

Office of Research Integrity

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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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Biennial RCR Conference Being Planned by ORI

ORI is planning to hold the first biennial conference on the responsible conduct of research (RCR) next spring to foster the growth of a community of RCR instructors, discuss issues in RCR training, and explore ways ORI may support the RCR effort.

“ORI believes the RCR community would benefit from a regularly scheduled national conference that provides its members with opportunities to network, share resources, discuss common problems, and advance ideas for the greater good of the enterprise,” Larry Rhoades,

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ORI Issues Revised Policy and Procedures

ORI has issued a Sample Policy and Procedures that complies with the PHS Policies on Research Misconduct (42 C.F.R. Part 93) and replaces the model policy and procedures that was based on the 1989 research misconduct regulation.

“This Sample Policy and Procedures is intended to meet the regulatory requirements, but it is not intended to represent the best or only way of meeting these requirements,” Chris Pascal, Director, ORI said. “We have sought to emphasize this by renaming it as a ‘sample’ rather than a ‘model,’ by further clarifying what

See Template, page 2

RRI Program Adopts New Award Mechanisms

Two new funding mechanisms designed to foster the development of emerging research areas will be used by the Research on Research Integrity (RRI) Program beginning this year, replacing the current RO1 mechanism.

The two mechanisms will be the Pilot or Small Grant (R03) and the Exploratory/Developmental Grant (R21). For more information on these mechanisms see <http://grants1.nih.gov/grants/funding/r03.htm> and <http://grants1.nih.gov/grants/funding/r21.htm>

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World Conference Attracts Worldwide Attendance

About 350 persons from 62 countries are expected to attend the first World Conference on Research Integrity: Fostering Responsible Research that will be held in Lisbon, Portugal, from September 16-19, 2007.

ORI is collaborating with the European Science Foundation (ESF) in organizing the conference which will be held at the headquarters of the Calouste Gulbenkian Foundation. The Portuguese Ministry for Science, Technology and Higher Education (PMSTHE) will host the conference as of part of the

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New DIO Scientist-Investigator Hired; Sam Merrill Retired in March

A new scientist-investigator joined the Division of Investigative Oversight (DIO) in May following the retirement of a veteran scientist-investigator in March.

Linda D. Youngman, Ph.D., joined DIO from the Food and Drug Administration (FDA) where she served as a toxicologist and risk analyst in the Office of New Animal Drug Evaluation, Center for Veterinary Medicine (CVM).

Samuel Merrill, Jr., Ph. D., retired from ORI after serving as a scientist-investigator for about 14 years to specialize in fishing in Florida.

At the CVM, Youngman previously served as the Deputy Director, Acting Director, and Director of the Office of Research and chairperson of the National Antimicrobial Resistance Monitoring System.

From 1990-2000, she was Director of Laboratories and Senior Research Fellow in the Clinical Trial Service and Epidemiological Studies unit at

the University of Oxford, England, where she received tenure in 1995.

Youngman holds a doctorate in toxicology and a master's and a bachelor's degree in biochemistry from Cornell University. She also holds a certificate in epidemiology and medical statistics from the London School of Hygiene and Tropical Medicine and a certificate in risk assessment from the University of Maryland.

Her research has been published in numerous journals including *New England Journal of Medicine*, *Journal of the American Medical Association*, *Lancet*, *British Medical Journal*, *Proceedings of the National Academy of Sciences*, *Cancer Research*, and *the American Journal of Epidemiology*.

Merrill joined DIO in June 1993 from the Library of Congress where he was a Life Sciences specialist in the Science Policy Research Division of the Congressional Research Service. He holds a doctorate in

nutritional science from the University of Maryland.

“For most of his years at ORI,” John Dahlberg, Director, DIO, said. “He specialized in clinical cases and participated in many audits with NIH and FDA auditors on for-cause audits to help sort out research misconduct issues from other problems.”

He continued, “Perhaps Sam’s most valuable contribution to DIO was his ability to view research misconduct from the perspective of all of the affected individuals. He was the one who often brought the rest of us up short by reminding us that the respondent’s actions were not very significant and perhaps did not warrant the permanent onus of a government misconduct finding. He was unfailingly thoughtful and tactful, and a friend to us all.”

**Retain Data Longer
Than Necessary**

Template for Institutional Compliance is 42 C.F.R. Part 93 (from page 1)

parts of the sample are required by the regulation, and by explicitly stating that it does not create a standard or expectation for institutional research misconduct policies and procedures. The template for institutional compliance is 42 C.F.R. Part 93.”

The Sample Policy and Procedures is posted on the ORI website along with a Preamble that addresses the “confusion about the expected content of, and the level of detail in, institutional policies vis-a-vis institutional procedures.”

The Preamble states, “The research misconduct regulation required institutions to have written policies and procedures for addressing research misconduct that meet the requirements of the regulation. It does not require that policies contain certain requirements or that procedures contain certain other requirements, or even that the policies and procedures be separate documents. To clarify that this document is intended to meet all of the requirements of the regulation for both policies and procedures, we

have expanded its title to include procedures. This combining of policy and procedures, however, is not intended to indicate that institutions should change their typical practice of having general misconduct policies and more detailed procedures.”

Appendix A lists the responsibilities that the institutional research integrity officer (RIO) has for implementing the PHS Policies on Research Misconduct.

First RIO Boot Camp Held; Next at an East Coast University in Fall

Sixteen institutional research integrity officers (RIOs) and eight general counsels from major mid-western universities attended the first RIO boot camp that was held at the University of Michigan from May 2-4, 2007.

The boot camp was developed by David Wright, former RIO at Michigan State University for 13 years, under contract with ORI, and in consultation with veteran RIOs. Contact Wright at dewrite@msu.edu.

A boot camp will be scheduled at an east coast university, fall 2007. Boot camps are scheduled for the University of Washington, spring 2008, and Duke University, fall 2008. These boot camps are designed initially for RIOs and general counsels from the 100 top NIH awardee institutions—the location of most research misconduct cases. Participation is by invitation only and will be limited to 25 per boot camp.

“ORI is offering the boot camps regionally so that the RIOs can get to know each other and begin to build informal networks,” Wright said. “At the end of the first two-year cycle, ORI will assess the outcome and determine whether to offer additional boot camps.”

“The boot camps take participating RIOs and their legal counsel step-by-step from receipt of an allegation through to preparation of the final investigative report—and its submission to ORI in cases involving PHS funding,” Wright said. “They utilize an active or hands-on learning model where RIOs mainly engage in exercises and problem-solving tasks rather than listen to lectures.”

The boot camps are part of an in-service education program being developed by Wright for ORI to provide training in the handling of research misconduct allegations and professionalize the RIO role.

An orientation video, *The Role of the RIO*, presents a 22-minute introduction to the handling of research misconduct allegations and interviews with veteran RIOs and ORI staff. The video is available on the ORI web site. Copies of the video have been sent to more than 1,200 institutions worldwide.

ORI is also offering mini-boot camps at scientific society and professional association meetings. The next mini-boot camp will be at

the SRA meeting in Nashville this October.

ORI plans to create a new, on-line RIO Manual to provide further support for RIOs. Boot camp alumni will be invited to contribute to and critique drafts of the manual. The manual will include many of the curricular materials from the boot camp, discussion of all major elements of the RIO’s role cross-reference to the regulation (42 C.F.R. Part 93), and video clips of RIOs performing various aspects of the job.

Given sufficient interest and participation, ORI plans to provide start-up support for a RIO professional organization.

Research Misconduct Activity Sets No Records in 2006

One hundred and eleven institutions that reported new or continuing research misconduct activity in their 2006 Annual Report on Possible Research Misconduct, came close but did not establish any records for such activity.

Current record highs are institutions reporting research misconduct activity, 113; institutions reporting new cases, 82; number of allegations received, 163, and number of new cases, 105.

Research misconduct activity is defined as receipt of an allegation or the conduct of an inquiry or investigation in the reporting year or prior to the reporting year. Reportable activities are limited to alleged research misconduct involving PHS-supported research, research training or other research related activities.

The 111 institutions that reported research misconduct activity were engaged in 73 continuing cases and 86 new cases in 2006.

Eighty-one of the 111 institutions reported opening new cases upon receipt of 151 allegations. Institutions received 69 allegations of falsification; 53 of fabrication; and 29 of plagiarism. These allegations resulted in 77 inquiries and 26 investigations in 2006.

Institutions reporting new cases included higher education, 59; research organizations, 9; independent hospitals, 9; educational organizations, 0; other health, human resources, 3 and small businesses, 1.

Announcement Due in Late July; Deadlines in November *(from page 1)*

The R03 supports pilot or feasibility studies, secondary analysis of existing data, small self-contained research projects or the development of research methodology or technology. These awards are limited to \$50,000 in direct costs for each of two years.

The R21 is intended to encourage new, exploratory and developmental research. The mechanism provides support for developing expertise, collecting data, and publishing in a new research area. These awards are limited to two years and a total direct cost of \$275,000.

“The R21 provides an opportunity to advance an area of science that has potential for providing sufficiently strong data to be competitive for an RO1,” said Andrea Sawczuk, the RRI program officer at the National

Center for Research Resources which will provide grant management and review services for the RRI Program beginning this year.

“The ‘07 RFA is a good place to start your planning,” Nick Steneck, Director, RRI Program, said. “The overall focus on the program, definitions and areas of interest will likely remain as they have in the past, but there will be new opportunities for projects and new priorities that are of interest to specific NIH institutes and centers.”

The Funding Opportunity Announcement (FAO) instead of a Request for Applications (RFA) will be issued in late July on the ORI web site and the *NIH Guide for Grants and Contracts*. The optional letters of intent will be due in mid-October. Application deadline for an

R03 award is November 20, 2007. Application deadline for an R21 award is November 21, 2007.

“ORI is very thankful to the National Institute of Nursing Research and the Center for Scientific Review for the grant management and review services they have provided for the last two years,” Chris Pascal, Director, ORI, said. “And warmly welcomes NCRR which is assuming those responsibilities this year. The support of NIH institutes and centers is essential to the continued success of this program.”

For further information contact Dr. Sawczuk at SawczukA@mail.nih.gov or Dr. Steneck at nsteneck@umich.edu.

First Global Forum for Fostering Responsible Research *(from page 1)*

Portuguese presidency of the European Union.

The World Conference is the first global forum convened to provide researchers, research administrators, research sponsors, journal editors, representatives from professional societies, policymakers, and others an opportunity to discuss strategies for harmonizing research misconduct policies and fostering responsible conduct in research.

The program is organized around five plenary and three parallel sessions. Plenary sessions engage important aspects of research integrity in ways that are relevant and useful to researchers and research policy makers. They feature

prominent scholars, administrators, and officials who have expertise in research misconduct. Parallel sessions will address focused topics and allow more time for discussion. Parallel sessions will be held on: research misconduct, institutional issues, and publication. Each parallel will include three concurrent sessions. See the conference

website at <http://www.esf.org/conferences/researchintegrity>.

The conference has been planned by Tony Mayer, ESF, and Nick Steneck, ORI consultant, with guidance from a planning committee.

Besides ESF and ORI, the conference is supported by the European Commission, the European Molecular Biology Organization, the Committee on Publication Ethics, the Portuguese Ministry of Science, Technology and Higher Education, the Portuguese Science Foundation, the Calouste Gulbenkian Foundation, the UK Research Integrity Office, International Council for Science and the North Atlantic Treaty Organization.

**ORI Annual Report –
2006**

See ORI Home Page

<http://ori.hhs.gov>

Randi Freedman 1963-2007

Randi Freedman, Assurance Program Manager, ORI, died May 27, 2007 from injuries sustained in a traffic accident the previous day when another motorist reportedly ran a traffic light and collided with the motorcycle on which she was riding with a friend.

Ms. Freedman held positions throughout ORI since she was hired in July 1993 as a program specialist in the Division of Investigative Oversight. Subsequently, she was promoted to information technology specialist in the Office of the Director, ORI, and eventually was transferred to the Division of Education and Integrity (DEI) where webmaster duties were added to her repertoire. She became the Assurance Program Manager in 2005.

“Randi will be missed personally and professionally,” Larry Rhoades, Director, DEI, said. “She was a very easy person to like. She constantly looked for ways to improve the Assurance Program and service her clients.”

Ms. Freedman was pursuing a degree in business administration in the evenings. She is survived by her 10-year old son, her former husband, her mother, a sister, and two brothers. A trust fund has been established for her son at the Westminster Union Bank, 1350 Liberty Road, Eldersburg, MD 21784. Donations should be made payable to Memorial in Trust to Matthew Lewis Nathan.

Assurance Program

Assurance Program inquiries should be sent to Robin Parker at Robin.Parker@hhs.gov.

Phone: 240-453-8400

CITI RCR Course Attracting Enrollees

More than 1,550 persons completed a CITI responsible conduct of research (RCR) course consisting of at least 14 modules between January 1 and June 1, 2007. Seventy-four percent completed either the biomedical or the social and behavioral science course; the rest finished the physical sciences or humanities courses.

During the same period, over 4,800 persons from 1,350 U. S. and 165 international organizations opened a Collaborative Institutional Training Initiative (CITI) RCR account which enables them to access the RCR course site for free at least until May 2008.

The course site, partially funded by ORI, 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.

Modifications will be made to the RCR course site in July 2007 to implement recommendations from the CITI RCR Developer Group which reviewed the site in April 2007.

More information on the CITI RCR Program and other CITI courses is available at www.citiprogram.org. 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 Abstracts Due October 15 (from page 1)

Director, Division of Education and Integrity, ORI, said.

“Four areas of instruction related to the responsible conduct of research have emerged over the years,” Nick Steneck, conference organizer, said. “Survival skills, research ethics, laboratory management, and RCR. It may be time for a conceptual reorganization.”

Numerous RCR resources are now available. In addition to programs developed for use at specific institutions, there are web-based resources that are generally available including the 30 modules developed by the ORI RCR Resource Development Program, the Open Seminar on Research Ethics created by a consortium of universities supported by NSF, and the modules developed by

the Collaborative Institutional Training Initiative (CITI).

“It may be time to assess what we have and do not have and where we want to go from here,” Rhoades said. “It may be time to develop a comprehensive vision.”

“RCR instruction currently is approached in different ways,” Steneck said. “It is time to discuss objectives, compare approaches and explore ways to assess the effectiveness of these and other approaches.”

Abstracts for sessions, panels and papers will be due October 15, 2007. Suggestions on the format and content of the RCR conference are welcomed before the abstract deadline and should be sent to Nick Steneck at nsteneck@umich.edu.

Academic Societies Produce Additional RCR Products

Several new products are available from awards made by the ORI-Association of American Medical Colleges (AAMC) Responsible Conduct of Research (RCR) Program for Academic Societies.

During the life of the program 39 awards were made to 33 different academic and scientific societies. The program has supported the development of guidelines, standards, policies, and publications (including RCR articles in journals, newsletters, and on society Web sites), committees, annual conferences, core competencies, curricula, and other resources related to the core RCR components.

Some program products recently made available include:

- The American College of Neuropsychopharmacology: a “Code of Conduct for Sustaining Corporations”;
- The American Society for Bioethics and Humanities: an article, “Educational Approaches to the Responsible Conduct of Clinical Research: An Exploratory Study” in *Academic Medicine*, January 2007, (Vol. 82, No. 1, p. 32-39);
- The Council on Social Work Education: a “National Statement on Research Integrity in Social Work” and an “Action Plan for

Promoting Research Integrity in Social Work”;

- The Gerontological Society of America: a “Guidebook for Multidisciplinary Clinical Geriatric Research”; and
- The American College of Physicians: a patient education brochure, “Volunteering for a Research Study?” They have also posted materials from their recent workshop on “Doing Research in the Office: Professionalism and Pitfalls”.

Links to all program products are available on a recently revised web page <http://www.aamc.org/ori/>.

Case Summaries

Kartik Prabhakaran, University of Pittsburgh: Based on the report of an inquiry conducted by the University of Pittsburgh (UP), extensive oral and written admissions by the Respondent, and additional analysis conducted by the Office of Research Integrity (ORI) during its oversight review, the U.S. Public Health Service (PHS) found that Mr. Kartik Prabhakaran, former graduate student in the joint M.D./Ph.D. program at UP, engaged in research misconduct while supported by National Institutes of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH), grant F30 NS50905-01 and National Eye Institute (NEI), NIH, grants 5 R01 EY005945, 5 P30 EY008098, and 5 R01 EY015291.

Specifically, Mr. Prabhakaran falsified and fabricated data that was included in a PowerPoint presentation and in a paper published in

Immunity (*Immunity* 23:515-525, November 2005). Mr. Prabhakaran’s research misconduct occurred while he was a student in the M.D./Ph.D. program for UP’s School of Medicine. He is no longer in UP’s Ph.D. program but is still enrolled in its M.D. program in the School of Medicine. The *Immunity* publication has been retracted (*Immunity* 24:657, May 2006).

Mr. Prabhakaran has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed, for a period of four (4) years, beginning on March 15, 2007:

- (1) To exclude himself 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) That any institution that submits an application for PHS support for

a research project on which Mr. Prabhakaran’s participation is proposed, that uses him in any capacity on PHS supported research, or that submits a report of PHS-funded research in which he is involved must concurrently submit a plan for supervision of his duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of his research contribution. Mr. Prabhakaran agreed to ensure that a copy of the supervisory plan also is submitted to ORI by the institution. Mr. Prabhakaran agreed that he will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI.

Rebecca Uzelmeier (formerly known as Rebecca Marcus), Michigan State University: Based on the report of an investigation by Michigan State University (MSU)

Case Summaries *(continued)*

and additional information obtained by the Office of Research Integrity (ORI) during its oversight review, ORI found that Rebecca Uzelmeier, former doctoral student, Department of Pharmacology and Toxicology, MSU, committed research misconduct by intentionally and knowingly fabricating and falsifying data in research supported by National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), grant R01 ES02520. ORI issued a charge letter enumerating the above research misconduct findings. However, on October 12, 2006, Ms. Uzelmeier filed a request for a hearing under 42 CFR Part 93 to dispute these findings before the U.S. Department of Health and Human Services (HHS) Departmental Appeals Board (DAB). On October 19, 2006, ORI moved to dismiss Ms. Uzelmeier's hearing request because it failed to create a genuine dispute of either material fact or law, as required under 42 CFR 93.504. On March 5, 2007, the Administrative Law Judge (ALJ) with the DAB ruled in ORI's favor and dismissed Ms. Uzelmeier's hearing request pursuant to 42 CFR 93.504(a)(2).

The ALJ found that Ms. Uzelmeier's hearing request raised defenses that either were immaterial to the charges of research misconduct or that the ALJ had no authority to grant Ms. Uzelmeier's request for relief under Part 93. Specifically, Ms. Uzelmeier knowingly and intentionally:

Fabricated and falsified data in her research notebook primarily by

multiple instances of using data/results generated from one experiment to represent data/results purportedly obtained from one or more entirely different experiments; and fabricated and falsified data in her thesis entitled "Characterization of the Molecular Mechanism(s) Underlying the Interaction(s) between 2,3,7,8-tetrachlorodibenzo-p-Dioxin Mediated and Interferon Gamma Mediated Signal Transduction," including falsifying and fabricating autoradiographic films, computer image files scanned from those films, numerical data reduced from those computer files, documentation of those results in her black three-ring binder, and data in associated multiple figures and projection slides.

Ms. Uzelmeier's research concerned the interaction between the environmental toxin, dioxin, and a cytokine, interferon, on cellular signaling in the immune system. The approach was to exploit dioxin, or "TCDD" (2,3,7,8-tetrachlorodibenzo-p-dioxin), as a probe that suppresses the immune system to delineate a role for the aryl hydrocarbon receptor protein (AhR), which is a cytosolic receptor that can be transported to the nucleus to also act as a nuclear transcription factor. The specific aim was to determine whether the mechanism of action of a naturally occurring regulatory factor, interferon-[gamma] (IFN-[gamma]), to antagonize the immunosuppressive actions of dioxin, was through reduced AhR signaling.

The following administrative actions have been implemented for

a period of five (5) years, beginning on March 12, 2007:

- (1) Ms. Uzelmeier has been 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 referred to as "covered transactions" as defined in the debarment regulations at 2 CFR 180 and 376; and
- (2) Ms. Uzelmeier 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 consultant.

Wei Jin, Colorado State University: Based on an investigation conducted by Colorado State University (CSU) and additional analysis and information obtained by the Office of Research Integrity during its oversight review, the U.S. Public Health Service (PHS) found that Mr. Wei Jin, former doctoral candidate, Department of Chemistry, CSU, engaged in research misconduct in research funded by National Cancer Institutes (NCI), National Institutes of Health (NIH), grant R01 CA85419.

Specifically, Mr. Jin falsified data/results by claiming he had performed a novel total synthesis of renieramycin G, when in fact, he obtained renieramycin G through a relatively simple reaction sequence from renieramycin M, a natural product that was a gift to the laboratory and that had been isolated by others from the Thai sponge. Mr. Jin

Case Summaries *(continued)*

included the falsified data/results in: his research notebooks and other records of his research; his dissertation, “Asymmetric total synthesis of (-)-Reineramycin G and studies toward the total synthesis of Ecteinascidin-743”; a manuscript, Jin, W. & Williams, R., “Asymmetric total synthesis of (-)-Renieramycin G,” accepted by the *Journal of the American Chemical Society*; and Supplemental information relative to the manuscript to be published online.

ORI has implemented the following administrative actions for a period of three (3) years, beginning on May 8, 2007:

(1) Mr. Jin is debarred from eligibility for 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 referred to as “covered transactions” as defined in HHS’ implementation of OMB Guidelines to Agencies on Government-wide Debarment and Suspension at 2 CFR Part 376, et seq.; and

(2) Mr. Jin 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.

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