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Office of Research Integrity Annual Report 2011



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I. ORI HIGHLIGHTS OF CY 2011

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 CFR 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.

- In 2011, ORI sustained findings of research misconduct in 44 percent of the cases (13/29). The historical average is 36 percent of the cases in a year.
- Administrative actions on those who committed research misconduct involved a varying number of years, four were debarred, 13 were prohibited from working as advisors, nine were required to be supervised, and seven had to have certification if working on research.
- ORI received 240 allegations in 2011, well above the 1992-2007 average of 198.
- DIO’s review process involved opening 44 new cases, closing 29, and carrying 39 cases into 2012. The number of open cases is the highest number in 15 years.
- For the 29 cases closed by ORI in 2011, it took institutions a mean of 14.5 months to close the institutional case after notifying ORI of the allegation. ORI took a mean of 5.6 months to review the reports, obtain additional information from the institution, complete the ORI analysis, negotiate any PHS findings and administrative actions, and then close the case.
- 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 63 occasions in 2011, above the 43 instances in 2010. Most of the rapid responses involved discussion with institutional officials who had concerns about how to manage newly identified or ongoing cases. The remainder involved interactions with journal editors who requested assistance on verifying problems with submitted manuscripts and anonymous complainants requesting guidance on how to proceed with complaints.
- ORI staff made 36 educational presentations during 2011.

- In 2011, ORI sponsored four regional conferences: (1) Quest for Research Excellence: Research Integrity-Challenges in Vaccine Development and Distribution for Public Health Emergencies; (2) Quest for Research Excellence: The Use of Human Tissue and Public Trust: The Chasm between Science and Ethics; (3) Quest for Research Excellence: Ethical Considerations in Research Collaborations; and (4) Quest for Research Excellence: Research Integrity, Community-Based Participatory Research, and the National Stakeholder Strategy for Achieving Healthy Equity. ORI also actively participated in one in-kind meeting on research integrity at the 2011 American Association for the Advancement of Science (AAAS) Annual Meeting.
- The ORI web site (ori.hhs.gov/) received 626,486 page reviews from 228,800 visits in 2011. The site was visited by 155,911 users from 182 countries. The top 10 countries visiting the ORI site were as follows: the United States, Canada, Netherlands, Japan, United Kingdom, India, China, Germany, Australia, and Puerto Rico.
- “The Lab: Avoiding Research Misconduct” is an interactive online video, which was released and distributed in February 2011. *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*.
- ORI financially supported the development of one new resource by the National Academy of Sciences, a new edition of *Responsible Science: Ensuring the Integrity of the Research Process*.
- The Research on Research Integrity (RRI) Program, in coordination with the National Institutes of Health (NIH), made four new awards in 2011. In the first 10 years, this action increased the number of studies supported to 59. The studies have produced 116 articles, in more than 30 different publications.
- The ORI Intramural Research Program completed the following two studies; papers based on these studies will be drafted and submitted to peer-reviewed journals:

 - Mathematica Policy Research, Inc.: “Evaluating Faculty Member’s Views on their Institutions’ Guidance to Faculty Members on their Roles in Advising Ph.D. Candidates.”
 - Research Triangle Institute International: “Evaluating the Effectiveness of Institutional Efforts to Educate their Staffs on their Policies for Dealing with Research Misconduct and Research Integrity.”
- Intramural study “RIOs Preparedness to Handle Possible Research Misconduct” was published in the *Journal for Science and Engineering Ethics*, in 2011.
- Institutions receiving research funding from PHS are required to annually report their research activity for the prior year to ORI. In 2011, the 6,378 funded institutions reported 303 allegations, inquiries, or investigations.

II. 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 45 Code of Federal Regulations [CFR], Section 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 is focused on RIOs from larger institutions because their institutions are most likely to receive the majority of the PHS funding to conduct research. Therefore, there is an increased likelihood that research misconduct may occur.

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 opening a formal case. 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 action reported, if found to be true, would represent 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:

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

(a) Fabrication is making up data or results and recording or reporting them.

(b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

(c) Plagiarism is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.

(d) Research misconduct does not include honest error or differences of opinion.”

For ORI to make a finding of research misconduct, it must prove by a preponderance of the evidence that there was fabrication, falsification, or plagiarism; who did it; that it was knowingly, intentionally, or recklessly done; and that the act was a significant departure from the relevant practices of the research community (42 CFR Part 93.104).

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

3. Plagiarism Definition

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

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

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

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

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

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

Institutional standards

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

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

Collaborative Disputes

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

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

Self-Plagiarism

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

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

B. Allegations Made to ORI

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

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

Typically, only about one-third of the substantive allegations, also known as pre-inquiry assessments, received by ORI, result in a formal case being opened. However, ORI carefully evaluates all allegations received and reaches an appropriate disposition. ORI also regularly requests additional information about allegations from an institution. Many assessments require appreciable ORI staff work, even when they do not evolve into a research misconduct case.

In 2011, ORI received 240 allegations. The dispositions of the allegations received by ORI are presented in Table 1. Allegations become active cases when the criteria outlined above are met. Allegations are administratively closed when ORI finds that the allegation:

1. does not fall under ORI jurisdiction or meet these criteria, or
2. cannot be referred to another agency, or
3. was resolved through further review and information.

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

If an allegation lacks sufficient specific information to permit a determination regarding disposition, ORI will not take any action. ORI classifies these allegations according to their origin and the action taken:

- If a complaint is received (in contrast to a request for information), an accession number is assigned.
- 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, Office of Management Assessment, 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 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 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 agency.

Pre-inquiry assessment refers to assessments that have been identified by institutions as active inquiries or investigations. Pre-inquiry assessments are followed continuously by DIO for these reasons: (1) to ensure that the institutional reporting requirements are met, (2) to determine whether extensions of time are required, and (3) to determine whether appropriate interim reports are received with requests for an extension.

As Table 1 indicates, of the 240 allegations made to ORI (or to NIH and reported to ORI) in 2011, 77 were assessed by ORI in detail, for a potential inquiry or investigation; 12 of the assessments were opened as cases in 2011. Of the remaining pre-inquiry assessments, 17 were administratively closed after review, and 48 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 240 allegations that ORI received in 2011 were an increase of 55 percent, over the 155 allegations handled in 2010.

Table 1: Disposition of Allegations in ORI, 2011

Handling of Allegations - Outcome in ORI	Processes	Outcome
No Action Possible Now or No Action	139	
Handled by Agency	7	
Handled by Agency to ORI	0	
Referred to Other Federal Agencies	10	
Pre-inquiry Assessment of Allegations Made Directly to ORI		77
Pre-inquiry Assessment of Allegations Made Initially to NIH		7
Pre-inquiry Assessment of All Allegations	84	
Total Allegations Handled	240	84
Handling of Pre-inquiry Assessments Made Directly to ORI		
Administratively Closed After Review		17
Remaining Pre-inquiry Assessments		48
Moved to Active Status		12
Total Pre-inquiry Assessments Made		77

Table 2 summarizes the distribution of time in days needed to resolve pre-inquiry assessments during 2011. It should be noted that in the past couple of years DIO has not opened as many of the pre-inquiry assessments and cases as quickly as in previous years. Mostly, this decrease is due to some uncertainty about the merits of many of the 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 preliminary review of the investigative record becomes possible, DIO determines whether the matter warrants opening a case for oversight review or, alternatively, administratively closing the accession at that stage.

Table 2: Time for Conduct of Pre-inquiry Assessments by ORI, 2011

Outcome of ORI Assessment	Number of Allegations	Distribution of Resolution Times (in Days)		
		Mean	Median	Range
Opened a Formal Case	12	125	100	1-299
Administratively Closed	17	66	61	1-191
Unresolved at End of Year 2011	48	120	113	1-284
Total	77			

C. ORI Caseload Includes Inquiries and Investigations

Table 3 summarizes the case type for the ORI caseload. The table includes 24 cases carried forward from 2010. Of the 44 cases opened by DIO in 2011, 20 arose from pre-inquiry assessments from earlier years. Interestingly, a majority of the pre-inquiry assessments carried into 2011 represented ongoing investigations at the institutional level.

The ORI caseload is divided into institutional inquiries and institutional investigations. ORI carried forward 24 cases from 2010, opened 44 new cases, and closed 29 cases during 2011 (see Table 3). The 44 cases opened in 2011 represent the largest number of cases opened since 1995 (16 years). At the end of calendar year 2011, ORI had 39 institutional investigations that were active formal cases, and they were all carried into 2012.

Table 3: ORI Research Misconduct Caseload Case Type, 2011

Case Type	Forwarded From 2010	Opened in 2011	Closed in 2011	Open Cases Forwarded to 2012
Institutional Inquiry	1	0	1	0
Institutional Investigations	23	44	28	39
Total	24	44	29	39

*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 conduct of inquiries to ORI unless they result in investigations. However, ORI may become involved in institutional inquiries when ORI receives an allegation directly from a complainant and then asks the institution to conduct the inquiry. Under these circumstances, the institution is required to report the outcome of the inquiry to ORI, even when a decision was made not to move to an investigation. Other institutions routinely submit inquiry reports to ORI (many are equivalent to reporting investigations or making findings). ORI reviews these reports to determine whether the inquiry complied with the PHS regulations and was thorough, competent, and objective.

In addition, an institution's inquiry process can lead to a recommendation to conduct an investigation. But if the institution decides, for any number of reasons, not to do so (see 42 CFR Part 93.316), the institution is required to first inform ORI of its decision. Then the institution should seek guidance from ORI on whether this decision is appropriate. For example, if the inquiry recommended an investigation into allegations of minor significance, after review of the matter, ORI might concur with an institutional decision not to conduct an investigation or make findings of research misconduct. On the other hand, if an institution chose not to conduct an investigation when the inquiry found substantial evidence of falsified or fabricated data because the respondent was no longer there, ORI would likely require the investigation to proceed.

There were no institutional inquiries carried into 2012.

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 to determine whether the conduct of the investigation complied with the PHS regulations; was thorough, competent, and objective; and provided a basis for a PHS finding of research misconduct.

ORI began 2011 with 24 cases carried forward from 2010. During the year, 44 new institutional investigations were opened; 28 institutional investigation cases were closed (see Table 4). Of the 28 closed investigations, 13 involved ORI findings of research misconduct; 15 did not have such findings.

Of the total 29 cases closed in 2011, 46 percent (13 cases) involved findings of research misconduct (see Table 4). The actual number of findings of research misconduct this year (13) is consistent with the average of 12 findings each year during 1993-2011. Summaries of the 2011 cases are located in section VI of this report.

Table 4: Outcome of Research Misconduct Closed Cases by ORI, 2011

Outcome of Cases					
Case Type	No Investigation	No Research Misconduct	Misconduct Finding	Administrative Closure	Total Closed
Inquiry	1				1
Investigations		15	13	0	28
Total	1	15	13	0	29

There were 39 investigations carried into 2012.

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 2011.

4. Types of allegations and administrative actions

During 2011, all the formal ORI cases closed (with or without a finding of misconduct) involved allegations of falsification, fabrication, plagiarism, or a combination of all three (see Table 5).

Table 5: Types of Allegations in Closed Investigations and Their Outcomes, 2011

Allegation	Investigation	ORI Findings or PHS Administrative Actions
Falsification	10	5
Fabrication	3	1
Fabrication/Falsification	9	3
Plagiarism	5	3
Plagiarism/Falsification	1	1
Total	28	13

5. Duration of time involved in resolving and closing cases

The average duration of 20.2 months for conducting, reviewing, and closing these cases involved 14.6 months by the institution and 5.6 months for ORI oversight and administrative action (see Table 6). It should be noted that even though the data are not reflected in any of the tables, 25 (86 percent) of the cases were closed within 8 months after receipt of the final action from the institution.

The action period for the 28 institutional investigations and 1 inquiry 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 the officials for the basis of their decision about whether research misconduct occurred. Additional ORI analysis is often required to make an ORI finding of research misconduct. In most instances involving a finding of misconduct, ORI is able to close its cases by reaching a voluntary settlement agreement with the respondent. Occasionally, such an agreement cannot be reached. In such instances, a charge letter is issued, giving the respondent 30 days to request a hearing before an Administrative Law Judge in the DAB. At such a hearing, a final determination is made.

Table 6: Duration of Research Misconduct Cases Closed by ORI, 2011

Distribution of Resolution Times (in Months)			
Location of Activity	Mean	Median	Range
Institution	14.6	10	2-43
ORI	5.6	2	1-43

E. Examination of Outcomes of Closed Cases in 2011

1. HHS administrative actions imposed in closed cases

A range of administrative actions are used by HHS to protect the integrity of future PHS-funded research (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 13 cases in 2011 in which PHS research misconduct was found or HHS administrative actions were imposed, three people were debarred or voluntarily excluded for 3 years, two individuals were debarred or voluntarily excluded for 2 years. Other administrative actions imposed on respondents in these 13 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 (13 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, 2011

HHS Administrative Action	Duration (Years)	Number of Actions
Debarment or Voluntary Exclusion	2	1
Debarment or Voluntary Exclusion	3	3
Prohibition from Service as an Advisor for PHS	2	4
Prohibition from Service as an Advisor for PHS	3	8
Prohibition from Service as an Advisor for PHS	4	1
Supervision Plan Required	2	1
Supervision Plan Required	3	7
Supervision Plan Required	4	1
Certification of Work	2	1
Certification of Work	3	5
Certification of Work	4	1
Retraction of Article		1

F. Rapid Response for Technical Assistance (RRTA) Program

ORI provided RRTA on 63 occasions in 2011. This number is an increase of 46 percent compared to the 43 instances in 2010. Most of these rapid responses involved discussion with institutional officials who had concerns about how to manage newly identified or ongoing cases. The remainder involved interactions with journal editors who requested assistance on verifying problems with submitted manuscripts, and with anonymous complainants who requested guidance on how to proceed with complaints.

G. Implementation of HHS Administrative Actions: PHS ALERT

The PHS ALERT system is a confidential system of record for collecting, controlling, and disseminating information about individuals found to have engaged in research misconduct. The purpose is to help federal agencies to 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 debar or exclude individuals from receiving support or serving in an advisory capacity to PHS, unless a PHS administrative action imposed on them specifically requires it.

The 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, (3) the individual has agreed to a voluntary corrective action as a result of an investigation of research misconduct, or (4) ORI has received a report of an investigation by an institution in which there was a finding of research misconduct concerning the individual and ORI has determined that PHS has jurisdiction.

Individuals are typically entered into the system when ORI receives an institutional investigation report in which there is a finding of research misconduct and the questioned research was supported by PHS funding. If ORI concurs with the institutional findings, the individual's name will remain in the system until the expiration of any administrative actions imposed by PHS, at the recommendation of ORI. If ORI does not make a finding of research misconduct, the individual's name is promptly removed from the system, and the file is removed and destroyed. Information on each individual in the system is limited and includes such identifying information as the individual's name, date of birth, institution, sources of research funding, and a summary of any administrative actions imposed. At the completion of the ORI oversight review, if PHS administrative actions are recommended, the nature and term of the administrative actions are made public and are disclosed on the ORI web site while the administrative actions are still active.

On January 1, 2011, ORI listed the names of 50 individuals in the ALERT system (see Table 8). During the year, ORI added 11 names and removed 14. On December 31, 2011, the names of 47 individuals were in the system.

The 11 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.

Of the 47 names in the system at year end, 39 individuals had HHS administrative actions imposed on them, and 8 remained as a result of an institutional investigation in which there was a finding of research misconduct.

When individuals in the PHS ALERT system have a PHS research misconduct finding made against them and/or have PHS administrative actions imposed on them, they are also listed on the PHS Administrative 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, 2011

PHS ALERT System Activity, 2011	
As of January 1, 2011	50
Additions	11
Action Expired/Removed	14
As of December 31, 2011	47

H. Research Integrity Officer (RIO) Boot Camp Training

An extensive training program for RIOs completed its fourth year according to David Wright, Ph.D., who first recognized the need to deal with the rapid turnover and inexperience of RIOs at many universities. Institutional RIOs, their staff, and legal counsel from major research universities attended the ninth RIO Boot Camp in San Francisco, CA, hosted by the University of California-San Francisco in June 2011. To date, a total of 129 RIOs and 44 university legal counsels have attended the RIO Boot Camps since their inception in early 2007.

The curriculum of 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 DIO Scientist-Investigators, who serve as facilitators. Each boot camp brings together 25-30 RIOs and their counsel. It provides a forum to discuss critical skills that RIOs need to accomplish their roles, which is the most important problem facing RIOs today. Attendees participate through hands-on 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 with best-practices knowledge to be able to function properly as a RIO.

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

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 established by Dr. Wright. Currently, ORI is developing plans for an Advanced Topics RIO Boot Camp. The "advanced" boot camp is designed for "standard" boot camp graduates to help them prepare for especially difficult cases

of research misconduct. This boot camp will draw heavily on problems encountered with actual cases. A group of senior RIOs will act as Advanced Topics RIO Boot Camp Advisors leading discussions on patterns emerging in the worst cases and on best practices to prevent those problems. The Advanced Topics RIO Boot Camp will help to build a foundation for future RIO leadership who may take over the boot camp effort and help to establish a supportive professional organization for RIOs.

II. INSTITUTIONAL COMPLIANCE

The U.S. Public Health Service (PHS) regulation place 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 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 NIH center that an institution is in compliance with 42 CFR Part 93 and is eligible to receive their awards.

In 2001, ORI switched to an electronic submission of the Annual Report, beginning with the report for calendar year 2000, to ease the burden on the 6,378 institutions required to file a report with ORI.

1. Assurance database

Maintaining an accurate assurance database is essential to the successful operation of the Assurance Program because 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 2010, there were a total of 6,378 institutional assurances on file with ORI, an increase of 411 from 2009. There were 155 assurances inactivated because the institution failed to submit its 2010 Annual Report in 2011 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 6,378) 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, 2010-2011

Type of Institution	Number 2009	Increased 2010	Total at End 2010	Increased 2011	Total at End 2011
Institutions of Higher Education	1,042	+28	1,070	+17	1,087
Research Organizations, Institutes, Foundations, and Laboratories	482	+10	492	+38	530
Independent Hospitals	292	+8	300	+6	306
Educational Organizations, Other Than Higher Education	42	+1	43	+1	44
Other Health, Human Resources, and Environmental Services Organizations	679	+40	719	+28	747
Other (Small Business)	3,430	+324	3,754	+254	4,008
Total	5,967	411	6,378	344	6,722

2. Policy reviews of institutional research misconduct

ORI completed 150 policy reviews in 2010-2011. Since 1995, ORI has reviewed 3,023 institutional policies.

3. Annual Report on Possible Research Misconduct

To keep its assurance active, each institution must submit to ORI an Annual Report on Possible Research Misconduct (PHS Form 6349) that provides aggregate information on allegations, inquiries, investigations, and other activities required by the PHS regulation. If the institution does not submit the required annual report, its institutional assurance lapses, and the institution becomes ineligible to apply for or receive PHS research funds.

The electronic submission of the 2010 Annual Report began in January 2011, for the 6,378 institutions that had an assurance on file with ORI as of December 31, 2010.

Completed Annual Reports were received from 3,833 institutions for a response rate of 60 percent. ORI inactivated 155 assurances, including 2,545 institutions that did not return their Annual Reports by the March 31 deadline. Many assurances were reactivated later because Annual Reports were submitted after the due date.

4. Reported research misconduct activity from Annual Reports

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

Research misconduct activity is defined as receipt of an allegation, the conduct of an inquiry, an investigation in the reporting year, or an investigation continued into the reporting year. Reportable activities are limited to alleged research misconduct involving PHS-supported research, research training, or other research-related activities. Clearly, from Table 10, the number of allegations reported each year is higher than the year before.

Table 10: Research Misconduct Activity: 1993-2011

Annual Institutional Report			
Year*	Continued	New Allegations	Total
2011	112	191	303
2010	111	175	286
2009	108	189	297
2008	117	113	230
2007	130	183	313
2006	111	151	262
2005	113	137	250
2004	101	120	221
2003	106	136	242
2002	99	163	262
2001	78	127	205
2000	82	103	185
1999	72	89	161
1998	67	69	136
1997	73	92	165
1996	88	127	215
1995	96	104	200
1994	79	89	168
1993	73	86	159

*The count in year 2011 is a record of what institutions submitted in their 2010 Annual Report, which is submitted to ORI in 2011. 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 reporting possible instances of research misconduct. The regulation specifically requires institutions to take all reasonable and practical steps to protect the positions and reputations of individuals making allegations of research misconduct in good faith. When a credible complaint of retaliation is made, ORI will direct the institution to formally address the complaint, utilizing a fair and rigorous process, and to submit a report of its review to ORI.

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

Cases

Case 1 - In this case, an individual contacted ORI, initially requesting information related to protections afforded to complainants alleging research misconduct and the process for resolving retaliation complaints. As part of the assessment of this complaint, DIO reviewed the institution's policies and determined that it did not have a specific process to resolve retaliation complaints. However, the complainant was assured that institutions have the obligation to protect whistleblowers and that DIO would work closely with an institution that did not have written procedures, to implement a fair process to address retaliation complaints when necessary.

The whistleblower was informed that DIO was prepared to assist him in forwarding his claim, but that DIO would need more complete information related to his allegations. DIO needed a clear description of what "adverse events" had been suffered, how such events were linked to the act of raising the allegations, and the relative timing of all the events, as well as any other facts that would support such a position. DIO never received any documents or other evidence needed to further evaluate and possibly pursue this case, and therefore closed this assessment with no further action.

Case 2 - The complainant in this case alleged both research misconduct as well as retaliation. She claimed that her reputation had been tarnished and that she had been removed as coauthor on a publication in retaliation for raising allegations of possible research misconduct. An institutional inquiry determined that her complaint was more accurately described as an authorship dispute, which is outside the PHS definition of research misconduct. As such, the institutional requirements under the PHS regulation did not apply, so no further action was taken by ORI.

Case 3 - An individual working as a research assistant raised issues that developed into allegations of research misconduct against her laboratory chief. An institutional review found her allegation to be without merit. This complainant also claimed that as a result of her raising allegations, her laboratory chief, the respondent, ceased in his efforts to

assist her in pursuing other academic objectives. Further, the complainant argued that her lab chief's efforts to find her employment were components of retaliation. DIO determined that the efforts to find her employment were separate and therefore could not be considered retaliatory under the provisions of the PHS regulation.

Case 4 - Institutions are required to complete the process of conducting an inquiry into allegations of research misconduct within 60 days. Although certain circumstances may delay the process, institutions are expected to notify DIO when delays are expected, and when appropriate, extensions are granted by DIO. In this case, the formal inquiry process was initiated in February 2010, and based on this date, a report of inquiry was expected in either April or May 2010. Despite a number of voice mails and emails, as well as a formal letter directed to the Assistant Vice President for Scientific Affairs and to the Dean of the College of Medicine in July 2010, DIO had received no firm response from institutional officials regarding the current status of the inquiry or the reason for the excessive delay. Such lack of responsiveness represents a failure to comply with the provisions of the PHS regulation. DIO drafted a letter to the President of this institution addressing both the federal and institutional notification requirements in the misconduct review process. The letter also addressed the general issue of fairness to the respondent in avoiding delays in evaluating the allegations against him. Institutional officials agreed to provide the required information on a timelier basis.

Case 5 - Institutions receiving PHS research funds are required to have written policies and procedures that incorporate the requirements of the PHS regulation at 42 CFR Part 93. Most institutions over time have developed a single document that is meant to guide officials in addressing allegations of research misconduct. In a preliminary review of some of the relevant documents in a report submitted in support of an ongoing inquiry at a major university, DIO found that the institutional process was guided by at least two separate documents. One was a "bridging" document to the PHS regulation, with the process being further refined for faculty, staff, and students through reference to various institutional citations. While these various documents contained most of the requirements of the current PHS regulation, some of the more important requirements were missing or outdated, such as the detailed requirements for the institutional investigation report, and the appropriate standard of proof requirement.

While noting its ongoing concern with the somewhat patchwork approach by this institution for complying with the requirements of the PHS regulation, DIO acknowledged that recent announcements on the institution's web site specifically identified an Associate Dean as the designated contact for issues related to research misconduct. Having a key official with knowledge of the federal requirements engaged at the onset of the institutional process for dealing with allegations of research misconduct will help institutional officials as well as committee members navigate this institution's less than optimal procedures for dealing with research misconduct allegations.

Case 6 - DIO received two separate transmittals from an institution related to two separate and unrelated misconduct cases it was managing concurrently. One case was complete, and the institution provided an investigation report with supporting documentation. The second case was beginning the investigation phase, with the institution submitting the required notifications and some related documentation, including the inquiry report.

In its preliminary review of the case documents provided, DIO found a number of procedural shortcomings in each of the cases. DIO also found the institutional misconduct policy was outdated and needed revision.

In the completed case, DIO determined that the investigative report was minimal and provided little analysis of the falsified figure or any significant assessment of whether the admitted alteration represented a material false claim. More significant, there was no submission of any response by the respondent to either the inquiry report or the investigation report. These shortcomings in the investigation process prevented ORI from conducting proper oversight of this case or making any findings of research misconduct.

In the second case, an inquiry report was submitted as part of its notification to ORI of its intention to conduct further investigation of research misconduct allegations. Although the institution reported on the initial allegations as well as additional allegations received during the inquiry process, it did not provide any documentation associated with the review of the initial allegations. The institution also did not provide any further type of assessment of the additional allegations submitted.

On the basis of its review, ORI directed the institution to develop a corrective action plan to update its misconduct policy. The institution was also directed, for a specific time period, to immediately notify DIO of all allegations of research misconduct received and to submit to DIO any assessment or inquiry report associated with any allegation of research misconduct upon completion.

Case 7 - The respondent in this case contacted DIO to allege that the allegations made against her were made in bad faith. She also alleged that the RIO had an unresolved conflict of interest and should be replaced.

DIO reviewed the respondent's charges and determined that there was no evidence to support the claim that the allegations were made in bad faith. In fact, there was clear evidence of data manipulation, and an institutional investigation was conducted in compliance with the PHS regulation to determine the extent and relevance of the manipulations, and who was responsible.

On the separate issue of possible conflict of interest, DIO determined that the role of the RIO was to facilitate the process of investigating the charges, and this individual had no decision-making responsibilities. The institutional process had in place various safeguards, such as the option by the respondent to challenge the selection of any panel member to ensure the absence of bias and appropriate expertise. Another safeguard was the right to provide written comments on the institutional investigation report that

ultimately would become part of the institution record. At the conclusion of its review, DIO determined that there was no evidence to suggest any improper actions on the part of the institutional RIO.

Case 8 - Compliance reviews are often initiated by DIO as a result of weaknesses noted in its oversight review of the institutional investigation process. In this case, a review of the institutional policies was conducted, and a report with suggested improvements was forwarded to institutional officials. However, a review of the supporting documentation associated with the institutional investigation found evidence of possible retaliation by the respondent against one of the complainants, and there is no evidence that the institution took any action to address this issue, as required under the PHS regulation.

The complainant reportedly had an argument with the respondent regarding her work schedule, and during this discussion, the complainant claimed that she and others in the laboratory were not confident about the respondent's research data. The complainant was dismissed shortly thereafter, reportedly based on poor job performance. While the complainant never contacted ORI directly to allege retaliation, the record noted a discussion between the complainant and a representative of the Human Resources Department in which the complainant was told that the real reason she was fired was that she had questioned the respondent's research data. DIO's concern remains that adverse employment action was possibly taken against the complainant in response to her allegations, and the issue, clearly documented in the investigation file, was not acknowledged or addressed by any official involved in the process, including representatives from Human Resources, the Investigation Panel, or the institutional RIO.

ORI directed the institution to develop a corrective action plan to ensure that all faculty and staff are aware of the requirements of the PHS regulation and the institutional policies related to the handling of research misconduct investigations. In particular, the institution was also to ensure that its faculty and staff are aware of their responsibility to recognize and address possible retaliation.

Case 9 - ORI could not concur with the institutional findings in this case because of a number of procedural violations on the part of institutional officials. Such violations included the unjustified limitation on the scope of the inquiry and investigation process, and the acceptance and reliance by the investigation committee on falsified documents in support of its findings.

The initial allegation in this case involved questionable data associated with a number of grant applications, as well as several publications and poster presentations. The inquiry committee focused on documentation related to the grant applications, as this evidence was more readily available, and determined that further investigation was warranted. While the PHS regulation is clear that the purpose of an initial inquiry is to determine only whether the evidence suggests that misconduct may have occurred, the scope of the investigation process is to include the comprehensive pursuit of all significant issues and leads. In this case, the possible falsification of data in the grant applications, the publications, and the poster presentations would be involved. The respondent and his attorneys prevailed over institutional officials in limiting the scope of the initial investigation only to the grant issues. The respondent and his attorneys were also

successful in placing further restrictions on the evaluation of allegations associated with the publications and presentations. By agreeing to limit the institutional response, institutional officials were in violation of a basic provision of the PHS regulation to pursue all relevant allegations.

In supporting its findings and conclusions, the investigation committee relied heavily on the statements provided by four separate federal officials on the interpretation of data included in grant applications submitted by the respondent. In reviewing these written statements, DIO determined that the text in each document had been modified prior to submission to the investigation committee to include fabricated and/or falsified statements in support of the respondent's position. Thus, the primary evidence in support of the institution's findings was invalidated. No steps were taken by either the investigation committee or institutional officials to authenticate these important documents, violating its obligation to conduct a thorough, competent, and objective investigation.

IV. DEI MISSION: TO PROMOTE A RESPONSIBLE CONDUCT OF RESEARCH 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:

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

A. Resource Development Program – Education on RCR

ORI created the RCR Resource Development Program in 2002, to support the creation of RCR instructional materials by the research community for use in the worldwide research community. In addition to creating instructional resources, this program has sparked interest in RCR at private and public research institutes. In 2009, NIH issued requirements for instruction in RCR, which has further increased 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 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 the nine core RCR instructional areas.

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

Current projects include the following:

1. Interactive video development: “The Lab: Avoiding Research Misconduct”

ORI initiated a contract in 2009 with WILL Interactive to work with ORI staff to develop a script that would address such topics as avoiding or handling research misconduct, mentorship, responsible authorship, and work-life balance. Video production was completed in 2010, the video was released in 2011, and then it was posted on the ORI web site.

2. RCR learning objectives, test battery, and casebook

To help institutions advance the education of researchers in RCR and to lessen the burden on these institutions to provide such education, ORI is creating an RCR training package that includes: (1) a set of objectives for RCR education, (2) a test battery for evaluating RCR knowledge and reasoning, and (3) a book of case studies that can be used in classroom settings. The learning objectives have been published (<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3322664/>) and the battery of test questions are written, verified, and validated. The casebook will be released in calendar year 2012.

B. Collaborations and Partnerships

1. Council of Graduate Schools Contract

ORI awarded a 3.5-year contract in 2007 to the Council of Graduate Schools (CGS), to foster acceptance of RCR training as an essential element in graduate education. CGS is the only national organization in the United States dedicated solely to representing and advancing the interests of graduate education. Its 479 member institutions award over 90 percent of the doctorates and more than 75 percent of the master’s degrees awarded by U.S. institutions.

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

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

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

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

2. 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 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 2012. The project web site is located at 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.

3. NAS Government-University-Industry Research Roundtable (GUIRR) Conference on International Collaborations

ORI and other federal agencies, industries, and academic institutions worked with the NAS GUIRR effort to plan a followup working conference to the 2010 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.

As a result of the 2010 conference, a working guidance document was created that addressed the issues and concerns that were raised and discussed at the conference. “Examining Core Elements of International Research Collaboration: Summary of a Workshop” (September 2011), http://www.nap.edu/catalog.php?record_id=13192#toc. Future conferences on this topic are in the planning stages.

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 ori.hhs.gov/conferences/.

1. Regional conferences

- (a) Quest for Research Excellence: *Research Integrity Challenges in Vaccine Development and Distribution for Public Health Emergencies*, Philadelphia, PA, September 12, 2011
- (b) Quest for Research Excellence: *The Use of Human Tissue and Public Trust: The Chasm between Science and Ethics*, Omaha, NE, September 19, 2011
- (c) Quest for Research Excellence: *Ethical Considerations in Research Collaborations*, Seattle, WA, September 22 and 23, 2011
- (d) Quest for Research Excellence: *Research Integrity, Community-Based Participatory Research, and the National Stakeholder Strategy for Achieving Healthy Equity*, Nashville, TN, September 27, 2011

2. RIO Boot Camp training

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. The program provides training for RIOs in (1) learning the details of the federal regulations about handling allegations of research misconduct; (2) conducting an assessment of an allegation of research misconduct; (3) sequestering research records and establishing a team of professionals to assist with sequestration; (4) establishing, coordinating, and advising institutional committees

for conducting inquiries and investigations of allegations of research misconduct; and (5) providing available forensic tools for data and image analysis. The RIO Boot Camps are highly interactive and strive to establish a RIO network, to provide support for the RIO's role at their home institutions, and to professionalize the position of RIO. Further details about the boot camps are reported in the DIO section of this report.

3. Conferences supported in-kind

(a) American Association for the Advancement of Science (AAAS) Annual Meeting, "Responsible Research Practices in a Changing Research Environment," Washington, DC; February 17, 2011.

D. Communication Venues

1. Web site

The ORI web site (ori.hhs.gov/) received 626,486 page views from 228,800 visits in 2011. The site was visited by a total of 155,911 users from 182 countries. The top 10 countries visiting the ORI sites were: the United States, Canada, Netherlands, Japan, United Kingdom, India, China, Germany, Australia, and Puerto Rico.

2. ORI Newsletter

ORI has been producing a newsletter since January 1993. In 2010, ORI produced three issues that are available on the ORI web site. The newsletter provides ORI updates, summaries of cases published in the *Federal Register*, discussions of timely issues, and information about conferences. In 2011, ORI produced four issues including thematic research commentaries (data integrity and data image manipulation) from subject matter experts from the research integrity community.

3. Educational presentations made by ORI staff

John Dahlberg, Ph.D. "The Office of Research Integrity: Spotting Fraud in Scientific Research Panel," Association of Health Care Journalists, Health Journalism 2011 Annual Meeting, *Philadelphia, PA*; April 15, 2011.

John Dahlberg, Ph.D. "Integrity in the Name of Research" NIH Regional Seminar, *Scottsdale, AZ*; April 29, 2011.

John Dahlberg, Ph.D. "Forensics: Examining Questioned Data," ORI/University of California, San Francisco RIO Boot Camp, University of California, *San Francisco, CA*; June 13, 2011.

John Dahlberg, Ph.D. "Integrity in the Name of Research," NIH Regional Seminar: Program Funding and Grants Administration, *Weston, FL*; June 24, 2011.

John Dahlberg, Ph.D. “Office of Research Integrity: Scope and Process of Handling Allegations of Misconduct,” Secretary’s Advisory Committee on Human Research Protections (SACHRP), Subcommittee on Harmonization (SOH), Tower Building, *Rockville, MD*; June 29, 2011.

John Dahlberg, Ph.D. “Office of Research Integrity: Scope and Process of Handling Allegations of Misconduct,” SACHRP, Humphrey Building, *Washington, DC*; July 20, 2011.

John Dahlberg, Ph.D. “The Office of Research Integrity: Working with Institutions on Handling Allegations of Research Misconduct,” Forum on Scientific Ethics Construction, 13th Annual Conference, China Association for Science and Technology, *Tianjin, China*; September 20, 2011.

John Dahlberg, Ph.D. “The Culture of Science: The Importance of Doing it Right – and the Risks of Doing it Wrong,” Nankai University, *Tianjin, China*; September 21, 2011.

John Dahlberg, Ph.D. “Responding to Allegations of Research Misconduct and Promoting Better Science through Responsible Conduct of Research (RCR),” National Council of University Research Administrators (NCURA) Annual Meeting, *Washington, DC*; November 8, 2011.

John Galland, Ph.D. “National Implementation of Research Integrity: Good Research Practice Education,” 2011 American Association for the Advancement of Science (AAAS) Annual Meeting, Reaching a Global Standard in Research Integrity Track, Washington Convention Center, *Washington, DC*; February 17, 2011.

John Galland, Ph.D. “Publication Misconduct: What Publication Professionals Need to Know,” International Society for Medical Publication Professionals, *Arlington, VA*; April 4, 2011.

John Galland, Ph.D. “Research Integrity Issues,” Scientific Integrity Officers’ Meeting, Department of the Interior, *Washington, DC*; April 26-27, 2011.

John Galland, Ph.D. “Training Workshop: Educating Scientists in Research Ethics for the 21st Century: A Trainer-of-Trainers Conference,” Georgetown University Bolger Center, *Potomac, MD*; August 25-28, 2011.

John Galland, Ph.D. “Training Workshop: Interpersonal Integrity Conflicts in Vaccine Research,” Research Integrity Challenges in Vaccine Development and Distribution for Public Health Emergencies, Region III Regional Conference, *Philadelphia, PA*; September 12, 2011.

John Galland, Ph.D. “Training Workshop: Interpersonal Integrity Conflicts in Human Tissue Research,” The Use of Human Tissue and Public Trust. The Chasm between Science and Ethics, Region VII Regional Conference, *Omaha, NE*; September 19, 2011.

John Galland, Ph.D. “Training Workshop: Interpersonal Integrity Conflicts in Research Collaborations,” Ensuring an Ethical Foundation for Interdisciplinary Collaborations in Biomedical Research and the Provision of Public Health Services, Region X Regional Conference, *Seattle, WA*; September 22-23, 2011.

John Galland, Ph.D. “Training Workshop: Interpersonal Integrity Conflicts in Community-Based Participatory Research,” Taking it to the Streets: Mutually Beneficial Relationships of Community-Based Participatory Research at the Forefront of Eliminating Health Disparities, Region IV Regional Conference, *Nashville, TN*; September 27, 2011.

John Galland, Ph.D. “Responsible Conduct of Research in Academic Medicine: From Neglect to Action Plan,” Charite Universitätsmedizin Berlin, *Berlin, Germany*; October 5-9, 2011.

Susan Garfinkel, Ph.D. “Misconduct: The ORI Perspective,” Council of Science Editors Annual Meeting, *Baltimore, MD*; May 3, 2011.

Susan Garfinkel, Ph.D. “Examining Images: Evidence in the Vogel Case,” RIO Boot Camp, University of California, *San Francisco, CA*; June 14, 2011.

Susan Garfinkel, Ph.D. “The Vogel Case: What are the Allegations?” RIO Boot Camp, University of California, *San Francisco, CA*; June 14, 2011.

Kristen Grace, M.D., Ph.D. “Safeguarding Sound Science: Avoiding the Pitfalls of Research Misconduct and Mentoring for Success in Scientific Integrity,” Frontiers in Reproduction, Marine Biological Laboratory, *Woods Hole, MA*; May 15, 2011.

Kristen Grace, M.D., Ph.D. “The Lab: Frontiers in Reproduction,” Marine Biological Laboratory, *Woods Hole, MA*; May 16, 2011.

Kristen Grace, M.D., Ph.D. “Safeguarding Sound Science: Avoiding the Common Pitfalls of Clinical Research Misconduct,” Clinical Center Dean’s Grand Rounds, *Bethesda, MD*; August 2011.

Kristen Grace, M.D., Ph.D. “Safeguarding Sound Science: Avoiding the Pitfalls of Research Misconduct and Mentoring for Success in Scientific Integrity,” Clinical Center Dean’s Grand Rounds, SUNY, Upstate Medical College, *Syracuse, NY*; September 22, 2011.

Kristen Grace, M.D., Ph.D. “Special Workshop: Detection of Manipulated Scientific Data,” SUNY, Upstate Medical College, *Syracuse, NY*; September 23, 2011.

Kristen Grace, M.D., Ph.D. “Special Workshop: The Lab,” SUNY, Upstate Medical College, *Syracuse, NY*; September 23, 2011.

John Krueger, Ph.D. “Wrestling with Research Misconduct,” ORI Presentation to NIH Extramural Scientist Administrator (ESA) Seminar Series, *Bethesda, MD*; January 28, 2011.

John Krueger, Ph.D. “Research Misconduct – It Happens,” ORI Presentation to NIH ESA Seminar Series, *Bethesda, MD*; March 11, 2011.

John Krueger, Ph.D. “Image Integrity in Scientific Publishing,” Council of Science Editors Annual Meeting, *Baltimore, MD*; May 1, 2011.

John Krueger, Ph.D. “Research Misconduct – Not ‘If’ but ‘When,’” ORI Presentation to NIH ESA Seminar Series, December 16, 2011.

Loc Nguyen-Khoa, M.S. “The Lab: Avoiding Research Misconduct,” 2011 Council of Graduate School Summer Workshop, *Monterey, CA*, July 12-14, 2011.

Sandra Titus, Ph.D. “Detecting Research Misconduct: It’s More Common Than You Think,” MAGI Clinical Research Conference, *Philadelphia, PA*; May 24, 2011.

Sandra Titus, Ph.D. “RCR and Community-Based Participatory Research,” Q4RE-Taking it to the Streets: Mutually Beneficial Relationships of Community-Based Participatory Research at the Forefront of Eliminating Health Disparities, Region IV Regional Conference, *Nashville, TN*; September 27, 2011.

Sandra Titus, Ph.D. “Incorporating the Lab into Research Education,” 2011 Public Responsibility in Medicine and Research (PRIM&R) Advancing Ethical Research (AER) Conference, *Washington, DC*; December 4, 2011.

Donald Wright, M.P.H. “Integrity Challenges in Research Collaborations,” Ensuring an Ethical Foundation for Interdisciplinary Collaborations in Biomedical Research and the Provision of Public Health Services, Region X Regional Conference, *Seattle, WA*, September 22-23, 2011.

4. ORI publications in 2011

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

5. Federal Register Notices – Misconduct*

1. 02/10/11 Office of the Secretary (OS). Findings of Research Misconduct. Notice Vol. 76, No. 28, Thursday, February 10, 2011 [Goodwill]
2. 04/27/11 OS. Findings of Research Misconduct. Notice Vol. 76, No. 81, Wednesday, April 27, 2011 [Bhrigu]

3. 04/27/11 OS. Findings of Research Misconduct. Notice Vol. 76, No. 81, Wednesday, April 27, 2011 [Shin]
4. 06/09/11 OS. Findings of Misconduct in Science/Research Misconduct. Notice Vol. 76, No. 111, Thursday, June 9, 2011 [Bois]
5. 08/05/11 OS. Findings of Research Misconduct. Notice Vol. 76, No. 151, Friday, August 5, 2011 [Wang]
6. 10/04/11 OS. Findings of Research Misconduct. Notice Vol. 76, No. 192, Tuesday, October 4, 2011 [Weber]
7. 10/11/11 OS. Findings of Research Misconduct. Notice Vol. 76, No. 196, Tuesday, October 11, 2011 [Sanyal]
8. 10/13/11 OS. Findings of Research Misconduct. Notice Vol. 76, No. 198, Thursday, October 13, 2011 [Solomon]
9. 10/19/11 OS. Findings of Research Misconduct. Notice Vol. 76, No. 202, Wednesday, October 19, 2011 [Manojlovic]
10. 11/04/11 OS. Findings of Research Misconduct. Notice Vol. 76, No. 214, Friday, November 4, 2011 [Jagannathan]
11. 12/23/11 OS. Findings of Research Misconduct. Notice Vol. 76, No. 247, Friday, December 23, 2011 [Lushington]

*If a finding of research misconduct and/or finding of misconduct in science are 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, only findings that were posted in the *Federal Register* for the reporting year are listed here.

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

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

Studies over the past 20 years have examined medical school guidelines for RCR; outcomes for whistleblowers and respondents; scientists’ awareness of possible research misconduct; 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 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 on 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 have raised with them as well as to ascertain the kind of information the RIOs provided. The study was completed in 2011. A subsequent paper based on the results will be submitted to a peer-reviewed journal in 2012.

ii. Evaluation of the Interactive Video “The Lab: Avoiding Research Misconduct” – 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 is being designed and 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 have experience with the ORI educational programs or who may soon have experience with RCR programs. This evaluation will inform ORI about the perceptions of whether the video is useful and has value.

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 include:

- 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 59 projects that have resulted in 116 publications consisting of peer-reviewed articles, commentaries, letters to the editor, abstracts, and literature reviews in more than 30 journals. Award abstracts are posted on the ORI web site along with a list of publications produced by projects supported by the RRI program.

1. RRI awards in 2011

The granting round requested proposals that would examine research integrity with an emphasis on bias. The four awards made in 2011 by the RRI program follow:*

- (a) Thomas Arcury, Wake Forest University Health Sciences, "Scientific Integrity in Community-Based Participatory Research"
- (b) Dan Ariely, Duke University, "Complex and Self-serving Altruism in Research"
- (c) Lisa Bero, University California, San Francisco, "Measuring Design, Reporting and Funding Bias in Nonclinical Research"
- (d) Michael Mumford, University Oklahoma, Norman, "Bias and Bias Management in Ethics Education"

*These four awards were supported by ORI through NIEHS.

ORI funded \$1,236,262 for the RRI program in 2011. New grants totaled \$905,767 and continuation grants totaled \$330,495. Twenty-five applications were received for the R21-awards, which can provide up to \$275,000 in direct costs, plus indirect costs, for 2 years. There were two continuation awards funded by ORI through NCRR.

2. RRI publications

RRI awardees' articles published in 2011.

- (a) Garner HR. [Combating unethical publications with plagiarism detection services \[Review\]](#). *J Urol Oncol*. January-February 2011;29 (1):95-99.
- (b) Horner J, Minifie FD. Research ethics III: publication practices and authorship, conflicts of interest, and research misconduct *J Speech Lang Hear Res*. February 1, 2011;54(1):S346-S362.
- (c) Horner J, Minifie FD. [Research ethics I: responsible conduct of research \(RCR\)--historical and contemporary issues pertaining to human and animal experimentation](#). *J Speech Lang Hear Res*. February 2011;54(1):S303-S329. Epub: November 16, 2010.
- (d) Horner J, Minifie FD. [Research ethics II: mentoring, collaboration, peer review, and data management and ownership](#). *J Speech Lang Hear Res*. February 2011;54(1):S330-S345. Epub: November 16, 2010.
- (e) Horner J, Minifie FD. [Research ethics III: publication practices and authorship, conflicts of interest, and research misconduct](#). *J Speech Lang Hear Res*. February 2011;54(1):S346-S362. Epub: November 16, 2010.
- (f) Ingham JC, Minifie FD, Horner J, Robey RR, Lansing C, McCartney JH, Slater SC, Moss SE. Ethical principles associated with the publication of research in ASHA's scholarly journals: importance and adequacy of coverage. *J Speech Lang Hear Res*. February 2011;54:S394-S416.
- (g) Klitzman R. [Members of the same club: challenges and decisions faced by US IRBs in identifying and managing conflicts of interest](#). *PLoS One*. 2011;6(7):e22796. Epub: July 29, 2011.
- (h) Klitzman R. [Views and experiences of IRBs concerning research integrity](#). *J Law Med Ethics*. Fall 2011;39(3):513-528. doi: 10.1111/j.1748-720X.2011.00618.x.
- (i) Kon AA, Schilling DA, Heitman E, Steneck NH, Dubois JM. [Content analysis of major textbooks and online resources used in responsible conduct of research instruction](#). *AJOB Prim Res*. 2011;2(1):42-46.

- (j) Martinson BC. [The academic birth rate. Production and reproduction of the research work force, and its effect on innovation and research misconduct.](#) *EMBO Rep.* July 8, 2011;12(8):758-762.
- (k) Minifie FD, Robey RR, Horner J, Ingham JC, Lansing C, McCartney JH, Alldredge E, Slater SC, Moss SE. Responsible conduct of research in communication sciences and disorders: faculty and student perceptions. *J Speech Lang Hear Res.* 2011;54:S363-S393.
- (l) Moss SE. [Research integrity in communication sciences and disorders: preface.](#) *J Speech Lang Hear Res.* February 2011;54(1):S300-S302.
- (m) Plemmons D. [A broader discussion of authorship.](#) *Sci Eng Ethics.* June 2011;17(2):389-398. Epub: April 27, 2011.
- (n) [Seiler SN, Brummel BJ, Anderson KL, Kim KJ, Wee S, Gunsalus CK, Loui MC. A broader discussion of authorship.](#) *Sci Eng Ethics.* June 2011;17(2):389-398. Epub: April 27, 2011.
- (o) Seiler SN, Brummel BJ, Anderson KL, Kim KJ, Wee S, Gunsalus CK, Loui MC. Outcomes assessment of role-play scenarios for teaching responsible conduct of research. *Account Res.* July-August 2011; 18(4):217-246. doi: 10.1080/08989621.2011.584760.
- (p) True G, Alexander LB, Richman KA. [Misbehaviors of front-line research personnel and the integrity of community-based research.](#) *J Empir Res Hum Res Ethics.* June 2011;6(2):3-12.

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 86 requests in 2011 and closed 32. Sixty-four requests were carried into 2012. In 2010, ORI received 49 and closed 26 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 one Privacy Act request in 2011.

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

VI. FINDINGS OF RESEARCH MISCONDUCT CASE SUMMARIES OR ADMINISTRATIVE ACTIONS – 2011

A. Summaries of Closed Investigations Resulting in Findings of Research Misconduct or Administrative Actions – 2011

Meleik Goodwill, Ph.D.
Wadsworth Center, N.Y.S. Department of Health

Based on the Wadsworth Center report and the oversight review conducted by ORI, PHS found that Meleik Goodwill, Ph.D., former postdoctoral fellow, Wadsworth Center, N.Y.S. Department of Health, engaged in research misconduct in research supported by National Institute of Environmental Health Sciences (NIEHS), NIH, grant R21 ES013269-02.

Specifically, PHS found that the Respondent engaged in research misconduct by the fabrication of data for growth curves presented in Figure 1 in the 2007 *Journal of Neuroimmunology* article (Goodwill, M.K., Lawrence, D.A., & Seegal, R.F. “Polychlorinated biphenyls induce proinflammatory cytokine release and dopaminergic dysfunction: Protection in interleukin-6 knockout mice.” *Journal of Neuroimmunology* 183(1-2):125-132, 2007), and by the use of composite images of Western-blot bands from unrelated experiments done in 2005 that were falsely labeled as if from different experiments to construct Figure 4A in the 2007 *Journal of Neuroimmunology* article. Figure 4B of the article also was falsified by use of identical sets of number for different treatments. The 2007 *Journal of Neuroimmunology* article was retracted in *J. Neuroimmunol.* 197(1):197, 2008.

Dr. Goodwill has entered into a Voluntary Settlement Agreement in which she has voluntarily agreed, for a period of three (3) years, beginning on January 21, 2011:

- (1) that any institution that submits an application for PHS support for a research project on which the Respondent’s participation is proposed or that uses her in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which she is involved, must concurrently submit a plan for supervision of her duties to ORI for approval; the supervisory plan must be designed to ensure the scientific integrity of her research contribution; Respondent agrees that she will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI;
- (2) that any institution employing her submits, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-funded research in which she was involved, a certification to ORI that the data provided are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application or report; and
- (3) to exclude herself voluntarily from service 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.

Vipul Bhrigu, Ph.D.
University of Michigan Medical School

Based on the findings of an investigation by the University of Michigan Medical School (UMMS) and additional analysis conducted by ORI during its oversight review, ORI found that Vipul Bhrigu, Ph.D., former postdoctoral fellow, Department of Internal Medicine, UMMS, engaged in research misconduct in research funded by National Cancer Institute (NCI), NIH, grant R01 CA098730-05.

Specifically, ORI found that the Respondent knowingly and intentionally tampered with research materials related to five (5) immunoprecipitation/Western blot experiments and switched the labels on four (4) cell culture dishes for cells used in the same type of experiments to cause false results to be reported in the research record. ORI also found that the Respondent tampered with laboratory research materials by adding ethanol to his colleague's cell culture media, with the deliberate intent to effectuate the death of growing cells, which caused false results to be reported in the research record. ORI has concluded that these acts seriously deviated from those that are commonly accepted within the scientific community for proposing, conducting, and/or reporting research.

ORI found that the Respondent's intentional tampering of his colleague's laboratory research constitutes research misconduct as defined by 42 CFR Part 93. ORI determined that the Respondent engaged in a pattern of dishonest conduct through the commission of multiple acts of data falsification. ORI also determined that the subterfuge in which he freely engaged for several months constitutes an aggravating factor. The Respondent attempted to mislead the University of Michigan (UM) police by initially denying involvement in the tampering and refusing to accept responsibility for this misconduct. The Respondent eventually made an admission only after the UM police informed him that his actions in the laboratory had been videotaped. This dishonest conduct established the Respondent's lack of present responsibility to be a steward of Federal funds (2 CFR § 376 *et seq.*; 42 CFR § 93.408).

The following administrative actions have been implemented for a period of three (3) years, beginning on April 7, 2011:

- (1) Dr. Bhrigu 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," pursuant to HHS' Implementation of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (2 CFR § 376 *et seq.*); and
- (2) Dr. Bhrigu is prohibited from serving in any advisory capacity to the PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

Junghee J. Shin, Ph.D.
New York Medical College

Based on the report of an investigation conducted by New York Medical College (NYMC) and additional analysis by the ORI in its oversight review, the PHS found that Junghee J. Shin, Ph.D., former graduate student, NYMC, engaged in research misconduct in research supported by National Institute of Allergy and Infectious Diseases (NIAID), NIH, grants R01 AI048856 and R01 AI043063.

PHS found that the Respondent engaged in research misconduct by falsifying data in Figure 4 of a manuscript submitted to the journal *Infection and Immunity* (Shin, J.J., Godfrey, H.P., & Cabello, F.C. "Expression and localization of BmpC in *Borrelia burgdorferi* after growth under various environmental conditions." Submitted to *Infection and Immunity*; hereafter referred to as the "manuscript") and Figure 5 of a paper published in *Infection and Immunity* (Shin, J.J. Bryksin, A.V., Godfrey, H.P., & Cabello, F.C. "Localization of BmpA on the exposed outer membrane of *Borrelia burgdorferi* by monospecific anti-recombinant BmpA rabbit antibodies." *Infection and Immunity* 72(4):2280-2287, April 2004; hereafter referred to as the "paper." Retracted in: *Infection and Immunity* 76(10):4792, October 2008). Specifically, NYMC and ORI found that:

Dr. Shin falsified microscopic immunofluorescence blank images in Figure 4 of the manuscript (top row, 1st, 2nd, 4th, and 5th panels, and bottom row, 1st panel) and Figure 5 of the paper (top row, 1st and 5th panels, lower 1st panel) by using one blank image from an unknown experiment to falsely represent the preimmunization control conditions (intact cells and methanol fixation) as well as the negative staining of anti-BmpC and anti-FlaBin Figure 4 and anti-FlaB in Figure 5 on intact cells.

Dr. Shin falsified at least one of two images in Figure 4 of the manuscript and Figure 5 of the paper by using different portions of a green-red pair of microscopic immunofluorescence images (1230036.tif and 1230037.tif) because unfixed cells staining positive for BmpA in the top row, 4th panel, of Figure 5 were the same unfixed cells purportedly positive for OspA in the top row, 3rd panel, of Figure 4.

Dr. Shin falsified at least one of two images in Figure 4 of the manuscript and Figure 5 of the paper by using different photo cropping from a single microscopic immunofluorescence image (1230039.tif) to represent fixed cells positive for BmpA and labeled with anti-FlaB in the lower row, 5th panel, of Figure 5 and to also represent fixed cells positive for BmpC and stained with anti-FlaB in the lower row, 5th panel, of Figure 4.

Dr. Shin has entered into a Voluntary Settlement Agreement in which she has voluntarily agreed, for a period of three (3) years, beginning on April 5, 2011:

- (1) that any institution that submits an application for PHS support for a research project on which the Respondent's participation is proposed or that uses her in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which she is involved, must concurrently submit a plan for supervision of her duties to ORI for approval; the supervisory plan must be designed to ensure the scientific integrity of her

research contribution; Respondent agrees that she will not participate in any PHS-supported research until such a supervision plan is submitted to ORI; and

- (2) to exclude herself voluntarily from service 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.

Philippe Bois, Ph.D.
St. Jude Children's Research Hospital

Based on the findings of an investigation report by St. Jude Children's Research Hospital (St. Jude) and additional analysis conducted by ORI during its oversight review, ORI found that Philippe Bois, Ph.D., former postdoctoral fellow, Department of Biochemistry, St. Jude, engaged in misconduct in science and research misconduct in research funded by National Institute of General Medical Sciences (NIGMS), NIH, grant R01 GM071596, and National Cancer Institute (NCI), NIH, grants P30 CA021765, P01 CA071907, R01 CA072996, and R01 CA100603.

ORI found that the Respondent knowingly and intentionally falsified data reported in two (2) papers:

1. Bois, P.R., Izeradjene, K., Houghton, P.J., Cleveland, J.L., Houghton, J.A., & Grosveld, C.G. "FOXO1a acts as a selective tumor suppressor in alveolar rhabdomyosarcoma." *J. Cell. Biol.* 170:903-912, September 2005 (hereafter referred to as "*JCB* 2005"); and
2. Bois, P.R., Borgon, R.A., Vornheim, C., & Izard, T. "Structural dynamics of α -actinin-vinculin interactions." *Mol. Cell. Biol.* 25:6112-6122, July 2005 (hereafter referred to as "*MCB* 2005").

Specifically, ORI found:

- Respondent committed misconduct in science and research misconduct by knowingly and intentionally falsely reporting in Figure 1A of *JCB* 2005 that FOXO1a was not expressed in cell lysates from alveolar rhabdomyosarcoma (ARMS) tumor biopsies, by selecting a specific FOXO1a immunoblot to show the desired result.
- Respondent engaged in misconduct in science and research misconduct by falsifying data presented in Figure 4B of *MCB* 2005 showing SDS-PAGE for papain digestion of VBS3 and α VBS, by falsely labeling lane 1 to represent papain only digestion, by falsely labeling lane 5 to represent papain digestion of the α VBS peptide, and by falsely inserting a band in lane 3 to represent the α VBS peptide.

ORI issued a charge letter enumerating the above findings of misconduct in science and proposing HHS administrative actions. Dr. Bois subsequently requested a hearing before an Administrative Law Judge (ALJ) of the Departmental Appeals Board (DAB) to dispute these findings. ORI moved to dismiss Dr. Bois' hearing request. On May 16, 2011, the ALJ of the

DAB ruled in ORI's favor and dismissed Dr. Bois' hearing request. The ALJ found that Dr. Bois had not raised a genuine dispute over facts or law material to the findings of research misconduct and dismissed the hearing request pursuant to 42 CFR § 93.504(a)(2),(3).

Thus, the misconduct in science and research misconduct findings set forth above became effective, and the following administrative actions have been implemented for a period of three (3) years, beginning on May 26, 2011:

- (1) Dr. Bois 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," pursuant to HHS' Implementation of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (2 CFR § 376 *et seq.*); and
- (2) Dr. Bois 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.

Sheng Wang, Ph.D.

Boston University School of Medicine Cancer Research Center

Based on the Respondent's acceptance of ORI's research misconduct findings, ORI found that Dr. Sheng Wang, who has been an Assistant Professor, Department of Medicine, Boston University School of Medicine Cancer Research Center (BUSM), engaged in research misconduct in research supported by National Cancer Institute (NCI), NIH, grants R01 CA102940 and R01 CA101992.

ORI found that the Respondent engaged in research misconduct by fabricating data that were included in two (2) published papers:

1. Zhang, B., Faller, D.V., Wang, S. "HIC1 regulates tumor cell responses to endocrine therapies." *Mol. Endocrinol.* 23(12):2075-85, 2009; and
2. Zhang, B., Chambers, K.J., Leprince, D., Faller, D.V., Wang, S. "Requirement for chromatin-remodeling complex in novel tumor suppressor HIC1-mediated transcriptional repression and growth control." *Oncogene* 28(5):651-61, 2009.

Specifically, ORI found that Respondent:

- fabricated RT-PCR and ChIP experiments represented in Figures 1b, 2b, 3a,b, 4b,c, 6a,b, 7c in *Mol. Endocrinol.* 23(12):2075-85, 2009; RT-PCR and/or ChIP experiments were included in six (6) of seven (7) figures in this publication; and
- fabricated RT-PCR and ChIP experiments represented in Figures 2a,b, 3a,b, 4a,c, 5a,b, 6b,c, 8a,b in *Oncogene* 28(5):651-61, 2009; RT-PCR and/or ChIP experiments were included in six (6) of eight (8) figures in this publication.

Respondent has entered into a Voluntary Exclusion Agreement (Agreement). Respondent and PHS want to conclude this matter without further expenditure of time or other resources. Respondent accepts ORI's findings of research misconduct as set forth above but neither admits nor denies committing research misconduct. The Agreement does not constitute an admission of liability on Respondent's part. Respondent agrees not to appeal the jurisdiction of ORI or request a HHS administrative hearing to review the findings as set forth in the Agreement.

As a condition of the Agreement, Respondent agrees that the *Mol. Endocrinol.* 23(12):2075-85, 2009, and *Oncogene* 28(5):651-61, 2009, publications be retracted.

In entering into the Agreement, Dr. Wang has voluntarily agreed for a period of two (2) years, beginning on July 18, 2011:

- (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 CFR Part 376 *et seq.*) of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension, 2 CFR Part 180 (collectively the "Debarment Regulations"); and
- (2) to exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

Scott Weber, Ed.D., MSN
University of Pittsburgh

Based on the letters from the Research Integrity Officer at the University of Pittsburgh (UP), ORI's oversight review, and an admission by the Respondent, ORI found that Dr. Scott Weber, former Assistant Professor, Health and Community Systems, School of Nursing, UP, engaged in research misconduct by (1) plagiarizing text and falsifying data from two publications supported by PHS funding (P30 MH60570; HS5 SM52671; PHS employee generated article) in two unpublished manuscripts, and (2) including significant portions of that plagiarized text in two grant applications to NIH (1 L30 NR010444-01; 1 R03 HD062761-01).

ORI found that the Respondent engaged in research misconduct by plagiarizing text, falsifying data and references, and fabricating data from two publications (Mufson, L., Dorta, K.P., Wickramaratne, P., Nomura, Y., Olfson, M., Weissman, M.M. "A randomized effectiveness trial of interpersonal psychotherapy for depressed adolescents." *Arch Gen Psychiatry* 61(6):577-84, 2004 June; hereafter referred to as "Mufson *et al.* 2004;" and Cho, M.J., Mościcki, E.K., Narrow, W.E., Rae, D.S., Locke, B.Z., Regier, D.A. "Concordance between two measures of depression in the Hispanic Health and Nutrition Examination Survey." *Soc Psychiatry Psychiatr Epidemiol.* 28(4):156-63, 1993 August; hereafter referred to as "Cho *et al.*, 1993") supported by PHS in two journal article submissions. Specifically, ORI found that the Respondent plagiarized more than 90 percent of the text from Mufson *et al.* 2004 in a manuscript entitled "A randomized effectiveness trial of psychiatric-mental health nurse practitioner-administered interpersonal psychotherapy for sexual minority adolescents with depression in primary care clinics" and submitted to the *Journal of the American Academy of Nurse Practitioners (JAANP MS)*.

Furthermore, the Respondent plagiarized approximately 66 percent of the text from Cho *et al.* 1993 in a manuscript entitled “Assessing the diagnostic predictive power of a screening tool for depression: Concordance between the CES-D and DIS in the Parent Identity Survey” and submitted to the *Journal of GLBT Family Studies (JGMS MS)*.

In both manuscripts, the Respondent falsified and fabricated tables and figures by using all or nearly all of the data in tables and graphs from the plagiarized articles while altering numbers and changing text to represent data as if from another subject population; he also copied most of the original bibliographic references but falsified 35 percent of the copied references from *JAANP MS* and 25 percent of the copied references from *JGMS MS*, by changing volume numbers and/or publication years, apparently to hinder detection of the plagiarism. The data fabrication occurred when the Respondent altered or added values to Table 2 in each manuscript describing the demographic characteristics of the study population that was never studied.

ORI also finds that the Respondent engaged in research misconduct by plagiarizing text from Cho *et al.* 1993 in two NIH grant applications (1 L30 NR010444-01 and 1 R03 HD062761-01) by copying substantial word-for-word portions of the text describing the test instrument to be used in the proposed study without citing the Cho *et al.* 1993 paper.

Dr. Weber has voluntarily agreed for a period of three (3) years, beginning on September 7, 2011:

- (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 CFR Part 376 *et seq.*) of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension, 2 CFR Part 180 (collectively the “Debarment Regulations”); and
- (2) to exclude himself from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

Shamarendra Sanyal, Ph.D.
Duke University

Based on an inquiry conducted by Duke University (Duke), admissions by the Respondent, and additional analysis conducted by ORI in its oversight review, ORI and Duke found that Dr. Shamarendra Sanyal, former postdoctoral scholar, Duke, engaged in research misconduct by falsifying data in a grant application submitted to the National Heart, Lung, and Blood Institute (NHLBI) of NIH.

Specifically, ORI found that the Respondent falsified Figure 2C of grant application 1 R01 HL107901-01, “Store-operated calcium entry in airway inflammation,” by altering the gain settings in the instrument used to measure store-operated current (SOC) densities in a whole cell patch clamp experiment comparing Stim 1^{+/-} mouse airway cells and wild type mouse airway cells. Respondent also falsified the calcium response data in Figure 5A (right panel) of the grant application referenced above by adding ATP as a reagent to the mouse airway epithelial cells to

sharpen the results purported to be caused by PGN without disclosing that ATP had been added and without disclosing that ATP was not added to the control sample.

The questioned research was not submitted for publication.

Dr. Sanyal has entered into a Voluntary Settlement Agreement with ORI and Duke, in which he voluntarily agreed to the administrative actions set forth below. The administrative actions are required for two (2) years beginning on the date of Dr. Sanyal's employment in a research position in which he receives or applies for PHS support on or after the effective date of the Agreement (September 16, 2011); however, if he has not obtained employment in a research position in which he receives or applies for PHS support within three (3) years of the effective date of the Agreement, the administrative actions set forth below will no longer apply.

Dr. Sanyal has voluntarily agreed:

- (1) to have his research supervised as described below and to notify his employer(s)/institutions(s) of the terms of this supervision; Respondent agrees to ensure that prior to the submission of an application for PHS support for a research project on which Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS supported research, the institution employing him will 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 will not participate in any PHS supported research from the effective date of this Agreement until a plan for supervision is submitted to and approved by ORI; Respondent agrees to be responsible for maintaining compliance with the agreed upon plan for supervision;
- (2) that any institution employing him must submit, in conjunction with each application for PHS funds, or report, manuscript, or contract 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 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.

Nicola Solomon, Ph.D.
University of Michigan Medical School

Based on an investigation conducted by the University of Michigan Medical School (UMMS) and a preliminary analysis conducted by ORI, ORI found that Dr. Nicola Solomon, former postdoctoral scholar, Department of Human Genetics, UMMS, engaged in research misconduct in research supported by National Institute of Child Health and Human Development (NICHD), NIH, grants R37 HD030428 and R01 HD034283.

Specifically, the Respondent did not perform DNA sequencing on 202 cDNA clones of homeobox genes to confirm their identity and integrity. Through multiple revision of the manuscript, the Respondent did not discuss this with the corresponding author or question and correct the corresponding author's addition of text indicating that the clones had been fully sequenced and were full length or longer (as indicated in Table 3) when compared to NCBI Mus musculus Unigene. This text supported the use of the Cap-Trapper technique to produce full length clones for the discovery of new genes without polymerase chain reaction (PCR).

Both the Respondent and PHS are desirous of concluding this matter without further expenditure of time and other resources and have entered into a Voluntary Settlement Agreement to resolve this matter. This settlement is not an admission of liability on the part of the Respondent.

Respondent and ORI agreed to settle this matter as follows:

- (1) Respondent agreed that for a period of two (2) years beginning on September 16, 2011, prior to the submission of an application for PHS support for a research project on which her participation is proposed in a research capacity, and prior to her participation in this capacity on PHS-supported research, Respondent shall ensure that a plan for supervising her duties is submitted to ORI for approval; the supervision must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agreed that she shall not participate as a researcher 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) Respondent agreed 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, for a period of two (2) years, beginning on September 16, 2011.

Marija Manojlovic
University of Pittsburgh

Based on an inquiry conducted and written admission obtained by the University of Pittsburgh (UP) and additional analysis conducted by ORI in its oversight review, ORI found that Ms. Marija Manojlovic, former graduate student, Department of Chemistry, UP, engaged in research misconduct in research supported by National Institute of General Medical Sciences (NIGMS), NIH, grant P50 GM067082, National Cancer Institute (NCI), NIH, grant P01 CA078039, National Institute of Mental Health (NIMH), NIH, grant U54 MH074411, and National Institute of Allergy and Infectious Diseases (NIAID), NIH, grant R01 AI033506.

ORI found that the Respondent engaged in research misconduct by falsifying and fabricating the synthesis and spectral data that were included in one (1) poster presentation and in one (1) pre-submission draft of a paper to be submitted for publication.

Specifically, ORI found that the Respondent knowingly falsified and fabricated the synthesis and characterization, largely in the form of manipulated ¹H- and ¹³C-NMR spectral data, for five intermediate steps and the final product, 9-desmethylpleurotin, and presented these false results in a poster, "Efforts Towards the Total Synthesis of Pleurotin," presented at the 2011 National

Organic Symposium, and in a manuscript, “Total Synthesis of 9-desmethylpleurotin,” prepared for submission to *Angewandte Chemie International Edition*.

Ms. Manojlovic has voluntarily agreed for a period of three (3) years, beginning on September 26, 2011:

- (1) to have her PHS-supported research supervised; Respondent agreed that prior to the submission of an application for PHS support for a research project on which her participation is proposed and prior to her participation in any capacity on PHS-supported research, she shall ensure that a plan for supervision of her duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of her research contribution; Respondent agreed that she 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 her shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which she 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 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.

Jayant Jagannathan, M.D.
University of Virginia Medical Center

Based on the report of an investigation conducted by the University of Virginia (UVA) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Jayant Jagannathan, former Resident Physician at UVA Medical Center, engaged in research misconduct by plagiarizing research supported by NIH research and training awards and by NIH intramural research funds from the National Institute of Neurological Disorders and Stroke (NINDS), Surgical Neurosurgery Branch (NSB), and from the National Institute of Dental and Craniofacial Research (NIDCR).

ORI found that the Respondent engaged in research misconduct by including, in five publications, large amounts of text and an illustration that he plagiarized from publications supported by the following NIH grant awards: T32 CA09677, P01 HL024136, R01 HL059157,

P50 CA090270, M01 RR01346, R01 CA075979, R01 DK064169, R01 NS027544, R01 NS052406, and K08 NS002197,¹ and by intramural funds from the Surgical Neurosurgery Branch, NINDS, and from NIDCR.

Publications in which Respondent reported plagiarized material were:

1. Jagannathan, J., Li, J., Szerlip, N., Vortmeyer, A.O., Lonser, R.R., Oldfield, E.H., Zhuang, Z. "Application and implementation of selective tissue microdissection and proteomic profiling in neurological disease." *Neurosurgery* 64:4-14, 2009 (to be retracted);
2. Jagannathan, J., Prevedello, D.M., Dumont, A.S., Laws, E.R. "Cellular Signaling Molecules as Therapeutic Targets in the Treatment of Glioblastoma Multiforme." *Neurosurgical Focus* 20(4):E8, 2006 (retracted "due to plagiarism," *Neurosurgical Focus* 30(2):E8r, 2011);
3. Kanter, A.S., Jagannathan, J., Shaffrey, C.I., Ouellet, J.A., Mummaneni, P.V. "Inflammatory and dysplastic lesions involving the spine." *Neurosurgical Clinics of North America* 19(1):93-109, 2008;
4. Jagannathan, J., Dumont, A.S., Prevedello, D.M., Oskouian, R.J., Lopes, B., Jane, J.A. Jr, Laws, E.R. Jr. "Genetics of pituitary adenomas: Current theories and future implications." *Neurosurgical Focus* 19(5):E4, 2005 (retracted "due to plagiarism," *Neurosurgical Focus* 30(2):E4r, 2011);
5. Jagannathan, J. "Role of calcium influx and modulation of local neurotransmitters as hallmarks of pediatric traumatic brain injury." *Biomarkers Med.* 3:95-97, 2009 (retracted online 9/11/2010).

Dr. Jagannathan has entered into a Voluntary Settlement Agreement (Agreement) and has voluntarily agreed for a period of four (4) years, beginning on October 20, 2011:

- (1) to have his research supervised; Respondent agreed to ensure 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, the institution employing him must submit a plan for supervision of his duties to ORI for approval; the plan for supervision must be designed to ensure the scientific integrity of his research contribution; Respondent agreed that he will not participate in any PHS-supported research after sixty (60) days from the effective date of the Agreement until a

¹T32 CA09677, Radiation Biology Training Grant," A. Kennedy, P.I.
P01 HL024136, "Mechanisms of Remodeling in Chronic Airway Inflammation," G. Caughey, P.I.
HL059157, "Angioproteins in Airway Vascular Leak and Angiogenesis," D. McDonald, P.I.
P50 CA090270, "UTMDACC Cancer Center SPORE in prostate cancer," C. Logothetis, P.I.
M01 RR01346, "UTHSC GCRC," R. Clark, P.I.
R01 CA075979, "Mechanisms for Pituitary Tumorigenesis," S. Melmed, P.I.
R01 DK064169, "Metabolic Consequences of Sccurin Disruption," S. Melmed, P.I.
R01 NS027544, "Loss of Developmental Plasticity after Head Injury," D.A. Hovda, P.I.
R01 NS052406, "Age-dependent Ketone Metabolism after Brain Injury," M.L. Prims, P.I.
K08 NS002197, "NMDA Receptor Dysfunction after Traumatic Brain Injury," C.C. Christopher, P.I.

plan for supervision 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 must 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;
- (3) to submit a letter to the journal editor for publication 3 (*Neurosurgical Clinics of North America*) listed above, requesting that the paper be retracted because Respondent had plagiarized portions of text reported in it; the letter must be sent to ORI for approval prior to being sent to the editor; 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.

Gerald Lushington, Ph.D.
Kansas University

Based on an inquiry conducted and written admission obtained by Kansas University (KU) and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Gerald Lushington, Director of the K-INBRE¹ Bioinformatics Core Facility, KU, and Director of the Molecular Graphics and Modeling Lab, KU, engaged in research misconduct in research supported by National Center for Research Resources (NCRR), NIH, grant P20 RR016475.

Specifically, ORI found that Respondent engaged in research misconduct by approving publication of three articles and one abstract he knew contained significant amounts of plagiarized text without attribution or citation from other writers' published papers. The specific published documents as well as the relevant source documents are:

- Visvanathan, M., Adagarla, B., Lushington, G., Sittampalam, S., Proceedings of the 2009 International Joint Conference on Bioinformatics, Systems, Biology and Intelligent Computing, 2009, 494-497. Greater than half (50%) of the total text was obtained from (1) Yang, C.-S., Chuang, L.-Y., Ke, C.-H., Yang, C.-H., *International Journal of Computer Science, International Association of Engineers*, August 2008 35(3), (2) Goffard, N. and Weiller, G., *Nucleic Acids Research*, 2007, 35L:W176-W181, and (3) Chuang, L.-Y., Yang, C.-H., Tu, C.-J., Yang, C.-H., Proceedings of the Joint Conference on Information Sciences, Atlantis Press, October 2006.

Retracted: Retracted administratively by IEEE on Jan 5, 2011
http://ieeexplore.ieee.org/xpl/freeabs_all.jsp?arnumber=5260432

¹ K-INBRE: The Kansas IDeA Network of Biomedical Research Excellence, which is a consortium of a number of schools and centers in Kansas.

- Vijayan, A.; Skariah, B. E., Nair, B.; Lushington, G., Subramanian, S., Visvanathan, M., Proceedings of the IEEE International Conference on Bioinformatics and Biomedicine Workshop, 2009, BIBMW2009, 267-271. Approximately 15% of the text was plagiarized from Goffard, N. and Weiller, G., *Nucleic Acids Research*, 2007, 35L:W176-W181.

Retracted: Retracted administratively by IEEE on Jan 5, 2011

<http://www.computer.org/portal/web/csdl/doi/10.1109/BIBMW.2009.5332106>

- Visvanathan, M., Netzer, M., Seger, M., Adagarla, B. S., Baumgartner, C., Sittampalam, S., Lushington, G., *International Journal of Computational Biology and Drug Design*, 2009, 2,236-251. A complete paragraph of the text was plagiarized from Goffard, N. and Weiller, G., *Nucleic Acids Research*, 2007, 35L:W176-W181.
- Adagarla, B., Lushington, G., Visvanathan, M., ISMB International Conference, January 2009; the entire abstract for this poster was obtained by plagiarizing text from Pihur, V., Datta, S., Datta S., *Genomics*, 2003, 92:400-403.

Dr. Lushington has entered into a Voluntary Settlement Agreement (Agreement) and has voluntarily agreed for a period of two (2) years, beginning on December 6, 2011:

- (1) to have any PHS-supported research supervised; ORI acknowledges that Respondent's research is currently being supervised by KU; Respondent shall ensure that a plan for supervision of his PHS-related duties is submitted to ORI for approval either within two weeks of this Agreement becoming final or prior to receiving or applying for PHS funds if such support is not current at the time this Agreement is completed; the supervision plan must be designed to ensure the scientific integrity of his research contribution; because of the ongoing review of Respondent's research by KU, ORI will only require a summary report on the first and second anniversary of the Agreement detailing how KU has ensured that Respondent's research and language in PHS grant applications and reports of PHS-supported research have been verified to be his own and accurately reported; Respondent agrees to maintain responsibility for compliance with the agreed upon supervision plan;
- (2) that this annual summary, 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.