

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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10 Misconduct Findings Result in 7 Debarments

Thirty-five percent of the 28 research misconduct cases closed by ORI in 2007 resulted in research misconduct findings. Seventy percent of the respondents in those cases were debarred from receiving government funding for periods ranging from three years to a lifetime.

The ten respondents against whom misconduct findings were made include an associate professor, a surgical resident, two postdocs, three graduate students, a research associate, and two phlebotomists. All ten respondents were prohibited

from serving in any advisory capacity to the PHS.

Administrative actions imposed on the three respondents who were not debarred include retraction of a published article, data certification, and the submission of a supervisory plan.

From 2002-2006, ORI averaged 11 misconduct findings per year. Misconduct was found in 40% of the closed cases. Sixty-six percent of the respondents against whom misconduct findings were made were debarred.

See Average, page 4

Get Involved in First RCR Conference

Several opportunities are still available for you to participate in the first biennial ORI Conference on the Responsible Conduct of Research (RCR) Education, Instruction and Training that will be held at the Renaissance St. Louis Grand and Suites Hotel from April 17-19, 2008, but time is running out.

“This conference is an opportunity for persons interested in RCR education to meet each other, to hear colleagues express their ideas about RCR education, to present their own ideas, and to help shape the future of RCR education,” Cynthia Ricard, conference co-chair, said.

“Besides the time allotted for discussion in plenary and concurrent sessions,” Cathy Striley, conference

co-chair, said, “we have built in specific opportunities for active involvement in the conference.” The specific opportunities for involvement include:

- Entering a poster that describes your unique RCR program. Mail to nsteneck@umich.edu.
- Bringing your RCR program materials to be shared with colleagues.
- Submitting and receiving the results of in-conference surveys.
- Helping shape closing recommendations on future directions and needs.

“Don’t miss out on the chance to shape the future of RCR education,”

See Help, page 2

Two Original ORI Members Retired on March 1

Two ORI members who have participated in the PHS effort to respond to research misconduct since 1989 retired from federal service on March 1, 2008.

John Butler, Compliance Officer, completed 34 years of service. Larry Rhoades, Director, Division of Education and Integrity, finished 31 years of service.

Butler joined the Office of Scientific Integrity (OSI) at NIH when it was created in 1989 where he worked on research misconduct allegations and assumed responsibility for addressing whistleblower protection issues. Shortly after ORI was formed in 1992, he joined the Division of Education and Integrity as the Assurance Program Manager.

“One of John’s major contributions to ORI,” Chris Pascal, Director, ORI, said, “was his work on establishing the system for electronically submitting the Annual Report on Possible Research Misconduct. Other major

contributions were his work on institutional compliance and whistleblower protection.”

In 2003, Butler returned to the oversight of institutional misconduct investigations while retaining whistleblower protection and compliance responsibilities. Butler plans to revitalize his cabinet making hobby and explore travel opportunities in his retirement.

Rhoades became Deputy Director of the Office of Scientific Integrity Review in the Office of the Assistant Secretary of Health in 1989. Shortly after the creation of ORI, he was appointed Director of the Division of Education and Integrity.

“Larry built the ORI educational program,” Pascal said. “He also was primarily responsible for keeping the worldwide research community informed about ORI activities and for developing partnerships with the research community to support our common
See Rhoades, page 7

Help Shape Future of RCR Education *(from page 1)*

Nick Steneck, conference co-chair, said. “Participants can listen and learn, but we are encouraging active participation.”

Conference participants may also attend a pre-conference luncheon for NIH research training grant and Clinical and Translational Science Award (CTSA) program faculty and staff at noon on April 17 on a space available basis. Keynote speaker Karla Zadnik, Associate Dean, College of Optometry, Ohio State Univ., will provide advice on ways

to engage trainees in RCR instruction.

Scholarships may still be available to cover expenses involved in attending the conference. The deadline for room reservations is March 28, 2008.

For further information on these opportunities contact nsteneck@mich.edu. See conference website for registration, agenda, and reservation information at <http://epi.wustl.edu/epi/rcr2008.htm>

Designing RCR Programs For Postdocs, Seed Grants

A half-day workshop focusing on strategies and mechanisms for creating a dynamic training program on the responsible conduct of research for postdocs will be held during the annual meeting of the National Postdoctoral Association in Boston on April 26, 2008.

The workshop is part of the Bring RCR Home project, supported by ORI, that is designed to assist institutional postdoc offices and postdoc associations to develop RCR training programs specifically tailored to the needs of postdocs.

“Participants will also learn how to apply for NPA seed grants to conduct RCR programs at their institutions and will be given favorable consideration in the 2008 seed grant competition,” Katy Flint, Project Manager, said. Twelve seed grants were awarded in 2007.

The first workshop session will feature presentations of effective practices in RCR education and approaches for tailoring an RCR program to address the particular challenges of the postdoc phase of a research career.

A panel of seed grant awardees will give an overview of their RCR programs and share lessons learned in the second session.

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Scientists Declare May 2008 Cell Line Authentication Global Awareness Month

Academic institutions, research institutes, and industrial laboratories worldwide are being asked by an ad hoc group of concerned scientists to organize at least one activity for their members on cell authentication in May 2008.

The ad hoc group has declared that month to be Cell Line Authentication Global Awareness Month to draw attention to the misidentification and cross-contamination of cell lines, a problem that has persisted for more than 45 years. The group estimates that 15-20 percent of cultured cell lines are misidentified or cross-contaminated.

“The activity could be a lecture, seminar, discussion or webinar/

webcast dealing with some facet of cell line authentication,” Roland Nardone, professor emeritus, Catholic University of America, and leader of the international ad hoc group of concerned scientists, said.

“Starting with the premise that most of the stewards and the scientific community at large are persons of principle and dedication, it follows that raising their level of awareness will inevitably be followed by appropriate corrective action that will lead to the eradication of misidentified and cross-contaminated cell lines,” Professor Nardone said.

The group called the problem to the attention of Secretary Michael Leavitt, HHS, and Director Elias

Zerhouni, NIH, last year. As a result NIH issued a Notice Regarding Authentication of Cultured Cell Lines (NOT-OD-08-017) which states, “Grant applications that fail to employ such practices would not be considered of the highest quality and such manuscripts would not fare well in the journal review process. We encourage all reviewers to consider these issues carefully in order to protect and promote the validity of the science we support.”

Several webinars/webcasts on cell misidentification, cross-contamination, or authentication will be available on the Internet in May 2008. For additional information visit the cell line authentication web site at <http://cellid.cua.edu>.

Research Integrity Certificate Program Created by SRA International

A Research Integrity Certificate Program has been created by the Society of Research Administrators (SRA) International to provide its members with a foundation for identifying, understanding and addressing the complex ethical dimensions of research.

The certificate program is designed to provide a basic understanding of topics associated with research integrity—including cultural aspects, goals for facilitating research integrity, and strategies for creating an institutional culture that values ethical and responsible practices in research.

Basic requirements of the certificate program are attendance at a half-day or full-day workshop on research integrity that focuses on general aspects of research integrity or any specific area associated with re-

search integrity and completion of at least one session from any five of the following six concentration areas: research integrity in general; research protections and compliance review boards (e.g., IACUC, IRB, ESCRO, biosafety, conflicts of interest); data management (e.g., recordkeeping, data ownership, data sharing); social responsibility; authorship, publication, and/or peer review; and problem-solving skills, tools and resources to address problems in the research environment. Participants must complete requirements within three years.

The certificate program is designed for research administrators, senior management, executives, and members of review boards who have interests and shared responsibilities associated with the ethical dimensions of research. The program is also

recommended for investigators interested in addressing NIH, NSF and DOD requirements specific to research ethics education and training.

For more information, contact the SRA Education and Professional Development Officer at (703) 741-0140. Email: info@srainternational.org.

Fifth Biennial Research Conference on Research Integrity

**The Conference Center
Niagara Falls, NY
May 15-17, 2009**

**Host: Roswell Park
Cancer Institute**

Average ORI Processing Time for Cases Closed in 2007 Was 7.1 Months *(from page 1)*

ORI opened 14 new cases for oversight review in 2007 and carried 39 open cases into 2008.

From 2002-2006, ORI averaged 30 new cases per year and carried an average of 51 open cases forward into the next year.

Most of the differences resulted from ORI following a greater number of accessions without opening them as cases until it was clear that the allegations met the PHS definition and PHS funding was involved in supporting the

questioned research. Accessions that may become ORI cases that require additional information prior to opening are called preinquiry assessments (PIAs).

ORI administratively closed 56 pre-inquiry assessments (PIAs) during 2007, most of which would have been opened as cases in previous years. "Most of these PIAs required as much oversight review as formal inquiries and investigations, so the 56 administrative closures may be justifiably considered equivalent to case openings and closures," Dahlberg said.

The average ORI processing time for cases closed in 2007 was 7.1 months. One case took 47 months; another 33 months. The remaining 26 cases took an average of 4.6 months to close.

ORI received 217 queries in 2007 that resulted in the following 256 actions because some queries required more than one action: 95 pre-inquiry assessments, 19 referrals to other agencies, and 142 no action possible now or no action.

RRI Researchers Publish Ten More Articles in Eight Journals

Researchers supported by the Research on Research Integrity (RRI) Program have published ten more articles in eight journals in late 2007 and early 2008.

Since the program was started in 2000, RRI investigators have produced 54 publications (41 articles, 8 abstracts, 2 review articles, 2 commentaries, and 1 letter to the editor) in 21 journals including *Nature*, *New England Journal of Medicine*, *Journal of the American Medical Association* and the *British Medical Journal*. See http://ori.hhs.gov/research/extra/rri_publications.shtml

Citations to the recently published articles follow:

- Anderson MS. Collective Openness and Other Recommendations for the Promotion of Research Integrity. *Science and Engineering Ethics* 2007, 13(4), 387-394.
- Anderson MS, Ronning EA, De Vries R, Martinson BC. The Perverse Effects of Competition on Scientists' Work and Relationships. *Science and Engineering Ethics* 2007, 13(4), 437-461.
- Anderson MS, Martinson BC, De Vries R. Normative Dissonance in Science: Results from a National Survey of U.S. Scientists. *Journal of Empirical Research in Human Research Ethics* 2007, 2(4), 3-14.
- Bulger RE, Heitman E. Expanding Responsible Conduct of Research Instruction across the University. *Academic Medicine* 2007, 82(9), 876-878.
- Errami M, Garner H. A Tale of Two Citations. *Nature* 2008, 451: 397-399.
- Errami M, Hick JM, Fisher W, Trusty D, Wren JD, Long TC, Garner HR. Deja vu – A Study of Duplicate Citations in Medline. *Bioinformatics Open Access*, December 1, 2007.
- Funk CL, Barrett KA, Macrina FL. Authorship and Publication Practices: Evaluation of the Effect of Responsible Conduct of Research Instruction to Postdoctoral Trainees. *Accountability in Research* 2007, 14: 269-305.
- Gorman DM, Conde E, Huber JC. The Creation of Evidence in 'Evidence-Based' Drug Prevention: A Critique of the Strengthening Families Program Plus Skills Training Evaluation. *Drug and Alcohol Review* 2007, 26: 585-593.
- Gorman DM, Conde E. Conflict of Interest in the Evaluation and Dissemination of 'Model' School-Based Drug and Violence Prevention Programs. *Evaluation and Program Planning* 2007, 30: 422-429.
- Mcgee R, Almquist J, Keller JL, Jacobsen SJ. Teaching and Learning Responsible Research Conduct: Influences of Prior Experiences on Acceptance of New Ideas. *Accountability in Research* 2008, 15: 30-62.

Revised Regulation Changes Institutional Reporting Requirements

The finalization of the Public Health Service Policies on Research Misconduct (42 C.F.R. Part 93) ("Part 93") in June, 2005 led to several significant changes in the way ORI operates and in how institutions are expected to conduct assessments, inquiries and investigations into allegations of research misconduct and provide reports to ORI. It is still the case that an institution need not report to ORI if, at the end of an inquiry, it is determined that there is insufficient evidence for research misconduct to warrant an investigation. However, institutions occasionally determine not to conduct an investigation despite an inquiry committee's recommendation to do so. There have been many reasons for this such as a determination by the committee or deciding official that the misconduct was minor and did not warrant further investigation; that because the respondent made an admission an investigation was not necessary; or because the respondent had been terminated or had resigned, an investigation was a waste of time.

Part 93 § 93.316 specifically addresses this issue and clearly establishes an express obligation on the part of the institution to report all instances to ORI where, in the presence of evidence supportive of a finding of misconduct, an alternative resolution is being considered. The regulation states:

Completing the research misconduct process.

(a) *ORI expects institutions to carry inquiries and investiga-*

tions through to completion and to pursue diligently all significant issues. An institution must notify ORI in advance if the institution plans to close a case at the inquiry, investigation, or appeal stage on the basis that the respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except the closing of a case at the inquiry stage on the basis that an investigation is not warranted or a finding of no misconduct at the investigation stage, which must be reported to ORI under Sec. 93.315.

(b) *After consulting with the institution on its basis for closing a case under paragraph (a) of this section, ORI may conduct an oversight review of the institution's handling of the case and take appropriate action including:*

(1) *Approving or conditionally approving closure of the case;*

(2) *Directing the institution to complete its process;*

(3) *Referring the matter for further investigation by HHS; or,*

(4) *Taking a compliance action.*

This provision requires institutions to first contact DIO before deciding whether and how to proceed to an expedited closure. Among the important reasons for this provision are:

- An institution's obligation to conduct a research misconduct investigation is not abrogated by its decision to terminate the researcher or the researcher's decision to sever the employment relationship.
- If an admission was obtained, it is vital that ORI be allowed to assess its legal adequacy prior to allowing a modified closure. Many so-called admissions are oral rather than written; may have been coerced by an angry lab chief; may not admit to anything more than making errors; and almost without exception do not encompass the full scope of the dishonest acts of the respondent.
- It is not uncommon for respondents to attempt to reach a settlement with the institution. This can involve an attempt to deny any responsibility for their acts and to prevent the institution from disclosing any information to a third party. It should be understood that these agreements do not hold for ORI. It is essential that prior to executing such agreements, the institution consult with ORI and/or the HHS Office of the General Counsel for advice on ORI's requirements.

ORI is aware that many allegations that are made in good faith nevertheless are not significant enough to warrant a Public Health Service misconduct finding. ORI in fact administratively closes a number of such cases each year.

However, it is important to note that this happens after ORI has had an opportunity to review the
See Plagiarism, page 6

Plagiarism and Curbstoning Cases Merit Special Attention *(from page 5)*

allegations and at least assess their potential significance.

It is worth noting that there are two general groups of allegations that frequently receive (and merit) special attention. As noted in the September 2007 ORI Newsletter (Vol. 15, No 4, p. 4), ORI's working definition of plagiarism is used to decline to pursue relatively insignificant cases of plagiarism that involve disputes between collaborators, past or present, and instances of improperly cited copied language that is in background or methodology sections of papers and grant applications and is not material to scientific claims or funding decisions. As noted at that time, however, this ORI policy does not excuse institutions from their obligation to report such instances of plagiarism so that ORI has an opportunity to approve not sending a report to ORI under § 93.316(b)(1). Furthermore, the article took pains to emphasize the continued capacity of the institution to pursue the allegations further and make findings based on its own generally stricter standards governing plagiarism.

Another area involving a significant number of cases that historically were generally not reported to ORI involves what are called "curbstoning" cases by the survey research community. Largely at ORI's initiative, ORI and the survey community discussed this issue and worked toward a mutual understanding about curbstoning misconduct and the obligation to report these allegations to ORI. ORI is deeply appreciative of the

willingness of these individuals and institutions to work with ORI on this matter, and notes that one positive outcome is already largely in place—a greater emphasis on internal quality control to monitor the performance of interviewers on a continuous basis.

It should be noted, however, that Part 93 requires institutions to report commenced investigations in all types of research misconduct cases, including curbstoning. As with allegations of plagiarism, if an institutional official contacts DIO soon after receipt of the allegations and an initial assessment, it is often possible for DIO to make a rapid determination that the facts of the case as stated would mean that further notification of DIO would not be required. Normally DIO would need to know how many interviews had been falsified or fabricated by the respondent out of the total number he or she had been responsible for, the time frame of the apparent falsifications, and the overall size and nature of the study.

In addition to dealing with reasons why institutions might wish to close a case without an investigation, there are additional reporting requirements defined in § 93.318:

Notifying ORI of special circumstances.

At any time during a research misconduct proceeding, as defined in Sec. 93.223, an institution must notify ORI immediately if it has reason to believe that any of the following conditions exist:

- (a) Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.*
- (b) HHS resources or interests are threatened.*
- (c) Research activities should be suspended.*
- (d) There is reasonable indication of possible violations of civil or criminal law.*
- (e) Federal action is required to protect the interests of those involved in the research misconduct proceeding.*
- (f) The research institution believes the research misconduct proceeding may be made public prematurely so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved.*
- (g) The research community or public should be informed.*

Please note that these special circumstances generally involve possible threats to human or animal health, possible criminal activity, or premature or inappropriate disclosure of an ongoing inquiry or investigation. Staff at ORI are available during business hours to answer questions about these or any other issues. Queries may also be directed to the "AskORI" link on ORI's web page, which has a justifiably excellent reputation for containing a vast amount of material on research misconduct.

Technical Assistance Requested by Variety of Organizations

ORI provided technical assistance by email and phone to 39 universities, medical centers, hospitals, research centers, corporations, government agencies and journals in 2007 including two in foreign countries.

Assistance was provided on what needs to be done when a research misconduct allegation is received, how to analyze figures and images, determining the authenticity of information submitted for publication, and institutional policies.

“We are gratified by the working relationships we have developed

with the institutions that have repeatedly contacted us for assistance,” John Dahlberg, Director, Division of Investigative Oversight (DIO), said. “We invite all institutions dealing with research misconduct allegations to contact us, especially those handling their first allegation.”

Dahlberg continued, “DIO staff have, over the years, developed a number of approaches, broadly called scientific forensic tools, designed to provide additional evidence for research misconduct. These tools range from statistical analysis of numbers, to comparisons

of questioned to control data sets to identify discrepancies, to detection of inappropriate alteration of images.”

“DIO has posted Photoshop ‘applets’ on the ORI website that have received international attention as being useful in examining questioned images,” Dahlberg said. “We have been receiving an increasing flow of queries from journal editors for informal assistance in evaluating questioned images.”

Technical assistance may be obtained by calling DIO at 240-453-8800. Requests for assistance may be made anonymously and assistance may be requested on “hypothetical” cases.

Updated Intro RCR Text Available from GPO

Contrary to a report that appeared on SciFraud, an updated version of the *ORI Introduction to the Responsible Conduct of Research* is available from the Government Printing Office (GPO) and at a reduced price for bulk orders.

Bulk orders of 50 copies cost \$495.00 or \$9.90 each; single copies are \$14.00 for U. S. order.

For foreign orders, bulk orders of 50 copies cost \$693.00; single copies are \$19.00. The cost of foreign orders only covers surface mail delivery; airmail delivery would

involve an additional charge. Copies may be ordered from the GPO at <http://bookstore.gpo.gov/collections/ori-research.jsp>

Over 7,550 copies of the publication have been sold since it was published in June 2004 making it a GPO “best seller.” The limited updating was done prior to the printing of more copies by GPO. All links were updated and a few references were added. The text was not changed.

The publication is available for online reading or downloading on the ORI web site at <http://ori.hhs.gov>.

Rhoades Built Education Program (from page 2)

pursuit of the responsible conduct of research and research integrity.”

Rhoades initiated or developed the newsletter, the ORI Annual Report, the web site, the RCR Resource

Development Program, conferences and workshops, and the research programs. He and his wife plan to move to Richmond, VA. to be with their daughters and granddaughter.

Case Summary

Scott E. Monte, Huntington Memorial Hospital, Pasadena, CA: Based on the findings of an investigation conducted by Huntington Memorial Hospital (HMH) and information obtained by the Office of Research Integrity (ORI) during its oversight review, the U.S. Public Health Service (PHS) found that Scott E. Monte, L.V.N., former Clinical Research Associate, HMH, engaged in scientific misconduct by knowingly and intentionally falsifying and fabricating clinical research records in HMH cancer prevention and treatment protocols supported by National Cancer Institute (NCI), National Institutes of Health (NIH), awards U10 CA69651, U10 A12027, U10 CA32012, and U10 CA86004. Specifically, Mr. Monte knowingly and intentionally:

See Case, page 8

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NEWSLETTER

Case Summary *(from page 7)*

(1) Entered falsified and fabricated laboratory data or physical examination results on five (5) research protocol case report forms (CRFs);

(2) Falsified a gynecological examination report in a physician's progress note and entered the falsified document in the patient's research chart; and

(3) Fabricated progress notes for four patients and a case report form for one of these patients.

ORI has implemented the following administrative actions for a period of three (3) years, beginning on January 7, 2008:

(1) Mr. Monte 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 pursuant to HHS' implementation of the OMB Guidelines to Agencies on government-wide Debarment and Suspension at 2 CFR Part 376; and

(2) Mr. Monte 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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