

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.



IN THIS ISSUE

Researcher Sentenced	2
Academic Society Awards	3
RCR Expo Space	5
Clinical Trial Principles	5
RRI Publications	7
Whistleblower Ranks	9

Plan Aims at Better Postdoctoral Training

A 10-step Plan for Better Postdoc Training that is designed to “reestablish the postdoc as a trainee” and “promote an environment in which postdocs can receive the advanced instruction they need to embark on successful careers” has been developed by the Postdoctoral Fellows Focus Group, according to *The Scientist*.

The Postdoctoral Fellows Focus Group was organized by six administrators who chose to discuss that topic as a focus group during the Teaching Survival Skills and Ethics conference in 2004. The complete white paper including the focus group members is available at <http://www.the-scientist.com/article/display/18834/>. Excerpts from the

See Need, page 6

More RCR Resources Posted on ORI Web Site

Six more instructional resources for responsible conduct of research (RCR) training developed with support from the RCR Resource Development Program are available on the ORI web site at http://ori.hhs.gov/education/rcr_resources.shtml.

tate the development of RCR resources by the research community for use within the research community. Twenty-three completed resources are posted at the address noted above. Resources developed through the program and independently by universities cover the nine core RCR instructional areas.

See Six, page 3

Forty-nine resource projects have been supported since the program was established in 2002 to facili-

Debarments Imposed on Six Respondents in 2005

Seventy-five percent of the respondents against whom research misconduct findings were made in 2005 were debarred from receiving Federal funding for periods ranging from two years to a lifetime, the first time an indefinitely extended PHS administrative action was imposed.

Vermont professor, whom ORI and the Department of Justice found to have falsified or fabricated data in at least 12 publications and 19 federal grant applications over more than a decade.

The lifetime administrative action was given to Eric T. Poehlman, Ph.D., a former University of

Eight of the 22 cases closed by ORI resulted in research misconduct findings. “The percentage of ORI misconduct findings and

See Cases, page 2

Research Specialist Sentenced to Federal Prison for Almost Six Years

A former cancer research specialist at the Stratton Veterans Affairs Medical Center was sentenced last November to 71 months in Federal prison, the maximum allowed under Federal sentencing guidelines, for criminally negligent homicide of a research subject who died in a drug trial, according to press reports.

Paul H. Kornak pled guilty in January 2005 to making a false statement, mail fraud, and criminally negligent homicide in U. S. District Court in Albany, N.Y. As a program specialist, Kornak coordinated research protocols at the medical center in Albany.

Mr. Kornak also was directed by the court to pay about \$639,000 in restitution to two pharmaceutical companies and the Department of Veterans Affairs (VA). In addition, the VA and the Department of

Health and Human Services imposed a lifetime debarment from receipt of Federal funding.

According to the U. S. Attorney's Office for the Northern District of New York, Kornak "participated in a scheme to defraud the sponsor of the clinical trials and studies...by means of false pretenses, in that he would and repeatedly did submit false documentation regarding patients and study subjects and enroll and cause to be enrolled persons as study subjects who did not qualify under the particular study protocol."

The U. S. Attorney's office reported that "Kornak had made and used false documents which were very important to the determination of whether (the subject) was eligible to participate in the study—a laboratory report, a blood chemistry form, and a patient registration form, each

of which falsely reflected the date and result of a test for creatinine, and a radiology display report and a past medical/surgical history in an outpatient progress record, from each of which information had been deleted."

The U. S. Attorney's office continued, "Kornak failed to perceive a substantial and unjustifiable risk that death would occur when he made and used documents falsely representing the results of blood chemistry analysis of a sample provided by (the subject). The false documents purposed that (the subject) met the inclusion and exclusion criteria for participation in (the study) when the actual results did not meet the inclusion and exclusion criteria and showed impaired kidney and liver function, and (the subject) thus was administered chemotherapeutic drugs in connection with (the study) and died as a result thereof."

Cases Forwarded to 2006 Highest in More Than Decade *(from page 1)*

administrative actions in 2005 (36 percent of cases closed) is in line with the historical ORI average of about 33 percent," Dr. Alan Price, Associate Director for Investigative Oversight, ORI, said. "However, about 75 percent of the cases still pending in ORI at the end of 2005 that had institutional determinations involved scientific misconduct findings." Summaries of the research misconduct cases are at <http://ori.hhs.gov/misconduct/cases/>.

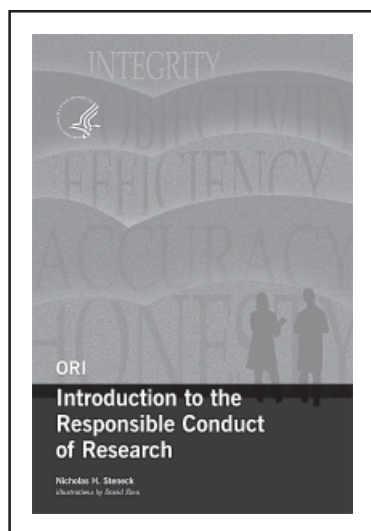
ORI opened 30 new cases and carried 59 open cases into 2006, eight more cases than the end of 2004, and the highest number of cases carried forward in more than 10 years.

Two of the misconduct findings involved fabrication and falsification, four involved falsification, one involved fabrication, one involved fabrication and other serious deviations.

In four cases, the PHS imposed debarment from federal funding for three years, one for two years, and one for a lifetime. In two cases, a three-year supervisory period was imposed. In five cases, the respondents were also prohibited from serving in any advisory capacity to PHS for three years, in one for four years, and in one for his lifetime. Of the others, two involved certification and one involved supervision.

Dr. Price noted that the number of allegations received by ORI in 2005 (265) was similar to that in 2004, however it increased 50% over 2003.

For the 22 cases involving inquiries or investigations closed by ORI in 2005, institutions took a mean of 8.4 months after their notification of ORI (range of 1-19 months) to complete their actions. ORI took a mean of 5.8 months (range of 1-24 months) to review the reports, obtain additional information from the institution, complete the ORI analysis, negotiate any PHS findings and administrative actions, and close these cases. ORI completed its oversight of 21 out of these 22 cases within one year.



ORI Intro to RCR Available for Fall

Over 5,500 copies of the *ORI Introduction to the Responsible Conduct of Research* have been sold since it was published in 2004, another 1,000 copies were downloaded from the ORI web site, and Japanese and Chinese translations were published.

Copies are available to fill fall semester book orders at the U. S. Government Printing Office at \$14.00 each for U. S. orders; \$19.60 each for non-U.S. orders; a 25 percent discount is available on purchases of every 100 copies sent to the same address. See <http://bookstore.gpo.gov>.

The publication is also available for on-line reading or downloading on the ORI web site at <http://ori.hhs.gov>. The 164-page booklet, written by Nicholas H. Steneck, University of Michigan, Ann Arbor, with illustrations by David Zinn, introduces the reader to the nine RCR core instructional areas.

RCR Awards Made to Four Academic Societies

Four awards were made in January by the RCR Program for Academic Societies to facilitate the institutionalization of infrastructure and activities within academic societies that will promote the responsible conduct of research by their members.

The program, a collaboration between the Association of American Medical Colleges and ORI, has supported 36 projects by 30 academic societies since it began in 2002. Award abstracts are posted on the ORI web site at http://ori.hhs.gov/education/aamc_funded_1-3.shtml

For further information contact Tony Mazzaschi, AAMC, at tmazzaschi@aamc.org or at 202-828-0059.

Six Resources Added; 23 Available (from page 1)

All products supported by the ORI program are in the public domain and may be used freely. Proper acknowledgment should be given to the originators and ORI.

For further information on the RCR Resource Development Program contact Loc Nguyen-Khoa at LNguyen-Khoa@osophs.dhhs.gov.

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

- **Video Vignettes on Research Ethics and Academic Integrity**
Derina Sara Samuel
Syracuse University
- **RCR Competency-based Assessment and Self-Study Program**
Lori Bakken
University of Wisconsin- Madison

Academic societies receiving awards and project titles follow:

- **American College of Neuropsychopharmacology**
“Code of Conduct for Sustaining Corporations and Corporate Representatives - Setting the Standard for Ethical Conduct.”
- **Society of University Surgeons**
“Surgical Innovation, Investigation and the IRB.”
- **Council on Social Work Education**
“Promoting Research Integrity in Social Work Education.”
- **Society of Research Subject Advocates**
“Orientation and Research Integrity Workshop.”
- **Educating Clinical Staff on Clinical Research Data Collection and Data Management**
Cheryl Chanaud
St. Jude’s Children’s Research Hospital
- **Data Acquisition and Management**
Daniel Vasegird
Columbia University
- **Collaborative Science**
Daniel Vasegird
Columbia University
- **Peer Review Guide**
Sara Rockwell
Yale University

Challenges for AAMC: Protecting Research Integrity and Human Subjects

In his final annual meeting address to members of the Association of American Medical Colleges (AAMC), outgoing president, Jordan J. Cohen, M.D., cited upholding the integrity of research and assuring the safety of human research subjects as one of “five present and future challenges for which a strong AAMC voice will be especially important.”

The complete address, “The Work Ahead,” is available at <http://www.aamc.org/newsroom/pressrel/2005/051106.htm>.

President Cohen said, “Nothing we do defines our ethics and our commitment to public welfare more than how we conduct research. Indeed, the general level of public

trust in medical schools and teaching hospitals is, in large measure, the direct result of our reputation for scientific integrity.

“We must recognize that the very nature of modern medical research poses many new threats to scientific integrity and, of even more concern, to the safety of human subjects involved in clinical research.

“The work ahead in this arena is certain to be even more challenging than it has been in the past. The increasingly important partnerships between academe and industry, while unquestionably accelerating the translation of discovery into useful products and services, will continue to raise the specter of pernicious conflicts of interest.

“We dare not allow those conflicts to undermine the public’s trust in our integrity. But preserving public trust in our research mission requires much more than monitoring and managing conflicts of interest. Ensuring the responsible conduct of research also requires that institutions remain mindful of the need to uphold the highest standards of research integrity, even in the most routine functions of basic and clinical investigation.

“As our research enterprise becomes more complex, more dispersed, and more collaborative, maintaining rigorous adherence to standards of ethical conduct will be an evermore-demanding challenge.”

Technical Assistance Program Offers Free Consultations to Institutions

The number of institutions contacting ORI for technical assistance in handling allegations of research misconduct in 2005 continued the upward spiral that has characterized the six year history of the Rapid Response for Technical Assistance (RRTA) program.

ORI provided 56 institutions with technical assistance in 2005 compared to 48 in 2004, 26 in 2003, 21 in 2002, 10 in 2001 and 6 in 2000. Technical assistance can be obtained by calling ORI’s Division of Investigative Oversight at 240-453-8800. The assistance may be provided over the phone or on-site.

“Institutional officials are gradually being convinced that contacting ORI about the handling of an allegation is helpful,” Dr. Alan Price, Associate

Director for Investigative Oversight, ORI, said. “We encourage those contacts, even about ‘hypotheticals’ with no names or details on the case, because we share a common objective with them—the relatively problem free processing of research misconduct allegations.”

He continued, “Many institutions contact us multiple times as different problems appear during the various stages of processing an allegation. We are a free consulting service.”

The RRTA program provides assistance in addressing the following potential problem areas: (1) reviewing institutional procedures to identify problem areas; (2) advising or assisting in sequestration and inventory of physical or computer evidence; (3) advising

on case strategy, including legal issues; (4) outlining specific PHS issues; (5) providing PHS grant applications; (6) educating or assisting on sophisticated analytical techniques for image comparisons and statistical or digit analyses of data to prove falsification or fabrication; (7) suggesting collateral evidence to confirm or refute questioned claims; (8) advising on “missing” records; (9) assisting in locating experts; (10) developing strategies to prevent incomplete or withdrawn “admissions;” (11) informing other Federal agencies; (12) notifying or requesting help from other institutions; (13) advising on potential whistleblower and confidentiality issues; (14) helping with contacts to national databases (such as Genbank); and (15) assisting journal editors with papers that require correction or retraction.

AAMC Proposes Integrity Principles for Clinical Trials

Twenty-two principles for protecting integrity in the conduct and reporting of clinical trials have been proposed by the Association of American Medical Colleges (AAMC).

The principles are a product of an invitational conference held in June 2005 by AAMC in collaboration with the Centers for Education and Research in Therapeutics and the BlueCross BlueShield Association. The report, *Principles for Protecting Integrity in the Conduct and Reporting of Clinical Trials*, is available at <http://www.aamc.org/research/clinicaltrialsreporting/start.htm>

“Despite a number of external initiatives that have heightened standards for reporting clinical trial results, the AAMC has been troubled by evidence that significant variation continues to exist within the academic community over the application of appropriate standards for analyzing and reporting the results of sponsored clinical research, especially clinical trials sponsored by industry,” the report states.

The principles are organized under the following categories: Publications and Public Availability of Research Results, Registration of Clinical Trials, Lead Investigator and Steering Committee, Publication and Analysis Committee, Individual Publication, and Authorship.

The report states that the principles “should apply to all clinical trials conducted in academic medical institutions regardless of the source of funding.” The definition of “medical intervention” used in the report, however, “explicitly excludes phase 1 and early phase 2 studies.”

Free Exhibit Space Available at RCR Expo

Free space is still available for exhibitors who want to display their responsible conduct of research (RCR) instructional materials at the fourth annual RCR Expo.

The RCR Expo will be held in the Quebec City (Canada) Convention Center on October 16-17, 2006 in conjunction with the annual meeting of the Society of Research Administrators (SRA) International that is attended by about 1400 research administrators.

“About half of the available exhibit spaces have already been taken,” Loc Nguyen-Khoa, Director, RCR Resource Development Program, said. “Applicants for the nine remaining spaces should contact me as soon as possible.”

Exhibit space has already been allocated to RCR modules on data management, conflict of interest, research misconduct, publication practices, research mentoring, collaborative science, peer review, human subjects, and animal welfare.

Tools for assessing RCR training and programs will also be exhibited.

“Exhibits are not limited to materials produced with ORI support,” Nguyen-Khoa said. “We want to display the full range of materials that have been produced by universities, academic societies, professional associations, and commercial firms. The only requirement is that the material be available for general use either for free or for a fee.”

ORI will provide the exhibit space, a table, two chairs, and electricity for free. Internet access to the exhibit space will be provided as needed for free. Exhibitors will be responsible for furnishing their own computers, projectors, and other display technology.

Exhibitors applying for space should contact Loc Nguyen-Khoa at 240-453-8400 or via email to Lnguyen-khoa@osophs.dhhs.gov. For more information about the SRA International meeting, please visit <http://www.srainternational.org>.

ORI Conference Schedule – 2006

March 31

Promoting Research Integrity in the Social and Behavioral Sciences
San Antonio, TX

Co-sponsors: University of Texas-San Antonio; American Association of State Colleges and Universities, National Science Foundation, National Institutes of Health

July 24-25

Mentoring and Supervision for the Responsible Conduct of Research
St. Louis, MO

Co-sponsor: Washington University School of Medicine

September 14-15

Research Bias and Misconduct: Statistics, Images and Perceptions of Truth

Birmingham, AL
Co-sponsors: University of Alabama School of Medicine

December 1-3

Research Conference on Research Integrity

Tampa, FL
Co-sponsors: Association of American Medical Colleges, American Association for the Advancement of Science

Need an Office in Authority Over Postdoctoral Training *(from page 1)*

recommendations are presented below:

- “Establish an institutionally defined, fixed training period of three to five years, with goals and milestones established by the mentor and trainee...and develop mechanisms for formal completion or extension of the training period and promotion to a faculty or research associate appointment.
- “Establish a regular annual or biannual review of training progress, and provide feedback to postdoctoral trainees and their mentors...a common element should be the participation of tenured professors who are not directly involved in or benefitting from the postdoc’s research efforts.
- “Offer, at the institutional or program level, course and workshops for postdocs to enhance professional development skills, including public speaking and presentation skills, grantsmanship and scientific writing, interviewing and negotiation skills, laboratory management, and mentoring skills, as well as responsible conduct of science.
- “Educate trainees about research employment opportunities in academia and industry, as well as nonresearch employment options such as careers in administration and management, science writing, patent law, and public policy.
- “Standardize benefits for postdocs...a minimal level of benefits should be guaranteed at each institution, with a standardized benefits package available for purchase by the advisor or mentor.

- “Establish a mechanism for grievances. Identify a senior academic officer or an appropriate office to serve as an ombudsperson for hearing grievances filed by postdocs.
- “Establish a postdoctoral committee to serve as liaison between the administration and the postdocs.
- “Establish a local postdoc society for meeting other postdocs, and networking with peers and potential colleagues.
- “Establish an orientation to the institution for new postdocs to help integrate them into the research community.
- “Establish an office of postdoctoral affairs, with a dedicated administrator to oversee postdoctoral training, aid in the recruitment of postdocs, and establish and support the nine points listed above.”

Implementation of these recommendations would be “most effective at

the institutional level but could also be successfully implemented by individual schools, programs or departments,” the report states. “Most importantly, someone...must be designated as the person or office in authority over postdoctoral training.”

The report further states that it is “essential that institutions develop a reliable method for counting and tracking postdocs, including their career outcomes, to evaluate the effectiveness of postdoctoral training policies.”

The report concluded, “In the end, successful implementation of widely accepted and consistently applied postdoctoral training will improve postdoc career outcomes and satisfaction, maximize use of laboratory and institutional resources, and enhance the reputation of both the lab and the institution while attracting more competitive postdoctoral trainees.”

Fourth Biennial ORI Research Conference on Research Integrity

Call for Abstracts

Deadline: April 28, 2006

<http://ori.hhs.gov/research/extra/rcri.html>

**Safety Harbor Resort and Spa
Tampa, FL
December 1-3, 2006**

New Program Provides Support for Postdocs

A new NIH program aimed at nurturing the research careers of promising postdocs provides up to 5 years of support in a single award to assist postdocs to traverse the problematic transition from mentored to research independence.

The Pathway to Independence Award program implements recommendations made by the National Research Council report: *Bridging to Independence: Fostering the Independence of New Investigators in Biomedical Research* which is available at <http://books.nap.edu/catalog/11249.html>.

NIH will make between 150 to 200 awards in the initial year, beginning in Fall 2006. Submission deadline for the first round is April 7, 2006. The same number of awards are expected to be made in the following five years.

According to the NIH announcement, "The initial 1-2 year mentored phase will allow investigators to complete their supervised research work, publish results, and search for an independent research position. The second, independent phase, years 3-5, will allow awardees who secure an assistant professorship, or equivalent position, to establish their own research program and successfully apply for an NIH Investigator-Initiated (RO1) grant."

More information on the award is available at http://grants.nih.gov/grants/new_investigators/pathway_independence.htm.

RRI Researchers Publish 7 More Articles

Researchers supported by the Research on Research Integrity (RRI) Program have recently published seven more empirical studies on research integrity and the responsible conduct of research in four journals.

The fourth biennial ORI Research Conference on Research Integrity will be held at the Safety Harbor Resort and Spa in Tampa, Florida from December 1-3, 2006. For information on submitting abstracts see conference web site at <http://ori.hhs.gov/research/extra/rcrri.html>. Submission deadline is April 28, 2006.

"The RRI researchers are beginning to publish at a steady rate," Mary Scheetz, Ph.D., program director, said. "Eight articles and a commentary were published in 2005 and another article has been published in early 2006."

In the first four years of the program, RRI researchers have published 18 articles, seven abstracts, a commentary, a review and a letter to the editor. A complete list of RRI publications is available on the ORI web site at http://ori.hhs.gov/research/rri_publications.shtml. Citations to the recently published articles follow.

- Barrett KA, Funk CL, Macrina FL. "Awareness of Publication Guidelines and the Responsible Conduct of Research." *Accountability in Research* (2005) 12, no. 3: 193-206.
- Broome ME, Pryor E, Habermann B, Pulley L, Kincaid H. "The

Scientific Misconduct Questionnaire - Revised (SMQ-R): Validation and Psychometric Testing." *Accountability in Research* (2005) 12, no. 4: 263-280.

- Heitman E, Bulger RE. "Assessing the Educational Literature in the Responsible Conduct of Research for Core Content." *Accountability in Research* (2005) 12, no. 3: 207-224.
- Keith-Spiegel P, Koocher GP. "The IRB Paradox: Could the Protectors Also Encourage Deceit?" *Ethics & Behavior* (2005)15, no. 4, 339-349.
- Mello MM, Clarridge BR, Studdert DM. "Researchers' Views of the Acceptability of Restrictive Provisions in Clinical Trial Agreements with Industry Sponsors." *Accountability in Research* (2005)12, no. 3: 163-191.
- Vogeli C, Yucel R, Bendavid E, Jones LM, Anderson MS, Louis KS, Campbell EG. "Data Withholding and the Next Generation of Scientists: Results of a National Survey." *Academic Medicine* (2006) 81: 128-136.
- Wright MC, Taekman JM, Barber L, Hobbs G, Newman MF, Stafford-Smith M. "The Use of High-fidelity Patient Simulation as an Evaluative Tool in the Development of Clinical Research Protocols and Procedures." *Contemporary Clinical Trials* (2005) 26, no. 6: 646-659.

Failure to Disclose Prompts Journal Actions

Journals are taking steps to protect the integrity of their publications by instituting actions against authors who fail to disclose conflicts of interest according to press reports.

Two journals announced that they would impose temporary publication bans on such authors. *The Journal of Thoracic and Cardiovascular Surgery (JTCS)* recently adopted a one to two year ban; last year the journal, *Environmental Health Perspectives (EHP)*, announced a three-year ban.

In 2003, the Nature Publishing Group broadened its competing financial interest policy to cover all Perspective, Analysis, Progress, Review, Brief Communication, Article and Letters submissions.

Audit Report Critical of Animal Care Program

An audit report that is critical of the inspection and enforcement activities of the Animal and Plant Health Inspections Service (APHIS) Animal Care Program has been issued by the Office of Inspector General, U. S. Department of Agriculture. The report is available at <http://www.usda.gov/oig/webdocs/33002-03-SF.pdf>

The recommendations call for (1) more aggressive enforcement action against violators of the Animal Welfare Act, especially in facilities east of the Mississippi; (2) higher fines for research facilities; (3) closer monitoring of the number of animals used in research, protocols and other records, and (4) increased effectiveness by Institutional Animal Care and Use Committees (IACUCs) including training of their members.

Under the policy authors are required to submit a declaration of competing financial interests. If an author refuses to disclose his/her financial interests, *Nature* journals publish the declination.

The journals acted after they discovered that authors of published papers did not disclose financial conflicts of interest. The JTCS found four authors on two papers did not report their financial ties to a company whose heart-surgery technology they had evaluated. A study found the first or last author of three articles

published in EHP did not disclose their financial interests.

The Nature Publishing Group extended its conflict of interest policy to cover all submissions because of controversy over a review article published in *Nature Neuroscience* that did not disclose an author's competing financial interests including a patent, stock options, and consulting fees from companies whose products were favorably discussed in the review. Previously, disclosure was limited to authors of primary research articles.

New Journal Focuses On Human Research Ethics

The inaugural issue of a journal that aims to improve ethical problem solving in research on humans by publishing empirical studies on such research will hit the journal shelves in libraries this month.

Joan E. Sieber, California State University-East Bay, is the editor-in-chief of *The Journal of Empirical Research on Human-Research Ethics* which will be published quarterly. For additional information and subscription rates see <http://www.csueastbay.edu/JERHRE/>

The first issue will carry 12 featured articles including three by research-

ers supported by the Research on Research Integrity (RRI) Program:

Normal Misbehavior: Scientists Talk About the Ethics of Research. Raymond De Vries, Brian C. Martinson, Melissa S. Anderson

What Scientists Want from Their IRBs. Patricia Keith-Spiegel, Gerald P. Koocher, Barbara G. Tabachnick

Scientists' Perceptions of Organizational Justice and Self-Reported Misbehavior. Brian C. Martinson, Melissa S. Anderson, Raymond De Vries, A. Lauren Crain

TRAVEL FELLOWSHIPS

12th Annual Conference

Teaching Survival Skills and Ethics

June 11-16, 2006

<http://www.survival.pitt.edu/events/trainer.asp>

Most Whistleblowers in Research Misconduct Investigations Come from Faculty Ranks

There were 289 whistleblowers in the 259 PHS research misconduct cases that resulted in formal investigations during the 10-year period, 1994-2003. Whistleblowers like respondents generally appear to act alone. Only 18 of the 259 investigations involved more than one whistleblower.

Most whistleblowers involved in the closed research misconduct investigations during the 10-year period were from faculty ranks rather than non-faculty ranks. The faculty ranks (dean, professor, associate professor, assistant professor) accounted for 57 percent of the whistleblowers while the non-faculty ranks (postdoctoral fellows, research associates/assistants, students, technicians) accounted for 19 percent of the whistleblowers. The percentage of whistleblowers from

the non-faculty ranks might increase substantially if the academic rank of the anonymous or confidential whistleblowers (25 percent) was known. The academic ranks that contributed the most whistleblowers were professors (30 percent) and associate professors (16 percent). See Table 1.

Allegations made by research associates resulted in the highest rate of misconduct findings (64 percent) followed by students (58 percent), professors (55 percent), and associate professors (51 percent). Allegations made by technicians resulted in the lowest rate of misconduct findings (29 percent) followed by postdoctoral fellows (36 percent). Fifty-five percent of the allegations made by whistleblowers whose identity was protected or unknown were substantiated.

Allegations made by whistleblowers in the faculty ranks resulted in 57 percent of the misconduct findings compared to 16 percent for the non faculty whistleblowers and 27 percent for the unknowns. Allegations made by professors and associate professors accounted for nearly half of the misconduct findings (48 percent).

Allegations made by whistleblowers in the faculty ranks resulted in 56 percent of the no misconduct findings compared to 20 percent for whistleblowers in the non faculty ranks and 24 percent for the unknown whistleblowers. Allegations made by professors and associate professors accounted for 44 percent of the no misconduct findings.

Table 1: Percent of substantiated allegations by academic rank of whistleblowers, 1994-2003.

Rank	Total Whistleblowers		Substantiated Whistleblowers		Percent Substantiated
	N	%	N	%	
Dean	4	1	2	1	50
Professor	86	30	47	32	55
Associate Professor	47	16	24	16	51
Assistant Professor	28	10	12	8	43
Postdoctoral Fellow	14	5	5	3	36
Research Assoc/Asst.	11	4	7	5	64
Student	12	4	7	5	58
Technician	14	5	4	3	29
Anon/Confid/Unknown	73	25	40	27	55
TOTAL	289	100	148	100	51

Science Launches Essay Series on Education

In an editorial last December, *Science* solicited submissions for a new essay series on “innovative educational ideas” that will be published in the last issue each month throughout this year.

The editorial states, “We (*Science* and the Howard Hughes Medical Institute) want to showcase new approaches to teaching that work even in large lecture classes, or bring other disciplines, such as physics and computer sciences, together with biology into a single course. Learning is not a spectator sport, and through active involvement in the material, students will understand and retain concepts much better.

We want to explore how to connect research and teaching for the benefit of both student and professor. We want to help faculty do what they would all love to do: teach better with less struggle. Above all, we hope to increase general interest in, and knowledge about, science; no matter what path our students embark on.”

The first essay, “The Merits of Training Mentors” by Christine Pfund, Christine Maidl Pribbenow, Janet Branchaw, Sarah Miller Lauffer and Jo Handelsman was published in the Education Forum in the January 27, 2006 issue. The article describes the Wisconsin Mentoring Seminar.

Mark S. Frankel, Director, Scientific Freedom, Responsibility & Law Program, AAAS, said, “While it’s obvious that the new essay series will focus primarily on science education, the language used in the editorial also leaves room for people doing empirical research on RCR instruction. After all, an integral part of science education is transmitting knowledge about the values and norms of science.”

The editor for the essay series is Pam Hines (phines@aaas.org) and she is looking for “good manuscripts”.

India Taking Steps to Increase Clinical Trials

Plans to create a clinical trial registry and conduct audits of some clinical trials have been announced by the Indian government to prepare for an expected increase in clinical trials in that country, according to the *British Medical Journal* (331:1044).

About 100 clinical trials were being conducted in India in 2005. India earned an estimated \$17 million in 2003 from clinical trials.

The registry of clinical trials conducted in India will be created by the Indian Council of Medical Research (ICMR). The audits will be conducted by inspectors being trained by the health ministry to ensure compliance with ethical guidelines and good clinical practice.

The ICMR drafted ethical guidelines for biomedical research on

human subjects in 2000 but legislation to enforce those guidelines and impose penalties on violators is still pending, according to the ICMR deputy director general. See guidelines at <http://ori.hhs.gov/international/websites/index.shtml>

Attendees at a conference called to consider India’s capacity for clinical trials said the country would have to strengthen its regulatory mechanisms and infrastructure, ensure the protection of human subjects, increase human resources available to conduct clinical trials, and monitor the behavior of doctors.

NIH COI Rule

The final rule on conflicts of interest issued by the National Institutes of Health on August 25, 2005 is available at http://www.nih.gov/about/ethics_COI.htm.

Retractions Generate \$1 Million Lawsuit

The retraction of two articles in major journals without the permission of one of the authors has triggered a lawsuit for more than \$1 million in punitive damages and legal fees, according to *The Scientist* (10/12/2005).

The offended author is suing her former supervisor because she claims the retractions based on an allegation of research misconduct damaged her scientific reputation, caused her economic loss, and cost her future opportunities for employment and publishing.

The supervisor and the other co-authors reportedly retracted the articles because three postdocs in the supervisor’s lab could not replicate the results. In addition, some biological reagents used in the original research could not be verified.

Case Summaries

Amy Beth Goldring, University of California at Los Angeles: Based on an investigation conducted by the University of California at Los Angeles (UCLA) and additional analysis conducted by the Office of Research Integrity (ORI) in its oversight review, ORI found that Ms. Goldring, former graduate student, Department of Psychology, UCLA, engaged in scientific misconduct by falsifying or fabricating data and statistical results for up to nine pilot studies on the impact of vulnerability on decision-making from Fall 2000 to Winter 2002 as a basis for her doctoral thesis research. The falsified or fabricated data was included in a manuscript submitted to *Psychological Science*, in National Institutes of Mental Health (NIMH), National Institutes of Health (NIH), grant application 1 R01 MH65238-01A1, and in NIMH, NIH, pre-doctoral training grant T32 MH15750.

Ms. Goldring has been debarred by another agency with joint jurisdiction for a period of three (3) years, beginning on May 13, 2005, and ending on May 13, 2008. On December 16, 2005, Ms. Goldring received a detailed explanation of ORI's proposed finding and was given thirty (30) days to contest the finding and the proposed administrative action. The thirty-day period has elapsed and ORI has not received a response. Accordingly, the following administrative action has been implemented for a period of three (3) years, beginning on January 18, 2006:

(1) Ms. Goldring is prohibited from serving in any advisory capacity to the U.S. Public Health Service (PHS), including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

April Swe, University of Wisconsin-Madison: Based on the report of an investigation conducted by the University of Wisconsin-Madison (UWM) and additional analysis conducted by the Office of Research Integrity (ORI) in its oversight review, PHS found that Ms. Swe, former graduate student at UWM, engaged in research misconduct by fabricating data on thirty-nine (39) questionnaires of sibling human subjects associated with an autism study. The research was supported by National Institute on Aging, National Institutes of Health (NIH), grant R01 AG08768.

In a final decision dated January 13, 2006, the HHS Debarring Official, on behalf of the Secretary of HHS, issued the final debarment notice based on the PHS findings of research misconduct. The following administrative action has been implemented for a period of three (3) years, beginning on January 13, 2006: (1) Ms. Swe has been debarred from eligibility for or involvement as a principal in nonprocurement transactions (e.g., grants and cooperative agreements) of the Federal Government and from contracting or subcontracting with any Federal Government agency, except as provided in 45 C.F.R. § 76.120. This action is being taken pursuant to the debarment regulations at 45 C.F.R. Part 76. (2) Ms. Swe has been 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.

Jessica Lee Grol, University of Pittsburgh: Based on the report of an investigation conducted by the University of Pittsburgh (UP) and additional analysis conducted by the Office of Research Integrity (ORI) in

its oversight review, HHS found on October 17, 2005, that Ms. Grol, former Research Project Coordinator, Department of Neurological Surgery, UP, engaged in scientific misconduct by fabricating study research records for 15 subjects, including the patient interview data, the forms tracking data, and the medical record extraction data in a study on the management of cerebral aneurysms. The research was supported by National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH), career development award K23 NS02159.

In a final decision dated November 23, 2005, the HHS Debarring Official, on behalf of the Secretary of HHS, issued the final debarment notice based on the PHS findings of scientific misconduct finding. The following actions have been implemented for a period of three (3) years, beginning on November 23, 2005: (1) Ms. Grol has been debarred 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 C.F.R. Part 76; and (2) Ms. Grol 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.

Human Subjects Resource Page Created by OHRP

A new resource page on human subject protections developed by the Office for Human Research Protections (OHRP) is available at <http://www.hhs.gov/ohrp/related.html>.

Conference, Workshop, and Meeting Proposals Due April 1, 2006.

ORI is seeking proposals from institutions, scientific societies, and professional associations that wish to collaborate with ORI in developing conferences, workshops, symposia, colloquiums, seminars, and annual meeting sessions that address the responsible conduct of research, research integrity, or research misconduct. ORI will provide up to \$20,000, depending on the event proposed.

The next target date for receipt of applications is **April 1, 2006**. Proposal instructions and an application form are available on the ORI web site at http://ori.hhs.gov/conferences/conf_cosponsor_instruc.shtml. Please submit your proposal electronically to stitus@osophs.dhhs.gov. Call Dr. Sandra Titus at 240-453-8400.

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

Div. of Investigative
Oversight (240) 453-8800
Fax (301) 594-0043

Research Integrity
Branch/OGC (301) 443-3466
Fax (301) 594-0041

<http://ori.hhs.gov>

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

Official Business
Penalty for Private Use \$300