

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.



Eight Research Misconduct Findings Made in 2004

Six of the eight individuals against whom findings of research misconduct were made in 2004 were debarred for three years from receiving federal support; two other individuals can only participate in PHS supported research for three years under a plan of supervision submitted by their employer. All eight individuals were prohibited from serving the PHS in any advisory capacity for three years.

ORI closed 23 cases in 2004; opened 30, and carried 51 into 2005. "That's the

most cases we carried forward since 1995, when 58 cases were forwarded," said Dr. Alan Price, Director, Division of Investigative Oversight, ORI.

The number of allegations (274) received by ORI in 2004 was 50 percent higher than 2003 and the highest since 1989 when the regulation was published and offices were created to implement it, Dr. Price said.

Falsification was involved in six misconduct cases, fabrication in five
See Major, page 6

New RCR Resources Posted; Most Core Areas Covered

Seven more instructional resources covering the protection of human subjects, conflicts of interest, data management, ethics in mental health research, and RCR training for foreign postdocs are available on the ORI website.

These new resources raise to 18 the number of resources created with support from the RCR Resource Development Program started by ORI in 2002. The completed projects include three comprehensive courses, collec-

tions of case studies and ethical dilemmas, and specialized courses in six of the nine core RCR topics.

In addition, a module on responsible literature searching, produced by the Association of Health Science Libraries and hosted by the University of Pittsburgh, was produced under the RCR Program for Academic Societies. That module may be accessed through the ORI home page through the Societies and Assns. section.

See RCR, page 2

IN THIS ISSUE

Conferences	3
NIH Conflict of Interest	4
Technical Assistance	5
Falsification	6
Gelsinger Case	7

Redesigned ORI Website Improves Access, Navigation

Visitors to the redesigned ORI web site will find it much easier to locate the information they are seeking because of improved navigation and organization provided by the new home page and the menus on subsequent pages.

The three-column format used on the home page contains 13 information

blocks that provide a comprehensive and coherent portal that enables visitors to easily obtain the information they are seeking about research misconduct, research integrity, the responsible conduct of research and the functions and programs of ORI.

See Home, page 5

RCR Resource Web Page Reorganized; Access Improved *(from page 1)*

The ORI web site has been reorganized to make it easier to access the RCR resources either through the home page or the Education section. All instructional materials are organized into 10 categories based on the nine core RCR areas and a general subject area for resources that deal with two or more core areas.

All of the products produced with funding from the RCR Resource Development Program are in the public domain and may be used freely. Proper acknowledgment should be given to the originators and ORI.

Questions concerning the resources or the Education page should be sent to James Egbert, webmaster, at jegbert@osophs.dhhs.gov.

“The research and academic communities owe the creators of these resources and their institutions a debt of gratitude,” Larry Rhoades, Director, Division of Education and Integrity, ORI, said, “because the time, effort, talent, and resources they are investing in the resources substantially exceed the support provided by 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:

ETHICS IN MENTAL HEALTH RESEARCH CASE COMPENDIUM

James DuBois, St. Louis University.

A compendium containing illustrative and decision-making ethics cases in mental health research. Illustrative cases simply illustrate a point, but do not promote critical thinking. Decision-

making cases ask participants to make an ethical decision. Also contains a case analysis framework, a justifying ethical decisions framework, and a facilitating case discussions handout.

ETHICS AND RESEARCH IN THE COMMUNITY

Leslie Alexander, Bryn Mawr College, and Ken Richmond, Massachusetts College of Pharmacy and Health Sciences.

This module is aimed at educating staff in community agencies about human subjects protection. It addresses people who do research work in communities including recruiting subjects for research, handing out questionnaires, and interviewing people. Research supervisors will also find it informative.

RESPONSIBLE CONDUCT IN DATA MANAGEMENT

Murali Krishnamurthi, Northern Illinois University.

This module covers seven topics related to integrity in data management: overview, selection, collection, handling, analysis, publication and reporting, and ownership. Besides content, this module employs quizzes, games, cases and opportunities for reflection.

GUIDEBOOK FOR TEACHING SELECTED RESPONSIBLE CONDUCT OF RESEARCH TOPICS TO A CULTURALLY DIVERSE TRAINEE GROUP

Madeline Alexander and Wendy Reed Williams, The Children’s Hospital of Philadelphia.

This guidebook addresses RCR training for foreign postdocs based on the results of focus group discussions with foreign postdocs. Teaching materials related to data management, sharing and ownership; intellectual property, and research misconduct are presented.

RESEARCH CONFLICTS OF INTERESTS COURSE

Melissa Proll, University of Texas Health Science Center-Houston.

This course uses a case-based approach where the student plays the role of a member of a university Conflict of Interest Committee that must review a financial disclosure for a faculty member with financial interests in a clinical study. The Committee must decide if the conflicts can be eliminated, reduced, or managed and if the research can go forward as proposed.

POTENTIAL CONFLICTS OF INTEREST—A COURSE FOR RESEARCHERS

Jeffrey Kahn, University of Minnesota.

This course is aimed at principal investigators and other researchers including faculty members, professionals, post-doctoral fellows and graduate students. The course highlights federal, state, and university policies regarding conflicts of interest, provides an overview of disclosure procedures and benefits, and demonstrates the development of plans to manage potential conflicts of interest.

REVIEWING & MANAGING RESEARCHERS’ CONFLICT OF INTEREST

Jeffrey Kahn, University of Minnesota.

This course is designed for deans, department chairs and conflict review committee members to promote consistency in applying policies and making decision regarding researchers’ disclosures and plans to resolve potential conflicts of interest.

**HONORARY AUTHORSHIP,
IS NOT HONORABLE**

Academic Societies Address Literature Searches and Ethics

A module on responsible literature searching and a code of ethics on research involving children are among the first resources produced by the RCR Program for Academic Societies which made awards to four more academic societies last January.

The module on responsible literature searching, produced by the Association of Health Science Libraries and hosted by the University of Pittsburgh, may be accessed through the ORI home page through the Societies and Assns. section.

The code of ethics, "Ensuring Integrity for Research with Children," was developed by the Ambulatory Pediatric Association. The statement was published in the January/February issue of *Ambulatory Pediatrics*. This policy statement is available on the ORI home page in the Societies and Assns. section.

The latest awards raise to 24 the number of academic societies that have been supported in the first three years of the program. Recipients of the newest awards and project titles follow:

- **The Society of Research Subject Advocates.** "Research Subject Advocates Development and Research Integrity Seminar."
- **The Endocrine Society.** "Workshop on Enhancing Integrity in Clinical Research."
- **The American Society for Clinical Pharmacology and Therapeutics.** "Workshop on Corporate Influence in Research."
- **The American College of Physicians.** "Training and Support in the Responsible Conduct of Practice-based Research in Internal Medicine."

Abstracts for all funded projects are posted on the ORI web site at http://ori.hhs.gov/education/aamc_funded_1-3.shtml.

The RCR Program for Academic Societies, a collaboration between the Association of American Medical Colleges and ORI, offers awards from \$5,000 to \$50,000 to academic societies to support activities aimed at promoting the responsible conduct of research among their members. These activities include, but are not limited to, meetings, workshops, conferences, publications, research guidelines, code of ethics, instructions to authors, curriculum development, and mentoring training.

All non-profit academic societies that are located in the United States in the fields of medicine and biomedical or behavioral sciences are eligible to apply. For more information see the ORI home page.

ORI Conferences and Workshops CY 2005

- **JUNE 3-4**
Responsible Conduct of Basic and Clinical Research
Warsaw, Poland
Co-sponsor: Polish Academy of Sciences
- **JUNE 13-14**
Promoting a Productive and Responsible Research Environment
Sacramento, CA
Co-sponsor: University of California - Davis
- **JUNE 16-17**
The Research Coordinator: Strategies for Promoting Integrity in Clinical Research
Bryn Mawr, PA
Co-sponsors: University of Pennsylvania School of Medicine, Thomas Jefferson University and Drexel College of Medicine
- **JUNE 23-25**
Rock Solid Research: The Responsibility of Research Integrity at Master-Baccalaureate Institutions
Billings, MT
Co-sponsor: Montana State University - Billings
- **AUGUST 4-5**
Mentoring in Human Research Studies
Little Rock, AR
Co-sponsor: University of Arkansas for Medical Sciences
- **OCTOBER 1**
Plagiarism in the Science Disciplines: The Good, the Bad, and the Really Ugly
New York, NY
Co-sponsors: New York University Medical School, St. John's University, Columbia University College of Physicians and Surgeons, City University of New York
- **OCTOBER 20-21**
Responsible Conduct of Research: Essentials for Research Success and Integrity
Pocatello, ID
Co-sponsor: Idaho State University
- **OCTOBER 25**
Promoting RCR in Research in the Social, Behavioral and Educational Sciences
San Antonio, TX
Co-sponsors: American Association of State Colleges and Universities and the University of Texas-San Antonio

**GIVING CREDIT,
RETURNS CREDIT**

NIH Conflict of Interest Rules Focus on Three Areas

The National Institutes of Health announced new conflict of interest rules in February that restricts compensated and uncompensated employment, financial investments and the receipt of awards by all of its federal employees, except Special Government Employees.

The interim rule became effective with its publication in the *Federal Register* on February 3, 2005. The rule remains effective unless changed by subsequent regulation. The rule will be evaluated at the end of a year. Additional information on the rule is available on the NIH web site at http://www.nih.gov/about/ethics_COI.htm.

Employment

The following types of outside activities are prohibited by the new regulations with certain exceptions noted below:

1. Compensated or uncompensated employment, including consulting and scientific and other board service, with substantially affected organizations (generally defined as pharmaceutical and biotechnology companies), supported research institutions (generally defined as grantees and contractors), health care providers and insurers, and related trade, professional or similar associations.
2. Compensated teaching, speaking, writing or editing for the above four groups; and
3. Self-employed business activity that involves the sale or promotion of products or services of a substantially affected organization or a health care provider or insurer.

Activities for which compensation is permitted providing prior approval is obtained include:

1. Teaching a course that is part of an established curriculum at a university that requires multiple presentations.
2. Outside practice of medicine, dentistry, pharmacy, nursing, or similar health-related professional practice that involves the personal provision of care, treatment, or other health-related professional services to or in connection with individual patients.
3. Clerical or similar services in retail stores, such as supermarkets, drug stores, or department stores.
4. Teaching, speaking, writing or editing that is part of a Continuing Medical Education program or other CME-like event. This activity may be permissible even if it is funded by a pharmaceutical or biotechnology company but only if such funding is through an unrestricted educational grant.

Investments

Generally, the new regulations define a prohibited holding as stock in pharmaceutical, biotechnology and other companies involved in research, development, or manufacture of medical devices, equipment, preparations, treatments or products and other substantially affected organizations.

All public and confidential financial disclosure report filers (and their spouses and minor children) are

prohibited from owning stock in substantially affected organizations. Employees who are not involved in intramural research or extramural funding programs may be permitted to hold up to \$15,000 worth of stock in any one company provided no other conflict arises.

Other exceptions also exist such as investments arising from pre-federal service employment (such as a pension or employee benefit) with an entity on the list and stock that is held by a diversified mutual fund.

Individuals owning prohibited holdings must sell such holdings within 150 days of the effective date of the regulations. Extensions may be granted.

Awards

Employees may not accept awards whose aggregate market value exceeds \$200 from an entity that is or seeks to do business with the NIH, seeks official action from the NIH, conducts activities substantially affected by the NIH or may be affected by the performance or nonperformance of their official duties. Exceptions may be made when very prestigious awards such as the Nobel Prize or Lasker Award or other awards that confer an exceptionally high honor in fields of medicine or scientific research are bestowed. Prior approval is required before accepting an award.

Conflict of Interest

“Research universities are concerned about financial conflict of interest (individual and institutional) because it strikes to the heart of the integrity of the institution and the public’s

confidence in that integrity.” *Report on Individual and Institutional Financial Conflict of Interest*. Association of American Universities, October 2001.

Biomedical Editors Revise Uniform Requirements

Editors are strongly encouraged to develop contributorship and guarantorship policies for their journals by The International Committee of Medical Journal Editors in its October 2004 update of the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Journals* which may be accessed through the ORI home page.

A contributorship policy would require journals to “request and publish information about the contributions of each person named as having participated in a submitted study, at least for original research.” This would include persons listed as authors and in acknowledgments.

A guarantorship policy would require journals to “request that one or more authors, referred to as “guarantors,” be identified as the persons who take responsibility for the integrity of the work as a whole, from inception to published article, and publish that information.”

The document also covers criteria for byline authors, conflicts of interest, privacy and confidentiality of patients and study participants, protection of human subjects, the obligation to publish negative studies, correction, retractions and “expressions of concern”, duplicate submission, redundant publication, acceptable secondary publication, and competing manuscripts based on the same study.

**RESEARCH ON RESEARCH
INTEGRITY PROGRAM**

*Request for Applications:
June 2005*

*Submission Deadline:
September 2005*

Home Page Provides Direct Access to Info (from page 1)



Headings for the information blocks are Sections, Top Links, ORI Newsletter, Related Offices, What’s New, Research Results, Societies and Associations, Listservs, Upcoming Events, Featured , RCR Resources, Programs, and Need Assistance.

“Generally speaking, the Section block which is included on every page provides an outline of the major areas that comprise the web site,” Larry Rhoades, Director, Division of Education and Integrity, said. “Each page within a section contains a menu that allows visitors to move easily within the section.

More Institutions Seek Technical Assistance from ORI

The number of requests made to the Rapid Response Technical Assistance (RRTA) program by institutions seeking assistance in handling allegations of research misconduct dramatically increased in 2004.

Forty-eights requests for assistance were received in 2004, almost doubling the number of requests received the previous year. The number of requests for assistance has grown steadily from 6 in 2000 to 10 in 2001 to 21 in 2002 and to 26 in 2003.

The most significant RRTA assistance provided in 2004 involved detailed strategy planning advice over several weeks on sequestering records at potentially multiple university and clinic sites with a potentially resistant respondent.

ORI created the RRTA program in 2000 to provide early and direct assistance to institutional officials

responsible for assessing research misconduct allegations in resolving difficult issues earlier in the assessment, inquiry, or investigation process.

“I am very pleased with the community response to the RRTA program,” said Dr. Alan Price, Director, Division of Investigative Oversight, ORI. “Although this program was designed to be helpful to institutions with little or no experience in handling cases, experienced institutions have also benefitted from ORI’s assistance in certain situations.”

Dr. Price continued, “I hope research integrity officers in all institutions will feel at ease in calling me (301-443-5330) early in a case, even with a ‘hypothetical’ before formal notification, so that ORI may help smooth and speed the case process.”

Major Research Misconduct Findings Described *(from page 1)*

cases and plagiarism in two cases. Misconduct findings were made against an assistant professor, three postdocs, a clinical research associate, an assistant research scientist, a senior interviewer, and a graduate student. Four respondents held Ph.D.s., one held M.D./Ph.D degrees, one was a registered nurse, and two did not hold graduate degrees.

Some major ORI misconduct findings in 2004 involved the following respondents:

- a research scientist found guilty in state court of felony theft, which required financial restitution; she then settled ORI's case for fabrication of her degree credentials in 4 NIH grant applications and interviews of at least 4 autistic families, as found in a university investigation

- a senior interviewer who fabricated 50 to 150 interviews of mental health patients; ORI used her written admission to local police, in a case that the local prosecutor declined to pursue, to make misconduct findings with the university inquiry report and to settle the ORI case
- an assistant professor who, after falsely blaming a postdoctoral fellow, admitted to plagiarism and falsification of images on the development of a malaria drug, waived the need for further investigation, and signed a 3-way settlement with the university and ORI
- a postdoctoral fellow who became an assistant professor, admitted to one instance of falsification of an image for a publication on microtu-

bule vesicle movement, claiming it was the only instance, but later agreeing with an ORI suggestion to the university that another paper might have a similar false claim, requiring its retraction; after he signed a settlement agreement with ORI, his foreign country, which had sponsored his fellowship, required him to repay it.

Of the 23 ORI cases closed, 19 (83%) were closed within 8 months of receiving the final decision or documentation from the institution. The average processing time for cases closed was 6.4 months, which is below the ORI goal of 8 months.

Explicit Standards

“... the absence of explicit institutional standards allows the research system to tolerate substandard activities by a small number of individual investigators who fail to observe generally accepted practices. Furthermore, the absence of a mechanism to enforce standards leads to a perception that the institution or the profession is unwilling or unable to correct abusive practices. The Responsible Conduct of Research in the Health Sciences, p. 2, IOM, 1989.

New Videos Available on Human Protection

Three new training videos on the protection of human subjects have been made publicly available by the Health Resources and Services Administration in cooperation with the Office for Human Research Protections.

The videos may be accessed through the ORI home page by clicking on Human Subjects in the RCR resources section. The three videos run a total of 90 minutes.

Falsification: Most Frequent Misconduct

The most frequent type of research misconduct in ORI cases closed from 1994-2003 was falsification which alone or in combination with fabrication or plagiarism accounted for 71 percent of the findings. Falsification alone accounted for 40 percent of the findings; fabrication for 22 percent, and the falsification and fabrication combination for 27 percent. Six percent of the findings were based on plagiarism alone; another 4 percent combined plagiarism with falsification.

The high frequency of falsification as the type of misconduct involved in

PHS research misconduct findings compared to fabrication and plagiarism needs explanation. Research misconduct cases handled by the National Science Foundation deal primarily with plagiarism.

Is falsification considered a lesser evil than fabrication or plagiarism in the research community? Is there a clear definition of what constitutes data falsification in the research community? Are the limits on data manipulation and data selection clearly understood?

Number of Research Misconduct Findings by Types of Research Misconduct: 1994-2003*

Type	1994-1998		1999-2003		Total	
	N	%	N	%	N	%
Fabrication	18	25	11	19	29	22
Falsification	26	35	27	46	53	40
Plagiarism	6	8	2	3	8	6
Fab/Fals	22	30	14	24	36	27
Other combos	2	2	5	8	7	5
TOTAL	74	100	59	100	133	100

*Only includes PHS misconduct findings.

Access to Raw Data Denied in Israel Misconduct Case

A professor of anthropology at the Hebrew University of Jerusalem has agreed to retire rather than face disciplinary proceedings over research misconduct allegations, according to *The Chronicle of Higher Education* (2/11/05).

Meira Weiss, the immediate past chairwoman of the Israel Anthropology Association, reportedly said she agreed to retire because legal costs associated with the proceedings could amount to \$100,000 and she had lost faith in the university because of its handling of the allegations.

Professor Weiss said she was angry because the university committee investigating the allegations demanded that she provide them with her field diaries, transcripts of interviews she conducted with research subjects, and the names of her subjects and informants.

According to Professor Weiss anthropologists in Israel are forbidden to betray the confidentiality of sources by the code of ethics of the American Anthropological Association. The current chairman of the Israel Anthropology Association, said “the demand to see field diaries is illegitimate no matter what the circumstances.”

A university spokeswoman declined to name the specific charges against Professor Weiss, but issued the following statement:

“In the wake of the heavy suspicions concerning the reliability of Prof. Meira Weiss’s scholarly work, a committee of experts was appointed. Professor Weiss, who was notified of the establishment of the committee and of the allegations against her, was given an opportunity to respond in writing both to the original allegations

against her and to the interim report of the committee. The committee, which carefully examined the allegations in light of Prof. Weiss’s responses, found that there was a prima facie basis for the allegations and thus recommended that she undergo disciplinary proceedings.”

The university statement provided the following rationale for accepting the offer of early retirement in lieu of disciplinary proceedings:

“The university’s consideration was the great importance of concluding the proceeding in the swiftest possible way. It was clear to the university that conducting a disciplinary proceeding on such a serious violation was liable to take a considerable time, during which the university would have to continue to employ Prof. Weiss, despite the suspicions against her. The suggestion of Prof. Weiss’s counsel made it possible to terminate her employment immediately, without her continuing to teach, to supervise students, and to receive research grants from the university.”

RCREC Announces Election Results

The RCR Education Consortium 2005:

- PRESIDENT - Michael Kalichman, UC-San Diego;
- PRESIDENT-ELECT – Frank Macrina, Virginia Commonwealth University;
- VICE PRESIDENT – Daniel Vasegird, Columbia University;
- SECRETARY-TREASURER – Karen Muskavitch, Boston College;
- COUNCILOR – Ed Gabriele, Henry M. Jackson Foundation for the Advancement of Military Medicine.

Settlements Reached in Gelsinger Case

Civil settlements reached in February between the U. S. Department of Justice and the physician-researchers who oversaw the gene therapy experiment that resulted in the death of Jesse Gelsinger included fines on two institutions and restrictions on the scientific practice of the researchers, according to the *Washington Post* (2/10/05).

The research team was composed of James M. Wilson and Steven E. Raper, both of the University of Pennsylvania, and Mark L. Batshaw, Children’s National Medical Center, Washington, D.C. The university and the medical center were fined \$517,496 and \$514,622, respectively.

Under the settlement, Wilson, the team leader, cannot conduct research on humans until 2010. He has been barred from conducting such studies since 2000. In addition, Wilson must take training on the protection of human subjects; subject his work to enhanced oversight and monitoring; and lecture on and write an article on lessons learned. Lesser restrictions were imposed on the two other researchers. The respondents did not admit any wrongdoing.

In its lawsuit, the government alleged that the research team had repeatedly failed to protect human subjects in the experiment by failing to halt the experiment when serious toxicities first arose; failing to disclose the study’s dangers in informed-consent documents; and falsely suggesting that earlier patients in the study had benefitted from the treatment.

**When Mentoring,
Clone a Better Model**

Conference, Workshop, and Meeting Proposals Due October 1, 2005.

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 **October 1, 2005**. 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 lrhoades@osophs.dhhs.gov. Call Dr. Larry Rhoades at 301-443-5300.

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