

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

# Office of Research Integrity

## Annual Report

### 2010



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## I. ORI HIGHLIGHTS OF CY 2010

The Office of Research Integrity (ORI) is a component of the Office of the Assistant Secretary for Health in the Office of the Secretary within the US 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 US Public Health Service (PHS); (2) education in the responsible conduct of research (RCR); (3) prevention of research misconduct; and (4) compliance with PHS Policies on Research Misconduct, 42 CFR Part 93 (“PHS regulation”). The ORI is composed of the Division of Investigative Oversight (DIO) and the Division of Education and Integrity (DEI) and receives legal assistance from HHS Office of the General Counsel (OGC).

### **Division of Investigative Oversight: Responding to Misconduct Allegations**

- In 2010, ORI opened 28 new cases and closed 31 cases, with 23 cases remaining open at the end of the calendar year, down from 27 remaining open at the end of 2009 or approximately a 15 percent decrease.
- Of the 31 cases closed by ORI, 9 cases resulted in sustained findings of research misconduct and/or PHS administrative actions against the respondents. DIO completed oversight review on a number of additional cases, including negotiating settlement agreements and providing litigation support in HHS administrative hearings. DIO staff assisted OGC in seeking voluntary settlements or producing charge documents to bring these cases to closure as well. In 1 of the cases, the PHS administrative actions included debarment for 7 years; another debarment was for 5 years, and 2 were for 3 years.
- Supervisory plans were utilized as administrative actions in several additional cases. Five respondents agreed to a 3 year period of supervision. In all of the ORI 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.
- 29% of the closed cases had a finding of research misconduct (9/31). This figure is somewhat lower than the historical average of 36 percent.

Of the 23 cases remaining open at the end of 2009, as well as the approximately 65 accessions not yet opened as cases, a large majority involved substantive allegations likely to lead to findings of research misconduct by the institutions conducting inquiries and investigations. It must be noted, however, that for a number of reasons such as; the insufficiency of the evidence, unavailability of witnesses, and other considerations, ORI does not always make findings of research misconduct when institutions do.

- ORI received 155 allegations in 2010, well below the 1992-2007 average of 198. For the 31 cases closed by ORI in 2010, institutions took a mean of 9 months after notifying ORI of the allegation to close its institutional case; ORI took a mean of 7.2 months to review the reports, obtain additional information from the institution, complete the ORI analysis, negotiate any PHS findings and administrative actions, and close these cases.
- ORI provided Rapid Response for Technical Assistance (RRTA) on 43 occasions in 2010, below the 71 instances in 2009. 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 and anonymous complainants requesting guidance on how to proceed with complaints.

### **Division of Education and Integrity: Fostering Education and Research to Promote Research Integrity**

- In 2010, ORI sponsored 3 regional conferences, a RIO Boot Camp, actively participated in 3 in-kind meetings and also in the 2<sup>nd</sup> World Conference on Research Integrity, an international conference held in Singapore.
- The ORI staff made 39 presentations during 2010.
- The ORI website ([ori.hhs.gov/](http://ori.hhs.gov/)) received 480,390 page views from 160,320 visits in 2010. The site was visited by 113,848 users from 184 countries. Respectively, the top 10 countries visiting the ORI site were: the US, Canada, United Kingdom, Australia, India, China, Japan, Germany, Spain, and Taiwan.
- Will Interactive has completed making the Interactive Video: “*THE LAB: Avoiding Research Misconduct*,” and when it has received clearance it is planned for release in 2011. It will be available on the web, as well as being distributed broadly to the US and international educators.
- ORI supported the development of 3 new resources:

Ensuring the Integrity, Accessibility, and Stewardship of Research Data in the Digital Age; National Academy of Sciences, National Academy of Engineering, Institute of Medicine of the National Academies, and The National Academies Press, Washington, DC; 2009; distributed in 2010.

Guide for the Care and Use of Laboratory Animals, Eighth Edition; Committee for the Update of the Guide for the Care and Use of Laboratory Animals; Institute for Laboratory Animal Research, Division on Earth and Life Studies; National Research Council of *The National Academies*; and The National Academies Press; Washington, DC; 2010; distributed in 2010.

The National Academy of Sciences updated book on Scientific Integrity. This is a cooperative effort with other agencies and stakeholders. The committee will meet in 2011 and produce the book by 2012.

- The Research on Research Integrity (RRI) Program in coordination with the National Institutes of Health (NIH), made 2 new awards in 2010. This action increased the number of studies supported in the first 10 years to 55. The studies have produced 110 articles in more than 30 different publications.
- The ORI Intramural Research Program completed the following two studies and papers from these studies will be submitted to peer-reviewed journals:

Mathematica Policy Research, Inc.: “Evaluating Faculty Member’s Views on their Institutions’ Guidance to Faculty Members on their Roles in Advising Ph.D. Candidates.”

Research Triangle Institute International: “Evaluating the Effectiveness of Institutional Efforts to Educate their Staffs on their Policies for Dealing with Research Misconduct and Research Integrity.”

- Institutions receiving research funding from PHS are required to annually report their research activity for the prior year to ORI. In 2010, the 4,122 funded institutions reported 288 allegations, inquiries, or investigations.

## **II. DIO MISSION: RESPONDING TO RESEARCH MISCONDUCT**

All institutions receiving research funds from Public Health Service (PHS) agencies must have on file an assurance with the Office of Research Integrity (ORI). This assurance means the institution promises ORI that it has in place the required policies and procedures for dealing with allegations of research misconduct, 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 an 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 by both PHS awardee-institutions and by the intramural components of PHS agencies. 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 is complete, recommendations for misconduct or no misconduct findings are forwarded to the Director of ORI, who makes the determination on research misconduct. Closure of cases, where research misconduct findings are made, is generally reached through voluntary agreements between the respondent and the US Department of Health and Human Services (HHS).

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

DIO staff organize conferences and workshops on the handling of research misconduct allegations, particularly to provide training for Research Integrity Officers (RIOs). The training is focused on larger institutions because they are most likely to receive a majority of the PHS support to conduct research and thus will have an increased likelihood that research misconduct can occur and the cases of research misconduct will need to be reported to ORI.

DIO also provides assistance and advice to institutions on the conduct of inquiries and investigations through the Rapid Response Training Assistance (RRTA) Program. 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.

### **A. Evaluating Allegations: Criteria Involved**

ORI staff assesses each allegation it receives to determine whether it meets the criteria for opening a formal case. 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 CFR Part 50, Subpart A or Part 93).**

For allegations that occurred prior to June 16, 2005, ORI assesses whether the action reported, if found to be true, would represent fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research (42 CFR 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 CFR 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 CFR Part 93.104).

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.

### 3. Plagiarism Definition

Below is ORI's **working definition** of plagiarism in the PHS policies on Research Misconduct 42 CFR Part 93. Institutions may exercise a more stringent definition of plagiarism and take appropriate institutional administrative actions.

#### **From the ORI Newsletter, Volume 15, No. 4, September, 2007:**

*“In its December 1994 newsletter, ORI published a brief note describing how ORI intended to interpret the definition of plagiarism in the PHS regulation (42 C.F.R. Part 50) as applied to ORI cases. A new regulation on “Public Health Service Policies on Research Misconduct” was published in the Federal Register on May 17, 2005, and became final on June 16, 2005 (42 C.F.R. Part 93) (abbreviated as ‘Part 93’ below). In this new regulation plagiarism is defined as “the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.”*

*ORI interpreted its definition of plagiarism to apply to the theft or misappropriation of intellectual property and/or the substantial unattributed textual copying of another’s work. ORI’s interpretation does not include authorship or credit disputes or “self-plagiarism” of one’s work from one paper to another or from a paper to a grant application.*

*ORI has been asked by various institutions and individuals whether this policy is applicable under Part 93. The answer is yes—ORI will continue to exercise a standard that is notably more forgiving than the standard in general use at institutions. There are multiple reasons for this.*

*The most important is the independent authority of an institution to impose additional and stricter standards of behavior on employees. This is explicitly spelled out in §93.319:*

#### *Institutional standards*

*(a) Institutions may have internal standards of conduct different from the HHS standards for research misconduct under this part. Therefore, an institution may find conduct to be actionable under its standards even if the action does not meet this part’s definition of research misconduct.*

*(b) An HHS finding or settlement does not affect institutional findings or administrative actions based on an institution’s internal standards of conduct. (§93.319)*

## *Collaborative Disputes*

*ORI generally pursues plagiarism allegations when, for example, wholesale copying of language and data has been used to produce crucial portions of a grant application such as the preliminary results. However, when reuse of data and language involves former or current collaborators, ORI does not consider this to be plagiarism, but an outcome of the joint development of ideas, data, or language where it frequently is impossible to objectively sort out who was responsible for what.*

*When modest amounts of language are reused (sentences, paragraphs, or even whole pages) without proper attribution that can be considered background information, or the boilerplate language often seen in descriptions of methods, and the copied material is not misleading, ORI generally does not consider this to be sufficient to be considered plagiarism under ORI's working definition. Certainly institutions are permitted to make their own findings on the reuse of language and seek suitable remedies. Most cases of "minor" plagiarism are not significant enough to warrant ORI oversight.*

## *Self-Plagiarism*

*ORI often receives allegations of plagiarism that involve efforts by scientists to publish the same data in more than one journal article. Assuming that the duplicated figures represent the same experiment and are labeled the same in both cases (if not, possible falsification of data makes the allegation significantly more serious), this so-called "self-plagiarism" does not meet the PHS research misconduct standard. However, once again, ORI notes that this behavior violates the rules of most journals and is considered inappropriate by most institutions. In these cases, ORI will notify the institution(s) from which the duplicate publications/grants originated, being careful to note that ORI had no direct interest in the matter.*

*The take home lesson is that little has changed in the way ORI deals with allegations of plagiarism in light of the issuance of the new Part 93. ORI will continue to exercise care and discretion on what is judged to be plagiarism which is significant enough for a PHS finding. Staff in the Division of Investigative Oversight (DIO) can be reached at 240-453-8800 if questions arise about specific plagiarism allegations at your institution."*

## **B. Allegations made to ORI**

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 requested. Even under those circumstances, ORI continues to track the allegation for up to two years in the event additional information is forthcoming from the complainant, or additional allegations or evidence are 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 HHS Office of Inspector General(OIG)).

Although typically only about one third of the substantive allegations, also known as pre-inquiry assessments, 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 2010, ORI received 155 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. Some allegations are referred to other Federal agencies or offices when they involve 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 PHS definition of research misconduct or warrant referral to an institution or other Federal agency, it would be coded NA for no action. If a complaint lacks sufficient specificity or information to permit further assessment but additional information was expected, it would be 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 of Human Research Protections, Office of Management Assessment, and OIG. Similarly if allegations of research misconduct are received that involve funding by other Federal agencies, such as the US Department of Veterans Affairs, the US Department of Defense, the US 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 the National Institutes of Health (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 informed so that alternative administrative actions can be considered.

Pre-inquiry assessment refers to assessments that have been identified by institutions as active inquiries or investigations. Pre-inquiry assessments are followed continuously by DIO to ensure that the institutional reporting requirements are met, if extensions of time are required, or appropriate interim reports are received with requests for the extension.

**Table 1: Disposition of Allegations in ORI, 2010**

<b>Handling of Allegations - Outcome in ORI</b>	<b>Number of Allegations</b>	
No Action Possible Now or No Action	76	
Handled by Agency	15	
Handled by Agency to ORI	0	
Referred to Other Federal Agencies	6	
Pre-inquiry Assessment of Allegations Made Directly to ORI	50	
Pre-inquiry Assessment of Allegations Made Initially to NIH	8	
<b>Total Allegations</b>	<b>155</b>	
<b>Handling of Pre-inquiry Assessments Made Directly to ORI</b>		
Administratively Closed After Review		11
Remaining Pre-inquiry Assessments		31
Moved to Active Status		8
<b>Total</b>		<b>50</b>

Of the 155 allegations made to ORI (or to NIH and reported to ORI) in 2010, 50 were assessed by ORI in detail for a potential inquiry or investigation, 8 of the assessments were opened as cases in 2010. Of the remaining pre-inquiry assessments, 11 were administratively closed after being reviewed and 31 remained open at the end of the year.

Table 2 summarizes the time and outcome for the 50 pre-inquiry assessments. Assessments of the allegations that resulted in new ORI cases took an average of 160 days; those that resulted in administrative closures took an average of 84 days. These data do not reflect the additional time taken by officials at NIH who handled (with advice, assessment, and assistance from ORI as appropriate) 15 allegations that were made directly to NIH by a complainant (see Table 1). The 155 allegations that ORI received in 2010 were somewhat less than the 179 allegations handled in 2009. The number of allegations that were classified as pre-inquiry assessments in 2010 by ORI (50) was similar to the number classified as pre-inquiry assessments in 2009 (49).

**Table 2: Time for Conduct of Pre-inquiry Assessments by ORI, 2010**

Outcome of ORI Assessment	Number of Allegations	Distribution of Resolution Times (Days)		
	155	Mean	Median	Range
Opened a Formal Case	8	160	142	1-304
Administratively Closed	11	84	65	1-253
Unresolved at End of Year 2010	31	139	126	1-359
<b>Total</b>	<b>50</b>			

Table 3 summarizes the ORI caseload case type. During 2010, including 27 carried forward from 2009. Of the 28 cases opened by DIO in 2010, 12 arose from pre-inquiry assessments from earlier years. Interestingly, a majority of the pre-inquiry assessments carried into 2010 represented ongoing investigations at the institutional level. It should be noted that in the past several years DIO has not opened as many of the pre-inquiry assessments and cases as quickly as in the past years. In large part, this is due to some uncertainty about the merits of many of the inquiries because of the paucity of information available to DIO prior to receiving a final investigation report and supporting documentation. Once a more complete preliminary review of the investigative record becomes possible, DIO can determine if the matter warrants opening as a case for oversight review or, alternatively, administratively closing the accession at that stage.

**Table 3: ORI Research Misconduct Caseload Case Type, 2010**

Case Type	Forwarded from 2009	Opened in 2010	Closed in 2009
Institutional Inquiry	2	1	1
Institutional Investigations	25	27	30
Total	27	28	31

\* Note: Institutional inquiries normally come into ORI as inquiries. However, during the course of the year, the institution may start an investigation, turning the inquiry into an investigation.

### **C. ORI Caseload Includes Inquiries and Investigations**

The ORI caseload is divided into institutional inquiries and institutional investigations. ORI carried forward 27 cases from 2009, opened 28 new cases, and closed 31 cases during 2010 (see Table 4). At the end of calendar year 2010, ORI had 24 active formal cases divided between inquiries and investigations. One institutional inquiry and 23 institutional investigations remained open at the end of 2010.

**Table 4: Outcome of Research Misconduct Cases Closed by ORI, 2010**

<b>Outcome of Cases</b>					
<b>Case Type</b>	<b>No Investigation</b>	<b>No Research Misconduct</b>	<b>Misconduct Finding</b>	<b>Administrative Closure</b>	<b>Total</b>
Inquiry	1				1
Investigation		20	9	1	30
<b>Total</b>	1	20	9	1	31

**1. When ORI becomes involved in Institutional Inquiries:**

Under the PHS regulations, institutions are not 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 a 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 even when a decision was made not to move to an investigation. 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 regulations 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 number of reasons not to do so (see 42 CFR Part 93.316), the institution is required to first inform ORI of its decision and seek guidance from ORI as to whether this decision is appropriate. For example, if the inquiry recommended an investigation into allegations of minor significance, after review of the matter, ORI might concur with an institutional decision not to conduct an investigation or make findings of research misconduct. On the other hand, 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.

There was 1 institutional inquiry carried into 2011.

**2. Institutional Investigations which are reported to ORI:**

Institutions are required by the PHS regulation to report to ORI at the initiation of an investigation and 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 regulations, was thorough, competent, and objective, and provided a basis for a PHS finding of research misconduct. ORI began 2010 with 27 cases carried forward from 2009. During the year, 27 new institutional investigations were opened; 30 investigation cases were closed (see Table 4). Of these 30 closed investigations, 9 involved ORI findings of research misconduct; 21 did not have such findings. Of the total 31 cases closed in 2010, 30 percent (9 cases) involved findings of research

misconduct (see Table 5). However, the actual number of findings of research misconduct this year (9) is consistent with the average of 12 findings each year during 1993-2010. Summaries of these cases are located in Appendix A. There were 23 investigations carried into 2011.

### 3. Administrative Closures

A formal ORI case file may be administratively closed when ORI 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 was one formal case administratively closed in 2010.

### 4. Types of Allegations and Administrative Actions

Types of Allegations Involved in Cases Closed: during 2010 all the formal ORI cases closed (with or without a finding of misconduct) involved allegations of falsification, fabrication, plagiarism, or a combination of all three (see Table 6).

### 5. Duration of Time Involved in Resolution and Closing Cases

ORI closed 31 cases in 2010; 30 were investigations conducted by institutions reported to ORI, and one was an inquiry reported to ORI. The average duration of 26.2 months for conducting, reviewing, and closing these cases involved 19 months by the institution and 7.2 months for ORI oversight and administrative action (see Table 3). Within 8 months of receipt of the final action of the institution, 25 cases were closed.

**Table 5: Duration of Research Misconduct Cases Closed by ORI, 2010**

Distribution of Resolution Times (Months)			
Location of Activity	Mean	Median	Range
Institution	19.0	10	1-47
ORI	7.2	1	1-49

The action period for the 30 institutional investigations and 1 inquiry included the institutions' inquiry, investigation, and adjudication phases, while 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 for the basis of their decision as to whether research misconduct occurred. Additional ORI analysis is often required to make an ORI finding of research misconduct. In most instances involving a finding of misconduct, ORI is able to close its cases by reaching a voluntary settlement agreement with the respondent. Occasionally such an agreement cannot be reached. In such instances, a charge letter is issued, giving



the respondent 30 days to request a hearing before an Administrative Law Judge in the DAB. At such a hearing, a final determination is made. One case that took 49 months for ORI to resolve involved the DAB.

## D. Examination of Outcomes of Cases Closed in 2010

**Table 6: Types of Allegations in Closed Investigations and Their Outcomes, 2010**

Allegation	Investigation	ORI Findings or PHS Administrative Actions
Falsification	13	2
Fabrication/Falsification	16	7
Plagiarism	1	
Total	30	9

### 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 DAB 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 defined by the Office of Management and Budget Guidance on Non-procurement Debarment and Suspension (see 2 CFR Part 180).

**Table 7: HHS Administrative Actions Imposed in Closed Investigations with Research Misconduct Findings or Administrative Actions, 2010**

HHS Administrative Action	Duration (Years)	Number of Actions
Debarment or Voluntary Exclusion	7	1
Debarment or Voluntary Exclusion	5	1
Debarment or Voluntary Exclusion	3	2
Prohibition from Service as an Advisor for PHS	7	1
Prohibition from Service as an Advisor for PHS	5	1
Prohibition from Service as an Advisor for PHS	3	7
Supervision Plan Required	3	5
Certification of Work	3	2

For the 9 cases in 2010 in which PHS research misconduct findings or HHS administrative actions were imposed, 1 person was debarred or voluntarily excluded for 7 years, another person was debarred or voluntarily excluded for 5 years, and 2 individuals were debarred or voluntarily excluded for 3 years. Other administrative actions imposed on respondents in these 9 cases included the following:

- (a) prohibition from serving in any advisory capacity to PHS, including service on PHS advisory committees, boards, and/or peer review committees or as a consultant for a specified period of time (9 persons).
- (b) participation in PHS-funded research is subject to supervision for a specified period of time, herein the institution is required to submit a plan of supervision that will ensure the scientific integrity of the individual's research contribution (5 persons).
- (c) certification by the institution that the respondent's performance meets generally accepted standards (2 persons).

## **E. Rapid Response for Technical Assistance Program (RRTA)**

ORI provided RRTA on 43 occasions in 2010, almost half of the 71 instances in 2009. 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 and with anonymous complainants who requested guidance on how to proceed with complaints.

## **F. Implementation of HHS Administrative Actions: PHS ALERT**

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 a 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. The PHS ALERT System is a confidential system of record for collecting, controlling, and disseminating information about individuals found to have engaged in research

misconduct. The purpose is to help in decision-making about funding, committee appointments, and Federal employment.

Individuals are typically entered into the system when ORI receives an institutional investigation report in which there is a finding of research misconduct and the questioned research was supported by PHS funding. If ORI concurs with the institutional findings, the individual's name will remain in the system until the expiration of any administrative actions imposed by PHS at the recommendation of ORI. If ORI does not make a finding of research misconduct, the individual's name is promptly removed from the system, and the file is removed and destroyed.

Information on each individual in the system is limited and includes such identifying information such as the individual's name, date of birth, institution, sources of research funding, and a summary of any administrative actions imposed. At the completion of the ORI oversight review, if PHS administrative actions are recommended, the nature and term of the administrative actions are made public and are disclosed on the ORI web site while active.

On January 1, 2010, ORI listed the names of 49 individuals in the ALERT system. During the year, ORI added 14 names and removed 11. On December 31, 2010, the names of 52 individuals were in the system.

ORI added 14 names because those individuals were found to have committed research misconduct in institutional investigations reported to ORI. Eleven names were removed during the year because the term of the HHS administrative actions expired.

Of the 52 names in the system at year end, 40 individuals had HHS administrative actions imposed on them, and 12 remained as a result of an institutional investigation in which there was a finding of research misconduct.

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

**Table 8: Summarizes the Additions and Deletions to the PHS ALERT System, 2010**

<b>PHS ALERT System Activity, 2010</b>	
As of January 1, 2010	52
Additions	6
Action Expired/Removed	8
As of December 31, 2010	<b>50</b>

## **G. Research Integrity Officer (RIO) Boot Camp Training**

An extensive training program for RIOs completed its fourth year according to David Wright, Ph.D., an 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 fifth Boot Camp for RIOs in Boston, MA, hosted by Harvard University in November 2010. A total of 108 RIOs and 38 counsels have attended the Boot Camps since their inception in early 2007.

The curriculum of the 3-day ORI boot camp has been developing and evolving over the last 2 years as a result of the extensive evaluations and debriefings conducted at the end of each boot camp. Designed to emphasize the interaction between experienced and newer RIOs with a minimum of input and direction from ORI staff, the goal is to bring together 25-30 RIOs and their counsels to learn from each other, establish a network, and help identify the position of a RIO as a profession. The boot camp provides time to observe, discuss, and practice skills of interviewing, assessing allegations of research misconduct, and guiding 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 established with Michigan State University. The audio-visual materials developed for the boot camps will eventually form an online resource available to all interested institutional officials.

ORI plans to create a new, online 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 regulations (42 CFR Part 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 online newsletter, and create confidential networks of mutual support.

### **III. INSTITUTIONAL COMPLIANCE**

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

#### **A. Assurance Program**

The Assurance Program is responsible for ensuring that PHS research funds are only awarded to eligible institutions. An institution is eligible when it has an active assurance on file with ORI stating that it has developed Research Misconduct Policies and will comply with 42 CFR Part 50 & 93 which specify the procedures for responding to allegations of research misconduct in PHS-supported research. 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; gathering and summarizing information from institutions in their Annual Report; reviewing institutional policies and procedures in conjunction with the Compliance Review Program; and coordinating with the appropriate center of the National Institutes of Health (NIH) that an institution is in compliance with 42 CFR Part 93 and is eligible to receive their awards.

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

##### **1. 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 and to communicate that information to NIH who will release the funding.

In 2009, there were 5,559 institutional assurances on file with ORI, an increase of 356 from 2008. There were 150 assurances inactivated because the institution failed to submit its 2009 Annual Report in 2010 or the institution requested that its assurance be withdrawn or that duplicate records be eliminated. Table 9 describes the type of institutions that have an active assurance.

**Table 9: Number and Type of Institutions with Active Assurances, 2009-2010**

<b>Types of Institution</b>	<b>Number 2008</b>	<b>Increased 2009</b>	<b>Total At End 2009</b>	<b>Increased 2010</b>	<b>Total At End 2010</b>
Institutions of Higher Education	988	+26	1,014	+28	1,042
Research Organizations, Institutes, Foundations, and Laboratories	459	+12	471	+11	482
Independent Hospitals	283	+7	290	+2	292
Educational Organizations, Other Than Higher Education	33	+8	96	+1	42
Other Health, Human Resources, and Environmental Services Organizations	604	+35	639	+40	679
Other (small business)	2,836	+268	3,104	+326	3,430
<b>Total</b>	<b>5,203</b>	<b>356</b>	<b>5,559</b>	<b>408</b>	<b>5,967</b>

## **2. Institutional Research Misconduct Policy Reviews**

ORI completed 176 policy reviews in 2009-2010. Since 1995, ORI has reviewed 2,873 institutional policies.

## **3. 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 2009 Annual Report began in January 2010 for the 5,559 institutions that had an assurance on file with ORI as of December 31, 2009.

Completed Annual Reports were received from 4,122 institutions for a response rate of 75 percent. ORI inactivated 150 assurances, including 1,437 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.

## **4. Reported Research Misconduct Activity from Annual Reports**

The Annual Report form requests institutions to report, not only their policies and procedures for responding to allegations of research misconduct, but also the number of

allegations of research misconduct received and the number of inquiries and investigations conducted.

Research misconduct activity is defined as receipt of an allegation; the conduct of an inquiry; an investigation in the reporting year; or an investigation 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 10: Research Misconduct Activity: 1993-2010**

<b>Annual Institutional Report</b>			
<b>Year *</b>	<b>Continue</b>	<b>New Allegations</b>	<b>Total</b>
2010	111	175	286
2009	108	189	297
2008	117	113	230
2007	130	183	313
2006	111	151	262
2005	113	137	250
2004	101	120	221
2003	106	136	242
2002	99	163	262
2001	78	127	205
2000	82	103	185
1999	72	89	161
1998	67	69	136
1997	73	92	165
1996	88	127	215
1995	96	104	200
1994	79	89	168
1993	73	86	159

\*The count in year 2010 is a record of what institutions submitted in their 2009 Annual Report, which is submitted to ORI in 2010. This count will not necessarily be consistent with DIO reported activity. This count is only derived from the reported activity of institutions.

## **B. Compliance Review Program**

The Compliance Program was established to evaluate institutional compliance with the requirements of the PHS regulation 42 CFR Part 93. Under this regulation, institutions receiving PHS research funding are required to develop and implement policies and procedures consistent

with the regulatory requirements for reporting and responding to allegations of research misconduct. Hence, the institutional policies and procedures are routinely examined as part of the Division of Investigative Oversight's (DIO) oversight review of institutional inquiries and investigations. Any shortcomings in the process of addressing allegations of research misconduct are identified and recommendations for corrective action frequently follow.

ORI places significant importance on the prevention of retaliation against individuals reporting possible instances of research misconduct. The regulation specifically requires institutions to take all reasonable and practical steps to protect the positions and reputations of individuals making allegations of research misconduct in good faith. When a credible complaint of retaliation is made, ORI will direct the institution to formally address the complaint, utilizing a fair and rigorous process, and submit a report of its review to ORI.

The use of "his" and "her" in the following cases does **not** necessarily reflect the actual gender of the person involved in the case:

### **Cases**

*Case 1* - In this case, an individual contacted ORI stating that she was a victim of retaliation, being placed on employment probation the day after she made allegations of research misconduct against her supervisor. A review of available documentation identified a variety of unrelated factors that may have contributed to the issuance of the probation letter; however, the timing of such an action one day after raising an allegation of research misconduct provided justification for further review. The institution conducted an inquiry into the retaliation allegation, which included a review of the relevant documentation and interviews with the complainant, respondent, and others with knowledge and responsibilities in this matter. In its report, the institution concluded that there was no evidence to substantiate the complainant's allegations, noting that other employment and performance issues were evident early on in this case, and that the weight of these issues, rather than a specific reaction to the misconduct allegations, formed the basis that justified the institutional actions taken against the complainant. ORI reviewed the report and related evidence and concurred with the institutional finding.

*Case 2* - ORI conducted a preliminary review of information and other documentation associated with this case and determined that the complainant had been dismissed from his Doctoral program around the same time he made his allegation against a number of colleagues. The record showed that the complainant raised his concerns, albeit with minimal details, just prior to the time the alleged retaliatory actions were taken. First ORI determined whether the allegation fell under the definition of PHS funded research misconduct, whether PHS funded research was involved and whether there was a link between the timing of the allegation and the alleged retaliatory action.

During the course of the assessment, ORI was informed that the complainant admitted that the concerns raised did not rise to the level of research misconduct, and he ultimately rescinded the allegation. Without an allegation of research misconduct (a critical



component necessary for ORI action), ORI has no regulatory authority to address the complainants' retaliation allegation. The case was administratively closed.

**Case 3** - ORI received a complaint from an individual who claimed that he was forced to resign his position at a major university as a result of him raising allegations of research misconduct against a faculty member. As part of this and any other review, ORI reviews documentation and other evidence to determine whether or not it has jurisdiction; that is, did the allegations fall within the PHS definition of research misconduct, and was the questioned research supported with PHS funding. If ORI determines that there is PHS jurisdiction, and if there is a direct and well defined link between the allegation and the alleged retaliation, ORI normally will ask the institution to address the allegations in conformance with the requirements of the PHS regulation. The most common options considered by institutions and whistleblowers are included in the "ORI Guidelines for Institutional Whistleblowers: Responding to Possible Retaliation against Whistleblowers in Extramural Research" which offers three choices for addressing the retaliation allegations: an institutional investigation, arbitration, or settlement. The guidelines also acknowledge that the whistleblower has the option of pursuing the allegation through other legal processes outside those suggested by the guidelines; however, if such an alternative process is pursued, ORI will consider that the institutional obligation under the PHS regulation has been met and ORI will require no further action related to the whistleblower complaint.

During this review, ORI became aware of a separate complaint the respondent filed under the state whistleblower's law that included essentially the same issues he brought to ORI. That is the whistleblower's right, and by policy, ORI accepted this process as fulfilling the institution's obligation to protect whistleblowers from retaliation, and did not recommend any additional institutional action related to the retaliation allegation.

**Case 4** - The primary responsibility for addressing and reporting on allegations of research misconduct rests by regulation on the institutions receiving PHS research support. The institutional assurance provides that the institution will comply with all the requirements of the PHS regulation, including a thorough, competent, objective and fair response to allegations of research misconduct.

In a review of the investigation report initially submitted by the institution, ORI found that while the investigation panel reviewed most of the issues in some depth, the report it prepared did not adequately document its analysis of each issue with enough detail for ORI to pursue the findings further. Based on this initial review, ORI requested that the institution provide additional documentation in support of its findings and simultaneously initiated a compliance review to evaluate both the institutional research misconduct policies and the investigative process to determine whether they met the requirements of the PHS regulation.

ORI determined that the institutional research misconduct policies generally complied with the requirements of the PHS regulation. However, in a more detailed review of the institutional process and the submitted investigation report, ORI noted a number of

concerns, including: 1) the failure to provide adequate analysis for each allegation, 2) the failure to consider the required standards of proof for each misconduct finding, and 3) the initial failure to provide a statement by the appropriate institutional deciding official accepting the investigation report, its findings, and the recommended institutional actions.

Although the institution provided additional supplemental reports in response to some of ORI stated concerns, ORI did not have an investigational record that would be legally sufficient to pursue a finding of research misconduct, and the research misconduct case was closed.

Based on this review, and as provided for in 42 CFR Part 93.413, DIO recommends that the institution develop a formal corrective action plan to address the procedural weaknesses noted above, and to insure that any report associated with the inquiry or investigation of allegations of research misconduct is prepared in conformance with the requirements of the PHS regulation.

**Case 5** - This case involved allegations and counter allegations of research misconduct and possible retaliation at a major university. After the submission of allegations, the respondents almost immediately made counter allegations of research misconduct against the complainant. The complainant made contact with ORI, claiming that these counter allegations were retaliatory and made in bad faith.

While the complainant wanted the charges against him dismissed, ORI reminded him that the institution, by PHS regulation, has to evaluate the allegations against him, and such a process could not be considered retaliatory by the institution. He agreed, and the allegations against him ultimately were closed at the inquiry stage. Furthermore, in follow-up with the complainant, ORI determined that no adverse actions against him were documented that could be linked to his allegations, thereby negating any retaliation claim.

Regarding the issue of bad faith allegations, the PHS regulation makes no specific redress to this issue, but in reviewing the institutional misconduct policy, there was a reference to the issue of bad faith allegations, and it provides for an institutional process to address that issue. ORI asked that the institution pursue this issue as a part of its investigative process and to include its determination on this issue in its investigation report.

**Case 6** - In this case, ORI was contacted about a claim of possible retaliation against a faculty member at a major university who raised concerns about some aspects of research associated with his grant award that was carried out at another institution. What is the difference between concerns and allegations? As part of its assessment, ORI initially reviews all the available evidence and documentation to determine whether ORI has jurisdiction.

After review, ORI determined that although the relevant project was supported by PHS research funds, the allegations were initially framed as concerns rather than research

misconduct, and no further evidence or testimony was provided to recast these concerns to allegations fitting the definition of research misconduct.

The PHS regulation requires that institutions counter potential or actual retaliation against individuals who make allegations of research misconduct in good faith. Because the issues raised in this case did not fall within the definition of research misconduct, ORI did not have jurisdiction and could take no further action in addressing this complaint.

## **IV. DEI MISSION: TO PROMOTE A RESPONSIBLE CONDUCT OF RESEARCH PREVENTION PROGRAM THROUGH EDUCATION AND RESEARCH**

The Office of Research Integrity (ORI) promotes research integrity and prevention of research misconduct through the Division of Education and Integrity (DEI). This division focuses on activities to promote responsible conduct of research through educational and research efforts.

In 2000, DEI was created and directed:

*To (1) develop and implement, in consultation with the PHS OPDIVs, activities and programs for PHS intramural and extramural research to teach the responsible conduct of research, promote research integrity, prevent research misconduct, and to enable the extramural institutions and PHS OPDIVs to respond effectively to allegations of research misconduct; (2) coordinate the dissemination of research integrity policies, procedures, and regulations; (3) conduct policy analyses, evaluations, and research to improve DHHS research integrity policies and procedures and build the knowledge base in research misconduct, research integrity, and prevention; (4) develop (in consultation with the PHS OPDIVs) policies, procedures, and regulations for review by the Director, Office of Research Integrity, and recommendations to the Secretary; (5) administer programs for: approval of institutional assurances; response to Freedom of Information Act and Privacy Act requests; review and approval of intramural and extramural policies and procedures; and response to allegations of whistleblower retaliation. Federal Register: May 12, 2000 (Volume 65, Number 93)]*

### **A. Resource Development Program – Education on the Responsible Conduct of Research (RCR)**

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. In 2009 the National Institutes of Health (NIH) issued requirements for instruction in RCR, which has further increased external training materials. The requirements are located on the NIH website at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html>.

The program has supported over 60 projects since it was established in 2002. Completed resources are posted at [ori.hhs.gov/education/products/](http://ori.hhs.gov/education/products/). Resources developed through the program and independently by universities, cover the 9 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.

Current projects include the following:

### **1. Interactive Video Development: THE LAB: Avoiding Research Misconduct**

ORI initiated a contract in 2009 with Will Interactive to work with ORI staff in developing a script that would address such topics as avoiding or handling research misconduct, mentorship, responsible authorship, and life-work balance. Video production was completed in 2010 and the release of the video will occur in 2011.

### **2. RCR Learning Objectives and Test Battery**

To help institutions advance the education of researchers in RCR and to lessen the burden on these institutions to provide such education, ORI entered into contracts to provide 1) a set of objectives for RCR education; 2) a battery of tests for evaluating RCR knowledge and reasoning; and 3) a book for use in case-based instruction of RCR that would help fulfill the learning and evaluation objectives.

The learning objectives have been published and the battery of test questions are written, verified, and validated. ORI will support the online testing program, as well as the development of a case-based manual.

## **B. Collaborations and Partnerships**

### **1. Council of Graduate Schools Contract**

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 (US) dedicated solely to representing and advancing the interests of graduate education. Its 479 member institutions award over 90 percent of the doctorates and more than 75 percent of the master's degrees awarded by the US 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 for the amount of \$50,000.

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

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

In 2009, the seven Universities focused on implementing their RCR efforts, and reports based on their experiences in evaluating and implementing were completed in 2010. Their evaluation reports will become available in 2011.

## **2. National Academy of Sciences Study on Integrity of Research Data**

ORI and other Federal agencies supported a study, “Ensuring the Utility and Integrity of Research Data in a Digital Age,” conducted by the National Academy of Sciences (NAS). The Committee on Science, Engineering, and Public Policy conducted the study and reviewed the issues of selection, collection, analysis, handling, oversight, reporting, publishing, ownership, access, and archiving of data. The study report is expected to be completed in 2010. The project website is located at [www8.nationalacademies.org/cp/projectview.aspx?key=48721](http://www8.nationalacademies.org/cp/projectview.aspx?key=48721)

The key issues being addressed include:

- (a) 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?
- (b) Who owns research data, particularly that which results from federally-funded research? Is it the public, the research institution, the lab, or the researcher?
- (c) 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?
- (d) 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?
- (e) What are the current standards for accessing and maintaining research data, and how should these evolve in the future? How might such standards differ for federally-funded and privately-funded research, and for research conducted in academia, government, non-governmental organizations, and industry?

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

## **3. National Academy of Sciences Government-University-Industry Research Roundtable Conference on International Collaborations**

ORI and other Federal agencies, industries, and academic institutions supported a NAS Government University Industry Research Roundtable (GUIRR) effort to create a

working conference on “Examining Core Elements of International Research Collaboration” held July 26-27, 2010. The goal of the conference was to create greater understandings that could be provided to all three sectors when working in different cultures. The conference examined ethical considerations, research integrity, financial risks, export controls, the role of intellectual property and diplomacy. A session specifically focused on responsible conduct of research by exploring specific data integrity and collaboration issues that are critical when working with foreign collaborators.

The conference planners hope to create a working guidance document that would address the issues and concerns that were raised and discussed at the conference. This will be developed and released in 2011. Future conferences on this topic may also occur at a later date.

## **C. Conferences and Workshop Program**

ORI has sponsored, supported, or developed three Quest for Research Excellence (Q4RE) Regional Conferences, one three-day training program in 2010 and supported in-kind, three other conferences. Historical and planned information about the conference and workshop program is available at [ori.hhs.gov/conferences/](http://ori.hhs.gov/conferences/).

### **1. Quest for Research Excellence (Q4RE) - Regional Conferences**

- (a) “Challenges in Research Collaborations in Underserved Populations,” Kansas University Medical Center; Kansas City, KS, February 5, 2010.
- (b) “The Intersection of Standards, Culture & Ethics in Childhood Obesity,” The Westin Tabor Center; Denver, CO; April 21, 2010.
- (c) “Partnering with Communities to Improve Health Outcomes,” The Sam Nunn Atlanta Federal Center; Atlanta, GA; April 30, 2010.

### **2. RIO Boot Camp Training**

Harvard University Boston, Massachusetts; November 14-17, 2010.

### **3. Conferences Supported In-Kind**

- (a) American Association for the Advancement of Science (AAAS); *Responsible Research Practices in a Changing Research Environment*; Washington, DC; February 17, 2010

More than 80 people from diverse professional backgrounds attended a one-day, five-session workshop supported jointly by ORI; the National Science Foundation’s, Office of Inspector General; and the American Association for the Advancement of Science. Topics included: fostering an institutional environment

of research ethics, communicating science to the public, developing research collaborative skills, learning about the research integrity requirements of funding agencies, and reflecting on policy advocacy and science.

(b) National Academy of Sciences (NAS), Government University Industry Research Roundtable (GUIRR) Conference on International Collaborations; Washington, DC; July 26, 2010

Facilitated the development of an RCR Track as a component of the overall program and participated in the discussion on how data integrity could be enhanced for international research. About 100 people attended the program and the discussion on RCR had about 20 participants.

(c) Public Responsibility in Medicine and Research RCR Track; San Diego, CA; December 12-14, 2010

ORI worked with the Public Responsibility in Medicine and Research (PRIM&R) to develop a RCR track to occur during their international meeting. Six different RCR topics were introduced into the program.

(d) 2<sup>nd</sup> World Conference on Research Integrity; Singapore; July 21-24, 2010

ORI participated in the 2<sup>nd</sup> World Conference on Research Integrity in Singapore by supporting the development of the conference as well as by presenting and participating during the meeting. The Acting Director and both Division Directors attended and presented a number of talks. In addition, Dr. David Wright and the DIO Director participated in a workshop on conducting investigations into allegations of research misconduct on the day following the formal convention.

## **D. Communication Venues**

### **1. Web Site**

The ORI website ([ori.hhs.gov/](http://ori.hhs.gov/)) received 480,390 page views from 160,320 visits in the calendar year 2010. The site was visited by total of 113,848 users from 184 countries. Respectively, the top 10 countries visiting the ORI site were: the US, Canada, United Kingdom, Australia, India, China, Japan, Germany, Spain and Taiwan.

### **2. ORI Newsletter**

ORI has been producing a newsletter since January 1993. In 2010, ORI produced three issues that are available on the ORI website. The newsletter provides ORI updates, summaries of cases published in the *Federal Register*, discussions of timely issues, and information about conferences. In 2010, ORI continued to include commentaries from the research integrity community.



### 3. Educational Presentations Made by ORI Staff

**Ranjini Ambalavanar, Ph.D.** “Digital Manipulation of Images in Science” *American Society for Microbiology*; Washington, DC; April 20, 2010

**Ranjini Ambalavanar, Ph.D.** “Workshop on Scientific Ethics: Investigating Research Misconduct” *NIH, NCCR Third Biennial National Symposium of Biomedical Research Excellence (NISBRE)*; Bethesda, MD; June 18, 2010

**John Dahlberg, Ph.D.** “Computer and Image Forensics at DIO” *National Institute of Child Health and Human Disease, NICHD Grants Management Branch*; Rockville, MD; January 14, 2010

**John Dahlberg, Ph.D.** “Revising Responsible Science - Issues and Priorities” *Held during the 196<sup>th</sup> Meeting of the Committee on Science, Engineering, and Public Policy (COSEPP), of the National Academies of Science*; The Beckman Center, Irvine, CA; February 18, 2010

**John Dahlberg, Ph.D.** “Integrity in the name of science” *NIH Regional Seminar on Program Funding and Grants Administration*; Philadelphia, PA; April 16, 2010

**John Dahlberg, Ph.D.** “Scientific Forensics: How the Division of Investigative Oversight Detects Falsified Data and Images” *Georgetown University*; Washington, DC; April 29, 2010

**John Dahlberg, Ph.D.** “Integrity in the name of science” *2010 NIH Regional Seminar on Program Funding and Grants Administration*; Portland, OR; June 25, 2010

**John Dahlberg, Ph.D.** “Detecting Misconduct-Some Approaches Used by DIO” *Boot Camp for RIOs*; Boston, MA; Nov. 16, 2010

**Susan Garfinkel, Ph.D.** “Detection of Manipulated Images” *Georgetown University*; Washington, DC; April 29, 2010

**Susan Garfinkel, Ph.D.** “Examining Images: Evidence in the Vogel Case” *RIO Boot Camp*; Harvard University; Boston, MA; November 16, 2010

**Susan Garfinkel, Ph.D.** “The Vogel Case: What are the Allegations?” *RIO Boot Camp*; Harvard University; Boston, MA; November 16, 2010

**John C. Galland, Ph.D.** “ORI” *NICHD Grants Mgmt Branch*; Rockville, MD; January 14, 2010

**John C. Galland, Ph.D.** “Challenges in Research Collaborations with Underserved Populations: Rural, African-American, Latino, and American Indian Communities” *Region VII*; Kansas City, KS; February 4-5, 2010

**John C. Galland, Ph.D.** "ORI" Nat'l Council of Ethics in Human Research (NCEHR) Pre-Conference - *Research Integrity in Canada*; Ottawa, Canada; February 17-18, 2010

**John C. Galland, Ph.D.** "ORI" Health Canada Scientist & Managers Workshop on *Scientific Integrity & Nat'l Council of Ethics in Human Research Annual Conference*; Ottawa, Canada; February 19, 2010

**John C. Galland, Ph.D.** "ORI Oversight, Assurance, & Education Program" *20th Annual HHMI EH&S Leadership Conference*; Ashburn, VA; April 6, 2010

**John C. Galland, Ph.D.** "ORI Oversight, Assurance, & Education Program" *CIRM-Policies Designed to Promote RCR Training*; San Francisco, CA; April 14, 2010

**John C. Galland, Ph.D.** "The ORI & Facilitation through Experimentation of Solutions to Issues in Childhood Obesity Research" *ORI/Q4RE: The Intersection of Standards, Culture, & Ethics in Childhood Obesity*; Region VIII; Denver, CO; April 20-21, 2010

**John C. Galland, Ph.D.** "The ORI & Facilitation through Experimentation of Solutions to Community Based Participatory Research" *ORI/Q4RE: Partnering with Communities to Improve Health Outcomes*; Region IV; Atlanta, GA; April 30, 2010

**John C. Galland, Ph.D.** "ORI's Responsibility for Fostering Research Integrity" *ORI/Q4RE: Creating the Future We Want to Be*; Region X; Portland, OR; May 12-15, 2010

**John C. Galland, Ph.D.** "Introduction to ORI" *CDC RCR Training Workshops*; Atlanta, GA; June 8-9, 2010

**John C. Galland, Ph.D.** "Practicing Research Responsibility" *2nd World Conference on Research Integrity*; Marina Square Singapore; July 21-24, 2010

**John Krueger, Ph.D.** "Investigating Research Misconduct -Tools-of-the Trade" *3rd Biennial IdeaA Conference; NISBRE, NCCR*; Bethesda, MD; June 18, 2010

**John Krueger, Ph.D.** "Digital Manipulation of Images in Science (Session 1-Overview)" *American Society for Microbiology*; Washington, DC; April 20, 2010

**John Krueger, Ph.D.** "Digital Manipulation of Images in Science (Session II- Technical Aspects and Demonstration)" *American Society for Microbiology*; Washington, DC; April 20, 2010

**John Krueger, Ph.D.** "Image Manipulation and Analysis" Videocast; *NIH Extramural Staff Training Seminar; Handling Allegations of Research Misconduct*; Natcher Bldg; NIH; Rockville, MD; July 13, 2010  
[http://odoerdb2.od.nih.gov/oer/training/esa/esa\\_training\\_20100713.htm](http://odoerdb2.od.nih.gov/oer/training/esa/esa_training_20100713.htm)

**John Krueger, Ph.D.** Discussant; *Panel for Session on Research Integrity, Government University-Industry Round Table (GUIRR)*; National Academy of Sciences; July 27, 2010

**Sandra Titus, Ph.D.** “ORI Update: Clinical Research Misconduct” PRIM&R; San Diego, CA; December 13, 2010

**Sandra Titus, Ph.D.** “The Lab: Avoiding Research Misconduct” *Discussion of DVD*; PRIM&R; San Diego, CA; December 14, 2010

**Sandra Titus, Ph.D.** “Authorship and Collaboration” *Society for Research Administrators*; National Meeting; October 12, 2010

**Sandra Titus, Ph.D.** “ORI Overview” *Society for Research Administrators*; National Meeting; October 11, 2010

**Sandra Titus, Ph.D.** “Research Integrity Officers: What do they do?” *Society for Research Administrators*; National Meeting; October 13, 2010

**Sandra Titus, Ph.D.** “How to build Data Integrity in International Collaborations” *IGUIR RCR Section Leader*; IGUIRR, NAS; June 28, 2010

**Sandra Titus, Ph.D.** “How to build Data Integrity in International Collaborations” *IGUIR RCR; Panel Discussion Leader*; IGUIRR, NAS; June 29, 2010

**Sandra Titus, Ph.D.** “Building Successful Collaborations” *CDC*; Atlanta, GA; June 9, 2010

**Sandra Titus, Ph.D.** “Study results: What do advisors and mentors do with their Ph.D. trainees?” *Society for Research Administrators*; Philadelphia, PA; April 28, 2010

**Sandra Titus, Ph.D.** “Authorship Integrity” *Society for Research Administrators*; Philadelphia, PA; April 27, 2010

**Sandra Titus, Ph.D.** “Study report on the Role of the Research Integrity Officers” *Society for Research Administrators*; Philadelphia, PA; April 27, 2010

**Sandra Titus, Ph.D.** “Collaboration and Authorship” *University of Delaware; Graduate Students*; Delaware; February 3, 2010

#### **4. ORI Financially Supported Publications in 2010**

- (a) Ensuring the Integrity, Accessibility, and Stewardship of Research Data in the Digital Age. National Academy of Sciences, National Academy of Engineering, and Institute of Medicine of the National Academies, The National Academies Press, Washington, DC; 2009; distributed in 2010.

(b) Guide for the Care and Use of Laboratory Animals, Eighth Edition, Committee for the Update of the Guide for the Care and Use of Laboratory Animals, Institute for Laboratory Animal Research, Division on Earth and Life Studies, National Research Council of *The National Academies*, The National Academies Press, Washington, DC; 2010.

## **5. Federal Register Notices - Misconduct\***

12/28/10 OS. Findings of Misconduct in Science; Correction. Vol. 75, No. 248, Tuesday, December 28, 2010 [Sezen]

12/13/10 OS. Findings of Research Misconduct. Notice Vol. 75 No. 238, Monday, December 13, 2010 [Mungekar]

11/29/10 OS. Findings of Misconduct in Science. Notice Vol. 75 No. 228, Monday, November 29, 2010 [Sezen]

08/31/10 OS. Findings of Research Misconduct. Notice Vol. 75 No. 168, Tuesday, August 31, 2010 [Chang]

08/25/10 OS. Findings of Scientific Misconduct. Notice Vol. 75 No. 164, Wednesday, August 25, 2010 [Goodwill]

07/09/10 OS. Findings of Research Misconduct. Notice Vol. 75 No. 131, Friday, July 9, 2010 [Paez]

05/05/10 OS. Findings of Misconduct in Science. Notice Vol. 75 No. 86, Wednesday, May 5, 2010 [Brodie]

04/13/10 OS. Findings of Research Misconduct. Notice Vol. 75 No. 70, Tuesday, April 13, 2010 [Cheskis]

04/13/10 OS. Findings of Research Misconduct. Notice Vol. 75 No. 70, Tuesday, April 13, 2010 [Horvath]

01/28/10 OS. Findings of Misconduct in Science. Notice Vol. 75 No. 18, Thursday, January 28, 2010 [Linn]

\*Acts of misconduct occurring prior to June 2005 fall under 42 CFR Part 50, Subpart A and are called scientific misconduct, while acts of misconduct occurring after June 2005 fall under 42 CFR Part 93 and are called research misconduct.

## E. Research on Research Integrity and Research Misconduct

As part of the Office of Research Integrity (ORI) mission, the Division of Education and Integrity (DEI) conduct policy evaluation studies and research through two programs – an intramural and extramural research program. Both programs have the same goal to expand the knowledge base on research misconduct, research integrity, and the responsible conduct of research (RCR). Intramural studies are conducted by ORI staff, contractors, and consultants. The studies are focused on questions relevant to ORI’s regulatory and preventive mission. In contrast, the extramural program operates through the Research on Research Integrity (RRI) Program with the National Institutes of Health (NIH). This program solicits investigator-initiated responses to request for from researchers at colleges, universities, medical schools, research centers, and other organizations. The two programs are building the knowledge base of research misconduct and prevention.

### 1. Intramural Research Program

ORI has conducted the Intramural Research Program since 1993. The program expanded after the year 2000 because the mission statement directed ORI to focus its resources to “conduct policy analyses, evaluations, and research to improve the HHS research integrity and build the knowledge base in research misconduct, research integrity, and prevention” (*Federal Register* Volume 65, Number 93, pages 30600-30601, May 12, 2000) (see Appendix C). As a result of this directive, the intramural program began to develop more research studies that focused on promoting research integrity as well as the prior focus on research misconduct.

Studies over the past 20 years have examined medical school guidelines for RCR; outcomes for whistleblowers and respondents; scientists’ awareness of possible research misconduct; depth of instructions to authors published by journals; mentoring of trainees; and research integrity measures utilized in biomedical research laboratories. For a complete list of study reports see [ori.hhs.gov/research/intra/studies\\_completed.shtml](http://ori.hhs.gov/research/intra/studies_completed.shtml).

#### (a) Evaluation Studies Completed

##### *i. Evaluating Faculty Members’ Views on their Institutions Guidance to Faculty Members on their Roles in Advising Ph.D. Candidates*

This study, developed with Mathematica Policy Research, Inc., focused on how faculty members perceived the relevance and usefulness of their institutions’ guidance documents on the role and responsibilities of the Advisor of a Ph.D. trainee. The assessment of the responses was based on faculty members verbatim statements made as part of the study “Training and Mentoring Ph.D.s: Faculty Views on their Role and their Institution’s Role to Promote the Development of Responsible Researchers.” Study results were based on over 5,000 faculty responses (53 percent response rate) and this evaluation will be disseminated in future peer-reviewed papers. This study was completed in 2010.

*ii. Evaluating the Effectiveness of Institutional Efforts to Educate Staff Members on Policies for Dealing with Research Misconduct and Research Integrity*

This study, developed with the Research Triangle Institute International (RTI), evaluated how effectively institutions have informed their faculty about the Public Health Service (PHS) Policies on Research Misconduct (42 CFR Part 93). The study collected data on how much faculty know about what constitutes research misconduct, their understanding of reporting an allegation, and the rights and responsibilities of respondents and whistleblowers. In addition, the study will ask faculty to evaluate the effectiveness and report their perceptions of integrity displayed by their institution's handling of research misconduct allegations and in their efforts made to protect whistleblowers. Data collection was completed in 2009, and the analysis and report were completed in 2010. The study findings will be submitted to a peer-reviewed journal.

(b) Evaluation Studies in Progress

*i. Issues and Questions Raised by Whistleblowers who Report Research Misconduct*

This study was originally planned to repeat the 1995 study on whistleblowers by conducting phone interviews with complainants. However, current legal interpretation on confidentiality protections provided to research misconduct complainants, precludes ORI from releasing the names of former complainants and therefore ORI cannot conduct such a study at this time.

The redesigned study, with RTI, will focus on interviews with Research Integrity Officers (RIOs) who have contact with whistleblowers. The RIOs will be asked to describe the kinds of questions and issues that complainants and potential complainants have raised with them as well as to ascertain the kinds of information the RIOs provide. The interviews will provide a perspective on the degree to which complainants report fear of making allegations of research misconduct and/or report retaliation for having made the allegation before, during, and after the investigation is over. Learning more about the RIOs range of responses to a complainant would inform us on how effective RIOs are in preparing and allaying whistleblowers' fears. The study was submitted to OMB for review in 2010 and will be conducted in 2011. A subsequent paper based on the results will be submitted to a peer-reviewed journal in 2012.

*ii. Evaluation of the Interactive Video "THE LAB: Avoiding Research Misconduct"*

ORI initiated a contract in 2010 with DS Federal, Inc., to develop and implement an evaluation study of the interactive video "THE LAB." The web-based survey is being designed and will be submitted for OMB review in 2011.

The evaluation will explore the views of RCR instructors, RIOs, and research administrators.

## **F. Extramural Research Program**

In 2000, DEI was officially directed to “conduct policy analyses, evaluations, and research to improve HHS research integrity and build the knowledge base in research misconduct, research integrity and prevention” (*Federal Register* Volume 65, Number 93, pages 30600-30601, May 12, 2000) (see Appendix C). As a result of this directive, the extramural program was created.

The RRI Program began in collaboration with the National Institute of Neurological Disorders and Stroke. Since the first awards were made in 2001, several NIH institutes have participated in the development of the program: National Institute of Drug Abuse; National Institute of Alcohol Abuse and Alcoholism; National Cancer Institute; National Heart, Lung and Blood Institute; National Institute of General Medical Sciences; National Human Genome Research Institute; and National Institute of Child Health and Development. Other partners include: Center for Scientific Review; National Library of Medicine; National Center for Research Resources (NCRR); and Agency for Healthcare Research and Quality.

Currently, the National Institute for Environmental Health Science is collaborating with ORI in the administration of the program.

The research integrity grant program was created to foster empirical research on societal, organizational, group, and individual factors that affect, both positively and negatively, integrity in research. Since it began in 2001, the RRI program has funded 55 projects that have resulted in 110 publications consisting of peer-reviewed articles; commentaries; letters to the editor; abstracts; and literature reviews in more than 30 journals. Award abstracts are posted on the ORI web site along with a list of publications produced by projects supported by the RRI program.

### **1. RRI Awards in 2010**

RRI in Collaborations was the main topic supported by the two awards made in 2010 by the RRI program.

- (a) Charles Lidz, University of Massachusetts, “Investigators and IACUCs: Integrity in Animal Research”
- (b) Michelle Mello, Harvard University, “Restrictive Provisions in Faculty Consulting Agreements with Industry (Phase I)”

These two awards were supported by ORI through the National Center for Research Resources

Total funding for the RRI program in 2010 by ORI was \$1,337,173. New grants received totaled \$607,688 and continuations received were \$729,485. Twenty-five applications were received for the R21-awards which can provide up to \$275,000 in direct costs, plus indirect costs, for two years. Four continuation awards were funded by ORI through NCRR.

## 2. RRI Publications

In the first 10 years of the program, RRI researchers have published 113 peer-reviewed articles, abstracts, commentaries, reviews, and letters to the editor. Researchers supported by the RRI Program published 12 articles in 2010 on research integrity and RCR in 11 journals:

Campbell, E.G. (2010). Public disclosure of conflicts of interest: moving the policy debate forward. *Arch Internal Med*, 170, (8) 667.

DuBois, J.M., Schilling, D.A., Heitman, E., Steneck, N.H., Kon, A.A. (2010). Instruction in the responsible conduct of research: an inventory of programs and materials within CTSA. *Clin Transl Sci*, 3, (3) 109-11.

Dubois, J.M. (2010). The ethics of creating and responding to doubts about death criteria. *J Med Philos*, 35, (3) 365-80.

Errami, M., Sun, J., Long, T., George, A., Garner, H.R. (2010). Identifying duplicate content using statistically improbable phrases. *Bioinformatics*, 26, (11) 1453-7.

George, A., Long, T., Garner, H.R. (2010). Quaere verum: Responding to the editorial, Primum non Nocere. *Clinical Chemistry*, 56, (4) 673-4.

Kesselheim, A.S., Studdert, D.M., Mello, M.M. (2010). Whistle-blowers' experiences in fraud litigation against pharmaceutical companies. *N Engl J Med*, 362, (19) 1832-9.

Kesselheim, J.C., Johnson, J., Joffe, S. (2010). Ethics consultation in children's hospitals: results from a survey of pediatric clinical ethicists. *Pediatrics*, 125, (4) 742-6.

Licurse, A., Barber, E., Joffe, S., Gross, C. (2010). The impact of disclosing financial ties in research and clinical care: a systematic review. *Arch Intern Med*, 170, (8) 675-82.

Martinson, B.C., Crain, A.L., Anderson, M.S. (2010). The importance of organizational justice in ensuring research integrity. *Journal of Empirical Research on Human Research Ethics*, 5, (3) 67-83.

Rose, S.L., Krzyzanowska, M.K., Joffe, S. (2010). Relationships between authorship contributions and authors' industry financial ties among oncology clinical trials. *J Clin Oncol*, 28, (8) 1316-21.



Solomon, M.Z. (2010). The ethical urgency of advancing implementation science. *Am J Bioeth*, 10, (8) 31-2.

Spector, N.D., Mann, K.J., Anderson, M.S., Narayan, A.P., McGregor, R. (2010). Facilitated peer group mentoring: a case study of creating leadership skills among the associate program directors of the APPD. *Acad Pediatr*, 10, (3) 161-4.

## **VI. INFORMATION AND PRIVACY**

The public may obtain Federal agency records through two methods: (1) the Freedom of Information Act and (2) the Privacy Act of 1974.

The number of requests for information under the Freedom of Information Act and the Privacy Act was virtually the same for the Office of Research Integrity (ORI) in 2010.

### **A. Freedom of Information Act**

ORI received 53 requests in 2010 and closed 59. Twenty requests were carried into 2011. In 2009, ORI received 54 and closed 61 requests.

The Freedom of Information Act (FOIA), 5 USC § 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 9 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 addressed to:

PHS FOIA Officer  
US Department of Health and Human Services  
Program Support Center  
Division of FOIA Services  
7700 Wisconsin Avenue, Suite 920  
Bethesda, 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 costs associated with the review, search, and duplication of the relevant documents.

### **B. Privacy Act**

ORI did not receive any Privacy Act requests in 2010.

The purpose of the Privacy Act of 1974, 5 USC § 552(a), is to balance the needs of the government, to obtain information about individuals but maintain the rights of the individual to be protected against unwarranted invasions of their privacy stemming from Federal agency collection, maintenance, use, and disclosure of personal information about the individual. Under

the Privacy Act, an agency is required to publish a notice of its system of records when the information in the system is about an individual that is retrieved by a personal identifier.

The inquiry and investigative records in ORI files are part of a system of records that was published in the *Federal Register* on January 6, 1995, (60 FR 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 (74 FR 44847, August 31, 2009). Nonetheless, each request for access is reviewed on a case-by-case basis. Additionally, if the record requested is denied under the Privacy Act due to an exemption, the requester of the record may still be entitled to obtain access to his or her own records, or portions thereof, under the provisions of FOIA. A request under the Privacy Act must be made by the subject of the records or his or her legal representative.

A Privacy Act request should be addressed to:

Privacy Act Officer  
Office of Research Integrity  
1101 Wootton Parkway, Suite 750  
Rockville, MD 20852

## APPENDIX A

### A. Summaries of Closed Investigations Resulting in Findings of Research Misconduct or Administrative Actions - 2010

**Scott J. Brodie, DVM, Ph.D., University of Washington:** Based on the findings in an investigation report by the University of Washington (UW) and additional analysis conducted by ORI in its oversight review, ORI found that Scott J. Brodie, DVM, Ph.D., former Research Assistant Professor, Department of Laboratory Medicine, and Director of the UW Retrovirology Pathogenesis Laboratory, UW, committed misconduct in science (scientific misconduct) in research supported by or reported in the following U.S. Public Health Service (PHS) grant applications:

- 1 P01 HD40540-01 (National Institute of Child Health and Human Development [NICHD], National Institutes of Health [NIH])
- 5 P01 HD40540-02 (NICHD, NIH)
- 1 P01 AI057005-01 (National Institute of Allergy and Infectious Diseases [NIAID], NIH)
- 1 R01 DE014149-01 (National Institute of Dental and Craniofacial Research [NIDCR], NIH)
- 2 U01 AI41535-05 (NIAID, NIH)
- 1 R01 HL072631-01 (National Heart, Lung, and Blood Institute [NHLBI], NIH)
- 1 R01 (U01) AI054334-01 (NIAID, NIH)
- 1 R01 DE014827-01 (NIDCR, NIH)
- 1 R01 AI051954-01 (NIAID, NIH).

Specifically, ORI made fifteen findings of misconduct in science based on evidence that Dr. Brodie knowingly and intentionally fabricated and falsified data reported in nine PHS grant applications and progress reports and several published papers, manuscripts, and PowerPoint presentations. The fifteen findings are as follows:

1. Respondent knowingly and intentionally falsified a figure that was presented in manuscripts submitted to the *Journal of Experimental Medicine* and the *Journal of Virology* and in several PowerPoint presentations that purported to represent rectal mucosal leukocytes in some instances and lymph nodes in other instances.
2. Respondent knowingly and intentionally falsified portions of a three-paneled figure included in several manuscript submissions, PowerPoint presentations, and grant applications.
3. Respondent knowingly and intentionally falsified a figure included as Figure 1N in *American Journal of Pathology* 54:1453-1464, 1999, three NIH grant applications, and several PowerPoint presentations.
4. Respondent knowingly and intentionally falsified a figure that was published as an insert within Figure 1K in *American Journal of Pathology* 54:1453, 1999, and included the

figure in a number of NIH grant applications.

5. Respondent knowingly and intentionally falsified a figure representing a panel of four green fluorescent cells and included it as a figure in several grant applications claiming that each cell had been subjected to different treatments when three of the cells came from a single image.
6. Respondent knowingly and intentionally falsified an image included as Figure 5A in a paper published in the *Journal of Clinical Investigations* 105:1407, 2000, and submitted to various journals and included in different grant applications.
7. Respondent knowingly and intentionally falsified a figure appearing as Figure 3.III.A, inset, in a manuscript submitted to *Science* entitled “A persistent reservoir of HIV-1 in pulmonary macrophages” and as figures in various grant applications and PowerPoint presentations.
8. Respondent knowingly and intentionally falsified multiple versions of a figure depicting green and red fluorescent cells used as Figures 3.III.H and I in a manuscript submitted to *Science*, as Figures 6C and 6D of NIDCR, NIH, grant application 1 R01 DE14827-01, as Figures C.2.1 1H and C.2.11I of NHLBI, NIH, grant application 1 R01 HL072631-01, and in PowerPoint presentations.
9. Respondent knowingly and intentionally falsified a figure, labeled as Figure 9E in NIDCR, NIH, grant application 1 R01 DE014827-01 and in various other grant applications and PowerPoint presentations.
10. Respondent knowingly and intentionally falsified the bottom half of Figure C.2.5 of NHLBI, NIH, grant application 1 R01 HL072631-01 by using the same image twice, labeling it once as being treated for 2 hours with lipopolysaccharide (LPS) and the second as being treated for 12 hours with LPS. Respondent also used a second image twice, labeling it once as “no LPS” and the second time as “24 hours with LPS.”
11. Respondent knowingly and intentionally falsified a figure that purports to represent viral decay in rectal mucosa and included the figure as a slide in two PowerPoint presentations and three NIH grant applications.
12. Respondent knowingly and intentionally falsified: (a) a histopathology figure that was described in a paper published in the *Journal of Infectious Diseases* 83:1466, 2001, as inguinal lymph nodes from an untreated AIDS patient using *in situ* PCR to show the presence of HIV-1 cells when it was actually from a tissue expressing the neomycin marker; (b) the gel images resembling Figures 2A and C, which Respondent claimed to be based on *lymph node cells*, although he reported the gel images elsewhere to represent results from *rectal tissue*; and (c) various versions of these blots that Respondent reported elsewhere and labeled differently with respect to the copy numbers detected and as detecting DNA in some instance and RNA in others.

13. Respondent knowingly and intentionally falsified Figures 2DI and 2DII included in a paper published in the *Journal of Leukocyte Biology* 68:351-359, 2000.
14. Respondent knowingly and intentionally falsified Figure 4, Panels A and B, in NIDCR, NIH, grant application 1 R01 DE014827-01 by manipulating the source images.
15. Respondent knowingly and intentionally falsified a number of figures and made false statements in the text of NIAID, NIH, grant application 1 R01 AI051954-01 submitted jointly with a colleague by relabeling figures based on research carried out with HIV-1 or HIV-2 and identifying the figures and text as research conducted with ovine lentivirus (OvLV).

ORI issued a charge letter enumerating the above findings of misconduct in science and proposing HHS administrative actions. Dr. Brodie subsequently requested a hearing before an Administrative Law Judge (ALJ) of the Departmental Appeals Board to dispute these findings. In January 2009, the ALJ issued a ruling holding that there were no triable issues challenging ORI's findings that there were materially false statements, images, and other data in the relevant publications, presentations, and grant applications. However, the ALJ held that Dr. Brodie raised triable issues about his intent to commit scientific misconduct and the reasonableness of the proposed debarment of seven (7) years.

On January 12, 2010, the ALJ issued a recommended decision to the HHS Assistant Secretary for Health (ASH) granting summary disposition to ORI. The ALJ also stated that Dr. Brodie committed scientific misconduct on multiple occasions and that its extent amply justified debarment for a period of seven (7) years. Pursuant to 42 CFR 93.523(c), the ASH forwarded the ALJ's recommended decision to the HHS Debarring Official, which constituted the findings of fact required under 2 CFR Parts 180 and 376.

On February 1, 2010, Dr. Brodie submitted a letter to the HHS Debarring Official with attachments to request that the ALJ's recommended decision be rejected. On February 26, 2010, Dr. Brodie submitted a letter requesting the opportunity to meet with the HHS Debarring Official to orally present the reasons supporting his request that the ALJ's recommended decision be rejected. However, the HHS Debarring Official determined that Dr. Brodie had been afforded an opportunity to contest ORI's findings of scientific misconduct in accordance with 42 CFR Part 93, Subpart E. Given the findings of facts in this case, the HHS Debarring Official determined that the issues in his presentation in opposition to the ALJ's recommended decision did not raise a genuine dispute over facts material to the recommended debarment. Accordingly, the HHS Debarring Official also denied Dr. Brodie's request to make an oral presentation and issued a notice of debarment to begin on March 18, 2010, and end on March 17, 2017.

On March 23, 2010, Dr. Brodie submitted a letter requesting a postponement of the effective date of the debarment. This request was denied by the Debarring Official on April 6, 2010.

Thus, the misconduct in science findings set forth above became effective, and the following

administrative actions have been implemented for a period of seven (7) years, beginning on March 18, 2010: (1) Dr. Brodie has been debarred from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government referred to as “covered transactions” pursuant to the Department of Health and Human Service’s Implementation (2 CFR Part 376 *et seq.*) of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension, 2 CFR Part 180; and (2) Dr. Brodie is prohibited from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as consultant.

**Hung-Shu Chang, Ph.D. Washington State University:** Based on the report of an investigation conducted by the Washington State University (WSU) and additional analysis by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Hung-Shu Chang, Ph.D., former postdoctoral fellow, WSU, engaged in research misconduct in research supported by National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), grant R01 ES012974.

PHS found that the Respondent engaged in scientific (42 CFR Part 50.102) and research misconduct by fabricating and falsifying data in Figure 3 of a paper published in *Endocrinology*.<sup>1</sup>

Specifically, (42 CFR Part 93.103) PHS found that:

- Respondent, by not conducting any of the claimed bisulfite sequencing, fabricated the methylation status of CpG sites in eight candidate genes identified in both Figures 3 and 4 as No. 11, No. 12, No. 13, No. 14, 15, No. 22, No. 26, No. 31, and No. 19, to support the hypothesis that the environmental compound, vinclozolin, induces a permanent alteration in the epigenetic reprogramming of the germline that promotes transgenerational disease states.
- Respondent, by conducting only a small fraction of the claimed bisulfite sequencing, and falsifying the results obtained, falsified the methylation status of CpG sites in eight additional candidate genes, identified in Figures 3 and 4 as No. 2, 3, 24, No. 5, 6, 9, No. 8, No. 16, No. 17, 18, No. 27, 28, No. 29, and No. 33.

Dr. Chang has entered into a Voluntary Settlement Agreement in which he has voluntarily agreed, for a period of three (3) years, beginning on July 21, 2010:

- (1) to exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant;
- (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 him in any capacity on PHS-support 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 while applying for or conducting PHS-supported research. Respondent agrees to ensure that a copy of the supervisory plan is submitted to ORI by the institution for ORI approval. Respondent agrees not to participate in any PHS-supported research until such a supervisory plan is submitted to ORI.

**Boris Cheskis, Ph.D., Wyeth Pharmaceuticals:** Based on the report of an investigation conducted by Wyeth Pharmaceuticals and additional analysis conducted by ORI in its oversight review, ORI found that Boris Cheskis, Ph.D., former senior scientist, Discovery Research, Women's Health, Wyeth Pharmaceuticals, engaged in research misconduct in grant applications 1 R01 DK072026-01 and 1 R01 DK072026-01A2 submitted to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH. Specifically, ORI found that:

- the Respondent engaged in misconduct in science, 42 CFR Part 50.102, in NIDDK, NIH, grant application 1 R01 DK072026-01, "MNAR Crosstalk with Steroid Receptors," submitted to NIH on September 28, 2004, by intentionally falsifying Figures 5 and 6.
- the Respondent engaged in research misconduct, 42 CFR Part 93.103, in NIDDK, NIH, grant application 1 R01 DK072026-01A2, "MNAR Crosstalk with Steroid Receptors," submitted to NIH on November 9, 2005, by intentionally falsifying Figures 6 and 9.

Dr. Cheskis' research was in an area of research (estrogen receptors and modulation of nongenomic phosphorylation cascades) that is of importance to women's health. Dr. Cheskis' team identified an adapter protein, MNAR, that coordinates interactions between certain nuclear receptors, Src and PI3K, and may play important roles in regulation of cell proliferation and survival.

Both Dr. Cheskis and the U.S. Public Health Service (PHS) were desirous of concluding this matter without further expense of time and other resources. Dr. Cheskis neither admits nor denies that ORI's findings represent findings of research misconduct. The settlement is not an admission of liability on the part of the Respondent.

Dr. Cheskis has entered into a Voluntary Settlement Agreement. Dr. Cheskis has voluntarily agreed, for a period of two (2) years, beginning on March 22, 2010: (1) to exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; (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 him in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which he is involved, must concurrently submit a plan for supervision of his duties to the funding agency for approval; the supervisory plan must be designed to ensure the scientific integrity of his research contribution; Respondent agreed that he will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI.



**Elizabeth Goodwin, Ph.D., University of Wisconsin-Madison:** Based on the report of an investigation conducted by the University of Wisconsin-Madison (UW-M) and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Elizabeth Goodwin, Ph.D., former associate professor of genetics and medical genetics, UW-M, engaged in scientific misconduct while her research was supported by National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), grants R01 GM051836 and R01 GM073183.

PHS found that the Respondent engaged in misconduct in science by falsifying and fabricating data that she included in grant applications 2 R01 GM051836-13 and 1 R01 GM073183-01.

PHS found that in grant application 2 R01 GM051836-13, Respondent knowingly and intentionally:

- falsified Figures 5A and 5B by reusing figures from two of her earlier published papers and falsely labeling them to claim results that had not been achieved in her laboratory
- falsified Figure 7B by reusing a figure from one of her published papers and both relabeling it to claim she had detected the STAR-2 protein rather than the TRA-1 protein actually detected and modifying the image in the application to disguise its origin
- falsified Figure 8C by using a figure produced by one of her students and relabeled it to show that RNAi treatment of *C. elegans* led to increased expression of the TRA-2 protein when this result had not been obtained by the student
- falsified the table on Page 20 of the application showing phenotypic frequencies of worms expressing *star-2* (ok483) mutants by significantly overstating the level of aberrant phenotypes and fabricating certain categories of phenotypes not seen by the student conducting the research.

PHS finds that in grant application 1 R01 GM073183-01, Dr. Goodwin knowingly and intentionally:

- falsified Figure 5 because she used the same two lanes in both Figure 5 and Figure 7, although they were flipped horizontally in one of the figures to disguise their reuse. In Figure 7, the lanes illustrated an effect on *laf-1* during developmental stages of *C. elegans*, and in Figure 5, the same lanes purportedly illustrated an effect on *laf-1* noncoding RNA. A witness testified that the result in Figure 5 had not been observed, while that in Figure 7 had, indicating that the claims for Figure 5 were falsified.
- falsified Figure 8 by reusing photographs prepared by a student that identified the location of *rRas-1* expression in adult worms and claiming instead that the images illustrated the location of *laf-1* mRNA. The images had been enlarged and cropped to disguise their location.

Dr. Goodwin has entered into a Voluntary Exclusion Agreement in which she has voluntarily agreed, for a period of three (3) years, beginning on July 22, 2010: (1) to exclude herself from any contracting or subcontracting with any agency of the U.S. Government and from eligibility for, or involvement in, nonprocurement programs of the U.S. Government referred to as “covered transactions” pursuant to the HHS Implementation of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension at 2 CFR 376 *et seq.*; and (2) to exclude herself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

This Agreement is entered into pursuant to the terms of a plea agreement by and between the Respondent and the United States Attorney for the Western District of Wisconsin.

ORI provided a voluntary agreement which was incorporated into the settlement.

**Emily M. Horvath, Indiana University:** Based on the Respondent’s own admissions in sworn testimony and as set forth below, Indiana University (IU) and the U.S. Public Health Service (PHS) found that Ms. Emily M. Horvath, former graduate student, IU, engaged in research misconduct in research supported by National Center for Complementary and Alternative Medicine (NCCAM), National Institutes of Health (NIH), grant R01 AT001846 and Predoctoral Fellowship Award F31 AT003977-01, and National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH, grant R01 DK082773-01.

Specifically, the Respondent admitted to falsifying the original research data when entering values into computer programs for statistical analysis with the goal of reducing the magnitude of errors within groups, thereby gaining greater statistical power. The Respondent, IU, and ORI agree that the figures identified below in specific grant applications and published papers are false and that these falsifications rise to the level of research misconduct:

- Respondent admitted to falsifying Figures 6B, 18, 22, 23B, and 24 in NCCAM, NIH, grant application R01 AT001846-06, “Chromium Enhanced Insulin & GLUT4 Action via Lipid Rafts,” Jeffery S. Elmendorf, P.I. (07/01/04-05/31/20) (application was withdrawn in May 2009).
- Respondent admitted to falsifying Figures 6B, 8, 9D, 16D, and 21 in NIDDK, NIH, grant application R01 DK082773-01, “Mechanisms of Membrane-Based Insulin Resistance & Therapeutic Reversal Strategies,” Jeffrey S. Elmendorf, P.I. (3/15/09-01/31/13).
- Respondent admitted to falsifying Figures 2C, 5, 6D, and 11 in the publication: Horvath, E.M., Tacket, L., McCarthy, A.M., Raman, P., Brozinick, J.T., & Elmendorf, J.S. “Antidiabetogenic Effects of Chromium Mitigate Hyperinsulinemia-induced Cellular Insulin Resistance via Correction of Plasma Membrane Cholesterol Imbalance.” *Molecular Endocrinology* 22:937-950, 2008.
- Respondent admitted to falsifying Figure 2C in the publication: Bhonagiri, P. Patter, G.R., Horvath, E.M., Habegger, K.M., McCarthy, A.M., Elmendorf, J.S. “Hexosamine biosynthesis pathway flux contributes to insulin resistance via altering membrane PIP<sub>2</sub> and cortical F-actin. *Endocrinology* 150(4):1636-1645, 2009.

Respondent also admitted to falsifying Figures 2C, 5, 6D, 11, 13C, 15A, 16A, 17A, 18, 19C, and 20A, which are included in her thesis, “Cholesterol-dependent mechanism(s) of insulin-sensitizing therapeutics.” The Ph.D. was awarded to the Respondent on December 31, 2008. Respondent was supported by a Predoctoral Fellowship Award F31 AT003977 from 09/30/2006 to 09/29/2009.

Ms. Horvath has entered into a Voluntary Settlement Agreement in which she has voluntarily agreed, for a period of three (3) years, beginning on March 22, 2010: (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; (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 her in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which she is involved, must concurrently submit a plan for supervision of her duties to the funding agency for approval; the supervisory plan must be designed to ensure the scientific integrity of her research contribution; respondent agreed that she will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI; (3) 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) that she will write letters, approved by ORI, to relevant journal editors of the published papers cited above to state what she falsified/fabricated and to provide corrections if she has not already done so. These letters should state that her falsifications/fabrications were the underlying reason for the retraction/corrections.

**James Gary Linn, Ph.D., Tennessee State University:** Based on the findings in an investigation report by Tennessee State University (TSU) and additional analysis conducted by ORI in its oversight review, ORI found that James Gary Linn, Ph.D., former Professor, School of Nursing, TSU, committed misconduct in science and research misconduct in research supported by National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), grant S06 GM008092, and National Center for Research Resources (NCRR), NIH, grant G12 RR03033. Specifically, ORI found:

- The Respondent knowingly and intentionally falsified and/or fabricated the data and results of a study in which he purportedly tested the effects of an intervention to reduce sexual risk behaviors in high risk, impaired populations of homeless men with mental illness by reporting false values for variables in Tables 2-5 of *Cellular and Molecular Biology* 49(7):1167-1175, 2003. In that published article, he falsified the values in Tables 2-5 by altering the values that he had obtained from another author’s manuscript.
- The Respondent provided a CD ROM disc to TSU’s Institutional Research Investigation Committee (RIC) that he claimed contained files supporting his analyses for the article in question but that contained fabricated and/or falsified data.

- The Respondent submitted falsified summary data to the TSU RIC during the TSU investigation and to ORI.

ORI issued a charge letter enumerating the above findings of misconduct in science and proposing HHS administrative actions. Dr. Linn subsequently requested a hearing before an Administrative Law Judge (ALJ) of the Departmental Appeals Board to dispute these findings. However, on November 30, 2009, Dr. Linn withdrew his request for a hearing. On December 18, 2009, the ALJ of the Departmental Appeals Board accepted Dr. Linn's withdrawal and dismissed his request for a hearing. Thus, the scientific misconduct findings set forth above became effective, and the following administrative actions have been implemented for a period of three (3) years, beginning on January 7, 2010: (1) Dr. Linn has been debarred from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government referred to as "covered transactions" pursuant to the Department of Health and Human Service's Implementation (2 CFR Part 376 *et seq.*) of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension, 2 CFR Part 180; and (2) Dr. Linn is prohibited from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as consultant.

**Sagar S. Mungekar, Ph.D., New York University School of Medicine:** Based on the Respondent's written admission and set forth below, the New York University School of Medicine (NYUSOM) and the Office of Research Integrity (ORI) found that Sagar S. Mungekar, Ph.D., former M.D./Ph.D. student in the Sackler Institute of Graduate Biomedical Sciences at NYUSOM, engaged in research misconduct in research supported by National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), grants R01 GM35769, R01 GM55624, and T32 GM07308, and National Institute of Allergy and Infectious Diseases (NIAID), NIH, grant T32 AI007180.

Dr. Mungekar admitted that in his Ph.D. thesis he "increased statistical significance of the calculated means and standards of deviation [*sic*] of the UV spectrophotometric [*sic*] data presented by discarding certain experimental data and thus presented data that was falsified. In addition, as the repression ratios calculated and conclusions reached based on these data that included falsified data, those values and conclusions are fabricated. Approximately, 60-75 of the [Respondent's] Ph.D. research data was changed or falsified." Dr. Mungekar also admitted "while doing these experiments, I did not sequence all of the constructs that I constructed, thus, I could not be certain of the exact identity of the plasmids in question."

ORI found that Dr. Mungekar engaged in research misconduct (42 CFR Part 93.103) by fabricating and falsifying data. Specifically, ORI found that Dr. Mungekar falsified five tables and five figures (Tables 2-1, 2-2, 3-1, 4-1, 4-2 and Figures 2-3, 3-1, 3-2, 4-3, and 4-4) in his Ph.D. thesis entitled "Augtoregulation of Ribonuclease E," by discarding certain spectrophotometric data, to increase statistical significance, used to calculate repression ratios and RNA decay rates. Dr. Mungekar also claimed to have constructed 53 different reporter plasmids with RNase E mutants, when sequencing data did not exist to support this claim.

Dr. Mungekar has entered into a Voluntary Settlement Agreement in which he has voluntarily agreed, for a period of three (3) years, beginning on November 22, 2010: (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 him in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which he is involved, must concurrently submit a plan for supervision of his duties to ORI for approval; the supervisory plan must be designed to ensure the scientific integrity of his research contribution; Respondent agrees that he will not participate in any PHS-supported research until such a supervision plan is submitted to ORI; (2) that any institution employing him submits, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-funded research in which he is involved, a certification to ORI 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; and (3) to exclude himself voluntarily from serving in any advisory capacity to the U.S. Public Health Service (PHS), including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

**Gerardo L. Paez, University of Pennsylvania:** Based on the reports of an inquiry and an investigation conducted by the University of Pennsylvania (UP) and analysis conducted by the ORI Division of Investigative Oversight (DIO), ORI found that Gerardo L. Paez, Ph.D., former postdoctoral fellow, Section of Medical Genetics, UP School of Veterinary Medicine, engaged in research misconduct in research supported by National Eye Institute (NEI), National Institutes of Health (NIH), awards R01 EY06855 and R01 EY13132.

ORI found that the Respondent engaged in research misconduct by falsifying and fabricating retinal gene profile data that he purportedly obtained from three-week old normal dogs and dogs with X-linked progressive retinal atrophy. Specifically, ORI found that:

1. Respondent committed research misconduct by falsifying/fabricating data for gene expression profiles in retinal tissue from three-week old normal dogs and dogs with X-linked progressive retinal atrophy in abstracts and poster presentations for the 2006<sup>1</sup> and 2007<sup>2</sup> Association for Research in Vision and Ophthalmology (ARVO) meetings and in an unsubmitted manuscript draft.<sup>3</sup>
2. Respondent falsely labeled data files in the UP bioinformatics core computer and submitted falsely identified files to his research mentors.

Dr. Paez has entered into a Voluntary Settlement Agreement in which he has voluntarily agreed, for a period of three (3) years, beginning on June 9, 2010: (1) to exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory

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<sup>1</sup> Paez, G.L., Zangerl, B., Acland, G.M., & Aguirre, G.D. "Abnormal gene expression profile in retinas with RPGR frameshift mutation."

<sup>2</sup> Paez, G.L., Zangerl, B., Acland, G.M., & Aguirre, G.D. "Photoreceptor degeneration and tumor suppressor gene expression in canine retinas with RGA frameshift mutation."

<sup>3</sup> Paez, G.L., Zangerl, B., Acland, G.M., & Aguirre, G.D. "Age-related changes in the transcriptional profile of normal and XLPRAlI retinas using a custom cDNA microarray."

committee, board, and/or peer review committee, or as a consultant; (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 him in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which he is involved, must concurrently submit a plan for supervision of his duties to the funding agency for approval; the supervisory plan must be designed to ensure the scientific integrity of his research contribution. A copy of the supervisory plan also must be submitted to ORI by the institution. Respondent agreed that he will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI.

**Bengu Sezen, Ph.D., Columbia University:** Based on the findings of an investigation by Columbia University (CU) and additional analysis conducted by the Office of Research Integrity (ORI) during its oversight review, ORI found that Bengu Sezen, Ph.D., former graduate student, Department of Chemistry, CU, engaged in misconduct in science in research funded by National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), grant R01 GM60326.

Specifically, ORI made twenty-one (21) findings of scientific misconduct against Dr. Sezen based on evidence that she knowingly and intentionally falsified and fabricated, and in one instance plagiarized, data reported in three (3) papers<sup>4</sup>Sezen, B. & Sames, D. "Selective and catalytic arylation of N-phenylpyrrolidine:  $sp^3$  C-H bond functionalization in the absence of a directing group." *J. Am. Chem. Soc.* 127:5284-5285, 2005. Retracted in *J. Am. Chem. Soc.* 128:3102, 2006. and her doctoral thesis.

The following administrative actions have been implemented for a period of five (5) years, beginning on December 13, 2010: (1) Dr. Sezen is debarred from eligibility for any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government, referred to as "covered transactions," pursuant to HHS' Implementation of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (2 CFR Part 376 *et seq.*); and (2) Dr. Sezen is prohibited from serving in any advisory capacity to the U.S. Public Health Service (PHS), including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

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<sup>4</sup> Sezen, B., Franz, R., & Sames, D. "C-C bond formation via C-H bond activations: Catalytic arylation and alkenation of alkane segments." *J. Am. Chem. Soc.* 124:13372-13373, 2002. Retracted in *J. Am. Chem. Soc.* 128:8364, 2006.

Sezen, B. & Sames, D. "Oxidative C-arylation of free (NH) – heterocycles via direct ( $sp^3$ ) C-H bond functionalization." *J. Am. Chem. Soc.* 126:13244-13246, 2004. Retracted in *J. Am. Chem. Soc.* 128:3102, 2006.

Sezen, B. & Sames, D. "Selective and catalytic arylation of N-phenylpyrrolidine:  $sp^3$  C-H bond functionalization in the absence of a directing group." *J. Am. Chem. Soc.* 127:5284-5285, 2005. Retracted in *J. Am. Chem. Soc.* 128:3102, 2006.