Department of Health and Human Services • Office of the Secretary • Office of Public Health and Science

Volume 16, No. 3 http://ori.hhs.gov June 2008

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. Please duplicate and circulate this newsletter freely. An electronic copy is available on the ORI home page.

IN THIS ISSUE

Study Finds Mismatch between Observing and Reporting Suspected Research Misconduct

A study of suspected research misconduct conducted by the Gallup organization in collaboration with ORI suggests there is a large discrepancy between the number of incidents of suspected research misconduct observed by researchers and the number of such incidents reported by institutions to ORI.

At press time, the study findings were scheduled to be published in *Nature* on June 19, 2008, as a commentary by Sandra Titus, Director of Intramural Research, ORI; James Wells, former Study Director, Gallup; and Lawrence Rhoades, former Director, Division of Education and Integrity, ORI. The final report is on the ORI web site at *http://ori.hhs.gov/publications/studies.shtml*

This finding is based on the responses from 2,212 NIH-supported

See Recommendations, page 4

Proposals Wanted from Grad Schools for Creating Institutional Models for RCR Education

The Council of Graduate Schools (CGS) is seeking proposals from its member institutions that wish to collaborate in a project designed to produce institutional models that take a comprehensive approach to intertwining the ethical and responsible conduct of research into the fabric of graduate education.

This project, supported by ORI, will make five $50,000 awards to institutions that are selected through a competitive review process. All U.S. CGS member institutions may apply. The application deadline is July 30, 2008; awards will be announced on September 20, 2008.

See Three, page 2

RRI Program Limited to R21 Mechanism

The Research on Research Integrity (RRI) Program will use only the Exploratory/Developmental Grant (R21) funding mechanism in FY 2009 because only one of the 23 applications submitted in FY 2008 was for a Pilot or Small Grant (R03).

The 2009 Funding Opportunity Announcement (FOA) for the RRI program is expected to be issued in September with application deadlines in mid-November. When issued, the FOA will be available on the ORI web site and in the *NIH Guide for Grants and Contracts*.

The R21 is intended to encourage new, exploratory, and developmental research. The mechanism provides support for developing expertise,

See RRI, page 3

Three Phenomena Call for Emphasis on Integrity in Grad Education *(from page 1)*

Universities that are not selected to receive awards will be invited to participate as affiliates. The projects will begin this September and conclude in July 2010.

A background paper, *The Project for Scholarly Integrity in Graduate Education: A Framework for Collaborative Action,* and the request for proposals (both available on the CGS home page) make the case for an institutional effort to weave responsible conduct of research into graduate education as follows:

"Research integrity is not simply an individual value, it is also an institutional value reflected in the culture that is reinforced by the processes in place and the daily decisions of individual researchers, faculty and mentors, campus leaders, and administrative staff."

"Recent efforts to place greater emphasis on research integrity in graduate education are important in the context of three phenomena: (a) an increase in the number of reported cases of misconduct, nationally and internationally; (b) the encroachment of external pressures upon academic research as interaction and interdependence intensifies among academic, commercial, and government sectors; and (c) the expanding scope of researchers' responsibilities as a consequence of the globalization of the scientific community."

"What is needed now, more than ever, is for university leaders and scholars to work together to ensure that a strong tradition of research integrity evolves to meet these new challenges."

Besides the development of institutional models, the project is also aimed at expanding the cadre of graduate deans fostering a climate of research integrity in graduate education and at promoting community-wide activity through publications, frequent meetings, a scholarly integrity web site, and interactive media.

The collaborative nature of the effort will be emphasized by sharing instruments, resources, and models for curricular and administrative integration among the participants throughout the project and with the graduate community through CGS meetings and workshops, on-line resources, and publications. University projects will be featured on an interactive web site that will serve as a resource clearinghouse and a forum for exchanging information and advice.

A monograph detailing the institutionalization efforts of the awardee institutions will emphasize what best practices are scalable and transferable to other institutional contexts. The monograph will be released in conjunction with a capstone conference in October 2010 that expects to attract graduate deans, researchers, corporate leaders, government officials, and foundation officers to discuss project results and additional efforts to make responsible conduct of research a vibrant part of graduate education.

Postdoc Association Creates Toolkit that Provides Advice on Postdoc RCR Training

Five general recommendations on developing responsible conduct of research (RCR) programming that is responsive to the particular needs and concerns of postdocs are available in a toolkit on the National Postdoctoral Association (NPA) web site.

The RCR toolkit, created with ORI support, was developed by the NPA to assist postdoc offices, postdoc associations, supervisors, and mentors in meeting the training needs of postdocs.

The toolkit provides advice and resources on how to plan and design a program, identify objectives and RCR topics pertinent to postdocs, tailor programs to postdocs, select program formats, evaluate programs, and market the activity to postdocs.

The toolkit offers the following five general recommendations for tailoring RCR programs to postdocs:

Supervisors Are Key to a Postdoc's RCR Training

"The relationship between a postdoc and his or her supervisor is a critical one, since postdocs are particularly reliant upon their supervisors for both financial and infrastructural support, as well as further career advancement. Thus it is important to involve postdoc supervisors with RCR training, whether they actively participate as a mentor in these topics or merely support the postdoc's participation in a more formal program."

See Advice, page 6

ORI Research Conference on Research Integrity Abstracts Are Due October 31

The deadline for submitting abstracts to the fifth biennial ORI Research Conference on Research Integrity scheduled for May 15-17, 2009, is October 31, 2008.

The ORI Research Conferences provide a forum for scholars from different disciplines to discuss crucial research problems, explore different research methods, and share research results, with the ultimate goal of furthering understanding about ways to foster integrity and deter misconduct in research. ORI is particularly interested in presentations that bring empirical evidence to bear on issues such as:

- the factors that encourage or discourage responsible professional practices in research,
- the impact of unprofessional practices on the research record and their costs to society,
- the relative importance of misconduct (fabrication, falsification, and plagiarism) vs. questionable research practices,
- the effectiveness of different ways to foster responsible conduct in research, and
- the role of research institutions in promoting responsible behavior and responding to irresponsible behavior in research.

The conference is open to studies of all fields of research and research methodologies. Presentations are welcomed that focus on specific aspects of research, from study design, to data collection and management, to publication and peer review.

Abstracts should be submitted to Cynthia Ricard, Director, Extramural Research, at Cynthia.Ricard@hhs.gov.

For further information and questions about appropriate research areas, please feel free to contact Cynthia Ricard.

RRI Program Limited to R21 *(from page 1)*

collecting data, and publishing in a new research area. These awards are limited to two years and a total direct cost of $275,000. For more information on the R21 mechanism, see *http://grants1.nih.gov/grants/funding/r21.htm*

For further information, contact Dr. Andrea Sawczuk, National Center for Research Resources (NCRR), at SawczukA@mail.nih.gov or Dr. Cynthia Ricard, ORI, at Cynthia Ricard@hhs.gov. NCRR provides grant management and review services for the RRI program.

UPCOMING CONFERENCE

October 2-3, 2008

Challenges and Tensions in International Research Collaborations

University of Minnesota

Sponsor:

University of Minnesota

Six New RRI Articles Published

Broome, ME. "Collaboration: The Devil's in the Detail." *Nursing Outlook* 2007, 55(1): 1-2.

Djulbegovic B, Kumar A, Soares HP, Hozo I, Bepler G, Clarke M, Bennett CL. "New Cancer Treatment Successes Identified in Phase 3 Randomized Controlled Trials Conducted by the National Cancer Institute-Sponsored Cooperative Oncology Groups, 1955 to 2006." *Archives of Internal Medicine* 2008, 168(6): 632-642.

Kligyte V, Marcy RT, Sevier ST, Godfrey ES, Mumford MD. "A Qualitative Approach to Responsible Conduct of Research (RCR) Training Development: Identification of Metacognitive Strategies." *Science and Engineering Ethics* 2007, 14(1): 3-31.

Klitzman R, Exner T, Correale J, Kirshenbaum SB, Remien R, Ehrhardt AA, Lightfoot M, Catz SL, Weinhardt LS, Johnson MO, Morin SF, Rotheram-Borus MJ, Kelly JA, Charlebois E. "It's Not Just What You Say: Relationships of HIV Disclosure and Risk Reduction among MSM in the Post-HAART Era." *AIDS Care* 2007, 19(6): 749-756.

Lind RA, Lepper TS. "Sensitivity to Research Misconduct: A Conceptual Model." *Medical Law*, 2007, 26(3): 585-598.

Mello MM, Joffe S. "Compact versus Contract-industry Sponsors' Obligations to Their Research Subjects." *New England Journal of Medicine 2007*, 356(26): 2737-2743.

Recommendations Made to Institutions for Fostering Culture of Integrity *(from page 1)*

principal investigators (a 51-percent response rate) in 2,212 academic departments from 605 institutions in the United States. One hundred and sixty-four investigators (7.4 percent) indicated that they had observed or had direct evidence of researchers in their own department committing one or more incidents of suspected research misconduct (total incidents 201) in the past three academic years (2002-2004).

Titus said, "Two hundred and one cases observed by 2,200 respondents over three years is essentially three cases per 100 persons per year. Assuming that non-responders (roughly half our sample) did not witness any misconduct, we reduced the ratio to 1.5 cases per 100 persons. Applying that ratio to the 155,000 people supported by NIH extramural research grants in 2007 suggests that there could be 2,325 possible research misconduct observations per year. If 60% of these cases were reported to institutional officials as in our survey, approximately 1,350 would have been reported whereas 1,000 would likely be unreported to officials."

Chris Pascal, Director of ORI, added that institutions receiving PHS research support are required to report the number of allegations received in their Annual Report on Possible Research Misconduct to ORI. From 1993-2006, institutions reported receipt of 1,592 allegations (114 per year). This gives further evidence that there is institutional underreporting.

The commentary poses the question: How can there only be 24 institutional reports submitted to ORI if there are so many observations of suspected misconduct?

There are several ways to account for the disconnect: the researcher may fear he or she will look foolish if the allegation is not substantiated or assumes someone else will or should report the suspected misconduct; he or she may not want to be distracted from his or her research by becoming involved in an inquiry or investigation, or may fear possible retaliation. Institutional leaders may worry about the public image of their institution; they might fire the accused so that the problem goes away or not act in order to protect the revenue stream the accused generates; they may avoid doing an investigation primarily to save time, money, and effort.

The study responded to criticisms of earlier studies of research misconduct by using a specific definition of research misconduct (the federal definition), stipulating a time period in which the suspected misconduct occurred (three academic years), limiting the respondents to one per department to prevent duplicate reporting, using a large sample (4,298), covering a wide range of disciplines instead of a few, and focusing on suspected research misconduct rather than actual research misconduct because most research misconduct allegations are not substantiated.

The study also has limitations including the following: (1) one observer per department; (2) principal investigators primarily in the biomedical, behavioral, and life sciences as the only respondents; and (3) no data on the funding involved in the suspected research.

Six recommendations are made to institutions for fostering a culture of integrity: (1) adopt a zero tolerance for research misconduct, (2) protect whistleblowers, (3) implement a clear system for reporting alleged research misconduct, (4) increase mentors' awareness of their roles in establishing and maintaining research rules and minimizing opportunities to commit research misconduct, (5) develop continuing mechanisms for reviewing and evaluating the research and training environments, and (6) promote role models of ethical behavior.

Report Outlines Ethical Review Systems in EU

The European Forum for Good Clinical Practice (EFGCP) has developed a report that serves as a reference to the different ethical review systems established by EU member states plus Norway and Switzerland for the conduct of clinical research.

The report, *The Procedure for the Ethical Review of Protocols for Clinical Research Projects in the European Union*, dated November 2006, may be ordered from EFGCP at *http://www.efgcp.be/*

The EFGCP web site also contains an index of web sites related to clinical research in the 31 countries. The report consisted of 35 questions concerning the ethical review systems in those countries. As of March 1, 2008, updates to the report questions are available as pdfs.

Thousands Complete CITI RCR Courses in 2007

Since February 1, 2007, when the Collaborative Institutional Training Initiative (CITI) adopted a new software platform, 7,074 persons (643 per month) completed one of four CITI RCR courses in 2007, according to Paul Braunschweiger, CITI Co-Founder.

In 2007, 2,866 persons (41%) completed an RCR course for free through the Public Access Portal at *www.citiprogram.org* and 4,208 completed a course through a CITI member institutional requirement. The most widely used course through the Public Access Portal was Social and Behavioral Research (1,318) followed by BioMedical (949), Humanities (487), and Physical Sciences (112). ORI partially supported the development of the RCR courses and the Public Access Portal.

The highest number of completed courses in 2007 was registered for the following institutions: Children's National Medical Center, 562; Purdue University, 553; Ohio State University, 332; Clemson University, 273; and the University of Miami, 238.

The course site provides an opportunity for individuals to complete RCR courses and allows organizations or instructors to set up a customized curriculum for their faculty and students.

For more information on how to implement the CITI RCR program at your organization, department, or classroom, contact the CITI RCR "helpdesk" at 305-243-7970 or at citisupport@med.miami.edu.

RCR Conference Papers, Presentations Available on Web Site

If you were unable to make the first biennial ORI Conference on Responsible Conduct of Research (RCR) Education, Instruction and Training in St. Louis last April, you can read or watch many of the presentations on the conference web site and comment on the conference or RCR education on the conference weblog.

The conference featured nearly 50 presenters and was attended by 183 registrants from nine countries and 45 institutions. The conference was a collaborative project between Washington University and ORI.

About 40 pdfs of presentations and posters are available on the conference web site at *http://epi.wustl.edu/epi/rcr2008.htm*

Detailed instructions for accessing nine presentation recordings are also on the conference web site.

To comment on the conference or to comment on RCR education, go to the conference weblog at *http://rcreit.wordpress.com/*

New RCR Resources Posted on ORI Web Site

Five new RCR resources were posted on the ORI web site this spring, bringing the number of resources made available to the worldwide research community by the RCR Resource Development Program to 41.

The new products are available at *http://ori.hhs.gov/education/products/* and include:

- A Peer Review Tool that walks a reviewer through every step of reviewing a research paper.
- A Lab Management Tool that will help researchers with budgeting, personnel, lab set-up, time management, and mentoring.
- A virtual walkthrough of an animal laboratory that uses IPIX technology to perform a 360-degree scan of various rooms of an animal lab and identify needed corrections.
- An instructional module that addresses the use of images in research.
- A comprehensive list of learning objectives for RCR core areas, excluding animal and human research that was identified in a Delphi study.

ORI Seeking Director for Education Division

ORI will be recruiting a Director for its Division of Education and Integrity this summer or fall to fill a vacancy created by the retirement of the previous director.

The position will be recruited at a GS 15 grade level, which has a salary range from $115,317 to $149,000.

The vacancy announcement will be posted on the USA Jobs web site at *http://www.usajobs.gov/* and the ORI home page when available.

New Resources Produced by the RCR Program for Academic Societies

Several new resources that address the publication process, practice-based research, and the development and application of surgical innovation have been created with support from the RCR Program for Academic Societies, a collaboration between the Association of American Medical Colleges (AAMC) and ORI to support the institutionalization of infrastructure and activities within academic societies that promote the responsible conduct of its members.

The American Speech-Language-Hearing Association (ASHA) has published *Guidelines for the Responsible Conduct of Research: Ethics and the Publication Process*. This was an initiative of ASHA's Committee on Research Integrity and Publication Practices and is now official policy of the society.

Further information can be obtained at *http://www.asha.org/docs/html/GL2007-0022.html*

Two recent publications resulted from the American College of Physicians' (ACP's) initiative on "Training and Support in the Responsible Conduct of Practice-based Research in Internal Medicine." A feature article on the initiative appeared in the January 2008 issue of *ACP Internist* at *http://www.acponline.org/clinical_information/journals_publications/acp_internist/jan08/research.htm*

Another article from the project, by Lois Synder and Paul Mueller, titled "Research in the Physician's Office: Navigating the Ethical Minefield," was featured in the March/April 2008 issue of the *Hastings Center Report*. For more information, see *http://www.thehastingscenter.org/publications/hcr/hcr.asp*

Last, the *Journal of the American College of Surgeons* has accepted for publication "Responsible Development and Application of Surgical Innovations: A Position Statement of the Society of University Surgeons." The article is expected to be in the May issue of the journal. A preprint of the article was posted as this article went to press. The overall goal of this important project was to develop consensus guidelines for the responsible development, testing, and application of surgical innovations, and broadly disseminate the guidelines to institutionalize them in surgical training and practice. The journal can be accessed at *http://www.journalacs.org/*

More details on the AAMC-ORI program are available on-line at *http://www.aamc.org/programs/ori/* The page features links and details on all of the resources generated by the program.

Advice on Tailoring RCR Programs to Postdocs *(from page 2)*

Establish a Postdoc Curriculum that Includes RCR Training

"One way to reinforce RCR education is to incorporate training in RCR into a core curriculum. As the postdoc position is increasingly acknowledged as a training period (as evidenced, for example, by the new NIH and NSF postdoc definitions), it is important to give coherence to that training via a curriculum."

Incorporate RCR with Everyday "Survival" Skills

"This is an increasingly popular approach that has become very successful as a vehicle for delivering research integrity training, especially for postdocs. Not only does this have pedagogical advantages by integrating the topic with other basic research skills and thus improving long-term retention, it also makes RCR training much more attractive for postdocs."

Address the Cultural Diversity among Postdocs

"It is important to take into account the range of cultural backgrounds among postdocs, since the majority will be visa holders. Expect postdocs trained in different countries to have a range of experiences with RCR, different scientific cultures and norms upon which to draw, and certainly different personal experiences with research."

Consider How to Attract Postdocs

"Postdocs will likely be more interested in a program where they receive something concrete upon completion that may help with future job prospects...The distance and time of day of a program can be critical for increasing postdoc participation."

ORI Is Partnering with More Federal Agencies

ORI is partnering with more federal agencies to bring research integrity and the responsible conduct of research educational programs to a larger segment of the federal research community.

This summer, ORI will collaborate with the Uniformed Services University of the Health Sciences (USU) to present the following conferences for federal personnel, contractors, special consultants, and collaborators:

- JULY 23 – Public Service, Public Trust: Deepening the Experience of Research Integrity for Medical Scientists and Clinicians
- SEPTEMBER 17 – A Research Integrity Education Conference for the Federal Nursing Community

Two ORI staff members have been appointed adjunct assistant professors in the Graduate School of Nursing, USU: Cynthia Ricard and Sandra Titus. USU provides medical and health science education for military and PHS personnel, both those in uniform and civilians.

For the first time, ORI members will present on the RCR core elements at the Department of Defense (DoD) Education Day attended by DoD Human Research Protections Program personnel from around the world.

The DoD education and training conference will be held on June 26-27, 2008.

RCR Discussion Series Set for National Press Club

ORI is collaborating with RxTrials Institute in organizing a Responsible Conduct of Research Discussion Series at the National Press Club in Washington, DC.

The discussions occur during breakfast meetings (continental) from 8 a.m. to 10:30 a.m. The RxTrials Institute is part of RxTrials, a multi-specialty clinical research organization.

The first meeting, Ethics, Laws and Regulatory Affairs: Comparisons and Contrasts, was held April 22. The dates and topics for the remaining meetings are as follows:

- JULY 29 – Principles of International Collaboration in Clinical Research
- SEPTEMBER 11 – Mentoring: Examining the Meaning, Roles and Challenges in the Contemporary Culture of Clinical Research
- NOVEMBER 6 – The Nature of Vulnerability and the Obstacles Inherent in Challenges of Internationalization and Multiculturalism

To get more information and to register, visit *http://www.fdanews.com/rxti/conferences*

Lois Bartsch, Ph.D., University of Nebraska Medical Center

Based on the report of an investigation conducted by the University of Nebraska Medical Center (UNMC) and additional analysis conducted by the Office of Research Integrity (ORI) during its oversight review, the U.S. Public Health Service (PHS) found that Lois Bartsch, Ph.D., former postdoctoral research trainee, Department of Genetics, Cell Biology, and Anatomy, UNMC, engaged in scientific misconduct in research supported by National Cancer Institute (NCI), National Institutes of Health (NIH), grants P30 CA36727 and R01 CA77876 and National Center for Research Resources (NCRR), NIH, grant P20 RR016469. Specifically, the PHS found that Dr. Bartsch:

Falsified DNA sequence files by deleting a nucleotide and changing nucleotide designations and reported the altered file as the ACI rat p16Cdkn2a sequence with a CpG dinucleotide polymorphism in the upstream region to GenBank, in grant application CA118151, and in the poster presented to Cold Spring Harbor Laboratory (CSHL);

Fabricated the claim in grant application CA118151 that GenBank entries for the human p16Cdkn2a gene had a CpG polymorphism near the transcription start site;

Falsified the differential methylation of CpG dinucleotides near the transcription start site of p16Cdkn2a DNA and reported that tumor tissue was more methylated than normal tissue in ACI rats treated with estrogen and that the ACI allele was

See Case, page 8

Case Summary *(from page 7)*

more methylated than the BN allele in tumor tissue from (BN x ACI)F1 animals treated with estrogen in grant application CA118151.

Dr. Bartsch has entered into a Voluntary Exclusion Agreement (Agreement) in which she neither admits nor denies ORI's finding of scientific misconduct; the settlement is not an admission of liability on the part of the respondent. In accordance with the terms of the Agreement, she has voluntarily agreed, beginning on April 15, 2008:

(1) To exclude herself from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in non-procurement programs of the United States Government referred to as "covered transactions" pursuant to HHS' Implementation (2 CFR Part 376 et seq.) of OMB Guidelines to Agencies on Government-wide Debarment and Suspension (2 CFR Part 180) for a period of two (2) years; and

(2) To exclude herself permanently from serving in any advisory capacity to the PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant or contractor to the PHS for a period of three (3) years.

Office of Research Integrity
1101 Wootton Parkway, Suite 750
Rockville, Maryland 20852

Office of the Director .... (240) 453-8200
Fax ..... (301) 443-5351

Division of Education
and Integrity ..... (240) 453-8400
Fax ..... (301) 443-5351

Assurances Program ..... (240) 453-8400
Fax ..... (301) 594-0042

Division of Investigative
Oversight ..... (240) 453-8800
Fax ..... (301) 594-0043

Research Integrity
Branch/OGC ..... (301) 443-3466
Fax ..... (301) 594-0041

http://ori.hhs.gov

DEPARTMENT OF
HEALTH AND HUMAN SERVICES

Office of the Secretary
Office of Research Integrity
1101 Wootton Pkwy, Suite 750
Rockville MD 20852

Official Business
Penalty for Private Use $300

DATED MATERIAL