ORI NEWSLETTER

Volume 6, No. 3, Office of Research Integrity, June 1998

*****

AGENDA, SPEAKERS NAMED FOR CONFERENCE ON BIOMED LABS

A national conference will be held at the University of Arizona from October 1-3 to explore a subject essential to the advancement of biomedical science, the career of scientists, and research integrity--the management of biomedical research laboratories. The conference is co-sponsored by the university and ORI.

This is the first conference to offer veteran, new, and prospective laboratory directors, research administrators, post-docs, and graduate students an opportunity to discuss 7 topics essential to productive laboratories with 16 experienced researchers and research administrators from 15 research institutions:

Role of the Laboratory Director: Authority, Responsibilities, Skills

Janet M. Oliver, Ph.D., Univ. of New Mexico School of Medicine
James Staros, Ph.D., Vanderbilt University
Frederick Grinnell, Ph.D., Univ. of Texas Southwestern Medical Center

Mentoring: Responsibilities, Effectiveness, Conflicts

David R. Challoner, M.D., University of Florida
Joan Y. Reede, M.D., Harvard Medical School
Alan N. Schechter, M.D., NIDDK, NIH

Managing the Research Agenda: Strategy, Change, Competing Interests

Ronald Newbower, Ph.D. Massachusetts General Hospital
Michael A. Cusanovich, University of Arizona

Quality Control: Experiments, Analysis, Reporting

Ronald B. Herberman, M.D., Univ. of Pittsburgh Cancer Institute
Thomas P. Davis, Ph.D., University of Arizona

Data Management: Recording, Retention, Access, Ownership

Walter J. Meyer, III, M.D., Univ. of Texas Medical Branch, Galveston

David E. Wright, Ph.D., Michigan State University

Collaborative Research: Expectations, Conflicts, Resolution

Bernard Janicki, Ph.D., Dana-Farber Cancer Center
Daniel M. Dorsa, Ph.D., Univ. of Washington School of Medicine

Assigning Credit for Productivity: How, By Whom, For What, When

Michael Kalichman, Ph.D., University of California-San Diego
Francis L. Macrina, Ph.D., Virginia Commonwealth University

The conference brochure may be accessed at http://conferences.arizona.edu/biomedlab98. A conference banquet will be held at the White Stallion Ranch, a scenic guest ranch outside of Tucson.

ORI expects the results of the conference to provide the basis for developing educational materials on the management of biomedical laboratories such as modules, a handbook, a course, or training workshop.

Registration is $295 before September 1; $350 after September 1. Full-time students may register for $150. The registration fee covers attendance, continental breakfast, lunch, the conference notebook, and the conference proceedings.

*****

48 INSTITUTIONS OPEN 64 MISCONDUCT CASES IN 1997

Sixty-four new scientific misconduct cases were opened in 1997 by 48 institutions that conducted 56 inquiries and 19 investigations in response to 92 allegations, according to their 1997 Annual Report on Possible Research Misconduct. The decision to proceed to an inquiry in response to eight allegations had yet to be made when the reporting period ended.

A total of 73 institutions were responding to allegations in 1997 because 38 were continuing to investigate allegations received before 1997, while 13 were dealing with allegations made before and during 1997.

In their submission, institutions report the receipt of allegations of scientific misconduct, the type of misconduct, and the conduct of an inquiry and/or allegation. 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 48 institutions reporting new allegations in 1997, 35 were institutions of higher education,

6 were research organizations, 6 were independent hospitals, and 1 was another health, human resources, or environmental services organization.

The 92 new allegations reported in 1997 included 26 of fabrication, 34 of falsification, 8 of plagiarism and 24 of other serious deviations. The number of new cases opened by the 48 institutions ranged from 1 to 4. Twenty-five cases involved multiple allegations.

*****

ORI REQUESTS 193 POLICIES FOR REVIEW IN MAY

One hundred and ninety-three institutions were asked in May to submit their policy for responding to allegations of scientific misconduct involving PHS-supported research to ORI within 60 days for review.

One hundred and eight policies (down from 179 in 1997) were requested because the institutions indicated in their 1997 Annual Report on Possible Research Misconduct that they did not have such a policy or they failed to answer the question about the availability of a policy. Eighty-five policies were requested for the 1998 annual sample of policies reviewed by ORI.

Institutions with fewer than 10 employees may submit a small organization policy statement in lieu of an administrative policy. A copy of that policy statement is in the *ORI Handbook for Institutional Research Integrity Officers*, see our home page or call ORI.

Besides fulfilling its monitoring responsibility, ORI views these reviews as a mechanism for assisting institutions in developing an administrative policy that complies with the Federal regulation (42 C.F.R. Part 50, Subpart A).

Each institution that submits a policy will receive the review results by the end of the year. Each institution will either receive a letter indicating that the policy complies with the regulation or a request for a revised policy within 90 days. The request for a revision will be accompanied by a report indicating the provisions of the regulation not adequately represented in the policy.

ORI will inactivate the assurance of any institution that fails to adopt a policy that complies with the regulation, thereby making that institution ineligible for PHS funds until the requested document is received.

*****

INSTITUTIONS REPORT SINGLE BAD FAITH ALLEGATION

Only 1 of the 48 institutions that reported new misconduct activities on their 1997 Annual Report on Possible Research Misconduct indicated receipt of a bad faith allegation. The ORI Model Policy for Responding to Allegations of Scientific Misconduct states that "an allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation."

In the single reported instance, the whistleblower alleged that a principal investigator (PI) had submitted fraudulent data in an application to NIH. The subsequent investigation demonstrated that the fraudulent data unknowingly submitted by the PI was provided by the whistleblower. Termination proceedings were begun against the whistleblower.

Data were requested on the incidence of bad faith allegations for the first time because of the concern within the scientific community about such allegations and because many institutional misconduct policies state that such acts are subject to disciplinary action.

*****

TOP FUNDED INSTITUTIONS REPORT MOST MISCONDUCT ACTIVITY

The top 75 NIH-funded institutions accounted for about two-thirds of the misconduct activity reported by institutions on their Annual Reports on Possible Research Misconduct covering the six-year period, 1991-96; the remaining activity was reported by institutions as far down the funding ladder as the 1,277th rung.

The amount of misconduct activity reported by institutions appears related to the amount of funding received by the institutions. The top 75 NIH-funded institutions conducted 71% of the inquiries and 63% of the investigations, produced 66% of the misconduct findings, and received 70% of the funds. See Table 1.

The next 75 ranked institutions reported considerably less misconduct activity, but also receive considerably less funding. Institutions ranked from 76-150 conducted 17% of the inquiries and 14% of the investigations; produced 12% of the misconduct findings, and received 14% of the funding. The remaining 1,449 institutions accounted for 12% of the inquiries, 23% of the investigations, 22% of the misconduct findings, and 16% of the funds.

Misconduct activity reported in the Annual Report should fall within the PHS definition of scientific misconduct and involve research supported by the PHS. This analysis is limited to cases that were started in 1991 through 1996 and completed by the end of 1996.

Sixty-six of the top 75 funded institutions (88%) have conducted inquiries; 52 or 69% have conducted investigations, and 25 or 33% have found misconduct. Thirty-eight or 51% of the next

75 institutions have conducted inquiries; 18 or 24% have conducted investigations; and 6 or 8% have found misconduct. Sixty-two or 4% of the remaining 1,449 institutions have conducted inquiries; 40 or 2.7% have conducted investigations, and .7% have found misconduct. See Table 2.

Table 1: Percent of Inquiries, Investigations, Misconduct Findings, and Funding by Funding Rank as Reported in Annual Reports on Possible Research Misconduct, 1991-96.

Funding Ranks*	Inquiries n=425	Investi-gations n=235	Mis-conduct Findings n=50	1996 Fundin g ($8.39 Billion)
1-25	40	37	32	39
26-50	16	14	20	19
51-75	15	12	14	12
76-100	7	8	8	6
101-125	7	5	0	5
126-150	3	1	4	3
151-1599	12	23	22	16
Total	100	100	100	100

*Based on FY 1996 NIH extramural research awards to 1,599 institutions.

Table 2: Number of Institutions within Funding Ranks by Inquiries, Investigations, and Misconduct Findings as Reported in Annual Reports on Possible Research Misconduct, 1991-96.

Funding Ranks*	No. Conducted Inquiries	No. Conducted Investigations	No. Finding Misconduct
1-25	24	23	10
26-50	24	15	8
51-75	18	14	7
76-100	16	8	4
101-125	13	7	0
126-150	9	3	2
150-1599	62	40	10
Total	166**	110	41

*Based on FY 1996 NIH extramural research awards to 1,599 institutions.

**This total is lower than the 174 institutions cited in the March article because misconduct activity that occurred in different components of the same institution were counted as one institution for ranking purposes. In addition, three institutions that reported allegations did not report an inquiry or investigation.

*****

RYAN HEADLINES CONFERENCE IN CHAPEL HILL

The incidence of scientific misconduct can be considerably reduced by routinely examining primary data, conducting audits, and implementing other quality control measures, according to Dr. Kenneth Ryan, Harvard Medical School.

Dr. Ryan was the keynote speaker at the conference, "Research Integrity from the Workplace to the Marketplace," on May 18-19, co-sponsored by the University of North Carolina at Chapel Hill and ORI. The conference, attended by 75 individuals, focussed on issues related to the introduction of research results into the marketplace of modern society, including public policy decisionmaking, product development, national security, and training the next generation of scientists.

Dr. Ryan suggested that scientists sometimes lose their objectivity and deceive themselves into acceptance of fabricated or falsified data that support the results they want. He also noted that more attention should be given to the incidence of falsified credentials.

Other issues discussed at the conference were incentives and disincentives to practicing research integrity, science in the courtroom, the responsible use of data, secrecy in research, and recordkeeping in research.

For more information, contact Judy Christman, UNC-Chapel Hill at phone: (919) 962-7757; fax: (919) 962-6769 or e-mail: rajpc.ors@mhs. unc.edu. Plans are also underway to publish the conference proceedings.

*****

CASE SUMMARIES

Cynthia King, Bienville Medical Group (BMG) and Patrina Lowe, (BMG): ORI made final findings of scientific misconduct against Ms. King and Ms. Lowe based on an investigation by ORI's Division of Research Investigations. ORI found that both respondents engaged in scientific misconduct in a multicenter clinical trial supported by the National Heart, Lung, and Blood Institute. Both parties falsified and/or fabricated data and information collected from patients for the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial at the clinical site in Terry, Mississippi. No scientific publications were required to be corrected. ORI acknowledges Ms. King's and Ms. Lowe's cooperation and assistance in completing its investigation.

Ms. King and Ms. Lowe accepted the ORI findings and entered into Agreements with ORI. Individually, they voluntarily agreed for the 3-year period beginning April 6, 1998, (1) to be excluded from serving in any advisory capacity to the Public Health Service (PHS), such as serving on a board, peer review committee, or as consultants; and (2) any institution that submits an application for PHS support for a research project on which Ms. King's or Ms. Lowe's participation is proposed, or which uses them in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which either one is involved, must concurrently submit for approval to the funding agency a plan for supervision of their duties, and a copy of the plan to ORI. The supervisory plans must be designed to ensure the scientific integrity of Ms. King's and Ms. Lowe's research contribution.

*****

FELLOWS, INTERNS WANTED

ORI is seeking faculty and students to serve as unpaid fellows and interns, respectively, to assist with computer programming, database management, web page development, conferences and workshops, studies and literature reviews. Send a résumé and letter indicating interests to Dr. Mary D. Scheetz, ORI. Phone: (301) 443-5300; fax (301) 443-5351; E-mail,: mscheetz@osophs.dhhs.gov.

*****

RESPONDENTS LOSE SUITS AGAINST UNIVERSITIES

Decisions in three cases filed against universities by respondents in scientific misconduct cases have been issued recently. In *Dr. Shovlin* v. *University of Medicine and Dentistry of New Jersey, et al*., No. 97-634, slip op. (D. N.J. April 3, 1998), a retired researcher sued the University for allegedly taking retaliatory action against him for supporting several scientists, including plaintiff, who were investigated for scientific misconduct. No findings were made against the plaintiff. In dismissing his claim that the University violated his First Amendment protected speech rights, the Federal district court stated that the researcher was "clearly out-of-order to attack the [scientific misconduct] inquiry as a ploy by the administration" and that the "Investigatory Panel conducted a thorough study." The court noted that "Even though the federal agency [ORI] to which the university reported may not have considered duplicate publications to constitute 'misconduct in science,' it recognized the University's right to hold such a practice to be unacceptable." The court also refused to recognize the plaintiff's Fourteenth Amendment claims that the University violated procedural and substantive due process rights by failing to appoint him to academic positions and by disseminating erroneous information regarding the scientific misconduct proceeding. The court held, among other things, that due process does not extend to prospective interests or benefits, such as academic appointments, unless one can demonstrate a legitimate claim of entitlement. Nor did the court accept the plaintiff's claim based on alleged damage to his reputation because he had not shown that he suffered from any accompanying deprivation such as a subsequent denial of employment due to the alleged defamatory conduct.

In *Kay* v. *University of Arizona, et al*., No. 98-146, slip op. (D. Ariz. April 24, 1998), a Federal court denied a researcher's request for injunctive relief and dismissed the case. The plaintiff alleged that the University's procedures for a public formal hearing on scientific misconduct and other charges violated Federal and State constitutional due process and State statutes and common law. Among other things, the court noted the University's argument that failure to proceed could jeopardize its Federal funding and that these were administrative, not court proceedings. The decision also stated that it appeared that the plaintiff had been provided a meaningful hearing, meaningful time to prepare, panel selection was unbiased, and "that all matters presented for consideration are indicative of due process, not the denial thereof."

In the third case, *Shen* v. *University of Minnesota, et al*., No. 96-12703, slip op. (Minn. May 5, 1998), a State court dismissed a researcher's claims of defamation and violation of the State's Human Rights Act. Although declining to find defamation by, among other things, allegations of possible scientific misconduct, the court considered whether an absolute or qualified privilege was an available defense. The court also declined to find that the academic misconduct proceedings constituted a discriminatory practice.

Although the above information is believed to be accurate, readers should review the actual decisions and draw their own legal conclusions.

*****

COMMISSION MAKES RECOMMENDATIONS TO SAFEGUARD GOOD SCIENTIFIC PRACTICE

An international commission established by Deutsche Forschungsgemeinschaft (DFG), the major research funding agency in Germany, has made 16 recommendations aimed at safeguarding good scientific practice in Germany.

Besides universities and independent research institutes, the 16 recommendations also address learned societies, authors, scientific journals, proposal reviewers, and research funding agencies. The commission recommended that universities and institutes be required to implement the following recommendations to be eligible for funding:

- Formulate rules of good scientific practice that will be binding on all their members and be incorporated into the education of young scientists. The rules of good scientific practice covers the fundamentals of scientific work--observing professional standards, documenting results, questioning one's findings, strict honesty in acknowledging the contributions of others, cooperation and leadership in working groups, mentoring, data management, and authorship.

- Provide an adequate organizational structure for conducting research that considers the size of each scientific unit and clearly allocates responsibilities for direction, supervision, conflict resolution, and quality assurance. The effectiveness of the organizational structure must be verifiable.

- Develop standards for mentorship that must be followed by heads of scientific units.

- Appoint an independent mediator to whom their members may turn in conflict situations, including cases of suspected scientific misconduct.

- Base performance evaluation primarily on originality and quality, secondarily on quantity.

- Require primary data reported in publications to be securely stored for 10 years in a durable form in the institution of their origin. The disappearance of primary data justifies a *prima facie* assumption of dishonesty or gross negligence.

- Establish procedures for dealing with allegations of scientific misconduct.

The commission further recommended that learned societies publish principles of good scientific practice for their disciplines that are binding on their members. The commission declared that authors of scientific publication are always jointly responsible for their content, scientific journals should enunciate authorship guidelines, reviewers of proposals should be required to respect confidentiality and to disclose conflicts of interest, and research funding agencies should issue clear guidelines on their requirements for information to be provided in research proposals

on the proposers' previous work and other work and information relevant to the proposal.

The DFG Senate has instructed the DFG staff to formulate a plan to implement the recommendations. However, the fate of the recommendations may be more discernible following the General Assembly meeting in mid-June.

Meanwhile, a university and a medical school have already issued codes of practice that include rules for handling allegations of scientific misconduct. Another university has appointed an ombudsman. The German Rectors Conference, an organization similar to the Association of American Universities, is developing a standard set of procedures for responding to misconduct allegations. The full text of the commission report is available in English on the DFG home page at http://www.dfg.de/aktuell/eng_index/what's_new.html.

*****

QUI TAM CASES CLOSED

Two *qui tam* cases filed under the False Claims Act, 31 U.S.C. § 3730(b), and related to scientific misconduct issues have closed. On April 6, 1998, the Federal district court approved a settlement in *U.S. ex rel. Sharma* v. *University of Southern California, et al.,* No. 96-3970 (C.D. Calif. filed June 5, 1996). *U. S. ex rel. Woolf* v. *University of California*, No. 97CV-1192-J (S.D. Calif. filed July 1997) was voluntarily dismissed by the relator without prejudice to refiling.

*****

RANGE OF INTEGRITY ISSUES DISCUSSED AT SRA MEETING

ORI and representatives from Harvard Medical School and Yale University presented a session on research integrity issues at a conference of the Society for Research Administrators in Newport, Rhode Island in May. The session "Beyond Scientific Misconduct: Designing and Implementing an Institutional System of Research Integrity" focussed on the responsibilities of institutions for a broad range of research integrity issues that do not constitute formal Public Health Service scientific misconduct matters, such as authorship and credit disputes, mentoring, data and recordkeeping issues, and policies and procedures of institutions designed to address these integrity concerns.

Chris Pascal, Acting Director, ORI, introduced the topic by contrasting the limitation of ORI jurisdiction to matters primarily involving fabrication, falsification, and plagiarism, and the plenary authority of institutions to address the broad range of research integrity disputes that arise in the lab. He described a "continuum of research integrity" at the institution that ranged from PHS scientific misconduct, infractions of institutional misconduct definitions, questionable research practices, to best research practices. Suggestions were offered for systematically addressing these various issues by coordinating institutional programs, policies, and processes

for handling the variety of problems arising across the research integrity continuum.

Margaret Dale, Associate Dean of Harvard Medical School, discussed a variety of policies and procedures adopted by Harvard to address research integrity issues, including policies on conflicts of interest, research sponsored by industry, guidelines for authors and editors, and guidelines for the responsible conduct of research. Many of these policies were adopted in response to particular types of problems such as disagreements over maundering or scientific disputes that had occurred in the lab but did not rise to the level of misconduct. She noted that while Harvard had several misconduct cases over the years, it also had many cases where initial allegations did not result in a finding of misconduct but identified sloppy research, poor laboratory management, or deviations from good scientific practices that warranted some level of institutional discipline or corrective action. These types of experiences were a driving force behind the adoption of some of the Harvard policies that address research integrity.

Suzanne Palmar, Director of Grants and Contracts, Yale University, discussed plans for the University to develop alternative mechanisms for handling research management disputes or research integrity allegations that do not amount to scientific misconduct. Many cases that previously have been referred initially for review under the system's procedure for investigating allegations of scientific misconduct ultimately reflected poor laboratory management, miscommunications, or disputes over authorship, collaborations, data management, or other issues not involving fabrication, falsification, or plagiarism. In response, Yale is considering establishing a system for scientists to raise such concerns with a confidential intake counselor that would allow a more customized response appropriate to the issue. Some problems might be resolved simply by providing advice to the scientists from someone experienced in resolving disputes while others might be handled by mediation or some other informal resolution process. More serious issues could be referred to the appropriate institutional office. In all cases, the scientist presenting the concern would have the opportunity for an informal discussion of the issues in a safe environment before presenting allegations of potential wrongdoing for formal institutional action.

*****

AVOIDING CONFLICTS OF INTEREST IN RESPONDING TO ALLEGATIONS

In responding to allegations, institutions need to select committee members and experts who are free from bias and have no real or apparent conflicts of interest either with the parties involved or the subject matter. Consequently, these individuals should be free of professional, financial, personal, or other substantial ties to the accused and the whistleblower.

Generally, it is the responsibility of the institution's Research Integrity Officer (RIO) to select committee members who have the necessary expertise to evaluate the evidence and issues related to the allegations. The RIO needs to notify the respondent of the proposed committee membership and the respondent should have the opportunity to submit a written objection to any appointed member of the investigation committee or expert based on bias or conflict. The whistleblower should also be provided with an opportunity to challenge the committee membership. The RIO then determines whether the challenged member or expert should be replaced with a qualified substitute.

The institution may use its own scientists as experts but should not select scientists who are directly responsible for the laboratory or research project where the alleged misconduct is said to have occurred. Such individuals have conflicts of interest as mentors, co-authors, and/or supervisors of the respondent that may compromise their objectivity in reviewing the allegations.

If it turns out that the scientist directly responsible for the laboratory or research project being investigated is the only person at the institution who is regarded as an expert in that particular field, then the RIO should consider using experts from other institutions. The use of outside experts or committee members lends credibility to an institution's investigation, and if the respondent holds a senior position, using an outsider also may be valuable.

All outside experts who agree to participate in the investigation should sign a confidentiality agreement to protect privacy interests of the accused individual and the institution.

*****

MEETINGS

October 1-3, 1998 "Conference on the Management of Biomedical Research Laboratories" at Univ. of Arizona in Tucson. See article on page 1 or contact Noah Lopez, tel. (520)-626-9060; Fax (520) 621-3269; noahl@u.arizona.edu.

October 3-5, 1998 "Communicating Science" in Clinton, NY. Contact Dr. Jinnie M. Garrett, Hamilton College, Biology Dept., 198 College Hill Rd., Clinton, NY 13323; Tel: (315) 859-4716; jgarrett@hamilton.edu.

*****

The *ORI Newsletter* is published quarterly by the Office of Research Integrity, Office of the Secretary of Health and Human Services, and distributed to applicant or awardee institutions and PHS agencies to facilitate pursuit of a common interest in handling allegations of misconduct and promoting integrity in PHS-supported research.

U.S. Department of Health and Human Services
Office of the Secretary
Office of Research Integrity
5515 Security Lane, Suite 700
Rockville, Maryland 20852
http://ori.dhhs.gov

Office of the Director	(301) 443-3400
FAX	(301) 443-5351
Division of Policy and Education	(301) 443-5300
FAX	(301) 443-5351
Assurances Program	(301) 443-5300
FAX	(301) 594-0042
Div. of Research Investigations	(301) 443-5330
FAX	(301) 594-0043
Research Integrity Branch/OGC	(301) 443-3466
FAX	(301) 594-0041