Office of Research Integrity

Annual Report 2002

November 2003

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

Table of Contents

Highlights of 2002 ORI Annual Report

The Office of Research Integrity (ORI) is a component of the Office of Public Health and Science (OPHS) which is in the Office of the Secretary (OS) within the Department of Health and Human Services (HHS). The ORI mission focuses on (1) oversight of institutional handling of research misconduct allegations, (2) education in the responsible conduct of research (RCR), (3) reduction of research misconduct, and (4) compliance with the PHS regulation, 42 C.F.R. Part 50, Subpart A.

Regulations and Policies

- Submitted a draft of revised Public Health Service (PHS) misconduct regulations to OPHS and OS for review.

- Contributed to an NPRM to revise the regulations on the Governmentwide Nonprocurement Common Rule for debarment and suspension that was published in 2002 (67 Fed. Reg. 3266). ORI pursues more debarment cases than any other office in HHS.

- Completed deliberations and consultations on the suspended PHS Policy on Instruction in the Responsible Conduct of Research. ORI expects to recommend a course of action to OPHS and OS in 2003.

Responding to Research Misconduct Allegations

- Opened 41 new cases in 2002, closed 32 cases, and carried 50 cases into 2003. The number of new cases and the number of cases forwarded to the next year are the highest since 1995. The number of allegations (191) received by ORI has also remained up for the last 2 years, about 10-13 percent over the preceding years.

- Found research misconduct in 13 of the 32 closed cases. All misconduct findings involved falsification and/or fabrication. Seven respondents made formal admissions of their misconduct; one respondent admitted to misconduct at two different institutions where he had been a graduate student and a postdoctoral fellow, respectively. The percentage of closed cases yielding PHS misconduct findings and administrative actions this year (41 percent) like last year (56 percent), continued to be higher than the historical average

(33 percent). About 80 percent of the cases pending in ORI with institutional determinations involve scientific misconduct findings.

- Recommended the following administrative actions to the Assistant Secretary for Health (ASH): debarment or voluntary exclusion for 3 to 5 years, 8 respondents; prohibition from serving as an advisor to Public Health Service (PHS) for 3 to 5 years, 13 respondents; supervision for 3 years, 3 respondents; certification of data provided in applications to the PHS, 1 respondent, and retraction of articles, 6 respondents. The recommended actions were approved by the ASH.

- Completed the 32 cases expeditiously (mean, 7 months; median, 6 months; range 1 to 27 months.) Institutions took a mean of 11 months after their notification of ORI (median, 17 months; range, 1 to 74 months) to complete their actions. ORI reviews the institutional reports, obtains additional information from the institution, completes the ORI analysis, negotiates any PHS findings and administrative actions, and closes the cases.

- Provided technical assistance to officials at 25 institutions responding to research misconduct allegations in 2002 through the Rapid Response for Technical Assistance (RRTA) program. ORI provided RRTA to institutional officials during the early stages of 10 of the 32 cases closed in 2002.

Education and Prevention

- Established the Responsible Conduct of Research (RCR) Resource Development Program to facilitate the creation of instructional materials for teaching the responsible conduct of research. Thirteen projects were supported in 11 universities and 2 commercial firms. The program is administered electronically.

- Initiated a collaborative agreement with the Association of American Medical Colleges (AAMC) to develop an RCR Program for Academic Societies to encourage those organizations to undertake activities aimed at promoting the responsible conduct of research in their respective disciplines. Awards were made to four academic societies.

- Expanded the ORI electronic communication system by adding a new network containing the e-mail addresses for 39,000 principal investigators supported by the National Institutes of Health.

- Developed an *ORI Introduction to the Responsible Conduct of Research* to provide small and mid-sized institutions and organizations that have few PHS-supported researchers with a text that covers the nine core RCR instructional areas. Copies will be mailed in 2003 to each of the 4,000 institutions and organizations that has an assurance on file with ORI.

- Collaborated with the National Institutes of Health (NIH) to develop a plan for an ongoing evaluation of the RCR education requirement that has been in National Research Service Award (NRSA) Institutional Research Training Awards since 1990.

- Co-sponsored nine conferences/workshops on RCR, research integrity, and research misconduct with four universities, a medical school, a research foundation, four professional associations, and three government agencies.

- Made 59 presentations at conferences, workshops, annual meetings, and seminars and published 3 journal articles.

Research on Research Integrity and Research Misconduct

- Distributed more than 2,000 copies of the Institute of Medicine (IOM) report, *Integrity in Scientific Research: Creating an Environment that Promotes Responsible Conduct*, to universities, medical schools, colleges, research centers, and hospitals that conduct PHS supported research. ORI commissioned the study in September 2000.

- Completed a content analysis of journal instructions to authors that suggests those instructions can be more effectively used to promote RCR.

- Completed a feasibility study that indicates ORI should develop a registry of advisors and institutions experienced with inquiries and investigations as a resource to assist institutions to respond to research misconduct allegations rather than support the development of consortia to do so.

- Awarded 10 grants through the Research on Research Integrity (RRI) Program that is supported by ORI, the National Institute of Neurological Disorders and Stroke and the National Institute of Nursing Research. Seven awards were made in the first year of the program.

- Organized the second Research Conference on Research Integrity to stimulate the development of a cadre of researchers focused on RCR, research integrity and research misconduct.

Institutional Compliance

- Converted to electronic administration of the Assurance Program. About 90 percent of all communications with institutions in the Assurance Program is done electronically.

- Completed the 2001 Annual Institutional Report on Possible Research Misconduct in which institutions reported increased misconduct activity for the third consecutive year. Sixty-one institutions reported opening 72 new scientific misconduct cases in response to 127 allegations.

- Inactivated assurances for 651 institutions for failing to submit the calendar year (CY) 2001 Annual Institutional Report on Possible Research Misconduct.

- Processed 198 institutional policies on handling allegations of research misconduct, requested 166 institutional policies for review, and increased the number of completed reviews to 1,769.

Information and Privacy

- Handled 54 FOIA requests; 51 new requests and 3 carry-overs from 2001. Fifty-three requests were completed; 1 was forwarded to 2003. The response rate ranged from 1 to 161 days (due to an appeal and acquiring documents from another agency). The median was 14 days; mode was 4 days; and the mean was 21 days.

- Responded to 11 Privacy Act requests in 2002; a total of 8 requests were received in the previous 3 years. All requests were completed in the year of receipt; none were carried into the next year. The average response rate was 4.5 days.

I. Regulations and Policies

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ORI took several actions in 2002 to revise and develop the regulatory and policy infrastructure that provides the authority for its functions and guidance to institutions and organizations for complying with the regulatory requirements.

Revised PHS Misconduct Regulations

A draft of revised PHS misconduct regulations was submitted to Office of Public Health and Science (OPHS) and the Office of the Secretary (OS) for review in 2002. The revised regulation incorporates the new Federal definition of misconduct and policies published by the Office of Science and Technology Policy in December 2000, formally adopts the policy changes made by the Department in 1999, and updates the regulation based on the past 10 years experience in implementing it.

Governmentwide Suspension and Debarment NPRM

A Notice of Proposed Rulemaking (NPRM) to revise the regulations on the Governmentwide Nonprocurement Common Rule for debarment and suspension was published in early 2002, 67 Fed. Reg. 3266 (2002). ORI pursues more debarment cases than any other office within the Department of Health and Human Services (HHS), and an attorney in ORI's Research Integrity Branch of the Office of the General Counsel played a key role in drafting the revision. Most of the substantive changes have to do with nonprocurement activities that focus on relationships between awarding agencies and institutions receiving awards, rather than ORI or the debarred individual.

Responsible Conduct of Research Policy

ORI completed its deliberations and consultations on the suspended PHS Policy on Instruction in the Responsible Conduct of Research. ORI expects to recommend a course of action to OPHS and OS in 2003.

A draft of revised PHS misconduct regulations was submitted to Office of Public Health and Science (OPHS) and the Office of the Secretary (OS) for review in 2002.

Regulation to Protect Whistleblowers

An NPRM was published in 2000 to implement Section 493(e) of the PHS Act, which requires the Secretary to establish regulatory standards for preventing and responding to occurrences of retaliation taken against whistleblowers by entities which have a research misconduct assurance. Under the NPRM, the entities, their officials and agents would be prohibited from retaliating against an employee with respect to the terms and conditions of employment when the employee has in good faith (1) made an allegation that the entity or its officials or agents, has engaged in, or failed to respond adequately to an allegation of research misconduct, or (2) cooperated with an investigation of such an allegation. The public comment period closed in 2001. Final adoption of the regulation has been postponed pending publication of the revised PHS misconduct regulations.

Policy Guidance and Technical Advice

To help provide guidance to individuals and institutional officials responsible for handling misconduct allegations, significant issues raised during ORI's oversight of institutional investigations are discussed and ORI's position explained in occasional articles in ORI's quarterly newsletter.

Two articles providing policy guidance or technical advice were published in the *ORI Newsletter* during 2002, and are reprinted below. A compilation of ORI's policies on 28 significant issues may be found at **http://ori.dhhs.gov/html/misconduct/inquiry_issues.asp**

1. Can Survey Research Staff Commit Scientific Misconduct?

Can fabrication or falsification of data by lower-level staff who conduct surveys or interviews or administer questionnaires with human subjects constitute scientific misconduct? The answer is "yes."

The Public Health Service (PHS) has made findings of scientific misconduct in several ORI cases involving this type of data These misconduct cases involved the acquisition of data through questionnaires or interviews, administered face-to-face, over the telephone, or through the use of a computer interface. The data were used in a variety of research situations, ranging from epidemiological studies of diseases to the assessment of the effectiveness of therapeutic interventions, or of health services delivery systems.

Since questionnaires are often administered by individuals who are not members of the faculty or the professional senior research staff, institutional officials have questioned whether these individuals were actually members of the "scientific community" subject to PHS regulations on scientific misconduct.

The PHS regulations apply to any individual involved in proposing, conducting, or reporting research supported by PHS funds or proposed in applications for PHS funds, regardless of their position.

For ORI, the question is whether it is an allegation of scientific misconduct that falls under the PHS definition in 42 C.F.R. Part 50, Subpart A.

Institutional officials have also asked ORI about the relationship of common "data quality control" problems and possible scientific misconduct-that organizations involved in the conduct of surveys expect a certain incidence of "curbstoning" (i.e., fabrication or falsification of data "on the street"). When detected by regular "quality control" measures, the problem is often handled by purging the tainted data from the database.

Such "quality control" measures may serve a preventive and a detection function and ORI encourages their continued use. However, the data should not be destroyed because it might provide evidence of research misconduct. When evidence of intentional fabrication or falsification of data in PHS-related research is detected in this way, the institutions should handle the case through the normal procedures for dealing with PHS scientific misconduct. Any investigative findings in these cases must be reported to ORI as required by PHS regulations.

2. Assessing Scientific Misconduct Allegations Involving Clinical Research

An allegation of wrongdoing in research involving human subjects must be assessed to determine under which Public Health Service (PHS) regulation or policy it should be handled. For ORI, the question is whether it is an allegation of scientific misconduct that falls under the PHS definition in 42 C.F.R. Part 50, Subpart A. The following are examples of falsification and fabrication that have formed the basis for PHS findings of scientific misconduct in clinical research. Generally, these incidents occurred in the context of conducting clinical research or reporting data (internally or externally), publishing data or results, or including data or research records in grant applications or progress reports.

Falsification

- substituting one subject's record for that of another subject;
- falsely reporting to a data coordinating center that certain clinical trial staff, who were certified to perform the procedures on the subjects, had done so, when they had not;

- altering the dates and results from subjects' eligibility visits;

- altering the dates on patient screening logs and/or submitting the same log with altered dates on multiple occasions;

- failing to update the patients' status and representing data from prior contacts as being current;

- altering the results of particular tests on blood samples to show that the test accurately predicted a disease or relapse;

- backdating follow-up interviews to fit the time window determined by the study protocol; and

- falsifying the times that blood samples were drawn from human subjects.

Fabrication

- creating records of interviews of subjects that were never performed;

- making up progress notes for patient visits that never took place and inserting them into the medical record to support published and unpublished research reports; and

- preparing records for calls and follow-up contacts to subjects who had already died.

PHS scientific misconduct regulations generally do **not** supersede or create an alternative to the established procedures for resolving fiscal or criminal improprieties or cases of abuse of animal and human subjects. In the absence of evidence of falsification or fabrication of the research record as described

above, the following problems would be forwarded to the appropriate agency, such as the Food and Drug Administration (FDA) and/or the Office for Human Research Protections (OHRP), would **not** be considered as scientific misconduct by ORI:

- failing to report an adverse event with a patient to the sponsor or the Institutional Review Board (IRB);
- deviating from the protocol (e.g., entering an ineligible subject in a trial, or administering an off-protocol drug);
- forging a physician's signature on medical orders;
- failing to obtain or properly document, informed consent;
- breaching human subject confidentiality; and
- failing to obtain IRB and/or FDA approval for changes implemented in an approved protocol.

II. Responding to Research Misconduct Allegations

ORI maintains oversight of institutional handling of research misconduct allegations through its Division of Investigative Oversight (DIO).

Allegations

ORI staff assess each allegation received by ORI to determine whether it meets the criteria for opening a formal case in ORI. These criteria are:

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

ORI searches agency computer records as well as publications involving the respondent for potentially-related 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 meet the definition of scientific misconduct set forth in the PHS regulation (42 C.F.R. Part 50, Subpart A).

ORI assesses whether the action reported, if found to be true, would represent "fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research."

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 this definition. If the allegation involves possible financial misconduct, other regulatory violations, criminal acts, or civil matters (such as harassment claims), ORI refers the allegation to another appropriate Federal office or agency.

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

ORI may request that the person who initiated the allegation provide further information or documentation to ORI. However, if an allegation is made anonymously or there is not adequate information available to proceed, ORI initiates a tracking file and waits to see whether additional information is forthcoming or can be requested from the complainant or other sources.

ORI's review of information available (such as grant applications, review summary statements, or correspondence with the funding agency) may result in a simple resolution of the allegation. Some allegations are found to have arisen because of a misunderstanding or incomplete information being available to the complainant. However, substantive allegations that meet the above three criteria will lead ORI to request an institution to conduct an inquiry (or may lead ORI to refer the allegation to the Office of Inspector General).

Although typically only about 15-20 percent of the allegations received by ORI result in a formal case being opened, ORI carefully evaluates all the allegations received and considers an appropriate disposition. In some instances, ORI requests preliminary information about a case from an institution. Many assessments require appreciable ORI staff work at this phase.

In 2002, ORI received 191 allegations. The disposition of the allegations received by ORI are presented in Table 1. Allegations become active cases when the criteria outlined above are met. Some allegations are administratively closed when ORI finds that (1) they do not fall under ORI jurisdiction or meet these criteria, (2) cannot be referred to another agency, or (3) are resolved through further review and information. Other allegations are referred to other Federal agencies or offices when they involve concerns about the use of humans or animals in research, financial issues, research funded or regulated by other agencies, etc. No action is possible for ORI if an allegation contains insufficient specific information to permit another disposition.

Table 1: Disposition of Allegations in ORI, 2002

Handling of allegations - outcome in ORI	*Number of allegations*
Pre-Inquiry Assessment by ORI of allegations:	
That were made to ORI directly	40
That were made to NIH initially	14
No Action Possible Now or No Action	114
Referred to other Federal agencies	20
Handled by NIH (for other allegations made to NIH)	3
TOTAL	191

Of the 191 allegations made to ORI in 2002, 54 were assessed in detail for a potential inquiry or investigation. Of the 191 allegations, 20 were immediately referred to other agencies, and 114 were closed without further action (Table 1). Of the 54 allegations that received a detailed assessment, 46 were resolved by ORI within 25 days from date of file assignment to date of administrative closure or of opening a formal case; the mean times were 9 and 10 days, respectively (Table 2). These data do not reflect the additional time taken by officials at the National Institutes of Health (NIH) who handled (with advice, assessment, and assistance from ORI as appropriate) the 14 allegations that were made directly to NIH by complainants.

Table 2: Time for Conduct by ORI of Pre-inquiry Assessments, 2002 (N=54)

Outcome of ORI assessment	*Number of allegations*	*Total days for resolution*	*Distribution of resolution times (days)*			
			Mean	*Median*	*Mode*	*Range*
Opened formal case	33	326	10	6	6	1–79
Administratively closed	17	157	9	6	1	1–41
Unresolved at end of year 2002	4	14	3.5	3	1	1-7
TOTAL	54	497	9	6	4	1-79

Cases Closed

ORI closed 32 cases in 2002, including 9 inquiries and 23 inquiries/ investigations. The average duration of 18 months for an open case was split between institutional actions (11 months) and ORI oversight and actions (7 months) (Table 3). Twenty-three cases (72 percent of total number) were closed by ORI within 8 months of the institutional actions being completed, and 27 (84 percent) were closed within 1 year.

Table 3: Duration of Research Misconduct Cases Closed, 2002 (N=32)

Site of action during case	*Distribution of resolution times (months)*			
	Mean	*Median*	*Mode*	*Range*
Institution	11	7	3	1–77
ORI	7	6	3	1–27
TOTAL (Inst. & ORI)	18	16	4	1-77

The action period for the 9 institutional inquiries included their inquiry and adjudication phases, and for 23 institutional investigations included their inquiry, investigation, and adjudication phases.

The action period for ORI oversight includes a detailed review of each institution's inquiry and/or investigation. ORI often makes requests to the institution for more information and analysis, or for explanation by the officials of the basis for their decision on whether misconduct occurred. Additional ORI analysis often is required to make a PHS finding of misconduct (in some cases, the period may include a hearing that is requested by the respondent before the HHS Departmental Appeals Board; there were none this year).

In the case that took 27 months for ORI to resolve, the institution had poorly documented its eight findings of scientific misconduct by a professor. ORI staff spent 2 years trying to obtain the complex evidence from the institution and subject it to additional ORI analysis. In the end, ORI found the evidence insufficient or the findings insignificant (as on old credentials) to warrant any further action by ORI. This action was followed by a long discussion with the institutional official and counsel to ensure a mutual understanding of why ORI was unable to agree with the institutional findings and take PHS actions against the respondent, who had resigned from university research.

In a case that took 18 months for ORI to resolve, the institution had done a rather incomplete analysis of the evidence in making three findings of scientific misconduct against a graduate student. ORI conducted additional forensic analysis of the notebooks and considered the arguments of the respondent, who had left the country for medical training and was no longer in research. In the end, ORI did not have sufficient evidence to warrant PHS findings and administrative actions.

One case that was closed quickly by ORI was done with a three-way agreement, using the institutional inquiry report and ORI's review to reach a settlement in 2 months with a respondent, an assistant professor who was willing to waive further investigation and agree to institutional and PHS administrative actions requiring his debarment from federal funding. Five other three-way agreements had been negotiated by ORI's counsel with

In 2002, 13 of the 23 investigations closed by ORI resulted in sustained findings of scientific misconduct and PHS administrative actions against the respondent.

institutional counsels and respondent's attorneys in prior years. Institutional officials are encouraged to call ORI about such matters early in the conduct of cases in which there are admissions.

In 2002, 13 of the 23 investigations closed by ORI resulted in sustained findings of scientific misconduct and PHS administrative actions against the respondent. Summaries of these cases may be found in Appendix A. Summaries of the 16 investigations closed by ORI that did not result in findings of scientific misconduct may be found in Appendix B. At the end of CY 2002, ORI had 50 active formal cases, as well as 7 allegations, under review (Table 4).

Caseload

The ORI caseload is divided into two elements: (1) institutional inquiries and (2) institutional investigations (Table 4).

Table 4: ORI Scientific Misconduct Caseload by Case Type, 2002

Case type	*Forwarded from 2001*	*Opened in 2002*	*Closed in 2002*	*Carried into 2003*
Institutional Inquiries	13	15	9	19
Institutional Investigations	28	26	23	31
TOTAL	41	41	32	50

The 41 formal cases opened in ORI in 2002 was the largest number of new cases opened by ORI in one year since 1995.

Institutional inquiries: Under the PHS regulation, institutions are not routinely required to report the conduct of inquiries to ORI unless they result in investigations. However, ORI may become involved in institutional

inquiries when ORI receives an allegation directly from the complainant and then asks the institution to conduct the inquiry; under these circumstances, the institution is required to report the outcome of the inquiry to ORI. Other institutions routinely submit inquiry reports to ORI (many are equivalent to reports of investigations, making findings). ORI reviews these reports to determine whether the conduct of the inquiry complied with the PHS regulation and was thorough, competent, and objective.

During 2002, ORI accepted 9 institutional inquiry reports that did not recommend further investigation (Table 5). Eight cases involved allegations of falsification, and one dealt with alleged fabrication and falsification. ORI carried 19 institutional inquiries into 2003.

Institutional investigations: Institutions are required by the PHS regulation to report to ORI at the initiation of an investigation and to submit a report to ORI upon completion of the investigation. ORI reviews the reports to determine whether the conduct of the investigation complied with the PHS regulation; was thorough, competent, and objective; and provided a basis for a PHS finding of misconduct. In 2002, ORI monitored 28 investigations at research institutions. During the year, 26 new institutional investigations were opened; 23 investigations cases were closed (Table 4). Of these 23 closed investigations, 13 involved ORI findings of scientific misconduct, 9 did not have such findings, and 1 was administratively closed by ORI (Table 5).

Table 5: Outcome of Research Misconduct Cases Closed by ORI, 2002 (N=32)

Case Type	*Outcome of Case*				*Total*
	No investigation	*No misconduct*	*Misconduct finding*	*Admin. Closed*	
Institutional Inquiry	7	-	-	2	9
Institutional Investigation	-	9	13	1	23
ORI Inquiry or Investigation	-	-	-	-	0
TOTAL	7	9	13	3	32

Respondents in 8 of the 13 cases with falsification or fabrication findings made formal admissions of their misconduct. One respondent admitted to misconduct at two different institutions; in the first case, he admitted to falsification of data in publications completed at one university as a postdoctoral fellow; when ORI questioned a statement by one of the witnesses in that case, alluding to questions about his graduate work, he admitted to falsifications in his Ph.D. thesis, which the institution was planning to rescind.

There were 50 active cases carried into 2003, the largest number since 1995. About 80 percent of the 25 cases in this group that were pending in ORI with institutional determinations involve scientific misconduct findings, more than doubling the frequency in all prior years.

Administrative Closures

A formal ORI case file may be administratively closed when ORI later concludes that no PHS funds or applications were actually involved, that continuing effort will not produce sufficient evidence to resolve a case satisfactorily, or that after additional review, ORI determines that the allegation did not fall under the PHS definition of scientific misconduct or warrant further action. There were three institutional inquiries or investigations, that were administratively closed by ORI in 2002.

Types of Allegations and Administrative Actions

Types of Allegations Involved in Closed Cases: During 2002, of the 7 closed inquiries and 22 closed investigations with findings, 7 inquiries and 21 investigations involved allegations of falsification, fabrication, or both. Of those 28 cases, 13 cases resulted in ORI findings and/or administrative actions. One investigation case involved plagiarism, with no finding of scientific misconduct (Table 6).

Table 6: Types of Allegations Involved in Closed Inquiries and Investigations and Their Outcomes, 2002

Allegation	*Inquiry*	*Investigation*	*ORI Findings or PHS Administrative Actions*
Fabrication	0	2	1
Falsification	6	8	3
Fals/Fab	1	11	9
Plagiarism	0	1	0
TOTAL	7	22	13

PHS Administrative Actions Imposed in Closed Cases: A range of administrative actions are used to protect the public fisc and the integrity of PHS-funded research. Persons may be debarred or voluntarily exclude themselves for several reasons, including a criminal conviction, fraud, or serious misconduct. Once debarred or excluded, a person may not receive any form of assistance, financial or non-financial, from the Federal Government for a set period.

For the 13 cases in 2002 in which ORI findings or PHS administrative actions were imposed, 8 persons were debarred or voluntarily excluded for periods from 3 to 5 years (Table 7). Other administrative actions imposed on respondents in these 13 closed cases included the following: (a) prohibition from serving in any advisory capacity to PHS, including service on PHS advisory committees, boards, and/or peer review committees or as a consultant for a specified period of time [13 persons]; (b) participation in an PHS-funded research is subject to supervision requirements for a specified period of time, wherein the institution is required to submit a plan of supervision that will ensure the scientific integrity of the individual's research contribution [3 persons]; (c) certification of any research data submitted in a PHS grant application [1 person] and (d) retraction of published articles [6 persons, required to or did retract a total of 9 publications].

Table 7: PHS Administrative Actions Imposed in Closed Investigations with Misconduct Findings or Administrative Actions, 2002

PHS Administrative Actions	*Duration*	Number of *Such Actions*
Debarment or	3 years	2
Voluntary Exclusion	4 years	2
	5 years	4
Prohibition from Serving	3 years	8
as an Advisor for PHS	4 years	2
	5 years	3
Supervision Plan Required	3 years	3
Certification of Research Required	3 years	1
Retraction/Correction of the Literature	-	6

Rapid Response for Technical Assistance Program (RRTA)

In 1999-2000, ORI created a Rapid Response for Technical Assistance (RRTA) program to provide aid to institutions conducting allegation assessments, inquiries, and investigations. RRTA from ORI includes: (1) rapidly reviewing institutional procedures to identify problem areas; (2) advising or assisting in sequestration and inventory of physical or computer evidence; (3) advising on case strategy, including legal issues; (4) outlining specific PHS issues; (5) providing PHS grant applications; (6) educating or assisting on sophisticated analytical techniques for image comparisons and statistical or digit analyses of data to prove falsification or fabrication; (7) suggesting collateral evidence to confirm or refute questioned claims; (8) advising on "missing" records; (9) assisting in locating experts; (10) developing strategies to prevent incomplete or withdrawn "admissions;" (11) informing other Federal agencies; (12) notifying or requesting help from other institutions; (12) advising on potential whistleblower and confidentiality issues; (13) helping with contacts to national databases (such as GenBank®); and (14) assisting with journal editors for papers that require correction or retraction.

Twenty-five institutions were provided with RRTA by DIO in 2002. Officials from four institutions that opened cases in 2002 accepted the offer of RRTA and called or visited ORI for substantive technical, administrative, or legal advice. An additional team of a research official and an attorney visited ORI to obtain strategic advice, guidance on handling of evidence, and recommendations for scientific experts in a small field in opening an inquiry. ORI additionally provided RRTA to 17 institutional officials who called ORI during their assessment or inquiry stages, before reporting formally any case to ORI, seeking assistance on handling evidence, strategic approaches to allegations and interviews, and general advice. Several institutions called ORI two or three times for assistance.

ORI also provided RRTA help to three institutions for which ORI had opened cases in the previous year; in one, ORI provided strategic advice on how to conduct statistical analysis of digits that appeared to be fabricated. Of the 32 cases closed by ORI in 2002, ORI had provided RRTA to 10 of them at the early stages of their process.

ORI intends for its RRTA program to facilitate institutional efforts to obtain high quality and well-documented investigation reports and to help resolve scientific misconduct cases promptly. Challenging problems include voluminous or missing evidence, multi-center clinical sites, involvement of outside parties, and premature or incomplete "admissions." ORI staff will provide such RRTA help over the telephone (phone DIO at 301-443-5330) or on-site.

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III. Education and Prevention

ORI conducts its education and prevention activities primarily through the Division of Education and Integrity (DEI). Two major programs were established in 2002 to stimulate research institutions and academic societies to develop instructional resources that could be used in RCR education programs for their members.

RCR Resource Development Program

ORI established the RCR Resource Development Program to facilitate the creation of instructional materials for institutional RCR education programs that address one or more of the following topics: Data acquisition, management, sharing, and ownership; mentor/trainee responsibilities; publication practices and responsible authorship; peer review; collaborative science; human research subjects; animal research subjects; conflict of interest and commitment, and research misconduct.

The new program facilitates implementation of the recommendations made by two national reports. In 1992, the National Academy of Sciences report on Responsible Science: Ensuring the Integrity of the Research Process recommended that "scientists and research institutions should integrate into their curricula educational programs that foster faculty and student awareness of concerns related to the integrity of the research process." In 1989, the IOM report, The Responsible Conduct of Research in the Health Sciences , recommended that "universities should provide formal instruction in good research practices. This instruction should not be limited to formal courses, but it should be incorporated into various places in the undergraduate and graduate curricula for all science students."

The RCR resource program offered up to $25,000 for the development of RCR instructional materials that can be made freely available to numerous institutions so that each institution is not required to develop its own resources. Indirect costs were not provided. The performance period was generally 1 year.

The number of applications (78) received in the first round was far beyond expectations. ORI responded by funding 13 projects instead of the originally

planned 8. The funded projects include comprehensive courses covering the nine core areas: collections of ethical dilemmas and case studies; videos, CD-ROMs, and web-based modules; specialized projects addressing authorship and publication practices; mentoring; conflicts of interest; human subjects; animal subjects; collaborations; and research misconduct. Abstracts of these projects are available on the ORI web site at http://ori.dhhs.gov/html/programs/rcr_requirements.asp

The title, principal investigator, and institution receiving awards follows:

- *Completion, Pilot Testing and Refinement of a Learn Anytime, Anywhere Online RCR Course.* Deni Elliott, University of Montana.

- *Ethical Dilemmas in Research Integrity*. Claire Gutkin, metaLinker.com.

- *Responsible Conduct of Research and Scholarly Activity Web-Based Instructional Program.* Julie Simpson, University of New Hampshire.

- *Web-Enhanced Curriculum for Responsible Authorship and Publication Practices.* Nalini Jairath, University of Maryland-Baltimore.

- *Faculty Guide for RCR Cases.* Wylie Burke, University of Washington.

- *A Documentary Film: A Round Table on Mentoring and Authorship.* Sara Vollmer and Harold Kincaid, University of Alabama-Birmingham.

- *Web-based Instruction on Protection of Human Subjects-Informed Consent.* Anne Edwards, Kestrel Corporation.

- *The Development of RCR Internet-based E-seminars on Mentor/Trainee Responsibilities and Conflict of Interest.* Ruth Fischbach, Columbia University.

- *Contemporary Science, Values and Animal Subjects in Research.* Joseph Herkert, North Carolina State University.

- *How Collaborators Don't Collaborate (A Video).* Thomas Dalglish, University of Louisville.

- *Avoiding Plagiarism, Self Plagiarism, and Other Questionable Writing Practices: A Guide to Ethical Writing.* Miguel Roig, St. John's University.

- *Research Integrity Training Program: Conflicts of Interest and Commitment Module.* Mark Tumeo, Cleveland State University.

- *Module Development for the University of Michigan Program for the Education and Evaluation of Responsible Research and Scholarship (PEERRS).* Fawwaz Ulaby, University of Michigan.

AAMC and ORI entered into a cooperative agreement aimed at encouraging academic societies to take measures to promote research integrity activities within their disciplines.

RCR Program for Academic Societies

Recognizing the role academic societies play in the creation and maintenance of professional identities, the Association of American Medical Colleges (AAMC) and ORI entered into a cooperative agreement aimed at encouraging academic societies to take measures to promote research integrity activities within their disciplines. All academic societies whose members conduct biomedical or behavioral research are eligible to participate in the program.

Reports by the National Academy of Sciences (NAS) and the IOM have recommended that academic societies play a greater role in promoting the responsible conduct of research. In *Responsible Science: Ensuring the Integrity of the Research Process,* the NAS recommended that "scientific societies and scientific journals should continue to provide and expand resources and forums to foster responsible research practices and to address misconduct in science and questionable research practices."

In *The Responsible Conduct of Research in the Health Sciences,* the IOM recommended that scientific organizations should "develop educational and training activities and materials to improve the integrity of research . . . assist universities in identifying substandard research and training practices that

compromise the integrity or quality of research . . . develop policies to promote responsible authorship practices, including procedures for responding to allegations or indications of misconduct in published research or reports submitted for publication."

The program supports awards in two categories. The first category funds grants of $5,000 each in support of single events or limited activities such as special meetings, sessions at annual meetings, national conferences, or a publication. The second category funds grants of $25,000 each for major program initiatives aimed at promoting the responsible conduct of research such as research guidelines, codes of research ethics, curriculum development, instructional materials, instructions to authors, or best practices.

Eleven proposals were submitted in the first round; four awards were made. The applications were reviewed by AAMC and ORI staff, and outside reviewers. ORI made the final funding decision based on the review results and recommendations from AAMC.

The recipients, project titles, and funding levels are presented below. Abstracts of these projects are available on the ORI web site at **http://ori.dhhs.gov/html/programs/rcr_requirements.asp.**

- Association of Academic Physiatrists, *Program on Ethical Elements of Rehabilitation Research,* $5,000.

- American Psychiatric Institute for Research and Education/American Psychiatric Association, *Developing an Ethics Curriculum for Psychiatric Research,* $25,000.

- Ambulatory Pediatric Association, *Promoting Research Integrity in General Pediatrics,* $25,000.

- American Thoracic Society, *Guidelines for the Ethical and Legal Conduct of Clinical Research Involving Critically Ill Patients,* $24,954.

Collaborating on Evaluation of RCR Training

ORI is collaborating with the NIH to develop an evaluation plan for the responsible conduct of research (RCR) requirement included in National Research Service Award (NRSA) institutional research training grants since 1990.

The project includes literature review, an invitational workshop that includes individuals who are experts in RCR training, scientific integrity, bioethics, and evaluation methodology, and the development of a comprehensive plan for an ongoing evaluation of the RCR requirement in NRSA training grants. ORI expects to use the results of the evaluations in planning and evaluating its educational programs.

E-mail Networking

ORI added another e-mail network to its electronic communication system. The new network contains e-mail address for 39,000 principal investigators (PI) supported by NIH grants. The PI network enables ORI to directly market RCR messages to researchers. Other components of the ORI electronic communication system are the listservs for institutional officials, RCR instructors, and researchers on research integrity; the network containing all institutions that have a misconduct assurance on file with ORI, and the ORI web site. Another e-mail network will be developed for academic societies.

Conferences and Workshops

ORI held nine conferences or workshops on topics related to the responsible conduct of research, research integrity and research misconduct in collaboration with four universities, a medical school, a research foundation, four professional associations, and three government agencies.

December 4, 2002
Workshop on Research Integrity Programs in Graduate Education
Washington, DC
Co-sponsor: Council of Graduate Schools

November 16-18, 2002
2002 Research Conference on Research Integrity
Potomac, MD
Co-sponsors: American Association for the Advancement of Science (AAAS), Association of American Medical Colleges (AAMC), NIH, and National Science Foundation (NSF)

October 10, 2002
Assessing Integrity in Research Environments
Washington, DC
Co-sponsor: Institute of Medicine

September 23-24, 2002
The Role of Institutional Rules, Guidelines, and Education in Promoting the Responsible Conduct of Research.
Philadelphia, PA
September 9-10, 2002
Fostering Integrity in Clinical Research at Academic Medical Centers
Baltimore, MD
Co-sponsors: Office for Human Research Protections (OHRP) and AAMC

June 19-22, 2002
Symposium on Research Responsibility and Undergraduates
New London, CT
Co-sponsor: Council on Undergraduate Research

May 2-3, 2002
Promoting Integrity in Clinical Research
Cleveland, OH
Co-sponsor: Cleveland Clinic Foundation

April 16-17, 2002
Conflicts of Interest and Research Integrity
St. Louis, MO
Co-sponsors: Washington University-St. Louis, University of Missouri-Columbia, St. Louis University

March 20-21, 2002
Advanced Investigative Techniques Workshop
Bethesda, MD
Co-sponsors: Harvard Medical School, University of Pittsburgh

Staff Presentations

Peter Abbrecht, Medical Expert, DIO, "ORI Guidance for Handling Allegations of Misconduct in Clinical Research," and case studies, ORI Advanced Investigative Techniques for Research Misconduct, Lister Hill Center, National Library of Medicine (NLM), Bethesda, MD, March 20, 2002.

Peter Abbrecht, Medical Expert, DIO, "ORI and Integrity in Clinical Research," National Patient Safety Foundation's Accountability in Clinical Conference, Indianapolis, IN, March 28, 2002.

Peter Abbrecht, Medical Expert, DIO, "ORI Case Studies of Scientific Misconduct in Clinical Research," Conference on Integrity in Clinical Research, Cleveland Clinic, Cleveland, OH, May 2, 2002.

Peter Abbrecht, Medical Expert, DIO, "Clinical Case Studies and Their Characteristics," ORI Conference on Fostering Integrity in Clinical Research at Academic Medical Centers, Baltimore, Maryland, September 9, 2002.

John E. Dahlberg, Scientist/Investigator, DIO, "Sequestering and Reviewing Computer Evidence," ORI Advanced Investigative Techniques for Research Misconduct, Lister Hill Center, NLM, Bethesda, MD, March 20, 2002.

John E. Dahlberg, Scientist/Investigator, DIO, "Forensic Analysis of Data," ORI Advanced
Investigative Techniques for Research Misconduct, Lister Hill Center, NLM, Bethesda, MD, March 20, 2002.

Nancy M. Davidian, Scientist/Investigator, DIO, "ORI and Scientific Misconduct in Clinical Research," Second Annual Medical Research Summit on Law, Regulation and Ethics, in Washington, DC, March 25, 2002.

Nancy M. Davidian, Scientist/Investigator, DIO, "Case Studies and Advice on Handling Allegations of Scientific Misconduct in Clinical Research," ORI Advanced Investigative Techniques for Research Misconduct, Lister Hill Center, NLM, Bethesda, MD, March 20, 2002.

Kay Fields, Scientist/Investigator, DIO, "ORI Review and the Departmental Appeals Board Process," ORI Advanced Investigative Techniques for Research Misconduct, Lister Hill Center, NLM, Bethesda, MD, March 20, 2002.

Kay Fields, Scientist/Investigator, DIO, "Dealing with Uncooperative Respondents," ORI Advanced Investigative Techniques for Research Misconduct, Lister Hill Center, NLM, Bethesda, MD, March 20, 2002.

Kay Fields, Scientist/Investigator, DIO, "Ethics Training Programs at Colleges and Universities: Federal Expectations," National Conference of the Council on Undergraduate Research: Undergraduate Research for All, Connecticut College, New London, CT, June 16, 2002.

Kay Fields, Scientist/Investigator, DIO, "Government Views of Scientific Misconduct: Fabrication, Falsification and Plagiarism," National Conference of the Council on Undergraduate Research: Undergraduate Research for All, Connecticut College, New London, CT, June 17, 2002.

Kay Fields, Scientist/Investigator, DIO, poster presentation on "Role of the Office of Research Integrity in Scientific Misconduct Investigations and Education on the Conduct of Research," Cell Biology and Neurobiology Symposium in honor of Dr. Martin Raff, University College London, UK, July 4, 2002.

Kay Fields, Scientist/Investigator, DIO, "On Scientific Misconduct and the ORI," Biology Department Seminar for Graduate Students, Catholic University, Washington, DC, September 16, 2002.

John W. Krueger, Scientist/Investigator, DIO, "Case Study: Uncooperative Respondent and Working with Experts - Scientific Preparation for Departmental Appeals Board (DAB) Hearing,"ORI Advanced Investigative Techniques for Research Misconduct, Lister Hill Center, NLM, Bethesda, MD, March 20, 2002.

John W. Krueger, Scientist/Investigator, DIO, "ORI Image Analyses - General Approach and Methods," ORI Advanced Investigative Techniques for Research Misconduct, Lister Hill Center, NLM, Bethesda, MD, March 21, 2002.

John W. Krueger, Scientist/Investigator, DIO, "Demonstrations of ORI Computer Analyses - Image Processing," walk-around demonstration table at the ORI Advanced Investigative Techniques for Research Misconduct, Lister Hill Center, Bethesda, MD, March 21, 2002.

John W. Krueger, Scientist/Investigator, DIO, "Recognizing and Investigating Scientific Misconduct, " National Council of University Research Administrators' Region IV Meeting, Madison, WI, April 30, 2002.

John W. Krueger, Scientist/Investigator, DIO, "Images as 'Evidence' - Recognizing and Investigating Scientific Misconduct," seminar for faculty and students at the Medical College of Wisconsin, Milwaukee, WI, May 1, 2002.

John W. Krueger, Scientist/Investigator, DIO "Color Tagging for Interpreting Overlap in Questioned Gray Scale Images," talk and poster at the 2002 ORI Research Conference on Research Integrity, Bolger Center, Potomac, MD, November 17, 2002.

Samuel Merrill, Jr., Scientist/Investigator, DIO, "An ORI Case Study on Getting Admissions of Scientific Misconduct in Clinical Research," ORI Advanced Investigative Techniques for Research Misconduct, Lister Hill Center, NLM, Bethesda, MD, March 21, 2002.

Marshall A. Narva, Scientist-Investigator, DIO, "Case Studies of Institutional 'Admissions' That Could Not Be Used by ORI," ORI Advanced Investigative Techniques for Research Misconduct Workshop, Lister Hill Center, NLM, Bethesda, MD, March 20, 2002.

Chris B. Pascal, Director, ORI, "Ethics and Diversity in Research," NIH Extramural Scientist Administrator (ESA) Seminar Series, Bethesda, MD, January 4, 2002.

Chris B. Pascal, Director, ORI, "Scientific Integrity and Scientific Misconduct: Background, Rules, Regulations," NIH ESA Seminar Series, Bethesda, MD, February 20, 2002.

Chris B. Pascal, Director, ORI, "The ORI View on RCR Education," National Council of University Research Administrators (NCURA) Video Conference, Washington, DC, March 18, 2002.

Chris B. Pascal, Director, ORI, "The History and Future of ORI," ORI Advanced Investigative Techniques for Research Misconduct, Lister Hill Center, NLM, Bethesda, MD, March 20, 2002.

Chris B. Pascal, Director, ORI, "Issues in Research Integrity," NIH Regional Seminar, Michigan State University, East Lansing, MI, April 11, 2002.

Chris B. Pascal, Director, ORI, "Conflict of Interest - Why Does It Matter?" Conflicts of Interest and Research Integrity, Washington University, St. Louis, MO, April 16, 2002.

Chris B. Pascal, Director, ORI, "What Is Research Integrity?" NCURA Region II Meeting, Cornell University, Ithaca, NY, April 22, 2002.

Chris B. Pascal, Director, ORI, "Conflict of Interest," NCURA Region II Meeting, Cornell University, Ithaca, NY, April 22, 2002.

Chris B. Pascal, Director, ORI, "Understanding Research Misconduct and Integrity," ORI Conference on Promoting Integrity in Clinical Research, Cleveland Clinic Foundation, Cleveland, OH, May 2, 2002.

Chris B. Pascal, Director, ORI, "Cost of Compliance," NCURA Teleconference, Washington, DC, May 14, 2002.

Chris B. Pascal, Director, ORI, "Ethics in Research," NIH ESA Seminar Series, Bethesda, MD, May 17, 2002.

Chris B. Pascal, Director, ORI, "Issues in Research Integrity," NIH Regional Seminar, University of Louisville, Louisville, KY, June 6, 2002.

Chris B. Pascal, Director, ORI, "The Mission of the Office of Research Integrity and Legal Issues Relating to Research Integrity," Symposium on Personal, Professional and Business Ethics, American Chemical Society, Boston, MA, August 18, 2002.

Chris B. Pascal, Director, ORI, "The Current Environment: An Overview of Cooperative Efforts with Institutions and the Federal Offices Overseeing Clinical Research", ORI Conference on Fostering Integrity in Clinical Research at Academic Medical Centers, Baltimore, MD, September 9, 2002.

Chris B. Pascal, Director, ORI, "Responding to Misconduct and Protecting Research Integrity" Graduate Research Ethics Course, Kansas University Medical Center, Kansas City, MO, September 17, 2002.

Chris B. Pascal, Director, ORI, "Responsible Conduct in Research: Promoting Scientific Integrity and Preventing Scientific Misconduct", Graduate Research Ethics Course, Kansas University Medical Center, Kansas City, MO, September 17, 2002.

Chris B. Pascal, Director, ORI, "Fostering Integrity in Research Environments", IOM Workshop, Washington, DC, October 10, 2002.

Chris B. Pascal, Director, ORI, "COGR Members Talk with the Office of Research Integrity's Directors," discussion with question and answer session at the Council on Government Relations Annual Meeting, Washington, DC, October 25, 2002.

Chris B. Pascal, Director, ORI, "Education in the Responsible Conduct of Research: New Programs, Developments, and Resources", The Society of Research Administrators (SRA) International, Orlando, FL, October 28, 2002.

Chris B. Pascal, Director, ORI, "Institute of Medicine Report on the Responsible Conduct of Research," The Society of Research Administrators (SRA) International, Orlando, FL, October 29, 2002.

Chris B. Pascal, Director, ORI, "Fostering Integrity in Research Environments," NCURA, Washington, DC, November 4, 2002.

Chris B. Pascal, Director, ORI, "Functions of the DHHS Office of Research Integrity," NIH ESA Seminar Series, Bethesda, MD, December 6, 2002.

Alan R. Price, Director, DIO, "How to Protect Your Department and Biochemistry Faculty from Research Misconduct Allegations in the Laboratory," Association of Medical and Graduate Departments of Biochemistry Chairperson's annual meeting, Grenada, WI, January 19, 2002.

Alan R. Price, Director, DIO, "ORI's Rapid Response for Technical Assistance (RRTA) Program," ORI Workshop on Advanced Investigative Techniques for Research Misconduct, Lister Hill Center, NLM, Bethesda, MD, March 20, 2002.

Alan R. Price, Director, DIO, "Paying Attention to Scientific Misconduct Issues," seminar for program, review, and grants management staff at the National Institute of Diabetes and Digestive and Kidney Diseases, Rockville, MD, April 24, 2002.

Alan R. Price, Director, DIO, "Integrity in Research: Advice from the Office of Research Integrity - or How to Protect Yourself from Research Misconduct in Your Laboratory," International Society for Magnetic Resonance Imaging in Medicine annual meeting, Honolulu, HI, May 23, 2002.

Alan R. Price, Director, DIO, "Jurisdictional Issues" ORI Conference on Fostering Integrity in Clinical Research at Academic Medical Centers, Baltimore, MD, September 9, 2002.

Alan R. Price, Director, DIO, "Essentials of Adequate Reporting," ORI Conference on Fostering Integrity in Clinical Research at Academic Medical Centers, Baltimore, MD, September 9, 2002.

Alan R. Price, Director, DIO, "The Office of Research Integrity and Cases Involving Graduate Students as Victims," Biology Department Seminar, Catholic University, Washington, DC, September 16, 2002.

Alan R. Price, Director, DIO, "How to Protect Yourself from Research Misconduct in the Laboratory," talk for students and faculty at the Biochemistry 8401 Ethics Course, Biochemistry Department, University of Minnesota Twin Cities Campuses, October 21, 2002.

Alan R. Price, Director, DIO, "COGR Members Talk with the Office of Research Integrity's Directors," discussion with question and answer session at the Council on Government Relations Annual Meeting, Washington, DC, October 25, 2002.

Lawrence J. Rhoades, Director, DEI, "Beyond Conflict of Interest: The Responsible Conduct of Research," International Conference on Conflict of Interest and Its Significance in Science and Medicine in Warsaw, Poland, April 6, 2002.

Lawrence J. Rhoades, Director, DEI, "The Responsible Conduct of Research," American Society for Gene Therapy, Boston, MA, June 5, 2002.

Lawrence J. Rhoades, Director, DEI, "The Responsible Conduct of Research," ORI Conference on the Role of Institutional Rules, Guidelines and Education in Promoting Responsible Conduct, Philadelphia, PA, September 23, 2002.

Lawrence J. Rhoades, Director, DEI, "COGR Members Talk with the Office of Research Integrity's Directors," discussion with question and answer session at the Council on Government Relations Annual Meeting, Washington, DC, October 25, 2002.

Lawrence J. Rhoades, Director, DEI, "The Responsible Conduct of Research," presentations to deans, department heads, faculty and students at Boston College, Boston, MA, November 21, 2002.

Lawrence J. Rhoades, Director, DEI, "The Responsible Conduct of Research," Workshop on Research Integrity Programs in Graduate Education, Council of Graduate Schools, Washington, DC, December 4, 2002.

Barbara R. Williams, Scientist/Investigator, DIO, "Evidence Strategy in Research Misconduct Cases," ORI Advanced investigative Techniques for Research Misconduct Workshop, Lister Hill Center, NLM, Bethesda, MD, March 20, 2002.

Barbara R. Williams, Scientist/Investigator, DIO, "Introduction to Interviewing in Research Misconduct," ORI Advanced Investigative Techniques for Research Misconduct Workshop, Lister Hill Center, NLM, Bethesda, MD, March 21, 2002.

Published Articles

Krueger, John W. "Forensic Examination of Questioned Scientific Images" in *Accountability in Research 9*: 105-125, 2002.

Mosimann, James E., John E. Dalhberg, Nancy M. Davidian, and John W. Krueger. "Terminal Digits and the Examination of Questioned Data" in *Accountability in Research* 9: 75-92, 2002.

Rhoades, Lawrence J. "Beyond Conflict of Interest: The Responsible Conduct of Research," *Science and Engineering Ethics*, 8:3, pp. 459-468, 2002.

Federal Register Notices

01/02/03 OS. Findings of Scientific Misconduct. Notice. 68 Fed. Reg. 123-124 (Jan. 2, 2002). [Ganz]

10/02/02 OS. Findings of Scientific Misconduct. Notice. 67 Fed. Reg. 61889 (Oct. 2, 2002). [Muenchen]

09/09/02 OS. Findings of Scientific Misconduct. Notice. 67 Fed. Reg. 57239-57241 (Sept. 9, 2002). [Yao]

09/05/02 OS. Findings of Scientific Misconduct. Notice. 67 Fed. Reg. 56842-56843 (Sept. 5, 2002). [Prasad]

07/15/02 OS. Findings of Scientific Misconduct. Notice. 67 Fed. Reg. 47554-47555 (July 19, 2002). [Shishov]

07/15/02 OS. Findings of Scientific Misconduct. Notice. 67 Fed. Reg. 46520 (July 15, 2002). [Pennington]

06/17/02 OS. Findings of Scientific Misconduct. Notice. 67 Fed. Reg. 41236 (June 17, 2002). [Arichi] The affected published papers have been retracted.

06/12/02 OS. Announcement of Cooperative Agreement With the Association of American Medical Colleges To Support Research Integrity Within Academic Societies. Notice. 67 Fed. Reg. 40301-40302 (June 12, 2002).

05/22/02 OS. Findings of Scientific Misconduct. Notice. 67 Fed. Reg. 36007-36008 (May 22, 2002). [Tracy] The affected published papers have been retracted.

05/17/02 OS. Findings of Scientific Misconduct. Notice. 67 Fed. Reg. 35114 (May 17, 2002). [Morrow]

05/10/02 OS. Agency Information Collection Activities: Proposed Collection Activities; Submission For OMB review; Comment Request. 67 Fed. Reg. 31807 (May 10, 2002). 1. Survey of Research Integrity Measures Utilized in Biomedical Research Laboratories—New. [Comments due 30 days from date of notice.]

04/19/02 OS. Findings of Scientific Misconduct. Notice. 67 Fed. Reg. 19438 (April 19, 2002). [deSales]

04/19/02 OS. Findings of Scientific Misconduct. Notice. 67 Fed. Reg. 19438-19439 (April 19, 2002). [Handa]

04/05/02 OS. Findings of Scientific Misconduct. Notice. 67 Fed. Reg. 16396-16397 (April 5, 2002). [Lipski]

01/02/02 OS. Findings of Scientific Misconduct. Notice. 67 Fed. Reg. 332 (Jan. 3, 2002). [Munjee]

IV. Research on Research Integrity and Research Misconduct

ORI operates intramural and extramural research programs to collect data that are useful in policy formation and program management and that expand the knowledge base related to RCR, research integrity and research misconduct. The research programs are part of DEI.

Intramural Research

ORI has conducted an intramural research program since 1994. The studies are done under contract with research organizations or by ORI staff. Funding is provided by HHS or ORI. Information on the studies, completed and in progress, is available on the ORI web site under Studies/Reports in the Publications section. Three studies were completed in 2002; two are in progress; none were initiated.

A. Completed Studies

Fostering Integrity in Research Environments

The IOM report, *Integrity in Scientific Research: Creating an Environment that Promotes Responsible Conduct,* urges institutions to implement comprehensive programs designed to promote integrity in research, including effective education programs in the responsible conduct of research.

A 1-day workshop, *Assessing Integrity in Research Environments,* was held at the National Academy of Sciences in Washington, DC, on October 10, 2002, to assess the recommendations and discuss their implementation.

The IOM report makes the following six recommendations:

- Funding agencies should establish research grant programs to identify, measure, and assess those factors that influence integrity in research.

- Each research institution should develop and implement a comprehensive program designed to promote integrity in research, using multiple approaches adapted to the specific environments within each institution.

- Institutions should implement effective educational programs that enhance the responsible conduct of research.

Integrity in research is defined on the individual and institutional levels in the IOM Report on Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct

- Research institutions should evaluate and enhance the integrity of their research environments using a process of self-assessment and external peer review in an ongoing process that provides input for continuous quality improvement.
- Institutional self-assessment of integrity in research should be part of existing accreditation processes whenever possible.
- The Office of Research Integrity should establish and maintain a public database of institutions that are actively pursuing or employing institutional self-assessment and external peer-review of integrity in research.

IOM Report Defines Integrity in Research

Integrity in research is defined on the individual and institutional levels in the IOM Report on *Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct:*

Individual Level

For the individual scientist, integrity embodies above all a commitment to intellectual honesty and personal responsibility for one's actions and to a range of practices that characterize the responsible conduct of research, including:

- intellectual honesty in proposing, performing, and reporting research;
- accuracy in representing contributions to research proposals and reports;
- fairness in peer review;
- collegiality in scientific interactions, including communications and sharing of resources;
- transparency in conflicts of interest or potential conflicts of interest;

- protection of human subjects in the conduct of research;
- humane care of animals in the conduct of research; and
- adherence to the mutual responsibilities between investigators and their research teams.

Institutional Level

Institutions seeking to create an environment that promotes responsible conduct by individual scientists and that fosters integrity must establish and continuously monitor structures, processes, policies, and procedures that:

- provide leadership in support of responsible conduct of research;
- encourage respect for everyone involved in the research enterprise;
- promote productive interactions between trainees and mentors;
- advocate adherence to the rules regarding all aspects of the conduct of research, especially research involving human participants and animals;
- anticipate, reveal, and manage individual and institutional conflicts of interest;
- arrange timely and thorough inquiries and investigations of allegations of scientific misconduct and apply appropriate administrative sanctions;
- offer educational opportunities pertaining to integrity in the conduct of research, and
- monitor and evaluate the institutional environment supporting integrity in the conduct of research and use this knowledge for continuous quality improvement.

The IOM report may be accessed through the ORI web site by clicking on Studies/Reports under Publications. Copies of the report are available from ORI while the supply lasts.

Instruction to Authors

An ORI study of instructions to authors in 41 journals that published articles involved in research misconduct findings suggests that instructions to authors can be more effectively used to promote the responsible conduct of research.

The study report is available on the ORI web site under Studies/Reports in the Publication section.

The analysis looked for content addressing authorship, reference practices, publishing practices, financial disclosures, human research, animal research, correcting the literature, research misconduct, peer review, and copyright. The study assumed that these areas are problematic for all journals with the possible exception of human or animal research. The study population contained 17 basic science journals, 13 clinical journals, and 11 journals that published basic and clinical research.

The study found that 58 percent of the journals addressed no more than 4 of the above topics, while 39 percent addressed 7 or more. Nineteen percent addressed no more than 2; 12 percent addressed 9 or more. The majority of journals covered copyright (73 percent), authorship and reference practices (68 percent each), publishing practices (63 percent), and financial disclosures (59 percent). Less than half included peer review (49 percent), human research (44 percent), animal research (36 percent), correcting literature and research misconduct (15 percent each).

Institutional Investigation Assistance Program: Feasibility Study

ORI should develop a registry of advisors and institutions experienced with inquiries and investigations as a resource to assist institutions to respond to allegations of research misconduct rather than support the development of consortia to do so, according to a study conducted by ROW Sciences, Inc.

The final report, *An Institutional Investigation Assistance Program: A Feasibility Study*, is based on responses from 312 institutions and organizations. Response rate was 32 percent. About 25 percent of the responding organizations had handled a research misconduct allegations in the previous 5 years.

According to the report, most organizations indicated that they were likely to use their own resources to respond to misconduct allegations. Preferred sources of outside assistance were ORI and advisors/consultants. Areas of needed assistance cited included general guidance on the process to respond

to an allegation, legal guidance, and subject area expertise. Cost was the deciding factor on whether outside assistance would be used.

Organizations were reluctant become a member of a consortium but would consider using services offered by a consortium. Study participants indicated that registries of consultants or institutions that have investigated allegations would be useful and require fewer resources to develop than consortia would.

B. Studies in Progress

Study on Incidence of Research Misconduct and Questionable Research Practices in Biomedical Research

The conduct of this study has been delayed because the Federation of American Societies of Experimental Biology (FASEB) and the Association of American Medical Colleges (AAMC) objected to the initial questionnaire developed for the study. FASEB and AAMC claimed that the definition of research misconduct was not based on the definition found in the Federal Research Misconduct Policy; the questions were asking about behavior that could not be easily observed; the data would not be interpretable; and the data were already available from other sources.

In response, the title of the study was changed from "Study on Incidence of Research Misconduct in Biomedical Research" to the title cited above; a new questionnaire was developed that based the definition of research misconduct found in the Federal Research Misconduct Policy; and the questions were focused on observable behavior. It is being submitted to OMB for approval. The Gallup Organization is conducting the study.

Survey of Research Integrity Measures Utilized in Biomedical Research Laboratories

The final report on this study is expected in 2003. Data collection has been completed; data analysis and final report preparation are underway. The study was conducted to determine the types of, and the extent to which, research integrity measures are used in biomedical research laboratories. Responses were received from 3,316 subjects of which 2,953 were regarded as complete. The total sample was composed of 4, 685 principal investigators

The Research on Research Integrity (RRI) Program made 10 awards in 2002.

whose research was supported by NIH. Data were also collected on the characteristics of the host institution, the laboratory, and the principal investigator.

Extramural Research

ORI established its extramural research program in 2000 in collaboration with the National Institute of Neurological Disorders and Stroke (NINDS) when the first request for applications was issued. The first Research Conference on Research Integrity was held in November 2000 to stimulate research on research integrity and create a cadre of researchers.

Research on Research Integrity (RRI) Program

The Research on Research Integrity (RRI) Program made 10 awards in 2002. These awards were made in response to 31 grant applications, yielding a success rate of 32 percent for the second round of the grant program. The RRI recorded a 24 percent increase in grant applications received, a 43 percent increase in the number of awards made, and a 14 percent increase in the success rate over the first round in 2001. In the first round, 25 applications were received, 7 awards were made, and the success rate was 28 percent.

The second year marked a total of 17 active grants; 7 in their second year, and 10 in their first year. The awards in the first two rounds were supported by the NINDS, the National Institute of Nursing Research, (NINR), and ORI. The National Institute on Drug Abuse (NIDA) joined the third round solicitation in 2002. ORI committed $1 million in fiscal year (FY) 2002. Total funding (new and continuations) for the second year was about $2.14 million, which doubled the $1.03 million allocated in the first year. The grants are limited to $100,000 in direct costs, plus indirect costs for each of 2 years.

The awards demonstrate the interdisciplinary nature and broad spectrum of research on research integrity. Research areas represented include: conflicts of interest, research integrity in clinical trials, editorial decision making, knowledge of the responsible conduct of research, and literature corrections after scientific misconduct.

In addition to the funding awarded in 2002, the 2nd Research Conference on Research Integrity was held at the Bolger Conference Center, Potomac, MD,

co-sponsored by the American Association for the Advancement of Science (AAAS), the AAMC, NIH, and NSF. More than 160 researchers from the U.S. and abroad attended the 2-day research conference where more than 50 papers were presented. First round investigators reported their preliminary findings.

Grant titles, principal investigators, and institutions for the 2002 awards follow:

- Correcting the Literature after Scientific Misconduct. Anne V. Neale, Wayne State University;
- Motivating Integrity in Research with Human Subjects. Wylie Burke, University of Washington;
- Trainee-Focused Training for Research Integrity. Richard McGee, Mayo Clinic Rochester;
- Equipoise and the Research Integrity of Clinical Trials. Benjamin Djulbegovic, University of South Florida;
- A Qualitative Study of Editorial Decision-Making. Lisa A. Bero, University of California- San Francisco;
- New Graduate Students' Baseline Knowledge of RCR. Elizabeth Heitman, University of Mississippi Medical Center;
- Nurses: Research Integrity in Clinical Trials. Joan Liaschenko, University of Minnesota;
- Industry-Sponsored Research Contracts: An Empirical Study. Michelle M. Mello, Harvard School of Public Health;
- Effectiveness of RCR Instruction. Francis L. Macrina, Virginia Commonwealth University; and

- Research Integrity in ASHA: Education and Publication. Sharon E. Moss, American Speech-Language-Hearing Association.

Grant titles, principal investigators, and institutions for the 2001 awards follow:

- Management Decisions in Financial Conflicts of Interest. Lisa Bero, University of California-San Francisco.

- Research Integrity in Pharmacological Clinical Trials. William Gardner, University of Pittsburgh.

- Quality Assurance and Data in Clinical Trials. Yuan Min, Johns Hopkins University.

- Work-Strain, Career Course and Research Integrity. Brian Martinson, Health Partners Research Foundation, Minnesota.

- Data Sharing and Data Withholding among Trainees in Science. Eric Campbell, Massachusetts General Hospital.

- Organizational Influences on Scientific Integrity. Michael Mumford, University of Oklahoma.

- Perceived Organizational Justice in Scientific Dishonesty. Gerald Koocher, Children's Hospital, Boston.

V. Institutional Compliance

The PHS regulation on misconduct in science (42 C.F.R. Part 50, Subpart A) places several requirements on institutions receiving funds under the PHS Act, 42 U.S.C. § 289b. ORI monitors institutional compliance with these regulatory requirements through two DEI programs, the Assurance Program and the Compliance Review Program.

A. Assurance Program

The Assurance Program is responsible for ensuring that PHS research funds are only awarded to eligible institutions. An institution is eligible when it has an active assurance on file with ORI stating that it has developed and will comply with an administrative process for responding to allegations of scientific 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 revised in 1996. Institutions keep their assurance active by submitting the Annual Institutional Report on Possible Research Misconduct (Annual Report), submitting their misconduct in science policy upon request by ORI, revising their misconduct in science policy when requested by ORI, and complying with the PHS regulation.

The Assurance Program meets its responsibilities by maintaining the assurance database, auditing awards to institutions, gathering and summarizing information from institutions in their Annual Report, and reviewing institutional policies and procedures in conjunction with the Compliance Review Program.

In 2001, ORI switched to electronic submission of the Annual Report beginning with the report for CY 2000 to reduce the reporting burden on the 4,000 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 and funding agencies to determine the eligibility of institutions to receive PHS research funds.

As of December 31, 2002, there were 4,111 active assurances on file in ORI, including 261 from 45 foreign countries. During 2002, 529 institutions filed their initial assurance. ORI deleted 555 institutions because their assurance was inactivated. Eight duplicate assurance records were deleted. There were 145 institutions that voluntarily withdrew their assurance because they (1) did not expect to apply for PHS funds, (2) did not conduct research, (3) merged with another institution, or (4) went out of existence. ORI withdrew the remaining 402 assurances because the institutions did not submit their Annual Report.

All of these changes had only slight impact on the total assurance database in 2002 (See Table11). The total number of institutions with an assurance increased by 51. Categorically, institutions of higher education decreased by 6; research organizations, institutes, foundations and laboratories decreased by 4; independent hospitals increased by 1; educational organizations other than higher education increased by 2; other health, human resources, environmental service organizations increased by 14; the small business category increased by 43; and unclassified increased by 1. The largest decline was in the institutions of higher education, while the largest increase was in the small business category.

Table 8: Type of Institution with Active Assurance by Frequency, 2002

Type of Institution	*Frequency*	*Change*
Institutions of Higher Education	902	-6
Research Organizations, Institutes, Foundations and Laboratories	322	-4
Independent Hospitals	274	+1
Educational Organizations, Other Than Higher Education	21	+2
Other Health, Human Resources, and Environmental Services Organization	411	+14
Other (small business)	2,180	+43
Unclassified	1	+1
TOTAL	4,111	+51

Electronic Administration

In 2002, the Assurance Program switched to electronic administration. The program now handles about 90 percent of its communication with institutions electronically. Electronic responses and notifications are sent for the following: requests for institutional policies for responding to research misconduct and their subsequent revision and acceptance notifications; the request for and acceptance of the Small Organization Statements, notifications of an IPF number change, response to inquiries concerning the Assurance Program, requests for overdue annual reports, and "Welcome" letters that inform institutions about their obligations under Federal regulation and introduces them to ORI.

Institutional Policy Reviews

ORI completed 209 policy reviews in 2002. Thirty-eight policy reviews were carried into 2002; another 175 institutional research misconduct policies were requested for review. One hundred eighty-two institutional policies were accepted as submitted; 22 others were accepted after revision, and 5 institutional assurances were inactivated because the institutions did not submit or revise their policy or requested inactivation of their assurance in lieu of submitting a policy. All four open reviews are pending revision by institutions.

Policy Review Database

A database was established in 1997 to consolidate information on the numerous reviews conducted by the assurance program. The database contains relevant information on the reviews, such as the initial outcome of the review, the number of revisions required, and the policy approval date. As of December 31, 2002, it contained information on 1,881 policy reviews conducted by ORI primarily since 1995. ORI completed 1,877 reviews; 4 are open pending revision by institutions.

Institutions reported increased misconduct activity in their Annual Report for the third consecutive year following a 3-year decline.

Annual Institutional Reports on Possible Research Misconduct

To keep its assurance active, each institution must submit to ORI an Annual Institutional 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 2001 Annual Report began in January 2002 for the 4,060 institutions that had an assurance on file with ORI as of December 31, 2001.

Completed Annual Reports were received from 3,320 institutions for a response rate of 82 percent. ORI inactivated 749 assurances, including 651 institutions that did not return their Annual Reports by the March 31 deadline, and 98 institutions that voluntarily withdrew their assurances rather than submit the Annual Report. Many assurances were reactivated later because annual reports were submitted after the due date. The 2001 report identified 32 institutions that did not have the required policies and procedures for handling allegations of scientific misconduct.

The Annual Report form requested institutions to report on (1) the availability of policies and procedures for responding to allegations of scientific misconduct, (2) the number of allegations of scientific misconduct received and the number of inquiries and investigations conducted, and (3) the number of bad faith allegations received.

Reported Misconduct Activity

Institutions reported increased misconduct activity in their Annual Report for the third consecutive year following a 3-year decline. Institutional annual reports for CY 2001 were filed with ORI in early 2002. Seventy-eight institutions reported misconduct activity in 2001 compared with 82 in 2000 and 72 in 1999 (Table 9). New cases were opened by 61 institutions in 2001 compared with 60 in 2000 and 46 in 1999.

New cases resulted in 67 inquiries in 2001 compared with 59 in 2000 and 51 in 1999. The new cases also resulted in 20 investigations in 2001 compared with 18 in 2000 and 9 in 1999.

The 127 new allegations received in 2001 were more than the 103 received in 2000 and the 89 received in 1999. The 72 new cases opened in 2001 were 10 more than in 2000 and 9 more than in 1999. Cases frequently involve more than one allegation.

In their submission, institutions report the receipt of an allegation of scientific misconduct, the type of misconduct, and the conduct of an inquiry and/or investigation. Reportable activities are limited to alleged misconduct involving PHS-supported research, research training, or other research-related activities.

The 127 new allegations included 46 of falsification, 37 of fabrication, 17 of plagiarism, and 27 others. Institutions reporting new cases include 54 in higher education, 2 research organizations, 3 independent hospitals, 1 health organization and 1 small business.

The 78 institutions reporting misconduct activity in 2001 conducted 67 inquiries and 20 investigations in response to allegations made in 2001 and before. Sixty-one institutions opened new cases; 17 were completing old cases, and 19 were handling new and old cases. The number of inquiries conducted by an institution ranged from 0 to 3. The number of investigations conducted by an institution also ranged from 0 to 2.

Table 9: Frequency of Institutions Reporting Misconduct Activities, Institutions Reporting New Cases, New Allegations, and New Cases Opened, 1997-2001.

Annual Report	*Institutions Reporting Activity*	*Institutions Reporting New Cases*	*New Allegations*	*New Cases*
2001	78	61	127	72
2000	82	60	103	62
1999	72	46	89	63
1998	67	41	69	54
1997	73	48	92	64

Bad Faith Allegations

One institution received one bad faith allegation during 2001 according to their Annual Report. Five bad faith allegations were reported during the 5-year reporting period of 1997 - 2001. The Annual Report will no longer ask for information on bad faith allegations.

The "ORI Model Policy for Responding to Allegations of Scientific Misconduct " states, "an allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation." Although institutions are not required to determine whether an allegation was made in bad faith, ORI requested data on bad faith allegations for a 5-year period because of the concern within the scientific community that such allegations are common and because many institutional misconduct policies state that these acts are subject to disciplinary action.

B. Compliance Review Program

The Compliance Review Program is responsible for ensuring that institutions that apply for or receive PHS funds establish the required policies and procedures and comply with them and 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 compliance reviews of institutional handling of an allegation of scientific misconduct and/or retaliation complaints of the whistleblower. Assessments are cases where ORI has received an allegation or other information to suggest that retaliation may have occurred in a misconduct case.

In 2002, 10 compliance cases were opened, and 11 cases were closed. Eight compliance cases were carried into the year and seven were still open at the end of the year.

Four compliance reviews were opened and three reviews were closed. The year began with five open assessments, six new assessments were opened, and eight assessments were closed (Table 10). Cases were closed primarily because ORI made a determination that it did not have jurisdiction, or the complainant did not respond to ORI's request for additional documentation supporting the complaint.

Of the compliance cases closed during 2002, one case involved both issues related to institutional compliance with the PHS misconduct regulations in the conduct of a misconduct investigation as well as the handling of a concurrent retaliation complaint. At ORI's request, the institution established a committee to conduct an internal review of the entire process utilized in this case, which included a review of its established research policy, the management of the scientific misconduct investigation, and the handling of the retaliation issue. In its report, the committee reported major policy gaps, including, among other things, 1) the lack of a clear process for the whistleblower to follow prior to the submission of a written allegation, 2) the ill defined roles of the senior officials that may allow for conflicts of interest, and 3) no detailed policy on whistleblower protection. The report provided a number of recommendations, including recommendations to formulate and implement a detailed whistleblower protection policy, to make institutional policies and procedures on research misconduct and whistleblower protection more readily available to all faculty and staff, and to redefine the roles and responsibilities of institutional officials for responding to allegations of research misconduct.

Table 10: Summary of Compliance Cases, 2002

Case Type	*Forwarded from 20001*	*Opened in 2002*	*Closed in 2002*	*Carried into 2003*
Review	3	4	3	4
Assessment	5	6	8	3
TOTAL	8	10	11	7

Implementation of ORI Administrative Actions

The implementation of ORI 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 scientific misconduct concerning the individual, (2) the individual is the subject of an administrative action imposed by the Federal Government as a result of a determination that scientific misconduct has occurred, (3) the individual has agreed to voluntary corrective action as a result of an investigation of scientific misconduct, or (4) ORI has received a report of an investigation by an institution in which there was a finding of scientific misconduct concerning the individual and ORI has determined that PHS has jurisdiction. The PHS ALERT is not a public system.

The PHS Administrative Actions Bulletin Board is a public system. Information on each individual in the system is limited to name, social security number, date of birth, type of misconduct, the name of the institution that conducted the investigation, a summary of the administrative actions imposed as a result of the misconduct, and the effective and expiration dates of the administrative actions.

The system was computerized in 1994 to facilitate checks of individuals subject to PHS administrative actions against incoming applications, pending awards, and proposed appointments to PHS advisory committees, boards, and peer review groups.

On January 1, 2002, ORI listed the names of 47 individuals in the system. During the year, ORI added 22 and removed 13 names. On December 31, 2002, the names of 56 individuals were in the system.

ORI added these 22 names after 1 respondents agreed to a voluntary exclusion agreement, and 21 others were found to have committed scientific misconduct in institutional reports to ORI. Ten names were removed during the year because the term of the administrative actions expired, and 3 names were removed where ORI did not recommend a finding of scientific misconduct after reviewing an institutional misconduct investigation report.

Of the 56 names in the system at year end, 36 individuals had PHS administrative actions imposed, and 20 remained as a result of an institutional report in which there was a finding of research misconduct.

Table 11: Summary of PHS ALERT System Activity, 2002

	PHS Actions	*Institutional Misconduct Finding*	*Total*
As of January 1, 2002	1	21	22
Additions	2	7	19
Action Expired/Removed	10	3	13
As of December 31, 2002	26	30	56

VI. Information and Privacy

ORI responds to Freedom of Information Act (FOIA) requests and Privacy Act requests through the DEI.

Freedom of Information Act

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

ORI records are primarily subject to Exemptions 5, 6, and 7 of the FOIA. Exemption 5 covers internal government communications and notices. Exemption 6 covers documents 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, Darlene Christian, Parklawn Building, 5600 Fishers Lane, Room 17-A-46, Rockville, MD 20857. The request must reasonably describe the records sought so that the agency official is able to locate the records with a reasonable amount of effort. Some requests may be subject to review, search, and duplication costs.

Privacy Act

The purpose of the Privacy Act of 1974, 5 U.S.C. § 552a, is to balance the needs of the government to maintain information about individuals with the rights of the individual to be protected against unwarranted invasions of their privacy stemming from Federal agency collection, maintenance, use, and disclosure of personal information about the individual. Under the Privacy Act, an agency is required to publish a notice of its system of records when the information in the system is about an individual 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 of records requests by the subject of the records. Nonetheless, each request for access is reviewed on a case-by-case basis. Additionally, if the records are denied under the Privacy Act for reasons of the exemptions, the subject of the records may still be entitled to obtain access to his or her records, or portions thereof, under the provisions of the Freedom of Information Act.

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

Appendix A

Summaries of Closed Investigations Resulting in Findings of Research Misconduct or Administrative Actions - 2002[1]

Tatsumi Arichi, Ph.D., National Cancer Institute (NCI), National Institutes of Health (NIH): Based the report of an investigation conducted by the NIH, Dr. Arichi's admissions, and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Tatsumi Arichi, Ph.D., former Visiting Fellow in the intramural program of the NCI, NIH, engaged in scientific misconduct by falsifying and fabricating published data. Specifically, PHS found that Dr. Arichi falsified data that purported to show potent long-lasting immunization of mice with plasmid DNA leading to protection from challenge with vaccinia virus expressing the hepatitis C core antigen as published in Figures 4, 5, and 6 in PNAS 97:297-302, 2000. This paper was retracted in PNAS 98:5943, 2001. The research involved use of a potential vaccine against hepatitis C, a virus that infects at least 3 million Americans, many of whom suffer serious health consequences such as cirrhosis and liver cancer.

Dr. Arichi entered into a Voluntary Exclusion Agreement in which he voluntarily agreed for 3 years beginning June 4, 2002, to exclude himself from any contracting, subcontracting, or involvement in grants and cooperative agreements with the U.S. Government, and to exclude himself from serving in any advisory capacity to PHS.

Joao Carlos deSales, San Francisco Department of Public Health (SFDPH): Based on the SFDPH investigation report and additional ORI analysis, the U.S. Public Health Service (PHS) found that Joao Carlos deSales, former study counselor at SFDPH, engaged in scientific mi sconduct by falsifying data supported by National Institutes of Health (NIH) subcontract SFP-N01-A1-35176-HMEISTERI-94 to SFDPH under the National Institute of Allergy and Infectious Diseases contract 5-N01-AI35176-019, "Domestic Master Contract for HIV Vaccine Efficacy Trials," awarded to ABT Associates, Inc. Specifically, from April through September 1999, Mr. deSales switched randomization assignments on four pairs of subjects and subsequently altered the research records to conceal his conduct.

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[1]As printed in the *ORI Newsletter.*

Mr. deSales' switching of the randomization assignments, if undetected, could have biased the study so as to invalidate the conclusions on the effectiveness of intensive counseling sessions on reducing the rate of new HIV infections. Mr. deSales entered into a Voluntary Exclusion Agreement in which he voluntarily agreed for a 3-year period beginning April 4, 2002, to exclude himself from serving in any advisory capacity to PHS, and that any institution that submits an application for PHS support for a research project on which his participation is proposed, or which uses him in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which Mr. deSales is involved, must concurrently submit a plan for supervision of his duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of his research contribution. A copy of the supervisory plan must also be submitted to ORI by the institution.

Michael B. Ganz, M.D., Case Western Reserve University (CWRU): Based on the CWRU investigation report and additional ORI analysis, PHS found that Dr. Ganz, Associate Professor of Medicine, CWRU, engaged in scientific misconduct by falsification and fabrication of research in grant application R01 DK058674-01A2, "The role of protein kinase C and shuttling proteins in diabetic kidney disease," submitted to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH. Specifically, PHS found that Dr. Ganz engaged in scientific misconduct by: (1) falsifying Figure 16 in NIH grant application R01 DK058674-01A2 by claiming that photomicrographs of glomeruli were from a streptozotocin model of induced diabetes in rat, while the photomicrographs were actually from tissue of human or other primate origin; (2) falsifying Figure 16 of this NIH grant application by claiming that six photomicrographs all represented glomeruli from different animals, whereas they actually were from only three different glomeruli, with each glomerulus being shown in two images with different orientations and/or magnifications; and (3) falsifying and fabricating documents, purportedly showing the source of the falsified Figure 16 in the NIH grant application, which Dr. Ganz provided to the CWRU inquiry committee. The research was significant because it was designed to develop a therapy to prevent the progressive glomerular hypertrophy and matrix deposition that occur with the renal disease associated with diabetes in animals and humans.

Dr. Ganz entered into a Voluntary Exclusion Agreement in which he voluntarily agreed for 5 years, beginning December 18, 2002: (1) to exclude himself from procurement and non-procurement transactions, including but not limited to contracts, subcontracts, grants and cooperative agreements with the U.S. Government; and (2) to exclude himself from serving in any advisory capacity to PHS.

Atsushi Handa, M.D., Ph.D., National Institutes of Health (NIH): Based on an NIH report of an investigation, and additional ORI analysis during its oversight review, PHS found that Atsushi Handa, M.D., Ph.D., former visiting fellow in the intramural program of the National Heart, Lung, and Blood Institute, NIH, engaged in scientific misconduct by falsifying and fabricating data published in two journals. Specifically, PHS found that Dr. Handa: (1) fabricated or falsified the following data in a paper published in J. Gen. Virol. 81:2077-2084, 2000: (A) data for the AAV-3 construct for days 2, 5, and 7 and data for the AAV-2 construct for days 5 and 7 in Table 1; (B) day 2 data in Table 2; and (C) Figure 4; and (2) falsified the following data in a paper published in J. Gen. Virol. 81:2461-2469, 2000: (A) Figure 3; and (B) data in Table 2; retracted at J. Gen. Virol. 82:2837, 2000. These actions were serious because the purported findings on the GV virus C/hepatitis G and AAV-2 viruses could have had major impact in areas such as hepatitis research and gene therapy.

Dr. Handa entered into a Voluntary Exclusion Agreement in which he voluntarily agreed for a 5-year period beginning April 4, 2002, to exclude himself from any contracting, subcontracting, or involvement in grants and cooperative agreements with the U.S. Government, and to exclude himself from serving in any advisory capacity to PHS. Additionally, he must submit a letter of retraction to the editor of the *Journal of General Virology* identifying the missing data as well as the falsified or fabricated data in Figure 3A and Table 2 of the paper published in *J. Gen. Virol*. 81:2461-2469, 2000. This retraction requirement will remain on the ALERT System until Dr. Handa sends, and ORI receives, a copy of the retraction letter that is consistent with the above language.

Matthew A. Lipski, Washington University in St. Louis (WUSL): Based on the WUSL investigation report and additional ORI analysis in the course of its oversight review of related records, PHS found that Matthew A. Lipski,

former WUSL research patient assistant on a subcontract from Hipco, Inc., engaged in scientific misconduct by falsifying and fabricating data in research supported by NIH Phase II Small Business Innovation Research (SBIR) grant 2 R44 AG12317-03, "Effect of padded underwear on hip fracture incidence." Specifically, PHS found that Mr. Lipski falsified and fabricated data in a study examining whether wearing an undergarment with force distributing and absorbing pads positioned over the trochanteric regions of elderly nursing home residents could significantly reduce the number of hip fractures. From July 2000 through October 2000, Mr. Lipski falsified and fabricated observational patient data in multiple research records. Due to concerns over the reliability of all of Mr. Lipski's data, none of his data were used in the study. No publications required correction or retraction.

Mr. Lipski entered into a Voluntary Exclusion Agreement in which he voluntarily agreed for a 3-year period beginning March20, 2002, to exclude himself from serving in any advisory capacity to PHS, and that any institution that submits an application for PHS support for a research project on which Mr. Lipski's participation is proposed or which uses him in any capacity on PHS supported research, or that submits a report of PHS-funded research in which he is involved, must concurrently submit a plan for supervision of his duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of his research contribution. A copy of the supervisory plan must also be submitted to ORI by the institution.

Aaron J. Morrow, B.S., Saint Louis University (SLU): Based on Mr. Morrow's admission, the SLU investigation report, and additional ORI analysis, the PHS found that Aaron J. Morrow, graduate student, SLU Graduate School, engaged in scientific misconduct by falsifying and fabricating data in research supported by National Institute of General Medical Sciences, NIH, grant 5 R01 GM54428-04, "Elucidation of the mechanisms of *in vitro* Golgi transport." Specifically PHS found that Mr. Morrow falsified data relating to the study of the mechanisms of protein transport using *in vitro* preparations. From October 1999 through January 2001, he falsified and fabricated data in his research notebook and produced false films and graphs of purported experiments to produce data for his thesis and misrepresent his progress. Mr. Morrow reported the falsified and fabricated data in: (1) laboratory group meetings; (2) a poster presentation at the American Society for Cell Biology meeting in December 2000; and (3) a

draft manuscript that he was preparing. Mr. Morrow also provided falsified data to his mentor, who unknowingly included it in a draft of NIGMS, NIH, application 2 R01 GM54428-05A2, "Elucidation of the mechanisms of in vitro Golgi transport." Given the extensive nature of Mr. Morrow's data falsification and fabrication, none of his research after July 2000 can be considered reliable. His actions adversely and materially affected the laboratory's ongoing research in protein transport mechanisms by creating uncertainty about all his experimental results, necessitating verification and repetition of experiments, preventing the reporting of results for publication, and preventing the principal investigator from submitting a competitive renewal application for a NIH grant.

Mr. Morrow entered into a Voluntary Exclusion Agreement in which he voluntarily agreed for a 3-year period to exclude himself from any contracting, subcontracting, or involvement in grants and cooperative agreements with the U.S. Government, and to exclude himself from serving in any advisory capacity to PHS.

Heather J. Muenchen, Ph.D., University of Michigan (UM): Based on the UM investigation report, Dr. Muenchen's admissions, and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Dr. Muenchen, former UM postdoctoral fellow, engaged in scientific misconduct in research funded by National Institutes of Health (NIH) Urology Research Training Grant T32 DK07758 and SPORE grant PSO CA69568. Dr. Muenchen falsified and fabricated research data by computer manipulation of 12 Western blot analyses in 3 publications and 2 draft manuscripts. Specifically, PHS found that Dr. Muenchen: (1) falsified Western blot data in Figures 3, 4A, and 4B in Muenchen, et al., "Tumor necrosis factor-alpha-induced apoptosis in prostate cancer cells through inhibition of nuclear factor-6B by an I6B" 'super-repressor'" Clinical Cancer Research 6(5):1969-1977, 2000; (2) falsified Western blot data in Figures 2 and 3 in Muenchen, H.J., Poncza, P.J., and Pienta, K.J. "Different docetaxel-induced apoptotic pathways are present in prostate cancer cell lines LNCaP and PC-3." *Urology* 57(2):366-370, 2001; (3) falsified Western blots and associated claims for Figures 1, 5A, 5B, and 8 in Muenchen, et al., "Re-expression of functional androgen receptor in androgen-independent prostate cancer cells." which was published electronically on November13, 2000, in the *Journal of Biological Chemistry* (JBC) (withdrawn January 16,

2001); and (4) falsified Western blot analyses in Figures 4A, 4B, and 7 of the original draft submitted for publication on September 29, 2000, and the corresponding Figures 5A, 5B, and 8 in the second draft of the JBC manuscript. Dr. Muenchen was the first and corresponding author on the above publications, which were supported in part by the above-cited grants. These falsifications are significant because they misrepresent the expression of the androgen receptor, the necessary control data, the evidence for "super-repressor" binding and its effect, and the control data for assaying apoptosis. These misrepresentations occurred through a series of separate and specific deceptions in an attempt to obviate the legitimate criticisms of publication reviewers. These falsifications were designed to be misleading about the experiments' true results and to wrongfully induce publication of the experiments. Dr. Muenchen's work could have provided tools for understanding metastasis in prostate cancer and ultimately impact on treatment of this disease.

Dr. Muenchen entered into a Voluntary Exclusion Agreement in which she voluntarily agreed for 5 years beginning September 5, 2002, to exclude herself from any contracting, subcontracting, or involvement in grants and cooperative agreements with the U.S. Government, and to exclude herself from serving in any advisory capacity to PHS. In addition, within 30 days of September 5, 2002, she agreed to submit letters to the editor of *Urology* retracting the published paper, and to the editor of *Clinical Cancer Research,* identifying and retracting the falsified or fabricated data in Figure 3 and Figures 4A and 4B. Dr. Muenchen submitted retraction letters to both journals.

Shaan F. Munjee, M.S., Wake Forest University School of Medicine (WFUSM): Based on the investigation report by WFUSM and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Shaan F. Munjee, M.S., former research fellow, Department of Cancer Biology, WFUSM, engaged in scientific misconduct by falsifying and fabricating data in research supported by National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health (NIH), grants 5 R29 DK52623-03 and 5 R29 DK52623-04, "PTHRP and prostate growth." Specifically, PHS found that Ms. Munjee falsified data relating to the signaling of protein kinase in prostate cancer cell lines. From March through October 2000, Ms. Munjee falsified and fabricated data in

her notebook from experiments to misrepresent her productivity and the significance of her findings.

Ms. Munjee reported the falsified and fabricated data in: (1) laboratory group meetings, a journal club, and a Cancer Biology retreat within WFUSM; (2) NIH grant application 5 R29 DK52623-04, and (3) an abstract submitted to the American Association for Cancer Research. Given the extensive nature of Ms. Munjee's data falsification and fabrication, none of her research can be considered reliable. Her actions adversely and materially affected the laboratory's ongoing research in prostate cancer by causing pursuit of an unproductive avenue of research and by preventing the principal investigator from submitting a competitive renewal application for an NIH grant. No publications required correction or retraction.

Ms.Munjee entered into a Voluntary Exclusion Agreement in which she voluntarily agreed for a period of 3 years, beginning December 17, 2001, to exclude herself from any contracting, subcontracting, or involvement in grants and cooperative agreements with the U.S. Government; and to exclude herself from serving in any advisory capacity to PHS.

James C. Pennington, Brown University (BU): Based on the BU report of an inquiry/investigation and additional ORI analysis, PHS found that James C. Pennington, formerly a graduate student in the Department of Cognitive and Linguistic Sciences, engaged in scientific misconduct by fabricating data in his master's thesis. The research was supported by National Institute on Deafness and Other Communication Disorders, NIH, grant R01 DC000314, "Speech and language processing in aphasia." Specifically, PHS found that (1) for Experiment 3, reported as having been conducted with 12 normal subjects, Mr. Pennington fabricated: (a) the mean reaction time data to auditory stimuli presented in Figures 5 and 6, and the results of the associated statistical analyses; and (b) the accuracy data presented in Tables 4 and 5, and the results of the associated statistical analysis; and (2) for Experiment 4, reported as having been conducted with 6 subjects with Broca's aphasia, he fabricated: (a) the mean reaction time data to auditory stimuli presented in Figures 7 and 8, and the results of the associated statistical analyses; and (b) the accuracy data presented in Table 6, and the results of the associated statistical analysis. The fabrication of Experiments 3 and 4, which were intended to incorporate improvements to the procedures used in Experiments

1 and 2, resulted in the premature termination of the planned experimental procedures and indeterminate or possibly misleading findings relative to the influence of negative priming on the processing of auditory stimuli in normal and aphasic subjects.

Mr. Pennington entered into a Voluntary Exclusion Agreement in which he voluntarily agreed for 3 years, beginning on June 21, 2002: (1) to exclude himself from serving in any advisory capacity to PHS, and (2) any institution that submits an application for PHS support for a research project on which his participation is proposed, or that uses him in any capacity on PHS supported research, or that submits a report of PHS-funded research in with he is involved, must concurrently submit a plan for supervision of his duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of Mr. Pennington's research contribution. The institution also must submit a copy of the supervisory plan to ORI.

M. Renuka Prasad, Ph.D., University of Kentucky School of Medicine (UK): Based on the UK investigation report and additional analysis conducted by ORI in its oversight review, PHS found that Dr. Prasad, a former Research Professor of Surgery, UK, engaged in scientific misconduct by fabricating and falsifying data. The research was supported by the National Institute of Neurological Disorders and Stroke (NINDS), NIH grant R01 NS34264, "Phospholipases in traumatic brain injury." This research is important to understanding the mechanism of breakdown of the blood-brain barrier and swelling from edema that occurs after traumatic injury of the brain. Specifically, PHS found that Dr. Prasad: (1) fabricated data to calculate a standard error of the mean for Bcl-2 mRNA intensity values for the sham group: 16 values (4 percentages for each of the 4 brain regions assayed), when only a single sham value of 100 percent was actually available, for the error bars shown in Figures 2 and 3 of a manuscript, "Regional expression of Bcl-2 MRNA and mitochondrial cytochrome c release after experimental brain injury in the rat," submitted to *Brain Research*, and included in Figures 11 and 12 of NINDS grant application R01 NS41918-01, "Neurochemical mechanisms in traumatic brain injury;" and (2) knowingly reported falsified data in Figures 1 and 3 and in the text of Dhillon, H.S. & Prasad, M.R. "Kynurenate attenuates the accumulation of diacylglycerol and free fatty acids after experimental brain injury in the rat." *Brain Research* 832:7-12, 1999.

Dr. Prasad entered into a Voluntary Exclusion Agreement in which he voluntarily agreed: (1) that for 3 years beginning August 19, 2002: (a) any institution that submits an application for PHS support for a research project on which Dr. Prasad'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 certify in every PHS research application or report that Dr. Prasad is prohibited from supervising other research staff; and (b) any institution employing him is required to submit a certification that the data he provided are based on actual experiments or are otherwise legitimately derived, and that the data, procedures, and methodology are accurately reported in the application or report; (2) to exclude himself from serving in any advisory capacity to PHS; and (3) within 30 days, Dr. Prasad must submit a letter to the journal *Brain Research* requesting retraction of the paper, stating that some of the data for the reported effects of kynurenate are falsified. Dr. Prasad sent a copy of the retraction letter to ORI.

Michael Shishov, M.D., Brigham and Women's Hospital, Inc. (BWH): Based on the investigation report by BWH, the respondent's admission, and additional ORI analysis, PHS found that the respondent, a former laboratory technician in the Intensive Physiological Monitoring Unit, BWH General Clinical Research Center, engaged in scientific misconduct in a program of sleep disorder research supported under National Center for Research Resources, NIH, grant M01 RR02635. Specifically, PHS found, and the respondent admitted, that on numerous occasions between May and August 1995, he registered on the Termiflex-computer terminal, as well as writing in hand on blood-draw sheets and laboratory logs, the times that he claimed he drew blood samples from human subjects in investigational sleep research. These times differed from the actual times when the samples were collected. The accurate assessment of the endogenous circadian phase and amplitude of the measured variables, including the timing and amount of blood cortisol, was essential for the studies. However, PHS acknowledges certain mitigating circumstances: (a) that occasionally during this time, the respondent may have been responsible for more protocol procedures than he could reasonably be expected to perform; and (b) that the BWH Report notes that he was respectful and honest during the investigation and that he has participated conscientiously in a program of professional ethics counseling. Therefore, PHS accepts the administrative actions previously imposed by BWH and

performed by the respondent: (1) attending an ORI conference on research misconduct; and (2) participating in ethics counseling over a 3-year period.

Dr. Shishov entered into a Voluntary Exclusion Agreement and agreed to exclude himself from serving in any advisory capacity to PHS for 3 years, beginning July 2, 2002.

Robert B. Tracy, Ph.D., University of Southern California (UCS) and University of California, Davis (UCD): Based on Dr. Tracy's admission, UCS and UCD reports, and additional ORI analysis in its oversight review, PHS found that Robert B. Tracy, Ph.D., former UCD doctoral student, and former USC postdoctoral student, engaged in scientific misconduct by falsifying and fabricating data in research supported by National Institute of Allergy and Infectious Diseases, NIH, grant R01 AI18987, "Mechanistic studies of genetic recombination," and NIGMS, NIH, grant 1 R01 GM56984, "Mechanism of DNA recombination at class switch sequences." Dr. Tracy's doctoral research at UCD involved the analysis of the mechanisms used by various enzymes to repair damaged DNA, while his postdoctoral research at USC dealt with the molecular mechanism used by B-lymphocytes when switching from producing one class of immunoglobulin to another. Specifically, PHS found that: (1) in 1996 and 1997, Dr. Tracy falsified research supported by NIH grant R01 AI18987, "Mechanistic studies of genetic recombination," while working on his UCD doctoral dissertation; he falsified Figure 6.2 of his Ph.D. thesis by adding discrete bands where there actually had only been a uniform smear of radioactivity, the effect suggesting an unobserved result, which was, therefore, falsified; the falsified image was not published; and (2) from 1998 to 2000, Dr. Tracy committed additional scientific misconduct while a USC postdoctoral research fellow funded by NIH grant R01 GM56984 "Mechanism of DNA recombination at class switch sequences." Dr. Tracy falsified values in Table 1 of supplemental web material that accompanied (Tracy, R.B., Hsieh, C.-L., & Lieber, M.B., "Stable RNA/DNA hybrids in the mammalian genome: Inducible intermediates in immunoglobulin class switch recombination." Science 288:1058-1061, 2000; the "Science paper"). In Table 1, Dr. Tracy misrepresented that lymphocytes from mice transgenic for ribonuclease H underwent significantly lower rates of isotope switching, when the actual data showed no such difference for IgG1, IgG2b, and IgE isotope classes. Dr. Tracy also falsified Figures 2 and 4 of the supplemental web material

published with the Science paper in that the results were not representative of multiple independent experiments as he claimed. In addition, Dr. Tracy falsified Figure 2C of the Science paper, which represented a crucial control to establish his claim that RNA/DNA hybrids were limited to immunoglobulin switch regions, by publishing a blot that was not representative of his overall results. He also falsified Figures 4 and 7 of a second paper (Tracy, R.B., & Lieber, M.R. "Transcription-dependent R-loop formation at mammalian class switch sequences." *EMBO J.* 19:1055-1067, 2000) using the PhotoShop computer program to move bands or regions of a lane vertically relative to the rest of the gel, thus falsifying the size of molecules described in the paper. He reported these falsified data in the progress report for NIH grant 5 R01 56984-03. Dr. Tracy and his coauthors retracted both papers, in Science 289:1141, 2000, and in *EMBO J.* 19:4855, 2000, respectively.

Dr. Tracy entered into a Voluntary Exclusion Agreement in which he voluntarily agreed for 4 years beginning May 1, 2002, to exclude himself from any contracting, subcontracting, or involvement in grants and cooperative agreements with the U.S. Government, and to exclude himself from serving in any advisory capacity to PHS.

Zhenhai Yao, M.D., Ph.D., The University of North Carolina at Chapel Hill (UNC): On August 20, 2002, PHS entered into a Voluntary Exclusion Agreement with UNC and Zhenhai Yao, M.D., Ph.D., an Associate Professor of Anesthesiology, School of Medicine at UNC. Based on the UNC Report, the respondent's admissions, and additional analysis conducted by ORI in its oversight review, PHS found that Dr. Yao engaged in scientific misconduct in research funded by the National Heart, Lung, and Blood Institute, NIH. Specifically, PHS and UNC found that Dr. Yao:

(1) falsified two flourescent micrographs for figures presented in three NIH grant applications:

Dr. Yao falsely claimed that two fluorescent micrographs in the figure represented neonatal rat cells transfected with an adenovirus-derived vector, when the cells actually were chick cells transfected with a cytomegalovirus-based vector, taken from another scientist at the University of Chicago.

(2) Falsified the same two fluorescence micrographs of CMV-transfected chick cells described in (1) above, by misrepresenting their description as

embryonic chick cells transfected with pcDNA, with and without green fluorescent protein in an NIH grant application.

(3) Falsified a flow cytometry histogram in Figure 1B on p. 22 of NIH application R01 HL66230-01A1, by claiming the histogram represented results with rat myocardiocyte cultures treated with an opiate antagonist (staurosporine).

However, this histogram had been published by Liu, H., McPherson, B.C., & Yao, Z. "Preconditioning Attentuates Apoptosis and Necrosis: Role of Protein Kinase C and - Isoforms." *Am. J. Physiology Heart Circ Physiol.* 281: H404-H410, 2001, as Figure 1f showing the result from embryonic chick cells treated for 12 hours with deoxy-glucose in the absence of oxygen (simulated ischemia).

(4) Falsified claims about research results in NIH grant application R01 HL66230-01A1, by claiming that data in Figure 3 on p. 23 represented experiments on cultures of neonatal rat cardiomyocytes as an in vitro model of hypoxia-reoxygenation, shown as data from four separate experiments measuring apoptosis by different means.

The data in the four separate experiments portrayed in Figure 3 are identical to Figure 1, p. 2009, in the publication by Liu, H., Zhang, H.Y., McPherson, B.C., Baman, T., Roth, S., Shao, Z., Zhu, X., & Yao, Z. "Role of Opioid $_{1}$ Receptors, Mitochondrial K_{ATP} Channels, and Protein Kinase C during Cardiocyte Apoptosis. *J. Mol. Cell. Cardio.* 33:2007-2014, 2001, which were reported as the results from experiments on cultures of embryonic chick cardiocytes.

(5) Falsified the micrographs in panels a and d, Figure 1, p. 2009, in the publication by Liu, H. et al., *J. Mol. Cell. Cardiol.* 33:2007-2014, 2001, by claiming they represented TUNEL data showing normal media and opioid antagonist (BTNX)-treated cultures of chick cardiocytes, respectively.

The same micrographs had been reported by Liu, H. et al., *Am. J. Physiology Heart Circ Physiol.* 281:H404-H410, 2001, in Figure 1 (panels a and e) and in Figure 2 (panels a and b), as representing cardiocyte cultures exposed for 24 hours to deoxy-glucose and no oxygen (simulated ischemia).

(6) Falsified the physiological effects of gene transduction into hearts, by copying and re-using the same pressure tracing for untreated rates as he did for rats purportedly treated by intracardial injection with adenovirus (AdEGFP) in 4 NIH grant applications.

(7) Falsified data in panels c and d in Figure 13, p. 26, in NIH grant application R01 HL66230-01A1. Dr. Yao claimed that panel c represented a TUNEL assay on histological sections of myocardium from a rat transfected with Ad.gal and subjected to ischemia-reperfusion and that panel d represented a tissue section from a rat transfected with Ad.PKC-FL.

Panel c is a horizontally compressed copy of panel b, purported to be a non-transfected rat subjected to ischemia-reperfusion, and panel d is a horizontally expanded version of panel a, purported to be a sham-operated, non-transfected control.

(8) Falsified claims about the micrograph of ischemic data in (7) above. In both examples, the figures, which are identical, consist of two panels purported to be TUNEL data showing sham operated controls (panel a)and the effect of transient ischemia for 30 minutes (panel b). However, these data are identical to Figure 10, p. 32, in NIH application K08 HL03881-01, reported a control and the effect of nontransient ischemia, i.e., 20 hours of ischemia followed by 24 hours of reperfusion.

(9) Falsified data in Figure 14 on p. 27 in NIH grant application R01 HL66230-01A1, as representing a gel electophoresis data from an in vivo experiment on rat myocardial ischemia.

However, the same data was represented as Figure 3, p. 23, of the application (and also as in Figure 1, *J. Cell. Mol. Cardiol.* 33:2007-2014, 2001), as results from a study of embryonic chick heart cell cultures for the effect of preconditioning on opioid receptors. Furthermore, that Dr. Yao falsified the stated size of the fragments in the DNA marker ladder by altering the position of the molecular weight markers in Figure 14.

(10) Falsified Figure 3, p. 27, in 1 R01 HL67416-01, a DNA-laddering gel electrophoresis experiment, showing that apoptosis in cardiocyte cultures is significantly increased by staurosporin and by 12 hours of simulated ischemia.

The same data was shown in Figure 1, p.26, in application HL03881-07 showing that apoptosis is significantly increased by 10 μM NE and by 15 nM TNF-$\propto$.

The research misconduct was significant because Dr. Yao's research involved the fundamental mechanisms for cardiac cell injury and pathogenesis after a heart attack. The falsified data were significant to reviewers' opinions on funding because they were advanced as preliminary results showing successful new experiments extending his experimental model to adult rat hearts.

Dr. Yao entered into a Voluntary Exclusion Agreement in which he voluntarily agreed for 5 years beginning August 20, 2002, to exclude himself from any contracting, subcontracting, or involvement in grants and cooperative agreements with the U.S. Government, and to exclude himself from serving in any advisory capacity to PHS. Additionally, he agreed to submit a letter to the *Journal of Molecular and Cellular Cardiology* requesting retraction of Figure 1 in the article by Hui Liu, et al., *J. Mol. Cell. Cardiol.* 33:2007-2014, 2001, within 30 days of August 20, 2002. This requirement will be noted on the ALERT System until Dr. Yao sends a copy of the retraction letter to ORI.

Appendix B

Summaries of Closed Inquiries and Investigations Not Resulting in Findings of Research Misconduct - 2002

Fabrication: The respondent, a project coordinator, allegedly fabricated results of cognitive tests in research involving head injuries in children. The questioned research was supported by a National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH), grant. The institution conducted an investigation into the matter. The institution concluded that while there were deviations from standard administrative procedures, there was no evidence of scientific misconduct. ORI concurred with the institution's conclusion that there was insufficient evidence that the respondent committed falsification or fabrication of data and did not make a finding of scientific misconduct.

Falsification: The respondent, a former Master's degree student, allegedly falsified research in a thesis and in two National Institute of Allergy and Infectious Diseases (NIAID), NIH, grant applications. The research in question involved vaccine development for *Haemophilus infuenzae*. The institution conducted an investigation into the matter. The institution concluded that the respondent had falsely claimed that two experiments had been obtained independently. However, ORI declined to pursue a PHS finding of scientific misconduct after consideration of the significance of the misconduct, the weight of the evidence, and the allocation of Federal resources in case of appeal, among other considerations.

Falsification: The respondent, an assistant professor, allegedly falsified figures in a manuscript submitted to a journal for publication. The questioned research involved antiretroviral therapy. The questioned research was supported by NIAID and National Institute of Dental and Craniofacial Research (NIDR), NIH, grants or contracts. The institution conducted an inquiry into the matter. The institution concluded that there was not sufficient evidence of possible scientific misconduct on the part of the respondent with regard to the specific allegations to warrant an investigation. ORI concurred with the institution's determination that there was insufficient evidence to warrant an investigation in this case.

Falsification: The respondent, an assistant professor, allegedly falsified data by misrepresenting a figure in a grant application submitted to the National Heart, Lung, and Blood Institute (NHLBI), NIH. The research involved a mechanism of death of heart muscle cells under certain physiological stress conditions. The institution conducted an inquiry into the matter and determined that an honest error was made in mislabeling the questioned figure. Thus, the institution concluded that there was no need to proceed to a formal investigation. ORI concurred with the institution's determination that there was insufficient evidence to warrant an investigation.

Falsification: The respondent, an assistant professor, allegedly falsified the legend to a figure in a grant application submitted to the NHLBI, NIH. The research involved regulation of genes in certain microorganisms that are human enteric pathogens. The institution conducted an inquiry into the matter and determined that erroneous statements were made by the investigator in the grant application, which were due to miscommunication with a laboratory staff member, whose research records were poorly documented. The institution concluded that these errors were reported to the funding agency for its reviewers before the review of the application took place and that the errors were inconsequential, given the decision of the agency to fund the research. Thus, the institution found there was no substance to the allegations of scientific misconduct. ORI concurred with the institution's conclusion that there was insufficient evidence of scientific misconduct to warrant any further investigation.

Falsification: The respondents, former clinical trial staff, allegedly falsified research records to enroll and follow ineligible patients in a clinical trial involving breast cancer research. The questioned research was supported by two U.S. Public Health Service (PHS) cooperative agreements. The institution conducted an inquiry into the matter. The institution determined that while there was some confusion as to the enrollment criteria and a general lack of oversight of the clinical trial process for a brief interval, there was insufficient evidence of falsification to warrant further investigation. ORI concurred with the institution's determination.

Falsification: The respondent, a former laboratory technician, allegedly falsified data on blood-draw sheets and laboratory logs in research using human subjects. The research was supported by a National Center for

Research Resources (NCRR), NIH, grant, and an NHLBI, NIH grant. The institution conducted an investigation into the matter and found that there was insufficient evidence to determine that the respondent had committed misconduct. However, the institution suggested that the respondent would benefit from extended ethics counseling. ORI concurred with the institution that based on a preponderance of the evidence, there is insufficient evidence to make a finding of scientific misconduct against the respondent.

Falsification: The respondent, a research associate, allegedly falsified or fabricated data in research involving the effects of radiation on the survival of cultured cells. Some of this data was included in a grant application submitted to the National Cancer Institute (NCI), NIH, and other data was supported by the subsequent grant. The institution conducted an inquiry into the matter and found that there was insufficient evidence to determine that the respondent had committed misconduct and that there was no cause for further investigation into the matter. Given the weaknesses in the available evidence, ORI concurred with the institution that there was insufficient evidence to warrant further investigation.

Falsification: The respondent, a technician, allegedly falsified research data included in Excel® spreadsheets in a study involving energy expenditure in humans. The research was supported by a National Institute of Child Health and Human Development (NICHD), NIH, grant. The institution conducted an investigation into the matter. Due to such factors as a lack of direct evidence, failing equipment at the time of the alleged incident, the respondent's huge backlog of work, a lack of training of the respondent, a lack of supervision of the respondent, and the strong possibility that the respondent did not know the consequences of transcribing the data incorrectly, the institution concluded that a preponderance of the evidence did not support a finding of misconduct. ORI accepted the institution's finding that based on a preponderance of the evidence, there was insufficient evidence to make a finding of scientific misconduct in this case.

Falsification/Fabrication: The respondents, two professors, allegedly falsified or fabricated data in research involving the measurement of receptors in the treatment of allergic animals. The allegedly falsified or fabricated graphs were reported in a published paper. The questioned research was supported by an NCI, NIH, grant, two NHLBI, NIH, grants, and was also

reported in two NIH small business grant applications. The institution conducted an inquiry into the matter. Although most of the original research records had been discarded on later moves between institutions, the institution determined that there was sufficient evidence to conclude that the experiments were performed as claimed and that the graphs in question were inaccurate due to honest errors made by inexperienced staff in plotting the results. ORI concurred with the institution's determination that there is insufficient evidence to warrant any further investigation.

Falsification/Fabrication: The respondent, an associate professor, allegedly falsified and/or fabricated claims in several publications involving the mechanism of cell death in lymphocytes. The research was supported by an NCI, NIH, grant application, and an NCI, NIH, cooperative agreement. The institution conducted an inquiry into the matter and concluded that there was insufficient evidence to establish a sound factual basis for an allegation of scientific misconduct. Thus, the institution did not recommend any further investigation. ORI concurred with the institution's determination that there was insufficient evidence of scientific misconduct to warrant further investigation.

Falsification/Fabrication: The respondents, an assistant professor and a project director, allegedly falsified research and/or staff credentials in research involving drug abuse and AIDS. The questioned research was proposed, reported, and/or supported by National Institute on Drug Abuse (NIDA), NIH, grant applications. The institution conducted an inquiry and an investigation into the matter. The institution concluded that one respondent did not commit scientific misconduct but that the other respondent did commit misconduct by: (1) misstating credentials of staff, and (2) deceptively reporting findings in published abstracts (considered to be falsification), along with other charges not falling under the PHS definition. However, while acknowledging that the institution is free to make its own findings in accordance with its own policy, ORI found insufficient evidence or impact to warrant a finding of scientific misconduct on the part of either respondent.

Falsification/Fabrication: The respondent, a former graduate student researcher, allegedly fabricated and/or falsified interview data for subjects in a study involving factors leading to physical activity in adults. The research was supported by an NICHD, NIH, grant. The institution conducted an

investigation into the matter and determined that while the respondent's conduct was less than professional, there was insufficient evidence to support a finding of scientific misconduct. ORI accepted the institution's finding that there was insufficient evidence that the respondent committed scientific misconduct.

Falsification/Fabrication: The respondent, an associate professor, allegedly falsified, fabricated, or misrepresented data in cytogenetics research involving two medical conditions or diseases. The questioned data were included in grant applications submitted to NIH and reported in meeting presentations and publications. The institution conducted an investigation into the matter. The institution concluded that in an effort to obtain extramural funding to maintain his research program, the respondent pushed the limits of acceptable scientific conduct in several areas. The institution recommended several administrative actions, including withdrawal of an NIH grant application and an abstract. ORI did not make a finding of scientific misconduct on any of the allegations in this case when defined as PHS issues. However, ORI noted that a determination by ORI under the PHS definition of scientific misconduct does not diminish the authority of the institution to independently set its own standards and to make determinations of when its employees have failed to meet the norms of behavior expected of scientists.

Falsification/Fabrication: The respondents, former graduate students, allegedly falsified data included in a publication and fabricated data included in a doctoral thesis. The questioned research focused on the understanding of molecular mechanisms that underlie initiation of cancer growth in certain cells. The research was supported by four NCI, NIH grants. The institution conducted an inquiry into the matter and concluded that there was insufficient evidence to warrant an investigation. ORI concurred with the institution's determination.

Plagiarism: The respondent, an assistant professor, allegedly plagiarized words and ideas from a publication by another investigator and included the plagiarized material in a National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control (CDC), grant application. The questioned research involved occupational biomechanical demands. The institution conducted an investigation into the matter and concluded that there was a breach of research ethics caused more by carelessness than intent

and did not make a finding of scientific misconduct. The institution set forth sanctions intended to be developmental rather than punitive. ORI accepts the institution's finding that, while there was evidence of plagiarism in the grant application, there is insufficient evidence to support a finding of scientific misconduct.

Appendix C

Research Misconduct Related Litigation During 2002[2]

CIVIL LITIGATION - Open Cases

Marquerite Kay, M.D.* v. *Arizona Board of Regents, No. C-328309 (D.AZ, May 2002). In this companion case to three previous cases (see *Kay v. Tolbert, supra*), Dr. Kay seeks review of the University of Arizona's final decision terminating her employment as a faculty member. Dr. Kay alleges denial of her property interest in her employment and liberty interest in her name without substantive due process, breach of contract, and tortuous interference with her employment relationship. She has requested an injunction, reinstatement, back pay, and compensatory and punitive damages. Dr. Kay was subject to several previous research misconduct and termination hearings which one of the court cases ordered redone due to procedural deficiencies. This suit focuses on the most recent research misconduct and termination hearings by the University's Committee on Academic Freedom and Tenure finding scientific misconduct and recommending dismissal and the concurring decisions by the University President.

Jessie L. S. Au* v. *Yulin Ma, No. C2-01-0596 (D.OH, June 20, 2002). Dr. Au is suing Dr. Ma, claiming libel for statements that Dr. Ma made in an e-mail to The Ohio State University alleging, among other things, research misconduct.

June M. Caruso, D.O.* v. *St. Jude Children's Research Hospital, Inc., et al., (No. 01-2643-G/V) (W.D.Tenn., filed Aug. 10, 2001). The Federal district court dismissed the suit brought by Relator, June M. Caruso, who filed this case under the Tennessee Whistleblower Statute, Tenn. Code Ann. § 50-1-304. Dr. Caruso, a former employee at defendant St. Jude Children's Research Hospital, alleged that St. Jude's committed scientific misconduct and medical mistreatment. Plaintiff sought $6,000,000 in compensatory damages and

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[2]OGC tracks all civil and criminal litigation cases related to ORI's mission. Many cases, especially those in which ORI is a named party, require active participation with the Department of Justice, including sharing of information, discovery, taking depositions, preparing briefs and pleadings, and assisting with strategy decisions. The litigation summaries provided here do not include *qui tam* cases which are under seal (and therefore are not yet publicly reported), cases in which ORI has only a peripheral interest, nor cases in which a complaint has not yet been filed or an indictment issued.

$6,000,000 in punitive damages. The Assistant Secretary for Health denied Dr. Caruso's request that an ORI scientist investigator be required to provide testimony in the suit.
St. Jude's filed a motion for summary judgment, which the court granted in July 2002. In August 2002, the court issued an order to show cause why claims against the remaining defendant, Children's National Medical Center, Inc., should not be dismissed for failure to obtain service. The court entered judgment dismissing the case in its entirety on September 23, 2002. Dr. Caruso continued to file petitions and motions seeking discovery, default judgment, and other relief. The court issued an order on October 31, 2002, enjoining the plaintiff from filing further documents, and noting that Dr. Caruso's time for filing a notice of appeal had expired on October 23, 2002. This case is now closed.

Marquerite Kay, M.D.* v. *Tolbert, No. 290-TUC-JMR (D.Az. March 30, 2001). In this companion case to now closed *Kay v. Arizona State Board of Regents*, Dr. Kay filed a breach of contract and section 1983 suit in state court, suing the University of Arizona and institutional employees, including members of the investigation committee, for damages relating to the scientific misconduct investigation against her. The University removed the case to Federal court, and the District Court dismissed it. The court granted the defendants' motion for summary judgment and dismissed the case with prejudice, awarding costs against Dr. Kay. The judge held that many of the issues raised by Dr. Kay were *res judicata* because of the decisions in her prior lawsuits. Relaying on *Harlow v. Fitzgerald*, 457 U.S. 800 (1982), the court also held that all the individual defendants were entitled to qualified immunity. With respect to Dr. Kay's substantive due process claims, the court held that the defendants were entitled to qualified immunity because at the time she was terminated, the law on this matter was unclear, and she had no clearly established constitutional right to substantive due process protection. With respect to her due process claims, the court held that the individual defendants were entitled to qualified immunity because they either did not cause the due process violation (the termination without hearing) or they acted reasonably and relied in good faith on the termination process used on the advice of counsel. Dr. Kay appealed the District Court decision to the 9th Circuit Court of Appeals. The parties submitted written briefs and oral argument is scheduled for summer 2002.

U.S. ex rel. Gene Ioli* v. *regents of the University of California, John Hiserodt, et al., No. SACV 98-473 GLT (C.D. Calif., filed June 1998). The Relator, Mr. Gene Ioli filed this *qui tam* suit under the False Claims Act, 31 U.S.C. § 3730, against the Regents of the University of California, Dr. John Hiserodt, and others. Mr. Ioli alleged, among other things, that Dr. Hiserodt violated the terms of his 5-year debarment for committing scientific misconduct by directing the PHS-supported research of others at the University of California at Irvine. Mr. Ioli further alleged that the University of California falsely certified compliance with NIH grant requirements in a grant application to the National Cancer Institute. The Federal government declined to intervene in the case, and the District Court lifted the seal. Based upon the U.S. Supreme Court decision in *Vermont Agency of Natural Resources* v. *U.S. ex rel. Steven*, which held that a private individual may not bring suit in federal court on behalf of the United States against a state under the False Claims Act, the court dismissed the *qui tam* suit as to the Regents of the University of California. The Court dismissed defendant Kikkawaa from the case for the counts involving the alleged false claims, but he is still a defendant for claims of whistleblower retaliation against the Relator. However, the Court denied the motion to dismiss Dr. Hiserodt as a defendant. The case was removed to Arizona.