The Office of Research Integrity
Annual Report 2009

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

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I. Responding to Research Misconduct Allegations

Introduction

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

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

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

DIO staff also organizes conferences and workshops on the handling of research misconduct allegations, particularly to provide training for Research Integrity Officers (RIOs). The training focuses on larger institutions, which are most likely to have cases of research misconduct that require reporting to ORI. DIO also provides assistance and advice to institutions on the conduct of inquiries and investigations through the Rapid Response for Technical Assistance Program (RRTA). In addition, DIO provides information on PHS policies and procedures, as requested, to individuals who have made an allegation or have been accused of research misconduct.

Allegations

ORI staff assesses each allegation it receives to determine whether it meets the criteria for opening a formal case. These criteria are:

1. The research in which the alleged research misconduct took place must be supported by, or involve an application for, PHS funds.

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

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

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

Alternatively, for allegations of research misconduct occurring subsequent to the effective date of PHS Policies on Research Misconduct on June 16, 2005, 42 CFR Part 93, the following definition applies:

> Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
>
> (a) Fabrication is making up data or results and recording or reporting them.
>
> (b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
>
> (c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
>
> (d) Research misconduct does not include honest error or differences of opinion.

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

Below is ORI's working definition of plagiarism. Institutions may exercise a more stringent definition of plagiarism and take appropriate institutional administrative actions.

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

ORI Policy on Plagiarism

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

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

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

Substantial unattributed textual copying of another's work means the unattributed verbatim or nearly verbatim copying of sentences and paragraphs which materially mislead the ordinary reader regarding the contributions of the author. ORI generally does not pursue the limited use of identical or nearly-identical phrases which describe a commonly-used methodology or previous research because ORI does not consider such use as substantially misleading to the reader, or of great significance.

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

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

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

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

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

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

In 2009, ORI received 179 allegations. The dispositions of the allegations received by ORI are presented in Table 1 below. Allegations become active cases when the criteria outlined above are met. Allegations are administratively closed when ORI finds that (1) they do not fall under ORI jurisdiction or meet these criteria, (2) cannot be referred to another agency, or (3) are resolved through further review and information. Some allegations are referred to other Federal agencies or offices when they involve concerns about the involvement of human subjects or animals in research, financial issues, research funded or regulated by other agencies, etc. No action is possible for ORI if an allegation lacks sufficient specific information to permit a determination regarding disposition.

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

funding by other Federal agencies, such as the Department of Veterans Affairs, the Department of Defense, the Department of Agriculture, or the National Science Foundation, ORI will ensure that the relevant allegations are shared with or referred to the other funding agency.

Allegations received from the extramural programs of the National Institutes of Health (NIH) are sent to DIO for confirmatory assessment. If DIO's assessment indicates that the matter should be referred to the institution where the questioned research took place, DIO will refer the matter for either an assessment or inquiry depending on the apparent scope of the alleged research misconduct. NIH officials are copied on these notifications. When DIO's assessment determines that ORI has no jurisdiction in the matter, NIH is informed so that alternative administrative actions can be considered. These assessments are handled by 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 to ensure that the institutional reporting requirements are met, or if extensions of time are required, appropriate interim reports are received with requests for the extension.

Table 1: Disposition of Allegations in ORI, 2009

Handling of Allegations - Outcome in ORI	Number of allegations	
No Action Possible Now or No Action	93	
Handled by Agency	23	
Handled by Agency to ORI	0	
Referred to Other Federal Agencies	1	
Pre-inquiry Assessment of Allegations Made Directly to ORI	49	
Pre-inquiry Assessment of Allegations Made Initially to NIH	13	
Pre-inquiry Assessment of All Allegations	62	
Total Allegations	**179**	
Handling of Pre-inquiry Assessments Made Directly to ORI		
Administratively Closed After Review		10
Remaining Pre-inquiry Assessments		30
Moved to Active Status		9
Total		**49**

Of the 179 allegations made to ORI (or to NIH and reported to ORI) in 2009, 49 were assessed by ORI in detail for a potential inquiry or investigation; 9 of the assessments were opened as cases in 2009. Of the remaining pre-inquiry assessments, 10 were administratively closed after being reviewed and 30 remained open at the end of the year.

Assessments of the allegations that resulted in new ORI cases took an average of 125 days; those that resulted in administrative closures took an average of 153 days. These data do not reflect the additional time taken by officials at NIH who handled (with advice, assessment, and assistance from ORI as appropriate) 13 allegations that were made directly to NIH by a complainant (see Table 1). The 179 allegations that ORI received in 2009 was slightly less than the 201 allegations handled in 2008. However, the number of allegations that were classified as

pre-inquiry assessments in 2009 by ORI (49) decreased by 5 percent compared to the number classified as pre-inquiry assessments in 2008 (52).

Table 2 summarizes the distribution of time in days needed to resolve pre-inquiry assessments during 2009, including 35 carried forward from 2008. Of the 17 cases opened by DIO in 2008, 12 arose from pre-inquiry assessments from earlier years. Interestingly, a majority of the 30 pre-inquiry assessments carried into 2009 (see Table 1) represented ongoing investigations at the institutional level. 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 the past. In large part, this is due to some uncertainty about the merits of many of the inquiries because of the paucity of information available to DIO prior to receiving a final investigation report and supporting documentation. Once a more complete preliminary review of the investigative record becomes possible, DIO can determine if the matter warrants opening as a case for oversight review or, alternatively, administratively closing the accession at that stage.

Table 2: Time for Conduct of Pre-inquiry Assessments by ORI, 2009

Outcome of ORI Assessment	Number of Allegations	Distribution of Resolution Times (Days)		
	179	Mean	Median	Range
Opened a Formal Case	9	116	85	1-263
Administratively Closed	10	158	185	1-259
Unresolved at End of Year 2009	30	158	163	1-342
Total	**49**			

Processing of Cases Closed

ORI closed 43 cases in 2009, 42 were investigations conducted by institutions reported to ORI and one was an inquiry reported to ORI. The average duration of 23.6 months for conducting, reviewing, and closing these cases involved 16.3 months by the institution and 7.3 months for ORI oversight and administrative action (See Table 3). Within 8 months of receipt of the final action of the institution, 28 cases were closed.

Table 3: Duration of Research Misconduct Cases Closed by ORI, 2009

Distribution of Resolution Times (Months)			
Location of Activity	**Mean**	**Median**	**Range**
Institution	16.3	13	1-39
ORI	7.3	3	1-28

The action period for the 42 institutional investigations and one inquiry included the institutions' inquiry, investigation, and adjudication phases, while ORI's oversight included a detailed review of each institution's inquiry and/or investigation. ORI often makes requests to the institution for more information and analysis or for explanation by the officials for the basis of their decision as to whether research misconduct occurred. Additional ORI analysis is often required to make an ORI finding of research misconduct. In most instances involving a finding of misconduct, ORI is able to close its cases by reaching a voluntary settlement agreement with the respondent. Occasionally such an agreement cannot be reached. In such instances, a charge letter is issued, giving the respondent 30 days to request a hearing before an Administrative Law Judge in the DAB. At such a hearing, a final determination is made. One hearing request was initiated in 2008 and is still currently ongoing. One case, which took 28 months for ORI to resolve, was linked to another ORI case where extensive negotiations were required to reach a voluntary agreement. These negotiations required the extensive involvement of OGC.

Caseload and Outcomes

The ORI caseload is divided into institutional inquiries and institutional investigations. ORI carried forward 39 cases from 2008, opened 31 new cases, and closed 43 cases during 2009 (see Table 4). At the end of calendar year 2009, ORI had 27 active formal cases divided between inquiries and investigations. Two institutional inquiries and 25 institutional investigations remained open at the end of 2009.

Table 4: ORI Research Misconduct Caseload by Case Type, 2009

Case type	Forwarded from 2008	Opened in 2009	Closed in 2009
Institutional Inquiry	6*	1	1
Institutional Investigation	33	30	42
Total	39	31	43

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

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

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

There were two institutional inquiries carried into 2010.

Institutional Investigations: Institutions are required by the PHS regulation to report to ORI at the initiation of an investigation and submit a report to ORI upon completion of the investigation. ORI reviews the reports to determine whether the conduct of the investigation complied with the PHS regulations, was thorough, competent, and objective, and provided a basis for a PHS finding of research misconduct. ORI began 2009 with 33 cases carried forward from 2008. During the year, 30 new institutional investigations were opened; 42 investigation cases were closed (see Table 4). Of these 42 closed investigations, 11 involved ORI findings of research misconduct; 31 did not have such findings. Of the total 43 cases closed in 2009, approximately 25 percent (11 cases) involved findings of research misconduct (see Table 5). However, the actual number of findings of research misconduct this year (11) is consistent with the average of 12 findings each year during 1993-2009. Summaries of these cases are located in Appendix A. Summaries of the 31 investigations closed by ORI that did not result in findings of research misconduct are located in Appendix B. There were 25 investigations carried into 2010.

Table 5: Outcome of Research Misconduct Cases Closed by ORI, 2009

Outcome of Cases					
Case type	**No Investigation**	**No Research Misconduct**	**Misconduct Finding**	**Administrative Closure**	**Total**
Inquiry	1	-	-	-	1
Investigation	-	31	11	-	42
Total	1	31	11	0	43

Administrative Closures

A formal ORI case file may be administratively closed when ORI concludes that no PHS funds or applications were actually involved, that continuing effort will not produce sufficient evidence to resolve a case satisfactorily, or that after additional review, ORI determines that the allegation did not fall under the PHS definition of research misconduct or warrant further action. There were no formal cases administratively closed in 2009.

Types of Allegations and Administrative Actions

Types of Allegations Involved in Cases Closed: During 2009, all the formal ORI cases closed (with or without a finding of misconduct) involved allegations of falsification, fabrication, or both (See Table 6).

Table 6: Types of Allegations Involved in Closed Investigations and Their Outcomes, 2009

Allegation	Investigation	ORI findings or PHS Administrative Actions
Falsification 19		5
Fabrication/Falsification 9		6
Plagiarism 2		
Fabrication/Falsification/ Plagiarism	2	
Total	32	11

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

For the 11 cases in 2009 in which PHS research misconduct findings or HHS administrative actions were imposed, 1 person was debarred or voluntarily excluded for 10 years, 2 people were debarred or voluntarily excluded for 3 years, and 2 individuals were debarred or voluntarily excluded for 2 years. Other administrative actions imposed on respondents in these 11 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 (11 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 (6 persons)

(c) certification by the institution that the respondent's performance meets generally accepted standards (3 persons)

Table 7: HHS Administrative Actions Imposed in Closed Investigations with Research Misconduct Findings or Administrative Actions, 2009

HHS Administrative Action	Duration (years)	Number of Actions
Debarment or Voluntary Exclusion	10	1
Debarment or Voluntary Exclusion	3	2
Debarment or Voluntary Exclusion	2	2
Prohibition from Serving as an Advisor for PHS	10	1
Prohibition from Serving as an Advisor for PHS	3	7
Prohibition from Serving as an Advisor for PHS	2	3
Supervision Plan Required	3	5
Supervision Plan Required	2	1
Certification of Work	3	2
Certification of Work	2	1

Rapid Response for Technical Assistance Program

ORI provided Rapid Response for Technical Assistance on 71 occasions in 2009, nearly double the 37 instances in 2008. 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.

Table 8: Summary of PHS ALERT System Activity, 2009

PHS ALERT System Activity, 2009	
As of January 1, 2009	49
Additions	14
Action Expired/Removed	11
As of December 31, 2009	**52**

The PHS ALERT System is used by ORI and PHS agencies to track individuals who have been sentenced or found guilty of research misconduct by their institution.

Information on each individual in the system is limited to name, social security number, date of birth, type of research misconduct, the name of the institution that conducted the investigation, a summary of the administrative actions imposed as a result of the misconduct, and the effective expiration dates of the administrative actions. Table 8 summarizes the activity of entering and removing names from the ALERT System.

Research Integrity Officer Boot Camp Training

An extensive training program for Research Integrity Officers (RIOs) completed its third year according to David Wright, PhD, the ORI consultant who first recognized the need to deal with the rapid turnover and inexperience of RIOs at many universities. Institutional RIOs and counsels from major research universities attended the fifth, sixth, and seventh Boot Camp for RIOs at Tulane University of New Orleans, Northwestern University in Chicago, and the University of Oregon in Eugene, Oregon, in 2009. A total of 91 RIOs and 33 counsels have attended the Boot Camps since their inception in early 2007.

The curriculum of the three-day ORI boot camp has been developing and evolving over the last two years as a result of the extensive evaluations and debriefings conducted at the end of each boot camp. Designed to emphasize the interaction between experienced and newer RIOs with a minimum of input and direction from ORI staff, the goal is to bring together 25-30 RIOs and their counsels to learn from each other, establish a network, and help identify the position of RIO as a profession. The boot camp provides time to observe, discuss and practice skills of interviewing, assessing allegations of research misconduct, and guiding an investigation of possible research misconduct.

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

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

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

II. Education and Prevention

Introduction

ORI conducts its education and prevention activities primarily through the Division of Education and Integrity (DEI). Those activities include the Responsible Conduct of Research (RCR) Resource Development Program, the RCR Program for Graduate Schools, partnerships with the National Academies, conferences and workshops, a web site, staff presentations and publications.

1. Responsible Conduct of Research (RCR) Resource Development Program

ORI created the RCR Resource Development Program in 2002 to support the creation of RCR instructional materials by the research community for use in the worldwide research community. In addition to creating instructional resources, this program has sparked interest in responsible conduct of research at private and public research institutes.

The program has supported over 60 projects since it was established in 2002. Completed resources are posted at http://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.

a. Interactive Video Development: THE LAB: Avoiding Research Misconduct

ORI initiated a contract in 2009 with Will Interactive to work with ORI staff in developing a script that would address such topics as avoiding or handling research misconduct, mentorship, responsible authorship, and life-work balance. Video production is planned for 2010 with a release date in 2011.

b. Laboratory Management Training Video

ORI awarded a two-year contract to the Laboratory Management Institute (LMI) at the University of California – Davis in 2007 to develop laboratory management training materials that will make online or face-to-face instruction widely available to graduate students, postdoctoral scholars, faculty, and other personnel

Under the contract, LMI produced a video based course that may be taken by individuals and would permit faculty to offer face-to-face instruction by organizing workshops or lab management training programs. The video vignettes were posted on the ORI website in 2009.

The interactive course provides instruction in skills useful in managing laboratories including: communication skills; establishing and maintaining a research program;

quality control and assurance; managing human resources; leadership, goal setting, and strategic planning; financial and business management; health, safety, and security; creativity, discovery, problem solving, and innovation; stewardship of resources; and interpersonal relations.

The short videos present two or more possible approaches to those issues. Viewers can then discuss outcomes as well as think about what could be done differently which might promote a better resolution.

2. RCR Program for Graduate Schools

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

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 to the amount of $50,000.

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

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

In 2009, the seven Universities focused on implementing their RCR efforts and reports based on their experiences in evaluating and implementing will be completed in 2010.

3. Collaborative Efforts

a. National Academy of Sciences Study on Integrity of Research Data

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

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

2. Who owns research data, particularly that which results from federally-funded research? Is it the public, the research institution, the lab, or the researcher?

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

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

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

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

b. National Academy of Sciences (NAS) Government-University-Industry Research Roundtable (GUIRR) Conference on International Collaborations

ORI and other Federal agencies, industries, and academic institutions are supporting a NAS GUIRR effort to create a working conference on "Examining Core Elements of International Research Collaboration" to be held in 2010. The goal of the conference is to create greater understandings that could be provided to all sectors when working in different cultures. The conference plans to examine ethical considerations, research integrity, financial risks, export controls, the role of intellectual property and diplomacy. A session will specifically focus on responsible conduct of research by exploring specific data integrity and collaboration issues that are critical when working with foreign collaborators. The conference planners hope to create a working guidance document that would address the issues and concerns that will be raised and discussed at the conference.

4. Conferences and Workshops

ORI has sponsored, supported, or developed 4 conferences, workshops, and training programs in 2009. The conferences and workshops are organized in collaboration with universities, medical schools, professional organizations, and government agencies. More information about the conference and workshop program is available at http://ori.hhs.gov/conferences/.

a. RIO Boot Camp Training

Tulane University New Orleans, LA, February 17, 2009.
Northwestern University Chicago, IL, June 7-10, 2009
University of Oregon Eugene, OR, October 11-13, 2009

b. Fifth Biennial Research in Research Integrity Conference

ORI held the fifth biennial Research in Research Integrity (RRI) Conference in St. Louis, MO, from May 15-17, 2009. ORI and Roswell Park Cancer Institute sponsored the conference at the Niagara Falls Convention Center. The 140 participants came from 27 states, 14 countries, and 5 continents. Most participants presented work funded by grants from the ORI-NIH RRI program, celebrating its 10th anniversary. RRI researchers represent biomedical and social sciences, engineering, law, business, and government. Graduate students, postdoctoral scholars, and faculty networked with administrators, officials from government agencies, journal editors, and economists.

More than 60 abstracts were presented. The conference program began with emerging issues and continued with presentations about conflicts of interest, authorship, and editorial issues in publication, value of RCR instruction. Other sessions focused on community-based participatory research, questionable research practices and research misconduct.

5. Communication Venues

a. ORI Web Site

According to Google Analytics, the ORI web site received 156,997 visits in 2009. Of the visits 81,741 visitors were from 174 countries who viewed 433,849 pages. New visitors totaled 80,804 (65%); repeat visitors totaled 43,104 (35%). Visitors viewed an average of 3.5 pages per visit. Top visitors were from the U.S., Canada, UK, Japan, Australia, India, China, Germany, Puerto Rico, and Taiwan.

b. ORI Newsletter

ORI has been producing a newsletter since January 1993. In 2009, ORI produced four issues and sent each publication to approximately 4,000 institutions or individuals. The newsletter also is available on the ORI homepage. The newsletter provides ORI updates, summaries of cases published in the *Federal Register*, discussions of timely issues, and

information about conferences. In 2009, ORI continued to include commentaries from the research integrity community; 30 individuals contributed during the year and presented their thoughts on areas such as evaluating RCR, new RCR tools, mentoring, international collaborations, questionable research practices, and conflict of interest.

6. ORI Presentations

Ranjini Ambalavanar, Scientist-Investigator, DIO. "Microscopy and Microanalysis: Recent Advances," Office of Research Integrity, Rockville, Maryland, August 6, 2009.

Ranjini Ambalavanar, Scientist-Investigator, DIO. "Framing Allegations Precisely: Examples from the Vogel Case," University of Oregon, Eugene, Oregon, October 12, 2009.

Ranjini Ambalavanar, Scientist-Investigator, DIO. "eTBLAST – a text similarity detection software developed by Skip Garner," RIO Boot Camp, University of Oregon, Eugene, Oregon, October 13, 2009.

John Dahlberg, Director DIO. "Detecting Misconduct-Some Approaches Used by DIO," Boot Camp for RIOs, hosted by Tulane University, New Orleans, Louisiana, February 15-18, 2009.

John Dahlberg, Director DIO. Panel Discussant on "Optimal Personnel Characteristics - Scientific and Professional Integrity and Compliance with Biosafety and Biosecurity Standards," Meeting of the National Science Advisory Board for Biosecurity, April 3, 2009.

John Dahlberg, Director DIO. "The Office of Research Integrity: Responding to Misconduct and Promoting Responsible Research," presented at the NIH Regional Seminar on Program Funding and Grant Administration, Atlanta, Georgia, April 16-17, 2009.

John Dahlberg, Director DIO. "The process used by ORI to handle cases of research misconduct," presented to a delegation from China and the Chinese Embassy, at ORI, Rockville, Maryland, May 1, 2009.

John Dahlberg, Director DIO. "Scientific Forensics," presented to extramural program staff at the National Cancer Institute, Bethesda, Maryland, June 5, 2009.

John Dahlberg, Director DIO. "Detecting Misconduct-Some Approaches Used by DIO," Boot Camp for RIOs, Northwestern University, Chicago, Illinois, June 6-9, 2009.

John Dahlberg, Director DIO. "The Office of Research Integrity: Responding to Misconduct and Promoting Responsible Research," presented at the NIH Regional Seminar on Program Funding and Grant Administration, Las Vegas, Nevada, June 25-26, 2009.

John Dahlberg, Director DIO, "RSNA Editor's Forum: ORI's Experience in Detection of Altered Images," presented at the Radiology Society of North America (RSNA) Editor's Forum in Reston, Virginia, August 21, 2009.

John Dahlberg, Director DIO. "Understanding Research Misconduct: The Current Landscape," presented at the Uniformed Services University, Bethesda, Maryland, Symposium entitled "2009 Research Ethics and Integrity Education Conference Series," September 22, 2009.

John C. Galland, Director DEI. "RIO Leadership in RCR Programming – Why it's Critical?" RIO Boot Camp, Chicago, Illinois, June 7-10, 2009.

John C. Galland, Director DEI. "Research Issues of Concern to Faculty," Graduate School of Nursing (GSN) Brown Bag, Bethesda, Maryland, July 20, 2009.

John C. Galland, Director DEI. "Research Ethics and Integrity," Uniformed Services University Graduate School of Nursing, Faye G. Abdellah Center for Research, and Navy Medicine, "2009 Research Ethics and Integrity Meeting," Bethesda, Maryland, July 21, 2009.

John C. Galland, Director DEI. "A Professional Curriculum and Pedagogy for Scientific Researchers," Chinese Association for Science and Technology (CAST) 11th Annual Meeting, Chongqing, (Sichuan Province) Beijing, China; September 7-10, 2009.

John C. Galland, Director DEI. Discussion Leader: "Ethical Legal, and Social Aspects of Medical Care," Uniformed Services University of Health Sciences; Bethesda, Maryland, September 15, 2009.

John C. Galland, Director DEI. ORI/Health Canada Meeting, ORI Conference Room, Rockville, Maryland, October 14, 2009.

John C. Galland, Director DEI. Clinical & Translational Science Awards (CTSA) Clinical Research Ethics Face-to-Face Meeting, Bethesda, Maryland, October 15, 2009.

John C. Galland, Director DEI. University of Washington, Seattle, Washington, October 21, 2009.

John C. Galland, Director DEI. 2009 CITI Developer's Group Meeting, Seattle, Washington, October 24, 2009.

John C. Galland, Director DEI. ESF-ORI Workgroup/Conference, Strasbourg, France, October 27-28, 2009.

John C. Galland, Director DEI. "ORI Update," PRIM&R International Conference, Nashville, Tennessee, November 13-16, 2009.

John C. Galland, Director DEI. "Learning to be a Responsible Researcher," Temple Medical University, Philadelphia, Pennsylvania, November 18, 2009.

Susan Garfinkel, Scientist-Investigator, DIO. "Detecting Research Misconduct: Some Approaches used by ORI," American Health Lawyers Association, Annual Academic Medical Centers Program, Legal Issues Affecting Academic Medical Centers and Other Teaching Institutes, Washington, D.C., Session: "Research Misconduct: How did we get in this mess and how can we avoid it in the future?" January 29-30, 2009.

Susan Garfinkel, Scientist-Investigator, DIO. "The Vogel Case: What are the Allegations?" RIO Boot Camp, Tulane University, New Orleans, Louisiana, February 16-18, 2009.

Susan Garfinkel, Scientist-Investigator, DIO. "Detection and Interpretation of Manipulated Scientific Images," Federation of American Societies for Experimental Biology (FASEB) Publications and Communications Committee Meeting, Cosmos Club, Washington, D.C., April 27, 2009.

Susan Garfinkel, Scientist-Investigator, DIO. "Detection of Manipulated Scientific Images," Delegation from China Ministries of Science and Technology, ORI Office, Rockville, Maryland, May 1, 2009.

Susan Garfinkel, Scientist-Investigator, DIO. "Detection of Manipulated Scientific Images," National Cancer Institute (NCI), Division of Extramural Activities (DEA), "Brown Bag" presentation on Research Integrity Oversight, Bethesda, Maryland, June 5, 2009.

Susan Garfinkel, Scientist-Investigator, DIO. "The Vogel Case: What are the Allegations?" RIO Boot Camp, Northwestern University, Chicago, Illinois, June 7-10, 2009.

Susan Garfinkel, Scientist-Investigator, DIO. "Handling Research Misconduct: Difficulties and Problems Identified by ORI," Health Canada, ORI Office, Rockville, Maryland, October 14, 2009.

John Krueger, Scientist-Investigator, DIO. "ORI 'Forensics': [Handling] Questioned Images in Science." Boot Camp V, Tulane University, New Orleans, Louisiana, February 17, 2009.

John Krueger, Scientist-Investigator, DIO. "How Evidence 'Informs' the Investigation - Vogel Case Analysis." Boot Camp V, Tulane University, New Orleans, Louisiana, February 18, 2009.

John Krueger, Scientist-Investigator, DIO. "Detection of Image Manipulation - How-to's and What-if's," American Physiological Society, Production Editors, at FASEB, Bethesda, Maryland, May 28, 2009.

John Krueger, Scientist-Investigator, DIO. "Image Demonstration and Points," American Physiological Society, at FASEB, Bethesda, Maryland, May 28, 2009.

John Krueger, Scientist-Investigator, DIO. "ORI 'Forensics': Examining Questioned Images." RIO Boot Camp VI, Northwestern University, Chicago, Illinois, June 9, 2009.

John Krueger, Scientist-Investigator, DIO. "Evidence in the Oversight of Investigations," RIO Boot Camp VI, Northwestern University, Chicago, Illinois, June 9, 2009.

John Krueger, Scientist-Investigator, DIO. "ORI 'Forensics': Examining Questioned Images." Boot Camp VII, University of Oregon, Eugene, Oregon, October 13, 2009.

John Krueger, Scientist-Investigator, DIO. "The Vogel Case: What are the Allegations? [Handling] Questioned Images." Boot Camp VII, University of Oregon, Eugene, Oregon, October 13, 2009.

John Krueger, Scientist-Investigator, DIO. "Evidence in the Oversight of Investigations," Boot Camp VII, University of Oregon, Eugene, Oregon, October 13, 2009.

Cynthia Ricard, Health Science Administrator, DEI. "Respecting the Public Trust: Scholarly Integrity" and "The Scientific Investigator within the University Structure," Louisville University of Louisville School of Medicine, Louisville, Kentucky, October 14-15, 2009.

Cynthia Ricard, Health Science Administrator, DEI. Discussion Leader: "Ethical, Legal and Social Aspects of Medical Care: Reproduction," Uniformed Services University of the Health Sciences, Bethesda, Maryland, September 29, 2009.

Cynthia Ricard, Health Science Administrator, DEI. Discussion Leader: "Ethical, Legal and Social Aspects of Medical Care: Research," Uniformed Services University of the Health Sciences, Bethesda, Maryland, September 15, 2009.

Cynthia Ricard, Health Science Administrator, DEI. "RCR: Research Integrity," University of North Carolina, Greensboro, North Carolina, August 26-27, 2009.

Cynthia Ricard, Health Science Administrator, DEI. "Ethics and Research Integrity" Federation of Societies for Experimental Biology (FeSBE) Federal University of Goias, Goiania, Brazil, June 5, 2009.

Cynthia Ricard, Health Science Administrator, DEI. "What is the RRI program for the future?" Research in Research Integrity Conference, Roswell Park Cancer Institute, Niagara Falls, New York, May 15-17, 2009.

Cynthia Ricard, Health Science Administrator DEI. "Research in Research Integrity" National Cancer Institute, Bethesda, Maryland, May 8, 2009.

Cynthia Ricard, Health Science Administrator DEI. "Regulatory Agency Update - Office of Research Integrity," North Carolina Society of Research Administrators, March 9-11, 2009.

Sandra Titus, Director, Intramural Research, DEI. Panel Discussion on "Adaptability of the Government to Changes," PRIM&R, Nashville, Tennessee, November 15, 2009.

Sandra Titus, Director, Intramural Research, DEI. "ORI Update," Society of Research Administrators, Seattle, Washington, October 22, 2009.

Sandra Titus, Director, Intramural Research, DEI. "Use of Ombudsman in Research Integrity," Society of Research Administrators, Seattle, Washington, October 21, 2009.

Sandra Titus, Director, Intramural Research, DEI. "Using Contracts to Build Collaborations," Society of Research Administrators, Seattle, Washington, October 21, 2009.

Sandra Titus, Director, Intramural Research, DEI. "Collaboration in Research Groups," Research in Research Integrity Conference, Roswell Park Cancer Institute, Niagara Falls, New York, May 15-17, 2009.

Sandra Titus, Director, Intramural Research, DEI. "Interview Study with Research Integrity Officers," Research in Research Integrity Conference, Roswell Park Cancer Institute, Niagara Falls, New York, May 15-17, 2009.

Sandra Titus, Director, Intramural Research, DEI. "What does ORI do?" Presentation to graduate students, Middle Tennessee University, March 31, 2009.

Sandra Titus, Director, Intramural Research, DEI. "Collaboration and Authorship," University of Buffalo, Niagara Falls, New York, January 29, 2009.

7. ORI Publications

Bosch, X., and Titus, S. "Cultural Challenges and their Effect on International Research." *THE LANCET* 373(9664):610-612, February 21, 2009.

8. Federal Register Notices - Misconduct*

OS. Finding of Research Misconduct. Notice Vol. 74 No. 230, Wednesday, December 2, 2009 [Robertson]

OS. Finding of Scientific Misconduct. Notice Vol. 74 No. 208, Thursday, October 29, 2009 [Deng]

OS. Finding of Research Misconduct. Notice Vol. 74 No. 195, Friday, October 9, 2009 [Couvertier]

OS. Finding of Scientific Misconduct. Notice Vol. 74 No. 184, Thursday, September 24, 2009 [Ningaraj]

OS. Finding of Research Misconduct. Notice Vol. 74 No. 177, Tuesday, September 15, 2009 [Arriaga]

OS. Finding of Research Misconduct. Notice Vol. 74 No. 158, Tuesday, August 18, 2009 [Wolfort]

OS. Finding of Scientific Misconduct. Notice Vol. 74 No. 128, Tuesday, July 7, 2009 [Contreras]

OS. Finding of Scientific Misconduct. Notice Vol. 74 No. 127, Monday, July 6, 2009 [Thomas]

OS. Finding of Research Misconduct. Notice Vol. 74 No. 120, Wednesday, June 24, 2009 [Wanchick]

OS. Finding of Scientific Misconduct. Notice Vol. 74 No. 62, Thursday, April 2, 2009 [Fogel]

OS. Finding of Scientific Misconduct. Notice Vol. 74 No. 26, Tuesday, February 10, 2009 [Tanaka]

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

III. Research on Research Integrity and Research Misconduct

ORI conducts intramural and extramural research programs to expand the knowledge base on research misconduct, research integrity, and the responsible conduct of research. Intramural studies are conducted by ORI staff, contractors, and consultants and are focused on questions relevant to ORI's regulatory and preventive mission. In contrast, the extramural program operates through the Research on Research Integrity (RRI) Program that solicits investigator-initiated proposals from researchers at colleges, universities, medical schools, research centers, and other organizations.

Intramural Research Program

ORI has conducted an intramural research program since 1993. DEI was formally directed to "conduct policy analyses, evaluations, and research to improve HHS research integrity and build the knowledge base in research misconduct, research integrity and prevention" (*Federal Register* Volume 65, Number 93, pages 30600-30601, May 12, 2000) (see Appendix C).

Studies have examined medical school guidelines for the responsible conduct of research, outcomes for whistleblowers and respondents, scientists' awareness of possible research misconduct, depth of instructions to authors published by journals, mentoring of trainees, and research integrity measures utilized in biomedical research laboratories. For a complete list see http://ori.hhs.gov/research/intra/studies_completed.shtml.

Completed Studies in 2009

Institutional Research Integrity Officer (RIO) Study

This study, conducted by the Research Triangle Institute International, focused on the role of the RIO, the institutional official responsible for implementing the PHS Policies on Research Misconduct (42 CFR Part 93). The study examined the responsibilities, authority, qualifications, training, organizational location, role set, resources, and turnover rates of individuals in this critical position. The study also examined how individual and institutional factors influence the preparedness of the RIO to handle research misconduct allegations and the promotion of research integrity. Half of the sample came from the top 100 NIH-funded institutions, and the remaining population was drawn from the other 1,600 educational or research institutions. Ninety-one interviews were completed along with 651 responses (59 percent response rate) to the web questionnaires. Study results from the two studies will be disseminated in future peer reviewed papers.

Training and Mentoring PhDs: Faculty Views on their Role and their Institution's Role to Promote the Development of Responsible Researchers

This study, conducted by Mathematica Policy Research, Inc., focused on how faculty and institutions promote the responsible conduct of research in training Ph.D. students. The objectives of the study were to understand (1) how faculty describe the differences between being an advisor versus being a mentor, (2) how these two roles work with doctoral students to promote the responsible conduct of research, and (3) to learn faculty views on what their institution is doing in terms of policies, programs, and incentives to promote quality research advising and research mentoring. Study results based on over 5,000 faculty responses (65 percent response rate) will be disseminated in future peer reviewed papers.

Studies in Progress

Evaluating Faculty Member's Views on their Institutions Guidance to Faculty Members on their Roles in Advising PhD Candidates

This study, conducted by Mathematica Policy Research, Inc., will focus on how faculty members perceive the relevance and usefulness of their institutions guidance documents on the role and responsibilities of the Advisor of a Ph.D. trainee. This assessment will be based on faculty members verbatim statements made as part of the study "Training and Mentoring PhDs: Faculty Views on their Role and their Institution's Role to Promote the Development of Responsible Researchers." This study is expected to be completed in 2010.

Evaluating the Effectiveness of Institutional Efforts to Educate Their Staffs on Their Policies for Dealing with Research Misconduct and Research Integrity

This study, conducted by the Research Triangle Institute International, will evaluate how effectively institutions have informed their faculty about the PHS Policies on Research Misconduct (42 CFR Part 93). The study will collect data on how much faculty know about what constitutes research misconduct, developing and reporting an allegation, and the rights and responsibilities of respondents and whistleblowers. In addition, the study will ask faculty to evaluate the effectiveness of institutions in handling research misconduct allegations and in protecting whistleblowers. The study completed OMB review; data collection was completed in 2009, with the analysis and report to be completed in 2010.

Issues and Questions Raised by Whistleblowers who Report Research Misconduct

This study was originally planned to repeat the 1995 study on whistleblowers by conducting phone interviews with complaints. However, because of the confidentiality protections provided to research misconduct complainants, ORI cannot release the names of former complainants and therefore cannot conduct such a study.

The redesigned study will focus on interviews with RIOs who have contact with whistleblowers to examine the kinds of questions and issues that complainants and potential complainants have raised with them as well as to ascertain the kinds of information the RIOs provide. The interviews will give us an observational perspective on the degree to which complainants report fear of making allegations of research misconduct and/or report retaliation for having made the allegation before, during, and after the investigation is over. The study will be submitted to OMB for review in 2010 and will be conducted in 2011.

Research Mentoring Dyad Study: Comparing the Research Advisor/Mentor and their PhD Student's Views on Training/Learning to be a Responsible Researcher

This study design and interview instrument were submitted and approved by OMB in 2009. The interviews will be framed as a discussion for faculty to describe their interaction with the Ph.D. students for whom they are advisors/mentors. The primary goal of the interview is to learn how a faculty member views the research training process. We want to determine how/if faculty prepares Ph.D. students to be responsible researchers and what they identify as their goals for successful outcomes for a Ph.D. student's graduate education. In addition interviews will be conducted with individual ABD (all but dissertation) students to determine their views on how they learned to become a responsible researcher. This study is on hold until funding is secured.

Extramural Research Program

Research on Research Integrity (RRI) Program

ORI established its extramural research program, Research on Research Integrity (RRI), in 2000 in collaboration with the National Institute of Neurological Disorders and Stroke (NINDS). Since the first awards were made in 2001, several NIH institutes have participated in the development of the program: the National Institute of Drug Abuse (NIDA), the National Institute of Alcohol Abuse and Alcoholism (NIAAA), the National Cancer Institute (NCI), the National Heart, Lung and Blood Institute (NHLBI), the National Institute of Alcohol Abuse and Alcoholism (NIAAA), the National Institute of General Medical Sciences (NIGMS), the National Human Genome Research Institute (NHGRI), and the National Institute of Child Health and Development (NICHD). Other partners include the Center for Scientific Review (CSR), the National Library of Medicine (NLM), the National Center for Research Resources (NCRR), and the Agency for Healthcare Research and Quality (AHRQ).

The research integrity grant program was created to foster empirical research on societal, organizational, group, and individual factors that affect, both positively and negatively, integrity in research.

RRI Awards

Since it began in 2001, the RRI program has funded 53 projects that have resulted in 99 publications consisting of peer-reviewed articles, commentaries, letters to the editor, abstracts, and literature reviews in more than 30 journals.

Research on *Research Integrity in Collaborations* was the main topic supported by 4 of the awards made in 2009.

Total funding for the RRI program in 2009 was $1,523,689. New grants received $925,081, and continuations received $598,608. ORI contributed $1,064,584; NIH institutes contributed $459,105. R21-awards provide up to $275,000 in direct costs, plus indirect costs, for 2 years.

There were 3 new awards supported by ORI through NCRR; 1 continuation award was funded by NIGM; 2 continuation awards were funded by ORI through NCRR. In addition NCRR provided administrative support for the grants review and grants management.

Award abstracts are posted on the ORI web site along with a list of publications produced by projects supported by the RRI program.

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

- James Dubois, Saint Louis University, MO: "Environmental Factors Predictive of Misbehavior in Collaborative Health Research"

- Celia Fisher, Fordham University, NY: "Ethical Challenges for Research Extenders Responsible for the Integrity of Community Addiction Research"

- Stephen Leff, Children's Hospital of Philadelphia, PA: "Using Community-Based Participatory Research and Qualitative Methods to Evaluate Intervention Integrity Procedures"

- Mildred Solomon, Education Development Center, Inc., MA: "Research Integrity in Collaborative Science: From Education to Behavioral Change"

RRI Publications

In the first 10 years of the program, RRI researchers have published 99 peer-reviewed articles, abstracts, commentaries, reviews, and letters to the editor. A complete list of RRI publications is available on the ORI web site at http://ori.hhs.gov/research/extra/rri_publications.shtml. Citations to the recently published articles follow.

Researchers supported by the RRI Program published 11 articles in 2009 on research integrity and the responsible conduct of research in 8 journals:

- Blom-Hoffman, J., Leff S.S., Franko, D.L., Weinstein, E., Beakley, K., Power, T.J. "Consent Procedures and Participation Rates in School-Based Intervention and Prevention Research: Using a Multi-Component, Partnership-Based Approach to Recruit Participants." *School Ment Health* 1(1):3-15, March 1, 2009.

- DuBois, J.M. "What counts as empirical research in bioethics and where do we find the stuff?" *Am J Bioeth* 9(6-7):70-72, 2009.

- Errami, M., Sun, Z., Long, T.C., George, A.C., Garner, H.R. "Deja vu: A database of highly similar citations in the scientific literature." *Nucleic Acids Res*. 37(Database issue):D921-4, January 2009.

- Gorman, D.M., Huber, J.C. Jr. "The social construction of 'evidence-based' drug prevention programs: A reanalysis of data from the Drug Abuse Resistance Education (DARE) program." *Eval Rev*. 33(4):396-414, August 2009

- Gullan, R.L., Feinberg, B.E., Freedman, M.A., Jawad, A., Leff, S.S. "Using Participatory Action Research to Design an Intervention Integrity System in the Urban Schools." *School Ment Health* 1(3):118-130, September 1, 2009.

- Leff, S.S, Hoffman, J.A., Gullan, R.L. "Intervention Integrity: New Paradigms and Applications." *School Ment Health* 1(3):103-106, September 1, 2009.

- Long, T.C., Errami, M., George, A.C., Sun, Z., Garner, H.R. "Scientific integrity. Responding to possible plagiarism." *Science* 323(5919):1293-1294, 2009.

- Martinson, B.C., Crain, A.L., Anderson, M.S., De Vries, R. "Institutions' expectations for researchers' self-funding, federal grant holding, and private industry involvement: manifold drivers of self-interest and researcher behavior." *Acad Med*. 84(11:1491-1499, 2009.

- Neale, A.V., Dailey, R.K., Abrams, J. "Analysis of Citations to Biomedical Articles Affected by Scientific Misconduct." *Sci Eng Ethics* 16(2):251-261, June 2010.

- Schwartz, P.H., Kalichman, M.W. "Ethical challenges to cell-based interventions for the central nervous system: Some recommendations for clinical trials and practice." *Am J Bioeth*. 9(5):41-43, 2009.

- Zimmer, D.E., Campbell, E.G. "Life-science research within US academic medical centers." *JAMA* 302(9):969-976, 2009 Sep 2. See also comment in: *JAMA* 302(9):1001-1002, September 2, 2009.

IV. Institutional Compliance

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

Assurance Program

The Assurance Program is responsible for ensuring that PHS research funds are only awarded to eligible institutions. An institution is eligible when it has an active assurance on file with ORI stating that it has developed and will comply with an administrative process for responding to allegations of research misconduct in PHS-supported research that complies with the PHS regulation. An institution establishes an assurance by filing an initial assurance form or signing the face page of the PHS grant application form. Institutions keep their assurance active by completing the Annual Report on Possible Research Misconduct (PHS for 6349), submitting their research misconduct policy upon request by ORI, revising their research misconduct policy when requested by ORI, and complying with the policies and procedures and PHS regulation.

The Assurance Program meets its responsibilities by maintaining the assurance database, gathering and summarizing information from institutions in their Annual Report, reviewing institutional policies and procedures in conjunction with the Compliance Review Program, coordinating with NIH that an institution is in compliance with 42 CFR 93, and is eligible to receive their awards

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

Assurance Database

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

In 2008, there were 5,202 institutional assurances on file with ORI, an increase of 376 from 2007. There were 376 institutions added to the assurance database because they filed their initial assurance or reestablished their assurance by submitting their Annual Report on Possible Research Misconduct for 2006 and 2007. There were 146 assurances inactivated because the institution failed to submit its Annual Report in 2008 or the institution requested that its assurance be withdrawn or that duplicate records be eliminated.

Table 8: Number and Type of Institutions with Active Assurances, 2009

Types of Institution	Number 2007	Increased 2008	Total At End 2008
Institutions of Higher Education	974	+14	988
Research Organizations, Institutes, Foundations and Laboratories	425	+34	459
Independent Hospitals	273	+10	283
Educational Organizations, Other Than Higher Education	31	+2	33
Other Health, Human Resources, and Environmental Services Organizations	552	+52	604
Other (small business)	2,571	+264	2,836
Total	**4,826**	**376**	**5,202**

Institutional Research Misconduct Policy Reviews

ORI completed 76 policy reviews in 2008. Since 1995, ORI has reviewed 2,697 institutional policies.

Annual Report on Possible Research Misconduct – Pending Update

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 2008 Annual Report began in January 2009 for the 5,202 institutions that had an assurance on file with ORI as of December 31, 2008.

Completed Annual Reports were received from 3,719 institutions for a response rate of 77 percent. ORI inactivated 146 assurances, including 1,337 institutions that did not return their Annual Reports by the March 31 deadline. Many assurances were reactivated later because annual reports were submitted after the due date.

The Annual Report form requested institutions to report on the availability of its policies and procedures for responding to allegations of research misconduct, and within PHS jurisdiction, the number of allegations of research misconduct received and the number of inquiries and investigations conducted.

Reported Research Misconduct Activity – Pending Update

Research misconduct activity is defined as receipt of an allegation or the conduct of an inquiry or investigation in the reporting year or continued into the reporting year. Reportable activities are limited to alleged research misconduct involving PHS-supported research, research training, or other research related activities.

Table 9: Research Misconduct Activity: 1993-2008

Year*	Institutional Reporting Activity**	New Allegations
2008	117	113
2007	130	183
2006	111	151
2005	113	137
2004	101	120
2003	106	136
2002	99	163
2001	78	127
2000	82	103
1999	72	89
1998	67	69
1997	73	92
1996	88	127
1995	96	104
1994	79	89
1993	73	86

*The count in year 2008 is a record of what institutions submitted in their 2008 Annual report, which is submitted to ORI in 2009. This count will not necessarily be consistent with DIO reported activity. This count is only derived from the reported activity of institutions.

**Institutional reporting activity is a composite count of ongoing inquiries or investigations from the prior year (53) as well as the 64 new inquiries and investigations reported in 2008. This means there were 230 reports of allegations, inquiries, or investigations made in institutions' annual reports.

Compliance Review Program

The Compliance Review Program is responsible for ensuring that institutions that apply for or receive PHS funds follow policies and procedures that comply with the PHS regulation in responding to allegations of research misconduct. In addition, the Compliance Review Program responds to retaliation complaints from whistleblowers and monitors the implementation of PHS administrative actions by institutions and PHS agencies.

Compliance Cases

Compliance cases involve reviews of institutional handling of an allegation of research misconduct or a retaliation complaint from a whistleblower. In 2009, 8 cases described below were closed.

1. In this case, an institution conducted an inquiry and investigation into allegations that a graduate student falsified a number of figures that were included in a manuscript, in grant application, and in his doctoral thesis proposal. The associated research was supported by PHS. The institution made a finding of research misconduct against the student and submitted its report to ORI. DIO conducted extensive oversight in this case to substantiate the institutional findings.

   During its oversight review, DIO noted a number of procedural weaknesses in the institutional process for addressing allegations of research misconduct. Subsequently, a compliance review was conducted to further evaluate these weaknesses and to recommend appropriate corrective institutional actions. Areas of concern included the failure to sequester relevant research data in a timely manner, the failure to provide appropriate documentation supporting the institutional report in its submission to DIO, the failure to consistently record, transcribe, and provide for comment the interviews conducted as part of the investigative process, and the failure to adhere to process time frames.

   Each of these issues was described in more detail in the body of the compliance report, and ORI recommended a series of actions, including the revision of the institutional misconduct policy, a corrective action plan to address the noted deficiencies, and the requirement that for a two year period the institution immediately inform ORI of all allegations of research misconduct.

2. A compliance review was initiated at the conclusion of a misconduct investigation at a large state institution, not only because of shortcomings noted during the most recent investigation, but also because a significant number of reports previously submitted to ORI included procedural deficiencies.

   In its closeout letter on the current case, ORI noted that the case was resolved primarily because of the respondent's cooperation with the institution as well as ORI, and despite a poorly documented admission by the respondent, irregular sequestration of data, and an excessive time frame for completion of the process. ORI viewed the deficiencies as symptomatic of an institutional process that was poorly defined and unevenly implemented.

   The basis for an institutional response to allegations of research misconduct is the institutional misconduct policy, and ORI reviewed this document as part of its review. ORI found that the document had not been updated to reflect the new requirements in the revised regulation (42 CFR Part 93) and also that the policy covered a broad range of faculty misconduct, including discrimination, harassment, neglect of duties, and other

violations of professional conduct of faculty as well as scientific misconduct. While the document referenced the PHS regulation in 42 CFR Part 50, the bulk of the document detailed a process inconsistent with the specific requirements of the PHS regulation. Without a specific and detailed process to guide the complainants, the responsible institutional officials, and the inquiry and investigation panel members, any resulting institutional report would likely not meet the PHS standards for thoroughness, competence, and objectivity.

ORI directed the institution to develop a corrective action plan to (1) develop a detailed and standalone policy for addressing allegations of research misconduct, incorporating all relevant provisions of the current PHS regulation, (2) develop a plan to insure that all faculty and staff were aware of the requirements of the PHS regulation and the institutional policies related to the handling of research misconduct allegations, (3) immediately notify ORI of all allegations of research misconduct received, and (4) submit any assessment or inquiry report associated with any allegation of research misconduct to ORI upon completion. The reporting and notification requirements were in effect for a two year period.

3. This case involved the allegation of possible retaliation against the complainant for raising allegations of possible research misconduct against a senior faculty member. ORI conducted an initial review to determine whether the jurisdictional requirements were met for any PHS or institutional action under the current PHS regulation. The primary concern was the timing and substance of the complaint and whether there was a direct and well defined link between the allegations and the reported adverse actions.

   The complainant stated that he was aware of certain unprofessional actions by the respondent, including possible falsification of data, and the complainant claimed, among other things, that his appointment at the institution was prematurely terminated as a result of the allegations. ORI determined that the decision to terminate the complainant's academic appointment was made prior to his formal allegations and was more likely a result of other interpersonal factors that were documented in the record.

   It was also noted that the complainant filed a complaint alleging retaliation with the institution's HR department, and that department conducted a formal and independent review of his complaint. By policy, ORI will accept any reasonable process agreed to by both parties for the resolution of retaliation complaints, where ORI has jurisdiction. The agreement to utilize an alternative investigation process fulfilled the institution's obligation under the PHS regulation to protect whistleblowers, and ORI required no further action in this case.

4. In this case, ORI was contacted independently by at least two individuals at an institution who provided information regarding the initiation of one or more inquiries into allegations and counter-allegations of possible research misconduct. Although institutions are not required to notify ORI about the initiation of an inquiry unless an investigation is subsequently deemed to be warranted, ORI was concerned about the management of simultaneous reviews of the claims and counter-claims. Under the PHS

regulation, institutions are required, among other things, to sufficiently document the inquiry process, to maintain these records for a seven year period, and to provide them to ORI upon request. ORI requested that the institution provide a copy of all inquiry reports prepared in response to the allegations and include the research record and other evidence to support the institutional findings.

The institution promptly provided ORI the requested information. Based on a review of the materials, ORI determined that the inquiry process had been conducted in a thorough, competent, objective, and fair manner and concurred that no further investigation of the allegations was warranted.

5. In this case, ORI was contacted by a complainant who claimed that he was being removed prematurely from his post as Department Chair by his Dean in retaliation for raising allegations against another faculty member. In reviewing documentation associated with this case, ORI determined that there was a misunderstanding regarding the actual term of the appointment, with both parties initially under the impression that the term expired a number of months before it actually did. It was at the time the Dean announced the formation of a search committee to identify candidates for the chairmanship that the complainant discovered that his original term actually extended six months further into the next calendar year, and the complainant claimed that the Dean's refusal to halt the recruitment process was retaliatory.

   ORI contacted the institutional RIO to attempt to resolve this issue. Because the complainant considered the premature termination of his position as Department Chair to be possible retaliation, ORI suggested that the claim could be most effectively addressed by having the Dean honor the original terms of the Chairman's appointment, with any announcement regarding the change being done in a manner consistent with usual departmental and institutional practices, with no references made to the misconduct issues or process. It was then mutually agreed to by all parties that the complainant would be allowed to complete his term as Department Chair. It also was understood by all parties that there would be no obligation to reappoint the complainant beyond his term. Furthermore, ORI noted that the legitimacy of a retaliation allegation is not dependent on an institutional finding that the allegations of research misconduct merit further formal review, as was presumed by one of the institutional officials associated with this case.

6. The PHS regulation provides that institutions, under their Federal misconduct assurance, must take all reasonable and practical steps to protect the positions and reputations of good faith whistleblowers, protect them from retaliation by respondents and other institutional members, and restore their reputations as appropriate. These provisions apply specifically to instances where the alleged misconduct falls within the PHS definition of research misconduct and involves research supported by PHS funds. Under those circumstances, ORI has the authority to take appropriate steps to protect good faith whistleblowers.

In this case, an individual made allegations against an individual at his institution and subsequently contacted ORI requesting that he be provided, as a whistleblower, a protection plan for his safety and his job. The initial task in evaluating a retaliation complaint is to determine whether or not the allegations fall under the jurisdiction of the PHS regulation. ORI evaluated the documentation the individual provided in support of his allegations and determined that the allegations did not conform to the requirements of the PHS regulation. Therefore, ORI had no jurisdiction in the matter and could not enforce the applicable provision in the PHS regulation related to whistleblower protection.

While ORI did not have authority to address his retaliation complaint under the PHS regulation, it did make note in its response to the individual that his institution's policies and procedures for dealing with academic fraud were broader in scope that the PHS regulation and did specifically provide protection from retaliation against individuals making allegations of academic fraud in good faith.

7. This misconduct case was initiated as a result of anonymous allegations initially received by ORI. After further clarification, ORI referred six specific allegations to the funding institution. The allegations involved possible falsification of data presented in six published papers, all of which cited PHS support. An inquiry was conducted and the inquiry committee recommended further investigation into the actions of two postdoctoral fellows and also recommended expanding the scope of the investigation to explore the involvement of a third postdoctoral fellow as well as the laboratory director. ORI received separate investigation reports for the postdoctoral fellows and the laboratory director.

   Based on its overall review, DIO found the institutional investigation reports provided limited documentation supporting the investigative findings, thus providing weak rationale for the final conclusions and for who was responsible for each instance of scientific misconduct. Because of these procedural weaknesses, ORI initiated a compliance review and evaluated issues of compliance that included (1) the collection and submission of research data and other evidence, (2) the review and analyses of research data and other evidence, (3) inconsistency between the findings of the two investigation committees, and (4) failure to fully examine all allegations.

   The compliance review evaluated each of these issues in depth, and a compliance review report was provided to the institution. The report recommend that the institution develop and implement a corrective action plan that addressed the deficiencies noted in the report and that the institution immediately inform ORI of all allegations of research misconduct under PHS jurisdiction for a period of two years.

8. This case involved a charge of plagiarism by a former post-graduate student against a former laboratory supervisor for what she claimed was the inappropriate inclusion of her research work in a grant application submitted to NIH. She claimed that he plagiarized

portions of her dissertation as well as two papers submitted as part of graduate course requirements and that this action materially misled the NIH reviewers regarding his contribution to the grant.

The laboratory supervisor, who had been a course instructor and co-advisor to the complainant, included in the grant application a statement specifically acknowledging her contributions in the Preliminary Data section. A review of the records determined that the research work in question was totally supported.

Implementation of HHS Administrative Actions

The implementation of HHS administrative actions is monitored through the PHS ALERT, a system of records subject to the Privacy Act. Individuals are entered into the PHS ALERT System when (1) PHS has made a finding of research misconduct concerning the individual, (2) the individual is the subject of an administrative action imposed by HHS as a result of a determination that research misconduct has occurred, (3) the individual has agreed to a voluntary corrective action as a result of an investigation of research misconduct, or (4) ORI has received a report of an investigation by an institution in which there was a finding of research misconduct concerning the individual and ORI has determined that PHS has jurisdiction. The PHS ALERT is not a public system.

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

On January 1, 2009, ORI listed the names of 49 individuals in the ALERT system. During the year, ORI added 14 names and removed 11. On December 31, 2009, the names of 52 individuals were in the system.

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

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

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

The number of requests for information under the Freedom of Information Act (FOIA) and the Privacy Act decreased in 2008.

ORI received 54 requests in 2009 and closed 61. Twenty-six requests were carried into 2010. In 2008, ORI received and closed 38 requests.

Two Privacy Act requests were received and closed.

Freedom of Information Act

The Freedom of Information Act (FOIA), 5 U.S.C. § 552, as amended, allows the public access to Federal agency records, except to the extent that those records, or portions thereof, are protected from disclosure by one or more of the 9 FOIA exemptions.

ORI records are primarily protected by Exemptions 5, 6, and 7 of the FOIA. Exemption 5 covers internal government communications and notices. Exemption 6 covers document information about individuals that, if disclosed, would constitute a clearly unwarranted invasion of personal privacy. Exemption 7 covers records that the government has compiled for law enforcement purposes.

A FOIA request for ORI records should be made to the PHS FOIA Officer, Parklawn Building, 5600 Fishers Lane, Room 17, Rockville, MD 20857. The request must reasonably describe the records sought so that the agency official is able to locate the records with a reasonable amount of effort. Some requests may be subject to review, search, and duplication costs.

Privacy Act

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

The inquiry and investigative records in ORI files are part of a system of records that was published in the *Federal Register* on January 6, 1995 (60 Fed. Reg. 2140). However, these records are specifically exempted from express provisions of the Privacy Act regarding notification, access, and correction and amendment by the subject of the records. Nonetheless, each request for access is reviewed on a case-by-case basis. Additionally, if the record requested is denied under the Privacy Act due to an exemption, the subject of the records may still be entitled to obtain access to his or her records, or portions thereof, under the provisions of FOIA. A Privacy Act request should be made to the Privacy Act Officer, ORI, at 1101 Wootton Parkway, Suite 750, Rockville, MD 20852. A request under the Privacy Act must be made by the subject of the records or his or her legal representative.

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Summaries of Closed Investigations Resulting in Findings of Research Misconduct or Administrative Actions – 2009

Rashanda Robertson, Emory University: Based on an assessment conducted by Emory University (EU), the Respondent's own admission, and additional oversight of that admission conducted by ORI, ORI and EU found that Ms. Rashanda Robertson, former Research Coordinator, Department of General Medicine, EU, engaged in research misconduct in research supported by National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grant K23 HL077597. The randomized study for which she coordinated was designed to assess whether patient medication compliance was improved by a meeting with a clinical pharmacist to discuss the patient's current and newly prescribed medications prior to the patient's discharge from the hospital. The enrolled subjects randomized to the intervention group received a card listing all of their medications and a "pill box" to help them with medication compliance. The subjects also were called three days after discharge to check on their medication compliance.

Specifically, the U.S. Public Health Service (PHS), EU, and Ms. Robertson, in a three-way Voluntary Settlement Agreement, agree that the Respondent committed the following acts of research misconduct, which she fully acknowledged. In an affidavit obtained by EU, the Respondent admitted that during the last two weeks of her employment at EU, she fabricated enrollment forms to create enrollees who did not exist and falsified the data of some enrollees who did not exist to cover up the data fabrication. To create the fabricated enrollment forms, the Respondent:

1. identified patients who were eligible for the study based on their charge screens but who were considered ineligible after a face-to-face screen

2. obtained patients' names from the screening records and used the names to obtain the personal information (address and telephone numbers) on these patients from the site hospital's pharmacy online system

3. created a fabricated enrollment form for each of the non-existent enrollees; specifically, Respondent fabricated a participant's name by using the name of a patient who had failed screening and then fabricated the date of enrollment by using the date of the patient's screening failure; using this method, Respondent fabricated the participant names, personal information, and enrollment dates on twenty-eight (28) enrollment forms

4. dispersed the fabricated enrollment forms among those enrollment forms, beginning around participant number 136 through 212

5. falsified the numbering of the enrollment forms for some individuals who had actually been enrolled to disperse the fabricated enrollment forms among the authentic enrollment forms; Respondent falsified the status of some actual participants to include them in the

intervention group, even though they had not actually received the intervention; Respondent falsified the data on both the enrollment form and the follow-up form for 16 participants between numbers 137 and 198

6. Respondent falsified data on the enrollment forms and follow-up forms for participant numbers 153 and 154 by changing their enrollment numbers.

ORI acknowledges that the Respondent was remorseful.

Ms. Robertson has entered into a Voluntary Settlement Agreement in which she has voluntarily agreed, for a period of three (3) years, beginning on October 14, 2009: (1) to exclude herself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; (2) that any institution that submits an application for PHS support for a research project on which the Respondent's participation is proposed or that uses her in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which she is involved, must concurrently submit a plan for supervision of her duties to the funding agency for approval; the supervisory plan must be designed to ensure the scientific integrity of her research contribution; respondent agreed that she will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI; and (3) that any institution employing her submits, in conjunction with each application for PHS funds or report, manuscript, or abstract of PHS-funded research in which the Respondent is involved, a certification that the data provided by the Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, analyses, and methodology are accurately reported in the application, report, manuscript, or abstract. The Respondent must ensure that the institution sends a copy of the certification to ORI.

Zhong Bin Deng, Medical College of Georgia: Based on the report of an investigation conducted by the Medical College of Georgia (MCG), the report of the MCG Adjudication Subcommittee, additional analysis conducted by ORI in its oversight review, and the Respondent's written and oral admissions and expressed remorse, ORI found that Dr. Zhong Bin Deng, former postdoctoral fellow at MCG in Augusta, GA, engaged in scientific misconduct in research supported by National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), grant 2 P01 AI42288.

ORI found that Dr. Deng engaged in scientific/research misconduct by falsifying research results reported in a paper published in *Nature Medicine*.[1] Specifically:

1. Figures 1 and 2 in the *Nature Medicine* paper purportedly show that the autoimmune regulator Arie controls iNKT cell development and maturation. In Figure 1(a), the Respondent falsified the Aire +/+ (thymus and liver) flow cytometry plots by substituting Aire +/- (thymus and liver) flow cytometry plots that were altered to disguise their origins and falsified the Aire -/- (bone marrow) flow cytometry plot by substituting the Aire +/- (bone marrow) flow cytometry plot, also altered to disguise its origin.

2. In supplementary Figure 2 of the *Nature Medicine* paper, the Respondent falsified flow cytometry plots as follows: (1) in row 1, the Aire -/- (thymus) flow cytometry plot [plot

2] and the Aire +/+ → -/- (thymus) flow cytometry plot [plot 3] are duplicates, thus one of the plots is falsified; (2) in row 2, the Aire -/- (spleen) flow cytometry plot [plot 2] and the Aire -/- → +/+ flow cytometry plot [plot 5] are duplicates, thus one of the plots is falsified; (3) in row 3, the Aire -/- (liver) flow cytometry plot [plot 2] and the Aire +/+ → -/- (liver) flow cytometry plot [plot 3] are duplicates, thus one of the plots is falsified; and (4) in row 4, the Aire -/- (thymus) flow cytometry plot [plot 2] and the Aire +/+ → +/+ flow cytometry plot [plot 4] are duplicates, thus one of the plots is falsified.

Dr. Deng has entered into a Voluntary Settlement Agreement in which he has voluntarily agreed, for a period of two (2) years, beginning on October 2, 2009: (1) that any institution that submits an application for PHS support for a research project on which the Respondent's participation is proposed or that uses him in any capacity on PHS-supported research or that submits a report of PHS-funded research in which he is involved must concurrently submit a plan for supervision of his duties to ORI; the supervisory plan must be designed to ensure the integrity of his research contribution; respondent agreed that he will not participate in any PHS-supported research until such a supervisory plan is approved by ORI; (2) that any institution employing him submits, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS funded research in which the Respondent is involved, a certification to ORI that the data provided by the Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application or report; and (3) to exclude himself from serving in any advisory capacity to the U.S. Public Health Service (PHS), including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

[1.] Mi, Q.-S., Deng, Z.-B., Joshi, S.K., Wang, Z.-Z., Zhou, L., Eckenrode, S., Joshi, R., Ly, D., Yi, B., Delovitch, D.L., & She, J.-X. "The autoimmune regulator 9Aire) controls iNKT cell development and maturation." *Nature Medicine* 12:624-626, 2006; hereafter referred to as the "*Nature Medicine* paper."

Norma Couvertier, APT Foundation: Based on the report of an investigation conducted by the APT Foundation and additional analysis conducted by ORI in its oversight review, ORI found that Norma Couvertier, former Research Assistant II, APT Foundation in New Haven, Connecticut, engaged in research misconduct in research supported by National Institute of Drug Abuse (NIDA), National Institutes of Health (NIH), award R37 DA015969.

Specifically, ORI found that Ms. Couvertier engaged in research misconduct by falsifying and fabricating data that were reported on Participant Urine Monitoring and Breathalyzer Result Forms (CRFs) completed by the Respondent for thirty two (32) of the enrolled study participants in the computer Based Training in Cognitive Behavioral Therapy (CBT4CBT) research study. A total of 253 alcohol breathalyzer (BALS) results were recorded for the 32 participants as being 0.000 indicating no alcohol detected, rather than the code 999 used when no breathalyzer test was done.

ORI also found that Ms. Couvetier, on 253 occasions, with 32 different study participants, falsified alcohol breathalyzer test results and knowingly and consistently entered a false negative test (indicated by 0.000) rather than identifying the result as a missing data collection (indicated by code 999).

ORI acknowledges Ms. Couvetier's verbal admissions and willingness to cooperate and assist during the APT Foundation's investigation.

Ms. Couvertier has entered into a Voluntary Settlement Agreement in which she has voluntarily agreed, for a period of three (3) years, beginning on September 18, 2009: (1) to exclude herself from serving in any advisory capacity to the U.S. Public Health Service (PHS), including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; (2) that any institution that submits an application for PHS support for a research project on which the Respondent's participation is proposed or that uses her in any capacity on PHS-supported research or that submits a report of PHS-funded research in which she is involved must concurrently submit a plan for supervision of her duties to ORI. The supervisory plan must be designed to ensure the integrity of her research contribution. Respondent agreed that she will not participate in any PHS-supported research until such a supervisory plan is approved by ORI.

Nagendra S. Ningaraj, Ph.D., Vanderbilt University School of Medicine: Based on the reports of an investigation conducted by Vanderbilt University School of Medicine (VUSM) and additional analysis by the Division of Investigative Oversight (DIO), ORI, in its oversight review, ORI found that Nagendra S. Ningaraj, Ph.D., former Associate Professor of Neurological Surgery and Cancer Biology, VUSM, engaged in scientific misconduct by falsifying MALDI-MS images and mass spectral tracings and associated text in Figure 21 reported in National Cancer Institute (NCI), National Institutes of Health (NIH), grant application 1 U54 CA119421-01 and by falsifying MALDI-MS images in a presentation during the American Association for Cancer Research (AACR) meeting held on April 16-20, 2005, which cited support from NCI, NIH, grants R25 CA92943 and P50 CA098131. Specifically, ORI found that:

1. Respondent reversed the images for the control and minoxidil-treated brains in Figure 21 of the 1 U54 CA119421-01 grant application, claiming that minoxidil increased delivery of Gleevec to the tumor. Respondent also reversed the same images in a presentation during the AACR meeting in April 2005.

2. In Figure 21 of the 1 U54 CA119421-01 grant application, Respondent reported mass spectral tracings as having been obtained from brain tumors in Gleevec-treated mice that had been pretreated with minoxidil, while in fact they were pretreated with another potassium channel opener, NS1619, and Respondent falsely stated the minoxidil pretreatment caused an 8-fold increase in Gleevec delivery to brain tumors (compared to non-minoxidil pretreated tumors).

3. Respondent further falsified Figure 21 of the 1 U54 CA119421-01 grant application by juxtaposing the reversed MALDI-MS images (obtained with mioxidil) with the mass spectral tracings (obtained with NS1619) in the same figure and by failing to report that the images and spectra in the figure were actually obtained in totally different experiments, performed on different dates and with different K^+ agonist pretreatments.

Dr. Ningaraj has entered into a Voluntary Settlement Agreement in which he has voluntarily agreed, for a period of three (3) years, beginning on August 31, 2009: (1) to be 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; (2) that any institution that submits an application for PHS support for a research project on which the Respondent's participation is proposed or which uses him in any capacity on PHS-supported research or that submits a report of PHS-funded research on which he is involved must submit a plan for supervision of his duties to the funding agency for approval no later than a month before the scheduled funding; the supervisory plan must be designed to ensure the scientific integrity of his research contribution; a copy of the supervisory plan also must be submitted to ORI by the institution; Respondent agreed that he will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI; and (3) Respondent will ensure that any institution employing him submits, in conjunction with each application for PHS funds or any report, manuscript, or abstract of PHS-funded research in which he is involved, a certification that the data provided by him are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application or report. Respondent must ensure that the institution send the certification to ORI. The certification shall be submitted no later than one month before funding and concurrently with any report, manuscript, or abstract.

Jennifer N. Arriaga, Universidad Central Del Caribe: Based on the findings of an investigation report by the Universidad of Central Del Caribe (UCC) and additional analysis and information obtained by the Office of Research Integrity (ORI) during its oversight review, ORI found that Jennifer N. Arriaga, former Research Assistant in a clinical trial project entitled Brief Strategic Family Therapy for Adolescent Drug Abusers (BSFT) at UCC, engaged in research misconduct in research funded by National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH), cooperative agreement U10 DA13720. Specifically, ORI found that Ms. Arriaga knowingly and intentionally engaged in research misconduct by fabricating 17 interviews and falsifying 10 subject incentive receipts in the BSFT. The interview record consisted of Timeline Follow Back information, confidentiality self-report forms, and urine drug test results.

The following administrative actions have been implemented for a period of two (2) years, beginning on August 18, 2009: (1) Ms. Arriaga is debarred from eligibility for any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States pursuant to HHS' Implementation (2 CFR Part 276 *et seq*.) of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (2 CFR Part 180); and (2) Ms. Arriaga is prohibited from serving in any advisory capacity to the U.S. Public Health Service (PHS), including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

Ryan M. Wolfort, M.D., Ph.D., Louisiana State University Health Science Center-Shreveport: Based on the report of an investigation conducted by Louisiana State University Health Sciences Center-Shreveport (LSUHSC-S) and additional analysis conducted by ORI in its

oversight review, the U.S. Public Health Service (PHS) found that Dr. Ryan M. Wolfort, who was a House Officer in the Department of Surgery, and a former graduate student, Department of Molecular and Cellular Physiology, LSUHSC-S, engaged in research misconduct in the reporting of research supported by National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grants R01 HL26441 and P01 HL55552.

Respondent's research misconduct related to his dissertation research as a graduate student, which he undertook at the same time that he also was serving as a House Officer at LSUHSC-S. ORI acknowledges Dr. Wolfort's cooperation with the LSUHSC-S misconduct proceedings.

PHS found that Dr. Wolfort engaged in research misconduct by falsifying and fabricating data reported in three publications[1] and one manuscript[2] that had been submitted for publication, reviewed, and returned for revision. Specifically, Dr. Wolfort falsified and fabricated data reported in research examining the contribution of immune mechanisms to early oxidative stress and endothelial dysfunction in mice with induced dietary hypercholesterolemia by:

1. admittedly fabricating tabulations and the associated statistical analyses of RT-PCR data on Nox-2 mRNA expression in the three publications and the manuscript

2. falsifying data and the associated statistical claims, specifically by (a) admittedly falsifying the measurements of endothelial function by myographic recordings of aortic ring dilation in reaction to vasoactive substances in the three papers and manuscript, (b) admittedly falsifying the measurement of cytokine by cytometric bead assay in paper 3, and (c) falsifying the measurement of superoxide production by cytochrome c reduction in papers 1 and 2, for which the underlying spreadsheet data the Respondent claims were unintentionally misrepresented, massaged, and improperly collated, but for which Respondent acknowledges that the raw data were missing for all three papers, admittedly because he intentionally erased files and discarded notebooks.

Dr. Wolfort has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed, for a period of two (2) years, beginning on July 13, 2009: (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 pursuant to HHS' Implementation (2 CFR Part 276 *et seq.*) of OMB Guidelines to Agencies on Government wide Debarment and Suspension (2 CFR Part 180); and (2) to exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

1. Wolfort, R.M., Stokes, K.Y., & Granger, D.N. "CN4+ T lymphocytes mediate hypercholesterolemia-induced endothelial dysfunction via a NAD(P)H oxidase-dependent mechanism." *Am J Physiol Heart Circ Physiol* 294:H2619-H2626, 2008; hereafter referred to as "paper 1." Identified for retraction.

- Wolfort, R.M., Manriquez, R., Stokes, K.Y., & Granger, D.N. "Platelet-derived RANTES mediates hypercholesterolemia-induced superoxide production and endothelial dysfunction." *Arterioscler. Thromb. Vasc. Biol*. Vol. 28 (pages unavailable), as Epub 2008, July 17; hereafter referred to as "paper 2." Identified for retraction.

- Wolfort, R.M., Stokes, K.Y., & Granger, D.N. "Immune cell-mediated endothelial cell dysfunction during

hypercholesterolemia involves interferon-γ dependent signaling." *Am J Physiol Heart Circ Physiol*, as Epub 2008, September 5; hereafter referred to as "paper 3." Retracted in *Am J Physiol Heart Circ Physiol* 295(5):H2219, 2008 November.

[2] Manuscript submitted to the journal *Free Radicals in Biology and Medicine*, by Ryan M. Wolfort, Katherine C. Wood, Robert P. Hebbel, and Neil Granger, "Mechanisms underlying the vasomotor dysfunction in sickle transgenic mice," Ms Number FRBM-D-08-00454; hereafter referred to as the "*FRBM*" manuscript.

Juan Luis R. Contreras, M.D., University of Alabama at Birmingham: Based on a finding of scientific misconduct made by the University of Alabama at Birmingham (UAB) on January 24, 2008, a report of the UAB Investigation Committee, dated November 21, 2007, and analysis conducted by ORI during its oversight review, and further discussion between UAB and ORI to clarify UAB's investigative findings and decision with respect to the requirements of 42 CFR Parts 50 and 93, the U.S. Public Health Service (PHS) found that Dr. Juan Luis R. Contreras, Assistant Professor, Department of Surgery – Transplantation, UAB, engaged in scientific misconduct in research supported by National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), grants R01 AI22293, R01 AI39793, and U19 AI056542, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH, grant U19 DK57958, and NIH/Novartis Cooperative Research and Development Agreement 96-MH-01 / NIHITC-0697.

PHS found that Respondent engaged in scientific misconduct by falsifying in seven publications reports of research results in NIH-supported experiments with non-human primate (NHP) renal allograft recipients.

Specifically, PHS found that Respondent engaged in scientific misconduct by falsely reporting in five publications[1] that at least 32 specific non-human primates in a renal allo-transplantation study had received bilateral nephrectomies, while in fact an intrinsic kidney was left in place in each animal, and generally, in two additional publications[2] by reporting that all long term surviving non-human primate renal allograft recipients had received bilateral nephrectomies of their native kidneys.

The objective of the research was to test the effectiveness of different immunomodulating agents, administered around the time of renal transplantation in non-human primates, in preventing rejection of the transplanted kidney. To determine whether or not the transplanted kidney was functioning (able to sustain life) after the immunomodulating therapy, the animals were to have both of their native kidneys removed at or shortly after the time of transplant, so that their survival would depend solely on the viability of the transplanted kidney. Failure to remove both native kidneys rendered it impossible to assess the effectiveness of the immunomodulating treatment.

Both Dr. Contreras and PHS were desirous of concluding this matter without further expense of time and other resources, and the parties entered into a Voluntary Exclusion Agreement to settle the matter. Dr. Contreras accepted responsibility for the reporting described above, but denied that he intentionally committed scientific misconduct. The settlement is not an admission of liability on the part of the Respondent.

Dr. Contreras has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed, for a period of three (3) years, beginning on June 17, 2009: (1) to exclude himself voluntarily from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government referred to as "covered transactions" and defined by 2 CFR Parts 180 and 376; 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.

[1] Hutchings, A., Wu, J., Asiedu, C., Hubbard, W., Eckhoff, D., Contreras, J., Thomas, F.T., Neville, D., & Thomas, J.M. "The immune decision toward allograft tolerance in non-human primates requires early inhibition of innate immunity and induction of immune regulation." *Transpl Immunol*. 11(3-4):335-344, July-September 2003. (Retraction required by UAB.)

Thomas, J.M., Eckhoff, D.E., Contreras, J.L., Lobashevsky, A.L., Hubbard, W.J., Moore, J.K., Cook, W.J., Thomas, F.T., & Neville, D.M. Jr. "Durable donor-specific T and B cell tolerance in rhesus macaques induced with peritransplantation anti-CD3 immunotoxin and deoxyspergualin: Absence of chronic allograft nephropathy." *Transplantation* 69(12):2497-2503, June 27, 2000. (Retracted.)

Thomas, J.M., Contreras, J.L., Jiang, X.L., Eckhoff, D.E., Wang, P.X., Hubbard, W.J., Lobashevsky, A.L., Wang, W., Asiedu, C., Stavrou, S., Cook, W.J., Robbin, M.L., Thomas, F.T., & Neville, D.M. Jr. "Peritransplant tolerance induction in macaques: Early events reflecting the unique synergy between immunotoxin and deoxyspergualin." *Transplantation* 68(11):1660-1673, December 15, 1999. (Retracted.)

Contreras, J.L., Eckhoff, D.E., Cartner, S., Frenette, L., Thomas, F.T., Robbin, M.L., Neville, D.M. Jr., & Thomas, J.M. "Tolerability and side effects of anti-CD3-immunotoxin in preclinical testing in kidney and pancreatic islet transplant recipients." *Transplantation* 68(2):215-219, July 27, 1999. (Retracted.)

Contreras, J.L., Wang, P.X., Eckhoff, D.E., Lobashevsky, A.L., Asiedu, C., Frenette, L., Robbin, M.L., Hubbard, W.J., Cartner, S., Nadler, S., Cook, W.J., Sharff, J., Shiloach, J., Thomas, F.T., Neville, D.M. Jr., & Thomas, J.M. "Peritransplant tolerance induction with anti-CD3-immunotoxin: A matter of proinflammatory cytokine control." *Transplantation* 65(9):1159-1169, May 15, 1998. (Retracted.)

[2] Hubbard, W.J., Eckhoff, D., Contreras, J.L., Thomas, F.T., Hutchings, A., & Thomas, J.M. "STEALTH on the preclinical path to tolerance." *Graft* 5(6):322-330, 2002. (Retraction required by UAB – Journal has ceased publication.)

Judith M. Thomas, Ph.D., University of Alabama at Birmingham: Based on a finding of scientific misconduct made by the University of Alabama at Birmingham (UAB) on January 24, 2008, a report of the UAB Investigation Committee, dated November 21, 2007, and additional analysis conducted by ORI during its oversight review, the U.S. Public Health Service (PHS) found that Dr. Judith M. Thomas, former Professor of Surgery, UAB, engaged in scientific misconduct in research supported by National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), grants R01 AI22293, R01 AI39793, and U19 AI056542, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH, grant U19 DK57958, and NIH/Novartis Cooperative Research and Development Agreement 96-MH-01 / NIHITC-0697.

The objective of the research was to test the effectiveness of different agents, such as Immunotoxin FN18-CRM9 or 15-deoxyspergualin (15-DSG), administered around the time of

renal transplantation in non-human primates, in preventing rejection of the transplanted kidney. To determine whether or not the transplanted kidney was functioning (able to sustain life) after the immunomodulating therapy, the animals were to have both of their native kidneys removed at or shortly after the time of transplant, so that their survival would depend solely on the viability of the transplanted kidney. It was postulated that the use of immunomodulating agents would increase tolerance of the host animal to the grafted kidney and thus eliminate the necessity for chronic administration of immunosuppressive medications commonly required to prevent rejection in renal transplant recipients. . Failure to remove both native kidneys would render it impossible to assess the effectiveness of the immunomodulating treatment, and could give totally misleading results, suggesting that the treatment worked while in fact survival was due entirely to the remaining native kidney.

PHS found that Respondent engaged in scientific misconduct by falsifying reports of research results in NIH-supported experiments with non-human primate (NHP) renal allograft recipients in 15 publications and in progress reports in two NIH research grant applications. Specifically, PHS found that:

1. Respondent falsely reported in 15 publications that NHP renal allograft recipients had received bilateral nephrectomies of their native kidneys, while in fact many of the animals retained an intrinsic kidney. Specifically:

    A. Respondent falsely reported in eight publications[1] that at least 32 specific NHPs in a renal allotransplantation study had received bilateral nephrectomies, while in fact an intrinsic kidney was left in place in each animal, and generally, in seven additional publications,[2] Respondent falsely reported that all long term surviving NHP renal allograft recipients had received bilateral nephrectomies of their native kidneys. The publications referenced are listed separately in the endnotes.

2. In seven publications,[3] Respondent falsely reported immunomodulating treatments given to NHP renal allograft recipients by not reporting the administration of donor bone marrow to seven recipients and not reporting administration of cyclosporine A to four recipients. She also falsely reported (by overstating by 15%) dosages of the immunomodulating agents that were given and/or duration by overstating the exceptional briefer duration of immunomodulating treatment given to four recipients and cited in at least eight publications.[4]

3. In progress reports for NIH research awards R01 AI39793 and U19 DK57958, Respondent falsely claimed that long term surviving (LTS) NHP renal allotransplantation recipients had received bilateral nephrectomies and falsely reported the immunomodulating therapies received by the graft recipients. Specifically:

    A. In the progress report in application 5 R01 AI39793-04, submitted in approximately May 1999, Respondent repeated falsified claims of successful LTS NHP allografts by citing two publications (*Transplantation* 68:1660-1673, 1999 and *Transplantation* 68:215-219, 1999) that reported LTS in renal allograft recipients that were falsely reported to have had bilateral intrinsic nephrectomies, while laboratory

records showed that at the most four of these animals had bilateral nephrectomies.

B. In the progress report in application 5 U19 DK57958-02 submitted in approximately May 2000, Respondent falsely reported that 10/13 LTS NHP renal allograft recipients had received bilateral nephrectomies of their native kidneys and falsified the immunomodulating treatment received by four of the animals by failing to report the administration of cyclosporine A (CSA) or donor bone marrow.

For the same award, in a progress report submitted in approximately May 2002, Respondent falsely reported that all of the 16 animals in the rhesus Ktx (kidney transplant) series had bilateral nephrectomies of their native kidneys, but in fact at least nine of the animals did not have the requisite bilateral nephrectomies.

In a competing renewal application 2 U19 DK057958-05, submitted on about 03/10/2003, Respondent reported that 14 Ktx long term survivors did not have an intrinsic kidney, while in fact at least 11 of those animals had a remaining intrinsic kidney.

Both Dr. Thomas and PHS were desirous of concluding this matter without further expense of time and other resources, and the parties entered into a Voluntary Exclusion Agreement to settle the matter. Dr. Thomas accepted responsibility for the reporting described above, but denied that she intentionally committed research misconduct. The settlement is not an admission of liability on the part of the Respondent.

Dr. Thomas has entered into a Voluntary Exclusion Agreement in which she has voluntarily agreed, for a period of ten (10) years, beginning on May 5, 2009: (1) to exclude herself voluntarily from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government referred to as "covered transactions" and defined by 2 CFR Parts 180 and 376; and (2) to exclude herself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

1. Asiedu, C.K., Dong, S.S., Lobashevsky, A., Jenkins, S.M., & Thomas, J.M. "Tolerance induced by anti-CD3 immunotoxin plus 15-deoxyspergualin associates with donor-specific indirect pathway unresponsiveness." *Cell Immunol.* 223(2):103-112, June 2003. (Retraction required by UAB.)

Hutchings, A., Wu, J., Asiedu, C., Hubbard, W., Eckhoff, D., Contreras, J., Thomas, F.T., Neville, D., & Thomas, J.M. "The immune decision toward allograft tolerance in non-human primates requires early inhibition of innate immunity and induction of immune regulation." *Transpl Immunol*. 11(3-4):335-344, July-September 2003. (Retraction required by UAB.)

Lobashevsky, A.L., Jiang, X.L., & Thomas, J.M. "Allele-specific *in situ* analysis of microchimerism by fluorescence resonance energy transfer (FRET) in nonhuman primate tissues." *Hum Immunol*. 63(2):108-120, February 2002. (Retraction required by UAB.)

Thomas, J.M., Eckhoff, D.E., Contreras, J.L., Lobashevsky, A.L., Hubbard, W.J., Moore, J.K., Cook, W.J., Thomas, F.T., & Neville, D.M. Jr. "Durable donor-specific T and B cell tolerance in rhesus macaques induced with

peritransplantation anti-CD3 immunotoxin and deoxyspergualin: Absence of chronic allograft nephropathy." *Transplantation* 69(12):2497-2503, June 27, 2000. (Retracted.)

Thomas, J.M., Contreras, J.L., Jiang, X.L., Eckhoff, D.E., Wang, P.X., Hubbard, W.J., Lobashevsky, A.L., Wang, W., Asiedu, C., Stavrou, S., Cook, W.J., Robbin, M.L., Thomas, F.T., & Neville, D.M. Jr. "Peritransplant tolerance induction in macaques: Early events reflecting the unique synergy between immunotoxin and deoxyspergualin." *Transplantation* 68(11):1660-1673, December 15, 1999. (Retracted.)

Contreras, J.L., Eckhoff, D.E., Cartner, S., Frenette, L., Thomas, F.T., Robbin, M.L., Neville, D.M. Jr., & Thomas, J.M. "Tolerability and side effects of anti-CD3-immunotoxin in preclinical testing in kidney and pancreatic islet transplant recipients." *Transplantation* 68(2):215-219, July 27, 1999. (Retracted.)

Contreras, J.L., Wang, P.X., Eckhoff, D.E., Lobashevsky, A.L., Asiedu, C., Frenette, L., Robbin, M.L., Hubbard, W.J., Cartner, S., Nadler, S., Cook, W.J., Sharff, J., Shiloach, J., Thomas, F.T., Neville, D.M. Jr., & Thomas, J.M. "Peritransplant tolerance induction with anti-CD3-immunotoxin: A matter of proinflammatory cytokine control." *Transplantation* 65(9):1159-1169, May 15, 1998. (Retracted.)

[2.] Thomas, J.M., Hubbard, W.J., Sooudi, S.K., & Thomas, F.T. "STEALTH matters: A novel paradigm of durable primate allograft tolerance." *Immunol Rev*. 183:223-233, October 2001. Review. (Retracted.)

Thomas, F., Ray, P., & Thomas, J.M. "Immunological tolerance as an adjunct to allogeneic tissue grafting." *Microsurgery* 20(8):435-440, 2000. (Retraction required by UAB.)

Hutchings, A., & Thomas, J.M. "Transplantation: Tolerance." *Current Opinion in Investigational Drugs* 4(5):530-535, 2003. (Retraction required by UAB.)

Hubbard, W.J., Eckhoff, D., Contreras, J.L., Thomas, F.T., Hutchings, A., & Thomas, J.M. "STEALTH on the preclinical path to tolerance." *Graft* 5(6):322-330, 2002. (Retraction required by UAB – Journal has ceased publication.)

Hutchings, A., Hubbard, W.J., Thomas, F.T., & Thomas, J.M. "STEALTH in transplantation tolerance." *Immunologic Res*. 26:143-152, 2002. (Retracted.)

Thomas, J.M., Asiedu, C., George, J.F., Hubbard, W.J., & Thomas, F.T. "Preclinical bridge to clinical tolerance." *Current Opinion in Organ Transplantation* 6:95-101, 2001. (Retraction required by UAB.)

[3.] Asiedu, C.K., Dong, S.S., Lobashevsky, A., Jenkins, S.M., & Thomas, J.M. "Tolerance induced by anti-CD3 immunotoxin plus 5-deoxyspergualin associates with donor-specific indirect pathway unresponsiveness." *Cell Immunol*. 223(2):103-112, June 2003. (Retraction required by UAB.)

Hutchings, A., Wu, J., Asiedu, C., Hubbard, W., Eckhoff, D., Contreras, J., Thomas, F.T., Neville, D., Thomas, J.M. "The immune decision toward allograft tolerance in non-human primates requires early inhibition of innate immunity and induction of immune regulation." *Transpl Immunol*. 11(3-4):335-344, July-September, 2003. (Retraction required by UAB.)

Thomas, J.M., Eckhoff, D.E., Contreras, J.L., Lobashevsky, A.L., Hubbard, W.J., Moore, J.K., Cook, W.J., Thomas, F.T., & Neville, D.M. Jr. "Durable donor-specific T and B cell tolerance in rhesus macaques induced with peritransplantation anti-CD3 immunotoxin and deoxyspergualin: Absence of chronic allograft nephropathy." *Transplantation* 69(12):2497-2503, June 27, 2000. (Retracted.)

Thomas, J.M., Contreras, J.L., Jiang, X.L., Eckhoff, D.E., Wang, P.X., Hubbard, W.J., Lobashevsky, A.L., Wang, W., Asiedu, C., Stavrou, S., Cook, W.J., Robbin, M.L., Thomas, F.T., & Neville, D.M. Jr. "Peritransplant tolerance induction in macaques: Early events reflecting the unique synergy between immunotoxin and deoxyspergualin." *Transplantation* 68(11):1660-1673, December 15, 1999. (Retracted.)

Contreras, J.L., Eckhoff, D.E., Cartner, S., Frenette, L., Thomas, F.T., Robbin, M.L., Neville, D.M. Jr., & Thomas, J.M. "Tolerability and side effects of anti-CD3-immunotoxin in preclinical testing in kidney and pancreatic islet transplant recipients." *Transplantation* 68(2):215-219, July 27, 1999. (Retracted.)

Contreras, J.L., Wang, P.X., Eckhoff, D.E., Lobashevsky, A.L., Asiedu, C., Frenette, L., Robbin, M.L., Hubbard, W.J., Cartner, S., Nadler, S., Cook, W.J., Sharff, J., Shiloach, J., Thomas, F.T., Neville, D.M. Jr., & Thomas, J.M. "Peritransplant tolerance induction with anti-CD3-immunotoxin: A matter of proinflammatory cytokine control." *Transplantation* 65(9):1159-1169, May 15, 1998. (Retracted.)

4. Includes those cited in Endnote 3 plus:

Jennifer Wanchick, MetroHealth System: Based on reports submitted by MetroHealth System's inquiry and investigation committees, the Respondent's own repeated admissions, and additional analysis conducted by ORI during its oversight review, the U.S. Public Health Service (PHS) found that Ms. Jennifer Wanchick, former Research Assistant, MetroHealth System (an affiliated hospital of Case Western Reserve University), engaged in research misconduct in research supported by National Center on Minority Health and Health Disparities (NCMHD), National Institutes of Health (NIH), grant P60 MD002265.

Specifically, by her own admission, Ms. Wanchick engaged in research misconduct by fabricating information in the electronic database purportedly collected from 150 individuals about their willingness to sign up to be an organ donor at the time they obtained a driver's license. Ms. Wanchick also admitted to fabricating the information on several survey instruments. The study at issue was entitled "Community Based Intervention to Enhance Signing of Organ Donor Cards."

ORI acknowledges Ms. Wanchick's cooperation and assistance in completing its oversight review and resolution of this matter.

Ms. Wanchick has entered into a Voluntary Settlement Agreement in which she has voluntarily agreed, for a period of three (3) years, beginning on June 5, 2009: (1) to exclude herself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and (2) that any institution that submits an application for PHS support for a research project on which the Respondent's participation is proposed or that uses the Respondent in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which the Respondent is involved, must concurrently submit a plan for supervision of the Respondent's duties to the funding agency for approval. The supervisory plan must be designed to ensure the research integrity of the Respondent's research contribution. Respondent agrees to ensure that a copy of the supervisory plan also is submitted to ORI by the institution. Respondent agrees that she will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI.

Robert B. Fogel, M.D., Harvard Medical School and Brigham and Women's Hospital: Based on information that the Respondent volunteered to his former mentor on November 7, 2006, and detailed in a written admission on September 19, 2007, and the Office of Research Integrity's (ORI) review of Joint Inquiry and Investigation reports by Harvard Medical School (HMS) and the Brigham and Women's Hospital (BWH), the U.S. Public Health Service (PHS) found that Dr. Robert B. Fogel, former Assistant Professor of Medicine and Associate Physician

at HMS, and former Co-Director of the Fellowship in Sleep Medicine at BWH, engaged in scientific misconduct in research supported by National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), awards P50 HL60292, R01 HL48531, K23 HL04400, and F32 HL10246, and National Center for Research Resources (NCRR), NIH, award M01 RR02635.

PHS found that Respondent engaged in scientific misconduct by falsifying and fabricating baseline data from a study of sleep apnea in severely obese patients published in the following paper: Fogel, R.B., Malhotra, A., Dalagiorgou, G., Robinson, M.K., Jakab, M., Kikinis, R., Pittman, S.D., and White, D.P. "Anatomic and physiologic predictors of apnea severity in morbidly obese subjects." *Sleep* 2:150-155, 2003 (hereafter referred to as the "*Sleep* paper"); and in a preliminary abstract reporting on this work. Specifically, PHS found that for the data reported in the *Sleep* paper, the Respondent:

1. changed/falsified roughly half of the physiologic data

2. fabricated roughly 20% of the anatomic data that were supposedly obtained from Computed Tomography (CT) images

3. changed/falsified 50 to 80 percent of the other anatomic data

4. changed/falsified roughly 40 to 50 percent of the sleep data so that those data would better conform to his hypothesis.

Respondent also published some of the falsified and fabricated data in an abstract in *Sleep* 24, Abstract Supplement A7, 2001.

Dr. Fogel has entered into a Voluntary Settlement Agreement in which he has voluntarily agreed, for a period of three (3) years, beginning on March 16, 2009: (1) to exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; (2) that any institution that submits an application for PHS support for a research project on which the Respondent's participation is proposed or that uses the Respondent in any capacity on PHS supported research, or that submits a report of PHS-funded research in which the Respondent is involved, must concurrently submit a plan for supervision of the Respondent's duties to the funding agency for approval; the supervisory plan must be designed to ensure the scientific integrity of the Respondent's research contribution; a copy of the supervisory plan must also be submitted to ORI by the institution; the Respondent agrees that he will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI; and (3) to ensure that any institution employing him submits, in conjunction with each application for PHS funds or report, manuscript, or abstract of PHS-funded research in which the Respondent is involved, a certification that the data provided by the Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application or report. The Respondent must ensure that the institution sends the certification to ORI.

Kazuhiro Tanaka, M.D., Ph.D., National Institute of Dental and Craniofacial Research, National Institutes of Health: Based on the report of an investigation conducted by the National Institutes of Health (NIH) and additional analysis conducted by the Office of Research Integrity (ORI) in its oversight review, the U.S. Public Health Service (PHS) found that Dr. Kazuhiro Tanaka, former Visiting Postdoctoral Fellow, Molecular Biology Section, Craniofacial Developmental and Biology and Regeneration Branch (CDBRB), National Institute of Dental and Craniofacial Research (NIDCR), NIH, engaged in scientific misconduct in research supported by PHS funds from the NIDCR, NIH Intramural Program.

PHS found that Respondent engaged in scientific misconduct by falsifying data that were included in three published papers: Kazuhiro Tanaka, Yoshihiro Matsumoto, Fumihiko Nakatani, Yukihide Iwamoto, and Yoshihiko Yamada, "A zinc finger transcription factor, αA-crystallin binding protein 1, is a negative regulator of the chondrocyte-specific enhancer of the α1(II) collagen gene," *Molecular and Cellular Biology* (*MCB*) 20:4428-4435, 2000; Kazuhiro Tanaka, Noriyuki Tsumaki, Christine A. Kozak, Yoshihiro Matsumoto, Fumihiko Nakatani, Yukihide Iwamoto, and Yoshihiko Yamada, "A Krüppel-associated box-zinc finger protein, NT2, represses cell-type-specific promoter activity of the α2(XI) collagen gene,"*Molecular and Cellular Biology* 22:4256-4267, 2002; and Ying Liu, Haochuan Li, Kazuhiro Tanaka, Noriyuki Tsumaki, and Yoshihiko Yamada, "Identification of an enhancer sequence with the first intron required for cartilage-specific transcription of the α2(XI) collagen gene," *Journal of Biological Chemistry* (*JBC*) 275:12712-12718, 2000. Specifically, PHS found that Respondent:

1. falsified the results for CRYBP1 or Sox9 binding to the Col2a1 DNA sequence in electrophoretic mobility shift assays in Figure 1D and Figure 7 in *MCB* 20:4428-4435, 2000. He used duplicate copies of bands or duplicate copies of parts of lanes to falsely represent results from reportedly different experimental conditions;

2. falsified the results for NT2 binding to the Col11a2 DNA sequence in electrophoretic mobility shift assays in Figures 2D and 6B, and falsified the Western blot for NT2 mutant proteins in Figure 8B in *MCB* 22:4256-4267, 2002. He used duplicate copies of bands, parts of bands, or duplicate copies of parts of lanes to falsely represent results from reportedly different experimental conditions in Figures 2D and 6B; and falsely represented results for the Figure 8B Western blot by using duplicate copies of bands to represent NT2△1 (lane 2) and NT2△4 (lane 5) mutant proteins;

3. falsified the Western blot for Sox9 protein expression in Figure 4B, *JBC* 275:12712-12718, 2000, by using duplicate copies of lanes 1 and 2 to represent the Sox9 expression in cell extracts from both Balb 3T3 and undifferentiated ATDC5 cells; and

4. falsified the Northern blots in multiple panels of Figure 3, *MCB* 20:4428-4435, 2000. He used duplicate copies of bands for CRYBP1, for Type II collagen, for Type X collagen, and for GAPDH and 18S EtBr stained control bands to falsely represent results of RNA expression from these different genes in ATDC5 cells. He also used duplicate copies of

bands to falsely represent the RNA expression in ATDC5 cells grown under different conditions for either collagen Type II in Figure 3, *MCB* 2000 or collagen α1(X) in Figure 5 in *MCB* 22:4256-4267, 2002. Similarly, duplicate copies of 18S EtBr stained control bands were used in both figures with reportedly different experimental conditions.

Both Respondent and PHS are desirous of concluding this matter without further expense of time and other resources, and the parties have entered into a Voluntary Exclusion Agreement (Agreement). The settlement is not an admission of liability on the part of the Respondent. Respondent neither admits nor denies ORI's finding of scientific misconduct. Respondent acknowledges that original data relating to the above referenced falsified figures are missing.

Dr. Tanaka has voluntarily agreed, for a period of three (3) years, beginning on January 14, 2009: (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 Government wide Debarment and Suspension (2 CFR Part 180); and (2) to exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.