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Office of Research Integrity

NEWSLETTER

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.

IN THIS ISSUE

RCR Expo Set for SRA Meeting in Pittsburgh

ORI will hold the first Responsible Conduct of Research (RCR) Expo on October 18-22, 2003, at the David Lawrence Convention Center in Pittsburgh at the national meeting of the co-sponsoring Society of Research Administrators (SRA) International.

Institutional officials or individuals interested in exhibiting at the RCR Expo should send a 150-word description of their RCR resource to Loc Nguyen-Khoa at lnguyen-khoa@osophs.dhhs.gov by April 30, 2003. Further information will be posted on the ORI web site as it becomes available.

John Feather, Executive Director, SRA, said, "This will be an opportunity to bring the most current and innovative practices on RCR directly to those who have responsibility for implementing and ensuring the responsible conduct of research." About 1,400 research administrators attend the SRA national meeting.

The RCR Expo will enable creators of RCR resources to display, demonstrate, and discuss their products while providing potential users with an

RCR Expo continued on page 6

RCR Guidebook Coming This Fall

ORI expects to make its long-awaited *Guide to the Responsible Conduct of Research* (*RCR*) available this fall following completion of the final review process.

ORI plans to send each organization that has an active misconduct assurance a single copy of the publication. The *Guide* will also be posted on the ORI web site. Additional information on the availability of the *Guide* will appear in this newsletter and on the ORI web site.

"Our goal in producing the *Guide*," Larry Rhoades, Director, Division of Education and Integrity, said, "is to provide mid-size research institutions and beginning researchers with a manageable introduction to the responsible conduct of research. The content is thought provoking, and not official ORI policy. It is intended as a helpful resource that can be used along

RCR Guidebook continued on page 3

4 Academic Societies Get RCR Awards

Four academic societies have received the first awards made under the Association of American Medical Colleges (AAMC)/ORI cooperative agreement to encourage academic societies to undertake activities aimed at promoting the responsible conduct of research (RCR).

Additional awards will be made in the second round that had a submission deadline of March 14, 2003. Submission deadline for the first round was November 15, 2002. Details are available at http://www.aamc.org/programs/ori/. Subsequent submission deadlines will be announced provided that funding is available.

The recipients, project titles, and funding levels are presented below. Abstracts of these projects are available on the ORI web site at http://

Academic Societies continued on page 3

2 Accrediting Human Research Protections

Two organizations are competing to accredit human research protection programs at universities, colleges, medical centers, and hospitals.

The newest organization, Partnership for Human Research Protection, Inc., is a collaboration between the Joint Commission on Accreditation of Healthcare Organizations and the National Committee for Quality Assurance.

Last year, the Association for the Accreditation of Human Research Protection Programs, Inc., was founded by the Association of American Medical Colleges, the Association of American Universities, the Consortium of Social Science Associations, the Federation of American Societies for Experimental Biology, the National Association of State Universities and Land Grant Colleges, the National Health Council, and Public Responsibility in Medicine and Research.

OPHS and OHRP Get Acting Heads

Two key positions related to responsible conduct of research (RCR) activities within the PHS will be directed by acting heads until permanent appointments are made.

Eve Slater, M.D., Assistant Secretary for Health (ASH), resigned in February to pursue other undisclosed opportunities. As the ASH, Dr. Slater headed the Office of Public Health and Science (OPHS), which includes the Office for Human Research Protections (OHRP) and ORI. Surgeon General Richard Carmona is the Acting ASH.

Last year, Greg Koski, M.D., OHRP Director, returned to the Massachusetts General Hospital. Bernard A. Schwetz, D.V.M., Ph.D., senior advisor for science and former Acting Commissioner of the Food and Drug Administration, was detailed February 1, 2003, to serve as Acting Director of OHRP

Electronic Administration Adopted for Conferences

ORI is converting its conference, workshop, and meeting program to electronic administration beginning with the proposals due on June 1, 2003, as part of the Federal Government effort to promote e-government.

The instructions for proposal preparation posted on the ORI web site at http://ori.dhhs.gov/ html/ programs/meetingprop.asp will be revised to accommodate the administrative change.

ORI has been gradually switching to electronic program administration since 2000 when abstracts and papers for the first Research Conference on Research Integrity were submitted electronically. Since then, electronic administration has been adopted for the Annual Report on Possible Research Misconduct, the RCR (Responsible Conduct of Research) Resource Development Program, and the Assurance Program.

Listservs Available

ORI operates listservs for RCR instructors, research integrity researchers, and research integrity officers. Subscribe to one or all by accessing the NIH listserv web site at http://list.nih.gov; click on Browse, select the listserv name, and provide your e-mail address and full name.

New Research on Research Integrity RFA Available in May

The new request for applications (RFA) for the Research Program on Research Integrity that is expected to be issued in May 2003 will target specific topics on which research is needed.

The RFA will be published in this newsletter and the *NIH Guide to Grants and Contracts* and posted on the ORI web site when available. The deadline for submissions is November 15, 2003.

Thirty-one applications were submitted in the third round. These applications were reviewed in March; awards will be made by September 30, 2003. Abstracts of the 16 studies underway are posted on the ORI web site at **ori.dhhs.gov/ html/programs/research.asp**.

Program sponsors are the National Institute of Neurological Disorders and Stroke, the National Institute of Nursing Research, the National Institute on Drug Abuse, and ORI.

Research on Research Integrity Topics Suggested by IOM Report

Numerous deficiencies in the knowledge base related to research integrity, the responsible conduct of research, and research misconduct are cited in the Institute of Medicine (IOM) report on *The Responsible Conduct of Research in the Health Sciences.*

The knowledge deficiencies are summarized on the ORI web site in Potential Research Topics, which may be found under Research in the Program section. The potential research topics are categorized under three main headings—Research Community, Professional Development, and Research Process—and 14 subheadings.

ORI Relocates to Tower Building in March

ORI moved in March to its new quarters in the Tower Building, 7th Floor, 1101 Wootton Parkway, Rockville, MD 20852. Phone and fax numbers, and e-mail addresses have not changed.

Besides ORI, the Tower Building houses several other units of the Office of Public Health and Science (OPHS), including the Office for Human Research Protections.

Visitors can still reach ORI by Metro, but after exiting the Red Line at the Rockville or White Flint stations they will have to take a cab to the Tower Building, which is adjacent to Interstate 270 near the Montrose Road exit. A shuttle is expected to be operating in the near future.

The most direct route to reach the Tower Building by car is to take Interstate 495 (the Beltway around Washington) to Interstate 270, and exit on Montrose Road East. Follow signs to Tower Oaks Road, turn left onto Wootton Parkway and right to the building. We expect to post a map on the ORI web site for your information.

Academic Societies Urged to Define Standards (from page 1)

ori.dhhs.gov/html/programs/rcr_requirements.asp.

American Psychiatric Institute for Research and Education/American Psychiatric Association, *Developing an Ethics Curriculum for Psychiatric Research,* $25,000.

Ambulatory Pediatric Association, *Promoting Research Integrity in General Pediatrics,* $25,000.

American Thoracic Society, *Guidelines for the Ethical and Legal Conduct of Clinical Research Involving Critically Ill Patients,* $24, 954.

Association of Academic Physiatrists, *Program on Ethical Elements of Rehabilitation Research,* $5,000.

Jordan Cohen, AAMC president, said, "AAMC believes academic societies should play a crucial role in defining and promoting standards for the responsible conduct of research in their respective disciplines. We believe academic societies must be more active in fulfilling this role and this program is intended to encourage such initiatives." Any academic society whose members conduct biomedical or behavioral research supported by the U.S. Public Health Service is eligible to apply.

The applications were reviewed by AAMC and ORI staff, and outside reviewers. ORI made the final funding decision based on the review results and AAMC's recommendations.

AAMC and ORI entered into the cooperative agreement to make awards to academic societies to undertake activities aimed at promoting the responsible conduct of research. The award program has two categories: The first category will fund awards of $5,000 each to support single events or limited activities such as special meetings, national conferences, or a publication. The second category will fund awards of up to $25,000 each for major program initiatives aimed at promoting the responsible conduct of research, such as the development of research guidelines, a code of research ethics, instructions for authors, a curriculum module, etc.

RIO Workshop Slated for Connecticut in October

A 2-day workshop for new and experienced institutional research integrity officers (RIOs) will be held at the Avon Old Farms Hotel in Farmington, Connecticut, on October 9-10, 2003, co-sponsored by the University of Connecticut Health Center, the University of Connecticut, and ORI.

The first day will introduce new RIOs to a description of the RIO role, maintaining an institution's eligibility for PHS funding, the development of institutional policies and procedures for responding to research misconduct allegations, the fundamentals of conducting an inquiry and investigation, the oversight mission of ORI, and the protection of whistleblowers and respondents.

The second day will further the development of experienced RIOs by addressing advanced issues in handling allegations of research misconduct and taking an institutional perspective on research integrity, continual quality improvement, self-assessment and evaluation. A mock misconduct case discussion will also be conducted.

In addition, a breakout session will focus on assessing and triaging allegations of research misconduct, legal issues associated with research misconduct cases, institutional assessment, and the recommendations made by the IOM report on *Integrity in Scientific Research: Creating an*

RIO Workshop continued on page 4

RCR Guidebook (from page 1)

with other books and web pages to learn about or teach RCR."

The *Guide* introduces the reader to the nine RCR core instructional areas in four sections that follow the normal flow of research from a consideration of shared values to planning, conducting, reporting, and reviewing research.

At roughly 100 pages in length, paperback-book size, and with a relaxed format, the *Guide* should be an easy 3-hour read. The basic text is supplemented with text-box inserts, discussion questions, bibliography, and illustrations.

NEJM to Verify Authors Before Publication

All authors of manuscripts submitted to the *New England Journal of Medicine* (NEJM) will be verified by e-mail after acceptance and before publication to prevent authors from claiming bogus coauthors by falsifying signatures on letters of transmission.

The new policy was announced by NEJM editors on March 6, 2003, in an editorial announcing the retraction of an article by several authors based on "incomplete manuscript review by the authors and false signatures on submitted documents."

"It is never acceptable for one author to sign on behalf of another, even with that coauthor's permission. In the matter of authorship, all signatures must be genuine," the editorial asserts.

"Of the eight persons named as authors of the article, some claimed that they had never reviewed the original data and most claimed that they had not seen or approved either the original version or one or more of the three revised versions of the manuscript. Thus, there was an egregious disregard of the principles of authorship, as specified by the International Committee of Medical Journal Editors," the editorial reported.

"To their credit," the editorial continues, "when the offense became apparent, several of the authors of the article promptly communicated the facts to us and concurred with the need for retraction."

A coauthor acknowledged to the editors that he had falsified signatures on the letters of transmission accompanying the original and revised versions of the manuscript. "Although we never proceed with our review of a manuscript until we have the signature of each of the authors," the editors said, "we cannot verify the authenticity of the signatures sent to us. We believe this to be a matter of basic trust between authors and editors."

". . . this unfortunate incident serves as a reminder to the medical community that with the privilege of authorship comes a mandate for personal and professional responsibility that must be taken seriously," the editorial stated.

How Many Cited Papers Are Not Read by Citing Authors?

A study of 4,300 citations to a seminal paper on condensed-matter physics concluded that 4 out of 5 citing authors did not read the paper because the miscitations of the paper were often identical to each other, according to *Nature*.

The study was conducted by Mikhail Simkin and Vwani Roychowdhury, UCLA electrical engineers, who wanted to estimate how often errors in citation lists are passed on through other papers. Simkin and Roychowdhury reasoned that these errors are repeated because the papers are copied from someone's citation list rather than read and cited independently.

A physicist who has studied citation statistics thought the above estimate (20 percent) on original reading may be low. His estimate is 50 percent.

RIO WORKSHOP (from page 3)

Environment That Promotes Responsible Conduct.

A conference web site will be created that will provide information on the program, registration, hotel reservations, and travel. Information will be posted on the ORI web site and published in this newsletter as it becomes available.

Retreat Scheduled On Journals' Role In Misconduct Cases

Controversial issues surrounding the journal's role in scientific misconduct cases will be debated during a retreat co-sponsored by the Council of Science Editors (CSE) and ORI from November 7-9, 2003 at the Landsdowne Conference Center, Leesburg, Virginia.

The retreat is open to any professional who works with scientific publications. Participants will have a chance to explore the ethical, legal, and pragmatic implications of scientific misconduct cases in discussion with a roster of experts including editors of preeminent scientific journals, officers of academic institutions, and representative of oversight agencies.

Sessions will focus on issues related to three controversial topics: handling suspect manuscripts, the aftermath of a research misconduct case, and prevention.

Handling suspect manuscripts will be approached from several perspectives and small group discussions of case studies will be conducted. The session on the aftermath of a research misconduct case will address such topics as retractions, corrections, uncooperative authors and journals, Medline issues, sanctions, and communication among journals. The final session will consider what role, if any, do journals have in preventing the publication of manuscripts based on research misconduct and adopting policies to prevent research misconduct.

For more information, visit the CSE web site [http://www.CouncilScience Editors.org] or contact CSE at 703-437-4377. Additional information will also be available on the ORI web site and in this newsletter.

Percentage of Cases in 2002 Finding Misconduct Exceeds Historical Average

The percentage of misconduct cases closed by ORI in 2002 that resulted in a finding of research misconduct was lower than in 2001, but still exceeded the historical average of 33 percent for the second straight year.

Thirteen of the thirty cases closed in 2002 concluded with research misconduct findings (43.3 percent). In 2001, 56 percent of the closed cases produced misconduct findings. ORI administratively closed two other cases because PHS jurisdiction could not be established.

Alan Price, Associate Director, Division of Investigative Oversight, has asked several institutional officials "whether an epidemic of misconduct is occurring " because 90 percent of the 25 other cases pending decision in ORI involve institutional findings of misconduct.

The 191 allegations or queries received in 2002 was slightly below the 197 received in 2001, and considerably above the 173 received in 2000. Pre-inquiry assessments on 52 allegations resulted in 41 new cases. Twenty allegations were referred to other agencies; no action could be taken on 119 allegations because of insufficient information.

Research misconduct findings were made against four faculty members, four postdoctoral and research scientists, two graduate students, and three undergraduate students and technicians. One fellow, who was found to have falsified data for his postdoctoral work, was later confirmed following ORI's questions regarding a statement made by his mentor, to have falsified one section of his doctoral thesis data.

All 13 misconduct findings involved fabrication and/or falsification; one findings also included plagiarism. Misconduct findings were made against 13 persons in these cases. Administrative actions imposed by PHS were debarment (eight), supervision plans (three), and /or certification requirements (one). All 13 persons were prohibited from serving in an advisory capacity to the PHS. Retractions were required for nine publications involved in six cases.

The average processing time for cases closed in 2002 was 7.0 months, which is below ORI's goal of 8 months. Twenty-three closed cases (72 percent) were closed within the 8-month goal.

Record Number of Institutions Accept ORI Technical Assistance

Ninety-five percent of the institutions ORI offered technical assistance in handling an allegation of research misconduct accepted the offer in 2002, establishing two records for the ORI Rapid Response Technical Assistance Program.

In 2002, technical assistance was offered to 21 institutions; 20 accepted; 9 were institutions that had not previously used the service. The same number of invitations were made in 2001 when 10 institutions accepted. In 2000, offers of technical assistance were made to 12 institutions and 6 accepted.

The 20 institutions assisted in 2002 also established a record. In the 2 previous years, 16 and 15 institutions received ORI service respectively. Some institutions initiated the request for assistance without an invitation from ORI. The program began in late 1999.

ORI generally offers technical assistance to institutions that do not have significant experience in handling allegations of research misconduct. In 2002, ORI offered technical assistance to institutions involved in 21 of 41 new cases.

Alan Price, Associate Director for Investigative Oversight, ORI, said, "Early discussion of cases is extremely important for institutions and ORI because it increases the probability that the cases will be efficiently processed and well-documented."

Almost all of the ORI assistance was provided by phone, letter, or e-mail. Two university officials, one from a foreign country, visited ORI for extensive discussions. In another case, ORI staff visited an institution with NIH program auditors to evaluate allegations of falsification in a clinical cancer prevention trial.

ORI staff provided specific and substantive advice on the handling of allegations and respondents, sequestration of evidence, evaluation of "admissions," technical analysis of images and digits, ORI-developed forensic techniques, possible waiver of investigations accompanied by full admissions, and negotiation of three-way agreements among the respondent, institution, and ORI.

The technical assistance was provided to a variety of institutions including universities, medical centers and schools, hospitals, and research institutes. Institutional officials may take advantage of this service by calling 301-443-5330.

Case Summaries

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

Mr. Eagan entered into a Voluntary Exclusion Agreement in which he voluntarily agreed 5 years, beginning January 13, 2003: (1) to exclude himself from procurement and non-procurement transactions, including but not limited to contracts, subcontracts, grants and cooperative agreements with the U.S. Government; and (2) to exclude himself from serving in any advisory capacity to PHS. Mr. Eagan had admitted to falsification of data in an earlier case.

Michael B. Ganz, M.D., Case Western Reserve University (CWRU): Based on the CWRU investigation report and additional ORI analysis, PHS found that Dr. Ganz, Associate Professor of Medicine, CWRU, engaged in scientific misconduct by falsification and fabrication of research in grant application R01 DK058674-01A2, "The role of protein kinase C and shuttling proteins in diabetic kidney disease," submitted to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH. Specifically, PHS found that Dr. Ganz engaged in scientific misconduct by: (1) falsifying Figure 16 in NIH grant application R01 DK058674-01A2 by claiming that photomicrographs of glomeruli were from a streptozotocin model of induced diabetes in rat, while the photomicrographs were actually from tissue of human or other primate origin; (2) falsifying Figure 16 of this NIH grant application by claiming that six photomicrographs all represented glomeruli from different animals, whereas they actually were from only three different glomeruli, with each glomerulus being shown in two images with different orientations and/or magnifications; and (3) falsifying and fabricating documents, purportedly showing the source of the falsified Figure 16 in the NIH grant application, which Dr. Ganz provided to the CWRU inquiry committee. The research was significant because it was designed to develop a therapy to prevent the progressive glomerular hypertrophy and matrix deposition that occur with the renal disease associated with diabetes in animals and humans.

Dr. Ganz entered into a Voluntary Exclusion Agreement in which he voluntarily agreed for 5 years, beginning December 18, 2002: (1) to exclude himself from procurement and non-procurement transactions, including but not limited to contracts, subcontracts, grants and cooperative agreements with the U.S. Government; and (2) to exclude himself from serving in any advisory capacity to PHS.

Notable Quote: Trimming and Cooking

"Whether or not you agree that trimming and cooking are likely to lead on to downright forgery, there is little to support the argument that trimming and cooking are less reprehensible and more forgivable. Whatever the rationalization is, in the last analysis one can no more be a little bit dishonest than one can be a little bit pregnant." *Honor in Science,* p. 14. Sigma Xi, The Scientific Research Society, 1997.

Psychological Association Expels 14 Members

Fourteen members were expelled by the American Psychological Association (APA) between June 10, 2001, and June 26, 2002, for convictions of felonies, delicensure, suspension of license, expulsion from a state association, or violations of the APA Ethics Code. Three other members resigned their membership while under ethics investigations.

The expulsions were recommended to the APA Board of Directors by the APA Ethics Committee. Notice of the expulsions was sent to APA members with their membership renewal notices.

Seven expulsions were based on license problems including revocation (two), surrender (two), and suspension (three). Four others were based on violations of the APA Ethics Code. The remaining three expulsion were based on a stayed suspension of a psychological associate certificate, surrender of a psychological assistant registration, and a felony conviction.

RCR Expo Seeks Range of Approaches (from page 1)

opportunity to review those resources and discuss their needs and available options, thereby generating a dialogue among and between creators and users of RCR resources.

Chris Pascal, Director, ORI, said, "We greatly appreciate the cooperation we are receiving from SRA in organizing this unprecedented event. The SRA national meeting provides an ideal setting for initiating this community-based effort."

ORI hopes the RCR Expo will attract a broad range of approaches to teaching RCR including various formats (in-lab mentoring to campus-wide web programs), subject matter (general and specialized treatments of the nine core areas or others), and audiences (undergraduates, graduate students, postdocs, experienced researchers, and research administrators). In addition, the resources could address training the trainers, recordkeeping, testing, and other aspects of implementing an RCR program.

IOM Report Defines Integrity in Research

Integrity in research is defined on the individual and institutional levels in the Institute of Medicine Report on *Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct:*

Individual Level

For the individual scientist, integrity embodies above all a commitment to intellectual honesty and personal responsibility for one's actions and to a range of practices that characterize the responsible conduct of research, including:

- intellectual honesty in proposing, performing, and reporting research;
- accuracy in representing contributions to research proposals and reports;
- fairness in peer review;
- collegiality in scientific interactions, including communications and sharing of resources;
- transparency in conflicts of interest or potential conflicts of interest;
- protection of human subjects in the conduct of research;
- humane care of animals in the conduct of research; and
- adherence to the mutual responsibilities between investigators and their research teams.

Institutional Level

Institutions seeking to create an environment that promotes responsible conduct by individual scientists and that fosters integrity must establish and continuously monitor structures, processes, policies, and procedures that

- provide leadership in support of responsible conduct of research;
- encourage respect for everyone involved in the research enterprise;
- promote productive interactions between trainees and mentors;
- advocate adherence to the rules regarding all aspects of the conduct of research, especially research involving human participants and animals;
- anticipate, reveal, and manage individual and institutional conflicts of interest;
- arrange timely and thorough inquiries and investigations of allegations of scientific misconduct and apply appropriate administrative sanctions;
- offer educational opportunities pertaining to integrity in the conduct of research, and
- monitor and evaluate the institutional environment supporting integrity in the conduct of research and use this knowledge for continuous quality improvement.

The IOM report may be accessed through the ORI web site by clicking on Studies/ Reports under Publications. Copies of the report are available in complete or summary form from ORI while the supply lasts.

Conference/Workshop/Meeting Proposals Due June 1, 2003

ORI is seeking proposals from institutions, scientific societies, and professional associations that wish to collaborate with ORI in developing conferences, workshops, symposia, colloquiums, seminars, and annual meeting sessions that address the responsible conduct of research, research integrity, or research misconduct. ORI will provide up to $20,000, depending on the event proposed.

Proposals are welcomed any time, with **June 1, 2003,** serving as the next target date for receipt of applications. Proposal instructions and an application form are available on the ORI web site at http://ori.dhhs.gov/ html/programs/ conf-workshops.asp. Please submit your proposal electronically to cfassi@osophs.dhhs.gov. Dr. Carolyn Fassi may be reached at 301-443-5300.

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