DEPARTMENT OF HEALTH AND HUMAN SERVICES • OFFICE OF THE SECRETARY • OFFICE OF PUBLIC HEALTH AND SCIENCE

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Office of Research Integrity

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. Please duplicate and circulate this newsletter freely. An electronic copy is available on the ORI home page.

IN THIS ISSUE

ORI Welcomes Dr. John C. Galland as Director of Division of Education and Integrity

John C. Galland, Ph.D., has been named the Director of the Division of Education and Integrity in the Office of Research Integrity (ORI). He comes to ORI with a diverse and extensive background in research and education, and he will provide new leadership for the division.

Dr. Galland created the Laboratory Management Institute at the University of California. While at the Institute, Dr. Galland developed a curriculum and unique pedagogy for educating scientists in the practical business of running a research program. This pedagogy was described in the journals *Nature*, *Science*, *Cell*, *The Scientist*, *The Chronicle of Higher Education*, the National Postdoctoral Association's The *POSTDOCket*, and *Laboratory Manager*. The curriculum was delivered through an annual program for postdoctoral scholars at the University of California, Davis, and a summer Certificate Program offered to people worldwide. Both programs consisted of 140 contact hours of instruction.

(See New Division Director, page 2)

Research Ethics and Research Compliance: You Cannot Have One Without the Other

James M. DuBois, Saint Louis University

With a contract from the Office of Research Integrity (ORI), Jeffrey Dueker and I recently completed a Delphi survey project with over 40 experts to determine what should be the overarching objectives and content of instruction in the responsible conduct of research (RCR). The project's aims, methods, results, and significance are under review for publication.

I would like to reflect briefly on one objective for RCR instruction that achieved a strong consensus among our experts: Understand how ethics may go beyond compliance with regulations. Ninety-four percent of our panelists rated this objective as important or very important. A proper understanding of what this objective means requires us to consider how research ethics and compliance are related to each other.

How Research Ethics Complement Compliance

There are several reasons why research ethics should not be separated from compliance. Regulations do not address every important matter in RCR. For example, there

(See Research Ethics, page 4)

Director's Corner

RCR2020: A Call for Envisioning the Future

John C. Galland, Ph.D., Director, Division of Education and Integrity

For more than 20 years, the Office of Research Integrity (ORI) has been developing and compiling educational resources for research administrators, integrity officers, and researchers that have defined what has come to be called the responsible conduct of research (RCR). That body of knowledge has been organized into nine core areas (*http://ori.dhhs.gov/education/*) posited in the late 1980s by the National Institutes of Health and developed further by the National Academies.

There is growing interest in updating and expanding this RCR curriculum, and ORI continually is committed to creating, compiling, and distributing educational resources that help institutions foster a positive environment for exceptional research. As RCR begins its third decade, perhaps now is a time to consider enhancing the RCR curriculum by asking researchers what educational resources would better enable them to advance their research responsibly as well as advance their professional development. The everyday burdens on researchers seems to be escalating exponentially, so perhaps the updated and expanded RCR curriculum should include the knowledge, abilities, and skills that will lessen those burdens or will provide skills to manage them more effectively.

To initiate discussion, I propose confirming with researchers their need for developing these research skills:

1. Leadership and management skills because being able to interact well with people and manage resources are necessary for the very practical business of running a successful research program

2. Daily decision-making skills informed by facts and a deep understanding of the ethics, values, and culture of research because having those skills helps foster the public trust in research

3. Critical thinking skills because they enable a healthy skepticism, stimulate discussion, and ultimately strengthen research design and interpretation of research results

4. Good research practice skills because they impact the quality of research and help ensure reliability of results

5. Innovation, ingenuity, creativity, and visionary skills, which can be strengthened through practice, because they determine a direction toward which scientific progress is made

Providing students and scholars with practice developing skills, such as those proposed above, during their formative education will avoid their having to learn them through trial-and-error and will put them quickly on the road to becoming successful and responsible researchers. What is your vision for RCR2020? Submit your thoughts online to the Director's Corner at *http://ori.hhs.gov/DirectorsCorner*

New Director of ORI's Division of Education and Integrity *(from page 1)*

Part of the unique curriculum involved an interactive training method. Actors were used to role play difficult issues such as negotiating authorship. The actors would portray possible ways to have a difficult conversation. Trainees would in turn suggest other ways to try to obtain a desired outcome. This training program led to an on-line training program for educating researchers and will be posted shortly on the ORI web site. This program is a unique and new way to promote the responsible conduct of research.

Dr. Galland also developed additional educational programs for industry, government, national laboratories, other academic institutions, and scientific associations.

Dr. Galland received both his M.S. and Ph.D. from the University of California, Davis. Before returning to California, he was a Professor of Veterinary Medicine at Kansas State University where he taught public health and zoonotic diseases and conducted research on foodborne pathogens.

ORI Updates

ORI Also Welcomes Drs. Ann A. Hohmann and Ranjini Ambalavanar to DIO Staff

Ann A. Hohmann, Ph.D., M.P.H., comes to the Division of Investigative Oversight (DIO) from the National Institutes of Health (NIH) where she was a program official at the National Institute of Mental Health (NIMH). During her 20 years at NIMH, she developed or led, or both, every research program in health services research except economics; these included primary care, special populations, homeless mentally ill, clinical services, quality of care, child and adolescent services, disablement and functioning, sociocultural, and methods.

Dr. Hohmann received the Mental Health Section Award from the American Public Health Association in 2002. She also received the NIMH Director's Merit Award in 1992, 2002, and 2004. For her work in creating liaisons between NIMH, the Indian Health Service, the Center for Mental Health Services, and the Indian Tribes, she was one of the recipients of Vice President Gore's Hammer Award.

Dr. Hohmann has been an advisor, spokesperson, panel member, invited speaker, and committee member in health services research and social science to the World Health Organization; components of NIH; NIH Roadmap, Committee on Summary Measures of Health; the National Advisory Mental Health Council workgroups; national social science and public health professional organizations; other federal agencies; and the Surgeon General.

Her research and writings on health services research have been published in numerous journals including the *American Journal of Psychiatry*, *Drug Intelligence and Clinical Pharmacy*, *Medical Care*, *Health Psychology*, *the British Journal of Psychiatry*, and *Quality of Life Research*. She co-edited a book published on mental disorders in primary care settings.

Dr. Hohmann attended Pomona College in Southern California, receiving a bachelor's degree in sociology. From Rutgers University, she completed a master's degree in sociology and a Ph.D. in medical sociology (with a minor in methods and statistics). Through the Public Health Service Epidemiology Fellows Program, Dr. Hohmann also completed an M.P.H. at the Harvard School of Public Health.

Dr. Ranjini Ambalavanar, Ph.D., is the second Investigator to join the DIO staff. She was a faculty member at the University of Maryland Dental School and was responsible for research, teaching, and mentoring. As a Neuroscientist with over 19 years of experience, she explored the neural mechanisms of chronic craniofacial pain disorders.

She published many peer-reviewed articles and provided creative direction in science by her unique contributions to the field, such as the recent publication posted in science news on the National Institute of Dental and Craniofacial Research web site *http://tinyurl.com/q3koob* For the first time, this paper demonstrates that microRNA species specific to neurons are quickly regulated after inflammatory muscle pain, providing a novel view of the mechanism of inflammatory muscle pain.

Dr. Ambalavanar has also written reviews and book chapters including "Emerging peripheral receptor targets for deep-tissue craniofacial pain therapies" (2009), *J Dent Res* 88(3):201-211 and a chapter in *Peripheral Receptor Targets for Analgesia: Novel Approaches to Pain Management*. In addition, she routinely reviews articles for more than 10 different journals in the field of Neuroscience.

Dr. Ambalavanar, a Veterinarian from Sri Lanka, has had international exposure to different scientific disciplines and institutions. She completed her Ph.D. in 1992 from the University of Liverpool, UK, and two years of postdoctoral training at Cambridge University, UK. She joined the laboratory of Christy Ludlow at the National Institutes of Deafness and Other Communication Disorders (NIDCD) at NIH as a visiting fellow in 1994 and received the NIDCD Research Excellence Award in 1996. She continues to collaborate wtih Dr. Ludlow on the pathophysiological mechanisms of laryngeal sensory-motor control disorders.

With the addition of these two members, there are now nine full time Investigators on the DIO staff.

RCR Developments

Research Ethics and Research Compliance *(from page 1)*

are no regulatory requirements to assess formally the decision-making capacity of potential research subjects; yet, in some instances—for example, in research with patients with mid-stage Alzheimer's disease—such a duty may exist.

Regulations cannot take into account all of the specific details of a concrete situation. Thus, regulations tend to leave a fair amount of discretion to researchers, institutions, and review committees. For example, 42 CFR 50, which provides regulations for financial conflicts of interest in research, allows institutions to decide when a conflict has been adequately managed, when management is insufficient and the conflict should be eliminated, and what constitutes an adequate enforcement mechanism. Presumably, institutions are given a lot of latitude because such judgments must take into account many specific facts.

Compliance divorced from ethical reasoning may fail to achieve its intended purpose. Consider for example the goals of RCR education. RCR educators hope that education might meet several important goals, such as improving institutional climate, fostering good decision making, enabling institutions to hold researchers accountable for meeting behavioral expectations, and ideally, increasing RCR. Yet, a focus on compliance alone has led some institutions to do the minimum required. They provide instruction only to trainees as mandated; they provide a one-size-fits-all RCR program, rather than providing instruction that meets the needs of different populations of researchers; and they make no effort to determine whether any reasonable goals of training are being met. Such a minimalist approach to compliance results from a failure to internalize the values behind mandates for RCR training.

How Compliance Complements Research Ethics

Above, we saw that ethical reasoning and ethical values provide important complements to compliance with regulations. But the converse is equally true.

Laws frequently communicate the values of a society. Scholars of jurisprudence sometimes call this the expressive function of law. Laws reinforce the notions that rape, murder, and illegal drug use—but also data falsification, fabrication, and plagiarism—are bad. Accordingly, they may shape the values of a citizenry.

There is a prima facie or presumptive ethical duty to comply with research regulations. For example, conflicts of interest in research are receiving tremendous attention because they have frequently accompanied high-profile lapses in professional duties. Social scientists tell us that conflicts of interest can affect our judgment even at a subconscious level. That being the case, it is not wise to leave all ethical decision making to individual researchers. Some things should be codified in regulatory law or institutional policies. Moreover, insofar as regulations and policies may further the best interests of science, research sponsors, society, animals, and human subjects, it is reasonable to foster compliance as an ethical duty or professional virtue.

Regulations, insofar as they include enforcement mechanisms, have the power to change behavior. When other measures fail, such as professional self-regulation or education, regulations may provide a useful way of increasing the performance of "right" behaviors.

In their own ways, ethics education, regulations, and ethical and regulatory oversight committees have the power to shape institutional and individual attitudes, values, and behaviors—arguably for better or for worse. It is our task to always be mindful that the true goal of ethical and regulatory activities is to ensure that responsible research is achieved.

We thank the following authors:

James M. DuBois, Sheila Rose Garrity, Mike Kalichman, Jennifer Ladd, Phil Langlais, Robert K. Leedham, Jr., Edward W. Lempinen, Jennifer Pudelko, Sara Vollmer, and David Wright

RCR Developments

Three RCR Videos on Image Guidelines

Sara Vollmer, University of Alabama at Birmingham

Twelve guidelines for best practices in image processing are now taught in a new web module. The guidelines cover many issues, such as saving a copy of the raw data, making modifications to only the entire image, and reporting all changes made to an image.

The first video section, which teaches the guidelines themselves, consists of 12 short Photoshop videos, each one illustrating a guideline.

The second video, a case study, teaches how the guidelines apply in an actual research group. This section shows how integrity of the research group may be raised when best practices in image processing and mentoring are used.

The third video is an interview with a journal editor, who provides insight on why guidelines are important.

The videos were developed to create effective teaching methods and to formulate standards for image manipulation and the acceptable ways to process images in science.

The site is now available at *http://tinyurl.com/q4hk8y* and is also on the ORI web site at *http://tinyurl.com/qj8ro4*

Sara Vollmer and Harold Kincaid, U. of Ala. at Birmingham, authored the site; Douglas Cromey, U. of Ariz., developed the guidelines; and the ORI Resource program supported the site development.

Announcement of Scientific Integrity Award

Dr. Drummond Rennie was honored by the American Association for the Advancement of Science.

He received the **Scientific Freedom and Responsibility Award** because of his years of advocacy for scientific integrity.

As a Deputy Editor for the *Journal of the American Medical Association*, he promoted discussions and focus on authorship, peer review, conflicts of interest, and reporting standards.

Fifth Biennial Conference for Research on Research Integrity—A Success

Cynthia Ricard, Ph.D., Office of Research Integrity

The Office of Research Integrity (ORI) and Roswell Park sponsored the conference at the Niagara Falls Convention Center. The 140 participants came from 27 states and 14 countries. Most participants presented work funded by grants from the ORI, National Institutes of Health, Research on Research Integrity (RRI) program that is celebrating its 10th anniversary. RRI researchers represent biomedical and social sciences, engineering, law, business, and government.

Provocative first sessions stimulated discussions and networking throughout the weekend. Brian Martinson spoke of the intense competition for funding when faculty are expected to cover increasing portions of their own salaries. Charles Lidz presented information about how, unlike Institutional Review Boards, animal use committees visit the laboratories to see how the animals are doing.

Susan Night described how disclosure can shift responsibility away from the person, but not actually eliminate conflicts. Kathleen Montgomery raised many questions about how well our system of regulation is understood by different disciplines.

Concurrent sessions covered authorship and editorial issues, community-based research, and critical reasoning skills. There were over 70 research projects presented at this conference.

A panel, led by Nick Steneck, discussed the future direction for the RRI program. Cynthia Ricard from ORI, Andrea Sawczuk from the National Center for Research Resources, Charles Lidz from the University of Massachusetts, Michael Mumford from the University of Oklahoma, and Lida Anestidou from the National Academies of Science all voiced their views on future direction and continued support for promoting future research opportunities.

RCR Developments

National Panel Recommends New Direction in Research Ethics & Integrity Education

Phil Langlais, Old Dominion University, and Mike Kalichman, University of California, San Diego

On April 9, 2009, over 20 individuals from universities, medical schools, federal agencies, and professional organizations met in the District of Columbia to share ideas on ways to enhance education on research ethics and responsible conduct of research (RCR). Organized by Drs. Michael Kalichman and Philip Langlais, the participants identified the following initiatives as necessary to produce effective education in research ethics:

1. establish clear definitions and expectations of ethics and research integrity training and methods to assess its effectiveness;
2. change the institutional culture in ways that recognize and promote research integrity at all levels;
3. increase attention to ethics and scientific integrity in our international education and research collaborations; and,
4. create a national resource and clearinghouse for sharing and disseminating information about training programs, funding sources, organizations, etc.

Participants noted that in the absence of a common language and a common set of expectations, too much variability undermines quality and meaningfulness of RCR education. The focus of the training should move beyond rigid adherence to the nine core RCR areas proposed by the U.S. Public Health Service in 2000. Instead, it would be helpful to the research community to clearly delineate common basic standards for instruction that would include, for example, mentoring, laboratory management, how to ask questions, and whistleblowing, all of which are vital to scientific and scholarly integrity. Unfortunately, we have little information about the effectiveness of existing programs. Research studies are needed to better understand the cultural and regulatory factors that support or undermine scholarly and research integrity and to examine the effectiveness of current training programs in promoting good research practices and in reducing misconduct and misbehaviors.

All participants strongly agreed that there is a critical need for leaders who recognize, promote, and reward ethical and responsible research practices within and across institutions. Presidents, Provosts, Vice Presidents, and upper level administrators have the unique ability and obligation to support the incorporation of ethics and research integrity within undergraduate and graduate curricula, tenure and promotion criteria, professional development programs, self- and external evaluations and the development of research ethics and RCR training programs. Their support is particularly needed to encourage outstanding mentoring of students and junior faculty.

Participants recommended the establishment of a searchable and indexed web-based national clearinghouse of information on training programs, materials, publications, professional organizations, research findings, and funding opportunities. Significant support was expressed for the transfer of the American Association for the Advancement of Science and the National Academy of Science resources to the Council of Graduate Schools (CGS) web site and for the National Science Foundation's intention to support a digital library of resources. A single national organization that could represent, coordinate, and advocate for ethics and RCR education and assessment was discussed, and recommendations will be more fully considered at future meetings.

All agreed on the urgent need to foster better understanding of cultural and practical differences in research ethics and professional standards within the international community. More outreach and cooperation among regulatory agencies, professional organizations, and higher education are needed to create educational programs that allow for productive conversations on ethics and scientific integrity within the international community.

The daylong meeting ended with participants committing to work in teams to follow through on recommendations for addressing each of these areas. It is intended that a variety of substantive products will come from these teams, including plans to prepare appropriate summaries of key workshop recommendations. Although not all issues are resolvable in the short-term, the workshop participants are confident that we have numerous opportunities to do better.

The panel thanks CGS for hosting the conference.

International Issues

Chinese, U.S. Science Scholars and Educators Plan Joint Ethics Education Projects

Edward W. Lempinen, American Association for the Advancement of Science

China has an ancient scientific culture and its ethical values date 2500 years to Confucius, whereas the United States (US) has been a leader in shaping research ethics over the past 30 years. But when scholars and educators from the two nations met recently, they quickly found common ground: A range of problems—from a lack of understanding to fierce competition and fear of failure—are contributing to chronic high rates of unethical research conduct.

During a three-day workshop organized by the China Association for Science and Technology (CAST) and the American Association for the Advancement of Science (AAAS), the two delegations agreed to explore the possibility of joint projects related to education in science ethics, including surveys on misconduct, exchanges on training ethics educators, a collection of case studies, and perhaps even a practical guidebook on ethics in science.

Li Jinghai, Vice President of the Chinese Academy of Sciences and Vice-Chair of CAST's Commission on Ethics and Rights of Scientists and Engineers said, in a keynote address, that scientists have an ethical obligation to make the innovation system more efficient so that it benefits more people. "We have a duty to minimize the negative effects and maximize the positive effects [of scientific research]," Li said.

Alan I. Leshner, AAAS Chief Executive Officer, stressed that building trust is crucial for the US and Chinese researchers because of their position as global leaders in addressing health, energy, climate, and other challenges. "We won't be taken seriously if we don't have credibility," said Leshner, who also serves as Executive Publisher of *Science*. "And our credibility depends on our ability to behave at the highest level ethically."

Workshop participants explored a range of topics—the history of science ethics in each country, ambitious new efforts by Chinese science leaders to bring ethics instruction into undergraduate teaching, and the potential of both formal and informal education to improve the ethics environment.

The workshop, hosted by the University of California-San Diego and the Reuben H. Fleet Science Center, brought nine Chinese science and education leaders—including several high-ranking CAST representatives and one university president—together with 14 US colleagues. A number of the Chinese and US delegates met for the first time in September 2007, when CAST and AAAS collaborated on a workshop in Beijing on scientists' social and ethical responsibilities.

Among those at both workshops was Nicholas Steneck, a Consultant to the Office of Research Integrity in the US Department of Health and Human Services and a member of the AAAS Committee on Scientific Freedom and Responsibility. Dr. Steneck said, "The meeting was important because it allowed us to appreciate our similarities and begin to understand how cultural understandings may impact on our expectations for responsible research."

Melissa Anderson, University of Minnesota, reported that her research found an estimated 24% of mid-career US scientists per year engaged in questionable use of funds, with nearly as many cutting corners in their research practices.

Wang Chunfa, Director-General of CAST's Department of Policy Studies and Publicity, cited a survey of 30,000 Chinese researchers in which 40% described misconduct as "very common," and over half reported they had never been educated about research ethics.

For both delegations, the critical question is how to create an environment in which researchers routinely discuss and evaluate ethical issues—and know how to respond to misconduct.

A new steering committee of experts from both countries is being considered to shape future collaborations, including possible materials for teaching science ethics.

[The above article is used with permission and condensed from a story first published on the AAAS web site.]

Authorship

Pharmacotherapy Announces New Rules on Ghost and Guest Authorship

Robert K. Leedham, Jr., RPh, MS, Graduate Student in Social & Administrative Pharmacy, University of Wisconsin-Madison

The American College of Clinical Pharmacy and its journal, ***Pharmacotherapy***, announces a new policy on authorship, ghost writing, and guest authorship.

Because of the recent controversy over the drug Rofecoxib (Vioxx® Merck) and questions about authorship for numerous published clinical studies, ***Pharmacotherapy*** has adopted new rules about ghost and guest authors. In December 2008, the journal's Board of Directors and Scientific Editor Council adopted new rules about authorship, which the Editor-in-Chief discussed, "to attain the highest quality and impact in scientific publication." These new rules described in the April 2009 issue[1] also appear on the journal's web page under Article Submission and Review. The policy states:

"We define authorship as follows: A person designated as an author must meet all of the following criteria:

1. contributed to the conception and design, or analyzed and interpreted the data;
2. drafted the article or revised it critically for important intellectual content; and
3. approved the final version to be published.

Supporting the study or collecting data does not constitute authorship. Authorship based solely on position (e.g., research supervisor or department chair) is not permitted." People who do not meet all three criteria should be listed in an acknowledgment.

"Manuscripts submitted for publication must list all authors, *including the person who drafted the original manuscript* and including paid or unpaid medical writers ('ghost writers')."

"'Ghost' authorship is defined as a person or entity contributing substantially to the creation of a manuscript (as defined above), but who is not acknowledged as an author."

"This situation most often arises when a commercial entity (e.g., a medical education company acting on behalf of a pharmaceutical manufacturer) actually creates the first or subsequent drafts of a manuscript." It is an ethical breach for these authors who created the drafts to be missing from the list of authors. All "real" authors, as well as their affiliations, should be revealed to the readers.

"'Guest' authorship occurs when a 'ghost' author truly creates a manuscript, and invites the 'guest' author to be named as the author, with little or no intellectual input to the manuscript from the 'guest' author. 'Guest' authorship in this context is never ethical."

The Editor stated the journal "carefully" redesigned its mandatory questions, requiring all authors to submit answers to ensure "ghost" and "guest" authorship is eliminated and to reveal all potential conflicts of interest.

The definitions of the "guest" and "ghost" authorship used by ***Pharmacotherapy*** have been adapted from those previously described in the *Journal of the American Medical Association (JAMA)*.[2,3,4]

Pharmacotherapy also requires all authors to declare they meet the qualifications to be considered an author, AND everyone who contributed to the manuscript as a qualified author has been named as an author.

I applaud the Editor and ***Pharmacotherapy*** for implementing this forthright policy on authorship because it is a positive, practical advancement for the effective promotion of the responsible conduct of research through good authorship practices.

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The Office of Research Integrity always welcomes your comments; please direct your comments to: *AskORI@hhs.gov*.

Authorship

The Importance of Institutional Authorship Policies

Sheila R. Garrity and Jennifer Pudelko, The Johns Hopkins University School of Medicine

When speaking to graduate students and postdoctoral fellows about research misconduct, we often say, "99.9% of you will not be accused of research misconduct during your tenure at Johns Hopkins but 100% of you will be involved in an authorship dispute." We remind them that authorship disputes are not research misconduct in the strict sense of fabrication, falsification, and plagiarism. Nevertheless, such disputes often land in our office with a request for mediation assistance.

In June 2008, the School of Medicine adopted revised *Rules and Guidelines for Responsible Conduct of Research*. These guidelines may be found at *http://tinyurl.com/a6h9jb*

The revised guidelines were the result of nearly a year of discussion among the members of the Standing Committee on Discipline. This group not only serves as the adjudicatory body for cases of misconduct; it also acts as the advisory body for the responsible conduct of research.

The resulting guidelines contained, for the first time, criteria for authorship. This decision was deliberate and based not only on authorship issues that arose during misconduct cases, but also a belief that a uniform standard is needed for the entire community.

Under the new guidelines, authorship requires:

A. All persons designated as authors should qualify for authorship, and all those who qualify should be listed.

B. Authorship credit for original, research-based works (in any medium) may be based on: (1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; (2) drafting the article or revising it critically for important intellectual content; (3) sufficient participation in the work to take public responsibility for appropriate portions of the content; and (4) final approval of the version to be published. Authors should meet conditions 1, 2, 3, and 4. Other contributions, such as provision of a key reagent or collection of data, may also be considered as long as conditions 2, 3, and 4 are met.

C. Authorship credit for reviews or commentaries not based in original research should be based on conditions 2, 3, and 4.

D. Acquisition of funding, collection of data (e.g., from a fee-for-service core facility), or general supervision of the research group (e.g., by former or current mentors not directly involved in the conception or execution of the publication), ***alone***, do not justify authorship.

E. Financial and material support should be disclosed.

F. Ghost writing, a practice whereby a commercial entity or its contractor writes an article or manuscript and a scientist is listed as an author, is not permissible. Making minor revisions to an article or manuscript that is ghost written does not justify authorship.

G. Besides a strict prohibition against ghost authorship, honorary authorship, a practice whereby an individual is added as an author to a manuscript, without meeting the authorship criteria listed above, is not permissible.

The guidelines were based in large part on the *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication*, written by the International Committee of Medical Journal Editors, found at *http://www.icmje.org/*

Okay, we have authorship guidelines, so what next? An online survey conducted this fall of those working in research laboratories at the School of Medicine revealed that some were unaware of how authorship was determined in their laboratories. Those unclear about authorship determination included graduate students, postdoctoral fellows, and also faculty members.

Policies are important but clearly education is key. We are working to publicize the revised guidelines to our community through seminars, lab meetings, and articles in internal publications. We will repeat the survey early next year to measure the effectiveness of our efforts.

Educational Opportunities

Research Integrity Officer (RIO) Boot Camp Plans for 2009

David Wright, Ph.D., Michigan State University

To deal with the rapid turnover and inexperience of the RIOs at many universities, an extensive training program, the RIO Boot Camp, was created four years ago.

The ORI RIO Boot Camp curriculum has been evolving as a result of debriefings conducted at the end of each meeting from experienced RIOs and ORI investigators. Designed to emphasize the interaction of experienced with less experienced RIOs with a minimum of input and direction from ORI staff, the goal is to bring together 25-30 RIOs, and their counsels who are interested in research misconduct matters, to learn from each other, establish a network of RIOs, and help identify the position of the RIO as a profession. The RIO Boot Camp provides time to observe, discuss, and practice skills of interviewing, assessing allegations of misconduct, and guiding an investigation of possible research misconduct.

In the initial five sessions, the focus has been on universities receiving the highest levels of the National Institutes of Health (NIH) funding and attendance has been primarily by invitation only. The program has trained approximately 150 RIOs and other officials and counsels involved in institutional compliance programs.

ORI anticipates funding three boot camps in 2009. One will be held in Chicago, and it is closed for enrollment. A second one will be held in Oregon in September 2009, and is open for representatives from universities not in the top 100 NIH funded. If you are interested in attending, please contact david.wright@hhs.gov. The third location has not yet been determined.

The RIOs who have attended the training programs have continued access to each other through a RIO web site that has been established with Michigan State University. The audiovisual materials developed for the boot camps will eventually form an on-line resource available to all interested institutional officials.

On Being a Scientist: 3rd Edition, National Academies

Reviewed by Rhonda J. Moore, Ph.D., Office of Research Integrity

This report is an important overview of the professional standards of science and offers an explanation of why continued adherence to those standards is essential for scientific progress. Similar to the second edition (1995), the report also provides an overview of professional standards of research.

In this recent update, there is also a stronger statement about not relegating responsible conduct of research (RCR) to a web-based tutorial. Rather, RCR is an essential component of good research and best practice and should be incorporated into various training curricula.

This edition also highlights the responsibilities and obligations of researchers in the conduct of science and RCR. Brief case scenarios are included (with answers in the appendix). The report also briefly highlights the significant role of conflicts of interest in ethical decision making and the role of new technologies, including digital communication technologies.

This book is available from the National Academies Press at *http://books.nap.edu/*

Research Ethics and Integrity Conference

"The Tradition that is Mentoring: Principles and Practices for Professional Development."

Date: July 21, 2009

Time: 7:30 a.m. to 3:00 p.m.

Location: Uniformed Services University (USU) Sanford Auditorium

Target Audience: Federal employees, contractors, and Federal collaborators

Purpose: To explore concepts, principles, and applications of mentoring as an essential element of professional and academic development in the healthcare and research professions.

For Full Information:
http://tinyurl.com/mhjdxl

Sponsored by: USU in collaboration with Navy Medicine

Case Summary

Robert B. Fogel, M.D., Harvard Medical School and Brigham and Women's Hospital

Based on information that the Respondent volunteered to his former mentor on November 7, 2006, and detailed in a written admission on September 19, 2007, and ORI's review of Joint Inquiry and Investigation reports by Harvard Medical School (HMS) and the Brigham and Women's Hospital (BWH), the U.S. Public Health Service (PHS) found that Dr. Robert B. Fogel, former Assistant Professor of Medicine and Associate Physician at HMS, and former Co-Director of the Fellowship in Sleep Medicine at BWH, engaged in scientific misconduct in research supported by National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), awards P50 HL60292, R01 HL48531, K23 HL04400, and F32 HL10246, and National Center for Research Resources (NCRR), NIH, award M01 RR02635.

PHS found that the Respondent engaged in scientific misconduct by falsifying and fabricating baseline data from a study of sleep apnea in severely obese patients published in the following paper: Fogel, R.B., Malhotra, A., Dalagiorgou, G., Robinson, M.K., Jakab, M., Kikinis, R., Pittman, S.D., and White, D.P. "Anatomic and physiologic predictors of apnea severity in morbidly obese subjects." *Sleep* 2:150-155, 2003 (hereafter referred to as the "*Sleep* paper"); and in a preliminary abstract reporting on this work.

Specifically, PHS found that for the data reported in the *Sleep* paper, the Respondent:

- falsified roughly half of the physiologic data
- fabricated roughly 20% of the anatomic data that were supposedly obtained from Computed Tomography (CT) images
- changed/falsified 50 to 80 percent of the other anatomic data
- changed/falsified roughly 40 to 50 percent of the sleep data so that those data would better conform to his hypothesis.

The Respondent also published some of the falsified and fabricated data in an abstract in *Sleep* 24, Abstract Supplement A7, 2001.

Dr. Fogel has entered into a Voluntary Settlement Agreement in which he has voluntarily agreed, for a period of three (3) years, beginning on March 16, 2009:

- to exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant;
- that any institution that submits an application for PHS support for a research project on which the Respondent's participation is proposed or that uses the Respondent in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which the Respondent is involved, must concurrently submit a plan for supervision of the Respondent's duties to the funding agency for approval; the supervisory plan must be designed to ensure the scientific integrity of the Respondent's research contribution; a copy of the supervisory plan must also be submitted to ORI by the institution; the Respondent agrees that he will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI; and
- to ensure that any institution employing him submits, in conjunction with each application for PHS funds or report, manuscript, or abstract of PHS-funded research in which the Respondent is involved, a certification that the data provided by the Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application or report. The Respondent must ensure that the institution sends the certification to ORI.

Save the Dates

SRA's 2009 International Annual Meeting:

RESEARCH WITHOUT BORDERS

Date: October 17–21, 2009

Location: Washington State Convention and Trade Center, Seattle, WA

Registration Information: *http://www.srainternational.org/sra03/index.cfm*

NCURA's 51st Annual Meeting:

ONE WORLD CONNECTED THROUGH RESEARCH

Date: October 21–24, 2009

Location: Washington Marriott Wardman Park Hotel, Washington, DC

Registration Information: *http://www.ncura.edu/content/educational_programs/conferences/index.php*

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