research Integrity Officers,” *Plagiarism Across the Science Disciplines: An  
Exploration of the Parameters of Scholarly and Scientific Publications*,  
New York, NY, October 1, 2005.

**Federal Register Notices - Scientific Misconduct**

- 1) Findings of Scientific Misconduct Notice. 70 Fed. Reg. 12490-12491  
(March 14, 2005) (Gary M. Kammer)
- 2) Findings of Scientific Misconduct Notice. 70 Fed. Reg. 15092-15095  
(March 24, 2005) (Eric T. Poehlman)
- 3) Findings of Scientific Misconduct Notice. 70 Fed. Reg. 32619-32620)  
(June 3, 2005) (Jason W. Lilly)
- 4) Findings of Scientific Misconduct Notice. 70 Fed. Reg. 46525  
(August 10, 2005) (Randall Luce)
- 5) Findings of Scientific Misconduct Notice. 70 Fed. Reg. 61443  
(October 24, 2005) (Xiaowu Li)
- 6) Findings of Scientific Misconduct Notice. 70 Fed. Reg. 75174-75175  
(December 19, 2005) (Jessica Lee Grol)
- 7) Findings of Scientific Misconduct Notice. 71 Fed. Reg. 119-120  
(January 3, 2006) (Hans E. Geisler)
- 8) Findings of Scientific Misconduct Notice. 71 Fed. Reg. 120  
(January 3, 2006) (Ralph A. Highshaw)

**Other Federal Register Notices**

- 1) Public Health Service Policies on Research Misconduct: Final Rule. 70 Fed.  
Reg. 28369-28400 (May 17, 2005)



### III. RESEARCH ON RESEARCH INTEGRITY AND RESEARCH MISCONDUCT

#### **Intramural Research Program**

The intramural research program within ORI focuses on research that examines how institutions handle cases of misconduct and/or promote research integrity. The studies, primarily descriptive, are done under contract with research organizations or ORI staff. Funding is provided by HHS or ORI. Information on completed studies and studies in progress is at <http://ori.hhs.gov/research/intra/index.shtml>. The intramural research program also works with extramural researchers who are interested in analyzing data that are available in ORI databases or case files. There are currently four studies in progress and one proposed study.

#### Studies in Progress

##### *Reporting Suspected Research Misconduct in Biomedical and Behavioral Research*

This study, conducted by The Gallup Organization, is aimed at estimating the frequency at which suspected research misconduct is observed and reported in biomedical and behavioral research. The questionnaire was sent to over 4,000 scientists supported by NIH in 2005. 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 Policies on Research Misconduct (42 C.F.R. Part 93). 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. 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 organizations. The study is expected to be completed in 2007.

##### *Institutional Role in Promoting Research Mentoring*

This study, conducted by the RAND Corporation, is examining the institutional infrastructure and support provided for mentoring research trainees. Data will be collected from multiple levels in 10 medical schools: deans, department chairs, faculty, and trainees. The study will focus on the policies and procedures for selecting, replacing, training, evaluating, and rewarding mentors. This study is expected to be completed in 2007.

*Misconduct by Graduate Students and Postdocs: Where Was the Mentor?*

ORI staff is analyzing 60 research misconduct cases involving graduate students and postdocs to determine what type of relationship the respondents had with their mentor/advisor. The case files are being examined to determine whether mentors/advisors supervised and examined original data. Other variables being examined are whether the respondent was under any stress to meet a deadline, and whether the laboratory had difficult interpersonal behaviors. The study is expected to be completed in 2006.

Proposed Research

*Evaluating the Effectiveness of Institutional Efforts to Educate Their Staffs on Their Policies for Dealing with Research Misconduct.*

This study will evaluate the efforts made by institutions to educate their staffs about the PHS Policies on Research Misconduct (42 C.F.R. Part 93). The study will be done in two phases. First, institutional officials will be interviewed about the steps they have taken to promulgate their institutional policy for responding to research misconduct allegations within their institution. Second, self-administered questionnaires will be sent to staff members to determine what they know about their institution's policy.

**Extramural Research Program - Research on Research Integrity (RRI)**

ORI established its extramural research program, RRI, in 2000 in collaboration with the National Institute of Neurological Disorders and Stroke (NINDS). First awards were made in 2001. Since then, the National Institute of Nursing Research (NINR), the National Institute on Drug Abuse (NIDA), and the Agency for Healthcare Research and Quality (AHRQ) have signed on to the request for applications (RFA).

Two new institutes, the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and the National Cancer Institute (NCI), joined the RFA in 2005. Two institutes, the National Heart, Lung and Blood Institute (NHLBI) and the National Institute on Alcohol Abuse and Alcoholism (NIAAA) provided funds for the first time. The research integrity grant program was created to foster empirical research on societal, organizational, group, and individual factors that affect, both positively and negatively, integrity in research. More information on the extramural research program is at <http://ori.hhs.gov/research/extra/index.shtml>



### Research on Research Integrity (RRI) Program

Seven awards were made by the RRI program in 2005, increasing the number of studies supported in the first 5 years to 34. Award abstracts are posted at <http://ori.hhs.gov/research/extra/award.shtml>

The program received 46 applications in 2005, the second highest application total in the history of the program. The funding rate was 15.3 percent. Maximum direct costs were \$175,000 per year; the project period was 3 years.

ORI funded four grants; NINR funded one grant and two new partners, the NHLBI and NIAAA, each funded a grant.

Funding for continuation awards was provided by NINR and ORI. Total funding for the round (new and continuations) totaled \$2.59 million, the highest level of funding since the program began in 2001. ORI provided \$1.82 million for the fifth round; NINR provided \$335,301; NHLBI \$249,309, and NIAAA provided \$181,875.

Grant titles, principal investigators, and institutions for the 2005 awards follow:

*Mentoring the Responsible Conduct of Research*  
Celia B. Fisher, Fordham University

*Procedural Justice, Identity, and Research Integrity*  
Brian Martinson, Health Partners Research Foundation

*Evaluation of the Quality of Clinical Trials*  
Benjamin Djulbegovic, Moffitt Cancer Center

*Data Analysis Practices in Drug Prevention Evaluation*  
Dennis Gorman, Texas A&M University

*A Collegial Defense Against Irresponsible Science*  
Gerald Koocher, Simmons College

*Looking into Common Daily Practices of Gene Therapy Clinical Research*  
Gwen Anderson, San Diego State University

*Research Extenders and Research Integrity*  
Leslie Alexander, Bryn Mawr College

### RRI Publications

Researchers supported by the RRI Program published eight articles, a commentary, and a literature review in seven journals including the *New England Journal of Medicine*, *Nature*, *the Journal of the American Medical Association (JAMA)*, and the *British Medical Journal* in 2005.

In the first 4 years of the program, RRI researchers have published 18 articles, 7 abstracts, a commentary, 2 reviews, and a letter to the editor. A complete list of RRI publications is at [http://ori.hhs.gov/research/rri\\_publications.shtml](http://ori.hhs.gov/research/rri_publications.shtml)

Barrett KA, Funk CL, and Macrina FL. "Awareness of Publication Guidelines and the Responsible Conduct of Research." *Accountability in Research* 2005; 2:193-206.

Gardner W, Lidz CW, and Hartwig KC. "Authors' Reports about Research Integrity Problems in Clinical Trials." *Contemporary Clinical Trials* 2005; 26(2):244-251.

Heitman E, Bulger RA. "Assessing the Educational Literature in the Responsible Conduct of Research for Core Content." *Accountability in Research* 2005; 12:207-224.

Keith-Spiegel P, Koocher GP. "The IRB Paradox: Could the Protectors also Encourage Deceit?" *Ethics and Behavior* 2005; 15(4): 339-349.

Kumar A, Soares HP, Wells R, Clarke M, Hozo I, Bleyer A, Reaman G, Chalmers I, Djulbegovic B. "What is the Probability That a New Treatment for Cancer in Children Will Be Superior to an Established Treatment? An Observational Study of Randomised Controlled Trials Conducted by the Children's Oncology Group." *British Medical Journal* 2005; 331:1295-1298.

Martinson BC, Anderson MS, DeVries R. "Scientists Behaving Badly." *Nature* 2005; 435:737-738.

Mello MM, Clarridge B, Studdert DM. "Academic Medical Centers' Standards for Clinical Trial Agreements with Industry." *New England Journal of Medicine* 2005; 352: 2202-2210.

Mello MM, Clarridge BR, Studdert DM. "Researchers' Views of the Acceptability of Restrictive Provisions in Clinical Trial Agreements with Industry Sponsors." *Accountability in Research*. 2005: 12:163-191.

Soares HP, Kumar A, Daniels S, Swann S, Cantor A, Hozo I, Clark M, Serdarevic F, Gwede C, Trotti A, and Djulbegovic B. "Evaluation of New Treatments in Radiation Oncology: Are They Better Than Standard Treatments." *JAMA* 2005; 293(8): 970-978.

Wright MC, Taekman JM, Barber L, Hobbs G, Newman MF, Stafford-Smith M. "The Use of High-fidelity Human Patient Simulation as an Evaluative Tool in the Development of Clinical Research Protocols and Procedures." *Contemporary Clinical Trials* 2005; 26(6):646-659.

Research Conference on Research Integrity - 2006

Planning began for the fourth biennial Research Conference on Research Integrity that will be held at the Safety Harbor Resort, Tampa, Florida, on December 1-3, 2006. The 2006 conference is being co-hosted by the University of South Florida College of Medicine, and co-sponsored by the American Association for the Advancement of Science and the Association of American Medical Colleges. Research will be 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), mentoring, and responsible conduct of research education. Several presentations will report findings from the RRI Program. A growing body of international research on research integrity will also be represented.



## IV. INSTITUTIONAL COMPLIANCE

The PHS regulation on misconduct in science (42 C.F.R. Part 93) places several requirements on institutions receiving funds under the PHS Act. ORI monitors institutional compliance with these regulatory requirements through two DEI programs, the Assurance Program and the Compliance Review Program.

### **Assurance Program**

The Assurance Program is responsible for ensuring that PHS research funds are only awarded to eligible institutions. An institution is eligible when it has an active assurance on file with ORI stating that it has developed and will comply with an administrative process for responding to allegations of scientific misconduct in PHS supported research that complies with the PHS regulation. An institution establishes an assurance by filing an initial assurance form or by 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 4,500 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 21 during 2005 to 4,451 (see Table 8). Four hundred and sixty-four institutions were added to the assurance database; 444 had filed their initial assurance and 20 reestablished their assurance by submitting their Annual Report on Possible Research Misconduct for 2003 and 2004. Four hundred and forty-three assurances were inactivated, 377 for failing to submit their Annual Report in 2005, and 66 at the request of the institution or because duplicate records existed.

**Table 8: Number and Type of Institutions With Active Assurances, 2005**

<i>Type of institution</i>	<i>Number</i>	<i>Change</i>
Institutions of Higher Education	970	+17
Research Organizations, Institutes, Foundations, and Laboratories	373	+10
Independent Hospitals	300	+ 6
Educational Organizations, Other Than Higher Education	24	- 1
Other Health, Human Resources, and Environmental Services Organizations	436	+16
Other (small businesses)	2,348	-27
TOTAL	4,451	+21

#### Institutional Misconduct Policy Reviews

ORI completed 207 policy reviews in 2005. Two policy reviews were carried into 2005; another 127 institutional research misconduct policies were requested for review. One hundred and sixty-nine institutional policies were accepted as submitted; 38 others were accepted after revision. Eighty-two reviews were carried into 2006; 4 of these policies are pending review; 16 policies are being revised by institutions; and 62 institutions have not submitted their policies. Since 1995, ORI has reviewed 2,355 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 2004 Annual Report began in January 2005 for the 4,430 institutions that had an assurance on file with ORI as of December 31, 2004.

Completed Annual Reports were received from 3,928 institutions for a response rate of 87 percent. ORI inactivated 443 assurances, including 377 institutions that did not return their Annual Reports by the March 31 deadline. Many assurances were reactivated later because Annual Reports were submitted after the due date.

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

One hundred and one institutions reported starting or continuing research misconduct activity in their 2004 reports; 63 institutions reported opening new cases; and institutions reported receiving 120 new allegations and opening 81 new cases (see Table 9).

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

The 101 institutions that reported research misconduct activity resulting from allegations received during or prior to 2004 conducted 111 inquiries and 52 investigations in 2004.

Sixty-three of the 101 institutions reported opening 81 new cases in 2004 upon receipt of 120 allegations. Institutions received 48 allegations of falsification; 22 of plagiarism; 36 of fabrications; and 14 others. These allegations resulted in 76 inquiries and 26 investigations in 2004.

Institutions reporting new cases included higher education, 47; research organizations, 10; health organizations, 3; independent hospitals, 3; and small businesses, 0.

**Table 9: Research Misconduct Activity: 1993-2004**

<i>Year</i>	<i>Institutions reporting activity</i>	<i>Institutions reporting new cases</i>	<i>New allegations</i>	<i>New cases</i>
2004	101	63	120	81
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 2005, two compliance cases were opened, and three were closed (see Table 10).



**Table 10: Summary of Compliance Cases, 2005**

<i>Case type</i>	<i>Forwarded from 2004</i>	<i>Opened in 2005</i>	<i>Closed in 2005</i>	<i>Carried into 2006</i>
Compliance	4	2	3	3

### *Institutional Handling of Allegations*

The three closed compliance cases involved the institutional handling of allegations and retaliation complaints. Site visits were conducted at two institutions.

### Treatment of Complainant and Witness

This case involved possible retaliation against two individuals, the complainant as well as an individual who served only as a witness in the institutional misconduct process. The complainant claimed that institutional officials attempted to improperly remove him as the Principal Investigator (PI) on an NIH grant in retaliation for his role in raising the misconduct allegations. Although the institutional officials provided some documentation in support of their actions, this request for his removal was rejected by NIH on technical grounds, and no further attempt was made to remove him. The witness in this case claimed that in response to his support of the complainant in this case, he was informed by institutional officials that he would no longer serve as the chairman of his department. Institutional officials did provide documentation in support of their decision, but this action to remove him as the chair was postponed pending the completion of an institutional investigation of his retaliation complaint, which was initiated in response to a request by ORI. ORI reviewed the subsequent report, and determined that the institution substantially followed all the requirements of the ORI Guidelines for the investigation of whistleblower complaints, and therefore was in compliance with the requirements of the PHS regulation. No further action on the part of the institution was requested.

### Shortcomings in Investigating Allegation

This case involved a compliance site visit by ORI staff to discuss potentially significant shortcomings in the handling of an investigation by this institution. The issues of concern included, among other things, the failure to (1) sequester evidence in a timely manner, (2) request additional information from the complainant, (3) conduct a detailed analysis of evidence, and (4) have appropriate scientific expertise in assessing allegations and analyzing evidence. ORI staff was satisfied with the responsive statements made by institutional officials clearly indicating their commitment to addressing these issues in future cases that arise at that institution.

### Unacceptable Delay in Completing an Investigation

This case also involved a compliance site visit by ORI staff to inquire about the unacceptable delay in the completion of an investigation involving possible falsification of survey data. Because institutional officials initially considered this a criminal case because of possible fraudulent participant reimbursements, the scientific misconduct issues were not initially addressed in a timely manner, as required by both the federal regulation as well as the institutional misconduct policy and procedures. In addition, the designated research misconduct officer at this institution repeatedly failed to provide requested information to ORI regarding the conduct of a misconduct investigation. At the completion of this site visit, ORI staff received assurances that the institution would pursue, through its police department, the necessary information needed to complete the process for ORI. To date, this information has not been received.

### 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 PHS unless a PHS administrative action imposed on them specifically requires it.

On January 1, 2005, ORI listed the names of 61 individuals in the ALERT system. During the year, ORI added 12 names and removed 14. On December 31, 2005, the names of 59 individuals were in the system (see Table 11).

ORI added 12 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 four names were removed when ORI did not recommend a finding of scientific misconduct after reviewing an institutional misconduct investigation report.

Of the 59 names in the system at year end, 37 individuals had PHS administrative actions imposed, and 22 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, 2005**

	Total
As of January 1, 2005	61
Additions	12
Action Expired/Removed	14
As of December 31, 2005	59

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/misconduct/admin\\_actions.shtml](http://ori.dhhs.gov/misconduct/admin_actions.shtml)

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 40 FOIA requests in 2005; 38 were closed. In 2004, ORI received 43 requests; 35 were closed.
- ORI received and closed one Privacy Act request in 2005. In 2004, ORI received and responded to two Privacy Act requests.

### 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 that was published in the *Federal Register* on January 6, 1995 (60 Fed. Reg. 2140). However, these records are specifically exempted from express provisions of the Privacy Act regarding notification, access, and correction and amendment of records requests by the subject of the records. Nonetheless, each request for access

is reviewed on a case-by-case basis. Additionally, if the 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 – 2005

**Hans E. Geisler, M.D., Saint Vincent Hospital and Health Care Center:** Based on the report of an inquiry and investigation conducted by Saint Vincent Hospital (SVH) in Indianapolis, Indiana, and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Hans E. Geisler, M.D., former Staff Physician and Principal Investigator for SVH's studies under the Gynecologic Oncology Group (GOC), engaged in research misconduct by soliciting a pathologist to falsify the originally correct tissue-type on the pathology report (omentum) as being another type (ovary) and submitting the falsified report to the GOG group member at the University of Iowa, in order to justify enrollment of a patient in GOG clinical protocol 182. The questioned research was supported by National Institutes of Health (NIH) funds to the University of Iowa through the American Society for Obstetrics and Gynecology under cooperative agreement U10 CA27469.

Dr. Geisler has entered into a Voluntary Exclusion Agreement (Agreement ) in which he has voluntarily agreed, for a period of three (3) years, beginning on December 2, 2005: (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 consultant; and (2) that any institution which uses the respondent in any capacity on PHS-supported research, or that submits an application for PHS support for a research project on which the respondent's participation is proposed or submits a report of PHS-funded research in which the respondent's participation is continuing, 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. A copy of the supervisory plan must also be 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 ORI. Respondent disagrees with the ORI finding set forth herein but executes this Agreement to avoid further proceedings and bring this matter to a close. The execution of this Agreement shall not be deemed an admission to the charge of scientific misconduct by the respondent.

**Jessica Lee Grol, University of Pittsburgh:** Based on the report of an investigation conducted by the University of Pittsburgh (UP) and additional analysis conducted by ORI in its oversight review, HHS found on October 17, 2005, that Ms. Grol, former Research Project Coordinator, Department of Neurological Surgery, UP, engaged in scientific misconduct by fabricating study research records for 15 subjects, including the patient interview data, the forms tracking data, and the medical record extraction data, in a study on the management of cerebral aneurysms. The research was supported by National Institute of Neurological Disorders and Stroke (NINDS),

National Institutes of Health (NIH), career development award K23 NS02159. In a final decision dated November 23, 2005, the HHS Debarring Official, on behalf of the Secretary of HHS, issued the final debarment notice based on the PHS findings of scientific misconduct finding. The following actions have been implemented for a period of three (3) years, beginning on November 23, 2005: (1) Ms. Grol has been debarred from any contracting or subcontracting with any agency of the U.S. government and from eligibility for or involvement in non-procurement programs of the U.S. government as defined in the debarment regulations at 45 C.F.R. Part 76; and (2) Ms. Grol is prohibited 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.

**Ralph A. Highshaw, M.D., M.D. Anderson Cancer Center:** Based on the report of an investigation conducted by the M.D. Anderson Cancer Center (MDACC) and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Ralph A. Highshaw, M.D., Fellow, Department of Urologic Surgery, MDACC, engaged in scientific misconduct while supported by National Cancer Institute (NCI), National Institutes of Health (NIH), postdoctoral training grant T32 CA079449-01A1. Specifically, PHS found that Dr. Highshaw engaged in scientific misconduct by plagiarizing 9 pages of a 21-page expert review article, entitled “Chemoprevention of Urologic Cancer.”

Dr. Highshaw has entered into a Voluntary Exclusion Agreement (Agreement) in which he has voluntarily agreed, for a period of three (3) years, beginning on December 12, 2005: (1) that he is required to certify in every PHS research application or report, and any other text, article, or manuscript, that all contributors are properly cited or otherwise acknowledged; the certification by the respondent must be endorsed by an institutional official, and a copy of the certification is to be sent to ORI by the institution; (2) to ensure that any institution employing him submits, in conjunction with each application for PHS funds, annual reports, manuscripts, or abstracts of PHS-funded research in which the respondent is involved, a certification that the data provided by the respondent are based on actual experiments or are otherwise legitimately derived, and that the data, procedures, and methodology are accurately reported in the application or report; the respondent must ensure that the institution also sends a copy of the certification to ORI; and (3) 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 consultant.

**Gary M. Kammer, M.D., Wake Forest University:** Based on the Wake Forest University (WFU) Investigation Report, the respondent’s admission, and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Gary M. Kammer, M.D., former Professor, Division of



Rheumatology, Department of Internal Medicine, and Department of Microbiology and Immunology at the WFU School of Medicine, engaged in scientific misconduct by falsification and fabrication of research in grant application 2 R01 AR39501-12A1, “T Lymphocyte Dysfunction in Lupus Erythematosus,” submitted to the National Institute of Arthritis and Musculoskeletal Skin Diseases (NIAMS), National Institutes of Health (NIH), and in 1 R01 AI46526-01A2, “Protein Kinase A-II in the Pathogenesis of Lupus,” submitted to the National Institute of Allergy and Infectious Diseases (NIAID), NIH. Specifically, PHS found that:

- the respondent fabricated Families 2 and 3 in Figure 6 and related text in application 2 R01 AR39501-12A1 (pp. 29-30), entitled “T Lymphocyte Dysfunction in Lupus Erythematosus”) by:
  - a. making up both of the pedigrees,
  - b. fabricating 13 PKA-I and 13 PKA-II values for these non-existent affected and unaffected family members, and
  - c. composing the false text describing these two fabricated families.
- the respondent falsified the text describing the results in Figure 20 (“Inhibition of c-fos luciferase activity in S49 T cells transiently transfected with pIRES2-RIIb-EGFP and treated with 8-Cl-cAMP”) in application 1 R01 AI46526-01A2 (p. 27), by falsely reporting N = 4, P less than 0.002, when the experiment had been performed only one time at the time that the application was submitted.

PHS also concluded that the respondent further demonstrated a lack of present responsibility as a Principal Investigator by submitting NIH grant proposals with additional unsupported experimental results:

- The pedigree and data for the family reported in grant application 2 R01 AR39501-12 and for Family 1 in grant application 2 R01 AR39501-12A1 are incorrect, and the data pertaining to this family that Dr. Kammer subsequently provided to WFU after the inquiry were not the data reported in the applications. Dr. Kammer stated that he did not recall who in his laboratory gave him this pedigree. ORI noted that the actual PKA data for the “proof-of-principle” family, while suggesting that low PKA values may be hereditary (the presence of low PKA-I values in three generations), do not support the claims of the fabricated and mixed-up pedigree and data that show that low PKA-I values were associated with Systemic Lupus Erythematosus (SLE) (application 2R01 AR39501-12).

- In application, R01 AI39501-12A1, the following unsupported statement was also included: “In both normal and disease controls, all T cells express CD59+ and there is no significant difference in its cell surface expression on CD4+,CD45RA+, CD4+,CD45RO+, CD8+,CD45RA+, CD8+,CD45RO+ subsets (n=4 each control group; data not shown).” No data could be produced to support the information in the grant application about these control experiments.

Dr. Kammer has entered into a Voluntary Exclusion Agreement (Agreement ) in which he has voluntarily agreed for a period of three (3) years, beginning on February 15, 2005: (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) to exclude himself from any contracting or subcontracting with any agency of the U.S. government and from eligibility or involvement in non-procurement programs of the U.S. government referred to as “covered transactions” as defined in the debarment regulations at 45 C.F.R. Part 76. This voluntary exclusion precludes the respondent from receiving federal research, research training, or other research-related funds from the federal government for three (3) years, but shall not apply to the respondent’s participation in a federal health care program as defined in section 1128B(f) of the Social Security Act and shall not apply to federal funds used solely for purposes of teaching or training medical students, residents, or fellows in clinical medical matters.

**Xiaowu Li, M.D., Ph.D., The University of California at San Francisco:** On September 16, 2005, the U.S. Public Health Service (PHS) entered into a Voluntary Exclusion Agreement with the University of California at San Francisco (UCSF) and Xiaowu Li, M.D., Ph.D., former postdoctoral fellow at UCSF. Based on the UCSF report and additional analysis conducted by ORI in its oversight review, PHS found that Dr. Li engaged in scientific misconduct in reporting research supported by grants P01 DE13904, “Adhesion and proliferation in oral cancer progression”; R01 DE12856, “Oral melanoma alpha v beta 3 expression and metastasis”; and R01 DE011930, “Regulatory function of fyn in oral SCC invasion,” all funded by the National Institute of Dental and Craniofacial Research (NIDCR), National Institutes of Health (NIH). Specifically, PHS found that Dr. Li falsified three images in Figure 5B of a paper, “Laminin-5 promotes cell motility by regulating the function of the integrin  $\alpha_6_1$  in pancreatic cancer,” published online in *Carcinogenesis Advance Access*, reporting studies on the role of integrin  $\alpha_6_1$  and laminin on the invasiveness of pancreatic cancer cells and their ability to metastasize. In all three images, mouse melanoma cells were falsely represented as being human pancreatic carcinoma cells; the cancer cells were falsely represented as having been plated on medium with laminin-1, whereas they were in fact plated on medium with vitronectin; and for two of the three images, the cancer cells were falsely represented as having been stained with anti-integrin  $\alpha_1$ , whereas they were actually stained with anti-integrin  $\alpha_3$ .

The misconduct was significant because pancreatic cancer has a poor prognosis for patients, because it tends to invade other tissues and to metastasize early in its course. Knowledge of the factors that facilitate cancer cell invasion and metastasis, which was the focus of the questioned figure and paper, is crucial to attempts to develop better treatments for pancreatic and other cancers. Thus, the falsified figure could have misled other investigators in this important area of medical research.

Dr. Li has entered into a Voluntary Exclusion Agreement (Agreement ) in which he has voluntarily agreed, for a period of three (3) years, beginning on September 16, 2005: (1) to exclude himself from any contracting or subcontracting with any agency of the U.S. government and from eligibility or involvement in non-procurement programs of the U.S. government referred to as “covered transactions” as defined in the debarment regulations at 45 C.F.R. Part 76; and (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 consultant.

**Jason W. Lilly, Ph.D., Boyce Thompson Institute:** Based on the report of an investigation conducted by the Boyce Thompson Institute (BTI Report), the investigation report of another federal agency, and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Jason W. Lilly, Ph.D., postdoctoral fellow at BTI, engaged in scientific misconduct in research supported by the National Research Service Award, National Institutes of Health (NIH) postdoctoral fellowship, F32 GM64276. This case has been jointly handled by ORI and another federal agency under the government-wide debarment regulations. Specifically, PHS found that:

- A. Dr. Lilly falsified Figure 4, presenting a hierarchical cluster analysis of differential mRNA accumulation in cells grown in medium deficient in sulfate or phosphate in “The *Chlamydomonas reinhardtii* organellar genomes respond transcriptionally and post-transcriptionally to abiotic stimuli,” *The Plant Cell* 14:2681:2706, 2002 (hereafter referred to as the *Plant Cell* paper) by claiming it was an average of three experiments when only one had been conducted;
- B. Dr. Lilly further falsified Figure 4 of the *Plant Cell* paper by falsely coloring two cells in the blown-up portion of the figure that illustrated the induction of high levels of mRNA from the *Sac1* gene;
- C. Dr. Lilly falsified the supplemental gene array experiments published online and claimed to be replicate assays by manipulation of both spreadsheet and image data from a single assay to make the altered data sufficiently different to appear to be separate assays;

- D. Dr. Lilly falsified the text describing Figure 5 of the *Plant Cell* paper by claiming that the run-on assays had been replicated when they had not been;
- E. Dr. Lilly falsified the purported replicates of run-on transcription experiments provided in the on-line supplemental material by manipulation of a single assay to make the variant versions appear different; and
- F. Dr. Lilly falsified Figure 1 of the *Plant Cell* paper by using the same 16S control bands for RNA blots of two different genes (psbF and PsalG).

Dr. Lilly has been debarred by the lead agency for a period of two (2) years, beginning on March 4, 2005, and ending on March 4, 2007, and has entered into a Voluntary Exclusion Agreement (Agreement) with PHS in which he has voluntarily agreed: (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 consultant, for a period of four (4) years, beginning on April 18, 2005; and (2) that he will ensure that any institution employing him submits, in conjunction with each application for PHS funds or report, manuscript, or abstract of PHS-funded research in which Dr. Lilly is involved, a certification that the data provided by Dr. Lilly are based on actual experiments or are otherwise legitimately derived, and that the data, procedures, and methodology are accurately reported in the application or report for a period of two (2) years, beginning on April 18, 2007, approximately corresponding to the termination date of the debarment period initiated by another federal agency. Dr. Lilly must ensure that the institution also sends a copy of the certification to ORI.

**Randall Luce, University at Buffalo, State University of New York:** Based on the report of an investigation conducted by the University of Buffalo (UB), State University of New York (SUNY) (UB Report), and a conviction of the criminal offense of grand larceny, as defined in section 110-155.30 of the New York Penal Law, in the Buffalo City Court of Erie County, State of New York (Case #2004ER009612M), the Department of Health and Human Services (HHS) debarred Mr. Randall Luce, former research technician in the UB Research Institute for Addictions (RIA), for a period of three (3) years, beginning on July 26, 2005, and ending on July 25, 2008. Mr. Luce pled guilty to grand larceny and admitted to the misappropriation of funds and the fabrication of research subject interviews in the conduct of an RIA study supported by U.S. Public Health Service (PHS), National Institutes of Health (NIH), National Institute on Alcohol Abuse and Alcoholism (NIAAA) grant RO1 AA12452, "A harm reduction approach for reducing DWI recidivism." This action is taken pursuant to the HHS non-procurement debarment and suspension regulation at 45 C.F.R. Part 76.

**Eric T. Poehlman, Ph.D., University of Vermont:** Based on the report of an investigation conducted by the University of Vermont (Report), admissions made by the respondent, and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Eric T. Poehlman, Ph.D., former Professor, Department of Medicine at the University of Vermont College of Medicine, engaged in scientific misconduct in research. The research was supported by National Institutes of Health (NIH) grants from the National Institute of Aging (NIA), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and the National Center for Research Resources (NCRR). Specifically, PHS found that the respondent is responsible for scientific misconduct by engaging in the misleading and deceptive practices set forth herein below. The report is available on the ORI web site under Case Summaries.

### **Group 1: Longitudinal study of aging; Protocol 678 and associated Excel spreadsheets**

#### Proposing Research (Report, pp. 22-25)

1. That the respondent falsified preliminary data purportedly obtained in a longitudinal study of aging in NIH grant application 1 R01 AG17906-01, submitted May 27, 1999; specifically, the claim of 130 subjects at visit one (T1) and 70 subjects at visit two (T2), mean values for total energy expenditure (TEE) obtained with a doubly-labeled water technique were falsified; additional parameters such as physical activity energy expenditure (PAEE), resting metabolic rate (RMR), fat-free mass, appendicular skeletal muscle mass, and percent body fat were falsified to show significant trends during the aging process that were not reflective of the actual data (Abstract and pp. 19, 21, 22, 23, 27, 29, 34, 41, 42).
2. That the respondent falsified preliminary data purportedly obtained in a longitudinal study of aging in NIH grant application 1 R01 AG17906-01A1, submitted February 2000, specifically, the claim of 130 subjects at visit one (T1) and 70 subjects at visit two (T2), mean values for total energy expenditure (TEE) obtained with a doubly-labeled water technique were falsified; additional parameters such as physical activity energy expenditure (PAEE), resting metabolic rate (RMR), fat-free mass, appendicular skeletal muscle mass, and percent body fat were falsified to show significant trends during the aging process that were not reflective of the actual data (Abstract and pp. 32, 34, 38, 39, 45, 46).

#### Conducting Research

3. That the respondent systematically falsified a number of metabolic and physical measures of subjects in the longitudinal study of aging; these

falsifications of specific types of data in the Protocol 678 spreadsheet commenced immediately after he assigned responsibility for maintenance of the data to a young technician and simultaneously arranged to have personal access to the data; his widespread alteration of data in specific fields has been detected in a number of different versions, often with cumulative effect, and several were transmitted to different co-workers for specific reasons, as detailed in the following sub issues:

- a. That in the spreadsheet labeled “678data3.xls,” produced during the late spring/early summer of 2000, the respondent falsified and fabricated numerous values in the fields called underwater fat mass (UWFM), underwater fat-free mass (UWFFM), leisure time activity (LTA), and maximum oxygen consumption (VO2 Max);
- b. That on July 16, 2000, the respondent transmitted a subset of the Protocol 678 spreadsheet to a witness (TB) entitled “RevisedTEE\_s.xls,” which had 135 values each for T1 and T2 for TEE; many values were fabricated and most of the remaining values had been falsified by reversing the original T1 and T2 values (Report, pp. 6-8);
- c. That the respondent falsified additional data fields in the version of the 678 data set called “ExcelLongitudinal2.xls,” on or about August 17, 2000; specifically, values for total cholesterol, insulin, resting metabolic rate (RMR), and glucose values of the subjects with names in the second half of the alphabet were falsified (often by reversing T1 and T2) or fabricated (Report, p. 10);
- d. That the respondent gave falsified data to another witness (MT) in August 2000 to provide him with data for a presentation to be given in September 2000 to UVM staff (initially postponed until February 2001); the spreadsheet given to MT contained the falsified and fabricated TEE and underwater body composition values of RevisedTEE\_s.xls; the spreadsheet, when subsequently obtained by ORI, was labeled “LongitudinalBodyCompMT.xls”;
- e. That the respondent falsified additional data in another version of “ExcelLongitudinal2.xls” that he sent to another witness (AT) on or about August 22, 2000; specifically, this version contained the falsifications already described above (Issues 3a through 3c) and, in addition, the remainder of the glucose values, and individual lipid components (triglycerides, HDL, and LDL) were extensively falsified and fabricated; this spreadsheet was transmitted to AT with the

expectation that he would write a paper describing the effect of aging on lipid metabolism (Report, pp. 8-10);

- f. That the respondent provided a falsified version of the Protocol 678 spreadsheet to a witness (ER) in the fall of 2000 so that ER could write a review article;
- g. That the respondent, in late September/early October 2000, extensively falsified body composition data (a number of parameters including, but not limited to, fat mass and fat-free mass) obtained with the DEXA method in a spreadsheet transmitted to a witness (CG) so that CG could write a paper using the DEXA method to demonstrate body composition changes with age (Report, pp. 5 and 39);

#### Reporting Research

- h. That the respondent reported falsified data from the longitudinal study of aging at the annual North American Association for the Study of Obesity (NAASO) meeting in October 2000, and to the Vermont community; the falsifications on his slides included falsified values for both the number of subjects tested at T1 and T2 for TEE and the claim of a significant difference between the means for TEE at T1 versus T2; values for RMR, PAEE, and body composition (fat mass and fat-free mass) were also falsely reported (Report, p. 34);
- i. From the falsified data set that the respondent provided him, ER developed a review article: Rawson, E., and Poehlman, E.T. "Resting metabolic rate and aging." *Recent Research Developments in Nutrition* 4, 2001, coauthored by the respondent, which included falsified yet unpublished results about the decline in RMR upon aging (p. R1792). These results, ORI determined, are very similar to the falsified results that the respondent presented at NAASO, based on the falsified Protocol 678 data set;

#### Conducting Research

- j. That on October 16, 2000, the respondent provided a witness (WD) a version of the Protocol 678 data set entitled "ExcelLongitudinal4.xls" that included falsified cholesterol and individual lipid component data (as well as falsified parameters such as insulin, glucose [all subjects], TEE, RMR, PAEE, and underwater body composition data) so that WD could write a paper on the effect of aging on lipid composition (Report, pp. 8-10); and

### Other

- k. That the respondent falsely testified to the University of Vermont Investigation Committee that he had never used data from the longitudinal study of aging in grant applications or in public presentations (Report, pp. 34 and 36).

### **Group 2: Muscle biopsy results**

#### Proposing Research

4. That the respondent reported fabricated muscle biopsy data in NIH grant application 1 R01 AG17906-01A1 (p. 27), submitted in February 2000; specifically, he falsely claimed to have successfully tested five individuals on two occasions (1994 and 1999) when he had not (Report, pp. 25-26).

### **Group 3: Protocol 467, including the “longitudinal menopause study” and other falsifications/fabrications**

#### Reporting Research

5. That the respondent published falsified thyroid hormone results for women entered in a cross-sectional study (Protocol 467) (Figures 3A and 3B and related text and the portion of Table 2 related to T3 and free T3) in the following paper: Poehlman, E.T., Goran, M.I. Gardner, A.W., Ades, P.A., Arciero, P.J., Katzman-Rooks, S.M., Montgomery, S.M., Toth, M.J., and Sutherland, P.T. “Determinants of decline in resting metabolic rate in aging females.” *American Journal of Physiology* 264(*Endocrinol Metab.* 27):E450-E455, March 1993 (correction required).
6. That the respondent published in November 1995 falsified and fabricated data from a longitudinal study of menopause in women in the following paper: Poehlman, E.T., Toth, M.J., and Gardner, A.W. “Changes in energy balance and body composition at menopause: A controlled longitudinal study.” *Annals of Internal Medicine* 123(9):673-675, November 1, 1995; the respondent has admitted that this longitudinal study was never conducted (the number of women seen at T1 was falsified, and there were at most 3, rather than 35, women seen at T2) (Report, pp. 27-32) (retracted by the editor; letter from the respondent required).



## Proposing Research

7. That the respondent repeatedly reported this non-existent longitudinal menopause study and cited the 1995 *Annals of Internal Medicine* paper in NIH grant applications as proof that the respondent could conduct such longitudinal studies, and the falsified and fabricated data supported his proposed hypotheses:
  - a. The respondent provided for the annual report for the University of Vermont General Clinical Research Center (GCRC) grant (M01 RR00109) for the period December 1, 1994-November 30, 1995, information about the falsified longitudinal menopause study, and the *Annals of Internal Medicine* paper was cited as having used the University of Vermont GCRC facilities;
  - b. In application 5 K04 AG00564-05, submitted July 18, 1995, the respondent reported the results of a seven (7) year<sup>1</sup> followup study of pre- and post-menopausal women, noting an article was in press in the *Annals of Internal Medicine* 1995 (unnumbered p. 3);
  - c. In application R01 AG13978-01, submitted in September 1995, the respondent reported falsified and fabricated data on menopause-related changes in metabolism, body composition, and other variables in Preliminary Data (pp. 35, 41, and 42), and cited the published *Annals of Internal Medicine* 1995 paper;
  - d. In application R01 AG13978-01A1, submitted in July 1996, the respondent reported falsified and fabricated data on menopause-related changes in metabolism, body composition, and other variables in Preliminary Data (p. 33), and cited the published 1995 paper in the *Annals of Internal Medicine* and a submitted manuscript on the same topic (pp. 25, 29, 33, 40, 44, and 49);
  - e. In Project 1 of application P01 AG16782-01, submitted in June 1998, the respondent reported (p. 233) fabricated data showing that menopause led to significant changes in body composition (pp. 229 233, 246, and 256) (Report, p. 32);

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<sup>1</sup>All other reports of the “longitudinal menopause study” claimed an average of six (6) years of follow-up.

- f. In application 1 R01 AG 18238-01, submitted in April 1999, the respondent reported falsified and fabricated data from his longitudinal menopause study (RMR, leisure time physical activity, fat-free mass, fat mass, waist-to-hip ratio, and insulin, pp. 9, 18-20, 22, 23, 33, 37, and 44);
- g. In application 1 R01 AG17906-01, submitted in May 1999, the respondent reported falsified and fabricated data in the description of his longitudinal menopause study (RMR, leisure time physical activity, and fat-free mass, p. 25);
- h. In Project 1 of application P01 AG16782-01A1, submitted in January 2000, the respondent reported the falsified and fabricated longitudinal menopause study (pp. 214, 220, 221, 228, and 250) (Report, p. 32);
- i. In application 1 R01 AG17906-01A1, submitted in February 2000, the respondent reported the falsified and fabricated longitudinal menopause study (pp. 31 and 59); and
- j. In application 1 R01 AG19800-01, submitted in September 2000, the respondent reported the falsified and fabricated longitudinal menopause study (pp. 18 and 43).

#### Reporting Research

- 8. That the respondent continued to publish papers on the fictitious longitudinal menopause study, referring to the same cohort of 35 women, 18 of whom purportedly went through the menopause transition during the 6-year followup period; all or parts of the following additional papers<sup>2</sup> reported this non-existent study and require correction or retraction:
  - a. Poehlman, E.T., Toth, M.J., Ades, P.A., and Rosen, C.J. “Menopause associated changes in plasma lipids, insulin-like growth factor I and blood pressure: A longitudinal study.” *European Journal of Clinical Investigation* 27(4):322-326, April 1997 (Report, p. 30) (retraction required);
  - b. Tchernof, A., and Poehlman, E.T. “Effects of the menopause transition on body fatness and body fat distribution.” *Obesity Research* 6(3): 246-254, May 1998 (pp. 249-251) (correction required);

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<sup>2</sup>The first paper describing the longitudinal menopause study, the 1995 *Annals of Internal Medicine* paper, was the subject of PHS Issue 6.

- c. Tchernof, A., Poehlman, E.T., and Despres, J.P. "Body fat distribution, the menopause transition, and hormone replacement therapy." *Diabetes and Metabolism* 26(1):12-20, February 2000 (Report, p. 31) (p. 17 correction required);
  - d. Rawson, E., and Poehlman, E.T. "Resting metabolic rate and aging." *Recent Research Developments in Nutrition* 4, 2001 (correction required);
  - e. Poehlman, E.T. "Menopause, energy expenditure, and body composition." *Acta Obstetrica et Gynecologica Scandinavica*. 81(7):603-611, July 2002 (retraction required); and
  - f. Poehlman, E.T., and Tchernof, A. "Traversing the menopause: Changes in energy expenditure and body composition." *Coronary Artery Disease* 9(12):799-803, 1998 (correction/retraction required).
9. That the respondent reported falsified and fabricated longitudinal menopause data in a talk presented in October 2000 at the annual NAASO meeting and to the Vermont community; specifically, he reported to NAASO falsified RMR and fat mass data on 40 women followed over 6 years (17 pre-menopausal, 18 post-menopausal, and 5 peri-menopausal) and RMR, FM, F-FM, PAEE, WHR, and insulin (Vermont Community) (Report, pp. 33-34).

Other

10. That the respondent falsely wrote to the University of Vermont Investigation Committee that the subjects in the longitudinal menopause study had not stayed overnight in the GCRC for the second visit. In fact, no women were seen a second time at the GCRC on an in patient or outpatient basis (Report, p. 29).

**Group 4: Protocol 646 - Hormone replacement therapy and visceral fat and weight loss; the genetics of an obesity gene.**

Proposing Research

11. That the respondent included Protocol 646 in grant application 2 M01 RR00109-33 (funding for the University of Vermont, GCRC), submitted in February-March 1996, in which he provided falsified and fabricated data on 40 women with and without the variant gene Trp64Arg; falsified parameters included body weight, body mass index, and percent body fat that were falsely claimed to be significantly different between the two groups.

12. That the respondent reported falsified and fabricated preliminary data and results in application 1 R01 AG18238 on HRT and its preferential effect on abdominal fat content:
  - a. The respondent, in grant application 1 R01 AG18238-01 (p. 24), submitted in April 1999, presented falsified data in Table 1, on a study of women who had reported to be on, or not on, hormone replacement therapy (HRT); specifically, he claimed that women on HRT had significantly lower intra-abdominal fat than non-users and that there was a significant difference in PAEE between the two groups;
  - b. The respondent also falsely claimed to have evaluated the effect of HRT on intra-abdominal fat loss in a double blind placebo controlled study of 27 weeks' duration (Figure 4); the actual study was not unblinded until 2002;
  - c. The respondent also falsely claimed (pp. 36-37) to have completed a 6-month pilot study on the effect of exercise weight loss on post-menopausal women administered HRT, compared to women not on HRT.
  
13. That the respondent, in grant application 1 P01 AG16782-01A1, submitted in January 2000, presented (p. 230) falsified data:
  - a. On a study of women reported to be on, or not on, HRT; specifically, the number of subjects in Table 4 was 25 for HRT users and 23 for non-users, while seven of eight values for PAEE and intra abdominal fat (3 means and 4 standard deviations) were unchanged from Table 1 of Application 1 R01 AG18328-01, where the number of subjects was 13 for each group;
  - b. The respondent repeated the false claim in the April 1999 application to have evaluated the effect of HRT on intra-abdominal fat in a double blind placebo controlled study of 27 weeks' duration; the actual study was not unblinded until 2002; the respondent admitted to falsifying the figure in this application relative to the version in the 1 R01 AG18328-01 application; and
  - c. The respondent falsely claimed (p. 231) to have studied eight post menopausal women on HRT and seven women not on HRT in a 6 month weight loss program, when the average ages, standard deviations, and certain mean values were unchanged from the smaller,

and purportedly different, groups described in the April 1999 application (see PHS Issue 12 c. above).

14. That the respondent, in grant application 2 R01 DK052752-05, submitted in June 2000:
  - a. Falsified the number of subjects carrying or not carrying the Trp64Arg genotype in Tables 4, 5, and 6 (pp. 30-31); specifically in the application, he falsely claimed to have tested 40 in each group; the respondent admitted that the actual number tested varied from 8 to 13, depending on the group and parameter being measured;
  - b. The respondent also falsely claimed that the number of women recruited to his funded grant on the menopause transition was 85 (p. 49).
  
15. That the respondent, in grant application 1 R01 AG19800-01, submitted in September 2000:
  - a-c. Made the same three false claims with respect to HRT as in application 1 P01 AG16782-01A1 (Findings 13 a-c); in addition, the respondent falsely claimed in Table 5 that the number of subjects with and without HRT participating in the 6-month weight loss program (see PHS Issue 13 c. above) was now 10 in each group rather than the group sizes of 8 and 7 claimed in Table 5 of the 1 P01 AG16782-01A1 application; many of the means and standard deviations in these two tables match the values obtained in a 6-month weight loss pilot study described on pp. 36-37 of application 1 R01 AG18238-01, where the two groups consisted of 3 and 4 individuals (pp. 13, 15, 17, 20, and 21; Tables 4 and 5; and Figure 6);
  - d. Falsely claimed (Table 3, p. 19) to have weight-reduced 70 obese women in the genetic study.

#### Reporting Research

16. That in public presentations or material prepared for these fora, the respondent falsified or fabricated data and results of the effects of HRT and of the effects of the Trp64Arg genotype:
  - a. That the respondent, at talks given at the annual NAASO meeting in October 2000, and to the Vermont Community (October 17, 2000), presented false information on the effects of HRT on visceral fat loss

and glucose disposal when the HRT users and non-users were on a 6 month weight loss program; and

- b. That the respondent, in both NAASO and Vermont Community talks, falsely claimed that Trp64Arg carriers have significantly lower rates of glucose disposal than non-carriers.

Other

- 17. That the respondent falsely testified to the University of Vermont Investigation Committee that the slide shown at NAASO regarding the loss of visceral fat in women on, or not on, HRT during a 6-month weight loss program (Issue 16a) had been labeled “hypothesized.” The respondent falsely labeled the NAASO slide “hypothesized” and submitted it to the University of Vermont Investigation Committee with the intention of misleading the committee (Report, pp. 34, 37).

**Group 5: Alzheimer’s disease**

- 18. That the respondent, in applications 2 R01 AG07857-06 and 7 R01 AG07857-07, submitted June 26, 1992, and March 28, 1994, respectively, falsified certain preliminary data (average ages, height, and fat-free weight values) to show that the Alzheimer’s and control patients were more closely matched for age than shown in the original data;
- 19. That the respondent, in application 5 R01 AG07857-09, submitted May 18, 1995, falsified preliminary data; specifically, compared to data in the preceding 5 R01 AG07857-08 application, where the number of Alzheimer’s and control subjects was 7 and 13, respectively, the number of Alzheimer’s and control subjects was doubled to 14 and 26, respectively, while many of the data values and standard deviations remained unchanged; in the latter application, however, the respondent claimed that Alzheimer’s patients had significantly lower fat-free mass and significantly higher fat mass than control patients, while no claim of significant differences had been made in the earlier application.

## Group 6: Effect of endurance training on metabolism

20. The respondent admitted to falsifying norepinephrine data (a measure of sympathetic nervous system activity) in two papers published in 1992 and 1994 and agreed to retraction of the papers.<sup>3</sup> Specifically:
  - a. The respondent falsified norepinephrine data in Table 2 and Figure 4 of Poehlman, E.T., Gardner, A.W., and Goran, M.I. "Influence of endurance training on energy intake, norepinephrine kinetics, and metabolic rate in older individuals." *Metabolism* 41(9):941-948, September 1992, in order to strengthen the relationship between endurance training and increased norepinephrine levels and rate of appearance (paper to be retracted);
  - b. The respondent falsified norepinephrine data in Table 2 and associated text of Poehlman E.T., Gardner, A.W., Arciero, P.J., Goran, M.I., and Calles-Escandon, J. "Effects of endurance training on total fat oxidation in elderly persons." *Journal of Applied Physiology* 76(6):2281-2287, June 1994, in order to make the claims that norepinephrine concentration and norepinephrine appearance were significantly enhanced following endurance training (paper to be retracted).

Dr. Poehlman has entered into a Voluntary Exclusion Agreement (Agreement ) in which he has voluntarily agreed, beginning on March 9, 2005:

- (1) to exclude himself permanently 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;
- (2) to exclude himself permanently from any contracting or subcontracting with any agency of the U.S. government and from eligibility or involvement in non-procurement programs of the U.S. government referred to as "covered transactions" as defined in the debarment regulations at 45 C.F.R. Part 76; the respondent agrees that he will not petition HHS to reverse or reduce the

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<sup>3</sup>Both the 1992 and 1994 papers were designed to reproduce, under more controlled conditions, an earlier result, published in Poehlman, E. and Danforth, E. "Endurance training increases metabolic rate and norepinephrine appearance rate in older individuals." *American Journal of Physiology* 261:E233-E239, 1991. These papers claimed that plasma levels of norepinephrine increased significantly in older individuals following endurance training. Because the norepinephrine results in the two carefully controlled studies conducted to verify this finding were falsified, it is apparent that this original report cannot be relied upon.

scope of the permanent voluntary exclusion or administrative actions that are the subject of this Agreement; and

- (3) to execute and deliver letters requesting retraction or correction to the editors of the journals that published the 10 papers named in the Agreement and cited above, and to sign the letters requesting the retraction or correction prepared for his signature by ORI without alteration or modification in any way.



## Summaries of Closed Inquiries and Investigations Not Resulting in Findings of Research Misconduct – 2005

**Falsification:** The respondent, a postdoctoral fellow, allegedly falsified a figure published online prior to publication in a journal. The paper cited support from a National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH), grant. The questioned research involved the biochemistry of reproductive cells. The institution conducted an investigation and concluded that the respondent had altered the figure. However, the falsification was corrected prior to print in the journal. ORI accepted the institution's report as fulfilling its reporting requirements to PHS and accepted many of its factual findings, but ORI declined to pursue a PHS finding of scientific misconduct. However, ORI recognized that this does not impact on the findings of misconduct made under institutional standards.

**Falsification:** The respondent, an associate professor, allegedly falsified images of confocal and fluorescent microscopy in yeast cells. The allegedly falsified data were included in four publications, a book chapter, and two grant applications submitted to the National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), and to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH. The questioned research was supported by an NIDDK, NIH, grant, and a National Institute of Child Health and Human Development (NICHD), NIH, grant. The institution conducted an investigation and concluded that the respondent did not commit research or professional misconduct in this case. ORI accepted the institution's conclusion and did not make a finding of scientific misconduct.

**Falsification:** The respondent, a graduate student, allegedly submitted falsified data to his mentor for inclusion in a publication, in a grant application to the National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), and in his own thesis. The questioned research involved the study of low blood sugar in heart development in animals. The institution conducted an investigation and concluded that the respondent had unethically manipulated data. ORI accepted the institution's report but concluded that, given the absence of primary research records, the allegations of research misconduct were not resolvable.

**Falsification:** The respondent, a postdoctoral fellow, allegedly falsified data in a manuscript involving research on regulation of cell death and treatment of leukemia. The questioned research was supported by a National Cancer Institute (NCI), National Institutes of Health (NIH), grant and a National Institute of Aging (NIA), NIH, grant. The institution conducted an investigation and did not make a finding of scientific misconduct. ORI accepted the institution's conclusion

and found that there was insufficient evidence to make a finding of scientific misconduct in this case.

**Falsification:** The respondent allegedly falsified data and results in a manuscript submitted to a journal for publication. The paper cited support from a National Cancer Institute (NCI), National Institutes of Health (NIH), grant. The questioned research involved assessing the need for exercise programs sponsored by specifically focused social organizations. The institution conducted an inquiry and an investigation and concluded that the respondent did not knowingly, willingly, or recklessly participate in falsification, fabrication, plagiarism, or other practices that seriously deviate from those commonly accepted within the scientific community. However, the institution concluded that poor communication, a poorly functioning system for manuscript management and revision, and a lack of attention to details led to the inappropriate submission of the manuscript that contained altered data. Thus, the institution recommended that the respondent refrain from using the manuscript. ORI accepted the institution's report and did not make a PHS finding of scientific misconduct in this case.

**Falsification:** The respondent, a postdoctoral fellow, allegedly falsified data included in a grant application submitted to the National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH). The questioned research involved molecules that play a role in activating resistance responses to pathogens in plants. The institution conducted an investigation and concluded that the allegation of scientific misconduct was not sustained by a preponderance of the evidence. ORI accepted the factual findings from the institution's investigation, but given the lack of evidence in the form of research records, ORI concluded that the allegations of research misconduct were not resolvable.

**Falsification:** The respondent, a research associate, allegedly falsified data in research involving an in vivo reporter system for imaging gene transfer. The questioned research was supported by a National Cancer Institute (NCI), National Institutes of Health (NIH), grant. The institution conducted an investigation and concluded that there was insufficient evidence to make a judgment of scientific misconduct. ORI concurred with the institution's conclusion and did not make a finding of scientific misconduct.

**Falsification:** The respondent, a professor, allegedly falsified data included in a progress report of a study supported by a National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH), grant. The questioned research involved the study of a treatment to prevent a serious condition in newborn infants. The institution conducted an investigation and concluded that the respondent had reported data to NIH for subjects from another study who were not part of an approved protocol for the grant. The institution determined that the

inclusion of these subjects constituted a serious deviation from commonly accepted practices for the conduct and reporting of research. ORI accepted the institution's report as fulfilling its reporting requirements to PHS and accepted many of its factual findings, but ORI declined to pursue a PHS finding of scientific misconduct. However, ORI recognized that this does not impact on the findings of misconduct made under institutional standards.

**Falsification:** The respondents, a professor and two research associates, allegedly falsified data included in a published paper and cited in a National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grant application. The questioned paper cited support from two NHLBI, NIH, grants. The questioned research examined the function of the calcium channel in the heart in a transgenic mouse model. The institution conducted an investigation and concluded that no evidence of falsification or fabrication could be found. ORI accepted the institution's determination that misconduct had not occurred and did not make a finding of scientific misconduct.

**Falsification:** The respondents, an assistant professor and a technologist, allegedly falsified medical records and study forms in a longitudinal study of ocular disorders. The questioned study was supported by a National Eye Institute (NEI), National Institutes of Health (NIH), cooperative agreement. The institution conducted an investigation and concluded that there was no evidence of intentional, knowing, or reckless falsification or fabrication of research data on the part of either respondent. ORI accepted the institution's findings and concluded that while there were errors and protocol deviations, there was insufficient evidence to warrant a finding of scientific misconduct.

**Falsification/Fabrication:** The respondent, an associate professor, allegedly falsified or fabricated data and misrepresented the statistical analysis for a figure in a published paper. The questioned research involved a study of stress in women who had experienced abuse in childhood. The study was supported by a National Institute of Mental Health (NIMH), National Institutes of Health (NIH), grant, and a General Clinical Research Center, National Center for Research Resources (NCRR), NIH, grant. The institution conducted two inquiries and concluded that there was not sufficient substantive evidence of possible research misconduct to warrant a formal investigation. ORI concurred with the institution's determination that there was insufficient evidence to warrant an investigation.

**Falsification/Fabrication:** The respondent, an associate professor, allegedly falsified and/or fabricated data included in a grant application submitted to the National Cancer Institute (NCI), National Institutes of Health (NIH). The questioned research involved the importance of the apoptotic signaling pathway in understanding how tumor cells evade the death response and grow uncontrollably.

The institution conducted an inquiry and determined that the allegations of scientific misconduct did not warrant further investigation. ORI accepted the institution's conclusion that the allegations of scientific misconduct did not warrant further investigation.

**Falsification/Fabrication:** The respondent, a professor, allegedly falsified and/or fabricated data included in published papers. The questioned papers cited support from a National Cancer Institute (NCI), National Institutes of Health (NIH), grant, a National Institute of General Medical Sciences (NIGMS), NIH, grant, a National Institute of Dental and Craniofacial Research (NIDCR), NIH, grant, and a National Institute of Arthritis and Musculoskeletal Skin Diseases (NIAMS), NIH, grant. The questioned research involved the role of antibodies in a debilitating disease. The institution conducted an inquiry and concluded that there was insufficient evidence to warrant further investigation. ORI accepted the institution's determination that for all issues, there was not a sufficient basis for proceeding with further investigation.

## Research Misconduct Related Litigation During 2005<sup>4</sup>

### CIVIL LITIGATION - Open Cases

*Jessie L.- S. Au, et al. v. Yulin Ma* (Case No. C-2-01-0596) (S.D. Oh.), (filed June 20, 2001). Drs. Au and Wientjes of Ohio State University (OSU) filed a defamation suit alleging that on January 14, 2001, Dr. Ma sent an e-mail to the OSU alleging, among other things, research misconduct, and that Dr. Ma made many disparaging statements to several colleagues and others in the scientific community. On June 8, 2005, the plaintiffs moved to amend their original complaint to include an anonymous letter sent to the U.S. Department of Health and Human Services alleging research misconduct. The trial began on September 26, 2005, and concluded on or about October 6, 2005. The jury unanimously found for the plaintiffs and awarded damages in the amount of \$750,000. On October 20, 2005, the defendant moved for a new trial to alter or amend the judgment.

*Justin D. Radolf v. University of Connecticut Health Center, et al.* (Case No. 303CV242) (D. Conn., filed March 21, 2003).<sup>5</sup> *Justin D. Radolf v. University of Connecticut* (No. 05-2003-CV) (2nd Cir., June 30, 2005). On March 30, 2005, the U.S. District Court for the District of Connecticut granted summary judgment for the defendants on all of Radolf's federal claims and declined to exercise supplemental jurisdiction over Radolf's state law claims. The district court decided that there were no issues of disputed fact regarding his federal claims that were material and thus stated that the defendants were entitled to summary judgment as a matter of law. *See Justin D. Radolf v. University of Connecticut Health Center, et al.*, (Nos. 303CV242 and 303CV672) (D. Conn., March 30, 2005). On April 20, 2005, Radolf filed an appeal to the U.S. Court of Appeals for the Second Circuit from the district court's judgment granting the defendant's motion for summary judgment. However, on June 30, 2005, both parties agreed to a stipulation to dismiss the case with prejudice and without attorneys' fees and costs for either party.

On March 10, 2003, the Public Health Service (PHS) entered into a Voluntary Exclusion Agreement with Radolf, who is currently a professor at the University of Connecticut Health Center (UCHC). Under the terms of his PHS agreement,

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<sup>4</sup>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 support 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.

<sup>5</sup>This case was consolidated with *Justin D. Radolf v. Peter J. Deckers* (No. 303CV672) (D. Conn., filed April 14, 2003).

Radolf agreed to accept supervision by any institution employing him until March 9, 2008. UCHC developed a supervision plan proposing restrictions in addition to those mandated by the PHS agreement. Radolf sought judicial review of UCHC's restrictions, in addition to other complaints.

Radolf voluntarily relinquished his position as the Director of the Center for Microbial Pathogenesis at UCHC, but claimed that his Fourteenth Amendment procedural due process rights were violated when he was not afforded a pre-decision hearing concerning his desired reinstatement. The court concluded that Radolf had no protectible property interest in the discretionary reappointment to his former post. The court also stated that even if Radolf had a protectible property interest, the Constitution does not require that he receive a hearing prior to a decision being made not to appoint him to that position.

Radolf alleged that his First Amendment right to academic freedom was violated when he was precluded from participation in the formulation of a grant proposal to the Department of Defense (DOD) and the subsequent research that was funded by the grant. The court held that a university professor does not have a First Amendment right of academic freedom to participate in writing any particular grant. The court also rejected Radolf's claim that his Fourteenth Amendment right to procedural due process was infringed when he was barred from participating in the DOD grant proposal.

In addition, Radolf asserted that the defendants retaliated against him when he expressed his opposition to the defendants' alleged wrongful use of funds from his two National Institutes of Health (NIH) grants. He claimed that the defendants retaliated against him by falsely accusing him of committing fraud in preparing and reporting on NIH grants. However, an internal institutional investigation found that there was no basis for a finding that Radolf committed fiscal fraud or engaged in improper fiscal misconduct in connection with the two grants. Radolf was unable to support this First Amendment retaliation claim because he did not demonstrate that he suffered any material disadvantage in his employment terms as a result of the internal investigation.

***Meena Chandok, Ph.D., v. Daniel F. Klessig, Ph.D.*** (Case No. 5:5 - cv - 1076) (N.D.N.Y.) (Filed August 26, 2005). Plaintiff filed a defamation suit in August seeking \$75,000 in compensatory damages and \$1 million in punitive damages from Klessig, a past president of the Boyce Thompson Institute for Plant Research (BTI). The plaintiff alleges that the defendant caused her irreparable harm when making an allegedly defamatory allegation of research misconduct to BTI. The plaintiff also alleges that the defendant's statements to BTI during the ensuing misconduct investigation, as well as statements made in two retraction letters, were knowingly false. A scheduling order was issued in the case stipulating that discovery shall be

completed on or before December 1, 2006, with the trial commencing on or before May 15, 2007.

***Dr. Eric T. Poehlman v. University of Vermont*** (Case No. 2:01-CV-120) (D.Vt.) (Filed April 16, 2001). On December 27, 2000, a research assistant to Poehlman (plaintiff), brought a formal complaint to the University of Vermont (UVM) alleging that Poehlman committed scientific misconduct. As a result of this allegation, UVM conducted a formal inquiry into the matter by reviewing the allegations, examining data sheets, reviewing correspondence between Poehlman and others, interviewing the plaintiff and others, and securing key evidence. UVM convened a formal panel to assess the significance of the allegation. On March 9, 2001, the UVM panel issued its formal inquiry report in which it concluded that there was sufficient enough evidence to warrant a full investigation. Because of the Public Health Service (PHS) funding in this matter, UVM was required to notify the Office of Research Integrity (ORI) about its decision to open a full investigation. The plaintiff filed this lawsuit seeking injunctive relief, including an order enjoining UVM from notifying ORI of its investigation. The plaintiff also moved to seal the proceedings, claiming that if the matter was made public, his reputation and livelihood would be damaged. The court granted the motion to seal.

Although the plaintiff did not name the Department of Health and Human Services (HHS) as a party to this action, HHS sought to intervene on June 18, 2001. The court held a hearing on pending motions, but prior to any court rulings, Poehlman and UVM agreed to dismiss the lawsuit without prejudice. At that time, the federal government moved to unseal the matter, but the court denied the motion. The district court lifted the seal in this case in December 2005, after the government filed a motion seeking the same relief. The plaintiff did not oppose the government's motion to unseal.

Subsequent to the dismissal of the plaintiff's lawsuit, UVM concluded its investigation into the allegations of scientific misconduct by the plaintiff, concluding that (1) he falsified and fabricated data associated with a longitudinal study of aging, and included this false and fabricated data in National Institutes of Health (NIH) and U.S. Department of Agriculture grant applications; (2) published false and fabricated data in the *Annals of Internal Medicine* in 1995; and (3) presented false and fabricated data to public and scientific audiences in October and November 2001.

UVM's investigation report was then forwarded to ORI for additional analysis. UVM's scientific misconduct findings, along with ORI's additional findings, triggered federal government criminal and civil fraud investigations.

***United States of America v. Eric T. Poehlman*** (Case No. 2:05-CV-66) (D.Vt.) (Filed April 16, 2001). On May 28, 2004, Walter E. DeNino filed a *qui tam* action pursuant

to the False Claims Act, 31 U.S.C. § 3730, captioned *United States of America, ex rel. Walter F. DeNino v. Eric T. Poehlman, Ph.D.* (Civil No.1:04-CV-310). The government contended that Dr. Poehlman (defendant) knowingly submitted, or caused to be submitted, false claims in numerous applications submitted to the National Institutes of Health (NIH) and the U.S. Department of Agriculture (USDA) for research grants. Specifically, the government contended that from 1992-2000, the defendant falsified and fabricated certain data in his federally funded research and presented false and fabricated data in grant applications proposing to conduct more federally funded research. During the period from 1996-2000, the defendant submitted 14 research grant applications to federal agencies or departments that included false and fabricated data, and during that period the NIH paid out approximately \$1.7 million in research funding based on the defendant's false and fabricated research data.

Among other things and as part of the agreement, the defendant agreed to pay \$180,000 in civil penalties for his fraudulent conduct. He also agreed to be permanently excluded from Medicare, Medicaid, and all other federal health care programs as defined in 42 U.S.C. § 1320(a)-7b(f). This exclusion included all federal procurement and non-procurement programs. As the relator in the *qui tam* action, Mr. DeNino received 12 percent of the settlement amount of \$180,000, and his attorney's fees were paid by the defendant.

***United States of America v. Eric T. Poehlman*** (Case No. 2:05-CV-66) and ***United States v. Poehlman*** (Criminal No. 2:05-cr-00038) were resolved together under the terms of global settlement agreement between Poehlman and the U.S. government.

***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. 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 because of 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\***

***United States v. Poehlman*** (Criminal No. 2:05-cr-00038) (D. Vt., filed March 17, 2005). On April 4, 2005, the defendant entered a plea of guilty to one felony charge of making a false statement in violation of 18 U.S.C. § 1001, arising from preparing, signing, and submitting a grant application to the National Institutes of Health in which he provided false and fabricated research data. On March 9, 2005, the defendant had entered into a Voluntary Exclusion Agreement (“Agreement”) with the Department of Health and Human Services. The defendant admitted to at least twenty (20) acts of scientific misconduct. Pursuant to the Agreement, he permanently excluded himself from advising, contracting, or subcontracting with any federal agency and from eligibility or involvement in federal non-procurement programs and to retract or correct all the scientific publications implicated by his misconduct. A sentencing hearing date is pending.

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





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