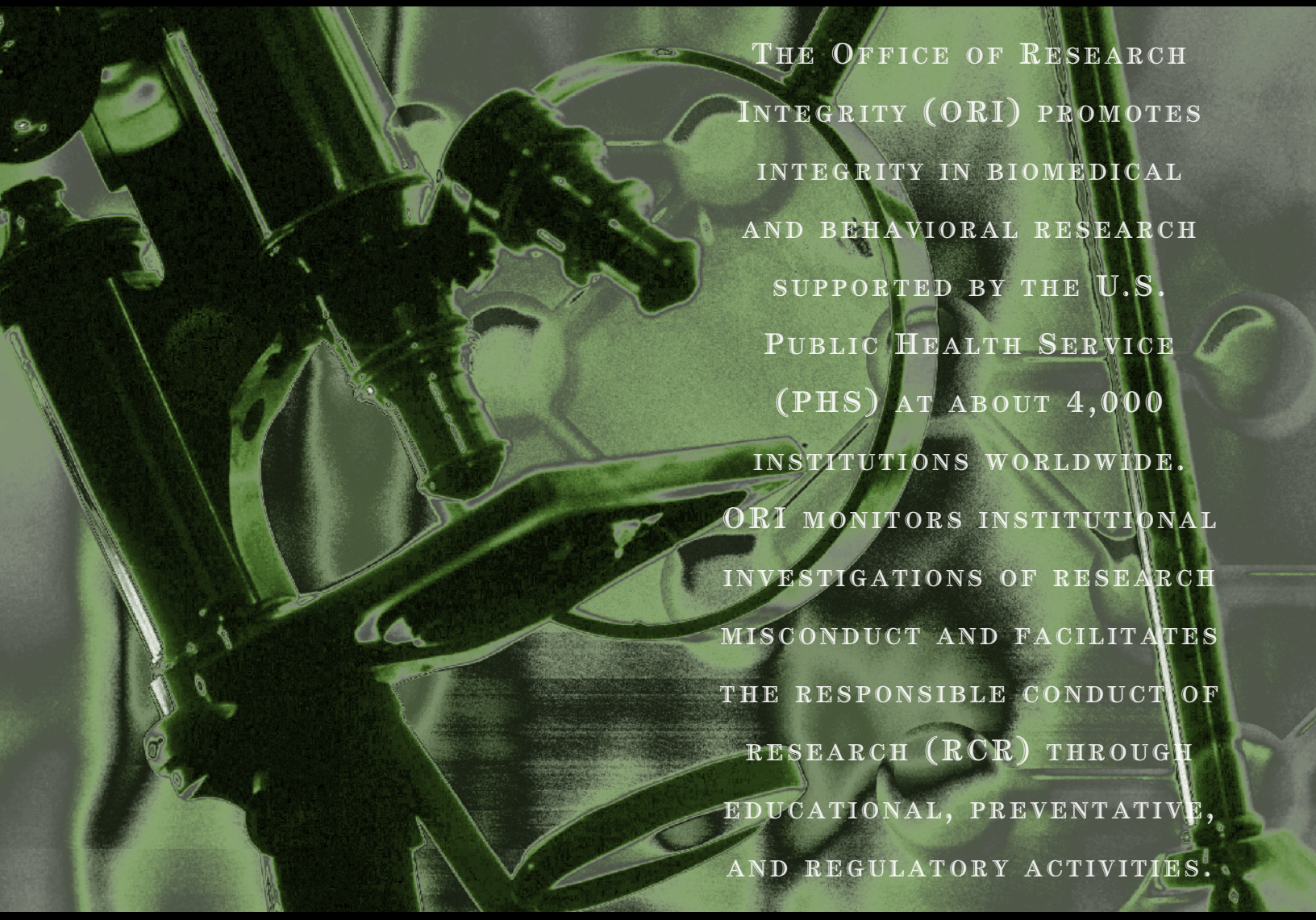
Office of Research Integrity

Annual Report 2007
June 2008



The Office of Research Integrity (ORI) promotes integrity in biomedical and behavioral research supported by the U.S. Public Health Service (PHS) at about 4,000 institutions worldwide. ORI monitors institutional investigations of research misconduct and facilitates the responsible conduct of research (RCR) through educational, preventative, and regulatory activities.

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

Table of Contents

Highlights of CY 2007 ORI Annual Report

The Office of Research Integrity (ORI) is a component of the Office of Public Health and Science (OPHS) 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

- In 2007, ORI opened 14 new cases and closed 28 cases, with 39 cases remaining open at the end of the calendar year, 14 fewer cases than ORI had at the end of 2006. However, as discussed in more detail below, the lower level of case openings reflects a modification in how ORI opened and closed cases in which there was insufficient evidence for a finding of research misconduct.
- Of the 28 cases closed by ORI, 10 cases resulted in sustained findings of research misconduct and/or PHS administrative actions against the respondents. The Division of Investigative Oversight (DIO) completed oversight review of 10 additional cases that are pending settlement or other legal disposition.
- Debarments were imposed in 7 of the 10 cases that resulted in research misconduct findings: 1 for life, 2 for 5 years, and 4 for 3 years. PHS administrative actions imposed in the remaining cases were one 4-year supervisory period, two 3-year supervisory periods, and a 3-year certification period. In all cases in which research misconduct is found, the respondent may not participate as an advisor to the PHS in any capacity for a period of time matching the other administrative actions agreed to or imposed.
- Thirty-five percent of ORI's closed cases in 2007 resulted in PHS misconduct findings and administrative actions, consistent with the historical average of about 33 percent. However, for all but 3 of the 39 pending cases, the institution has made findings of research misconduct. The discrepancy between the fraction of open versus closed cases involving misconduct reflects both the longer time typically required by both the institution and DIO to investigate and review a misconduct case compared to a no-misconduct case.
- The number of allegations received by ORI (222 in 2007) is somewhat lower than the 2004-2006 average of 271, but still above the 1992-2007 average of 198. Of these 222 accessions, DIO administratively closed 56. The historical average of administrative closures from 1992-2007 is 40.

- For the 28 cases involving inquiries or investigations reviewed and closed by ORI in 2007, institutions took a mean of 12 months after notification to ORI (median 8 months; range 1-44 months) to complete their actions. ORI took a mean of 7.2 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 78 percent of the 28 cases within 8 months. One case required 47 months to close, and a second required 33 months to close. The remaining cases required an average of 4.6 months to close.
- ORI provided Rapid Response for Technical Assistance (RRTA) on 40 occasions in 2007. Thirty-four of these rapid responses involved discussion with institutional officials who had concerns about how to manage newly identified or ongoing cases, and six involved interactions with journal editors who wished assistance on verifying problems with submitted manuscripts. The 40 RRTAs in 2007 were up from 24 in 2006.
- Thirty-four institutional Research Integrity Officers (RIOs) and 19 general counsels from major research universities attended the first two intensive 3-day boot camps held in 2007 at the University of Michigan and Johns Hopkins University on the handling of research misconduct allegations.

Education and Prevention

- ORI awarded a 3.5-year contract in 2007 to the Council of Graduate Schools (CGS) to foster acceptance of RCR training as an essential element in graduate education. CGS is the only national organization in the United States dedicated solely to representing and advancing the interests of graduate education. Its 479 member institutions award over 90 percent of the doctorates and more than 75 percent of the master's degrees awarded by U.S. institutions.
- Twelve institutions received seed grants in 2007 to develop RCR education programs specifically tailored to the postdoc experience under a 2-year contract ORI awarded to the National Postdoctoral Association (NPA). The purpose of the contract is to facilitate the creation of RCR programming for postdoctoral fellows by institutional postdoc offices or postdoc associations. The NPA, founded in 2004, is the only national organization devoted entirely to serving the needs of the postdoctoral research community. Its 135 institutional members represent more than 40,000 postdoctoral scholars.

- ORI awarded a 2-year contract to the Laboratory Management Institute at the University of California-Davis in 2007 to develop laboratory management training materials that will make on-line or face-to-face instruction widely available to graduate students, postdocs, faculty, and other personnel.
- ORI collaborated with the European Science Foundation to organize the first World Conference on Research Integrity: Fostering Responsible Research, which was attended by 275 participants from 47 countries in Lisbon, Portugal, from September 16-19, 2007.
- ORI organized the first biennial RCR conference scheduled for St. Louis from April 17-19, 2008, to foster the growth of a community of RCR instructors by promoting networking, collaborations, sharing of resources, the pursuit of common goals, and the generation of ideas for the greater good of the enterprise.
- Seven instructional resources for teaching the responsible conduct of research, developed with support from the RCR Resource Development Program, were added to the ORI web site for use by the worldwide research community in 2007. Thirty-six resources are now available on the ORI web site.
- Ten more products were produced by the RCR Program for Academic Societies, a collaboration between the Association of American Medical Colleges and ORI, to facilitate efforts by academic societies to promote the responsible conduct of research among their members.
- An updated version of the *ORI Introduction to the Responsible Conduct of Research* became available in 2007 from the U.S. Government Printing Office at a substantially reduced price for bulk orders.
- ORI and other federal agencies are supporting a study being conducted by the National Academy of Sciences (NAS), *Ensuring the Utility and Integrity of Research Data in a Digital Age*. The NAS may recommend data integrity standards to the research community, and the study is expected to be completed in 2008.
- ORI held three conferences or workshops in 2007. The conferences or workshops were organized in collaboration with universities, medical schools, professional organizations, and government agencies.
- The ORI web site received 123,007 visits in 2007 from 79,979 unique visitors from 166 countries who viewed 460,192 pages, according to Google Analytics. New visitors totaled 47,987; repeat visitors totaled 31,992. Visitors viewed an average of 3.74 pages per visit. Forty countries had 100 or more visits.

- ORI staff and consultants made 62 presentations at universities, medical schools, research institutes, federal agencies, conferences, and scientific meetings in 2007 and published one article.

Research on Research Integrity and Research Misconduct

- The ORI intramural research program has two manuscripts under review by refereed journals. Both are expected to be published in 2008. Four studies are underway.
- ORI, in conjunction with the National Institutes of Health, made seven awards through the Research on Research Integrity (RRI) Program, increasing the number of studies supported in the first 5 years to 46. The studies have produced 39 publications including 14 in 2007.

Institutional Compliance

- Completed the 2006 Annual Report on Possible Research Misconduct in which 111 institutions reported they were responding to allegations of research misconduct received in 2006 or earlier. Eighty-one institutions reported receiving 151 new allegations in 2006 that resulted in the opening of 86 new cases.

- Inactivated assurances for 329 institutions or organizations for failing to submit the calendar year 2006 Annual Report on Possible Research Misconduct by the March 31, 2007, deadline.

- Processed 74 institutional policies on handling allegations of research misconduct, increasing the number of completed reviews to 2,556.

- Opened 12 compliance cases, closed 10 compliance cases, and carried 9 compliance cases into 2008. Seven compliance cases were carried into 2007.

Information and Privacy

- Received 42 requests in 2007 and closed 44. Seventeen requests were carried into 2008. No Privacy Act requests were received in 2007.

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 are conducted by Public Health Service (PHS) awardee institutions and PHS agencies such as the National Institutes of Health (NIH). Institutional reports and supporting documentation 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 for research misconduct hearings conducted 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 (RRTA) Program, conducts the Research Integrity Officer Training Program, 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 applicable definition of research misconduct set forth in the Public Health Service Policies on Research Misconduct (hereinafter the "PHS regulation") (42 C.F.R. Part 93).

ORI assesses whether the action reported, if it occurred prior to June 2005 and was found to be true, would constitute "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. § 50.102 (1989)).

Alternatively, for allegations of misconduct occurring subsequent to the effective date of the PHS regulation on June 16, 2005, 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 differences in interpretations or judgments of data" that are specifically excluded from the definition of research misconduct, 42 C.F.R. § 93.103(d). Also, ORI finds that some "plagiarism" allegations are actually authorship or credit disputes between former collaborators, which ORI does not consider under these definitions. 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 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 federal definition of research misconduct. Even when a reported allegation is unsupported by sufficient information, ORI continues to track the allegation for up to 2 years in case additional information is obtained.

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 because of the unavailability of complete information for 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 Office of the Inspector General, HHS).

Although typically only about 15-20 percent of the allegations received by ORI result in a formal case being opened, ORI carefully evaluates all the allegations received and 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 2007, ORI received 217 allegations. The disposition of the allegations received by ORI is presented in Table 1. Allegations become open cases when the criteria outlined above are met. Allegations are administratively closed when ORI finds that they (1) do not fall under ORI jurisdiction or meet these criteria, (2) cannot be referred to another agency, or (3) are resolved through further review. 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.

ORI classifies these allegations according to their origin and action taken. If a complaint is received (in contrast to a request for information), an accession number is assigned. If no follow-up is needed, as would be the case if a complaint did not meet the definition of research misconduct or warrant referral to an institution or other federal agency, it would be coded NA for no action. If a complaint lacked sufficient specificity or information to permit further assessment, but additional information was expected, it would be coded NAPN, or no action possible now. If complaints involve issues such as human subject concerns, financial fraud, abuse of animal rights, or possible criminal activity, ORI promptly refers them to appropriate sister agencies such as the Office for Human Research Protections, Office of Management Assessment, the Office of the Inspector General, and so forth. Similarly, if allegations of research misconduct are received that involve funding by other federal agencies such as the Department of Veterans Affairs, the Department of Defense, the Department of Agriculture, or the National Science Foundation, ORI will ensure that the relevant allegations are shared with the other funding agency.

Allegations received from NIH are sent to DIO for confirmatory assessment. If DIO's assessment concurs with NIH's that either no action is required or that an inquiry by the institution where the alleged misconduct occurred was called for, DIO will provide its assessment to NIH. When an inquiry is called for, NIH will so inform the institution and request that the report be provided to ORI. These assessments are coded HBA for handled by agency; if an inquiry is called for, the assessment is coded HBA-PIA for handled by agency-pre-inquiry assessment. PIA refers to assessments that have been identified to ORI or NIH as active inquiries or investigations, and are followed continuously by DIO to ensure that the institutional reporting requirements are met, or if extensions of time are required, appropriate interim reports are received with requests for the extension.

Table 1: Disposition of Allegations in ORI, 2007

Handling of allegations – outcome in ORI	*Number of allegations*	
No action possible now or no action		122
Handled by agency		21
HBA to ORI		5
Referred to other federal agencies		21
PIA allegations made directly to ORI	47	
PIA allegations made initially to NIH	1	
PIA of allegations		48
TOTAL ALLEGATIONS		217
Handling of PIAs		
Administratively closed after review		16
Remain as PIA		26
Moved to active status		5

Of the 217 allegations made to ORI (or to NIH and reported to ORI) in 2007, 48 were assessed by ORI in detail for a potential inquiry or investigation; 5 of the assessments were opened as cases in 2007. Of the remaining PIAs, 16 were administratively closed after being reviewed, and 26 remained open at the end of the year.

Assessments of the allegations that resulted in new ORI cases took an average of 248 days; those that resulted in administrative closures took an average of 115 days. One assessment was resolved by ORI within 25 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) one allegation that was made directly to NIH by a complainant (see Table 1). The number

of allegations that ORI received in 2007 (217) was less than for the prior year (267). The number of all allegations that were the subject of formal PIAs in 2007 by ORI (47) decreased by (64 percent) compared to the number assessed (71) in 2006.

Table 2: Time for Conduct of PIAs by ORI, 2007

Outcome of ORI assessment	*Number of allegations*	*Distribution of resolution times (days)*		
		Mean	*Median*	*Range*
Opened formal case	14*	248	216	27-651
Administratively closed	16	115	104	13-304
Unresolved at end of year 2007	27	–	–	0
TOTAL	57	–	–	13-651

*Includes nine PIAs from 2006

Table 2 summarizes the distribution of times in days needed to resolve PIAs during 2007, including nine carried forward from 2006. Of the 14 cases opened by DIO in 2007, 9 arose from 2006 PIAs. Nearly all of the 27 PIAs carried into 2008 represented ongoing investigations at the institutional level.

PROCESSING OF CASES CLOSED

ORI closed 28 cases in 2007, including 5 inquiries and 23 investigations. The average duration of 19.2 months for an open case was split between institutional actions (12 months) and ORI oversight and actions (7.2 months) (see Table 3). Twenty-two cases (78 percent of the 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, 2007 (N=35)

Distribution of resolution times (months)			
Location of activity	*Mean*	*Median*	*Range*
Institution	12	8	1-44
ORI	7.2	4	1-47

The action period for the 5 institutional inquiries included their inquiry and adjudication phases, and for 23 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. There were no Departmental Appeals Board cases in 2007.

In 2007, 10 of the 23 investigation cases closed by ORI resulted in sustained findings of scientific misconduct and PHS administrative actions against the respondent (see 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 scientific misconduct are located in Appendix B.

CASELOAD AND OUTCOMES

The ORI caseload is divided into two elements: institutional inquiries and institutional investigations. ORI carried forward 53 cases from 2006, and ORI opened 14 new cases and closed 28 cases during 2007 (see Table 4). At the end of calendar year 2007, ORI had 39 active formal cases divided between inquiries and investigations. Three institutional inquiries and 36 institutional investigations remained open at the end of 2007.

TABLE 4: ORI RESEARCH MISCONDUCT CASELOAD BY CASE TYPE, 2007

Case type	*Forwarded from 2006*	*Opened in 2007*	*Closed in 2007*
Institutional inquiry	23	4	5
Institutional investigation	30	10	23
TOTAL	53	14	28

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 2007, ORI accepted five institutional inquiry reports that did not recommend further investigation (see Table 5). Two cases involved allegations of falsification; three dealt with both falsification and fabrication. ORI carried three such institutional inquiries into 2008. Nineteen inquiries resulted in the opening of formal investigations during 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 2007 with 30 cases carried forward from 2006. During the year, 10 new institutional investigations were opened; 23 investigation cases were closed (see Table 4). Of these 23 closed investigations, 10 involved ORI findings of research misconduct; 13 cases did not have such findings. Of the total of 28 cases closed in 2007, 35 percent (10 cases) involved findings of research misconduct (see 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.

There were 30 active investigations carried into 2007. About 75-80 percent of these investigations had completed institutional findings of misconduct.

TABLE 5: OUTCOME OF RESEARCH MISCONDUCT CASES CLOSED BY ORI, 2007 (N=28)

	Outcome of case				
Case type	*No investigation*	*No misconduct*	*Misconduct finding*	*Administrative closure*	*Total*
Institutional inquiry	5	–	–	–	5
Institutional investigation	–	8	10	5	23
TOTAL	5	8	10	5	28

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. There were five cases administratively closed in 2007.

TYPES OF ALLEGATIONS AND ADMINISTRATIVE ACTIONS

Types of Allegations Involved in Cases Closed: During 2007, of the 5 closed inquiries and the 23 investigations closed with findings, all involved allegations of falsification, fabrication, or both. Of those 28 cases, 10 cases resulted in ORI misconduct findings and/or administrative actions (see Table 6).

Table 6: Types of Allegations Involved in Closed Inquiries and Investigations and Their Outcomes, 2007

Allegation	*Inquiry*	*Investigation*	*ORI findings or PHS administrative actions*
Fabrication	–	1	0
Falsification	2	12	6
Falsification/fabrication	3	9	4
Plagiarism/falsification	–	1	–
TOTAL	5	23	10

HHS Administrative Actions Imposed in Closed Cases: A range of administrative actions are used by HHS to protect the public fiscally 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 10 cases in 2007 in which PHS research misconduct findings or HHS administrative actions were imposed, one person was debarred for life in 2007, two persons were debarred or voluntarily excluded for 5 years, and four debarred or excluded for 3 years. Other administrative actions imposed on respondents in these 10 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 (10 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 (3 persons); (c), certification by the institution that the respondent's performance meets generally accepted standards, and (d) retraction and/or correction of articles in one case (see Table 7).

Table 7: HHS Administrative Actions Imposed in Closed Investigations with Misconduct Findings or Administrative Actions, 2007

HHS administrative action	*Duration*	*Number of actions*
Debarment or voluntary exclusion	Lifetime	1
Debarment or voluntary exclusion	5 years	2
Debarment or voluntary exclusion	3 years	4
Prohibition from serving as an advisor for PHS	Lifetime	1
Prohibition from serving as an advisor for PHS	5 years	2
Prohibition from serving as an advisor for PHS	4 years	1
Prohibition from serving as an advisor for PHS	3 years	6
Supervision plan required	4 years	1
Supervision plan required	3 years	2
Certification of work	3 years	1
Retraction and/or correction of articles	–	1

RAPID RESPONSE FOR TECHNICAL ASSISTANCE (RRTA) PROGRAM

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 accurately document admissions to research misconduct; (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 40 institutional officials and journal editors in 2007. 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 240-453-8800) over the telephone or on-site.

RESEARCH INTEGRITY OFFICER (RIO) TRAINING PROGRAM

Thirty-four institutional RIOs and 19 general counsels from major research universities attended the first two intensive 3-day boot camps held in 2007 at the University of Michigan and Johns Hopkins University on the handling of research misconduct allegations.

ORI created the RIO Training Program in 2006 to improve the implementation of the PHS regulation by institutions by providing RIOs with training in the handling of research misconduct allegations.

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 is by invitation only and is limited to 25 per camp.

The boot camp was developed by David Wright, former RIO at Michigan State University for 13 years, under contract with ORI, and in consultation with veteran RIOs.

"ORI is offering the boot camps regionally so that the RIOs can get to know each other and begin to build informal networks," Wright said. "At the end of the first 2-year cycle, ORI will assess the outcome and determine whether to offer additional boot camps." Two boot camps are scheduled for 2008.

"The boot camps take participating RIOs and their legal counsel step-by-step from receipt of an allegation through to preparation of the final investigative report – and its submission to ORI in cases involving PHS funding," Wright said. "They utilize an active or hands-on learning model where RIOs mainly engage in exercises and problem-solving tasks rather than listen to lectures."

A 1-day mini boot camp was held during the annual meeting of the Society of Research Administrators International in Nashville on October 14, 2007.

An orientation video, *The Role of the RIO*, presents a 22-minute introduction to the handling of research misconduct allegations and interviews with veteran RIOs and ORI staff. The video is available on the ORI web site. Copies of the video have been sent to more than 1,200 institutions worldwide.

ORI plans to create a new, on-line RIO manual to provide further support for RIOs. Boot camp alumni will be invited to contribute to and critique drafts of the manual. The manual will include many of the curricular materials from the boot camp, discussion of all major elements of the RIO's role cross-referenced to the regulation (42 C.F.R. 93), and video clips of RIOs performing various aspects of the job.

Given sufficient interest and participation, ORI plans to provide start-up support for a RIO professional organization that may host conferences, publish an on-line newsletter, and create confidential networks of mutual support.

II. Education and Prevention

ORI conducts its education and prevention activities primarily through the Division of Education and Integrity (DEI). Those activities include the Responsible Conduct of Research (RCR) Program for Graduate Schools, RCR Program for Postdocs, Laboratory Management Training, the RCR Resource Development Program, the RCR Program for Academic Societies, conferences and workshops, a web site, and staff presentations and publications.

RCR PROGRAM FOR GRADUATE SCHOOLS

ORI awarded a 3.5-year contract in 2007 to the Council of Graduate Schools (CGS) to foster acceptance of RCR training as an essential element in graduate education.

CGS is the only national organization in the United States dedicated solely to representing and advancing the interests of graduate education. Its 479 member institutions award over 90 percent of the doctorates and more than 75 percent of the master's degrees awarded by U.S. institutions.

Debra Stewart, President, CGS, said, "Preparing the next generation of researchers and professionals in the responsible conduct of research is a core obligation of every graduate program in the U.S."

This contract extends previous efforts by developing a framework for institutionalizing RCR training in graduate programs that will be tested in 2-year demonstration projects at five research institutions. Application procedures for the demonstration projects will be announced in spring 2008. Institutions selected for the demonstration projects will receive $50,000 awards.

The project also will further the development of an RCR leadership cadre of graduate deans, produce a monograph describing the demonstration projects and the best practices for addressing issues and challenges in RCR education, construct an e-mail network to facilitate rapid and regular communication with graduate deans during and after completion of this project, and create a plan for continuing the institutionalization process after this contract ends.

This contract builds on an effort initiated in 2004 by CGS with ORI support and extended in 2005 with National Science Foundation (NSF) support to promote the integration of RCR training into graduate education programs.

A monograph, *Graduate Education for the Responsible Conduct of Research*, was published in 2006 at the end of the initial ORI-supported project. The monograph is available for purchase from the CGS bookstore at http://www.cgsnet.org/Default.aspx?tabid=79&List=0. The NSF project ended in December 2007.

RCR PROGRAM FOR POSTDOCS

Twelve institutions received seed grants in 2007 to develop RCR education programs specifically tailored to the postdoc experience under a 2-year contract ORI awarded to the National Postdoctoral Association (NPA). This contract facilitates the creation of RCR programming for postdoctoral fellows by institutional postdoc offices or postdoc associations.

The NPA, founded in 2004, is the only national organization devoted entirely to serving the needs of the postdoctoral research community. Its 135 institutional members represent more than 40,000 postdoctoral scholars.

"Postdocs play very important roles in biomedical research," Chris Pascal, Director, ORI, said. "They do much of the lab work and frequently supervise undergraduate and graduate students. Nevertheless, their marginal status, neither student nor faculty, frequently reduces their participation in RCR programming offered to graduate students or faculty, thereby putting them at greater risk when encountering RCR issues."

Postdoctoral fellows accounted for 20 percent of the misconduct findings made by ORI from 1994-2003. At least 5 percent of the whistleblowers during that period were postdoctoral fellows.

Under the contract, postdoc offices or postdoc associations at 12 institutions received seed grants in 2007 to develop RCR education programs specifically tailored to the postdoc experience. Thirty seed grants will be awarded during the contract. Additional awards will be made in spring 2008. For more information, see the "Bring RCR Home" project on the NPA web site.

The following institutions received $1,000 seed grants to help support the development of RCR programming for postdocs:

- Brown University
- Howard University
- Indiana University
- Massachusetts General Hospital
- Medical University of South Carolina
- Pennsylvania State University
- Stanford University
- University of Iowa
- University of Kansas
- University of Pennsylvania
- University of Pittsburgh
- University of Washington

Katy Flint, Project Manager, said, "We hope the current projects and those that will come later will provide a source of inspiration and information to others. We would like to see RCR training and associated topics become an essential part of the postdoc experience." Abstracts of current awardees are available on the NPA web site.

The NPA also convened a project advisory committee composed of postdocs, faculty, administrators, and an ORI representative to assist with planning and review activities. The contract also requires the NPA to organize two train-the-trainer workshops in conjunction with its national meetings in 2007 and 2008. The workshops will focus on organizing an effective RCR program at institutions.

In addition, the NPA is developing an on-line and paper toolkit on how to organize RCR programs for postdocs. The toolkit will include sample agendas, suggested speakers, sample handouts, curriculum, resource list, sample pre- and post-tests, evaluations forms, and a planning guide. The toolkit will continue to be posted on the NPA web site after the contract is concluded.

Finally, the NPA will provide technical assistance, including site visits, to awardee postdoc offices and postdoc associations. Data will be collected throughout the project to evaluate their effectiveness.

LABORATORY MANAGEMENT TRAINING

ORI awarded a 2-year contract to the Laboratory Management Institute (LMI) at the University of California-Davis (UC Davis) in 2007 to develop laboratory management training materials that will make on-line or face-to-face instruction widely available to graduate students, postdocs, faculty, and other personnel.

Under the contract, LMI will produce a web-based course that may be taken by individuals and would permit faculty to offer face-to-face instruction by organizing workshops or lab management training programs. The course and guidebook will be posted on the ORI web site for free use by the worldwide research community.

"The course will be based on the day-to-day practice of scientific research," John Galland, Ph.D., Director, LMI, said. "It will be interactive and learner-centered."

"This instruction is essential because knowledge of science is a necessary but not a sufficient condition for success in science," Larry Rhoades, Director, Division of Education and Integrity, ORI, said. "Researchers who direct labs

face production, personnel communication, facility, and financial problems similar to those faced by chief executive officers of small businesses."

The interactive course will provide instruction in skills useful in managing laboratories including: new communication skills; establishment and maintenance of a research program; quality control and assurance; human resources management; leadership, goal setting, and strategic planning; financial and business management; health, safety, and security; creativity, discovery, problem solving, and innovation; stewardship of resources; and interpersonal relations.

The course will feature LabAct, a pedagogical technique that employs actors to illustrate issues in short videos related to the general topics mentioned above. The short videos will present two or more possible approaches to those issues. In addition, behavioral objectives, background materials, and references will be provided.

The downloadable guidebook will contain chapters on the following topics related to laboratory management: leadership, mentoring, best practices, innovation, and management. The guidebook will also include PowerPoint presentations, behavioral objectives, background material, and assessment instruments.

LMI was started in 2005 at UC Davis because "researchers devote years of study in their scientific disciplines, but receive little or no laboratory management training that is essential to their success," Galland said.

FIRST WORLD CONFERENCE ON RESEARCH INTEGRITY

ORI collaborated with the European Science Foundation (ESF) to organize the first World Conference on Research Integrity: Fostering Responsible Research that was attended by 275 participants from 47 countries in Lisbon, Portugal, from September 16-19, 2007.

The World Conference was the first global forum convened to provide researchers, research administrators, research sponsors, journal editors, representatives from professional societies, policymakers, and others an opportunity to discuss global strategies for harmonizing research misconduct policies and fostering responsible conduct of research.

The final report on the first World Conference on Research Integrity offers the following rationale for international cooperation on research misconduct policies and the responsible conduct of research:

"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, plagiarism or other key terms that describe acceptable and unacceptable research practices."

"Even where there is general agreement on key elements of research behaviour, 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 organisation to organisation."

"The research community worldwide has to address these problems in order to retain public confidence and to establish clear best practice frameworks at an international level."

The report recommends that subsequent actions focus on three crucial needs:

- to study research behavior (misconduct and questionable research practice, following or not following best practice) and the factors that influence the behaviors;
- to clarify, harmonize, and publicize standards for best practice and procedures for reporting improper conduct; and
- to incorporate global standards for best practice and policies for responding to misbehavior into training and research environments.

Subsequent actions recommended to meet those crucial needs are the following:

Recommendation 1
ESF and ORI should continue to work with the Global Science Forum and other organizations to achieve the common objective of encouraging all countries that support active research programs to develop guidelines for best practice and procedures for responding to misconduct in research.

Recommendation 2
ESF and ORI should take the lead in developing a Global Clearinghouse for Research Integrity.

Recommendation 3
ESF and ORI should take the lead initiating planning and fundraising for a second World Conference to be held in late 2009 or early 2010.

The first World Conference was planned by Tony Mayer, ESF, and Nick Steneck, ORI consultant, with guidance from a planning committee. The Portuguese Ministry for Science, Technology and Higher Education (PMSTHE) hosted the conference as part of the Portuguese presidency of the European Union.

Besides ESF and ORI, the conference was 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 United Kingdom (UK) Research Integrity Office, International Council for Science, and the North Atlantic Treaty Organization.

The final conference report and six appendices are available at http://www.esf.org/activities/esf-conferences/details/confdetail242.html

FIRST BIENNIAL RCR CONFERENCE

ORI organized the first biennial RCR conference scheduled for St. Louis from April 17-19, 2008, to foster the growth of a community of RCR instructors by promoting networking, collaborations, sharing of resources, the pursuit of common goals, and the generation of ideas for the greater good of the enterprise.

More than 50 abstracts have been accepted for presentation. The conference program includes overviews of current efforts and a session exploring different views on goals, methods, and the value of RCR instruction. Other sessions focus on assessment tools, web-based instruction, targeting different audiences, innovative teaching materials and approaches, international programs, and other aspects of RCR instruction. Time has been allocated for interactive demonstration sessions and poster presentations. Attendees were invited to bring materials to display and share with others.

The conference was organized by Cathy Striley, Washington University; Cynthia Ricard, ORI; and Nick Steneck, consultant to ORI.

RCR RESOURCE DEVELOPMENT PROGRAM

Seven instructional resources for teaching RCR, developed with support from the RCR Resource Development Program, were added to the ORI web site for use by the worldwide research community in 2007.

ORI created the RCR Resource Development Program in 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 responsible conduct of research at private and public research institutes.

The program has supported 54 projects since its establishment. Thirty-six 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.

An on-line version of the *ORI Introduction to the Responsible Conduct of Research* has also been added to the web site.

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

- **CITI Responsible Conduct of Research Program**
  Collaborative Institutional Training Initiative (CITI)
  University of Miami School of Medicine

- **Video Vignettes on Research Ethics and Academy Integrity**
  Derina Samuel
  Syracuse University

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

- **Teaching RCR in Humans**
  Stanley Korenman

University of California-Los Angeles

- **Peer Review Quick Guide**
  Murali Krishnamurthi
  Northern Illinois University

- **Responsible Authorship Quick Guide**
  Murali Krishnamurthi
  Northern Illinois University

- **Administrators and the Responsible Conduct of Research**
  Stephen Erickson
  Boston College

RCR PROGRAM FOR ACADEMIC SOCIETIES

ORI established the RCR Program for Academic Societies in 2002 to facilitate the institutionalization of infrastructure and activities within academic and scientific societies that would 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 33 academic and scientific societies from 2002-2006 to develop guidelines, standards, policies, conferences, curricula, and other resources designed to promote the responsible conduct of research among members of their societies.

Although funding for the program ended in 2006, additional products continue to become available as earlier funded projects are completed. Recently available products include:

- **Alliance of Independent Academic Medical Centers** – Proceedings of a symposium on *An Ethical Framework for Managing Clinical Trials in the Independent Academic Center*.
- **American College of Neuropsychopharmacology** – *Code of Conduct for Sustaining Corporations*.
- **American College of Physicians** – A patient education brochure, *Volunteering for a Research Study?* Also posted materials from a

workshop on *Doing Research in the Office: Professionalism and Pitfalls*.

- **American Society for Bioethics and Humanities** – An article, *Educational Approaches to the Responsible Conduct of Clinical Research: An Exploratory Study*.
- **American Speech-Language-Hearing Association** – A policy statement, *Guidelines for the Responsible Conduct of Research: Ethics and the Publication Process*.
- **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*.
- **Council on Social Work Education** – *National Statement on Research Integrity in Social Work* and an *Action Plan for Promoting Research Integrity in Social Work*.
- **Federation of American Societies for Experimental Biology** – *A Conflict of Interest (COI) Toolkit*.
- **Research and Assessment Corporation for Counseling, Inc.** – A DVD and training manual on *Conducting Research Responsibly*.
- **The Gerontological Society of America** – *Guidebook for Multidisciplinary Clinical Geriatric Research*.

A list of products produced by academic and scientific societies supported by the RCR Program for Academic Societies is available at http://www.aamc.org/programs/ori/

ORI INTRODUCTION TO THE RESPONSIBLE CONDUCT OF RESEARCH

An updated version of the *ORI Introduction to the Responsible Conduct of Research* became available in 2007 – $495.00 per 50 copies sent to the same address. Single copies remain at $14.00 for U.S. orders.

For foreign bulk orders, 50 copies cost $693.00; single copies are $19.00. The cost of foreign orders covers only surface mail delivery; airmail delivery would involve an additional charge.

"We appreciate the effort made by GPO to lower the bulk price on the text," Chris Pascal, Director, ORI, said. "The lower price which works out to $9.90 per copy may allow the text to be more widely used in graduate and undergraduate research courses."

Over 7,550 copies of the publication have been sold since it was published in June 2004, making it a GPO "best seller." The text also has been translated into Chinese, Japanese, and Korean. The Chinese version was published by Tsinghua University Press; the Japanese version by Maruzen Co., Ltd., Tokyo; and the Korean version by the South Korean Ministry of Education and the Korea Research Foundation. A Spanish translation is in preparation.

The limited updating was done prior to the printing of more copies by GPO. All links were updated, and a few references were added. The text was not changed.

Copies may be ordered from GPO at http://bookstore.gpo.gov/collections/ori-research.jsp. The publication is available for on-line reading or downloading at http://ori.hhs.gov. An on-line module is available at http://ori.hhs.gov/education/products/RCRintro/

CITI RCR COURSE

Since February 1, 2007, when the Collaborative Institutional Training Initiative (CITI) adopted a new software platform, 7,074 persons (643 per month) have completed one of four CITI RCR courses. ORI partially supported the development of the RCR courses and is supporting the Public Access Portal until May 2008.

In 2007, 2,866 people (41 percent) completed an RCR course through the Public Access Portal at www.citiprogram.org, and 4,208 completed a course through a CITI member institution requirement. The most widely used course through the Public Access Portal was Social and Behavioral Research (1,318) followed by BioMedical (949), Humanities (487), and Physical Sciences (112).

The top five institutions that had research personnel complete the courses were the following: Children's National Medical Center, 562; Purdue University, 553; Ohio State University, 332; Clemson University, 273; and University of Miami, 238.

The course site provides an opportunity for individuals to complete RCR courses and allows organizations or instructors to set up a customized curriculum for their faculty and students.

More information on the CITI RCR program and other CITI courses is available at www.citiprogram.org. For more information on how to implement the CITI RCR program at your organization, department, or classroom, contact the CITI RCR "helpdesk" at 305-243-7970 or at citisupport@med.miami.edu

NATIONAL ACADEMY OF SCIENCES (NAS) STUDY ON INTEGRITY OF RESEARCH DATA

ORI and other federal agencies are supporting a study being conducted by the NAS, *Ensuring the Utility and Integrity of Research Data in a Digital Age*. The NAS may recommend data integrity standards to the research community.

The study, conducted by the Committee on Science, Engineering, and Public Policy, will review the selection, collection, analysis, handling, oversight, reporting, publishing, ownership, access, and archiving of data. The study report is expected to be completed in 2008. The project web site at http://www8.nationalacademies.org/cp/projectview.aspx?key=48721 lists the key issues being addressed as:

1. What are the growing varieties of research data? In addition to issues concerned with the direct products of research, what issues are involved in the treatment of raw data, pre-publication data, materials, algorithms, and computer codes?

2. Who owns research data, particularly those which result from federally funded research? Is it the public? The research institution? The lab? The researcher?

3. To what extent is a scientist responsible for supplying research data to other scientists (including those who seek to reproduce the research) and to other parties who request them? Is a scientist responsible for supplying data, algorithms, and computer codes to other scientists who request them?

4. What challenges does the science and technology community face arising from actions that would compromise the integrity of research data? What steps should be taken by the science and technology community, research institutions, journal publishers, and funders of research in response to these challenges?

5. What are the current standards for accessing and maintaining research data, and how should these evolve in the future? How might such standards differ for federally funded and privately funded research, and for research conducted in academia, government, non-governmental organizations, and industry?

The study will not address privacy issues and other issues related to human subjects.

CONFERENCES AND WORKSHOPS

ORI held three conferences or workshops in 2007. The conferences or 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/

Data Fabrication and Falsification: How to Avoid, Detect, Evaluate and Report

Boston, MA

Co-sponsors: Harvard Medical School, Harvard School of Public Health, and Harvard Teaching Hospitals

March 29-30, 2007

Workshop on Teaching Survival Skills and Ethics

Snowmass, CO

Co-sponsors: NIH, University of Pittsburgh

June 10-15, 2007

First World Conference on Research Integrity

Lisbon, Portugal

Co-sponsor: European Science Foundation

September 16-19, 2007

ORI has conferences in the planning stage with 10 organizations, including the American Society for Microbiology, the Society of Research Administrator, Carnegie-Mellon University, Georgetown University, Bristol University (England), the Smithsonian Institution, the Uniformed Services University, the Joint Task Force, Capitol Region Medical Command, and RxTrials. These conferences are being planned for 2008 or 2009.

ORI WEB SITE

The ORI web site received 123,007 visits in 2007 from 79,979 visitors from 166 countries who viewed 460,192 pages, according to Google Analytics. New visitors totaled 47,987; repeat visitors totaled 31,992. Visitors viewed an average of 3.74 pages per visit.

Visitors were most frequently from Canada, the UK, Spain, Japan, Australia, South Korea, Germany, China, India, and the United States. Forty countries had 100 or more visits.

STAFF PRESENTATIONS

Edward Gabriele, Director for Educational Conferences and Liaison Development. "Research, Ethics and the Life of the University," "The Spirit and Challenge of Research Ethics," "Trust and Troth: Our Passion for Protecting Human Subjects," and "Responsible Conduct of Research," Michigan Technological University. Houghton, MI, September 27-28, 2007.

Edward Gabriele, Director for Educational Conferences and Liaison Development. "Research for Administrators: Learning the Science We Serve," Society of Research Administrators (SRA) International, Nashville, TN, October 14, 2007.

Edward Gabriele, Director for Educational Conferences and Liaison Development. "From Hierarchy to History: Re-imagining the Organizational Paradigm in the Culture of Research," The Kuhn Keynote Lecture Series, SRA Senior Executive Institute, SRA International, Nashville, TN, October 16, 2007.

Edward Gabriele, Director for Educational Conferences and Liaison Development. "Through the Looking Glass: Who We Are and What We Do as Research Administrators," SRA International, Nashville, TN, October 16, 2007.

Edward Gabriele, Director for Educational Conferences and Liaison Development. "Informed Consent: Principles, Policy, and Practical Applications," SRA International, Nashville, TN, October 17, 2007.

Edward Gabriele, Director for Educational Conferences and Liaison Development. "The Spirit and Challenge of Research Ethics," SRA International, Nashville, TN, October 17, 2007.

Edward Gabriele, Director for Educational Conferences and Liaison Development. "Surveying the Research Integrity Landscape," Office of Sponsored Projects, Smithsonian Institution, Washington, DC, December 5, 2007.

Edward Gabriele, Director for Educational Conferences and Liaison Development. "Informed Consent: Principles, Policy, and Practical Applications," "The Spirit and Challenge of Research Ethics," "Through the Looking Glass: Who We Are and What We Do as Research Administrators," and "Research for Administrators: Learning the Science We Serve," SRA International, Nashville, TN, October 13-17, 2007.

Edward Gabriele, Director for Educational Conferences and Liaison Development. "Surveying the Research Integrity Landscape," Office of Sponsored Projects, Smithsonian Institution, Washington, DC, December 5, 2007.

Susan J. Garfinkel, Scientist-Investigator. "Image Forensics," Nature Publishing Group, New York City, April 25, 2007, with J. Krueger.

Susan J. Garfinkel, Scientist-Investigator. "ORI and Research Misconduct," Boyce Thompson Institute, Ithaca, NY, July 19, 2007.

Susan J. Garfinkel, Scientist-Investigator. "Bright Lines of Deception in Research," The Advanced Science & Technology Adjudication Resource Center, 2007 National Judges' Science School, Johns Hopkins University School of Medicine, Baltimore, MD, October 5-7, 2007.

Susan J. Garfinkel, Scientist-Investigator. "Handling Research Misconduct: Difficulties and Problems Identified by ORI," RIO Boot Camp, Johns Hopkins University, Baltimore, MD, November 6, 2007.

Chris B. Pascal, Director, ORI. "Providing Education in the Responsible Conduct of Research." International Conference on Responsible Conduct of Research, Waseda University, Tokyo, Japan, January 12-13, 2007.

Chris B. Pascal, Director, ORI. "Conflict of Interest" and "Federal Update," Biomedical Research Challenges: Evolving Issues & Contemporary Solutions in Protecting Human Subjects, Baylor University Medical Center, Dallas, TX, January 26, 2007.

Chris B. Pascal, Director, ORI. "Clinical Research Misconduct: Lessons to be Learned" and "Panel IV – A Washington Update." OHRP Research Community Forum: Challenges in Protecting Human Subjects in Research: Seven Years into the Millennium, Orlando, FL, February 26, 2007.

Chris B. Pascal, Director, ORI. "Research Misconduct, the Responsible Conduct of Research and Research Integrity," NIH Regional Seminar on Program Funding and Grants Administration, Salt Lake City, UT, March 5-7, 2007.

Chris B. Pascal, Director, ORI. "Misconduct, Research Integrity and the Responsible Conduct of Research," FDA Research Involving Human Subjects Training Program, Silver Spring, MD, March 14, 2007.

Chris B. Pascal, Director, ORI. "Government Agency Perspective on Charge Questions," Committee on Assuring the Integrity of Research Data, Committee on Science, Engineering, and Public Policy, The National Academies, Washington, DC, April 16-17, 2007.

Chris B. Pascal, Director, ORI. "The Office of Research Integrity: Responding to Misconduct and Promoting Responsible Research," NIH Regional Seminar on Program Funding and Grants Administration, Duke University, Durham, NC, April 24-26, 2007.

Chris B. Pascal, Director, ORI. "Research Integrity: Issues to Consider When Conducting Government-Funded Research," FDA Research Involving Human Subjects Training Program, Bethesda, MD, May 9, 2007.

Chris B. Pascal, Director, ORI. "Global Symposium on Research Misconduct," International Cooperation Team, KISTEP, Korean Ministry of Science and Technology, Seoul, South Korea, June 14, 2007.

Chris B. Pascal, Director, ORI. "Research Misconduct and the Responsible Conduct of Research," "Case Studies on Misconduct," and "Managing the Research Data," Association of Minority Health Professions Schools and Agency for Toxic Substances and Disease Registry (AMHPS/ATSDR) Sponsored Research Administration and Research Personnel Retreat, Stone Mountain, GA, August 1-3, 2007.

Chris B. Pascal, Director, ORI. "Misconduct, the Responsible Conduct of Research and Research Integrity," FDA Research Involving Human Subjects Training Program, Silver Spring, MD, September 13, 2007.

Chris B. Pascal, Director, ORI. "Handling Cases of Research Misconduct," ESF-ORI World Conference on Research Integrity: Fostering Responsible Research, Lisbon, Portugal, September 16-19, 2007.

Chris B. Pascal, Director, ORI. "Research Misconduct, the Responsible Conduct of Research and Research Integrity," Scientific Integrity and Academic Medicine Conference, University Medical Center, Groningen, The Netherlands, September 20, 2007.

Chris B. Pascal, Director, ORI. "Handling Allegations of Research Misconduct under the New Regulation (42 CFR Part 93)," and "ORI Introduction to the Responsible Conduct of Research," Society of Research Administrators International Annual Meeting, Nashville, TN, October 13-16, 2007.

Chris B. Pascal, Director, ORI. "Problem Areas in Research Misconduct," Mini RIO Boot Camp, Nashville, TN, October 14, 2007.

Chris B. Pascal, Director, ORI. "Discussing the NSF Requirement for Mentoring and RCR Education," Council on Governmental Relations Meeting, Washington, DC, October 25, 2007.

Chris B. Pascal, Director, ORI. "Research Misconduct, Responsible Conduct of Research and Research Integrity," 118th Annual Meeting of the Association of American Medical Colleges Conference, Washington, DC, November 5-7, 2007.

Lawrence J. Rhoades, Director, DEI. "How Can RCR Be Mainstreamed in Graduate Education?" Open Seminar in Research Ethics, Raleigh, NC, April 12, 2007.

Lawrence J. Rhoades, Director, DEI. "Culture of Science: A Deviant View," Albert Einstein College of Medicine, New York, NY, May 8, 2007.

Sandra Titus, Director, Intramural Research. "The Dilemma: To Report or Be Silent," Data Fabrication and Falsification: How to Avoid, Detect, Evaluate and Report, Harvard University, Cambridge, MA, March 30, 2007.

Sandra Titus, Director, Intramural Research. "Research Misconduct: Examination of the Dark Side," Walter C. Randall Lecture in Biomedical Ethics, The American Physiological Society, Washington, DC, May 1, 2007.

Sandra Titus, Director, Intramural Research. "Research Misconduct: Could It Happen to You?" NIH – Undergraduate Special Program, Bethesda, MD, June 4, 2007.

Sandra Titus, Director, Intramural Research. "Research Integrity and Lab Management" and "Research Integrity: Role of Project Manager," University of California-Davis, October 22-26, 2007.

Nicholas H. Steneck, Consultant. "The United States and the US Office of Research Integrity (ORI)," Research Integrity: Toward a Canadian Approach, Canadian Research Integrity Committee, Ottawa, Canada, January 22-23, 2007.

Nicholas H. Steneck, Consultant. "Promoting Research Integrity: Historical Background & Current Trends: From a Misconduct- to an Integrity-centered Universe." Workshop on Best Practices for Ensuring Scientific Integrity & Preventing Misconduct, Organisation for Economic Co-Operation and Development, Global Science Forum, Tokyo, Japan, February 22-23, 2007.

Nicholas H. Steneck, Consultant. "Research Integrity as a Guarantee for Excellence," Excellence in Science, European Science Foundation, Strasbourg, France, March 16, 2007.

Nicholas H. Steneck, Consultant. "Is Research Misconduct Fraud? The Development of US Policy for Responding to Misbehavior in Research," Fraud in Research, Fraud Advisory Panel, London, UK, May 8, 2007.

Nicholas H. Steneck, Consultant. "RCR Instruction in the US," UK Research Integrity Office, Advisory Board Meeting, Edinburgh, Scotland, May 11, 2007.

Nicholas H. Steneck, Consultant. "RCR Instruction in the US," University of Michigan Undergraduate Research Opportunity Program, Campus Institute for Undergraduate Research Programs, Ann Arbor, MI, May 25, 2007.

Nicholas H. Steneck, Consultant. "What Do We Know? Two Decades of Research on Research Integrity," World Conference on Research Integrity, Lisbon, Portugal, September 16-19, 2007.

Nicholas H. Steneck, Consultant. "The Regulation & Promotion of Research Ethics in the US: Past Developments and Future Challenges," China-U.S. Workshop on Scientists' Social and Ethical Responsibilities, Beijing, China, September 26-27, 2007.

Nicholas H. Steneck, Consultant. "The 2007 World Conference on Research Integrity: The Future of Global Strategies," Fogarty International Center Conference, NIH, Bethesda, MD, October 17, 2007.

Nicholas H. Steneck, Consultant. "Research Misconduct: Is It All Just a Storm in a Tea Cup?", United European Gastroenterology Week 2007, Paris, France, October 30, 2007.

Nicholas H. Steneck, Consultant. "Responsibility and Integrity in Biomedical Research," Introductory Course in Clinical Research, Michigan Institute for Clinical and Health Research, Ann Arbor, MI, November 7, 2007.

Nicholas H. Steneck, Consultant. "Everyday Practices that Compromise Integrity in Research and How to Respond to Them," Research Integrity Workshop, Sick Kids Research Institute, Toronto, Canada, November 19, 2007.

STAFF PUBLICATION

Gabriele, E.F. "Stretching Wide the Boundaries Within: Clinical Research in Search of Its Self." *Proceedings of the Institute for Clinical Research 28th Annual Conference*. 2007, 3-17.

FEDERAL REGISTER NOTICES – SCIENTIFIC MISCONDUCT

Findings of Research Misconduct Notice. Vol. 72, No. 64, 16366-16367, Wednesday (April 4, 2007) [Uzelmeier]

Findings of Research Misconduct Notice. Vol. 72, No. 97, 28493, Wednesday (May 21, 2007) [Prabhakaran]

Findings of Research Misconduct Notice. Vol. 72, No. 111, 32123, Thursday (Monday, June 11, 2007) [Jin]

Findings of Research Misconduct Notice. Vol. 72, No. 118, 34016, Wednesday (June 20, 2007) [Murillo]

Findings of Scientific Misconduct Notice. Vol. 72, No. 121, 34689, Monday (June 25, 2007) [Bryant]

Findings of Scientific Misconduct Notice. Vol. 72, No. 121, 34690, Monday (June 25, 2007) [Layman]

Findings of Misconduct in Science Notice. Vol. 72, No. 135, 38836-38837, Monday (July 16, 2007) [Roovers]

Findings of Research Misconduct Notice. Vol. 72, No. 140, 40157, Monday (July 23, 2007) [Lieber]

Findings of Misconduct in Science Notice. Vol. 72, No. 156, 45427, Tuesday (August 14, 2007) [Jorge-Rivera]

Findings of Scientific Misconduct Notice. Vol. 72, No. 194, 57337-57338, Tuesday (October 9, 2007) [Sudbo]

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

Completed Studies

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 based on this study is expected to be published in a peer review journal in 2008.

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

ORI staff analyzed 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 were examined to determine whether mentors/advisors supervised or delegated that responsibility to others, the principal investigator/advisor examined original data, the respondent was under any stress to meet a deadline, or the laboratory had difficult interpersonal behaviors. An article based on this study is expected to be published in a peer review journal in 2008.

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 regulation. 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. Ninety-one interviews have been completed, and the data are being analyzed. The second data collection effort with a wider sample will be undertaken 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 regulation. 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 has been designed, will be piloted in 2008, and will be completed in 2009.

Training and Mentoring Ph.Ds.: 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 (1) to understand how faculty describe the differences between being an advisor versus being a mentor; (2) to understand how these two roles work with doctoral students to promote the responsible conduct of research; and (3) to learn faculty views on what 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.

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 and during the investigative process, and after it ended. A proposal has received funding by HHS and has been awarded to RTI. The study design and submission to the Office of Management and Budget is expected to occur in 2008.

The intramural research program anticipates development of future studies on graduate student-faculty views on mentoring and a study on cooperation and competition in conducting research and publishing.

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 Alcohol Abuse and Alcoholism (NIAAA); the National Institute of General Medical Sciences; 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.

RRI Awards

Research on ethical decision making, government industry research relationships, standards of scientific conduct, and record-keeping and data-sharing practices are among the topics supported by the seven awards made in 2007 by the RRI program.

Since it began in 2001, the RRI program has funded 46 projects that have resulted in 39 publications – 27 articles, 1 commentary, 1 letter to the editor, 8 abstracts, and 2 literature reviews – in 15 journals.

Total funding for the RRI program in 2007 was $2,815,761, just slightly below the all-time high of $3,070,404 in 2006. New grants received $2,040,243; continuations received $775,518. ORI contributed $1,488,228; NIH Institutes contributed $1,327,533.

The new awards were supported by the National Library of Medicine and ORI. Continuation awards were funded by the National Human Genome Research Institute, the National Cancer Institute, and the National Institute of General Medical Sciences. The National Institute of Nursing Research provided grants management support and the Center for Scientific Review provided grant review services.

Seven of the 22 applications were supported for a funding rate of 31 percent. Awards provide up to $175,000 in direct costs, plus indirect costs, for each of 2 years.

Award abstracts are posted on the ORI web site along with a list of publications produced by projects supported by the RRI program. For information on the RRI program, contact Cynthia Ricard, Ph.D., at Cynthia.Ricard@hhs.gov.

The grant titles, principal investigators, and awardee institutions follow:

Government Industry Relationships in Science

Eric G. Campbell

Massachusetts General Hospital

Quality of Research on Treatment Harms in Cancer

Benjamin Djulbegovic

H. Lee Moffitt Cancer Center & Research Institute

Duplicate Article/Plagiarism Discovery

Harold R. Garner

University of Texas Southwestern Medical Center

Standards of Scientific Conflict

Michael W. Kalichman

University of California-San Diego

Development of Strategies for Improving Ethical Decision-Making in the Sciences

Michael D. Mumford

University of Oklahoma

Barriers and Opportunities for Sharing Research Data

Amy Mehraban Pienta

University of Michigan

Responsible Record Keeping Practices: Standards & Practices of Funded Researchers

Kenneth R. Wilson

East Carolina University

RRI Publications

Researchers supported by the Research on RRI program published 14 articles in 2007 on research integrity and the responsible conduct of research in three journals.

In the first 6 years of the program, RRI researchers have published 39 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:

- Anderson, M.S. "Collective Openness and Other Recommendations for the Promotion of Research Integrity." *Science and Engineering Ethics* 2007, 13(4):387-394.
- Anderson, M.S., Horn, A.S., Risbey, K.R., Ronning, E.A., DeVries, R., and Martinson, B.C. "What Do Mentoring and Training in the Responsible Conduct of Research Have to Do with Scientists' Misbehavior? Findings from a National Survey of NIH-Funded Scientists." *Academic Medicine* 2007, 82(9):853-860.
- Anderson, M.S., Martinson, B.C., and DeVries, R. "Normative Dissonance in Science: Results from a National Survey of U.S. Scientists." *Journal of Empirical Research in Human Research Ethics* 2007, 2(4):3-14.
- Anderson, M.S., Ronning, E.A., DeVries, R., and Martinson, B.C. "The Perverse Effects of Competition on Scientists' Work and Relationships." *Science and Engineering Ethics* 2007, 13(4):437-461.
- Bulger, R.E., and Heitman, E. "Expanding Responsible Conduct of Research Instruction across the University." *Academic Medicine* 2007, 82(9):876-878.

- Deming, N., Fryer-Edwards, K., Dudzinski, D., Starks, H., Culver, J., Hopley, E., Robins, L., and Burke, W. "Incorporating Principles and Practical Wisdom in Research Ethics Education: A Preliminary Study." *Academic Medicine* 2007, 82(1):18-23.
- Errami, M., Hick, J.M., Fisher, W., Trusty, D., Wren, J.D., Long, T.C., and Garner, H.R. "Déjà vu – A Study of Duplicate Citations in Medline." *Bioinformatics Open Access*, December 1, 2007.
- Funk, C.L., Barrett, K.A., and Macrina, F.L. "Authorship and Publication Practices: Evaluation of the Effect of Responsible Conduct of Research Instruction to Postdoctoral Trainees. *Accountability in Research* 2007, 14:269-305.
- Gorman, D.M., and Conde, E. "Conflict of Interest in the Evaluation and Dissemination of 'Model' School-Based Drug and Violence Prevention Programs." *Evaluation and Program Planning* 2007, 30:422-429.
- Gorman, D.M., Conde, E., and Huber, J.C. "The Creation of Evidence in 'Evidence-Based' Drug Prevention: A Critique of the Strengthening Families Program Plus Skills Training Evaluation." *Drug and Alcohol Review* 2007, 26:585-593.
- Heitman, E., Olsen, C.H., Anestidou, L., and Bulger, R.E. "New Graduate Student's Baseline Knowledge of the Responsible Conduct of Research." *Academic Medicine* 2007, 82(9):838-845.
- Louis, K.S., Holdsworth, J.M., Anderson, M.S., and Campbell, E.G. "Becoming a Scientist: The Effects of Work-Group Size and Organizational Climate." *Journal of Higher Education* 2007, 78(3):311-336.
- Neale, A.V., Northrup, J., Dailey, R., Marks, E., and Abrams, J. "Correction and Use of Biomedical Literature Affected by Scientific Misconduct." *Science and Engineering Ethics* 2007, 13:5-24.
- Pryor, E., Habermann, B., and Broome, M. "Scientific Misconduct from the Perspective of Research Coordinators: A National Survey." *Journal of Medical Ethics* 2007, 33:365-369.

IV. Institutional Compliance

The PHS regulation places several requirements on institutions receiving funds under the Public Health Service 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 research misconduct in PHS-supported research that complies with the PHS regulation. An institution establishes an assurance by filing an initial assurance form or signing the face page of the PHS grant application form revised in 1996. Institutions keep their assurance active by submitting the Annual Report on Possible Research Misconduct (Annual Report), submitting their misconduct in science policy upon request by ORI, revising their misconduct in science policy when requested by ORI, and complying with the PHS regulation.

The Assurance Program meets its responsibilities by maintaining the assurance database, auditing awards to institutions, gathering and summarizing information from institutions in their Annual Report, and reviewing institutional policies and procedures in conjunction with the Compliance Review Program.

In 2001, ORI switched to electronic submission of the Annual Report, beginning with the report for CY 2000, to reduce the reporting burden on the 5,000 institutions required to file a report with ORI.

Assurance Database

Maintaining an accurate assurance database is essential to the successful operation of the Assurance Program because the database is used by ORI to determine the eligibility of institutions to receive PHS research funds.

The number of institutional assurances on file with ORI increased by 77 during 2007 to 4,559 (see Table 8). Four hundred and fifty-three institutions were added to the assurance database because they filed their initial assurance or reestablished their assurance by submitting their Annual Report on Possible Research Misconduct for 2005 and 2006. Three hundred and seventy-six

assurances were inactivated because the institution failed to submit its Annual Report in 2007, the institution requested that its assurance be withdrawn, or duplicate records existed.

Table 8: Number and Type of Institutions with Active Assurances, 2007

Type of Institution	*Number*	*Change*
Institutions of Higher Education	946	+ 5
Research Organizations, Institutes, Foundations, and Laboratories	404	+ 25
Independent Hospitals	271	- 10
Educational Organizations, Other Than Higher Education	29	+ 5
Other Health, Human Resources, and Environmental Services Organizations	519	+ 54
Other	2,390	- 2
TOTAL	4,559	+77

Institutional Misconduct Policy Reviews

ORI completed 74 policy reviews in 2007. One hundred and three policy reviews were carried into 2008. Seventy-four institutional policies were accepted as submitted; three others are pending review. Since 1995, ORI has reviewed 2,556 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 2006 Annual Report began in January 2007 for the 5,014 institutions that had an assurance on file with ORI as of December 31, 2006.

Completed Annual Reports were received from 4,194 institutions for a response rate of 83 percent. ORI inactivated 397 assurances, including 335 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 eleven institutions that reported new or continuing research misconduct activity in their 2006 Annual Report on Possible Research Misconduct came close but did not establish any records for such activity (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 continued into the reporting year. Reportable activities are limited to alleged research misconduct involving PHS-supported research, research training, or other research-related activities.

The 111 institutions received a total of 151 allegations, and 81 of these institutions opened a total of 86 new cases. An additional 73 cases were carried forward from 2006 by institutions.

Institutions received 69 allegations of falsification, 53 of fabrication, and 29 of plagiarism. These allegations resulted in 77 inquiries and 26 investigations in 2006.

Institutions reporting new cases included higher education, 59; research organizations, 9; independent hospitals, 9; other health, human resources, and environmental services organizations, 3; and small businesses, 1.

TABLE 9: RESEARCH MISCONDUCT ACTIVITY: 1993-2006

Year	*Institutions reporting activity*	*Institutions reporting new cases*	*New allegations*	*New cases*
2006	111	81	151	86
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 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 reviews of institutional handling of an allegation of research misconduct or a retaliation complaint from a whistleblower. In 2007, 12 compliance cases were opened, and 10 were closed (see Table 10). Seven closed cases involved institutional handling of allegations of research misconduct, and four cases involved retaliation complaints. Seven compliance cases and two retaliation complaints were carried into 2008.

TABLE 10: SUMMARY OF COMPLIANCE CASES, 2007

Case type	*Forwarded from 2006*	*Opened in 2007*	*Closed in 2007*	*Carried into 2008*
Compliance/retaliation	7	12	10	9

Institutional Handling of Allegations

Four summaries below provide details on the steps taken by ORI to address a variety of compliance issues that arose during the course of an institutional investigation or ORI oversight.

Other areas of compliance concern that were addressed by ORI during the reporting period include the following: Two cases involved the institutional handling of allegations and retaliation complaints; one case involved the coordination of an institutional misconduct review by a major educational institution related to allegations of research misconduct at an affiliated small business; in two cases, ORI reviewed the institutional process in the conduct of completed investigations and noted procedural shortcomings and provided suggested remedies; in one case, ORI determined that significant procedural deficiencies contributed to its decision to close the case without making a research misconduct finding.

Institution Required to Establish Protocol for Reporting to ORI

This case involved a variety of allegations, initially including alleged irregularities relative to claims of inventorship and the alleged unauthorized use of data in an NIH grant application, against an assistant professor at a state university. The institution conducted an inquiry and investigation, and during the course of the investigation, the institution examined additional claims of falsification associated with some preliminary experiments submitted in the grant application. The institution made a finding of research misconduct against the respondent.

In its review, ORI noted that the inventorship claims were outside the definition of research misconduct, and the investigative process did not adequately isolate the misconduct issues from concerns over invention reports and patent applications. The record of the institutional investigation included significant materials related to this concern, and being presented in this context may have unfairly influenced the investigation committee. In addition, ORI felt that there could have been a more meaningful effort to evaluate the respondent's explanations and rebuttals, including the possibility of honest error on the part of the respondent.

ORI determined that the respondent's falsifications did not warrant a PHS finding of research misconduct. Compliance issues noted included failure to properly segregate the non-misconduct issues (inventorship claims) from the misconduct allegations (possible falsification of data in an NIH grant application), to have the inquiry committee interview the respondent (as required by institutional policy), and to include details in the inquiry report that are required by regulation. On the basis of ORI's decision to administratively close this case without a finding, and in reference to ORI's review of the compliance issues, the institution subsequently rescinded its findings of research misconduct against the respondent.

ORI required that institutional officials develop a detailed protocol outlining the specific reporting requirements to ORI to be used as a supplement to the institutional misconduct policies.

Institution Required to Notify ORI of All Allegations Received

In this case, an institution received allegations of possible research misconduct against a postdoctoral fellow, conducted an inquiry, and notified ORI that it was proceeding to an investigation. ORI reviewed the materials provided by the institution and determined that the allegations represented possible falsification or fabrication of data in PHS-supported research. ORI was subsequently notified by institutional officials that the university had decided to reopen the inquiry, based on objections made by the respondent's attorney regarding certain aspects of the inquiry process. The inquiry was reopened; additional information was reportedly submitted; and the inquiry committee concluded that based on its re-review of the information, the matter now did not warrant an investigation.

ORI reviewed the additional documentation and information submitted by the respondent and, based on additional analysis, determined that misconduct had occurred and made a PHS finding of research misconduct against the respondent. Furthermore, ORI concluded that the institutional officials in this case failed to comply with both the institutional misconduct policies and the requirements of the PHS regulation. ORI proposed a number of enforcement actions as provided for in the current PHS regulation, including the requirement that the institution immediately notify ORI of all allegations of research misconduct received and submit any assessment or inquiry report associated with any allegation of research misconduct to ORI upon completion.

Institution Required to Develop Corrective Action Plan

The director of a laboratory was informed of allegations of research misconduct against a research technician after that research technician was confronted by a senior member in the laboratory about improper measurement procedures. The director immediately met with a number of laboratory members who were aware of the respondent's alleged actions, and within days, the respondent was terminated from the institution. ORI was notified approximately 2 weeks later by e-mail and informed that the issue appeared to be faked data, and because the data were not published, and because the respondent had been terminated, there was no need for a formal inquiry or investigation. ORI responded and informed the institution that despite the respondent's termination, the institution had an obligation to pursue allegations or other evidence of research misconduct. The institution subsequently conducted an inquiry and investigation, and the investigation committee determined that the respondent had indeed falsified data.

After oversight review by ORI, it was determined that a number of procedural deficiencies in the institutional process prevented ORI from pursuing a finding of research misconduct against the respondent. The shortcomings included the actions taken by the laboratory director to initiate a review of the allegations rather than to submit them to the institutional Research Integrity Officer (RIO) as required by the institution's misconduct policies and procedures. In addition, by dismissing the respondent, institutional officials forfeited any opportunity to both question the respondent regarding the questioned data and possibly secure an admission. After a detailed review of the institutional process by ORI, it was determined that the institutional failures were primarily caused by the lack of awareness by both faculty and staff of institutional procedures for dealing with research misconduct.

ORI provided the institution with a detailed assessment of its findings on these compliance matters, and recommended, among other things, that the institution develop a corrective action plan to ensure that all faculty and staff are aware of the requirements of the PHS regulation and the institutional policies related to the handling of research misconduct allegations. The institution responded to ORI's recommendations by initiating a number of new procedures, including the publication of an executive summary of its policies and procedures on its web site; the distribution of this document by e-mail to all faculty; and a more focused distribution of information to department chairs because they are most likely to interact with faculty, students, postdocs, and staff on such issues before they are brought to the attention of the institutional RIO. The institution also implemented a number of other programs, seminars, and information-sharing initiatives.

State Institution and Private Research Company
Fail to Properly Address Allegation

This case involved what was initially described as errors in a published paper that included authors who were employed at one time or another by a private research company as well as a state institution. The state institution held equity in the research company. In its announcement to ORI, institutional officials noted that certain errors in the paper were most likely the result of research misconduct, but they could not determine who was responsible. The institutional report noted problems obtaining records associated with the research from the private research company and testimony from some of its employees.

While ORI's jurisdiction would not normally apply to research supported and conducted at a private concern, a number of factors supported ORI's contention that the state institution had the right and responsibility to address the alleged research misconduct. The research paper cited NIH support, and while there initially was some dispute about whether the citation was proper, ORI established that the respondent's entire research effort was supported by the PHS. Therefore, the work he conducted at the private research company would be considered under PHS jurisdiction. In addition, the respondent cited the questioned work he did at the private research company in a separate NIH grant application.

Although ORI believes that the state institution would be primarily responsible for examining these allegations, the private research company also has some responsibility in this instance. By accepting and utilizing research efforts supported by the PHS, the private research company, by regulation, would be required to provide the PHS with an assurance of compliance. The private research company would also be required to comply with all the requirements of the PHS regulation, including the investigation of misconduct allegations. In this case, the private research company did not have an assurance of compliance, and the state university officials stated that there was no formal agreement between it and the private research company with respect to the handling of research misconduct allegations. ORI concluded that both organizations failed to properly address this allegation in compliance with the requirements of the federal regulation.

Implementation of HHS Administrative Actions

The implementation of HHS 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) the 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 the 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, 2007, ORI listed the names of 55 individuals in the ALERT system. During the year, ORI added 14 names and removed 15. On December 31, 2007, the names of 54 individuals were in the system (see Table 11).

ORI added 14 names because those individuals were found to have committed research misconduct in institutional investigations reported to ORI. Fourteen names were removed during the year because the term of the HHS administrative actions expired, and one name was removed when ORI did not recommend a finding of research misconduct after reviewing an institutional misconduct investigation report.

Of the 54 names in the system at year end, 37 individuals had HHS administrative actions imposed on them, and 17 remained as a result of an institutional investigation in which there was a finding of research misconduct.

Table 11: Summary of PHS ALERT System Activity, 2007

As of January 1, 2007	55
Additions	14
Action expired/removed	15
As of December 31, 2007	54

When individuals in the PHS ALERT system have a PHS research misconduct finding made against them, have PHS administrative actions imposed on them, or both, they are also listed on the PHS Administrative Actions Bulletin Board (AABB). The PHS AABB is a public system of records that may be accessed through the ORI web site at http://ori.hhs.gov/misconduct/admin_actions.shtml

Information on each individual in the system is limited to name, social security number, date of birth, type of misconduct, the name of the institution that conducted the investigation, a summary of the administrative actions imposed as a result of the misconduct, and the effective and expiration dates of the administrative actions.

V. Information and Privacy

The number of requests for information under the Freedom of Information Act (FOIA) and the Privacy Act decreased in 2007.

- Nineteen FOIA requests were carried into 2007. ORI received 42 requests in 2007 and closed 44. Seventeen requests were carried into 2008. In 2006, ORI received and closed 55.
- No Privacy Act requests were received in 2007. In 2006, ORI 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, Parklawn Building, 5600 Fishers Lane, Room 17A-46, Rockville, MD 20857. The request must reasonably describe the records sought so that the agency official is able to locate the records with a reasonable amount of effort. Some requests may be subject to review, search, and duplication costs.

PRIVACY ACT

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

The inquiry and investigative records in ORI files are part of a system of records that was published in the *Federal Register* on January 6, 1995 (60 Fed. Reg. 2140). However, these records are specifically exempted from

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

Appendix A

Summaries of Closed Investigations Resulting in Findings of Research Misconduct or Administrative Actions – 2007[1]

Joy Bryant, University of Oklahoma Health Sciences Center: Based on the report of an investigation conducted by the University of Oklahoma Health Sciences Center (OUHSC) and additional analysis conducted by the Office of Research Integrity during its oversight review, the U.S. Public Health Service (PHS) found that Ms. Joy Bryant, Tribal Efforts Against Lead (TEAL) phlebotomist, OUHSC, engaged in scientific misconduct in research supported by National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), grant R01 ES008755. Specifically, Ms. Bryant falsified research in the TEAL study by substituting or conspiring with another phlebotomist to substitute her blood or blood of another phlebotomist for blood samples of 10-15 child participants in the TEAL study. The TEAL study was aimed at measuring the blood levels of lead in Indian children living in Tar Creek, where abandoned mines and piles of mining wastes left lead (and other heavy metals) leaching into the area's waterways and yards.

Ms. Bryant has entered into a Voluntary Exclusion Agreement (Agreement) in which she has voluntarily agreed, for a period of three (3) years, beginning on May 30, 2007: (1) to exclude herself from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in non-procurement programs of the United States Government, as defined in HHS' implementation of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension at 2 C.F.R. Part 376 *et seq.*; and (2) to exclude herself from serving in any advisory capacity to the PHS, including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

Juan Carlos Jorge-Rivera, Ph.D., Dartmouth College: Based on the findings of an inquiry conducted by Dartmouth College, an investigation conducted by another federal agency, and additional analysis conducted by the Office of Research Integrity (ORI) during its oversight review, the U.S. Public Health Service (PHS) found that Juan Carlos Jorge-Rivera, Ph.D., former postdoctoral fellow, Department of Physiology, Dartmouth College, engaged in misconduct in science in research funded by National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH), grant R01 NS28668. Specifically, Dr. Jorge-Rivera knowingly and intentionally falsified

[1]The summaries of closed investigations resulting in findings of research misconduct or administrative actions for 2007 have been published in the *Federal Register* and are available on the ORI web site at http://ori.hhs.gov

amplifier gain in at least eleven (11) experiments of his postdoctoral research aimed at measuring the effects of anabolic steroids on GABAnergic current in brain cells and reported the falsified data in Figures 4 and 6 of the following paper: Jorge-Rivera, J.C., McIntyre, K.L., & Henderson, L.P. "Anabolic steroids induce region- and subunit-specific modulations of GABA receptor mediated currents in the rat forebrain." *Journal of Neurophysiology* 83:3299-3309, 2000.

Dr. Jorge-Rivera has been debarred by the federal agency with joint jurisdiction for a period of two (2) years, beginning on January 11, 2007, and ending on January 11, 2009. ORI has implemented the following administrative actions: (1) for a period of three (3) years, beginning on June 23, 2007, and ending on June 22, 2010, Dr. Jorge-Rivera is prohibited from serving in any advisory capacity to the PHS, including but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and (2) for a period of three (3) years, beginning at the end of his debarment period (January 11, 2009), and ending on January 10, 2012, Dr. Jorge-Rivera must submit, in conjunction with each application for PHS funds, annual reports, manuscripts, or abstracts of PHS-funded research in which he is involved, a certification that the data he provides 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.

Diana Layman, University of Oklahoma Health Sciences Center: Based on the report of an investigation conducted by the University of Oklahoma Health Sciences Center (OUHSC) and additional analysis conducted by the Office of Research Integrity during its oversight review, the U.S. Public Health Service (PHS) found that Ms. Diana Layman, Tribal Efforts Against Lead (TEAL) phlebotomist, OUHSC, engaged in scientific misconduct in research supported by National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), grant R01 ES008755. Specifically, Ms. Layman falsified research in the TEAL study by substituting or conspiring with another phlebotomist to substitute her blood or blood of another phlebotomist for blood samples of 10-15 child participants in the TEAL study. The TEAL study was aimed at measuring the blood levels of lead in Indian children living in Tar Creek, where abandoned mines and piles of mining wastes left lead (and other heavy metals) leaching into the area's waterways and yards.

Ms. Layman has entered into a Voluntary Exclusion Agreement (Agreement) in which she has voluntarily agreed, for a period of three (3) years, beginning on May 30, 2007: (1) to exclude herself from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in non-procurement programs of the United States Government,

as defined in HHS' implementation of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension at 2 C.F.R. Part 376, *et seq*.; and (2) to exclude herself from serving in any advisory capacity to the PHS, including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

James David Lieber, University of California at Los Angeles: Based on the findings of an inquiry report by the University of California at Los Angeles (UCLA) 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 Mr. James David Lieber, Staff Research Associate, Semel Institute for Neuroscience and Human Behavior, Integrated Substance Abuse Programs, UCLA, engaged in research misconduct in research funded by National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH), grant R01 DA15390. Mr. Lieber knowingly and intentionally falsified and fabricated multiple followup interviews, urine samples, and urine sample records of human subject study participants and entered such false and fabricated data into the study's database. A total of 914 followup interviews of opiate users were planned to be completed as part of a study of gender differences in a follow-up of opiate users in California. Mr. Lieber was assigned to interview 53 of the 132 subjects located for the followup study. Over a 6-month period, Mr. Lieber falsely claimed to have conducted face-to-face interviews for the study while subsequent contacts with the subjects revealed that they had not been interviewed for the study. A review by the institution determined that the respondent fabricated interviews for 20 of the 53 interviews assigned to him. In addition, he falsified the urine specimens for those 20 subjects and caused the entry of false information into the study tracking and locating database for 11 subjects. Aggravating factors included the theft of $5,180 for incentive payments to subjects and travel expenses.

ORI has implemented the following administrative actions for a period of three (3) years, beginning on July 2, 2007: (1) Mr. Lieber is debarred from eligibility for any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in non-procurement programs of the United States Government, referred to as "covered transactions," as defined in HHS' implementation of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension at 2 C.F.R. Part 376, *et seq*.; and (2) Mr. Lieber is prohibited from serving in any advisory capacity to the PHS, including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

Carlos A. Murillo, M.D., University of Texas Medical Branch at Galveston: Based on the report of an inquiry conducted by the University of Texas Medical Branch at Galveston (UTMB) 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 Carlos A. Murillo, M.D., former Surgical Resident, Department of Surgery, UTMB, engaged in research misconduct in research supported by National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH), grants R01 DK48498 and T32 DK07639. Specifically, Dr. Murillo falsified research on the amelioration by antisense RNA (siRNA) of dextran-induced colonic toxicity in mice. He altered the concentrations of dextran solution fed to mice to induce colonic inflammation, by intentionally including little or no dextran in the drinking water of siRNA-treated mice, so that the animals that received siRNA would have few or no colonic lesions.

Dr. Murillo has entered into a Voluntary Exclusion Agreement (Agreement) in which he has voluntarily agreed, for a period of three (3) years, beginning on May 30, 2007: (1) that any institution that submits an application for PHS support for a research project on which Dr. Murillo's participation is proposed, that 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 Dr. Murillo's research contribution; Dr. Murillo agrees to ensure that a copy of the supervisory plan is also submitted to ORI by the institution and agrees that he will not participate in any PHS-supported research until such a supervision plan is submitted to ORI; (2) to exclude himself from serving in any advisory capacity to the PHS, including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and (3) to request retraction of the abstract entitled "Inhibition of Phosphoinositol 3-kinase Using Anti-p85 siRNA Attenuates Dextran-Sulfate-Induced Inflammatory Bowel Disease" (*Gastroenterology* 126:A49, 2004), by signing the letter of retraction prepared by ORI attached as Attachment 2 and made part of the Agreement.

Kartik Prabhakaran, University of Pittsburgh: Based on the report of an inquiry conducted by the University of Pittsburgh (UP), extensive oral and written admissions by the respondent, and additional analysis conducted by the Office of Research Integrity (ORI) during its oversight review, the U.S. Public Health Service (PHS) found that Mr. Kartik Prabhakaran, former graduate student in the joint M.D./Ph.D. program at UP, engaged in research misconduct while supported by National Institutes of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH), grant F30

NS50905-01 and National Eye Institute (NEI), NIH, grants 5 R01 EY005945, 5 P30 EY008098, and 5 R01 EY015291. Specifically, Mr. Prabhakaran falsified and fabricated data that were included in a PowerPoint presentation and in a paper published in *Immunity* (*Immunity* 23:515-525, November 2005). Mr. Prabhakaran's research misconduct occurred while he was a student in the M.D./Ph.D. program for UP's School of Medicine. He is no longer in UP's Ph.D. program but is still enrolled in its M.D. program in the School of Medicine. The *Immunity* publication has been retracted (*Immunity* 24:657, May 2006).

Mr. Prabhakaran has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed, for a period of four (4) years, beginning on March 15, 2007: (1) to exclude himself from serving in any advisory capacity to the PHS, including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and (2) that any institution that submits an application for PHS support for a research project on which Mr. Prabhakaran's participation is proposed, that 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. Prabhakaran agreed to ensure that a copy of the supervisory plan also is submitted to ORI by the institution. Mr. Prabhakaran agreed that he will not participate in any PHS-supported research until such a supervision plan is submitted to ORI.

Kristin Roovers, Ph.D., University of Pennsylvania: Based on an investigation conducted by the University of Pennsylvania (UP) and additional analysis and information obtained by the Office of Research Integrity during its oversight review, the U.S. Public Health Service (PHS) found that Kristin Roovers, Ph.D., former postdoctoral fellow, Departments of Medicine, Cell and Developmental Biology, and Pharmacology, and Howard Hughes Medical Institute, and former graduate student, Department of Pharmacology, UP, engaged in misconduct in science in research funded by National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grants R01 HL061567, P50 HL057278, and T32 HL07873; National Institutes of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH, grants P30 DK52574 and R01 DK066886; National Cancer Institute (NCI), NIH, grant R01 CA72639; and National Institute of General Medical Sciences (NIGMS), NIH, grants R01 GM48224, R01 GM58224, R01 GM51878, and R01 GM69064. Dr. Roovers's manipulations and falsification of data were extensive, encompassing 19 panels of Western blot data, appearing in 11 figures in 3 publications from her research as a graduate student and her first postdoctoral position and in 9 panels of immunoblot data in 8 figures of an unpublished manuscript. Specifically, the findings involved falsification by duplication and reuse

of immunoblot data to misrepresent the results as data from different experiments that had been reported in the following manuscript and three publications:

- Figures 2C, 3C, 4D, 4E, 6C, 7B, and supplement Figures 1, 2B, and 3B in a manuscript submitted to the *Journal of Clinical Investigation* entitled: "Akt1 promotes physiologic, but antagonizes pathologic, cardiac growth."

- Figures 3A, 3C, and 4A in: Welsh, C.F., Roovers, K., Villanueva, J., Liu, Y., Schwartz, M.A., & Assoian, R.K. "Timing of cyclin D1 expression within G1 phase is controlled by Rho." *Nature Cell Biology* 3(11):950-957, 2001.

- Figures 1, 2A, 2B, 3A, 3C, 4A, 4B, 6C, 6D, and 6E in: Roovers, K., & Assoian, R.K. "Effects of rho kinase and actin stress fibers on sustained extracellular signal-regulated kinase activity and activation of G(1) phase cyclin-dependent kinases." *Molecular and Cellular Biology* 23(12):4283-4294, 2003. Retracted in *Molecular and Cellular Biology* 26(13):5203, July 2006.

- Figures 1C, 2C, 5B, 5D, 6B, and 6D in: Roovers, K., Klein, E.A., Castagnino, P., & Assoian, R.K. "Nuclear translocation of LIM kinase mediates Rho-Rho kinase regulation of cyclin D1 expression." *Developmental Cell* 5(2):273-284, 2003. Retracted in *Developmental Cell* 10(5):681, May 2006.

UP recommended corrections for the *Nature Cell Biology* paper. Dr. Roovers's falsified Western blot data from the publications in *Nature Cell Biology* and in *Developmental Cell* were included in NIH grant applications CA 72639-07 and GM 69064-01.

The Office of Research Integrity has implemented the following administrative actions for a period of five (5) years, beginning on June 7, 2007: (1) Dr. Roovers is debarred from eligibility for any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in non-procurement programs of the United States Government, referred to as "covered transactions," as defined in HHS' implementation of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension at 2 C.F.R. Part 376, *et seq.*; and (2) Dr. Roovers is prohibited from serving in any advisory capacity to the PHS, including, but not limited, to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

Jon Sudbø, D.D.S., Norwegian Radium Hospital: Based on the findings of an investigation conducted by the Investigation Commission appointed by Norwegian Radium Hospital (NRH) and the University of Oslo, the respondent's own admission, and additional analysis and information obtained by the Office of Research Integrity during its oversight review, the U.S. Public Health Service (PHS) found that Jon Sudbø, D.D.S., former doctoral student and faculty member, University of Oslo, and former physician in the Department of Medical Oncology and Radiotherapy, NRH, engaged in scientific misconduct by reporting fabricated and/or falsified research in grant application 1 P01 CA106451-01 submitted to the National Cancer Institute (NCI), National Institutes of Health (NIH), and its first-year progress report. Specifically, the PHS found that Dr. Sudbø engaged in scientific misconduct by falsifying and fabricating research that served as the rationale for Project 1, "Oral Cancer Prevention with Molecular Targeting Therapy," with Dr. Jon Sudbø, as project leader, in the grant application, and by falsifying a progress report for the awarded grant. In particular, in Figure 1 of the Background and Significance section of the grant application, Dr. Sudbø reported fabricated/falsified results for the effects of lesion ploidy upon survival in patients with oral pre-malignant lesions. In the Preliminary Data section of the grant application, Dr. Sudbø reported several events intended to demonstrate his experience in the research field that the Investigation Commission stated "appear as pure fiction." Also, in the first yearly progress report for the funded grant, Dr. Sudbø falsified the number of patients that had been screened for admission to the study. In addition to three publications for which Dr. Sudbø admitted falsifying and/or fabricating data, the Investigation Commission found at least 12 other publications that warranted retraction because they could not be considered valid. The research reported in these publications was not supported by PHS funds. However, the publications address the same general research area as that addressed in the grant application and demonstrate a pervasive pattern of falsification/fabrication in research reporting on the part of Dr. Sudbø. The falsified/fabricated data presented in the grant application purport to demonstrate the feasibility of preventing cancer in a high-risk population with non-toxic oral agents.

Dr. Sudbø has entered into a Voluntary Exclusion Agreement (Agreement) in which he has voluntarily agreed, beginning on August 31, 2007: (1) to exclude himself permanently from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in non-procurement programs of the United States Government, as delineated in the OMB Guidelines to Agencies on Governmentwide Debarment and Suspension at 2 C.F.R. Part 376, *et seq.*; Dr. Sudbø agrees that he will not petition HHS to reverse or reduce the scope of the permanent voluntary exclusion or other administrative actions that are the subject of this Agreement; and (2) to

exclude himself permanently from serving in any advisory capacity to the PHS, including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant or contractor to the PHS.

Rebecca Uzelmeier (formerly known as Rebecca Marcus), Michigan State University: Based on the report of an investigation by Michigan State University (MSU) and additional information obtained by the Office of Research Integrity (ORI) during its oversight review, ORI found that Rebecca Uzelmeier, former doctoral student, Department of Pharmacology and Toxicology, MSU, committed misconduct in science by intentionally and knowingly fabricating and falsifying data in research supported by National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), grant R01 ES02520.

ORI issued a charge letter enumerating the following findings of misconduct in science:

- Ms. Uzelmeier knowingly and intentionally fabricated and falsified data in her research notebook primarily by multiple instances of using data/results generated from one experiment to represent data/results purportedly obtained from one or more entirely different experiments; and

- Ms. Uzelmeier knowingly and intentionally fabricated and falsified data in her thesis entitled "Characterization of the Molecular Mechanism(s) Underlying the Interaction(s) between 2,3,7,8-tetrachlorodibenzo-*p*-Dioxin Mediated and Interferon Gamma Mediated Signal Transduction," including falsifying and fabricating autoradiographic films, computer image files scanned from those films, numerical data reduced from those computer files, documentation of those results in her black three-ring binder, and data in associated multiple figures and projection slides.

However, on October 12, 2006, Ms. Uzelmeier filed a request for a hearing under 42 C.F.R. Part 93 to dispute these findings before the Department of Health and Human Services (HHS) Departmental Appeals Board (DAB). On October 19, 2006, ORI moved to dismiss Ms. Uzelmeier's hearing request because it failed to create a genuine dispute of either material fact or law, as required under 42 C.F.R. § 93.504. On March 5, 2007, the Administrative Law Judge (ALJ) with the DAB ruled in ORI's favor and dismissed Ms. Uzelmeier's hearing request pursuant to 42 C.F.R. § 93.504(a)(2). The ALJ found that Ms. Uzelmeier's defense was immaterial to the charges of misconduct in science or that the ALJ had no authority to grant Ms. Uzelmeier's request for relief under Part 93.

Because of the hearing dismissal, ORI's findings against Ms. Uzelmeier were finalized and HHS imposed a 5-year debarment. On April 25, 2007, Ms. Uzelmeier filed a complaint in the United States District Court for the District of Columbia challenging the 5-year debarment and the ALJ's decision to dismiss her hearing request. On March 31, 2008, the United States District Court for the District of Columbia ruled in HHS' favor.

The following administrative actions have been implemented for a period of five (5) years, beginning on March 12, 2007: (1) Ms. Uzelmeier has been debarred from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in non-procurement programs of the United States Government, referred to as "covered transactions," as defined in the debarment regulations at 2 C.F.R. §§ 180 and 376; and (2) Ms. Uzelmeier is prohibited from serving in any advisory capacity to the PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

Wei Jin, Colorado State University: Based on an investigation conducted by Colorado State University (CSU) 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 Mr. Wei Jin, former doctoral candidate, Department of Chemistry, CSU, engaged in research misconduct in research funded by National Cancer Institute (NCI), National Institutes of Health (NIH), grant R01 CA85419. Specifically, Mr. Jin falsified data/results by claiming he had performed a novel total synthesis of renieramycin G, when in fact, he obtained renieramycin G through a relatively simple reaction sequence from renieramycin M, a natural product that was a gift to the laboratory and that had been isolated by others from the Thai sponge. Mr. Jin included the falsified data/results in:

- his research notebooks and other records of his research;
- his dissertation, "Asymmetric total synthesis of (-)- Renieramycin G and studies toward the total synthesis of Ecteinascidin-743";
- a manuscript, Jin, W., & Williams, R., "Asymmetric total synthesis of (-)-Renieramycin G," accepted by the *Journal of the American Chemical Society*; and
- supplemental information relative to the manuscript to be published online.

The total synthesis of natural products, such as the antitumor antibiotic renieramycin G, is exploited to make new, less toxic, more potent, and more selective antitumor drugs and to study the interaction of these compounds with cellular nucleic acids. Synthesis thus provides supplies of these compounds for clinical applications (some natural products are in scarce supply), as well as for establishing their mode of action.

ORI has implemented the following administrative actions for a period of three (3) years, beginning on May 8, 2007: (1) Mr. Jin is debarred from eligibility for any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in non-procurement programs of the United States Government, referred to as "covered transactions," as defined in HHS' implementation of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension at 2 C.F.R. Part 376, *et seq*.; and (2) Mr. Jin is prohibited from serving in any advisory capacity to the PHS, including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

Appendix B

Summaries of Closed Inquiries and Investigations Not Resulting in Findings of Research Misconduct – 2007

Falsification: The respondents, a professor and a research coordinator, allegedly falsified patient data in a clinical trial. The questioned research was supported by a National Heart, Lung, and Blood Institute (NHLBI), NIH, cooperative agreement. The research involved a comparison of initial treatments of coronary artery disease. The institution conducted an inquiry and an investigation. The institution concluded that serious scientific errors had occurred, but research misconduct was not demonstrated by a preponderance of the evidence. ORI accepted the institution's report for the purpose of closing its oversight review. ORI determined that the question of whether the respondents had committed research misconduct could not be resolved.

Falsification: The respondent, a postdoctoral fellow, allegedly falsified and/or fabricated data in figures included in a grant application submitted to the National Cancer Institute (NCI), National Institutes of Health (NIH). The research involved the mechanism of action of the p53 tumor suppressor protein. P53 is important because it is implicated in the development of the majority of human tumors. The institution conducted an inquiry and an investigation and determined that the respondent's actions did not constitute scientific misconduct. ORI concurred with the institution's determination and did not make a finding of misconduct in this case.

Falsification: The respondent, a postdoctoral fellow, allegedly falsified data in research supported by a National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), grant. The research concerned biochemical and cell biological studies of vesicle trafficking in the Golgi apparatus of yeast, specifically a protein termed kes1p that was thought to bind to the snare proteins T1g1p, T1g2p, and gos1p and thus affect vesicular traffic. The institution conducted an inquiry and an investigation and determined that the respondent acted unprofessionally and violated the institution's policies on ethics in research. However, the institution further concluded that the respondent did not act with an intent to mislead or deceive; thus, the respondent's behavior did not rise to the level of research misconduct. ORI accepted the factual findings of the institution's investigation but concluded that the allegations of research misconduct were not resolvable because of the lack of evidence in the form of research records.

Falsification: The respondent, a postdoctoral fellow, allegedly falsified or manipulated images included in a publication. The research was supported by a National Cancer Institute (NCI), National Institutes of Health (NIH), grant. The research involved cell-signaling experiments in a yeast screening system, showing how a protein called Bax that can trigger cell death is controlled by another protein. The institution conducted an investigation. ORI accepted the institution's investigation report as fulfilling its reporting requirements to ORI and declined to pursue a U.S. Public Health Service finding of scientific misconduct.

Falsification: The respondent, a graduate student, allegedly falsified data in a draft article that was to be part of her Ph.D. dissertation. The questioned research involved electrophysiological studies designed to identify the key sequence of the calcium-release channel in skeletal muscle. The research was supported by a National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), National Institutes of Health (NIH), grant. The institution conducted an inquiry and an investigation and concluded that there was insufficient evidence to support a finding of research misconduct. ORI concurred with the finding of the institution that it was not possible to prove that the respondent intentionally or knowingly falsified or fabricated data and concurred with the institution's recommendation that the allegation be dismissed.

Falsification: The respondent, a postdoctoral research fellow, allegedly falsified data in figures that were included in a grant application submitted to the National Cancer Institute (NCI), National Institutes of Health (NIH). The research was supported by a National Heart, Lung, and Blood Institute (NHLBI), NIH, grant. The research involved the role of Rac GTPases in mediating cell proliferation and apoptosis in chronic myelogenous leukemia (CML) and their potential role as novel therapeutic targets for CML. The institution conducted an investigation and concluded that misconduct had occurred. ORI accepted the institution's report. However, ORI declined to propose PHS findings of 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: The respondent, a professor, allegedly falsified data in research supported by a National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grant. The research involved flow cytometry analysis to identify characteristics of specific cells from murine bone marrow. The institution conducted an inquiry and determined that there was not sufficient evidence of misconduct on the part of the respondent to warrant further investigation. ORI concurred with the institution's report and conclusion that the evidence does not warrant proceeding to an investigation.

Falsification: The respondent, an assistant professor, allegedly falsified data in research supported by a National Eye Institute (NEI), National Institutes of Health (NIH), grant. The allegedly falsified data were included in a published paper and an NEI, NIH, grant application. The research involved use of laser energy to produce a model of age-related macular degeneration (AMD) in monkey eyes and then injecting the eyes with a small interfering RNA (siRNA) directed against vascular endothelial growth factor (VEGF). It was postulated that inhibition of VEGF would reduce the new vessel formation and associated vessel leakage that causes the visual loss in the wet form of AMD. Leakage amount was measured at several times in eyes that had received either high, medium, or low doses of siRNA or just inert vehicle. The institution conducted an inquiry and an investigation and determined that the incorrect matching of data in the published paper were unlikely to have occurred by accident. ORI accepted the institution's reports and conclusion, but found that it was not possible to resolve whether there was intent to falsify the questioned data or who was responsible for the incorrect matching.

Falsification/Fabrication: The respondents, a professor and a postdoctoral fellow, allegedly falsified a figure in research supported by a National Institute on Aging (NIA), National Institutes of Health (NIH), grant, and a National Institute of Neurological Disease and Stroke (NINDS), NIH, contract. The research involved the isolation and characterization of a small double-stranded RNA that was shown to bind to a transcription factor complex known to repress various neuronal genes. The institution conducted an inquiry and determined that no further investigation was warranted. ORI concurred with the institution's conclusion that a formal investigation was not warranted.

Falsification/Fabrication: The respondents, a principal investigator and a postdoctoral fellow, allegedly falsified and/or fabricated data in a publication. The research was supported by a National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), grant. The research involved ultra-structured studies of dynein and its binding to both its protein cargo and microtubules. The institution conducted an inquiry and determined that no further investigation was warranted. ORI concurred with the institution's conclusion that the evidence did not warrant proceeding to an investigation.

Falsification/Fabrication: The respondent, a research assistant professor, allegedly falsified and/or fabricated data in research supported by a National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), contract. The research involved studies of *Myobacterium tuberculosis*. The institution conducted an inquiry and an investigation and determined that the respondent had committed scientific misconduct by

fabricating data. ORI completed a careful oversight review of the institution's investigation and findings but decided to close this matter without further action or pursuit of the institution's misconduct findings.

Falsification/Fabrication: The respondent, a graduate student, allegedly falsified and/or fabricated data in research supported by a National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), grant. The research involved a genetic analysis of the non-ribosomal synthesis of beta lactam antibiotic. The institution conducted an investigation and determined that there was no direct evidence that the respondent had committed research misconduct. ORI concurred that in the absence of relevant research records, the matter was unresolvable and that there was insufficient evidence to warrant a finding of research misconduct.

Falsification/Fabrication: The respondents, both professors, allegedly falsified clinical data in annual Progress Reports submitted to the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH). The research involved efforts to identify non-invasive methods of assessing liver damage caused by the Hepatitis C virus (HCV) and to follow disease progression in HCV-infected children and adults. The institution conducted an inquiry and determined that research misconduct had not occurred and that the allegations appeared to have been made in bad faith. ORI concurred with the institution's conclusions and determined that a formal investigation was not warranted.

Appendix C

Research Misconduct Related Litigation During 2007[2]

CIVIL LITIGATION – Open Cases

Meena Chandok, Ph.D., vs 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 August 16, 2007, the cross-motions for summary judgment were pending.

G. Uberto Meduri, M.D., v. Tennessee Health Sciences Center, et al. (Case No. 04-2415) (W.D. Tenn.) (filed June 2, 2004). The plaintiff, G. Umberto Meduri, M.D., filed this suit in the United States District Court for the Eastern District of Tennessee alleging that officials at the University of Tennessee (UT), in their official and private capacity, violated his entitlement to due process of law guaranteed under the Fourteenth Amendment in prosecuting a research misconduct investigation against him. On July 12, 2005, the court dismissed all of the plaintiff's claims against the University of Tennessee Health Sciences Center (UTHSC) and most of the claims against the UT officials, Henry G. Herrod, M.D., Michael E. Dockter, Ph.D., and Diana Johnson, Ph.D. The six remaining issues under litigation are that: (1) Dr. Dockter appointed a biased member to UT's second Inquiry Board and that the Board did not give the plaintiff an opportunity to respond to adverse evidence; (2) Dr. Johnson denied the plaintiff's request to remove Dr. Dockter as the Research Integrity Officer (RIO); (3) the Investigation Committee contained members who had conflicts of interest; (4) the Investigation Committee first drafted a report finding no scientific misconduct and only issued its report after the plaintiff refused to waive all legal claims against UTHSC and its employees; (5) the Investigation Committee ignored evidence and reached an erroneous final report finding

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

scientific misconduct; and (6) the final decision finding the plaintiff responsible for scientific misconduct and imposing sanctions was based on his race and/or ethnicity. Cross-motions for summary judgment are pending before the court.

G. Uberto Meduri, M.D., v. State of Tennessee (Claim Nos. 20-301-720 and 20-401-126) (Tenn. Claims Comm.) (filed May 14, 2003, consolidated February 15, 2006). The plaintiff sued the State of Tennessee, alleging that Elizabeth Tolley, Ph.D., professor at the University of Tennessee, Memphis, was acting within the scope of her employment when she defamed him by making false accusations of scientific misconduct. The plaintiff also alleges that Tolley's actions and statements constituted false light invasion of privacy, a tort under Tennessee law. The plaintiff alleges that as a result of Tolley's statements he suffered injuries and damages including severe and permanent injury to his reputation, emotional anguish, and other reputational harm. The plaintiff is seeking compensatory and punitive damages from the State of Tennessee. The parties have filed cross-motions for summary judgment. ORI submitted the declaration of Director Chris B. Pascal in this litigation to present testimony on relevant provisions of the Public Health Policies on Research Misconduct, and other HHS research misconduct policies.

United States ex rel. Bauchwitz v. William K. Holloman, et al. (Case No. 04-CV-2892) (U.S.D.C. E.D.Pa.). On June 30, 2007, the plaintiff and *qui tam* relator Robert P. Bauchwitz, Ph.D., filed a first amended civil complaint on behalf of the United States alleging that defendants William K. Holloman, Ph.D., Cornell University Medical College, Eric B. Kmiec, Ph.D., and Thomas Jefferson University violated the False Claims Act, 31 U.S.C. § 3729, *et seq.* The plaintiff alleges in this *qui tam* suit that the individual defendants made false statements and misrepresented research data in scientific journal articles, which were in turn cited by defendant universities in grant applications to obtain payment from the National Institutes of Health. The relator is seeking treble damages on seven counts of fraud, including civil penalties, attorneys' fees, and costs. The district court ordered that the amended complaint filing be unsealed.

Rebecca Uzelmeier v. HHS, et al. (Case No.07-CV-0753) (D.D.C.). Plaintiff Rebecca Uzelmeier filed this civil action on April 25, 2007, against the Department of Health and Human Services (HHS) seeking judicial review of the Department's decision to debar her for research misconduct, and for allegedly violating the Privacy Act by not acceding to the plaintiff's request that ORI release her research misconduct case file. On September 6, 2006, ORI found the plaintiff responsible for research misconduct and HHS debarred her for 5 years pursuant to the debarment regulation, 2 C.F.R. §§ 180 and 376.

The plaintiff subsequently requested a hearing before the HHS Departmental Appeals Board (DAB). On March 5, 2007, the DAB dismissed her hearing request because it failed to raise a genuine dispute over facts or law material to ORI's finding of research misconduct. See *Office of Research Integrity v. Rebecca Uzelmeier* (DAB Docket No. C-07-32). The plaintiff now argues that the 5-year debarment should be reversed as punitive, and that ORI's findings of research misconduct should be reversed as untimely. Both parties filed summary judgment motions. On March 31, 2008, the district court granted HHS' motion for summary judgment and dismissed the plaintiff's complaint.

CRIMINAL LITIGATION – None reportable for this period*

* The criminal litigation list does not include ongoing criminal matters that are still in the investigational stages, the existence of which is confidential.

DEPARTMENT OF
HEALTH AND HUMAN SERVICES

Office of the Secretary
Office of Research Integrity
Suite 750
1101 Wootton Parkway
Rockville, MD 20852

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