



ORI Newsletter

Volume 10, No. 1

<http://ori.hhs.gov>

December 2001

Study Indicates Need for Training in RCR; Handling Allegations

Results of an educational needs assessment, funded by ORI, indicate wide agreement among institutional research integrity officers (RIOs) and responsible conduct of research (RCR) instructors on the need for training in both RCR and managing scientific misconduct allegations.

A large majority (90 percent) of the respondents answering the RCR needs assessment questionnaire agreed that RCR training was needed for all researchers including principal investigators, research associates, postdoctoral fellows, and graduate students, as well as the institutional RIOs. A majority also felt that laboratory assistants and laboratory technicians should receive RCR training (66 percent and 68 percent, respectively).

Concerning training in managing scientific misconduct allegations, over 80 percent of the RIOs responding to the survey felt that the Vice President for Research, science deans, department heads, and RIOs, should receive training. Over 70 percent reported that laboratory directors, inquiry committee chairs, and investigation committee chairs needed training, while 68 percent felt that principal investigators should receive it.

Under contract with ORI, the Center for Health Policy Studies collected information regarding the needs of extramural research organizations for educational materials and programs related to (1) responsible conduct of research and (2) managing scientific misconduct allegations.

The RCR educational needs assessment survey was administered to a sample of 200 RCR instructors and 100 RIOs. Surveys were sent via e-mail and participants were given three options for responding, including (1) completing a web survey, (2) printing,

See Top Topics on page 2.

Research Guidelines: More Exist; Narrowly Focused; Little Agreement

Considerably more medical schools provide some written guidelines for the conduct of research for their faculty to follow than in 1990. However, the majority of guidelines are narrowly focused, and do not reflect much agreement on what topics guidelines should cover or what specific guidance should be offered.

The report of the *Analysis of Guidelines for the Conduct of Research Adopted by Medical Schools or Their Components* is available from the ORI home page by clicking on Studies/Reports under Publications. A resource document on developing research guidelines is being prepared by ROW Sciences, Inc., which also is organizing a conference on creating effective research guidelines in September 2002.

Guidelines from 98 of the 125 accredited U.S. medical schools were analyzed by ROW Sciences, Inc., under contract with ORI. Eighty-one medical schools submitted guidelines upon request. The remainder of the 98 guidelines were obtained from medical school or university websites. At a minimum, 78 percent of accredited medical schools had some guidelines for the conduct of research in 2000, compared to only 13 percent in 1990. Sixty-three percent of the guidelines were developed at the university level; 31 percent at the school level; and 6 percent were combinations of both levels.

See Research Guidelines on page 4.

What's Inside

RCR Listserv Created	3
Grant Applications Increase	4
Annual Reports Due	5
Case Summaries	8

Top Topics: Data Management; Authorship; Proof; Evidence Handling

(from page 1)

completing, and faxing an attachment sent with the e-mail, and (3) requesting a hard copy of the survey with a stamped, addressed envelop. Of the 300 RCR surveys, 153 (51 percent) were completed and returned.

Regarding the need for training to manage scientific misconduct allegations, surveys were sent to a sample of RIOs representing 200 institutions. The sample consisted of 150 institutions that have experienced an allegation of misconduct in the past, and 50 other institutions. Options for responding were the same as for the RCR educational needs assessment survey. The return rate was 57 percent (114 returned). Sixty percent of the RIOs from institutions that have experienced a research misconduct allegation returned a completed survey.

Approximately 61 percent of the responses on the RCR survey indicated that more adequate instructional materials are needed in scientific recordkeeping and data management. Over 50 percent also selected authorship and publication practices, intellectual property, conflicts of interest, and scientific misconduct as topics in which adequate educational materials were lacking. Overall, principal investigators and graduate students were the primary audiences identified as needing more RCR educational materials.

When asked what are the top 4 topics that should be addressed in RCR training for researchers, more than 95 percent of the responses to this question indicated scientific misconduct, conflicts of interest, authorship and publication practices, intellectual property, and peer review as the topics needing attention.

Approximately 65 percent of RIOs answering the scientific misconduct allegations survey agreed that more and better instructional materials are needed on the topic of requirements of proof. Over 62 percent also felt that more instructional materials were needed in protection against conflicts of interest, handling evidence, and sequestering data, while nearly 60 percent indicated a need for materials in regulatory requirements and developing investigational plans.

The complete report on the educational needs assessment will be available for downloading or printing from the ORI web site by the end of 2001. ☺

ORI Constructing Web Page On RCR Instructional Resources

ORI is constructing a page on instructional resources on its web site to facilitate the teaching of the responsible conduct of research by calling attention to existing materials that could be used in such instruction, thereby, decreasing the need for each institution to develop its own material.

The instructional resources page may be accessed through the ORI home page <http://ori.hhs.gov> by selecting Programs and clicking on “RCR Instructional Resources” under RCR Education.

The material is categorized as *comprehensive resources* that cover or intend to cover more than one of the core instruction areas named in the suspended PHS Policy on Instruction in the Responsible Conduct of Research and as *specialized resources* that address one of the core instruction areas. All of the materials can be accessed on the Internet; some require payment.

Several comprehensive resources are listed as well as specialized resources on mentor/trainee responsibilities, collaborative science, human subjects, research involving animals, and conflict of interest and commitment. Specialized resources are needed for data acquisition, management, sharing and ownership; peer review; publication practices and responsible authorship, and research misconduct.

This web page needs to be considerably expanded so ORI invites members of the research community to contribute to the development of the instructional resource page by identifying existing materials or contributing ideas and materials. ☺

ORI Has Access to Records Under HIPAA

Several institutional officials have asked whether the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, 45 C.F.R. Parts 160 and 164, will permit them to continue providing ORI with patient, medical, lab, or other records related to research misconduct oversight cases involving clinical trials. Because ORI is considered a health oversight agency under the Privacy Rule, entities covered by the Rule may disclose individually identifiable health information to ORI for its oversight functions authorized by statute and regulation. See 42 U.S.C. § 289b and 42 C.F.R. Part 50, Subpart A. In making a disclosure to ORI, covered entities may reasonably rely on ORI's representation that the information requested is the minimum necessary for the stated purpose(s).

ORI Listservs Created to Provide Discussion Venues

ORI has created three listservs to foster discussion and networking among institutional officials and others interested in preventing research misconduct, teaching the responsible conduct of research (RCR), or conducting research on research integrity. These listservs are being administered through the National Institutes of Health server and managed by ORI.

“We hope members will use the new institutional official listserv to exchange ideas, strategies, and concerns about promoting research integrity and preventing research misconduct among the institutions,” says Chris Pascal, Director, ORI. This group has more than 4,500 potential members. To join the institutional official listserv, send an e-mail to the list manager at instlist@osophs.dhhs.gov.

The research listserv was created to provide a forum for scholarly debate and to encourage more research on the sociological, psychological, educational, organizational, and cultural factors that influence integrity in research. To join the research listserv, send an e-mail message to the list manager at rri@osophs.dhhs.gov.

The RCR instruction listserv was designed to promote discussion and networking among researchers, research administrators, and RCR course instructors, and currently has 165 members. To be added to the RCR instruction listserv, send an e-mail message to the list manager at rcrlist@osophs.dhhs.gov.

Instructions for joining any of these lists will be sent in response to your e-mail.☺

AAU Addresses Individual And Institutional Conflicts of Interest

The Report on Individual and Institutional Financial Conflict of Interest issued by the Association of American Universities (AAU) in October is available on its web site at www.aau.edu.

For **individual** conflicts of interest, the report contains several specific guidelines that exceed current federal regulations:

- annual disclosure of all relevant financial interests;
- disclosure of financial interests related to nonfederally sponsored research as well as federally sponsored research;
- not allowing researchers to have financial interests in research involving human participants unless there are “compelling circumstances” to justify an exception; and
- connecting conflict of interest review processes with IRB processes.

The report breaks new ground on previously ignored **institutional** conflicts of interests which are defined as involving conflicts between campus research and a university's equity holdings or royalty arrangements as well as financial holdings of senior university officers.

The report recommends that “institutions should also ensure that policies, procedures, definitions, and sanctions for non-compliance are well-understood by all persons involved with research, including students and research participants” and lists as a successful practice “regular education to individuals engaged in research on the purpose of conflict of interest policies, and on the procedures to be followed.”☺

Research Guidelines: Diverse Origins; Multiple Documents & Locations

(from page 1)

Each medical school was asked to submit its guidelines on nine topics, eight of which are listed in Table 1, and on any other topic for which guidelines were available. Guidelines were provided in one additional area - intellectual property rights. No specific guidelines were submitted on two requested topics: collaborative research among scientists and laboratory management. When addressed, they were included in the topic areas of responsibilities of principal investigators, authorship, and data management.

Conflict of interest was most frequently addressed in the guidelines; intellectual property rights was a distant second. These areas heavily reflect legal, regulatory, and financial concerns. The remaining six topics were each included in less than half of the guidelines.

About 32 percent of the guidelines were limited to conflicts of interest and/or intellectual property rights. Almost 43 percent of the guidelines were limited to two of the eight topics; more than 61 percent covered three topics or less. Only two guidelines addressed all eight topics. (See Table 2.)

Table 1: Number of Guidelines Discussing 8 Topics N=98

Topic	Frequency	Percent
Conflicts of Interest	86	87.8
Intellectual Property	65	66.3
Principal Investigator	48	49.0
Data Management	45	45.9
Authorship	34	34.7
Mentoring	23	23.5
Publication Practices	16	16.3
Peer Review	8	8.2

Table 2: Number of Topics Covered in Guidelines

Number of Topics	Frequency	Percent
One	16	16.3
Two	26	26.5
Three	18	8.4
Four	13	13.3
Five	9	9.2
Six	10	10.2
Seven	4	4.1
Eight	2	2.0
Totals	98	100.0

A content analysis examining behavioral recommendations made under the eight topics found in the 98 guidelines produced 48 content areas. The number of content areas under each topic ranged from 3-12. (See Table 3.) On average, guidelines included about half of the total content areas cited under each topic.

The study also indicated that the guidelines generally were not available in a single document or from a single source. Instead, the guidelines were present in multiple documents generated by various units within the institution and available at different locations.

Table 3: Topics and Content Areas Cited under Each Topic in Research Guidelines

Topic	# Content Areas	Average # Per Guideline
Data Management	5	2.0
Publication Practices	4	2.0
Authorship	5	2.2
Peer Review	3	1.8
Principal Investigator	4	1.6
Mentoring	5	2.2
Conflicts of Interest	12	5.2
Intellectual Property	10	4.0

Grant Program Applications Increase by 12 Percent in 2nd Round

The Research on Research Integrity Grant Program (RRIGP) received 28 applications during the second round that closed on November 19, 2001. The new submissions are a 12 percent increase over the 25 applications received in the first round when \$1.03 million was awarded in 7 grants for a 28 percent funding rate. The new applications are scheduled for review in February 2002. Awards will be made in July 2002. The RRIGP is supported by the National Institute for Neurological Disorders and Stroke, the National Institute for Nursing Research, and ORI.

The next RRIGP announcement will appear in this newsletter, the ORI web site, and the *NIH Guide for Grants and Contracts*. For more information on the RRIGP click on "Research" under Programs on the ORI web site or contact Mary Scheetz, Ph.D., at 301-443-5300 or mscheetz@osophs.dhhs.gov.

Annual Report Submission Period Begins January 1, 2002

Institutional officials should experience smoother sailing when electronically filing their Annual Report on Possible Research Misconduct for calendar year (CY) 2001 during the January 1 to March 1, 2002, submission period because the problems experienced in the initial electronic submission have been largely eliminated.

Revised and clarified instructions for submitting the Annual Report can be accessed on the ORI home page by clicking on "Annual Report Electronic Submission Instructions" under Featured Attraction. The instructions provide a link to the electronic reporting system. Direct access to the reporting system is available by clicking on "Electronic Submission of Annual Report" under Quick Links on the home page.

To access the reporting system, institutional officials must provide their User ID number and their password. Institutional officials filing the Annual Report for the first time should contact ORI for their User ID number and initial password.

Institutions may update the Institutional Information section at any time. This section contains the name of the institution, address, phone and fax numbers, name of responsible official, and an e-mail address. All changes made to this section will be confirmed by e-mail so institutions should furnish an e-mail address and keep it current.

The Annual Report section, which can be accessed only during January and February of each year, replicates the hard copy form previously used. This section asks about the availability of a policy for responding to allegations of research misconduct, the misconduct activity that occurred, if any, and the receipt of any bad faith allegations. Please check the appropriate box in Section B if misconduct activity did not occur at your institution during CY 2001. Information provided in the Institutional Information section will be automatically inserted in the Annual Report section only during the submission period and prior to submission of the Annual Report.

Beginning with this Annual Report, the question about the availability of a policy for responding to research misconduct allegations must be answered to proceed further. Previously, many institutions did not answer the question. Please determine whether your institution has a policy before answering the question. Previously, many officials indicated that their institution did not have a policy when ORI records indicated that the institution had submitted its policy to ORI.

When the Annual Report is electronically submitted, a receipt acknowledgment will appear on the user's screen. A signature is not required when the Annual Report is electronically submitted and a hard copy should not be sent to ORI. MacIntosh® users should contact ORI if they need a hard copy of the report and are unable to print one.

The Password Management System allows institutions to restrict access to the institutional record. This section permits institutional officials to change the password at any time. Contact Doug Brown at 301-443-5300 or dbrown@osophs.dhhs.gov for information and assistance. ☺

Chemistry Journal Responds to Dispute

An American Chemical Society journal decided to handle a heated clash between a physicist and a chemist by publishing the paper along with an addendum that disputes some of its conclusions. *Nature* reported that the addendum indicates that the scientist who supervised the work takes issue with some of its content, ownership, and aspects of the way the work was done.

The nanotechnology paper describes a way of patterning very thin lines of DNA onto a gold surface. The chemist notified the society that the data in the paper were incomplete, and that the physicist was trying to pass off collaborative work as his own. The journal agreed to publish the work after the physicist accepted the inclusion of the addendum. ☺

Fake Survey Causes Business School To Expand Ethics Requirement

A Columbia business school assistant professor's phony letter to New York City restaurateurs prompted the school to adopt a new ethics policy, according to *The Chronicle of Higher Education*. The new policy, requiring all business-school faculty members to receive certification in research ethics, followed an embarrassing episode that was highlighted on the front page of *The New York Times* last summer.

Francis Flynn wrote on business-school stationery to the owners of about 250 restaurants in the city, complaining that he and his wife had gotten severe food poisoning after dining at their establishment. He sent the letters as part of an unapproved research project on how business owners responded to polite versus irate customer complaints. These letters were meant to be polite.

A restaurant owner suspected the complaint was bogus, and notified the administration at the business school. The dean of the school determined Mr. Flynn's research approach was inappropriate, and quickly dispatched messengers to deliver apology letters to all restaurateurs contacted by Mr. Flynn. The business school's associate deans personally spoke to about 60 of the restaurant owners, and Mr. Flynn sent out his own apology letters as well.

Characterized as "a serious lapse in judgement," this incident also caused the school to review its research guidelines. The executive committee of the business school will decide whether Mr. Flynn violated any provisions of their research code. ☹

UPCOMING WORKSHOP

May 15-18, 2002 - **Teaching Research Ethics, Indiana University, Bloomington, IN**

This annual workshop includes an overview of ethical theory, using animals and human subjects in clinical and non-clinical research, data management, and teaching and assessing the responsible conduct of research. Contact Kenneth Pimple, 812-855-0261; or pimple@indiana.edu ☹

Biochemist Questions Practices Followed by Researchers in China

A biochemist in San Diego is trying to improve research ethics in his native country by writing about questionable practices used by some researchers in China and maintaining a Chinese-language web site to disseminate his findings, according to *Science*.

Shi-min Fang received his doctorate in biochemistry from Michigan State University and was a postdoc at the Salk Institute for Biological Studies in La Jolla, CA. Currently, he is a consultant to a bioinformatics company.

In his latest book, *Ulcer: Confronting China's Academic Corruption*, which received favorable reviews in the Chinese scientific and academic press, Fang challenges the scientific merit of work published in lay publications by 18 researchers at a dozen institutions or their credentials. He also names about 30 media organizations that publish the dubious claims. His seven books have been written under the pseudonym Fang Zhouzi. His web site is at www.xys2.org/pages/dajia.html. ☹

British Physicians Propose National Misconduct Panel

Physicians have proposed the formation of a national panel to handle investigations of misconduct in biomedical research in Britain, according to *Nature*. The panel would also provide research institutions with guidelines for good scientific practice and advice for dealing with misconduct allegations.

Currently, only physicians who conduct research are subject to investigation by the United Kingdom's General Medical Council. British scientists conducting similar work are not monitored by any national group. The physicians hope the panel will include members from academia, medicine, and industry. The panel would focus on helping institutions set their own guidelines and conduct their own investigations. The proposal's backers are seeking government funding to support the panel. ☹

ORI Increases Exhibits, Poster Sessions

ORI held exhibits or poster sessions at seven meetings of scientific societies or professional associations in 2001 (almost doubling the four held in 2000) to increase contact and generate a dialogue with members of the research and academic communities. Some exhibits and poster sessions were held in collaboration with the Office of Human Research Protections (OHRP).

Exhibits were held at the following meetings: Experimental Biology 2001, Orlando, in March; Association of Clinical Research Professionals, San Francisco, in April; American Society for Reproductive Medicine, Orlando, in October; National Council of University Research Administrators, Washington, in November; and the American Society for Cell Biology, Washington, in December. ORI also held an exhibit at an OHRP workshop in Long Beach, CA, in July.

Poster sessions were held at the following meetings: American Psychological Society, Toronto, in June; and the Society of Research Administrators, Vancouver, in October.

The exhibits and poster sessions enable ORI staff to talk to researchers, research administrators, postdocs, graduate students, and professional and institutional association officials about the research program on research integrity, the responsible conduct of research education program, opportunities to collaborate with ORI in developing workshops and conferences, ORI studies, reports and publications, institutional policies for responding to allegations of research misconduct, and emerging issues.

Scientific societies and professional and institutional associations that are interested in an ORI exhibit or poster session at their meeting should call ORI at 301-443-5300.

Conflict of Interest Conference Draws Participants from 19 Countries

Conflicts of interest will be addressed as a problem affecting the global research community when researchers and representatives from 19 countries, the Council of Europe, and the European Union participate in the *International Conference on Conflict of Interest and its Significance in Science and Medicine* in Warsaw, Poland, on April 5-6, 2002.

Countries represented include Austria, Bulgaria, Canada, Croatia, Czech Republic, England, France, Germany, Hungary, India, Italy, Latvia, Lithuania, Poland, Romania, Russia, Slovakia, Ukraine, and the United States. See the September issue of the *ORI Newsletter* for a list of American speakers.

The conference is co-sponsored by the European Union, the State Committee for Research (Poland), the Council of Europe, the Polish Academy of Sciences, and the Soros Foundation.

For additional information, visit the conference web site at <http://surfer.iitd.pan.wroc.pl/events/conferenceApril2002.html>.

Conference Proposals Due June 1

ORI is seeking proposals from institutions, professional associations, and scientific societies that wish to collaborate with ORI in developing a conference or workshop on promoting research integrity or handling scientific misconduct allegations.

ORI intends to hold four to six regional conferences or workshops each year in strategic locations around the country. The amount of funding available generally ranges from \$5,000 to \$20,000.

June 1, 2002, is the next target date for the receipt of applications. Proposal instructions and an application form are available on ORI's web site, <http://ori.hhs.gov>, by calling 301-443-5300, or sending an e-mail to askori@osophs.dhhs.gov

CASE SUMMARIES

Steven F. Arnold, Ph.D., Tulane University (TU):

Based on the report of an investigation conducted by TU dated July 16, 1999, and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Dr. Arnold, former Research Assistant Professor at the Center for Bioenvironmental Research, TU Medical Center, engaged in scientific misconduct by intentionally falsifying the research results reported in Table 3 of “Synergistic Activation of Estrogen Receptor with Combinations of Environmental Chemicals.” *Science* 272:1489-1492 (June 7, 1996) (the *Science* paper) and by providing falsified and fabricated materials to investigating officials at TU in response to a request for original data to support the research results and conclusions reported in the *Science* paper. These research results and conclusions were important to the public health because they suggested that the Environmental Protection Agency may need to adjust its guidelines on exposure limits to environmental chemicals, such as certain insecticides and hydroxylated polychlorinated biphenyls (PCBs). The *Science* paper was withdrawn on July 25, 1997. See *Science* 277:462 (July 25, 1997). This research formed the basis of National Institute of Diabetes and Digestive and Kidney Diseases, NIH, grant application 1 R29 DK52420-01, “Two Estrogen Binding Sites on the Estrogen Receptor.”

Dr. Arnold entered into a Voluntary Exclusion Agreement (VEA) with PHS in which he voluntarily agreed to exclude himself for 5 years beginning September 20, 2001, from any contracting, subcontracting, or involvement in grants and cooperative agreements with the U.S. Government and from serving in any advisory capacity to PHS. During discussions about the proposed Agreement, Dr. Arnold was cooperative with ORI and accepted responsibility for his actions, admitted to scientific misconduct, and conceded that there were no original data or other corroborating evidence to support the conclusions reported in the *Science* paper.

Jason Elster, Saint Louis University (SLU):

Based on the report of an investigation conducted by

SLU, Mr. Elster’s admission, and additional analysis conducted by ORI in its oversight review, PHS found that Mr. Elster, former undergraduate research assistant, School of Public Health, SLU, engaged in scientific misconduct by falsifying or fabricating data in at least 8 of the 125 questionnaires he collected with support from Centers for Disease Control and Prevention (CDC) cooperative agreement U48 CCU710806, “Rural Chronic Disease Prevention Center.” Specifically, the objective of the questionnaire was to assess the extent of media exposure by the community and opinions regarding local media coverage of health issues as well as to determine baseline health-related behavior. The intent of the study was to use this information in developing effective strategies for delivering information on disease prevention to the public. No publications were affected, but because of the removal of Mr. Elster’s 125 questionnaires from the study, interviews with 125 new participants were required to achieve the sample size needed to have sufficient statistical power.

Mr. Elster entered into a VEA with PHS in which he voluntarily agreed for 3 years, beginning on November 13, 2001: (1) to exclude himself from serving in any advisory capacity to PHS; and (2) that any institution that submits an application for PHS support for a research project which proposes his participation, or submits a report of PHS-funded research in which he is involved, must concurrently submit a supervision of his duties to the funding agency for approval.

David A. Padgett, Ph.D., Ohio State University (OSU):

Based on the OSU report, Dr. Padgett’s admissions, and additional analysis conducted by ORI in its oversight review, PHS found that Dr. Padgett, Assistant Professor at the OSU College of Dentistry, engaged in scientific misconduct in grant application 1 R01 AG20102-01 submitted to the National Institute of Aging, NIH. PHS found that Dr. Padgett plagiarized and misrepresented as his own research data for Figures 1 and 2 of this NIH grant application, data which represented unpublished experiments originally conducted by a researcher at another institution for a private company. The plagiarism was a significant

CASE SUMMARIES (continued)

misrepresentation because the data appeared in the preliminary results section of the NIH grant application. He used these experiments, which were relevant to the proposed research, to support his request for funding.

Dr. Padgett entered into a VEA with PHS and OSU, in which he voluntarily agreed for 3 years beginning October 4, 2001: (1) to exclude himself from serving in any advisory capacity to PHS, and (2) that he and any institution employing him are required to certify, in every PHS application or report in which he is involved, that all persons who contribute original sources of ideas, data, or research results to the applications or reports are properly cited or otherwise acknowledged.

Karen M. Ruggiero, Ph.D., Harvard University (HU): PHS entered into a VEA with Harvard University and Karen M. Ruggiero, Ph.D., former Assistant Professor, Department of Psychology at HU. Based on the HU inquiry report, related actions and findings by HU, and additional ORI analysis, conducted by ORI in its oversight review, PHS found that Dr. Ruggiero fabricated data in research supported by NIH.

Dr. Ruggiero fabricated three experiments published in: Ruggiero, K.M. & Marx, D.M. "Less pain and more to gain: Why high-status group members blame their failure on discrimination." *Journal of Personality and Social Psychology*, 77(4):774-784, 1999 (*JPSP* paper). These experiments were proposed in her application to the National Institute of Mental Health (NIMH), NIH, in September 1997 for grant 1 R03 MH58586-01. She admitted that she fabricated the data in the *JPSP* paper and requested a notice of retraction, published in *JPSP* 81(2):178, 2001.

Dr. Ruggiero fabricated two experiments published in: Ruggiero, K.M., Steele, J., Hwang, A., & Marx, D.M. "Why did I get a 'D'? The effects of social comparisons on women's attributions to discrimination." *Personality and Social Psychology Bulletin* 26(10):1271-1283, 2000 (*PSPB* paper). These experiments were also proposed in her 1997

grant application, 1 R03 MH58586-0. She admitted fabricating the data in the *PSPB* paper, and she requested a notice of retraction, which was published in *PSPB* 27(9):1237, 2001.

Dr. Ruggiero's fabricated research from the *JPSP* and *PSPB* papers was cited in, and served as the basis for, an NIH Individual National Service Award application, F32 MH12868-01 and -01A1, formerly F32 HD41874. Also, in connection with a Harvard School of Public Health grant application to NIH, 1 R01 HL065220-01, "Measuring racial discrimination for health research," she submitted a subcontract citing the fabricated research from the *JPSP* and *PSPB* papers in support of her qualifications. Additionally, Dr. Ruggiero cited and included her fabricated, PHS-supported research from the *JPSP* and *PSPB* papers in applications she submitted to the National Science Foundation.

Dr. Ruggiero entered into a VEA with PHS and HU in which she voluntarily agreed to exclude herself for 5 years beginning November 26, 2001, from any contracting, subcontracting, or involvement in grants and cooperative agreements with the U.S. Government and from serving in any advisory capacity to PHS. Additionally, she agreed to submit letters requesting retraction of: 1) Ruggiero, K.M. & Major, B.N. "Group status and attributions to discrimination: Are low- or high-status group members more likely to blame their failure on discrimination?" *PSPB* 24:821-838, 1998, and 2) Ruggiero, K.M., Mitchell, J.P., Krieger, N., Marx, D.M., & Lorenzo, M.L. "Now you see it, now you don't: Explicit versus implicit measures of the personal/group discrimination discrepancy." *Psychological Science* 22:57-67, 2000.

David D. Sanchez, Public Health Foundation Enterprises, Inc. (PHFE): Based on the report of an investigation conducted by PHFE and additional analysis conducted by ORI in its oversight review, PHS found that Mr. Sanchez, former research assistant for PHFE's California Emerging Infections Program (CEIP), engaged in scientific misconduct in

CASE SUMMARIES (continued)

research supported by CDC cooperative agreement U50 CCU915546-03. PHS found that Mr. Sanchez falsified and fabricated data in interview questionnaires involving 21 cases and 27 controls for the “Campylobacter Ethnicity Case Control Study.” As a result of his actions, none of his research could be considered reliable, and the research project was terminated. Mr. Sanchez also falsified and fabricated an additional 15 data records relating to PHFE’s “E. Coli O157 Case-Control Study,” which he also submitted to the CEIP coordinator. These actions adversely and materially affected CEIP’s ability to determine risk factors for Campylobacter infections among Latino and Chinese-American children. No publications required correction.

Mr. Sanchez entered into a VEA with PHS in which he voluntarily agreed for 3 years beginning September 4, 2001, to exclude himself from any contracting, subcontracting, or involvement in grants and cooperative agreements with the U.S. Government, and from serving in any advisory capacity to PHS.

Sherman Smith, University of California at San Francisco (UCSF): Based on the report of an investigation conducted by UCSF and information obtained by ORI during its oversight review, PHS found that Mr. Smith, former research technician, Division of Occupational and Environmental Medicine, UCSF, engaged in scientific misconduct by intentionally and knowingly fabricating and falsifying patient interview data as the sole interviewer in the PHS-funded UCSF Asthma Disability Study (Asthma Study). The UCSF Asthma Study was funded by National Heart, Lung, and Blood Institute, NIH, grants K04 HL03225, R01 HL56438, and R29 HL48959, and National Institute for Occupational Safety and Health, CDC, grant R01 OH03480. Mr. Smith intentionally falsified and fabricated the interviews of 107 patients in the Asthma Study with an intent to deceive. This deception had a material, negative impact on the Asthma Study in particular, and on asthma research in general. The falsified and fabricated data were reported in 10 publications, and fellow members of the

Asthma Study Team spent more than 2 years correcting the research data, and were required to submit retractions or corrections for all 10 publications.

PHS implemented the following administrative actions for the 5-year period beginning October 9, 2001: Mr. Smith is prohibited from any contracting, subcontracting, or involvement in grants and cooperative agreements with the U.S. Government and from serving in any advisory capacity to PHS.

Momiao Xiong, Ph.D., The University of Texas Health Science Center at Houston (UTHSCH): PHS entered into a VEA with UTHSCH and Momiao Xiong, Ph.D., an Assistant Professor. Based on the UTHSCH inquiry report and related UTHSCH actions and findings, as well as additional ORI analysis, PHS found that Dr. Xiong plagiarized and fabricated data in National Institute of General Medical Sciences (NIGMS), NIH, grant application R01 GM64353-01, “Genetics of Human Pigmentation and Skin Response” (Pigmentation Application), on which he was a co-investigator. The plagiarized and fabricated data were essential to the scientific validity of the proposed research, and were important for NIH’s scientific evaluation of the Pigmentation Application. Dr. Xiong admitted his actions.

Specifically, PHS and UTHSCH found that Dr. Xiong: (1) plagiarized text from another researcher’s grant application, which Dr. Xiong had obtained during the NIH confidential review process and used without appropriate citation in the Pigmentation Application; and (2) falsified research in the Pigmentation Application by (a) falsely claiming that he had performed an extensive series of simulations to evaluate the power to detect genes influencing pigmentation traits by the proposed statistical analysis, and (b) falsely representing estimates from previous work on unrelated individuals as being appropriate for large families in the proposed research.

Dr. Xiong voluntarily agreed, beginning November 26, 2001, 1) that he will not serve as a principal investigator

Wellcome Trust Proposes Research Misconduct Policy

The Wellcome Trust (WT), Britain's largest biomedical charity, issued new guidelines and procedures for handling allegations of scientific misconduct that are likely to be controversial, since the proposal broadens the definition of misconduct beyond the U.S. Government's current standard, and offers relatively little protection to whistleblowers, according to *Science*.

The draft guidelines define scientific misconduct as:

The fabrication, falsification, plagiarism or deception in proposing, carrying out, or reporting results of research or deliberate, dangerous or negligent deviations from accepted practices in carrying out research. It includes failure to follow established protocols if this failure results in unreasonable risk or harm to humans, other vertebrates, or the environment and facilitating of misconduct in research by collusion in, or concealment of, such actions by others. It also includes intentional, unauthorized use, disclosure, or removal of or damage to research related property of another including apparatus, materials, writings, data, hardware or software or any other substances or devices used in or produced in the conduct of research.

It does not include honest error or honest differences in the design, execution, interpretation or judgement in evaluating research methods or results or misconduct unrelated to the research process. Similarly it does not include poor research unless this encompasses the intention to deceive.

The guidelines would apply only to institutions receiving WT funds. According to *Nature*, WT funds nearly 20% of Britain's biomedical research, and plans that all institutions receiving its grants adhere to the standards. A WT spokesperson indicated that the final guidelines, set to be issued in the fall of 2002, may include stronger protections for whistleblowers.

The United Kingdom has no national body to investigate misconduct cases, and each of the six research councils, which distribute government grant money to researchers, has its own guidelines for universities. ☹

Notable Quote

"One thing institutions learn is that their reputation is much better protected by being very rigorous about these (misconduct) cases, rather than trying to cover them up or trying to push them down. Taking these cases seriously becomes the reputation protecting strategy of an institution." Margaret Dale, Associate Dean for Faculty Affairs, Harvard Medical School, in *Ethical Challenges and Practical Solutions for Managers in Research: Workshop Proceedings*, Sigma Xi, The Scientific Research Society, 2000.

CASE SUMMARIES (continued)

on PHS grants for 1 year; 2) to exclude himself from serving in any advisory capacity to PHS for 3 years; 3) that he and any institution employing him are required to certify, in every PHS application or report in which he is involved, that all persons who contribute original sources of ideas, data, or research results are properly cited or acknowledged, and that applications or reports do not contain any falsified, fabricated, or misleading information. Dr. Xiong and the institution are also subject to certification requirements.

Additionally, Dr. Xiong accepted UTHSCH administrative actions, which include 1) an apology to the principal and co-investigators, 2) participation in a course in the responsible conduct of research, and 3) within 2 years, Dr. Xiong must write a publication-quality formal essay, in English and Chinese, on plagiarism for submission to the Executive Vice President for Research, UTHSCH, and for publication. ☹

UPCOMING MEETINGS

April 16-17, 2002
Conflicts of Interest and Research Integrity
St. Louis, MO

May 2-3, 2002
Promoting Integrity in Clinical Research
Cleveland, OH

June 19-22, 2002
Symposium on Research Responsibility and Undergraduates
New London, CT

Office of Research Integrity
5515 Security Lane, Suite 700
Rockville, Maryland 20852

Office of the Director (301) 443-3400
 Fax (301) 443-5351

Division of Education and Integrity (301) 443-5300
 Fax (301) 443-5351

Assurances Program (301) 443-5300
 Fax (301) 594-0042

Div. of Investigative Oversight (301) 443-5330
 Fax (301) 594-0043

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

<http://ori.hhs.gov>

ORI NEWSLETTER

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Research Integrity
Suite 700
5515 Security Lane
Rockville MD 20852

Official Business
Penalty for Private Use \$300

PRESORTED STANDARD
 POSTAGE & FEES PAID
 OS/OPHS
 PERMIT NO. G-45

DATED MATERIAL