

Office of Research Integrity

N E W S L E T T E R

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.



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Mandatory RCR Training Urged for Graduate Students

Mandatory training in the responsible conduct of research (RCR) for all graduate students is one of six interventions recommended by the Council of Graduate Schools (CGS) in its report on a research and demonstration project on integrating RCR education into graduate programs.

Other interventions recommended in the report, *Graduate Education for the Responsible Conduct of Research*, include establishing an advisory board, providing public forums, offering two-tiered instruction, teaching ethical reasoning, and developing multi-level assessments.

The report, published last October, may be purchased from the CGS Online Bookstore at <http://www.cgsnet.org/Default.aspx?tabid=79&List=0>.

The report is based on the “best practices” that emerged from a two-year project, funded by ORI, that involved the efforts of ten institutions to establish RCR programs: Arizona State University, Duke University, Florida State University, New York Medical College, Old Dominion University, University of Kansas, University of Missouri-Columbia, University of New

See Recommends, page 2

CITI RCR Course Offers Customized Instruction

By Paul Braunschweiger, Ph.D., CITI Co-Founder

The Collaborative Institutional Training Initiative (CITI) course in the responsible conduct of research (RCR), developed with support from ORI and hosted by the University of Miami School of Medicine, is freely available to the worldwide research community through May 2008 at www.citiprogram.org.

This is not just another web tutorial. The CITI RCR Program consists of a virtual library of textual content, case studies and assessments that can be used individually or electronically combined in any number of ways, to render comprehensive discipline specific instruction in

RCR in the biomedical, social, behavioral, and physical sciences and the humanities.

The course covers seven of the nine core RCR instructional areas: data management, mentoring, authorship and publication practices, peer review, research misconduct, collaborative science, and conflict of interest. CITI offers a separate course on human research subjects. Training in animal welfare will be available in early 2007 from CITI.

Course material was selected by the CITI RCR Developer Group from **See CITI, page 4**

Recommends Advisory Board, Public Forums, 2-Tiered Instruction (from page 1)

Hampshire, University of Rhode Island, and the University of Utah.

The demonstration project will continue through December 2007 with funding from the National Science Foundation. Last fall, CGS made awards to Bradley University, Brown University, Old Dominion University, Rockhurst University, University of Alabama-Birmingham, University of Kansas, University of Nebraska-Lincoln, and the University of Oklahoma.

Recognizing that instituting mandatory training for all graduate students would be “a very difficult thing to do,” the report suggested three strategies that appeared to be effective: (1) offering small grants to departments for the development of the needed RCR courses or course elements; (2) embedding RCR education into existing voluntary programs such as Preparing Future Faculty, and (3) including or expanding RCR segments in courses that are already mandatory.

Establishing an advisory board composed of “high-profile senior faculty members whose reputation is beyond reproach” is an effective way for institutional leadership to “exhibit its commitment to academic integrity prominently,” the report said. “The steering committee or advisory board would develop, deliberate, and advance RCR education interventions throughout the institution. It might be set up to report to the graduate dean, the graduate council, or the provost. Its charge should be to promote campus-wide awareness of RCR through public forums, as well as to design and propose curriculum strategies to

expand and improve RCR training for graduate students.”

The report further suggests that providing well-publicized, regularly offered public forums can enhance the ethical climate for research at an institution. “Such forums serve not just the purpose of educating the public and the university community about the ethical dimensions of scientific practice,” the report said, “but also of exhibiting the institution’s commitment to integrity in research.”

The report also recommends that institutions establish two-tiered

RCR instruction programs. The first tier would consist of “departmental-level, disciplinary programs with involvement and commitment from program faculty.” The second tier would consist of interdisciplinary, cross-departmental seminars and coursework.

“The primary interest of departmental faculty may be to enculturate students into their disciplines, and not to develop their ‘characters’ or otherwise try to inoculate them against misbehavior. Perspectives from outside the discipline, on the

See CGS Report, page 3

Grad Students Cheating at an Alarming Rate

One out of every two graduate students in medical, health care and physical science programs who participated in a study of academic cheating admitted to doing so at least once in the previous year, according to press reports.

The study “Academic Dishonesty in Graduate Business Programs: Prevalence, Causes, and Proposed Action” was published in the September 2006 issue of *Academy of Management Learning and Education*.

The *Washington Post* (9/27/06) reported the study collected data from 5,331 business and non-business graduate students at 54 colleges and universities in the United States and Canada during the 2002-03 and 2003-04 academic years.

The *Post* said students were asked whether “they had engaged in 13 specific behaviors, including cheating on tests and exams, plagiarism, faking a bibliography or submitting work

done by someone else.” Frequency of cheating ranged from zero to three or more times in the previous year.

According to the journal press release the authors concluded that graduate students “are cheating at an alarming rate and business students are cheating even more than others.” The authors are Donald L. McCabe, Rutgers University; Kenneth D. Butterfield, Washington State University, and Linda Klebe Trevino, Penn State University.

Percent of Grad Students by Discipline Admitting Cheating in Past Year

Business	56%
Engineering	54
Physical Sciences	50
Medical Students & Health Care	49
Education	48
Law	45
Arts	43
Humanities & Social Sciences	39

Verify Contact Info; Submit Annual Report on Possible Misconduct by March 1

Institutional officials should have received an email from the ORI Assurance Manager in November requesting that they login to the Annual Report on Possible Research Misconduct system to update and verify their contact information.

If you are the responsible institutional official who signs the Annual Report on Possible Research Misconduct (PHS 6349 form) and have not received the above email, please contact Randi Freedman at Randi.Freedman@hhs.gov or phone 240-453-8402.

The filing period for about 4,500 institutions and organizations to submit their 2006 Annual Report begins January 1, 2007 and ends February 28, 2007. Institutions that fail to renew their research misconduct assurance by submitting their

CGS Report *(from page 2)*

other hand, may prove challenging and broadening for students....," the report said.

Graduate students should be taught ethical reasoning skills "primarily to help students develop consistency, coherence, and confidence in their opinions and behaviors," the report argues.

Citing assessment as "the most difficult of all challenges in establishing quality RCR programs" the report declared, "Assessment will be required at the departmental and course level, and at the level of the individual student. And assessment of the many different aspects of RCR will need to be implemented, making assessment truly a multi-dimensional task."

Annual Report become ineligible to receive PHS research support. Institutional officials will receive periodic reminders to file their 2006 Annual Report during the filing period.

The "Other" column where "other practices that seriously deviate from those that are commonly accepted within the scientific community" were previously reported was removed from the online and hard copy versions of the form to bring it into compliance with the PHS Policies on Research Misconduct (42 C.F.R. Part 93) which became effective on June 16, 2005. The new regulation limits research misconduct to fabrication, falsification and

New RRI Program Director Named; Scheetz Resigns

Nick Steneck, an ORI consultant, will assume the directorship of the Research on Research Integrity (RRI) Program on January 1, 2007 replacing Mary Scheetz who resigned from Federal service last June.

Steneck has been a major contributor to the RRI program since it was created in 2000 and a co-organizer of the four biennial Research Conferences on Research Integrity.

Scheetz continued to manage the RRI program and research conference until December 31, 2006 under contract with ORI. Effective in January 2007, Scheetz will become an Assistant Professor of Medical Education, Department of Bioethics, University of Virginia, in a new program in Ethics and Policy in Health Care. She and her family live in Crozet. She may be contacted at mary@researchintegrity.us.

plagiarism. Additional incident boxes were also added to the online form to allow institutional officials to report more than three incidents of possible research misconduct. Officials using the hard copy version of the Annual Report may attach additional sheets when reporting more than three incidents of possible research misconduct.

To provide feedback to institutional officials, a "Date report submitted/ approved by ORI" column has been added to the "Submit/review 200X Annual Report on Possible Misconduct" screen. The new information allows officials to instantly see when their report was submitted and when it was approved by ORI.

Under her leadership, the RRI program provided \$13 million to support 28 research grants on research integrity, the responsible conduct of research, and research misconduct that produced 34 publications in 12 journals including *Nature*, *the New England Journal of Medicine*, *the Journal of the American Medical Association*, and *the British Medical Journal*.

"The success of the RRI program was largely due to Mary's ability to generate support for the program in NIH institutes and PHS agencies," Larry Rhoades, Director, Division of Education and Integrity, said. "By the time she left she had involved 10 NIH institutes and the Agency for Healthcare Research and Quality."

See Scheetz, page 5

CITI Course Provides Data and Feedback for Administrators *(from page 1)*

projects supported by the RCR Resource Development Program created by ORI in 2002. Members of the Developer Group are Dan Vasgird, University of Nebraska-Lincoln; Ruth Fischbach and Joyce Plaza, Columbia University; Steve Fliesler, Saint Louis University; Marianne Elliot, Department of the Navy; Michael Fallon, Department of Veteran Affairs, Atlanta, and Emory University, and Reid Cushman, Kenneth Goodman, and Braunschweiger, University of Miami. The CITI RCR Developer Group will conduct semi-annual reviews of the Program.

Organizations may establish a complimentary CITI RCR Program account to design and implement a customized RCR curriculum for their organization and subunits (e.g.,

school specific, department specific). The Program will be particularly useful for individual course instructors with a desire to weave RCR pedagogy into the fabric of a specific course or class activity.

CITI provides a “Help Desk Technician” to aid organizations who want to take full advantage of the Program’s capabilities. “Unaffiliated” learners also may access a pre-programmed RCR course at www.citiprogram.org.

The unique CITI platform, designed by Fallon, provides learner completion certificates and features utilities for institutional administrators to download user data and feedback.

The software also provides the opportunity for organizations to post

their own RCR materials in modular fashion. User satisfaction surveys are employed to gauge software functionality, user attitudes, opinions and suggestions for improvement.

Although CITI provides basic and advanced courses in the protection of human research subjects on an institutional subscription basis, the CITI RCR Program will be publicly accessible at least through May 2008. The program is hosted by The University of Miami Medical IT on dedicated servers and administered by the Office of Research Education under Braunschweiger’s direction. For more information on how your organization can use the Program, contact the CITI Help Desk at citisupport@med.miami.edu or call 305-243-7970.

RCR Resources Created by Societies Are Available Online at AAMC Website

Products produced by ten academic societies with ORI support through the RCR Program for Academic Societies are now available online at <http://www.aamc.org/programs/ori/>.

The program, a collaboration between the Association of American Medical Colleges and ORI, made 39 awards to 31 societies from 2002 to 2006 to develop guidelines, standards, policies, articles, conferences, curricula and other resources designed to promote the responsible conduct of research among members of their societies.

“We expect more products to be become available as the projects still underway are completed,” Tony Mazzaschi, AAMC, said. Funding for the program ended in September 2006.

Among the available on-line products are an RCR curriculum developed by the American Occupational Therapy Foundation; a module on responsible literature searching created by the Association of Academic Health Sciences Libraries and a module on ethics for researchers, educators and mentors created by AcademyHealth.

Also available are proceedings from a consensus conference held on the ethical conduct of resuscitation research organized by the Society for Academic Emergency Medicine and a consensus statement on protecting participants in family medicine research published by the Society of Teachers of Family Medicine.

Links are also available to policy statements issued on ensuring integrity

for research with children by the Ambulatory Pediatric Association and the ethical conduct of clinical research involving critically ill patients by the American Thoracic Society.

Articles were published on education in the responsible conduct of research by the Association of Chairpersons of Departments of Physiology, and on incorporating ethics in clinical research study design and on institutional review boards and ethics by the Endocrine Society.

Workshop materials are available on responsible conduct of research by the Association of Rheumatology Health Professionals and on enhancing integrity in clinical research by the Endocrine Society.

RCR Training for Postdocs Moves into Laboratories at UT-Southwestern

A research ethics course for postdocs has been developed at the University of Texas Southwestern Graduate School of Biomedical Sciences that partially embeds responsible conduct of research training in the structure of individual laboratories.

“I have always felt that research integrity needs to be embedded in the structure of individual laboratories rather than dispersed through ancillary courses,” said Fred Grinnell, Professor of Cell Biology and former Director of the Ethics in Science and Medicine Program, UT-Southwestern.

“Although this program is designed for postdoctoral fellows, it influences graduate students as well by creating a university culture in which notebook and authorship policies are developed and ethics discussions are held at the laboratory level,” Grinnell added.

Three requirements of the course are laboratory based: discussion of case studies that explore aspects of research integrity; development or discussion of a lab policy on authorship, and development or discussion of a lab policy on how to keep a notebook.

Postdocs are required to lead or participate in discussions of the case

studies. Postdocs are also required to read their lab’s current policies on authorship and notebooks and discuss them with their lab groups. If the policies do not exist, postdocs are required to consult with their mentor in developing the policies and discussing them with their lab groups.

Postdocs are referred to http://ori.hhs.gov/education/products/montana_round1/issues.html for case studies; to <http://www.icmje.org/> for the authorship policy and to an optional checklist provided by UT-Southwestern for developing the notebook policy.

NSF Geosciences Directorate Urges Mentoring for PostDocs and Grad Students

Guidelines for principal investigators that highlight the importance of providing professional development and mentoring for postdocs and graduate students were issued by the Directorate for Geosciences (GEO) at the National Science Foundation last August.

The “dear colleague” letter states, “provision of quality mentoring (or access to the appropriate mentors) and advisement on a continuing basis to all postdocs and to graduate students supported by NSF awards should be documented and highlighted as ‘Broader Impacts’ outcomes in annual and final project reports.”

The letter continued, “GEO encourages all awardees, project managers, and their institutions to provide their postdocs with access to professional activities that provide formal or informal training in (for example) proposal preparation, lab and project management, research ethics, verbal and written communication, teaching,

education and public outreach, negotiating, and time management.”

“Measures of success include, in addition to publications and research results, documentation of specific activities related to professional career development and how these activities contributed to the progress of individuals capable of functioning as independent professionals,” the letter stated, “PIs may also find it useful to track the career pathways of postdocs after the appointment, in order to document successes that may have resulted from their professional development efforts. Reports on highly effective or innovative ways that PIs have contributed to the professional development of postdocs are of particular interest to NSF.”

The letter which also includes other resources that may be useful in developing professional development programs is available at <http://www.nsf.gov/pubs/2006/nsf06038/nsf06038.jsp>.

The course also requires postdocs to attend two lectures on research integrity and ethical issues, attend at least one Ethics Grand Round, and complete a plagiarism course developed by the publisher Prentice Hall that is available at http://wps.prenhall.com/hss_understand_plagiarism_1/0,6622,427064-,00.html.

For more information about the course contact susanne.mumby@utsouthwestern.edu or frederick.grinnell@utsouthwestern.edu.

Scheetz (from page 3)

Before she became the RRI director, Scheetz worked in the compliance program reviewing institutional research misconduct policies, conducted research on inquiry reports prepared by institutions and instructions to authors published by journals, and served as liaison to Council of Science Editors and the World Association of Medical Editors. She also prepared *Managing Allegations of Scientific Misconduct: A Guidance Document for Editors*.

Number of Institutions Reporting Misconduct Activity Steadily Increases from 1992-2001

The number of institutions reporting research misconduct activity - receipt of an allegation or conduct of an inquiry or investigation - steadily increased from 1992-2001, but at a decreasing rate, according to an ORI study of Annual Reports on Possible Research Misconduct submitted by institutions.

During the 10-year period, 529 institutions reported research misconduct activity, of which 248 were reporting misconduct activity for the first time. The study, *New Institutional Research Misconduct Activity: 1992-2001* is available at <http://ori.hhs.gov/publications/studies.shtml>.

Percent of Institutions Reporting Research Misconduct Activity in Their Annual Reports for the First Time by Year: 1992-2001

Year	All Institutions Reporting Activity	New Institutions Reporting Activity	Percent New Institutions
1992	40	40	100
1993	33	22	67
1994	57	34	60
1995	64	41	64
1996	59	27	46
1997	53	20	38
1998	42	9	21
1999	57	20	35
2000	62	20	32
2001	62	15	24
TOTAL	529	248	

ORI Conference Schedule - 2007

March 29-30

Data Fabrication and Falsification: How to Prevent, Detect and Evaluate

Boston, MA

CO-SPONSORS: Harvard Medical School, Harvard School of Public Health, and Harvard Teaching Hospitals

May 31-June 1

Costs and Benefits of Responsible Conduct of Research Education Programs

Minneapolis, MN

CO-SPONSOR: University of Minnesota

September 17-19

First World Conference on Research Integrity

Lisbon, Portugal

CO-SPONSOR: European Science Foundation

Teaching Research Ethics Workshop Scheduled

The fourteenth annual Teaching Research Ethics Workshop will be held in the Indiana Memorial Union at Indiana University in Bloomington from May 15-18, 2007.

Session topics include ethical theory, trainee and authorship issues, conflict of interest, human subjects, and responsible data management. Techniques for assessing RCR will be featured in many sessions. Registration deadline is March 30, 2007. See <http://poynter.indiana.edu/tre/>.

MSU Newsletter Focuses on Research Integrity

A semi-annual newsletter, *Research Integrity*, published by the Graduate School at Michigan State University (MSU) can serve as a valuable resource for RCR courses because each issue focuses on one or more of the core RCR instruction areas.

The newsletter has been published since 1997 by the Office of Intellectual Integrity, The Center for Ethics and Humanities in the Life Sciences. The newsletter may be reproduced without permission as long as proper acknowledgment is given, according to the MSU website.

Previous issues have addressed plagiarism, research mentoring, conflict of interest, data control and management, authorship, human subjects, ethical environment, and preventive ethics. The newsletter is available at <http://grad.msu.edu/integrity.htm>.

If your institution has a newsletter, guidelines, or other resources related to research integrity or RCR and is willing to share it with the research community, send information and web address to Lawrence.Rhoades@hhs.gov.

Case Summaries

Ms. Sylvia Okoro, University of Maryland at Baltimore: Based on the University of Maryland at Baltimore (UMAB) investigation committee report and additional analysis and information obtained by ORI during its oversight review, the U.S. Public Health Service (PHS) found that Ms. Okoro, former Research Assistant, UMAB, engaged in misconduct in science by fabricating and falsifying patient data in research supported by National Institute on Aging (NIA), National Institutes of Health (NIH), grant R01 AG18461.

Specifically, Ms. Okoro intentionally and knowingly fabricated and falsified data for six visit dates on one patient data form and falsified and fabricated patient condition information on two additional study subjects by failing to note that each patient had experienced a fall as documented in their medical charts.

ORI has implemented the following administrative actions for a period

Research Misconduct Office Established in China

A regulation on research misconduct among Chinese scientists working on state-funded science programs will take effect on January 1, 2007 when the Ministry of Science and Technology opens an office to handle research misconduct cases, according to SciDevNet. (11/10/06)

A national committee composed of national and international experts will also be established to advise the government on the promotion of research integrity.

These actions were taken in response to several high-profile cases in China earlier this year.

of three (3) years, beginning July 17, 2006:

(1) Ms. Okoro is prohibited from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and

(2) Any institution that submits an application for PHS support for a research project on which Ms. Okoro's participation is proposed or which uses her services in any capacity on PHS supported research must concurrently submit a plan for supervision of her duties. The supervisory plan must be designed to ensure the scientific integrity of Ms. Okoro's research contribution and must be submitted to ORI by the institution.

Kui Zhu, Ph.D., Cleveland Clinic Research Foundation: Based on accumulated evidence including the Cleveland Clinic Research Founda-

tion (CCF) investigation report (CCF Report) and additional analysis and information obtained by the Office of Research Integrity (ORI) during its oversight review of the CCF Report, the U.S. Public Health Service (PHS) found that Kui Zhu, Ph.D., former postdoctoral fellow, CCF, engaged in misconduct in science by intentionally and knowingly fabricating and falsifying data for figures in two publications and with research funded by National Cancer Institute (NCI), National Institutes of Health (NIH), grants R21 CA84038, R01 CA76204, and T32 CA09056.

Among the behaviors defined as research misconduct are submitting false resumes, plagiarism, fabricating or falsifying data, and violating regulations governing clinical trials and laboratory animal protection.

Sanctions imposed on guilty parties include warnings, loss of funding, suspended projects, demotion, loss of job and a ban on applying for funding "between one year and forever."

Allegations of research misconduct will be sent to the new office and be investigated by a team that is free of conflicts of interest and composed of experts in law, ethics, and the relevant scientific discipline.

ORI has implemented the following administrative actions for a period of three (3) years, beginning June 7, 2006:

(1) Dr. Zhu is debarred from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government as defined in the debarment regulations at 45 C.F.R. part 76; and

(2) Dr. Zhu is prohibited from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

No RCR Resources RFP Issued for 2007

ORI will not issue a request for proposals for its RCR Resource Development Program this year while it is completing a template for the creation of future resources. For more information about the program visit <http://ori.hhs.gov/education/rcrrdp/>.

ORI Changing Procedures for Funding Conferences

ORI is changing the procedures institutions must follow to request support for conferences related to the responsible conduct of research, research integrity, and research misconduct. Conference proposals are now solicited through Requests for Proposals (RFP) issued by the PSC contract office. An RFP will be issued for each conference ORI intends to support in FY 2008. RFPs will be issued for four conferences focused on: (1) authorship and publication practices; (2) research misconduct, (3) education on the responsible conduct of research

(RCR) and (4) mentoring. Suggestions for other relevant conference topics for future RFPs are also welcomed. The conferences should be 1.5 to 2 days in length, designed for a national audience, and be held in an easily accessible U. S. city. Maximum award will be \$25,000. To receive the RFPs your institution must be on the PSC source list, so if your institution is interested in organizing conferences supported by ORI, please send your name, mailing address, phone and fax numbers and email address to ***Lawrence.Rhoades@hhs.gov*** or call **240-453-8434**.

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