Highlights of 1999 ORI Annual Report

1999 turned out to be a busy and productive year for ORI. Two significant events that took place had the potential for significant impact on the office—the proposal of a new Federal-wide definition of research misconduct and the adoption by the Department of Health and Human Services ("Department" or "HHS") of 14 recommendations made by a special HHS Review Group on Research Misconduct and Research Integrity to improve the quality, effectiveness, and efficiency of the Department's response to misconduct allegations. Other significant ORI activities included managing its caseload of misconduct allegations, establishing a new research program, taking affirmative steps to foster responsible conduct of research, and responding to legal challenges.

Major Policy Changes Underway

The Department will adopt through rulemaking a new definition of research misconduct that focuses on improper behaviors related specifically to the conduct of research. The definition, proposed by the National Science and Technology Council, will also be adopted by other Federal agencies engaged in research. Misconduct will be limited to "fabrication, falsification, or plagiarism in proposing, performing or reviewing research or in reporting research results." Other types of misconduct such as theft, harassment, or discrimination that might occur in the course of research will be addressed through other laws and regulations. The final Government-wide definition and procedures for responding to misconduct allegations are expected to be published in the *Federal Register* sometime in 2000. All Government agencies that fund research will be expected to implement the final definition and procedures either administratively or through regulatory change within a year of the publication date.

In December 1999, ORI published a special 5-page section on the implementation of the recommendations made by the HHS Review Group on Research Misconduct and Research Integrity in the first 12-page edition of the *ORI Newsletter*.

Institutions that administer Public Health Service (PHS)-supported grants will maintain responsibility for conducting initial inquiries and investigations when allegations of misconduct are made. However, when an investigation is required by the Federal Government, it will be carried out by the HHS Office of Inspector General rather than ORI.

Inquiries and investigations into potential research misconduct will be separated from the decision-making process of determining if misconduct occurred. ORI will conduct an oversight review for institutional investigations and will recommend findings and administrative actions to the Assistant Secretary for Health, who will make the final decision regarding misconduct, subject to appeal.

The Departmental Appeals Board (DAB) will continue to hear appeals from individuals who contest findings of misconduct. Each DAB appeals panel will include up to 2 scientists, and the DAB guidelines have been revised to establish procedures for selection of these scientists.

Through ORI, HHS will expand the existing requirement to provide education in the responsible conduct of research to all staff engaged in research or research training with PHS funds. This new policy is expected to be announced by October 1. ORI's mission has been refocused on oversight, the prevention of misconduct, and promotion of research integrity through expanded education programs. In addition, publication of a Notice of Proposed Rule Making on the protection of whistleblowers is anticipated sometime in 2000. Updated information on the implementation of HHS policy changes is available on the ORI web site at **http://ori.dhhs.gov**.

These recent actions fit nicely into the three main components of ORI's mission: (1) to develop a system for responding to allegations of research misconduct, where institutions have the primary responsibility for investigating and resolving allegations; (2) to develop a system that fosters the responsible conduct of research; and (3) to ensure regulatory compliance by institutions receiving PHS research and training funds.

Responding to Misconduct Allegations

ORI continues to succeed in reducing its backlog of older cases. Last year there were 13 cases that had been open for over 2 years. As of December 1999, there were just five such cases. ORI offered Rapid Response Technical Assistance on four cases, and two were accepted by novice institutions for assistance with sequestration of evidence or investigative strategy.

In 1999, 10 cases were closed in less than 6 months, 16 cases were closed within 6 to 12 months and 7 cases were closed after more than 12 months. The average processing time for misconduct cases was 14.2 months, and the average processing time for no misconduct cases was 6.2 months. Seventy-nine percent of all cases were closed within 12 months, which approximated ORI's goal for the year of closure of 80 percent of cases within 12 months.

ORI opened 30 new cases in 1999 and closed 33 cases. At the end of the calendar year, 32 cases remained open. Thirteen of the thirty-three closed cases resulted in sustained findings of scientific misconduct. Historically, ORI has made a finding of misconduct in about one third of its cases.

New Research Program

ORI plans to initiate a new research program in 2000, and is convening a conference in Washington, D.C. on November 18-20, 2000, "Research on Research Integrity: A Conference on the Emerging Challenges for the Responsible Conduct of Research." Scholars from various disciplines submitted 86 abstracts on issues related to research integrity. Some areas of research interest include career development, career pressures, mentoring practices, responsible conduct of research training programs and their efficacy, development of normative standards for research, data recording, data retention, data analysis, quality control and the management of laboratories, authorship and publication practices, and differential opportunities to commit research misconduct across scientific disciplines. ORI expects the meeting will produce a research agenda on research integrity to strengthen educational efforts and to enhance the responsible conduct of research. ORI expects to announce a new grant program in late 2000 for research studies on research integrity issues and to make a limited number of awards in late 2001. More details will be available on ORI's web site at **http://ori.dhhs.gov**.

Fostering Responsible Conduct in Research

In line with expansion of the education program, ORI co-sponsored a total of six conferences with institutions across the country in 1999. On November 17, 1999, ORI collaborated with several Federal agencies to hold a 1-day open meeting at the National Academies of Sciences to promote discussion of the new Government-wide research misconduct definition and basic guidelines for the conduct of investigations.

Five additional conferences were held nationwide during 1999. The first was an introductory workshop on handling misconduct allegations that was held at the University of California at San Diego on February 18, 1999. A research integrity conference was held in Houston, Texas, that examined the professional, ethical and social obligations of researchers on March 11-12, 1999. The third conference of the year was held in Bethesda, Maryland, on May 13-14, 1999, and was designed to provide pragmatic advice to participants in developing courses on the responsible conduct of research. On May 24, 1999, a 1-day retreat in Montreal examined authorship issues under the co-sponsorship of ORI and the Council of Biology Editors (now the Council of Science Editors). On September 10, 1999, research managers gathered in Albuquerque, New Mexico, to consider ethical challenges and practical solutions for instilling and maintaining integrity when

managing research. Conference proceedings were produced for the Houston and Albuquerque meetings, and proceedings will be made available in 2000 for the Bethesda meeting.

To help in planning an expansion of ORI's educational efforts in the areas of research integrity, the responsible conduct of research, and the prevention of research misconduct, ORI hired a contractor to assess the educational needs of the extramural research community. The results of focus groups and a survey will be used to develop a strategic plan for the educational program. Other studies begun in 1999 included a study of characteristics of medical school guidelines for the responsible conduct of research, an attempt to identify the range of procedures used by institutions in their misconduct policies, a study of why researchers commit misconduct, and a content analysis of the instructions to authors for journals that have published articles involved in misconduct cases. All these studies will help ORI refine the materials and assistance it provides to institutions for responding to and preventing research misconduct.

ORI staff also served as a guest editor and wrote articles for a special issue of *Science and Engineering Ethics* on scientific misconduct published in April 1999. ORI issued a new guidance document for journal editors in early 2000 on reporting suspect manuscripts, facilitating investigation of misconduct allegations, and improving correction of the literature.

During 1999, ORI expanded or began developing four different educational networks with officials from outside organizations. These networks focused on PHS research integrity officers, a consortium of DC area extramural research integrity officials, research misconduct officials at other Federal agencies, and collaborations with scientific societies and professional and institutional associations.

Ensuring Regulatory Compliance

ORI processed a total of 374 institutional policies during 1999, closing 258 reviews and carrying 116 into 2000. The closed reviews included 225 accepted policies and 33 inactivated assurances because policies were not submitted. Of the 116 open reviews, 78 required institutional action before further progress could be made. A total of 1,279 reviews have been completed.

In 1999, ORI also completed a study of the policies and procedures created by parent institutions and their affiliates to determine whether viable systems for responding to allegations of scientific misconduct exist. The report analyzed the assurances of 251 institutions in 73 parent/affiliate units composed of 73 parents and 178 affiliates to determine whether (1) the parent policy complied with the regulation, (2) the affiliate policy (if different than parent) complied with the regulation, (3) the parent policy acknowledged responsibility for responding to allegations at the affiliates, and (4) the affiliates accepted the parent policy. The study found that only 10 of the 73 units (14%) initially met all 4 of these criteria. After requesting that their policies be modified or other appropriate actions be taken, all 73 units met the four criteria by the end of the study.

Meeting Legal Challenges

ORI responded to a number of different legal challenges during 1999, which are summarized below. For a more detailed discussion of these items, see appendices A and C.

DAB Affirms ORI's Scientific Misconduct Findings Against Angelides

On February 9, 1999, a Panel of the HHS Departmental Appeals Board (DAB) released its February 5th decision in the scientific misconduct and debarment proceeding against Dr. Kimon Angelides, a former researcher at Baylor Medical College. Based upon its *de novo* review of all the evidence, the DAB affirmed ORI's findings of scientific misconduct and further determined that the proposed administrative actions were justified. In particular, the DAB concluded that Dr. Angelides intentionally falsified research data in 20 figures and 5 tables that were contained in 5 grant applications seeking a total of over $4 million, and in 5

published scientific papers. The administrative actions included a 5-year debarment, a 5-year prohibition against Dr. Angelides serving on any PHS advisory committee, board, and/or peer review board, and retraction of the five scientific papers containing falsified data.

Dr. Angelides Settles Liability Suit

On February 10, 1999, shortly following receipt of the DAB's scientific misconduct decision, see above, Dr. Angelides agreed to settle the State civil suit he had filed against the Baylor College of Medicine and several institutional officials. As part of the settlement, Dr. Angelides agreed to the dismissal of his suit, to accept the scientific misconduct findings made by ORI and affirmed by the DAB, and not to appeal the DAB's debarment recommendation to the HHS Debarring Official.

Fourth Circuit Affirms Dismissal of Researcher's Torts Suit

The Fourth Circuit affirmed a district court's dismissal of a civil suit related to a scientific misconduct investigation brought by a former NIH scientist, Dr. Mikulas Popovic. Dr. Popovic filed his claims under the Federal Tort Claims Act (FTCA) under which the Government specifically waives its sovereign immunity for some torts. In its April 20, 1999, decision, the appeals court agreed that although Dr. Popovic had claimed the torts of negligent investigation and invasion of privacy, which are covered by the FTCA, an examination of the facts showed that in reality he was claiming that he was defamed by actions taken during the course of the scientific misconduct investigation. The FTCA specifically excludes from its coverage intentional torts such as defamation. The appeals court further held that Dr. Popovic's due process claims about the scientific misconduct investigation were constitutional in nature. Therefore, those claims also could not be brought under the umbrella of the FTCA.

State Court Rules Against University in Faculty Termination Suit

An Arizona state court ruled that Dr. Marguerite Kay, a former faculty member and researcher, had been wrongfully terminated by the University of Arizona. The University had fired Dr. Kay after it found, among other things, that she had committed scientific misconduct. The court stated that the University had failed to follow its own policies for termination of faculty and remanded the issue of her dismissal back to the University. However, the court held it did not have jurisdiction to order her reinstatement or back pay. Although the court made its ruling on April 30, 1999, it did not issue a final decision until December 7, 1999.

CONTENTS

ORI's investigative workload associated with handling allegations of scientific misconduct includes allegations, cases, and administrative closures. The ORI caseload includes oversight and review of institutional inquiries and investigations as well as the conduct of inquiries and investigations in the PHS intramural program or at extramural institutions under special circumstances (*e.g.*, when the institution is unable or unwilling to do the inquiry or investigation, or multiple institutions are involved, as in multi-center clinical trials). In the future, investigations in the PHS intramural program will be conducted by the pertinent PHS operating division (*e.g.*, NIH or CDC) and extramural allegations requiring an HHS investigation will be conducted by the HHS Office of Inspector General (OIG).

Allegations

Each allegation received by ORI is assessed against criteria that must be met in order to open 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 makes a search of computer records and publications for potentially related PHS grants, contracts, and cooperative agreements. The relevant grant applications and/or publications are obtained to determine the 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."

   Many allegations involve questions of "honest differences in interpretations or judgments of data" that are specifically excluded from the PHS definition. If the allegation involves possible financial misconduct, other regulatory violations, criminal acts, or civil matters (*e.g.*, harassment claims), ORI refers the allegation to the appropriate Federal office or agency. If the allegation involves a credit or author-

ship dispute between former collaborators, ORI refers the complainant to the responsible institutional official for resolution.

3. There is adequate information to proceed with an inquiry.

   ORI may request additional information from the person who initiated the allegation, if the person is identified. If an allegation is made anonymously or there is not adequate information to proceed, ORI initiates a tracking file to wait to see whether additional information is forthcoming or can be requested from the complainant.

   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 if it is found to have arisen because of a misunderstanding or incomplete information. However, substantive allegations that meet the three criteria above will lead ORI to request an institution to conduct an inquiry or for ORI to refer the allegation to OIG.

Although only about 15-20 percent of the allegations received by ORI result in a formal case being opened by ORI, all the allegations are evaluated carefully for appropriate disposition. In certain situations, ORI requests additional preliminary information from an institution. Many assessments require appreciable ORI staff work at this phase.

In 1999, ORI received 129 allegations. The disposition of the allegations are presented in Table 1 below. Allegations become active cases when the criteria outlined above are met. However, some allegations are administratively closed when they do not fall under ORI jurisdiction, cannot be referred to another agency, or are resolved through further review and information. Allegations are referred to other Federal agencies or offices when the allegation concerns the use of humans and animals in research, financial issues, research funded or regulated by other agencies, and so on. No action is possible when an allegation does not contain sufficient specific information to permit another disposition to be made.

Table 1: **Disposition of Allegations, 1999**

Pre-Inquiry Assessment of Allegation	38
No Action Possible Now Or No Action	73
Referred to Other Federal Agencies	18
TOTAL	129

Of the 129 allegations made to ORI in 1999, 38 (29%) were assessed in detail for a potential inquiry or investigation, 18 were immediately referred to other agencies, and 73 were closed without further action. Of the 38 allegations requiring a detailed assessment, 36 (93%) were resolved by ORI within 30 days (from time of file assignment to administrative closure or to opening of a formal case). See Table 2. Two other recent allegations were still under review at the end of the calendar year. Of the 36 completed assessments, 22 (61%) resulted in formal cases being opened in ORI.

Table 2: **Conduct of Pre-Inquiry Assessments, 1999 (N=38)**

Category	*Number*	*Total Days*	*Average No. Days*	*Median No. Days*
Cases	22	758	34.5	22.6
Administrative Closure	14	343	24.5	20
Unresolved at Year End	2	4	2	—
TOTAL	38	1,105	29.1	—

Cases

ORI closed 33 cases in 1999 including 8 inquiries and 25 inquiries/investigations. The average case duration of 22 months was almost equally split between institutional action (11.5 months) and ORI oversight (10.5 months). (See Table 3.) The time period for institutional action includes the inquiry and the adjudication phase for 8 inquiries and the inquiry, investigation, and adjudication phase for 25 investigations. The ORI oversight period covers the review of the inquiry and/or the investigation which may include requests to institutions for more information or analysis or additional ORI analysis and a hearing before the Departmental Appeals Board (DAB). One case closed in 1999 went to a DAB hearing; the process lasted 22 months.

In 1999, 13 of the 25 investigations closed by ORI resulted in sustained findings of scientific misconduct and PHS administrative actions against the respondent. Summaries of these cases may be found in Appendix A (Note: two different cases are summarized for one respondent, Mr. Thomas Philpot). Summaries of the 10 investigations closed by ORI that did not result in findings of scientific misconduct may be found in Appendix B. Two cases were closed administratively. At the end of the calendar year, ORI had 32 active formal cases and 2 allegations under review.

Table 3: **Duration in Months of Research Misconduct Cases Closed, 1999 (N=33*)**

Measure	*Institutional Action*	*ORI Oversight*	*Total Duration*
Average	11.5	10.5	22
Median	9	8	18
Mode	5	6	30
Range	1-36	1-47	2-72

*Includes 25 investigations and 8 inquiries.
Institutional Action - months from receipt of allegation to final institutional action.
ORI Oversight - from final institutional action to final notification of finding.

The ORI caseload is divided into four elements, (1) institutional inquiries, (2) institutional investigations, (3) ORI inquiries, and (4) ORI investigations (See Table 4).

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 asked to report the outcome of the inquiry to ORI. ORI reviews the reports to determine whether the conduct of the inquiry complied with the PHS regulation and was thorough, competent, and objective.

During 1999, ORI accepted eight institutional reports on inquiries that did not recommend investigations Four cases alleged falsification and four cases alleged plagiarism. ORI requested that 16 institutions conduct inquiries, accepted 8 reports, and carried 12 active cases into 2000.

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. The ORI reviews the reports to determine whether the conduct of the investigation complied with the PHS regulation and was thorough, competent, and objective, and provided a basis for a PHS finding of misconduct. In 1999, ORI continued monitoring 31 investigations at research institutions. During the year, 13 new institutional investigations were opened and 25 investigation cases were closed. There were 19 active investigations carried into 2000.

ORI inquiries: Previously, ORI has reviewed all inquiries conducted into allegations of scientific misconduct within the PHS intramural research programs. In addition, ORI has occasionally conducted inquiries at extramural institutions if ORI determined that there was a need to do so, *e.g.*, a multi-center clinical trial or a small business. There was one institution (involving a small business with fewer than six employees) in this category in 1999; the case moved into the ORI investigation stage. There were no PHS intramural cases active in 1999.

ORI investigations: One ORI investigation was opened in 1999 (involving a small business), and it was carried into 2000. There were no PHS intramural cases active in 1999.

Table 4: **ORI Scientific Misconduct Caseload by Case Type, 1999**

Case Type	*Forwarded from 1998*	*Opened in 1999*	*Closed in 1999*	*Carried into 2000*
Institutional Inquiries	4	16	8	12
Institutional Investigations	31	13	25	19
ORI Inquiries	0	0	0	0
ORI Investigations	0	1	0	1
TOTAL	35	30	33	32

Administrative Closures

A formal case may be administratively closed when ORI later concludes that no PHS funds or applications were actually involved, or that continuing effort will not produce sufficient evidence to resolve a case satisfactorily, or further review indicates that the allegation does not fall under the PHS definition of scientific misconduct. There was one inquiry case and one investigation case administratively closed by ORI in 1999.

II. EDUCATION AND OUTREACH

ORI's education and outreach activities continued to expand in 1999. Notable actions and achievements include:

- Conducted six regional research integrity conferences in collaboration with research institutions, as well as one update workshop for NIH research integrity officers, involving a total of nearly 900 participants. Conference proceedings were produced or will be made available in 2000 for four of the six regional meetings.

- Produced two publications: the *ORI Annual Report - 1998* (Aug. 1999) and guidance for journal editors, *Managing Allegations of Scientific Misconduct: A Guidance Document for Editors* (Jan. 2000). ORI staff also wrote articles for two special issues of *Science and Engineering Ethics*.

- Published four issues of the *ORI Newsletter*, including a special 12-page issue containing a 5-page section featuring reports on implementation of the recommendations of the HHS Review Group on Research Misconduct and Research Integrity.

- Began development of a new web site designed to assist institutions in developing new programs on the responsible conduct of research. In addition, the ORI web site located at **http://ori.dhhs.gov** was redesigned to be more visually appealing as well as easier to navigate and maintain.

- Created a research program focussing on key elements of research integrity and misconduct in science. The first year of this program involved initiating a process to develop a research agenda for research on research integrity. The following studies were also initiated in 1999: (1) an educational needs assessment, (2) content analysis of institutional research misconduct policies, (3) why researchers commit misconduct and the impact that a finding of research misconduct has on their careers, (4) topics covered by medical school guidelines for the conduct of research, (5) content analysis of instructions to journal authors, and (6) the feasibility of organizing consortia to assist novice institutions in conducting inquiries or investigations (actually awarded in early 2000).

- Expanded or began developing four different educational networks: PHS research integrity officers, consortium of DC area institutional officials, Federal agency misconduct officials, and collaborative

relationships with professional associations and scientific societies.

- Gave 25 presentations at conferences, workshops, or meetings, and published 4 journal articles.

- Provided technical assistance to institutions, and invited speakers to address ORI staff.

- Established a presence at scientific meetings.

A. Conference and Workshop Program

ORI conducted six conferences in collaboration with institutions and held an annual update workshop for NIH Research Integrity Officers. The conferences were held in San Diego, Houston, Bethesda, Montreal, Albuquerque, and Washington, DC.

Introductory Workshop for Institutional Misconduct Officials

The ORI Introductory Workshop for Institutional Research Integrity Officers was held February 18, 1999, at the University of California-San Diego (UCSD) under the co-sponsorship of UCSD, University of California-Los Angeles (UCLA), and the University of Washington. Aimed at those institutional officials responsible for ensuring compliance with the PHS regulation related to scientific misconduct, this workshop, conducted by university officials and ORI staff, provided 78 participants with practical advice on handling particular case situations and meeting regulatory requirements. The attendees rated the meeting, speakers, and presentations from very good to excellent.

"Research Integrity: A Professional, Ethical, and Social Obligation"

ORI co-sponsored a conference with 6 Houston-area institutions on March 11-12, 1999, for 143 participants. Co-sponsors were the University of Texas-Houston Health Science Center, the University of Houston, the University of Texas M.D. Anderson Cancer Center, Texas Woman's University-Houston Center, Texas Southern University, and Prairie View A&M University. The conference focused on shared accountability among members of the scientific community and the general public. The audience was intentionally broad and included diverse representation from the scientific community, specialty groups such as science writers and reporters, and members of the lay public. The goal of the conference was to have each participant leave the conference with an enhanced appreciation for the shared professional and public accountabilities necessary to achieve the highest quality of biomedical research. Conference proceedings were distributed to all participants and are available on the ORI web site. At least 75 percent of those attendees who submitted evaluation forms found the information useful, the conference format effective, and the opportunity for questions and discussion very helpful.

"Educating for the Responsible Conduct of Research in the Next Millennium: New Dilemmas, Continuing Questions, and Effective Strategies"

The conference on "Educating for the Responsible Conduct of Research in the Next Millennium: New Dilemmas, Continuing Questions, and Effective Strategies" held May 13-14, 1999, in the Bethesda Marriott was attended by 222 participants. The conference was co-sponsored by Public Responsibility in Medicine and Research, the Association of American Medical Colleges (AAMC), the Applied Research Ethics National Association, Tufts University School of Medicine, NIH, and ORI. Sixty-four percent of the attendees who completed the evaluation form gave the conference an overall rating of excellent or very good. The conference was designed to provide pragmatic advice regarding course development and didactic methods for teaching the responsible conduct of research. Workshops formed the core of the meeting, and more than 200 pages of reference materials were handed out to all participants. Conference proceedings are being developed, and should be available in 2000.

"Authorship in Biomedical Publication: Progress and Challenges"

ORI co-sponsored a workshop in Montreal, Canada, on May 24, 1999, with the Council of Biology Editors ((CBE), now the Council of Science Editors) for about 150 attendees to discuss the manner in which contributions to published articles should be acknowledged. A task force drafted a white paper on authorship that summarized the history and development of the problem, and relevant research on the subject was examined, including the results of several research projects underway at journals experimenting with proposed solutions to the problems of authorship. ORI funds were used to defray the cost of travel and related expenses for approximately six graduate students or other participants who otherwise would not have been able to attend the meeting. A revised white paper and report on the workshop are planned, with publication on the CBE web site anticipated sometime in 2000.

"Ethical Challenges and Practical Solutions for Managers in Research"

ORI co-sponsored a workshop with Sigma Xi, The Scientific Research Society for 60 participants in Albuquerque, New Mexico, on September 10, 1999, that focused on ethical challenges and practical solutions for managers in research. Workshop participants considered a variety of views on building a system of research integrity, and the program featured talks by Sigma Xi and ORI officials, academic research directors, and national laboratory managers. Sigma Xi introduced its new publication, *The Responsible Researcher: Paths and Pitfalls*. Seventy-five percent of the attendees who completed the evaluation form rated the overall quality of the workshop as above average or excellent. An executive summary of the workshop was made available on ORI's web site and a printed transcript of the workshop proceedings will be mailed to participants in 2000.

Town Meeting on Research Misconduct

On November 17, 1999, ORI collaborated with several Federal agencies to hold a 1-day open meeting at the National Academies of Sciences (NAS) to promote discussion of the new Government-wide research misconduct definition and basic guidelines for the conduct of investigations of alleged or suspected misconduct that was published for public comment in the *Federal Register* on October 14. Representatives from nine Federal agencies and seven scientific societies or institutional associations made presentations. Approximately 175 individuals attended the meeting and an additional 404 logged on to the live audio Internet web broadcast, which enabled them to hear the live discussion and submit questions. Audio files were available on the NAS web site during the 60-day comment period that ended on December 13, 1999. Co-sponsors included the Office of Science and Technology Policy, the NIH, and the National Science Foundation (NSF).

Federal officials endorsing the proposed definition and procedures represented the NIH, NSF, ORI, Veterans Administration, Department of Agriculture, Office of Naval Research, National Aeronautics and Space Administration, Department of Energy, the Environmental Protection Agency, and the National Oceanographic and Atmospheric Administration. Other speakers commenting on the definition and procedures represented the AAMC, the Association of American Universities, the National Association of State Universities and Land Grant Colleges, the Federation of American Societies of Experimental Biology, the American Society for Microbiology, the American Society for Biochemistry and Molecular Biology, and the American College of Surgeons.

RIO Update Workshop

The annual update workshop for NIH research integrity officers (RIOs) was held on November 10, 1999. At the request of the RIOs, the first hour of the workshop was held in conjunction with the NIH Extramural Program Management Committee for the first time. Attendees numbered more than 60 because of the joint meeting. Presentations were made by RIOs, ORI, and Office of the General Counsel (OGC) staff. Although the evaluations were generally favorable, some attendees were dissatisfied with certain presentations and answers to questions.

B. Publications

Special Issues of Science and Engineering Ethics

A special issue of *Science and Engineering Ethics* on scientific misconduct was published in April 1999. Chris Pascal wrote a peer-reviewed article on the history and future of ORI, and Alicia Dustira served as guest editor. The issue reviewed the recent history of scientific misconduct in the U.S. by documenting differing approaches to handling misconduct issues, examining the complexity of developing a Government-wide definition, and predicting concerns for the future. The articles and accompanying commentaries presented and extended perspectives shared by participants in a special symposium held at the 1998 Annual Meeting of the American Association for the Advancement of Science (AAAS) entitled "Misconduct in Science: A Decade of Progress or Merely Years of Controversy?"

An article, "The American Experience: Lessons Learned," written by Larry Rhoades was published in a special issue of *Science and Engineering Ethics* - Scientific Misconduct: An International Perspective - in January 2000. Dr. Rhoades also co-authored the conference overview. The paper was originally presented at an international conference on scientific misconduct held at The Medical University of Warsaw in November 1998.

ORI Annual Report - 1998

ORI published its Annual Report for calendar year 1998 in August 1999 and distributed it to all institu-

tions, except small businesses, that have an assurance on file with ORI, as well as to professional and scientific societies, the media, the network of Federal misconduct officials, PHS research integrity officers, and included it in the Quarterly Report to the Secretary for the third quarter. The annual report contained a listing of significant accomplishments, summaries of closed investigations, summaries of scientific misconduct related litigation, compliance review case summaries, and descriptions of ORI educational activities. Information in the report may be used in courses and seminars on the responsible conduct of research. The report is available on the ORI web site.

ORI Newsletter

ORI published four issues of the *ORI Newsletter* in 1999, and published its first 12-page edition in December. The December issue contained a five-page special section with reports on the implementation of the recommendations of the HHS Review Group on Research Misconduct and Research Integrity. Major articles in 1999 covered the proposed Federal definition of research misconduct, guidance for editors on managing misconduct allegations, conferences scheduled for 2000, planning for a research conference and program on research integrity, tips for handling and sequestering physical evidence, case summaries including *Angelides* and *Liburdy*, a 5-year analysis on misconduct investigations closed by ORI, the development of a conference and web site on the responsible conduct of research, the release of case information by institutions, an international conference on scientific misconduct, and the first national conference on the management of biomedical research laboratories.

Guidance for Editors

ORI published a guidance document, *Managing Allegations of Scientific Misconduct: A Guidance Document for Editors* (Jan. 2000), for journal editors and their staffs on reporting suspect manuscripts, facilitating the investigation of misconduct allegations, improving correction of the literature, and promoting research integrity. This document was developed to inform journal editors and publishers that ORI is committed to working with them to address research misconduct detected in manuscripts and published articles. Since ORI was established in 1992, 78 publications involving scientific misconduct findings have required corrections or retractions of text, data, figures, or the entire article. In the guidance document, ORI urges editors to contact ORI or the institution(s) of the author(s) when research misconduct is suspected. ORI also suggests that editors consider taking preventive steps to protect themselves from legal actions that may result from reporting suspect manuscripts by placing notification in the journal's instructions to authors. Other steps suggested include developing policies or guidelines concerning reporting suspect manuscripts, handling suspect manuscripts, obtaining co-author signatures on manuscripts, submitting data, retaining or circulating copies of manuscripts under review, and publishing corrections and retractions.

C. Web Sites

Web Site on Teaching Responsible Conduct of Research

With support from ORI, development began in 1999 of a new web site designed to assist any institution in developing a program on the responsible conduct of research (RCR). Expected to be operational by fall 2000, further evolution and elaboration of the site is scheduled for the second year of this collaborative effort involving Michael Kalichman, UCSD; Francis Macrina, Virginia Commonwealth University; and Jeff Kahn, University of Minnesota. The web site is expected to include ready access to a variety of up-to-date materials, the ability to select key elements needed to construct an RCR course or program, and an ongoing means for evaluating methods and materials. The second year of this project will be devoted to soliciting additional materials from RCR instructors at 20 or more institutions, modifying the site framework to accommodate new resources, annotating available resources, and seeking continued support.

ORI Web Site Redesign

ORI hired a contractor in 1999 to redesign and update its existing web site so that it would be more visually appealing as well as easier to navigate and maintain. The refurbished site will feature improved navigation, structural flow, content organization, and technical utility for users. Color-coded sections will make it easier to determine one's location within the site, and new graphics and shortcuts will make it simpler to find other materials. A prototype of the web site was developed in 1999, and the new design is expected to be operational in 2000. The new design will replace the design currently located at **http://ori.dhhs.gov**. New items also have been added to the existing web site including the Federal definition, the recommendations of the HHS Review Group on Research Misconduct and Research Integrity, and upcoming conferences.

To increase usage, the web site is being publicized in the *ORI Newsletter* and in e-mail messages.

D. Research Program

Research on Research Integrity

In 1999, ORI started a process to develop a research agenda. This new research program will focus on the responsible conduct of research, the promotion of research integrity, the prevention of misconduct, and the handling of allegations of scientific misconduct. Two planning meetings for developing an agenda for research on research integrity and organizing a conference on research on research integrity were held June 3, 1999, and November 18-19, 1999. The first meeting involved representatives from the AAMC, the Federation of American Societies of Experimental Biology, the AAAS, the NIH, the NSF, and ORI. The second meeting involved nine investigators who do research on organizational behavior, occupations and professions, deviant behavior, biomedicine, social psychology, and the social organization of research. As a result of those meetings, ORI plans to convene a conference on "Research on Research Integrity" in the Washington metropolitan area on November 18-20, 2000. A call for abstracts was publicized in the December issue of the *ORI Newsletter*, posted on the ORI web site, and in four other newsletters. Abstracts for papers and poster sessions were solicited on programs to promote research integrity, ways to improve programs and assess their effectiveness, and research opportunities related to such programs. A research program announcement is expected to be published in early 2001. Nicholas Steneck, Ph.D., professor of history of science and integrity in engineering, University of Michigan, and former chairman of the PHS Advisory Committee on Research Integrity, is serving as a consultant for both projects.

Education Needs Assessment

ORI intends to expand it educational efforts related to the promotion of research integrity, the responsible conduct of research, and the prevention of research misconduct. To help in planning this expansion, the Center for Health Policy Studies of Columbia, MD (CHPS), is assessing the educational needs of the extramural research community to see how those needs may be addressed through conferences, publications, the ORI web site, CD-ROM, web-based courses, and so on. The needs assessment will employ focus groups and a survey, with the results being used to develop a strategic plan for the educational program.

Study of Institutional Misconduct Policies

ORI has begun analyzing institutional policies for responding to allegations of misconduct to determine the range of procedures that have been adopted to perform the following tasks: making allegations, maintaining confidentiality, preventing conflicts of interest, determining appropriate expertise, the role of the whistleblower, protection of the whistleblower, treatment of respondents, restoration of reputations, roles of lawyers, etc. Identifying the range of procedures that have been adopted will provide institutions with options for meeting the regulatory requirement and will assist ORI in providing technical assistance to institutions in developing their policies. This study is also being conducted by CHPS.

Etiology of Scientific Misconduct

This ORI-sponsored study will address two questions: Why do researchers commit misconduct? What impact does a finding of misconduct have on the career of a researcher? The study population will be the more than 100 researchers or research personnel against whom the PHS has made a finding of scientific misconduct since 1992. Semi-structured interviews will be conducted with each respondent who agrees to participate in the study and the identity of individual participants will be kept confidential. Results of the study will be submitted to refereed journals for publication and will be used in the ORI education program. This study complements the previous ORI study on the effect of misconduct allegations on exonerated respondents. The study is being conducted by Justice Research and Advocacy, Inc., Columbus, OH.

Study of Medical School Guidelines for the Conduct of Research

A contract was awarded to R.O.W. Sciences, Inc., Rockville, MD, in July 1999 to conduct a study of guidelines for the conduct of research adopted by the 125 medical schools in the United States, or their components. In consultation with the AAMC, the contractor and ORI developed a letter of solicitation and checklist for requesting the guidelines after an effort to locate the guidelines on medical school web sites produced an insufficient sample size. This study will determine how many medical schools or their components have such guidelines, what topics are covered by the guidelines, and what behavior is recommended

by the guidelines. Following completion of the study, ORI intends to hold a conference to discuss the study results.

Instructions to Authors Study

ORI is conducting a content analysis of the instructions to authors published in 41 journals that have published articles involved in scientific misconduct cases to determine whether those instructions address research integrity issues. Among the issues to be included in the analysis are the referral of suspect manuscripts, authorship, conflicts of interest, access to data, and retractions/corrections. Preliminary findings were presented at the Council of Science Editors (formerly CBE) annual meeting in San Antonio, Texas, in May 2000.

Consortium Development: Feasibility Study

ORI initiated steps in 1999 to commission a study to determine the feasibility of organizing consortia to assist institutions that do not have adequate resources nor capability to conduct inquiries or investigations and to further reduce any need for Federal fact-finding in extramural scientific misconduct cases. The study will seek to (1) determine the interest in developing consortia between institutions and professional organizations, (2) assess the expected utilization of consortia, expected costs and cost reimbursement, (3) stipulate the principles for organizing consortia, (4) suggest steps ORI may take to encourage the development of consortia, (5) determine whether the ORI on-site technical assistance program can be an effective means of assisting institutions in conducting their own fact-finding, and (6) determine whether the desired assistance could be provided through other mechanisms.

E. Intern/Fellowship Program

A research fellow and a summer intern were recruited through announcements about the intern/fellows program in the *ORI Newsletter* and from the ORI web site in 1999. The research fellow is conducting a study of the etiology of scientific misconduct and the stigma associated with a finding of scientific misconduct. The intern, a UCLA junior, worked on projects involving ORI databases and conducted searches of the Internet for web sites and literature related to scientific misconduct and the responsible conduct of research.

F. Educational Networks

PHS Research Integrity Officers Network

A plan for developing the PHS Research Integrity Officers Network was completed in October 1999. The plan calls for orientation sessions for new members, meetings as needed, an e-mail network to keep members informed about "breaking news," employing members as reviewers on drafts of publications, regulations, proposed studies, programs, policies, and plans, briefings on cases, technical assistance, and collaborative activities.

Greater Washington Area Consortium on Research Integrity

Meetings of the Greater Washington Area Consortium on Research Integrity were held on June 8, 1999, at the University of Maryland-Baltimore and on December 14, 1999, at ORI. During the first meeting, an ORI staff member spoke about the use of scientific forensics in developing evidence of scientific misconduct. The second meeting addressed the Federal definition of research misconduct and the recommendations of the HHS Review Group on Research Misconduct and Research Integrity. During 1999, consortium members adopted a charter, and the membership was enlarged to include several scientific/professional organizations.

Federal Research Misconduct Officials Network

Meetings of the Federal Scientific Misconduct Officials Network (Network) were held May 7, 1999, at the NSF and on November 29, 1999, at the Department of Agriculture. The first meeting focused on cases handled by NSF and ORI, especially the litigation associated with the *Angelides* case that threatened the existing system for responding to allegations of scientific misconduct involving PHS-supported research. The second meeting centered on the Federal definition of research misconduct and the recommendations of the HHS Review Group on Research Misconduct and Research Integrity. Representatives from about 10 agencies attended the meetings. An e-mail network has been established to facilitate communication with Network members between meetings.

Collaborations With Professional Associations and Scientific Societies

A plan for developing inter-organizational relationships between ORI and scientific societies, professional, and institutional associations, was developed in January 1999. The plan provides a rationale for establishing the relationship, lists potential activities that may be pursued by the relationship, identifies the mechanisms to be employed in maintaining the relationship, and names organizations with

which relationships might be beneficially pursued. During 1999, ORI began developing relationships with eight organizations.

G. Additional Educational Activities

Technical Assistance

On a pilot basis in 1999, ORI offered a Rapid Response Technical Assistance (RRTA) service to institutions that have decided to initiate an inquiry or investigation, particularly to those institutions that rarely, or never, handled a scientific misconduct allegation. A review of cases opened in 1995-1998 revealed that during each of those 3 years, investigations were opened by seven or eight institutions with no prior experience in conducting investigations. ORI can offer institutions with little or no experience an immediate conference call or on-site visit by an ORI scientist-investigator and attorney to advise institutional officials on the crucial initial steps for handling a misconduct case. ORI can also provide guidance on analyzing the evidence, developing and following up on investigative leads, and preparing the written report. The availability of this service was announced in the *ORI Newsletter* and publicized on the ORI web site. ORI offered RRTA on four cases, two of which were accepted by novice institutions for assistance with sequestration of evidence or investigative strategy.

Outreach at Scientific Meetings

ORI launched a program in 1999 that will take its educational message directly to researchers by establishing a presence at annual meetings of scientific societies. ORI initiated the program by staffing a display table at the AAAS annual meeting in Washington, DC from February 18-21, 2000. ORI staff was present to discuss the proposed research conference and program, collaborative workshops and conferences, the intern and fellows programs, the recommendations of the HHS Review Group on Research Misconduct and Research Integrity, the proposed Federal definition and procedures, the responsible conduct of research, the handling of allegations of research misconduct, the review of institutional policies, current studies underway, and the assurance program.

Staff Education Program

Four speakers made presentations as part of the ORI in-service education program during 1999:

- Ivor Pritchard, Ph.D., Department of Education, spoke on "Integrity versus Misconduct: Learning the Difference between Right and Wrong."
- Howard Gadlin, Ph.D., NIH Ombudsman, described the mission and functioning of his office.
- Thomas Hoffman, Ph.D., Food and Drug Administration (FDA), talked about "Basic Skills for Successful Research Laboratory Management."
- Dr. Paul Ekman, Professor of Psychology and Director, Human Interaction Laboratory, Department of Psychiatry, Langley Porter Psychiatric Institute, School of Medicine, University of California, San Francisco, talked about "Deception, Demeanor, and Debunking."

H. Presentations

John Butler, Compliance Review Coordinator, DPE, talked about the compliance and assurance programs during the annual update workshop for NIH Research Integrity Officers at NIH on November 10, 1999.

Marcus H. Christ, Chief, Research Integrity Branch (RIB)/OGC, gave a presentation on the legal issues affecting institutional misconduct officials at a workshop co-sponsored by ORI and UCSD, UCLA, and the University of Washington, in San Diego, CA, on February 19, 1999.

Marcus H. Christ, Chief, RIB/OGC, gave a presentation at the Federal Research Misconduct Officials Network meeting on the impact and significance of the Departmental Appeals Board decision in the *Angelides* case at the NSF, in Washington, DC, on May 7, 1999.

Nancy M. Davidian, Senior Scientist, DRI, gave a presentation on scientific misconduct and research integrity in clinical settings at a session of the 1999 National General Clinical Research Centers Meeting sponsored by the Society of Research Administrators on March 13, 1999.

Alicia Dustira, Deputy Director, DPE, co-chaired a workshop on "Sensitizing the More Senior Scientists to the Need for Training in Research Integrity" during the Public Responsibility in Medicine and Research (PRIM&R) Conference on Educating for the Responsible Conduct of Research in the Next Millennium cosponsored by ORI in Bethesda, MD, on May 13, 1999.

Gail L. Gibbons, Deputy Chief, RIB/OGC, made a presentation and served as a panel member for a session of the conference "Educating for Responsible Conduct of Research in the Next Millennium: New Dilemmas, Continuing Questions, and Effective Strategies," sponsored by ORI and PRIM&R, held in Bethesda, MD, on May 13-14, 1999.

Chris B. Pascal, Acting Director, ORI, gave a presentation on "Scientific Misconduct and Research Integrity for the Working Scientist," at Cedars-Sinai Medical Center for Health Care Ethics Program in Los Angeles, CA, on February 17, 1999.

Chris B. Pascal, Acting Director, ORI, gave the opening remarks on "Institutional Approaches to Responding to Misconduct and Promoting Integrity," at a Workshop for Institutional Misconduct Officials at UCSD, San Diego, CA, on February 18, 1999.

Chris B. Pascal, Acting Director, ORI, gave a presentation, "Avoiding Problems in Disclosure of Case Information," at a Workshop for Institutional Misconduct Officials at the UCSD, San Diego, CA, on February 18, 1999.

Chris B. Pascal, Acting Director, ORI, gave a presentation entitled, "PHS Perspectives on Scientific Misconduct and Research Integrity" at the University of Texas Health Science Center Conference on Research Integrity: A Professional, Ethical, and Social Obligation, co-sponsored by ORI in Houston, TX, on March 11, 1999.

Chris B. Pascal, Acting Director, ORI, delivered a presentation entitled "Developing a System to Promote Research Integrity: The Institutional View," at the Society of Research Administrators' Northeast Section Meeting, "Opening the Door to the Millennium," in Baltimore, MD, on May 5, 1999.

Chris B. Pascal, Acting Director, ORI, gave one presentation entitled, "Research Integrity: The ORI View" and another entitled "Promoting Responsible Conduct and Preventing Misconduct: Institutional Approaches" at the PRIM&R Conference on Educating for the Responsible Conduct of Research in the Next Millennium in Bethesda, MD, on May 13-14, 1999.

Chris B. Pascal, Acting Director, ORI, participated in a panel discussion on authorship in biomedical publication at a meeting of the Council of Biology Editors in Montreal, Quebec, Canada, on May 24, 1999.

Chris B. Pascal, Acting Director, ORI, gave a presentation on the "Proposed Federal Definition and Policies" at the Society of Research Administrators' Annual Meeting in Denver, CO, in October 1999.

Chris B. Pascal, Acting Director, ORI, gave a briefing on the new HHS Policies on Misconduct to the Council on Government Relations in Washington, DC, on October 27, 1999.

Alan Price, Acting Director, DRI, gave a presentation on "Ethics of Authorship and Publication" at the University of Texas Health Science Center conference on Research Integrity: A Professional, Ethical, and Social Obligation, co-sponsored by ORI in Houston, TX, on March 11, 1999.

Alan Price, Acting Director, DRI, gave presentations on "Comparison of NSF and ORI Policies on Handling Allegations of Research Misconduct" and "Data Ownership, Sharing and Access" as part of panel presentations at the PRIM&R conference on Educating for the Responsible Conduct of Research in the Next Millennium, co-sponsored by ORI in Bethesda, MD, on May 13, 1999.

Alan Price, Acting Director, DRI, gave a presentation on "Institutional and Governmental Interactions in Scientific Misconduct Investigations" as part of a panel presentation at the Conference on Ethical Challenges and Practical Solutions for Managers in Research co-sponsored by Sigma Xi, The Research Society, and ORI in Albuquerque, NM, on September 10, 1999.

Alan Price, Acting Director, DRI, gave a presentation on "Evolution of Policies on Research Integrity and Handling of Research Misconduct" to a faculty regulatory training workshop at Drexel and MCP Hahnemann University, in Philadelphia, PA, on December 14, 1999.

Lawrence Rhoades, Director, DPE, gave presentations on "Maintaining Funding Eligibility" and "Protecting Complainants and Respondents" during a Workshop for Institutional Misconduct Officials at UCSD in San Diego, CA, on February 18, 1999.

Lawrence Rhoades, Director, DPE, gave a presentation on "ORI's Views on Building a System of Research Integrity" during the Conference on Ethical Challenges and Practical Solutions for Managers in Research co-sponsored by Sigma Xi, The Research Society, and

ORI in Albuquerque, NM, on September 10, 1999.

Lawrence Rhoades, Director, DPE, gave a presentation on the ORI education and outreach programs during the annual update workshop for NIH Research Integrity Officers at NIH on November 10, 1999.

Mary Scheetz, Program Analyst, DPE, chaired a panel on the mentor-student relationship in research and publication at the 42nd Annual Council of Biology Editors Meeting in Montreal on May 23, 1999.

Mary Scheetz, Program Analyst, DPE, gave a presentation on "The Office of Research Integrity: Promoting Research Integrity" at the University of Zagreb Medical School in Croatia on October 18, 1999.

Mary Scheetz, Program Analyst, DPE, spoke about "The Office of Research Integrity: Lessons Learned from the U.S. Experience" at the University of Rijeka Medical School in Croatia on October 19, 1999.

I. Published Articles

Bird, S.J. and **Dustira, A.K.** "Misconduct in Science: Controversy and Progress" *Science and Engineering Ethics* 5(2):131-136 (1999).

Pascal, C.B. "Scientific Misconduct and Research Integrity: Federal Definitions and Approaches" *Professional Ethics* 7(1):9-32 (1999).

Pascal, C.B. "The History and Future of the Office of Research Integrity: Scientific Misconduct and Beyond" *Science and Engineering Ethics* 5(2):183-198 (1999).

Scheetz, M.D. "Office of Research Integrity: A Reflection of Disputes and Misunderstandings," *Croatian Medical Journal* 40(3):321-25 (1999).

J. *Federal Register* Notices

OS. Findings of Scientific Misconduct. Notice. 65 Fed. Reg. 3717 (Jan. 24, 2000). [Ho]

Office of Science and Technology Policy. Proposed Federal Policy on Research Misconduct to Protect the Integrity of the Research Record. Request for public comment on proposed Federal policy on research misconduct. 64 Fed. Reg. 55722-55725 (Oct. 14, 1999).

OS. Findings of Scientific Misconduct. Notice. 64 Fed. Reg. 49188 (Sept. 10, 1999). [Recknor]

OS. Agency Information Collection Activities: Proposed Collections; Comment Request. Proposed Project 1. Survey of Opinions of Principal Investigators on Managing a Biomedical Research laboratory. 64 Fed. Reg. 43816 (Aug. 9, 1999)

OS. Findings of Scientific Misconduct. Notice. 64 Fed. Reg. 42380 (Aug. 4, 1999). [Arenburg]

OS. Findings of Scientific Misconduct. Notice. 64 Fed. Reg. 32503-32504 (June 17, 1999). [Liburdy]

OS. Agency Information Collection Activities: Proposed Collections; Comment Request. 64 Fed. Reg. 27992 (May 24, 1999). 42 C.F.R. Part 50 and PHS 6349, Revision.

OS. Findings of Scientific Misconduct. Notice. 64 Fed. Reg. 23836 (May 4, 1999). [Huang]

OS. Findings of Scientific Misconduct. Notice. 64 Fed. Reg. 14450-14451 (March 25, 1999). [Diaz]

OS. Findings of Scientific Misconduct. Notice. 64 Fed. Reg. 12341 (March 12, 1999). [Angelides]

OS. Findings of Scientific Misconduct. Notice. 64 Fed. Reg. 5658 (Feb. 04, 1999). [Philpot]

OS. Findings of Scientific Misconduct. Notice. 64 Fed. Reg. 5298-5299 (Feb. 03, 1999). [Bodily]

OS. Findings of Scientific Misconduct. Notice. 64 Fed. Reg. 4664 (Jan. 29, 1999). [Thackeray]

OS. Findings of Scientific Misconduct. Notice. 64 Fed. Reg. 4664 (Jan. 29, 1999). [Briggs-Brown]

OS. Findings of Scientific Misconduct. Notice. 64 Fed. Reg. 4108 (Jan. 27, 1999). [Roy]

III. 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 programs, the Assurance Program and the Compliance Review Program. Notable actions and achievements in 1999 include:

- Completed the 1998 Annual Report on Possible Research Misconduct with a response rate of 90 percent. Forty-one institutions reported opening 54 new scientific misconduct cases; a total of 67 institutions reported misconduct activities because of cases carried from 1997. Ninety percent of the responding institutions indicated they have the required policy for handling allegations of scientific misconduct.

- Inactivated assurances for 297 institutions for failure to submit an Annual Report, an institutional policy upon request, or a revised policy following review.

- Processed 374 institutional policies on handling allegations of scientific misconduct; requested 175 institutional policies for review, and increased the number of completed reviews to 1,279.

- Revised the Annual Report on Possible Research Misconduct form for calendar year 1999 and eliminated questions concerning the protection of whistleblowers, the restoration of reputations, and the imposition of administrative actions. Additionally, in instances where inquiries or investigations were reported, the grant numbers of the supporting research is no longer requested.

- Completed a study of misconduct policies at 73 institutions that had created affiliated relationships with 178 other institutions to determine whether viable systems for responding to allegations of scientific misconduct existed within the framework of the affiliation agreement.

- Initiated the development of a system to allow for the electronic submission of the Annual Report on Possible Research Misconduct for calendar year 2000.

- Continuously updated the database containing scientific misconduct assurances for nearly 4,000 institu-

tions to ensure that eligible institutions received their research awards without unnecessary delay.

- Maintained the PHS ALERT system and the PHS Administrative Actions Bulletin Board (AABB) to track misconduct findings and the imposition of administrative actions.

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, submitting their misconduct in science policy upon request by ORI, revising their misconduct in science policy when requested by ORI, and complying with the PHS regulation.

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

Assurance Database

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

As of December 31, 1999, there were 3,950 active assurances on file in ORI, including 180 from 34 foreign countries. During 1999, 494 institutions filed their initial assurance. ORI deleted 297 institutions because their assurance was inactivated. There were 119 institutions that voluntarily withdrew their assurance because they (1) did not expect to apply for PHS funds, (2) did not conduct research, (3) merged with another institution, or (4) went out of existence. ORI withdrew the remaining 178 assurances because the institutions did not submit their Annual Report on Possible Research Misconduct, did not submit a copy of their policies and procedures for responding to allegations of research misconduct upon request, or did not have policies and procedures that complied with the PHS regulation.

All of these changes had only slight impact on the total assurance database in 1999 (See Table 5). The total number of institutions with an assurance increased by 253. Categorically, institutions of higher education increased by 13; research organizations, institutes, foundations and laboratories increased by 10; independent hospitals increased by 4; educational organizations other than higher education remained the same; other health, human resources, environmental service organizations increased by 26; the small business category increased by 203; and unclassified decreased by 3. The largest gain was in the small business category.

Table 5: **Type of Institution with Active Assurance by Frequency, 1999**

Type of Institution	*Frequency*	*Change*
Institutions of Higher Education	894	+13
Research Organizations, Institutes, Foundations and Laboratories	327	+10
Independent Hospitals	286	+4
Educational Organizations, Other Than Higher Education	24	0
Other Health, Human Resources, and Environmental Services Organizations	398	+26
Other (small business)	2,021	+203
Unclassified	0	-3
TOTAL	3,950	+253

E-Mail Network

The effort to establish an e-mail network covering all institutions that have an active assurance is progressing well. About 80 percent of the institutions have submitted e-mail addresses for their responsible official. The e-mail network enables ORI to quickly contact institutional officials individually or *en masse*. It has been used to inform institutional officials about upcoming conferences/workshops. Information regarding the implementation of the Electronic Transmission of the Annual Report on Possible Research Misconduct will also be provided to institutional contacts via the e-mail network.

Annual Reports 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 1998 Annual Report forms were mailed in January 1999 to the 3,509 institutions that had an assurance on file with ORI as of December 1, 1998.

Completed Annual Reports were received from 3,144 institutions for a response rate of 90 percent. ORI inactivated 516 assurances, including 440 institutions that did not return their Annual Reports by the March 31 deadline and 76 institutions that voluntarily withdrew their assurances rather than submit the Annual Report. Many assurances were reactivated because annual reports were submitted after the due date. The 1998 report identified 109 institutions that did not have the required policies and procedures for handling allegations of scientific misconduct. In addition, it provided corrected information on the name of the responsible official or the institutional addresses of 566 institutions (18%). Institutions named 378 new responsible officials.

The Annual Report form requested institutions to report on (1) the availability of policies and procedures for responding to allegations of scientific misconduct, (2) the number of allegations of scientific misconduct received and the number of inquiries and investigations conducted, (3) actions taken to restore the reputation of exonerated respondents, (4) actions taken to protect the position and reputation of complainants, (5) sanctions imposed by institutions when misconduct was found, and (6) the number of bad faith allegations received.

Reported Misconduct Activity

According to their 1998 Annual Report on Possible Research Misconduct, which was filed in 1999, 54 new scientific misconduct cases were opened in 1998 by 41 institutions that conducted 38 inquiries and 7 investigations in response to 69 allegations.

A total of 67 institutions responded to allegations in 1998 because 39 institutions were continuing to investigate allegations received before 1998 while 13 were dealing with allegations made prior to and in 1998.

In their submissions, institutions report the receipt of allegations of scientific misconduct, the type of misconduct, and the conduct of an inquiry and/or investigation. Reportable activities are limited to alleged misconduct that falls under the PHS definition of scientific misconduct and involves research supported by the PHS.

Of the 41 institutions reporting new allegations in 1998, 34 were institutions of higher education, 2 were research organizations, 4 were independent hospitals, and 1 was a small business organization.

The 69 new allegations reported in 1998 included 15 of fabrication, 22 of falsification, 10 of plagiarism, and 22 of other serious deviations. The number of new cases opened by the 41 institutions ranged from 1 to 4.

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.

Institutional Policy Reviews

ORI processed 374 institutional policies during 1999. ORI requested 175 policies in 1999; the other 199 policies were forwarded from 1998. ORI closed 258 reviews in 1999; 116 were carried into 2000. The closed reviews included 225 accepted policies and 33 inactivated assurances because policies were not submitted. Of the 116 open reviews, 78 require institutional action before further progress can be made.

Policy Review Database

A database, GenRev, was established in 1997 to consolidate information on the numerous reviews conducted by the assurance and compliance programs. The database contains relevant information on the reviews, such as the initial outcome of the review, the number of revisions required, and the policy ap-

proval date. As of December 31, 1999, GenRev contained information on 1,395 policy reviews conducted by ORI primarily since 1995. ORI completed 1,279 reviews; 116 are open.

Compliance Cases

In 1999, the ORI compliance caseload was decreased by one, for a total of one open case at the end of the year. Compliance cases involve compliance reviews of institutional handling of an allegation of scientific misconduct and/or retaliation complaints of the whistleblower.

At the beginning of 1998, ORI changed the method of tracking compliance cases. Because several of the alleged retaliation complaints reviewed previously by ORI were closed due to lack of jurisdiction, an assessment category was established to track these cases until PHS jurisdiction could be established. At the beginning of the year there were four open assessments, two new assessments were opened during 1999, and four assessments were closed during 1999. Cases were closed primarily because ORI made a determination that it did not have jurisdiction, or the complainant did not respond to ORI's request for additional documentation supporting the complaint.

Table 6: **Summary of Compliance Cases, 1999**

Case Type	*Forwarded from 1998*	*Opened in 1999*	*Closed in 1999*	*Carried into 2000*
Compliance Review	2	1	2	1
Assessment	4	2	4	2
TOTAL	6	3	6	3

Parent/Affiliate Study

ORI conducted a study of the policies that support the assurances submitted by 251 institutions, 73 parent institutions, and 178 affiliates to determine whether viable systems for responding to allegations of scientific misconduct existed at these institutions. To be viable, the policy of the parent institution had to comply with the PHS regulation and contain provisions covering its affiliates. In addition, an affiliate had to acknowledge the right of the parent institution to conduct investigations of allegations received by the affiliate.

Slightly less than 60 percent of the institutions involved in a parent/affiliate arrangement were covered by the policies that complied with the PHS regulation.

Four criteria were used to determine the compliance status of each parent/affiliate unit: 1) compliant parent policy, 2) compliant affiliate policy, 3) acknowledgment of responsibility by the parent, and 4) affiliate acceptance of parental right to handle allegations. On the basis of these criteria, only 14 percent of the parent/affiliate units were in compliance at the start of this review. In the policies that were reviewed, the affiliate arrangement was acknowledged by only 20 percent of the institutions; 18 percent of the parents indicated responsibility for responding to allegations at the affiliates and 22 percent of the affiliates endorsed the right of the parent to do so. During the review, the parent/affiliate units were asked to revise their policies to bring them into compliance with the regulation and to explicitly acknowledge the affiliation. By the end of the study, all parent/affiliate units were in compliance and acknowledged.

Most of the parent/affiliate units would probably run into difficulty in responding to an allegation of scientific misconduct at an affiliate because the policy under which the units operate do not adequately address the multi-institutional environment to which they are applied. Although most policies centralize the response to allegations in the parent institution, the implementation of the policy may encounter logistical and practical problems in those units that have components located in different cities.

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) ORI 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, (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, or (5) FDA has determined that there is sufficient reason to believe that official action is warranted against the individual for violation of an FDA regulation governing research.

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 ad-

ministrative actions imposed as a result of the misconduct, and the effective and expiration dates of the administrative actions.

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

On January 1, 1999, ORI listed the names of 51 individuals in the system. During the year, ORI added 15 and removed 18 names. On December 31, 1999, the names of 48 individuals were in the system.

ORI added these 15 names after 5 respondents agreed to a voluntary exclusion agreement, 8 others were found to have committed scientific misconduct in institutional reports to ORI, and 2 individuals had administrative actions imposed by PHS. Seventeen names were removed during the year because the term of the administrative actions expired, and one name was removed where ORI did not make a finding of scientific misconduct after reviewing an institutional misconduct investigation report.

Of the 48 names in the system at year end, 40 individuals have had administrative actions imposed by ORI, and 8 remained as a result of an institutional report in which there was a finding of scientific misconduct.

In 1997, the FDA published on the Internet a Debarment list, as well as a Disqualified/ Restriction/Assurance list, for clinical investigators sanctioned by the FDA. Because of the overlap in the FDA lists and the PHS Administrative Actions Bulletin Board (AABB), which is also available on the Internet, the PHS AABB carried the FDA information only until the end of 1997. Thereafter, only information regarding individuals with PHS administrative actions was listed on the AABB, and information regarding FDA actions can be viewed separately on the FDA Internet sites.

The number of requests for information under the Freedom of Information Act (FOIA) increased this year. However, Privacy Act requests declined.

- ORI received 88 FOIA requests in 1999 compared to 52 in 1998 and 90 in 1997. Six requests were carried into 2000 compared to 8 into 1999 and 24 into 1998.

- Four Privacy Act requests were handled in 1999 compared to 8 in 1998 and 12 in 1997. All requests were completed in the year of receipt; none were carried into the next year.

Freedom of Information Act

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

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

A FOIA request for ORI records should be made to the PHS FOIA Officer, Darlene Christian, Parklawn Building, 5600 Fishers Lane, Room 17-A-46, Rockville, MD 20857. The request must reasonably describe the records sought so that the agency official is able to locate the records with a reasonable amount of effort. Some requests may be subject to review, search, and duplication costs.

Privacy Act

The purpose of the Privacy Act of 1974, 5 U.S.C. § 552a, is to balance the needs of the government to maintain information about individuals with the rights of the individual to be protected against unwarranted invasions of their privacy stemming from Federal agencies 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 5515 Security Lane, Suite 700, 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.

Kimon J. Angelides, Ph.D., Baylor College of Medicine (BCM): Based on a report of an investigation conducted by BCM and information obtained by ORI during its oversight review, ORI found on March 10, 1997, that Dr. Angelides, former Professor, Department of Molecular Physiology and Biophysics and Department of Cell Biology, BCM, engaged in scientific misconduct by intentionally falsifying data and misrepresenting research results in five NIH grant applications and in five papers published while he was at the BCM. The research involved the study of the voltage-gated sodium channel protein in nervous tissue and its location in myelinated nerves. The falsifications involved the location of disulfide bridges within the structure of the sodium channel protein, the development of antibodies specific to peptides within the intact sodium channel protein, the alteration of the protein structure by introducing fluorescently-labeled amino acids at identified sites, and the characterization and use of a polyclonal antibody to the sodium channel. In a decision dated February 5, 1999, the HHS Departmental Appeals Board affirmed ORI's findings of scientific misconduct and determined that the PHS administrative actions recommended by ORI, and proposed by the debarring official, were justified. The following actions have been implemented: Dr. Angelides has been debarred from any contracting, subcontracting, or nonprocurement transactions with the United States Government, and he is prohibited from serving in any advisory capacity to PHS for a period of 5 years, beginning on February 22, 1999. Additionally, within 30 days of February 22, 1999, Dr. Angelides was required to submit a letter to the editors of *Proceedings of the Royal Society of London*, *Annals of the New York Academy of Science*, *Glia*, and *Proceedings of the National Academy of Science (USA)* requesting retraction of the falsified figures and text in each of the following scientific papers:

- Black, J.A., Friedman, B., Waxman, S.G., Elmer, L.W., and Angelides, K.J. "Immuno-ultrastructural localization of sodium channels at nodes of Ranvier and perinodal astrocytes in rat optic nerve." *Proc. R. Soc. London* 238:39-51, 1989.

- Minturn, J.E., Sontheimer, H., Black, J.A., Angelides, K.J., Ransom, B.R., Ritchie, J.M., and Waxman, S.G. "Membrane-Associated Sodium Channels and Cytoplasmic Precursors in Glial Cells." *Ann. N.Y. Acad. Sci.* 633:255-272, 1991.

- Black, J.A., Waxman, S.G., Friedman, B., Elmer, L.W., and Angelides, K.J. "Sodium channels in astrocytes of rat optic nerve in situ: Immuno-electron microscopic studies." *Glia* 2:353-369, 1989.

- Ritchie, J.M., Black, J.A., Waxman, S.G., and Angelides, K.J. "Sodium channels in the cytoplasm of Schwann cells." *Proc. Natl. Acad. Sci. (USA)* 87:9290-9294, 1990.

A retraction of the following scientific paper was published (*Brain Research* 761(2), 1997) at the request of the coauthors:

- Elmer, L.W., Black, J.A., Waxman, S.G., and Angelides, K.J. "The voltage dependent sodium channel in mammalian CNS and PNS: Antibody characterization and immunocytochemical localization." *Brain Research* 532:222-231, 1990.

Deborah Arenburg, University of Maryland (UM): Based on a report dated December 23, 1998, by the UM Investigation Committee, Ms. Arenburg's admissions, and information obtained by ORI during its oversight review, ORI found that Ms. Arenburg, former Research Associate, Maryland Psychiatric Research Center, UM, engaged in scientific misconduct arising out of certain biomedical research supported by two National Institute of Mental Health (NIMH), NIH, grants. Ms. Arenburg was responsible for administering and scoring neuropsychological, neurological, and cognitive tests on patients during the course of two studies, "Neural Basis of the Deficit Syndrome of Schizophrenia" (Study No. 1) and "Clozapine Treatment of Schizophrenic Outpatients" (Study No. 2). ORI found that Ms. Arenburg failed to conduct the required tests on 3 patients in Study No. 1 and on 10-12 patients in Study No. 2. Instead, Ms. Arenburg fabricated the experimental records for those tests, and she admitted fabricating the data. The fabricated data were included in "Association Between Eye Tracking Disorder in Schizophrenia and Poor Sensory Integration," *American Journal of Psychiatry* 155(10):1352-1357, 1998. The principal investigator on the grants at issue reanalyzed the research data, eliminated all data produced by Ms. Arenburg, and found no significant difference in the results. A correction, including the reanalyzed data, was published in the *American Journal of Psychiatry* 156(4):603-609, 1999.

Ms. Arenburg accepted the ORI finding and entered into a Voluntary Settlement Agreement with ORI in which she voluntarily agreed, for the 3-year period beginning July 15, 1999, to exclude herself from serving in any advisory capacity to the PHS, and her participation in any PHS-funded research is subject to supervision requirements.

Janell Bodily, B.S., M.S.W., University of Utah (UU): Based on the report of an investigation conducted by the UU and information obtained by ORI during its oversight review, ORI found that Ms. Bodily, former interviewer, Health Education Department, College of Health, UU, engaged in scientific misconduct in research supported by an NIMH, NIH, grant. Ms. Bodily intentionally falsified patient signatures and responses to questions for at least 75 patient interviews for an NIMH-funded research project, "Evaluation of the Utah Prepaid Mental Health Plan," which involved indigent patients. The study required annual interviews of the participating subjects. The falsified information was damaging to the research project because researchers had to expend substantial time and additional money to re-interview patients. Because the data for the previous year could not be recollected, the response rate for that year was substantially below the response rate for other years of the study and may have reduced the overall statistical reliability of the multi-year study. None of the questioned data was published. ORI implemented the following administrative actions for the 3-year period beginning January 25, 1999: Ms. Bodily is prohibited from any contracting, subcontracting, or nonprocurement transactions with the United States Government, and she is prohibited from serving in any advisory capacity to PHS.

Nellie Briggs-Brown, Rush-Presbyterian-St. Luke's Medical Center (RP/SLMC): Based on the report of an investigation conducted by RP/SLMC dated December 3, 1997, ORI found that Ms. Briggs-Brown, former employee, Department of Neurology, engaged in scientific misconduct in clinical research supported by two National Institute of Neurological Disorders and Stroke (NINDS), NIH, grants. Ms. Briggs-Brown: (1) falsified 7 monthly screening logs for a NINDS-funded study involving stroke victims (Randomized Trial of Org 10172 in Acute Ischemic Stroke Treatment) and submitted the same logs with altered dates on multiple occasions to the University of Iowa Coordinating Center; and (2) falsified several Human Investigation Committee research approval forms. Each of the 38 participating centers was required to keep a log of patients screened for the trial and to submit the logs to the coordinating center so that the impact of inclu-

sion and exclusion criteria could be assessed and to provide information about the generalizability of the trial's results. None of the questioned data was published. ORI implemented the following administrative actions for the 3-year period beginning January 25, 1999: Ms. Briggs-Brown is prohibited from serving in any advisory capacity to PHS, and her participation in any PHS-funded research is subject to supervision requirements.

Maria Diaz, Rush-Presbyterian-St. Luke's Medical Center (RP/SLMC): Based on the report of the RP/SLMC Research Integrity Investigation Committee dated May 13, 1998, which included a report of a special National Cancer Institute (NCI) audit, and additional information obtained by ORI during its oversight review, ORI found that Ms. Diaz, former data manager for two multi-center cancer prevention clinical trials at RPMC, engaged in scientific misconduct in clinical research supported by NCI, NIH, cooperative agreements. Specifically, Ms. Diaz intentionally falsified and/or fabricated research data and information collected at RPMC for the Breast Cancer Prevention Trial (BCPT) under the National Surgical Adjuvant Breast and Bowel Project (NSABP) and a secondary prevention trial for lung cancer sponsored by the M.D. Anderson Cancer Center and Eastern Cooperative Oncology Group. Ms. Diaz falsified data related to entry criteria and treatment compliance on the secondary lung cancer prevention trial. She fabricated reports of followup examinations for subjects entered on the BCPT, falsified laboratory test results, and forged signatures of physicians on informed consent documents. ORI implemented the following administrative actions for the 3-year period beginning March 13, 1999: Ms. Diaz is prohibited from serving in any advisory capacity to PHS, and her participation in any PHS-funded research is subject to supervision requirements.

John L. Ho, M.D., Cornell University (CU): Based on a report dated June 16, 1999, by CU, as well as information obtained by ORI during its oversight review, ORI found that Dr. Ho, Associate Professor, Department of Medicine and Department of Microbiology at CU Medical College, engaged in scientific misconduct by reporting falsified and fabricated research results in a National Heart, Lung, and Blood Institute (NHLBI), NIH, grant application. ORI found that Dr. Ho committed scientific misconduct in connection with the data contained in Figure 10 of the grant application that purportedly demonstrated cytokine production heterogeneity. He falsified the text describing Panel 2 of Figure 10 by representing that the interferon- values reflected data from 25 donors when values from only four donors had been obtained. Additionally, he falsified the data entries for Panels 1 and 3 of Figure 10 by representing that approximately 19 and 25 donor samples, respectively, were studied when only 3 and 6 genuine values were obtained, the remaining symbols reflecting fabricated results. Dr. Ho accepted the ORI finding and entered into a Voluntary Exclusion Agreement with ORI in which he voluntarily agreed to comply with all terms and conditions of the plan for remedial training and scientific and administrative oversight imposed by CU and that, for a period of 3 years beginning on December 28, 1999, to exclude himself from serving in any advisory capacity to PHS, and his participation in any PHS-funded research is subject to supervision requirements.

Chang-Fen Huang, Ph.D., State University of New York at Stony Brook (SUNY/SB): Based on the report of an investigation conducted by SUNYSB dated December 18, 1997, ORI found that Dr. Huang, former graduate student, Department of Biochemistry, SUNY/SB, engaged in scientific misconduct in the reporting and conducting of research supported by a grant from the NINDS, NIH. ORI found that Dr. Huang falsely mislabeled and relabeled six autoradiographs that she had obtained from earlier unrelated experiments to make them appear to have come from several different and separate experiments. She used these falsified data as figures in her dissertation and in a publication (C.F. Huang, et al. "Depolarization-transcription signals in skeletal muscle use calcium flux through L channels, but bypass the sarcoplasmic reticulum." *Neuron* 13:167-177, 1994). The publication was retracted at *Neuron* 13(1):1294, 1998. Dr. Huang accepted the ORI finding and entered into a Voluntary Exclusion Agreement with ORI in which she voluntarily agreed, for the 3-year period beginning April 20, 1999, to exclude herself from any contracting, subcontracting or procurement transactions wit the United States Government, and from serving in any advisory capacity to PHS.

Robert P. Liburdy, Ph.D., Lawrence Berkeley National Laboratory (LBNL): Based on an investigation report by the LBNL dated July 7, 1995, and an analysis of the data and information from Dr. Liburdy obtained by ORI during its oversight review, ORI found that Dr. Liburdy, former staff biochemist at LBNL, engaged in scientific misconduct in biomedical research by intentionally falsifying and fabricating data and claims about the purported cellular effects of electric and magnetic fields (EMF) that were reported in two sci-

entific papers: Liburdy, R.P. "Biological interactions of cellular systems with time-varying magnetic fields. *Annals of the New York Academy of Sciences* 649:74-95, 1992 ("*ANYAS* paper"); and Liburdy, R.P. "Calcium signaling in lymphocytes and ELF fields." *FEBS Letters* 301:53-59, 1992 (the "*FEBS Letters* paper"). The *ANYAS* and *FEBS Letters* papers were supported by a NCI, NIH, grant.

The *ANYAS* and *FEBS Letters* papers reported data indicating that EMF exert a biological effect by altering the entry of calcium across a cell's surface membrane. EMF, which are ubiquitous forms of radiation that arise from diverse sources such as power lines, home wiring, and household appliances, have been of public concern for potential health effects.
Dr. Liburdy's claims were potentially very important when published in 1992 because they purported to link EMF and calcium signaling, a fundamental cell process governing many important cellular functions.

Dr. Liburdy entered into Voluntary Exclusion Agreement with ORI in which he neither admitted nor denied ORI's finding of scientific misconduct, and the settlement is not an admission of liability. Dr. Liburdy voluntarily agreed, for the 3-year period beginning May 28, 1999, to exclude himself from any contracting, subcontracting, or nonprocurement transactions with the United States Government, and from serving in any advisory capacity to PHS. Additionally, he agreed to submit letters requesting retraction of Figure 12 of the *ANYAS* paper and of Figures 6 and 7 of the *FEBS Letters* paper.

Thomas Philpot, R.N., B.S.N., Rush-Presbyterian-St. Luke's Medical Center and Northwestern University (RP/SLMC&NU): Based on the report of an investigation conducted by RP/SLMC, a report of an inquiry conducted by NU, and information obtained by ORI during its oversight review, ORI found that Mr. Philpot, former data manager for the NSABP at RPMC and McNeal Cancer Center, formerly an NSABP affiliate of NU, engaged in scientific misconduct in clinical research supported by two NCI, NIH, cooperative agreements. Mr. Philpot intentionally falsified and/or fabricated followup data in seven separate reports related to three patients enrolled in NSABP clinical trials for breast cancer (B-09, B-12, and B-22). The falsified and/or fabricated data were submitted to the NSABP Biostatistical Center on NSABP reporting forms and were recorded in the NSABP research records maintained at the clinical sites. ORI has implemented the following administrative actions for the 3-year period beginning January 19, 1999: Mr. Philpot is prohibited from serving in any advisory capacity to PHS, and his participation in any PHS-funded research is subject to supervision requirements.

Karrie Recknor, University of Washington (UW): Based on a report dated January 27, 1999, by UW, Ms. Recknor's admission, and information obtained by ORI during its oversight review, ORI found that Ms. Karrie Recknor, former Graduate Research Assistant, Department of Psychology, UW, engaged in scientific misconduct arising out of certain biomedical research supported by a National Institute of Allergy and Infectious Diseases (NIAID), NIH, grant. Ms. Recknor admitted to falsifying electronic mail responses presented to the Principal Investigator as part of a project, "Prognosis of Chronic Fatigue Syndrome."

Ms. Recknor was responsible for conducting interviews on the impact of life events for six subjects and for assigning preliminary Brown and Harris' Life Events and Difficulties Schedule (B&H) scores to each interview. She was required to send the interview notes and preliminary scores to a collaborator. The collaborator was to reassess the scores and e-mail the corrected scores or an agreement statement back to Ms. Recknor. Ms. Recknor failed to send the interview notes and preliminary scores for these six interviews to the collaborator for evaluation and instead falsified electronic mail responses to indicate that the collaborator's evaluation had been conducted. Ms. Recknor entered these scores into the research database for the above-mentioned project. The falsified scores were not in any publications.

Ms. Recknor accepted the ORI finding and entered into a Voluntary Settlement Agreement with ORI in which she voluntarily agreed, for the 2-year period beginning August 19, 1999, to exclude herself from serving in any advisory capacity to the PHS, and her participation in any PHS-funded research is subject to supervision requirements.

Samar N. Roy, Ph.D., New York Blood Center (NYBC): Based on a report forwarded to ORI by NYBC on February 26, 1998, and information obtained by ORI during its oversight review, ORI found that Dr. Roy, assistant member, Laboratory of Membrane Biology, NYBC, engaged in scientific misconduct in biomedical research supported by an NIH grant. Dr. Roy intentionally falsified the claim that he had obtained the expression of wild type and mutant fibrinogen in yeast cells published in (Roy, S.N., Kudryk, B., & Redman, C.M. *J. Biol. Chem.* 270:23761-23767, 1995; referred to as

the "*JBC* 270 paper"). Dr. Roy falsified the claim by "spiking" various samples with fibrinogen obtained from mammalian sources that were submitted to other laboratories for analysis. Also, he intentionally falsified the data reported in Figure 2A of the *JBC* 270 paper by using a different exposure of the same autoradiogram that he later used in the first six lanes of Figure 2 reported in another published paper (Roy, S., Sun, A., & Redman, C. *J. Biol. Chem*. 271:24544-24550, 1996; referred to as the "*JBC* 271 paper"). The falsified autoradiogram in Figure 2A of the *JBC* 270 paper was described differently, though correctly, in Figure 2 of the *JBC* 271 paper. The *JBC* 270 paper has been retracted. Dr. Roy entered into a Voluntary Exclusion Agreement with ORI in which he voluntarily agreed, for the 3-year period beginning January 7, 1999, to exclude himself from any contracting, subcontracting, or nonprocurement transactions with the United States Government, and from serving in any advisory capacity to PHS.

Robert J. Thackeray, R.N., M.P.H., University of Pittsburgh (UP): Based on an investigation report prepared by the UP, dated June 24, 1998, and information obtained by ORI during its oversight review, ORI found that Mr. Thackeray, former program coordinator, Multi center AIDS Cohort Study (MACS), Department of Infectious Diseases and Microbiology, Graduate School of Public Health, UP, engaged in scientific misconduct in research supported by the NIAID, NIH. The Pitt Men's Study is a component of the MACS funded by a cooperative agreement with NIAID, NIH. Mr. Thackeray falsified and/or fabricated research data that he recorded from various tests that he was responsible for conducting on voluntary subjects enrolled in the MACS. He falsified and/or fabricated data for five subjects and reported that data on the "Neurological Assessment Form 10" and on the "Instrumental Activities of Daily Living Scale" questionnaire. The fabricated and/or falsified research data were not compiled elsewhere and were not published. Mr. Thackeray entered into a Voluntary Exclusion Agreement with ORI in which he voluntarily agreed, for the 3-year period beginning January 19, 1999, to exclude himself from serving in any advisory capacity to the PHS, and his participation in any PHS-funded research is subject to supervision requirements.

Falsification: The respondent allegedly falsified a figure in a grant application submitted to the NIH involving the characterization of antibodies directed at receptors in cultured cells. The institution conducted an investigation into the matter and found that the figure in the grant application bore a falsified legend. However, there was insufficient evidence for ORI to determine who was responsible for the apparent falsification. Therefore, ORI accepted the institution's factual findings but did not make a finding of scientific misconduct in this case.

Falsification: The respondent, a professor, allegedly falsified research results on monoclonal antibodies in two manuscripts. The research in question was supported by two NIH grants. The institution conducted an investigation into the matter and concluded that one instance of data falsification had taken place. However, because of several factors, including the University's failure to follow proper procedures in the sequestration, documentation, and handling of the evidence and shortcomings in its review, ORI did not make a finding of scientific misconduct in this case.

Falsification: The respondent, a laboratory assistant, allegedly falsified results on the effect of a neuropeptide in brain slices for a published abstract and a poster presentation. The research in question was supported by three NIH grants. The institution conducted an investigation into the matter and concluded that falsified data had been included in the poster presentation. However, questions of intent and culpability remained unresolved, and there was insufficient evidence to conclude that the respondent had committed scientific misconduct. Based on a preponderance of the evidence, ORI accepted the institution's conclusion that there was insufficient evidence to warrant a finding of scientific misconduct in this case.

Falsification: The respondent allegedly falsely claimed in several NIH grant applications that he had been awarded a Ph.D. degree before he had completed the requirements for the degree. The institution conducted an investigation into the matter and concluded that the respondent had misrepresented his credentials. However, the institution noted that there had been a delay in the awarding of the respondent's degree due to factors beyond his control. Thus, the institution concluded that while the misrepresentation constituted a grave error, it did not rise to the level of scientific

misconduct. ORI noted that the Ph.D. was a second doctoral level degree for the respondent, who already held another qualifying degree. ORI accepted the institution's analysis and did not make a finding of scientific misconduct in this case.

Falsification: The respondents allegedly intentionally mislabeled mouse cage cards to disguise the experimental inoculation of mice with a virus absent appropriate institutional review committee approval. The research in question was supported by NIH grants. The institution conducted an investigation into the matter and concluded that the respondents had committed misconduct. However, ORI determined that the acts involved, and the institutional findings in this case, were more appropriately considered questions about the use of animals and the safety of employees, which falls outside of the PHS definition of scientific misconduct. Therefore, ORI accepted the institution's factual findings in this matter but did not make a finding of scientific misconduct under the PHS definition.

Plagiarism: The respondent allegedly plagiarized text from another investigator's application for use in his own grant application submitted to the NIH. The institution conducted an inquiry and determined that there was sufficient evidence that the respondent had incorporated text directly from another investigator's application. However, the institution determined that the text did not represent the investigator's original ideas and was not central or extensive in the respondent's grant application. ORI accepted the institution's report and did not make a finding of scientific misconduct in this matter.

Plagiarism: The respondent, a graduate student, allegedly included material plagiarized from another student's thesis, two journal articles, and a textbook chapter in the first draft of a doctoral thesis. The research in question was supported by an NIH grant. The institution conducted an investigation into the matter and concluded that the respondent had plagiarized the statements of others and included them in the background section of a first draft of a thesis without appropriate citation and attribution. ORI accepted the institution's investigation report but did not make a finding of scientific misconduct based on the following factors: the material represented background information, most of which was obtained from the respondent's own laboratory; the lack of significance of the background material; the lack of intent to deceive; and the plausibility of an honest but mistaken judgment by the accused scientist.

Falsification/Fabrication: The respondent, a professor, allegedly falsified and/or fabricated data on the drug treatment of animals as a human disease model, which were included in a manuscript that was submitted for publication. The research in question was supported by an NIH grant, and the questioned results were included in applications for an NIH cooperative agreement. The institution conducted an investigation into the matter and concluded that some of the data in one table of the manuscript had been falsified or fabricated. The falsified and fabricated data were also presented in various talks by both the respondent and complainant. However, the institution was not able to determine who had falsified the data and did not make a finding of scientific misconduct. Given that the institution could not determine who was ultimately responsible for the false data, ORI did not make a finding of scientific misconduct and did not take any further action in this case.

Falsification/Fabrication: Falsified or fabricated data and information were allegedly collected and submitted to the coordinating center of a multi-center clinical study involving hormonal and other treatments of normal postmenopausal women. The institution conducted an investigation into the matter. The institution determined that the data discrepancies were symptomatic of the overall mismanagement and disorganization of the study at the site in question and were not the result of scientific misconduct. ORI accepted the institution's conclusion that the discrepancies in the questioned data were not the result of falsification or fabrication but did not make a finding of scientific misconduct in this case.

Falsification/Plagiarism: The respondent allegedly falsified a figure in a grant application submitted to NIH, and committed plagiarism or seriously deviated from commonly accepted practices for conducting research within the scientific community. The respondent allegedly retained a grant application and an unpublished manuscript that he had obtained as a member of an NIH scientific review committee and used these documents to plan similar experiments. The questioned research involved the characterization of antibodies directed at receptors in cultured cells. The institution conducted an investigation into the matter and found that one figure in the grant application was false. However, there was insufficient evidence for ORI to determine who was responsible for the falsification. The institution also determined that the respondent had violated the confidentiality provisions that he had agreed to as a member of an NIH scientific review group by retaining a grant application and unpublished manuscript for use in his own research, which was a serious deviation from commonly accepted practices

within the scientific community for conducting research, but was not serious plagiarism. ORI determined that the respondent's abuse of the NIH peer review process should be referred to NIH for handling, but did not make a finding of scientific misconduct in this case because the respondent's experiment was directed at a different biological specimen and was undertaken after similar experiments were published and then in the public domain.

Note: 2 cases were closed administratively dur-

ing 1999.

CIVIL LITIGATION

Angelides* v. *Baylor College of Medicine, No. 95-24248 (11th D.C. Harris County, filed Aug. 29, 1995); No. H-95-4640, *slip op*. (S.D. Tex. June 13, 1996) *aff'd,* 117 F.3d 830 (5th Cir. 1997); No. 95-042305, (11th D.C. Harris County). Dr. Kimon Angelides, a former research scientist at the Baylor College of Medicine (BCM) sued BCM for various acts arising out of BMC's finding that Dr. Angelides had committed scientific misconduct. Dr. Angelides claimed, among other things, wrongful termination, interference with a contractual relationship, and defamation. He supported his defamation claim by arguing that BMC improperly reported its scientific misconduct findings to ORI. ORI agreed with the BMC findings, and Dr. Angelides requested a hearing before a Panel of the HHS Departmental Appeals Board (DAB). The Texas state court dismissed several of Dr. Angelides' claims but declined to dismiss his claims for libel/defamation, intentional infliction of emotional distress, and illegal conversion of property. The trial began on January 25, 1999, but on February 10, after 3 weeks of proceedings and within hours after receiving the DAB decision affirming ORI's scientific misconduct findings and administrative actions, Dr. Angelides agreed to settle, and the case was dismissed. As part of the settlement, Dr. Angelides agreed to accept ORI's findings of scientific misconduct as affirmed by the DAB, and not to appeal the administrative actions, including the DAB's 5-year debarment recommendation to the HHS Debarring Official. BCM agreed to pay $500,000 of Dr. Angelides legal expenses with the provision that he not receive any of the monies.

Kay* v. *Arizona Board of Regents, No. 328309 (Sup. Ct. of Arizona, filed August 17, 1998). Dr. Marguerite Kay, a former researcher, filed suit in state court against the University of Arizona (UA). She claimed wrongful discharge and violation of the Arizona Administrative Procedure Act, A.R.S. § 12-901, *et seq.*, and the United States and Arizona Constitutions. She

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

claimed the alleged violations occurred because UA terminated her employment as a tenured professor without providing her with the required substantive or procedural due process and without adherence to the policies of the State Board of Regents. The UA had conducted several investigations and found that Dr. Kay had committed PHS scientific misconduct, in addition to other internal institutional charges. In 1998, after the UA's inquiry, investigations, and subsequent public administrative hearing, the institution fired her. Dr. Kay had previously filed in Federal court for a restraining order claiming violation of substantive and due process on similar grounds, but that case was dismissed. ORI conducted an oversight review of the PHS-related portion of the UA's scientific misconduct proceedings. On April 30, 1999, the Arizona state court ruled that UA had failed procedurally to follow its policies for termination of faculty and remanded the termination matter back to the UA for further proceedings. The court held it did not have jurisdiction to order her reinstatement or back pay. However, it wasn't until December 7, 1999, that the state court finally entered its decision on the April 30 ruling. The decision reaffirmed that UA failed to follow its own termination procedures and, based on a recent Arizona Supreme Court ruling, had also violated the Arizona Administrative Procedure Act by prohibiting Dr. Kay's attorney from actively participating during the administrative hearing which was the basis for her being fired. The court also awarded Dr. Kay attorney's fees.

Popovic* v. *United States, No. PJM-96-3106, *slip op.,* (D.Md. Feb. 27, 1998); No. 98-1432 *appeal dismissed,* (4th Cir. 1999). On April 20, 1999, the Fourth Circuit affirmed a district court's dismissal of a 1996 civil suit related to a scientific misconduct investigation brought by a former NIH scientist, Dr. Mikulas Popovic, who brought a complaint under the Federal Tort Claims Act (FTCA), 28 U.S.C. § 2671 *et seq.*, against NIH and other defendants. Under the FTCA, the government specifically waives its sovereign immunity for some torts. However, in this instance, the appeals court agreed with the lower court that although Dr. Popovic had claimed the torts of negligent investigation and invasion of privacy, which are covered by the FTCA, an examination of the facts showed that in reality he was claiming that he was defamed. Actions may not be brought for defamation under the FTCA, because the act specifically excludes such intentional torts. The appeals court further held that Dr. Popovic's due process claims about the scientific misconduct investigation were constitutional in nature. Therefore, those claims also could not be brought under the umbrella of the FTCA. Dr. Popovic did not file a petition for a rehearing.

Shovlin* v. *University of Medicine and Dentistry of New Jersey, No. CV97-634 (DRD), 50 F. Supp. 2d 297 (1998), *appeal dismissed*, (3rd Cir.1999). On May 28, 1999, the Third Circuit held that a district court was correct in all respects when it dismissed Dr. Shovlin's 1997 suit against the University of Medicine and Dentistry of New Jersey (UMDNJ). Dr. Shovlin had claimed, among other things, that the UMDNJ's decision to deny him Professor Emeritus status after he resigned was retaliation for his actions during a scientific misconduct investigation. With respect to the retaliation claim, the appeals court agreed with the lower court that Dr. Shovlin had not met the elements for a claim. To qualify as a protected activity, the employee's speech first must be a matter of public concern, and second, the public interest favoring the speech must not be outweighed by any injury the speech could cause the interest of the state as an employer in promoting the efficiency of the public services it performs through its employees. Here, the court agreed with Dr. Shovlin that some of his comments, although out of proportion to the activities he was criticizing, could be considered protected. However, when the court balanced the value of his actions to the public concern, versus their impact upon the effectiveness and efficiency of the UMDNJ's mission, it found that, given the context of his comments, the UMDNJ's need to pursue effectively matters such as scientific misconduct allegations outweighed his right as an employee to speak. The court also rejected Dr. Shovlin's 14th Amendment claims regarding the UMDNJ's refusal to appoint him to academic positions and by disseminating erroneous information regarding the scientific misconduct proceeding. The court held, that as Dr. Shovlin had no right to any position at the UMDNJ once he had resigned, the only possible rights violated were those related to his reputation or standing in the scientific community. Damage to reputation or good name alone are not enough to establish a due process claim. Dr. Shovlin did not file a petition for *certiorari*.

U.S. ex rel. Cantekin* v. *University of Pittsburgh, No. 91-0715 (W.D. Pa., filed May 1991). In September 1999, the Third Circuit gave Dr. Erdem I. Cantekin, a researcher at the University of Pittsburgh (UP), another chance to prove his long running *qui tam* action under the False Claims Act (FCA), 31 U.S.C. § 3730(b). Originally filed in 1991, Dr. Cantekin, alleged in this case that the UP and others defrauded the United States by making false financial disclosure statements in applications for NIH grants. The United States declined to intervene, and Dr. Cantekin

pursued the suit independently. In 1997, the district court dismissed Dr. Cantekin's pre-October 1986 FCA claims, and subsequently, also dismissed his post-October 1986 FCA claims, holding that the defendant researcher at issue lacked the requisite intent and did not "knowingly" submit false or fraudulent information to the government. The court ruled that the Federal grant application and instructions were unclear and subject to varying interpretations with respect to what was required in the "other support" section. Thus, the court held that there was insufficient evidence of record to create a genuine issue of material fact to support Dr. Cantekin's claims. On appeal, the Third Circuit partially disagreed. On September 29, 1999, the appeals court affirmed the dismissal of the pre-October 1986 FCA claims, but reversed the dismissal of the post-October 1986 FCA claims. With respect to the pre-October 1986 FCA claims, the Court held that the 1986 amendments to the *qui tam* provisions of the FCA do not apply retroactively to false claims submitted before the effective date of the amendments, and that retroactivity is determined based on the submission date rather than the date on which a false claim is disclosed to the government. However, regarding the post-October 1986 FCA false claims, the Court held that: (1) evidence was presented which created a genuine dispute as to whether the defendants had knowingly submitted a grant application to NIH without disclosing required information and, therefore, state of mind should not have been decided on summary judgment; (2) there was ample evidence that the grant application instructions were clear; (3) the disclosure letter sent by the researcher defendant to NIH, was sent after he was under investigation and, therefore, was too late to qualify for a reduction in liability under the FCA; and, (4) the information which the defendants failed to disclose was material to the information in the letter. 192 F.3d 402 (3rd Cir. 1999).

U.S. ex rel. Karuturi* v. *John Wayne Cancer Institute, No. 95-7939-CMB (C.D. Cal., filed Nov. 21, 1995). Dr. Satyanarayana Karuturi, a former researcher at the John Wayne Cancer Institute (JWCI), filed this *qui tam* complaint under the False Claims Act (FCA), 31 U.S.C. § 3730(b). Dr. Karuturi alleged that JWCI and other defendants submitted false claims for payment to the National Cancer Institute (NCI) by failing accurately to describe research results in grant applications and progress reports submitted to NCI. ORI had concurred with JWCI's findings that there was insufficient evidence to pursue Dr. Karuturi's allegations of scientific misconduct. In 1996, the United States declined to intervene, and Dr. Karuturi elected to pursue his complaint independently. In 1998, the district court dismissed all defendants except JWCI and all claims except for the FCA charges on specified grant applications and the wrongful termination claim under the whistleblower section of the FCA, 31 U.S.C. § 3730(h). JWCI and Dr. Karuturi both filed motions for summary judgement, and on December 9, 1999, the Court denied Dr. Karuturi's motion but granted JWCI's motion, thus dismissing the last remaining defendant. The time for appeal had not run by the end of 1999.

U.S. ex rel. Scott* v. *Dr. Robert J. McKenna, Jr., No. 96-5176CBM (C.D. Ca., filed July 25, 1996). The relator, Ms. Scott, filed this *qui tam* action under the False Claims Act (FCA) 31 U.S.C. § 3730(b), *pro se,* against Dr. Robert J. McKenna, Jr., and other defendants including various physicians, nurses, hospitals, and the University of California at Irvine (Irvine). Ms. Scott alleged that false claims were submitted to the Health Care Financing Administration (HCFA), NIH, and the Department of Energy. Ms. Scott claimed that the defendants inappropriately billed HCFA for unapproved lung reduction surgery and misrepresented specifics about the surgical procedure, including mortality rates. She also filed a scientific misconduct allegation with ORI, but ORI determined that only one of the named defendants had submitted a grant application to the NIH, and none of his grant applications were funded. In 1997, the United States declined to intervene, and Ms. Scott pursued the case independently. In 1998, the district court dismissed, with prejudice, Ms. Scott's claims against Irvine and the Tustin Rehabilitation Hospital, but declined to dismiss the claims against Dr. McKenna and other named physicians and hospitals.

U.S. ex rel. Streed* v. *The Regents of the University of California, No. 97 CV0443K (RBB) (D.S.Cal. 1997). Relator, Thomas B. Streed, Ph.D., filed a *qui tam* action under the False Claims Act (FCA), 31 U.S.C. § 3729, against the University of California and other defendants (UC, et al.). Dr. Streed alleged that the defendants: 1) illegally imported and conducted research using NIH grant funds on "human neurological disease;" 2) contaminated other NIH-funded research materials with the imported material; 3) improperly transferred NIH grant funds and medical technology to a defendant; 4) improperly used NIH funds to pay defendants for work done at a private company; 5) filed patent applications without disclosing to the Government that the inventions were made using NIH grant funds; 6) failed to disclose to NIH conflicts of interest in conducting grant reviews

and administering grant funds; 7) made false statements to NIH about compliance with environmental and health safety regulations and safety records; and 8) fabricated research data. In 1998, the United States declined to intervene, and Dr. Streed pursued the case independently. On May 27, 1999, the court granted the defendants' omnibus motion to dismiss the complaint, but also granted Dr. Streed leave to refile his complaint. The United States again declined to intervene. The remaining parties have stipulated to stay this case pending the outcome of a U.S. Supreme Court case that will determine whether state agencies may be sued either by the Federal Government or by a *qui tam* relator under FCA. As one of the defendants, the Regents of the University of California, is an arm of a state agency, this Supreme Court case will impact the outcome of this and many other *qui tam* proceedings.

CRIMINAL LITIGATION[2]

U.S.A.* v. *Resnick, No. 96-0706, (S.D. Fla. filed Aug. 21, 1996). The United States charged Dr. Lionel Resnick with violations of 18 U.S.C. §§ 1341 and 1342 (mail fraud), and § 1957 (money laundering). The indictment alleged that he and his corporation, Vironc, Inc., sought to defraud Mt. Sinai Lab of the proceeds due it from the University of Miami and All Children's Hospital for AIDS-related testing performed at the Mt. Sinai Lab. The indictment also alleged that Dr. Resnick and Vironc arranged with the University and All Children's for testing previously done at Mt. Sinai to be done by Vironc and that invoices should be submitted to Vironc. However, the testing continued to be performed at the Mt. Sinai Lab by Mt. Sinai personnel using Mt. Sinai equipment. Additionally, ORI performed an oversight review of a related University of Miami investigation alleging that Dr. Resnick had committed scientific misconduct. On February 22, 1999, Dr. Resnick pled guilty to 18 counts of mail fraud, and was sentenced on May 5, 1999. On June 17, 1999, HHS and Dr. Resnick also settled the related civil suit with a 5-year Medicare and Medicaid exclusion and a Government-wide debarment, payment by Dr. Resnick of $600,000.00, and his relinquishment of all claims for reimbursement for suspended Medicare and Medicaid payments.

---

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

AAAS	American Association for the Advancement of Science
AABB	Administrative Actions Bulletin Board
AAMC	Association of American Medical Colleges
ADF	Aaron Diamond Foundation
BCM	Baylor College of Medicine
BCPT	Breast Cancer Prevention Trial
CBE	Council of Biology Editors (now the Council of Science Editors)
CDC	Centers for Disease Control and Prevention
CHPS	Center for Health Policy Studies of Columbia, MD
CU	Cornell University
FDA	Food and Drug Administration
FOIA	The Freedom of Information Act, 5 U.S.C. § 552, as amended
HHS	U.S. Department of Health and Human Services
LBNL	Lawrence Berkeley National Laboratory
NAS	National Academies of Sciences
NHLBI	National Heart, Lung, and Blood Institute
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NINDS	National Institute of Neurological Disorders and Stroke
NSABP	National Surgical Adjuvant Breast and Bowel Project
NSF	National Science Foundation
OIG	Office of Inspector General, HHS
OGC	Office of the General Counsel, HHS
OS	Office of the Secretary, HHS
PRIM&R	Public Responsibility in Medicine and Research
RCR	Responsible Conduct of Research
RIB	Research Integrity Branch, OGC
RIO	Research Integrity Officers
RP/SLMC	Rush-Presbyterian-St. Luke's Medical Center
SUNY/SB	State University of New York at Stony Brook
UCLA	University of California-Los Angeles
UCSD	University of California-San Diego
UM	University of Maryland
UU	University of Utah