Office of Research Integrity

Annual Report 2006

May 2007

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

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Highlights of CY 2006 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 Policies on Research Misconduct, 42 C.F.R. Part 93.

Responding to Research Misconduct Allegations

- Opened 29 new cases and closed 35 cases, with 53 cases remaining open at the end of the calendar year, 6 fewer cases than ORI had at the end of 2005.

- Made sustainable research misconduct findings and/or imposed PHS administrative actions in 15 of the 35 closed cases. Debarments or voluntary exclusions were imposed in 10 cases; 4 for 5 years; 5 for 3 years, and 1 for a lifetime. A respondent, who signed a voluntary agreement in 2005 agreeing to a lifetime debarment and at the same time had pled guilty to civil and criminal charges stemming from his research misconduct, was sentenced to a year plus a day in federal prison. Three-year supervisory periods were imposed in four cases, and a data certification process was imposed in one case. All respondents against whom research misconduct findings were made were prohibited from serving in any advisory capacity to PHS for a period comparable to the other administrative actions taken against them.

- Achieved a higher percentage of cases in 2006 that closed with a finding of research misconduct. Forty-three percent of the closed cases resulted in PHS misconduct findings and administrative action, compared to the historical average of about 33 percent. This percentage reflects the high level of cases with likely misconduct findings that were pending at the beginning of the year. The discrepancy between the fraction of open versus closed cases involving misconduct is generally due to the longer time typically required by both the institution and the Division of Investigative Oversight (DIO) to investigate and review a misconduct case compared to a no-misconduct case. This discrepancy also reflects the length of time required by the attorneys to either negotiate a settlement or prepare a charge letter and try the case. The ORI case load at the end of 2006 remained similar to that of the previous year, with at least 75 percent of the pending cases involving likely research misconduct findings. The number of allegations received by ORI (266 in 2006) nearly matched the 2005 level of 265, but the levels for both years represent nearly a 50 percent increase over the 2003 level.

- 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. ORI completed its oversight of 21 of the 22 cases within 1 year.

- Provided Rapid Response for Technical Assistance (RRTA) on 25 occasions in 2006. Twenty-one of these rapid responses involved discussion with institutional officials who had concerns about how to manage newly identified or ongoing cases, and four involved interactions with journal editors who wished assistance on verifying problems with submitted manuscripts.

Education and Prevention

- Funded 5 instructional resources through the Responsible Conduct of Research (RCR) Resource Development Program, raising to 54 the number of projects supported since 2002. Six 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 24 resources were available on the ORI web site at the end of 2006.

- Held the fourth annual RCR Expo in conjunction with the annual meeting of the Society of Research Administrators International. Nine developers of RCR resources, including eight universities and the Cleveland Clinic, exhibited their creations.

- Finished development of the RCR course being created by the Collaborative Institutional Training Initiative (CITI) Program with ORI support and posted the course on the CITI web site, where it will be freely available to the research community until May 2008.

- Completed the first phase of the Research Integrity Officer (RIO) training program, being developed at Michigan State University with ORI support, by posting the orientation video, *The Role of the RIO*, on the ORI web site. Began the second phase of the training program, which focuses on the development of intensive 3-day boot camps for RIOs.

- Made awards to seven academic societies to develop RCR infrastructure, activities, and educational programs and to institutionalize them into the culture

of the societies and the disciplines they represent. A list of products produced by academic societies supported by the RCR Program for Academic Societies, a collaboration with the Association of American Medical Colleges, is available at http://www.aamc.org/programs/ori/. Funding for the program ended in 2006.

- Completed a 2-year collaboration with the Council of Graduate Schools (CGS) to institutionalize RCR education in graduate schools with the publication of the CGS report, *Graduate Education for the Responsible Conduct of Research*, which recommended mandatory RCR training in graduate programs.

- Collaborated with the European Science Foundation to organize the first World Conference on Research Integrity, which will be held in Lisbon, Portugal, from September 16-19, 2007.

- Sponsored six conferences or workshops related to research integrity, the responsible conduct of research, and research misconduct, which were supported by ORI in collaboration with six universities, two institutional associations, two government agencies, and one scientific society.

- Added four features to the ORI home page to enable ORI to keep in touch with its clients and enable the clients to keep in touch with ORI: RSS Feeds, e-mail subscriptions, submit your news, and web site feedback. Had 131,765 visitors from 147 countries to the web site in 2006, according to Google Analytics.

- Increased the number of languages in which the *ORI Introduction to the Responsible Conduct of Research* is available to four when the Ministry of Education and the Korea Research Foundation translated the text into Korean and distributed 20,000 copies to Korean scientists. This publication is also available in English, Japanese, and Chinese.

- Made 22 staff presentations at conferences, workshops, meetings of professional associations, universities, and federal agencies. Published four journal articles and two book chapters.

Research on Research Integrity and Research Misconduct

- Completed a study, *Reporting Suspected Research Misconduct in Biomedical and Behavioral Research*, conducted by The Gallup Organization. The study indicates that a substantial number of cases of suspected research misconduct are not being reported. The manuscript has been submitted to a refereed journal.

- Awarded contracts for studies of the effectiveness of institutions' efforts to educate their staffs on their policies for dealing with research misconduct and on the role of faculty and institutions in developing responsible researchers. Proposed a study of the impact on whistleblowers who report research misconduct.

- Made five awards through the Research on Research Integrity (RRI) Program, increasing the number of studies supported in the first 5 years to 39. The studies have produced 35 publications.

- Held the fourth biennial Research Conference on Research Integrity in Tampa, FL, from December 1-3, 2006. One hundred and forty-one researchers attended from 27 states and 7 foreign countries.

Institutional Compliance

- Completed the 2005 Annual Report on Possible Research Misconduct in which 113 institutions reported they were responding to allegations of research misconduct received in 2005 or earlier. Sixty-six institutions reported receiving 137 new allegations in 2005 that resulted in the opening of 92 new cases.

- Inactivated assurances for 329 institutions or organizations for failing to submit the CY 2005 Annual Report on Possible Research Misconduct by the March 31, 2006, deadline.

- Processed 127 institutional policies on handling allegations of research misconduct, increasing the number of completed reviews to 2,167 since 1996.

- Opened 12 compliance cases, closed 8 compliance cases, and carried 7 compliance cases into 2007. Three compliance cases were carried into 2006.

Information and Privacy

- Received 77 Freedom of Information Act (FOIA) requests; 55 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 reviews agency records and publications to identify possible PHS grant support for the research identified by complainants as being possibly falsified, fabricated, and/or plagiarized. Possible PHS support can be in the form of PHS grants, fellowships, contracts, or cooperative agreements. ORI obtains the relevant grant applications and/or publications to determine whether there was PHS support for the questioned research.

2. The alleged misconduct must also meet the definition of scientific misconduct set forth in PHS regulations (42 C.F.R. Part 50 or 93).

ORI assesses whether the action reported, if it occurred prior to June 2005 and is found to be true, would represent "fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research" (42 C.F.R. Part 50, Subpart A).

Alternatively, for allegations of misconduct occurring subsequent to the effective date of the new Public Health Policies on Research Misconduct governing research misconduct (42 C.F.R. Part 93.103), the following definition applies:

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

(a) Fabrication is making up data or results and recording or reporting them.
(b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
(c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
(d) Research misconduct does not include honest error or differences of opinion.

ORI finds that many allegations involve questions of "honest error or differences of opinion 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 the PHS definition. When allegations involve possible financial misconduct, other regulatory violations, criminal acts, or civil matters (such as harassment claims), ORI refers them to the appropriate federal, or state 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 to allow ORI to frame possible issues that meet the PHS definition of research misconduct. Even when an allegation is made anonymously, precluding ORI from requesting more specific information, or adequate information is not made available when asked for, ORI continues to track the allegation for up to 2 years in case additional information is forthcoming from the complainant, or additional allegations or evidence is obtained from other sources.

ORI's review of the available information (such as grant applications, study section 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 necessary criteria will lead ORI to request an institution to conduct an inquiry (or may lead ORI to refer the allegation to the HHS Office of the Inspector General for a direct investigation).

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 reaches an appropriate disposition. ORI regularly requests additional information about allegations from an institution. Many assessments require appreciable ORI staff work at this phase.

In 2006, ORI received 267 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. 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, 2006

Handling of allegations – outcome in ORI	*Number of allegations*	
No action possible now or no action	174	
Referred to other federal agencies	22	
PIA allegations made directly to ORI		59
PIA allegations made initially to NIH		12
Pre-Inquiry Assessment (PIA) of allegations:	71	
TOTAL ALLEGATIONS	**267**	

Of the 267 allegations made to ORI (or to NIH and reported to ORI) in 2006, 71 were assessed by ORI in detail for a potential inquiry or investigation; 29 assessments resulted in the opening of formal cases. Of these, 23 were from 2006 allegations and 6 were from previous year allegations. One 2005 case developed into two cases in 2006 when a second respondent was identified. In total, 20 allegations were administratively closed (Table 2); 22 were referred to other agencies (Table 1).

Assessments of the allegations that resulted in new ORI cases took an average of 78 days; those that resulted in administrative closures took 96 days. Ten assessments were resolved by ORI within 25 days; of these, the mean time was 12 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 12 allegations that were made directly to NIH by complainants (Table 1). The number of allegations that ORI received in 2006 (267) were about the same as that for the prior year (265). The number of all allegations that were the subject of formal PIAs in 2006 by ORI (71) increased by 9 percent over the number assessed (64) in 2005.

Table 2: Time for Conduct of PIAs by ORI, 2006

Outcome of ORI assessment	*Number of new allegations*	*Total days for resolution*	*Distribution of resolution times (days)*			
			Mean	*Median*	*Mode*	*Range*
Opened formal case	29	2,249	78	42	7	2-425
Administratively closed	20	1,925	96	86	N/A	6-285
Unresolved at end of year 2006	22	–	–	–	–	0
TOTAL	71	4,145	178	135	7	2-425

Processing of Closed Cases

ORI closed 35 cases in 2006, including 7 inquiries and 28 investigations. The average duration of 24.1 months for an open case was split between institutional actions (16.6 months) and ORI oversight and actions (7.5 months) (Table 3). Thirty cases (85 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, 2006 (N= 35)

	Distribution of resolution times (months)			
Location of activity	*Mean*	*Median*	*Mode*	*Range*
Institution	16.6	9	1	1-108
ORI	7.5	4	2	1-54
TOTAL (Inst. + ORI)	24.1	12	16	2-109

The action period for the 7 institutional inquiries included their inquiry and adjudication phases, and for 28 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 action period may include an administrative hearing that is requested by the respondent before the HHS Departmental Appeals Board. One appeal filed in late 2005 was dismissed by the Administrative Law Judge because the request for an appeal lacked sufficiency and did not meet the requirements of the PHS regulation. The effect of the judge's decision was to uphold the Department's findings. Another appeal was filed in late 2006, but was not ruled upon by the end of the year.

In 2006, 15 of the 28 investigation cases closed by ORI resulted in sustained findings of research misconduct and PHS administrative actions against the respondent (Table 5). Summaries of these cases may be found in Appendix A. Summaries of the 13 investigations closed by ORI that did not result in findings of research 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 59 cases from 2005, and ORI opened 29 new cases and closed 35 cases during 2005. At the end of CY 2006, ORI had 53 active formal cases divided between inquiries and investigations (Table 4).

Table 4: ORI Research Misconduct Caseload by Case Type, 2006

Case type	*Forwarded from 2005*	*Opened in 2006**	*Closed in 2006*	*Carried into 2007*
Institutional inquiry	20	10	7	23
Institutional investigation	39	19	28	30
TOTAL	59	29	35	53

*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. Other 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 2006, ORI accepted seven institutional inquiry reports that did not recommend further investigation (Table 5). Six cases involved allegations of falsification; one dealt with both falsification and fabrication. ORI carried 23 such institutional inquiries into 2007.

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 2006 with 39 cases carried forward from 2005. During the year, 19 new institutional investigations were opened; 28 investigation cases were closed (Table 4). Of these 28 closed cases, 15 involved ORI findings of research misconduct; 9 cases did not have such findings; and 4 were administratively closed. Of the total of 35 cases closed in 2006, 43 percent (15 cases) involved findings of research misconduct, which is somewhat higher than the historical average of about 33 percent of ORI cases with such findings (Table 5).

There were 39 active investigation cases carried into 2006, and 30 active investigations carried into 2007. About 75-80 percent of the cases with an institutional decision that ORI carried over in these 2 years included institutional findings of misconduct.

Table 5: Outcome of Research Misconduct Cases Closed by ORI, 2006

	Outcome of case				
Case type	*No investigation*	*No misconduct*	*Misconduct finding*	*Administrative closure*	*Total*
Institutional inquiry	5	-	-	2	7
Institutional investigation	-	9	15	4	28
ORI inquiry or investigation	-	-	-	-	-
TOTAL	5	9	15	6	35

Administrative Closures

A formal ORI case file may be administratively closed when ORI later concludes that no PHS funds or applications were actually involved, that continuing effort will not produce sufficient evidence to resolve a case satisfactorily, or that after additional review, ORI determines that the allegation did not fall under the PHS definition of research misconduct or warrant further action. Four cases were administratively closed in 2006.

Types of Allegations and Administrative Actions

Types of Allegations Involved in Cases Closed: During 2006, of the 7 closed inquiries and the 28 investigations closed with findings, all involved allegations of falsification, fabrication, or both. Of those 35 cases, 15 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, 2006

Allegation	*Inquiry*	*Investigation*	*ORI findings or PHS administrative actions*
Fabrication	-	7	3
Falsification	6	14	6
Falsification/Fabrication	1	7	6
Plagiarism	-	-	-
TOTAL	7	28	15

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 15 cases in 2006 in which ORI misconduct findings or PHS administrative actions were imposed, one person who had been debarred for life in 2005 was sentenced to federal prison for 1 year and a day after pleading guilty to a felony related to extensive grant fraud, four persons were debarred or voluntarily excluded for 5 years, and five debarred or excluded for 3 years. Other administrative actions imposed on respondents in these 15 cases included the following: (a) prohibition from serving in any advisory capacity to PHS, including service on PHS advisory committees, boards, and/or peer review committees or as a consultant for a specified period of time (14 persons); (b) participation in 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 (five persons); (c) certification of work (one person) and (d) correction and/or retraction of articles in two cases (Table 7).

Table 7: PHS Administrative Actions Imposed in Closed Investigations with Misconduct Findings or Administrative Actions, 2006

PHS administrative actions	*Duration*	*Number of actions*
Debarment or voluntary exclusion	lifetime	1
Debarment or voluntary exclusion	5 years	4
Debarment or voluntary exclusion	3 years	5
Prohibition from serving as an advisor for PHS	5 years	4
Prohibition from serving as an advisor for PHS	3 years	9
Prohibition from serving as an advisor for PHS	2 years	1
Supervision plan required	2 years	1
Supervision plan required	3 years	4
Certification of work	3 years	1
Retraction or correction of articles	–	2

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: (a) rapidly reviewing institutional procedures to identify problem areas; (b) advising or assisting in sequestration and inventory of physical or computer evidence; (c) advising on case strategy, including legal issues; (d) outlining specific PHS issues; (e) providing PHS grant applications; (f) educating on or assisting with sophisticated analytical techniques for image comparisons and statistical or digit analyses of data to prove falsification or fabrication; (g) suggesting collateral evidence to confirm or refute questioned claims; (h) advising on "missing" records; (i) assisting in locating experts; (j) developing strategies to prevent incomplete or withdrawn "admissions"; (k) informing other federal agencies; (l) notifying or requesting help from other institutions; (m) advising on potential whistleblower and confidentiality issues; (n) helping with contacts to national databases (such as Genbank); and (o) assisting with journal editors for papers that require correction or retraction.

ORI provided RRTA help to 25 institutional officials and journal editors in 2006. The assistance provided by ORI included giving advice to institutional officials on how to conduct inquiries and assessments, interacting with sister agencies seeking advice on how to handle allegations of research misconduct in their own agency, and advising journal editors who had concerns about possibly falsified or fabricated data and images appearing in manuscripts under review.

Challenging problems for institutions with which DIO can help 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.

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, RIO Training Program, RCR Program for Academic Societies, RCR Program for Graduate Schools, conferences and workshops, a web site, 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 made five awards through the RCR Resource Development Program in 2006 to support the creation of sophisticated hands-on resources with specific applications to data analysis, animal welfare, laboratory management, peer review, and learning assessment.

With these awards, the program has supported 54 projects since its establishment. Twenty-four completed resources are posted at http://ori.hhs.gov/education/rcr_resources.shtml. Resources developed through the program and independently by universities cover the nine core RCR instructional areas.

All products supported by the ORI program are in the public domain and may be used freely. Proper acknowledgment should be given to the originators and ORI.

Project titles, project directors, awardee institutions, and a brief description of the proposed resources follow:

RCR Instructional Assessment Project
James Dubois, Saint Louis University

An extensive list of learning objectives for seven RCR core instructional areas and a battery of test items categorized by RCR topic and learning objectives.

Teaching Research Integrity in Analysis and Reporting: A Web Site with Case-Based Vignettes
Harold Kincaid and Sara Vollmer, University of Alabama-Birmingham

A multimedia course to address questionable practices in power analysis, microarray analysis, handling of outliers, and image processing.

IACUC Animal Facility Inspections Training Module: "Virtual Walk-Through"
David Lyons, Wake Forest University

A virtual walk-through of an animal laboratory that will enable trainees to use their computers to navigate through the laboratory to inspect for violations.

Multimedia Software to Ensure Responsible Laboratory Management Skills
Derina Sara Samuel, Syracuse University

A computer-based tool to help new and experienced laboratory directors with the following tasks: hiring personnel, working with administrators, maintaining budgets, time management, and mentoring junior scientists or graduate students.

Peer Review Tool: Data Analysis
Min Qi Wang, University of Maryland

A complete "Peer Review Tool" package that covers hypothesis formation, methodology, data analysis, and interpretation. The software will produce a report that will include possible errors in the paper along with explanations.

Six instructional RCR resources developed with support from the program were added in 2006 to the ORI web site http://ori.hhs.gov./education/rcr_resources.shtml

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

Video Vignettes on Research Ethics and Academic Integrity
Derina Sara Samuel
Syracuse University

RCR Competency-based Assessment and Self-Study Program
Lori Bakken
University of Wisconsin-Madison

Educating Clinical Staff on Clinical Research Data Collection and Data Management
Cheryl Chanaud
St. Jude's Children's Research Hospital

Data Acquisition and Management
Daniel Vasgird
Columbia University

Collaborative Science
Daniel Vasgird
Columbia University

Ethics of Peer Review: A Guide for Manuscript Reviewers
Sara Rockwell
Yale University

RCR Expo

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.

Exhibits focus 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.

Instructional materials on data management, peer review, publication practices, mentoring, research misconduct, and laboratory management were on display at the fourth annual RCR Expo on October 16-17, 2006, in the Quebec City (Canada) Convention Center in conjunction with the annual meeting of the Society of Research Administrators (SRA) International.

The exhibiting organizations and the title and description of their resource follow:

Data Acquisition, Retention, Storage, Custody, Sharing, Ownership, Interpretation and Reporting
Cleveland Clinic

This computer-based training (CBT) assists in complying with increasingly complex regulations in the areas of data acquisition, retention, storage, custody, sharing, ownership, interpretation, and reporting.

Multi-media Software to Ensure Responsible Laboratory Management Skills
Graduate School of Syracuse University

The product provides video vignettes and web-based decision tree-style questions and responses designed to increase the retention and transference of ethical behavior related to data acquisition, management, sharing, and ownership in the biomedical and behavioral sciences.

Peer Review Tool: A Sample Size Determination for Experimental Studies
University of Maryland College Park

This computer-based product helps peer reviewers evaluate journal submissions in a step-by-step fashion. Using an easy-to-follow method, the tool walks the reviewer through each section of the paper, including the background, methodology, data analysis, and discussion, and provides the reviewer with a summary of possible errors in the paper based on the reviewer's responses to several checklist-type items.

Peer Review Quick Guide
Responsible Authorship Quick Guide
Northern Illinois University

Two on-line tutorials addressing peer review and publication practices were on display. The tutorials serve as quick guides on mistakes and dilemmas that researchers encounter when peer reviewing or authoring publications.

Mentoring Relationships for Multi-cultural Populations
Howard University

This product addresses the role that culture plays in the mentor/mentee relationship. Five discussion groups composed of faculty and students analyze instances of mentorship and consider the impact of diverse cultural perspectives.

Development of Web-Based Intervention on Research Misconduct
University of Texas Health Science Center

This web-based educational intervention is designed to help investigators and administrators develop knowledge and skills to prevent, recognize, report, and manage research misconduct. The intervention uses case-based pedagogy and features four cases on plagiarism, fabrication, falsification, and whistleblowers. The cases are presented in video vignettes that are analyzed by experts in on-camera interviews, and the vignettes are accompanied by resource materials.

Baseline RCR Testing Program
Vanderbilt University Medical Center

This is an online version of a validated test of basic RCR concepts and standards with 14 demographic items to be used in determining students' pre-course baseline level of knowledge.

Lab Management: Training and Education for the Principal Investigator and Associated Technical Personnel
Washington State University

This project developed educational materials for university faculty and key laboratory management personnel, focusing on five topic areas: (1) data/notebook management, (2) training/mentoring, (3) writing skills, (4) fiscal/administrative management, and (5) general safety training.

Basic Research Concepts
San Diego State University

The Training in Research and Ethics Standards (TRES) curriculum provides an accessible, culturally appropriate, and translated training program to increase awareness of the ethical aspects of conducting research within the Hispanic/Latino community. Skill development in applying ethical practices associated with research involving human participants is stressed.

Collaborative Institutional Training Initiative (CITI) Program

The Collaborative Institutional Training Initiative (CITI) course in RCR, developed with support from ORI and hosted by the University of Miami School of Medicine, is freely available to the worldwide research community at http://www.citiprogram.org

The course covers seven of the nine core RCR instructional areas: data management, mentoring, authorship and publication practices, peer review, research misconduct, collaborative science, and conflict of interest. CITI offers a separate course on human research subjects. Training in animal welfare will be available in early 2007 from CITI.

Course material was selected by the CITI RCR Developer Group from projects supported by the RCR Resource Development Program created by ORI in 2002. Members of the Developer Group are Dan Vasgird, University of Nebraska-Lincoln; Ruth Fischbach and Joyce Plaza, Columbia University; Steve Fliesler, Saint Louis University; Marianne Elliot, Department of the Navy; Michael Fallon, Department of Veterans Affairs, Atlanta, and Emory University; and Reid Cushman, Kenneth Goodman

and Paul Braunschweiger, University of Miami. The CITI RCR Developer Group will conduct semiannual reviews of the program.

The CITI program permits institutions to customize the course to meet the specific needs of various disciplines and institutions, provides learner completion certificates, and features utilities for institutional administrators to download user data and feedback. The software also provides the opportunity for organizations to post their own RCR materials in modular fashion. User Satisfaction Surveys are employed to gauge software functionality, user attitudes, opinions, and suggestions for improvement.

Although CITI provides basic and advanced courses in the protection of human research subjects on an institutional subscription basis, the CITI RCR Program will be available for free at least through May 2008. The program is hosted by the University of Miami Medical Information Technology on dedicated servers and administered by the Office of Research Education.

Research Integrity Officer (RIO) Training Program

The first phase of the RIO Training Program was completed in 2006 with the posting of an orientation video, *The Role of the RIO*, on the ORI web site, and the second phase, the creation of mini and intensive boot camps, was begun.

The video contains two parts: program and interviews. The 24-minute program provides RIOs, the institutional officials responsible for implementing the PHS Policies on Research Misconduct (42 C.F.R. Part 93), with an introduction to receiving and responding to allegations, sequestering data, protecting whistleblowers, and instructing inquiry and investigative committees; their additional responsibilities; their involvement with RCR training; and advice to new RIOs.

Extensive interviews, indexed by subject, are presented with four veteran RIOs and three ORI staff. The RIOs are Joe Corless, Duke University; Margaret Dale, Harvard University; Todd Guttman, Ohio State University; and David Wright, Michigan State University (MSU), the Project Director. The ORI staff members are Chris Pascal, Director; Alan Price, former Director, Division of Investigative Oversight; and Larry Rhoades, Director, Division of Education and Integrity.

The video was 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.

ORI also launched the second phase of its RIO training program by creating mini camps and intensive boot camps designed to equip RIOs with the knowledge and skills required by that position.

Mini camps, lasting 1 day or less, will be held in conjunction with regularly scheduled professional meetings. Participation will be open to all RIOs and counsels who are members of the professional association holding the meeting. Enrollment will be limited.

Boot camps, lasting 3 days, will be held at universities located around the country. These boot camps are designed initially for RIOs and counsels from the top 100 NIH awardee institutions, the location of most research misconduct cases. Participation will be by invitation and will be limited to 25 per boot camp.

The camps will cover interviewing complainants, respondents, and witnesses; sequestering and safeguarding data; training inquiry and investigative panels; using advanced forensic techniques; performing case file management; writing (or helping panels write) adequate inquiry and investigative reports; providing liaison with federal oversight agencies (e.g., ORI) and sponsors; providing liaison with colleagues administering other regulatory processes (e.g., IRBs) in triaging complex cases; and operating successfully in complex research institutions. Experienced current and former RIOs and ORI staff will provide instruction.

The first mini camp was held at the annual meeting of the Society of Research Administrators (SRA) International in Quebec City, Canada, on October 15, 2006. The first boot camp was held at the University of Michigan in May 2007.

RCR Program for Academic Societies

Seven awards were made in 2006 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, made 39 awards to 31 societies from 2002 to 2006 to develop guidelines, standards, policies, articles, conferences, curricula, and other resources designed to promote the responsible conduct of research among members of their societies. Funding for the program ended in 2006.

Award abstracts are available at http://ori.hhs.gov/education/aamc_funded_1-3.shtml. Academic societies receiving awards in 2006 and project titles follow:

American College of Neuropsychopharmacology
Code of Conduct for Sustaining Corporations and Corporate Representatives - Setting the Standard for Ethical Conduct

American College of Rheumatology/Association of Rheumatology Health Professionals
Data Management in Research: Getting It Right the First Time

American Society of Hematology
Clinical Research Training Institute

Federation of American Societies for Experimental Biology
Shared Responsibility, Individual Integrity: Scientists Addressing Conflicts of Interest in Biomedical Research

Council on Social Work Education
Promoting Research Integrity in Social Work Education

Society of Research Subject Advocates
Orientation and Research Integrity Workshop

Society of University Surgeons
Surgical Innovation, Investigation, and the IRB

A list of products produced by academic societies supported by the RCR Program for Academic Societies that are available online is at http://www.aamc.org/programs/ori/. Additional products will become available as recently funded projects are completed.

AcademyHealth
"Ethics Interactive: A Learning Module for Researchers, Educators, and Mentors"

Ambulatory Pediatric Association
"Ensuring Integrity for Research With Children"

American Occupational Therapy Foundation
"A Responsible Conduct of Research Curriculum"

Association of Academic Health Sciences Libraries
"Responsible Literature Searching"

Association of Chairpersons of Departments of Physiology
"Education in the Responsible Conduct of Research"

Association of Rheumatology Health Professionals
"Responsible Conduct of Research"

Endocrine Society
"Incorporating Ethics in Clinical Research Study Design"

Society for Academic Emergency Medicine
"Ethical Conduct of Resuscitation Research"

Society of Teachers of Family Medicine
Protecting Participants in Family Medicine Research: A Consensus Statement on Improving Research Integrity and Participants' Safety in Educational Research, Community-based Participatory Research, and Practice Network Research"

Six additional products supported by the program are available from the producing societies or in journals. The name of the academic society, the title of its product, and its availability follow:

Alliance of Independent Academic Medical Centers
Proceedings of a symposium on "An Ethical Framework for Managing Clinical Trials in the Independent Academic Center"
Available from Kimberly@aiamc.org

American Society for Bioethics and Humanities
An article on "Educational Approaches to the Responsible Conduct of Clinical Research" in *Academic Medicine*, January 2007, 82:1, pp. 32-39.

American Thoracic Society
A policy statement on "The Ethical Conduct of Clinical Research Involving Critically Ill Patients in the United States and Canada: Principles and Recommendations" in the *American Journal of Respiratory and Critical Care Medicine,* December 2004, 170:12, pp. 1375-1384

The Council on Social Work Education
National statement on "Research Integrity in Social Work"
Available from jholmes@cswe.org

The Gerontological Society of America
Guidebook for Multidisciplinary Clinical Geriatric Research
Order at http://www.geron.org/guidebook2006.htm

Research and Assessment Corporation for Counseling, Inc.
A DVD and training manual on "Conducting Research Responsibly"
Available from klwester@uncg.edu

RCR Program for Graduate Schools

Mandatory training in the responsible conduct of research for all graduate students is one of six interventions recommended by the Council of Graduate Schools (CGS) in its report on a research and demonstration project on integrating RCR education into graduate programs.

Other interventions recommended in the report, *Graduate Education for the Responsible Conduct of Research*, include establishing an advisory board, providing public forums, offering two-tiered instruction, teaching ethical reasoning, and developing multi-level assessments.

The report, published in October 2006, may be purchased from the CGS Online Bookstore at http://www.cgsnet.org/Default.aspx?tabid=79&List=0

The report is based on the "best practices" that emerged from a 2-year project, funded by ORI, that involved the efforts of 10 institutions to establish RCR programs: Arizona State University, Duke University, Florida State University, New York Medical College, Old Dominion University, University of Kansas, University of Missouri-Columbia, University of New Hampshire, University of Rhode Island, and the University of Utah.

The demonstration project will continue through December 2007 with funding from the National Science Foundation. Last fall, CGS made awards to Bradley University, Brown University, Old Dominion University, Rockhurst University, University of Alabama-Birmingham, University of Kansas, University of Nebraska-Lincoln, and the University of Oklahoma.

Recognizing that instituting mandatory training for all graduate students would be "a very difficult thing to do," the report suggested three strategies that appeared to be effective: (1) offering small grants to departments for the development of the needed RCR courses or course elements; (2) embedding RCR education into existing voluntary programs such as Preparing Future Faculty, and (3) including or expanding RCR segments in courses that are already mandatory.

Establishing an advisory board composed of "high-profile senior faculty members whose reputation is beyond reproach" is an effective way for institutional leadership to "exhibit its commitment to academic integrity prominently," the report said. "The steering committee or advisory board would develop, deliberate, and advance RCR education interventions throughout the institution. It might be set up to report to the graduate dean, the graduate council, or the provost. Its charge should be to promote campus-wide awareness of RCR through public forums, as well as to design and propose curriculum strategies to expand and improve RCR training for graduate students."

The report further suggests that providing well-publicized, regularly offered public forums can enhance the ethical climate for research at an institution. "Such forums serve not just the purpose of educating the public and the university community about the ethical dimensions of scientific practice," the report said, "but also of exhibiting the institution's commitment to integrity in research."

The report also recommends that institutions establish two-tiered RCR instruction programs. The first tier would consist of "departmental-level, disciplinary programs with involvement and commitment from program faculty." The second tier would consist of interdisciplinary, cross-departmental seminars and coursework.

"The primary interest of departmental faculty may be to enculturate students into their disciplines, and not to develop their 'characters' or otherwise try to inoculate them against misbehavior. Perspectives from outside the discipline, on the other hand, may prove challenging and broadening for students...," the report said.

Graduate students should be taught ethical reasoning skills "primarily to help students develop consistency, coherence, and confidence in their opinions and behaviors," the report argues.

Citing assessment as "the most difficult of all challenges in establishing quality RCR programs" the report declared, "Assessment will be required at the departmental and course level, and at the level of the individual student. And assessment of the many different aspects of RCR will need to be implemented, making assessment truly a multi-dimensional task."

First World Conference on Research Integrity

Over the last two decades, research misconduct has been investigated in at least 16 countries: Australia, Canada, China, Denmark, England, Finland, Germany, India, Israel, Japan, Norway, Poland, South Africa, South Korea, Sweden, and the United States.

The possibility of international cooperation, coordination and action on research misconduct, questionable research practices, research environments, and RCR education will be explored during the first World Conference on Research Integrity that will be held in Lisbon, Portugal, from September 16-19, 2007.

The conference web site explains the rationale for this pioneering gathering: "Research regulations and commonly accepted research practices vary significantly from country to country and among professional organizations. There is no common definition worldwide for research misconduct, conflict of interest or plagiarism. Even where there is general agreement on key elements of research behavior, such

as the need to restrict authorship to individuals who make substantive contributions to the research or to provide protection for research subjects, the policies that implement this agreement can vary widely from country to country and organization to organization. The research community worldwide has to address these problems in order to retain public confidence and to establish a clear best practice framework at an international level."

ORI is collaborating with the European Science Foundation (ESF) in organizing the conference that will be held at the headquarters of the Calouste Gulbenkian Foundation. The Portuguese Ministry for Science, Technology and Higher Education (PMSTHE) will host the conference as of part of the Portuguese presidency of the European Union.

Besides ESF and ORI, the conference is supported by the European Commission, the European Molecular Biology Organization, the Committee on Publication Ethics, the PMSTHE, the Portuguese Science Foundation, the Calouste Gulbenkian Foundation, the UK Research Integrity Office, International Council for Science, and the North Atlantic Treaty Organization. See the conference web site at www.esf.org/conferences/researchintegrity

Conferences and Workshops

ORI held six conferences or workshops in 2006. The workshops were organized in collaboration with universities, medical schools, professional organizations, and government agencies. More information about the conference and workshop program is available at http://ori.hhs.gov/conferences/

February 17
Responsible Conduct in Research in the Social and Behavioral Sciences
Chicago, IL
Co-sponsors: University of Illinois-Chicago, American Association of State Colleges and Universities, National Science Foundation, and National Institutes of Health

March 31
Promoting Research Integrity in the Social and Behavioral Sciences
San Antonio, TX
Co-sponsors: University of Texas-San Antonio, American Association of State Colleges and Universities, National Science Foundation, and National Institutes of Health

July 24-25
Mentoring and Supervision for the Responsible Conduct of Research
St. Louis, MO
Co-sponsor: Washington University School of Medicine

September 14-15
Statistics, Images, and Perceptions of Truth: Detecting Research Bias and Misconduct
Birmingham, AL
Co-sponsor: University of Alabama-Birmingham

September 28-29
New Capabilities, Emerging Issues and Responsible Conduct in Data Management
Baltimore, MD
Co-sponsor: University of Maryland-Baltimore

December 1-3
Research Conference on Research Integrity
Tampa, FL
Co-sponsors: University of South Florida, Association of American Medical Colleges, and the American Association for the Advancement of Science

ORI Web Site

The ORI web site received 131,765 visitors in 2006 from 147 countries that viewed 477,407 pages, according to Google Analytics. Unique visitors totaled 91,178 visits, while return visitors totaled 40,587 visits. Visitors viewed an average of 3.62 pages per visit.

Visitors were most frequently from Canada, the United Kingdom, Japan, Australia, Korea, Hungary, India, Germany, China, Denmark, France, Singapore, Netherlands, Switzerland, Slovenia, Philippines, Israel, Spain, Sweden, South Africa, Brazil, Italy, and the United States.

ORI added four features to its home page to enable it to keep in touch with its clients and enable them to keep in touch with ORI: RSS Feeds, e-mail subscriptions, submit your news, and web site feedback.

The RSS Feeds allow visitors to receive the news as soon as it is released on the ORI web site through an RSS News Aggregator or a customized home page through Google or Yahoo. The front page of the ORI web site provides three links to automatically subscribe through Google, Yahoo, or NewsGator. Visitors who use other RSS readers can simply enter http://ori.hhs.gov/feed.xml into their news reader.

Visitors may also subscribe to the ORI e-mail database to receive periodic advance notices concerning the latest newsletter, upcoming conferences, study findings, provocative articles, new funding opportunities, RCR resources, and other important topics related to the responsible conduct of research, research integrity, or research misconduct. Visitors can subscribe to the e-mail database by clicking on Subscribe to ORI on the ORI home page.

ORI also created an on-line feature to assist visitors in drawing attention to activities, events, publications, web sites, resources, and programs related to responsible conduct of research, research integrity, or research misconduct. The submitted news may be published in the ORI newsletter, posted on the web site, or sent out through ORI listservs or e-mail databases. ORI makes the final determination on the suitability of the submitted items. Visitors may send news to ORI by clicking on Submit Your News on the ORI home page.

In addition, ORI has added a simple on-line form in the feedback section to encourage visitors to provide comment on the content, navigation, organization, appearance, and other features of its web site. All submissions are completely anonymous.

Publications

Twenty thousand copies of the *ORI Introduction to the Responsible Conduct of Research* were distributed free to researchers in South Korea in 2006 by the Ministry of Education and the Korea Research Foundation in the aftermath of the stem cell research misconduct case.

The Korean translation also includes appendices containing the PHS Policies on Research Misconduct and the 2004 ORI Annual Report. The ORI publication has also been translated into Chinese and Japanese. The publication is available at http://ori.hhs.gov for online reading or downloading. More information on ORI publications is at http://ori.hhs.gov/publications/

Staff Presentations

John Dahlberg, Director, DIO. "Scientific Forensics: Some Techniques Used by DIO to Show that Data Have Been Falsified," at the Inter-Institute Bioethics Interest Group, NIH, October 16, 2006.

John Dahlberg, Director, DIO. "Detecting and Investigating Falsified Analyses" and "Statistics, Images, and Perceptions of Truth: Detecting Research Bias and Misconduct," University of Alabama, Birmingham, AL, September 14-15, 2006.

Chris B. Pascal, Director, ORI. "Issues in Research Integrity: A Dialogue with Nobel Laureates," Fourth Symposium on Ethics and Integrity in Science and Research, the Association of Anatomy, Cell Biology, and Neurobiology Chairs, Aruba, January 18-22, 2006.

Chris B. Pascal, Director, ORI. "Research Integrity," Extramural Scientist Administrators (ESA) Seminar, NIH, Bethesda, MD, April 21, 2006.

Chris B. Pascal, Director, ORI. "Federal Update" and "Promoting Integrity and Avoiding Misconduct in Research," Office for Human Research Protections (OHRP) Research Community Forum (RCF), Bridging the Regulatory Gap: Biomedical and Social/Behavioral Research Are Closer Than You Think, University of Notre Dame, South Bend, IN, May 16, 2006.

Chris P. Pascal, Director, ORI. "ORI: Financial Conflict of Interest & Conflicts of Research Integrity" and "ORI Federal Update," National Human Subject Protections Conference (OHRP), Denver, CO, June 1-2, 2006.

Chris P. Pascal, Director, ORI. "Research Misconduct, The Responsible Conduct of Research and Case Studies," Marquette University, Milwaukee, WI, July 13, 2006.

Chris P. Pascal, Director, ORI. "Research Misconduct and the Responsible Conduct of Research," American Congress of Rehabilitation Medicine-American Society of Neurorehabilitation (ACRM-ASNR) Joint Conference, Translating Research into Practice, Boston, MA, September 27-October 1, 2006.

Chris P. Pascal, Director, ORI. "Ten Easy Ways to Commit Misconduct and Create Havoc in the Lab," New Capabilities, Emerging Issues and Responsible Conduct in Data Management, Baltimore, MD, September 28-29, 2006.

Chris P. Pascal, Director, ORI. "ORI and the Public Trust: Research Misconduct, Protecting the Literature, Questionable Practices, and the Health Care Consumer," Biomedical Research and the Law, Hofstra Law School, Boston, MA, October 4-5, 2006.

Chris B. Pascal, Director, ORI. "The Office of Research Integrity Mission, Introduction to the Responsible Conduct of Research," FDA's Research Involving Human Subject Training Program, Rockville, MD, November 8, 2006.

Chris B. Pascal, Director, ORI. "Ensuring the Public Trust: Responding to Research Misconduct and Promoting Responsible Research," University of Wisconsin, Madison, WI, December 6-8, 2006.

Nicholas H. Steneck, Consultant. "Overview of Federal Funding Agencies' RCR Training," American Association for the Advancement of Science Annual Meeting, St. Louis, MO, February 20, 2006.

Nicholas H. Steneck, Consultant. "Protecting the Integrity of Science: Scientific Misconduct," American Association for the Advancement of Science Forum on Science & Technology Policy, Washington, DC, April 21, 2006.

Nicholas H. Steneck, Consultant. "Integrity vs. Accountability: Institutional/ Investigator Interaction," Forum for Institutional Review Boards (IRBs)/Research Ethics Boards (REBs) in Canada and the United States (FOCUS), 4th Annual Conference, Washington, DC, June 2, 2006.

Nicholas H. Steneck, Consultant. "Foundations for RCR," Conference on Mentoring and Supervision for the Responsible Conduct of Research, Washington University, School of Medicine, St. Louis, MO, July 24, 2006.

Nicholas H. Steneck, Consultant. "Research Integrity in the Life Sciences," Fin/Bio/Net Ph.D. Student Symposium, Life Sciences in Today's Society, Harjattula, Finland, October 9, 2006.

Nicholas H. Steneck, Consultant. "The History, Impact and Future of Responsible Conduct of Research (RCR) Education in the U.S.," Symposium on Education in Research Ethics, Helsinki, Finland, October 11, 2006.

Nicholas H. Steneck, Consultant. "Research Integrity in the Life Sciences," European Molecular Biology Organization Postdoctoral Meeting, Salk Institute, La Jolla, CA, November 11, 2006.

Sandra Titus, Director, Intramural Research. "Research Integrity," Howard University, Washington DC, February 8, 2006.

Sandra Titus, Director, Intramural Research. "Mentoring and Supervision for the Responsible Conduct of Research," Washington University, July 24, 2006.

Sandra Titus, Director, Intramural Research. "Difficulties in Trying to Determine Incidence of Research Misconduct," Research Conference on Research Integrity, Tampa, FL, December 2, 2006.

Staff Publications

Dahlberg, J.E., and Mahler, C.C. "The Poehlman Case: Running Away from the Truth." *Science and Engineering Ethics* 2006, 12(1):157-173.

Pascal, C.B. "Complainant Issues in Research Misconduct: The Office of Research Integrity Experience." *Experimental Biology and Medicine* 2006, 231:1264-1270.

Pascal, C.B. "Managing Data for Integrity: Policies and Procedures for Ensuring the Accuracy and Quality of the Data in the Laboratory." *Science and Engineering Ethics* 2006, 12(1):23-39.

Pascal, C.B. "Issues on Research Integrity: A Perspective." *Experimental Biology and Medicine* 2006, 231:1262-1263.

Pascal, C.B. "Education in the Responsible Conduct of Research: Opportunities and Potential Impact on the Research Institution" (Chapter 43), "Beyond the Federal Definition: Other Forms of Misconduct" (Chapter 50) in "Research Administration and Management." Editors, Elliott Kulakowski and Lynne Chronister, 2006, Jones and Bartlett Publishers.

Federal Register Notices - Scientific Misconduct

Findings of Scientific Misconduct Notice. Vol. 71, No. 32, 8304, Thursday (February 16, 2006) [Swe]

Findings of Scientific Misconduct Notice. Vol. 71, No. 32, 8304, Thursday (February 16, 2006) [Goldring]

Finding of Debarment Notice. Vol. 71, No. 37, 9555-9556, Friday (February 24, 2006) [Kornak]

Finding of Scientific Misconduct Notice. Vol. 71, No. 57, 14895-14896, Friday (March 24, 2006) [Woreta]

Finding of Scientific Misconduct Notice. Vol. 71, No. 62, 16308-16309, Friday (March 31, 2006) [Aronica]

Finding of Scientific Misconduct Notice. Vol. 71, No. 110, 33308-33309, Thursday (June 8, 2006) [Leadon]

Finding of Research Misconduct Notice. Vol. 71, No. 128, 38166-38167, Wednesday (July 5, 2006) [Zhao]

Finding of Misconduct in Science Notice. Vol. 71, No. 152, 45056-45057, Tuesday (August 8, 2006) [Okoro]

Finding of Scientific Misconduct Notice. Vol. 71, No. 164, 50064, Tuesday (August 24, 2006) [Zhu]

Finding of Research Misconduct Notice. Vol. 71, No. 226, 67870, Friday (November 24, 2006) [Lin]

Finding of Misconduct in Science Notice. Vol. 71, No. 226, 67870-67871, Friday (November 24, 2006) [Robinson]

Finding of Research Misconduct Notice. Vol. 71, No. 235, 70966-70967, Thursday (December 7, 2006) [Blaisdell]

Finding of Research Misconduct Notice. Vol. 71, No. 236, 71172, Friday (December 8, 2006) [McMaster]

Finding of Research Misconduct Notice. Vol. 72, No. 5, 966-967, Tuesday (January 9, 2007) [Park]

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 the studies 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. One study was completed in 2006; three others are continuing, and another is proposed.

Completed Study

Reporting Suspected Research Misconduct in Biomedical and Behavioral Research

This study, conducted by The Gallup Organization, provides a description of the frequency and types of suspected misconduct that 2,212 scientists observed in 3 academic years (2002-2004). The study indicates that a substantial amount of suspected research misconduct is not being reported. Twenty percent of the scientists wrote that the most important way to promote reporting research misconduct is the degree of protection offered to whistleblowers. An article has been submitted to a peer-reviewed journal.

Studies in Progress

Institutional Research Integrity Officer (RIO) Study

This study, conducted by the Research Triangle Institute International, is focused on the role of the RIO, the institutional official 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 and the promotion of research integrity. Half of the sample will come from the top 100 NIH-funded institutions, and the remaining population will be drawn from the other 1,600 educational or research institutions. The study is expected to be completed in 2008.

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

This study, conducted by the Research Triangle Institute International, is to evaluate how effectively institutions have informed their faculty about the PHS Policies on

Research Misconduct (42 C.F.R. Part 93). The study will collect data on how much faculty know about what constitutes research misconduct, developing and reporting an allegation, and the rights and responsibilities of respondents and whistleblowers. In addition, the study will ask faculty to evaluate the effectiveness of institutions in handling research misconduct allegations and in protecting whistleblowers. The study is expected to be completed in 2008.

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

ORI staff is analyzing 50 research misconduct cases involving postdocs and research associates to determine the type of relationship the respondents had with their mentor/advisor. The case files are being examined to determine whether mentors/advisors supervised or delegated that responsibility to others, the Principle Investigator (PI)/advisor examined original data, the respondent was under any stress to meet a deadline, or the laboratory had difficult interpersonal behaviors. The study is expected to be completed in 2007.

Training and Mentoring PhDs: Faculty Views on their Role and their Institution's Role to Promote the Development of Responsible Researchers

This study, conducted by Mathematica Policy Research, Inc., focuses on how faculty and institutions promote the responsible conduct of research in training Ph.D. students. The objectives of the study are to (1) be able to understand how faculty describe the differences between being an advisor versus being a mentor, (2) how these two roles work with doctoral students to promote the responsible conduct of research, and (3) to learn what they report their institution is doing in terms of policies, programs, and incentives to promote quality research advising and research mentoring. The study is expected to be completed in 2008.

Proposed Study

Evaluating the Impact on Whistleblowers Who Report Research Misconduct

This study will interview whistleblowers in closed research misconduct cases to determine what happened to them prior to, during, and after the investigative process ended. A proposal has been submitted for funding by HHS. If funded, the study is expected to be completed in 2009.

Extramural Research Program

Research on Research Integrity (RRI) Program

ORI established its extramural research program, RRI, in 2000 in collaboration with the National Institute of Neurological Disorders and Stroke (NINDS). Since the first

awards were made in 2001, several NIH Institutes have participated in the program including the National Institute of Nursing Research (NINR), the National Institute on Drug Abuse (NIDA), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Cancer Institute (NCI), the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of General Medical Sciences (NIGMS), and the National Human Genome Research Institute (NHGRI). Other partners include the Center for Scientific Review (CSR), the National Library of Medicine (NLM), and the Agency for Healthcare Research and Quality (AHRQ).

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.

Since it began in 2001, the RRI program has produced 34 publications in 13 journals including *Nature, New England Journal of Medicine, Journal of the American Medical Association*, and the *British Medical Journal*.

Total funding for the RRI program in 2006 was $3,070,404, the highest in the 6-year program. New grants received $1,116,974; continuations received $1,953,430. ORI contributed $1,524,520; NIH components, $1,320,134; and AHRQ, $225,750.

Award abstracts are posted on the ORI web site along with a list of publications produced by projects supported by the RRI program. The grant titles, PIs, and awardee institutions follow:

Compliance with Adverse Event Reporting Requirements in Cancer Clinical Trials
Steven Joffe, Dana Faber Cancer Institute

Views and Approaches toward Research Integrity among IRBs
Robert L. Klitzman, New York State Psychiatric Institute

Analysis of Research Misconduct Policies: Survey of Research Integrity Officers
Rebecca Ann Lind, University of Illinois

Research Culture of Practice-based Research Networks
Anne Victoria Neale, Wayne State University

Board of Trustees: Systemic Conflict of Interest at Research Universities
Sheila Slaughter, University of Georgia

Nick Steneck, an ORI consultant, assumed the directorship of the RRI program on January 1, 2007, replacing Mary Scheetz, who resigned from federal service in June 2006. Scheetz had directed the program since its inception. Steneck has been a major

contributor to the RRI program since it was created and a co-organizer of the four biennial Research Conferences on Research Integrity. Scheetz became an Assistant Professor of Medical Education, Department of Bioethics, University of Virginia, in January 2007.

RRI Publications

Researchers supported by the RRI Program published six articles in 2006 on research integrity and the responsible conduct of research in three journals.

In the first 5 years of the program, RRI researchers have published 23 articles, 8 abstracts, a commentary, 2 reviews, and a letter to the editor. A complete list of RRI publications is available on the ORI web site at http://ori.hhs.gov/research/extra/rri_publications.shtml. Citations to the recently published articles follow:

- Vogeli, C., Yucel R., Bendavid, E., Jones, L.M., Anderson, M.S., Louis, K.S., and Campbell, E.G. "Data Withholding and the Next Generation of Scientists: Results of a National Survey." *Academic Medicine* 2006, 81:128-136.

- deVries, R., Anderson, M.S., and Martinson, B.C. "Normal Misbehavior: Scientists Talk about the Ethics of Research." *Journal of Empirical Research on Human Research Ethics* 2006, l(1):43-50.

- Martinson, B.C., Anderson, M.S., Crain, A.L., and deVries, R. "Scientists' Perceptions of Organizational Justice and Self-Reported Misbehaviors." *Journal of Empirical Research on Human Research Ethics* 2006, l(1): 51-66.

- Keith-Spiegel, P., Koocher, G.P., and Tabachnick, B. "What Scientists Want from Their Research Ethics Committees." *Journal of Empirical Research on Human Research Ethics* 2006, l(1): 67-82.

- Gardner, W., and Lidz, C.W. "Research Sponsorship, Financial Relationships, and the Process of Research in Pharmaceutical Clinical Trials." *Journal of Empirical Research on Human Research Ethics* 2006, l(2):11-18.

- Mumford, M., Davenport, L.D., Ryan, P.B., Connelly, S., Murphy, S.T., Hill, J.H., and Antes, A.L. "Validation of Ethical Decision Making Measures: Evidence for a New Set of Measures." *Ethics and Behavior* 2006, 16(4):319-345.

Research Conference on Research Integrity - 2006

One hundred and forty-one researchers from 27 states and 7 foreign countries attended the fourth biennial Research Conference on Research Integrity in Tampa, FL, on December 1-3, 2006. The conference was co-hosted by the University of South Florida and co-sponsored by the American Association for the Advancement of Science and the Association of American Medical Colleges.

Sixty presentations were made on research misconduct and questionable research practices, authorship and publication issues, conflict of interest, research environments, human subjects' research, peer review, and RCR education. More information on the research conference is available at http://ori.hhs.gov/conferences/past_conf.shtml

Ana Marusic, M.D., Ph.D., Professor, Department of Anatomy, Zagreb University School of Medicine, Croatia, gave the keynote address, *The Role of Editors and Journals in Detecting Scientific Misconduct: Strengths, Weaknesses, Opportunities and Threats*. Marusic is editor in chief of the *Croatian Medical Journal* and President-elect of the Council of Science Editors (CSE).

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 awarded only to eligible institutions. An institution is eligible when it has an active assurance on file with ORI stating that it has developed and will comply with an administrative process for responding to allegations of scientific misconduct in PHS-supported research that complies with the PHS regulation. An institution establishes an assurance by filing an initial assurance form or signing the face page of the PHS grant application form revised in 1996. Institutions keep their assurance active by submitting the Annual Report on Possible Research Misconduct (Annual Report), submitting their research misconduct 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 127 during 2006 to 4,573 (see Table 8). Four hundred and fifty-six institutions were added to the assurance database; 413 had filed their initial assurance, and 43 reestablished their assurance by submitting their Annual Report on Possible Research Misconduct for 2004 and 2005. Three hundred and twenty-nine assurances were inactivated, 295 for failing to submit their Annual Report in 2006 and 34 at the request of the institution or because of duplicate records.

Table 8: Number and Type of Institutions with Active Assurances, 2006

Type of Institution	*Number*	*Change*
Institutions of Higher Education	980	+15
Research Organizations, Institutes, Foundations, and Laboratories	391	+18
Independent Hospitals	302	+ 2
Educational Organizations, Other Than Higher Education	27	+ 3
Other Health, Human Resources, and Environmental Services Organizations	457	+21
Other (small businesses)	2,416	+68
TOTAL	4,573	+127

Institutional Misconduct Policy Reviews

ORI completed 127 policy reviews in 2006. No policy reviews were carried into 2006. One hundred and twenty-five institutional policies were accepted as submitted; two others were accepted after revision. Since 1996, ORI has reviewed 2,167 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 2005 Annual Report began in January 2006 for the 4,446 institutions that had an assurance on file with ORI as of December 31, 2005.

Completed Annual Reports were received from 3,964 institutions for a response rate of 89 percent. ORI inactivated 329 assurances, including 295 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 thirteen institutions reported starting or continuing research misconduct activity in their 2005 reports; 66 institutions reported opening new cases; and institutions reported receiving 137 new allegations and opening 92 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 113 institutions that reported research misconduct activity resulting from allegations received during or prior to 2005 conducted 108 inquiries and 78 investigations in 2005.

Sixty-six of the 113 institutions reported opening 92 new cases in 2005 upon receipt of 137 allegations. Institutions received 71 allegations of falsification, 34 of plagiarism, 31 of fabrications, and 1 other. These allegations resulted in 59 inquiries and 36 investigations in 2005.

Institutions reporting new cases included higher education, 51; research organizations, 4; independent hospitals, 4; educational organizations, 0; other health, human resources, and environmental services organizations, 6; and small businesses, 1.

Table 9: Research Misconduct Activity, 1993-2005

Year	*Institutions reporting activity*	*Institutions reporting new cases*	*New allegations*	*New cases*
2005	113	66	137	92
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 follow policies and procedures that comply with the PHS regulation (42 C.F.R. Part 93) 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 research misconduct or retaliation complaints from the whistleblower. In 2006, 12 compliance cases were opened, and 8 were closed (see Table 10). Four closed cases involved institutional handling of allegations of research misconduct, and four cases involved retaliation complaints.

Table 10: Summary of Compliance Cases, 2006

Case type	*Forwarded from 2005*	*Opened in 2006*	*Closed in 2006*	*Carried into 2007*
Compliance/retaliation	3	12	8	7

Institutional Handling of Allegations

Four closed compliance cases involved the institutional handling of allegations and retaliation complaints. Site visits were conducted at two institutions. Two other cases were closed administratively; a specific misconduct allegation was never made in the third; and the shortcomings of an institutional investigation were noted in the close-out letter sent to the institution in the fourth case because the shortcomings did not affect the case outcome.

Failure to Process Allegations Against a Part-time Staff Member

In this case, DIO became aware of correspondence between officials at a major institution and NIH regarding possible falsification of data in survey questionnaires. Because the respondent in this case was not a faculty member, the institutional officials (incorrectly) concluded that this issue was outside the criteria for review by the institutional committee on scientific integrity. An internal review within the respondent's department was conducted, and it was determined that a significant portion of the respondent's work was in question, and that work was deleted from the study. The respondent, a part-time employee, was dismissed.

DIO contacted institutional officials and reminded them that even though the respondent was not a faculty member, they still had an obligation under the PHS regulation to address this allegation under its institutional misconduct policy. The responsible institutional official assured DIO that the allegations would be reviewed under its research misconduct policy and that the actual policy would be modified to address allegations not only against faculty, but also staff members and trainees.

Retaliation Complaints

Criteria for Claiming Retaliation Not Met

DIO was contacted by an individual who claimed that her employer, a major university, declined to renew her employment contract as a result of her filing an allegation of research misconduct. All relevant documentation associated with this complaint was reviewed by DIO, including those provided by the complainant. DIO determined that the complainant's initial allegation related to animal care did not

meet the definition of research misconduct, as defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. DIO also noted that it would be impossible to establish a direct and well-defined link between it and the employment actions taken against her because of the numerous other employment issues being addressed by institutional officials on or about the same time. Retaliation is described as any adverse action taken against an individual in response to the submission of a good faith allegation of research misconduct. In this case, not only did the allegation not fit the definition of research misconduct, there was no direct link between the allegation and the alleged retaliation. Therefore, the criteria for claiming retaliation under the PHS regulation were not met, and DIO took no further action in this case.

Counter Allegation Must Be Investigated by an Institution

In this case, the RIO from a major university contacted DIO regarding a retaliation claim. The institution had completed an investigation into allegations of research misconduct, and was now prepared to initiate another investigation into counter allegations of research misconduct made by the respondent against the complainant. The complainant considered this claim to be retaliation by the respondent, and objected to the institution initiating another investigation. The RIO requested guidance on how to proceed. DIO cited two relevant sections of the PHS regulation, noting the institutional obligation to (1) take all reasonable steps to protect the positions and reputations of good faith complainants and (2) to respond to each allegation of research misconduct for which it is responsible under this regulation. While the complainant argued that the initiation of an investigation against him was retaliation, DIO noted that there had been no documented adverse action against him; that is, he had suffered no negative effects in the terms and conditions of his status at the institution, and therefore had no basis to claim retaliation. And the institution had an obligation under the PHS regulation to pursue misconduct allegations that are presented without evaluating possible motive. Both the complainant and the responsible institutional official were informed of the institutional dual requirements to protect him as well as its obligation to address the allegation made against him.

Retaliation Occurred Before Allegation Made

DIO received a request from the Assistant Secretary for Health to review its handling of a misconduct case and related charges of retaliation in a case closed by ORI several years previously. DIO reviewed all the materials provided, and determined that no new substantive information was presented to justify a reversal of an ORI decision on the misconduct findings. With respect to the retaliation complaint, DIO noted that all the alleged acts of retaliation predated the complainant's initial allegation to ORI, therefore establishing no connection between the alleged retaliatory acts and the misconduct allegation. DIO also noted that a civil action was

filed by the complainant in this case. The ORI Whistleblower Guidelines provide a process for an institution to follow in addressing an allegation of retaliation, but the guidelines also acknowledge that a complainant may alternatively utilize the courts to address the retaliation complaint. If the complainant opts out of the institutional process provided in the whistleblower's guidelines, ORI concludes that the institution has fulfilled its obligation under the PHS regulation to address the retaliation complaint.

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 research 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 research misconduct has occurred, (3) the individual has agreed to voluntary corrective action as a result of an investigation of research misconduct, or (4) ORI has received a report of an investigation by an institution in which there was a finding of research misconduct concerning the individual and ORI has determined that PHS has jurisdiction. The PHS ALERT is not a public system.

The ALERT system was computerized in 1994 to facilitate checks of individuals in the above categories against incoming applications, pending awards, and proposed appointments to PHS advisory committees, boards, and peer review groups. Listing in the PHS ALERT system does not necessarily debar or exclude individuals from receiving support or serving in an advisory capacity to the PHS unless a PHS administrative action imposed on them specifically requires it.

On January 1, 2006, ORI listed the names of 59 individuals in the ALERT system. During the year, ORI added 12 names and removed 16. On December 31, 2006, the names of 55 individuals were in the system (see Table 11).

ORI added 12 names because those individuals were found to have committed research misconduct in institutional reports to ORI. Twelve 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 research misconduct after reviewing an institutional misconduct investigation report.

Of the 55 names in the system at year end, 40 individuals had PHS administrative actions imposed on them, and 15 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, 2006

	Total
As of January 1, 2006	59
Additions	12
Action expired/removed	16
As of December 31, 2006	55

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

Information on each individual in the system is limited to their name, 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) increased in 2006, but Privacy Act requests did not.

- ORI received 77 FOIA requests in 2006; 55 were closed. In 2005, ORI received 40 FOIA requests; 38 were closed.

- ORI received and closed one Privacy Act request in 2006. In 2005, ORI also received and closed one Privacy Act request.

Freedom of Information Act

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

ORI records are primarily subject to Exemptions 5, 6, and 7 of the FOIA. Exemption 5 covers internal government communications and notices. Exemption 6 covers documents about individuals that, if disclosed, would constitute a clearly unwarranted invasion of personal privacy. Exemption 7 covers records that the government has compiled for law enforcement purposes.

A FOIA request for ORI records should be made to the PHS FOIA Officer, Darlene Christian, Parklawn Building, 5600 Fishers Lane, Room 17A-46, Rockville, MD 20857. The request must reasonably describe the records sought so that the agency official is able to locate the records with a reasonable amount of effort. Some requests may be subject to review, search, and duplication costs.

Privacy Act

The purpose of the Privacy Act of 1974, 5 U.S.C. § 552a, is to balance the needs of the government to maintain information about individuals with the rights of the individual to be protected against unwarranted invasions of their privacy stemming from federal agency collection, maintenance, use, and disclosure of personal information about the individual. Under the Privacy Act, an agency is required to publish a notice of its system of records when the information in the system is about an individual that is retrieved by a personal identifier.

The inquiry and investigative records in ORI files are part of a system of records 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 due to 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 – 2006

Susan M. Aronica, Ph.D., Indiana University-Purdue University Indianapolis: Based on the evidence and findings of an investigation report by Indiana University-Purdue University Indianapolis (IUPUI) and additional analysis conducted by the Office of Research Integrity (ORI) in its oversight review, ORI found that Susan M. Aronica, Ph.D., former Postdoctoral Student/Fellow, IUPUI, committed 21 acts of scientific misconduct by knowingly and intentionally falsifying and fabricating data in her notebooks, in 17 figures and figure panels, in two tables published in the *Journal of Biological Chemistry* (J. Biol. Chem. 270:21998-22007, 1995) and *Blood* (Blood 89:3582-3595, 1997), and in two figures in a manuscript submitted for publication to *Blood* in August 1997.

ORI issued a charge letter enumerating the above findings of scientific misconduct. However, Dr. Aronica requested a hearing to dispute these findings to the Departmental Appeals Board. Based upon the insufficiency of Dr. Aronica's hearing request, ORI filed a Motion to Dismiss. On February 10, 2006, the Administrative Law Judge (ALJ) ruled in ORI's favor by dismissing Dr. Aronica's request for a hearing. ORI's research misconduct regulation specifically delineates the requisite content for an acceptable hearing request. A sustainable hearing request must admit or deny each finding of research misconduct, and each denial must be detailed and substantive. 42 CFR 93.501(c). Dr. Aronica's hearing request contained only a general denial of the proposed findings. The regulation states that a general denial is not sufficient to establish a genuine dispute. 42 CFR 93.503. The regulation also states that the ALJ must dismiss a hearing request if the respondent does not raise a genuine dispute over facts or law material to the research misconduct findings. 42 CFR 93.504(a)(2). The ALJ concluded that the determination of whether the hearing request raises a genuine dispute is a threshold jurisdictional determination. Thus, the ALJ decided that Dr. Aronica's request did not show a genuine dispute, because it did not specifically deny any allegation. As a result, the ALJ concluded that Dr. Aronica's hearing request could not be granted, but was required to be dismissed pursuant to 42 CFR 93.504(a)(2).

Specifically, ORI found that Dr. Aronica falsified and fabricated data in: Figures 1, 2, 3, 4, 5A, 5B, 5C, 6A, and 6B, and Tables III and IV in: Aronica, S.M., Mantel, C., Gonin, R., Marshall, M.S., Sarris, A., Cooper, S., [[Page 16309]] Hague, N., Zhang, X., & Broxmeyer, H.E. ``Interferon-inducible Protein 10 and Macrophage Inflammatory Protein-1 [alpha] Inhibit Growth Factor Stimulation of Raf-1 Kinase Activity and Protein Synthesis in a Human Growth Factor-dependent Hematopoietic Cell Line.'' JBC 270:21998-22007, 1995 (September 15) (``JBC paper''). Figures 1 (both panels), 3A, 3B, 3D, 3E, 4A, and 8A in: Aronica, S.M., Gingras, A.C., Sonenberg, N., Cooper, S., Hague, N., & Broxmeyer, H.E. ``Macrophage

Inflammatory Protein-1 [alpha] and Interferon-inducible Protein 10 Inhibit Synergistically Induced Growth Factor Stimulation of MAP Kinase Activity and Suppress Phosphorylation of Eukaryotic Initiation Factor 4E and 4E Binding Protein 1.'' *Blood* 89:3582-3595, 1997 (May 15) (``Blood paper''). Figures 1B and 2B in: Aronica, S.M., Reid, S.L., & Broxmeyer, H.E. ``Chemokine Inhibition of Stress-Activated Kinase Activity in a Human Hematopoietic Cell Line.'' Blood, submitted August 4, 1997 (``Blood manuscript''). The research was supported by or reported in the following U.S. Public Health Service (PHS) grants from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health:

RO1 HL49202, ``Myeloid Regulation by Growth-Suppressing Cytokines.''

R01 HL54037, ``Stem Cell Transduction of SLF/FLT-3-Ligand Genes by AAV.''

R01 HL56416, ``Mechanisms of Synergistic Regulation of Stem/Progenitors.''

T32 DK07519, ``Regulation of Hematopoietic Cell Production.''

The following administrative actions have been implemented: (1) Dr. Aronica has been debarred from any contracting or subcontracting with any agency of the U. S. Government and from eligibility or involvement in nonprocurement programs of the U. S. Government referred to as ``covered transactions'' as defined in the debarment regulations at 45 CFR part 76 for a period of five (5) years, beginning on February 10, 2006; (2) Dr. Aronica 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 consultant for a period of five (5) years, beginning on February 10, 2006; and (3) Within 60 days of February 10, 2006, the authors of the following papers will be requested to submit a letter to the editors of *Journal of Biological Chemistry* and *Blood*, requesting their retraction of: Aronica, S.M., Mantel, C., Gonin, R., Marshall, M., Sarris, A., Cooper, S., Hague, N., Zhang, X-f., & Broxmeyer, H.E. ``Interferon-Inducible Protein 10 and Macrophage Inflammatory Protein-1 [alpha] inhibit Growth Factor Stimulation of Raf-1 Kinase Activity and Protein Synthesis in a Human Growth Factor-Dependent Hematopoietic Cell Line.'' *J. Biol. Chem.* 270:21998-22007, 1995. Aronica, S.M., Gingras, A.-C., Sonenberg, N., Cooper, S., Hague, N., and Broxmeyer, H.E. ``Macrophage Inflammatory Protein-1 [alpha] and Interferon-Inducible Protein 10 Inhibit Synergistically Induced Growth Factor Stimulation of MAP Kinase Activity and Suppress Phosphorylation of Eukaryotic Initiation Factor 4E and 4 Binding Protein 1.'' *Blood* 89:3582-3595, 1997.

Jennifer Blaisdell, University of Pennsylvania and Retinal Consultants of Arizona, Ltd.: Based on the report of an investigation conducted by the University of Pennsylvania (UP) and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Ms. Jennifer Blaisdell, former Clinical Coordinator for Retinal Consultants of Arizona, Ltd. (RCA), committed research misconduct in a study sponsored by two cooperative agreements funded by the National Eye Institute (NEI), National Institutes of Health (NIH): U10 EY012261, "Age-related Macular Degeneration Prevention Trial," Dr. Stuart Fine, Principal Investigator (P.I.), and U10 EY012279, "Coordinating Center for AMD, Complications of Age-Related Macular Degeneration Prevention Trial" (CAPT), Dr. Maureen McGuire, P.I. Specifically, PHS found that Ms. Blaisdell knowingly and intentionally committed research misconduct by:

1. fabricating a CAPT data form dated May 29, 2002, reporting a 30-month telephone followup visit with patient 01-026; this patient died on May 3, 2002;

2. fabricating a CAPT data form dated February 20, 2003, reporting a 43-month telephone followup visit with patient 01-019; this patient died on February 10, 2003;

3. falsifying a CAPT data form dated February 13, 2001, reporting a visit to the clinic on that date for patient 01-049; this patient's visit was on February 20, 2001; and

4. falsifying the CAPT data form for patient 01-055 dated April 11, 2001, when no clinic visit took place, by substituting information purportedly obtained at a non-study visit on February 28, 2001.

Ms. Blaisdell has entered into a Voluntary Exclusion Agreement in which she has voluntarily agreed, for a period of two (2) years, beginning on November 14, 2006:

(1) to exclude herself from serving in any advisory capacity to PHS, including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and

(2) that any institution that submits an application for PHS support for a research project on which Ms. Blaisdell's participation is proposed or which uses her in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which she is involved, must concurrently submit a plan for supervision of Ms. Blaisdell's duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of her research contribution. Ms. Blaisdell also agrees to ensure that the institution submits a copy of the supervisory plan to

ORI. She further agrees that she will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI.

Amy Beth Goldring, University of California at Los Angeles: Based on an investigation conducted by the University of California at Los Angeles (UCLA) and additional analysis conducted by the Office of Research Integrity (ORI) in its oversight review, ORI found that Ms. Amy Beth Goldring, former graduate student, Department of Psychology, UCLA, engaged in research misconduct by falsifying or fabricating data and statistical results for up to nine pilot studies on the impact of vulnerability on decision-making from fall 2000 to winter 2002 as a basis for her doctoral thesis research. The falsified or fabricated data were included in a manuscript submitted to *Psychological Science*, in National Institutes of Mental Health (NIMH), National Institutes of Health (NIH), grant application 1 R01 MH65238-01A1, and in NIMH, NIH, pre-doctoral training grant T32 MH15750.

Ms. Goldring has been debarred by another agency with joint jurisdiction for a period of three (3) years, beginning on May 13, 2005, and ending on May 13, 2008. On December 16, 2005, Ms. Goldring received a detailed explanation of ORI's proposed finding and was given thirty (30) days to contest the finding and the proposed administrative action. The 30-day period has elapsed and ORI has not received a response. Accordingly, the following administrative action has been implemented for a period of three (3) years, beginning on January 18, 2006:

(1) Ms. Goldring is prohibited from serving in any advisory capacity to the U.S. Public Health Service (PHS), including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

Paul H. Kornak, Stratton VA Medical Center, Albany, New York: Upon recommendations from the Office of Research Integrity (ORI), Acting Assistant Secretary for Health for the Department of Health and Human Services (HHS), the Office of Research Oversight (ORO), and the Under Secretary for Health, Department of Veterans Affairs (VA), which were based on the criminal convictions of making and using a materially false statement, in violation of 18 USC § 1001(a)(3); mail fraud, in violation of 18 USC §§ 1341 and 1346; and criminally negligent homicide, in violation of 18 USC § 13 and New York Penal Law § 125.10, the HHS debarring official has permanently debarred Mr. Paul H. Kornak, former Research Coordinator at the Stratton VA Medical Center. This action is taken pursuant to the HHS government-wide non-procurement debarment and suspension regulation at 45 C.F.R. Part 76. As such, Mr. Kornak is excluded for life from participating in any and all federal agency transactions, both procurement and non-procurement, as set forth in Part 76.

Of the 48 criminal charges contained in his Indictment, Mr. Kornak pled guilty to the three criminal charges listed above. See *United States of America v. Paul H. Kornak*, Criminal Action No. 03-CR-436 (FJS), U.S. District Court (N.D.N.Y.) (January 18, 2005). In addition to the 71-month term of imprisonment imposed, Mr. Kornak was directed to pay restitution to two pharmaceutical companies and the VA in the amount of approximately $639,000.

As part of his guilty plea, Mr. Kornak admitted to the following facts:

- In August 2000, Mr. Kornak applied for employment to the VA, submitting a false "Declaration for Federal Employment" form. Mr. Kornak denied that he had been convicted or on probation in the preceding 10 years, whereas in fact, he had been convicted of mail fraud in 1992 and placed on probation for 3 years;

- By October of 2000, Mr. Kornak was responsible for organizing, coordinating, implementing, and directing all research elements in the Stratton VA Medical Center oncology research program. Specifically, Mr. Kornak was the site coordinator at the Stratton VA Medical Center for the "Iron (Fe) and Atherosclerosis Study" (FeAST), cancer studies known as Tax 325 and Tax 327, and a bladder cancer study. The FeAST study was a clinical trial that tested a novel procedure for controlling atherosclerosis, also known as hardening of the arteries, by reducing the iron in the body through blood drawing. The Tax 325 cancer treatment study involved the administration of pharmaceutical products to patients with metastatic or locally recurrent gastric cancer previously untreated with chemotherapy for advanced disease. The Tax 327 study involved the administration of pharmaceutical products to patients with metastatic hormone refractory prostate cancer. The purpose of the bladder cancer study, which was co-sponsored by the National Cancer Institute (NCI), National Institutes of Health (NIH), was to compare the use of difluoromethylornithine (DFMO) to the use of a placebo in patients with low-grade superficial bladder cancer according to time to first recurrence of the tumor and toxicities;

- From May 14, 1999, to July 10, 2002, in connection with the above protocols, Mr. Kornak participated in a scheme to defraud the sponsors of the clinical studies in that "he would and repeatedly did submit false documentation regarding patients and study subjects and enroll and cause to be enrolled persons as study subjects who did not qualify under the particular study protocol"; and

- Mr. Kornak caused the death of a study subject when he "failed to perceive a substantial and unjustifiable risk that death would occur when he knowingly and willfully made and used . . . documents falsely stating and representing

> the results of [the study subject's] blood chemistry analysis . . . , which false documents purported that [the study subject] met the inclusion and exclusion criteria for participation in Tax 325 when the actual results did not meet the inclusion and exclusion criteria and showed impaired kidney and liver function, and [the study subject] thus was administered the chemotherapeutic drugs docetaxel, cisplatin, and 5-FU in connection with Tax 325 on or about May 31, 2001, and died as a result thereof on or about June 11, 2001."

Based on the criminal conviction and the facts admitted to above, HHS and the VA believe that a debarment period longer than the standard length of debarment is warranted in this case. Mr. Kornak admitted to a dishonest handling of the research records and demonstrated a complete disregard for the well-being of vulnerable human subjects under his care. In pleading guilty to criminally negligent homicide, Mr. Kornak admitted that a reasonable person would have perceived a substantial and unjustifiable risk of death if an ineligible subject were enrolled in the cancer study in question and that his failure to perceive such a risk in enrolling the ineligible subject constituted a gross deviation from the standard of care.

Moreover, a longer debarment period is warranted in this case because of an established pattern of misconduct and criminal behavior on the part of Mr. Kornak. As stated above, Mr. Kornak has a prior conviction of mail fraud. In addition, the Office of Personnel Management excluded Mr. Kornak from all federal non-procurement transactions for an indefinite period, effective July 22, 1993. Nonetheless, beginning in 1999, Mr. Kornak actively participated in federally sponsored research protocols in violation of the imposed exclusion.

A lifetime debarment of Mr. Kornak is necessary to protect the public interest overall. Given the scope of his criminal conviction, his longstanding pattern of criminal behavior, and his total disregard for the safety and well-being of human subjects, Mr. Kornak's responsibility to engage in transactions with the federal government cannot be assured at any time in the future.

Steven Anthony Leadon, Ph.D., University of North Carolina: Based on the report of an investigation conducted by the University of North Carolina (UNC) at Chapel Hill and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Steven Anthony Leadon, Ph.D., former Professor of Radiation Oncology, Department of Radiology, School of Medicine, UNC, engaged in research misconduct while supported by National Cancer Institute (NCI), National Institutes of Health (NIH), grant R01 CA40453-09 to 15.

Specifically, PHS found that Dr. Leadon engaged in research misconduct by falsifying DNA samples and constructing falsified figures for experiments done in his laboratory to support claimed findings of defects in a DNA repair process. The process involved rapid repair of DNA damage in the transcribed strand of active genes, included in four grant applications and in eight publications and one unpublished manuscript as an Appendix to the Voluntary Exclusion Agreement entered into by Dr. Leadon and are as follows:

- Figures 1, 2, and 3 in the article by Gowen, L.C., Avrutskaya, A.V., Latour, A.M., Koller, B.H., & Leadon, S.A. "BRCA1 required for transcription-coupled repair of oxidative DNA damage." *Science* 281:1009-1012, 1988. In grant application 2 R01 CA40453-14 (p. 9), this article was used as justification for proposed research on BRCA1 and related proteins that may be required for transcription-coupled DNA repair of oxidative DNA damage. Data from the research reported in this paper were also used as preliminary data (Figure 2, p. 16) to support proposed experiments on BRCA1;

- Figures 1A, 2A, and 3 in the article by Leadon, S.A., & Avrutskaya, A.V. "Differential involvement of the human mismatch repair proteins, hMLH1 and hMSH2, in transcription-coupled repair." *Cancer Research* 57:3784-3791, 1997;

- Figures 1 and 3 in the article by Leadon, S.A., & Avrutskaya, A.V. "Requirement for DNA mismatch repair proteins in the transcription-coupled repair of thymine glycols in saccharomyces cerevisiae." *Mutation Research* 407:177-187, 1998;

- Figures 7B and 7C in the article by Cressman, V.L., Backlund, D.C., Avrutskaya, A.V., Leadon, S.A., & Koller, B.H. "Growth retardation, DNA repair defects, and lack of spermatogenesis in BRCA1-deficient mice." *Molecular and Cellular Biology* 19:7061-7075, 1999;

- Figures 1A-D, 3A, 3C, and 3D and graphs in the unpublished manuscript by Rauscher, F.J. III, Jensen, D.E., Patel, G., Fredericks, W.J., Schultz, D.C., Proctor, M., Sekido, Y., Minna, J., Chernova, T.A., Wilkinson, K.D., Avrutskaya, A.V., & Leadon, S.A. "BRCA1-associated ubiquitin hydrolase required for transcription-coupled repair of oxidative DNA damage." Submitted to *Science* on May 16, 2001. In Figure 4 in grant application 2 R01 CA40453-14 (pp. 17-18), data from this unpublished manuscript were used regarding BAP1 defects in transcription-coupled repair;

- Figures 1A and 3A in the article by Cooper, P.K., Nouspikel, T., Clarkson, S.G., & Leadon, S.A. "Defective transcription-coupled repair of oxidative

base damage in Cockayne syndrome patients from XP group G," *Science* 275: 990-993, 1997. In NIH grant application R01 CA40453-10A1, some of the same data for XPG or XP-G/CS cells from this *Science* article were included by Dr. Leadon as graphs (Figures 4 and 5, pp. 25-27) before the *Science* paper was published;

- Figures 1C, 2A, and 2B in the article by LePage, F., Kwoh, E.E., Avrutskaya, A., Gentil, A., Leadon, S.A., Sarasin, A., & Cooper, P.K. "Transcription-coupled repair of 8-oxoguanine: Requirement for XPG, TFIIH, and CSB and implications for Cockayne syndrome." *Cell* 101:159-171, 2000. Figure 7 in grant application 1 R01 CA092390-01;

- Figures 1 and 2 and Table 1 in the article by Leadon, S.A., Barbee, S.L., & Dunn, A.B. "The yeast RAD2, but not RAD1, gene is involved in the transcription-coupled repair of thymine glycols." *Mutation Research* 337:169-178, 1995; and

- Figure 6 in the article Nouspikel, T., Lalle, P., Leadon, S.A., Cooper, P.K., & Clarkson, S.G. "A common mutational pattern in Cockayne syndrome patients from xeroderma pigmentosum group G: Implications for a second XPG function." *Proceedings of National Academy of Sciences* USA 94: 3116-3121, 1997.

Dr. Leadon's position is that he did not engage in research misconduct. His position is that a systematic error was introduced into the experiments in question, and he recognizes that it could have influenced or accounted for the results. Dr. Leadon states that he has entered into a Voluntary Exclusion Agreement (Agreement) because he cannot sustain the significant financial burden of a legal proceeding to resolve the disagreements between his position and that of HHS. By entering into this Agreement, Dr. Leadon has voluntarily agreed:

(1) to exclude himself from knowingly contracting or subcontracting with any agency of the U.S. government and from eligibility or knowing 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 for a period of five (5) years, beginning on May 10, 2006;

(2) to exclude himself from serving in any advisory capacity to PHS, including, but not limited, to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of five (5) years, beginning on May 10, 2006; and

(3) to submit letters of retraction to the editors of the journals listed below within ten (10) business days from the effective date of this Agreement:

A. "I have recently had the opportunity to review some of the raw data used for this paper in the above-referenced publication, and it is clear that the data as reported in this paper cannot be relied upon. Therefore, I request that you retract this paper." A letter using only the aforementioned language in this subsection will be sent to *Mutation Research* to retract the following paper: Leadon, S.A., Barbee, S.L., & Dunn, A.B. "The yeast RAD2, but not RAD1, gene is involved in the transcription-coupled repair of thymine glycols." *Mutation Research* 337:169-178.

B. "I have recently had the opportunity to review some of the raw data used for Figure 6 in this paper in the above-referenced publication, and it is clear that the data as reported in this figure cannot be relied upon. Therefore, I request that you retract Figure 6 of this paper." A letter using only the aforementioned language in this subsection will be sent to *Proceedings of National Academy of Sciences* concerning the following article: Nouspikel, T., Lalle, P., Leadon, S.A., Cooper, P.K., & Clarkson, S.G. "A common mutational pattern in Cockayne syndrome patients from xeroderma pigmentosum group G: Implications for a second XPG function." *Proceedings of the National Academy of Sciences* USA 94:3116-3121, 1997.

C. "I have recently had the opportunity to review some of the raw data used for Figures 7B and 7C in this paper in the above-referenced publication, and it is clear that the data as reported in these figures cannot be relied upon. Therefore, I request that you retract Figures 7B and 7C of this paper." A letter using only the aforementioned language in this subsection will be sent to *Molecular and Cellular Biology* concerning the following article: Cressman, V.L., Backlund, D.C., Avrutskaya, A.V., Leadon, S.A., & Koller, B.H. "Growth retardation, DNA repair defects, and lack of spermatogenesis in BRCA1-deficient mice." *Molecular and Cellular Biology* 19:7061-7075, 1999.

James C. Lin, Ph.D., University of Illinois at Chicago: Based on the findings from an inquiry by the University of Illinois at Chicago (UIC) and on additional analysis conducted by ORI during its oversight review, the U.S. Public Health Service (PHS) found that James C. Lin, Ph.D., Professor, Department of Electrical and Computer Engineering, Physiology, and Biophysics, UIC, engaged in research misconduct concerning National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH), grant application 1 R01 NS47238-01, "Blood-Brain Barrier Interactions of Cellular-Phone Radi." Specifically, PHS found that Dr. Lin committed research misconduct relative to the legend and related text for Figure 2 (data from a colleague on other experiments) for his NIH application 1 R01 NS47238-01. Dr. Lin falsely claimed the figure represented preliminary results of his independent experiments that differed from the source

of the figure and the prior research in the field, in which he purported to have selectively exposed the rat's head to microwave irradiation, to have utilized higher peak exposure, of shorter duration and of different radio frequencies, and which reported injury of a more acute nature to the blood barrier. Dr. Lin denies all allegations of research misconduct and contends that some of his original data are missing as a result of the involuntary relocation of his laboratory. Dr. Lin makes no admission of guilt in connection with the charges or PHS' findings of research misconduct herein. Both Dr. Lin and PHS are desirous of concluding this matter without further expense of time and other resources.

Dr. Lin has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed, for a period of three (3) years, beginning on October 24, 2006:

(1) that any institution which submits an application for PHS support for a research project on which Dr. Lin's participation is proposed, or which uses him in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which Dr. Lin is involved, must concurrently submit a plan for supervision of Dr. Lin's duties to the funding agency for approval; the supervisory plan must be designed to ensure the scientific integrity of his research contribution; Dr. Lin agrees to ensure that a copy of the supervisory plan also is submitted to ORI by the institution; and he also agrees that he will not participate in any PHS-supported research until such a supervision plan is submitted to ORI;

(2) that any institution employing Dr. Lin submit in conjunction with each application for PHS funds or reports, manuscripts, or abstracts of PHS-funded research in which Dr. Lin is involved a certification that the data provided by Dr. Lin 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; Dr. Lin 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 a consultant.

Nicholas McMaster, University of Chicago: Based on a College Discipline Hearing report and on additional analysis conducted by the Office of Research Integrity (ORI) in its oversight review, the U.S. Public Health Service (PHS) found that Mr. Nicholas McMaster, undergraduate student, Biological Sciences Collegiate Division in the Departments of Psychology and Comparative Human Development at the University of Chicago (UC), engaged in research misconduct in research supported by National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), grant P50 ES12382 and National

Institute on Aging (NIA), NIH, grant P01 AG018911. Specifically, PHS found that Mr. McMaster fabricated data in recording the score for the lordosis reflex and in recording the cell types present in vaginal epithelium from rats in two experimental psychology protocols.

Mr. McMaster has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed, for a period of three (3) years, beginning on November 14, 2006:

(1) to exclude himself from serving in any advisory capacity to PHS, including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and

(2) that any institution which submits an application for PHS support for a research project on which Mr. McMaster's participation is proposed, or which uses him in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which he is involved, must concurrently submit a plan for supervision of his duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of his research contribution. Mr. McMaster also agrees to ensure that the institution submits a copy of the supervisory plan to ORI. He further agrees that he will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI.

Sylvia Okoro, University of Maryland at Baltimore: Based on the University of Maryland at Baltimore (UMAB) investigation committee report and additional analysis and information obtained by ORI during its oversight review, the U.S. Public Health Service (PHS) found that Ms. Sylvia Okoro, former Research Assistant, UMAB, engaged in research misconduct by fabricating and falsifying patient data in research supported by National Institute on Aging (NIA), National Institutes of Health (NIH), grant R01 AG18461. Specifically, Ms. Okoro intentionally and knowingly fabricated and falsified data for six visit dates on one patient data form and falsified and fabricated patient condition information on two additional study subjects by failing to note that each patient had experienced a fall as documented in their medical charts.

ORI has implemented the following administrative actions for a period of three (3) years, beginning July 17, 2006:

(1) Ms. Okoro 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; and

(2) Any institution that submits an application for PHS support for a research project on which Ms. Okoro's participation is proposed or which uses her services in any capacity on PHS-supported research must concurrently submit a plan for supervision of her duties. The supervisory plan must be designed to ensure the scientific integrity of Ms. Okoro's research contribution and must be submitted to ORI by the institution.

Jong Hyuk Park, Ph.D., University of Pittsburgh: Based on accumulated evidence including the University of Pittsburgh (UP) investigation committee report and additional analysis and information obtained by the Office of Research Integrity (ORI) during its oversight review, the U.S. Public Health Service (PHS) found that Jong Hyuk Park, Ph.D., former postdoctoral fellow, Pittsburgh Development Center of the Magee-Womens Research Institute, UP, engaged in research misconduct in research funded by National Center for Research Resources (NCRR), National Institutes of Health (NIH), grant R24 RR13632 and NIH grant P01 HD047675. Specifically, Dr. Park:

(1) intentionally and knowingly falsified various versions of two figures in a manuscript entitled "Rhesus Embryonic Stem Cells Established by Nuclear Transfer: Tetraploid ESCs Differ from Fertilized Ones" that was being prepared for submission to *Nature*; (2) repeatedly misrepresented to the UP investigative panel the accuracy of one of the figures; (3) presented the false figures as true to members of the laboratory; and (4) falsified the record of revisions of the figures by deleting all prior versions from the laboratory server.

ORI has implemented the following administrative actions for a period of three (3) years, beginning on November 29, 2006:

(1) Dr. Park is debarred 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 as defined in the debarment regulations at 45 C.F.R. Part 76; and

(2) Dr. Park 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.

Clifford R. Robinson, Ph.D., University of Delaware: Based on the reports of investigations conducted by 3-Dimensional Pharmaceuticals, Inc. (3DP), and the University of Delaware (UD) and additional analysis conducted by ORI during its oversight review, the U.S. Public Health Service (PHS) found that Clifford R. Robinson, Ph.D., Assistant Professor, Department of Chemistry and Biochemistry, UD, engaged in research misconduct involving research supported by National

Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), grants 1 R43 GM58950-01 and 2 R44 GM58950-02, "Four-helix bundle analog of a G-protein coupled receptor (C. Robinson, Principal Investigator [PI]). The following grant applications also were involved in Dr. Robinson's misconduct in science:

- 1 R43 GM62708-01, "Improved method for protein refolding" (C.R. Robinson, P.I.), submitted March 30, 2000; approved but not funded, withdrawn;

- 1 P20 RR017716-01, "Design of hierarchical recognition motifs," Project V, "Determinants of stability and assembly of integral membrane proteins" (C.R. Robinson, PI), submitted March 1, 2002; funded September 16, 2002, to August 30, 2007;

- 1 R01 GM074789-01, "Folding and stability of integral membrane proteins" (C.R. Robinson, PI), submitted October 1, 2004; scored not competitive, not funded;

- 1 R01 GM075891-01, "Membrane protein expression, solubilization, and refolding" (C.R. Robinson, PI), submitted January 24, 2005; approved but not funded, pending; and

- 1 R21 GM07953-01, "Mini-receptor analogs of GPCRs" (C.R. Robinson, PI), submitted January 25, 2005; not funded.

Specifically, PHS found that Dr. Robinson engaged in the following acts of research misconduct. With regard to the following paragraphs numbered 1-6, nothing herein shall be deemed as an admission of liability on the part of Dr. Robinson:

1. While at 3DP, Dr. Robinson systematically substituted crystallized chicken ovalbumin in place of β_2-AR-NQ and repeatedly provided these crystalline preparations to other scientists to conduct molecular analyses. Dr. Robinson made false claims about his progress on characterizing β_2-AR-NQ and falsely claimed to have supplied purified β_2-AR-NQ to 3DP staff in project team meetings (PTMs) held on at least five occasions between July 14, 1998, and July 7, 1999;

2. Dr. Robinson made multiple false claims about his research on β_2-AR-NQ in NIH grant applications R44 GM58950-02, submitted April 1, 1999; supplemental material for the same application submitted on July 7, 1999; and NIH grant application R43 GM62708-01, submitted March 30, 2000;

3. Dr. Robinson made similar claims as in item 1 above concerning the wild-type form of β_2-AR, by substituting canine ovalbumin. Dr. Robinson's false claims were made to 3DP staff at PTMs on at least three occasions between September 7, 1999, and March 30, 2000, and in NIH grant application R43 GM62708-01, and after moving to UD, in NIH grant application 1 P20 RR017716-01, submitted on March 1, 2002;

4. Dr. Robinson was unable to adequately produce recombinant β_2-AR in *E. coli* and made false claims at PTMs in September and October 1999 that he had successfully expressed active protein and had purified it for crystallization trials. Dr. Robinson also made false claims in NIH grant applications R43 GM62708-01 and 1 R01 GM07589-01, submitted January 24, 2005, that he had purified large amounts of β_2-AR-NQ from *E. coli* and that he had reconstituted the protein into its native biologically active form;

5. Dr. Robinson made false claims about his ability to produce, purify, and characterize a recombinant fragment of β_2-AR-NQ containing four transmembrane domains (β_2-AR-4HB) at PTMs in October 1998 and in NIH grant applications R44 GM58950-02 and 1 P20 RR017716-01;

6. Dr. Robinson falsified fluorescence spectra and circular dichroism measurements in Figure 7 (both left and right panels) of NIH grant application R44 GM58950-02 by substituting results obtained with different proteins;

7. After moving to UD, Dr. Robinson made false claims in NIH grant application 1 P20 RR017716-01, including presenting falsified data in both panels of Figures V.5 (fluorescence spectra and circular dichroism measurements) and V.9 (falsified experimental conditions);

8. While at UD, Dr. Robinson falsified circular dichroism and fluorescence data in NIH grant application 1 R01 GM074789-01 (Figures 5A, 5B, and 6) and circular dichroism data in NIH grant applications 1 R01 GM075891-01 (Figure 6) and 1 R21 GM075953-01 (Figure 5); and

9. In presentations at the Biophysical Society annual meeting and a Cornell University Consortium meeting, both in 1999, Dr. Robinson falsely represented data obtained with cytochrome b562 as being obtained with β_2-AR.

Dr. Robinson has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed, for a period of five (5) years, beginning on October 23, 2006:

(1) to exclude himself 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) 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.

April Swe, University of Wisconsin-Madison: Based on the report of an investigation conducted by the University of Wisconsin-Madison (UWM) and additional analysis conducted by the Office of Research Integrity (ORI) in its oversight review, PHS found that Ms. April Swe, former graduate student, UWM, engaged in research misconduct by fabricating data on thirty-nine (39) questionnaires of sibling human subjects associated with an autism study. The research was supported by National Institute on Aging (NIA), National Institutes of Health (NIH), grant R01 AG08768.

In a final decision dated January 13, 2006, the HHS Debarring Official, on behalf of the Secretary of HHS, issued the final debarment notice based on the PHS findings of research misconduct. The following administrative action has been implemented for a period of three (3) years, beginning on January 13, 2006:

(1) Ms. Swe has been debarred from eligibility for, or involvement as a principal in, non-procurement transactions (e.g., grants and cooperative agreements) of the federal government and from contracting or subcontracting with any federal government agency, except as provided in 45 C.F.R. § 76.120. This action is being taken pursuant to the debarment regulations at 45 C.F.R. Part 76.

Hiwot A. Woreta, Duke University Medical Center: Based on the report of an inquiry into admitted fabrication of data conducted by the Duke University Medical Center (DUMC) and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Ms. Hiwot A. Woreta, former medical student, DUMC, engaged in research misconduct while supported by National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH), grant P30 DK034987. Specifically, PHS found that Ms. Woreta engaged in research misconduct by fabricating data included in Figure 2 of her third-year Medical School Thesis at DUMC. These data were also included in a poster presented during the Alpha Omega Alpha Honor Society symposium in May 2004.

Ms. Woreta has entered into a Voluntary Exclusion Agreement in which she has voluntarily agreed, for a period of three (3) years, beginning on February 24, 2006:

(1) to exclude herself from serving in any advisory capacity to PHS, including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as consultant; and

(2) that any institution which submits an application for PHS support for a research project on which the respondent's participation is proposed, or which uses the respondent in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which the respondent is involved, must concurrently submit a plan for supervision of the respondent's duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of the respondent's research contribution. The respondent agreed to ensure that a copy of the supervisory plan is also submitted to ORI by the institution. The respondent agreed that she will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI.

Lingjie Zhao, University of Iowa: Based on the investigation reports drafted by the University of Iowa (UI) and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Ms. Lingjie Zhao, former doctoral student, UI, engaged in research misconduct. The research was supported by National Cancer Institute (NCI), National Institutes of Health (NIH), grant P01 CA66081. PHS found that Ms. Zhao engaged in research misconduct by falsifying research records included in (a) a manuscript submitted for publication in *Cancer Research*, (b) drafts of her work reported in the laboratory, and (c) drafts of her work reported to her dissertation committee. Specifically, PHS found:

1. that Ms. Zhao darkened with a marking device the thioredoxin (Trx) band of Lanes 1 and 2 on the autoradiographic film that was to become part of Figure 9 of the manuscript;

2. that Ms. Zhao (a) falsified this same original film of the western blot by darkening Lanes 1, 2, 4, and 5 with a marking device at the origin of the gel and (b) further falsified Figure 9 of the *Cancer Research* manuscript by claiming falsely that these marked bands were thioredoxin reductase (TR) untreated and with mismatch oligodeoxynucleotide in the presence and absence of tumor necrosis factor alpha;

3. that Ms. Zhao falsified the glutathione reductase (GR) activity data in either Figure 4 or Figure 9 of the *Cancer Research* manuscript (the data are identical but stated to be from entirely different experimental conditions);

4. that Ms. Zhao falsified the actin data in either Figure 4 or Figure 9 of the *Cancer Research* manuscript or in the experiments simultaneously using Prx

III-As and Phospholipid hydroperoxide glutathione peroxidase-As reported in slide presentations (the actin data are identical under three entirely different experimental conditions);

5. that Ms. Zhao falsified the manganese superoxide dismutase (MnSOD) data in either Figure 1A or Figure 4 of the *Cancer Research* manuscript (these MnSOD data are identical while being clearly described as coming from different experiments); and

6. that Ms. Zhao falsified the MnSOD data in Figure 2 of the *Cancer Research* manuscript by enhancing with a marking device Lanes 6 and 7, mismatch and antisense Prx oligos at 3 days of incubation (unmarked, Prx III-As decreased the expression of MnSOD).

Ms. Zhao has entered into a Voluntary Exclusion Agreement in which she has voluntarily agreed, for a period of three (3) years, beginning on June 3, 2006:

(1) to exclude herself 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 as defined in the debarment regulations at 45 C.F.R. Part 76; and

(2) to exclude herself from serving in any advisory capacity to PHS, including, but not limited, to service on any PHS advisory committee, board, and/or peer review committee, or as consultant.

Kui Zhu, Ph.D., Cleveland Clinic Research Foundation: Based on accumulated evidence including the Cleveland Clinic Research Foundation (CCF) investigation report (CCF Report) and additional analysis and information obtained by the Office of Research Integrity (ORI) during its oversight review of the CCF Report, the U.S. Public Health Service (PHS) found that Kui Zhu, Ph.D., former postdoctoral fellow, CCF, engaged in research misconduct by intentionally and knowingly fabricating and falsifying data for figures in two publications and with research funded by National Cancer Institute (NCI), National Institutes of Health (NIH), grants R21 CA84038, R01 CA76204, and T32 CA09056.

ORI has implemented the following administrative actions for a period of three (3) years, beginning June 7, 2006:

(1) Dr. Zhu is debarred 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 as defined in the debarment regulations at 45 C.F.R. Part 76; and

(2) Dr. Zhu 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.

Summaries of Closed Inquiries and Investigations Not Resulting in Findings of Research Misconduct – 2006

Falsification: The respondent, an assistant professor, allegedly fabricated data for research involving the determination of the prevalence and the identification of trematodes. The research was supported by a National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), grant. The institution conducted an investigation and found that scientific misconduct had occurred. ORI accepted the institution's report as fulfilling its reporting requirements to the U.S. Public Health Service (PHS), but concluded that the misconduct did not warrant further PHS action. Thus, ORI did not pursue the institution's misconduct findings.

Falsification: The respondent, an associate professor, allegedly misrepresented and/or falsified claims made in a published paper. The questioned research involved the study of a bone morphogenic protein inhibitor and its effects on osteoblast differentiation and bone formation, especially during biological aging. The research was supported by two National Institute on Aging (NIA), National Institutes of Health (NIH), grants, and two National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), NIH, grants. The institution conducted an inquiry and concluded that there was no evidence of misconduct to warrant proceeding to an investigation. However, the institution noted that the allegations would never have been brought forth if better laboratory management practices had been followed. Thus, the institution directed the respondent to complete a laboratory management and ethics course. ORI accepted the institution's conclusion that further investigation was not warranted.

Falsification: The respondent, a professor, allegedly falsified or misrepresented data in research involving an apparently unique regulatory DNA sequence in a gene thought to play a significant role in human prostate cancer. The questioned research was supported by a National Cancer Institute (NCI), National Institutes of Health (NIH), grant. The institution conducted an assessment and concluded that there was insufficient evidence in the record to warrant an inquiry. ORI accepted the institution's report and concurred with its determination in this case.

Falsification: The respondent, a professor, allegedly falsified data in a grant application submitted to the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH). The research involved viral vectors used in gene therapy. The institution conducted an investigation and concluded that there was insufficient evidence that the respondent had intentionally falsified data. ORI concurred with the institution and did not make a finding of scientific misconduct in this case.

Falsification: The respondents, a research instructor and a division director, allegedly falsified data in a manuscript and other publications. The research was supported by a National Institute of Heart, Lung, and Blood (NHLBI), National Institutes of Health (NIH), grant, and three National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH, grants. The questioned research involved gene regulation through alterations in RNA stability and post-transcriptional processing. The institution conducted an investigation and found that research misconduct had occurred. ORI accepted the institution's report as fulfilling its reporting requirements to the U.S. Public Health Service (PHS), but concluded that the allegations of research misconduct were not resolvable. Thus, ORI decided to close this matter without further action and did not pursue the institution's misconduct findings.

Falsification: The respondent, a professor, allegedly falsified a figure in a published paper on a human cancer of the blood. The questioned study was supported by a National Cancer Institute (NCI), National Institutes of Health (NIH), grant. The institution conducted an inquiry and concluded that there was insufficient credible evidence of research misconduct to warrant further investigation. ORI accepted the factual findings of the institution and concurred that further investigation was not warranted in this case.

Falsification: The respondents, a professor and a graduate student, allegedly falsified data in research involving the molecular causes of cardiac hypertrophy and congestive heart failure. The research was supported by two National Heart, Lung, and Blood (NHLBI), National Institutes of Health (NIH), grants, and a National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH, grant. The institution conducted an investigation and did not make a finding of misconduct. ORI concurred with the institution's conclusion.

Falsification: The respondent, a postdoctoral associate, allegedly falsified multiple images in manuscripts submitted to two journals for publication. The questioned research involved the molecular characterization of the Akt signaling pathway in human cancers and identification of components in the pathway as potential targets for drug therapies. The research was supported by two National Cancer Institute (NCI), National Institutes of Health (NIH), grants. The institution conducted an investigation. The institution determined that while the primary data were not accurately depicted in the paper and the respondent acted carelessly, there was no intent to deceive and the errors did not alter the conclusions drawn in the questioned papers. Thus, the institution did not make a finding of misconduct. ORI concurred with the institution that the respondent's poor record-keeping and lack of adequate laboratory notebooks contributed to honest errors. ORI accepted the institution's determination and did not make a finding of research misconduct.

Falsification: The respondents, an associate professor and a research associate, allegedly falsified data in three figures included in a grant application submitted to the National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH). The questioned research involved confocal visualizations for studying mechanisms of resensitization through endocytic recycling of G-protein coupled receptors. The institution conducted an inquiry and determined that while insufficient care was obvious in the preparation of the figures, the experiments in question had been conducted and the results had been achieved as claimed. Thus, the institution concluded that further investigation was not warranted. ORI concurred with the institution's determination that there was insufficient evidence to warrant an investigation.

Falsification: The respondent, a staff clinician, allegedly falsified data in research supported by the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), National Institutes of Health (NIH). The questioned research involved the transfection of T-cells with a gene linked to yellow fluorescent protein to study autoimmunity. The institution conducted an inquiry and concluded that no further investigation was warranted. ORI accepted the institution's report as fulfilling the institution's reporting requirement and concurred with the institution that no further investigation was warranted. However, ORI noted that there were several compliance issues in this case and addressed these with the institution.

Falsification: The respondent, a senior research associate, allegedly falsified data in research supported by a National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grant. The questioned research involved the development of novel therapies for patients with Fanconi Anemia. The institution conducted an investigation and concluded that the respondent had conducted negligent research that led to falsification of data. However, while the respondent was negligent in managing the data, based on a preponderance of the evidence, the institution could not conclude that the falsification was intentional, knowing, or in reckless disregard of expected standards of the research community. ORI accepted the factual findings of the investigation committee, but the procedural deficiencies and the lack of explicit documentation to establish an intentional falsification of data were problematic in this case. Thus, ORI was unable to resolve whether research misconduct had occurred.

Falsification: The respondent, an associate professor, allegedly falsified data in supplementary information to a grant application submitted to the National Cancer Institute (NCI), National Institutes of Health (NIH). The questioned research involved a mouse model designed to study genes thought to play an essential role in the development of human uterine cancer. The institution conducted an inquiry and an investigation and concluded that misconduct had occurred. ORI concurred with the institution's determination that there was sufficient evidence to warrant a

finding of research misconduct. However, after a thorough review of all available documentation, ORI determined that no further U.S. Public Health Service (PHS) action was warranted. ORI recognized the institution's authority to establish and implement its own standards for integrity and to make its own determination in this matter.

Fabrication: The respondent, a graduate student, allegedly fabricated data to be used in a poster presentation at an external meeting. The questioned research involved the study of the regulation of a "timeless" (TIM) protein important in the control of circadian rhythm in fruit flies. The research was supported by a National Institute of Neurological Disorders and Strokes (NINDS), National Institutes of Health (NIH), grant. The institution conducted an inquiry and an investigation and concluded that misconduct had occurred. ORI accepted the institution's report and concluded that the allegations of research misconduct were substantiated. However, ORI did not find the misconduct to be significant enough to warrant PHS action and found that the administrative actions taken by the institution in this case were sufficient. ORI recognized the institution's authority to establish and implement its own standards for integrity and to make its own determination in this matter.

Fabrication: The respondent, a senior research coordinator, allegedly fabricated research records, including survey instruments, for several patients in a study of emotional writing and cancer. The research was supported by a National Cancer Institute (NCI), National Institutes of Health (NIH), grant. The institution conducted a process after the respondent's limited admission and found that research misconduct had occurred. ORI could not accept the institution's report as fulfilling its reporting requirements to the U.S. Public Health Service (PHS) and could not pursue the institution's misconduct findings.

Fabrication: The respondent, an interviewer, allegedly fabricated interview data for a study that examined, by surveying 1,000 young healthy adults, how race/ethnicity, socioeconomic status, socio-demographic factors, and exposure to environmental toxicants can lead to racial and socioeconomic disparity in cardiovascular disease. The questioned work was supported by a National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), grant. The study director concluded that the respondent had fabricated massive amounts of information in 42 interviews. Because of the failure of the institution to conduct an adequate inquiry or investigation, ORI declined to make or propose any PHS findings of research misconduct.

Fabrication/Falsification: The respondents, an assistant professor and a clinical research coordinator, allegedly fabricated and/or falsified experimental data in a clinical trial supported by a National Institute of Mental Health (NIMH), National Institutes of Health (NIH), contract. The questioned research involved a comparison of the effectiveness and side effects of five different medications for treating people with a psychiatric disorder. The institution conducted an inquiry and an investigation. The institution determined that the respondents had fabricated and/or falsified experimental data. However, ORI found no evidence of intent or motivation to commit research misconduct and found that the factual evidence presented in the institution's investigation was weak, incomplete, ambiguous, and in some cases contradictory. Thus, DIO concluded that there was insufficient evidence to make a PHS finding of research misconduct. ORI recognized the institution's authority to establish and implement its own standards for integrity and to make its own determination in this matter.

Falsification/Fabrication: The respondent, a postdoctoral fellow, allegedly falsified and fabricated data in research supported by a National Institute of Mental Health (NIMH), National Institutes of Health (NIH), grant. The questioned research broadly involved the interactions among the prefrontal cortex, hippocampus, and dopaminergic systems toward developing an animal model of schizophrenia. The institution conducted an investigation and found that the respondent had falsified and fabricated data. ORI accepted the institution's report as fulfilling its reporting requirements to the U.S. Public Health Service (PHS), but decided to close this matter without further action and did not pursue the institution's misconduct findings.

Research Misconduct Related Litigation During 2006[1]

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. The court denied the defendant's motion, and the case is now closed.

Meena Chandok, Ph.D., v. Daniel F. Klessig, Ph.D. (Case No. 5:5-cv-1076) (N.D.N.Y.) (filed August 26, 2005). The 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. As of December 31, 2006, the parties have deposed all expert witnesses in the case. April 30, 2007, is the deadline to file any remaining motions in the case.

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

[1]The HHS Office of the General Counsel tracks all civil and criminal litigation related to ORI's mission. Many cases, especially those in which HHS is a named party, require legal support to the Department of Justice (DOJ). This 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.

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 research 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.

Dr. Kay filed an appeal with the U.S. Court of Appeals for the Ninth Circuit on March 12, 2004 (No. 04-15483). On December 22, 2005, the Ninth Circuit affirmed the Arizona district court, holding *inter alia* that the University did not violate Dr. Kay's procedural due process rights. See *Marguerite M. Kay v. Likens, et al.*, 2005 WL 3525618 (9th Cir., December 22, 2005).

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 agreed to permanently exclude 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. On June 28, 2006, the district court sentenced Poehlman to a term of 1 year and 1 day imprisonment. This is the first occasion that a research scientist was sentenced to a term of federal imprisonment for committing fraud in PHS-supported research. Poehlman commenced serving his sentence in July 2006 at a federal correctional facility in Cumberland, MD.

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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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