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

Office of Research Integrity Annual Report 2012

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I. ORI HIGHLIGHTS OF CALENDAR YEAR 2012

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 U.S. 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 U.S. 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 Code of Federal Regulations Part 93 ("PHS regulation"). ORI is composed of the Division of Investigative Oversight (DIO), the Division of Education and Integrity (DEI), and the Office of the Director.

- Institutions receiving research funding from PHS are required to report annually their research activity for the prior year to ORI. In 2012, the 6,714 funded institutions reported 323 allegations, inquiries, or investigations. The count in year 2012 is a record of what institutions submitted in their 2011 Annual Report, which is submitted to ORI in 2012. This count will not necessarily be consistent with DIO reported activity. This count is derived from only the reported activity of institutions.

- From all sources, ORI received 423 allegations in 2012, an increase of 56 percent over the 240 allegations handled in 2011, and well above the 1992-2007 average of 198.

- DIO's review process involved opening 41 new cases, closing 35, and carrying 45 cases into 2013. The number of open cases is the highest number in 16 years.

- For the 35 cases closed by ORI in 2012, it took institutions a mean of 20.1 months to close the institutional case after notifying ORI of the allegation. ORI took a mean of 7.5 months to review the reports, obtain additional information from the institution, complete the ORI analysis, negotiate any voluntary settlement agreements with respondents and administrative actions, and then close the case.

- In 2012, ORI made findings of research misconduct in 40 percent of the cases (14/29). In contrast, 36 percent of the cases, the historical average, are found guilty in a year.

- Administrative actions imposed on those who committed research misconduct included: debarred 6 respondents for a varying number of years, prohibited 14 from working as advisors, and required 9 to be supervised in any PHS-supported research activity.

- 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 the Office of the General Counsel (OGC) in seeking voluntary settlement agreements or producing charge documents, to bring the cases to closure, as well.

- ORI provided Rapid Response for Technical Assistance (RRTA) on 47 occasions in 2012, a decrease of 25 percent from the 63 instances in 2011. Most of the rapid responses involved discussion with institutional officials who had concerns about forensic analysis for their cases. The remainder involved interactions with journal editors who requested assistance on verifying problems with submitted manuscripts or requested guidance on how to proceed with anonymous complaints.

- ORI staff made 39 educational presentations during 2012. In 2012, ORI sponsored the Quest for Research Excellence: Georgetown University, Washington, DC, March 15-16, 2012.

- ORI also actively participated in a meeting on research integrity at the 2012 American Association for the Advancement of Science (AAAS) Annual Meeting, Vancouver, BC, Canada, February 16-20, 2012.

- The ORI web site (http://ori.hhs.gov/) received 1,033,722 page views from 366,465 visits in the 2012 calendar year. The site was viewed by 278,352 unique users from 204 countries. The top 10 countries visiting the ORI sites were, respectively: the United States, India, United Kingdom, Canada, Philippines, Australia, Netherlands, Mexico, Puerto Rico, and Germany. The vast majority of users viewed findings of research misconduct and educational resources for RCR.

- "The Lab: Avoiding Research Misconduct" is an interactive online video, which was released and distributed in February 2011. It has been translated into Chinese. *The Lab* allows users to assume the roles of four "playable" characters including: a graduate student, a postdoctoral researcher, a principal investigator, and a research integrity officer. This educational resource has been integrated into worldwide RCR training programs and has received positive reviews from the media such as *USA Today*, *the Journal of the American Medical Association (JAMA)*, *Science*, and *Nature*.

- In the 2012 calendar year, ORI developed a prototype interactive video on the topic of clinical research. The video allows learners to make decisions for a clinical research coordinator who must make numerous decisions that affect the outcomes of a study on a new drug treatment. The prototype was screened at the Public Responsibility in Medicine and Research (PRIM&R) annual conference. The final product will include three additional "playable" characters and is planned to be released in 2014.

- The Research on Research Integrity (RRI) Program, in coordination with the National Institutes of Health (NIH), made one new award in 2012. In the first 11 years, this action increased the number of studies supported to 60. The studies have produced 124 articles, in more than 30 different publications.

II. DIVISION OF INVESTIGATIVE OVERSIGHT (DIO) MISSION: RESPONDING TO RESEARCH MISCONDUCT

All institutions receiving research funds from U.S. Public Health Service (PHS) agencies must have an assurance with ORI on file. This assurance means an institution promises ORI that (1) it has the required policies and procedures in place for dealing with allegations of research misconduct (stipulated in 42 Code of Federal Regulations [CFR] Part 93); (2) it has provided ORI with contact information for its assurance official; and (3) it 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 allegations result in a decision by an 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 the intramural components of PHS agencies. When the investigation is completed by the institution, the report, pertinent evidence, other records, and a decision letter are sent to DIO for oversight review. Upon completion of the review, recommendations for either misconduct or no misconduct findings are forwarded to the Director of ORI, who makes the determination on research misconduct. Closure of cases, in which research misconduct findings are made, is generally reached through voluntary agreements between the respondent and HHS.

If a respondent contests ORI's proposed findings, the respondent may request the HHS Departmental Appeals Board (DAB) for a hearing before an Administrative Law Judge, where ORI is represented by the HHS Office of General Counsel (OGC). On an as-needed basis, DIO Scientist-Investigators provide litigation support and expert testimony for and through OGC.

DIO staff organizes conferences and workshops on the handling of research misconduct allegations, particularly providing training to Research Integrity Officers (RIOs). The training was focused on RIOs from institutions that received larger amounts of PHS funding to conduct research, because it has been determined that there is a direct correlation between the amount of research funds and the amount of research misconduct. Training has expanded to include RIOs from institutions with less PHS funding because those RIOs are less prepared to handle allegations when they arise.

DIO staff protects the position and reputation of individuals who raise allegations of research misconduct in good faith. Based on the circumstances, specific guidance is often provided to a whistleblower detailing options under both the federal regulation and institutional policies. If necessary, institutional officials are reminded of their obligations to promptly address instances of possible retaliation in a fair and equitable manner.

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, if requested, DIO will provide information on PHS policies and procedures to individuals who have made an allegation or who have been accused of research misconduct.

A. Criteria for Evaluating Allegations

ORI staff assesses each allegation received to determine whether it meets the criteria for ORI's jurisdiction. These criteria are as follows:

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 allegation represents falsification, fabrication, 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, June 16, 2005, the following definition of PHS Policies on Research Misconduct, 42 CFR Part 93, applies, and DIO assesses these allegations based on the final definition:

> "*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). Allegations that involve questions of honest error or differences in scientific interpretations or judgments of data are excluded from the PHS definition.

3. Plagiarism Definition

ORI has developed a **working definition** of plagiarism that excludes authorship or credit disputes between former collaborators. Institutions may exercise a more stringent definition of plagiarism and take appropriate institutional administrative actions regardless of ORI's determinations (see 42 CFR Part 93.319).

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 allow ORI to assess whether the allegations meet the PHS definition of research misconduct. When an allegation is made anonymously, it may preclude ORI from obtaining additional specific data. Even if no action can be taken, ORI continues to track the allegation for up to two years. ORI continues tracking an allegation in the event that additional information is provided by the complainants or that additional allegations or evidence is obtained from other sources.

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

ORI carefully evaluates all allegations received and reaches an appropriate disposition. ORI also regularly requests additional information about allegations from an institution. The initial assessment of many allegations requires appreciable ORI staff work, even when they do not evolve into a research misconduct case.

In 2012, ORI received 423 allegations. The dispositions of the allegations received by ORI are presented in Table 1. All allegations are recorded and assigned an accession number, and the case is coded as a pre-inquiry assessment (PIA). Accessions are administratively closed when ORI finds that the allegations:

1. do not fall under ORI jurisdiction or meet these criteria, or

2. do not warrant referral to another agency, or

3. were resolved through further review and information.

Some allegations are referred to other federal agencies or offices when they involve concerns about human subjects or animal protection in research, financial issues, research funded, or matters funded by other agencies, etc.

If an allegation is not within ORI's jurisdiction or lacks sufficient specific information to permit a determination regarding disposition, ORI assigns an accession number and classifies these allegations with specific codes:

- If follow-up is not needed, which would be the case if a complaint did not meet the definition of research misconduct or warrant referral to an institution or other federal agency, it is coded "NA" for no action.

- If a complaint lacks sufficient specificity or information to permit further assessment, but additional information is expected, it is coded "NAPN" for no action possible now.

- If complaints involve issues such as human subject concerns, financial fraud, abuse of animal rights, or possible criminal activity, ORI promptly refers them to appropriate agencies such as the Office of Human Research Protections, the Office of Management Assessment, the Office of Laboratory Animal Welfare, and OIG. Similarly, if allegations of research misconduct are received that involve funding by other federal agencies, such as the Department of Veterans' Affairs, the Department of Defense, the Department of Agriculture, or the National Science Foundation, ORI ensures that the relevant allegations are shared with or referred to the other funding agency.

Allegations received from National Institutes of Health (NIH) extramural programs 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 an 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. These assessments are handled by each individual funding component.

ORI accessions that originate from allegations made to ORI are coded as pre-inquiry assessments (PIAs). A PIA is also assigned to assessments that have been identified by institutions as active inquiries or investigations. PIAs are followed continuously by DIO to (1) ensure that the institutional reporting requirements are met, (2) determine whether extensions of time are required, and (3) determine whether appropriate interim reports are received with requests for an extension.

As Table 1 indicates, of the 423 allegations made to ORI (or to NIH and reported to ORI) in 2012, 116 were assessed by ORI in detail, and 12 of the accessions were opened as formal cases in 2012. Of the remaining accessions, 25 were administratively closed after review, and 79 remained open at the end of the year.

The process and time duration to handle a case of research misconduct is complex. Assessments of the allegations that resulted in new ORI cases took an average of 131 days; those that resulted in administrative closures took an average of 66 days. These data do not reflect the additional

time taken by NIH officials, who handled (with advice, assessment, and assistance from ORI as appropriate) seven allegations that were made directly to NIH by a complainant.

The 423 allegations that ORI received in 2012 were an increase of nearly 57 percent over the 240 allegations handled in 2011.

Table 1: Disposition of Allegations in ORI, 2012

Handling of Allegations - Outcome in ORI	Processes	Outcome
No Action Possible Now or No Action	247	
Handled by Agency	21	
Referred to Other Federal Agencies	20	
Allegations Made Directly to ORI		116
Allegations Made Initially to NIH		19
All Allegations	135	
Total Allegations Handled	**423**	**135**
Handling of Accessions		
Administratively Closed After Review		25
Unresolved Accessions		79
Moved to Active Case Status		12
Total Accessions Made		**116**

Table 2 summarizes the distribution of time in days needed to resolve accessions coded as PIAs during 2012. DIO accessions are not converted to formal ORI cases as quickly as in previous years. This decrease is due to some uncertainty about the merits of many of the institutional inquiries and because of the inadequacy of information available to DIO prior to receiving the final investigation report and supporting documentation. After a more complete review of the investigative record becomes possible, DIO determines whether the matter warrants opening a formal case for oversight review or, alternatively, administratively closing the accession.

Table 2: Time for Conduct of PIAs by ORI, 2012

Outcome for ORI Accessions	Number of Allegations	Distribution of Resolution Times (in Days)		
	423	Mean	Median	Range
Opened a Formal Case	12	178	188	42-298
Administratively Closed	25	89	77	5-328
Unresolved at End of Year 2012	79	164	146	25-356
Total	**116**			

C. ORI Caseload Includes Inquiries and Investigations

Table 3 summarizes the case status regarding cases. The table includes 39 cases carried forward from 2011. Of the 41 cases opened by DIO in 2012, 23 arose from PIAs from earlier years. The ORI caseload is divided into institutional inquiries and institutional investigations. ORI carried forward 39 cases from 2011, opened 41 new cases, and closed 35 cases during 2012 (see Table 3). At the end of calendar year 2012, ORI had 45 institutional investigations that were active formal cases, and they were all carried into 2013.

Table 3: ORI Research Misconduct Caseload Case Type, 2012

Case Type	Forwarded From 2011	Opened in 2012	Closed in 2012	Open Cases Forwarded to 2013
Institutional Inquiry	0	2	2	0
Institutional Investigations	39	39	33	45
Total	**39**	**41**	**35**	**45**

*Note: Institutional inquiries are normally received by ORI as inquiries. However, throughout the course of the year, the institution may start an investigation, turning the inquiry into an investigation.

D. Processing of Inquiries and Investigations

1. When ORI becomes involved in institutional inquiries

Under the PHS regulations, institutions are not required to report the initiation or progress of inquiries to ORI unless they result in investigations. However, ORI may become involved in institutional inquiries when ORI receives an allegation directly from a complainant and then requests that the institution conduct the inquiry. Under these circumstances, ORI asks that the institution provide the outcome of the inquiry to ORI, even when a decision was made not to move to an investigation.

An institution's inquiry process can lead to a recommendation to conduct an investigation. Under certain circumstances, an institution may want to close a case at the inquiry stage (see 42 CFR Part 93.316); the institution is required first to inform ORI of its decision. Then the institution should seek guidance from ORI on whether this decision is appropriate. For example, if the inquiry found that evidence would result in research misconduct findings but the misconduct was of minor significance, ORI might concur with an institutional decision not to conduct an investigation. Alternatively, ORI might make findings of research misconduct after

reviewing the data. 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 there, ORI would likely require the investigation to proceed.

2. Institutional investigations reported to ORI

Institutions are required by the PHS regulation to submit a report to ORI at the initiation of an investigation and then again upon completion of the investigation. ORI reviews the reports and supporting documents to determine whether 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 2012 with 39 cases carried forward from 2011. During the year, 39 new institutional investigations were opened; 33 institutional investigation cases were closed (see Table 4). Of the 33 closed oversight investigations, 14 (40 percent) resulted in ORI findings of research misconduct; 19 did not lead to findings. The number of findings of research misconduct this year is consistent with the average of 12 findings each year during 1993-2012. Summaries of the 2012 cases may be found in section VI of this report. There were 45 oversight investigations carried into 2013.

Table 4: Outcome of Research Misconduct Cases Closed by ORI, 2012

Outcome of Cases					
Case Type	**No Investigation**	**No Research Misconduct**	**Misconduct Finding**	**Administrative Closure**	**Total Closed**
Inquiry	2	2			2
Investigations		17	14	0	33
Total	**2**	**19**	**14**	**0**	**35**

3. Administrative closures

A formal ORI case file may be administratively closed when ORI concludes the following: that no PHS funds or applications were actually involved, that continuing effort will not produce sufficient evidence to resolve a case satisfactorily, or that after additional review, ORI determines that the allegation did not fall under the PHS definition of research misconduct or warrant further action. There were no formal cases administratively closed in 2012.

4. Types of allegations and administrative actions

During 2012, all the formal ORI closed cases (with or without a finding of misconduct) involved allegations of falsification, fabrication, plagiarism, or a combination of all three (see Table 5).

Table 5: Types of Allegations in Closed Investigations and Their Outcomes, 2012

Allegation	Investigation	ORI Findings or PHS Administrative Actions
Falsification	15	5
Fabrication	2	1
Fabrication/Falsification	13	7
Plagiarism	2	0
Plagiarism/Falsification	1	1
Total	**33**	**14**

5. Duration of time involved in resolving and closing cases

The average duration of 20.1 months for conducting, reviewing, and closing these cases involved 12.6 months by the institution and 7.5 months for ORI oversight and administrative action (see Table 6). ORI closed 27 (82 percent) of the cases within 8 months after receipt of the final action from the institution.

The action period for the 33 institutional investigations included the institutions' inquiry, investigation, and adjudication phases, whereas 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 institutional officials for the basis of their decision about whether research misconduct occurred. Additional ORI analysis is usually required to make an ORI finding of research misconduct. In most instances where it makes a finding of misconduct, ORI is able to close its cases by reaching a voluntary settlement agreement with the respondent. When such an agreement cannot be reached, 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 HHS determination is made, although subject to possible appeal in federal court.

Table 6: Duration of Research Misconduct Cases Closed by ORI, 2012

Distribution of Resolution Times (in Months)			
Location of Activity	**Mean**	**Median**	**Range**
Institution	12.6	9	3-45
ORI	7.5	2	1-60

E. Examination of Outcomes of Closed Cases in 2012

1. HHS administrative actions imposed in closed cases

HHS takes a range of administrative actions to protect the integrity of future PHS-funded research (see Table 7). 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 Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) (see 2 CFR Part 180).

Of the 14 cases in 2012 in which PHS found research misconduct or HHS administrative actions were imposed, two respondents were debarred or voluntarily excluded for 7 years. One individual was debarred or voluntarily excluded for 3 years. One was debarred for 5 years; one for 2 years; and one for 1 year. Other administrative actions imposed on respondents in these 14 cases included the following:

(a) Prohibition from serving in any advisory capacity to PHS, including service on PHS advisory committees, boards, and/or peer review committees or as a consultant for a specified period of time (14 persons).

(b) Participation in PHS-funded research is subject to supervision 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 (9 persons).

(c) Certification by the institution that the respondent's performance meets generally accepted standards (6 persons).

Table 7: HHS Administrative Actions Imposed in Closed Investigations with Research Misconduct Findings or Administrative Actions, 2012

HHS Administrative Action	Duration (Years)	Number of Actions
Debarment or Voluntary Exclusion	7	2
Debarment or Voluntary Exclusion	5	1
Debarment or Voluntary Exclusion	3	1
Debarment or Voluntary Exclusion	2	1
Debarment or Voluntary Exclusion	1	1
Prohibition from Service as an Advisor for PHS	2	4
Prohibition from Service as an Advisor for PHS	3	7
Prohibition from Service as an Advisor for PHS	5	1
Prohibition from Service as an Advisor for PHS	7	2
Supervision Plan Required	4	1
Supervision Plan Required	3	5
Supervision Plan Required	4	0
Certification of Work	2	2
Certification of Work	3	4
Certification of Work	4	
Retraction of Article		2

F. Rapid Response for Technical Assistance (RRTA) Program

ORI provided RRTA on 47 occasions in 2012. This number is a decrease of 25 percent compared to the 63 instances in 2011. Most of these rapid responses involved discussion with institutional officials who had concerns about how to manage newly identified or ongoing cases or needed assistance in forensic image analysis. The remainder involved interactions with journal editors who requested assistance with problems concerning submitted manuscripts and with anonymous complainants who requested guidance on how to proceed with complaints.

G. Implementation of HHS Administrative Actions: PHS ALERT

The PHS ALERT system is a confidential system of records subject to the Privacy Act for collecting, controlling, and disseminating information about individuals found to have engaged in research misconduct. The purpose is to help federal agencies make decisions about funding, committee appointments, and federal employment.

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. Being listed in the PHS ALERT system does not necessarily mean that individuals are debarred and cannot receive PHS support or serve in an advisory capacity to PHS, unless a PHS administrative action imposed on them specifically requires it.

The implementation of HHS administrative actions is monitored through the PHS ALERT, a non-public system of records that is 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, or (3) the individual has agreed to a voluntary corrective action as a result of an investigation of research misconduct. If ORI concurs with the institutional findings, the individual's name will remain in the ALERT system until the expiration of any administrative actions imposed by PHS, at the recommendation of ORI.

Information on each individual in the system is limited and includes such identifying information as the individual's name, date of birth, institution, sources of research funding, and a summary of any administrative actions imposed.

As of January 1, 2012, ORI listed the names of 47 individuals in the ALERT system (see Table 8). During the year, ORI added 15 names and removed 14. On December 31, 2012, the names of 48 individuals were in the system.

The 15 names added are those individuals who were found to have committed research misconduct in an institutional investigation that was reported to ORI. Fourteen names were removed during the year because the term of the HHS administrative actions had expired.

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 Action 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: Summary of PHS ALERT System Activity, 2012

PHS ALERT System Activity, 2012	
As of January 1, 2012	47
Additions	15
Action Expired/Removed	14
As of December 31, 2012	**48**

H. Research Integrity Officer (RIO) Boot Camp Training

An extensive training program for RIOs has now completed its sixth year after it was initiated to deal with the rapid turnover and inexperience of RIOs at many universities. David Wright, Ph.D., former ORI Consultant and current ORI Director, has been leading these boot camps. In 2012, institutional RIOs, their staff, and legal counsel from major research universities attended the 10th and 11th RIO Boot Camps. The 10th program was held in Chicago, IL, hosted by Northwestern University in June 2012, and the 11th program was held in Washington, DC, hosted by Howard University in December 2012. To date, a total of 173 RIOs and 53 university legal counsels have attended the RIO Boot Camps since their inception in early 2007.

The curriculum for the 3-day ORI-sponsored RIO Boot Camp is built on a model of peer-to-peer education taking advantage of experienced university RIOs and Scientist-Investigators from the Division of Investigative Oversight (DIO) at ORI as facilitators. Each boot camp brings together 25-30 RIOs and their counsel and provides a forum to discuss critical skills RIOs need to accomplish their roles and the most important problems facing RIOs today. Attendees participate through written exercises and role-playing in the context of a fictional misconduct case, to practice the key elements of their role in handling allegations of research misconduct and problem-solving for difficult scenarios. Each participant leaves the boot camp with an electronic compilation of Standard Operating Procedures and knowledge of best practices to function as a RIO. All participants gain experience with handling simulated allegations of research misconduct and will be able to critique strengths and weaknesses of their own and alternative approaches.

The RIO Boot Camp program has continually been monitored by evaluations and debriefings at the end of each RIO Boot Camp. Its success has been described by Drs. Rebecca Henry and Brian Mavis, Michigan State University, in an evaluation of two RIO Boot Camps held in 2010-2011 (*ORI Newsletter*, 20(1), Dec 2011). The evaluation revealed that participants were considerably more confident in performing specific functions essential to their roles as RIO upon completion of the boot camp program.

The RIO Boot Camps have worked to professionalize the RIO's role and establish a network for the boot camp attendees through access to a RIO web site. Currently, an Advanced Topics RIO Boot Camp is planned for 2014. The "advanced" boot camp is designed for graduates of the "standard" boot camp to help RIOs and counsel prepare for especially difficult cases of research misconduct. This boot camp will draw heavily on problems encountered with actual cases and should help institutions make sustainable findings of misconduct when the evidence so warrants.

The RIO Boot Camps have helped to create a network of RIOs and have built a foundation for a future RIO Association that is currently being formed. This RIO leadership may help administer the boot camp effort and may help to establish a supportive professional organization for RIOs that may host conferences, publish an online newsletter, and create confidential networks of mutual support.

III. INSTITUTIONAL COMPLIANCE

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

A. Assurance Program

The Assurance Program is responsible for ensuring that PHS research funds are awarded to only 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 Code of Federal Regulations (CFR) Parts 50 and 93. These regulations 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 and revising it upon ORI request, and complying with the policies and procedures and PHS regulation.

The Assurance Program meets its responsibilities by doing the following: maintaining the assurance database, gathering and summarizing information from institutions in their Annual Report, reviewing institutional policies and procedures associated with the Compliance Review Program, and coordinating with the appropriate National Institutes of Health (NIH) center that an institution is in compliance with 42 CFR Part 93 and is eligible to receive their awards.

1. Assurance database

Maintaining an accurate assurance database is essential to the successful operation of the Assurance Program because ORI uses the database to determine the eligibility of institutions to receive PHS research funds. ORI also uses the database to communicate that information to NIH, which then releases the funding. In 2011, there were a total of 6,714 institutional assurances on file with ORI, an increase of 336 from 2010. There were 95assurances inactivated because the institution failed to submit its 2011 Annual Report in 2012, 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. There are 425 foreign institutions (7 percent of the 6,714) that hold an assurance; they are included and part of each of the six categories listed in Table 9. There has been an increase in each type of organization that conducts research.

Table 9: Number and Type of Institutions with Active Assurances, 2011-2012

Type of Institution	Number 2010	Increased 2011	Total at End 2011	Increased 2012	Total at End 2012
Institutions of Higher Education	1,070	+20	**1,090**	+40	**1,130**
Research Organizations, Institutes, Foundations, and Laboratories	492	+18	**510**	+29	**539**
Independent Hospitals	300	+6	**306**	+30	**336**
Educational Organizations, Other Than Higher Education	43	+3	**46**	+2	**48**
Other Health, Human Resources, and Environmental Services Organizations	719	+31	**750**	+33	**783**
Other (Small Business)	3,754	+258	**4,012**	+300	**4,312**
Total	**6,378**	**336**	**6,714**	**434**	**7,148**

2. 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 receive PHS research funds.

The electronic submission of the 2011 Annual Report began in January 2012, for the 6,714 institutions that had an assurance on file with ORI as of December 31, 2011.

Completed Annual Reports were received from 4,065 institutions for a response rate of 61 percent. ORI inactivated 2,554 institutions that did not return their Annual Reports by the March 31 deadline. Inactivation can lead to substantial delay in funding. All but 95 were reactivated later because Annual Reports were submitted after the due date.

3. Reported research misconduct activity from Annual Reports

The Annual Report form requests institutions to report not only that they have completed 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. Clearly, from Table 10, the number of allegations reported each year is higher than the year before.

Table 10: Research Misconduct Activity, 1993-2012

Annual Institutional Report		
Year*	**New Allegations**	**Total**
2012	154	**323**
2011	191	**303**
2010	175	**286**
2009	189	**297**
2008	113	**230**
2007	183	**313**
2006	151	**262**
2005	137	**250**
2004	120	**221**
2003	136	**242**
2002	163	**262**
2001	127	**205**
2000	103	**185**
1999	89	**161**
1998	69	**136**
1997	92	**165**
1996	127	**215**
1995	104	**200**
1994	89	**168**
1993	86	**159**

*The count in year 2012 is a record of what institutions submitted in their 2011 Annual Report, which is submitted to ORI in 2012. This count will not necessarily be consistent with DIO reported activity. This count is derived from only the reported activity of institutions.

B. Compliance Review Program

The Compliance Program was established to evaluate institutional compliance with the requirements of 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 DIO's 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 (complainants, witnesses testifying about possible misconduct, or institutional committee members investigating misconduct (93.226)). 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 to submit a report of its review to ORI.

The following are anonymized cases during 2012. 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

1. This case involved a claim by an individual who was terminated from his position as a result of raising a misconduct allegation against his laboratory chief. ORI reviewed the available evidence and materials associated with the allegation and determined that the issues raised did not fall within the definition of research misconduct. The issues involved a disagreement over the conduct of research and the interpretation of data. Because such differences of opinion are explicitly excluded from the definition of research misconduct, ORI had no jurisdiction in the matter and could not address the retaliation claim.

2. The lengthy case record chronicles the interactions between a graduate student and institutional officials over the substance and direction of his graduate program. When he was ultimately dismissed from graduate school, the student claimed such action represented retaliation in response to his challenges to the research. In a preliminary review of available evidence and other documentation, ORI determined that the record lacked evidence of a clear and direct connection between the allegation and the adverse action. Furthermore, the complaint was never presented as an allegation of research misconduct, and more likely represented a difference between the two in the interpretation of data. To address his concerns, the institution proceeded to address the retaliation allegations under its applicable institutional policy. Prior to the completion of the process, ORI was informed that the institution had reached a settlement with the complainant, and the institutional process to address the retaliation allegation was terminated with the withdrawal of the retaliation complaint. On the basis of these actions, ORI closed its review.

3. This case involved an individual's allegations of possible harassment and other retaliatory acts as a result of making an allegation of plagiarism against a coauthor and a principal investigator (PI) on an NIH grant. The complainant stated that he had coauthored with the PI and others a draft of a manuscript a number of years ago that was never submitted for publication. There was a subsequent falling-out between the complainant and the PI, and the complainant was removed from the funded project. The complainant then learned the PI and others published a paper in 2011 that included significant portions of the prior manuscript he had coauthored, including many word-for-word text passages, five of six figures, experimental data, and references. There was no acknowledgment of the complainant's contributions to the reported research in the 2011 publication. As a result of his raising these allegations of plagiarism, the complainant claimed that he suffered a number of retaliatory acts by the PI, including the removal from his office, and accusations of other serious improprieties. ORI's policy on plagiarism specifically excludes authorship disputes, which this case clearly involved. Because the allegation fell outside ORI's jurisdiction, the institution had no obligation under the federal regulation to investigate and report on the allegation or to address the retaliation complaint. While ORI was precluded from taking any action because of the lack of jurisdiction, the institution did conduct an investigation of the matter under its own internal policies. The institution determined that the PI and others were guilty of irresponsible conduct of research by failing to give credit to the complainant for his contribution to the reported research. ORI also noted that the institutional policy specifically addressed its obligation to prevent retaliation, regardless of the funding source.

4. ORI was contacted by an individual claiming that as a result of raising allegations of misconduct he was threatened by his supervisor, placed on administrative leave and banned from campus, and finally terminated from his position. The federal regulation required institutions to protect the position and reputation of individuals making allegations of research misconduct on research supported by PHS. After assessing the allegations and supporting materials provided, ORI determined that the primary complaint involved alleged violations of radiation safety regulations. ORI's authority is limited to allegations of research misconduct involving research funded by PHS, so it was unable to take any further action in addressing this retaliation complaint because of its lack of jurisdiction. However, ORI subsequently was contacted by the Occupational Safety and Health Administration, U.S. Department of Labor, and provided information that had been submitted by the complainant in support of his claim.

5. During the course of an oversight review by ORI, it was noted that the investigative process was possibly compromised by the failure of an institution to properly sequester evidence, as well as other infractions. The involvement, at least initially, of another institution in the process complicated many of the procedural issues. A more detailed review of the institutional research misconduct policies was conducted, and the lack of clear guidance with respect to proper sequestration was noted. The policy did assign general responsibility for compliance with federal regulations to the Director of Research Administration, and it was suggested that ORI be contacted for guidance in addressing unusual circumstances that occur during the course of the institutional process.

6. This case was a follow-up to a previous case regarding possible retaliation against a faculty member at a major university after raising concerns about some aspects of research associated with his grant award that was carried out at another institution. ORI reviewed all the available evidence and other documentation and determined that ORI did not have jurisdiction. ORI determined that although the relevant project was supported by PHS research funds, the allegations were initially framed as concerns rather than research misconduct. ORI also determined that no further evidence or testimony was provided to recast these concerns to allegations fitting the definition of research misconduct. The complainant was informed of ORI's determination, and the case was closed.

In a subsequent contact, the complainant alleged additional instances of adverse actions and believed that they were retaliatory because the institution had described his allegations as research misconduct. ORI reviewed additional information provided by the complainant and determined that the new materials provided no basis for ORI to reconsider its initial assessment.

7. During the course of its oversight review of an institutional investigation, ORI noted a number of procedural deficiencies in the institutional process and determined that the investigation report lacked sufficient detail in the analysis of the research misconduct allegations for ORI to pursue the misconduct finding. A full compliance review was initiated to address these concerns.

Part of the compliance review included an examination of the institutional research misconduct policies. They were found to be generally compliant with the requirements of the PHS regulation, with a limited number of omissions and weaknesses that were noted for correction. A more extensive review was conducted to evaluate the institutional process of reviewing the allegation in this case to determine its adherence to the requirements of both the PHS regulation and the institutional misconduct policy. Issues of concern in the process included improper sequestration of evidence, possible conflicts of interest, inadequate interview procedures, and failure to pursue additional leads. The ORI compliance review provided a detailed assessment of all the significant issues and recommended that the institution develop a corrective action plan to (1) provide institutional officials with appropriate notification and training in the handling of research misconduct allegations in accordance with the PHS regulation, (2) revise the institutional misconduct policy to address the omissions and weaknesses noted in this review, (3) immediately notify ORI of all allegations of research misconduct received, and (4) submit any assessment or inquiry report associated with any allegation of research misconduct received in the next 2 years. A timely and generally responsive plan was received from the institution, but lacked specific details on initiatives to disseminate information on the institutional requirements under the PHS regulations. In response to ORI's follow-up request for more detailed information, the institution provided additional details on its plan to utilize aspects of its website, its curriculum, and a series of presentations to better publicize the requirements of the PHS regulation.

8. This case involved compliance issues associated with both a research misconduct allegation as well as a retaliation complaint. Although the institution has a research misconduct policy that generally followed the requirements of the PHS regulation, it had a similar policy that was to be used in the reporting and investigating of allegations of suspected improper governmental activities. The misconduct allegation was initially reviewed under the institutional handling of this policy, and a determination was made that the research misconduct allegations did not fall within the definition of an improper governmental activity. Therefore, the allegations were not misconduct, primarily because the data were not published or used as the basis for further research. Based on its own assessment of the facts of the case, ORI determined that the institutional report was not adequate and the process flawed, and further investigation was necessary, utilizing the appropriate institutional misconduct policy. Likewise, based on its initial finding that there was no research misconduct, the institution dismissed the retaliation claim. ORI also directed the institution to reassess the retaliation complaint, utilizing the appropriate criteria.

ORI continued to monitor both processes and was informed while the retaliation investigation was still ongoing that the complainant had decided to initiate independent legal action with respect to the retaliation allegation. The ORI whistleblower guidelines provide that a complainant may opt out of an institutional process, but if they do so, it represents a rejection of the investigation process required by the ORI guidelines. Under these circumstances, once the intentions of the complainant were confirmed, ORI deemed that the institution had met its obligation under the guidelines and would not be required under its misconduct policy to pursue the whistleblower complaint further.

9. This case involved, in part, the possible identification of multiple respondents who were coauthors on a publication with alleged falsified data. A more specific issue involved the fact that one of the coauthors had moved to another institution prior to the submission of the allegation. Institutional officials believed that the responsibility for assessing this individual's involvement with the possible falsification belonged to the institution to which he had moved. After being informed of this issue and the possible misunderstanding surrounding it, ORI contacted institutional officials and advised them that it was ORI's position that the institution where the research had been conducted was responsible for reviewing the allegations regardless of whether or not the respondent was still located there.

IV. DIVISION OF EDUCATION AND INTEGRITY (DEI) MISSION: TO PROMOTE A RESPONSIBLE CONDUCT OF RESEARCH (RCR) PREVENTION PROGRAM THROUGH EDUCATION AND RESEARCH

ORI promotes research integrity and prevention of research misconduct through DEI. This division focuses on activities to promote RCR through educational and research efforts.

In 2000, DEI was created and directed by DHHS:

> *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)

To meet this mandate, ORI operates the following programs:

A. Resource Development Program – Education on RCR

DEI created the RCR Resource Development Program in 2002, to support the creation of RCR instructional materials by the research community for worldwide use. 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 for recipients of its training grants, which have further increased the need for development of external training materials. The requirements are located on the NIH web site at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html

The Education in RCR program has supported over 60 projects since it was established in 2002. Completed resources are posted at ori.hhs.gov/education/products/. Resources developed through the program, and independently by universities, cover nine core RCR instructional areas.

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

Current projects include the following:

1. Interactive video development:

In the 2012 calendar year, ORI developed a prototype interactive video on the topic of clinical research. The video allows learners to role play making numerous decisions as a clinical research coordinator that affect the outcomes of a study on a new drug treatment. The prototype was screened at the Public Responsibility in Medicine and Research (PRIM&R) annual conference. The final product will include three additional "playable" characters and is planned to be released in 2014.

2. The National Academy of Sciences (NAS) 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 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 was delayed a year and did not get started until 2011. The study is expected to be completed in 2013. The project web site is located at 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 those resulting 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.

B. Collaborations and Partnerships

ORI and other federal agencies, industries, and academic institutions worked with the NAS Government-University-Industry Research Roundtable (GUIRR) effort to plan a follow-up working conference to the 2013 conference. The 2010 conference focused on "Examining Core Elements of International Research Collaboration" and was held July 26-27, 2010. The goal of the next conference will be to create greater cultural awareness of multiple issues that could be provided to all three sectors when working in different cultures.

C. Conference and Workshop Program

ORI has sponsored, supported, or developed a conference and workshop program for the past 20 years. Historical and planned information about the conference and workshop program is available at http://ori.hhs.gov/conferences/.

1. Quest for Research Excellence (Q4RE)

Q4RE Conference, Georgetown University, Washington, DC, March 15-16, 2012. The conference created opportunities for members of the research integrity community to discuss their current and future research. There were 358 attendees, 97 talks, and 29 posters.

2. RIO Boot Camp training

Under the DEI umbrella of conference and workshop program, the RIO Boot Camp programs educate RIOs to properly handle allegations of research misconduct through the stages of assessment, inquiry, investigation, and reporting to ORI. Further details about the boot camps are reported in the DIO section of this report. The two RIO Boot Camps in 2012 were:

Standard Boot Camp, Northwestern University, Chicago, IL, July 15-18, 2012

Standard Boot Camp, Howard University, Washington, DC, December 9-12, 2012

3. Conferences supported in-kind

American Association for the Advancement of Science (AAAS) Annual Meeting, Vancouver, BC, Canada, February 16-20, 2012

D. Communication Venues

1. Web site

The ORI web site (http://ori.hhs.gov/) received 1,033,722 page views from 366,465 visits in calendar year 2012. The site was viewed by 278,352 unique visitors from 204 countries. The top 10 countries visiting the ORI sites were, respectively: the United States, India, United Kingdom, Canada, Philippines, Australia, Netherlands, Mexico, Puerto Rico, and Germany. The vast majority of users viewed findings of research misconduct and educational resources for RCR.

2. ORI Newsletter

ORI has been producing a newsletter since January 1993. In 2012, ORI produced four issues that included information from ORI as well as contributions from subject matter experts from the research integrity community.

3. Educational presentations made by ORI staff

Ranjini Ambalavanar, Ph.D. "Research Integrity, Misconduct 1 Workshop," Quest for Research Excellence 2012 Conference, Georgetown University, Washington, DC, March 15-16, 2012.

Ranjini Ambalavanar, Ph.D. "Workshop on Scientific Ethics: Research Integrity – Avoiding Misconduct in Research," NIH, National Institute of General Medical Sciences (NIGMS) Fourth Biennial National IDeA Symposium of Biomedical Research Excellence (NISBRE), Omni Shoreham Hotel, Washington, DC, June 26, 2012.

Ranjini Ambalavanar, Ph.D. "Workshop on Scientific Ethics: Research Integrity – Investigating Research Misconduct," NIH, NIGMS Fourth Biennial NISBRE, Omni Shoreham Hotel, Washington, DC, June 27, 2012.

John Dahlberg, Ph.D. (coauthor with **David Wright, Ph.D.**, and Alice Tayman, J.D.), **"**RIO Mini-Boot Camps," Quest for Research Excellence 2012 Conference, Washington, DC, March 15-16, 2012.

John Dahlberg, Ph.D. "Integrity in the Name of Research," NIH Regional Seminar: Program Funding and Grants Administration, Indianapolis, IN, April 18, 2012.

John Dahlberg, Ph.D. "The Office of Research Integrity: Overview and Future Directions," Indiana University, Bloomington, IN, April 19, 2012.

John Dahlberg, Ph.D. "The Office of Research Integrity: Overview and Future Directions," Indiana University Purdue University Indianapolis (IUPUI), Indianapolis, IN, April 20, 2012.

John Dahlberg, Ph.D. "The ORI-RIO Partnership: Current Issues with an Emphasis on Clinical Research" to a forum of research integrity officers (RIOs), IUPUI, at Indianapolis, IN, April 20, 2012.

John Dahlberg, Ph.D. "Integrity in the Name of Research," NIH Regional Seminar: Program Funding and Grants Administration, held in Washington, DC, June 22, 2012.

John Dahlberg, Ph.D. "A Major Case Involving Obstruction, Computer Forensics and 'Extra Effort' by DIO," ORI 10th Boot Camp for RIOs, Chicago, IL, July 15-18, 2012.

John Dahlberg, Ph.D. "Forensic Examination of Data and Images," ORI 10th Boot Camp for RIOs, Chicago, IL, July 15-18, 2012.

John Dahlberg, Ph.D. "Sequestering Computer Evidence: A Few Suggestions," ORI 10th Boot Camp for RIOs, Chicago, IL, July 15-18, 2012.

John Galland, Ph.D. "Session 1: Passion + Ethics + Trust: Recipe for a Successful Career in Science" Workshop on Responsible Professional Practices in a Changing Research Environment, 2012 AAAS Annual Meeting, "International Research: Moving Towards Best Practices," Vancouver, BC, Canada, February 16, 2012.

John Galland, Ph.D. "Session 3: The World is Flat and Science is No Outlier" Workshop on Responsible Professional Practices in a Changing Research Environment, 2012 AAAS Annual Meeting, "International Research: Moving Towards Best Practices," Vancouver, BC, Canada, February 16, 2012.

John Galland, Ph.D. "Setting the Context for Ethical Conduct in International Research," Workshop on Responsible Professional Practices in a Changing Research Environment, 2012 AAAS Annual Meeting, "International Research: Moving Towards Best Practices," Vancouver, BC, Canada, February 16, 2012.

John Galland, Ph.D. (coauthor with Susan Brust Silk, M.S., NIH, Office of Laboratory Animal Welfare [OLAW]; Elyse Summers, J.D., NIH, Office for Human Research Protections [OHRP]; Sally Rockey, Ph.D., NIH, Office of Extramural Research; and Richard Weiss, Office of Science and Technology Policy [OSTP]), "Regulators' Studio," Quest for Research Excellence 2012 Conference, Georgetown University, Washington, DC, March 15-16, 2012.

John Galland, Ph.D. "Workshops for Postdocs and Grad Students," Quest for Research Excellence 2012 Conference, Georgetown University, Washington, DC, March 15-16, 2012.

Susan Garfinkel, Ph.D. "ORI Oversight: Detection of Manipulated Scientific Data," South Korean Delegation; ORI, April 17, 2012.

Susan Garfinkel, Ph.D. "Handling ORI Cases: Image Forensics," Georgetown University, Washington, DC, June 21, 2012.

Susan Garfinkel, Ph.D. "Handling Cases: From Allegations to Closure Problems to Avoid," University of California Webinar, June 27, 2012.

Susan Garfinkel, Ph.D. "Examining Images: Evidence in the Vogel Case," RIO Boot Camp, Chicago, IL, July 17, 2012.

Susan Garfinkel, Ph.D. "The Vogel Case: What Are the Allegations?" RIO Boot Camp, Chicago, IL, July 17, 2012.

Susan Garfinkel, Ph.D. "Handling Cases: From Allegations to Closure, Problems to Avoid," Committee on Responsible Science, National Academies of Science, Washington, DC, August 14, 2012.

Susan Garfinkel, Ph.D. "Examining Images: Evidence in the Vogel Case," RIO Boot Camp, Washington, DC, December 11, 2012.

Susan Garfinkel, Ph.D. "The Vogel Case: What Are the Allegations?" RIO Boot Camp, Washington, DC, December 12, 2012.

Kristen Grace, M.D., Ph.D. "Safeguarding Sound Clinical Science: Lessons from the Past" Research Integrity Misconduct 2 Workshop, Quest for Research Excellence 2012 Conference, Georgetown University, Washington, DC, March 15-16, 2012.

Shara Kabak, Ph.D. "Research Integrity Data Management Workshop," Quest for Research Excellence 2012 Conference, Georgetown University, Washington, DC, March 15-16, 2012.

Shara Kabak, Ph.D. "Research Misconduct: What Is It and What Is ORI's Role?" NIH Extramural Scientist Administrator (ESA) Seminar Series, NIH (Rockledge II), Bethesda, MD, May 4, 2012.

Shara Kabak, Ph.D. "Research Misconduct: How Does ORI Handle Allegations?" NIH Extramural Scientist Administrator (ESA) Seminar Series, NIH (Rockledge II), Bethesda, MD, November 2, 2012.

John W. Krueger, Ph.D. "Setting the Research Record Straight," Presentation and Panel Member, Science Online New York City (SoNYC), Rockefeller University, New York, NY, March 20, 2012, http://sonyc9-eorg.eventbrite.com/ and http://www.livestream.com/sonyc

John W. Krueger, Ph.D. "Principles in Assessing Image Allegations," Training Demonstration, Nature Publishing Group, New York, NY, July 23, 2012.

John W. Krueger, Ph.D. "Public Awareness and the Detection of Research Misconduct," Nature Publishing Group, New York, NY, July 23, 2012.

John W. Krueger, Ph.D. "Image Integrity in Publishing Scientific Data," The Borden Institute, Fort Detrick, MD, September 7, 2012.

John W. Krueger, Ph.D. "Confronting Integrity Issues in Publishing," American Society for Biochemistry and Molecular Biology (ASBMB) Publications Committee (Web Meeting), October 23, 2002.

John W. Krueger, Ph.D. "Retractions, Problem Images, and Their Detection," Discussion/Demonstration for the American Society for Nutrition and the Publication Editors, Federation of American Societies for Experimental Biology (FASEB), Bethesda, MD, December 14, 2012.

Rhonda Moore, Ph.D. "Plagiarism from Different Perspectives. Office of Extramural Research," NIH Extramural Research Integrity Training 2012, National Institutes of Health, Rockville, MD, July 10, 2012.

Cynthia Ricard, Ph.D. (coauthor with Martha Barnes, M.S., NIEHS; Maria Stagnitto, R.N., M.S.N., NIH; Andrea Sawczuk, D.D.S., National Center for Research Resources [NCRR]; and Nicholas Steneck, Ph.D., University of Michigan), "Research on Research Integrity: The First Decade," Quest for Research Excellence 2012 Conference, Georgetown University, Washington, DC, March 15-16, 2012.

Sandra Titus, Ph.D. "Faculty View on Their Roles to Educate Ph.D.s: Is there a Difference Between Mentors and Advisors?" Quest for Research Excellence 2012 Conference; Georgetown University, Washington, DC, March 15-16, 2012.

Sandra Titus, Ph.D. "Views About Whistleblowers: 102 RIOs' Observations," Quest for Research Excellence 2012 Conference, Georgetown University, Washington, DC, March 15-16, 2012.

Sandra Titus, Ph.D. "International Research Collaboration Challenges," Children's Hospital of Philadelphia, Philadelphia, PA, May 10, 2012.

Sandra Titus, Ph.D. "The Clinic," DVD Screening; San Diego, CA, December 6, 2012.

4. ORI publications in 2012

Publications:

Bonito AJ, **Titus SL, Wright DE**. Assessing the preparedness of Research Integrity Officers (RIOs) to appropriately handle possible research misconduct cases. *Sci Eng Ethics.* 2012;18(4):605-619. DOI: 10.1007/s11948-011-9274-2, ISSN: 1353-3452 (Print) 1471-5546 (Online).

Bonito AJ, **Titus SL**, Green AM, Amoozegar J, Eicheldinger C, **Wright, DE**. Preparing whistleblowers for reporting research misconduct. *Account Res.* 2012;19(5):308-328.

Titus SL, Ballou JM. Faculty members' perceptions of advising versus mentoring: does the name matter? *Sci Eng Ethics*. 2012 Apr. DOI: 10.1007/s11948-012-9366-7.

5. Federal Register Notices – Misconduct

Findings of research misconduct are published in the *Federal Register* and listed in greater detail beginning on page 40.

E. Research on Research Integrity (RRI) and Research Misconduct

As part of its mission, DEI conducts 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 RCR. ORI staff, contractors, and consultants conduct intramural studies. The studies are focused on questions relevant to ORI's regulatory and preventive mission. In contrast, the extramural program operates through the RRI Program with NIH. This program solicits investigator-initiated requests for 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 ORI was directed 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; a 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 http://ori.hhs.gov/research/intra/studies_completed.shtml.

(a) Evaluation Studies

i. Preparation of Whistleblowers by Research Integrity Officers – Completed

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

The redesigned study with Research Triangle Institute (RTI) focused on interviews with RIOs who had handled an allegation. The RIOs were asked to describe the kind of questions and issues that complainants and potential complainants had raised with them before they made their allegations. The study also examined what kind of information the RIOs provided the complainants. The study was completed in 2011. A subsequent paper based on the results was published in 2012 in *Accountability in Research*.

ii. Evaluation of the Interactive Video "The Lab: Avoiding Research Misconduct" – Continuing

ORI initiated a contract in 2010 with DSFederal, Inc., to develop and implement an evaluation study of the interactive video titled "The Lab." The web-based survey evaluation was submitted to OMB for review in 2011. The web-based survey evaluation will solicit the opinions from respondents (i.e., research instructors/faculty, RIOs, and Research Administrators) who had experience with the ORI educational programs or who may soon have experience. This evaluation informed ORI about the ways the video was viewed and used.

F. Extramural Research Program

The RRI program began with ORI's collaborating with the National Institute of Neurological Disorders and Stroke. Since the first awards were made in 2001, the following is a list of nine NIH institutes and four other partners that have participated in the program development:

1) National Institute of Environmental Health Sciences (NIEHS);
2) National Institute of Neurological Disorders and Stroke (NINDS);
3) National Institute on Drug Abuse (NIDA);
4) National Institute on Alcohol Abuse and Alcoholism (NIAAA);
5) National Cancer Institute (NCI);
6) National Heart, Lung, and Blood Institute (NHLBI);
7) National Institute of General Medical Sciences (NIGMS);
8) National Human Genome Research Institute (NHGRI); and
9) National Institute of Child Health and Human Development (NICHD).

Other partners have included:

1) Center for Scientific Review (CSR),
2) National Library of Medicine (NLM),
3) National Center for Research Resources (NCRR), and
4) Agency for Healthcare Research and Quality (AHRQ).

The Research Integrity Grant Program was created to foster empirical research on societal, organizational, group, and individual factors that affect, both positively and negatively, integrity in research. Since it began in 2001, the RRI program has funded 60 projects that have resulted in 124 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. NIEHS collaborated with ORI in the administration of the program for 2012.

1. RRI awards in 2012

The granting round requested proposals that would examine research integrity with an emphasis on bias. The award made in 2012 by the RRI program follows:

Dmitry Khodyakov, RAND Corporation, "The Impact of Partnerships with Community on Research Integrity"

Total funding for the RRI program in 2012 by ORI was $961,812. The new grant received $207,713 and continuations totaled $754,806. Twenty-three applications were received for the R21 awards, which can provide up to $275,000 in direct costs, plus indirect costs, for 2 years. Four continuation awards were funded by ORI through NIEHS.

2. RRI publications in 2012

Researchers supported by the RRI program published one article in 2012 on research integrity and the responsible conduct of research in one journal.

Richman V, Richman A. A tale of two perspectives: regulation versus self-regulation. A financial reporting approach (from Sarbanes-Oxley) for research ethics. *Sci Eng Ethics.* 2012 Jun;18(2):241-246.

V. INFORMATION AND PRIVACY

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

A. Freedom of Information Act

ORI received 63 requests in 2012 and closed 35. Twenty-eight requests were carried into 2013. In 2011, ORI received 86 and closed 32 requests.

FOIA, 5 United States Code (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 nine FOIA exemptions.

ORI records are primarily protected by Exemptions 5, 6, and 7 of 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
U.S. Department of Health and Human Services
Program Support Center
Division of FOIA Services
7700 Wisconsin Avenue, Suite 920
Bethesda, MD 20857

The request must 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 received no Privacy Act request in 2012.

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 were 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 because of 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

The request must 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.

VI. FINDINGS OF RESEARCH MISCONDUCT CASE SUMMARIES OR ADMINISTRATIVE ACTIONS – 2012

Summaries of Closed Investigations Resulting in Findings of Research Misconduct or Administrative Actions – 2012

Federal Register Notices – Misconduct*

*If a finding of research misconduct is found within the last several days of the year, sometimes the finding may not be published in the *Federal Register* until the first several days of the following year. Therefore, these are the only findings that were posted in the *Federal Register* for the reporting year.

Martin Biosse-Duplan, D.D.S., Ph.D., Harvard School of Dental Medicine: Based on the report of an investigation conducted by the Harvard School of Medicine (HSM) and Harvard School of Dental Medicine (HSDM), the admission of the Respondent, and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Martin Biosse-Duplan, former Research Fellow, Department of Oral Medicine, Infection, and Immunity, HSDM, engaged in research misconduct in research supported by National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), National Institutes of Health (NIH), grant R01 AR054450.

ORI found that the Respondent engaged in research misconduct involving one (1) laboratory presentation and two (2) published abstracts:

- Boisse-Duplan, M., Stephens, S., Lai, F.P.L., Oelkers, M., Kitamura, D., Rottner, K., Horne, W., & Baron, R. "The Association Between the Microtubule Plus End Protein EB1 and Cortactin Controls Podosomes and Bone Resorption." *J Bone Min Res* 26:Supl.1, pS215.

- Boisse-Duplan, M., Stephens, S., Lai, F.P.L., Oelkers, M., Rottner, K., Horne, W., & Baron, R. "In Osteoclasts, Dynamic Microtubules and their Associated Protein EB1 Control Podosomes and Bone Resorption through Cortactin." *Bone* 48:Suppl. 2, pS97.

As a result of HSM's and HSDM's investigation, the data were not presented at the meetings, and the experiments reported in the abstracts are being redone.

Specifically, ORI finds that Respondent:

- falsified PowerPoint slides and spreadsheets for histomorphometric and microCT results by using the values of HS1 knockout (KO) mice and their controls to represent the CathepsinK cre-Cortactin KO mice and their controls; Dr. Biosse-Duplan also switched two sets of numbers between the HS1 KO mice and their controls to falsely demonstrate a difference in bone density when there was none. The numerical data were presented at

a lab meeting, and false text was included in two submitted meeting abstracts published in *Bone* 48:Suppl 2, pS97 and *J Bone Min Res* 25:Suppl 1, pS215.

Both the Respondent and HHS wanted to conclude this matter without further expenditure of time or other resources and have entered into a Voluntary Settlement Agreement (Agreement) to resolve this matter.

Dr. Boisse-Duplan has entered into a Voluntary Settlement Agreement and has voluntarily agreed:

(1) that if within two (2) years from the effective date of the Agreement Respondent does receive or apply for PHS support, Respondent agrees to have his research supervised for a period of two (2) years beginning on the date of his employment in a research position in which he receives or applies for PHS support and to notify his employer(s)/institutions(s) of the terms of this supervision; Respondent agrees that prior to the submission of an application for PHS support for a research project on which the Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of Respondent's duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agrees that he shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agrees to maintain responsibility for compliance with the agreed-upon supervision plan;

(2) that if within two (2) years from the effective date of the Agreement, Respondent does receive or apply for PHS support, Respondent agrees that any institution employing him shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract; and (3) to exclude himself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of two (2) years, beginning on December 4, 2012.

Terry S. Elton, Ph.D., The Ohio State University: Based on the reports of two investigations conducted by The Ohio State University (OSU) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Terry S. Elton, Professor, College of Pharmacy and Davis Heart and Lung Research Institute, OSU, engaged in research misconduct in research supported by National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grants R01 HL048848, R01 HL084498, and P01 HL70294, National Institute of Child Health

and Human Development (NICHD), NIH, grant R21 HD058997, National Institute on Aging (NIA), NIH, grant R01 AG021912, National Institute of Allergy and Infectious Diseases (NIAID), NIH, grant R01 AI39963, and National Eye Institute (NEI), NIH, grant R01 ES012241.

ORI found that the Respondent engaged in research misconduct by falsifying and/or fabricating data that were included in 1 R21 HD058997-01, 1 R21 HD058997-01A1, 1 R21 HD058997-01A2, 1 RC1 HL100298-01, and in:

1. Kuhn, D.E., Nuovo, G.J., Terry, A.V. Jr., Martin, M.M., Malana, G.E., Sansom, S.E., Pleister, A.P., Beck, W.D., Head, E., Feldman, D.S., & Elton, T.S. "Chromosome 21-derived microRNAs provide an etiological basis for aberrant protein expression in human Down syndrome brains." *J Biol Chem* 285(2):1529-43, 2010 Jan 8.

2. Kuhn, D.E., Nuovo, G.J., Martin, M.M., Malana, G.E., Pleister, A.P., Jiang, J., Schmittgen, T.D., Terry, A.V. Jr., Gardiner, K., Head, E., Feldman, D.S., & Elton, T.S. "Human chromosome 21-derived miRNAs are overexpressed in Down syndrome brains and hearts." *Biochem Biophys Res Commun* 370(3):473-7, 2008 Jun 6.

3. Martin, M.M., Buckenberger, J.A., Jiang, J., Malana, G.E., Knoell, D.L., Feldman, D.S., & Elton, T.S. "TGFß1 stimulates human AT1 receptor expression in lung fibroblasts by cross talk between the Smad, p38 MAPK, JNK, and PI3K signaling pathways." *Am. J. Physiol. Lung Cell. Mol. Physiol*. 293(3):L790-9, 2007 Sept. (Retracted: *Am. J. Physiol. Lung Cell. Mol. Physiol*. 302(7):L719, 2012 Apr.)

4. Martin, M.M., Buckenberger, J.A., Jiang, J., Malana, G.E., Nuovo, G.J., Chotani, M., Feldman, D.S., Schmittgen, T.D., & Elton, T.S. "The human angiotensin II type 1 receptor +1166 A/C polymorphism attenuates microRNA-155 binding." *J Biol Chem* 282(33):24262-9, 2007, Aug 17.

5. Martin, M.M., Buckenberger, J.A., Knoell, D.L., Strauch, A.R., & Elton, T.S. "TGF-beta(1) regulation of human AT1 receptor mRNA splice variants harboring exon 2." *Mol Cell Endocrinol* 249(1-2):21-31, 2006 Apr 25.

6. Duffy, A.A., Martin, M.M., & Elton, T.S. "Transcriptional regulation of the AT1 receptor gene in immortalized human trophoblast cells." *Biochim. Biophys. Acta*. 1680(3):158-70, 2004 Nov 5.

As a result of its investigation, OSU has recommended that all of the above publications be retracted.

Specifically, ORI finds that Respondent:

- falsified and/or fabricated Western blots in an NIH grant application in three submissions of the same grant application:

  a. Figures 4, 7, 11C: 1 R21 HD058997-01
  b. Figures 7B, 7E, 8B: 1 R21 HD058997-01A1
  c. Figures 3C, 3F, 6C: 1 R21 HD058997-01A2

  and false Western blots were also included in Figure 6 in grant application 1 RC1 HL100298-01.

- falsified and/or fabricated Western blots in eighteen (18) figures and in six (6) published papers. Specifically, false and/or fabricated images were included in:

  d. Figures 2C, 2D, 2F, 3C, 3E, 4G, 5C, 5F: *J Biol Chem* 285(2):1529-43, 2010 Jan 8
  e. Figures 3B, 3C, 3F, 3H, 3I, 3J: *Biochem Biophys Res Commun* 370(3):473-7, 2008 Jun 6
  f. Figures 2, 3, 4B, 5B, 6, 7B, 8A, 9B: *Am. J. Physiol. Lung Cell. Mol. Physiol.* 293(3):L790-9, 2007 Sept
  g. Figure 6: *J Biol Chem* 282(33):24262-9, 2007 Aug 17
  h. Figure 6: *Mol Cell Endocrinol* 249(1-2):21-31, 2006 Apr 25
  i. Figures 5, 6B, 7B, 9B: *Biochim. Biophys. Acta* 1680(3):158-70, 2004 Nov 5.

Dr. Elton has entered into a Voluntary Exclusion Agreement and has voluntarily agreed:

(1) to exclude himself 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 HHS' Implementation (2 C.F.R. Part 376 *et seq.*) of OMB Guidelines to Agencies on Govermentwide Debarment and Suspension, 2 C.F.R. Part 180 (collectively the "Debarment Regulations") for a period of three (3) years, beginning on November 26, 2012;

(2) to exclude himself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of three (3) years, beginning on November 26, 2012; and

(3) to request that the following publications be retracted:

- *J Biol Chem* 285(2):1529-43, 2010 Jan 8
- *Biochem Biophys Res Commun* 370(3):473-7, 2008 Jun 6
- *J Biol Chem* 282(33):24262-9, 2007, Aug 17
- *Mol Cell Endocrinol* 249(1-2):21-31, 2006 Apr 25
- *Biochim. Biophys. Acta*. 1680(3):158-70, 2004 Nov 5.

Peter J. Francis, M.D., Ph.D., Oregon Health Sciences University: Based on the report of an investigation conducted by Oregon Health Sciences University (OHSU) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Peter J. Francis, Associate Professor, Casey Eye Institute, OHSU, engaged in research misconduct in research reported in two grant applications, R01 EY021214-01 and resubmitted as R01 EY021214-01A1, that he submitted to the National Eye Institute (NEI), National Institutes of Health (NIH).

Specifically, ORI finds that the Respondent fabricated results of a pilot experiment in which he claimed to have injected retinal pigment epithelial (RPE) cells obtained from Rhesus monkey embryonic stem cells (ECS) into a strain of rats (RCS) that develops retinal degeneration.

Respondent claimed that after the injection of ECS-derived RPE cells 21 days postnatal, the rats were tested at day 60 postnatal for optomotor acuity, and that the retinal histology of eyes receiving ECS-derived RPE cells, compared to mock-injected controls, showed enhanced photoreceptor preservation and no adverse effects. Respondent admitted that this experiment had not been conducted either by the time the original grant application had been submitted or by the time the later R01 EY021214-01A1 application was submitted.

Dr. Francis has entered into a Voluntary Settlement Agreement (Agreement) and has voluntarily agreed for a period of two (2) years, beginning on March 29, 2012:

(1) to have his research supervised; Respondent agrees to ensure that prior to the submission of an application for U.S. Public Health Service (PHS) support for a research project on which the Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, the institution employing him must submit a plan for supervision of Respondent's duties to ORI for approval; the plan for supervision must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agrees that he shall not participate in any PHS-supported research after sixty (60) days from the effective date of this Agreement until such a supervision plan is submitted to and approved by ORI; Respondent agrees to maintain responsibility for compliance with the agreed-upon supervision plan;

(2) that this supervisory plan provided by any institution employing him shall provide assurance that each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent was involved was based on actual experiments or was otherwise legitimately derived, that the data, procedures, and methodology were accurately reported in the application, report, manuscript, or abstract, and that the text in such submissions was his own or properly cited the source of copied language and ideas; and

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

Marc Hauser, Ph.D., Harvard University: Based on the report of an investigation conducted by Harvard University (Harvard) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Marc Hauser, former Professor, Department of Psychology, Harvard, engaged in research misconduct in research supported by National Center for Research Resources (NCRR), National Institutes of Health (NIH), grants P51 RR00168-37 and CM-5-P40 RR003640-13, National Institute on Deafness and Other Communication Disorders (NIDCD), NIH, grant 5 R01 DC005863, and National Institute of Mental Health (NIMH), NIH, grant 5 F31 MH075298.

ORI found that Respondent engaged in research misconduct as follows:

- Respondent published fabricated data in Figure 2 of the paper Hauser, M.D., Weiss, D., & Marcus, G. "Rule learning by cotton-top tamarins." *Cognition* 86:B15-B22, 2002, which reported data on experiments designed to determine whether tamarin monkeys habituated to a sound pattern consisting of three sequential syllables (for example AAB) would then distinguish a different sound pattern (i.e., ABB). Figure 2 is a bar graph showing results obtained with 14 monkeys exposed either to the same or different sound patterns than they were habituated to. Because the tamarins were never exposed to the same sound pattern after habituation, half of the data in the graph was fabricated. Figure 2 is also false because the actual height of the bars for the monkeys purportedly receiving the same test pattern that they had been habituated to totaled 16 animals (7.14 subjects as responding and 8.87 subjects as non-responding).

  Respondent retracted the paper in 2010 (*Cognition* 117:106).

- In two unpublished experiments designed to test whether or not tamarin monkeys showed a greater response to certain combinations of unsegmented strings of consonants and vowels than others, Respondent falsified the coding of some of the monkeys' responses, making the results statistically significant when the results coded by others showed them to be non-significant. Respondent acknowledged to his collaborators that he miscoded some of the trials and that the study failed to provide support for the initial hypothesis. This research was never written up for publication.

- In versions of a manuscript entitled "Grammatical Pattern Learning by Human Infants and Monkeys" submitted to *Cognition*, *Science*, and *Nature*, Respondent falsely described the methodology used to code the results for experiments 1 and 3 on "grammar expectancy violations" in tamarin monkeys either by claiming coding was done blindly or by fabricating values for inter-observer reliabilities when coding was done by only one observer, in both cases leading to a false proportion or number of animals showing a favorable response.

  Specifically, in three different experiments in which tamarin monkeys were exposed first to human voice recordings of artificial sounds that followed grammatical structure and then exposed to stimuli that conformed to or violated that structure, Respondent (1) provided an incorrect description of the coding methodology by claiming in the early versions of the manuscripts that "two blind observers" coded trials and a third coded trials to resolve differences, while all of the coding for one experiment was done just by the Respondent, and (2) in a revised manuscript, while Respondent no longer mentioned "two blind observers, he claimed that "Inter-observer reliabilities ranged from 0.85 to 0.90," a statement that is false because there was only one observer for one of the experiments.

  Furthermore, in an earlier version of the manuscript, Respondent falsely reported that "16 out of 16 subjects" responded more to the ungrammatical rather than the grammatical stimuli for the predictive language condition, while records showed that one of the sixteen responded more to grammatical than ungrammatical stimuli, and one responded equally to grammatical and ungrammatical.

  Respondent and his collaborators corrected all of these issues, including recoding of the data for some of the experiments prior to the final submission and publication in *Cognition* 2007.

- In the paper Hauser, M.D., Glynn, D., Wood, J. "Rhesus monkeys correctly read the goal relevant gestures of a human agent." *Proceedings of the Royal Society B* 274:1913-1918, 2007, Respondent falsely reported the results and methodology for one of seven experiments designed to determine whether rhesus monkeys were able to understand communicative gestures performed by a human.

Specifically, (1) in the "Pointing without food" trial, Respondent reported that 31/40 monkeys approached the target box, while the records showed only 27 approached the target (both results are statistically significant), and (2) there were only 30 videotapes of the "Pointing without food" trials, while Respondent falsely claimed in the paper's Materials and Methods that "each trial was videotaped." Respondent was not responsible for the coding, analyses or archiving but takes full responsibility for the falsifications reported in the published paper. Respondent and one of his coauthors replicated these findings with complete data sets and video records and published them in *Proceedings Royal Society B* 278(1702):58-159, 2011.

- Respondent accepts responsibility for a false statement in the Methodology section for one experiment reported in the paper Wood, J.N., Glynn, D.D., Phillips, B.C., & Hauser, M.D. "The perception of rational, goal-directed action in nonhuman primates." *Science* 317:1402-1405, 2007. The statement in the paper's supporting online material reads that "All individuals are . . . readily identifiable by natural markings along with chest and leg tattoos and ear notches." In fact, only 50% of the subjects could be identified by this method, thus leading to the possibility of repeated testing of the same animal.

  Respondent and one of his coauthors replicated these findings with complete data sets and video records and published them in *Science* 332:537, 2011 (www.sciencemag.org/cgi/content/full/317/5843/1402/DC2 - published online 25 April 2011).

- Respondent engaged in research misconduct by providing inconsistent coding of data in his unpublished playback experiment with rhesus monkeys exploring an abstract pattern in the form of AXA by falsely changing the coding results where the prediction was that habituated animals were more likely to respond to an ungrammatical stimulus than a grammatical one. After an initial coding of the data by his research assistant, in which both Respondent and assistant agreed that an incorrect procedure was used, the Respondent recoded the 201 trials and his assistant coded a subset for a reliability check. The Respondent's codes differed from the original in 36 cases, 29 of them in the theoretically predicted direction, thereby producing a statistically significant probability of $p = <0.01$. Respondent subsequently acknowledged to his collaborators that his coding was incorrect and that the study failed to provide support for the initial hypothesis. This research was never written up for publication.

Respondent neither admits nor denies committing research misconduct but accepts ORI has found evidence of research misconduct as set forth above and has entered into a Voluntary Settlement Agreement to resolve this matter. The settlement is not an admission of liability on the part of the Respondent. Dr. Hauser has voluntarily agreed for a period of three (3) years, beginning on August 9, 2012:

(1) to have any U.S. Public Health Service (PHS)-supported research supervised; Respondent agreed that prior to the submission of an application for PHS support for a research

project on which the Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of Respondent's duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agreed that he shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed-upon supervision plan;

(2) that any institution employing him shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived, that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract, and that the text in such submissions is his own or properly cites the source of copied language and ideas; and

(3) to exclude himself voluntarily 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.

Sinae Kim, Ph.D., Emory University: Based on the report of an investigation conducted by Emory University (EU) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Sinae Kim, former Postdoctoral Fellow, Department of Medicine, EU, engaged in research misconduct in research supported by National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grants R01 HL079137, R01 HL084471, and R03 HL096325, and National Institute of General Medical Sciences (NIGMS), NIH, grant RC1 GM092035.

ORI found that the Respondent engaged in research misconduct by falsifying data that were included in five (5) manuscripts submitted in 2009 for publication to *Blood*, *Nature*, *Nature Biotechnology*, *Nature Medicine*, and *Science*, one (1) poster presented at the 2009 American Heart Association (AHA) meeting, four (4) laboratory meeting presentations, one (1) image file, three (3) funded NIH grants (RC1 GM092035, R01 HL079137, and R03 HL096325), and five (5) submitted NIH grant applications (RC1 HL100648-01, RC2 HL101600-01, RC4 HL106748-01, R01 HD067130-01, and U01 HL107444-01). The manuscripts submitted in 2009 were not accepted for publication.

Specifically, ORI finds that the Respondent knowingly and intentionally:

1. Falsified three (3) figures for immunocytochemistry and alkaline phosphatase (AP) staining images, karyotyping and real-time reverse transcription polymerase chain reaction (RT-PCR) results by using experimental results from her prior work in Korea with human embryonic stem cells (hESCs) to confirm the generation, differentiation, and verification of human induced pluripotent stem cells (iPSCs). The false data were included in:
    a. Figures 1c and 2i (panels #4 & 13) in the *Nature* 2009, *Science* 2009, and *Nature Biotechnology* 2009 manuscripts and Supplementary Figure 4 in the *Nature* 2009 manuscript
    b. Supplementary Figure 5 in the *Nature Biotechnology* 2009 manuscript
    c. Figures S1B and S1D (panels #4 & 13) in the *Blood* 2009 manuscript
    d. Supplementary Figures 8B and 8D (panels #4 & 13) in the *Nature Medicine* 2009 manuscript
    e. Figure 9 in the RC1 GM092035 grant
    f. Figure 8 in the R01 HL079137 grant
    g. Figure 2 in the RC1 HL100648 grant
    h. Figure 8 in the RC2 HL101600 grant
    i. Figure 3 in the R01 HD067130 grant
    j. Figure 1 in the RC4 HL106748 grant
    k. Figures 1C, 1H, and 1I (panel #3) in the R03 HL096325 grant
    l. Figure 5 in the U01 HL107444 grant
    m. Figures 2C and 3I (panels #4 & 13) in the poster presented at the 2009 AHA meeting
    n. the presentations 'Figures_Sinae Kim_120808.ppt' and 'Figures_Sinae Kim_121508.ppt'
    o. the image file 'HiPS_E1_x100.jpg'.

2. Falsified one (1) figure for the real-time RT-PCR data for endogenous SOX2 expression in human iPSCs derived from dermal (HiPS-E1) and cardiac (HiPS-E2) fibroblasts and iPSCs generated from peripheral blood mononuclear cells derived from coronary artery disease patients (HiPS-ECP1, HiPS-ECP2, and HiPS-ECP3) by substituting real-time RT-PCR data for endogenous OCT4 expression in the aforementioned cell lines. Specifically, the false data were included in:
    a. Figure 2i (panels #2 & 5) in the *Nature* 2009, *Science* 2009, and *Nature Biotechnology* 2009 manuscripts
    b. Figure S1D (panels #2 & 5) in the *Blood* 2009 manuscript
    c. Supplementary Figure 8D (panels #2 & 5) in the *Nature Medicine* 2009 manuscript
    d. Figure 3I (panels #2 & 5) in the poster presented at the 2009 AHA meeting
    e. the presentations ''Figures_Sinae Kim_120808.ppt' and 'Figures_Sinae Kim_121508.ppt'.

3. Falsified data in two (2) PowerPoint presentations for RT-PCR data of osteogenic-specific gene expression in bone marrow cells by substituting data for RT-PCR data in primary bone-derived and Saos2-osteosarcoma cells.

4. Falsified one (1) figure for the real-time RT-PCR data of OCT4, SOX2, KLF4, c-MYC, NANOG, hTERT, REX1, and GDF3 fold-change expression levels in H1 hESCs, human cardiac and dermal fibroblasts, HiPS-E1, HiPS-E2, HiPS-ECP1, HiPS-ECP2, and HiPS-ECP3 cell lines by substituting data from various other cell lines that did not exist. Specifically, the false data were included in:
    a. Figures 2a-h in the *Nature* 2009, *Science* 2009, and *Nature Biotechnology* 2009 manuscripts
    b. Figure 10 in the RC1 GM092035 grant
    c. Figure 9 in the R01 HL079137 grant
    d. Figure 5 in the R01 HD067130 grant
    e. Figure 3A-H in the poster presented at the AHA meeting
    f. the presentations ‘‘Figures_Sinae Kim_120808.ppt’ and ‘Figures_Sinae Kim_121508.ppt’.

5. Falsified research materials when the Respondent distributed cells to laboratory members that she claimed were chemical/non-viral factor induced-mouse iPSCs and human iPSCs generated from peripheral blood of coronary artery disease patients, when she knew they were of other origin.

Dr. Kim has entered into a Voluntary Exclusion Agreement (Agreement) and has voluntarily agreed for a period of two (2) years, beginning on June 5, 2012:

(1) to exclude herself voluntarily 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 HHS’ Implementation (2 C.F.R. Part 376 *et seq.*) of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension, 2 C.F.R. Part 180 (collectively the “Debarment Regulations”); 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.

Jian Ma, Ph.D., Brigham and Women’s Hospital and Harvard Medical School: Based on evidence and findings of an inquiry conducted jointly by Brigham and Women’s Hospital (BWH) and Harvard Medical School (HMS) and additional evidence gathered by the Office of Research Integrity (ORI) during its oversight review, ORI found that Dr. Jian Ma, former Research Fellow, BWU, engaged in research misconduct in research supported by National Cancer Institute (NCI), National Institutes of Health (NIH), grant 5 P01 CA120964.

ORI found that the Respondent knowingly and intentionally fabricated and falsified data in portions of figures in an unpublished manuscript titled "TSC1 loss synergizes with KRAS activation in lung cancer development and confers rapamycin sensitivity" by M.-C. Liang, J. Ma, L. Chen, P. Kozlowski, W. Qin, D. Li, T. Shimamura, M.L. Sos, R. Thomas, D. Neil Hayes, M. Meyerson, D.J. Kwiatkowski, and K.-K. Wong, submitted to the *Journal of Clinical Investigation* (*JCI*) on August 5, 2008, and in revised form on October 21, 2008 (hereafter referred to as the "*JCI* manuscript"). Specifically, Respondent committed research misconduct by knowingly and intentionally:

- falsifying and/or fabricating those portions of the immunoblots in *JCI* manuscript Figure 1C, to show that in $Tscl^{L/L}$ and $Tsc^{L/+}$ mouse lung cancer cells compared with KRAS induced lung cancer cells, there were reduced Tsc1 and Tsc2 protein levels, reduced phospho-AKT-S473 levels, and increased phospho-S6-S249/244 levels, consistent with the hypothesis that introduction of the $Tsc1^{L}$ gene resulted in mTORC1 activation

- falsifying and/or fabricating those portions of the immunoblots in Figure 3A of the *JCI* manuscript to show data consistent with the hypothesized TNS null signaling lung tumor cells: functional loss of Tsc1/Tsc2, high phospho-S6-S249/244 levels, and low phospho-AKT-S473, with recovery of phospho-AKT-S473 after Rapamycin treatment

- falsifying and/or fabricating those portions of the immunoblots in Figure 3B of the *JCI* manuscript by (i) adding a band in the Tsc2 lane for control cells for the IP blot, and (ii) weakening the Tsc2 band for one of the tumor lysates

- falsifying and/or fabricating immunoblots in Figures 5A and 5B of the *JCI* manuscript so that the data appeared to indicate that TSC reconstitution in TSC null (TNS) cell lines led to reduction of pS6-S240/244 levels during serum deprivation (in the absence of growth factors), as well as increased pAKT(S473) levels in response to serum stimulation.

The *JCI* manuscript was accepted by *JCI* on December 8, 2008, but it was withdrawn by one of the authors on January 6, 2009.

ORI found that Respondent's knowing and intentional falsification and fabrication of data constitutes research misconduct within the meaning of 42 C.F.R. § 93.103.

The following administrative actions have been implemented for a period of three (3) years, beginning on May 12, 2012:

(1) any institution that submits an application for U.S. Public Health Service (PHS) support for a research project on which Respondent's participation is proposed or that uses him in any capacity on PHS-supported research 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 must ensure that a copy of the supervisory plan is also submitted to ORI by the institution; Respondent will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI;

(2) Respondent will ensure that any institution employing him submits, in conjunction with application for PHS funds or any report, manuscript, or abstract of PHS-funded research in which he is involved, a certification that the data provided by him are accurately reported in the application or report; Respondent must ensure that the institution send the certification to ORI; this certification shall be submitted no later than one month before funding and concurrently with any report, manuscript, or abstract; and

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

Shane Mayack, Ph.D., Joslin Diabetes Center: Based on the report of an investigation conducted by the Joslin Diabetes Center (Joslin) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Shane Mayack, former postdoctoral fellow, Department of Developmental and Stem Cell Biology, Joslin, engaged in research misconduct in research supported by National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH), grants T32 DK07260-29 and P30 DK036836 and the 2008 NIH Director's New Innovator Award Program grant DP2 OD004345-01.

ORI found that Respondent engaged in research misconduct involving two (2) published papers:

- Mayack, S.R., Shadrach, J.L., Kim, F.S., & Wagers, A.J. "Systemic signals regulate ageing and rejuvenation of blood stem cell niches." *Nature* 463:495-500, 2010

- Mayack, S.R., & Wagers, A.J. "Osteolineage niche cells initiate hematopoietic stem cell mobilization." *Blood* 112:519-531, 2008.

As a result of Joslin's investigation, both *Nature* 463:495-500, 2010 (hereafter referred to as the "*Nature* paper") and *Blood* 112:519-531, 2008 (hereafter referred to as the "*Blood* paper") have been retracted by the corresponding author.

Specifically, ORI found that:

- Respondent falsely represented von Kossa-stained bone nodule images in two (2) published papers:
    a. Figure 2B in the *Blood* paper was copied from an unrelated published experiment in Figure 3, J *Orth Surg Res* 1:7, 2006, and was used to falsely represent Respondent's own experiment for bone nodules formed in cultured osteoblastic niche cells

b. Figure S2c in the *Nature* paper was copied from an online image for an unrelated experiment (at http://skeletalbiology.uchc.edu/30_ResearchProgram/304_gap/3042_Lineage%20in%20Vitro/3042_01_aCellCult.htm#mCOB) and was used to falsely represent Respondent's own experiment for bone nodules formed in osteoblastic niche cells from young and aged mice.

- Respondent falsely represented eight (8) flow cytometry contour plots as different experimental results by using identical plots but with different labels and different numerical percentages. Specifically, the following contour plots in the *Blood* paper, the *Nature* paper, an earlier version of the *Nature* paper submitted to *Science* (hereafter referred to as the "*Science* manuscript"), and a July 2008 PowerPoint presentation were identical but were labeled differently:
  a. panels 4 and 2 in Figure 6C, *Blood* paper, and panels 1 and 2, respectively, in supplementary Figure 3b, *Nature* paper
  b. panel 3 in Figure 6C, *Blood* paper, and panel 1 in Figure 2, July 2008 PowerPoint presentation
  c. panels 1 and 2, Figure 2b, *Science* manuscript, and panels 2 and 3, respectively, in Figure 2, July 2008 PowerPoint presentation
  d. panels 2, 3, and 4, supplemental Figure 4A, Blood paper, and panels 3, 1, and 2, respectively, in Figure 4B, *Science* manuscript

Both the Respondent and HHS want to conclude this matter without further expenditure of time or other resources and have entered into a Voluntary Settlement Agreement to resolve this matter. Respondent neither admits nor denies ORI's finding of research misconduct. This settlement does not constitute an admission of liability on the part of the Respondent. Dr. Mayack has voluntarily agreed:

(1) if within three (3) years from the effective date of the Agreement, Respondent does receive or apply for U.S. Public Health Service (PHS) support, Respondent agrees to have her research supervised for a period of three (3) years beginning on the date of her employment in a research position in which she receives or applies for PHS support and to notify her employer(s)/ institution(s) of the terms of this supervision; Respondent agrees that prior to the submission of an application for PHS support for a research project on which the Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of Respondent's duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agrees that she shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agrees to maintain responsibility for compliance with the agreed-upon supervision plan;

(2) if within three (3) years from the effective date of the Agreement, Respondent does receive or apply for PHS support, Respondent agrees that any institution employing her shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract; and

(3) to exclude herself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of three (3) years, beginning on July 27, 2012.

Michael W. Miller, Ph.D., State University of New York, Upstate Medical University:
Based on the report of an investigation conducted by the State University of New York, Upstate Medical University (SUNY UMU) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Michael W. Miller, former Professor and Chair, Department of Neuroscience and Physiology, SUNY UMU, engaged in research misconduct in research supported by National Institute of Alcohol Abuse and Alcoholism (NIAAA), National Institutes of Health (NIH), grants R01 AA07568-18A1, R01 AA06916, and P50 AA017823-01.

ORI finds that the Respondent engaged in research misconduct by falsifying and/or fabricating data that were included in grant applications R01 AA07568-18, R01 AA07568-18A1, R01 AA006916-25, and P50 AA017823-01 and in the following:

- Miller, M.W., Hu, H. "Lability of neuronal lineage decisions is revealed by acute exposures to ethanol." *Dev. Neurosci*. 31(1-2):50-7, 2009 ("*Dev. Neurosci*. 2009")

- Bruns, M.B., Miller, M.W. "Functional nerve growth factor and trkA autocrine/paracrine circuits in adult rat cortex are revealed by episodic ethanol exposure and withdrawal." *J. Neurochem*. 100(5):1115-68, 2007 ("*J. Neurochem*. 2007")

- a prepared manuscript submitted to *PNAS* for publication.

As a result of its investigation, SUNY UMU recommended that *Dev. Neurosci*. 2009 and *J. Neurochem*. 2007 be retracted. Both publications have now been retracted:

- *Dev. Neurosci*. 2009 was retracted online on January 19, 2012, at: **http://content.karger.com/ProdukteDB/produkte.asp?Aktion=ShowPDF&ArtikelNr=323471&Ausgabe=0&ProduktNr=224107&filename=323471.pdf**

- *J. Neurochem*. 2007 was retracted online on January 23, 2012, at: **http://onlinelibrary.wiley.com/doi/10.1111/j.1471-4159.2012.07662.x/full**.

Specifically, ORI finds that the Respondent:

- falsified Figure 5 in NIH grant application R01 AA07568-18A1 by altering the bar graphs to make the experimental results appear valid and consistent with his hypothesis that ethanol exposure *in-utero* alters the transition of cells from Pax 6 expression to Tbr2 expression, which is critical to normal brain development. Specifically:

    a. in the VZ/SZ panel (upper row, right), Dr. Miller decreased the values by 50% for the bar graphs representing control and treated mice for "Tbr2," "both," and "both/Ki-67" to falsely report an equivalent frequency of Tbr2 expressing cells in the right and left panels; this result was required for the experiment to appear valid;

    b. in the MGE panel (lower row, right), Dr. Miller altered the bar graphs representing control and treated mice for "Ki-67," "Pax6," and "both" to falsely report that ethanol increased the frequency of K-67+ cells and to report an equivalent frequency of Pax expressing cells in the right and left panels.

- fabricated bar graphs in Supplemental Figure 2 in a manuscript submitted to *PNAS* and text in the manuscript also appearing in the grant application AA00616-25 to support the hypothesis that ethanol exposure during postnatal weeks 1 and 2 causes specific neuronal cell death in layers II/III and V of the cortex. Specifically, Dr. Miller:

    a. fabricated bar graphs in Supplemental Figure 2 and related text in the *PNAS* manuscript to show that in select layers of the cortex, ethanol induced neuronal death occurred in postnatal day 10 (P10) mice;

    b. included fabricated text in the *PNAS* manuscript and the grant application citing results of experiments using 15-25-day-old mice treated with ethanol during the second postnatal week, when these mice were never generated.

- falsified Figure 6 in a manuscript submitted to *PNAS* by altering data points for the labeling index of caspase3 and TUNEL in cortex layers II/III and V after exposure to ethanol in postnatal day 7 (P7) mice, such that the two assays confirmed each other. The same data were also included as Figure 4 in NIH grant application R01 AA06916 and as Figure 7 in a poster presentation at the 2009 Research Society on Alcoholism.

- falsified the figure legends and/or text in a published paper and multiple grant applications to support the primary hypothesis of the published paper that gestational alcohol exposure had an effect on brain development by affecting the way neurons differentiate and migrate into the cortex, rather than by changes to cell growth or death.

- Specifically, Dr. Miller falsely reported the number of animals (n) that were used in figure legends and/or text in the following:

  - Figures 2 and 5, *Dev. Neurosci*. 2009, also included as Figures 3 and 4, respectively, in R01 AA07568-18;

  - Figure 4 and Table 2 in P50 AA017823-01.

- falsified Figures 4 and 6 in *J. Neurochem*. 2007 by altering bar graphs to increase the significance of the effect of ethanol exposure and/or withdrawal on NGF or trkA protein expression, thereby conforming with the paper's hypothesis that ethanol exposure and withdrawal affect the normal NGF/trkA circuits in cortical layer V. Specifically, Dr. Miller:

  a. increased the value of the ethanol treated NGF expression in Figure 4 and decreased the value of withdrawal NFG to alter the difference between the two from approximately 2.2% to 11.6%, thereby falsely reporting significance where there was none;

  b. in Figure 6:

     a) increased the value of withdrawal trkA data by approximately 70% to falsely report significance with relation to the ethanol treated value and increase significance with relation to the control;

     b) increased the value of the ethanol treated phospho-trkA data by approximately 100% to increase the significance with relation to the control;

     c) falsely reported the results for Figure 6 as showing a nearly doubled ratio of p-trkA to total trkA after ethanol exposure when there was no increase at all.

Dr. Miller has entered into a Voluntary Exclusion Agreement (Agreement). Dr. Miller neither admits nor denies committing research misconduct but accepts ORI has found evidence of research misconduct as set forth above.

Dr. Miller has voluntarily agreed:

(1) to exclude himself voluntarily 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 HHS' Implementation (2 C.F.R. Part 376 *et seq.*) of OMB Guidelines to Agencies on

Government wide Debarment and Suspension, 2 C.F.R. Part 180 (collectively the "Debarment Regulations") for a period of one (1) year, beginning on February 6, 2012; (2) to have his research supervised for a period of two (2) years immediately following the one (1) year period of exclusion; Respondent agrees that prior to the submission of an application for U.S. Public Health Service (PHS) support for a research project on which the Respondent's participation is proposed and prior to the Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of Respondent's duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent's research contribution as outlined below; Respondent agrees that he shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agrees to maintain responsibility for compliance with the agreed-upon supervision plan; the requirements for Respondent's supervision plan are as follows:

i. a committee of 2-3 senior faculty members at the institution who are familiar with Respondent's field of research, but not including Respondent's supervisor or collaborators, will provide oversight and guidance for two (2) years immediately following the period of exclusion; the committee will review primary data from Respondent's laboratory on a quarterly basis and submit a report to ORI at six (6) month intervals setting forth the committee meeting dates, Respondent's compliance with appropriate research standards, and confirming the integrity of Respondent's research; and

ii. the committee will conduct an advance review of any PHS grant applications (including supplements, resubmissions, etc.), manuscripts reporting PHS-funded research submitted for publication, and abstracts; the review will include a discussion with Respondent of the primary data represented in those documents and include a certification to ORI that the data presented in the proposed application/publication are supported by the research record;

(3) that any institution employing him during the two (2) years during which the supervisory plan is in effect shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract; and

(4) to exclude himself from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of three (3) years, beginning on February 6, 2012.

Paul J. Muchowski, Ph.D., The J. David Gladstone Institutes: Based on the report of an investigation conducted by The J. David Gladstone Institutes (Gladstone) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Paul J. Muchowski, former Senior Investigator, Gladstone Institute of Neurological Disease, Gladstone, engaged in research misconduct in research supported by National Institute of Neurological Diseases and Stroke (NINDS), National Institutes of Health (NIH), grant R01 NS054753-06A1.

ORI found that the Respondent engaged in research misconduct by falsifying and fabricating data that were included in one (1) funded NIH grant R01 NS054753-06A1 and two (2) submitted NIH grant applications R01 NS054753-06 and R01 NS047237-06.

Specifically, ORI finds that the Respondent knowingly and intentionally:

- falsely reported research experiments when the results did not exist at the time the grant applications were submitted. Specifically:

    - in Figures 19-21 and related text of grant application R01 NS047237-06, the Respondent claimed he had successfully transduced human neuroblastoma SH-SY5Y cells expressing α-synuclein (αSyn) with lentiviruses containing small hairpin RNAs (shRNAs) that targeted *Cog6, Stx7, Vps52,* or *Vps33a*. The Respondent reported lentiviral expressed *Cog6* significantly exacerbated α-Syn toxicity in SH-SY5Y cells, when only plasmid shRNAs were generated and utilized at the time the grant application was submitted.
    - in Figure 5 and the accompanying text of grant R01 NS054753-06A1, the Respondent described the insertion of toxic and inert mutant Huntington (htt) fragments into maltose binding protein-Htt-Cerulean constructs with a nonpathogenic (25Q) or pathogenic (46Q) polyQ repeat, with and without Cerulean. The modified proteins were claimed to have been purified, when the constructs had not been made at the time the grant was submitted.
    - in Figures 5 and 6 and the accompanying text of grant R01 NS054753-06A1, the Respondent claimed to have cloned toxic and inert mutant htt fragments into lentiviral constructs and generated lentiviruses, when the constructs were not made.

    - in Figure 6 and related text in grant R01 NS054753-06A1, the Respondent claimed to have tested immunoblots of lysates from primary neurons with an antibody against mutant htt, which demonstrated that levels of htt expression in transduced cells were roughly equivalent to levels in normal neurons, when the experiment was not conducted.

- falsified Figure 3 of grant application R01 NS054753-06 by labeling the Western blot images for the expression of mutant htt in lentiviral-transduced primary neurons as ‘Cortex’ (left panel) and ‘Striatum’ (right panel), when the results were actually from the microglial cell lines N9 and BV2, respectively.

Dr. Muchowski has entered into a Voluntary Settlement Agreement and has voluntarily agreed for a period of two (2) years, beginning on December 10, 2012:

(1) to have his research supervised; Respondent agreed that prior to the submission of an application for PHS support for a research project on which his participation is proposed and prior to his participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of his duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of his research contribution; he agreed that he shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed-upon supervision plan; and

(2) to exclude himself voluntarily 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.

Mepur H. Ravindranath, Ph.D., John Wayne Cancer Institute: Based on the report of an investigation conducted by the John Wayne Cancer Institute (JWCI) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Mepur H. Ravindranath, former Director of the Laboratory of Glycoimmunotherapy, JWCI, engaged in research misconduct in research supported by National Cancer Institute (NCI), National Institutes of Health (NIH), awards R21 CA107316 and R03 CA107831.

ORI found that the Respondent engaged in research misconduct by falsifying results reported for research supported by U.S. Public Health Service (PHS) grants R21 CA107316 and R03 CA107831, in progress reports for those grants and in two publications in scientific journals.

It is expressly understood that by entering into a Voluntary Settlement Agreement (Agreement), Respondent is not admitting to any of the allegations made against him by JWCI and/or ORI, or any of their respective agents, employees, associates, or related persons, including, but not limited to, the findings made by ORI listed in the Agreement. Respondent agreed to enter into the Agreement and not to contest the findings contained therein solely because contesting the findings would cause Respondent undue financial hardship and stress, and Respondent wished to seek finality.

Specifically:

1. Respondent falsified the number of subjects accrued in the double-blind study reported in the paper Ravindranath, M.H., Muthugounder, S., Presser, N., Ye, X., Brosman, S., & Morton, D.L. “Endogenous immune response to gangliosides in patients with confined

prostate cancer." *Int. J. Cancer* 166:368-377, 2005 (subsequently referred to as the "*IJC* paper) and later reviewed in Ravindranath, M.H., Yesowitch, P., Sumobay, C., & Morton, D.L. "Glycoimmunomics of human cancer: Current concepts and future perspectives." *Future Oncology* 3(2):201-214, 2007 (subsequently referred to as the "*Future Oncology* paper"), by reporting data of 7 of 63 patients with serial bleeds taken at different points in time and reporting that the values from the 7 patients were for different patients. This same reporting data of individual patients with serial bleeds taken at different points in time and reporting that those values were for different patients was presented in the CA107316 and CA107831 final reports.

2. The methodology used for the Tables of ANOVA results comparing Log Titers of IgM antibodies for the different subject groups in the *IJC* and *Future Oncology* papers and the CA107316 and CA107831 final reports is incorrect and false, since the papers and reports fail to state that the results are not for a simple ANOVA but include various degrees of repeated measures on the variables.

3. In Table 1 of the CA107831 Final Report, Respondent reported mean log titer values for GM1b for healthy, BHP, and T3/4 CaP patients. These values exactly matched with values published for a different ganglioside, GM1, for healthy, BHP, and T3/4 CaP patients, earlier in the *IJC* (Table II) and *Future Oncology* publications. The only exception was the log titer value for T1/2 CaP patients for GM1b (n = 20), which matched with the earlier published mean log titer value for GT1b (6.22 ± 1.40; n = 36). ORI finds the pairwise-difference in the log titer values of GM1b between the T1/2 CaP and healthy patients, claimed to be significant ($p<0.01$), to therefore be incorrect and false. Respondent contends otherwise.

4. Because Respondent included serial bleed values from individual patients in Table 1 of the *IJC* paper, the summary data for anti-ganglioside antibody values, and the statistical analyses derived from them in Tables II and III of the *IJC* paper, Tables 1 and 2 of the *Future Oncology* paper, published Tables A and B of the CA107316 final report, and Tables 1 and 2B of the CA107831 final report are incorrect and false. The inclusion of serial bleeds from individual patients in Table 1 of the *IJC* paper and their inappropriate impact on the antibody values reported in Table II of the *IJC* paper were reported in detail by Respondent to the Managing Editor in *IJC* in e-mail communications dated September 24 and 29, 2008.

Dr. Ravindranath has entered into a Voluntary Settlement Agreement and has voluntarily agreed for a period of three (3) years, beginning on July 2, 2012:

(1) to have any PHS-supported research supervised; Respondent agreed that prior to the submission of an application for PHS support for a research project on which the Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision

Respondent agreed that he shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed-upon supervision plan;

(2) that any institution employing him shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived, that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract, and that the text in such submissions is his own or properly cites the source of copied language and ideas; and

(3) to exclude himself voluntarily 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.

Eric J. Smart, Ph.D., University of Kentucky: Based on the report of an investigation conducted by the University of Kentucky (UK) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Eric J. Smart, former Professor of Pediatrics and Physiology, Department of Pediatrics and Physiology, UK, engaged in research misconduct in research supported by National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grants R01 HL062844, R01 HL058475, R01 HL064056, R01 HL068059, and R01 HL073693, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH, grant R56 DK063025, and National Center for Research Resources (NCRR), NIH, grant P20 RR105592.

ORI found that the Respondent engaged in research misconduct by falsifying and/or fabricating data that were included in ten (10) published papers, one (1) submitted manuscript, seven (7) grant applications, and three (3) progress reports over a period of ten (10) years. Respondent reported experimental data for knockout mice that did not exist in five (5) grant applications and three (3) progress reports and also falsified and/or fabricated images in 45 figures included in the following:

- *J. Biol. Chem*. 277(7):4925-31, 2002
- *Am J. Physiol. Cell Physiol*. 291(6):C1271-8, 2006
- *Am J. Physiol. Cell Physiol*. 294(1):C295-305, 2008
- *J. Lipid Res*. 42:1444-1449, 2001
- *J. Biol. Chem*. 275:25595, 2000
- *J. Biol. Chem*. 277(26):23525-33, 2002
- *Proc. Natl. Acad. Sci. USA* 101(10):3450-5, 2004
- *J. Biol. Chem*. 280(33):29543-50, 2005
- *J. Biol. Chem*. 273:6525-6532, 1998

- *Am J. Physiol. Cell Physiol.* 282:C935-46, 2002
- "Effects of HIV protease and nucleoside reverse transcriptase inhibitors on macrophage cholesterol accumulation in humans," submitted August 6, 2008
- R01 HL078976-01
- R01 HL078979-01A1
- R01 DK063025-01A2
- R01 HL088150-01
- U54 CA116853-01
- R01 HL093155-01
- R01 HL068509-01A1
- Progress reports HL078976-02, -03, and -04.

As a result of its investigation, UK recommended that the publication(s) listed above be retracted or corrected.

Specifically, ORI finds that Respondent:

- falsely reported in Figure 14 and associated text in NIH grant applications R01 HL07897601 and -01A1 that experiments were performed to determine if endothelial-specific caveolin-1 null mice were protected from saturated fatty acid-induced atherosclerosis, when these mutant mice did not exist in the laboratory at the time; Dr. Smart also falsely reported the use of these mice in related progress reports R01 HL078976-02, -03, and -04 and in three (3) additional NIH grant applications: Figure 11 in R01 HL088150-01, Figure 11 in U54 CA116853, and Figure 9 in DK063025-01A2

  falsified and/or fabricated images in NIH grant application R01 HL078976-01A1 by duplicating and altering bands in 14 Western blot images and one (1) RT-PCR image included in Figures 3, 6, 11, 12, 13, 14, and 15; false Western blots were also included in the earlier version of the grant application R01 HL078976-01, Figures 3, 6, 11, 13, and 14

- falsified and/or fabricated Western blots and one (1) RNase protection assay by duplicating and altering bands in thirty-three (33) figures included in ten (10) published papers, one (1) submitted manuscript, and two (2) NIH grant applications. Specifically, false or fabricated images were included in:
  - Figures 5 and 7, *J. Biol. Chem*. 277(7):4925-31, 2002
  - Figure 4B, *Am J. Physiol. Cell Physiol*. 291(6):C1271-8, 2006
  - Figures 2A, 3A, 6A, and 7A, *Am J. Physiol. Cell Physiol*. 294(1):C295-305, 2008
  - Figures 3, 5, and 6, *J. Lipid Res*. 45:1444-1449, 2001
  - Figure 2A, *J. Biol. Chem*. 275(33):25595-99, 2000
  - Figures 2A/B/C and 4A/B, *J. Biol. Chem*. 277(26):23525-33, 2002
  - Figures 2B/D and 4, *Proc. Natl. Acad. Sci. USA* 101(10):3450-5, 2004
  - Figures 1A and 5B, *J. Biol. Chem*. 280(33):29543-50, 2005
  - Figures 1A, 2A/B, and 4A, *J. Biol. Chem*. 273:6525-6532, 1998

- Figure 1B, *Am J. Physiol. Cell Physiol*. 282:C935-46, 2002
- Figures 2A, 4, 6B, 7, and 8 in a submitted manuscript
- Figures 7A, 8A, 9A, and 10B in grant application HL093155-01
- Figures 4, 7, and 13 in grant application HL068509-01A1.

Dr. Smart has entered into a Voluntary Exclusion Agreement and has voluntarily agreed for a period of seven (7) years, beginning on October 23, 2012:

(1) to exclude himself 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 HHS' Implementation (2 C.F.R. Part 376 *et seq.*) of OMB Guidelines to Agencies on Govermentwide Debarment and Suspension, 2 C.F.R. Part 180 (collectively the "Debarment Regulations");

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

(3) to request that the following publications be retracted or corrected: *J. Biol. Chem*. 277(7):4925-31, 2002; *Am J. Physiol. Cell Physiol*. 291(6):C1271-8, 2006; *Am J. Physiol. Cell Physiol*. 294(1):C295-305, 2008; *J. Lipid Res*. 42:1444-1449, 2001; *J. Biol. Chem.* 275:25595, 2000; *J. Biol. Chem*. 277(26):23525-33, 2002; *Proc. Natl. Acad. Sci. USA* 101(10):3450-5, 2004; *J. Biol. Chem*. 280(33):29543-50, 2005; *J. Biol. Chem*. 273:6525-6532, 1998; *Am J. Physiol. Cell Physiol*. 282:C935-46, 2002.

Mona Thiruchelvam, Ph.D., University of Medicine and Dentistry of New Jersey: Based on the report of an investigation conducted by the University of Medicine and Dentistry of New Jersey (UMDNJ) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Mona Thiruchelvam, former Assistant Professor, Department of Environment and Occupational Health Science Institute (EOHSI), UMDNJ, engaged in research misconduct in research supported by National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), grants P30 ES05022, P30 ES01247, and R01 ES10791 and the intramural program at the National Institute on Drug Abuse (NIDA), NIH.

ORI found that the Respondent engaged in research misconduct by falsifying and fabricating cell count data that she claimed to have obtained through stereological methods in order to falsely report the effects of combined exposure of the pesticides paraquat and maneb on dopaminergic neuronal death and a neuroprotective role for estrogen in a murine model of Parkinson's disease. The Respondent provided to the institution corrupted data files as the data for stereological cell counts of nigrostriatal neurons in brains of several mice and rats by copying a single data file from a previous experiment and renaming the copies to fit the description of 13 new experiments composed of 293 data files when stereological data collection was never performed for the questioned research.

The fabricated data, falsified methodology, and false claims based on fabricated and falsified data were reported in two NIEHS, NIH, grant applications, two publications, a poster, and a manuscript in preparation:

- R01 ES016277, "Development Pesticide Exposure: The Parkinson's Disease Phenotype" (Dr. Mona J. Thiruchelvam Principal Investigator [P.I.]), submitted 1/26/2007 and funded.

- R01 ES015041, "Gender and the Parkinson's Disease Phenotype" (Dr. Mona J. Thiruchelvam, P.I.), submitted 12/19/05.

- Rodriguez, V.M., Thiruchelvam, M., & Cory-Slechta, D.A. "Sustained Exposure to the Widely Used Herbicide, Atrazine: Altered Function and Loss of Neurons in Brain Monamine Systems." *Environ Health Perspect*. 113(6):708-715, 2005 ("*EHP* paper").
- Thiruchelvam, M., Prokopenko, O., Cory-Slechta, D.A., Richfield, E.K., Buckley, B., & Mirochnitchenko, O. "Overexpression of Superoxide Dismutase or Glutathione Peroxidase Protects against the Paraquat + Maneb-induced Parkinson Disease Phenotype." *J. Biol. Chem*. 280(23):22530-22539, 2005 ("*JBC* paper").

- Harvey, K., Victor, A.I., Wang, Y., Kochar, Y., Cory-Slechta, D.A., & Thiruchelvam, M. "Gene Delivery of GDNF Impedes Progressive Neurodegeneration in Paraquat and Maneb Exposure Model of Parkinson's Disease." Poster presentation, *Neuroscience* 2006 ("*Neuroscience* poster").

- Thiruchelvam, M., Kochar, Y., Mehta, H., Prokopenko, O., Cory-Slechta, D.A., Richfield, E.K., & Mirochnitchenko, O. "Mechanisms associated with gender difference in the paraquat and maneb animal model of Parkinson's disease, 2006 ("manuscript").

Specifically, ORI finds that the Respondent engaged in research misconduct by knowingly and intentionally:

- falsifying and fabricating summary bar graphs and methodology for stereological cell counts in a murine model of Parkinson's disease, when the stereological counts were never performed

- copying and altering in multiple ways a single stereology ".dat" computer file generated on August 18, 2002, and renaming it to generate 293 data files representing counts for 13 new experiments that were never performed, by altering the files to make them unreadable and claiming that these files were from valid stereological cell count experiments carried out at UMDNJ between 2004 and 2006

- falsifying a bar graph representing brain proteasomal activity, by selectively altering data for relative fluorescent unit (RFU) values to support the hypothesis that development of

- Parkinson's disease entails proteasomal dysfunction with a higher effect in males compared to females

- by failing to perform stereological cell counts, the following figures of summary bar graphs, reported methodology, and related claims of the Respondent's *JBC* paper, *EHP* paper, a manuscript, a poster, and two grant applications were falsified:
  - Figure 7B and the related text in R01 ES016277-01and the *Neuroscience* 2006 poster
  - Figure 4 and the related text in R01 ES016277-01
  - Figure 9 and the related text in R01 ES016277-01 and R01 ES015041
  - Figure 3 and the related text in the *JBC* paper
  - Figure 4 and the related text in the *EHP* paper
  - Figure 5 and the related text in a *manuscript* in preparation

- by falsifying and selectively altering experimental data for relative fluorescent unit values of brain proteasomal activity, the summary bar graph in Figure 6 and the claim that combined exposure of the pesticides causes significant decreases in proteasomal activity with a higher effect in males than in females were falsified in NIH grant application R01 ES016277.

Dr. Thiruchelvam has entered into a Voluntary Exclusion Agreement (Agreement) and has voluntarily agreed for a period of seven (7) years, beginning on June 13, 2012:

(1) to exclude herself 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 HHS' Implementation (2 C.F.R. Part 376 *et seq.*) of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension, 2 C.F.R. Part 180 (collectively the "Debarment Regulations");

(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; and

(3) to request retraction of the following two papers:
  - *Environ Health Perspect*. 113(6):708-715, 2005
  - *J. Biol. Chem*. 280(23):22530-22539, 2005.

Calleen S. Zach, Creighton University: Based on evidence obtained from Creighton University (CU) and additional evidence gathered by the Office of Research Integrity (ORI) during its oversight review, ORI found that Ms. Calleen S. Zach, former Research Assistant and Data Base Manager, CU, engaged in research misconduct in research funded by National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH), grant R01 HD046991.

Specifically, ORI found that the Respondent provided falsified subject enrollment numbers in an application to NIH for continued funding of R01 HD046991 in 2008, a no-cost, one-year extension request for R01 HD046991 (April 8, 2009, letter to NICHD, NIH), and an application for additional funding of R01 HD046991 (June 30, 2009, to NICHD, NIH). In addition, she knowingly and intentionally provided falsified subject enrollment numbers in reports to the CU Institutional Review Board (IRB) in 2008 and 2009.

ORI concluded that Respondent's knowing and intentional falsification of data constitutes research misconduct as defined by 42 C.F.R. § 93.103. In addition, ORI found that Respondent's intentionally deceptive behavior, including false statements made to the CU institutional officials, forgery of petty cash receipts, and theft of NIH research grant funds establish a lack of trustworthiness and present responsibility to be a steward of Federal funds. 2 C.F.R. §§ 180.125, 180.800(d), 376.10.

The following administrative actions have been implemented for a period of five (5) years, beginning on January 23, 2012:

(1) Ms. Zach is debarred from eligibility for any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement programs of the United States Government, referred to as "covered transactions" as defined in 2 C.F.R. §§ 180.200, 376.10; and

(2) Ms. Zach 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.

Shuang-Qing Zhang, Ph.D., Texas Tech University Health Sciences Center: Based on the report of an investigation conducted by the Texas Tech University Health Sciences Center (TTUHSC) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Shuang-Qing Zhang, former Postdoctoral Researcher, Department of Pharmaceutical Sciences, TTUHSC, engaged in research misconduct in research supported by National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), grant R01 GM069869.

ORI found that Respondent engaged in research misconduct by the falsification and fabrication of plagiarized data that were included in the publication: Zhang, S.Q., & Mehavr, R. "Determination of dextra-methylprednisolone conjugate with glycine linker in rat plasma and liver by high-performance liquid chromatography and its application in pharmacokinetics." *Biomed. Chromatogr*. 24(4):351-357, 2010 (hereafter the "*BC* 2010 article"). Specifically, ORI found that the Respondent:

- falsified Figures 2(c) and 3(c) of the *BC* 2010 article by misrepresenting HPLC data that he had plagiarized, originally generated prior to the Respondent's arrival in the laboratory by a former postdoctoral researcher; in Figure 2(c), the Respondent claimed that the HPLC chromatogram was of a "plasma sample obtained 12 h after intravenous injection of DMP to rats at a single dose of 5 mg/kg," while the actual chromatogram was of a calibration test of 1 μg/ml of DMP added to rat plasma, and similarly in Figure 3(c), the Respondent claimed that the HPLC chromatogram was of a "liver homogenate obtained 3 h after intravenous dose of DMP at a dose of 5 mg/kg," while the actual chromatogram was of a calibration test of 2 μg/ml DMP added to rat liver homogenate.

- falsified and fabricated Figure 4 of the *BC* 2010 article; in the top panel, the Respondent reported the measurement of DMP concentrations in plasma samples of three rats after a single injection of 5 mg/kg DMP, while the actual data that he had plagiarized, originally generated prior to the Respondent's arrival in the laboratory by a former postdoctoral researcher, was from a single rat. In the bottom panel, the Respondent reported the measurement of DMP concentrations in liver samples obtained from three rats at 1, 30, 90, 180, 300, and 720 minutes after a single injection of 5 mg/kg DMP, requiring a total of 18 rats, while the actual data that he had plagiarized, originally generated prior to the Respondent's arrival in the laboratory by a former postdoctoral researcher, were from plasma samples from a single rat, and the error bars for both panels were fabricated.

Dr. Zhang has entered into a Voluntary Settlement Agreement and has voluntarily agreed:

(1) to have his research supervised for a period of three (3) years; Respondent voluntarily agrees that within sixty (60) days of the effective date of the Agreement, any institution that submits an application for PHS support for a research project on which the Respondent's participation is proposed or that uses the Respondent in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which the Respondent is involved, must concurrently submit a plan for supervision of the Respondent's research to ORI for approval; Respondent agrees that he will not participate in any PHS-supported research after sixty (60) days from the effective date of the Agreement until an appropriate supervision plan is submitted to ORI; the supervision plan must be designed to ensure the scientific integrity of the Respondent's research contribution; and

(2) to exclude himself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of three (3) years, beginning on December 4, 2012.

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