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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

Assistant Secretary for Health: New Vision to Tackle Childhood Obesity

Ryan Van Ramshorst, ORI, and Trina Carter, GovSource

In the past 28 years, the prevalence of obesity among children aged 6-11 years tripled, climbing to 19.6% in 2008 from 6.5% in 1980. There was also a threefold increase in the prevalence of obesity among adolescents aged 12-19 years, to 18.1% from 5%, over the same time span.[1,2]

To stem this tide of childhood obesity, "a new vision for 2020" is called for, said Dr. Howard Koh, Assistant Secretary for Health, U.S. Department of Health and Human Services, and the keynote speaker at the Quest for Research Excellence conference: "The Intersection of

(See New Vision, page 5)

Responsible Conduct of Research and Advocacy

Mark S. Frankel, AAAS

The time has come to advocate for advocacy; that is, "responsible advocacy" by scientists should be added to the Responsible Conduct of Research (RCR) curriculum. Although advocacy may occur at any point in the process of proposing, performing, or reviewing research, or in reporting research results, it is during the latter that problems have emerged for science in its relationship with society. In recent years, that relationship has been described by numerous commentators as under significant stress. At this point, issues of scientific responsibility can arise, and the consequences are anything but trivial.

Advocacy is a complex concept, whose definition is far from clear. What is clear, however, is that scientists are change agents, whose expertise is increasingly in demand by a vortex of competing claims from an expanding number of stakeholders. Today, advocacy is very much part of the scientific life, for better or worse, so that is why it is time to give advocacy its due as part of what it means "to do" science, placing it on a level with other components of RCR.

Questions about scientists' engagement in advocacy are timely and controversial not only within the scientific community, but also among policymakers and the general public. One need only consider the debates over stem cell research in the early part of the decade, when scientists vigorously opposed restrictive policies by touting, well beyond scientific understanding at that time, the medical revolution that was at hand. More recently,

(See RCR and Advocacy, page 3)

ORI Welcomes Two New Investigators to the Division of Investigative Oversight

Kristen Grace, M.D., Ph.D., received her M.D. and Ph.D. through the National Institutes of Health (NIH) funded Medical Scientist Training Program at the State University of New York (SUNY) at Stony Brook. Dr. Grace's interests in reproductive biology began while researching the genetics of plant development and gametogenesis at Cold Spring Harbor Laboratory in NY. She subsequently shifted her attention to the mechanisms of sea urchin gamete interaction and fertilization in the Department of Cellular and Molecular Biology at SUNY Stony Brook. During her medical-scientist training, Dr. Grace focused her studies on human fertilization and infertility. Her specific concentration was male gamete biology and fertility, in which she investigated novel roles of immunomodulatory molecules on sperm and their involvement in sperm-egg interactions.

Upon completion of her training, she entered into an Obstetric and Gynecologic Residency at Albert Einstein in NY. Dr. Grace continued to pursue her research interests in fertility by developing clinical research protocols to evaluate the association of elevated Follicle-Stimulating Hormone levels in premenopausal women as well as women suffering from premature ovarian failure.

Prior to embarking on a career in science and medicine, Dr. Grace was employed as a professional photographer and image processor. Currently, Dr. Grace comes to the Office of Research Integrity from the National Institute of Diabetes and Digestive and Kidney Diseases, Laboratory of Cellular and Molecular Biology, at NIH, where she was working to develop fluorescent live cell imaging systems for confocal studies on mouse models regarding maternal effect genes and their role in early embryogenesis.

Shara Kabak, Ph.D., comes to the Office of Research Integrity from the National Institutes of Health (NIH), most recently the National Eye Institute, where she was a Science Staff Assistant in the Office of the Director. She was a Science Writer and the Institute & Center Representative at the NIH International Representative Meeting at the Fogarty International Center. Before that, she was an American Association for the Advancement of Science, Science and Technology Policy Fellow. Working with Joan Schwartz in the Office of Intramural Research, she was the Executive Secretary for Inquiries and Investigations into Research Misconduct. As a member of the Committee on Scientific Conduct and Ethics, she participated in rewriting the NIH intramural policy and procedures for addressing scientific misconduct. In addition, she wrote an online training course for summer students at the National Cancer Institute about the responsible conduct of research.

Dr. Kabak has worked in the areas of muscle development and B cell signal transduction, co-authoring papers in journals such as the *Journal of Immunology*, *Immunity*, *Molecular and Cellular Biology*, and the *Journal of Biological Chemistry*. She also spent time working in a human immunology laboratory, resulting in publications in the journals *AIDS*, *Journal of Experimental Medicine*, and *Proceedings of the National Academy of Sciences*.

Dr. Kabak received her bachelor's degree in Statistics and Biometry from Cornell University in Ithaca, NY. After working as a technician at Cornell University Medical College with Dr. David Posnett, she attended the University of Chicago, where she got her Ph.D. in Immunology in the laboratory of Dr. Marcus Clark. As a recipient of the Ruth L. Kirschstein National Research Service Award Individual Fellowship, she did postdoctoral work in the laboratory of Dr. Thomas Kadesch, the University of Pennsylvania, Department of Genetics.

2010 Annual Report on Possible Research Misconduct

In December, the institutional signing officials will be reminded to prepare for the institution's electronic submission of the 2010 Annual Report on Possible Research Misconduct. ORI will send the Username and Password. Please log on to the ORI web site at: *http://ori.hhs.gov/assurance/electronic_submissions.shtml*

The electronic submission of the Annual Report starts January 1-March 1, 2011. For additional information and assistance, please contact Robin Parker at robin.parker@hhs. gov or (240) 453-8400.

ORI would like to thank the following contributors to the *ORI Newsletter*:

Trina Carter, Mark S. Frankel, John C. Galland, Susan Garfinkel, and Ryan Van Ramshorst

"Quest for Research Excellence" Initiative: Enabling the Pursuit of Professional Integrity Within the Research Enterprise

John C. Galland, ORI

The pursuit of research excellence is a quest—a noble journey—that has its fair share of challenges. No single researcher can take this journey alone. Every researcher needs help along the way, be it from loyal team members following a line of investigation or from the entire research enterprise supporting individuals with the necessary resources to reach their goal.

Our job at ORI is to help the researcher. Tremendous efforts have been made not only by this office, but also most notably by the National Institutes for Health (NIH), the National Science Foundation (NSF), prestigious scientific societies, rigorous publishers and editors, and **(See Quest, page 7)**

RCR and Advocacy *(from page 1)*

debate over climate change and the controversy fueled by infamous leaked e-mails have raised questions about the impartiality of scientists arguing for sweeping international responses to global warming and about the degree to which their policy preferences have influenced their science.

Bad advocacy, whatever that may mean, can undermine scientific independence and credibility, perhaps depriving society of the benefits science could bring to a wide range of critical social problems. In thinking about issues that might be covered in RCR instruction associated with "advocacy in science," these come readily to mind:

1. Although some scientists believe it is possible to engage in advocacy while adhering to the highest standards of "objective" research and reporting, others firmly believe this is not possible, and that the role of advocate is entirely inappropriate for scientists. Fundamentally, the question is whether scientists should engage in advocacy in the policy process. Are there times when their professional obligations require them to be advocates? What are the appropriate boundaries of "responsible advocacy"?

2. Must advocacy inevitably detract from the objectivity and dispassion typically expected of scientists? If so, what are the implications for the public's need for reliable and independent advice on highly technical matters?

3. When does a scientist cross the line from being an independent source of valued information to advocating for preconceived notions about what policy is "best"? What are the professional and societal risks associated with advocacy?

4. Are there "rules of the road" or best practices that can guide the scientist-advocate? Are they adequate in today's highly politicized environment? Can they be usefully applied in other cultures?

For RCR to be relevant for scientists who engage in advocacy, it is necessary that its scope be broadened to cover the issues described above, and undoubtedly many more not mentioned in this brief essay. In reality, scientists are typically unprepared for engaging the policy process. They may find that their standards of conduct are out of sync with those of non-scientists with whom they interact. Unexpected events beyond their control or politically motivated attacks on their research may challenge them to act quickly, perhaps in ways they find very uncomfortable. For those scientists, current RCR education is likely to fail them.

In 2006, the Council of Graduate Schools issued a report emphasizing that "One of the most important justifications for training in ethical reasoning is the contribution that it can make to students' abilities to participate effectively in public policy debates. Graduate programs, then, have a responsibility to prepare future scientists for the social responsibility that goes with being a scientist."

RCR education has yet to catch up with that very wise counsel.

Fifth Graders' Views on Science and Honesty

Susan Garfinkel, ORI

Recently, I had the opportunity to speak about science to fifth-grade students at K.W. Barrett Elementary School in Arlington, VA. I spoke about what motivated me to become a scientist and what it was like to work in a research laboratory and as a Scientist at the Office of Research Integrity (ORI).

I was very impressed with how interested and engaged the students were in learning what it is like to be a scientist and amazed at all the insightful questions that were asked. The following are some excerpts from many thank-you notes I received from the students.

Thank you I really liked the lesson that you did I think its cool that you're a scientist. I think your job is cool. I want to be a scientist when I grow up.

Thank you for . . . coming to teach us about science, cells and cheating . . . I thank you very much for inspiring me to go to college and that's a big deal to me because I didn't even think about going to college.

I was very much intrigued by crime within the science world, I didn't know it ever happened! Your job seems very interesting to me.

Thank you for coming to our school and taking your day off to teach us about science. I was really interested in your presentation. It made me think about science in a whole new angle.

Thank you for giving up your time at Barrett. I really loved it when you were explaining about cells. I learned so much I might even tell my mom and dad what I learned. Also thank you for answering our questions.

Thank you for giving up your time to inform us about O.R.I. I had no idea this organization existed. I thought it was a fascinating presentation. I didn't know scientists lied and cheated.

Thank you for coming to our school . . . When you were telling us about your job it sounded pretty cool. Why do people even cheat if they know they're going to get caught . . .

Thank you for coming to our school to teach us about falsification, fabrication and about plagiarism. I liked the speech you made and I did not know adults can cheat.

Thank you for telling us about science . . . explaining about cells . . . I learned a lot from what you taught me. Your career is really COOL! . . . I'd love to be a scientist like you but I'm planning to be a doctor.

Thank you for that presentation! It was great! Being a scientist sounds like fun. It could be one of my choices . . . I never got bored, not even once. You taught me a lot about scientists.

Thank you for taking your time to come to our school to teach us about your job. I liked how you shared with us your own experiences. I learned that a human starts as one cell . . . I think your presentation was awesome.

Thank you for coming to Barrett. Before now I did not know that the body originated from one cell.

Thank you for coming on your day off and for answering all of our questions and talking about your career. I wish I was you because you must have the coolest job in the world . . . you rock with your job.

Thank you for telling us about science. Cells are very interesting to me. The presentation kept me hooked on cells. I consider being in the business of cells. Time went by like I was struck by a baseball bat. I learned a lot from you.

This opportunity to speak to the class was coordinated through the Washington, DC-area Coalition on the Public Understanding of Science (DC-COPUS). COPUS is a grassroots effort whose objective is to increase the public's understanding of science and its value to society. See *http://www.copusproject.org/*

The D.C. Scientists in the School program encourages scientists to visit area classrooms to help stimulate students' curiosity and enthusiasm for science. The program is being tested in the Washington, DC, area with the potential to develop a nationwide effort.

New Vision *(from page 1)*

Standards, Culture and Ethics in Childhood Obesity," held in Denver, CO, April 20-21, 2010, and co-sponsored by the Office of Research Integrity (ORI).

Dr. Koh stated, "We're seeing progress in coronary disease deaths, but we're seeing worsening obesity trends. We have to stop this backward slide." He also noted that childhood obesity is a "critical realm" and emphasized the need to pursue "true health for all people." This statement also echoes First Lady Michelle Obama's efforts to increase awareness of childhood obesity with her *Let's Move!* campaign, which encourages children to be more active, families to make healthy food choices, and the public to become more involved.[3]

The conference challenged those with a stake in the research enterprise to think collaboratively about childhood obesity from multiple perspectives: the parent, child, researcher, community member, and healthcare provider. In many respects a call to action, the conference stressed the importance of working together for the betterment of the next generation of our country. According to the Centers for Disease Control and Prevention (CDC), American society has increasingly become obesogenic. Obesogenic societies are characterized by environments that promote increased food intake, non-healthful foods, and physical inactivity.[4]

To meet these and other public health challenges, researchers are finding they have to adjust. New ways of thinking include viewing parents, children, and other research participants as partners in a study and seeking their input, their needs, and their wants. In childhood obesity research, "Children may not be the best focal point," stated Dr. Maile Taualii, Director of the Native Hawaiian Health Board. The emphasis is now on "pre-parent" education and on community participation.

The new community-based participatory research (CBPR) approach values contributions from researchers and group members equally. According to Beverly Becenti-Pigman, Chair of the Navajo Nation Human Research Review Board, there has to be a tangible benefit to the community as well as to the individual participant. "Otherwise, it's not successful research," she stated.

Laura Fillingame Knudtson, Postdoctoral Fellow at the Center for Human Nutrition at the University of Colorado, Denver, described the crucial need to recognize the applicability, acceptance, and burden of research intervention. "When research is burdensome on families, it also makes it challenging for researchers," she noted.

"Research priorities should be coming from communities and then matched with the researcher," said Dr. Don Warne, Executive Director of the Aberdeen Area Tribal Chairmen's Health Board in South Dakota. He pointed out that we have excelled at growing a large body of knowledge, but we are not implementing what we know. He called for increased focus on policy research, health systems research, and translational research from the lab bench to bedside to community. Robert Chavez, Project Coordinator for the Rocky Mountain Prevention Research Center, works as a community liaison to help facilitate such research, ensuring that it is responsive to and respectful of community needs.

Overall, the conference brought together a community of research leaders committed to addressing pressing public health issues such as childhood obesity. It presented unique opportunities to begin to move forward in improving research approaches and benefiting from shared experiences.

References

1. Ogden CL, Carroll MD, Curtin LR, Lamb MM, Flegal KM. Prevalence of high body mass index in US children and adolescents, 2007-2008. *JAMA* 2010;303(3):242-249.

2. National Center for Health Statistics. Health, United States, 2004 with Chartbook on Trends in the Health of Americans [pdf 3.8M]. Hyattsville, MD; 2004.

3. http://www.letsmove.gov/. Accessed July 6, 2010.

4. CDC. http://www.cdc.gov/HealthyYouth/obesity/index.htm. Accessed July 6, 2010.

Put That in Your Protocol: Build Community Trust Before Doing Research

Trina Carter, GovSource

Researchers are wrestling with new ways of doing research in communities. In community-based participatory research (CBPR), the process of conducting research is now as important as the research outcome. The emphasis is on participants working together in order to empower communities to achieve their fullest health potential and to transform their health, according to RADM Clara H. Cobb, U.S. Public Health Service (USPHS), and organizer of the "Partnering with Communities to Improve Health Outcomes" conference in Atlanta, GA.

One of a series of Quest for Research Excellence conferences being held in different regions of the country, the Atlanta conference challenged people with a stake in the research enterprise to think about doing research *with* the community rather than merely *in* it.

Participatory research "presents people as researchers in pursuit of answers to questions encountered in daily life," according to practitioner Ajit Krishnaswamy. CBPR methodology has several components: sensitivity, accountability, reciprocity, and sustainability. Researchers have to find out what a community wants and the work that needs to be done.

Involving the people being studied is a way to address health disparities, especially among African-Americans and Native Americans. "The community must be the pipeline," said Dr. Bill Jenkins, Co-Director of the Minority Health Project at the University of North Carolina at Chapel Hill, and a keynote speaker at the Atlanta conference. The rationale for combining efforts is to improve health outcomes.

The idea is to start building community trust before doing the research and to build the capacity of people to conduct and use research. "Equality means full disclosure of the research," said Dr. Reuben Warren, Director of Tuskegee University National Center for Bioethics in Research, speaking in Atlanta. To him, CBPR is about "fixing the wrong, making it fair," alluding to breaches of trust such as that in the USPHS syphilis study from 1932 to 1972 at Tuskegee.

The "Healthy People 2020" initiative from the Office of Public Health and Science (OPHS) seeks to promote public health for all people. Its success depends on community-based research because traditional research studies have lagged behind in adequately addressing the problem of health disparities. The goal of the CBPR approach is to help researchers understand the community they serve and to help the community understand the research. For this approach to work, there must be a tangible benefit for the community, for the individual participant, and for the researcher.

Communities have traditionally not had any say in research that involves members of their community. Research today requires cooperation. Researchers are working with communities to develop more effective and relevant interventions.

World Conference in Singapore Pushes for Statement on Research Integrity

The Second World Conference on Research Integrity was held July 21-24, 2010, in Singapore. During his opening remarks, Dr. Ng Eng Hen, the Minister for Education, emphasized the importance of research integrity worldwide and to Singapore, a rapidly rising leader in research and development. The conference theme was leadership challenges and responses.

"Knowledge without integrity can harm," stated Dr. Ng. He called for "a global code of conduct and protocols." In fact, the more than 350 attendees representing 58 countries were charged by the international planning committee to adopt a landmark document on research integrity called the Singapore Statement. The document will list professional standards that are considered to be universal, facilitating more collaborative international research. The First World Conference was held in Lisbon, Portugal, in 2007.

Several people from the Office of Research Integrity (ORI) spoke at the Second World Conference in Singapore. Dr. Don Wright, Acting Director, ORI, participated in

(See World Conference, page 7)

World Conference *(from page 6)*

welcoming attendees at the opening reception and chaired the plenary session on "Developing, Sharing, and Promoting Best Practices." Dr. John Galland, Director of ORI's Division of Education and Integrity, stressed the importance of supporting researchers and promoting best practices for researchers who continue to be so vitally important to the health and well-being of this world. Dr. John Dahlberg, Director of the Division of Investigative Oversight, talked about ORI's forensic approach to reviewing questioned data and images; he also presented talks with Dr. David Wright, an ORI consultant and professor at Michigan State University, in a daylong workshop and training session after the conference. The long-time ORI consultant, Dr. Nick Steneck, co-chaired both world conferences.

The closing plenary focused on formulating an international statement on the fundamental principles of professionally responsible research. The Singapore Statement is expected to "become a landmark event in good research practice throughout the world," stated Tony Mayer, acting for the European Science Foundation at the conference. The Singapore Statement highlights the need for consistent policies and "meaningful steps for us to achieve a common set of global standards," according to Lim Chuan Poh, Chairman of Singapore's Agency for Science, Technology and Research.

"Cutting across all disciplines, research integrity has become increasingly important today, given that innovation and R&D are key drivers of economic growth worldwide," pointed out Dr. Su Guaning, President of Nanyang Technological University. The Singapore Statement is the first-ever research integrity code to be drawn up on a global scale.

Quest for Research Excellence *(from page 3)*

our exceptional research institutions to foster strong professional practices among researchers. We all believe that the stronger the integrity of researchers, the greater their chances of triumphing over new and formidable challenges.

When a society depends so much on researchers, what can we do to enhance their ability to be innovative and productive?

Through a new "Quest for Research Excellence" initiative, ORI is developing additional educational tools and resources to help researchers succeed. For more than 20 years, ORI has been helping researchers realize their greatest potential for excellence by providing training materials and workshops and by shaping positive attitudes about research as a profession. Now, ORI is going one step further and using the Quest for Research Excellence name and logo extensively to brand its products and services, including a series of Quest regional conferences. This year, three of our Public Health Service offices partnered with local academic institutions and non-profit organizations in their region to hold conferences on research integrity in Atlanta, Denver, and Kansas City. Next year, ORI, in collaboration with NIH and others, will hold a national Quest for Research Excellence conference.

Conferences are just one component of the "Quest for Research Excellence" initiative. As resources become available, ORI plans to collaborate with research institutions and supporting sectors of the research enterprise to provide educational resources, tools, and workshops for researchers early in their careers to learn more about establishing responsible research programs. In addition, the ORI web site, publications, webcasts, social networks, and interactive videos will all carry the Quest for Research Excellence mark.

Through leading new initiatives such as "Quest for Research Excellence," ORI is determined to meet the challenges of reaching out to researchers, coordinating efforts to support them, and developing resources for them. Now more than ever, there is a need to promote research integrity and to strengthen the abilities of researchers to flourish in their profession.

GovSouce Writer Trina Carter contributed to this report.

". . . scientists are change agents . . ."

Mark S. Frankel, AAS

Case Summaries

Gerardo L. Paez, Ph.D.
University of Pennsylvania

Based on the reports of an inquiry and an investigation conducted by the University of Pennsylvania (UP) and analysis conducted by the ORI Division of Investigative Oversight (DIO), ORI found that Gerardo L. Paez, Ph.D., former postdoctoral fellow, Section of Medical Genetics, UP School of Veterinary Medicine, engaged in research misconduct in research supported by National Eye Institute (NEI), National Institutes of Health (NIH), awards R01 EY06855 and R01 EY13132.

ORI found that the Respondent engaged in research misconduct by falsifying and fabricating retinal gene profile data that he purportedly obtained from three-week-old normal dogs and dogs with X-linked progressive retinal atrophy. Specifically, ORI found that:

1. The Respondent committed research misconduct by falsifying/fabricating data for gene expression profiles in retinal tissue from three-week-old normal dogs and dogs with X-linked progressive retinal atrophy in abstracts and poster presentations for the 2006[1] and 2007[2] Association for Research in Vision and Ophthalmology (ARVO) meetings and in an unsubmitted manuscript draft;[3] and

2. The Respondent falsely labeled data files in the UP bioinformatics core computer and submitted falsely identified files to his research mentors.

Dr. Paez has entered into a Voluntary Settlement Agreement in which he has voluntarily agreed, for a period of three (3) years, beginning on June 9, 2010:

(1) to exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant;

(2) 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 him in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which he is involved, must concurrently submit a plan for supervision of his duties to the funding agency for approval; the supervisory plan must be designed to ensure the scientific integrity of his research contribution. A copy of the supervisory plan also must be submitted to ORI by the institution. Respondent agreed that he will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI.

1. Paez, G.L., Zangerl, B., Acland, G.M., & Aguirre, G.D. "Abnormal gene expression profile in retinas with RPGR frameshift mutation."

2. Paez, G.L., Zangerl, B., Acland, G.M., & Aguirre, G.D. "Photoreceptor degeneration and tumor suppressor gene expression in canine retinas with RGR frameshift mutation."

3. Paez, G.L., Zangerl, B., Acland, G.M., & Aguirre, G.D. "Age-related changes in the transcriptional profile of normal and XLPRAII retinas using a custom cDNA microarray."

James Gary Linn, Ph.D.
Tennessee State University

Based on the findings in an investigation report by Tennessee State University (TSU) and additional analysis conducted by ORI in its oversight review, ORI found that James Gary Linn, Ph.D., former Professor, School of Nursing, TSU, committed misconduct in science and research misconduct in research supported by National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), grant S06 GM008092, and National Center for Research Resources (NCRR), NIH, grant G12 RR03033. Specifically, ORI found that:

Case Summaries *(continued)*

1. the Respondent knowingly and intentionally falsified and/or fabricated the data and results of a study in which he purportedly tested the effects of an intervention to reduce sexual risk behaviors in high risk, impaired populations of homeless men with mental illness by reporting false values for variables in Tables 2-5 of *Cellular and Molecular Biology* 49(7):1167-1175, 2003. In that published article, he falsified the values in Tables 2-5 by altering the values that he had obtained from another author's manuscript;

2. the Respondent provided a CD-ROM disc to TSU's Institutional Research Investigation Committee (RIC) that he claimed contained files supporting his analyses for the article in question but that contained fabricated and/or falsified data; and

3. the Respondent submitted falsified summary data to the TSU RIC during the TSU investigation and to ORI.

ORI issued a charge letter enumerating the above findings of misconduct in science and proposing HHS administrative actions. Dr. Linn subsequently requested a hearing before an Administrative Law Judge (ALJ) of the Departmental Appeals Board to dispute these findings. However, on November 30, 2009, Dr. Linn withdrew his request for a hearing. On December 18, 2009, the ALJ of the Departmental Appeals Board accepted Dr. Linn's withdrawal and dismissed his request for a hearing. Thus, the scientific misconduct findings set forth above became effective, and the following administrative actions have been implemented for a period of three (3) years, beginning on January 5, 2010:

(1) Dr. Linn has been debarred from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in non-procurement programs of the United States Government referred to as "covered transactions" pursuant to the Department of Health and Human Services' Implementation (2 C.F.R. Part 376 *et seq.*) of OMB Guidelines to Agencies on Governmentwide Debarment and Suspension, 2 C.F.R. Part 180; and

(2) Dr. Linn is prohibited from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

Emily M. Horvath
Indiana University

Based on the Respondent's own admissions in sworn testimony and as set forth below, Indiana University (IU) and the U.S. Public Health Service (PHS) found that Ms. Emily M. Horvath, former graduate student, IU, engaged in research misconduct in research supported by National Center for Complementary and Alternative Medicine (NCCAM), National Institutes of Health (NIH), grant R01 AT001846 and Predoctoral Fellowship Award F31 AT003977-01, and National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH, grant R01 DK082773-01.

Specifically, the Respondent admitted to falsifying the original research data when entering values into computer programs for statistical analysis with the goal of reducing the magnitude of errors within groups, thereby gaining greater statistical power. The Respondent, IU, and ORI agree that the figures identified below in specific grant applications and published papers are false and that these falsifications rise to the level of research misconduct:

1. The Respondent admitted to falsifying Figures 6B, 18, 22, 23B, and 24 in NCCAM, NIH, grant application R01 AT001846-06, "Chromium enhanced insulin & GLUT4 action via lipid rafts," Jeffery S. Elmendorf, P.I. (07/01/04-05/31/20) (application was withdrawn in May 2009);

2. The Respondent admitted to falsifying Figures 6B, 8, 9D, 16D, and 21 in NIDDK, NIH, grant application R01 DK082773-01, "Mechanisms of membrane-based insulin resistance & the therapeutic reversal strategies," Jeffrey S. Elmendorf, P.I. (3/15/09-01/31/13);

3. The Respondent admitted to falsifying Figures 2C, 5, 6D, and 11 in the publication: Horvath, E.M., Tacket, L., McCarthy, A.M., Raman, P., Brozinick, J.T., & Elmendorf, J.S. "Antidiabetogenic effects of chromium mitigate hyperinsulinemia-induced cellular insulin resistance via correction of plasma membrane cholesterol imbalance." *Molecular Endocrinology* 22:937-950, 2008.

4. The Respondent admitted to falsifying Figure 2C in the publication: Bhonagiri, P., Patter, G.R., Horvath, E.M., Habegger, K.M., McCarthy,

Case Summaries *(continued)*

A.M., Elmendorf, J.S. "Hexosamine biosynthesis pathway flux contributes to insulin resistance via altering membrane PIP_2 and cortical F-actin. *Endocrinology* 150(4):1636-1645, 2009; and

5. The Respondent also admitted to falsifying Figures 2C, 5, 6D, 11, 13C, 15A, 16A, 17A, 18, 19C, and 20A, which are included in her thesis, "Cholesterol-dependent mechanism(s) of insulin-sensitizing therapeutics." The Ph.D. was awarded to the Respondent on December 31, 2008. The Respondent was supported by a Predoctoral Fellowship Award F31 AT003977 from 09/30/2006 to 09/29/2009.

Ms. Horvath has entered into a Voluntary Settlement Agreement in which she has voluntarily agreed, for a period of three (3) years, beginning on March 22, 2010:

(1) to exclude herself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant;

(2) 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 her in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which she is involved, must concurrently submit a plan for supervision of her duties to the funding agency for approval; the supervisory plan must be designed to ensure the scientific integrity of her research contribution; the Respondent agreed that she will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI;

(3) that any institution employing her 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, analyses, and methodology are accurately reported in the application, report, manuscript, or abstract; the Respondent must ensure that the institution sends a copy of the certification to ORI; and

(4) that she will write letters, approved by ORI, to relevant journal editors of the published papers cited above to state what she falsified/fabricated and to provide corrections if she has not already done so. These letters should state that her falsifications/fabrications were the underlying reason for the retraction/corrections.

Rashanda Robertson
Emory University

Based on an assessment conducted by Emory University (EU), the Respondent's own admission, and additional oversight of that admission conducted by ORI, ORI and EU found that Ms. Rashanda Robertson, former Research Coordinator, Department of General Medicine, EU, engaged in research misconduct in research supported by National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), grant K23 HL077597. The randomized study that she coordinated was designed to assess whether patient medication compliance was improved by a meeting with a clinical pharmacist to discuss the patient's current and newly prescribed medications prior to the patient's discharge from the hospital. The enrolled subjects randomized to the intervention group received a card listing all of their medications and a "pill box" to help them with medication compliance. The subjects also were called three days after discharge to check on their medication compliance.

Specifically, the U.S. Public Health Service (PHS), EU, and Ms. Robertson, in a three-way Voluntary Settlement Agreement, agree that the Respondent committed the following acts of research misconduct, which she fully acknowledged. In an affidavit obtained by EU, the Respondent admitted that during the last two weeks of her employment at EU, she fabricated enrollment forms to create enrollees who did not exist and falsified the data of some enrollees who did not exist to cover up the data fabrication. To create the fabricated enrollment forms, the Respondent:

1. identified patients who were eligible for the study based on their charge screens but who were considered ineligible after a face-to-face screen;

2. obtained patients' names from the screening records and used the names to obtain the personal information (address and telephone numbers) on these patients from the site hospital's pharmacy online system;

3. created a fabricated enrollment form for each of the non-existent en-

Case Summaries *(continued)*

rollees; specifically, fabricated a participant's name by using the name of a patient who had failed screening and then fabricated the date of enrollment by using the date of the patient's screening failure; using this method, the Respondent fabricated the participant names, personal information, and enrollment dates on twenty-eight (28) enrollment forms;

4. dispersed the fabricated enrollment form)s among those enrollment forms, beginning around participant number 136 through 212;

5. falsified the numbering of the enrollment forms for some individuals who had actually been enrolled to disperse the fabricated enrollment forms among the authentic enrollment forms; falsified the status of some actual participants to include them in the intervention group, even though they had not actually received the intervention; falsified the data on both the enrollment form and the follow-up form for 16 participants between numbers 137 and 198; and

6. falsified data on the enrollment forms and follow-up forms for participant numbers 153 and 154 by changing their enrollment numbers.

ORI acknowledges that the Respondent was remorseful.

Ms. Robertson has entered into a Voluntary Settlement Agreement in which she has voluntarily agreed, for a period of three (3) years, beginning on October 14, 2009:

(1) to exclude herself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant;

(2) 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 her in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which she is involved, must concurrently submit a plan for supervision of her duties to the funding agency for approval; the supervisory plan must be designed to ensure the scientific integrity of her research contribution; the Respondent agreed that she will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI; and

(3) that any institution employing her 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, analyses, and methodology are accurately reported in the application, report, manuscript, or abstract. The Respondent must ensure that the institution sends a copy of the certification to ORI.

Boris Cheskis, Ph.D.
Wyeth Pharmaceuticals

Based on a report of an investigation conducted by Wyeth Pharmaceuticals and additional analysis conducted by ORI in its oversight review, ORI found that Boris Cheskis, Ph.D., former Senior Scientist, Discovery Research, Women's Health, Wyeth Pharmaceuticals, engaged in research misconduct in grant applications 1 R01 DK072026-01 and 1 R01 DK072026-01A2 submitted to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH. Specifically, ORI found that:

1. the Respondent engaged in misconduct in science, 42 C.F.R. 50.102, in NIDDK, NIH, grant application 1 R01 DK072026-01, "MNAR Crosstalk with Steroid Receptors," submitted to NIH on September 28, 2004, by intentionally falsifying Figures 5 and 6; and

2. the Respondent engaged in research misconduct, 42 C.F.R. 93.103, in NIDDK, NIH, grant application 1 R01 DK072026-01A2, "MNAR Crosstalk with Steroid Receptors," submitted to NIH on November 9, 2005, by intentionally falsifying Figures 6 and 9.

Dr. Cheskis's research was in an area of research (estrogen receptors and modulation of non-genomic phosphorylation cascades) that is of importance to women's health. Dr. Cheskis's team identified an adapter protein, MNAR, that coordinates interactions between certain nuclear receptors, Src and PI3K, and may play important roles in regulation of cell proliferation and survival.

Both Dr. Cheskis and the U.S. Public Health Service (PHS) wanted to conclude this matter without further expense of time and other

Case Summaries *(continued)*

resources. Dr. Cheskis neither admits nor denies that ORI's findings represent findings of research misconduct. The settlement is not an admission of liability on the part of the Respondent.

Dr. Cheskis has entered into a Voluntary Settlement Agreement. Dr. Cheskis has voluntarily agreed, for a period of two (2) years, beginning on March 22, 2010:

(1) to exclude himself from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant; and

(2) that any institution that submits an application for PHS support for a research project on which the Respondent's participation is proposed or that uses him in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which he is involved, must concurrently submit a plan for supervision of his duties to the funding agency for approval; the supervisory plan must be designed to ensure the scientific integrity of his research contribution; the Respondent agreed that he will not participate in any PHS-supported research until such a supervisory plan is submitted to ORI.

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HEALTH AND HUMAN SERVICES

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