

Office of
**Research
Integrity**

2008 ANNUAL REPORT



OFFICE OF PUBLIC HEALTH AND SCIENCE
OFFICE OF THE SECRETARY
US DEPARTMENT OF HEALTH AND HUMAN SERVICES

TABLE OF CONTENTS

Highlights of CY 2008 ORI Annual Report	I
Responding to Misconduct Allegations.....	I
Education and Research.....	III
Institutional Compliance.....	IV
Information and Privacy Requests	IV
I. Responding to Research Misconduct Allegations	1
Introduction	1
Allegations	2
<i>Table 1: Disposition of Allegations in ORI, 2008</i>	6
<i>Table 2: Time for Conduct of Pre-Inquiry Assessments by ORI, 2008</i>	7
Processing of Cases Closed.....	7
<i>Table 3: Duration of Research Misconduct Cases Closed by ORI, 2008 (N=17)</i>	8
Caseload and Outcomes.....	8
<i>Table 4: ORI Research Misconduct Caseload by Case Type, 2008</i>	8
<i>Table 5: Outcome of Research Misconduct Cases Closed by ORI, 2008 (N=17)</i>	10
Administrative Closures	10
Types of Allegations and Administrative Actions.....	10
<i>Table 6: Types of Allegations Involved in Closed Inquiries and Investigations and Their Outcomes, 2008</i>	11
<i>Table 7: HHS Administrative Actions Imposed in Closed Investigations with Research Misconduct Findings or Administrative Actions, 2008</i>	12
Rapid Response for Technical Assistance (RRTA) Program	13
Research Integrity Officer (RIO) Boot Camp Training.....	14
II. Education and Prevention	17
Introduction	17
RCR Program for Academic Societies	17
RCR Resource Development Program.....	19
RCR Program for Graduate Schools.....	19
RCR Program for Postdoctoral Fellows	20
Laboratory Management Training.....	22
First Biennial RCR Conference	23
National Academy of Sciences Study on Integrity of Research Data.....	23
Conferences and Workshops	24
ORI Web Site	25
ORI Newsletter	25
ORI Presentations.....	26
ORI Publications.....	33
Federal Register Notices	34

III. Research on Research Integrity and Research Misconduct	35
Intramural Research Program	35
Completed Studies	35
Studies in Progress	35
Extramural Research Program	37
Research on Research Integrity (RRI) Program	37
RRI Awards	38
RRI Publications	39
IV. Institutional Compliance.....	41
Assurance Program.....	41
Assurance Database	41
<i>Table 8: Number and Types of Institutions with Active Assurances, 2008.....</i>	<i>42</i>
Institutional Research Misconduct Policy Reviews	42
Annual Report on Possible Research Misconduct	42
Reported Research Misconduct Activity	43
<i>Table 9: Research Misconduct Activity: 1993-2008</i>	<i>43</i>
Compliance Review Program.....	44
Compliance Cases	44
<i>Table 10: Summary of Compliance Cases, 2008.....</i>	<i>44</i>
Institutional Handling of Cases	44
Compliance Case 1	44
Retaliation Case A.....	45
Retaliation Case B.....	46
Retaliation Case C.....	47
Implementation of HHS Administrative Actions.....	47
<i>Table 11: Summary of PHS ALERT System Activity, 2008.....</i>	<i>48</i>
V. Information and Privacy	51
Freedom of Information Act.....	51
Privacy Act	51
VI. Summaries of Research Misconduct Cases	53

HIGHLIGHTS OF CY 2008 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 (“the PHS regulations”). The Office is composed of the Division of Investigative Oversight (DIO) and the Division of Education and Integrity (DEI).

Responding to Misconduct Allegations

- In 2008, ORI opened 17 new cases and closed 17 cases, with 35 cases remaining open at the end of the calendar year, the same number that ORI had open at the end of 2007. However, as described below, the lower level of case openings reflects a modification in 2007 in how ORI opened and closed cases when there was insufficient evidence for a finding of research misconduct.
- Of the 17 cases closed by ORI, 13 cases resulted in sustained findings of research misconduct and/or PHS administrative actions against the respondents. DIO completed oversight review of a number of additional cases, including negotiating settlement agreements and providing litigation support in the HHS administrative hearings, and DIO staff are assisting attorneys in the Office of the General Counsel in seeking voluntary settlements or producing charge documents to bring these cases to closure as well. In three of the cases, the PHS administrative actions included debarment for 5 years, one debarment was for 4 years, two were for the most customary period of 3 years, and one was for 2 years.
- Supervisory plans were utilized as administrative actions in several additional cases. In one instance, a 5-year supervisory period was imposed, although three respondents agreed to a 3-year period of supervision that was proposed. In the remaining three cases in which findings of research misconduct were made, the administrative action agreed to by all parties was to ensure compliance with good scientific reporting practice by a certification process: for 5 years in one case and for 3 years for two respondents. In all of ORI’s cases in which research misconduct is found, the respondent may not participate as an advisor to PHS in any capacity for a period of time matching the other administrative actions agreed to or imposed.

- Seventy-six percent of the closed cases had a finding of research misconduct (13/17). This calculation is much higher than the historical average of 33 percent. In large part, this is the result of ORI opening far fewer of the pre-inquiry assessments (PIAs) occurring when institutions report their decision to ORI to proceed to an investigation and provide their inquiry report. Historically, ORI has routinely opened a case at this point. Starting in 2007, DIO determined that ORI would not open a case for oversight review unless the inquiry report and supporting documentation clearly identified research misconduct issues and evidence in support of fabrication, falsification, or plagiarism. Such issues and evidence were considered likely to lead to findings of research misconduct. In a significant number of cases, it was determined that, for a variety of reasons, the accession could be administratively closed. Such closures, although not rising to the level of a formal case, nevertheless often required comparable resources and staff time to conduct the oversight review allowing this type of determination.
- Notably, of the 35 cases remaining open at the end of 2008, nearly all appear likely to lead to findings of research misconduct. This result largely reflects the longer time typically required by both the institution and DIO to investigate and review a research misconduct case compared to a no-misconduct case. It also largely reflects DIO's more rapid administrative closure of institutional inquiries and occasionally investigations that lack PHS funding jurisdiction and/or sufficient and legally sufficient evidence to support PHS findings.
- The number of allegations recently received by ORI (217 in 2007 and 201 in 2008) is lower than the 2004-2006 average of 271, but still above the 1992-2007 average of 198. For the 17 cases involving investigations reviewed and closed by ORI in 2008, institutions took a mean of 20.9 months after notification of ORI (median 29 months; range 1-51 months) to complete their actions. ORI took a mean of 14.1 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 provided Rapid Response for Technical Assistance (RRTA) on 37 occasions in 2008, approximately the same as the 40 instances in 2007. Most of these rapid responses involved discussion with institutional officials who had concerns about how to manage newly identified or ongoing cases. The remainder involved interactions with journal editors who requested assistance on verifying problems with submitted manuscripts. These numbers are an increase from the 24 RRTAs in 2006.

Education and Research

- The Research on Research Integrity (RRI) Program in coordination with the National Institutes of Health made three new awards in 2008. This action increased the number of studies supported in the first 10 years to 49. The studies have produced 78 articles, 2 commentaries, a letter to the editor, 8 abstracts, and 2 literature reviews.
- The ORI Intramural Research Program published two manuscripts in refereed journals in 2008. The results of an ORI study on suspected research misconduct were published as a commentary in *Nature*. The study indicated that, on average, 3 percent of scientists observed suspected research misconduct in a year. The second study found that mentoring of postdoctoral scholars and graduate students in ORI closed cases was very minimal and two thirds of the mentors/advisors had failed to review source data or set research standards. This finding was published in *Science and Engineering Ethics*.
- ORI organized the first biennial responsible conduct of research (RCR) conference in St. Louis on April 17-19, 2008, to foster the growth of a community of RCR instructors. The purpose of the conference was to promote networking, form collaborations, share resources, encourage the pursuit of common goals, and generate ideas for the greater good of the research enterprise.
- Two 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 2008. Thirty-eight resources are now available on the ORI web site.
- The final report was produced by the RCR Program for Academic Societies, collaboration between the Association of American Medical Colleges and ORI to facilitate efforts by academic societies to promote RCR among their members. Overall, 78 awards were made to 72 academies and scientific societies from 2002-2008.
- ORI and other federal agencies are supporting a study, *Ensuring the Utility and Integrity of Research Data in a Digital Age*, being conducted by the National Academy of Sciences that may recommend data integrity standards to the research community. The study is expected to be completed in 2009.
- ORI sponsored two conferences and two workshops and helped to develop four other meetings in 2008. The conferences or workshops

were organized in collaboration with universities, medical schools, professional organizations, and government agencies.

- The ORI web site received 118,750 visits in 2008 from 81,741 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 presentations at universities, medical schools, research institutes, federal agencies, conferences, and scientific meetings in 2008 and published seven articles.

Institutional Compliance

- 4,559 institutions completed the 2007 Annual Report on Possible Research Misconduct in which they reported they were responding to allegations of research misconduct received in 2007 or earlier. One hundred and thirty institutions reported receiving one hundred and eighty-three new allegations in 2007. (The report is collected in 2008 but reflects the activity of the institution in 2007.)
- ORI inactivated assurances for 176 institutions or organizations for failing to submit the required calendar year 2008 Annual Report on Possible Research Misconduct by the March 31, 2008, deadline.
- ORI processed 65 institutional policies on handling allegations of research misconduct, increasing the number of completed reviews to 2,621.
- ORI opened 7 compliance cases, closed 4 compliance cases, and carried 12 compliance cases into 2009. Nine compliance cases were carried into 2008.
- 4,283 institutions completed annual reports on time.

Information and Privacy Requests

- ORI received 37 Freedom of Information Act (FOIA) requests in 2008 and closed 35. Nineteen requests were carried into 2009. ORI's Privacy Act System of Records is exempt from access, but consultation is given to requests addressed to the system manager. No Privacy Act requests were received in 2008.

I. RESPONDING TO RESEARCH MISCONDUCT ALLEGATIONS

Introduction

All institutions receiving research funds from Public Health Service (PHS) agencies must have on file an assurance form with ORI. This assurance is to ensure that the institution has in place policies and procedures for dealing with allegations of research misconduct, has provided ORI with contact information for its assurance official, and will submit an annual report to ORI identifying any activity from the previous year requiring inquiries and investigations into allegations of possible research misconduct involving research supported by PHS funds. The assurance database provides each institution with the Institution ProFile (IPF) number needed on each PHS grant application.

ORI has jurisdiction over allegations of possible research misconduct concerning research funded by PHS that are made with suitable specificity that permit assessment and that are deemed credible and significant. When these allegations result in a decision by the institution to move from the inquiry stage to the investigation stage, the institution must inform ORI of the decision. Research misconduct investigations are conducted both by PHS awardee-institutions and by the intramural components of PHS agencies. The largest intramural research program is NIH. When the investigation is completed, the report, pertinent evidence and other records, and a decision letter are sent to the Division of Investigative Oversight (DIO) within ORI for oversight review. When this review has been completed, recommendations for misconduct or no misconduct findings are forwarded to the Director of ORI, who makes findings of research misconduct. Closure of cases where research misconduct findings are made is generally reached through voluntary agreements between the respondent and the Department of Health and Human Services (HHS).

If the respondent contests ORI's proposed findings, he or she may request a hearing before an Administrative Law Judge (ALJ) of the HHS Departmental Appeals Board (DAB). DIO staff then provides litigation support and expert testimony, as needed, to the HHS Office of the General Counsel, which represents ORI before the DAB.

DIO staff also organizes conferences and workshops on the handling of research misconduct allegations, particularly to provide training for Research Integrity Officers (RIOs). The training focuses on the larger institutions which are most likely to have cases of research misconduct that require reporting to ORI. DIO also provides assistance and advice to institutions on the conduct of inquiries and investigations through the Rapid Response for Technical Assistance Program (RRTA). In addition, DIO provides information on PHS 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 research misconduct took place must be supported by, or involve an application for, PHS funds.

ORI reviews agency records and publications to identify possible PHS grant support for the research identified by complainants as being possibly falsified, fabricated, and/or plagiarized. Possible PHS support can be in the form of PHS grants, fellowships, contracts, or cooperative agreements. ORI obtains the relevant grant applications and/or publications to determine whether there was PHS support for the questioned research.

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

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

Alternatively, for allegations of research misconduct occurring subsequent to the effective date of PHS Policies on Research Misconduct on June 16, 2005, 42 C.F.R. Part 93, 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.

For ORI to make a finding of research misconduct, it must prove by a preponderance of the evidence that there was fabrication, falsification, or plagiarism; who did it; that it was knowingly, intentionally, or recklessly done; and that the act was a significant departure from the relevant practices of the research community (42 C.F.R. § 93.103).

ORI finds that many allegations involve questions of honest differences in interpretations or judgments of data that are specifically excluded from the PHS definition. Also, ORI finds that some plagiarism allegations are actually authorship or credit disputes between former collaborators, which ORI does not consider under these definitions.

ORI has, by policy, relied on a working definition of plagiarism that excludes minor plagiarism from consideration as an allegation rising to a level warranting ORI jurisdiction. At the same time, ORI recognizes and expects institutions will exercise their own often more stringent definition for cases of plagiarism and take appropriate administrative actions. ORI's working definition of plagiarism can be found on the ORI web page at <http://www.ori.dhhs.gov/policies/plagiarism.shtml>

From ORI Newsletter, Volume 3, No. 1, December 1994

ORI Policy on Plagiarism

Although there is widespread agreement in the scientific community on including plagiarism as a major element of the PHS definition of research misconduct, there is some uncertainty about how the definition of plagiarism itself is applied in ORI cases.

As a general working definition, ORI considers plagiarism to include both the theft or misappropriation of intellectual property and the substantial unattributed textual copying of another's work. It does not include authorship or credit disputes.

The theft or misappropriation of intellectual property includes the unauthorized use of ideas or unique methods obtained by a privileged communication, such as a grant or manuscript review.

Substantial unattributed textual copying of another's work means the unattributed verbatim or nearly verbatim copying of sentences and paragraphs which materially mislead the ordinary reader regarding the contributions of the

author. ORI generally does not pursue the limited use of identical or nearly-identical phrases which describe a commonly-used methodology or previous research because ORI does not consider such use as substantially misleading to the reader, or of great significance.

Many allegations of plagiarism involve disputes among former collaborators who participated jointly in the development or conduct of a research project, but who subsequently went their separate ways and made independent use of the jointly developed concepts, methods, descriptive language, or other products of the joint effort. The ownership of the intellectual property in many such situations is seldom clear, and the collaborative history among the scientists often supports a presumption of implied consent to use the products of the collaboration by any of the former collaborators.

For this reason, ORI considers many such disputes to be authorship or credit disputes rather than plagiarism. Such disputes are referred to PHS agencies and extramural institutions for resolution.

3. There is sufficient information about the alleged research misconduct to proceed with an inquiry.

ORI may request that the person who initiated the allegation provide further information or documentation to ORI to allow ORI to frame possible issues that meet the PHS definition of research misconduct. When an allegation is made anonymously, it often precludes ORI from requesting more specific information or from obtaining adequate information because such information is not made available when asked for. Even under those circumstances, ORI continues to track the allegation for up to 2 years in the event additional information is forthcoming from the complainant, or additional allegations or evidence is obtained from other sources.

ORI's review of the available information (such as grant applications, study section summary statements, correspondence with the funding agency, or image analysis of figures in questioned papers, manuscripts, and/or grant applications) may result in a simple resolution of the allegation. Some allegations are found to have arisen because of either a misunderstanding or incomplete information being available to the complainant. However, substantive allegations that meet the necessary criteria will lead ORI to request an institution to conduct an inquiry (or may lead ORI to refer the allegation to the Office of the Inspector General, HHS).

Although typically only about one third of the substantive allegations (pre-inquiry assessments, or PIAs) received by ORI result in a formal case being

opened, ORI carefully evaluates all the allegations received and reaches an appropriate disposition. ORI also regularly requests additional information about allegations from an institution. Many assessments require appreciable ORI staff work even when they do not evolve into a research misconduct case.

In 2008, ORI received 201 allegations. The dispositions of the allegations received by ORI are presented in Table 1 below. Allegations become active cases when the criteria outlined above are met. Allegations are administratively closed when ORI finds that (1) they do not fall under ORI jurisdiction or meet these criteria, (2) cannot be referred to another agency, or (3) are resolved through further review and information. Other allegations are referred to other federal agencies or offices when they include concerns about the involvement of human subjects or animals in research, financial issues, research funded or regulated by other agencies, etc. No action is possible for ORI if an allegation lacks sufficient specific information to permit a determination regarding 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 is coded NA for no action. If a complaint lacks sufficient specificity or information to permit further assessment, but additional information is expected, it is coded NAPN for 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, the Office of Management Assessment, and the Office of the Inspector General. 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 or referred to the other funding agency.

Allegations received from the extramural programs of NIH are sent to DIO for confirmatory assessment. If DIO's assessment indicates that the matter should be referred to the institution where the questioned research took place, DIO will refer the matter for either an assessment or inquiry depending on the apparent scope of the alleged research misconduct. NIH officials are copied on these notifications. When DIO's assessment determines that ORI has no jurisdiction in the matter, NIH is so informed so that alternative administrative actions can be considered. These assessments are coded HBA for handled by agency.

Pre-inquiry assessment (PIA) refers to assessments that have been identified by institutions as active inquiries or investigations. PIAs 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, 2008

Handling of Allegations – Outcome in ORI	Number of Allegations
No action possible now or no action	113
Handled by agency	16
Handled by agency to ORI	5
Referred to other federal agencies	13
Pre-inquiry assessment of allegations	ORI/NIH
Pre-inquiry assessment of allegations made directly to ORI	52
Pre-inquiry assessment of allegations made initially to NIH	2
Pre-inquiry assessment of all allegations (<i>subtotal of ORI and NIH</i>)	54
Total allegations	201
Handling of Pre-Inquiry Assessments Made Directly to ORI	Number of Pre-Inquiry Assessments
Administratively closed after review	12
Remaining pre-inquiry assessments	35
Moved to active status	5
Total pre-inquiry assessments	52

Of the 201 allegations made to ORI (or to NIH and reported to ORI) in 2008, 52 were assessed by ORI in detail for a potential inquiry or investigation; 5 of the assessments were opened as cases in 2008. Of the remaining PIAs, 12 were administratively closed after being reviewed and 35 remained open at the end of the year.

Assessments of the allegations that resulted in new ORI cases took an average of 185 days; those that resulted in administrative closures took an average of 77 days. These data do not reflect the additional time taken by NIH officials who handled (with advice, assessment, and assistance from ORI, as appropriate) two allegations that were made directly to NIH by a complainant (refer to Table 1). The 201 allegations that ORI received in 2008 were slightly less than the 217 allegations handled in 2007. However, the number of allegations that were classified as PIAs in 2008 by ORI (54) increased by 12.5 percent compared to the number classified as PIAs in 2007.

Table 2 summarizes the distribution of time in days needed to resolve pre-inquiry assessments during 2008, including 35 carried forward from 2007. Of the 17 cases opened by DIO in 2008, 12 arose from PIAs from earlier years. Interestingly, a majority of the 35 PIAs carried into 2009 (refer to Table 1) represented ongoing investigations at the institutional level.

Table 2: Time for Conduct of Pre-Inquiry Assessments by ORI, 2008

Outcome of ORI Assessment	Number of Allegations	Distribution of Resolution Times (Days)		
		Mean	Median	Range
	198			
Opened a formal case	17* 5 (2008)	427	439	1-1,048
Administratively closed	12	77	75	1-312
Unresolved at end of year 2008	35	134	80	1-480
Total	52**	638	594	

* Includes 12 PIAs from previous years that became cases in 2008. Five PIAs from 2008 became cases in 2008.

** Total does not include the 12 PIAs carried forward from 2007.

Processing of Cases Closed

ORI closed 17 cases in 2008, all of which were investigations conducted by institutions and reported to ORI. The average duration of 35 months for conducting, reviewing, and closing these cases involved 20.9 months by the institution and 14.1 months for ORI oversight and administrative action (see Table 3).

Table 3: Duration of Research Misconduct Cases Closed by ORI, 2008 (N=17)

Distribution of Resolution Times (Months)			
Location of activity	Mean	Median	Range
Institution	20.9	29	1-51
ORI	14.1	12	1-29

The action period for the 17 institutional investigations included their inquiry, investigation, and adjudication phases, and ORI's oversight included 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 of their decision about whether research misconduct occurred. Additional ORI analysis is often required to make an ORI finding of research misconduct. In most instances, ORI is able to close its cases by reaching a voluntary settlement agreement with the respondent. Occasionally, such an agreement cannot be reached and the respondent chooses to request a hearing before an Administrative Law Judge (ALJ) with the HHS Department of Appeals Board (DAB). A hearing request was initiated in 2008 and is ongoing.

Caseload and Outcomes

The ORI caseload is divided into two elements: institutional inquiries and institutional investigations. ORI carried forward 39 cases from 2007, and ORI opened 17 new cases and closed 17 cases during 2008 (see Table 4). At the end of calendar year 2008, ORI had 39 active formal cases divided between inquiries and investigations. Two institutional inquiries and 37 institutional investigations remained open at the end of 2008.

Table 4: ORI Research Misconduct Caseload by Case Type, 2008

Case Type	Forwarded from 2007	Opened in 2008	Closed in 2008
Institutional inquiry	4	2	0
Institutional investigation	35	15	17
Total	39	17	17

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 allegations 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.

In addition, if an institution's inquiry process leads to a recommendation to conduct an investigation but nevertheless decides for any of a number of reasons not to do so (see 42 C.F.R. § 93.316), the institution is required to first inform ORI of its decision and seek guidance from ORI on whether this decision is appropriate. For example, if the inquiry recommended an investigation into allegations of minor plagiarism, ORI, after review of the matter, might concur with an institutional decision to not conduct an investigation or make findings of research misconduct. But, if an institution chose not to conduct an investigation when the inquiry found substantial evidence of falsified or fabricated data because the respondent was no longer at the institution, ORI would likely require the investigation to proceed.

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 research misconduct. ORI began 2008 with 35 cases carried forward from 2007. During the year, 15 new institutional investigations were opened; 17 investigation cases were closed (refer to Table 4). Of these 17 closed investigations, 13 involved ORI findings of research misconduct; 4 cases did not have such findings. Of the total of 17 cases closed in 2008, 76 percent (13 cases) involved findings of research misconduct (see Table 5). Summaries of the 13 cases can be found in Section VI.

There were 37 active investigations carried into 2009. About 75 percent of these investigations had completed institutional findings of research misconduct.

Table 5: Outcome of Research Misconduct Cases Closed by ORI, 2008 (N=17)

Case Type	Outcome of Cases				Total
	No Investigation	No Research Misconduct	Misconduct Finding	Administrative Closure	
Inquiry	-	-	-	-	0
Investigation	-	4	13	0	17
Total	0	4	13	0	17

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 no formal cases administratively closed in 2008.

However, PIAs may also be administratively closed, and during 2007 and 2008, a significant number were administratively closed that in earlier years would usually have been opened as a formal case. In large part, this modification of how accessions were handled has accounted for the lower number of cases that were opened during these 2 years.

Types of Allegations and Administrative Actions

Types of Allegations Involved in Cases Closed: During 2008, all the formal ORI cases closed with or without a finding involved allegations of falsification, fabrication, or both (see Table 6).

Table 6: Types of Allegations Involved in Closed Inquiries and Investigations and Their Outcomes, 2008

Allegation Type	Inquiry	Investigation	ORI Findings or PHS Administrative Actions
Fabrication	0	0	0
Falsification	0	10	6
Fabrication/ falsification	0	7	7
Total	0	17	13

HHS Administrative Actions Imposed in Closed Cases: A range of administrative actions are used by HHS to protect the integrity of future PHS-funded research. HHS may propose the debarment or suspension of persons found responsible for research misconduct to protect federal assistance, loans, benefits, and other non-procurement activities from waste, fraud, and abuse. The HHS Departmental Appeals Board has held that research misconduct is cause for debarment. A debarred or excluded person may not participate in or receive benefits from non-procurement or procurement transactions as defined by the Office of Management and Budget Guidance on Non-procurement Debarment and Suspension (2 C.F.R. Part 180).

For the 13 cases in 2008 in which PHS research misconduct findings or HHS administrative actions were imposed, 3 persons were debarred or voluntarily excluded for 5 years; 1 person was debarred or voluntarily excluded for 4 years; 2 individuals were debarred or voluntarily excluded for 3 years; and 1 person was debarred or voluntarily excluded for 2 years (see Table 7).

Other administrative actions imposed on respondents in these 13 cases included the following:

1. 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 (13 persons);
2. 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 (4 persons);

3. certification by the institution that the respondent's performance meets generally accepted standards;
4. retraction and/or correction of published articles in one case;
5. monitoring of the respondent's work for 3 years was imposed in two cases; and
6. requiring one respondent to offer to make restitution by restoring the reputation of any person harmed by the falsification.

Table 7: HHS Administrative Actions Imposed in Closed Investigations with Research Misconduct Findings or Administrative Actions, 2008

HHS Administrative Action	Duration (Years)	Number of Actions
Debarment or voluntary exclusion	5	3
Debarment or voluntary exclusion	4	1
Debarment or voluntary exclusion	3	2
Debarment or voluntary exclusion	2	1
Prohibition from serving as an advisor for PHS	5	4
Prohibition from serving as an advisor for PHS	4	1
Prohibition from serving as an advisor for PHS	3	8
Supervision plan required	5	1
Supervision plan required	3	3
Certification of work	5	1
Certification of work	3	2
Monitoring of work	3	3
Retraction and/or correction of articles	0	1
Restitution of reputation	0	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 includes:

- rapidly reviewing institutional procedures to identify problem areas;
- advising or assisting in sequestration and inventory of physical or computer evidence;
- advising on case strategy, including legal issues;
- outlining specific PHS issues;
- providing PHS grant applications;
- educating on or assisting with sophisticated analytical techniques for image comparisons and statistical or digit analyses of data to prove falsification or fabrication;
- suggesting collateral evidence to confirm or refute questioned claims;
- advising on “missing” records;
- assisting in locating experts;
- developing strategies to accurately document admissions to research misconduct;
- assisting with referrals to other federal agencies;
- notifying or requesting help from other institutions;
- advising on potential whistleblowers and confidentiality issues;
- helping with contacts to national databases (such as GenBank); and
- assisting with journal editors for papers that require correction or retraction.

ORI provided RRTA assistance to 37 institutional officials and journal editors in 2008. 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

determining whether images appearing in manuscripts under review were fabricated or falsified.

ORI has assisted institutions with other challenging problems, including (a) voluminous or missing evidence, (b) multi-center clinical sites, (c) involvement of aggressive outside parties, and (d) premature or incomplete admissions. ORI staff will also provide RRTA assistance over the telephone (240-453-8800) or on-site.

ORI staff also has been developing on-line tools to assist institutions with their investigations. For example, a number of Photoshop “Actions” and “Droplets” have been developed to assist with rapid detection of evidence for manipulation of images. These tools have been posted on the ORI web site (<http://www.ori.dhhs.gov/tools/>) for a couple of years and have received favorable responses from an international spectrum of users ranging from journal editors, peer reviewers of papers, and anonymous complainants who are increasingly scrutinizing the high-quality images published online by nearly every journal.

ORI also has licensed “GoToMeeting” to permit on-line sharing of the computer desktop of ORI investigators with institutional officials and investigation committee members who wish to learn about the forensic approaches developed by ORI investigators. This process allows sharing of computer screens and toggling between various computers to facilitate discussions and obviates the need for expensive and time-consuming travel to provide such training. It is anticipated that as the various forensic procedures that institutions find useful are identified, they can be recorded into brief video streams that can be made available to qualified individuals on a suitable web site.

Research Integrity Officer (RIO) Boot Camp Training

“An extensive training program for RIOs completed its third year,” said David Wright, Ph.D., the ORI consultant who first recognized the need to deal with the rapid turnover and inexperience of RIOs at many universities. Institutional RIOs and counsels from major research universities attended the third and fourth boot camps for RIOs at the University of Washington and Indiana University in Indianapolis in 2008. Forty RIOs and nine counsels attended the 3-day meetings and received intensive training on the handling of allegations of research misconduct. Thus, the boot camp has trained 77 RIOs and 28 counsels since 2007.

The curriculum of the 3-day ORI boot camp has been developing and evolving over the last 2 years as a result of responses to the extensive evaluations and debriefings conducted at the end of each meeting. Designed to emphasize the

interaction of experienced with less experienced RIOs, with a minimum of input and direction from ORI staff, the goal is to bring together 25-30 RIOs, and their counsels who are interested in research misconduct matters, to learn from each other, establish a network of RIOs, and help identify the position of RIO as a profession. The boot camp provides time to observe, discuss, and practice skills of interviewing; assess allegations of research misconduct; and guide an investigation of possible research misconduct.

The RIOs who attended the training programs have continued access to each other through a RIO web site that Dr. Wright has established with Michigan State University. The audiovisual materials developed for the boot camps will eventually form an on-line resource available to all interested institutional officials.

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

Introduction

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 Postdoctoral Scholars, 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 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 RCR by their members.

The program, collaboration between the Association of American Medical Colleges and ORI, made 78 awards to 72 academic and scientific societies from 2002-2008 to develop guidelines, standards, policies, conferences, curricula, and other resources designed to promote RCR among members of their societies.

A final report was submitted in 2008. The following lists all the societies that had one or more RCR development projects:

- AcademyHealth
- Alliance of Independent Academic Medical Centers
- Ambulatory Pediatric Association
- American Academy of Family Physicians
- American College of Medical Genetics
- American College of Neuropsychopharmacology
- American College of Physicians
- American College of Rheumatology/Association of Rheumatology Health Professionals (ARHP)
- American Educational Research Association
- American Occupational Therapy Foundation
- American Psychiatric Institute for Research and Education

- American Society for Bioethics and Humanities
- American Society for Clinical Pharmacology and Therapeutics
- American Society of Hematology
- American Speech-Language-Hearing Association
- American Thoracic Society
- Association of Academic Health Sciences Libraries
- Association of Academic Physiatrists
- Association of Anatomy, Cell Biology and Neurobiology Chairpersons
- Association of Chairpersons of Departments of Physiology
- Association of Professors of Medicine
- Council on Social Work Education
- Endocrine Society
- Federation of American Societies for Experimental Biology
- North American Association for the Study of Obesity
- Public Health Leadership Society
- Research and Assessment Corporation for Counseling, Inc.
- Society for Academic Continuing Medical Education
- Society for Academic Emergency Medicine
- Society of Research Subject Advocates
- Society of Teachers of Family Medicine
- Society of University Surgeons
- The Gerontological Society of America

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/>

RCR Resource Development Program

Two resources for teaching RCR, developed with support from the RCR Resource Development Program, were completed in 2008. The first resource is an instructional module entitled "Online Learning Tool for Research Integrity and Image Processing," by Harold Kincaid and Sara Vollmer from the University of Alabama. This web-based resource addresses guidelines, questionable practices, and case studies on image processing. Case studies are approached using a Query-Video Presentation-Query (QVQ) method to engage learners through video vignettes. The module can be viewed at <http://www.ori.hhs.gov/education/products/RIandImages/>

The second resource is a list of educational objectives for RCR instructions and learning topics for seven of the nine core areas of RCR. James DuBois, from Saint Louis University, developed the list; he performed a Delphi study by using panels of subject matter experts in the core areas of RCR. The list of objectives and topics will be available on the ORI web site.

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 RCR at private and public research institutes.

The program has supported over 60 projects since it was established in 2002. Completed resources are posted at <http://www.ori.hhs.gov/education/products/>. 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.

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 grant over 90 percent of the doctorates and more than 75 percent of the master's degrees awarded by U.S. institutions.

This contract extends previous efforts by developing a framework for institutionalizing RCR training in graduate programs. In its second year, CGS released a request for proposals and issued five subcontracts to research institutions. Each subcontract was awarded at \$50,000.

The list of research institutions funded under the program includes Columbia University, Emory University, the University of Alabama at Birmingham, the University of Arizona, and a consortium of three universities including Michigan State University, Pennsylvania State University, and the University of Wisconsin-Madison.

In 2008, the program launched a new web site entitled the "Project for Scholarly Integrity," <http://www.scholarlyintegrity.org/>. The site serves as a clearinghouse for RCR resources as well as a means to promote open dialogue about scholarly integrity. Summaries for each project can also be found at the CGS web site.

RCR Program for Postdoctoral Fellows

Twelve institutions received seed grants in 2008 to develop RCR education programs specifically tailored to the postdoctoral experience under a 2-year contract ORI awarded to the National Postdoctoral Association (NPA) to facilitate the creation of RCR programming for postdoctoral fellows by institutional postdoctoral offices or postdoctoral 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.

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

Under the contract, postdoctoral offices or associations at 12 institutions received seed grants in 2007 to develop RCR education programs specifically tailored to the postdoctoral experience. Thirty seed grants will be awarded during the contract. Additional awards were made in 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 postdoctoral scholars:

- Michigan State University
- Oak Ridge Associated Universities
- San Diego Postdoctoral Training Consortium
- Stevens Institute of Technology
- Syracuse University
- Tufts University
- University at Buffalo, State University of New York (SUNY)
- University Health Network
- University of California, San Diego
- University of California, Irvine
- University of California, Los Angeles
- University of Cincinnati
- University of North Carolina at Chapel Hill
- University of South Alabama
- University of South Florida
- University of Tennessee Health Science Center Postdoctoral Association
- University of Texas MD Anderson Cancer Center Postdoctoral Association
- Wake Forest University

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 postdoctoral experience." Abstracts of current awardees are available on the NPA web site.

The NPA also convened a project advisory committee composed of postdoctoral scholars, 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 2008 and 2009. 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 postdoctoral scholars. The toolkit will include sample agendas, suggested speakers, sample handouts, curricula, resource lists, sample pre- and post-tests, evaluation 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 postdoctoral offices and 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, postdoctoral scholars, faculty, and other personnel.

Under the contract, LMI produced a video-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 video vignettes will be posted on the ORI web site in 2009.

"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."

The interactive course will provide instruction in skills useful in managing laboratories including: communication skills; establishment and maintenance of a research program; quality control and assurance; managing human resources; 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.

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 Biennial RCR Conference

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

More than 50 abstracts were presented. The conference program included overviews of current efforts and a session exploring different views on goals, methods, and the value of RCR instruction. Other sessions focused on assessment tools, web-based instruction, targeting different audiences, innovative teaching materials and approaches, international programs, and other aspects of RCR instruction. Time was allocated for interactive demonstration sessions and poster presentations.

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

National Academy of Sciences Study on Integrity of Research Data

ORI and other federal agencies are supporting a study, *Ensuring the Utility and Integrity of Research Data in a Digital Age*, being conducted by the National Academy of Sciences that 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 2009. The project web site at <http://www8.nationalacademies.org/cp/projectview.aspx?key=48721> lists the key issues being addressed:

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 that which results from federally funded research? Is it the public, the research institution, the lab, or 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, nongovernmental organizations, and industry?

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

Conferences and Workshops

ORI has sponsored, supported, or developed eight conferences, workshops, and training programs in 2008. The conferences and workshops are organized in collaboration with universities, medical schools, professional organizations, and government agencies. More information about the conference and workshop program is available at <http://www.ori.hhs.gov/conferences/>

ORI-RIO Boot Camp Training

Bloomington, IN
Poynter Center, Indiana University
April 1-3, 2008

ORI Conference on RCR

St. Louis, MO
University of St. Louis
April 19, 2008

ORI-RIO Boot Camp Training

Seattle, WA
University of Washington
June 1-4, 2008

Research Integrity

Washington, DC
Department of Defense
June 26, 2008

Research Integrity

Bethesda, MD
Uniformed Services University of the Health Sciences
July 23, 2008

Mentoring

Washington, DC
The Smithsonian Institution
September 11, 2008

Public Service, Public Trust

Bethesda, MD
Uniformed Services University of the Health Sciences
September 17, 2008

ORI Conference on Fostering International Collaborations

Minneapolis, MN
University of Minnesota
October 2, 2008

ORI Web Site

The ORI web site received 123,908 visits in 2008 from 81,741 visitors from 174 countries who viewed 433,849 pages, according to Google Analytics. New visitors totaled 80,804 (65 percent); repeat visitors totaled 43,104 (35 percent). Visitors viewed an average of 3.5 pages per visit. Visitors were most frequently from the United States, Canada, the United Kingdom, Australia, South Korea, Germany, India, Puerto Rico, Japan, and Singapore.

ORI Newsletter

ORI has been producing a newsletter since January 1993. In 2008, ORI produced four issues and sent each publication to approximately 7,000 institutions or individuals. The newsletter is also available on the ORI home

page. The newsletter provides ORI updates, posting of cases published in the *Federal Register*, discussions of timely issues, and information about conferences. In 2008, ORI began to focus on encouraging voices and opinions from the research integrity community. Ten individuals made contributions during the year and extended the discussions into areas such as handling plagiarism, research administration, new RCR tools, mentoring, blacklisting, international collaborations, and conflict of interest.

ORI Presentations

John Dahlberg, Director, DIO. "Panel Discussant on Misconduct in Science," American Health Lawyers Association, Ritz Carlton Hotel, Washington, DC, January 24, 2008.

John Dahlberg, Director, DIO. "How DIO Handles Allegations, Provides Assistance, and Conducts Oversight Review," National Institutes of Health (NIH), Institute of Research Integrity Officers and Extramural Program Staff, February 20, 2008.

John Dahlberg, Director, DIO. "Scientific Forensics," Seminar at Johns Hopkins University, Baltimore, MD, May 30, 2008.

John Dahlberg, Director, DIO. "Detecting Misconduct – Some Approaches Used by DIO," Boot Camp for RIO, Johns Hopkins University, June 3, 2008.

John Dahlberg, Director, DIO. "The Role of the Office of Research Integrity" Uniformed Services University of the Health Sciences (USUHS), July 23, 2008.

John Dahlberg, Director, DIO. "Scientific Forensics," Second Biennial National Idea Symposium of Biomedical Research Excellence NISBRE, NIH-National Center for Research Resources (NCRR) Meeting, Wardham Park Marriott, Washington, DC, August 8, 2008.

Susan J. Garfinkel, Scientist-Investigator, DIO. "Detecting Misconduct: Some Approaches Used by DIO," RIO Boot Camp, Poynter Center, Indiana University, IN, April 1-3, 2008.

Susan J. Garfinkel, Scientist-Investigator, DIO. "Research Misconduct – Integrity in Research: What Has Been Going on Since 2005?" American Health Lawyers Association, Life Sciences Law Institute, Bethesda, MD, May 7-9, 2008.

Susan J. Garfinkel, Scientist-Investigator, DIO. "Detecting Misconduct: Some Approaches Used by DIO and The Vogel Case: What Are the Allegations?" RIO Boot Camp, University of Washington, Seattle, WA, June 1-4, 2008.

Susan J. Garfinkel, Scientist-Investigator, DIO. "How to Resolve Research Misconduct Allegations: Practical Suggestions," National Association of College and University Attorneys – 48th Annual Conference, New York, NY, June 22-25, 2008.

Susan J. Garfinkel, Scientist-Investigator, DIO. "Falsification, Fabrication and Plagiarism: What Can Be Done?" City University of New York (CUNY) Research Integrity Series, New York, NY, November 13, 2008.

John Krueger, Scientist-Investigator, DIO. "ORI's Forensic Examination of Questioned Images in Science," RIO Boot Camp, Poynter Center, Indiana University, IN, April 2, 2008.

John Krueger, Scientist-Investigator, DIO. "Analysis of the Case Images," RIO Boot Camp, Poynter Center, Indiana University, IN, April 3, 2008.

John Krueger, Scientist-Investigator, DIO. "Image Manipulation/Falsification in Science – Detection and Choices," Emerging Trends in Scholarly Publishing, Allen Press Seminar, National Press Club, Washington, DC, April 17, 2008.

John Krueger, Scientist-Investigator, DIO. "How Evidence Informs the Investigations," RIO Boot Camp, University of Washington, Seattle, WA, June 1-4, 2008.

John Krueger, Scientist-Investigator, DIO. "ORI's Forensics: Questioned Images in Science," RIO Boot Camp, University of Washington, Seattle, WA, June 4, 2008.

John Krueger, Scientist-Investigator, DIO. "Falsified Images in Science," Discussion Group in Research Misconduct, Public Service, Public Trust, Uniformed Services University in the Health Sciences, Bethesda, MD, July 23, 2008.

John Krueger, Scientist-Investigator, DIO. "Falsification of Images in Science," Workshop on "Investigating Research Misconduct," Second Biennial NISBRE, NIH-NCRR Meeting, Wardham Park Marriott, Washington, DC, August 8, 2008.

Chris B. Pascal, Director, ORI. "Overview of Research Misconduct," ESA Seminar, Bethesda, MD, February 1, 2008.

Chris B. Pascal, Director, ORI. "Research Misconduct Issues," National Academy of Sciences – E-Journal Summit, Washington, DC, March 18, 2008.

Chris B. Pascal, Director, ORI. "The Office of Research Integrity: Responding to Misconduct and Promoting Responsible Research," San Antonio, TX, March 24-26, 2008.

Chris B. Pascal, Director, ORI. "Federal Perspective," Office of Human Research Protections (OHRP) Research Community Forum, New Orleans, LA, April 4-6, 2008.

Chris B. Pascal, Director, ORI. "Building a Culture of the Responsible Conduct of Research," Division of Research Colloquium, University of Albany, Albany, NY, April 24, 2008.

Chris B. Pascal, Director, ORI. "The Mission of the Office of Research Integrity," ESA Seminar, Bethesda, MD, May 2, 2008.

Chris B. Pascal, Director, ORI. "RCR Training Program," National Council of University Research Administrators (NCURA) Region 1 Annual Meeting, Brewster, MA, May 3-5, 2008.

Chris B. Pascal, Director, ORI. "Research Integrity," Chicago, IL, June 18-20, 2008.

Chris B. Pascal, Director, ORI. "Research Misconduct Update," Council of Graduate Schools, Washington, DC, October 30, 2008.

Cynthia Ricard, Director, Extramural Research, DEI. "What We Do at ORI," Johns Hopkins School of Nursing Ph.D. Students, ORI Workshop, Baltimore, MD, January 14, 2008.

Cynthia Ricard, Director, Extramural Research, DEI. "The Role of Mentorship in Responsible Conduct of Research," Responsible Conduct of Research Education Consortium (RCREC) of Association for Practical and Professional Ethics; San Antonio, TX, February 21-24, 2008.

Cynthia Ricard, Director, Extramural Research, DEI. "Future Plans of the Office of Research Integrity," First Biennial Conference in Responsible Conduct of Research, St. Louis, MO, April 17-19, 2008.

Cynthia Ricard, Director, Extramural Research, DEI. "Ethical Decision-making," ORI Technology Demonstration Workshop, May 7, 2008.

Cynthia Ricard, Director, Extramural Research, DEI. "Peer Review and the Commitment to Scientific Excellence," Achieving Excellence Training Conference, Arlington, VA, June 26, 2008.

Cynthia Ricard, Director, Extramural Research, DEI. “Publications and Responsible Authorship,” Public Service, Public Trust, Uniformed Services University of the Health Sciences, Bethesda, MD, July 23, 2008.

Cynthia Ricard, Director, Extramural Research, DEI. “Student RCR Discussions,” Moderator, Uniformed Services University of the Health Sciences, Bethesda, MD, September 2, 2008.

Cynthia Ricard, Director, Extramural Research, DEI. “Research Integrity: Authorship, Collaboration, and Mentoring,” Uniformed Services University of the Health Sciences, Bethesda, MD, September 17, 2008.

Cynthia Ricard, Director, Extramural Research, DEI. “Peer Review, Publication, and Good Authorship,” Georgetown University, Washington, DC, September 22, 2008.

Cynthia Ricard, Director, Extramural Research, DEI. “Facilitating Publication Processes and Good Authorship: New Horizons for Research Administration,” Society of Research Administrators, National Harbor, MD, October 13, 2008.

Cynthia Ricard, Director, Extramural Research, DEI. “Conflict of Interest/Commitment,” and “Research Misconduct,” Research Integrity Conference, University of Tennessee, Memphis, TN, December 4, 2008.

Nicholas H. Steneck, ORI Consultant. “Studying and Promoting Professionalism and Integrity in Research,” Symposium on the Formation of an Ethical Professional Identity, University of St. Thomas School of Law and Holloran Center for Ethical Leadership in the Professions, Minneapolis, MN, February 2, 2008.

Nicholas H. Steneck, ORI Consultant. “Advocacy and the AAAS: Actions and Policies” and “Advocacy in Science: Opportunities, Limits, Responsibilities, and Risks,” the American Association for the Advancement of Science (AAAS) Annual Meeting, AAAS, Boston, MA, February 21, 2008.

Nicholas H. Steneck, ORI Consultant, and Anthony Mayer. “Report to the European Commission: First World Conference on Research Integrity,” European Commission Special Meeting, European Science Foundation and European Commission, Brussels, Belgium, March 27, 2008.

Nicholas H. Steneck, ORI Consultant. "Current Perspectives on Research Integrity and Training and Monitoring Programs," Responsible Conduct of Research: Fostering Quality & Integrity, Old Dominion University, Norfolk, VA, April 9, 2008.

Nicholas H. Steneck, ORI Consultant. "What Are the Key Issues in Good Research Conduct?" Policy Workshop, The Governance of Good Research Conduct in the United Kingdom (UK), Keele University and the UK Research Integrity Office, Keele, UK, April 15, 2008.

Nicholas H. Steneck, ORI Consultant. "History and Current Status of RCR Education, Instruction, and Training," First Biennial ORI Conference: Responsible Conduct of Research Education, Instruction, and Training, Washington University/Office of Research Integrity, St. Louis, MO, April 17, 2008.

Nicholas H. Steneck, ORI Consultant. "Everyday Practices that Compromise Integrity in Research and How to Respond to Them," Responsible Conduct of Research: Principle and Practice, University of Cincinnati, Cincinnati, OH, April 23, 2008.

Nicholas H. Steneck, ORI Consultant. "Research Ethics and Integrity," Young Investigators' Course on Clinical Trials Methods, University of Michigan, Ann Arbor, MI, May 7, 2008.

Nicholas H. Steneck, ORI Consultant. "Everyday Practices that Compromise Integrity in Research and How to Respond to Them," Special Lecture, Oxford University, Oxford, UK, May 20, 2008.

Nicholas H. Steneck, ORI Consultant. "Integrity in Research: Challenges and Opportunities for Faculty in the Sciences," Lecture, Nanyang Technological University, College of Science, Singapore, September 16, 2008.

Nicholas H. Steneck, ORI Consultant. "Integrity in Research: Challenges and Opportunities for Faculty in the Humanities and Social Sciences," Lecture, Nanyang Technological University, College of Humanities, Arts and Social Sciences, Singapore, September 17, 2008.

Nicholas H. Steneck, ORI Consultant. "Integrity in Research: Challenges and Opportunities for Students and Trainees," Lecture, Nanyang Technological University, Singapore, September 17, 2008.

Nicholas H. Steneck, ORI Consultant. "Research Universities and Research Integrity: A Fruitful but Neglected Area for High Education Research," Lecture, University of Minnesota, Postsecondary Education Research Institute, Minneapolis, MN, October 1, 2008.

Nicholas H. Steneck, ORI Consultant. "Integrity in Research: I. Global Challenges and Responses; II. Climate and Training," Lectures, Ministry of Science and Technology, Beijing, China, October 28, 2008.

Nicholas H. Steneck, ORI Consultant. "Integrity in Research: Challenges and Opportunities for Trainees," Lecture, Tsinghua University, Beijing, China, October 29, 2008.

Nicholas H. Steneck, ORI Consultant. "Integrity in Research: Challenges and Opportunities for Trainees," Lecture, Chinese Academy of Sciences Graduate University, Beijing, China, October 30, 2008.

Nicholas H. Steneck, ORI Consultant. "Conflict of Interest: Challenges and Principles," Responsibilities and Training Symposium, City University of New York, Office of the Vice President for Research, New York, NY, November 7, 2008.

Nicholas H. Steneck, ORI Consultant. "Report on Efforts to Develop a Global Clearinghouse for Research Integrity," From Principles to Practice: How European Research Organizations Implement Research Integrity Guidelines, European Science Foundation, Madrid, Spain, November 17, 2008.

Sandra Titus, Director, Intramural Research, DEI. "What Role Does a RIO Have in RCR?" (Preliminary Research Data) ORI Conference on RCR, St. Louis, MO, April 18, 2008.

Sandra Titus, Director, Intramural Research, DEI. "Building Collaborative Research Groups: Using an Authorship Agreement," ORI Conference on RCR, St. Louis, MO, April 19, 2008.

Sandra Titus, Director, Intramural Research, DEI. "Research Integrity: The Nature and Challenge of Collaboration in Research," Department of Defense, Washington, DC, June 26, 2008.

Sandra Titus, Director, Intramural Research, DEI. "Publications and Responsible Authorship," Uniformed Services University of the Health Sciences, Bethesda, MD, July 23, 2008.

Sandra Titus, Director, Intramural Research, DEI. "Absentee Mentor," Smithsonian Institution, Washington, DC, September 11, 2008.

Sandra Titus, Director, Intramural Research, DEI. "Responsible Conduct of Research: Authorship," Collaboration and Mentoring, Uniformed Services University of the Health Sciences, Bethesda, MD, September 17, 2008.

Sandra Titus, Director, Intramural Research, DEI. "Complexities in Learning a New Culture," Fostering International Collaborations, University of Minnesota Conference, Minneapolis, MN, October 2, 2008.

Sandra Titus, Director, Intramural Research, DEI. "ORI Update: Scientists Say They Can Self Regulate – Is It Working?" Society of Research Administrators, Washington, DC, October 10, 2008.

Sandra Titus, Director, Intramural Research, DEI. "Establishing Authorship Agreements in Research Collaboration," Society of Research Administrators, Washington, DC, October 11, 2008.

Sandra Titus, Director, Intramural Research, DEI. "The Mentoring Service of the Research Ethics Counselor," Society of Research Administrators, Washington, DC, October 11, 2008.

Sandra Titus, Director, Intramural Research, DEI. "Research Misconduct and Integrity Issues," Hopkins University Public Health Nursing Program, Baltimore, MD, October 20, 2008.

David Wright, ORI Consultant and RIO Boot Camp Leader. "Training to Enhance RIOs' Assessment Skills," Indiana University, IN, April 1-3, 2008.

David Wright, ORI Consultant. "Organizing and Operating Regulatory Compliance Programs: Decreasing Investigator Burden and Promoting Research Integrity," Poynter Center, Indiana University, IN, May 15, 2008.

David Wright, ORI Consultant. "Responsible Handling of Research Data," Poynter Center, Indiana University, IN, May 16, 2008.

David Wright, ORI Consultant and RIO Boot Camp Leader. "Training to Enhance RIOs' Assessment Skills," University of Washington, Seattle, WA, June 1-4, 2008.

Linda D. Youngman, Scientist-Investigator, DIO. "Research Misconduct in Clinical Research and Clinical Trials," Uniformed Services University of the Health Sciences Conference, National Naval Medical Center, Bethesda, MD, July 23, 2008.

Linda D. Youngman, Scientist-Investigator, DIO. "Clinical Research and Clinical Trials – Suggestions for Dealing with Research Misconduct," American Health Lawyers Association (AHLA) Conference, Ritz Carlton, Washington, DC, January 29-30, 2009.

ORI Publications

Susan J. Garfinkel and Holley Thames Lutz. "Clinical Research Compliance," *Health Law Practice Guide*, Thomson Reuters/West, November 2008, Chapter 8.

Nicholas H. Steneck. "Fostering Professionalism and Integrity in Research," *University of St. Thomas Law Journal*, 2008, 5(2), 522-541.

Nicholas H. Steneck. "An interpretive history of research misconduct policy in the USA and Canada," In *Fraud and Misconduct in Biomedical Research*, edited by F. Wells and M. Farthing. London, UK: Royal Society of Medicine, 2008.

Nicholas H. Steneck. "History and Current Status of RCR Education, Instruction, and Training," First Biennial ORI Conference: Responsible Conduct of Research Education, Instruction, and Training, Washington University and the Office of Research Integrity, St. Louis, MO, April 17, 2008.

Sandra Titus, James Wells, and **Lawrence Rhoades.** "Repairing Research Integrity," *Nature*, June 19, 2008, 453, 980-982.

Sandra Titus. "Facing the Dark Side: Research Misconduct Strategies to Improve Self Regulation," *The Physiologist*, Walter C. Randall Lecture, February 2008, 51(1), 1-6.

David Wright, **Sandra Titus**, and Jered Cornelison. "Mentoring and Research Misconduct: An Analysis of Research Mentoring in Closed ORI Cases," *Science and Engineering Ethics*, 2008, 14, 323-336.

Federal Register Notices

Acts of misconduct occurring prior to June 2005 fall under 42 C.F.R. Part 50, Subpart A, and are called scientific misconduct, whereas acts of misconduct occurring after June 2005 fall under 42 C.F.R. Part 93 and are called research misconduct.*

Office of the Secretary. Findings of Research Misconduct. Notice Vol. 73, No. 15, Wednesday, January 23, 2008 [Monte]

Office of the Secretary. Finding of Research Misconduct. Notice Vol. 73, No. 88, Tuesday, May 6, 2008 [Bartsch]

Office of the Secretary. Finding of Research Misconduct. Notice Vol. 73, No. 141, Friday, July 18, 2008 [Hampton]

Office of the Secretary. Finding of Research Misconduct. Notice Vol. 73, No. 141, Tuesday, July 22, 2008 [Gonzalez]

Office of the Secretary. Findings of Scientific Misconduct. Notice Vol. 73, No. 196, Wednesday, October 8, 2008 [Sperber]

Office of the Secretary. Findings of Research Misconduct. Notice Vol. 73, No. 196, Wednesday, October 8, 2008 [Gu]

Office of the Secretary. Findings of Research Misconduct. Notice Vol. 73, No. 214, Tuesday, November 4, 2008 [Yang]

Office of the Secretary. Findings of Scientific Misconduct. Notice Vol. 73, No. 238, Wednesday, December 10, 2008 [Venters]

* Afshar, Nguyen, and Parijs, which are five cases of research misconduct, were covered by the *Federal Register* in 2009.

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 research misconduct and/or promote research integrity. The studies, primarily descriptive, are done under contract with research organizations by ORI staff. Information on the studies is at <http://www.ori.hhs.gov/research/intra/index.shtml>

Completed Studies

Research Misconduct with Graduate Students and Postdoctoral Scholars: Where Was the Mentor?

ORI staff analyzed 50 research misconduct cases involving postdoctoral scholars and research associates to determine the type of relationship the respondents had with their advisor, whom we commonly refer to as their mentor. Specifically, the record was examined to determine whether the advisor had reviewed source data, set laboratory standards, or assessed the stress level of their trainee. Two thirds of the advisors had not paid attention to standard setting or reviewing source data. No assessment could be made about the trainee's stress level and whether the advisor contributed to it or was aware of it. An article was published in *Science and Engineering Ethics*, 2008, "Mentoring and Research Misconduct: Analysis of Research Mentoring in Closed ORI Cases."

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 was published as a commentary, "Repairing Research Integrity," *Nature*, June 19, 2008.

Studies in Progress

Institutional Research Integrity Officer (RIO) Study

This study, conducted by Research Triangle Institute (RTI) International, is focused on the role of the RIO, the institutional official responsible for implementing the PHS Policies on Research Misconduct (42 C.F.R. Part 93). The study will examine the responsibilities, authority, qualifications, training, organizational location, role set, resources, and turnover rates of individuals

in this critical position. The study will also examine how individual and institutional factors influence the preparedness of the RIO to handle research 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 was completed in 2008. It is anticipated that one or more articles will be submitted for publication in 2009.

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 RTI International, is to evaluate how effectively institutions have informed their faculty about the Public Health Service (PHS) Policies on Research Misconduct (42 C.F.R. Part 93). The study will collect data on how much faculty know about what constitutes research misconduct, developing and reporting an allegation, and the rights and responsibilities of respondents and whistleblowers. In addition, the study will ask faculty to evaluate the effectiveness of institutions in handling research misconduct allegations and in protecting whistleblowers. The study has been designed and was awaiting Office of Management and Budget (OMB) approval in order to start the data collection. It is anticipated that data collection and analysis will occur 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 began data collection in late 2008 and will complete data collection and analysis in 2009.

Evaluating the Impact on Whistleblowers Who Report Research Misconduct

This study will interview whistleblowers in closed research misconduct cases to determine what happened to them prior to, during, and after the investigative process ended. A proposal has received funding by HHS and been awarded to

RTI International. The study design and submission to OMB are expected to occur in 2009.

Research Mentoring Dyad Study: Comparing the Research Advisor/Mentor and Their Ph.D. Student's Views on Training/Learning to be a Responsible Researcher

This study will start to design an interview instrument, pilot the instrument, and submit the design to OMB in 2009. The interviews will be framed as a discussion for faculty to describe their interaction with the Ph.D. students for whom they are advisors, mentors, or both. The primary goal of the interview is to learn how faculty views the research training process. The study seeks to determine how faculty prepares Ph.D. students to be responsible researchers, whether they prepare Ph.D. students to be responsible researchers, and what they identify as successful outcomes for a Ph.D. student's graduate education. In addition, interviews will be conducted with an ABD (all but dissertation) student to determine his or her views on how he or she learned to become a responsible researcher.

The Intramural Research Program anticipates development of future studies on faculty views on helpful resources and collaboration issues.

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 development of the program: National Institute on Drug Abuse (NIDA), the National Institute of 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 (NIGMS), the National Human Genome Research Institute (NHGRI), and the National Institute of Child Health and Development (NICHD). Other partners include the Center for Scientific Review (CSR), the National Library of Medicine (NLM), the National Center for Research Resources (NCRR), 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 three awards made in 2008 by the RRI program.

Since it began in 2001, the RRI program has funded 49 projects that have resulted in 91 publications – 78 articles, 2 commentaries, 1 letter to the editor, 8 abstracts, and 2 literature reviews – in 30 journals.

Total funding for the RRI program in 2008 was \$2,222,706, below the all-time high of \$3,070,404 in 2006. New grants received \$458,162 and continuations received \$1,017,720. ORI contributed \$1,474,882; NIH institutes contributed \$747,824.

Two new awards were supported by ORI through the National Center for Research Resources (NCRR) and one new award by the National Institute of General Medical Sciences (NIGMS). Two continuation awards were funded by NLM. Four continuation awards were funded by ORI through the National Institute of Nursing Research, NCI, and NIGMS. NCRR provided grants management support and grant review services.

Three of the 23 applications were supported. R21 awards provide up to \$275,000 in direct costs, plus indirect costs, for 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:

RCR Multi-component Mentoring Model, Elizabeth Ripley, Virginia Commonwealth University

Propagating the Uniform Research Integrity Climate Assessment (U-RICA), Brian Martinson, Health Partners Research Foundation

Integrity in International Research Collaborations, Melissa Anderson, University of Minnesota Twin Cities

RRI Publications

In the first nine years of the program, RRI researchers have published 78 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://www.ori.hhs.gov/research/extra/rri_publications.shtml. Citations to the recently published articles follow.

Researchers supported by the RRI program published five articles in 2008 on research integrity and the responsible conduct of research in five journals:

Brock, M. E., Vert, A., Kligyte, V., Waples, E. P., Sevier, S. T., & Mumford, M. D. (2008). Mental models: An alternative evaluation of a sensemaking approach to ethics instruction. *Science and Engineering Ethics, 14*(3), 449–472.

Djulgovic, B., Kumar, A., Soares, H. P., Hozo, I., Bepler, G., Clarke, M., et al. (2008). Treatment success in cancer: New cancer treatment successes identified in phase 3 randomized controlled trials conducted by the National Cancer Institute-sponsored cooperative oncology groups, 1955 to 2006. *Archives of Internal Medicine, 168*(6), 632–642.

Errami, M., & Garner H. (2008). A tale of two citations. *Nature, 451*(7177), 397–399.

Errami, M., Hicks, J. M., Fisher, W., Trusty, D., Wren, J. D., Long, T. C., et al. (2008). Déjà vu – a study of duplicate citations in Medline. *Bioinformatics, 24*(2), 243–249.

Mcgee, R., Almquist, J., Keller, J., & Jacobsen, S. (2008). Teaching and learning responsible research conduct: Influences of prior experiences on acceptance of new ideas. *Accountability in Research, 15*(1), 30–62.

IV. INSTITUTIONAL COMPLIANCE

The PHS regulation places several requirements on institutions receiving research funds under the Public Health Service Act. ORI monitors institutional compliance with these regulatory requirements through two programs, the Assurance Program and the Compliance Review Program.

Assurance Program

The Assurance Program is responsible for ensuring that PHS research funds are awarded only to eligible institutions. An institution is eligible when it has an active assurance on file with ORI stating that it has developed and will comply with an administrative process for responding to allegations of 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. Institutions keep their assurance active by completing the Annual Report on Possible Research Misconduct (PHS Form 6349), submitting their research misconduct policy upon request by ORI, revising their research misconduct policy when requested by ORI, and complying with the policies and procedures and 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 calendar year 2000, to ease 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.

In 2008, there were 4,826 institutional assurances on file with ORI, an increase of 267 from 2007 (see Table 8). Three hundred and ninety-seven 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 2006 and 2007. One hundred and thirty assurances were inactivated because the institution failed to submit its Annual Report in 2008; the institution requested that its assurance be withdrawn or duplicate records be eliminated.

Table 8: Number and Types of Institutions with Active Assurances, 2008

Institution Type	Number	Change
Institutions of higher education	974	+28
Research organizations, institutes, foundations, and laboratories	425	+21
Independent hospitals	273	+2
Educational organizations, other than higher education	31	+2
Other health, human resources, and environmental services organizations	552	+33
Other (small business)	2,571	-408
Total	4,826	322

Institutional Research Misconduct Policy Reviews

ORI completed 65 policy reviews in 2008. 167 policy reviews were carried into 2009. Sixty-five institutional policies were accepted as submitted; five others are pending review. Since 1995, ORI has reviewed 2,621 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 2007 Annual Report began in January 2008 for the 4,559 institutions that had an assurance on file with ORI as of December 31, 2007.

Completed Annual Reports were received from 4,283 institutions for a response rate of 88 percent. ORI inactivated 176 assurances, including 543 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 its policies and procedures for responding to allegations of research misconduct, and within PHS jurisdiction, the number of allegations of research misconduct received and the number of inquiries and investigations conducted.

Reported Research Misconduct Activity

One hundred and thirty institutions reported 183 new or continuing research misconduct activity in their 2007 Annual Report on Possible Research Misconduct. This is a 15-percent increase over 2006 and is almost two times more activity than in 1993 (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.

Table 9: Research Misconduct Activity, 1993-2008

Year*	Institution Reporting Activity	New Allegations
2007	130	183
2006	111	151
2005	113	137
2004	101	120
2003	106	136
2002	99	163
2001	78	127
2000	82	103
1999	72	89
1998	67	69
1997	73	92
1996	88	127
1995	96	104
1994	79	89
1993	73	86

* The year 2007 is a record of what institutions submitted in their 2008 Annual Report.

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 2008, seven compliance cases were opened and four were closed (see Table 10). One closed case involved the institutional handling of allegations of research misconduct and three cases involved retaliation complaints. Nine compliance cases and three retaliation complaints were carried into 2009.

Table 10: Summary of Compliance Cases, 2008

Case Type	Forwarded from 2007	Opened in 2008	Closed in 2008	Carried into 2009
Compliance/retaliation	9	7	4	12

Institutional Handling of Cases

Compliance Case 1

This case initially involved a dispute over priority on an invention report, and during the institutional process additional claims were developed involving allegations of possible research or scientific misconduct in a National Institutes of Health (NIH) grant application. While the initial allegations were clearly outside the jurisdiction of ORI, the additional allegations required that they be addressed under the specific requirements of the PHS regulation as well as the institution's research misconduct policies.

It is clear from the documentation provided that the original concerns about the respondent's research arose from concerns about an intellectual property dispute. Despite statements that these matters were not considered by the investigation committee, it does not appear to ORI that the inquiry and investigation process was adequately isolated from the ongoing concerns over invention reports and patent applications. The record of the institutional

investigation included significant materials related to this concern, and presented in this context the record may have unfairly influenced the investigation committee. Furthermore, much of the record appears to reflect an effort to reduce the respondent's credibility, and there does not appear to have been any meaningful effort to evaluate his explanations and rebuttals as required under the regulation. The committee's charge was to evaluate the research misconduct allegations against the respondent, and its efforts clearly exceeded its mandate.

ORI also noted that the five members of the investigation committee were a subset of the Research Council, who may or may not have the particular expertise to evaluate specific scientific issues raised as allegations. The single relevant research misconduct issue in this case was finally identified as the inclusion of inappropriate text in an NIH grant application, which, upon evaluation, did not require a high level of scientific expertise. However, the initial process of sorting out the specific scientific research involved, identifying and evaluating the research misconduct allegations, and assessing inter-laboratory interactions requires specific expertise that is not always present on standing committees. In ORI's experience, many institutions supplement the investigation committee membership with one or more individuals who have specific expertise in the scientific matter under review.

As a result of its compliance review in this case, ORI recommended that the institutional officials reevaluate the use of its Research Council as its primary investigation committee. ORI also recommended that these institutional officials develop a detailed protocol outlining the specific reporting requirements to ORI, to be used as a supplement to the institutional misconduct policies.

Retaliation Case A

This case involves claims of possible retaliation against a complainant, specifically the non-renewal of the complainant's position at the institution, as a result of making allegations of research misconduct against the complainant's laboratory chief.

By regulation, institutions are required to protect the positions of individuals who make allegations of research misconduct in good faith, and ORI works aggressively within the framework of the PHS regulation to enforce this provision. Because institutions are not required to notify ORI of ongoing inquiries prior to the initiation of an investigation, ORI had no information related to this case at the time of the complainant's initial contact with ORI. Therefore, ORI was not in a position to determine whether or not there was PHS jurisdiction. However, because time is so important in many retaliation

complaints, ORI requested that the institution provide more information related to the specific allegations to determine whether they fell within the PHS definition of research misconduct. ORI also wanted to determine whether the allegations involved PHS research funding. Furthermore, ORI requested any additional information available to assess whether there was a clear and definitive link between the allegations of research misconduct and the alleged retaliatory action.

The PHS regulation defines “retaliation” as an adverse action taken against a complainant by an institutional member in response to a good faith allegation of research misconduct or good faith cooperation with a research misconduct proceeding (42 C.F.R. § 93.226). The substance and timing of both the allegation and the adverse action must be properly evaluated.

After reviewing the documentation provided, ORI determined that there was other evidence unrelated to the complainant’s allegation of research misconduct to support a justification for terminating the complainant’s position. ORI also determined that this action was considered before the allegations were made. Based on this assessment, ORI concluded that the complainant’s claim of retaliation was not supported; therefore, the institution had not violated the PHS regulation by taking this action.

Retaliation Case B

In any case of alleged retaliation, ORI initially evaluates all available information to determine (1) whether there is PHS jurisdiction in the matter, that is, was there an allegation of research misconduct involving a PHS-supported project, and (2) where there is a causal link between the allegation and the alleged adverse action. Upon ORI inquiry into this particular case, there was conflicting testimony regarding the timing of the research misconduct allegation. The complainant insisted that it was made prior to the notification of his termination, and institutional officials stated that, although he raised concerns about the validity of certain data prior to being notified of his termination, the specific research misconduct allegations were not articulated until later.

Despite this conflict, the institution voluntarily initiated an investigation of the retaliation complaint utilizing the process outlined in the ORI Whistleblower’s Guidelines. The institution also began, as a separate process, an examination of the research misconduct allegations under its institutional misconduct policy. The retaliation review involved the examination of all relevant documentation and interviews with selected institutional members. Despite numerous requests, the complainant chose not to be interviewed by the panel investigating the retaliation complaint.

After its review, the panel investigating the retaliation complaint determined that the decision to terminate the position of the complainant was primarily based on performance and behavioral issues, and not retaliatory. ORI determined that the institutional process was consistent with the standards published in the ORI Whistleblower's Guidelines, so the retaliation case was closed.

Retaliation Case C

This case involved a contentious set of allegations and counter allegations of research misconduct, as well as other interpersonal disputes, between a faculty member and a postdoctoral fellow. The faculty member also claims being subject to continuous harassment, intimidation, and other retaliatory actions from the postdoctoral fellow. The separate misconduct allegations were addressed by the institution under its misconduct policy, and each was closed at the inquiry stage.

ORI was contacted by the complainant regarding the alleged retaliation. The complainant specifically claimed that subsequent to the research misconduct allegations, steps were taken to censor and otherwise interfere with issues related to academic freedom, access to certain institutional facilities was curtailed, and the complainant's annual departmental evaluation was negatively affected. Because of the contentious history and lack of a clear documented link between the allegations and the alleged retaliation, ORI asked the institution to conduct an assessment to determine whether there was sufficient evidence to support the retaliatory claims.

The institution conducted an assessment, as requested, and a detailed evaluation of all the claimed retaliatory actions against the complainant and determined that the evidence did not support the complainant's claim of retaliation. The institution found either no evidence to support the claims, or there were other factors that weighed more heavily in the institutional actions. ORI evaluated the institutional assessment and concurred with its determination.

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) PHS has made a finding of research misconduct concerning the individual, (2) the individual is the subject of an administrative action imposed by HHS as a result of a determination that research misconduct has occurred, (3) the individual has agreed to voluntary corrective action as a result of an investigation of

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

The ALERT system was computerized in 1994 to facilitate checks of individuals in the above categories against incoming applications, pending awards, and proposed appointments to PHS advisory committees, boards, and peer review groups. Listing in the PHS ALERT system (item 4 in the prior paragraph) does not necessarily debar or exclude individuals from receiving support or serving in an advisory capacity to PHS unless a PHS administrative action imposed on them specifically requires it.

On January 1, 2008, ORI listed the names of 54 individuals in the ALERT system. During the year, ORI added four names and removed nine. On December 31, 2008, the names of 49 individuals were in the system (see Table 11).

ORI added four names because those individuals were found to have committed research misconduct in institutional investigations reported to ORI. Nine names were removed during the year because the term of the HHS administrative actions expired.

Of the 49 names in the system at year end, 36 individuals had HHS administrative actions imposed on them, and 13 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, 2008

System Activity	
As of January 1, 2008	54
Additions	4
Action expired/removed	9
As of December 31, 2008	49

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), a public system of records that may be accessed through the ORI web site at <http://www.ori.dhhs.gov/misconduct/AdminBulletinBoard.shtml>

Information on each individual in the system is limited to name, social security number, date of birth, type of research 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 2008.

- Seventeen FOIA requests were carried into 2008. ORI received 37 requests in 2008 and closed 35. Nineteen requests were carried into 2009. In 2007, ORI received 42 and closed 44 requests.
- No Privacy Act requests were received in 2008.

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 protected by Exemptions 5, 6, and 7 of the FOIA. Exemption 5 covers internal government communications and notices. Exemption 6 covers document information 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 who is retrieved by a personal identifier.

The inquiry and investigative records in ORI files are part of a system of records that were 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 by the subject of the records. Nonetheless, each request for access is

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

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

VI. SUMMARIES OF RESEARCH MISCONDUCT CASES

Lois Bartsch, Ph.D., University of Nebraska Medical Center: Based on the report of an investigation conducted by the University of Nebraska Medical Center (UNMC) and additional analysis conducted by the Office of Research Integrity (ORI) during its oversight review, the U.S. Public Health Service (PHS) found that Lois Bartsch, Ph.D., former postdoctoral research trainee, Department of Genetics, Cell Biology, and Anatomy, UNMC, engaged in scientific misconduct in research supported by National Cancer Institute (NCI), National Institutes of Health (NIH), grants P30 CA36727 and R01 CA77876 and National Center for Research Resources (NCRR), NIH, grant P20 RR016469. Specifically, PHS found that Dr. Bartsch:

(1) falsified DNA sequence files by deleting a nucleotide and changing nucleotide designations and reported the altered file as the ACI rat *p16Cdkn2a* sequence with a CpG dinucleotide polymorphism in the upstream region to GenBank, in grant application CA118151, and in the poster presented to Cold Spring Harbor Laboratories (CSHL);

(2) fabricated the claim in grant application CA118151 that GenBank entries for the human *p16Cdkn2a* gene had a CpG polymorphism near the transcription start site; and

(3) falsified the differential methylation of CpG dinucleotides near the transcription start site of *p16Cdkn2a* DNA and reported that tumor tissue was more methylated than normal tissue in ACI rats treated with estrogen and that the ACI allele was more methylated than the BN allele in tumor tissue from (BN x ACI)_{F₁} animals treated with estrogen in grant application CA118151.

Dr. Bartsch has entered into a Voluntary Exclusion Agreement (Agreement) in which she neither admitted nor denied ORI's finding of scientific misconduct; the settlement was not an admission of liability on the part of the respondent. In accordance with the terms of the Agreement, she has voluntarily agreed, beginning on April, 15, 2008:

(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 referred to as "covered transactions" pursuant to HHS' Implementation (2 C.F.R. Part 376 *et seq.*) of OMB Guidelines to Agencies on Government-wide Debarment and Suspension (2 C.F.R. Part 180) for a period of two (2) years; and

(2) to exclude herself permanently from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant or contractor to PHS for a period of three (3) years.

Roxana Gonzalez, Carnegie Mellon University: Based on reports submitted by Carnegie Mellon University's (CMU's) inquiry and investigation committees, the respondent's own admission in sworn testimony, and additional analysis conducted by the Office of Research Integrity (ORI) during its oversight review, the U.S. Public Health Service (PHS) found that Roxana Gonzalez, graduate student, Department of Social and Decision Sciences and Psychology, CMU, engaged in scientific misconduct in research supported by National Institute of Mental Health (NIMH), National Institutes of Health (NIH), grants R01 MH56880, R03 MH62376, and R24 MH67346. Specifically, PHS found that Ms. Gonzalez engaged in the following acts of scientific misconduct:

(1) Respondent altered the main dependent variable (life events; life expectation) in the electronic file and the manipulation check variables for ease-of-thought generation so that the reported study results are largely unsupported in:

(a) Publication: Lerner, J.S., & Gonzalez, R.M. "Forecasting one's future based on fleeting subjective experiences." *Personality and Social Psychology Bulletin* 31:454-466, 2005;

(b) 2005 Manuscript: Lerner, J.S., & Gonzalez, R.M. "On perceiving the self as triumphant when happy or angry"; and

(c) Review Article: Lerner J.S., Tiedens, L.Z., & Gonzalez, R.M. "Portrait of the angry decision maker: How appraisal tendencies shape anger's influence on cognition." *Journal of Behavioral Decision Making: Special Issue on Emotion and Decision Making*.

(2) Respondent falsified cortisol values, and possibly cardiovascular measures and optimistic appraisals (as measured by LOT), so that a large portion of the mediation analyses of Table 3 does not reflect the data actually collected and analyzed for the study reported in a publication (Lerner, J.S., Gonzalez, R.M., Dahl, R.E., Hariri, A.R., & Taylor, S.E. "Facial expressions of emotion reveal neuroendocrine and cardiovascular stress responses." *Biological Psychiatry* 58:743-750, 2005). Respondent further allowed one of her collaborators to report the results from this study at the Annual Meeting of the American Psychological Society held in Los Angeles, California, in May 2005, although respondent's collaborator did not know at the time that the results were tainted by respondent's acts of research misconduct.

(3) Respondent falsified the analyses based on participants' responses to the manipulation check items (including the data for self-reported fear) in a study reported in a publication (Fischhoff, B., Gonzalez, R.M., Lerner, J.S., & Small,

D.A. "Evolving judgments of terrorism's risks: Foresight, hindsight, and emotion." *Journal of Experimental Psychology: Applied* 11:124-139, 2005.

(4) Respondent falsified the main dependent variable (reservation price, BDM) in the electronic file for 48 of the 175 subjects participating in a study reported in a 2005 manuscript (Lerner, J.S., Gonzalez, R.M., Small, D.A., Lowenstein, G., & Dahl, R.E. "Emotional influence on economic behavior among adolescents"). Respondent directed the alteration of the paper files for those subjects in order to match the altered electronic file. One of the respondent's collaborators included a qualitative description of the results of the research that is the subject of this study in an NIH grant application, although the respondent's collaborator did not know at the time that the results were tainted by the respondent's acts of research misconduct.

ORI acknowledges Ms. Gonzalez' extensive cooperation with CMU's research misconduct proceedings.

Ms. Gonzalez has entered into a Voluntary Exclusion Agreement (Agreement) in which she has voluntarily agreed, beginning on June 26, 2008:

(1) to exclude herself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant or contractor to PHS, for a period of three (3) years;

(2) that for a period of three (3) years, any institution that submits an application for PHS support for a research project on which the respondent's participation is proposed or that uses the respondent in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which the respondent is involved, must concurrently submit a plan for supervision of the respondent's duties to the funding agency for approval; the supervisory plan must be designed to ensure the scientific integrity of the respondent's research contribution; the respondent agrees to ensure that a copy of the supervisory plan is also submitted to ORI by the institution; the respondent agrees that she will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI;

(3) for a period of three (3) years to ensure that any institution employing her submits, in conjunction with each application for PHS funds or report, manuscript, or abstract of PHS-funded research in which the respondent is involved, a certification that the data provided by the respondent are based on actual experiments or are otherwise legitimately derived, and that the data, procedures, analyses, and methodology are accurately reported in the

application, report, manuscript, or abstract; the respondent must ensure that the institution sends a copy of the certification to ORI; and

(4) to write ORI-approved letters to:

(a) collaborators/coauthors of the manuscripts and published papers cited above, stating what she falsified/fabricated and offering restitution; and

(b) editors of the journals in which papers were published (even if they have been retracted/corrected) to state that her falsifications/fabrications were the underlying reason for the retraction/correction.

Peili Gu, Ph.D., Baylor College of Medicine: Based on the report of an investigation conducted by the Baylor College of Medicine (BCM) and an initial review conducted by the Office of Research Integrity (ORI), the U.S. Public Health Service (PHS) found that Dr. Peili Gu, former postdoctoral researcher, Department of Molecular and Cellular Biology, BCM, engaged in scientific misconduct in research supported by National Institute of Diabetes and Kidney Diseases (NIDDK), National Institutes of Health (NIH), grant R01 DK073524, National Institute of Child Health and Human Development (NICHD), NIH, grants T32 HD07165 and U54 HD07495, and National Institute of General Medical Sciences (NIGMS), NIH, grant R01 GM066099.

ORI acknowledges Dr. Gu's full cooperation with the BCM misconduct proceedings.

Specifically, PHS found that the respondent committed misconduct in science with respect to reporting falsified data in the following three papers:

(1) Gu, P., LeMenuet, D., Chung, A., & Cooney, A.J. "Differential Recruitment of Methylated CpG Binding Domains [MBDs] by the Orphan Receptor GCNF Initiates the Repression and Silencing of Oct4 Expression." *Molecular and Cellular Biology* 26(24):9471-9483, December 2006 (hereafter referred to as the "MBD paper"):

(a) Respondent falsified the relative expression level of Oct4 in differentiated P19 cells and embryonic stem cells treated with MBD2 and MBD3 small interfering RNA presented in Figures 5E and 6E, respectively.

(b) Respondent falsified Figure 6A depicting wild-type and GCNF-/-embryonic stem cells to compare the binding of GCNF, MBD2, and

MBD3 to the Oct4 gene and the measurement of expression at the RNA and protein levels by deleting in Photoshop the GCNF Western blot data in the GCNF^{-/-} cells (to match the lack of expression at the RNA level) and falsified the MBD 2 Western blot data in the GCNF^{-/-} cells (or that depicted in Figure 7C, which shows the exact same data but reportedly from DNA methylation-deficient embryonic stem cells [Dnmt3A/Dnmt3B/ES cells]).

(c) Respondent falsified the MBD2 wild-type and GCNF^{-/-}-chromatin Immunoprecipitation (ChIP) data in Figure 6B.

(2) Gu, P., Morgan, D.H., Sattar, M., Xu, X., Wagner, R., Raviscioni, M., Lichtarge, O., & Cooney, A.J. "Evolutionary Trace-Based Peptides Identify a Novel Asymmetric Interaction that Mediates Oligomerization in Nuclear Receptors." *Journal of Biological Chemistry* 280(36):31818-31829, September 2005:

(a) In Figures 3C and 3D, depicting transfected wild-type and mutated HA-GCNF expression levels in undifferentiated and differentiated P19 cells, respondent planned not to show the data for the Asp307 mutant (the data for the Asp307 mutant were deleted in panel D); however, she falsified Figure 3C by deleting the least intensive band instead of the Asp307 mutant in order to make the overall data appear more consistent and support the claim that there were no significant differences in the expression levels between the GCNF mutants and the wild-type HA-GCNF in P19 cells.

(b) In Figure 4A, where the respondent intended not to show the data for the Asp307 mutant, she falsified the reported results by deleting the least intensive band instead of the Asp307 mutant in order to make the overall data appear more consistent in support of the claim that all mutants were expressed at similar levels in COS1 cells and that the various point mutations had not altered the stability of the protein.

(c) Respondent falsified Figures 4C and 4D depicting supershift of HA-GCNF homodimers expressed in COS1 cells using anti-GCNF and anti-HA antibodies, respectively, by inserting non-specific bands in each of three lanes of each figure where non-specific bands were not visible in the original data.

(d) Respondent falsified Figure 5A, which reported the detection of HA-GCNF point mutant expression in retinoic acid-differentiated P19 cells by Western blot with anti-HA antibody, by duplicating a series of lanes in the published figure: Lane 2 is the same as lane 4; lane 3 is the same as lanes 5, 7, and 9; and lane 6 is the same as lanes 8, 10, and 11.

(e) Respondent falsified Figure 6C, which reported on the dimerization abilities of various GCNF mutants, by cutting and pasting (in Photoshop) bands into original lanes 7 and 8 to demonstrate the homodimer; certain of the comparisons reported in the text describing this figure do not appear to be confirmed in a repeat experiment.

(3) Gu, P., LeMenuet, D., Chung, A., Mancini, M., Wheeler, D., & Cooney, A.J. Orphan Nuclear Receptor GCNF Is Required for the Repression of Pluripotency Genes during Retinoic Acid-Induced Embryonic Stem Cell Differentiation." *Molecular and Cellular Biology* 25(19):8507-8519, October 2005:

(a) Respondent falsified Figure 1A by cutting out lanes and relocating them, wild-type GCNF lanes 7 and 8 of the original data becoming lanes 1 and 2 in the published figure; the effect of the falsification was to demonstrate the inverse correlation with expression of Oct4, which did not appear to be confirmed in a repeat of the experiment.

(b) Respondent falsified Figure 4A by switching the 6-hour and 12-hour Oct4 expression data in the wild-type embryonic stem cells (these falsified data also appear in Figure 5B).

Dr. Gu has entered into a Voluntary Settlement Agreement (Agreement) in which she has voluntarily agreed, for a period of three (3) years, beginning on September 12, 2008:

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

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

Dr. Gu also agreed that she would immediately cooperate with BCM officials to request retraction of the MBD paper. In the retraction letter, she will state that she alone was responsible for the falsification and fabrication of some of the data reported in the paper.

J. Keith Hampton, St. Luke's Hospital: Based on the report of an investigation conducted by St. Luke's Hospital (SLH) in Chesterfield, MO, and additional analysis conducted by the Office of Research Integrity (ORI) during its oversight review, the U.S. Public Health Service (PHS) found that J. Keith Hampton, MSN, APRN, former Clinical Research Associate, SLH, engaged in scientific misconduct in research supported by National Cancer Institute (NCI), National Institutes of Health (NIH), awards U10 CA69651, U10 CA12027, and U10 CA33601.

PHS found that Mr. Hampton engaged in scientific misconduct by falsifying and fabricating data that were reported to the National Surgical Adjuvant Breast & Bowel Project (NSABP) and Cancer and Leukemia Group B (CALGB) cooperative research groups.

Specifically, PHS found that:

(1) For protocol CALGB 90206, the respondent:

(a) falsified a patient's CT scan reports and registration forms and reported the falsified CT scan reports and registration worksheet to CALGB; and

(b) falsified a patient's performance status records (giving 80% performance status) and registration forms and reported the falsified performance status report and registration form to CALGB.

(2) For protocol NSABP B-35, the respondent:

(a) falsified eligibility data related to hematology and chemistry assays and to the performance of a pelvic exam on one patient's registration form and reported the falsified registration forms to the National Cancer Institute Cancer Trial Support Unit (CTSU);

(b) falsified pelvic exam eligibility on a second patient's registration form and reported the falsified registration form to the CTSU; and

(c) falsified hematology and chemistry assay eligibility on a third patient's registration form and reported the falsified registration form to the CTSU.

(3) For protocol NSABP B-36, the respondent falsified a patient's multigated acquisition test (MUGA – a test of heart function) records, cardiac function, and registration forms, certified the patient's eligibility, and reported the falsified MUGA test, cardiac function, and registration forms to the CTSU.

(4) For protocol NSABP B-38, the respondent falsified hematology, chemistry, and MUGA eligibility for a patient on the registration form and reported the falsified registration form to the CTSU.

(5) For protocol NSABP C-08, the respondent:

(a) falsified urine protein/creatinine ratio eligibility for one patient on the registration form and reported the falsified registration form to the CTSU;

(b) falsified urine protein/creatinine ratio eligibility for a second patient on the registration form and reported the falsified registration form to the CTSU; and

(c) falsified claims of the urine protein/creatinine ratio and PT(INR) eligibility on a third patient's registration form and reported the falsified registration form to the CTSU.

(6) For protocol NSABP R-04, the respondent falsified a patient's colonoscopy report and eligibility at registration and reported the falsified colonoscopy report and registration form to the CTSU.

Mr. Hampton has entered into a Voluntary Exclusion Agreement (Agreement) in which he has voluntarily agreed for a period of three (3) years, beginning on June 17, 2008:

(1) to exclude himself 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" pursuant to HHS' Implementation (2 C.F.R. Part 376 *et seq.*) of OMB Guidelines to Agencies on Government-wide Debarment and Suspension (2 C.F.R. Part 180); and

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

Scott E. Monte, Huntington Memorial Hospital: Based on the findings of an investigation conducted by Huntington Memorial Hospital (HMH) and information obtained by the Office of Research Integrity (ORI) during its oversight review, the U.S. Public Health Service (PHS) found that Scott E. Monte, L.V.N., former Clinical Research Associate, HMH, engaged in scientific misconduct by knowingly and intentionally falsifying and fabricating clinical

research records in HMH cancer prevention and treatment protocols supported by National Cancer Institute (NCI), National Institutes of Health (NIH), awards U10 CA69651, U10 CA12027, U10 CA32012, and U10 CA86004. Specifically, Mr. Monte knowingly and intentionally:

- (1) entered falsified and fabricated laboratory data or physical examination results on five research protocol case report forms (CRFs);
- (2) falsified a gynecological examination report in a physician's progress note and entered the falsified document in the patient's research chart; and
- (3) fabricated progress notes for four patients and a case report form for one of these patients.

ORI has implemented the following administrative actions for a period of three (3) years, beginning on January 7, 2008:

- (1) Dr. Monte is 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 pursuant to HHS' implementation of the OMB Guidelines to Agencies on Government-wide Debarment and Suspension at 2 C.F.R. Part 376; and
- (2) Dr. Monte is prohibited from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

Kirk Sperber, Mount Sinai School of Medicine: Based on the report of an investigation conducted by the Mount Sinai School of Medicine (MSSM) and additional analysis conducted by the Office of Research Integrity (ORI) in its oversight review, the U.S. Public Health Service (PHS) found that Dr. Kirk Sperber, former Associate Professor, Department of Medicine, Division of Clinical Immunology, MSSM, engaged in scientific misconduct while supported by National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), grants R01 AI45343 and P01 AI44236, and National Cancer Institute, NIH, grant R29 CA256990.

PHS found the respondent engaged in scientific misconduct by falsifying and fabricating data that were included in NIAID, NIH, grant applications R01 AI45343-01A1, R01 AI45343-04A2, and P01 AI44236-05. Respondent's scientific misconduct occurred while he was a faculty member at MSSM. Respondent is no longer employed at MSSM. Specifically, PHS found that the respondent

engaged in scientific misconduct by falsifying and fabricating data in the following publications:

(1) In multiple figures reported in Sperber, K., Beuria, P., Singha, N., Gelman, I., Cortes, P., Chen, H., & Kraus, T. "Induction of Apoptosis by HIV-1-infected Monocytic Cells." *Journal of Immunology* 170:1566-1578, 2003 (2003 *Journal of Immunology* paper) (retracted in December 2005), by duplicating and reusing panels of FACS data in Figures 1A, 2, 4A, 4B, and 7; by duplicating and reusing lanes of polyacrylamide gels in Figure 3, of Western blot analyses in Figures 5A, 5C, 6C, and 9, and of agarose gels in PCR analyses in Figure 5B; and by duplicating and reusing laser confocal micrographs in Figures 10 and 11. Respondent's claims that Figures 1A, 2, 4A, and 7 were representative of experiments repeated five times and that Figures 3, 4B, 5A, 6C, and 9 were representative of experiments repeated three times constitute additional falsifications. The effect of these misrepresentations was to falsely demonstrate the proapoptotic activity of a protein from a novel cDNA clone isolated from an HIV-infected human macrophage cell line and to falsify its presence in brain and lymphoid tissue from patients with HIV-associated dementia.

(2) In Figure 10 reported in Rakoff-Nahoum, S., Chen, H., Kraus, T., George, I., Oei, E., Tyorlin, M., Salik, E., Beuria, P., & Sperber, K. "Regulation of Class II Expression in Monocytic Cells after HIV-1 Infection." *Journal of Immunology* 167:2331-2342, 2001 (retracted in November 2006), by duplicating and reusing four confocal micrographs to misrepresent different panels for the Cath D, 43pol and CD-63, 43neve data; for the Cath D, 43gag and Cath D, 43nef data; for the DAMP, 43 nef and M6PR, 43nef data; and for the M6PR, 43gag and the CD-63, 43gag data. Respondent's reported claim that the results were representative of an experiment repeated five times constitutes an additional falsification.

(3) In Figures 3B, 4B, and 6B reporting flow cytometry analyses (FACS) in Chen, H., Yip, Y.K., George, I., Tyorkin, M., Salik, E., & Sperber, K. "Chronically HIV-1-Infected Monocytic Cells Induce Apoptosis in Cocultured T Cells." *Journal of Immunology* 161:4257-4267, 1998 (retracted in November 2006), by reusing two FACS histograms, each to represent two different experiments in Figure 3B; by reusing the same FACS histogram as the negative control for CD-4 cells and for the CD-8 cells in Figure 4B; and by duplicating the top two panels, the middle two panels, and the bottom two panels of data as graded dilutions of different fractions in Figure 6B to falsely show that a soluble factor from 43 HIV cells induced apoptosis. Figure 6B was also presented in grant application AI45343-01A1 as Figure 5B. Respondent's reported claims that the results in Figures 3B, 4B, and 6B were each representative of experiments that were repeated three times constitutes additional falsifications.

PHS also finds that the respondent engaged in scientific misconduct by falsifying and fabricating the following data in NIAID, NIH, research applications R01 AI45343-04A2 and P01 AI44236-05:

(4) The results of Figures 1, 6C, 7, 9, 10, and 11 from the 2003 *Journal of Immunology* paper were reported in NIAID, NIH, grant application R01 AI45343-04A2; nearly all of the figures in the paper were falsified, so that the claims in the grant application derived from those figures were also false.

(5) Two figures in NIAID, NIH, grant application P01 AI44236-05 contained falsified data: In Figure 1b, panels of confocal microscopy images of intestinal biopsies from four patients were falsified by duplication; and in Figure 3, one panel of PCR data was duplicated and similarly misrepresented as data from the same four biopsy specimens.

Dr. Sperber has entered into a Voluntary Exclusion Agreement in which he neither admitted nor denied HHS' findings of scientific misconduct. However, he recognized that if this matter were to proceed to an administrative hearing, there is sufficient evidence upon which an Administrative Law Judge could make findings of scientific misconduct against him.

Dr. Sperber agreed not to contest or appeal the jurisdiction of the PHS or HHS findings of scientific misconduct as set forth above and in the MSSM report. Dr. Sperber has voluntarily agreed, for a period of four years, beginning on September 12, 2008:

(1) to exclude himself 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 pursuant to HHS' Implementation (2 C.F.R. Part 376 *et seq.*) of OMB Guidelines to Agencies on Government-wide Debarment and Suspension (2 C.F.R. Part 180); and

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

Homer D. Venters, Jr., M.D., University of Illinois at Urbana-Champaign:

Based on the report of an investigation conducted by the University of Illinois at Urbana-Champaign (UIUC) and extensive additional image analysis conducted by the Office of Research Integrity (ORI), the U.S. Public Health Service (PHS) found that Dr. Homer D. Venters, former graduate student, Neuroscience Program, UIUC, engaged in scientific misconduct in research

supported by National Institute of Mental Health (NIMH), National Institutes of Health (NIH), awards R01 MH051569 and F30 MH12558 and National Institute on Aging (NIA), NIH, award R01 AG06246. Specifically, PHS found that the respondent committed misconduct in science:

(1) by intentionally and knowingly preparing and including duplicate image data in Figures 5 and 10 of PHS fellowship application F31 MH12558, "Neurodegeneration via TNF-alpha Inhibition of IGF-1," submitted in 1999, which was funded as F30 MH12558 from June 1, 2000, to May 31, 2003. Because the duplicate data were labeled as having been obtained from different experiments, the results for at least one of the two figures were intentionally falsified and constitute an act of scientific misconduct.

(2) by intentionally and knowingly preparing and including duplicate image data in Figures 3 and/or 4 of a manuscript submitted and published as: Venters, H.D., et al. "A New Mechanism of Neurodegeneration: A Proinflammatory Cytokine Inhibits Receptor Signaling by a Survival Peptide." *Proceedings of the National Academy of Sciences U.S.A.* 96:9879-9884, 1999.

(3) by preparing and providing to his dissertation committee in March 2000 a thesis proposal entitled "An Alternate Mechanism of Neurodegeneration: Silencing of Insulin-like Growth Factor-I Survival Signals by Tumor Necrosis Factor- α ," which contained five falsified figures: Figures 1.3, 1.4a, 2.1b, 2.3e, and 2.5b. In each figure, he reused data within the same figure or in another thesis proposal figure as representing differently treated samples or as data obtained with different immunoblotting antisera.

(4) in March and April 2001, the respondent included several of the same falsified figures as in the thesis proposal and multiple additional falsified figures in his dissertation "Silencing of Insulin-like Growth Factor I Neuronal Survival Signals by Tumor Necrosis Factor-alpha." In all, Figures 3.3, 3.4a, 3.4b, 4.1b, 4.3a, 4.5b, 5.1a, 5.2, 5.4a, 5.5a, 5.6a, 5.7a, and 5.8a were falsified. In each instance, he assembled figures by reusing significant data, on some occasions after manipulating the orientation of the data, either within the same figure or in other figures related to his thesis, and represented the data falsely as coming from different samples or different experiments.

Dr. Venters has entered into a Voluntary Settlement Agreement (Agreement) in which he has voluntarily agreed, for a period of three (3) years, beginning on November 19, 2008:

(1) that any institution that submits an application for PHS support for a research project on which the respondent's participation is proposed or that

uses the respondent in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which the respondent is involved, must concurrently submit a plan for monitoring of the respondent's research to the funding agency and ORI for approval; the monitoring plan must be designed to ensure the scientific integrity of the respondent's research contribution; the respondent agreed that he will not participate in any PHS-supported research until such a monitoring plan is submitted to ORI and the funding agency;

(2) that the respondent will ensure that any institution employing him will submit to ORI, in conjunction with each application for PHS funds or report, manuscript, or abstract of PHS-funded research in which the respondent is involved, a certification that the data provided by the respondent are based on actual experiments or are otherwise legitimately derived, and that the data analyses, procedures, and methodology are accurately reported in the application or report; the respondent must ensure that the institution sends a copy of each certification to ORI;

(3) to exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant or contractor to PHS. Respondent also voluntarily agreed that within 30 days of the effective date of this Agreement:

(4) that he will submit a letter to the journal editor, with copies to his coauthors, identifying his falsification of Figures 3 and/or 4 in the following article:
Venters et al. "A New Mechanism of Neurodegeneration: A Proinflammatory Cytokine Inhibits Receptor Signaling by a Survival Peptide." *Proceedings of the National Academy of Sciences* 96:9879-9884, 1999.

Jusan Yang, M.S., M.D., University of Iowa: Based on the report of an investigation conducted by the University of Iowa (UI) and additional analysis conducted by the Office of Research Integrity (ORI) in its oversight review, this settlement resolves proposed U.S. Public Health Service (PHS) findings that Dr. Jusan Yang, former Assistant Research Scientist, UI, engaged in scientific misconduct in research supported by National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grant R01 HL48058. PHS found the respondent engaged in scientific misconduct by falsifying and fabricating data that were reported in a scientific manuscript intended for publication entitled "Increased Renin Transcription after Inhibition of NF- κ B with Rnai

Reveals through Regulation of Ea Element and Ear2" and at two professional scientific meetings. Specifically, PHS found that:

(1) Respondent falsified Figure 1 in the manuscript that purports to show the effectiveness of four plasmids targeting different parts of the NF-Y coding sequence in inhibiting NF-Y expression by:

(a) claiming in Figure 1A that the loading control bands were obtained by reprobing a Western blot with antibody to GAPDH when he used a prominent background (non-specific) band from the blot probed with antibody to NF-YA;

(b) inappropriately enhancing and manipulating the NF-YA band in Figure 1A claiming decreased expression of NF-YA in cultures transfected with two of the four constructs; and

(c) falsely claiming in Figure 1B that the quantitative data for NF-YA expression obtained by scanning Western blot films were based on an n of 4 and that the expression of NF-YA in cultures treated with two constructs was statistically significantly lower than the control. Versions of the same falsified blot and histogram also were reported in several of the respondent's public presentations.

(2) Respondent falsified Figures 4, 5, 6, and 8 in the manuscript by claiming in the figure legends that four independent repetitions contributed to each figure's results when the actual numbers of repetitions were n=3 for Figure 4, n=1 for Figure 5, n=3 for Figure 6, and n=2 for Figure 8; in Figure 5, error bars based on the Student's t test further falsely claim that n was >2. He further falsified Figures 6 and 8 by reporting smaller standard errors of the mean than were obtained from the actual data, thereby giving an enhanced impression of rigor for the reported experiments.

Respondent reported Figures 5, 6, and 8 (without legends) at the American Heart Association Council for High Blood Pressure meeting in September 2003, and he reported Figures 5 and 8 at the Experimental Biology meeting in April 2004.

Respondent stated that he does not intend to apply for or engage in PHS-supported research. However, if such a circumstance were to arise, the respondent agreed for a period of five (5) years, beginning on October 14, 2008:

(1) that any institution that submits an application for PHS support for a research project on which the respondent's participation is proposed or which uses him in any capacity on PHS support research, or that submits a report of

PHS-funded research in which he is involved, must concurrently submit a plan for supervision of the respondent's duties to the funding agency for approval; the supervisory plan must be designed to ensure the scientific integrity of the respondent's research contribution; the respondent agreed to ensure that a copy of the supervisory plan is also submitted to ORI by the institution; and the respondent agreed that he will not participate in any PHS-supported research until such a supervision plan is approved by ORI;

(2) that any institution employing the respondent submits, in conjunction with each application for PHS funds or report, manuscript, or abstract of PHS-funded research in which he is involved, a certification that the data provided by the respondent are based on actual experiments or are otherwise legitimately derived, and that the data, procedures, and methodology are accurately reported in the application or report; the respondent must ensure that the institution also sends a copy of the certification to ORI; and

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

Nima Afshar, Ph.D., University of California, San Francisco: Based on a University of California, San Francisco (UCSF) report and respondent's own admission, the U.S. Public Health Service (PHS) found that Dr. Nima Afshar, former postdoctoral fellow at UCSF engaged in research misconduct in research supported by National Cancer Institute (NCI), National Institutes of Health (NIH), grant T32 CA108462 and National Institute of General Medical Sciences (NIGMS), NIH, grant R01 GM59704. PHS found that respondent engaged in research misconduct in the performance of research on yeast to test whether disruption of the tight controls, to prevent re-replication, on the initiation of DNA replication, could produce gene amplifications with a copy number greater than two (2). Specifically, respondent falsified files containing raw scanned microarray images from another researcher's experiments to demonstrate that in experiments that she claimed to have conducted, she successfully observed gene amplifications with a copy number greater than two (2); there were 36 such instances of falsifying data files.

Dr. Afshar has entered into a Voluntary Settlement Agreement in which she has voluntarily agreed, for a period of three (3) years, beginning on December 22, 2008:

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

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

M. Nguyen, M.D., University of California, Los Angeles: Based on a University of California, Los Angeles (UCLA) report and respondent's own admission, the U.S. Public Health Service (PHS) found that Dr. M. Nguyen, former Associate Professor at UCLA, engaged in scientific misconduct in research supported by National Cancer Institute (NCI), National Institutes of Health (NIH), grant 1 R01 CA69433, National Center for Complementary and Alternative Medicine (NCCAM), NIH, grant 1 P50 AT00151-01, and National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH, grant T32 DK03688. Specifically, PHS found that respondent engaged in scientific misconduct by:

(1) Dr. Nguyen's laboratory conducted a single experiment on the effect of Livistona extract on the growth of 10^6 mouse fibrosarcoma (FSA) cells injected into C3H mice. The drug was administered in the drinking water of the treated mice, and tumor sizes were measured twice weekly with calipers. Dr. Nguyen falsified and fabricated the results of this experiment in Figure 3 of *Oncology Reports* 8:1355-1357, 2001:

(a) The data reported for the control group were from an experiment in nude mice implanted with human breast tumor implants, rather than with mouse fibrosarcoma cell implants, as Dr. Nguyen reported in the paper. The control data for FSA implanted C3H mice could not be located in the laboratory records.

(2) Dr. Nguyen's laboratory conducted a single experiment on the effect of Livistona extract on the growth of 10^8 MDA-MD-231 cells injected into nude mice. The drug was administered in the drinking water of the treated mice, and tumor sizes were measured twice weekly with calipers. Dr. Nguyen

falsified and fabricated the results of this experiment in Figure 9 of NIH grant application P50 AT00151-01, dated May 19, 1999, by:

(a) falsely stating in the associated text that there were ten mice per group and that the experiments were repeated once, while in fact, there were only five mice per group with no repetition of this experiment;

(b) omitting data on the control curve for two of the measurement times (at 2 and 3.5 weeks) and falsely reporting the times at which three other measurements were taken.

(3) Dr. Nguyen's laboratory conducted a single experiment (1998-99) testing the anti-angiogenic effects of *Livistona chinensis* extract on human umbilical vein endothelial cells (HUVEC). HUVEC cells were counted from duplicate wells when exposed to extract, and controls were counted from single wells:

(a) Figure 8 of NIH grant application P50 AT00151-01, dated 5/19/99, plots the data as a bar graph. However, the same data were reported in Figure 1 of *Oncology Reports* 8:1355-1357, 2001, by falsely expressing them as the rate of growth obtained by measuring the uptake of radioactive thymidine into cellular DNA and plotting the data as normalized to control values. UCLA concluded that Figure 1 was falsified by claiming the data were obtained by a state-of-the-art technique not actually employed by the respondent to obtain the data for that figure (Admission). This falsification did not bear upon the findings of the paper.

(4) Dr. Nguyen's laboratory tested whether the levels of bFGF (basic fibroblast growth factor) and VEGF (vascular endothelial growth factor) in nipple fluid aspirates were significantly elevated in breast cancer patients in comparison to values from normal lactating and non-lactating breasts. Dr. Nguyen falsified the number of subjects who were lactating in *The Lancet* 356:567-569, 2000, by claiming that bFGF data were obtained from four separate subjects while in fact the data were from both breasts of two subjects.

Dr. Nyugen has entered into a Voluntary Settlement Agreement with ORI. As part of that Agreement, Dr. Nyugen admits to UCLA's findings of fact but denies ORI's findings that the actions rise to the level of scientific misconduct. The settlement is not an admission of liability on the part of the respondent.

Dr. Nyugen voluntarily agreed, for a period of three (3) years, beginning on December 29, 2008:

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

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

Luk Van Parijs, Harvard Medical School, Brigham and Women's Hospital, California Institute of Technology, and Massachusetts Institute of

Technology: Based on the reports of separate investigations conducted by Harvard Medical School (HMS)/Brigham and Women's Hospital (BWH), California Institute of Technology (CalTech), and Massachusetts Institute of Technology (MIT) and additional analysis conducted by the Office of Research Integrity (ORI) in its oversight review, the U.S. Public Health Service (PHS) found that Dr. Luk Van Parijs, former Graduate Student, Department of Pathology, HMS, former Research Fellow and Instructor of Pathology, BWH, former Postdoctoral Fellow, Department of Biology, CalTech, and former Associate Professor, Department of Biology, Center for Cancer Research, MIT, engaged in scientific misconduct in research supported by National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), grants U19 AI56900, R21 AI49897, R01 AI42100, P01 AI35297, R37 AI25022, R01 AI32531, National Cancer Institute, NIH, grant R01 CA51462, and National Institute of Environmental Health Sciences (NIEHS), NIH, grant P30 ES02109, and National Institute of General Medical Sciences (NIGMS), NIH, grant R01 GM57931. PHS found that respondent engaged in scientific misconduct by including false data in NIAID, NIH, grant applications R01 AI54519-01A1, R01 AI54973-01, and R01 AI54973-01A1, NCI, NIH, grant application 2P30 CA14051-34, and National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH, grant application R21 DK69277-01. Specifically, PHS found that respondent engaged in scientific misconduct by including false data in seven published papers, three submitted papers (with two earlier

versions submitted for one of these), one submitted book chapter, and multiple presentations as follows:

(1) While at HMS/BWH, Dr. Luk Van Parijs falsified the expression of IFN-gamma and KJ-126 in flow cytometry dot plots for the immunized, naive, tolerized, and tolerized + IL-12 experimental groups in Figure 4, *JEM* 186:1119-1128, 1997, by using the same non-stained cell population in the lower left quadrant to falsely represent CD4+ T cells negative for IFN-gamma and KJ-126 in each experimental group.

(2) That Dr. Luk Van Parijs falsified the expression of different proteins in flow cytometry dot plots in Figure 1, *Immunity*, 8:265-274, 1998, in Figure 1C, *Immunity*, 11:281-288, September 1999, and in Figure 5, *Immunity* 11:763-770, December 1999, by using portions of the same dot plot to represent different cell populations expressing different proteins. Specifically:

(a) While at HMS/BWH, Dr. Van Parijs used portions of the same dot plot to represent T cell populations expressing the 3A9 T cell receptor and CD4+ (top panel) or CD8+ (bottom panel) in 3A9+ (wild type), in 3A9/lpr (Fas-), or in 3A9/gld (FasL-) transgenic mice in Figure 1, *Immunity*, 1998, where:

i. the CD4/3A9 dot plots for the 3A9+ and 3A9/gld transgenic mice were the same, and the 3A9+ dot plot was a subset of the 3A9/lpr dot plot; and

ii. the CD8/3A9 dot plots for the 3A9+ and 3A9/lpr transgenic mice were the same in the lower left and lower right quadrants, and the 3A9/gld dot plot was a subset of the wild-type dot plot.

(b) While at CalTech, Dr. Van Parijs used portions of the same dot plot to represent the expression of hIL-2Rbeta and GFP in T cells infected with WT or Delta 355+8F IL-2R mutant in Figure 1C, *Immunity*, September 1999, where the Delta 355+8F dot plot was a subset of the WT dot plot.

(c) While at CalTech, Dr. Van Parijs used portions of the same dot plot to represent the expression of B220 and IgM in infected (GFP+) and not infected (GFP-) spleen cells isolated from reconstituted mice in Figure 5, *Immunity*, December 1999, where the Infected (GFP+) dot plot for control mice was a subset of the not infected (GFP-) dot plot for FLIP mice.

(3) While at MIT, Dr. Luk Van Parijs falsely claimed in the text of *RNA Interference Technology* (Cambridge University Press, July 2004) and in Figure 2 of *Nature Genetics* 33:401-406 (2003) that experiments depicting the functional

silencing of genes in hematopoietic stem cells (HSCs) and in non-cycling dendritic cells by lentiviral-mediated RNAi were performed, when they were not. Specifically, in *Nature Genetics*:

(a) Figure 2b falsely showed the transduction of bone marrow-derived dendritic cells infected with pLL3.7 Bim by flow cytometry, and knockdown of Bim expression by Western blot.

(b) Figure 2d falsely showed the efficiency of pLL3.7 CD8 lentiviral infection in HSCs by flow cytometry for GFP expression (left panel), and falsely showed stable gene expression in progeny by flow cytometry for GFP expression in spleen cells from chimeras derived from infected HSCs (right panel).

(c) Figure 2e falsely showed the reduction of CD8+ T cells in spleen cells from chimeras derived from pLL3.7 CD8 infected HSCs (right panel) and controls (left panel).

(4) While at MIT, Dr. Luk Van Parijs falsified figures in grant applications submitted to the National Institutes of Health (NIH), a presentation in 2003, and Figure 6A, *Immunity* 19:243-255 (2003), by falsely claiming that the image in the figure represented an immunoprecipitation assay for Ras-GTP and a Western blot for total Ras protein, when it actually represented a Western blot for Bcl-2 and beta-actin in T cells, previously published as Figure 5C, *J. Immunol.*, 168:597-603 (2002).

Dr. Van Parijs also admitted to falsification or fabrication of data in multiple submitted manuscripts, grant applications submitted to NIH, and presentations as follows:

(5) While at MIT, Dr. Luk Van Parijs admitted that in multiple presentations and submitted manuscripts in 2004, he falsely claimed that the bifunctional lentiviral vectors, U6-shRNA-rat insulin promoter (RIP)-Myc had been made, when they had not, and that transgenic mice carrying these lentiviral vectors with shRNA silencing Bim or Pten proteins in pancreatic cells showed accelerated tumorigenesis and death.

(6) While at MIT, Dr. Luk Van Parijs admitted that in multiple presentations in 2003 and 2004 and in grant application R21 DK69277-01 submitted to NIH in 2003, he falsely claimed that the number of CD8+ T cells and the incidence of diabetes was reduced by silencing CD8 expression with the pLL3.7 CD8 lentivirus in non-obese diabetic (NOD) transgenic mice, when the NOD transgenic mice data did not exist.

(7) While at MIT, Dr. Luk Van Parijs admitted that in multiple presentations, submitted manuscripts, and grant applications submitted to NIH in 2004, he falsely claimed that transgenic mice had been generated with the mono-functional lentiviral vectors with c-Myc, Ras, or Akt under the control of the CD4 promoter, when they had not, and that transgenic mice had been generated with the bi-functional lentiviral vectors with CD4-c-Myc, Ras, or Akt- and U6-shRNAs targeting luciferase, Bcl-2, or Bim proteins, when they had not. The effect of these misrepresentations was the reported false conclusion that a cytokine-stimulated proto-oncogene network regulated CD4+ T-cell survival and responses to foreign and self antigens.

(8) While at MIT, Dr. Luk Van Parijs admitted that in presentations and submitted manuscripts in 2004, he falsely claimed that mice injected with plasmids carrying shRNAs for Bcl-2, Akt1, and Akt2, complexed to polyethylene imine (PEI), showed a significant reduction in c-Myc-induced tumor growth, when the experiments had not been done.

(9) While at MIT, Dr. Luk Van Parijs admitted that in presentations in 2004, he falsely claimed that shRNAs designed using algorithms developed in 2004 were more effective to silence target genes than the shRNAs designed with algorithms in 2002.

(10) While at MIT, Dr. Luk Van Parijs admitted that in multiple presentations, submitted manuscripts, a grant application submitted to NIH, and in the text of *Current Opinions in Molec. Therapeutics*, 6:136, 2004, he falsely claimed that an in vivo RNAi screen was developed to identify genes in cytokine and apoptosis pathways that accelerated or suppressed Myc-induced tumorigenesis in lethally irradiated mice, by using bi-functional lentiviral vectors that expressed c-Myc under control of the CMV enhancer-beta-actin promoter (CAG) and U6-driven shRNAs designed to silence 168 selected genes, when the experiments had not been done.

(11) While at MIT, Dr. Luk Van Parijs admitted that in a submitted manuscript in 2004 and a grant application submitted to NIH in 2003, he falsely claimed that with the use of retroviral vectors with Bim and activated Ras, Akt, or Myc, he showed that the IL-2-stimulated activation of proto-oncogene pathways functioned to promote the survival of T cells following antigen encounter by regulating Bim and Bcl-2 pathways, when the experiments that were performed were inconclusive.

Dr. Van Parijs has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed, for a period of five (5) years, beginning on December 22, 2008:

(1) to exclude himself 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” pursuant to HHS’ implementation (2 C.F.R. Part 376 *et seq.*) of OMB Guidelines to Agencies on Government-wide Debarment and Suspension (2 C.F.R. Part 180); and

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



Office of
**Research
Integrity**

2008 ANNUAL REPORT

OFFICE OF RESEARCH INTEGRITY
OFFICE OF PUBLIC HEALTH AND SCIENCE
OFFICE OF THE SECRETARY
US DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, SW
Washington, DC 20201