

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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Pre-register by April 27 for World Conference on Integrity

Researchers, research administrators, sponsors, editors, professional society representatives, and policymakers have an opportunity to participate in the initial effort to create a global framework for harmonizing research misconduct policies and fostering the responsible conduct of research by pre-registering for the first World Conference on Research Integrity that will be held September 16-19, 2007 in Lisbon, Portugal. Attendance at the World Conference will be by

invitation to ensure geographical and experiential diversity among attendees. Persons wishing to attend the conference should go to www.esf.org/conferences/researchintegrity and pre-register by April 27, 2007. Formal letters of invitation will be sent in early May. Deadline for formal registration and payment of the conference registration fee (150 Euros) is June 11, 2007.

See **Integrity**, page 2

Bringing RCR Education to Postdoctoral Fellows

ORI awarded a two-year contract to the National Postdoctoral Association (NPA) in February to facilitate the development of responsible conduct of research (RCR) programming for postdoctoral fellows by institutional postdoc offices or postdoc associations.

postdoctoral research community. Its 135 institutional members represent more than 40,000 post-doctoral scholars.

“Postdocs play very important roles in biomedical research,” Chris Pascal, Director, ORI, said. “They do much of the lab work and frequently supervise undergraduate and graduate students.

See **RCR**, page 3

15 Misconduct Findings, 35 Cases Closed in 2006

Two-thirds of the researchers against whom a finding of research misconduct was made in 2006 were excluded or debarred from receiving federal funding for three years to a lifetime.

Exclusions or debarments were instituted in ten cases. One debarred respondent had been at two institutions, each with a case number. Each excluded or debarred researcher was also prohibited from serving the PHS in any advisory or consultant capacity.

ORI made 15 research misconduct findings and closed 35 cases in 2006, the highest number of misconduct findings and closed cases since 1996.

Administrative actions taken against the remaining 5 researchers included
See **Highest**, page 4

Integrity Conference Seeks International Framework for Research (from page 1)

The conference web site explains the rationale for this pioneering gathering: “Research regulations and commonly accepted research practices vary significantly from country to country and among professional organizations. There is no common definition worldwide for research misconduct, conflict of interest or plagiarism. 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 policies that implement this agreement can vary widely from country to country and organization to organization. The research community worldwide has to address these problems in order to retain public confidence and to establish a clear best practice framework at an international level.”

The program will feature plenary, concurrent and working group sessions. Plenary sessions present an overview of the steps taken to address research misconduct in major research regions of the world, the need to change the focus of research integrity discussions from the individual to systemic and institutional issues, the factors that influence research behavior and approaches to training in the responsible conduct of research.

Two concurrent sessions will be held. The session on guidelines for authorship and publications will cover authorship, peer review, and editorial practices. The session on international codes and guidelines will focus on codes of conduct, conflict of interest guidelines, data

management and sharing, and human subjects and clinical research.

Time will also be set aside during the conference for the five working groups to discuss and make recommendations concerning the topics covered by the plenary and concurrent sessions. Background material for the working groups will be available prior to the conference.

The working groups will cover:

- **Global Response to Research Misconduct** – standards and responsible approaches for responding to, investigating, and reporting research misconduct.
- **Institutional Responsibility for Promoting Research Integrity** – steps research institutions can take to promote research integrity and responsible research practices.
- **Codes and Guidelines for Best Practices** – developing global and practical best practices.
- **Responsible Publication Practices** – global standards for

authorship, peer review, and responsible publication practices.

- **Prevention and Training** – global guidelines for research training and the responsible conduct of research and the implementation of those guidelines.

The conference has been planned by Tony Mayer, European Science Foundation (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.

RRI Researchers Publish Three More Articles

Three more articles have been published by investigators supported by the Research on Research Integrity Program. Thirty-six publications—articles, abstracts, commentaries, reviews, letters to the editor—have been produced by RRI investigators since the program began in 2000. See http://ori.hhs.gov/research/extra/rri_publications.shtml.

Deming N, Fryer-Edwards K, Dudzinski, D, Starks H, Culver J, Hopley E, Robins L, Burke, W. “Incorporating Principles and Practical Wisdom in Research Ethics Educa-

tion: A Preliminary Study.” *Academic Medicine* 2007, 82 (1): 18-23.

Gardner W, Lidz CW. “Research Sponsorship, Financial Relationships, and the Process of Research in Pharmaceutical Clinical Trials.” *Journal of Empirical Research on Human Research Ethics* 2006, 1 (2): 11-18.

Mumford M, Davenport LD, Ryan PB, et al. “Validation of Ethical Decision Making Measures: Evidence for a New Set of Measures.” *Ethics and Behavior* 2006: 16(4):319-345.

Survival Skills and Ethics Workshop Scheduled for June; Apply Now

Applications are being accepted online for the thirteenth annual Workshop on Teaching Survival Skills and Ethics that will be held from June 10-15, 2007 in Snowmass, Colorado with support from ORI.

The workshop is presented by the Survival Skills and Ethics Program at the University of Pittsburgh that is directed by Beth Fischer and Michael Zigmond.

The workshop provides faculty and administrators with the instruction and materials necessary to implement a program in professional development and ethics at their institution. Over 353 faculty and administrators from 235 institutions have participated in previous workshops.

“We encourage two members of the same institution to apply together to assist with the implementation of the program once they get back,” Fischer said.

Applicants must agree to attend the entire workshop, Sunday afternoon through Friday evening, establish or improve an existing course in survival skills and ethics at their institution by Fall 2008, and participate in evaluating the course they establish. This evaluation will include surveying the participants of that course and providing the workshop organizers with additional information such as a description of the program and permission to conduct an on-site, follow-up evaluation.

Among those who meet the above requirements, preference is given to individuals who will train the largest number of students, have a detailed plan for implementation of instruction, will provide training to a significant number of individuals from underserved populations, and show evidence of institutional support for this project (e.g., funding, release time, etc.).

Applications are considered on a rolling basis, and individuals will be notified of the outcome within a month of the receipt of their application. For more information see <http://www.survival.pitt.edu/events/trainer.asp>.

RCR for Postdocs Includes Workshops, Grants and Toolkit *(from page 1)*

Nevertheless, their marginal status, neither student nor faculty, frequently reduces their participation in RCR programming offered to graduate students or faculty, thereby, putting them at greater risk when encountering RCR issues.”

Postdoctoral fellows accounted for 20 percent of the misconduct findings made by ORI from 1994-2003. At least 5 percent of the whistleblowers during that period were postdoctoral fellows.

Under the contract, NPA will convene a project advisory committee composed of postdocs, faculty, administrators and an ORI representative to assist with planning and review activities.

The NPA will also organize two train the trainer workshops in

conjunction with its national meetings, possibly in Berkeley, CA, in 2007 and in Bethesda, MD in 2008. The workshops will focus on organizing an effective RCR program at institutions.

In addition, the NPA will develop an application and review process for awarding seed grants to institutional postdoc offices or postdoc associations. Fifteen \$1,000 awards would be competitively awarded each year; a total of 30 awards will be made over the two year period. Each award will last for one year.

The NPA will also develop and publish an on-line and paper toolkits on how to organize RCR programs for postdocs. The toolkit will include sample agendas, suggested speakers, sample handouts, sample curriculum, resource list, sample pre- and post-

tests, evaluation forms and a planning guide. The toolkit will continue to be posted on the NPA website after the contract is concluded.

Finally, the NPA will provide technical assistance, including site visits, to awardee postdoc offices and associations. Data will be collected throughout the project to evaluate its effectiveness.

Research on Research

Integrity Program

RFP

Due May 2007

Seven RCR Instructional Resources Added to ORI Website; 36 Available

Seven instructional resources for teaching the responsible conduct of research (RCR) developed with support from the RCR Resource Development Program have recently been added to the ORI web site for use by the worldwide research community.

Thirty-six resources are posted on the ORI web site at <http://ori.hhs.gov/education/products/>. Fifty-four projects have been supported since the program was started in 2002 to facilitate the creation of RCR resources by the research community for use in the research community.

An on-line version of the *ORI Introduction to the Responsible Conduct of Research* has also been added to the website. "With that

number of resources available," Loc Nguyen-Khoa, program director, said. "It is time to assess what we have and make some decisions about where we go from here. That is why we have not issued a request for proposals for FY 2007."

The titles, project directors and originating institutions or organizations for the new resources follow:

- **CITI Responsible Conduct of Research Program**
Collaborative Institutional Training Initiative (CITI)
University of Miami School of Medicine
- **Video Vignettes on Research Ethics and Academic Integrity**
Derina Samuel
Syracuse University

- **Research Conflicts of Interest Training Course**

Melissa Proll
University of Texas Health
Science Center-Houston

- **Teaching RCR in Humans**

Stanley Korenman
University of California-Los
Angeles

- **Peer Review Quick Guide**

Murali Krishnamurthi
Northern Illinois University

- **Responsible Authorship Quick Guide**

Murali Krishnamurthi
Northern Illinois University

- **Administrators and the Responsible Conduct of Research**

Stephen Erickson
Boston College

Highest Number of Findings in 10 Years (from page 1)

submission of a supervisory plan, certification of data, or prohibition from serving the PHS in any advisory capacity.

The 35 closed cases included 28 investigations and 7 inquiries. Forty-three percent of the closed cases resulted in misconduct findings; 20 articles were retracted or corrected. Eighty-five percent of the cases were closed within 12 months from receipt of the final institutional action. Average processing time was 7.5 months. The pre-2005 cases were reduced by 50 percent to 17.

"This is the highest number of misconduct findings and closed cases we have had in 10 years," John Dahlberg, Director, Division of Investigative Oversight (DIO), said.

"This reflects the dedication and hard work of the DIO and the OGC staffs, both of which are short-handed."

"ORI obtained several significant findings in 2006, particularly in the Leadon and Robinson cases," Dahlberg continued. "Another notable event was the sentencing of Eric Poehlman to prison for large scale data falsification in federal grant applications."

ORI opened 29 cases, 19 investigations and 10 inquiries, and handled 266 queries in 2006. The queries resulted in 88 pre-inquiry assessments to determine if ORI should open a case, 19 referrals to other agencies, and 174 administrative closures because no action was possible. Fifty-three cases were carried into 2007.

Case Summaries

Jennifer Blaisdell, University of Pennsylvania and Retinal Consultants of Arizona, Ltd.: Based on the report of an investigation conducted by the University of Pennsylvania (UP) and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Ms. Jennifer Blaisdell, former Clinical Coordinator for Retinal Consultants of Arizona, Ltd. (RCA), committed research misconduct in a study sponsored by two cooperative agreements funded by the National Eye Institute (NEI), National Institutes of Health (NIH): U10 EY012261, "Age-related Macular Degeneration Prevention Trial," Dr. Stuart Fine, Principal Investigator (P.I.), and U10 EY012279, "Coordinating Center for AMD, Complications of

Case Summaries *(continued)*

Age-Related Macular Degeneration Prevention Trial” (CAPT), Dr. Maureen McGuire, P.I.

Specifically, PHS found that Ms. Blaisdell knowingly and intentionally committed research misconduct by:

- 1) Fabricating a CAPT data form dated 5/29/02 reporting a 30-month telephone follow-up visit with patient 01-026; this patient died on 5/3/02;
- 2) Fabricating a CAPT data form dated 2/20/03 reporting a 43-month telephone follow-up visit with patient 01-019; this patient died on 2/10/03;
- 3) Falsifying a CAPT data form dated 2/13/01 reporting a visit to the clinic on that date for patient 01-049; this patient’s visit was 2/20/01;
- 4) Falsifying the CAPT form for patient 01-055 dated 4/11/01, when no clinic visit took place, by substituting information purportedly obtained at a non-study visit on 2/28/01.

Ms. Blaisdell has entered into a Voluntary Exclusion Agreement in which she has voluntarily agreed, for a period of two (2) years, beginning on November 14, 2006:

- 1) To exclude herself 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 Ms. Blaisdell’s participation is proposed or which uses her in any capacity on PHS supported research, or that

submits a report of PHS-funded research in which she is involved, must concurrently submit a plan for supervision of Ms. Blaisdell’s duties to the funding agency for approval. The supervisory plan must be designed to ensure the scientific integrity of her research contribution. Ms. Blaisdell also agrees to ensure that the institution submits a copy of the supervisory plan to ORI. She further agrees that she will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI.

James C. Lin, Ph.D., University of Illinois at Chicago: Based on the findings from an inquiry by the University of Illinois at Chicago (UIC) and on additional analysis conducted by ORI during its oversight review, the U.S. Public Health Service (PHS) found that James C. Lin, Ph.D., Professor, Department of Electrical and Computer Engineering, Physiology, and Biophysics, UIC, engaged in research misconduct concerning National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH), grant application 1 R01 NS47238-01, “Blood-Brain Barrier Interactions of Cellular-Phone Radi.”

Specifically, PHS found that Dr. Lin committed research misconduct relative to the legend and related text for Figure 2 (data from a colleague on other experiments) for his NIH application 1 R01 NS47238-01, by falsely claiming the figure represented preliminary results of his independent experiments that differed from the source of the figure and the prior research in the field, in which he purported to

have selectively exposed the rat’s head to microwave irradiation, to have utilized higher peak exposure, of shorter duration and of different radio frequencies, and which reported injury of more acute nature to the blood barrier.

Dr. Lin denies all allegations of research misconduct and contends that some of his original data is missing as a result of the involuntary relocation of his laboratory. Dr. Lin makes no admission of guilt in connection with the charges or PHS’ findings of research misconduct herein. Both Dr. Lin and PHS are desirous of concluding this matter without further expense of time and other resources.

Dr. Lin has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed, for a period of three (3) years, beginning on October 24, 2006:

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

Case Summaries (continued)

2) that any institution employing Dr. Lin submit in conjunction with each application for PHS funds or reports, manuscripts, or abstracts of PHS-funded research in which Dr. Lin is involved a certification that the data provided by Dr. Lin 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. Dr. Lin must ensure that the institution also sends a copy of the certification to ORI; and

3) 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.

Nicholas McMaster, University of Chicago: Based on a College Discipline Hearing report and on additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Mr. Nicholas McMaster, undergraduate student, Biological Sciences Collegiate Division in the Departments of Psychology and Comparative Human Development at the University of Chicago (UC), engaged in research misconduct in research supported by National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), grant P50 ES12382 and National Institute on Aging (NIA), NIH, grant P01 AG018911.

Specifically, PHS found that Mr. McMaster fabricated data in recording the score for the lordosis reflex and in recording the cell types present in vaginal epithelium from rats in two experimental psychology protocols.

Mr. McMaster has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed, for a period of three (3) years, beginning on November 14, 2006:

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 which submits an application for PHS support for a research project on which Mr. McMaster's participation is proposed or which 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. McMaster also agrees to ensure that the institution submits a copy of the supervisory plan to ORI. He further agrees that he will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI.

Jong Hyuk Park, Ph.D., University of Pittsburgh: Based on accumulated evidence including the University of Pittsburgh (UP) investigation committee report 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 Jong Hyuk Park, Ph.D., former postdoctoral fellow, Pittsburgh Development Center of the Magee-Womens Research Institute, UP, engaged in

research misconduct in research funded by National Center for Research Resources (NCRR), National Institutes of Health (NIH), grant R24 RR13632 and National Institute of Child Health and Human Development (NICHD), NIH, grant P01 HD047675.

Specifically, Dr. Park:

1) Intentionally and knowingly falsified various versions of two figures in a manuscript entitled "Rhesus Embryonic Stem Cells Established by Nuclear Transfer: Tetraploid ESCs Differ from Fertilized Ones" that was being prepared for submission to *Nature*;

2) Repeatedly misrepresented to the UP investigative panel the accuracy of one of the figures;

3) Presented the false figures as true to members of the laboratory; and

4) Falsified the record of revisions of the figures by deleting all prior versions from the laboratory server.

ORI has implemented the following administrative actions for a period of three (3) years, beginning on November 29, 2006:

1) Dr. Park 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 CFR Part 76; and

(2) Dr. Park 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.

Case Summaries *(continued)*

Clifford R. Robinson, Ph.D., University of Delaware: Based on the reports of investigations conducted by 3-Dimensional Pharmaceuticals, Inc. (3DP) and the University of Delaware (UD) and additional analysis conducted by ORI during its oversight review, the U.S. Public Health Service (PHS) found that Clifford R. Robinson, Ph.D., a former Assistant Professor, Department of Chemistry and Biochemistry, UD, engaged in misconduct in science involving research supported by National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), grants 1 R43 GM58950-01 and 2 R44 GM58950-02, "Four-helix bundle analog of a G-protein coupled receptor (C. Robinson, Principal Investigator [P.I.]). The following grant applications also were involved in Dr. Robinson's misconduct in science:

- 1 R43 GM62708-01, "Improved method for protein refolding" (C.R. Robinson, P.I.), submitted March 30, 2000; approved but not funded, withdrawn.
- 1 P20 RR017716-01, "Design of hierarchical recognition motifs," Project V, "Determinants of stability and assembly of integral membrane proteins" (C.R. Robinson, Project Investigator), submitted March 1, 2002, funded September 16, 2002, to August 30, 2007.
- 1 R01 GM074789-01, "Folding and stability of integral membrane proteins" (C.R. Robinson, P.I.), submitted October 1, 2004; scored not competitive, not funded.
- 1 R01 GM075891-01, "Membrane protein expression, solubilization,

and refolding" (C.R. Robinson, P.I.), submitted January 24, 2005; approved but not funded, pending.

- 1 R21 GM07953-01, "Mini-receptor analogs of GPCRs" (C.R. Robinson, P.I.), submitted January 25, 2005; not funded.

Specifically, PHS found that Dr. Robinson engaged in the following acts of misconduct in science. With regard to the following paragraphs numbered 1-6, nothing herein shall be deemed as an admission of liability on the part of Dr. Robinson.

1) While at 3DP, Dr. Robinson systematically substituted crystallized chicken ovalbumin in place of [beta]2-AR-NQ and repeatedly provided these crystalline preparations to other scientists to conduct molecular analyses. Dr. Robinson made false claims about his progress on characterizing [beta]2-AR-NQ and falsely claimed to have supplied purified [beta]2-AR-NQ to 3DP staff in project team meetings (PTM) held on at least five occasions between July 14, 1998, and July 7, 1999.

2) Dr. Robinson made multiple false claims about his research on [beta]2-AR-NQ in NIH grant applications R44 GM58950-02, submitted April 1, 1999, supplemental material for the same application submitted on July 7, 1999, and NIH grant application R43 GM62708-01, submitted March 30, 2000.

3) Dr. Robinson made similar claims as in item 1 above concerning the wild type form of [beta]2-AR, by substituting canine ovalbumin. Dr. Robinson's false claims were made to 3DP staff at PTM meetings on at least three occasions between September 7, 1999, and March 30,

2000, and in NIH grant application R43 GM62708-01, and after moving to UD, in NIH grant application 1 P20 RR017716-01, submitted on March 1, 2002.

4) Dr. Robinson was unable to adequately produce recombinant [beta]2-AR in *E. coli* and made false claims at PTM meetings in September and October 1999 that he had successfully expressed active protein and had purified it for crystallization trials. Dr. Robinson also made false claims in NIH grant applications R43 GM62708-01 and 1 R01 GM07589-01, submitted January 24, 2005, that he had purified large amounts of [beta]2-AR-NQ from *E. coli* and that he had reconstituted the protein into its native biologically active form.

5) Dr. Robinson made false claims about his ability to produce, purify, and characterize a recombinant fragment of [beta]2-AR-NQ containing four transmembrane domains ([beta]2-AR-4HB) at PTM meetings in October 1998 and in NIH grant applications R44 GM5 8950-02 and 1 P20 RR017716-01.

6) Dr. Robinson falsified fluorescence spectra and circular dichroism measurements in Figure 7 (both left and right panels) of NIH grant application R44 GM58950-02 by substituting results obtained with different proteins.

7) After moving to UD, Dr. Robinson made false claims in NIH grant application 1 P20 RR017716-01, including presenting falsified data in both panels of Figures V.5 (fluorescence spectra and circular dichroism measurements) and V.9 (falsified experimental conditions).

Case Summaries *(continued)*

8) While at UD, Dr. Robinson falsified circular dichroism and fluorescence data in NIH grant application 1 R01 GM074789-01 (Figures 5A, 5B, and 6) and circular dichroism data in NIH grant applications 1 R01 GM075891-01 (Figure 6) and 1 R21 GM075953-01 (Figure 5).

9) In presentations at the Biophysical Society annual meeting and a Cornell University Consortium meeting, both in 1999, Dr. Robinson falsely represented data obtained with cytochrome b562 as being obtained with [beta]2-AR.

Dr. Robinson has entered into a Voluntary Exclusion Agreement in

which he has voluntarily agreed, for a period of five (5) years, beginning on October 23, 2006:

1) To exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility for or involvement in nonprocurement programs of the United States Government as defined in the debarment regulations at 45 CFR Part 76; and

2) 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.

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