



ORI Newsletter

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ORI Closes 25 Cases in 2001; 14 Cases Found Misconduct

Over half of the research misconduct cases (56 percent) closed by ORI in 2001 resulted in misconduct findings, more than doubling the rate of misconduct findings of the previous year, and far exceeding the historical average of 33 percent.

“It is not clear that misconduct rate will persist,” Alan Price, Director, Division of Investigative Oversight, said, “but several nearly-completed cases with possible misconduct findings were carried into 2001.”

“ORI used a new mechanism to close four misconduct cases when institutional officials told us about admissions or willingness by a respondent to close the matter,” Price said. “After the scope of the misconduct and admission were documented, ORI negotiated three-way agreements promptly to settle the cases, all of which involved faculty members.” A three-way agreement involves the respondent, the institution, and ORI.

The 14 cases that ORI concluded with misconduct findings resulted in debarments or voluntary exclusions for 10 respondents ranging from 1-5 years; prohibition from serving as an advisor to PHS for all 14 respondents from 3-5 years; required supervision for 4 respondents for 3 years each, and citation certification of all contributions for 2 respondents for 2 years each. On average, two administrative actions were imposed on each respondent.

“Five-year debarments or voluntary exclusions were imposed on four respondents because of the seriousness of their misconduct,” Price said. Generally, debarments are for 3 years.

The misconduct findings involved 10 cases of falsification and/or fabrication of data, 3 cases of

See ORI Receiving More Allegations on page 4.

Research Conference Announced; Abstracts Due April 8

ORI will convene the 2nd Research Conference on Research Integrity (RRI) at the William F. Bolger Center for Leadership Development in Potomac, MD, on November 16-18, 2002. The keynote speaker will be Kenneth I. Shine, M.D., President, Institute of Medicine.

Continuing the tradition of the 2000 ORI Research Conference on Research Integrity, the second conference will gather scholars from different disciplines to discuss crucial research problems, explore research methods, and share research results to further understand fostering research integrity and deterring research misconduct. The conference will also highlight preliminary findings from the first seven awards made by the ORI research grant program in 2001 with the support of NINDS and NINR (see story in September 2001 *ORI Newsletter*). Abstracts for papers, poster sessions, panel discussions, and working groups related to RRI are welcome. Research areas of particular interest include: authorship and publication, clinical, human or animal subjects, conflict of interest, data management, institutions (universities, centers, hospitals, institutes or societies), mentoring, teaching responsible conduct of research, research climate, and research misconduct. In addition, papers and posters are invited on programs to promote research integrity or assess their effectiveness.

See Conference Abstracts Due on page 6.

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Integrity in Clinical Research May 2-3, 2002

The Cleveland Clinic Foundation and ORI are co-sponsoring a 2-day conference in Cleveland, OH, that will focus on the ethical, institutional, and scientific issues related to integrity in the design and conduct of clinical research. The conference will address the unique questions regarding the responsible conduct of research when the subjects of research are also patients receiving medical care.

Eve E. Slater, M.D., Assistant Secretary for Health, will make the keynote presentation, *Human Subjects Protection: Where Should Responsibility Be Placed?*

Attendees of the conference will have the opportunity to learn about best ethical practices in the context of clinical research, principal investigator and institutional responsibilities for management of clinical research records, mentorship problems and responsibilities, current standards for authorship and publication of the results of clinical investigations, as well as ways of meeting emerging Federal standards for research ethics education.

The conference will fulfill an important need for identifying and reviewing best ethical practices in designing and conducting clinical research, and is organized into plenary sessions, panel discussions, and breakout sessions. Participants will also receive a wide variety of resource materials, including copies of presentations, suggested readings, and a list of resources and references that can be used later for additional staff training. For additional conference information, see <http://www.clevelandclinicmeded.com/courses/research2002.asp>.

UPCOMING MEETING

April 16-17, 2002, Conflicts of Interest and Research Integrity, St. Louis, MO

For information and registration, see <http://research.wustl.edu/vc/news/conflicts.html>

Research Responsibility and Undergraduates, June 19-22, 2002

The Council on Undergraduate Research is planning a special symposium on research responsibility and undergraduate research during its 9th National Conference at Connecticut College, New London, CT. This meeting is being co-sponsored by ORI and Sigma Xi, The Scientific Research Society.

Researchers at primarily undergraduate institutions may not be as familiar with research responsibility issues as those at research universities. Researchers engaged in work with undergraduates have their own especially important ethical issues, and they also should be conveying a solid research ethics perspective to their students.

Therefore, the symposium is focusing on two key issues: (1) ethical issues of special importance to faculty doing research with undergraduates, and (2) ways to instill ethical/responsible research behaviors in undergraduates. The symposium is organized into plenary sessions, workshops and poster sessions.

For conference information, including the agenda and an on-line registration form, see <http://www.cur.org/conferences.html>.

Conference Proposals Due June 1

ORI is seeking proposals from institutions, professional associations, and scientific societies that wish to collaborate with ORI in developing a conference or workshop on promoting research integrity or handling scientific misconduct allegations. The funding available generally ranges from \$5,000 to \$20,000. ORI intends to hold four to six regional conferences or workshops each year in strategic locations around the country.

June 1, 2002, is the next target date for receiving applications. Instructions and an application form are available at <http://ori.hhs.gov>, or call 301-443-5300, or e-mail askori@osophs.dhhs.gov

CONFERENCES CONFERENCES CONFERENCES CONFERENCES

Fostering Integrity in Clinical Research at Academic Medical Centers September 9-11, 2002

A conference focusing on major issues involved in protecting the integrity of clinical research at academic medical centers will be held at the Radisson Plaza Hotel by the Inner Harbor in Baltimore, MD.

Dr. Eve E. Slater, Assistant Secretary of Health, will give the keynote address. The conference, *Fostering Integrity in Clinical Research at Academic Medical Centers* is co-sponsored by the Association of American Medical Colleges (AAMC), the Office for Human Research Protections (OHRP), and ORI.

Other confirmed speakers include Drs. Greg Koski, OHRP; David Clark of Rush-Presbyterian-St. Luke's Medical Center; Eric Gislason, U. Illinois at Chicago; and Chi Van Dang, Johns Hopkins University School of Medicine.

Conference organizers intend to present a comprehensive and coherent program that fosters presentations and discussions of practices which promote high integrity of clinical research at academic medical centers. Certain factors in the management, conduct, and assessment of research programs are known to prevent mishandling the research opportunity with human participants and to enhance the quality of data obtained.

In order to promote consideration of these factors, the conference will include several approaches: the characteristics of an integrated program for coherent oversight and monitoring at the institutional level, the cooperative government programs for oversight of clinical trials, research into the design and monitoring of medical research programs, the perspectives of various personnel responsible for aspects of the research program, reports on experiences in training principal investigators, and specific techniques which prevent or quickly identify and adequately address research integrity problems that may arise.

A workshop following the conference on Wednesday morning, September 11, will provide the opportunity for staff to discuss approaches for implementing a well-run clinical research trial in various settings.

For more information about the agenda or to obtain registration materials, please contact Ms. Tracy Morgan, phone 301-443-5330, fax 301-594-0039, or e-mail: tmorgan@osophs.dhhs.gov.

Research Guidelines Conference September 23-24, 2002

A conference on the role of research guidelines in promoting the responsible conduct of research will be held at the Sheraton Hotel at Society Hill in Philadelphia on September 23-24, 2002. Information on the conference web site, expected to be on-line by the end of March, will be posted on the ORI web site when available.

The conference is part of a threefold effort to stimulate thinking and discussion about the usefulness of research guidelines in preventing misconduct and promoting the responsible conduct of research. It is a followup to the *Analysis of Guidelines for the Conduct of Research Adopted by Medical Schools or Their Components* that is available on the ORI web site under Studies/Reports in the Publications section.

The effort also includes the development of a resource document for developing effective guidelines that will be based, to some extent, on the completed analysis of the medical school research guidelines. The conference and resource document are being developed by NGIT Health Solutions (formerly R.O.W. Sciences, Inc.), under contract with ORI. The study of the medical school research guidelines was also conducted by the same contractor.

3 Listservs Available; Building Community

ORI has created three listservs to facilitate interaction among members of three communities that play important roles in the handling of research misconduct allegations, the promotion of the responsible conduct of research (RCR), and the conduct of research on research integrity: institutional research integrity officers (RIOs), RCR instructors, and researchers on research integrity.

“ORI would like to see these mechanisms provide collegial advice and support for the members of these communities and stimulate productive collaborations,” Chris Pascal, Director, ORI, said. “There is no reason to do this in isolation. ORI will make these listservs prime channels for communicating information to members of these communities.”

The listserv for RIOs is called INSTI-OFFICIALS; for RCR instructors it is RCR-INSTRUCTION, and for researchers on research integrity it is RRI-PROGRAM. You can subscribe to these listservs by accessing the NIH listserv web site at <http://list.nih.gov> by clicking on Browse, selecting the name of the listserv, and providing your e-mail address and full name. Your subscription will be confirmed by e-mail, and you will receive instructions for participating in the listserv. When you access the listserv, you will be asked to create a password that will also be confirmed by e-mail.

Subscribers may post messages on the listservs for RIOs and RCR instructors. Messages on the listserv for researchers may only be posted by the listserv manager.

The listserv managers may be contacted at the following addresses: INSTI-OFFICIALS at instlist@osophs.dhhs.gov; RCR-INSTRUCTION at rcrlist@osophs.dhhs.gov, and RRI-PROGRAM at rri@osophs.dhhs.gov. ☺

Notable Quote

“To maintain the privilege of self-regulation, research institutions must exercise vigilance and diligence in examining the conduct of their own members.” *Responsible Science: Ensuring the Integrity of the Research Process*. Vol. 1:11, NAS, 1992.

Fostering Integrity in Research Environments Conference Slated

A one-day conference will be held October 10, 2002, at the National Academy of Sciences in Washington, DC, to discuss the recommendations that will be made in the Institute of Medicine (IOM) report on *Fostering Integrity in Research Environments* that will be available on-line in July 2002.

In September 2000, ORI commissioned the IOM to produce a report on the conceptual issues related to measuring integrity in research environments. In September 2001, ORI asked the IOM to include in the report recommended actions that could be taken by research organizations to improve the integrity of their research environments. ☺

Conference Proceedings Available

Proceedings from the first ORI Research Conference on Research Integrity, held November 18-20, 2000, are available under “Conference Proceedings” in the Publications section on the ORI web site, <http://ori.hhs.gov>.

ORI Receiving More Allegations

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plagiarism in combination with fabrication or falsification, and 1 case of plagiarism.

In 2001, ORI opened 35 new cases and closed 25 cases, with 41 cases remaining open at the end of the calendar year, slightly more cases than ORI had in 2000. The total processing time for the 25 cases closed in 2001 was 14.6 months, average; 9 months, median, and 4 months, mode. For institutions, processing time was 8.7 months, average; 4 months, median, and 2 months, mode. For ORI, processing time was 5.9 months average; 4 months, median, and 3 months, mode.

The number of allegations received by ORI has increased for 3 consecutive years from 112 in 1998, to 129 in 1999, to 173 in 2000, and to 196 in 2001. ORI has received more than 196 allegations in a single year only once since 1991—244 in 1995. ☺

ORI Technical Assistance Program Expands Institutional Clientele

Institutions are increasingly taking advantage of the technical assistance program begun in late 1999 by ORI to provide support for institutions responding to allegations of research misconduct, especially for the first time.

In 2001, ORI offered technical assistance to 20 institutions; 10 accepted. Six other institutions asked for help on their own. Of the 16 institutions assisted in 2001, 8 were new clients. In 2000, ORI offered assistance to 12 institutions; 6 accepted. Nine other institutions initiated calls for help. A total of 15 institutions were assisted in 2000.

“We are very pleased that institutional officials are accepting our offers of assistance or requesting help when they are responding to research misconduct allegations,” Alan Price, Director, Division of Investigative Oversight, said.

ORI offers assistance to institutions (even experienced ones) that are facing complex or difficult cases as well as to institutions handling their first case. ORI responds to calls for help from any institution or Federal agency.

“In most cases we can provide the needed assistance by phone,” Price said. “Occasionally, we do site visits when the need is significant.” In one case, an ORI analyst spent a week at an institution providing assistance in organizing records. In another case, institutional officials and attorneys visited ORI to resolve questions over ORI jurisdiction and to obtain guidance in opening an inquiry.

ORI also has provided assistance on possible image falsifications, informing a respondent about an allegation, developing investigative strategies, the sequestration of data and other records, and addressing legal questions.

ORI staff will provide such assistance over the telephone at 301-443-5330 or on-site. ☎

Notable Quotes Listed On RCR Instructional Resources Page

Over 60 notable quotes taken from journals, reports, and other documents produced by scientific organizations, associations, and government agencies that may provoke discussion about research integrity, research misconduct, and the responsible conduct of research (RCR) are available on the ORI web site.

The notable quotes are grouped under the following 14 topics: research integrity, research misconduct, whistleblowing, self-regulation, institutional responsibilities, standards, research environments, collaborations, authorship, conflict of interest, mentoring, data management, scientists, and scientific journals. The quotes may be accessed by clicking on Notable Quotes under Quick Links on ori.hhs.gov.

Notable quotes is one of nearly three dozen resources listed on the RCR Instructional Resources page that can also be accessed through Quick Links. At least one resource is listed under eight of the nine core RCR instructional areas proposed by the Public Health Service (PHS). Ten resources are listed in the Comprehensive Resources section, including resources that cover more than one core instructional area.

Instructional resources listed on the web page have been created by Oklahoma State University, the University of Medicine and Dentistry of New Jersey, the University of Nebraska Medical Center, the University of Pittsburgh, the National Academy of Sciences, the American Academy of Microbiology, the American Association for the Advancement of Science, the American Association for Laboratory Animal Science, the American College of Physicians, the American Society of Internal Medicine, the Association for Research Integrity, the Canadian Council on Animal Care, the National Institutes of Health, and ORI.

ORI invites members of the research community, institutions, and organizations to post their resources on the web page, call attention to existing materials on the web, or suggest ideas for resources development. Contact: lrhoades@osophs.dhhs.gov. ☎

CASE SUMMARY

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

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

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

British Funding Agencies Creating Standards for Research Supervisors

British funding agencies are taking steps to establish new standards by 2003 for scientists who supervise research degrees to improve the training of graduate students because those students have complained about poor research supervision in British universities, according to *Nature*.

The Higher Education Funding Council for England, the agency that distributes teaching and infrastructure funding to English universities, expects to tie the new standards to the funding it provides to universities and departments.

The Biotechnology and Biological Sciences Research Council, a life-sciences funding agency, has announced a voluntary national training and accreditation program for research supervisors that is not linked to funding. The program assesses the qualifications of researchers to plan research projects and monitors student progress. ☺

Conference Abstracts Due April 8

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Preference will be given to original investigations that open new research areas, use new research methods, or provide new insights into recognized research problems. Proposals for theoretical or methodological presentations, historical analyses, and interpretive literature reviews will also be considered. Abstracts for all presentations and proposals must be submitted electronically. Abstracts are due **April 8, 2002**.

See the ORI web site for details on submitting abstracts and conference schedule as it develops at <http://ori.hhs.gov> or e-mail conference co-chairs, Nick Steneck at nsteneck@umich.edu or Mary Scheetz at mscheetz@osophs.dhhs.gov. ☺

Notable Quote

"For research universities to retain their standing as independent arbiters of knowledge, research must continue to be conducted according to the highest ethical standards." *Report on Individual and Institutional Financial Conflict of Interest*. Association of American Universities, Oct. 2001.

German Investigators Protest Editing of Misconduct Report

Scientists who investigated the biggest research misconduct case in Germany are questioning whether DFG, the country's main research funding agency, is the appropriate body for handling allegations of research misconduct after the agency altered the report submitted by its task force, according to *Nature*.

The DFG president said the press conference announcing the final report would have had to be canceled if the passages describing alleged irregularities in two papers were not deleted because of pressure being applied by a lawyer for one of the respondents. All three authors associated with those papers were banned by DFG from serving as peer reviewers for specified periods. In total, the investigation involved 6 scientists and about 94 suspicious papers.

The head of the task force argues that the DFG did not have the authority to alter the task force report. He further stated, "What we need is a truly independent panel to handle investigations."☺

ORI MAIL DELIVERY PROBLEMS

Institutional officials who send notices or reports to ORI should be aware that, given the concerns in recent months about contamination of Federal mail, items sent to ORI in the regular U.S. mail may be delayed or returned by the mail handlers. Thus, it is best in the interim to send short items to ORI by facsimile, or, for larger items, call ORI about using an express mail service for direct delivery to ORI.

AAMC Issues COI Guidelines; Calls for Education, Training

The first of two reports on financial conflicts of interest (COI) in clinical research slated to be developed by the AAMC Task Force on Financial Conflicts of Interest in Clinical Research is available at <http://www.aamc.org/members/coitf/start.htm>.

Under a section on policy implementation, the report states that institutions should adopt mechanisms for disseminating conflict of interest policies to all faculty, staff, students, and trainees, and for providing appropriate education and training in these policies.

The first report, *Protecting Subjects, Preserving Trust, Promoting Progress - Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research*, will be followed by a second report on institutional financial interests in human subjects research later this year.

The report contains 6 principles that the Task Force recommends be addressed in institutional policies on individual financial interests in human subjects research. Those principles are related to (1) a presumption against a researcher having a significant financial interest in the human subjects research he/she conducts; (2) compelling circumstances that would permit an individual to conduct human subjects research even though he/she may have a significant financial interest in that research; (3) procedures for reporting significant financial interests in research; (4) transparent implementation, monitoring, and enforcement of the conflict of interest policy; (5) rigorous monitoring of research when a financial interest is justified by compelling circumstances; and (6) the shared responsibility for oversight of financial interests in human subjects research.

The Task Force warns, "The credibility of academic medicine - and the public trust we prize so highly - could be undermined by revelations that an institution has failed to exercise rigorous oversight of financial interests in human subjects research and may thereby have exposed those subjects to avoidable harms."☺

Wellcome Trust Publishes New Grant Conditions

Institutions that apply for research funding from the Wellcome Trust will have to establish guidelines for good research practice and procedures for investigating allegations of research misconduct by October 1, 2002. These requirements cover all the research that the Trust funds at host institutions in the United Kingdom and the Republic of Ireland. Host institutions in other countries will be expected to adhere to the spirit of the Trust's guidelines on good research practice. See <http://www.wellcome.ac.uk/en/1/awtvispolgrpgid.html> 

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ORI NEWSLETTER

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