

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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Registration Opens for First Biennial RCR Conference

Registration is open for the first biennial Conference on Responsible Conduct of Research (RCR): Education, Instruction and Training in St. Louis at the Renaissance St. Louis Grand and Suites Hotel from April 17-19, 2008.

A lower registration fee is offered to individuals who register before February 15, 2008. For registration and reservation information see the

ORI home page for access to the conference web site.

More than 50 abstracts have been accepted for presentation. The Conference will open with overviews of current efforts, followed by a session exploring different views on goals, methods, and the value of RCR requirements. Other sessions will focus on assessment tools, web-based

See RCR Conference, page 6

RCR Award Made to Council of Graduate Schools

ORI has awarded a 3.5 year contract to the Council of Graduate Schools (CGS) to foster acceptance of responsible conduct of research (RCR) training as an essential element of graduate education.

CGS is the only national organization in the U. S. dedicated solely to representing and advancing the interests of graduate education. Its 479 member institutions award over

90 percent of the doctorates and more than 75 percent of the master's degree awarded by U. S. institutions.

Debra Stewart, President, CGS, said, "Preparing the next generation of researchers and professionals in the responsible conduct of research is a core obligation of every graduate program in the U. S. Graduate deans have already made significant

See ORI Supports, page 2

Postdoc RCR Training Funded at 12 Institutions

Postdoc offices or postdoc associations at 12 institutions are developing responsible conduct of research education programs specifically tailored to the postdoc experience under seed grants awarded by the National Postdoctoral Association (NPA) with support from ORI.

The seed grants are part of a two-year project that also includes workshops, the development of an

RCR toolkit, and consultation and technical support. Thirty seed grants will be awarded during the contract. Additional awards will be made in spring 2008. For more information see the "Bring RCR Home" project on the NPA web site and click on Postdocs.

Alyson Reed, Executive Director, NPA, said, "The Bring RCR Home project is a national initiative to

See ORI Aids, page 4

ORI Supports Effort to Institutionalize RCR Education in Graduate Programs *(from page 1)*

progress in establishing RCR programs on their campuses.

The CGS partnership with ORI is crucial to our commitment to our member institutions as they work to fulfill their research and education missions.”

“We are very pleased that CGS has made the institutionalization of RCR training in graduate education programs a part of its strategic plan,” Chris Pascal, Director, ORI, said. “And we look forward to working with CGS to implement that element of its plan.”

This contract extends previous efforts by developing a framework for institutionalizing RCR training in graduate programs that will be tested in two-year demonstration projects at five research institutions. Application procedures for the demonstration projects will be

announced in spring 2008. Institutions selected for the demonstration projects will receive \$50,000 awards.

The project will also further the development of an RCR leadership cadre of graduate deans; produce a monograph describing the demonstration projects and the “best practices” for addressing issues and challenges in RCR education, construct an email network to facilitate rapid and regular communication with graduate deans during and after completion of this project; and create a plan for continuing the institutionalization process after this contract ends.

Daniel Denecke, Ph.D., Program Director in Best Practices, CGS, is serving as project director. He has directed the Ph.D. Completion Project and managed the Preparing Future Faculty program at CGS.

Diana Carlin, Ph.D., Dean of the Graduate School and International Programs at the University of Kansas, is serving as co-project director. Carlin is the current Dean in Residence at CGS.

This contract builds on an effort initiated in 2004 by CGS with ORI support and extended in 2005 with National Science Foundation (NSF) support to promote the integration of RCR training into graduate education programs.

A monograph, *Graduate Education for the Responsible Conduct of Research*, was published in 2006 at the end of the initial ORI supported project. The monograph is available for purchase from the CGS bookstore at <http://www.cgsnet.org/Default.aspx?tabid=79&List=0>. The NSF project will end this December.

2007 Annual Report on Possible Research Misconduct Due by March 1, 2008

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

Current contact information is required so that institutions may be sent their IPF numbers and their passwords prior to the beginning of the filing period for the 2007 Annual Report.

If you are the responsible institutional official who signs the Annual Report on Possible Research Misconduct (PHS 6349) and have not received the email, please contact

Robin Parker at Robin.Parker@hhs.gov or phone 240-453-8400.

The filing period for about 4,500 institutions and organizations to submit their 2007 Annual Report begins January 1, 2008 and ends March 1, 2008. Institutions that fail to renew their research misconduct assurance by submitting their Annual Report become ineligible to receive PHS research support. Institutional officials will receive periodic reminders to file their 2007 Annual Report during the filing period if they have not already done so.

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 Research Misconduct” screen. This feature allows officials to instantly see when their report was submitted and when it was approved by ORI.

Updated Version
ORI Intro to RCR

Purchase from

<http://bookstore.gpo.gov/collections/ori-research.jsp>

Global Science Forum Develops Steps for Lessening Research Misconduct

Specific steps institutions, governments, scientific societies and publishers may take to lessen the prevalence of research misconduct were developed during a workshop held by the Global Science Forum (GSF) of the Organisation for Economic Co-operation and Development (OECD) in Tokyo last February that was attended by over 50 government-appointed representatives of 23 countries.

The GSF of OECD “is a venue for consultations among senior science policy officials of the OECD member and observer countries on matters relating to fundamental scientific research. The Forum’s activities produce findings and recommendation for actions by governments, international organisations, and the scientific community,” the report states.

The specific steps were reported in the unofficial workshop report, *Best Practices for Ensuring Scientific Integrity and Preventing Misconduct*, that was presented at the World Conference on Research Integrity that was held in Lisbon last September. The unofficial report is available at <http://www.esf.org/activities/esf-conferences/details/confdetail242.html>

A verbatim description of the specific steps contained in the report follow:

- Designing and implementing a formal system for addressing allegations of misconduct in research that is tailored to local conditions and requirements.
- Making the results of each investigation known in the scientific

community, as a deterrent to similar occurrences.

- Adopting definitions, standards, rules and codes of conduct. These can cover three areas: (1) good scientific practice (e.g., experimental design, laboratory safety, error analysis, data curation and access); (2) traditional ethics issues (e.g., rights of human subjects, handling of experimental animals, philosophical/moral aspects of research in human reproductive biology, defense-related research); and (3) misconduct.
- Promoting the internalisation of rules and standards via carefully designed and implemented educational measures. Curriculum design is a key issue, as is the question of when (at what stage of a scientific career) education measures can be most effective.
- Incorporating instruction about responsible conduct of research in student curricula, and in the training of faculty, staff and technical personnel. Of particular value is instructing graduate students about the realities of scientific careers, including a realistic description of the pressures that can destabilise the lives of postdoctoral fellows and assistant professors.
- At the level of research institutions (e.g., university departments, large laboratories), actively fostering open and frank discussion of misconduct-related matters. Promoting collegiality and networking among colleagues to discourage isolation of the type that can harm susceptible individuals (‘lone wolf’ scientists) and to clarify collaborators’

responsibilities within research collaborations. At the institutional level, rewarding those leaders who set an example by visibly adopting the standards of integrity in research.

- In hiring and promotion, rewarding quality of work rather than quantity of publications.
- To the extent possible, streamlining, rationalising, and simplifying the grant application and award system.
- In scientific publishing (and in grant applications) adopting clear, uniform standards for
 - authorship criteria for papers, including obligations of co-authors
 - allowable types of image processing in published images
 - requirements for making primary and secondary data available to the general scientific community
 - conditions under which results will be published (i.e., with or without permission of the sponsor).
- Making use of computer-assisted tools (software) for detecting plagiarism in publications, proposals, reports, etc. Promoting the development of software for detecting fraud in images, data, figures, etc.

Publishing

Publishing an article once is sufficient. Duplicate publication wastes resources.

World Conference Report Recommends Actions to Meet Crucial Needs

The final report on the first World Conference on Research Integrity: Fostering Responsible Research makes three recommendations to further world dialogue on research integrity, responsible conduct of research, and research misconduct.

The World Conference, held September 16-19, 2007 in Lisbon, Portugal, was attended by 275 participants from 47 countries. The conference was initiated and organized by the European Science Foundation (ESF) and ORI and supported by several other organizations.

“Research regulations and commonly accepted research practices vary significantly from country to country and among professional organisations,” the report states. “There is no common definition world-wide for research misconduct, conflict of interest, plagiarism or other key terms that describe acceptable and unacceptable research practices.”

“Even where there is general agreement on key elements of

research behaviour, such as the need to restrict authorship to individuals who make substantive contributions to the research or to provide protection for research subjects,” the report said, “the policies that implement this agreement can vary widely from country to country and organisation to organisation.”

“The research community world-wide has to address these problems in order to retain public confidence and to establish clear best practice frameworks at an international level,” the report asserts.

The report recommends that subsequent actions focus on three crucial needs:

- “for better information about research behavior and the factors that influence it;
- to clarify, harmonize, and publicize standards for best practice and procedures for reporting improper conduct; and
- to incorporate global standards for best practice and policies for responding to misbehavior into

training and research environments.”

Subsequent actions recommended to meet those crucial needs are

Recommendation 1. ESF and ORI should continue to work with the Global Science Forum and other organizations to achieve the common objective of encouraging all countries that support active research programs to develop guidelines for best practice and procedures for responding to misconduct in research.

Recommendation 2. ESF and ORI should take the lead in developing a Global Clearinghouse for Research Integrity.

Recommendation 3. ESF and ORI should take the lead initiating planning and fund raising for a second World Conference, to be held in late 2009 or early 2010.

The final conference report and six appendices are available at <http://www.esf.org/activities/esf-conferences/details/confdetail242.html>

ORI Aids RCR Efforts by Postdoc Offices and Associations *(from page 1)*

foster RCR programming for postdoctoral institutions. It aims to support postdoc offices and associations in the development and execution of local programs tailored to the unique role postdocs play in the research enterprise.”

The following institutions received \$1,000 seed grants to help support the development of RCR programming for postdocs:

- Brown University
- Howard University

- Indiana University
- Massachusetts General Hospital
- Medical University of South Carolina
- Pennsylvania State University
- Stanford University
- University of Iowa
- University of Kansas
- University of Pennsylvania
- University of Pittsburgh
- University of Washington

Katy Flint, Project Manager, said, “We hope the current projects and those that will come later will

provide a source of inspiration and information to others. We would like to see RCR training and associated topics become an essential part of the postdoc experience.” Abstracts of current awardees are available on the NPA web site.

The NPA, founded in 2003, is the only national organization devoted entirely to serving the needs of the postdoctoral research community. Its 135 institutional members represent more than 40,000 postdoctoral scholars.

Innovative RCR Resources to be Available On-Line in Spring 2008

Five new RCR products will be posted on the ORI web site in early 2008 that feature desktop applications, computer-based guides, and learning modules that utilize innovative features for RCR training, education, and application.

“I’m excited about these upcoming products,” says Loc Nguyen-Khoa, Director, RCR Resource Development Program, “These products have extremely high potential to be used by a wide market and will greatly facilitate the jobs of researchers and educators.”

The vast majority of products previously funded through the RCR Resource Development Program have been educational modules geared as a resource for RCR teachers. The upcoming products are more advanced in nature, geared towards peer reviewers, IACUC inspectors, researchers, as well as educators.

Peer Review Tool

Dr. Min Qi Wang of the University of Maryland is completing the development of a free computer application designed to facilitate the review process for journal editors and reviewers. Similar to commercial tax preparation programs, the “Peer Review Tool” walks the reviewer through every step of reviewing a research paper. Using information submitted by the reviewer, the Peer Review Tool outputs a summary of the paper, providing warnings of possible inconsistencies within the research paper. The Tool is currently undergoing final review with a sample of editors and reviewers and is expected to be released by April 1, 2008.

Lab Management Tool

Establishing a laboratory can be an overwhelming process. Dr. Derina Samuel of Syracuse University is in the process of finishing a Lab Management Tool that will help researchers with budgeting, personnel, lab set-up, time management, and mentoring. The free desktop application can be used by new researchers to establish a new laboratory or by advanced researchers to increase laboratory efficiency. This lab tool is expected to be completed by the end of April.

IACUC Animal Laboratory Virtual Walkthrough

Dr. David Lyons of Wake Forest University is currently developing an advanced training tool for IACUC animal laboratory inspectors. The tool uses IPIX technology that provides an interactive virtual walkthrough of an animal lab. Using this technology, users are able to perform a 360 degree scan of various rooms of an animal lab and click on possible violations. This image-based tool provides an excellent simulation that develops and maintains skills for inspectors. The product is expected to be released by mid-April.

Attorney Joins Research Oversight Legal Team

A new lawyer has joined the Research Oversight Legal Team in the Office of the General Counsel, Department of Health and Human Services (HHS), where she works on legal matters related to ORI.

Alice Tayman, formerly of the Office of the Attorney General

Training Module for Use of Image Data

Drs. Harold Kincaid and Sara Vollmer from the The University of Alabama-Birmingham will release a training module addressing the use of images in research in April. The module is geared towards researchers employing image processing, providing acceptable protocols for saving, manipulating, and reporting image data. Interactivity is added through use of video vignettes, quizzes, and self-reflection questions.

RCR Learning Objectives

Dr. James Dubois of St. Louis University has completed a delphi study resulting in a comprehensive list of learning objectives for core areas of RCR, excluding animal and human research. The delphi study involved experts in data management, peer review, collaborative science, conflicts of interest, authorship & publications, mentorship, research misconduct, and general RCR concepts. The final list of objectives will be extremely useful for educators setting up programs and courses for RCR. Dr. Dubois is expected to publish his results in early 2008.

for Maryland, replaces Brian Bewley who transferred to the Office of the Inspector General, HHS. In the Maryland Attorney General’s office, Tayman handled disciplinary cases against health care institutions and health professionals.

Misconduct Activity Reported Once by Most Institutions from 1992-2001

Almost 60 percent of the institutions reporting research misconduct activity in their Annual Report on Possible Research Misconduct from 1992-2001 did so in only one year.

Misconduct activity is defined as receipt of an allegation of research misconduct or the conduct of an inquiry or investigation involving research supported by the Public Health Service (PHS).

During the 10 year period, 248 unique institutions reported misconduct activity; 145 (58 percent) reported the activity in only one year. Almost 30 percent reported misconduct activity in two to four years and 13 percent reported such activity in five to nine years.

For more data on the misconduct activity reported by institutions see New Institutional Research Miscon-

duct Activity: 1991-2001 at <http://ori.hhs.gov/publications/studies.shtml>.

Number of Years Research Misconduct Activity Reported By Number of Institutions: 1992-2001

<i>Number of Years Reporting</i>	<i>Number of Institutions</i>	<i>Percent</i>
One	145	58
Two	32	13
Three	24	10
Four	16	6
Five	18	7
Six	7	3
Seven	2	1
Eight	2	2
Nine	2	1
TOTAL	248	100

New RRI Pubs

Anderson MS, Horn AS, Risbey KR, Ronning EA, DeVries R, Martinson BC. "What Do Mentoring and Training in the Responsible Conduct of Research Have to Do with Scientists' Misbehavior? Findings from a National Survey of NIH Funded Scientists." *Academic Medicine* 2007, 82 (9), 853-860.

Heitman E, Olsen CH, Anestidou L, Bulger RE. "New Graduate Student's Baseline Knowledge of the Responsible Conduct of Research." *Academic Medicine* 2007, 82 (9), 838-845.

Louis KS, Holdsworth JM, Anderson MS, Campbell EG. "Becoming a Scientist: The Effects of Work-Group Size and Organizational Climate." *Journal of Higher Education* 2007, 78 (3), 311-336.

RCR Conference Seeks Widespread Participation (from page 1)

instruction, targeting different audiences, innovative teaching materials and approaches, international programs, and other aspects of RCR instruction. Time will also be set aside for interactive demonstration sessions and poster presentations. Everyone attending is invited to bring materials to display and share with others.

"We would like to see widespread participation from instructors in RCR, research ethics, survival skills, lab management, human subjects, animal welfare, instructional design, and the social sciences as well as principal investigators in NIH research training grants and the new NIH Translational Research (CTSA) programs," said conference co-chair Cathy Striley, Washington University.

"We also invite participation from the physical sciences and engineer-

ing which are required under the America COMPETES Act (HR 2272) to provide appropriate training in responsible and ethical research to undergraduates, graduate students, and postdoctoral fellows participating in NSF-funded research projects," said conference co-chair Nick Steneck.

"ORI hopes these biennial meetings will promote a sense of community among RCR instructors by promoting networking, collaborations, sharing of resources, discussion and the pursuit of common goals," Larry Rhoades, Director, Division of Education and Integrity, ORI, said.

**Peer review is constructive;
not destructive**

Case Summaries

Juan Carlos Jorge-Rivera, Ph.D., Dartmouth College: Based on the findings of an inquiry conducted by Dartmouth College, an investigation conducted by another Federal agency, and additional analysis conducted by the Office of Research Integrity (ORI) during its oversight review, the U.S. Public Health Service (PHS) found that Juan Carlos Jorge-Rivera, Ph.D., former postdoctoral fellow, Department of Physiology, Dartmouth College, engaged in misconduct in science in research funded by National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH), grant R01 NS28668.

Specifically, Dr. Jorge-Rivera knowingly and intentionally falsified amplifier gain in at least eleven (11) experiments of his postdoctoral research aimed at measuring the effects of anabolic steroids on GABAergic current in brain cells and reported the falsified data in Figures 4 and 6 of the following paper: Jorge-Rivera, J.C., McIntyre, K.L., & Henderson, L.P. "Anabolic steroids induce region- and subunit-specific modulations of GABA receptor mediated currents in the rat forebrain." *Journal of Neurophysiology* 83:3299-3309, 2000.

Dr. Jorge-Rivera has been debarred by the Federal agency with joint

jurisdiction for a period of two (2) years, beginning on January 11, 2007, and ending on January 11, 2009.

ORI has implemented the following administrative actions:

(1) For a period of three (3) years, beginning on June 23, 2007, and ending on June 22, 2010, Dr. Jorge-Rivera 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) for a period of three (3) years, beginning at the end of his debarment period (January 11, 2009), and ending on January 10, 2012, Dr. Jorge-Rivera must submit, in conjunction with each application for PHS funds, annual reports, manuscripts, or abstracts of PHS-funded research in which he is involved, a certification that the data he provides are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application or report.

Jon Sudb[oslash], D.D.S., Norwegian Radium Hospital: Based on the findings of an investigation conducted by the Investigation Commission appointed by Norwegian Radium Hospital (NRH) and the University of Oslo, the respondent's own admission, and additional analysis and information obtained by the Office of Research Integrity (ORI) during its oversight review, the U.S. Public Health Service (PHS) found that Jon Sudb[oslash], D.D.S., former doctoral student and faculty member, University of Oslo, and

former physician in the Department of Medical Oncology and Radiotherapy, NRH, engaged in scientific misconduct by reporting fabricated and/or falsified research in grant application 1 P01 CA106451-01 submitted to the National Cancer Institute (NCI), National Institutes of Health (NIH), and its first-year progress report.

Specifically, PHS found that Dr. Sudb[oslash] engaged in scientific misconduct by falsifying and fabricating research that served as the rationale for Project 1, "Oral Cancer Prevention with Molecular Targeting Therapy," with Dr. Jon Sudb[oslash], as project leader, in the grant application, and by falsifying a progress report for the awarded grant. In particular, in Figure 1 of the Background and Significance section of the grant application, Dr. Sudb[oslash] reported fabricated/falsified results for the effects of lesion ploidy upon survival in patients with oral pre-malignant lesions. In the Preliminary Data section of the grant application, Dr. Sudb[oslash] reported several events intended to demonstrate his experience in the research field that the Investigation Commission stated "appear as pure fiction." Also, in the first yearly progress report for the funded grant, Dr. Sudb[oslash] falsified the number of patients that had been screened for admission to the study.

In addition to three publications for which Dr. Sudb[oslash] admitted falsifying and/or fabricating data, the Investigation Commission found at least twelve other publications that warranted retraction because they could not be considered valid. The research reported in these

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RCR Conference**

April 17-19, 2008

<http://epi.wustl.edu/epi/rcr2008.htm>

Case Summaries *(continued)*

publications was not supported by PHS funds. However, the publications address the same general research area as that addressed in the grant application and demonstrate a pervasive pattern of falsification/fabrication in research reporting on the part of Dr. Sudb[oslash]. The falsified/fabricated data presented in the grant application purport to demonstrate the feasibility of preventing cancer in a high risk population with nontoxic oral agents.

Dr. Sudb[oslash] has entered into a Voluntary Exclusion Agreement (Agreement) in which he has voluntarily agreed, beginning on August 31, 2007:

(1) To exclude himself permanently 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 delineated in the OMB Guidelines to Agencies on Governmentwide Debarment and Suspension at 2 CFR Part 376, et seq.; and

(2) To exclude himself permanently 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 or contractor to PHS.

**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

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**DEPARTMENT OF
HEALTH AND HUMAN SERVICES**

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

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