Office of Research Integrity

Annual Report 2003

August 2004

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

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Highlights of 2003 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 involving research, research training or related research activities supported by the Public Health Service (PHS), (2) education in the responsible conduct of research (RCR), (3) prevention of research misconduct, and (4) compliance with the PHS regulation, 42 C.F.R. Part 50, Subpart A.

Responding to Research Misconduct Allegations

- Found research misconduct in 12 of the 29 cases closed. The percentage of closed cases yielding PHS misconduct findings or PHS administrative actions (41 percent) exceeded the historical average of 37 percent for the third consecutive year. All 12 misconduct findings involved falsification and/or fabrication of data; none involved plagiarism. Eight respondents made documented admissions of their misconduct. Three respondents were survey interview staff from a single research study. Another respondent had failed to be excluded from federal funding as previously required, and he was given additional years on the administrative actions imposed. An additional respondent in 2003 was a recidivist from a decade ago, but at a neighboring institution. About 70% 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) in the 12 cases that resulted in research misconduct findings: debarment or voluntary exclusion for 3 to 10 years, 7 respondents; supervision plans, 5 respondents; certification of data or sources, 2 respondents; and prohibition from serving PHS in an advisory capacity, 12 respondents. All recommendations were approved by the ASH.

- Opened 22 new cases, closed 29 cases, and carried 41 cases into 2004. These numbers are below the 10-year averages of 34 new cases, 37 closed cases, 44 carried forward cases. The number of new allegations (179) is slightly above the 177 average.

- For the 29 cases involving inquiries or investigations reviewed and closed by ORI in 2003, institutions took a mean of 9.6 months after their notification of ORI (median, 7 months; range, 1 to 21 months) to complete their actions. ORI took a mean of 4 months (median, 7 months; range 1 to 23 months) to review the reports, obtain additional information from the institution, complete the ORI analysis, negotiate any PHS findings and administrative actions, and close these cases.

- Offered Rapid Response for Technical Assistance (RRTA) formally to 26 institutional officials in the cases opened by ORI in 2003, 25 of whom accepted ORI help (up from 21 in the prior year); 9 of them were new clients, requesting from ORI specific and substantive advice, including advice on the handling of allegations, working with respondents and the sequestration of evidence during their assessment or inquiry stages. Of the 29 cases closed by ORI in 2003, ORI had provided RRTA during the early stages to 7 of them. ORI also provided guidance to two editors who each contacted ORI about two allegations that they had received and wanted advice in handling the allegations or referring them to ORI.

Education and Prevention

- Made 17 awards through the Responsible Conduct of Research (RCR) Resource Development Program to 11 universities, 2 hospitals, 1 college, 1 professional association, and 1 commercial firm for the development of instructional materials for RCR education programs. Twenty-eight projects were funded in the first two years of the program; 11 have been completed.

- Held the first RCR Expo at the annual meeting of the Society of Research Administrators International in Pittsburgh. Exhibitors included 15 universities, 2 federal agencies, 1 non-profit organization, and 2 commercial firms. The RCR Expo enabled creators of RCR resources to display, demonstrate and discuss their products while providing potential users with an opportunity to review those resources and discuss their needs, options, and desires, thereby, generating a dialogue among and between creators and users of RCR resources.

- Made 7 awards through the RCR Program for Academic Societies, a collaboration between the Association of American Medical Colleges and ORI, to institutionalize infrastructure, activities, and programs aimed at promoting RCR among their members, including publication policies, guidelines or standards, development of committees or sections, annual meeting sessions, training of postdocs, graduate and undergraduate students, and continuing education programs for their members.

- Distributed the *ORI Introduction to the Responsible Conduct of Research* to 4,000 institutions and organizations that have a research misconduct assurance on file with ORI. The publication was produced 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. The publication may be purchased from the Government Printing Office. A revised edition was published in 2004.

- Co-sponsored 9 conferences or workshops on topics related to the responsible conduct of research, research integrity, or research misconduct in collaboration with 5 universities, 2 medical schools, 2 medical centers, 4 professional associations, and the Office for Human Research Protections, HHS.

- The ORI web site had 74,602 visits by 38,359 unique visitors in FY 2003. The web site averaged 204 visits per day with the average visit lasting a little more than 17 minutes. Eighty-four percent of the visits were from individuals within the United States; 16 percent were visits from individuals in 18 other countries.

- Made 52 presentations at conferences, workshops, annual meetings of professional associations and scientific societies, and symposia, seminars and training sessions at universities, medical schools, hospitals, and federal agencies.

Research on Research Integrity and Research Misconduct

- Completed a survey of research integrity measures utilized in biomedical research laboratories and collaborated with NIH on a project designed to develop a plan for evaluating the implementation of the RCR training requirement in institutional research training grants.

- Initiated studies of institutional research integrity officers (RIOs), research misconduct investigations closed from 1994-2003, and research misconduct activity reported by institutions from 1991-2000. Continued to develop the questionnaire for a study of the incidence of research misconduct in biomedical research, and provided ORI data, under strict confidentiality requirements, to a researcher/consultant who wanted to study misconduct cases involving clinical trial staff.

- Awarded 5 grants through the Research on Research Integrity Program, increasing the number of studies supported to 21. The program is a collaboration with the National Institute of Neurological Disorders and Stroke (NINDS) that is also supported by the National Institute of Nursing Research (NINR), the National Institute on Drug Abuse (NIDA), and the Agency for Healthcare Research and Quality (AHRQ).

- Began organizing the third Research Conference on Research Integrity, which will be held in San Diego, CA, from November 12-14, 2004. Over 70 abstracts have been accepted for presentation as research papers or posters during the biennial event.

Institutional Compliance

- Completed the 2002 Annual Report on Possible Research Misconduct in which institutions reported the highest level of research misconduct activity since 1993. Seventy-one institutions reported opening 83 new cases in response to 163 allegations.

- Inactivated assurances for 651 institutions or organizations for failing to submit the calendar year 2002 Annual Report on Possible Research Misconduct by the March 31, 2003 deadline.

- Processed 199 institutional policies on handling allegations of research misconduct, requested 209 institutional policies for review, and increased the number of completed reviews to 2,117.

Information and Privacy

- Handled 34 Freedom of Information Act (FOIA) requests. Completion time ranged from 1 to 103 days. The median was 14 days; the mean was 17 days, with a modal response time of 1 day. One Privacy Act request was also processed. One FOIA request was carried into 2004.

Regulations

Drafting on a revised PHS research misconduct regulation incorporating a new definition of research misconduct was largely completed in 2003. The regulation was submitted to the Office of the Secretary for Health and Human Services for review and approval and published for public comment in April 2004.

A new proposed regulation to protect whistleblowers who make allegations of research misconduct was published in 2000. This regulation has been indefinitely stayed until the revised PHS research misconduct regulation is finalized.

I. Responding to Research Misconduct Allegations

Introduction

ORI maintains oversight of institutional handling of research misconduct allegations through its Division of Investigative Oversight (DIO). Research misconduct investigations conducted by PHS awardee institutions and PHS agencies are reviewed by DIO staff for timeliness, objectivity, thoroughness and competence. On the basis of those reviews DIO makes recommendations on findings and administrative actions to the Director, ORI. The DIO staff also assists the Office of the General Counsel (OGC) in preparing cases that will be heard by the Research Integrity Adjudications Panel of the Departmental Appeals Board, HHS, organizes conferences and workshops on the handling of research misconduct allegations, provides assistance and advice to institutions on the conduct of inquiries and investigations through the Rapid Response for Technical Assistance Program (RRTA), and provides information on HHS policies and procedures, as requested, to individuals who have made an allegation or have been accused of research misconduct.

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 a PHS source of 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 some 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 the Inspector General, HHS).

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 makes an appropriate disposition. In some instance, ORI requests preliminary information about a case from an institution. Many assessments require appreciable ORI staff work at this phase.

In 2003, ORI received 179 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, 2003

Handling of allegations - outcome in ORI		*Number of allegations*
Pre-Inquiry Assessment by ORI of allegations:		38
that were made to ORI directly	27	
that were made to NIH initially	11	
No Action Possible Now or No Action		83
Referred to other Federal agencies		15
Handled by NIH (for other allegations made to NIH)		5
TOTAL		179

Of the 179 allegations made to ORI in 2003, 27 were assessed in detail for a potential inquiry or investigation. Fifteen were immediately referred to other agencies, and 121 were closed without further action (Table 1). Of the 27 allegations that received a detailed assessment, 24 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 10 and 20 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 11 allegations that were made directly to NIH by complainants (Table 1). The 5 other allegations handled by NIH did not fall under the research misconduct regulation. The number of allegations that ORI has received over the past three years has averaged 27% higher than that for the prior three years.

Table 2: Time for Conduct by ORI of Pre-inquiry Assessments, 2003 (N= 179)

Outcome of ORI assessment	*Number of new allegations*	*Total days for resolution*	*Distribution of resolution times (days)*			
			Mean	*Median*	*Mode*	*Range*
Opened formal case	17	334	20	5	2	1 - 173
Administratively closed	9	92	10	11	11	2 - 20
Unresolved at end of year 2003	1	8	8	-	-	8
TOTAL	27	434	-	-	-	1 - 173

Processing of Closed Cases

ORI closed 29 cases in 2003, including 5 inquiries and 24 investigations. The average duration of 14 months for an open case was split between institutional actions (9.6 months) and ORI oversight and actions (4.4 months) (Table 3). Twenty-seven (27) cases (93% of total number) were closed by ORI within 8 months of the institutional actions being completed.

Table 3: Duration of Research Misconduct Cases Closed, 2003 (N= 29)

Site of action during case	*Distribution of resolution times (months)*			
	Mean	*Median*	*Mode*	*Range*
Institution	9.6	7	6	1 - 21
ORI	4.4	4	4	1 - 23
TOTAL (Inst & ORI)	14	14	14	1 - 44

The action period for the 5 institutional inquiries included their inquiry and adjudication phases, and for 24 institutional investigations included their inquiry, investigation, and adjudication phases.

The action period for ORI oversight includes a detailed review of each institution's inquiry 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 23 months for ORI to resolve, the institution had poorly documented the evidentiary record, so ORI staff spent many months obtaining and reviewing the research notebooks of the respondent, who then was unresponsive to ORI requests for a negotiated settlement. Thus, ORI spent months writing a charge letter, for approval by the Assistant Secretary for Health, which led, when he was again unresponsive, to his debarment.

In a case that took 13 months for ORI to resolve, ORI staff again had to reanalyze the research records, given an incomplete report from the institution, and ORI had to negotiate with the respondent's attorney for many months, including meeting

his request for an interview by ORI officials, before a settlement was reached with five years of supervision and a full personal admission, which was published in the *Federal Register* and *ORI Newsletter*.

No cases were closed in 2003 with a three-way agreement, but six (6) other such three-way agreements had been negotiated by ORI's counsels with institutional counsels and respondent's attorneys in prior years. Institutional officials are encouraged to call ORI early in the conduct of cases in which there are full admissions of misconduct and the respondent appears to be ready to settle the case quickly.

In 2003, 12 of the 24 investigation cases closed by ORI resulted in sustained findings of scientific misconduct and PHS administrative actions against the respondent (Table 5). Summaries of these cases may be found in Appendix A. Summaries of the 12 investigations closed by ORI that did not result in findings of scientific misconduct are located in Appendix B.

Caseload

The ORI caseload is divided into two elements: institutional inquiries and institutional investigations. ORI carried forward 48 cases from 2002, and ORI opened 22 new cases and closed 29 cases during 2003. At the end of calendar year 2003, ORI had 41 active formal cases divided between inquiries and investigations, as well as 17 allegations, under review (Table 4).

Table 4: ORI Scientific Misconduct Caseload by Case Type, 2003

Case type	*Forwarded from 2002*	*Opened in 2003*	*Closed in 2003*	*Carried into 2004*
Institutional inquiries	14	10	5	19
Institutional investigations	34	12	24	22
TOTAL	48	22	29	41

***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 2003, ORI accepted 5 institutional inquiry reports that did not recommend further investigation (Table 5). Two (2) cases involved allegations of falsification, two dealt with alleged fabrication and falsification, and one involved plagiarism. ORI carried 19 such institutional inquiries into 2004.

***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 2003, ORI continued monitoring 34 investigations at research institutions. During the year, 12 new institutional investigations were opened; 24 investigations cases were closed (Table 4). Of these 24 closed cases, 12 involved ORI findings of scientific misconduct; 12 did not have such findings. Of the total of 29 cases closed in 2003, 41% (12 cases) involved findings of scientific misconduct, which is close to the 2002 average (45%) and above the historical average of about one-third of ORI cases with such findings (Table 5).

Respondents in 8 of the 27 cases involving falsification or fabrication findings made documented admissions of their misconduct.

There were 22 active investigation cases carried into 2004. About 70% of the cases that ORI carried over in 2004 include institutional findings of misconduct.

Table 5: Outcome of Research Misconduct Cases Closed by ORI, 2003 (N= 29)

Case Type	*Outcome of Case*				*Total*
	No investigation	*No misconduct*	*Misconduct finding*	*Admin. Closed*	
Institutional inquiry	5	-	-	0	5
Institutional investigation	-	12	12	0	24
ORI inquiry or investigation	-	-	-	-	-
TOTAL	5	12	12	0	29

Three of the cases with misconduct findings arose from the same research study; the institutional investigation showed that three interviewers, working in pairs for survey research conducted in homes on risk behaviors of adolescents, each fabricated data, on a total of at least 20 interviews. In another case, a respondent, who had previously agreed to a voluntary exclusion for three years, was discovered by an institutional official (who was reviewing his recent publication) to have continued to receive salary and research support for over two years from his mentor's Federal grant; PHS' agreement, based ORI's review of the institution's investigation report, imposed upon him another four year period of exclusion from Federal funding. An additional case involved recidivism; an institutional report led a five-year exclusion for a senior technician who falsified and fabricated experiments, a person who had been debarred by ORI for three years a decade ago for similar admitted misconduct at a neighboring institution.

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 no cases administratively closed by ORI in 2003.

Types of Allegations and Administrative Actions

Types of Allegations Involved in Cases Closed: During 2003, of the 5 closed inquiries and the 24 investigations closed with findings, 4 inquiries and 23 investigations involved allegations of falsification, fabrication, or both. Of those 27 cases, 12 cases resulted in ORI misconduct findings or administrative actions. One (1) investigation case involved only plagiarism, with no finding of scientific misconduct (Table 6).

Table 6: Types of Allegations Involved in Closed Inquiries and Investigations and Their Outcomes, 2003

Allegation	*Inquiry*	*Investigation*	*ORI Findings or PHS Administrative Actions*
Fabrication	-	1	-
Falsification	2	9	5
Falsif./Fabric.	2	11	5
Falsif./Plag.	-	1	1
Falsif./Fabric./Plag.	-	1	1
Plagiarism	1	1	-
TOTAL	5	24	12

***PHS Administrative Actions Imposed in Closed Cases*:** A range of administrative actions are used by the Public Health Service 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 12 cases in 2003 in which ORI misconduct findings or PHS administrative actions were imposed, 7 persons were debarred or voluntarily excluded, for periods from 3 to 10 years. Other administrative actions imposed on respondents in these 12 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 [12 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 [5 persons]; (c) certification of data or sources [3 persons]; and (d) retraction of published articles [2 persons, required to or did retract a total of 9 publications] (Table 7).

Table 7: PHS Administrative Actions Imposed in Closed Investigations with Misconduct Findings or Administrative Actions, 2003

PHS Administrative Actions	*Duration*	*Number of Such Actions*
Debarment or Voluntary Exclusion	3 years	3
	4 years	2
	5 years	1
	10 years	1
Probation from Serving as an Advisor for PHS	3 years	7
	4 years	2
	5 years	2
	10 years	1
Supervision Plan Required	3 years	4
	5 years	1
Certification of Research Required	3 years	1
	5 years	2
Respondent required to or did retract articles	-	2

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; (13) advising on potential whistleblower and confidentiality issues; (14) helping with

contacts to national databases (such as Genbank); and (15) assisting with journal editors for papers that require correction or retraction.

The Division of Investigative Oversight (DIO), ORI, made RRTA offers to 5 of the 22 institutions handling new cases in 2003. Officials from all 5 institutions called ORI for substantive technical, administrative, or legal advice.

ORI also provided RRTA help to 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 29 cases closed by ORI in 2003, ORI had provided RRTA to 7 of them at the early stages of their process.

ORI additionally provided RRTA to 19 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. Some of these institutions called ORI two to four times for assistance. ORI also provided guidance to two editors who each contacted ORI about two allegations that they had received and wanted advice in handling the allegations or referring them to ORI.

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. Twenty-six (26) institutions were provided with RRTA in 2003, up from 21 in the prior year. Challenging problems for institutions 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 (phone DIO at 301-443-5330) over the telephone or on-site.

II. Education and Prevention

ORI conducts its education and prevention activities primarily through the Division of Education and Integrity (DEI). Those activities include the RCR Resource Development Program, RCR Expo, RCR Program for Academic Societies, conferences and workshops, a web site, exhibits and publications.

RCR Resource Development Program

ORI created the RCR Resource Development Program in FY 2002 to support the creation of RCR instructional materials by the research community that may be used by various institutions and organizations requesting or receiving research funds from the Public Health Service. In 2003, ORI received 11 finished products from projects funded in 2002, funded 17 new projects, and released a request for proposals (RFP) for 2004.

The completed projects included several web-based RCR resources as well as videos formatted for DVD and Internet use. Out of the 13 projects awarded in 2002, two were terminated because the project directors left the institutions, seven required no-cost extensions to complete, and four were completed as scheduled. Several of these projects were exhibited at the ORI-sponsored RCR Expo which was held in conjunction with the Society of Research Administrators (SRA) International Annual Meeting.

In 2003, ORI received 44 proposals in response to the RFP. Approximately $425,000 was allocated to 17 projects at $25,000 per project. These projects will create products such as web-based education, video vignettes, online games, and online assessments. In addition, these projects will also address several crucial areas of RCR that were not previously addressed. These areas include training and education for culturally diverse researchers, training resources for community agencies, and education for the social sciences.

In November 2003, ORI released an RFP for 2004. The new RFP aimed to attract projects that will create more sophisticated resources such as advanced-level educational materials, resources specifically designed for international post-docs, and backbone technology to create interactive features such as on-line quizzes, games, and assessments.

Project titles, project director, and awardee institutions for the 2003 awards follow:

Educating Staff in Community Agencies about Human Subjects Protection in Research, Leslie Alexander, Bryn Mawr College.

A Guidebook for Teaching Selected RCR Topics to Culturally Diverse Trainee Groups, Madeline Alexander, The Children's Hospital of Philadelphia.

Research Integrity: A Novel Approach, Jan Allen, Northwestern University.

RCR Education Support Using Online Games, Parham Baker, Educational Online Systems, LLC.

An Online Competency-based Assessment and Self-Study Program for the Responsible Conduct of Research, Lori Bakken, University of Wisconsin, Madison.

Health Research with Human Subjects: A Web-based Course on Making Responsible Decisions, Alan Benjamin and Ruth Levy Guyer, The Pennsylvania State University.

Educating Clinical Staff on Clinical Research Data, Cheryl Chanaud, St. Jude Children's Research Hospital.

Behavioral Health Research: An Ethics Case Compendium and Instructional Method, James DuBois, Saint Louis University.

Development of Online Learning Courses for Fundamental Procedures for Working with Laboratory Mice, Nicole Duffee, American Association for Laboratory Animal Science.

Development and Pilot Testing of a Comprehensive Assessment Tool for RCR, Deni Elliot, University of Montana.

RCR for the Rest of Us, Jeffrey Hecht, Northern Illinois University.

Web-based Research Integrity Training for Medical Device Researchers, Linda Hogle, University of Wisconsin.

Improving Disclosure and Decisions on Conflicts of Interests: An E-Curriculum, Jeffrey Kahn, University of Minnesota.

Online Decision Instruction on Data Integrity, Murali Krishnamurthi, Northern Illinois University.

Development of a Web-based Course on Conflicts of Interest in Research as a Prototype for Educational Interventions on Responsible Research Conduct, Melissa Proll, University of Texas Health Science Center at Houston.

Video Vignettes to Actively Foster the Mentor/Trainee Relationship and the Promotion of the Responsible Conduct of Research, Derina Sara Samuel, Syracuse University.

Ethics of Peer Review: A Guide for Manuscript Reviewers, Sara Rockwell, Yale University School of Medicine.

Project descriptions are posted on the ORI web site in the RCR Education section under Programs. Contact Loc Nguyen-Khoa at 301-443-5300 or lnguyen-khoa@osophs.dhhs.gov for additional information on the program.

RCR Expo

ORI held the first RCR Expo on October 18-19, 2003 at the David Lawrence Convention Center in Pittsburgh in conjunction with the annual meeting of the Society of Research Administrators International.

The RCR Expo enabled creators of RCR resources to display, demonstrate and discuss their products while providing potential users with an opportunity to review those resources and discuss their needs, options, and desires, thereby, generating a dialogue among and between creators and users of RCR resources.

Exhibitors focused one or more of the RCR core areas: (1) data acquisition, management, sharing, and ownership; (2) mentor/trainee responsibilities; (3) publication practices and responsible authorship; (4) peer review; (5) collaborative science; (6) human subjects; (7) research involving animals; (8) research misconduct, and (9) conflict of interest and commitment:

Columbia University - Two training e-seminars that require learners to develop problem solving and critical thinking skills related to mentoring and conflict of interest. Interactive multi-media seminars include video, audio and text.

Indiana University: Poynter Center - An on-line short course, *The Least of My Brothers,* that explores ethical issues surrounding the PHS Syphilis Study at Tuskegee. An 80-page booklet: *Moral Reasoning in Scientific Research: Cases for Teaching and Assessment.* A Web-based test for training courses on human subjects protection.

The Medical College of Georgia - A WebCT course on the responsible conduct of research that covers 13 subject areas; the nine core RCR areas plus fiscal compliance, technology transfer, biosafety and chemical safety, and radiation safety. The course will be required for doctoral students and postdoctoral fellows beginning this fall.

Michigan State University - An RCR workshop series for graduate students and a three-hour graduate course that focus on professional development needs and the associated skills to improve the practice of scholarship/research rather than on the ethical conduct of research as a specific outcome.

North Carolina State University - A course, *Contemporary Science, Values, and Animal Subjects in Research,* that integrates applied philosophy and scientific practice for researchers working with animals. *A Primer for Research Ethics* developed for undergraduates. *The Research Ethics Modules* includes 11 modules on various aspects of research ethics for faculty and graduate student training.

St. John's University - An on-line instructional resource for identifying and discussing several varieties of unethical writing practices including plagiarism, self-plagiarism, inappropriate paraphrasing practices, inappropriate citations, selective reporting of literature and methodology, and authorship issues.

University of Alabama: Birmingham - An hour video that addresses mentoring and authorship that features discussion between PIs and graduate students, acted scenarios about dilemmas in the lab, and interviews.

University of Maryland: Baltimore - A web-based curriculum on responsible authorship and acceptable publication practices that informs researchers about the process of manuscript preparation.

University of Miami/The Collaborative IRB Training Initiative (CITI) - A web-based course on human research protection that contains 13 content modules. Over 22,000 persons at 230 institutions have registered for the course.

University of Pennsylvania - A web-based course, *Responsible Conduct of Research Fundamentals,* that covers the core RCR areas and material transfer, intellectual property, environmental safety, preparing grant proposals, and research administration.

Cleveland State University - A CD-ROM-based training module on conflicts of interest and commitment. The interactive course requires about 45-60 minutes to complete. Some video and audio are incorporated to provide guided instruction through the material.

University of Pittsburgh - A modular web-based training program in research ethics that includes a testing component, certificates of completion, and verification of certification. Over 9,000 persons have been certified in the basic research integrity module since 2001.

University of Washington - Case-based modules designed to promote an institutional climate conducive to research integrity through a broad-based teaching program that engages many research faculty. Each module includes a faculty guide to support faculty in the role of discussion leader.

University of Michigan - A web-based foundational instruction and certification program for faculty, staff, and students engaged in research. Provides individualized "curriculum" for each user according to an individual's research role. Besides core RCR areas, the resource includes sponsored project administration.

University of Montana - A web-based course that includes six sections that cover the major topics in research ethics. Employs case studies that require a minimum of three levels of responses to complete the case. Participants are encouraged to repeat the case analyses, choosing alternative decision paths.

Centers for Disease Control and Prevention - An interactive, web-based training program to teach the responsible conduct of research that uses animation to bring the RCR message to life. The training offers a testing and certification process, including continuing education credits.

Family Health International - The *Research Ethics Training Curriculum* is based on 30 years of experience conducting research in developing countries. The RETC provides updated and standardized basic training on human research ethics for international and multidisciplinary audiences.

RCR Program for Academic Societies

Recognizing the instrumental role that academic societies play in establishing and upholding normative standards of research professionalism, the Association of American Medical Colleges (AAMC) and ORI entered into a cooperative agreement in 2002 to encourage academic societies to provide leadership to the research community through initiatives designed to promote the responsible conduct of research. The overarching goal of the program is to assist academic societies to develop, and mainstream or institutionalize RCR infrastructure, activities, and educational programs into the culture of the societies and disciplines. All academic societies with headquarters in the U.S., whose mission includes advancing biomedical and behavioral research or medical education are eligible for this 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."

Awards for the program are provided to fund academic societies to specifically address some, or all, of the nine core components of the responsible conduct of research: (1) data acquisition, management, sharing, and ownership (2) mentor/trainee responsibilities (3) publication practices and responsible authorship (4) peer review (5) collaborative science (6) human subjects (7) research involving animals (8) research misconduct, and (9) conflicts of interest and commitment. Of special interest are projects focused on developing guidelines, standards, policies, publications (including RCR articles in journals, newsletters, and on society web sites), committees, annual conferences, core competencies, curricula, and other instructional resources related to the core RCR components.

In 2003 awards were made in two categories. The first category funded contracts up to $5,000 each in support of single events or limited activities. The second category provided support up to $25,000 for major program initiatives. In the fall of 2003, a third category was added to the request for proposals (RFP) with up to $50,000 in funding. Eleven awards were made in 2003 bringing the total number of awards made by the program to 15. Academic society recipients, and project titles for 2003 follow.

Alliance of Independent Academic Medical Centers for "2003 Research Symposium: An Ethical Framework for Managing Clinical Trials in the Independent Academic Medical Center" that will result in a draft set of best practices that will be posted for comment on the Alliance listserv.

American College of Medical Genetics for "Defining and Communicating Ethical Guidelines for Clinical Research for Genetic Disease Interventions" that will generate a clinical trials training program that focuses on the responsible conduct of research and ethics.

American Educational Research Association for a workshop on "Assessing Research Integrity in Education in Science and the Professions" that will produce assessment strategies that will be posted on the AERA web site.

American Psychiatric Institute for Research and Education/American Psychiatric Association for "Disseminating and Evaluating an Ethics Curriculum for Psychiatric Research."

American Society for Bioethics and Humanities for "Promoting the Responsible Conduct of Clinical Research" that will produce a compilation of best practices.

Association of Academic Health Sciences Libraries for "Responsible Literature Searching for Research: A Self-Paced Interactive Educational Program."

Association of Academic Physiatrists for "Ethical Elements of Responsible Rehabilitation Research - Part II" to prepare several educational materials including a white paper on the "Elements of Responsible Research," and a guidebook of case studies and commentaries suitable for use as an RCR teaching tool for training residents and young faculty.

Association of Chairpersons of Departments of Physiology for "A Mini-Conference in RCR for Department Chairpersons" that will assist physiology chairpersons in improving RCR instruction within their departments and institutions.

Association of Professors of Medicine for a plenary session on "Conducting Responsible Research: What Chairs Should Know"; the proceedings will be published in the *American Journal of Medicine.*

North American Association for the Study of Obesity for a session on "Promoting Research Integrity in Obesity Research: What are the issues? What are some solutions?" that will begin the process of identifying best practices for researchers on obesity.

Society for Academic Emergency Medicine for "A Course in Responsible Research."

Conferences and Workshops

ORI held nine conferences and workshops on topics related to the responsible conduct of research, research integrity, and research misconduct in collaboration with 5 universities, 2 medical schools, 2 medical centers, 4 professional associations, and the HHS Office of Human Research Protections.

December 3, 2003
Ethics and Responsible Conduct of Research Workshop
San Francisco, CA
Co-sponsor: Council of Graduate Schools

November 15, 2003
Enhancing Integrity in Clinical Research
Los Angeles, CA
Co-sponsor: University of California-Los Angeles

November 7-9, 2003
The Journal's Role in Research Misconduct Cases
Leesburg, VA
Co-sponsor: Council of Science Editors

November 7, 2003
RCR 101 Educational Workshop
New Orleans, LA
Co-sponsors: Public Responsibility in Medicine and Research and Tulane University

October 10, 2003
Advanced Workshop for Institutional Research Integrity Officers: A Dialogue on Research Misconduct and the Promotion of Research Integrity
Farmington, CT
Co-sponsors: University of Connecticut Health Center and University of Connecticut-Storrs

October 9, 2003
Introductory Workshop for Institutional Research Integrity Officers
Farmington, CT
Co-sponsors: University of Connecticut Health Center and University of Connecticut-Storrs

September 8-9, 2003
Respect for All Involved: A National Research Integrity and Human Subjects Protection Workshop
New York, NY
Co-sponsors: Columbia University, Einstein College of Medicine, Montefiore Medical Center, Weill Medical College of Cornell University, the City University of New York, the HHS Office for Human Research Protections

June 3, 2003
The Role of Sponsored Program Administrators and Scientists in Promoting Research Integrity
Normal, AL
Co-sponsor: Alabama A&M University

May 1-3, 2003
Building a Research Agenda in Communication Sciences and Disorders: Lessons for Success
Savannah, GA
Co-sponsor: American Speech-Language-Hearing Association

Staff Presentations

Peter Abbrecht, Medical Expert, DIO, "Scientific Misconduct and Research Integrity," a presentation at a course on "Essential Skills for Clinical Investigators," Inova Institute of Research and Education, Inova Fairfax Hospital, Falls Church, VA, April 24, 2003.

John Dahlberg, Scientist/Investigator, DIO, "Oversight of Scientific Misconduct: Analysis of Data," a presentation at the Medical University of South Carolina, Charleston, SC, September 30, 2003.

Nancy M. Davidian, Scientist-Investigator, DIO, "Clinical Cases: Misconduct versus Protocol Violations," a presentation at a conference on Enhancing Integrity in Clinical Research, at the University of California-Los Angeles, Los Angeles, CA, November 15, 2003.

Carolyn R. Fassi, Educational Specialist, DEI, "An Overview of ORI," a presentation at a conference on The Role of Sponsored Program Administrators and Scientists in Promoting Research Integrity, Alabama A & M University, Normal, AL, June 3, 2003.

Carolyn R. Fassi, Educational Specialist, DEI, "Ethics and Responsible Conduct of Research," a presentation at a workshop on Ethics and Responsible Conduct of Research at the annual meeting of the Council of Graduate Schools, San Francisco, CA, December 3, 2003.

Kay Fields, Scientist-Investigator, DIO, "Handling Allegations of Misconduct in Research: Your Interactions with ORI," a panel presentation at the Respect for All Involved: A National Research Integrity and Human Research Protections Workshop, Columbia University, New York, NY, September 8, 2003.

Kay Fields, Scientist-Investigator, DIO, "Federal Oversight and Resolution," a panel presentation at the Introductory Workshop for Institutional Research Integrity Officers, co-sponsored by the University of Connecticut Health Center, Avon Old Farms Hotel, Avon, CT, October 9, 2003.

Kay Fields, Scientist-Investigator, DIO, "Problems Arising from Misconceptions about the Ownership of Research," a presentation at the Second Symposium on Research Integrity, Ana G. Mendez University System, San Juan, PR, November 20, 2003.

Susan Garfinkel, Scientist-Investigator, DIO, "Research Misconduct and the Office of Research Integrity," a panel presentation on Responsible Human Research at the

Third Annual Somatic Cell Therapy Symposium, Cambridge, MD, September 13, 2003.

John Krueger, Scientist-Investigator, DIO, "Falsification of Images in Science," a presentation at the Medical University of South Carolina, Charleston, SC, September 30, 2003.

Samuel Merrill, Scientist-Investigator, DIO, "An Ethical Framework For Managing Clinical Trials in the Independent Academic Medical Center," a presentation at the Alliance of Independent Academic Medical Centers Research Symposium, Philadelphia, PA, April 24, 2003.

Samuel Merrill, Scientist-Investigator, DIO, "Essential Skills for Clinical Investigations," a presentation at a course, "Essential Skills for Clinical Investigators," Inova Fairfax Hospital, Inova Institute of Research and Education, Falls Church, VA, May 22, 2003.

Samuel Merrill, Scientist-Investigator, DIO, "The Meaning of Research Misconduct and the Regulation, Policies, and Guidelines that Govern Research Misconduct in PHS-funded Institutions," a presentation at a conference on The Role of Sponsored Program Administrators and Scientists in Promoting Research Integrity, Alabama A & M University, Normal, AL, June 3, 2003.

Samuel Merrill, Scientist-Investigator, DIO, "Current Issues in Clinical Research," a presentation at the VA Medical Center, sponsored by the Association of Clinical Research Professionals, Decatur, GA, October 25, 2003.

Samuel Merrill, Scientist-Investigator, DIO, "Clinical Case Studies in Research Misconduct," a presentation at a conference on Enhancing Integrity in Clinical Research at the University of California - Los Angeles, Los Angeles, CA, November 15, 2003.

Chris B. Pascal, Director, ORI, "Functions of the DHHS Office of Research Integrity," NIH ESA Seminar Series, Bethesda, MD, March 7, 2003.

Chris B. Pascal, Director, ORI, "Responsible Conduct of Research (RCR) Training," Society of Research Administrators International (SRA), Spring Meeting, Providence, RI, April 12-16, 2003.

Chris B. Pascal, Director, ORI, "Research Integrity," NIH Regional Seminar on Program Funding and Grants Administration, Stanford University, Palo Alto, CA, April 24 - 25, 2003.

Chris B. Pascal, Director, ORI, "Research Integrity," National Council of University Research Administrators (NCURA) Regional Meeting, Portsmouth, NH, May 18 - 20, 2003.

Chris B. Pascal, Director, ORI, "Overview of Research Misconduct and Integrity," Protecting Human Research Subjects: Theory and Practice IRB/OHRP Research Protection Conference, Tulane University Health Sciences Center for Continuing Education, New Orleans, LA, June 4 - 6, 2003.

Chris B. Pascal, Director, ORI, "Federal Updates & Ask the Feds," Protecting Human Subjects in the 21st Century: Issues in Social & Behavioral Research, Georgia Center for Continuing Education, Athens, GA, July 28 - 30, 2003.

Chris B. Pascal, Director, ORI, "On Being a Scientist: Responsible Conduct of Research," The National Academies, Advisers to the Nation on Science, Engineering and Medicine Committee on Science, Engineering and Public Policy, Washington, DC, August 28 - 29, 2003.

Chris B. Pascal, Director, ORI, "Federal Update - ORI Update and Regulatory Overview"; "Conflict of Interest - How They Involve the Rights of Subjects"; and "Regulatory Flexibility," Respect for All Involved: A National Research Integrity & Human Research Protections Conference, The Graduate Center of CUNY, Columbia University, New York, NY, September 8 - 9, 2003.

Chris B. Pascal, Director, ORI, "Washington/Federal Update - ORI Overview"; "ORI Update, Research Integrity - RCR Education Issues," OHRP Conference Today's Research, Tomorrow's Issues, University of California, San Francisco School of Medicine, San Francisco, CA, September 23 - 24, 2003.

Chris B. Pascal, Director, ORI, "Functions of the DHHS Office of Research Integrity," NIH ESA Seminar Series, Bethesda, MD, October 31, 2003.

Chris B. Pascal, Director, ORI, "The Sweet Spot: Intersection of RCR and Research Quality," Office of Research Compliance Lecture Series: The Responsible Conduct of Research, Harvard Medical School, Boston, MA, December 5, 2003.

Alan R. Price, Director, DIO, "NCURA on-line with The Office of Research Integrity," on-line bulletin board/conference call for the members of the National Council of University Research Administrators, Washington, D.C., January 14, 2003.

Alan R. Price, Director, DIO, "Handling Allegations Involving Extramural Research at the National Institutes of Health," a panel presentation for the Research Integrity Officers of the NIH Institutes, Bethesda, MD, February 3, 2003.

Alan R. Price, Director, and Nancy M. Davidian, Scientist-Investigator, DIO, "Dealing with Scientific Misconduct Issues at NHLBI," a seminar for extramural research administrative staff at the National Heart Lung and Blood Institute, Rockville, MD, March 18, 2003.

Alan R. Price, Director, DIO, "Welcome to the Office of Research Integrity," a presentation at the University of Michigan Summit Conference on Interviewer Falsification in Survey Research, Survey Research Center, University of Michigan, Ann Arbor, MI, April 4, 2003.

Alan R. Price, Director, DIO, "Responsible Scientific Writing and Related Research Misconduct Case Studies," a lecture at a conference on Secrets for Success for New Research Investigators, American Speech Language Hearing Association, Savannah, GA, May 1, 2003.

Alan R. Price, Director, DIO, "Update on Office of Research Integrity: Regulations and Research and Education Grants Programs," panel presentation at a conference on Secrets for Success for New Research Investigators, American Speech Language Hearing Association Savannah, GA, May 2, 2003.

Alan R. Price, Director, DIO, "Is 'Curbstoning' in Surveys ORI Research Misconduct?" a presentation to the Department of Health and Human Services' Data Council, Washington, DC, May 14, 2003.

Alan R. Price, Director, DIO, "Is 'Curbstoning' in Surveys ORI Research Misconduct?" a panel presentation at a workshop at the annual meeting of the American Association for Public Opinion Research, Nashville, TN, May 16, 2003.

Alan R. Price, Director, DIO, "National Institutes of Health Intramural Officials' Responsibilities in Handling Allegations of Misconduct," a presentation to the National Institutes of Health Intramural Program Scientific Directors, Bethesda, MD, May 21, 2003.

Alan R. Price, Director, DIO, "Reporting to or Getting Help from the Office of Research Integrity," a panel presentation at the National Institutes of Health Regional Seminar, Baltimore, MD, June 11, 2003.

Alan R. Price, Director, DIO, "Authorship Issues - Avoiding Plagiarism and Credit Disputes," a panel presentation at a workshop on Respect for All Involved: A National Research Integrity and Human Research Protection, co-sponsored by Columbia University, OHRP, and ORI, The Graduate Center, City University of New York, September 8, 2003.

Alan R. Price, Director, DIO, "Welcome to the ORI / University of Connecticut Conference on Research Misconduct and Integrity," a talk at the Introductory Workshop for Institutional Research Integrity Officers, co-sponsored by the University of Connecticut Health Science Center, Avon Old Farms Hotel, Avon, CT, October 9, 2003.

Alan R. Price, Director, DIO, "Handling Allegations of Research Misconduct as a Research Integrity Officer," a panel presentation at the Introductory Workshop for Institutional Research Integrity Officers, co-sponsored by the University of Connecticut Health Science Center, Avon Old Farms Hotel, Avon, CT, October 9, 2003.

Alan R. Price, Director, DIO, "Outcomes from Research Misconduct Cases for ORI," a panel presentation at the Introductory Workshop for Institutional Research Integrity Officers, co-sponsored by the University of Connecticut Health Science Center, Avon Old Farms Hotel, Avon, CT, October 9, 2003.

Alan R. Price, Director, DIO, "Dealing with Scientific Misconduct: Responses from Academe, Oversight and Advisory Bodies, and Regulatory Agencies," a panel presentation at the Council of Science Editors' Retreat, Landsdowne, VA, November 8, 2003.

Alan R. Price, Director, DIO, "Coming Full Circle: Can Misconduct Be Prevented?" a panel presentation at the Council of Science Editors' Retreat, Landsdowne, VA, November 9, 2003.

Alan R. Price, Director, DIO, "Meet the Feds: Questions and Answers Off the Record," a panel session at the Public Responsibility in Medicine and Research 2003 Annual IRB Conference, Washington, DC, December 6, 2003.

Lawrence J. Rhoades, Director, DEI, "Responsible Conduct of Research (RCR) Education", a presentation at a workshop on Respect for All Involved: A National Research Integrity and Human Research Protection, co-sponsored by Columbia University, OHRP, and ORI, The Graduate Center, City University of New York, September 8, 2003.

Lawrence J. Rhoades, Director, DEI, "What Is a Research Integrity Officer?" and "Policies and Procedures: Minimal or Useful", presentations at an Introductory Workshop for Institutional Research Integrity Officers, co-sponsored by the University of Connecticut Health Science Center, Avon Old Farms Hotel, Avon, CT, October 9, 2003.

Lawrence J. Rhoades, Director, DEI, "Why RCR Education?", a presentation at the Responsible Conduct of Research (RCR) Workshop, annual meeting of the Society of Research Administrators International, Pittsburgh, October 18, 2003.

Lawrence J. Rhoades, Director, DEI, "ORI: Mission, Issues, Programs," a presentation at the Colleges of Liberal Arts Sponsored Programs Conference, Bryn Mawr College, November 13, 2003.

Mary D. Scheetz, Director, Extramural Research, DEI, "Can Misconduct be Prevented," a presentation at the Council of Science Editors: The Journal's Role in Scientific Misconduct. Leesburg, VA, November 9, 2003.

Mary D. Scheetz, Director, Extramural Research, DEI, "Forging a Research Agenda on Research Integrity," a presentation at the annual meeting of the Association for the Study of Higher Education, Portland, OR, November 15, 2003.

Mary D. Scheetz, Director, Extramural Research, DEI, "Investigating Misconduct: A New Federal Initiative," a presentation at the annual meeting of the American Society of Criminology, Denver, CO, November 20, 2003.

Sandra Titus, Director, Intramural Research, DEI, "Mentoring," a presentation at the Medical University of South Carolina, Charleston, SC, September 30, 2003.

Sandra Titus, Director, Intramural Research, DEI, "How Accessible Are Your Research Misconduct Policies and Procedures," a presentation on the Panel on Developing Policies and Procedures, co-sponsored by the University of Connecticut Health Center, Avon Old Farms Hotel, Avon, CT, October 9, 2003.

Web Site

The ORI web site is the pre-eminent web site in the world on the responsible conduct of research, research integrity, and research misconduct. In FY 2003, the web site had 74,602 visits by 38,359 unique visitors. Repeat visitors totaled 7, 855. The web site averaged 204 visits per day with the average visit lasting a little more than 17 minutes. Eighty-four percent of the visits were from individuals within the United States; 16 percent were international visits from Canada, the United Kingdom, Australia, China, Germany, Japan, Netherlands, South Korea, Philippines, France, India, Singapore, Israel, Poland, Malaysia, Hong Kong, Italy and Sweden.

Exhibits

ORI has been exhibiting at meetings of professional associations and scientific societies to facilitate a dialogue with researchers, research administrators, postdocs, graduate students, and association and society officials on the responsible conduct of research, research integrity and the prevention of research misconduct for three years. In 2003, ORI held exhibits at three meetings: American Institute of Biological Sciences, Arlington, VA, March 21-23; National Council of University Research Administrators, Washington, DC, November 2-5; and Public Responsibility in Medicine and Research/Applied Research Ethics National Association, Washington, DC, December 4-7.

Publications

Besides publishing the quarterly *ORI Newsletter* and the *ORI Annual Report - 2002*, the ORI worked with Nicholas H. Steneck, a professor of history at the University of Michigan and an ORI consultant, on the *ORI Introduction to the Responsible Conduct of Research.* The 138-page publication introduces the reader to the nine RCR core instructional areas in four sections that follow the normal flow of research from a consideration of shared values to planning, conducting, reporting, and reviewing research. The basic text is supplemented with text-box inserts, discussion questions, bibliography, and illustrations.

In January 2004, the text was mailed to 4,000 institutions or organizations that have a research misconduct assurance on file with ORI. Unfortunately, errors occurred in the printing of the publication (i.e., illustrations and case studies were deleted), that required a revision of the publication. The revised version was published in June 2004. The text is being translated into Japanese by a publisher in Japan. Inquiries have also been received concerning possible translation of the text into Chinese and Russian.

Federal Register Notices

12/09/03 OS. Findings of Scientific Misconduct. Notice. 68 Fed. Reg. 68627-68628 (Dec. 9, 2003). [Xu]

12/09/03 OS. Additional Action on Findings of Scientific Misconduct. Notice. 68 Fed. Reg. 68632 (Dec. 9, 2003). [Lin]

12/02/03 OS. Findings of Scientific Misconduct. Notice. 68 Fed. Reg. 67450 (Dec. 2, 2003). [Woodard]

12/02/03	OS. Findings of Scientific Misconduct. Notice. 68 Fed. Reg. 67449-67450 (Dec. 2, 2003). [Creek]
12/02/03	OS. Findings of Scientific Misconduct. Notice. 68 Fed. Reg. 67449 (Dec. 2, 2003). [Blackwell]
11/25/03	OS. Findings of Scientific Misconduct. Correction. 68 Fed. Reg. 66112 (Nov. 25, 2003). [Gelband]
11/21/03	OS. Findings of Scientific Misconduct. Correction. 68 Fed. Reg. 65714 (Nov. 21, 2003). [Smith, Timothy R.]
11/13/03	OS. Findings of Scientific Misconduct. Notice. 68 Fed. Reg. 64350-64351 (Nov. 13, 2003). [Smith, Timothy R.]
11/10/03	OS. Findings of Scientific Misconduct. Notice. 68 Fed. Reg. 63797-63799 (Nov. 10, 2003). [Gelband]
10/30/03	OS. Findings of Scientific Misconduct. Notice. 68 Fed. Reg. 61811 (Oct. 30, 2003). [Koltover]
08/29/03	OS. Announcement of Continuation of a Cooperative Agreement for the Responsible Conduct of Research (RCR) for Academic Societies. Notice. 68 Fed. Reg. 52036-520340 (Aug. 29, 2003).
08/06/03	OS. Findings of Scientific Misconduct. Notice. 68 Fed. Reg. 383-46642 (Aug. 6, 2003). [Karunakaran]
06/27/03	OS. Findings of Scientific Misconduct. Notice. 68 Fed. Reg. 38341-38342 (June 27, 2003). [Rooney]
03/24/03	OS. Findings of Scientific Misconduct. Notice. 68 Fed. Reg. 14240 (March 24, 2003). [Radolf]
02/20/03	OS. Findings of Scientific Misconduct. Correction. 68 Fed. Reg. 8296-8297 (Feb. 20, 2003). [Ganz]
01/28/03	OS. Findings of Scientific Misconduct. Notice. 68 Fed. Reg. 4213 (Jan. 28, 2003). [Eagan]

III. Research on Research Integrity and Research Misconduct

Intramural Research Program

The intramural research program within ORI focuses on institutional implementation of the research misconduct regulation and research misconduct. The studies, primarily descriptive, are done under contract with research organizations or 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. The intramural research program also works with extramural researchers who are interested in analyzing data that are available in ORI databases or case files. Two studies were completed in 2003, while five others were continuing or starting.

Completed Studies

Survey of Research Integrity Measures Utilized in Biomedical Research Laboratories conducted by the American Institutes for Research.

The purpose of this study was to determine the measures that are being utilized to prevent misconduct and promote research integrity in the primary research environment - the biomedical research laboratory. About 2,900 basic scientists, epidemiologists, and clinical researchers responded to the survey. Basic scientists accounted for about 2,200 responses; these scientists had been principal investigators for an average of 16 years and currently had 2.3 grants (mean).

The study shows that several research integrity measures are used, but their use varies considerably in biomedical laboratories. Two sets of questions were used to measure the utilization of research integrity measures so the below findings are based on responses from about 1000-1100 basic scientists.

- Whether published or not, data are retained for an average of about 12 years; about 13 percent retain their data for less than 4 years.

- Laboratory notebooks of each supervised researcher are examined an average of 22 times per year; about 17 percent examine notebooks less than 12 times per year.

- Laboratory meetings are held an average of 33 times per year, last 1.5 hours, and devote about 84% of the time to ongoing research results; about 25 percent of the principal investigators hold 12 or less meetings per year.

- Principal investigators spend an average of 2.7 hours per week with each supervised researcher (mean = 5.81); about 25 percent spend less than 1 hour per week.

- When research guidelines exist they primarily are communicated verbally; less than 5 percent of the principal investigators reported having written guidelines on authorship, publication practices, retractions, or data sharing.

ORI will present the results in presentations at conferences and workshops, in manuscripts submitted for publication, and on its website.

Evaluation of RCR Training Requirement conducted by the American Institutes for Research

ORI completed its collaboration 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 included a literature review, an invitational workshop that included 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. The contractor delivered the plan in 2003 to NIH where it is under consideration.

Studies in Progress

Incidence of Research Misconduct in Biomedical Research conducted by The Gallup Organization.

This study is aimed at estimating the incidence of suspected research misconduct in biomedical research. The study is being conducted by The Gallup Organization. The questionnaire was revised to respond to comments from the research community and HHS. The OMB clearance package was submitted to the HHS OMB Clearance Officer in March 2004.

Institutional Research Integrity Officer (RIO) Study conducted by the Research Triangle Institute.

ORI submitted a proposal for a study of institutional research integrity officers (RIOs), the officials responsible for the implementation of the research misconduct regulation (42 CFR Part 50, Subpart A), to the Office of Public Health and Science, HHS, for support as a 1 percent evaluation study. The study proposed to examine the responsibilities, authority, qualifications, training, organizational location, role set, resources and turnover rates of individuals in this critical position. The study was funded in 2004.

Closed Investigations into Misconduct Allegations Involving Research Supported by the Public Health Service: 1994-2003 conducted by ORI.

This study will analyze 259 research misconduct investigation cases involving research supported by the Public Health Service that were closed by ORI from 1994-2003 inclusive. Data for this secondary analysis were collected from the research misconduct case database maintained by ORI to administratively track the progress made in processing cases. Variables included in the analysis are frequency of allegations; types of misconduct; organizational locations of misconduct activity; academic rank, highest degree and gender of respondents and whistleblowers; frequency of misconduct and no misconduct findings; administrative actions taken by the PHS and institutions; size of inquiry and investigation panels, and length of inquiries and investigations. The study is expected to be completed in 2004.

Institutional Research Misconduct Activity: 1991-2000 conducted by ORI

This is a secondary analysis of data on misconduct activity reported by institutions in their Annual Report on Possible Research Misconduct from 1991-2000. Each institution annually reports the number of inquiries and investigations conducted and the type of research misconduct alleged. The database has been augmented with the ranking of each reporting institution in the NIH funding hierarchy and the number of research misconduct findings made. This analysis will focus on the growth in the number of institutions reporting research misconduct activity, the frequency and pattern of reported research misconduct activity, the outcomes of inquiries and investigations, and the ranking of reporting and non-reporting institutions by funding. The study is expected to be completed in 2004.

Problematic Contextual Factors in Cases of Research Misconduct by Clinical Trial Staff conducted by a visiting fellow.

ORI granted access to its cases files to an extramural researcher/consultant who was working on a master's degree in bioethics to gather data on clinical trial staff who were involved in research misconduct cases. Data collection and analysis were completed in 2003. Results are expected to be submitted for publication in 2004.

For additional information on the ORI intramural research program contact Sandra L. Titus, Ph.D., Director, Intramural Research Program, at 301-443-5300 or at stitus@osophs.dhhs.gov.

Extramural Research Program

ORI established its extramural research program, Research on Research Integrity (RRI), in 2000 in collaboration with the National Institute of Neurological Disorders

and Stroke (NINDS). Since then the National Institute of Nursing Research (NINR) and the National Institute on Drug Abuse (NIDA) have joined the program. The grant program was created to foster empirical research on societal, organizational, group, and individual factors that affect, both positively and negatively, integrity in research.

Research on Research Integrity Program

Five awards were made by the Research on Research Integrity Program (RRI) in 2003, increasing the number of studies being supported to 21. Abstracts of the studies are posted on the ORI web site under Research in the Programs section.

The 31 applications submitted in response to the third request for applications topped the previous high by 1. The success rate was 16 percent. Previous, success rates were 28.6 percent and 30 percent. The number of awards in the first 2 years was seven and nine, respectively. One first-year award was withdrawn at the request of the institution because of potential legal problems.

ORI supported three new awards; NINR and NIDA supported one award each. Grants were limited to $100,000 in direct costs, plus indirect costs for each of 2 years.

Total funding for the third round (new and continuations) totaled $1.9 million, which is slightly lower than the funding for the second round ($2.1 million) and almost double the funding for the first round ($1.0 million). ORI provided $1.4 million for the third round; NINR and NINDS provided $0.5 million.

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

Industry-Sponsored Research Contracts..Phase II. Michelle Mello, Harvard School of Public Health.

Research Integrity and Financial Conflicts of Interest. Patricia Tereskerz, University of Virginia.

Dilemmas Academic Scientists Face. Karen Seashore, University of Minnesota.

Educating for Responsible Research Conduct in Behaviorial Sciences. Margaret Gibelman, Yeshiva University.

Scientific Misconduct: Role of the Research Coordinator. Marion Broome, University of Alabama-Birmingham.

Contact Mary Scheetz, Ph.D., Director, Extramural Research Program, at 301-443-5300 or mscheetz@osophs.dhhs.gov for further information on the program.

Research Conference on Research Integrity

Planning began for the third, biennial Research Conference on Research Integrity that will be held at the Paradise Point Resort, San Diego, CA, on November 12-14, 2004.

Over 70 abstracts have been accepted for presentation as research papers or posters. Research will be reported on misconduct and questionable research practices; authorship and publication issues; conflict of interest; data management and data sharing, the influence of the research environment on research behavior; human-subject research (IRBs, informed consent, and clinical trials); mentoring and responsible conduct of research education.

Several presentations will report findings from the NIH/ORI Research on Research Integrity Program, which gave its first awards in 2001. A growing body of international research on research integrity will also be represented.

IV. 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 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, 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 to determine the eligibility of institutions to receive PHS research funds.

The number of institutional assurances on file with ORI increased by 152 during 2003 to 4,263. Five hundred and eighty-eight institutions were added to the assurance database; 534 had filed their initial assurance and 54 reestablished their assurance by submitting their Annual Report on Possible Research Misconduct for 2001 and 2002. Four hundred and thirty-six assurances were inactivated; 348 for failing to submit their Annual Report in 2003 and 88 other were deleted at the request of the institution or because duplicate records existed.

Table 8: Number and Type of Institutions with Active Assurances, 2003

Type of Institution	*Number*	*Change*
Institutions of Higher Education	928	+26
Research Organizations, Institutes, Foundations and Laboratories	345	+23
Independent Hospitals	277	+3
Educational Organizations, Other than Higher Education	23	+2
Other Health, Human Resources, and Environmental Services Organization	398	-13
Other (small business)	2,292	+112
Unclassified	0	-1
TOTAL	4,263	+152

Institutional Misconduct Policy Reviews

ORI completed 199 policy reviews in 2003. Four policy reviews were carried into 2003; another 209 institutional research misconduct policies were requested for review. One hundred seventy-six institutional policies were accepted as submitted; 23 others were accepted after revision, and 7 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. Seven policy reviews were carried into 2004; two of these policies are pending review; five other policies are being revised by institutions. Since 1995, ORI has reviewed 2,117 institutional policies.

Annual Report on Possible Research Misconduct

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

The electronic submission of the 2002 Annual Report began in January 2003 for the 4,060 institutions that had an assurance on file with ORI as of December 31, 2001.

Completed Annual Reports were received from 3,460 institutions for a response rate of 85 percent. ORI inactivated 600 assurances, including 545 institutions that did not return their Annual Reports by the March 31 deadline, and 55 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 2002 report identified 59 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 the availability of policies and procedures for responding to allegations of scientific misconduct, the number of allegations of scientific misconduct received and the number of inquiries and investigations conducted.

Reported Misconduct Activity

The alleged research misconduct activity reported by institutions in their 2002 Annual Report on Possible Research Misconduct set the highest levels since 1997 on all indicators, except one where the previous high was matched.

Ninety-nine institutions reported misconduct activity stemming from allegations received in 2002 or prior. The previous high was 82. Seventy-one institutions received new allegations in 2002 compared to the existing apex of 61. The 83 new cases topped the previous mark of 72.

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

The 163 allegations received by institutions in 2002 exceeded the previous high by 36. All types of alleged misconduct were reported at new highs since 1997: fabrication 45 vs 37; falsification 58 vs 46, plagiarism 27 vs 17, and other 33 vs 27.

The 31 investigations conducted on the new allegations surpassed the previous high by 11. The 67 inquiries resulting from the new allegations equaled the previous ceiling.

Types of institutions reporting new misconduct activity were higher education 50; research organizations 7; independent hospitals 6; health organizations 5; and small organizations 3.

The 99 institutions reporting alleged research misconduct activity conducted 110 inquiries and 63 investigations in response to allegations made in 2002 and before.

Table 9: Number of Institutions Reporting Misconduct Activities, Institutions Reporting New Cases, New Allegations, and New Cases Opened, 1993-2002.

Year	*Institutions Reporting Activity*	*Institutions Reporting New Cases*	*New Allegations*	*New Cases*
2002	99	71	163	83
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
1996	88	54	127	70
1995	96	61	104	81
1994	79	50	89	64
1993	73	53	86	77

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 2003, two compliance cases were opened and two cases were closed. Four compliance cases were carried into the year and 4 were still open at the end of the year.

The year began with 3 open assessments, 1 new assessment was opened, and 4 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 compliance or retaliation complaint.

Case 1: Closed for Lack of Nexus between Complaint and Termination of Appointment.

In this case, DEI reviewed a complainant's claim that his position was terminated in response to making allegations of scientific misconduct against other faculty members at the same institution. A review of the records showed that the complainant's position was a term appointment that was scheduled to expire on December 31, 2002. The record also showed that the complainant was informed in the spring 2002 that his appointment would not be extended beyond the end of the year, and this notification predated his submission of the scientific misconduct allegations. Based on this review, DEI determined that there was no link between the purported adverse action, the termination of the complainant's appointment, and the misconduct allegation, and the actions of the institution could not be considered retaliatory.

Case 2: Whistleblower Retaliation Complaint Closed When Complainant Filed Civil Suit.

In this case, the complainant asserted that he was subject to ongoing acts of retaliation for making allegations of research misconduct against two collaborators. He claimed, among other things, that as a result of his making allegations, his salary was decreased without notification, certain lab personnel were dismissed, and he was reassigned to work a significant portion of his time outside his laboratory. The institutional policies and procedures provided for a process to address allegations of retaliation; prior to his contacting DEI, the institution had conducted an investigation of the alleged retaliation. At DEI's request, the report was shared with the complainant. In lieu of conducting a further investigation, efforts were made to encourage the institution and the complainant to pursue a negotiated settlement, which is one of the options provided in the ORI Whistleblower's Guidelines. Prior to any settlement being reached between the parties, DEI was informed that the complainant has filed a civil suit against the institution that included his claim of retaliation. The ORI Whistleblower Guidelines acknowledge that a whistleblower may pursue any legal rights available for resolution of a retaliation complaint, but once such a course of action is initiated, the institution has no more obligation under the PHS regulation to address the complaint. Based on this action by the complainant, DEI closed the case.

Table 10: Summary of Compliance Cases, 2003

Case Type	*Forwarded from 2002*	*Opened in 2003*	*Closed in 2003*	*Carried into 2004*
Compliance Review	4	2	2	4
Assessment	3	1	4	0
TOTAL	7	3	6	4

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 ALERT 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, 2003, ORI listed the names of 56 individuals in the ALERT system. During the year, ORI added 17 and removed 10 names. On December 31, 2003, the names of 63 individuals were in the system.

ORI added 17 names because those individuals were found to have committed scientific misconduct in institutional reports to ORI. Seven names were removed during the year because the term of the PHS 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 63 names in the system at year end, 42 individuals had PHS administrative actions imposed, and 21 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, 2003

	Total
As of January 1, 2003	56
Additions	17
Action Expired/Removed	10
As of December 31, 2003	63

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

V. Information and Privacy

The number of requests for information under the Freedom of Information Act (FOIA) and the Privacy Act decreased in 2003.

- One FOIA request was carried into calendar year 2003. There were 34 new requests received and 34 were closed. One request remained open and was forwarded into 2004. Completion time ranged from 1 to 103 days. The median was 14 days; the mean was 17 days, with a modal response time of 1 day. Fifty-one FOIA requests were received in 2002.

- ORI received and responded to 1 Privacy Act request in 2003, compared with 11 in 2002. All requests were completed in the year of receipt.

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, 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 Privacy Act Officer, ORI, at 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.

Summaries of Closed Investigations Resulting in Findings of Research Misconduct or Administrative Actions - 2003

George E. Eagan, University of Albany, State University of New York: Based on the report of an investigation conducted by the University of Albany, State University of New York (UA-SUNY) and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Mr. Eagan, former laboratory technician at UA-SUNY, engaged in scientific misconduct by falsification and fabrication of data supported by a subcontract to UA-SUNY on National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), grant R01 GM46312-11, "Structural Biochemistry of DNA Base Excision Repair." Specifically, PHS found that Mr. Eagan engaged in scientific misconduct by falsifying and fabricating the data for two experiments, conducted on February 12 and 13, 2002, designed to test the survival of strains of bacteria exposed to different base analog mutagens. Mr. Eagan's experiments were significant because they would have contributed to the overall objective of the grant to understand the structural and biochemical interaction of enzymes involved in base-excision repair with various substrates, including the base analogs studied by Mr. Eagan.

Mr. Eagan has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed for a period of five (5) years, beginning on January 13, 2003: (1) to exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement transactions (e.g., grants and cooperative agreements) of the United States Government referred to as "covered transactions" as defined in 45 C.F.R. Part 76 (Debarment Regulations); and (2) to exclude himself from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant. Mr. Eagan had admitted to falsification of data in an earlier case.

Sheila Blackwell, University of Maryland, Baltimore: Based on the report of an investigation conducted by the University of Maryland, Baltimore (UMB Report), the respondent's admission of responsibility, and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Sheila Blackwell, former contractual employee, Department of Pediatrics at UMB, engaged in scientific misconduct in research supported by National Institute of Mental Health (NIMH), National Institutes of Health (NIH), grant 2 R01 MH54983, entitled "Effectiveness of Standard versus Embellished HIV Prevention." Specifically, PHS found that Ms. Blackwell engaged in scientific misconduct by fabricating interview records for the Focus on Teens HIV Risk Prevention Program for nine interviews that had not been performed over the period of May through July 2001.

Ms. Blackwell has entered into a Voluntary Exclusion Agreement (Agreement) in which she has voluntarily agreed for a period of three (3) years, beginning on October 30, 2003: (1) to exclude herself from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and (2) that her participation in any PHS-supported research will be conditioned on an appropriate plan of supervision of her duties (Supervision Plan) as follows: (i) any institution that submits an application for PHS support for a research project in which Ms. Blackwell's participation is proposed or anticipated must concurrently submit a Supervision Plan to the funding agency for approval; and (ii) any institution using Ms. Blackwell in any capacity in PHS-supported research must submit a Supervision Plan to the funding agency for approval. The Supervision Plan must be designed to ensure the scientific integrity of her research contribution. A copy of the Supervision Plan must also be submitted to ORI by the institution. Ms. Blackwell agreed that she will not participate in any PHS-supported research until the Supervision Plan has been submitted to ORI.

Khalilah Creek, University of Maryland, Baltimore: Based on the report of an investigation conducted by the University of Maryland, Baltimore (UMB Report), the respondent's admission of responsibility, and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Khalilah Creek, former contractual employee, Department of Pediatrics at UMB, engaged in scientific misconduct in research supported by National Institute of Mental Health (NIMH), National Institutes of Health (NIH), grant 2 R01 MH54983, entitled "Effectiveness of Standard versus Embellished HIV Prevention." Specifically, PHS found that Ms. Creek engaged in scientific misconduct by fabricating interview records for the Focus on Teens HIV Risk Prevention Program for eight interviews that had not been performed over the periods of July and December 2000 and January, February, and May through August 2001.

Ms. Creek has entered into a Voluntary Exclusion Agreement (Agreement) in which she has voluntarily agreed for a period of three (3) years, beginning on October 30, 2003: (1) to exclude herself from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and (2) that her participation in any PHS-supported research will be conditioned on an appropriate plan of supervision of her duties (Supervision Plan) as follows: (i) any institution that submits an application for PHS support for a research project in which Ms. Creek's participation is proposed or anticipated must concurrently submit a Supervision Plan to the funding agency for approval; and (ii) any institution using Ms. Creek in any capacity in PHS-supported research must submit a Supervision Plan to the funding agency for approval. The Supervision Plan must be designed to ensure the scientific integrity of her research contribution. A copy of the Supervision Plan must also be submitted to ORI by the

institution. Ms. Creek agreed that she will not participate in any PHS-supported research until the Supervision Plan has been submitted to ORI.

Craig H. Gelband, Ph.D., University of Florida: Based on the reports of two investigations conducted by the University of Florida (UF) (UF Reports) and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Craig H. Gelband, Ph.D., Associate Professor, Department of Physiology, College of Medicine at UF, engaged in scientific misconduct in research. Publications and manuscripts containing the falsified data cited support from National Institutes of Health (NIH) grants, or falsified data was included in NIH grant applications, as follows: R29 HL52189-01A2 (then R01 HL52189-05), R01 HL56921, F32 HD08496, R01/R37 HL49254, F32 HL08531, P01 DK41315, and R01 HL69034-01. Specifically, PHS found that:

I. Dr. Craig H. Gelband falsified data based on contractile tension recording in antisense experiments on the angiotensin enzyme (ACE), purportedly using renal arteriolar smooth muscle tension preparation:

A. by falsely labeling the tension recordings in Figures 5, 6, and 7 in a publication by Wang, H., Reaves, P.Y., Gardon, M.L., Keene, K., Goldberg, D.S., Gelband, C.H., Katovich, M.J. & Raizada, M.K. "Angiotensin I-converting enzyme antisense gene therapy causes permanent antihypertensive effects in the SHR." *Hypertension* 35[part 2]:2002-208, 2000 (subsequently referred to as the "*Hypertension* 2000 paper #1"), when he had earlier reported the same contractile records as being from experiments on the angiotensin receptor (not the enzyme), in Figures 6, 7, and 8 of an earlier mini-review by Martens, J.R. & Gelband, C.H. "Ion channels in vascular smooth muscle: Alterations in essential hypertension." *PSEBM* 218:192-200, 1998 (subsequently referred to as the *PSEBM* paper);

B. by falsifying three of the four sets of the mean data that were in fact the same for both the F0 and F1 mean data in Figures 5 and 6 of the *Hypertension* 2000 paper #1. Dr. Gelband also dishonestly provided the institution with the falsified/fabricated tables of the mean data and the associated false standard error values as evidence that he had conducted the experiments for Figures 5 and 6; and

C. by falsifying EC_{50} values in Table 1 in NIH grant application HL52189-05; the EC_{50} values had been interpolated from the falsified mean and SEM data shown in Figures 5 and 6 in the *Hypertension* 2000 paper #1.

II. Dr. Gelband falsified data in the reporting of research, misrepresenting current/voltage (I/V) data to be results from totally different experimental models or preparations in six publications (including one manuscript "In-Press") and in NIH grant application HL52189-05, specifically:

A. as Figure 1A, in Gelband, C.H., Wang, H., Gardon, M.L., Keene, K., Goldberg, D.S., Reaves, P., Katovich, M.J., Raizada, M.K. "Angiotensin 1-converting enzyme antisense prevents altered renal vascular reactivity, but not high blood pressure, in spontaneously hypertensive rats." *Hypertension* 35 [part 2]:209-213, 2000 (subsequently referred to as the "*Hypertension* 2000 paper #2").

B. as Figure 2, in Martens, J.R., Fergus, D.J., Tamkun, M.M., England, S.K., Gelband, C.H. "Identification of voltage-gated K^+ channel genes contributing to the decreased renal arteriolar K^+ current in hypertension." *J. Biol. Chem* (MS M01389200), online, in press (subsequently referred to as the "*JBC* paper"). *J. Biol Chem Online* (submitted and withdrawn).

C. as Figure 4A, in Gelband, C.H. "Protein kinase C regulation of renal vascular K*v* and Ca^{++} channels in hypertension." *Hypertension Online* paper, withdrawn (subsequently referred to as the "*Hypertension Online* paper").

D. as Figure 3, in Gelband, C.H., Reaves, P.Y., Evans, J., Wang, H., Katovich, M.J., & Raizade, M.K. "Angiotensin II Type 1 receptor antisense gene therapy prevents altered renal vascular calcium homeostasis in hypertension." *Hypertension* 33[partII]:360-365, 1999 (subsequently referred to as the "*Hypertension* 1999 paper").

E. as Figures 4A and 4B in Martens, J.R., Reaves, P.Y., Lu, D., Katovich, M.J., Berecek, K.H., Bishop, A.P., Raizade, M.K., & Gelband, C.H. "Preventions of renovascular and cardiac pathophysiological changes in hypertension by angiotensin II type 1 receptor antisense gene therapy." *Proc. Natl. Acad. Sci.* 95:2664-2669, 1998 (subsequently referred to as the "*PNAS* paper").

F. as Figure 5A, in Reaves, P.Y., Gelband, C.H., Wang, H., Yang, H., Lu, D., Berecek, K.H., Katovich, M.J., Raizada, M.K. "Permanent cardiovascular protection from hypertension by the AT1 receptor antisense gene therapy in hypertensive rat offspring." *Circ. Res.* 85: 344-350, 1999 (subsequently referred to as the "*Circ. Res.* 1999 paper").

1. Dr. Gelband also falsified data in the proposing of research by submitting the above data as Figures 3, 14A, 14B, and 15 in NIH grant application HL52189-05.

III. Dr. Gelband falsified traces of potassium currents in Figure 4 of the *J. Biol. Chem* paper (see PHS Finding II) where they were claimed to have been recorded from smooth muscle cells from rats treated with antisense to potassium channels, and/or in Figure 3 of the *Hypertension Online* paper (see PHS Finding II) where they were claimed to have been records from rat renal cells treated with phorbol esters and PKC inhibitors. Furthermore, the potassium currents were recorded from neurons, not from smooth muscles as falsely reported in these publications.

A. Dr. Gelband falsified data in the proposing of research by submitting the falsified traces of potassium currents as Figure 9 in NIH grant application HL52189-05.

IV. Dr. Gelband falsified data by claiming in Figure 8 of NIH grant application HL52189-05 and in Figure 2 of the *Hypertension Online* paper (see PHS Finding II) to have generated in his laboratory Western blot data on protein kinase C isoenzymes in renal vascular smooth muscle cells, while in fact the data were actually from cultured neurons collected in another laboratory and published in Pan, S.J., Zhu, M., Raizada, M.K., Sumners, C., & Gelband, C.H. "Angiotensin II-mediated inhibition of neuronal delayed rectifier K^+ current: Role of protein kinase C-a." *American Journal of Physiology* 281: C17-C23, 2001 (subsequently referred to as the *AJP* paper).

V. Dr. Gelband falsified data by misrepresenting experimental traces he provided as the unnumbered topmost figure on Page 26 of NIH grant application HL69034-01, as being recordings showing effect of indolactam inhibition in posterior cerebral arteriolar smooth muscle cells, while the identical tracings had been published by Dr. Gelband as Figures 2C and 7D of the *AJP* paper (see PHS Issue 4), where they had been reported as being tracings from neuronal cells.

VI. Dr. Gelband falsified data in the unnumbered rightmost figure on Page 25 of NIH grant application HL69034-01, by misrepresenting the data as showing potential changes induced in cerebral arterial myocytes by IP3 and heparin, while the same data were published by Dr. Gelband as Figure 5C in a 1997 publication: Gelband, C.H. & Gelband, H. "CA^{2+} release from intracellular stores is an initial step in hypoxic pulmonary vasoconstriction of rat pulmonary artery resistance vessels." *Circulation* 96:3647-3654, 1997 (subsequently referred to as the "*Circulation* paper") as representing changes

in intracellular calcium concentration of pulmonary artery cells induced by ryanodyne and hypoxia.

VII. Dr. Gelband falsified electro-physiological records by reusing the same current-voltage trace as the resonse of renal vascular cells exposed for 2 seconds to Angiotensin II (Figure 4C) and to Caffeine (Figure 4B) on p. 124 of the publication Gelband, C.H. & Hume J.R. "$[Ca^{2+}]_I$ Inhibition of K^+ Channels in Canine Renal Artery. A Novel Mechanism for Agonist-Induced Membrane Depolarization." *Circulation Research* 77(1):121-130, 1995 (subsequently referred to as the *Circ. Res*. 1995 paper).

A. Dr. Gelband also submitted the falsified data above in Figure 4 in NIH grant application R29 JL52189-01A2.

VIII. Dr. Gelband fabricated laboratory research records for four Western blot experiments during the investigation, withholding from the institution his associate's notebook from which he had removed four labeled autoradiographic films from separate and different experiments, and using the removed films to fabricate a laboratory notebook containing falsified Western blots, which he provided to UF as evidence that he had conducted the experiments under investigation.

The terms of this Agreement are as follows:

(1) Respondent agreed to exclude himself voluntarily from any contracting or subcontracting with any agency of the United States government and from eligibility or involvement in nonprocurement programs of the United States Government referred to as "covered transactions" as defined in the debarment regulations at 45 C.F.R. Part 76, for a period of ten (10) years, beginning on October 3, 2003.

(2) Respondent agreed to exclude himself voluntarily from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant, for a period of ten (10) years, beginning on October 3, 2003.

(3) Within 30 days of the effective date of this Agreement, Respondent agreed to submit letters of retraction to the following journals concerning the specified data in the listed articles:

A. *Hypertension* 2000 paper #1: Figures 5, 6, and 7 merited retraction. A retraction has been submitted relevant to this paper.

B. *Hypertension* 2000 paper #1: Figure 1A merited retraction. A retraction has been submitted relevant to this paper.
C. *JBC* paper: Figure 2 and Figure 4 merited retraction. It has already been withdrawn.
D. *Hypertension Online* paper: Figure 4A and Figure 3 merited retraction. It has already been withdrawn.
E. *Hypertension* 1999 paper: Figure 3 must be retracted.
F. *PNAS* paper: Figure 4A and 4B must be retracted.
G. *Circ. Res*. 1999 paper: Figure 5A must be retracted.
H. *Circ. Res*. 1995 paper: Figure 4C or 4B must be retracted.

Thonthi Karunakaran, Boston Medical Center: Based on the report of an investigation conducted by Boston Medical Center (BMC Report) and additional analysis performed by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Thonthi Karunakaran, Ph.D., former Research Scientist at BMC, engaged in scientific misconduct by plagiarizing, falsifying, and fabricating research that he reported to his supervisor for the project "Hemin Utilization by *Porphyromonas gingivalis*," funded by National Institute of Dental and Craniofacial Research, (NIDCR), National Institutes of Health (NIH), grant R01 DE09161-11. Specifically, PHS found that Dr. Karunakaran engaged in scientific misconduct by: (1) plagiarizing a P. gingivalis strain W83 DNA sequence from an Internet database and misrepresenting to his supervisor that the Internet database printout represented his own cloning and sequencing of strain A7436 fur gene X; (2) fabricating the claim to have obtained sequence data for a strain A7436 cloned fur gene X from a sequencing facility at Massachusetts Institute of Technology (MIT); and (3) falsifying unrelated sequencing data from a graduate student's notebook in the laboratory by trimming off the identifying header and misrepresenting it to his supervisor as primary data from his sequencing of the A7436 fur gene X. There were no published papers that required correction or retraction.

The following administrative actions have been implemented for a period of three (3) years, beginning on July 17, 2003: (1) Dr. Karunakaran is debarred from eligibility for or involvement in Federal covered transactions (i.e., any Federal transaction other than a procurement transaction) and from contracting or subcontracting with any Federal government agency; this action is being taken pursuant to the debarment regulation pertaining to grants and other forms of assistance (45 C.F.R. Part 76); and (2) Dr. Karunakaran is prohibited from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

Ilya Koltover, Ph.D., California Institute of Technology: Based on the report of an investigation conducted by the California Institute of Technology (CIT) (CIT Report), an admission by the respondent, and additional analysis conducted by

ORI in its oversight review, the U.S. Public Health Service (PHS) found that Ilya Koltover, Ph.D., former postdoctoral fellow at CIT, engaged in scientific misconduct in research supported by PHS Postdoctoral Fellowship F32 GM20588 entitled "Design of targeted synthetic gene delivery vehicles." Specifically, PHS found that Dr. Koltover plagiarized a scanning micrograph (STM) from a graduate student, falsified it as an atomic force micrograph (AFM) of a separate molecule, and falsely represented it (1) to his research group at Caltech; (2) in his grant application to the Petroleum Research Fund (PRF); and (3) to his mentor, who then included it as an AFM figure in a proposal to the National Science Foundation (NSF).

Dr. Koltover has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed for a period of three (3) years, beginning on October 3, 2003: (1) to exclude himself from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; (2) that any institution which submits an application for PHS support for a research project on which Dr. Koltover'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; Dr. Koltover agreed to ensure that a copy of the supervisory plan is also submitted to ORI by the institution and that he will not participate in any PHS-supported research until such a supervision plan is submitted to ORI; and (3) that any institution employing Dr. Koltover submits, in conjunction with each application for PHS funds or report, manuscript, or abstract of PHS funded research in which he is involved, a certification that the data provided by Dr. Koltover 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. Dr. Koltover must ensure that the institution sends a copy of the certification to ORI.

Kuie-Fu (Tom) Lin, D.V.M., Medical University of South Carolina (MUSC): Based on the report of an investigation conducted by MUSC and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found on June 12, 2002, that Dr. Lin, a former graduate student, Department of Biochemistry and Molecular Biology at MUSC, engaged in scientific misconduct in research supported by the National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grants R01 HL29397, "Regulation and Function of Renal Kallikrein," and R01 HL56686, "Gene Therapy in Experimental Hypertension and Renal Diseases," by falsifying data published in publications in *Hypertension* 26:847-853, 1995, *Hypertension Research* 20:269-277, 1997, and *Human Gene Therapy* 9:1429-1438, 1998. However, subsequent to the execution of a three-year Voluntary Exclusion Agreement (Agreement), Dr. Lin continued to receive PHS funds through April 30, 2003, in material violation of the Agreement. Based on

Dr. Lin's aforementioned violation, and in lieu of initiation of debarment proceedings authorized by 45 C.F.R. § 76.305(c)(4) for Dr. Lin's violation of a material provision of the Agreement, the parties have agreed to extend the term of Dr. Lin's voluntary exclusion through April 29, 2007.

Justin Radolf, M.D., University of Connecticut Health Center: Based on the report of an investigation conducted by the University of Connecticut Health Center (UCHC Report), Dr. Radolf's admissions, and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Dr. Radolf, Professor at UCHC's Center of Microbial Pathogenesis, engaged in scientific misconduct in research supported by National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), grant R01 AI29735-11 and incorporated false claims into a grant application entitled "Tick Inhibitors of Hemostatis: Novel Therapeutic Agents and an Anti-Tick Vaccine" to the United States Department of Agriculture (USDA). Dr. Radolf falsified and fabricated preliminary research data to falsely claim that the genes that he proposed to characterize were specifically expressed in the tick salivary gland. Dr. Radolf represented the products of control samples as positive tests for mRNA expression from different genes and presented data as positive for genes that had not been tested. Specifically, PHS finds that Dr. Radolf falsified and fabricated data in January 2000 by altering the labeling of a figure included in a USDA grant application and by falsifying the text in both the USDA application and in an overlapping application to a state-sponsored program. This incident of falsification and fabrication is significant because the data was the first direct evidence that the isolated clones represented genes expressed in the tick salivary gland, and therefore represented proteins that could be targets of vaccine development to protect the hosts from tick-transmitted microbial diseases. The misinformation of the extent of the progress in this project had the potential to mislead grant reviewers and the scientific community about an area of research that could have led to the prevention of Rocky Mountain Spotted Fever and other tick-transmitted diseases. The Respondent submitted the following admission to ORI:

> In January of 2000, I engaged in scientific misconduct involving research supported by the National Institutes of Health. The misconduct occurred during the preparation of grant proposals submitted to the United States Department of Agriculture and Connecticut Innovations, Inc. More specifically, I falsified and fabricated preliminary data by intentionally altering the labeling of an ethidium bromide-stained agarose gel purporting to demonstrate the expression of genes in the salivary glands of feeding *Dermacentor andersoni* ticks. In so doing, I misrepresented the products of control samples as positive tests for the presence of mRNAs derived from unrelated genes, and I fabricated data to show the expression of genes that, in fact, were not tested. The texts of the two proposals

> also contained inaccurate statements relating to these falsified and fabricated data. By inaccurately portraying the extent of our progress in characterizing salivary gland proteins that might interfere with tick feeding, my actions would have misled the reviewers of the proposals into thinking that we were closer to the development of an anti-tick vaccine than we actually were.
>
> Truthfulness in the recording, presentation, and reporting of data–the accuracy and reliability of the research record–is the foundation of all scientific research. By intentionally misrepresenting preliminary findings in the two grant proposals, my actions violated this basic precept, compromised my scientific integrity and placed my 20-year career as a biomedical researcher in jeopardy. My actions also could have compromised the integrity and careers of individuals with whom I work, individuals who place their trust in me and who look to me for scientific leadership. I take full and complete responsibility for this misconduct. I committed this wrongful act without prompting by other individuals and without the consent or knowledge of others. I am deeply remorseful for my behavior and offer my strongest assurance to the Office of Research Integrity that it will never recur.

Dr. Radolf has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed for a period of five (5) years, beginning on March 10, 2003: (1) to exclude himself from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; (2) that any institution which submits an application for PHS support for a research project on which Dr. Radolf's participation is proposed or which uses Dr. Radolf in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which Dr. Radolf is involved, must concurrently submit a plan for supervision of Dr. Radolf's duties to the funding agency for approval; the supervisory plan must be designed to ensure the scientific integrity of Dr. Radolf's research contribution; a copy of the supervisory plan must also be submitted to ORI by the institution; Dr. Radolf agrees that he will not participate in any PHS-supported research until such a supervision plan is submitted to ORI; and (3) to ensure that any institution employing him submits, in conjunction with each application for PHS funds or report, manuscript, or abstract of PHS-funded research in which Dr. Radolf is involved, a certification that the data provided by Dr. Radolf 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. Dr. Radolf must ensure that the institution sends the certification to ORI.

John W. Rooney, Ph.D., Columbia University: Based on the report of an investigation conducted by Columbia University (CU) (CU Report), an admission by the respondent, and additional analysis performed by ORI in its oversight review, the U.S. Public Health Service (PHS) found that John W. Rooney, Ph.D., former postdoctoral research fellow, CU, engaged in scientific misconduct by falsifying research supported by National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grant T32 HL007343, National Institute of Allergy and Infectious Diseases (NIAID), NIH, grant R01 AI043576, National Institute of General Medical Sciences (NIGMS), NIH, grant R01 GM029361, and National Cancer Institute (NCI), NIH, grants P01 CA075399 and R01 CA076496. Specifically, PHS found that Dr. Rooney engaged in scientific misconduct by: (1) falsifying Panels A-C of Figure 1 in the following paper: Rooney, J.W. & Calame, K.L. "TIF1beta functions as a coactivator for C/EBPbeta and is required for induced differentiation in the myelomonocytic cell line U937." Genes and Development 15:3023-3038, 2001; the respondent falsely claimed that high levels of expression of the TIF1ß gene were induced by dimethylsulfoxide and a phorbol ester; and (2) falsifying Figure 3 in the original and Figures 6 and 7 in a revised version of a manuscript (Rooney, J.W., Postel, E.H., & Calame, K.L. "The DNA-cleavage function of NM23-H2/Puf is essential for myeloid differentiation and for transcription of myeloid-specific genes," submitted to Molecular and Cellular Biology). The respondent falsely claimed that wild-type NM23-H2/Puf protein could cleave DNA promoter sequences in all five purported target genes and that the K12Q mutant protein could not cleave any of them. The respondent also falsely claimed in electrophonetic mobility shift assays that two authentic oligonucleotides bound to the NM23-H2/Puf protein when they did not do so. The Genes and Development paper has been retracted (Genes and Development 16:2170, 2002), and CU has indicated that the Molecular and Cellular Biology manuscript will not be resubmitted until all of Dr. Rooney's data have been replaced by the work of others.

Dr. Rooney has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed for a period of three (3) years, beginning on May 16, 2003: (1) to exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement transactions of the United States Government as defined in 45 C.F.R. Part 76; and (2) to exclude himself from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

Timothy R. Smith, Ph.D., Michigan State University: Based on the findings of Michigan State University, the respondent's admission, and analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Timothy R. Smith, Ph.D., former Postdoctoral Fellow, Department of Biochemistry and Molecular Biology at Michigan State University, engaged in scientific

misconduct in research supported by National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH) grant P01 GM57323, entitled "Oxygen utilizing membrane heme proteins." Specifically, PHS found that Dr. Smith falsified and fabricated data involving research into the physical interaction of prostaglandin endoperoxide synthase-2 (PGHS-2) with cell membranes, and the effects of arachidonate and nonsteroidal anti-inflammatory drugs (NSAIDs) on PGHS-2 structure. Dr. Smith committed scientific misconduct by falsifying and fabricating data for the following tables and figures in his 2000 doctoral dissertation and in a paper in the *Journal of Biological Chemistry* (275:40407-40415, 2000) entitled "Arachidonic Acid and Nonsteroidal Anti-inflammatory Drugs Induce Conformational Changes in the Human Prostaglandin Endoperoxide H_2 Synthase-2 (Cyclooxygenase-2)" (*JBC* paper):

I. *JBC* paper Table II, entitled "Comparison of inter-residue distances as determined by EPR spectroscopy and as calculated from the x-ray crystal structures" (and corresponding Dissertation Table 6 entitled "EPR determined and X-ray crystal modeled inter-nitroxide distances of PGHS-2 MBD mutants");

II. *JBC* paper Table III entitled "Changes in inter-nitroxide differences between PGHS-2 holoenzyme and the apoenzyme, and the arachidonate, flurbiprofen, and SC58125 complexes" (and corresponding Dissertation Table 7), entitled "Relative changes in inter-nitroxide distances for NSAID and arachidonate complexes compared to the unliganded enzyme");

III. JBC paper Figure 4 (binding curves) (and corresponding Dissertation Figure 20 entitled "Binding curves for the association of heme, flurbiprofen and arachidonic acid with PGHS-2 double mutants");

IV. Dissertation Table 8 entitled "EPR determined inter-nitroxide distances for NSAID and arachidonate complexes of PGHS-2 MBD mutants";

V. Dissertation Table 9 entitled "Relative changes in inter-nitroxide distances for NSAID and arachidonate complexes compared to the unliganded enzyme";

VI. Dissertation Table 10 entitled "Kinetic properties and NSAID sensitivities of PGHS-2 active site mutants";

VII. Dissertation Table 11 entitled "EPR determined inter-nitroxide distances for NSAID and arachidonate complexes of PGH-2 MBD mutants";

VIII. Dissertation Table 12 entitled "Relative PGHS-2 protein incorporation of PGHS-2 into lipsomes of varying composition";

IX. Dissertation Table 13 entitled "EPR determined inter-nitroxide distances for detergent solubilized and lipsome reconstituted PGHS-2 mutants"; and

X. Dissertation Figure 27 entitled "Lipid and activity profile of sucrose gradient fractions."

The research misconduct was significant for several reasons. First, the *JBC* paper was novel in that it reported that binding of arachidonate and NSAIDs induced structural changes in PHS-2. For the naturally occurring fatty acid arachidonate, this had not previously been shown. These results could be interpreted as having important implications for understanding the catalytic mechanism of this enzyme. In addition, a considerable expenditure of other researchers' time and resources was prompted by using results generated from the falsified and fabricated data in the *JBC* paper.

Dr. Smith has entered into a Voluntary Exclusion Agreement (Agreement) in which he has voluntarily agreed:

(1) to exclude himself from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of three (3) years, beginning on October 27, 2003;

(2) to exclude himself voluntarily from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government defined as "covered transactions" in the debarment regulations at 45 C.F.R. Part 76 for a period of three (3) years, beginning on October 27, 2003. During the three (3) year period of voluntary exclusion, PHS grant funds may be used to pay for page charges for any written work currently being prepared for submission and/or publication on which Dr. Smith is listed as an author only if (i) such written work is unrelated to the misconduct findings described in the Agreement, (ii) Dr. Smith is not listed as first author, and (iii) the publication does not state that Dr. Smith was supported by a PHS grant. Dr. Smith must certify that all data supporting such written work is true and accurate to the best of his knowledge; and

(3) to submit a letter within 30 days of notification of this action to *JBC* requesting retraction of the following paper: Smith, T., McCracken, J., Shin, Y.K., & DeWitt, D. "Arachidonic Acid and Nonsteroidal Anti-inflammatory

Drugs Induce Conformational Changes in the Human Prostaglandin Endoperoxide H_2 Synthase-2 (Cyclooxygenase-3)." *J. Biol. Chem*. 275: 40407-40415, 2000. Dr. Smith agreed that the retraction will state that he alone was responsible for the falsification and fabrication of the results and will specifically list the falsified figures delineated on page 1 of the Agreement (Findings I, II, and III). Dr. Smith must submit a draft of the retraction letter for ORI approval prior to sending it to *JBC*. This requirement for retraction will be noted on the ALERT System until Dr. Smith sends a copy of the retraction letter to ORI.

Lajuane Woodard, University of Maryland, Baltimore: Based on the report of an investigation conducted by the University of Maryland, Baltimore (UMB Report), the respondent's admission of responsibility, and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Lajuane Woodard, former contractual employee, Department of Pediatrics at UMB, engaged in scientific misconduct in research supported by National Institute of Mental Health (NIMH), National Institutes of Health (NIH), grant 2 R01 MH54983, entitled "Effectiveness of Standard versus Embellished HIV Prevention." Specifically, PHS found that Ms. Woodard engaged in scientific misconduct by fabricating interview records for the Focus on Teens HIV Risk Prevention Program for one interview claimed to have been performed in June 2001.

Ms. Woodard has entered into a Voluntary Exclusion Agreement (Agreement) in which she has voluntarily agreed for a period of three (3) years, beginning on October 30, 2003: (1) to exclude herself from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and (2) that her participation in any PHS-supported research will be conditioned on an appropriate plan of supervision of her duties (Supervision Plan) as follows: (i) any institution that submits an application for PHS support for a research project in which Ms. Woodard's participation is proposed or anticipated must concurrently submit a Supervision Plan to the funding agency for approval; and (ii) any institution using Ms. Woodard in any capacity in PHS-supported research must submit a Supervision Plan to the funding agency for approval. The Supervision Plan must be designed to ensure the scientific integrity of her research contribution. A copy of the Supervision Plan must also be submitted to ORI by the institution. Ms. Woodard agreed that she will not participate in any PHS-supported research until the Supervision Plan has been submitted to ORI.

Jianhua (James) Xu, M.S., University of Alberta: Based on the University of Alberta (UA) Report, the respondent's admissions, and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Jianhua (James) Xu, M.S., former technician at UA, engaged in scientific misconduct in research funded by National Heart, Lung, and Blood Institute (NHLBI), National

Institutes of Health (NIH), grant R01 HL61751-01. Mr. Xu performed experiments on the enzyme lipid phosphate phosphatase-1 (LPP-1) from a family of enzymes that affect signal transduction by glycerolipid and sphingolipid phosphate esters as second messengers. A typical experiment involved the investigation of the effects on various glycerolipids, sphingolipids, and other related effector compounds on the activity of LPP-1 either in tissue culture cells or isolated enzyme preparations. Mr. Xu falsified data by adding vanadate to inhibit the enzyme LPP-1, in experiments that purported to show that the inhibition was the result of adding natural lipid effectors. He was also observed deliberately falsifying other colleagues' experiments in a similar manner. Mr. Xu admits that he alone was responsible for the falsification. Specifically, Mr. Xu committed scientific misconduct by falsifying data for Figures 1A, 1B, 1C, 2B, 2D, 3, 4, 5, 6, 7, and 8A that he published in: James Xu, *et al*. "Lipid phosphate phosphatase-1 and Ca^{2+} control lysophosphatidate signaling through EDG-2 receptors." *Journal of Biological Chemistry* 275:27520-27530, 2000. The paper was retracted in *Journal of Biological Chemistry* 278:38104, 2003. Due to the falsified data, Manuscript #C0007049 by Xu et al. entitled "Transactivation of platelet-derived growth factor receptors by lysophosphatidate causes tryrosine phosphorylation of lipid phosphate phosphatase-1 and feedback inhibition of EDG-2 receptor activation" was withdrawn. Also, ORI concluded Mr. Xu committed scientific misconduct by deliberately falsifying experiments of other colleagues in the laboratory by adding vanadate to their experiments without the authorization or knowledge of his colleagues. Mr. Xu provided the following in an admission statement dated March 23, 2003:

> For the purpose of disposition of this matter by the Office of Research Integrity ("ORI") of the U.S. Department of Health and Human Services, I confirm that I began falsifying results of experiments, relating to the inhibition of the enzyme lipid phosphate phosphatase (LPP-1), in which I was initially involved. The falsification consisted of the addition of vanadate to tubes containing certain substances. In order to cover up my initial falsification, I also falsified the experiments of others who were doing related experiments. I only falsified these subsequent experiments to the extent necessary to cover up the original falsification and did not falsify any other experiments.

The research misconduct was significant because the research focused on the study of signal transduction by lipid messenger molecules, which play an important role in regulating cellular processes as diverse as wound repair, regeneration of injured corneal tissues, adipocyte growth obesity, and cell division potentially involved in the development of cancers.

Mr. Xu has entered into a Voluntary Exclusion Agreement (Agreement) in which he has voluntarily agreed for a period of four (4) years, beginning on November 10, 2003: (1) to exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government referred to as "covered transactions" as defined in the debarment regulations at 45 C.F.R. Part 76; and (2) to exclude himself from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

Appendix B

Summaries of Closed Inquiries and Investigations Not Resulting in Findings of Research Misconduct - 2003

Fabrication: The respondent, a clinical research coordinator, allegedly fabricated follow up data in a research study involving preterm infants. The study in question was supported by a National Institute for Child Health and Human Development (NICHD), National Institutes of Health (NIH), cooperative agreement. The institution conducted an investigation into the matter. The institution determined that there was insufficient evidence that the respondent's alleged actions constituted intentional fabrication of data; furthermore, the original records containing allegedly fabricated data are now missing from the evidence in this case. ORI concurred with the institution's determination and did not make a finding of misconduct in this case.

Fabrication: The respondent, an assistant professor, allegedly fabricated research data included in an NICHD, NIH, grant application. The questioned research involved molecular biological underlying nerve development in the mammalian brain. The institution conducted an investigation into the matter. The institution concluded that while fabrication of research data may have occurred, scientific misconduct could not be determined for any specific individual. ORI concurred with the institution's conclusion and did not make a finding of scientific misconduct in this case.

Fabrication: The respondent, a patient recruiter for a clinical study, allegedly fabricated recruitment questionnaire records for more than 50 subjects in a study of a hereditary blood disorder. The questioned research was supported by a National Institute for Heart, Lung, and Blood Institute (NHLBI), NIH, contract. The institution conducted an investigation into the matter and concluded that based on a preponderance of the evidence, the respondent had fabricated questionnaires for numerous subjects. ORI accepted the institution's report. However, after assessing the evidence supporting the alleged fabrication, ORI determined that there was insufficient evidence to pursue a PHS finding of scientific misconduct against the respondent. Nonetheless, ORI recognized the authority of the institution to establish and implement its own institutional standards for integrity in science.

Falsification: The respondent, a research scientist, allegedly falsified scientific data by altering subjects' diagnoses so that subjects who did not meet the study eligibility requirements would be eligible for a study involving depression. The questioned research was part of a multi-site collaborative study supported by a National Institutes of Mental Health (NIMH), NIH, grant. The institution conducted an investigation into the matter. The institution concluded that a preponderance of the evidence did not support a finding of scientific misconduct in this case. ORI accepted the institution's determination and did not make a finding of scientific misconduct.

Falsification: The respondent, a research associate, allegedly falsified data reported in a manuscript submitted to a journal for publication. The research in question was supported by an NHLBI, NIH, grant. The research involved coronary blood flow in diabetic rats. The institution conducted an investigation into the matter. The institution concluded that the preponderance of the evidence in this case did not support a finding of scientific misconduct, but rather serious errors, precipitated by negligence and sloppiness, had occurred. ORI accepted the institution's determination and did not make a finding of scientific misconduct in this case.

Falsification: The respondent, an adjunct associate professor or research professor, allegedly misrepresented key study personnel, falsified his credentials, falsified the numbers of enrolled subjects, and falsified or fabricated data for pilot studies in research involving behavioral interventions on the risk of HIV/AIDS. The questioned research was supported by National Institute on Alcohol Abuse & Alcoholism (NIAAA), National Institute on Drug Abuse (NIDA), and NICHD, NIH, grants. The institution conducted an investigation into the matter. The institution could not find records to support the claims for pilot research studies and concluded that a falsified number for subjects had been reported in a progress report. The institution also determined that the respondent, as principal investigator, had neglected his responsibilities, including those to obtain proper informed consent from research subjects and Institutional Review Board (IRB) approval for research projects, which represented serious deviations from the standards for the conduct of research expected at the institution. ORI accepted the institution's report, but ORI declined to propose PHS findings of scientific misconduct on any of the issues in this case. Nonetheless, ORI recognized the authority of the institution to establish and implement its own institutional standards for integrity in science and to make findings on issues that include and go beyond those considered by ORI in this matter.

Falsification: The respondent, a research assistant professor, allegedly falsified data included in a National Institute of Aging (NIA), NIH, career development award application. The research involved the potential role of cell cycle regulatory proteins in different degenerative diseases of neural tissues, including an animal model of Alzheimer's Disease. The institution conducted an inquiry into the matter. The institution concluded that honest errors had been made by two members of the research group and that further investigation was unwarranted. ORI concurred with the institution's determination and did not make a finding of scientific misconduct in this case.

Falsification: The respondent, a professor, allegedly misrepresented study data, procedures, and results from a clinical trial in a publication on a medical syndrome. The research was supported by an NIH National Center for Research Resources (NCRR) General Clinical Research Centers (GCRC) Program grant. The institution conducted an investigation into the matter. The institution concluded that numerous

misrepresentations had been made in the questioned publication and that the respondent had the opportunity to avoid these misrepresentations but failed to do so. Based on a preponderance of the evidence, the institution found that the respondent had committed scientific misconduct in reporting study results in the questioned publication. ORI accepted the institution's report, but, given the evidence, ORI declined to propose PHS findings of scientific misconduct on any of the issues in this case. Nonetheless, ORI recognized the authority of the institution to establish and implement its own institutional standards for integrity in science and to make findings on issues that include and go beyond those considered by ORI in this matter.

Falsification: The respondents, an associate professor and an assistant professor, allegedly falsified data presented in a manuscript supported by two National Cancer Institute (NCI), NIH, grants. The questioned research involved a 2D sinogram restoration filter for PET reconstruction. The institution conducted an inquiry into the matter. The institution determined that there was no basis to proceed further with an investigation. ORI concurred with the institution's determination that there was insufficient evidence that this allegation involved scientific misconduct to warrant an investigation.

Falsification: The respondent, a technician, allegedly falsified results in a study involving examination of the effects of growth factors on cells. The questioned results were included in two abstracts and the progress reports of two NHLBI, NIH, grants. The institution conducted an inquiry into the matter. Based on the respondent's admission that she did not follow the protocol relating to the research project, the institution concluded the respondent had committed misconduct. ORI accepted the institution's report. However, after assessing the evidence supporting the alleged falsification, the minimal role these experiments played in the overall focus of the research, and the respondent's statements, ORI determined that appropriate institutional actions had been taken and did not recommend any further PHS action, thus declining to propose a PHS finding of scientific misconduct. Nonetheless, ORI recognized the authority of the institution to establish and implement its own institutional standards for integrity in science and to make findings on issues that include and go beyond those considered by ORI in this matter.

Falsification: The respondent, a professor, allegedly falsified research results included in a poster presentation and published abstract. The research involved neurotrophins and an animal model of fibromyalgia. The research in question was supported by a National Institute for Neurological Disorders and Stroke (NINDS), NIH, grant. The institution conducted an inquiry into the matter. The institution concluded that the misunderstandings and mistrust that had evolved between two researchers did not constitute misconduct nor warrant further inquiry or investigation. ORI concurred with the institution's determination that there was insufficient evidence to warrant an investigation.

Plagiarism: The respondent, an associate professor, allegedly plagiarized scientific ideas from a grant application and allegedly included the plagiarized ideas in a published paper. The research in question involved the study of the basic biology of urologic tissue. The paper in question cited support from an NCI, NIH, grant and a National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH, grant. The institution conducted an inquiry into the matter and determined that there was no basis that would support a finding that the grant application had been a source for the published paper in question. Thus, the institution concluded that an investigation of this matter was not warranted. ORI accepted the institution's determination that no further investigation was warranted.

Plagiarism: The respondent, a medical consultant, allegedly plagiarized published materials from uncited sources in material prepared for National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) and National Institute of Dental and Craniofacial Research (NIDCR), NIH, grant applications. The research involved development of new synthetic biomaterials for use in bone grafting. The institution conducted an investigation into the matter. The institution concluded that plagiarized materials had been presented in the background sections of the questioned grant applications, but it could not be determined who was responsible for the inclusion of the plagiarized materials. Further, the institution concluded that the plagiarized materials were in the background sections only and were of relatively small significance to the evaluation of the grant applications. Therefore, the institution did not make a finding of scientific misconduct. ORI accepted the institution's conclusion that there was insufficient evidence to make a finding of plagiarism in the insertion of the questioned material into NIH grant applications by a specific person, and ORI did not make a finding of scientific misconduct.

Fabrication/Falsification: The respondent, a research assistant, allegedly fabricated or falsified demographic data for control subjects in a research study involving cognitive symptoms of a debilitating disease. The questioned research was supported by an NICHD, NIH, grant. The institution conducted an investigation into the matter. The institution found that the respondent had committed misconduct of a minor nature that did not affect the results of the study. ORI accepted the institution's report but declined to pursue a finding of scientific misconduct in this case.

Falsification/Fabrication: The respondents, a professor and/or coauthors, allegedly falsified and/or fabricated data and results presented in a published paper. The questioned research involved the effect of abnormalities in catalase import into peroxisomes. The research was supported by an NINDS, NIH, grant. The institution conducted an inquiry into the matter. The institution determined that there was not sufficient evidence available to conduct a scientific misconduct investigation. ORI accepted the institution's conclusion that, based on the available evidence and given

the absence of other relevant evidence that could be pursued, no further investigation was warranted.

Falsification/Fabrication: The respondent, a former study coordinator, allegedly falsified or fabricated pill count forms and symptom checklists in a breast cancer prevention trial supported by an NCI, NIH, cooperative agreement. The institution conducted an investigation into the matter. The institution concluded that the respondent had engaged in falsification or fabrication on two pill count forms and symptom checklists. 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, among other considerations.

Plagiarism, Falsification, and Fabrication: The respondent, an associate professor, allegedly plagiarized, falsified, and fabricated data in a grant application submitted to the NHLBI, NIH. The research involved signals for cell survival in endothelial tissues. The institution conducted an investigation into the matter. The institution concluded that while there was some evidence that plagiarism had occurred, there was no evidence that the respondent had been knowingly involved. ORI accepted the institution's determination and did not make a finding of scientific misconduct against the respondent in this case.

Research Misconduct Related Litigation - 2003[1]

CIVIL LITIGATION–Open Cases

Justin D. Radolf v. University of Connecticut Health Center, et al., (No. 303CV242). (D. Conn., filed March 21, 2003). On March 21, 2003, plaintiff Justin D. Radolf, M.D., filed a motion for preliminary injunction seeking to enjoin a University of Connecticut Health Center (UCHC) investigation concerning allegations that plaintiff falsely reported time and effort reports to the National Institutes of Health (NIH). Plaintiff alleged that the investigation was spawned by a vengeful motive to intimidate and threaten him for his refusal to accede to UCHC's unlawful attempt to encumber the funds by paying an unwarranted proportion to the plaintiff's research associate. A recommended ruling was issued to deny injunctive relief, from which plaintiff has appealed. On December 29, 2003, the court upheld the magistrate's recommended ruling denying plaintiff's request to enjoin UCHC's investigation.

A settlement conference held in August was unsuccessful. Discovery is due by June 2004, and summary judgment motions are due by September 2004.

Justin D. Radolf v. Peter J. Deckers**,** (No. 303CV672). (D. Conn., filed April 14, 2003). On March 10, 2003, the Public Health Service (PHS) entered into a Voluntary Exclusion Agreement with Justin D. Radolf, M.D., who is a Professor at the University of Connecticut Health Center (UCHC). Under the terms of his PHS agreement, Radolf agreed to accept supervision by any institution employing him until March 9, 2008. UCHC, Dr. Radolf's current employer, developed a supervision plan proposing restrictions in addition to those mandated by the PHS agreement.

Dr. Radolf is seeking judicial review of UCHC's additional restrictions. On April 14, 2003, Radolf filed a complaint and a motion for a preliminary injunction in the U.S. District Court in the District of Connecticut against Peter Deckers, in his official capacity as the Executive Vice President and Dean of the School of Medicine at UCHC. The complaint alleges general deprivation of Radolf's constitutional right to due process of law in violation of the Fourteenth Amendment.

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[1]The HHS Office of the General Counsel tracks all civil and criminal litigation related to ORI's mission. Many cases, especially those in which HHS is a named party, require legal support to the Department of Justice (DOJ). This includes drafting litigation summaries and reports, drafting discovery requests and responses, preparing briefs and pleadings, and developing legal strategy. The litigation summaries included in this Annual Report exclude *qui tam* cases that are under seal and hence confidential, pending DOJ civil and criminal investigations, and cases in which ORI has only a peripheral interest.

Radolf alleges that the defendant unlawfully 1) removed the plaintiff from any academic and/or administrative leadership position on behalf of UCHC; 2) expelled the plaintiff from the existing academic/departmental structure of UCHC; 3) negated the plaintiff from existing departmental appointments 4) imposed upon the plaintiff four additional years of academic probation; 5) expunged the plaintiff's name from the list of available mentors for new MD/PhD candidates; and 6) revoked the plaintiff's appointment to the Steering Committee of the MD/PhD program.

Both of the preceding cases involving Dr. Radolf were consolidated.

***Marguerite M. Kay v. Peter Likins, et al.*,** (No. Civ. 02-307) (D. Ariz., removed from Ariz. Super. Ct., June 20, 2002). In this companion case to three previous cases, including the case below, Dr. Kay seeks review of the University of Arizona's final decision terminating her employment as a faculty member. Dr. Kay had been subject to several previous research misconduct and termination hearings that 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 of Arizona's Committee on Academic Freedom and Tenure, which found scientific misconduct and recommended dismissal, and the concurring decisions by the University's president.

Defendants named in the suit include the University's president and provost and their spouses, members of the Committee on Academic Freedom and Tenure and their spouses, and the State of Arizona Board of Regents. Dr. Kay alleges denial of her property interest in her employment and liberty interest in her name without procedural or substantive due process, breach of contract, and tortious interference with her employment relationship. She has requested reinstatement, back pay, and compensatory and punitive damages.

The Federal district court dismissed the case without prejudice in April 7, 2003. Dr. Kay filed an amended complaint on May 5, 2003. ORI anticipates a final ruling in 2004.

Marguerite Kay, M.D. v. State of Arizona Board of Regents, (No. 2 CA-CV 2003 0049) (Ariz. Ct. App.). In this companion cases to several previous cases, Dr. Kay seeks review of the University of Arizona's final decision terminating her employment as a faculty member. Dr. Kay had been subject to several previous research misconduct and termination hearings that one of the court cases ordered redone due to procedural deficiencies. Subsequent misconduct and termination hearings conducted by the University's Committee on Academic Freedom and Tenure found scientific misconduct and recommended dismissal. On April 2, 2002,

the University's president issued a final concurring decision terminating Dr. Kay's employment.

On May 22, 2002, Dr. Kay filed a motion for leave to join new claims against the Arizona Board of Regents (ABOR) under the caption of a previously closed related case. The motion attached a new complaint seeking judicial review of the termination decision. ABOR opposed the motion on several grounds. On June 27, 2002, Dr. Kay filed a new complaint under a new caption seeking judicial review of the termination decision before a different judge. ABOR moved to dismiss this complaint.

The Superior Court consolidated argument on both filings. The court denied Dr. Kay's May 22, 2002 request for leave to supplement her earlier complaint, and granted ABOR's motion to dismiss the June 27, 2002 complaint. On November 19, 2002, the court amended its order by affirming the University's termination decision. Dr. Kay appealed the decision to the Arizona Court of Appeals. The Court of Appeals affirmed the trial court's dismissal on December 24, 2003.

Jessie L. S. Au v. Yulin Ma**,** (No. C2:01-0596) (S.D. Ohio, filed June 20, 2001). Dr. Au is suing Dr. Ma, claiming libel for statements that Dr. Ma made in an email to The Ohio State University alleging, among other things, research misconduct. Dr. Ma filed a motion for summary judgment in August 2002, which the court denied in September 2003.

CRIMINAL LITIGATION

State of Iowa v. Pat J. Palmer (FECR 062994) (Iowa Distr. Ct.). After the University of Iowa's Research Misconduct Committee found Pat J. Palmer responsible for misconduct, the Johnson County, Iowa prosecutor charged Ms. Palmer with three criminal counts: one count of felony theft and one count of tampering with records, both arising from false claims of automobile mileage of approximately $53,000 charged against a University of Iowa research grant; and one count of falsifying her academic record in an employment application by falsely claiming to have received an undergraduate degree from the University of Northern Iowa, two masters degrees from the University of California at Berkeley, and dual doctorate degrees from the University of Iowa.

On October 30, 2003, Palmer plead guilty in the Johnson County District Court to the counts of theft in the first degree (violation of Iowa Code §§ 714.1(3), 714.2(1)) and falsifying academic degrees (in violation of Iowa Code § 715A.6A). The court sentenced Palmer to three years of supervised probation and a $1,000 fine on the first count, one year supervised probation and a $250 fine on the second count,

and $18,976.80 restitution for falsified travel vouchers. PHS findings of research misconduct were made against Palmer in 2004.

* The criminal litigation list does not include ongoing criminal matters which are still in the investigational stages, or those for which no indictment has been sought.

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