ORI NEWSLETTER

Volume 6, No. 2, Office of Research Integrity, March 1998

NORTH CAROLINA CONFERENCE TO DISCUSS "WORKPLACE" TO "MARKETPLACE" ISSUES

ORI and the University of North Carolina at Chapel Hill are jointly sponsoring a regional conference on May 18-19, 1998. The conference will explore issues in research integrity that challenge scientists in a variety of work settings--universities, industry, government, and other private, non-profit organizations. The conference will examine issues related to the introduction of the results of scientific research into the "marketplace" of modern society, including public policy decisionmaking, product development, national security, and the training of the next generation of scientists. In each marketplace setting, the incentives and disincentives to practicing research integrity will be explored.

Registration fees will be $125. For additional information or to register for the workshop, contact the conference coordinator, Judith Christman, UNC-Chapel Hill, at (919) 962-7757; e-mail: rajpc.ors@mhs.unc.edu or Alicia Dustira, ORI, at (301) 443-5300; email: adustira@osophs.dhhs.gov.

Agenda

Monday, May 18, 1998

9:00	a.m.	Registration
10:00	a.m.	Welcoming Remarks
10:10	a.m.	Keynote Address
10:40	a.m.	Federal Definitions and Approaches
11:10	a.m.	Panel Discussion: Workplace Perspectives
12:00	noon	Lunch
1:15	p.m.	Concurrent Sessions I
	A.	Workplace Incentives, Disincentives and Constraints on Research Integrity
	B.	Science in the Courtroom
	C.	The Responsible Use of Data
2:30	p.m.	Break
2:45	p.m.	Concurrent Sessions II
	D.	Secrecy in Research
	E.	The Federal Government: Friend or Foe?
	F.	Recordkeeping as an Issue of Integrity
4:00	p.m.	Break
4:15	p.m.	Plenary Session: Open Microphone
5:00	p.m.	Adjourn (first day)

Tuesday, May 19, 1998

8:30	a.m.	Plenary Session: Mentoring
10:00	a.m.	Break
10:15	a.m.	Concurrent Sessions III

	G.	Research Integrity in the Public Arena
	H.	Integrity and Issues of Authorship
	I.	When Allegations of Misconduct Strike Close to Home
12:00	noon	Lunch
1:15	p.m.	Concurrent Session IV
	J.	Graduate Students and Post-docs
	K.	Young Scientists
	L.	Senior Scientists
	M.	Research Administrators
2:45	p.m.	Break
3:00	p.m.	Plenary Session: Ownership of Ideas and Data
4:00	p.m.	Plenary Session: Conference Summary
4:30	p.m.	Adjourn

*****

RESEARCH INTEGRITY CONFERENCE DRAWS ABOUT 150 AT ANN ARBOR

The University of Michigan (UM) and ORI sponsored a 2-day conference in Ann Arbor, Michigan, on February 10-11, 1998, "Managing Integrity in Research," with an associated "Alternative Dispute Resolution (ADR) Workshop." Nearly 150 people attended the conference, primarily faculty, graduate students, and research administrators with responsibilities at the universities for teaching, demonstrating, and encouraging high standards of integrity in biomedical research.

The keynote speaker was Dr. Harold Shapiro, President of Princeton University, former President of UM, and current Chairman of the President's National Bioethics Advisory Commission. The Commission was charged with quickly making recommendations regarding the ethics of the proposed cloning of human beings. Dr. Shapiro described the Commission's process of debate, involving scientists, academicians, philosophers, and religious leaders. The social and scientific implications of this debate were discussed by distinguished faculty and administrators from UM departments of medical affairs, counseling, economics, human genetics, philosophy, and business.

In a session on Designing Research Integrity Programs, senior administrators described unique approaches to encouraging integrity in research. Examples included training modules, a Bioethics Institute held each summer for faculty to develop ethical enrichment sections for their regular courses, a four-credit course for first-year graduate students that used small group discussions, videotapes, and student presentations, and some theme-based symposia that preceded development of a university policy on authorship requirements and on data management and retention.

In the session on Using Existing Organizational Mechanisms, speakers talked about solving a dispute between coauthors, the difficulties in an institutional review board's consideration of behavioral research (where some manipulation and deception of the human subjects is needed), some examples of unprofessional behavior between faculty and students, and the role of university grants administrators in assisting faculty in meeting Federal agency reporting requirements.

A session on The Ethical Climate in the Academy included concerns about an undergraduate student's dependence on a faculty mentor in research and a discussion of the results of a survey of graduate student attitudes, and awareness of ethical issues. Particularly strong views were expressed on credit disputes and about controversial public cases. A university administrator outlined the need to address integrity in research at many levels, and demonstrated the ease by which digital immuno-protein images could be changed and falsified.

The session on Public and Media Perceptions reviewed the history of ORI's interactions with editors, the press, and Congress in various highly publicized misconduct cases. The role of lawyers and the difficulties in dealing with State freedom of information disclosures was discussed, standards of proof in scientific misconduct cases were compared to criminal and civil court actions, and the political history of scientific misconduct was summarized. University faculty and public relations staff were encouraged to deal forthrightly with alleged misconduct and humanize the public presentations of research.

The Emerging Issues session touched on issues related to potential liability of institutional committee members, the role of the whistleblower in detecting misconduct, and rehabilitation of respondents. Also covered were the legal issues surrounding institutional review boards and protection of human subjects, developing standards of care, pursuing emergency room research, and managed health care. Principles of humane use of animals in research, as well as controversies in genetic engineering and xenotransplantation, were also described. Other topics included principles of dealing with apparent conflicts of interest, problems of paperwork impeding sharing of research materials, and fears that industrial license restrictions may hinder faculty research and Federal agencies will assert rights to university inventions.

Closing remarks observed that a community of academicians interested in research integrity (including historians, ethicists, philosophers, laboratory scientists, teachers, and administrators) has developed locally and nationally over the past decade. Continued efforts at all levels were needed.

The ADR Workshop explored the role of the mediator and the principles of dispute resolution and its use in cases that do not fall under the Federal definitions of scientific misconduct. UM reported that a voluntary process agreed to by two parties with a confidential complaint handler and mediator was quite effective. Many disputes in science are over authorship and credit for ideas and work among collaborators and coworkers. ORI does not consider such disputes under

the definition of scientific misconduct, while the National Science Foundation staff does. Participants were reminded to deal with allegations of falsification, fabrication, and plagiarism under their normal policies and procedures for scientific misconduct.

A detailed summary of the conference is available on the ORI home page and from ORI upon request by calling (301) 443-5300.

*****

ORI HOME PAGE ADDRESS IS HTTP://WWW.DHHS.GOV/PHS/ORI

*****

ALLEGATIONS RAISED, MISCONDUCT FOUND IN ALMOST ALL INSTITUTIONAL TYPES

Analysis of the Annual Reports on Possible Research Misconduct submitted to ORI during the 6-year period 1991-96 showed that 174 institutions reported 432 allegations of scientific misconduct. These allegations resulted in 50 findings of misconduct at 41 institutions. Allegations reported on the Annual Report form should fall within the PHS definition of scientific misconduct and involve research supported by the PHS.

This analysis of the information reported on the forms is limited to the allegations that were received during the 6-year period; it does not include any allegations that were carried into the reporting period nor those still open at the end of 1996. Fifteen cases begun in this period are still open.

All types of institutions reported allegations and mis-conduct findings except for educational organizations other than higher education. The variance between types most likely results from several factors, including funding level, which will be explored in a later article.

Institutions of higher education, which represent 26.5% of the organizations with an active assurance on file with ORI, reported nearly 70% of the allegations and 68% of the misconduct findings. Allegations were reported by 14.2% of the higher education institutions; misconduct findings by 3.3%.

At the other end, small businesses, which are 43% of the organizations with an active assurance, reported 3.5% of the allegations and 4.9% of the misconduct findings. Allegations were reported by 0.4% of the small businesses and misconduct findings by 0.1%.

Table 1: Institution type by number with active assurances, reporting allegations and finding misconduct, 1991-96.

Type of Institution	Assurance		Allegations		Misconduct	
	N	%	N	&	N	%
Higher Education	851	26.5	121	69.5	28	68.3
Research org.	310	9.6	25	14.4	3	7.3
Independent hosp.	293	9.1	15	8.6	6	14.6
Other Education org.	21	0.1	0	0.0	0	0.0
Other Health	360	11.2	7	4.0	2	4.9
Small Businesses	1,380	43.0	6	3.5	2	4.9
Total	2,847*	100.0	174	100.0	41	100.0

*Number of institutions that submitted the 1996 Annual Report.

The total number of allegations reported by an institution ranged from 1 to 17 over the 6-year period. Eighty-nine institutions (51%) reported a single allegation; 85 (49%) institutions reported two or more allegations. The number of allegations reported in a single year by an institution ranged from one to seven.

Table 2: Total number of allegations reported by number of institutions, 1991-1996.

Allegations	Institutions	
	N	%
One	89	51
Two	30	17
Three	19	11
Four	13	8
Five	11	6
More than five	12	7
Total	174	100

The number of years an institution reported an allegation during the reporting period ranged from 1-6. One hundred and one institutions (58%) reported allegations in only 1 year; 73 institutions (42 %) reported allegations in 2 or more years.

Table 3: Number of years reporting an allegation by number of institutions, 1991-96.

Years	Institutions	
	N	%
One	101	58
Two	37	21
Three	21	12
Four	11	7
Five	2	1
Six	2	1
Total	174	100

The 174 institutions reported conducting 425 inquiries and 235 investigations. Fifty-five percent of the inquiries recommended an investigation; 45% did not. Twenty-one percent of the investigations resulted in a finding of misconduct; 73% did not, and 6% are undetermined at this time.

Twelve percent of the 432 allegations received in the 6-year period resulted in findings of scientific miscon-duct; 84% did not; 4% were undetermined at reporting time. Twenty-four percent of the 174 institutions reported receipt of an allegation found scientific misconduct; 76% did not.

*****

ORI STATES POLICY ON NON-PHS SCIENTIFIC MISCONDUCT ISSUES

Occasionally, someone will ask ORI to assume responsibility for a scientific misconduct investigation or for a compliance or retaliation issue related to non-PHS funded research. ORI does not accept these cases. One argument made by these requestors is that by having an assurance on file with ORI, an institution affirms that it has policies and procedures in compliance with the ORI scientific misconduct regulation codified at 42 C.F.R. Part 50, Subpart A. Therefore, ORI should take jurisdiction over any investigation conducted under those policies and procedures regardless of the funding source. ORI believes its jurisdiction only extends to projects for which PHS funds are requested or provided. (42 U.S.C. § 289b(b), 42 C.F.R. Part 50, Subpart A.)

The mere existence of an assurance does not give ORI authority over non-PHS matters. Nor does an institution's use of ORI-approved policies and procedures for non-PHS matters extend ORI's authority to these issues. Rather, an institution may choose to have only one set of policies and procedures for all of its scientific misconduct cases, regardless of the funding

source. ORI's regulation, unlike the Office for Protection from Research Risks' regulation, which is designed to protect human subjects from harm, does not require institutions to use specifically designated procedures for all allegations of research misconduct or retaliation, regardless of funding.

Another argument offered is that any institution that accepts PHS support receives indirect costs to support its research infrastructure. Thus, all research conducted at the institution should be considered to fall under ORI's authority. This would subject all research at the PHS-funded institution to ORI jurisdiction, extending ORI authority beyond that which is granted in the regulation.

Frequently, an institution's report will contain both PHS and non-PHS issues. In these instances, ORI conducts its oversight only on those issues that meet the PHS definition of scientific misconduct. Although ORI may consider non-PHS issues as relevant to demonstrating a larger pattern of conduct or in support of a Government-wide debarment, it will make scientific misconduct findings only on the PHS issue[s]. ORI will not review any scientific misconduct investigation nor any compliance or retaliation matter that is not connected to a PHS-funded research project or to an application to receive funding. Therefore, even if ORI initially accepts a case, if it subsequently determines that there was no PHS funding, ORI will adminis-tratively close the case and take no further action except a referral to another agency, if warranted.

*****

REDUCTION IN ORI CASELOAD CONTINUES IN 1997

In 1997, ORI closed 39 cases and reduced its active caseload to an all-time low of 35. Only six of the active cases preceded 1996. Of those six, one was pending before the Departmental Appeals Board at the end of the year, one was suspended pending final action by the Department of Justice, one was still under review by the institution, and two were in prelitigation review by OGC.

ORI opened 26 new cases in 1997. This is below the range of 35-40 cases opened in previous years. Furthermore, the number of new allegations received dropped to 166 from an average of about 200 in previous years. While it is too early to identify a trend, it is worth noting that the number of misconduct findings in 1997 was identical to the average of 14 findings per year since 1992, suggesting that individuals and institutions are now reporting and pursuing only the most serious allegations. Further observations on case activity may be possible after ORI analyzes the results of the institutions' annual reports due this month.

*****

1997 COMPLIANCE ACTIVITIES EMPHASIZE TECHNICAL ASSISTANCE

In 1997, ORI closed almost all of its compliance cases, reducing the number of open cases from 10 to 1. This reflects both a concerted effort to clean up the backlog of cases, as well as a shift in resources from case compliance activities to policy reviews, which provide a useful opportunity for institutional education and technical assistance.

ORI continued to make progress in ensuring that all major research institutions have appropriate policies and procedures for investigating alleged misconduct by reviewing institutional policies for compliance with the regulatory requirements. ORI completed a total of 338 policy reviews in 1997, resulting in 290 policies being accepted and 48 assurances being inactivated, usually by the institution voluntarily relinquishing its assurance. When asked to submit or revise the existing policy, 66 institutions adopted ORI's model policy.

*****

ARIZONA CONFERENCE EXPLORES MANAGEMENT OF BIOMEDICAL RESEARCH LABORATORIES

A conference will be held in October that will provide various stakeholders--research administrators, laboratory directors, researchers, postdocs, technicians, students and sponsors--with an opportunity to discuss the management of biomedical research laboratories from their perspectives.

The Conference on the Management of Biomedical Research Laboratories will be held October 1-3, 1998, in Tucson under the sponsorship of the University of Arizona and ORI.

"Learning to be a lab director appears to be largely a trial and error experience," Chris Pascal, ORI Acting Director, said. "There is little formal training, guidance, or technical assistance available. We want to address this situation because sound laboratory management is integral to the success of the scientific enterprise. I believe proper training in this area will promote quality and productivity in the lab, but also facilitate research integrity and reduce the opportunity for scientific misconduct."

Pascal continued, "We see the conference as the first step in developing educational materials in this area. The end result of this effort, which we intend to conduct in collaboration with PHS awardee institutions and professional associations, will be educational modules, a handbook, a course, or a standard training workshop."

Because of its exploratory nature, the conference format has been designed to encourage an exchange of views. Presentations on each agenda topic will be followed by extended open discussion and summary sessions. Seven topics will be addressed during the conference--the role of the laboratory director; mentoring; managing the research agenda; quality control; data management; collaborative research; and assigning credit for productivity.

The role of the laboratory director and mentoring will be examined on opening day. The first session will center on the authority and responsibilities of the lab director whose functions are similar to those of a CEO or first-line supervisor. The session will also address managerial skills required by lab directors--communicative, motivational, supervisory, entrepreneurial, negotiating, and conflict resolution.

The first day's afternoon session will explore the requirements of mentoring, the various roles played by a mentor, and the responsibilities of the trainee.

Three topics will be discussed on the second day--managing the research agenda, quality control, and data management. Managing the research agenda or product line requires the selection of research areas, determining the breadth, depth, diversity, and volume of research to be done, handling changes in direction, and responding to competing interests and conflicts of pur-pose generated by multiple funding sources, intellectual property concerns, and the needs of diverse learners--postdocs, graduate and undergraduate students.

The second morning session will examine the means for maintaining quality in the conduct of experiments, and the analysis and reporting of results. This session will also address regulatory compliance. The afternoon session on data management will focus on record-keeping, data retention, data access and ownership, and data sharing.

The final day will deal with collaborative research and the assignment of credit. The morning session will address the exigencies of collaborative research whether the collaboration is at the individual or organizational level. Among the topics to be covered include the elements of a collaborative agreement, the responsibility of collaborators, the rights to collaborative products, technology transfer, conflicts of interest, and the dismantling of collaborative arrangements. The afternoon session will discuss the criteria for assigning credit for productivity, when the assignment will be made, the process by which it is made, and who participates in the process.

For information, call Larry Rhoades, ORI, at (301) 443-5300; e-mail: lrhoades@osophs.dhhs.gov or Alice Langen, University of Arizona, at (520) 621-5196; e-mail: langena@u.arizona.edu.

*****

CASE SUMMARY

S. Ashraf Imam, Ph.D., University of Southern California (USC): Based on a report from USC, as well as information obtained by ORI during its oversight review, ORI found that Dr. Imam, an Associate Professor in the Department of Pathology, USC, engaged in scientific misconduct by including plagiarized material in a grant application submitted to the National Cancer Institute (NCI).

Specifically, Dr. Imam's grant application contained extensive paraphrasing of the text of another researcher's independent grant application to a State agency. Dr. Imam had been given that application by a colleague in confidence. The colleague was a reviewer on the State grant application and requested that Dr. Imam evaluate it and return the application to him. The other researcher's application was subsequently funded. Dr. Imam paraphrased or copied into his NCI application all of the other researcher's specific aims, the background on proposed methods, the experimental design and research plan, and most of the references; only the preliminary results sections of Dr. Imam's application were different.

Dr. Imam has accepted the ORI finding and entered into a Voluntary Exclusion Agreement with ORI in which he has voluntarily agreed, for the 3-year period beginning December 8, 1997, to exclude himself from any Federal grants, contracts or cooperative agreements and to exclude himself from serving in any advisory capacity to the PHS. No scientific publications were required to be corrected.

*****

COURT RULES AGAINST AIDS RESEARCHER

A Federal court recently dismissed a lawsuit brought by Dr. Mikulas Popovic seeking damages relating to the OSI/ORI investigation about the discovery of the AIDS virus. The court ruled that Dr. Popovic had consistently received appropriate due process throughout the investigation and that the OSI/ORI investigation did not intentionally or recklessly inflict any emotional distress on him. Popovic v. United States, No. PJM 96-3106, slip op. (D. MD. Feb. 27, 1998).

*****

POSSIBLE PLAGIARISM FOUND USING MEDLINE® SEARCHES

A researcher's questions about a cryptic note in a Danish medical journal ended up making headlines in Polish newspapers, and creating concerns about that country's ability to investigate charges of research misconduct, according to the January 23, 1998, issue of Science. Danish authors of a paper published in 1989 found a duplicate of their abstract on MEDLINE® under other names, which subsequently led a Danish committee to report that the principal Polish author had admitted the plagiarism and apologized. No names were given in the notice.

A subsequent search of the MEDLINE® database found 125 medical papers published in a variety of specialties over a 13-year period by Andrzej Jendryczko, a Polish engineer who does not hold a medical degree. Comparisons of the texts of 90 papers with suspected-source papers using MEDLINE®'s "find related articles" function turned up nearly 30 questionable papers. The Polish-educated M.D.-Ph.D. who identified the extensive pattern of possible plagiarism was dissatisfied with the Polish authorities' initial reactions to the Danish findings, which was to put

the researcher on 6 months of paid leave.

*****

MORE THAN ONE WAY TO "REPORT" RESEARCH

Scientific misconduct is defined as fabrication, falsification, or plagiarism, etc., in "proposing, conducting, or reporting research." In carrying out investigations into allegations of falsified or fabricated research, most institutions view published abstracts and articles as examples of "reporting research." However, they sometimes neglect to consider other sources in which the questioned research may be "reported."

Research results do not need to be published before they fall within the scientific misconduct definition as reporting research. Data presented in manuscripts or theses or given to a mentor or lab chief as representing the results of experiments also can be considered examples of reporting research, and are covered by the PHS definition of scientific misconduct.

In its oversight of institutional investigations, ORI is particularly interested in reports of questioned research that were made in documents submitted to PHS, notably progress reports included in either competing renewal applications (Type 2) or applications for the continuing years of an approved project (Type 5). Questioned results also may be presented as preliminary data in new grant applications (Type 1). All of these possibilities should be considered during an investigation.

Institutional investigation committees should consider preliminary reports of the questioned research presented at scientific meetings, and evaluate records of these presentations, e.g., slides shown during an oral presentation or text and figures from a poster presentation.

Questioned research data or results also may have been reported to central databases. In multicenter clinical trials or epidemiological research, the questioned data may have been reported to a coordinating center for entry into a central database. Clinical or preclinical data may have been submitted to another agency or falsified or fabricated data may have been reported in a patent application. All these reports may require followup or referral to the appropriate agency or office.

*****

ORI SEEKS STUDENT INTERNS & FACULTY FELLOWS

ORI is seeking undergraduate and graduate students in the biomedical sciences, social sciences, computer science, education, and communications to serve as an unpaid intern this summer to provide assistance in the development of several projects. Projects may include computer

programming/database management, ORI home page development, designing conferences, workshops, and conducting studies and literature reviews.

ORI also invites faculty members to serve as unpaid fellows during the summer or while on sabbatical to provide assistance in devising a research agenda and developing a research group or invisible college focused on research integrity, establishing a fellows program, and the projects listed above.

Send résumé and letter indicating interests to Mary D. Scheetz, ORI. Phone: (301) 443-5300. E-mail: mscheetz@osophs.dhhs.gov.

*****

ERRATUM:

In "Administrative Actions . . . Explained" on page 4 of the December 1997 ORI Newsletter, the last sentence of the fifth paragraph should have read: "The requirement remains in the ALERT system until the letter is received."

*****

PROPOSAL DUE DATES

March 31, 1998
Proposals due for Scientific Misconduct or Research Integrity Conferences/Workshops to be held September - December 1998.

May 29, 1998
Proposals due for Scientific Misconduct or Research Integrity Conferences/Workshops to be held in calendar year 1999.

For proposal guidelines, call ORI at (301) 443-5300 and ask for "Support of Research Integrity Meetings" or see ORI home page.

*****

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

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